COVID-19

P0477

EVALUATION OF POOLING TECHNIQUE FOR DETECTION OF SARS-COV-2 FROM NASOPHARYNGEAL SPECIMENS IN A SMALL SIZED LABORATORY IN GERMANY.

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BACKGROUND-AIM

Diagnosis of SARS-Cov-2 infection is mainly performed by detection of viral genetic material in nasopharyngeal swabs using a polymerase chain reaction (PCR) technique. During the pandemic, not only symptomatic patients have been tested, but also asymptomatic individuals have been screened prior to travel, hospitalization or a surgical procedure. This has increased the workload in all laboratories.
The objectives of the study were to evaluate the efficiency of the pooling technique for diagnosing SARS-COV-2 infection as well as to test the sensitivity of the BD Max System (Becton Dickinson) in detecting positive specimens contained in pools.

METHODS

Nasopharyngeal swabs were collected in E-Swab Liquid Amies preservation medium COPAN. We used the instrument BD MAX System (Becton Dickinson), which performs nucleic acid extraction and real time polymerase chain reaction (RT-PCR) and two different kits were evaluated. Only samples from individuals with low probability of being infected with SARS-CoV-2 were pooled. We consider a positive individual sample only if the ct-value of at least one gene target is less than 35.

RESULTS

962 samples were analysed in 201 pools in a frame time of three months from March until June 2022. Each pool contained maximum 5 samples and a final volume of 750 µl. We had 26 positive pools. All samples contained in positive pools were tested again individually and we obtained in total 30 positive samples. The prevalence of positive cases was 3.12%. The ct-values of the positive pools and positive individual samples were compared and the differences for each gen target (N1, N2 and N) were calculated. The mean difference (ct-pool / ct-sample) was 3,0 (1,3 - 4.4) for N gen target, 2,6 (0,5 – 6,1) for N1 gen target and 3,0 (1,5 – 5,6) for N2 gen target. The correlation of ct-values of pools and positive samples was (r 0.952 for N, r 0,977 for N1 and r 0,984 for N2). We stablished therefore that pools with ct-values above 38 could be considered as negative.

CONCLUSIONS

The data demonstrate excellent repeatability and reliability of the pooling technique. Pooling of nasopharyngeal specimens can be used with BD Max System (Becton Dickinson) to shorten turnaround time and reduce laboratory consumption.

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STRUCTURAL BASIS OF POTENTIAL SARS-COV-2 MAIN PROTEASE INHIBITORS FROM THYMUS SCHIMPERI

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BACKGROUND-AIM

Although the coronavirus disease 19 (COVID-19) pandemic, caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is still instigating significant social and economic chaos worldwide, there is no approved antiviral drug yet. Here, we investigated the structural basis of potential SARS-CoV-2 main protease (Mpro) inhibitors from Thymus schimperi which could provide structural insights to discover potent anti-SARS-CoV-2 phytochemicals.

METHODS

SARS-CoV-2 Mpro amino acid sequence data were retrieved from national center for biotechnology information (NCBI) and multiple sequence alignment was done by using T-Coffee and phylogenetic analysis was constructed using DNA star (DNASTAR, Inc.). The absorption, distribution, metabolism, excretion, and toxicity (ADMET) profiles of compounds was determined through SwissADME and ProToxII servers. AutoDock tools were used for molecular docking analysis while Chimera, DS studio and LigPlot were used for post docking studies. Figures were illustrated using PyMoL.

RESULTS

Evolutionary relationship analysis showed that SARS-CoV-2, SARS-CoV and Bat-CoV Mpros are distantly related with human, rat and MERS-CoV Mpros. High substitution frequency was observed between threonine and serine, alanine and serine, arginine and serine, and arginine and asparagine. All compounds have a bioavailability score of ≥ 0.55 entailing that at least 55% of drugs can be absorbed unchanged. Only five (9%), nine (16%) and two (3.6%) of the compounds exhibited active hepatotoxicity, carcinogenicity and immunotoxicity, respectively. Except for flourazophore P with a little mutagenicity, all other compounds didn't show mutagenic properties. On the other hand, only pinene beta was found to have a little cytotoxicity. Five compounds demonstrated effective binding to the catalytic dyad of the SARS-CoV-2 Mpro substrate binding pocket while two of them (geranylisobutanoate and 3-Octane) are found to be the best hits that formed hydrogen bonds with Glu166 and Ser144 of SARS-CoV-2 Mpro.

CONCLUSIONS

Our in-silico analysis showed that top hits from Thymus schimperi may serve as potential anti-SARS-CoV-2 compounds. Further in vitro and in vivo studies are recommended to characterize the drug ability of these compounds.

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TRANSFERRIN ISOFORMS IN PATIENTS WITH COVID-19

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BACKGROUND-AIM

The aim of the study was to assess the changes in protein glycosylation in the course of COVID-19 on the example of transferrin (TF).

METHODS

The study group consisted of 96 patients (57 men, 39 women) with Covid-19, aged 22 to 89 years. The patients were admitted to the Department of Gastroenterology, Hepatology and Internal Diseases with the Center for Diagnostics and Endoscopic Treatment between November 29 and December 31, 2021. Blood for tests was drawn twice, the first time after admission (first sample) and the second time (second sample) after 9 days on average. The control group consisted of 30 healthy subjects, aged 21-84. Capillary electrophoresis was used to determine the profile of TF isoforms.

RESULTS

A significant decrease in the total concentration of TF was observed (median in the control group - 2.48 g/l, and median in the first tested sample - 1.60 g/l, and 1.64 g/l in the second sample, $P<0.001$ for both comparisons). The changes in TF isoforms profile have been demonstrated. The concentration of pentasialoTF was significantly higher in the study group (median for the first sample: 14.20%, range: 9.30-35.90; median for the second sample: 14.70%, range: 10.20-26.50) than that in the control group (median: 11.95%, range 9.00-17.00). In contrast, the concentration of trisialoTF was significantly decreased in both tested samples (median for the first sample: 2.40%, range:0.80-7.80; median for the second sample: 2.70%, range: 0.70-10.10) compared to the control group (median: 4.00%, range: 2.10-7.00). In the second tested sample, there was also significant decrease in the level of tetrasialoTF (median: 81.15%, range: 62.70-86.60) in comparison with the control group (median: 83.05%, range: 79.80-86.50). Thus, in the course of COVID-19, the share of TF isoforms rich in sialic acid residues increases at the expense of the share of isoforms with a lower content of sialic acid.

CONCLUSIONS

These results indicate that in the course of COVID-19, not only the total concentration of TF as acute phase protein changes (which is obvious), but also there are shifts in the profile of the isoforms of this glycoprotein.

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P0480

CLINICAL PERFORMANCE OF SERS-BASED ANTIGEN-DETECTION RAPID DIAGNOSTIC TEST FOR SARS-COV-2

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BACKGROUND-AIM

A surface-enhanced Raman scattering (SERS)-based antigen-detection rapid diagnostic test (Ag-RDT) for coronavirus disease 2019 (COVID-19), ACROSIS COVID-19 Ag (ACROSIS; SG Medical, Inc., Seoul, Korea), has been recently developed. We evaluated its clinical performance and compared it with another COVID-19 Ag-RDT, STANDARD Q COVID-19 Ag Test (STANDARD Q; SD Biosensor, Inc., Suwon, Korea).

METHODS

In total, 286 nasopharyngeal swab specimens severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-positive or -negative in real-time reverse transcription polymerase chain reaction (rRT-PCR) were tested using ACROSIS and STANDARD Q. SARS-CoV-2-positive specimens were divided according to the number of days after symptom onset (DASO) and the cycle threshold (Ct) value of RNA-dependent RNA polymerase (RdRp)/spike (S) genes in rRT-PCR test. The clinical performance of ACROSIS was compared with STANDARD Q.

RESULTS

The overall sensitivity of ACROSIS was significantly higher than that of STANDARD Q (92.3% vs. 85.6%, P = 0.02). In particular, the sensitivity of ACROSIS was higher than that of STANDARD Q in specimens with $25 \leq Ct < 30$ (78.6% vs. 42.9%). In each Ag-RDT, there was no significant difference in sensitivity according to the number of DASO, whereas the sensitivity tended to decrease as the Ct value increased. ACROSIS and STANDARD Q showed a strong agreement ($\kappa = 0.944$).

CONCLUSIONS

This is the first study that evaluated the performance of SERS-based Ag-RDT for COVID-19. ACROSIS showed reliable performance for diagnosing SARS-CoV-2 infection. Its sensitivity was particularly improved in specimens with $25 \leq Ct < 30$. The SERS-based Ag-RDT is expected to effectively diagnose COVID-19 patients with a low viral load that can be missed in the early stages of COVID-19.

COVID-19

P0481

SARS-COV-2-SPECIFIC ANTIBODY AND T-CELL RESPONSES AND PRE-EXISTING HUMORAL IMMUNITY TO HUMAN COMMON COLD CORONAVIRUSES: A HEAD-TO-HEAD COMPARISON OF DIFFERENT COMMERCIAL ASSAYS

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BACKGROUND-AIM

Reliable tests are needed to determine both antibody and T-cell response to SARS-CoV-2 (hereafter T-cell response) to assess the protection level against COVID-19 (re)infection. We aimed to investigate: (1) the performance of Quan-T-Cell Interferon-Gamma Release Assay (IGRA) by Euroimmun (Lübeck, Germany); (2) the agreement between venous serum- and dried blood spot (DBS)-based methods of anti-S1-IgG testing by using Anti-SARS-CoV-2-QuantiVac-ELISA (IgG) kit by Euroimmun; (3) the impact of pre-existing immunity against four human common cold coronaviruses (hCoVs) on SARS-CoV-2-specific cellular and humoral responses.

METHODS

We conducted a cross-sectional study in 20 subjects, of whom four were SARS-CoV-2-naïve and 16 vaccinated. Spike-specific T-cell response was assessed by IGRA (Euroimmun) in venous serum samples. Anti-S1-SARS-CoV-2-IgG levels were measured by Anti-SARS-CoV-2-QuantiVac-ELISA (Euroimmun) in venous serum and DBS samples. Anti-nuclecapsid-protein-IgG-antibodies against hCoVs 229E, NL63, OC43 and HKU1 as well as anti-nuclecapsid-protein, anti-receptor binding domain and anti-S1-protein of SARS-CoV-2 were assessed by semi-quantitative RecomLine SARS-CoV-2-IgG line immunoblot assay by Mikrogen (Neuried, Germany).

RESULTS

Venous serum- and DBS-based methods of SARS-CoV-2-IgG detection showed a very strong concordance (Spearman's rho=0.983, $p<0.0001$). A strong positive correlation was revealed between T-cell response and SARS-CoV-2-IgG levels (rho=0.757, p=0.0001 and rho=0.738, p=0.0002 vs venous serum- and DBS-based IgG assessment methods, respectively). Neither T-cell response nor SARS-CoV-2-IgG levels demonstrated significant correlations with hCoVs antibodies.

CONCLUSIONS

IGRA test by Euroimmun is a reliable method of quantifying T-cell response which can complement serological data. T-cell response positively correlates with SARS-CoV-2 antibody levels. DBS-based SARS-CoV-2-IgG determination can serve as a good alternative to routine venous serum-based testing. We did not observe associations between anti-SARS-CoV-2-immune response (IGRA data, SARS-CoV-2-antibodies) and the immune response to infections caused by common cold coronaviruses (antibodies to 229E, NL63, OC43 and HKU1 species). However, these complex relations remain to be explored in depth by further large cohort studies.

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RETINOL-BINDING PROTEIN 4 IS ASSOCIATED WITH SECRETORY IMMUNOGLOBULIN A IN COVID-19 OUTPATIENTS

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BACKGROUND-AIM

The respiratory tract mucosal immune response is crucial in controlling the infection of airborne viruses, such as the COVID-19 causative agent. Immunoglobulin A (IgA) is the most abundant antibody on mucosal surfaces. Preclinical research has revealed that vitamin A boosts IgA production. Moreover, retinol-binding protein 4 (RBP4) has been shown to correlate with serum IgA in influenza patients. This study aimed to analyze the association between RBP4 and secretory IgA (SIgA) in COVID-19 outpatients.

METHODS

We conducted a cross-sectional study on day 14 after SARS-CoV-2 positive diagnosis on Mexican COVID-19 outpatients who met the inclusion criteria. To define the vitamin A status of the patients, we assessed the dietary intake through the 24-hour recall method and a food frequency questionnaire. As a surrogate for retinol, we analyzed serum RBP4 with a sandwich enzyme immunoassay. Salivary SIgA was determined by the same method. We analyzed the data with a p-value <0.05 for statistical significance.

RESULTS

Of the 39 patients enrolled, 59% were female. The patient's mean age was 38.3±12.6 years. At the time of evaluation, 18.7±2.1 days had elapsed since the beginning of COVID-19 symptoms. The mean vitamin A intake was 757.6±365.1 μg RAE, while RBP4 levels were 27.8±9.4 μg/mL. In turn, the mean SIgA was 160.1±68.3 μg/mL. Patients classified with high vitamin A intake (>716.7 μg RAE) based on the median had higher RBP4 (30.3±8.1 vs. 24.2±8.8 μg/mL, p=0.019) and SIgA levels (182.5±66 vs. 136.8±66.3 μg/mL, p=0.037) than the low intake group. There was a trend difference in SIgA levels between patients with RBP4 insufficiency and sufficiency (134.1±69.5 vs. 174.6±64.5 μg/mL, p=0.068). Vitamin A intake was not correlated with SIgA (rs=0.232, p=0.161), whereas RBP4 was positively correlated (rs=0.348, p=0.03). The ROC curve analysis showed a RBP4 cutoff of >25.1 μg/mL for high SIgA (>152.4 μg/mL) based on the median (AUC=0.763 [95% CI: 0.613-0.914], p=0.005).

CONCLUSIONS

RBP4 is associated with SIgA in COVID-19 outpatients. Therefore, although we did not perform a cause-effect study, we suggest that adequate vitamin A status may enhance the humoral immune response of the upper respiratory tract for decreased susceptibility to respiratory infections.

COVID-19

P0483

T CELL AND B CELL IMMUNE RESPONSE AFTER ADMINISTRATION OF FOUR DIFFERENT COVID-19 VACCINES IN KOREA

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BACKGROUND-AIM

Administration of vaccines was predicted as the crucial step to prevent further outbreak of COVID-19. Monitoring of the development and kinetics of immune responses is essential to determine the efficacy of COVID-19 vaccines.

METHODS

We measured IFN-γ levels upon administration of homologous adenovirus vector-based (AstraZeneca, AZ; Jansen, JAN), and mRNA-based (Pfizer-BioNTech, PF; Moderna, MO) vaccines, and heterologous vaccine (AZ/PF) in healthy Korean individuals using two platforms of IFN-γ release assays (IGRA), i.e., Covi-FERON ELISA assay (SD Biosensor, Korea) and T-SPOT Discovery SARS-CoV-2 assay (Oxford Immunotec, UK). The B cell response was evaluated by assessing the production of neutralizing antibodies by measuring the percentage inhibition in a surrogate virus neutralization test (sVNT). Data were analyzed by comparing the immune response among vaccine groups, after adjusting for vaccination dose and interactions between vaccine group and vaccination dose.

RESULTS

Administration of COVID-19 vaccines triggered both T cell and B cell responses, regardless of the brand of the vaccine. The AZ triggered the highest response of T cell after the first dose; however, the AZ showed instability after the second dose. Meanwhile, mRNA-based vaccines, i.e., PF and MO, yielded a stable and higher increment of T cell and B cell responses across time. Nevertheless, compared to PF, MO vaccine showed a relatively higher immune response after administration. The administration of JAN vaccine, triggered T cell and B cell responses, but its level was lower compared to the other vaccine group. In addition, administration of the booster dose demonstrated a significant increase in the response of T cell and B cell, suggesting that a booster dose is needed for longer protection from SARS-CoV-2 considering the possibility of a waning immune response.

CONCLUSIONS

Administering two doses of mRNA vaccines was most effective among administered vaccines in triggering the immune response specific to SARS-CoV-2 in Korean healthy individuals. Furthermore, booster doses that were administered three months after the second dose demonstrated a significant increase in immune response and may provide a longer protection against SARS-CoV-2.

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P0484

DETECTION OF SARS-COV-2 RNA IN DIFFERENT TYPES OF CLINICAL SPECIMENS AMONG SUSPECTED COVID-19 PATIENTS IN SELECTED HOSPITALS, ADDIS ABABA

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BACKGROUND-AIM

While nasopharyngeal swabs (NPS) are the recommended and most frequently used sample to confirm the clinical diagnosis of severe acute respiratory syndrome (SARS-CoV-2), saliva might also be utilized as an alternative clinical specimen. Moreover, studies reported opposing findings on whether this virus could be detected in urine or not. We therefore aimed to evaluate the diagnostic utility of NPS, saliva, and urine specimens in suspected COVID-19 patients.

METHODS

This was a cross-sectional study that recruited a total of 604 specimens from 219 COVID-19 suspected individuals from February to July 2022 at two COVID-19 Isolation and Treatment Centers. The specimens were analyzed using an RT-PCR (Cobas 8800) automated system. We assessed SARS-CoV-2 positivity and estimated viral loads using Ct values in NPS, urine, and saliva samples. The data was analyzed using SPSS v23, and the level of significance was set at a P-value of <0.05.

RESULTS

In total, 57.5% (126/219) of participants tested positive for SARS-CoV-2 either by NPS, saliva, urine, or all three specimens. The detection rate of SARS-CoV-2 was significantly higher in NPS (53.88%, 118/219) than in saliva (35.16%, 77/219; P = 0.001) and urine (9.0%, 15/166; P = 0.001). Overall, there was a moderate but considerable agreement between NPS and saliva (75.8%; 166/219, Kappa = 0.527, P < 0.001). Additionally, there was a statistically significant correlation between the viral load of NPS and saliva (p = 0.01) and NPS and urine (p = 0.01). Interestingly, the low, intermediate, and high viral load distribution among the participants was similar in NPS and saliva.

CONCLUSIONS

Although NPS is a better SARS-CoV-2 testing specimen, saliva could be used as an alternative clinical specimen. The SARS-CoV-2 detection rate in NPS was significantly higher than that in saliva and urine (P < 0.001). This study indicates that both saliva and urine could be sources of viral transmission.

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P0485

SOLUBLE ST2 AS A USEFUL BIOMARKER FOR PREDICTING CLINICAL OUTCOMES IN COVID-19

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BACKGROUND-AIM

Soluble suppression of tumorigenesis-2 (sST2) is an emerging biomarker for heart failure, and it is released in inflammation. We investigated the prognostic utility of sST2 for predicting clinical outcomes in hospitalized coronavirus disease 2019 (COVID-19) patients.

METHODS

In a total of 52 hospitalized COVID-19 patients, sST2 levels were measured using the ichroma ST2 assay (Boditech Med Inc., Chuncheon-si, Gang-won-do, Korea). Clinical outcomes included intensive care unit (ICU) admission, ventilator use, extracorporeal membrane oxygenation (ECMO) use, and 30-day mortality. sST2 was analyzed according to clinical outcomes. sST2, sequential organ failure assessment (SOFA), critical disease, and 4C mortality score were compared using the receiver operating characteristic (ROC) curve and Kaplan-Meier methods for clinical outcomes.

RESULTS

sST2 level differed significantly according to ICU admission, ventilator use, ECMO use, and 30-day mortality (all $p < 0.05$). On ROC curve analysis, sST2 predicted ICU admission, ventilator use, ECMO use, and 30-day mortality comparable to SOFA, but significantly better than critical disease. sST2 predicted ICU admission, ventilator use, and ECMO use significantly better than 4C mortality score. On Kaplan -Meier survival analysis, hazard ratios (95% confidence interval) were 8.4 (2.7 − 26.8) for sST2, 14.8 (3.0 − 71.7) for SOFA, 1.8 (0.5 − 6.5) for critical disease, and 11.7 (3.4 − 40.1) for 4C mortality score.

CONCLUSIONS

This study demonstrated that sST2 could be a useful biomarker to predict ICU admission, ventilator use, ECMO use, and 30-day mortality in hospitalized COVID-19 patients. sST2 may be implemented as a prognostic COVID-19 biomarker in clinical practice.

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P0486

THE EFFECT OF SARS-COV-2 INFECTION ON HEMATOLOGICAL AND INFLAMMATION PARAMETERS IN OUTPATIENTS

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BACKGROUND-AIM

The coronavirus disease (COVID-19), caused by the new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is one of the deadliest infectious diseases that has appeared in recent history. A large number of scientific research indicate the exceptional importance of laboratory diagnostics in a pandemic. The aim of this study was to examine the impact of SARS-Cov-2 infection on hematological and inflammation parameters in outpatients and to examine the relationship between the duration of the inflammation period and the investigated parameters of inflammation in patients with confirmed infection.

METHODS

This study analyzed the results of 104 primary healthcare outpatients, 53 male, and 51 female over the age of 18. Patients had a confirmed SARS-Cov-2 infection in the period between November 2020 and July 2022. Hematological parameters were determined on a 5-part diff hematology analyzer CELL-DYN Ruby, and the MULTIGENT CRP Vario test (CRPVa) was used to determine the concentration of C-reactive protein (CRP) in the serum of analyzed patient samples.

RESULTS

A statistically significant impact of SARS-Cov-2 infection on leukocytes, lymphocytes, platelets, CRP, and hematological indices was determined ($P<0.05$). Binary logistic regression showed that there is a higher probability that people over 60 years of age have higher CRP values at the beginning of treatment, as well as higher platelet and CRP values at the end of treatment compared to people under 60 years of age (Exp(B)=1.061, P=0.024; Exp(B)=1.098, P=0.001; Exp(B)=1.051, P=0.013). It is noted that there is a significant trend of decreasing CRP values from the fifteenth to the thirtieth day of treatment ($P<0.05$).

CONCLUSIONS

The results of this retrospective analysis show that SARS-CoV-2 infection affects the change of certain parameters of inflammation in ambulatory patients during the duration of treatment. It is important to determine the concentration of CRP and the complete blood count for the purpose of primary triage of outpatients, as an aid in the further prognosis of the course of the disease, and assessment of the progression and severity of the disease, especially in elderly patients with chronic diseases.

COVID-19

P0487

SUSCEPTIBILITY TO RE-INFECTION WITH SARS-COV-2 VIRUS RELATIVE TO EXISTING ANTIBODY CONCENTRATIONS AND T CELL RESPONSE

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BACKGROUND-AIM

This is an Abu Dhabi Department of Health funded prospective investigation in which our aim was to study a post convalescent SARS-CoV-2 population of guest workers in Abu Dhabi to determine immune protection and reinfection. This population was identified in a prior study to have a very high seroprevalence prevalence to SARS-CoV-2 largely due to dormitory style housing despite rigorous surveillance and quarantine measures. The aims of the study were to determine the relative contribution of humoral protection including trimeric (S1, S2 and RBP) and blocking antibodies and measured T helper and cytotoxic killer cell response to protection from reinfection. The cohort recruited for this study reflects an accelerated community picture of viral infectivity, protection and reinfection.

METHODS

Trimeric spike, nucleocapsid, and neutralizing antibodies were measured along with a T cell stimulation assay targeting SARS-CoV-2 memory in CD4+ and CD8+ T cells. The subjects were then followed up for reinfection for up to six months.

RESULTS

Seroprevalence positivity at enrollment was greater than 99%. T cell reactivity in this population was 38.2%. Of the 149 (15.9%) participants that were re-infected during the follow up period (74.3%) had nonreactive T cells at enrollment. Those who had greater than 100 BAU/mL increase from the median concentration of Anti-S IgG antibodies had a 6% reduction in the risk of infection. Those who were below the median concentration had a 78% greater risk of infection.

CONCLUSIONS

SARS-CoV-2 continues to infect individuals across the globe. Recent immunity pressures have driven selection to variants that can escape humoral responses. In this study, we were able to estimate a serological cut off value that provides some degree of protection from reinfection for a defined period. We have also determined that T cell antigen stimulation response is closely linked to immunocompetence to SARS-CoV-2 infection in our study population

COVID-19

P0488

EVALUATION OF LONG-TERM PERSISTENCE OF ANTI-SARS-COV-2 NUCLEOCAPSID PROTEIN IGG ANTIBODIES

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BACKGROUND-AIM

Implementation of the nucleocapsid antigen in future vaccines could help in preventing SARS-CoV-2 transmission. Our objective was to evaluate the nucleocapsid IgG antibody (anti-N) seropositivity and to test the influence of gender, age, smoking, disease duration, months post-recovery and vaccination on serostatus.

METHODS

339 participants were enrolled in this study. We used the SARS-CoV-2 IgG assay on the integrated Abbott Architect ci4100 analyzer. Although this assay is qualitative, we hypothesized that the resulting index value is directly proportional to the concentration of anti-N IgG antibodies present in the sample, and the values were considered as continuous data.

RESULTS

There was no significant difference between anti-N S/C means and gender (p=0.513). There was a positive correlation between age and anti-N S/C (r=0.07, 95% CI:-0.07-0.20, p=0.321), and a negative correlation between anti-N S/C and disease duration (r=-0.02, 95% CI:-0.16-0.11, p=0.751). Smokers had a positive correlation between anti-N S/C and disease duration (r=0.20, 95% CI:-0.07-0.44, p=0.14) and a statistically significant negative correlation between anti-N S/C and months post-recovery (r=-0.39; 95% CI:-0.59--0.14, p=0.003). Non-smokers had a statistically non-significant negative correlation (r=-0.13, 95% CI:-0.28-0.03, p=0.101). There was no significant difference in anti-N S/C means between vaccinated and unvaccinated participants (p=0.091). A significant difference was seen in anti-N S/C means between participants vaccinated with BNT162b2 and BBIBP-CorV (p=0.002) and between BNT162b2 and unvaccinated participants (p=0.001). The lowest mean was observed in participants vaccinated with BNT162b2 (2.04 S/C±2.76, 95% CI:1.57-2.51, IQR=3.4) while BBIBP-CorV elicited a higher mean (3.36 S/C±3.31, 95% CI:2.27-4.45, IQR=4.3).

CONCLUSIONS

Non-smokers sustained seropositivity for 34 months and smokers for 25 months. While vaccines protect from severe disease, the high mutation frequency of the spike protein prevents them from providing robust protection. The high immunogenicity, lower mutation frequency of the nucleocapsid protein of the SARS-CoV-2 virus and the long-term persistence of anti-N antibodies suggest that the implementation of the nucleocapsid antigen in future vaccines could be very beneficial.

COVID-19

P0489

TIME SERIES ANALYSIS REVEALED PROGNOSTIC VALUE OF CONTINUOUS NASOPHARYNGEAL SARS-COV-2 NUCLEIC ACID QUANTIFICATION FOR COVID-19: A RETROSPECTIVE STUDY OF OVER 3.000 COVID-19 PATIENTS FROM TWO CENTERS

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BACKGROUND-AIM

Early stratification of disease progression remains one of the major challenges towards the post-coronavirus disease 2019 (COVID-19) era. The clinical relevance of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleic acid load is debated due to the heterogeneity in patients' underlying health conditions. This study aimed to determine the prognostic value of nasopharyngeal viral load dynamic conversion for COVID-19.

METHODS

The cycling threshold (Ct) values of 28,937 nasopharyngeal SARS-CoV-2 reverse transcription-polymerase chain reactions (RT-PCRs) were retrospectively collected from 3,364 COVID-19 patients during hospitalization and coordinated to the onset of disease progression. The receiver operating characteristic (ROC) curve was utilized to determine the predictive performance of the rate of Ct value alteration between two consecutive RT-PCR runs within 48 hours (∆Ct%) for disease transformation across patients with different COVID-19 severity and immune backgrounds, and further validated with 1,860 SARS-CoV-2 RT-PCR results from an independent validation cohort of 262 patients. For the 67 patients with severe COVID-19, Kaplan-Meier analysis was performed to evaluate the difference in survival between patients stratified by the magnitude of Ct value alteration between the late and early stages of hospitalization.

RESULTS

The kinetics of viral nucleic acid conversion diversified across COVID-19 patients with different clinical characteristics and disease severities. The ∆Ct% is a clinical characteristic- and host immune status-independent indicator for COVID-19 progression prediction (AUC = 0.79, 95% CI = 0.76 to 0.81), which outperformed the canonical blood test markers, including c-reactive protein, serum amyloid A, lactate dehydrogenase, D-dimer, and lymphocyte count. Patients with persistent high SARS-CoV-2 viral load (an increase of mean Ct value < 50%) during the first three days of hospitalization demonstrated a significantly unfavorable survival (HR = 0.16, 95% CI = 0.04 to 0.65, P = 2.41×10^{-3}).

CONCLUSIONS

Viral nucleic acid dynamics of SARS-CoV-2 eliminates the inter-patient variance of basic health conditions, and therefore can serve as a prognostic marker for COVID-19.

COVID-19

P0490

INTERRELATIONS BETWEEN SARS-COV-2 VIRAL LOAD AND CELLULAR IMMUNITY

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BACKGROUND-AIM

Studying the relationship between SARS-CoV-2 viral load (VL) in respiratory tract samples and immunological laboratory parameters is an important step towards finding reliable clinical markers of COVID-19 severity. The aim of this research was to quantify VL in patients with COVID-19 and to identify the relationship between VL and changes in the parameters of the cellular component of the immune system.

METHODS

A laboratory examination was carried out on 74 patients diagnosed with COVID-19, they were divided into 3 groups based on the severity of the disease: mild, moderate, severe. The total VL in clinical samples was determined by the number of SARS-CoV-2 RNA copies per 100 copies of the reference RNaseP gene. A comprehensive assessment of the cellular component of the immune system was performed using flow cytometry and direct monoclonal antibodies.

RESULTS

In our study, the median VL in the group of severe patients was 16.5 times higher in comparison with the moderately ill group. The median absolute lymphocyte and cytotoxic lymphocyte (CD3+CD8+) count for the group of severe patients was 0.6 (0.4-1.0)*10^9/l, p=0.000006 and 0.16 (0.08-0.22)*10^9/l, p=0.000012, respectively. Concurrently, we identified a subgroup of patients (n=8) in which the median VL was almost 100 times higher than VL level in severe patients. The median absolute lymphocyte and CD3+CD8+ count for this subgroup was 0,6 (0,44-1,3)*10^9/l and 0.3 (0.1-0.4)*10^9/l respectively. It is noteworthy that this subgroup followed a moderate disease trajectory that eventually led to recovery. In the subgroup of patients with an extremely high VL, strong positive correlations were found between the relative number of CD3+CD8+, activated T-lymphocytes (CD3+HLA-DR+), absolute and relative numbers of activated B-lymphocytes and NK cells (CD3-CD25+), p<0.05.

CONCLUSIONS

We identified a relationship between the development of a serious condition in patients with COVID-19 and VL level. High levels of viral RNA in biological samples correlate with the main indicators of the T-cell component of the immune system that are associated with disease severity. Changes in expression levels of activation markers on immune cells can be potentially viewed as indicators of recovery during COVID-19.

COVID-19

P0491

COMPARISON OF ANTIBODY IMMUNE RESPONSES BETWEEN BNT162B2 AND MRNA-1273 SARS-COV-2 VACCINES IN NAïVE AND PREVIOUSLY INFECTED INDIVIDUALS

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BACKGROUND-AIM

Two mRNA vaccines, Pfizer-BNT162b2 and Moderna-mRNA-1273, obtained the Emergency Use Listing by WHO for preventing COVID-19. However, little is known about the difference in antibody responses induced by these two mRNA vaccines in naïve and previously infected (PI) individuals.

METHODS

We investigated the levels of anti-S-RBD (total, IgG and IgA) levels in naïve and PI individuals, 1–13 (median=6) weeks following the second dose of either vaccine.

RESULTS

Results in the naïve-vaccinated group, the mRNA-1273 vaccine induced significantly higher levels of anti-S-RBD total antibodies (3.5-fold; $P < 0.001$), IgG (2-fold, $P < 0.01$) and IgA (2.1-fold, $P < 0.001$) as compared with the BNT162b2 vaccine. In addition, both vaccines produced significantly higher anti-S-RBD total antibody levels in the PI-group compared with naïve-vaccinated group. The PI group elicited a higher level of anti-S-RBD IgG than the naïve-BNT162b2 ($P = 0.05$), but not more than the naïve-mRNA-1273 ($P = 0.9$) group. Interestingly, the PI vaccinated group elicited a comparable level of IgA ratio to the naïve-mRNA-1273 group but significantly higher than the naïve-BNT162b2 group (1.6-fold, $P < 0.001$)

CONCLUSIONS

Our results showed that the PI-vaccinated group produces a higher level of antibodies than the naïve vaccinated group, particularly for those vaccinated with BNT162b2.

COVID-19

P0492

REAL-WORLD ASSESSMENT OF THE CLINICAL PERFORMANCE OF COVID-VIRO ALL IN RAPID SARS-COV-2 ANTIGEN TEST

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BACKGROUND-AIM

Since the external validation of severe acute respiratory syndrome coronavirus 2 antigen rapid diagnostic tests (SARS-CoV-2 RDT-Ags) is a necessary requisite before they can be introduced into routine clinical practice, this study reports the results of a real-world assessment of the clinical performance of the new COVID-VIRO ALL IN device.

METHODS

The study population consisted in 165 outpatients (median age: 43 years, range: 14-68 years; 66.1% females) who had paired nasal and nasopharyngeal samples collected upon hospital presentation. The samples were concomitantly tested with the AAZ-LMB COVID-VIRO ALL IN SARS-CoV-2 RDT-Ag and with Cepheid Xpert Xpress SARS-CoV-2 real-time reverse transcription polymerase chain reaction (RT-PCR).

RESULTS

The number of subjects with positive RT-PCR results (i.e., mean Ct value <45) was 116 (70.3%), 109 (66.1%) and 86 (52.1%) with mean Ct values <37 and <30, respectively. In all RT-PCR positive samples, COVID-VIRO ALL IN displayed 78.8% agreement, 0.698 sensitivity, 1.000 specificity, 0.583 negative predictive value (NPV) and 1.000 positive predictive value (PPV) compared to RT-PCR. The median Ct value of samples testing positive with COVID-VIRO ALL IN was significantly lower than those testing negative (22.8 vs. 32.2; p<0.001). In samples with high viral load (i.e., Ct value <30), COVID-VIRO ALL IN displayed 92.1% agreement, 0.895 sensitivity, 0.949 specificity, 0.983 NPV and 0.951 PPV compared to RT-PCR.

CONCLUSIONS

Although the diagnostic performance of COVID-VIRO ALL IN do not exactly match those of the manufacturer, its high NPV in high viral load samples would enable fast-track and rapid identification of highly contagious subjects.

COVID-19

P0493

A SIMPLE EPIDEMIOLOGIC MODEL FOR PREDICTING IMPAIRED NEUTRALIZATION OF NEW SARS-COV-2 VARIANTS

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BACKGROUND-AIM

This study is aimed at developing a simple epidemiologic model that could help predict impaired neutralization of new SARS-CoV-2 variants.

METHODS

We explored the potential association between neutralization of recent and more prevalent SARS-CoV-2 sublineages belonging to the Omicron family (i.e., BA.4/5, BA.4.6, BA.2.75.2, BQ.1.1 and XBB.1) expressed as FFRNT50 (>50% suppression of fluorescent foci fluorescent focus reduction neutralization test) in recipients of 4 doses of monovalent mRNA-based coronavirus disease 2019 (COVID-19) vaccines, with date of emergence and number of spike protein mutations of these sub-lineages, cumulative worldwide COVID-19 cases, and cumulative number of COVID-19 vaccine doses administered worldwide both at the time of SARS-CoV-2 Omicron sublineage emergence.

RESULTS

In univariate analysis, the FFRNT50 value for the different SARS-CoV-2 Omicron sublineages was significantly associated with all such variables except with the number of spike protein mutations. Such associations were confirmed in multivariate analysis, which enabled the construction of the equation: "-0.3917× [Emergence (date)] + 1.403×[COVID-19 cases (million)] - 121.8×[COVID-19 Vaccine doses (billion)] + 18250", predicting the FFRNT50 value of the five SARS-CoV-2 Omicron sublineages with 0.996 accuracy (p=0.013).

CONCLUSIONS

We have shown with this work that a simple mathematical approach encompassing a limited number of widely available epidemiologic variables such as date of emergence of new variants, number of COVID-19 cases and vaccinations, could help identify the emergence and surge of future linages with major propensity to impair humoral immunity.

COVID-19

P0494

HARMONIZATION OF SARS-COV-2 ANTIGEN IMMUNOASSAYS: ARE THEY MEASURING THE SAME "THING"?

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BACKGROUND-AIM

This study was planned to assess accuracy and comparability of two commercially available, laboratory-based severe acute respiratory syndrome (SARS-CoV-2) antigen (Ag) immunoassays.

METHODS

We studied a cohort of subjects with acute SARS-CoV-2 infection, from whom a nasopharyngeal swab was taken and tested with a molecular assay (Altona Diagnostics RealStar SARS-CoV-2 RT-PCR Kit) and two laboratory-based, fully automated SARS-CoV-2 Ag immunoassays (Fujirebio Lumipulse G SARS-CoV-2 Ag and Roche Elecsys SARS-CoV-2 Ag).

RESULTS

The final population consisted in 93 subjects positive for SARS-CoV-2 RNA, 34 with cycle threshold (Ct) values <29.5. The values of two SARS-CoV-2 Ag immunoassays were significantly intercorrelated (r= 0.77; p<0.001) in the entire cohort, but the correlation considerably improved in those with high viral load (cycle threshold values <29.5: r= 0.96; p<0.001). The accuracy for identifying samples with high viral load was excellent for both Lumipulse G SARS-CoV-2 Ag (AUC, 0.99; p<0.001) and Elecsys SARS-CoV-2 Ag (AUC, 0.99; p<0.001), with best cut-offs of 2.03 ng/mL for Lumipulse G SARS-CoV-2 Ag (1.00 sensitivity and 0.88 specificity) and 0.70 COI for Elecsys SARS-CoV-2 Ag (1.00 sensitivity and 0.80 specificity), respectively.

CONCLUSIONS

The results emerged from this study provide valuable support to the usability of fully automated, rapid, high throughput and accurate SARS-CoV-2 Ag tests for surrogating molecular assays.

COVID-19

P0495

THE BIOCHEMISTY ANALYSES IN PATIENTS WITH COVID-19

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BACKGROUND-AIM

The aim of our study was to analyze the specificity and sensitivity laboratory parameters such as alanine aminotransferase (ALT), aspartate aminotransferase (AST), lactate dehydrogenase (LDH), gamma-glutamyl transferase (GGT), C-reactive protein (CRP) and Ferritin in positive COVID-19 patients.

METHODS

The study covered 200 patients, 100 positive COVID-19 patients and 100 healthy subjects. We determined ALT, AST, GGT, LDH, CRP and Ferritin in patients' serum. CRP and Ferritin concentration in serum were analyzed using ARCHITECT (ABBOTT). The enzymes (ALT, AST,LDH and GGT) were analyzed using DIMENSION LxR (DADE BEHRING).

RESULTS

The difference in percentages for COVID-19 positive subjects have higher activity values of LDL is 47.5 %, AST 37.5 % ALT 28.2 % and GGT 7.2 % compared to the control group. Patients with positive RT-PCR had significantly higher C-reactive protein (CRP) ($p = 0.03$), Ferritin ($p = 0.001$), (LDH) ($p = 0.0001$), (AST) ($p = 0.001$), (ALT) ($p = 0.0001$), and GGT ($p = 0.01$) levels in serum compared to the control group. LDH were strongly associated with the COVID-19 disease might be explained by the facts that this enzyme is known to be a marker of lung damage. The area under the ROC curve studied parameters in predicting cases with positive RT-PCR for COVID-19 of laboratory parameters such as Ferritin (0.899), CRP (0.860), LDH (0.853), AST (0.640), ALT (0.553) indicated that they could be used to predict the presence of COVID-19 disease. The AUC was for GGT (0.113).

CONCLUSIONS

Higher values of the investigated parameters were detected in patients who are positive for COVID-19 compared to the control group. The AUC of laboratory parameters such as Ferritin, CRP, LDH ALT and AST indicated that they could be used to predict the presence of COVID-19 disease, while GGT indicating that they was poor predictors of the disease. Laboratory tests such as CRP, Ferritin and LDH identify risk of disease with greater severity, myocardial damage, and worse prognosis of disease.

COVID-19

P0496

ROLE OF SURFACTANT PROTEIN D (SP-D) AS BIOMARKER OF SARS-COV-2 INFECTION

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BACKGROUND-AIM

In the pulmonary surfactant, protein-D (SP-D) is a low abundant hydrophilic protein which promotes pathogens clearance binding highly conserved glycosidic residues on their surface, and is involved in the modulation of lung resident immune cells activity. Recently, SP-D has emerged as a potential biomarker for COVID-19. Indeed, previous investigations on acute respiratory distress syndrome patients demonstrated that SP-D serum levels significantly increase in pathological conditions due to an impairment of the pulmonary barrier caused by prolonged inflammation. The final goal of this study was to determine if SP-D levels could represent a risk factor for COVID-19 severity and mortality.

METHODS

A retrospective investigation of hematic SP-D concentrations was conducted on a relatively large cohort of patients of Hospital Pio XI of Desio aimed to assess differences among COVID-19 patients and healthy donors.

RESULTS

A statistical analysis, based on an ANOVA-model, showed a significant difference in the mean of log SP-D levels between COVID-19 patients and healthy donors and significant variations were also observed between dead vs survived patients. Threshold values of 150 and 250 ng/mL SP-D concentrations in plasma were detected for both hospitalized COVID-19 and dead patients, respectively, and can be therefore proposed as cut-off values to predict the disease incidence and mortality. A logistic mixed models, highlighted that higher SP-D levels at admission and increasing differences among follow-up play a significant role in identifying the main risk factors of mortality.

CONCLUSIONS

This is the first study in Europe in which a significant correlation between SP-D levels and mortality has been determined by an accurate statistical analysis on a large number of patients. The early detection of this protein should be considered for scheduling adequate therapeutic intervention for COVID-19 patients.

COVID-19

P0497

VISCOELASTIC HEMOSTATIC ASSAY AND CONVENTIONAL LABORATORY COAGULATION TESTS IN SEVERE SARS-COV-2 PNEUMONIA.

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BACKGROUND-AIM

Critically ill patients with COVID-19 pneumonia suffered both high thrombotic and bleeding risk. The effect of SARS-CoV-2 on coagulation and fibrinolysis is not well known.

METHODS

In a retrospective study of critically ill patients admitted to an intensive care unit (ICU) for severe COVID-19 pneumonia (Group 1), we assessed coagulation function using coagulation standard parameters on the day of admission (T 0) and 10 days later (T 10), as well as a viscoelastic hemostatic assay (ClotPro ®). Furthermore, we compared conventional coagulation measures in individuals with severe non-COVID-19 pneumonia (Group 2).

RESULTS

Eighty-four patients participated in our study. Traditional coagulation parameters were similar between groups 1 and 2. Only D-dimer levels (2,442.11 ng/ml vs. 370 ng/ml, p = 0.03) were significantly higher in COVID-19 pneumonia. In addition, we concluded an increase in D-dimer levels during the hospital stay (T 0 = 2,442.11 ng/ml vs. T 10 = 8,564.39 ng/ml, p=0.0001). Finally, blood thromboelastometry profiles were consistent with hypercoagulability characterized by higher clot strength (MCF or maximum clot firmness close to upper limit in FIBTEM test, MCF median value= 25.9 mm). Clotting time presented normal results in INTEM (163.41 s) and EXTEM (68.74 s). No sign of secondary hyperfibrinolysis were found during the study period. In six patients a deep vein thrombosis and in six patients a thromboembolic event. Eighteen patients (43%) died during hospitalization due to coagulopathy produced by SARS-Cov-2 pneumonia.

CONCLUSIONS

The results observed in our study support hypercoagulability in a severe inflammatory state, rather than a disseminated intravascular coagulation (DIC). More research is needed to have a better understanding of the coagulopathy caused by severe COVID-19 pneumonia.

COVID-19

P0498

PREDICTIVE MODEL BASE ON CELL POPULATION DATA FOR 30 DAYS -MORTALITY IN COVID-19

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BACKGROUND-AIM

Leukocyte differential present certain features in SARS-CoV2 infected patients: neutrophilia, lymphopenia and morphology alterations. Cell population data (CPD) are reported as part of leukocyte differential by Sysmex XN analyzers; they are morphometric parameters that characterize neutrophils, lymphocytes and monocytes and classify them according to their volume, granularity and their content in nucleic acids. CPD reflects in numbers the changes in morphology and activation status triggered by infection and can indicate its occurrence and severity. We aimed to evaluate the predictive power of CPDs in the prognosis of COVID-19 in terms of mortality in 30 days.

METHODS

The prospective, observational, multicenter study was conducted in 3 hospitals, including adult patients at admission with the diagnosis of COVID-19 in the period November 2019 - October 2020. These inpatients were warded in general ward or intensive care unit. Complete blood counts were analyzed using Sysmex XN counters. Diagnosis of COVID-19 was made using real-time reverse transcription-polymerase chain reaction. Sociodemographic characteristics and severity of disease were compared using chi-square and non-parametric Wilcoxon tests. The latter test was used to compare CPDs according to vital status in the referral cohort. Subsequently, a logistic regression model was developed in order to determine those CPDs relevant to the prognosis. The area under the ROC curve (AUC) was calculated. Statistical significance was set $p<0.05$.

RESULTS

1333 patients were recruited. The cohort was randomly divided into two groups: referral (791, 59.6%) and validation (542, 40.6%). In the univariate analysis NE-WY 638.1 (Standard Deviation, SD 64.0), LY-WZ 557.4 (SD 137.6), MO-WX of 252.0 (SD 36.7) and MO-WZ 588.8 (SD 104.1) were statistically significant for 30-day mortality. All CPDs except LY-WZ were statistically significant in the logistic regression model. In the validation group this model showed good discrimination AUC 0.722 (95% confidence interval 0.68-0.76).

CONCLUSIONS

Leukocyte differential and CPDs could be useful in the evaluation of patients at admission to predict the severity of COVID-19 infection.

COVID-19

P0499

REDEFINING THE THRESHOLD VALUE OF HYPERSENSITIVE CARDIAC TROPONIN I IN SHORT-TERM COVID-19 MORTALITY PREDICTION

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BACKGROUND-AIM

Elevation of hypersensitive cardiac troponin I (hsTrp) has been proposed as a prognostic marker for COVID-19. The aim of this study was to define the threshold at which the risk of short-term mortality is significantly increased.

METHODS

This is a single-center cohort study, including 158 subjects with severe forms of COVID-19, admitted to the medical reanimation service of the university hospital of Blida. The hsTrpI was determined by fluorescent immuno-enzymatic method. The ROC curve was used to define the cut-off. The association with in-hospital mortality was assessed by the Kaplan-Meier method and Cox proportional regression.

RESULTS

The prevalence of elevated hsTrpI above the 99th percentile was 38.6%, the mortality rate was 39.9%. The newly defined cut-off was 10.8ng/l, which was below the 99th percentile threshold. This new cut-off improves the sensitivity of hsTrpI in early mortality prediction by 18% (73% Vs. 55%). The hsTrpI was significantly associated with in-hospital mortality (pLog-Rank<0.0001). The hazard ratio was 2.6, 95% CI [1.4-4.8], p=0.002).

CONCLUSIONS

High hsTrpI levels were associated with a higher risk of early mortality, even below the 99th percentile; therefore it would be reasonable to introduce systematic measurement of hsTrpI in the admission evaluation of COVID-19 subjects in order to improve their care.

COVID-19

P0500

COMPARISON AND HARMONIZATION OF DIFFERENT SEMI-AUTOMATED AND AUTOMATED QRT-PCR ASSAYS IN THE ASSESSMENT OF SARS-COV-2

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BACKGROUND-AIM

In SARS-CoV-2 diagnostics, cycle threshold (Ct) values from quantitative reverse transcriptase-polymerase chain reactions (qRT-PCR) semi-quantitatively estimate patient´s viral load. However, relevant analytical differences between qRT-PCR assays are often neglected. This study was designed (i) to identify such differences between five commonly used assays and (ii) to demonstrate a straightforward strategy to harmonize them.

METHODS

qRT-PCRs for SARS-CoV-2 were carried out in 55 oropharyngeal swab samples collected at the emergency department of the University Medical Center Göttingen, using three fully automated (Alinity m, cobas®6800 and GeneXpert) and two semi-automated (genesig® and RIDA®GENE) assays.

RESULTS

Qualitative results (positive or negative) showed excellent comparability between fully automated assays, but not between Alinity m and semi-automated methods. Ct values, however, significantly varied between all five methods (all $p<0.01$), with median values ranging from 22.76 (Alinity m) to 30.89 (RIDA®GENE) and 31.50 (genesig®) indicating lowest sensitivity for semi-automated methods. Passing-Bablok analysis further revealed systemic biases between the assays. Assay-specific viral load concentration calculations - based on generated individual standard curves - resulted in much better comparability between the different assays. Applying these calculations, significant changes between methods were no longer detectable with median virus concentrations ranging from 5.10*105 (Alinity m) to 1.70*106 (cobas®6800) copies/mL.

CONCLUSIONS

This study highlights relevant analytical differences between five SARS-CoV-2 qRT-PCR assays, leading to divergent decisions about mandatory isolation of infected individuals. Secondly, we propose a strategy to harmonize qRT-PCR assays in order to achieve better comparability. Our findings are of particular interest for laboratories utilizing different assays.

COVID-19

P0501

CIRCULATING MYELOID-DERIVED SUPPRESSOR CELLS MAY BE A USEFUL BIOMARKER IN THE FOLLOW-UP OF UNVACCINATED COVID-19 PATIENTS AFTER HOSPITALIZATION

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BACKGROUND-AIM

SARS-CoV-2 infection is the cause of the disease named COVID-19, which has been a major public health challenge worldwide. Differences in the severity, complications and outcomes of the COVID-19 are intriguing and, even though co-morbidities may play a relevant role, COVID-19 patients with similar baseline clinical conditions may have very different evolution. Myeloid-derived suppressor cells (MDSCs) have been previously found to be recruited by the SARS-CoV-2 infection and may be a marker of clinical evolution in these patients. We have studied COVID-19 patients admitted in the hospital before the vaccination program started in the general population, to measure MDSCs and lymphocyte subpopulations at admission and one week after, to assess the possible association with deleterious outcomes (dead or Intensive Care Unit -ICU- admission)

METHODS

We analyzed MDSCs and lymphocyte subpopulations by flow cytometry in peripheral blood from 90 consecutive COVID-19 patients admitted in the hospital.

RESULTS

In the 72 patients discharged from the hospital, there were significant decreases in the monocytic and total MDSC populations measured in peripheral blood after one week but, most importantly, the number of MDSCs (total and both monocytic and granulocytic subsets) were much higher in the 18 patients with deleterious outcome. In addition, there was a lower number of circulating activated T lymphocytes in the group of patients with a deleterious evolution.

CONCLUSIONS

Data suggest that MDSCs may participate in the pathophysiology of COVID-19 impairing T-lymphocyte activation, although further studies are needed to confirm this hypothesis. Nevertheless, the number of circulating MDSCs may be a good marker of evolution in the follow-up of the patients admitted in the hospital with the diagnosis of COVID-19.

COVID-19

P0502

SARS-COV-2 ANTIBODY RESPONSE AFTER A THIRD DOSE OF BNT162B2 IN HEALTHCARE WORKERS AT HEALTH PROMOTION CENTERS

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BACKGROUND-AIM

Vaccines against COVID-19 offer substantial protection against COVID-19, but antibody titers wane after receiving two doses of vaccine. Thus, a third dose has been recommended. The aim of this study was to determine the antibody response and to evaluate the persistence of the immunogenicity after a third dose of BNT162b2 (BNT) in homologous [ChAdOx1 (AZ)/AZ, BNT/BNT, Moderna-mRNA-1273 (M)/M] and heterologous (AZ/BNT) vaccinations of two doses in different vaccination schemes.

METHODS

In this prospective observational study, consenting healthcar workers (HCWs) were recruited from 16 health checkup centers in 13 Korean citis. Three points blood tests, T3-1 (1 month after third dose), T3-3 (3 months after third dose), and T3-5~7 (5~7 months after third dose), were analyzed as the post-third vaccination antibody response. SARS-CoV-2 antibodies were measured using a chemiluminescence microparticle immunoassay with SARS-CoV-2 IgG II Quant in the ARCHITECT system (Abbott Diagnostics).

RESULTS

Overall, 869 HCWs paricipated in this study (vaccinated with AZ/AZ,25; BNT/BNT, 206; M/M,57; AZ/BNT, 581). The antibody levels were significantly increased after the third vaccine in all groups ($p<0.05$). Those were significantly higher in the M/M and BNT/BNT groups than in AZ/AZ and AZ/BNT groups ($p<0.05$) at T3-1. At T3-3, antibody levels decreased from 29.1% reduction (in BNT/BNT group) to 45.3% reduction (in AZ/AZ group) compared to the antbody levels at T3-1. M/M group had significantly higher mean antibody levels before and after the third vaccnes than the AZ/AZ group ($p<0.05$). However, these differences became less prominent at T3-5~7. There were no participants who had antibodies <50 AU/ml (seronegative) after the third vaccine until T3-3.

CONCLUSIONS

The third vaccine, BNT, induced increased humoral response in various vaccination schemes, which was more prominent in two dose of homologous mRNA vaccines. However, these immunogenicity decreased within three to seven months after third vaccination.

COVID-19

P0503

FIRST-HAND EXPERIENCE FROM THE SECOND PEAK OF THE SARS-COV-2 PANDEMIC – ANTIBODY RESPONSE AFTER ADMINISTRATION OF THE BNT162B2 VACCINE

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BACKGROUND-AIM

Health care workers (HCW) carried significant risks during the phases of the pandemic, with estimates that up to 11% of all samples from this population were positive in the first year of the pandemic, despite use of personal protection. The HCW were the first group of population that were offered access to vaccines. The aim of the present report is to estimate the previous exposure to a sample of HCW that were involved in treating patients with SARS-CoV-2 and to estimate the levels of specific neutralizing antibodies (NAbs) after administration of the BNT162b2 vaccine.

METHODS

The study enrolled 131 HCWs during the second peak of the pandemic that accepted the call for vaccination with the BNT162b2 vaccine. The participants were checked for known past positivity and sickness due to SARS-CoV-2 by checking previous records. The vaccine was administered with two specific doses 28 days apart. HCWs were again checked 6 months afterwards for checking the levels of NAbs. Analysis for neutralizing antibodies (NAbs) was conducted by the CLIA method. Patients with titer of NAbs above 0.3 were considered as patient with sufficient antibody response.

RESULTS

Final sample was consisted of 131 health workers, out of which 85 (64.9%) patients were female. The median age of the sample was 36 years (IQR 32-42). From the whole sample, 32 patients reported previous known SARS-CoV-2 infection (24.4%). Six months after the vaccination, all patients with previous infection achieved NAbs above the threshold value of 0.3 , while two patients from the other group did not reach the above-mentioned value. The median value of the NAbs in the whole sample was 1.56 (IQR 0.42 – 5.73), while patients with previous SARS-CoV-2 infection had median value of 6.45 (IQR 4.16 – 9.03), reaching striking difference when compared to patients without previous infection ($p < 0.001$).

CONCLUSIONS

In a convenience sample consisted of health workers, the immunization with BNT162b2 produced NAbs titer above the threshold value in 98.5% of the participants, six months after the second dose. Participants with previous documented infection had substantially higher titer of NAbs, leaving room for further exploration on the best practice for spacing between the subsequent doses of the vaccine.

COVID-19

P0504

ANTI-N AND ANTI RBD SARS-COV-2 IGG ANTIBODIES SIX MONTHS FOLLOWING TWO DIFFERENT COVID-19 VACCINATION PROTOCOLS

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BACKGROUND-AIM

Coronaviruses are composed of four structural proteins that are a colorful palette of antigens for our immune system to produce antibodies against Spike (S), Envelope (E), Membrane protein (M), and Nucleocapsid (N). While the S antigen was mostly used in different testing platforms as a marker of successful immunization with mRNA and adenoviral vaccines, the N protein can be used to determine viral infection with the SARS-CoV-2 virus.

METHODS

We analyzed the immune response against the Nucleocapsid (N) protein in 185 healthcare workers six months after completing two-dose vaccination series, 139 of which were vaccinated with the PfizerBioNTech vaccine, and 46 were vaccinated with the Sputnik V vaccine. The Elecsys® SARS-CoV-2 N IgG immunoassay was (Roche Diagnostics International Ltd., Rotkreuz, Switzerland.), based on eCLIA method utilizing a recombinant protein in a double-antigen sandwich assay. For the detection of SARS-CoV-2 S-RBD IgG antibodies, the CLIA assay from Snibe was used (Maglumi 800 Snibe Co.,Ltd.).

RESULTS

In total, SARS-CoV-2 N IgG antibodies were detected in 19 participants (10.27%), 13 of them in the PfizerBioNTech group (9.35%), and 6 in the Sputnik V group (13.04%).
There was no statistical significance between the groups, p=0.47. However, elevated SARS-CoV-2 S-RBD IgG antibody titers were detected in 33 (17.8%) six months after completion of the vaccination protocol. The average SARS-CoV-2 S-RBD IgG titer in this group was 258.42±480.44 in comparison to the average titer of 35.72±43.84 in the group without SARS-CoV-2 S-RBD IgG elevation.

CONCLUSIONS

Even though SARS-CoV-2 N IgG antibodies were detected in only 19 participants, we assume that the elevation of SARS-CoV-2 S-RBD IgG in all 33 participants was due to a breakthrough infection with SARS-CoV-2. A Possible explanation for the lack of SARS-CoV-2 N IgG in all of the participants with SARS-CoV-2 S-RBD IgG elevation might be the shorter life span of the (N) antibodies. Another, could be the phenomenon of so-called “original antigenic sin” that makes the immune system “tricked” by the first immune response to a dominant antigen (S antigen in this case), rendering the secondary immune response not very effective in additionally producing antibodies to different viral antigens (such as N antigen).

COVID-19

P0505

CLINICAL SIGNIFICANCE OF TOTAL LEUCOCYTE COUNT, ABSOLUTE LYMPHOCYTE COUNT AND C-REACTIVE PROTEIN CONCENTRATION IN SARS-COV-2 INFECTED PATIENTS

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BACKGROUND-AIM

The course of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection and the incidence of complications is often unpredictable. The aim was to examine the significance of total leucocyte count (WBC), absolute lymphocyte count (#LY), and C-reactive protein (CRP) concentration, in triaging patients for hospitalization.

METHODS

The retrospective study included coronavirus disease 2019 (COVID-19) patients – 299 in-patients and a control group of 150 out-patients. The values at the admission of WBC, #LY, and CRP in the two groups were compared with patients' age, comorbidity with diabetes mellitus (DM), and peripheral blood oxygen saturation (sO2), as well as with the outcome.

RESULTS

The group of in-patients was divided into two subgroups – those who recovered and who died. The median age was 75 (67–83), 63 (50–71), and 48 (40–60) years, in fatal outcome, recovered, and control groups, respectively. DM was detected in 23.9% of in-patients and 6.1% of out-patients. The median sO2 at admission in recovered was 96 (93–98) %, 89 (77–95) % in fatal outcome, and 98 (96–99) % in the control group. The median concentrations of CRP at admission were 44.3 (17.8–79.4) mg/L, 53.7 (21.0–112.2) mg/L, and 7.4 (1.9–20.5) mg/L in the recovered, fatal outcome, and in the control group, respectively. The median WBC was 7.9 (4.4–11.3) $*10^9$/L in the fatal outcome, 5.8 (4.5–7.7) $*10^9$/L in the recovered, and 5.6 (4.5–7.1) $*10^9$/L in the control group. The median #LY in fatal outcome was 0.79 (0.56–1.32) $*10^9$/L, in the recovered 1.08 (0.78–1.56) $*10^9$/L, and in the control group 1.4 (1.1–1.9) $*10^9$/L. All these differences were statistically significant. The values of WBC, #LY, and CRP were statistically significantly correlated with each other, with age and sO2. The significant odds ratios of the influence of examined parameters at admission on the probability of fatal outcome were 5.55 (95% CI 1.36–22.6, p=0.017) for DM, 1.13 (95% CI 1,01–1,26, p=0.040) for WBC, and 0.89 (95% CI 0.82–0.96, p=0.005) for sO2.

CONCLUSIONS

Patients who were triaged for hospitalization had lower #LY and higher CRP values compared to the control group. DM, higher WBC, and lower sO2 on admission were associated with a higher probability of a fatal outcome.

COVID-19

P0506

LIMITED USEFULNESS OF RED BLOOD CELLS PARAMETERS IN THE RISK ASSESSMENT OF COVID-19 PATIENTS

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BACKGROUND-AIM

COVID-19 affected over 650 million people all over the world, becoming a death cause of 6.7 million of them. SARS-CoV-2 infection has different course and results with impairment of respiratory, neurological, renal or cardiovascular system, among others. Severe infection is associated with cytokines storm, endotheliopathy, disseminated intravascular coagulation, shock, finally multiorgan disfunction and death. There are many research that aim to define parameters, which will help to predict fatal outcome of the disease. We aimed to analyze if red blood cells parameters would be helpful to distinguish between COVID-19 patients who are at great risk of death due to infection.

METHODS

In the retrospective analysis results of 300 COVID-19 patients at moderate and severe stage of the disease were included. There were 127 women and 173 men aged 71±15 years old. Among study group 230 patients died and 70 survived hospitalization due to infection of SARS-CoV-2. At the day of admission complete blood count was performed for every individual, using Sysmex XN-2000 hematology analyzer. Statistical analysis was performed using Graph Pad Prism 9.0 with Kolmogorov-Smirnov and chi-square tests. A p value of less than 0.05 was considered significant.

RESULTS

We found that among RBC count, hemoglobin concentration, hematocrit, MCV, MCH, MCHC, RDW, reticulocyte hemoglobin equivalent and nucleated red blood cells only absolute count of NRBC differed between groups of patients who died and survived (0.0 (0.0-20.199 million per microliter) in deceased and 0.0 (0.0-0.027 million per microliter in survivors, p=0.0158). There were no difference between groups when analyzed with chi-square test with regard to RDW, NRBC and Ret-He.

CONCLUSIONS

Severe infection of SARS-CoV-2 may lead to erythropoiesis stimulation which is expressed by increased erythroblasts release to peripheral blood. Evaluation of NRBC absolute count could be useful in primary risk assessment of COVID-19 patients.

COVID-19

P0507

INCLUDING PEPTIDE ENRICHMENT IN A MASS SPECTROMETRY-BASED WORKFLOW FOR THE ABSOLUTE QUANTITATION OF SARS-COV-2

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BACKGROUND-AIM

SARS-CoV-2 particles contain proteins that are biomarkers of a COVID-19 infection that may be detected by bottom-up mass spectrometry (MS). Proteolytic digestion of proteins generates peptides, which can be separated by liquid chromatography (LC). The addition of a peptide enrichment step, such as Stable Isotope Standards and Capture by Anti-Peptide Antibodies (SISCAPA), could increase sample purity. This may reduce background, thereby improving detection limits and reducing LC run-times. Furthermore, SISCAPA could remove any need for sample clean-up and allow the concentration of samples, thereby increasing detection limits.

METHODS

A mass spectrometry-based SARS-CoV-2 absolute peptide quantification method was developed using a Thermo Scientific™ Vanquish™ MD LC system and a Thermo Scientific TSQ Altis™ MD MS. Recombinant SARS-CoV-2 proteins and stable isotope-labeled standards (SISs) were spiked into pooled nasal fluids, before being added to VTM. Samples were then precipitated, centrifuged, and enzymatically digested. The resulting peptides were enriched with peptide-specific SISCAPA antibodies and separated using a 2-minute LC gradient with a Hypersil GOLD™ C18 column (1.9 um, 2.1 x 50 mm), coupled with a single reaction monitoring method. All assays were performed in triplicate and data was analyzed using Thermo Scientific TraceFinder™ LDT software.

RESULTS

Full workflow testing with four peptide-specific antibodies confirmed the antibodies specificity and ability to work in conjunction. Coupling a mass spectrometry-based method with peptide enrichment allowed robust data acquisition with a 2 minute LC run time. Absolute quantitation of targeted peptides was then performed and clear chromatographic separation was observed for each nucleocapsid peptide with minimal variance in retention times observed (± 0.01 minutes). LODs and LOQs were determined to be between 0.25 and 2.5 femtomole on column for the three best performing peptides.

CONCLUSIONS

SISCAPA increased the detection limits meaning that the protein could be detected at lower concentrations or on swabs with less spiked nasal fluid present. The increased sample purity also facilitated the reduction of LC-MS run-times from 4 to 2 minutes.

COVID-19

P0508

IMPACT OF MEASUREMENT UNCERTAINTY OF C-REACTIVE PROTEIN ON PROGNOSTIC CLASSIFICATION OF COVID-19 PATIENTS

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BACKGROUND-AIM

C-reactive protein (CRP) is an acute phase protein and its measurement in serum is widely used to detect inflammation and infection. Currently, all major CRP measuring systems are harmonized through traceability to secondary reference materials ERM-DA472/IFCC and ERM-DA474/IFCC, allowing worldwide application of common clinical cut-offs. During the recent pandemic, we established two new interpretative CRP cut-offs related to different outcomes in hospitalized COVID-19 patients: <141 mg/L to exclude the need for admission in intensive care unit (outcome 1), and >303 mg/L to predict in-hospital death (outcome 2). To successfully implement clinical cut-offs in practice, it is essential that the measurement uncertainty (MU) associated with CRP results of clinical samples (uresult) fulfills the established analytical performance specifications (APS) (3.76% and 5.64% for desirable and minimum quality, respectively), as an excessively high MU may potentially confound the clinical information associated with CRP results. We evaluated the impact of CRP uresult increase on the prognostic classification of a COVID-19 patient cohort.

METHODS

For CRP measurements, we used the Abbott Alinity c measuring system with stated traceability to ERM-DA472/IFCC. After evaluating our laboratory random uncertainty (uRw) according to the ISO/TS 20914:2019, we estimated uresult associated with CRP measurements as $\sqrt{(uERM\text{-}DA472^2 + ucal^2 + uRw^2)}$. The impact of a uresult increase on patient results in relation to the CRP prognostic power was then estimated by determining CRP value ranges for each patient based on specific MU values and assessing related misclassification rates.

RESULTS

In our laboratory, uresult was 4.8%, then fulfilling the minimum APS. On a cohort of 2045 COVID-19 patients, a uresult of 4.8%, 5.8%, 6.8%, and 7.8% led to a potential patient misclassification rate for outcome 1 of 4.8%, 5.8%, 7.3%, and 8.2% (corresponding to 99, 119, 150, and 167 patients), respectively. For outcome 2, the corresponding misclassification rate was of 2.8%, 3.3%, 3.6%, and 4.0% (corresponding to 57, 67, 74, and 81 patients), respectively.

CONCLUSIONS

Monitoring and maintaining CRP uresult as low as possible is crucial for COVID-19 patient care and their correct clinical category allocation.

COVID-19

P0509

SERUM HYALURONIC ACID CONCENTRATION IN PATIENTS WITH COVID-19

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BACKGROUND-AIM

The aim of this study was to evaluate the effect of the SARS-Cov-2 infection on the serum level of hyaluronic acid (HA) in the COVID-19 patients.

METHODS

The study group included 96 patients (39 females and 57 males; mean age: 59.2 years; range: 22-89) with COVID-19. The patients were admitted to the Department of Gastroenterology, Hepatology and Internal Diseases with the Center for Diagnostics and Endoscopic Treatment between November 29 and December 31, 2021. Blood samples were taken twice: on admission (first sample) and after 9 days of hospitalization (second sample). The control group consisted of 45 healthy volunteers (27females and 18 males), aged 22-60 years (mean age 31.7). They were asymptomatic and had a negative test for COVID-19. Hyaluronic acid concentration was measured by the immunochemical method with WAKO reagents.

RESULTS

The median serum HA concentrations were significantly elevated in COVID-19 patients on admission and after hospitalization in comparison to the control group (83.3 vs. 13.7 ng/mL, P<0.001; 67.6 vs. 13.7 ng/mL, P<0.001, respectively). There was no significant difference in HA level before and after hospitalization (P=0.148). HA concentration correlated positively with the severity of COVID-19 (R=0.238, P=0.026). Values of HA in critical patients were higher than those in moderate subjects (281 vs. 57.5 ng/mL, P<0.001). Differences in HA concentration were found in the distribution of the groups of patients according to lung respiratory capacity (H=13.418, P=0.004). The serum HA level increased with degree of lung insufficiency and was significantly higher in the hospitalized patients who required respiratory support in comparison to those not requiring oxygen therapy (417 vs. 50.9 ng/mL, P=0.002), and was close to significant compared to those hospitalized patients who required supplemental oxygen (417 vs. 89.7 ng/mL, P=0.09). Also, HA concentrations were significantly higher in patients with cytokine storm than those without it (187 vs. 56.9 ng/mL, P<0.001).

CONCLUSIONS

The present study indicates that HA can be a marker for early prediction of COVID-19 severity. Changes in serum concentrations of HA may reflect its alterations in ECM (remodelling) of which it is a major component, in the course of COVID-19.

COVID-19

P0510

COVID-19 SEVERITY IN AFRICA INVERSELY CORRELATES TO INTESTINAL PARASITE CO-INFECTIONS

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BACKGROUND-AIM

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection results in a spectrum of clinical presentations. Evidence from Africa indicates that significantly less COVID-19 patients suffer from serious symptoms than in the industrialized world. We and others previously postulated a partial explanation for this phenomenon, being a different, more activated immune system due to parasite infections. Here, we aimed to test this hypothesis by investigating a potential correlation of co-infection with parasites with COVID-19 severity in an endemic area in Africa.

METHODS

Ethiopian COVID-19 patients were enrolled and screened for intestinal parasites, between July 2020 and March 2021. The primary outcome was the proportion of patients with severe COVID-19. SARS-CoV-2 infection was confirmed by RT-PCR on samples obtained from nasopharyngeal swabs, while direct microscopic examination, modified Ritchie concentration and Kato-Katz methods were used to identify parasites and ova from fresh stool sample. Ordinal logistic regression models were used to estimate the association between parasite infection, and COVID-19 severity. Models were adjusted for sex, age, residence, education level, occupation, body mass index, and comorbidities.

RESULTS

A total of 751 SARS-CoV-2 infected patients were enrolled, of whom 284 (37•8%) had intestinal parasitic infection. Only 27/255 (10•6%) severe COVID-19 patients were co-infected with intestinal parasites, while 257/496 (51•8%) non-severe COVID-19 patients appeared parasite positive (p<0.0001). Patients co-infected with parasites had lower odds of developing severe COVID-19, with an adjusted odds ratio (AOR) of 0•14 (95% CI 0•09–0•24; p<0•0001) for all parasites, AOR 0•20 ([95% CI 0•11–0•38]; p<0•0001) for protozoa, and AOR 0•13 ([95% CI 0•07–0•26]; p<0•0001) for helminths. When stratified by species, co-infection with Entamoeba spp., Hymenolopis nana, and Schistosoma mansoni implied lower probability of developing severe COVID-19. There were 11 deaths (1•5%), and all were among patients without parasites (p=0•009).

CONCLUSIONS

Parasite co-infection is associated with a reduced risk of severe COVID-19 in African patients. Parasite-driven immunomodulatory responses may mute hyper-inflammation associated with severe COVID-19

COVID-19

P0511

A LONGITUDINAL ANALYSIS OF HUMORAL AND T CELLULAR RESPONSE AND INFLUENCING FACTORS IN A COHORT OF HEALTHCARE WORKERS: IMPLICATIONS FOR PERSONALIZED SARS-COV-2 VACCINATION STRATEGIES

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BACKGROUND-AIM

SARS-CoV-2 mRNA vaccinations elicit both virus-specific humoral and T-cell responses, but a complex interplay of different influencing factors, such as natural immunity, gender, and age, guarantees host protection.
The present study aims to assess the immune dynamics of humoral, T-cell response, and influencing factors to stratify individual immunization status up to 10 months after Comirnaty-vaccine administration.

METHODS

To this aim, we longitudinally evaluated the magnitude and kinetics of both humoral and T-cell responses by serological tests and enzyme-linked immunospot assay at 5 time points. Furthermore, we compared the kinetics of the two branches of adaptive immunity and we evaluated putative influencing factors collected by an anonymized survey through multiparametric analysis. In details, among 984 healthcare workers evaluated for humoral immunity, 107 individuals were further analyzed to describe SARS-CoV-2-specific T-cell responses. Participants were divided into 4 age groups: <40 and >40 years for men, <48 and >48 years for women. Furthermore, results were segregated according to SARS-CoV-2-specific serostatus at baseline.

RESULTS

The disaggregated evaluation of humoral responses highlighted antibody levels decreased in older subjects. The humoral responses were higher in females than in males ($p=0.002$) and previously virus-exposed subjects compared to naïve subjects ($p<0.001$). The vaccination induced a robust SARS-CoV-2 specific T-cell response at early time points in seronegative subjects compared to baseline levels ($p<0.0001$). However, a contraction was observed 6 months after vaccination in this group ($p<0.01$). On the other hand, the pre-existing specific T-cell response detected in natural seropositive individuals was longer-lasting than the response of the seronegative subjects, decreasing only 10 months after vaccination. Our data suggest that T-cell reactiveness is poorly impacted by sex and age. Of note, SARS-CoV-2-specific T-cell response was not correlated to the humoral response at any time point.

CONCLUSIONS

These findings suggest prospects for rescheduling vaccination strategies by considering individual immunization status, personal characteristics, and the appropriate laboratory tests to portray immunity against SARS-CoV-2 accurately.

COVID-19

P0512

PROCALCITONIN AS A COINFECTION BIOMARKER IN PATIENT WITH COVID-19: A CASE REPPORT

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BACKGROUND-AIM

Procalcitonin (PCT) is the peptide precursor of the hormone calcitonin, which is secreted from the thyroid, lung and intestine.PCT mainly used as a biomarker specific for bacterial infections, is used to guide and monitor antibiotic therapy. While the baseline levels in healthy individuals are undetectable (less than <0.05 ng/ml), during severe infection the level of PCT may rise to over 100 ng/ml. COVID-19 is a viral infection and studies demonstrated that PCT level usually remain normal. The aim of this study is to show that serial PCT measurements may help identifying secondary infection in patient with COVID-19 and help to guide and shorten the antibiotic therapy.

METHODS

A 20 years old pregnant woman was diagnosed with COVID-19 and admitted to hospital due to fever, cough, weariness. On admission, C- Reactive Protein (CRP) was 10.06 mg/dl (normal range <5 mg/dl). The blood culture drawn at the patient admission come back negative. Two days later, her condition deteriorated. She developed sepsis and gave birth by cesarean section. She was transferred to the intensive care units (ICU) and a serial PCT tests were analyzed, as well as serial blood culture drawn.

RESULTS

The first PCT result in ICU was very high (>100 ng/ml). Despite negative blood culture results, antibiotic therapy was started. PCT gradually decreased. Two days later PCT was 52.66 ng/ml. After 5 days' treatment, PCT continued to decrease to 1.37 ng/ml. Two weeks from the beginning of the antibiotics therapy, PCT returned to a normal range (PCT was 0.12ng/ml), the general patient condition improved, antibiotic therapy was stopped and the patient transferred to a general ward.

CONCLUSIONS

Even though the validity of PCT needs to be further investigated, in this case, the serial PCT measurement helped to determine co-infection in patient with COVID-19, allow a targeted use of antimicrobials and permitted monitoring the treatment's efficacy.PCT serial measurement also helped the physician in his decision when to stop the antibiotic therapy.

COVID-19

P0513

HEALTH ECONOMIC BURDEN OF LABORATORY TESTING DURING COVID 19 PANDEMIC IN TERTIARY CARE HOSPITAL IN R. MACEDONIA

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BACKGROUND-AIM

The coronavirus disease 2019 (COVID-19) pandemic is the defining global health crisis of our time placing a massive economic burden on health systems worldwide. From an economic perspective, the spread of COVID-19, the ever-increasing number of patients, and the complications of the disease have imposed high direct medical and indirect costs on patients, the health system, and the government. Republic of Macedonia is one of the numerous countries that have been economically affected by this pandemic. The aim of this study is to analyze the costs incurred in a laboratory in a tertiary care hospital over a three-year period during the Covid-19 pandemic, compared to the three-year period before the pandemic.

METHODS

Materials and methods: This is a retrospective study, conducted in University clinic for Gynecology and obstetrics, R. Macedonia. We study the total laboratory investigation done in three years; before the Covid -19 era (1-3-2018 to 1-3-2019) and two consecutive years (1-3-2020 to 1-3-2021 and 1-3-2021 to 1-3-2022) to exclude the effect of COVID-19 pandemic on the results.

RESULTS

Results: The total number of laboratory tests ordered in three (pre and during COVID-19 pandemic) years show a significant increment in the last year (256392, 266352, and 448701) respectively. Test ordering index, in the same way, shows significant increments over years (0.65, 0.64 and 11.2) respectively. Biochemistry investigations constitute the largest proportion (50%) of all investigations that have been ordered last year. CBC is the most commonly ordered single test, in outpatient clinics.

CONCLUSIONS

Conclusion: For years, laboratory testing has been overused, but during the pandemic, it was done in a big way. Full laboratory analytics is ranked as a high-cost service, so a need for deep analysis and well-defined test ordering rules is felt as a necessity to reduce unnecessary costs in healthcare.

COVID-19

P0514

CT-VALUE DIFFERENCES BETWEEN TWO COMMERCIAL SARS-COV-2 PCR ASSAYS

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BACKGROUND-AIM

The implementation of cycle-threshold (Ct)-values in the clinical management of SARS-CoV-2-positive patients is still under debate. Ct-values are generally not approved as quantitative markers for the clinical decision process. Objections against their use include the lacking standardization and comparability between different PCR test systems. Therefore, the aim of this study was the comparison of the Ct-values provided by two commercially available PCR systems used in our laboratory.

METHODS

Nasopharyngeal swab specimens from 154 SARS-CoV-2 positive patients were collected and stored at -80°C. After one freeze-thaw cycle they were tested for SARS-CoV-2 in parallel on the GeneXpert (Cepheid) and the NeuMoDx (Qiagen). The Ct-values were obtained for each tested PCR gene target (GeneXpert: N2- and E-genes; NeuMoDx: N- and Nsp-genes).

RESULTS

With both PCR systems statistically significant differences were observed between all pairwise comparisons of the different gene targets (all p-values <0.01). Ct-values obtained from the GeneXpert were higher than from the NeuMoDx. The GeneXpert platform showed higher Ct-values for the N2 gene target compared to the E gene target. The NeuMoDX showed higher Ct-values for the Nsp2-target compared to the N-target. The highest difference was observed between the N2 gene target on the GeneXpert and the N gene target on the NeuMoDx (mean absolute difference 3.6, 95% limits of agreement 1.0 – 6.5). Between all gene targets, statistically significant correlations were observed (all p-values < 0.01).

CONCLUSIONS

Ct-values for SARS-CoV-2 differ distinctly between various PCR assays. Hence, they cannot replace actual quantification and standardization procedures.

COVID-19

P0515

DOES COVID-19 INFECTION CAUSE AN INCREASED RISK OF DEVELOPING PLASMA CELL DYSCRASIA?

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BACKGROUND-AIM

Introduction: During an infectious event, a large humoral immune response occurs on the part of B cells caused by the massive release of proinflammatory cytokines that act on plasma cell maturation and secretion. Stressed plasma cells produce large quantities of antibodies which can cause the appearance of monoclonal components (MC) in the serum detectable by serum protein electrophoresis (SPEP). This study aims to investigate whether there is a significant relationship between SARS-CoV-2 infection and MC development in hospitalized patients (pt), compared to a control group, who had medical history suggestive of plasma cell dyscrasia in the 6 months prior to infection.

METHODS

Methods: 786 pt admitted to the main hospitals of the Province of Modena were included in our study. Pt were divided into the study group with a positive nasopharyngeal swab for Sars-CoV-2 by RT-PCR(COV+) and the control group with a negative swab (COV-). Subsequent SPEP was performed during hospitalization.

RESULTS

Results: Of the 786 pt enrolled, 182 (23.2%) were COV+ and 604 (76.8%) were COV-.
During hospitalization on 27 (14.8%) pt COV+ were found to have MC by SPEP and 67 (11.1%) pt COV- had the same finding. The most common immunoglobulin (Ig) isotype in both groups was IgG-k. The Chi-square analysis did not evidence a statistically significant difference between COV+ and COV- pt and the MC development (p-value=0.173). Applying the logistic regression model, with age and gender as independent variables, no statistical significance was reached (p-values 0.264 and 0.496, respectively).
Applying Cox regression, the risk of MC remaining in the COV+ group at follow-up is lower than in the COV- group (HR=0.591, p=0.05).

CONCLUSIONS

Conclusions: Our data show that MCs that develop in COV+ pt are transient (8 months on average) and even have a lower risk of persisting the MC at follow-up than in COV- pt.
This transience confirms that the appearance of MC during infection is due to hyperstimulation of the immune system with the resulting loss of regulatory mechanisms to eliminate B-cell clones and dysregulated antibody production, as also occurs for other viral infections.
Further longitudinal clinical and biological studies are needed to better understand how viruses affect the immune system.

COVID-19

P0516

CLINICAL EVALUATION OF ANTIGEN HOME TEST USING SURFACE-ENHANCED RAMAN SPECTROSCOPY AND STACKING PAD FOR SARS-COV-2 SCREENING WITH NASAL AND SALIVARY SWAB SAMPLES

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BACKGROUND-AIM

This prospective study aimed to evaluate the performance of the InstaView COVID-19 (coronavirus diseases 2019) Antigen Home Test (InstaView AHT) which detects severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigens samples collected by the self. In this test kit, surface-enhanced Raman spectroscopy was used, a stacking pad was inserted, and nasal swab and salivary swab samples were used simultaneously to improve performance.

METHODS

A total of 91 reverse transcription polymerase chain reaction (RT-PCR) positive patients and 485 RT-PCR negative controls were enrolled in this study. The participants without any prior training were recruited and performed the sample collection, testing, and interpretation of the results by themselves. The clinical performance of the InstaView AHT was compared to that of RT-PCR using nasopharyngeal samples.

RESULTS

Of the 91 PCR-positive patients, 85 had positive InstaView AHT results. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the InstaView AHT were 93.4% (95% confidence interval [CI]: 86.2–97.5), 99.4% (95% CI: 98.2–99.9), 96.6% (95% CI: 90.2–98.8) and 98.8% (95% CI: 97.4–99.3), respectively. The sensitivity of the InstaView AHT was above 90% for all samples obtained from patients with Ct ≤ 20, 20 < Ct ≤ 25, and 25 < Ct ≤ 30 (100%, 95.1%, and 92.0%, respectively); however, for patients with 30 < Ct, the sensitivity of the InstaView AHT decreased to 75.0% (6/8). The onset of symptoms in all RT-PCR-positive patients was within 5 days. There was no difference in sensitivity according to the duration from symptom onset to confirmation (93.6% for 1–2 days and 93.2% for 3–5 days).

CONCLUSIONS

The InstaView AHT can be used as an alternative to RT-PCR testing because of its relatively high sensitivity and specificity, especially when SARS-CoV-2 prevalence is high, and the availability of RT-PCR testing is very limited.

COVID-19

P0517

THYROID FUNCTION ASSOCIATION WITH D-DIMER LEVELS IN PATIENTS HOSPITALIZED WITH COVID-19: A PILOT STUDY

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BACKGROUND-AIM

The thyroid gland is one of the numerous organs whose functions appear to be distorted by COVID-19, with the exact underlying pathophysiologic mechanisms having yet to be fully understood. Thyroid function has been studied in relation to COVID-19 severity with conflicting results, despite the evidence pointing towards adverse prognosis in patients with lower thyrotropin (TSH) levels. This study aimed to evaluate the association between TSH and D-dimer (D-d) levels in patients admitted with COVID-19.

METHODS

The electronic records of 110 patients admitted to a Greek tertiary public general hospital in Athens from December 2021 to February 2022 were reviewed retrospectively. The files were chosen randomly, based on the availability of both TSH and D-d results upon admission. D-d levels after one week were also included in the analysis. Patients with known history or TSH levels indicative of pre-existing thyroid disease were excluded. Statistical analyses were executed by IBM SPSS 20.0.

RESULTS

Upon admission, mean TSH and D-d were 1.023 mIU/L and 1744.3 ng/mL respectively and did not correlate with each other, nor with patient hospitalization length. Nevertheless, admission TSH levels were significantly lower in patients with increased D-d levels one week later versus those whose levels remained stable or decreased (p=0.045, Independent samples T test). TSH levels differed significantly between patients <50 and 50-80 years old, whereas D-d between those 50-80 and >80 years old [p=0.02 (1.233/0.787 mIU/L και p=0.000 (334.2/1932.8 ng/mL), Independent samples T test].

CONCLUSIONS

Although TSH levels have been associated with prognostic and severity markers in COVID-19, in our study they did not correlate with those of D-d upon admission, nor with patient hospitalization length. Interestingly though, lower TSH was associated with a subsequent D-d increase, suggesting a link between the hormone and the progression of the infection. As the present study was designed as a pilot analysis of data collected from an electronic medical database, further clinical studies evaluating large number of patients and including more critical points should be planned.

COVID-19

P0518

BIOMARKERS PREDICTING THE 30 DAY MORTALITY OF PATIENTS WHO UNDERWENT ELECTIVE SURGERY AND WERE INFECTED WITH SARS COV 2 DURING THE POST OPERATIVE PERIOD: A RETROSPECTIVE STUDY.

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BACKGROUND-AIM

The coronavirus disease 2019 (COVID-19) pandemic is a significant global concern that has had major implications for the healthcare system. Patients with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) undergoing elective or emergency surgical procedures have a substantial risk of mortality and peri-operative complications. The present study aimed to describe the characteristics of patients who underwent elective surgery and developed nosocomial SARS-CoV-2 infection post-surgery.

METHODS

Patients who underwent thoracic, upper and lower abdominal or peripheral elective surgery with a polymerase chain reaction diagnosis of COVID-19, at 3-7 days after the surgery, were enrolled in the present retrospective study. Demographics, vaccination status against SARS-CoV-2, Charlson comorbidity index (CCI) and laboratory data were recorded upon admission to the hospital unit.

RESULTS

In total, 116 subjects (80 males, 36 females; mean age, 67.31±16.83 years) fulfilling the inclusion criteria were identified. Among the 116 participants, 14 (12.1%) were intubated. From the 116 individuals analyzed, 84 were alive after 30 days (survivors), and 32 had succumbed to the disease (non-survivors). The mortality rate was 27.6% (32/116). The non-survivors had an older age and a higher CCI score. At the evaluation upon admission to the hospital unit, the survivors presented with higher serum albumin levels and a higher number of blood lymphocytes. In addition, the survivors exhibited lower levels of lactate dehydrogenase, aspartate aminotransferase, alkaline phosphatase (ALP) and C-reactive protein (CRP), as well as a higher neutrophil to lymphocyte ratio (NLR) and CRP to albumin ratio (CAR) ($P<0.05$). The patients that were intubated had higher levels of gamma glutamyl-transferase (GGT), ALP and ferritin, as well as a higher NLR and platelet to lymphocyte ratio upon admission to the hospital unit ($P<0.05$). According to the Cox proportional hazards multivariate regression analysis, the only independent predictors of mortality and intubation were ALP and GGT upon admission, respectively ($P<0.05$).

CONCLUSIONS

On the whole, the findings of the present study suggest that more stringent guidelines are required in order to prevent infection during the post-operative period.

COVID-19

P0519

HYPERFERRITINEMIA IN COVID-19: WHEN AND WHY DOES FERROPTOSIS DEVELOP IN COVID-19?

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BACKGROUND-AIM

Ferritin in COVID-19 is a positive reactant of the acute phase and it protects the organism from the virus by sequestration of iron, simultaneously minimising the oxidative stress. In hyperinflammation, the cytokine storm causes a system dysfunction of the iron metabolism, leading to an intracellular overload with iron and ferritin, thus promoting ferroptosis. Ferroptosis, a cell death triggered by iron accumulation and lipid peroxidation, can emphasise inflammation. Nuclear receptor coactivator 4 (NCOA4) has a vital role in the intracellular homeostasis of iron. The increased amount of free iron induces the formation of parafibrin and hypercoagulability. The aim of this study was to analyze if there is a correlation between the values of ferritin, CRP and D-dimer in hospitalized COVID-19 patients and whether ferritin is a predictor of disease severity.

METHODS

The retrospective study involves 143 COVID-19 patients, 66.4% men and 33.6% women, hospitalized at the COVID hospital of the Health Centre in Vranje (Serbia). Patients were divided into two groups depending of disease severity: 90 examinees with a mild and moderate illness, and 53 with a severe and critical illness. Ferritin and CRP were analyzed on an Alinity ci-Abbott analyzer, D-dimer on a Sysmex CA-1500 System.

RESULTS

Pearson correlation analysis confirmed a high positive correlation of ferritin with the CRP values ($r=0.648$) and D-dimer ($r=0.528$). A multiple regressive analysis resulted in a statistically significant model ($p<0.0005$; $F=44.379$), that can predict ferritin values. The most important predictor for ferritin were values of CRP ($\beta=0.537$), then D-dimer values ($\beta=0.273$), which confirms a significant inflammatory reaction. Pearson coefficient proved a high positive correlation between ferritin and disease severity, more emphasized for men ($r=0.826$) than for women ($r=0.706$). Independent samples t-Test presented that ferritin value is significantly higher ($t=12.399$; $p<0.0005$) in patients with severe/critical than mild/moderate COVID-19.

CONCLUSIONS

Hypeferritinemia correlates with a disease severity and it's an important predictive biomarker in COVID-19. Hyperferritinemia is an immunomodulator in the pathogenesis of COVID-19. Ferroptosis is a possible mechanism of multiorgan dysfunction in severe forms of COVID-19.

COVID-19

P0520

CORRELATION OF PYROPTOSIS AND LACTATE DEHYDROGENASE ACTIVITY IN COVID-19 PATIENTS

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BACKGROUND-AIM

Pyroptosis is a inflammatory form of lytic programmed cell death that depends on caspase-1 activation. Virus Sars Cov 2 activates NLRP3 inflammasome. These inflammasome activates caspase-1, which leads to the perforating protein gasdermin D lysis. The N-terminus of gasdermin D is then able to interact with the cell membrane and this interaction results in a formation of pores that causes swelling cell, cell membrane rupture and cell lysis. During cell lysis, the cytoplasmic enzyme lactate dehydrogenase (LDH) is released. The fact that the level of LDH in patients with a severe clinical form of Covid-19 is increased suggests that pyroptosis may be one of the key mechanisms in the pathogenesis of Covid-19. The aim of this study was to determine the diagnostic and prognostic value of the initial LDH levels in Covid 19 patients with a severe / moderate clinical form.

METHODS

A total of 100 patients with moderate Covid 19 who were hospitalized in Healt Center Vranje (Serbia) and 50 patients with a severe Covid 19 who required treatment in the intensive care unit (ICU) were analyzed. LDH values were done within 24 hours of admission on a clinical chemistry system Abbott Alinity c.

RESULTS

Pearson's correlation analysis confirms that patients who had higher LDH values on admission were hospitalized longer ($r=0.517$). LDH mean values in patients who required ICU treatment (489.53 ± 116.79) versus LDH mean values in hospitalized patients (283.30 ± 56.99) indicates that patients who needed ICU treatment showed a statistically significant higher LDH levels ($t=11.804$ $p<0.0005$). Patients who had higher LDH values on admission to the hospital required treatment in the ICU ($r=0.767$). Initial LDH value was the most significant predictor ($\beta=0.774$ $p<0.0005$) of treatment in ICU and the need for mechanical ventilation.

CONCLUSIONS

LDH shows a correlation with the length of hospitalization, indicating the severity of lung damage and reflecting the severity of the disease. LDH also correlates with the need for ICU treatment, so LDH can be a good prognostic biomarker of respiratory insufficiency associated with Covid 19. The initial level of LDH enables an early assessment of disease aggressiveness and allows the selection of patients who are candidates for aggressive supportive therapy or mechanical ventilation.

COVID-19

P0521

CIRCULATION OF INFLUENZA VIRUS AMONG PATIENTS OF IBN SINA UNIVERSITY HOSPITAL CENTER (RABAT, MOROCCO) DURING THE COVID-19 PANDEMIC.

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BACKGROUND-AIM

Influenza viruses typically circulate in the temperate climates of the northern hemisphere from late fall through early spring and constitute a considerable burden on population health and healthcare systems. The emergence of the SARS-CoV-2 in late 2019 had an immense impact on the circulation of influenza viruses worldwide.
The aim of our study is to determine the prevalence of influenza virus infection in hospitalized patients for acute respiratory distress syndrome (ARDS) during COVID-19 pandemic in our Hospital and to compare their distribution between adults and children.

METHODS

It's a cross-sectional retrospective study included all patients hospitalized for ARDS at the Ibn Sina University Hospital Center in Rabat between December 2020 and February 2022 for whom the diagnosis of influenza infection was made by the FilmArray® Respiratory Panel 2 plus (RP2plus) at the Central Laboratory of Virology of the same Center.

RESULTS

We diagnosed Influenza virus infection in 6.5% (69/1064) of patients. The Influenza virus presented a seasonal peak during the winter season 2021 precisely on December 2021 (75%, 52/69) and the frequency was significantly higher in the pediatric population: 64% (n=44) versus 36% (n= 25) in adults (p= 0.013). During this season, influenza A (H1N1) virus infections were the most frequent (81%) and 64% of A H1N1 cases were detected in respiratory samples taken from infants aged 0-2 years, while 85% of H3N2 cases were isolated in respiratory samples from patients over 2 years of age (p = 0.01). Multiple viral infections were identified in 36% of cases, especially in children with Human Rhinovirus/enterovirus (10%), parainfluenza virus 3 (10%), respiratory syncytial virus (7%), Adenovirus (6%), human metapneumovirus (6%) and SARS-CoV-2 (6%).

CONCLUSIONS

In our institution, we observed the absence of detection of the influenza virus from December 2020 to October 2021 and a peak in December 2021 mainly in children, this is probably explained by general prevention measures to prevent the spread of SARS-CoV-2 and the initial pandemic spread of SARS-CoV-2.

COVID-19

P0522

INCREASED DETECTION OF ECHOVIRUS 6-ASSOCIATED MENINGITIS IN PATIENTS HOSPITALIZED DURING THE COVID-19 PANDEMIC, ISRAEL 2021-2022

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BACKGROUND-AIM

Outbreaks of enteroviral meningitis occur periodically and may lead to hospitalizations and severe disease. Our objective was to analyze and describe the meningitis outbreak in patients hospitalized in 2021-2022 during the COVID-19 pandemic.

METHODS

Cerebrospinal fluid (CSF) samples were collected from 1,846 patients hospitalized at Sheba Medical Center in Israel due to symptoms characteristic of aseptic meningitis. Enterovirus was detected using reverse Real-Time transcription-PCR assay and sequenced with Sanger sequencing method. A phylogenetic tree was then constructed using MEGA software.

RESULTS

In December 2021, before the emergence of the SARS-CoV-2 omicron variant, an off-season increase in enterovirus (EV) cases was observed among patients hospitalized with meningitis. One month later, Enterovirus rates decreased by 66% during the omicron wave and then increased rapidly (+78% comparing to February) after a decline in COVID-19 (March 2022). Sequencing of the Enterovirus-positive samples showed a dominance of echovirus 6 (E-6) (29%) %) before and after the Omicron wave. Phylogenetic analysis found all 29 samples are very similar and clustered in the E-6 C1 subtype. The main E-6 symptoms observed were fever and headache, along with vomiting and neck stiffness. The median patient age was 25 years, with a broad range (0-60 years).

CONCLUSIONS

The upsurge in enterovirus cases was observed after the decline of the SARS-CoV-2 omicron wave. The dominant subtype was E-6, which was present before the omicron variant emergence but increased rapidly only after the omicron wave decline. We hypothesize that the omicron wave delayed the rise in E-6-associated meningitis.

COVID-19

P0523

UTILITY OF PRESEPSIN AND INTERFERON-λ3 FOR PREDICTING DISEASE SEVERITY AND CLINICAL OUTCOMES IN HOSPITALIZED COVID-19 PATIENTS

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BACKGROUND-AIM

We explored the utility of novel biomarkers, presepsin and interferon-λ3 (IFN-λ3), for predicting disease severity and clinical outcomes in hospitalized Coronavirus disease 2019 (COVID-19) patients.

METHODS

A total of 55 patients were classified into non-critical (N = 16; low, moderate, high) or critical (N = 39) disease according to the COVID-19 severity index. Disease severity and clinical outcomes (in-hospital mortality, intensive care unit admission, ventilator use, and kidney replacement therapy) were explored using receivers operating characteristic (ROC) curve analysis. Kaplan-Meier method was also used for in-hospital mortality. Presepsin and IFN-λ3 were compared with sequential organ failure assessment (SOFA) score.

RESULTS

SOFA score, presepsin, and IFN-λ3 predicted disease severity comparably (area under the curve [AUC]; 0.67 – 0.73). SOFA score and IFN-λ3 predicted all four clinical outcomes comparably (AUC; 0.68 – 0.88 and 0.66 – 0.74, respectively); presepsin predicted only in-hospital mortality (AUC = 0.74). In Kaplan-Meier method, hazard ratios (95% confidence interval) were 3.6 (1.1 - 12.1) for SOFA score, 6.7 (1.8 - 24.1) for presepsin + IFN-λ3, and 8.5 (6.8 - 24.6) for SOFA score + presepsin + IFN-λ3. In the eldery (≥ 65 years), proportion of in-hospital mortality was significantly higher when both presepsin and IFN-λ3 levels increased than when either one or both biomarker levels did not increase (88.9% vs. 14.3%, $P < 0.001$).

CONCLUSIONS

Presepsin and IFN-λ3 predicted disease severity and clinical outcomes in hospitalized COVID-19 patients. Both biomarkers, alone or added on the clinical assessment could be useful to manage COVID-19 patients, especially in the eldery.

COVID-19

P0524

DYNAMIC CHANGES IN THE RESPIRATORY TRACT AND GUT ANTIBIOTIC RESISTOME OF PATIENTS WITH COVID-19 AND ITS ASSOCIATION WITH DISEASE SEVERITY

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BACKGROUND-AIM

The antibiotic resistome is the collection of all the antibiotic resistance genes (ARGs) present in an individual. Whether an individual's susceptibility to infection and the eventual severity of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is influenced by their respiratory tract antibiotic resistome is unknown.

METHODS

We recruited 66 patients with COVID-19 at three disease stages (admission, progression and recovery) and conducted a metagenome sequencing analysis of 143 sputum and 97 fecal samples obtained from them. Respiratory tract, gut metagenomes, and peripheral blood mononuclear cell (PBMC) transcriptomes are analyzed to compare the gut and respiratory tract ARGs of intensive care unit (ICU) and non-ICU (nICU) patients and determine relationships between ARGs and immune response.

RESULTS

Among the respiratory tract ARGs, we found that Aminoglycoside, Multidrug and Vancomycin are increased in ICU patients compared with nICU patients. In the gut, we found that Multidrug, Vancomycin and Fosmidomycin were increased in ICU patients. Upon further investigation a significantly positive correlation was found between the relative abundance in ARGs (i.e., subtypes of the Aminoglycoside and Tetracycline types) in the respiratory tract and gut. We discovered that the relative abundances of Multidrug were significantly correlated with clinical indices, and there was a significantly positive correlation between ARGs and microbiota in respiratory tract and gut. We found that immune related pathways in PBMC were enhanced, and they were significantly correlated with the relative abundance of Multidrug, Vancomycin and Tetracycline ARGs.

CONCLUSIONS

Cumulatively, our findings provide some of the first insights into the dynamic alterations of respiratory tract and gut antibiotic resistome in the progression of COVID-19 and disease severity. They also provide a better understanding of how this disease affects different cohorts of patients. As such, these findings should contribute to better diagnosis and treatment scenarios.

COVID-19

P0525

INFLUENCE OF THE SARS-COV 2 PANDEMIC ON THE TRANSMISSION OF SYPHILIS IN OUR POPULATION

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BACKGROUND-AIM

Treponema pallidum (TP) is a spirochete bacteria that cause diseases such as syphilis and yaws.
According to the National Epidemiology Center of Spain (NECS), the trend in the last two decades has been increasing year by year.
We propose to study the evolution of syphilis transmission since 2019 to 2022 with the aim of assessing the influence of the COVID-19 pandemic.

METHODS

It consists of a retrospective descriptive study based on the analysis of the diagnostic results of our hospital. If a positive result is obtained by RPR test, samples will be confirmed by ELISA tests (positive EATP ratio>1.1).

RESULTS

A total of 12595 pacients were tested since 01/01/2019 to 01/01/2023, 242 were positive(1,92%). The distribution by years was: 3113 pacients (84 positive(2,69%)) in 2019; 2560 pacients (43 positive(1,67%)) in 2020; 2810 pacients (51 positive(1,81%)) in 2021 and 4112 (64 positive(1,55%)) in 2022.

CONCLUSIONS

The number of tests performed in 2020 was affected by the Covid-19 pandemic because of lockdown measures, showing a drastic drop as well in the rate of positive patients (-1.02%) . In 2021, with less restrictive measures, occurred a little rebound (+0.14%). In 2022, with a situation with hardly any restrictions, we reached a maximum of TP screenings, concluding with a slight downward trend (-0.26%). In our area, the Covid-19 situation meant a decrease in the upward trend of syphilis in recent decades. Statistical analysis of laboratory tests for syphilis allows a better understanding of the diagnostic context of this disease and implement prevention policies and campaigns.

COVID-19

P0526

ASSOCIATION OF VITAMIN D AND CALCIUM METABOLISM RELATED BIOMARKERS WITH SEVERITY AND MORTALITY IN SARS-COV-2 PATIENTS.

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BACKGROUND-AIM

Vitamin D, a fat-soluble vitamin, aids the body in the absorption and retention of calcium and phosphorus. Aside from its major function, it has powerful antibacterial and anti-inflammatory capabilities due to immune-modulatory features. Vitamin D has been demonstrated to decrease the production of pro-inflammatory cytokines such as TNF-alpha and IL-6 through a variety of methods, including down-regulation of viral-induced NF-kB activation. As a result, the current study sought to investigate the association of calcium related biomarkers (Calcium, Phosphorus, Vitamin D and PTH) with the severity and mortality of SARS-CoV-2 patients.

METHODS

A total of 150 individuals infected with COVID-19 and 50 healthy individuals were recruited. Cases were divided based on severity (mild, moderate and severe) and outcome (discharged or deceased). Serum Ca, Phosphorus and ALP were analysed by the direct colourimetric method. Vitamin D and PTH levels were measured using the chemiluminescence immunoassay by DiaSorin XL (DiaSorin, Italy).

RESULTS

The median serum calcium, Phosphorus, ALP, vitamin D and PTH levels in COVID-19 patients were 8.02 mg/dL (IQR, 7.24-8.71), 3.93 mg/dL (IQR, 2.97-4.36), 115 IU/L (IQR, 94-146) 17.2 ng/mL (IQR, 11.6-25.9) and 34.45 (21.5-49.1) pg/mL respectively. All the bone related biomakers were found to be low in cases but significant diffrence was only found in Calcium ($p<0.01$) , Phosphorus $p<0.01$), ALP ($p<0.01$) and PTH ($p<0.01$). On comparing the different severity groups a significant difference was found in Vitamin D ($p<0.002$), ALP ($p<0.00001$) and calcium ($p<0.0001$). Patients with low calcium and vitamin D were found to have a fatal outcome. The multivariable analysis showed that a combination of low calcium and vitamin D with higher age is associated with mortality in COVID-19 patients.

CONCLUSIONS

Serum calcium and Vitamin D were associated with the clinical severity and prognosis of patients with COVID-19.

COVID-19

P0527

FACTORS AFFECTING THE PROGRESSION OF CHRONIC CORONARY SYNDROMES AFTER COVID-19

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BACKGROUND-AIM

there is a bidirectional relationship between cardiovascular diseases and infection caused by coronavirus, however, the mechanisms of mutual influence have not been established, which determined the purpose of the study: to identify factors affecting the progression of chronic coronary syndromes (CCS) after Covid.

METHODS

We studied 103 patients with CCS: group I (67 people) - had verified Covid, group II (36 people) - who did not have Covid. Test I was performed in the pre-Covid period, Test II - within 1-3 months after Covid. We performed: echocardiography (EchoCG) - using the Vivid-7, computed tomographic angiography (CTA) of the coronary arteries (CA) using the Siemens Somatom Force, cardiac magnetic resonance imaging (MRI) - using a high-field magnetic - Siemens Magneto Aera resonance tomograph. Laboratory tests: a complete blood count, determination of C-reactive protein (CRP), cardiac troponin and coagulograma.

RESULTS

According to EchoCG data, in patients of group I, post-systolic wave PSm, systolic pressure in the pulmonary artery (PAP) (p=0.04), right atrial volume (RA) (p=0.017) increased significantly after Covid, diastolic function of the pancreas worsened significantly. No negative dynamics of EcoCG was detected in group II. In group I, at all stages, we found lower number of egmented neutrophils and platelets, also - higher erythrocyte sedimentation rate (ESR), higher levels of troponin and CRP compared to group II were detected. The dynamics of the hemostasis system was ambiguous which requires further research.
We revealed a significantly greater increase in the degree of coronary atherosclerosis in patients group I with CCCS after Covid compared to those who did not have the disease. According to MRI data in group I, during test II, there was a deterioration in systolic and diastolic function of the left ventricle in comparison with the initial level. There were no signs of myocarditis.

CONCLUSIONS

factors influencing the progression of CCS after Covid were: levels of CRP, cardiac troponin, D-dimer that remained elevated for >1 month, accelerated ESR, which contributed to the progression of atherosclerosis of the coronary arteries, deterioration of the structural and functional characteristics of the myocardium.

COVID-19

P0528

DOES RH NEGATIVITY PREDISPOSE TO MILDER COVID-19 COURSE? A PRELIMINARY STUDY.

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BACKGROUND-AIM

Infection with the SARS-CoV-2 virus can lead to the development of COVID-19. Currently, more than 180 million people worldwide have been diagnosed with coronavirus infection, of which nearly 4 million have died from the severe course of the disease. Recent reports suggest that patients with blood group A are most at risk of developing COVID-19, and people with natural anti-A antibodies (especially those with blood type 0) have a milder course of the disease.
The aim of this study was to assess the humoral response to infection with SARS-CoV-2 depending on the patient's blood type.

METHODS

The study group consisted of 147 patients with confirmed previous COVID-19 (convalescents) and 147 individuals who declared no previous infection with SARS-CoV-2. All enrolled subjects were blood donors registered at Regional Blood Center. The titer of SARS-CoV-2 anti-nucleocapsid antibodies was determined in the serum of the patients using Elecsys Anti-SARS-CoV-2 test. The blood group was determined by a manual method using anti-A, anti-B and anti-D monoclonal sera and A, B and 0 standard red blood cells.

RESULTS

Basing on anti-SARS-CoV-2 detection 68 people who denied contact with SARS-CoV-2 had previous asymptomatic infection. In the group of convalescents patients with A blood type dominated (61 0Rh+, 20 0Rh-, 68 ARh+, 14 ARh-, 29 BRh+, 9 BRh-, 11 ABRh+, 3 ABRh-) and in the non-infected group - 0 blood type (23 0Rh+, 6 0Rh-, 19 ARh+, 6 ARh-, 14 BRh +, 5 BRh-, 5 ABRh+, 1 ABRh-) with no statistical significance. Blood types distribution differed between convalescents group who did not know about previous infection and declared convalescents, p=0.0013. People with ARh-, BRh+, BRh-, 0Rh- blood type were more often asymptomatically infected. Moreover, Rh negative subjects more often didn't know about previous infection than these with Rh+, p=0.0009.

CONCLUSIONS

It seems that subjects with Rh negative blood type have significantly milder course of disease than Rh positive.

COVID-19

P0529

EVALUATION OF LYMPHOCYTE SUBSETS IN HOSPITALIZED PATIENTS WITH COVID-19

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BACKGROUND-AIM

COVID-19 caused by SARS-CoV-2 has led to the public health emergency. T-lymphocytes such as CD4+ and CD8+ cells are important in combating infections caused by viruses, promoting both the activation of humoral immunity and ensuring direct cytotoxic action against the virus-infected cells. Changes in peripheral lymphocyte subsets have been associated with COVID-19 severity and mortality. The study aims to evaluate lymphocyte subsets in hospitalized COVID-19 patients in the Latvian population.

METHODS

A retrospective analysis included 119 patients with confirmed COVID-19 infection. Lymphocyte subsets CD4+ and CD8+ were assessed using flow cytometry. Patients were classified into the following groups according to disease severity – mild, moderate, and severe – and according to the in-hospital mortality – survivors and non-survivors. Kruskal–Wallis and Mann–Whitney tests were used to compare the groups. Spearmen's correlation was used for comparison between the above parameters and patients' age. Statistical analysis was performed using MedCalc software.

RESULTS

119 patients were included (53.8% female, 46.2% male) in the study with a median age of 65 (IQR 53-74) years. 16.0% of patients had mild disease, 56.3% - moderate, 27.7% - severe disease. Lymphocyte, CD3+, CD4+, and CD8+ counts were significantly lower in severe disease ($P < 0.001$, for all) and in non-survivors ($P < 0.001$). No statistically significant difference between groups was found in the CD4+/CD8+ ratio. Only CD8+ showed a correlation with age ($r = -0.250$, $P = 0.006$). No statistically significant differences were found in the lymphocyte subsets based on patients' sex.

CONCLUSIONS

The results demonstrated that lymphopenia, decreased CD4+, and CD8+ cell counts are associated with a more severe course of COVID-19 and higher mortality.

COVID-19

P0530

TREND IN RESPIRATORY INFECTIONS FOR THE RESPIRATORY SYNCYTIAL VIRUS (RSV) IN NEW-BORNS AND CHILDREN DURING THE PRE-PANDEMIC PERIOD AND THE COVID-19 PANDEMIC

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BACKGROUND-AIM

In the months of October and November 2021, there was throughout Italy and in our specific case in the area of Lucca and Versilia, a disturbing increase, of SARS-CoV-2 infections and cases of Respiratory Syncytial Virus in new-borns; the latter is a virus that generally circulates in the cold season. The aim of this paper is to compare the cases of RSV infection diagnosed in recent years to the cases recorded during the SARS-CoV-2 pandemic to November 2022. In order to optimise the number of samples to be processed, quickly and at moderate costs, it was decided to routinely introduce from September 2021, in the Molecular Biology sector, a diagnostic platform based on the use of an analytical panel for a correct differential diagnosis of RSV from other pathogens.

METHODS

The study consisted of evaluating the results of requests for RSV diagnosis from 2015 to November 2022. A population of 500 patients was analysed, which included new-borns and children up to 10-12 years old affected by respiratory tract diseases, using molecular biology techniques.

RESULTS

The data obtained show that the number of cases of RSV infection in children during the winter season had a constant trend from 2015 to 2019. From November 2020 to February 2021 there were no cases of RSV respiratory infections. Starting from September 202 there was a resumption of cases of RSV infections in conjunction with an increase in the number of children affected by Covid-19. From January 2022, after a peak in cases of SARS-CoV-2 infection, there has been a decrease in RSV infections. From September 2022 to November 2022, there was no increase of cases of RSV infections in new-borns but on the contrary, there was a trend in respiratory infections comparable to the pre-pandemic period.

CONCLUSIONS

The data that emerged from the study conducted in our laboratory show the onset of an outbreak of RSV in new-borns, starting from September 2021. This incidence is linked to the implementation of rigorous non-pharmacological public health interventions in 2020, aimed at combating Covid-19 infection. The use of the molecular panel made it possible to draw attention to mixed infections in children with similar clinical symptoms, thus identifying the responsible agent and highlighting the most suitable therapeutic path.

COVID-19

P0531

WHOLE GENOME SEQUENCING REVEALS DIVERSIFIED CIRCULATION OF SARS-COV2 IN JEDDAH, SAUDI ARABIA

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BACKGROUND-AIM

Coronavirus Disease designated COVID-19 was declared a global pandemic by World Health Organization (WHO) on March 2020. The emergence of multiple SARS-COV2 variants posed the most significant risk to controlling the pandemic as variants may increase infectivity, treatment, and vaccine effectiveness.
The emergence and continued evolution of the SARS-COV2 Omicron variant and its sub-lineages mandated surveillance of those circulating lineages in Saudi Arabia. Here, we targeted the occurrence of diversified circulation of SARS-COV2 in Saudi Arabia.

METHODS

Whole genome sequencing was performed and reported for 94 SARS-CoV-2 samples from SARS-CoV-2 positive patients (using nasopharyngeal swab samples), in the city of Jeddah Saudi Arabia, that were obtained in the period between February and April 2022, using Illumina CovidSeq sequencing kit. Global phylogenetic analysis was performed to these samples.

RESULTS

Global phylogenetic analysis indicated that all sequenced samples belonged to the Omicron variant of the SARS-CoV-2, BA.2 (n=56) and BA.1.1 (n=20) while other frequencies were BA.2.3 (n=6), BA.1 (n=4), BA.2.40.1 (n=2), BA.1.14 (n=1), BA2.32 (n=1), BA.2.5 (n=1), BA.2.57 (n=1), and BA.2.64 (n=1). Mutational profiles were elucidated and potential implications on transmissibility and immune escape were discussed.

CONCLUSIONS

Continuous surveillance is warranted to assess travel and religious tourism impact on genomic epidemiology of the SARS-CoV-2 in the city of Jeddah, and the greater Saudi Arabia. These results could stand as a starting point for further studies on the functional impact of these mutations and the possible development of booster vaccines.

COVID-19

P0532

PRELIMINARY ASSESSMENT OF SNIBE MAGLUMI SARS-COV-2 ANTIGEN FULLY-AUTOMATED CHEMILUMINESCENT IMMUNOASSAY

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BACKGROUND-AIM

The ongoing coronavirus disease 2019 (COVID-19) pandemic is challenging for many political, social, clinical and even diagnostic reasons. An unprepared and frequently inefficient laboratory response has been evidenced in the past, so that rapid, accurate and relatively inexpensive SARS-CoV-2 antigen tests represent a pillar for surrogating molecular testing in the endemic period. We have hence explored here the clinical performance of the new SNIBE Maglumi SARS-CoV-2 antigen fully-automated chemiluminescent immunoassay (MAG-CLIA).

METHODS

The study population included 100 consecutive subjects (median age 67 years, interquartile range 49-80 years; 48% females) screened for suspected COVID-19 (bearing clinical symptoms within 1 week) at the Laboratory Medicine Service of Pederzoli Hospital (Peschiera del Garda, Verona, Italy) from December 2022 to January 2023. Local routine diagnostic practice consists of collecting a nasopharyngeal swab (Virus swab UTM Copan, Brescia, Italy), which is then analyzed in duplicate with SARS-CoV-2 antigen and molecular tests. SARS-CoV-2 antigen testing was locally performed with MAG-CLIA SARS-CoV-2 Ag, whilst molecular testing was performed with Altona Diagnostics RealStar SARS-CoV-2 RT-PCR Kit (Altona Diagnostics GmbH; Hamburg, Germany).

RESULTS

A significant Spearman's correlation was found between MAG-CLIA SARS-CoV-2 Ag and measurable Ct values of both S ($r = -0.949$; $p<0.001$) and E genes ($r = -0.952$; $p<0.001$). In all samples, the area under the curve (AUC) of MAG-CLIA SARS-CoV-2 Ag was 0.90 (95%CI, 0.84-0.95), with 0.78 sensitivity and 1.00 specificity at the 25 pg/mL manufacturer-declared cut-off, increasing to 0.98 (95%CI, 0.96-1.00) AUC and 0.95 sensitivity (with 0.97 specificity) in high viral load samples (i.e., mean Ct <29.5).

CONCLUSIONS

These preliminary results reveal excellent analytical performance of MAG-CLIA SARS-CoV-2 antigen test, which could hence be regarded as a valid surrogate of molecular testing for especially identifying potential super-spreaders.

COVID-19

P0533

BNT162B2 ELICITED AN EFFICIENT CELL-MEDIATED RESPONSE AGAINST SARS-COV-2 IN FRAGILE PATIENTS

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BACKGROUND-AIM

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination is the standard of care for the prevention of COVID-19 disease, with a positive impact in countries in which vaccination has been promoted. Since the emergence of variants of concern, European Medicines Agency recommended an extra dose of the COVID-19 vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna) for patients with severely weakened immune system and booster doses for subjects with normal immune system to ensure a lasting response. Although vaccination triggers both humoral and cellular immune response, COVID-19 vaccination efficacy is evaluated by measuring antibodies only, whereas adaptive cellular immunity is unexplored. Our aim is to test humoral and cell-mediated response after three doses of BNT162b vaccine in healthy donors compared to two cohort of fragile patients: Common Variable Immunodeficiency (CVID) patients and Kidney Transplant Recipients (KTR) patients.

METHODS

We enrolled 10 health care workers in our department, 17 CVID patients and 17 KTR patients. Blood samples were analysed using LIAISON “SARS-COV-2 S1/S2 IgG” assay from DIASORIN to evaluate humoral immune response and QuantiFERON SARS-CoV-2 assay from Qiagen to evaluate cell-mediated response.

RESULTS

We confirm that in healthy subjects BNT162b third dose had successfully mounted humoral immune response. Conversely, the CVID and KTR group showed a statistically significant reduction of median IgG levels compared to healthy controls (healthy controls: 11750 BAU/ml, Q3-Q1 20425-5172; CVID: 138 BAU/ml, Q3-Q1 1205-12; KTR: 1295 BAU/ml, Q3-Q1 1930-351; $p<0.0001$). Regarding cell-mediated response, we found that IFN-γ release induced by epitopes derived from the S1 and S2 subunits of the Spike protein in stimulated CD4+ and CD8+ T cells was similar among vaccinated controls, CVID and KTR patients (healthy controls: 0.455, Q3-Q1 0.86-0.17; CVID: 0.34, Q3-Q1 0.76-0.21; KTR: 0.09, Q3-Q1 0.68-0; $p>0.99$). Moreover, hybrid immunized patients had more efficient humoral and cell-mediated response compared to only vaccinated patients.

CONCLUSIONS

In conclusion, CVID and KTR patients had an efficient cell-mediated but not humoral response to SARS-CoV-2 vaccine suggesting that the evaluation of T cell responses could be a more sensitive clinical marker of immunization.

COVID-19

P0534

SERUM GALECTIN-3 CONCENTRATION IN PATIENTS WITH COVID-19

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BACKGROUND-AIM

The early biomarker to identify patients with high risk of severe COVID-19 is still needed. Galectin-3 plays many important regulatory roles both in physiological and pathological conditions. It is one of the important mediator of inflammation and fibrogenesis. Therefore, the aim of this study was to assess the changes in serum galectin-3 concentration during COVID-19 course.

METHODS

Serum samples were obtained from 96 patients (57 males and 39 females; aged 22 to 89 years) with COVID-19, admitted to the Department of Gastroenterology, Hepatology and Internal Diseases with Center of Endoscopic Diagnostics and Treatment from 29th November to 31st December 2021. Blood samples were taken twice: on admission - first sample and average after 9 days of hospitalization - second sample. The control group comprised 45 healthy volunteers (18 males and 27 females; aged 22 to 60 years). Galectin-3 concentration was measured by the chemiluminescent microparticle immunoassay.

RESULTS

The serum galectin-3 concentrations were significantly elevated, both in COVID-19 patients on admission (median: 17.05 ng/mL; range: 4.7-89.5) and after 9 days of hospitalization (median: 22.3 ng/mL; range: 5.3-69.6), in comparison to the control group (median: 11.2 ng/mL; range: 3.6-19.4) ($P< 0.001$ for both comparisons). There were no significant differences in serum galectin-3 levels between samples from first and second drawn ($P=0.146$). Galectin-3 concentration in COVID-19 patients with cytokine storm (median: 21.35 ng/mL; range: 9.6-89.5) was significantly higher than those without it (median: 12.9 ng/mL; range: 4.7-66.3) ($P<0.001$). Moreover, there were significant differences in galectin-3 concentrations according to severity of COVID-19 ($H=21.487$, $P<0.001$). Post-hoc analysis showed that galectin-3 concentration in moderate state (median: 12.9 ng/mL; range: 4.7-40.7) was significantly lower than those with severe (median: 22.45 ng/mL; range: 11.5-51.6) and critical state (median: 27.1 ng/mL; range: 9.6-89.5) ($P=0.010$, $P<0.001$; respectively).

CONCLUSIONS

We conclude that COVID-19 affect the serum galectin-3 concentration. We suggest that galectin-3 may be a good early marker and may reflects the severity of COVID-19 course.

COVID-19

P0535

ROTATIONAL THROMBOELASTOMETRY (ROTEM) PROFILING OF EARLY STAGE COVID-19 PATIENTS AND ITS PROGNOSTIC VALUE: A PROSPECTIVE OBSERVATIONAL STUDY

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BACKGROUND-AIM

There is emerging evidence for enhanced blood coagulation in coronavirus 2019 (COVID-19) patients, contributing to mortality. The mechanisms underlying this pro-thrombotic state remain enigmatic and optimal criteria to assess for the highest-risk patients for death remain unclear. The aim of this study was to test whether rotational thromboelastometry (ROTEM) could indicate hypercoagulopathy in an early stage of severe COVID-19 patients and if ROTEM variables eventually in combination with D-dimer could correlate with mortality.

METHODS

The study was designed as a prospective, observational study. We used ROTEM in a single-center cohort of 35 adult critically ill COVID-19 patients admitted to an intermediate ward. Conventional coagulation assays and D-dimer levels were also analyzed.

RESULTS

The median age of the study population was 74 years and 74% were males. The median number of comorbidities and of SOFA score were 3 and 3 respectively. The median duration of symptoms before admission was 5 days. The median D-dimer value was 1.07 mg/L. The median EXTEM Maximum Clot Firmness (MCF) and maximum lysis (ML) values were 71.0 mm and 97% respectively. The overall 30 day-mortality was 40% (14/35). The 30 day-mortality among those patients without risk factor was 0% (0/8) and with the following risk factor was: a) fibrinolysis shutdown, defined as ML < 3.5%: 50% (9/18) (p=0.01); b) fibrinolysis shutdown defined as the criterion (maximum D-dimers—ML EXTEM) > 3.7: 57% (4/7) (p=0.01); c) D-dimer > 1 mg/L 58% (11/19) (p=0.005); d) EXTEM clotting time (CT) > 79sec: 75% (4/5) (p=0.002). In particular, 4 patients with a specific profile characterized by a high D-Dimer value, ROTEM variables of fibrinolysis shutdown, and high EXTEM CT presented an early-onset after-admission death.

CONCLUSIONS

Our results suggest that hypercoagulopathy and fibrinolysis shutdown seems to be present early in patients with severe COVID-19. Moreover, the combination of D-dimer concentrations and ROTEM CT may prove valuable in identifying patients at high risk of death and potentially requiring specific therapies.

COVID-19

P0536

BOOSTER ANTI SARS-COV-2 VACCINATION ACTS MORE ON ELDERLY

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BACKGROUND-AIM

A reliable quantification of the antibody response to the SARS-CoV-2 virus is very relevant to estimate the vaccine protection time and identify those who are still at risk of infection. Anti-spike antibodies have played an essential role in the management of the SARS-CoV-2 pandemic. A descriptive study was carried out on a sample of about 20,000 health workers with the aim of monitoring the antibody response after the first, second and third doses of Pfizer anti SARS-CoV-2 vaccine 30 days after each administration.

METHODS

Two methods were used for the detection of anti-Spike antibodies, authorized by the FDA under the EUA for use by authorized laboratories: Anti SARS-CoV-2S, by Roche Diagnostic on Cobas 6000; the SARS Kit Cov2trimericsIgG, by the company Diasorin performed on LiASON instrumentation.

RESULTS

After the 3rd dose the recovery of the antibody response is greater in subjects without previous SARS-CoV-2 infection. In addition, while the antibody response after the 1st and the 2nd dose is greater in 18-35 years old, lower in 36-55 years old and even less in 56-70 years old, after the 3rd dose is significantly higher in the 56-70 age group.

CONCLUSIONS

Since immunity to infection decreases with time, vaccination booster is important both in subjects with and without previous SARS-CoV-2 infection. The booster acts more on the elderly.

COVID-19

P0537

ROTATIONAL THROMBOELASTOMETRY (ROTEM) PROFILING IN COVID-19 PATIENTS 7 MONTHS AFTER HOSPITAL DISCHARGE: A PRELIMINARY REPORT

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BACKGROUND-AIM

Hypercoagulability and thrombosis significantly impact mortality in coronavirus disease 2019 (COVID-19) patients. Long-term data regarding persisting hypercoagulable state after recovering from the acute phase are currently scarce. Here, we studied the hemostatic status of patients with a resolved COVID-19 infection by means of rotational thromboelastometry (ROTEM).

METHODS

This is a prospective, observational study. In a cohort of 14 critically ill COVID-19 adult patients admitted to an intermediate ward, ROTEM assays were performed at a median of 7 months after discharge.

RESULTS

The median age of the patients was 66 years and 64% were males. On ROTEM maximum clot firmness (MCF) values were significantly higher and clot formation time (CFT) levels were significantly lower at admission compared with follow-up. (FIBTEM MCF: median 26.0 [IQR 25-75%] 24.3-29.5 vs 14.0 [IQR 12.3-15.8], p<0.0001 and INTEM CFT: median 51.0 [IQR 25-75%] 40.8-63.5 vs 64. 0 [IQR 59.5-72.0], p=0.01 respectively at admission and at follow-up). Maximum lysis (ML) values were similar at admission and at follow-up.

CONCLUSIONS

Our results confirm that ROTEM parameters are restored in patients with resolved severe COVID-19 infection. However, a mild hypofibrinolysis seems to persist months after clinical resolution of the infection.

COVID-19

P0538

IMPACT OF AGE, GENDER, POST INFECTION AND POST VACCINATION STATUS ON ANTIBODY RESPONSE IN COVID 19 PATIENTS.

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BACKGROUND-AIM

To evaluate severe acute respiratory syndrome coronavirus-2 spike protein antibodies against coronavirus disease-2019 in post-infection and post-vaccinated individuals

METHODS

The cross-sectional study was conducted from June, 1 to July 31, 2021 at the Rehman Medical Institute, Peshawar, Pakistan, and comprised subjects of either gender in whom immunogenicity was checked 35 days' post-vaccination and 90 days' post-infection. Correlation with age and gender was checked. Specimens were collected and investigated for severe acute respiratory syndrome coronavirus-2 spike protein antibodies by consuming electro-chemiluminescence immunoassay. Data was analyzed using SPSS 23

RESULTS

Of the total 256 patients enrolled, 70(27.34%) were included; 49(69%) males and 21(29.6%) females. The overall mean age was 44±7.75 years. Among 30(42.8%) patients with positive polymerase chain reaction test, the mean time between the positive test and antibody screening was 90±30 days. Among the 40(57.2%) vaccinated individuals, the time between vaccination and antibody screening was 35±9.74 days. Overall, 68(97%) patients revealed robust positive findings to severe acute respiratory syndrome coronavirus-2 spike proteins antibodies >50IU/mL. Male subjects had significantly higher immunogenic response compared to females (p=0.001), and immunogenicity decreased with advancing age (p<0.001). Also, post-vaccinated patients' antibody response was significant compared to post-infection patients' response(p=0.001).

CONCLUSIONS

Majority of the patients had significantly higher antibody titers against severe acute respiratory syndrome coronavirus-2 post-infection and post-vaccination. Males and younger individuals developed a significant humoral immunity compared to females and the elderly.

COVID-19

P0539

QUINOLINIC ACID AS A PROGNOSTIC MARKER IN PATIENTS WITH SARS-COV-2

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BACKGROUND-AIM

The kynurenine pathway is the main route of the metabolic degradation of tryptophan (TRP). It is involved in the immunological response against viral infections such as SARS-CoV-2. Quinolinic acid (QA) is generated by the degradation of tryptophan via kynurenine and 3-OH kynurenine. The aim of this study was to get insight into the behavior of this parameter in SARS-CoV-2 positives and its possible prognostic value.

METHODS

104 patients with a SARS-CoV-2 infection hospitalized between August 2020 and April 2021 were included. 80 of these patients survived the disease (survival group), whereas 24 died (deceased group). A healthy control cohort (N=99) was included in the study. The plasma concentrations of tryptophan and QA were measured on admission and 7 days after admission. The quinolinic acid/tryptophan ratio (QA/KYN ratio) was calculated.

RESULTS

At admission, Patients infected with SARS-CoV-2 showed a statistically significant higher QA and QA/TRP ratio than the healthy controls (QA medians 1210 and 342 nmol/L; QA/TRP medians 27.1 and 5.7; p-values < 0.001). Seven days after admission, QA and QA/TRP were significantly higher in the deceased group (QA medians 1960 and 1060 nmol/L; QA/TRP medians 34.3 and 24.7; p-values < 0.001). The increase of QA and QA/TRP in the deceased group between the measurements on admission and after 7 days were statistically significant (QA medians 1410 and 1960 nmol/L; QA/TRP medians 27.6 and 34.3; p-values < 0.001).

CONCLUSIONS

Quinolinic acid and the QA/TRP ratio are elevated in patients infected with SARS-CoV-2. Quinolinic acid is a potentially useful parameter in the survival prognosis of patients with SARS-CoV-2.

COVID-19

P0540

SERUM CALPROTECTIN AND CRP CONCENTRATIONS IN COVID-19 DISEASE

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BACKGROUND-AIM

The aim of this study was to evaluate the usefulness of serum calprotectin (sCAL) determination as well as the relationship between sCAL and CRP levels considering activity and severity of COVID-19. Both sCAL and CRP play important roles in the inflammatory response and could give different perspective on the course of the disease.

METHODS

Study included 143 subjects (70 female and 73 male) divided into four groups: patients that needed intensive care and mechanical ventilation (IC group, N=48), non-critical patients with oxygen treatment (RC group, N=22), patients in postcovid follow-up (PC, N=39) and healthy controls (HC, N=34).
sCAL and CRP were determined on the AU5800 analyser (Beckman Coulter, Tokyo, Japan)
Kruskal-Wallis and correlation analysis were used to test differences and connection between sCAL and CRP using MedCalc Statistical Software version 18.11.6 (MedCalc Software Bvba, Ostend, Belgium).

RESULTS

Median concentration with interquartile ranges were as follows: 6.27 [1.58-21.78] mg/L for sCAL and 100.4 [12.5-210.9] mg/L for CRP in IC group; 5.04 [1.43-12.31] mg/L for sCAL and 69.3 [7.5-389.2] mg/L for CRP in RC group; 1.68 [0.52-3.02] mg/L for sCAL and 2.2 [0.3-27.9] mg/L for CRP in PC group; 0.68 [0.31 - 1.59] for sCAL and 1.3 [0.4-16.4] for CRP in HC group.
We found statistically significant differences for both sCAL and CRP between tested groups ($P<0.001$). Post-hoc analysis showed significant difference in CRP between hospitalized patients (IC and RC group) and non-hospitalized subjects (PC and HC group). sCAL showed similar statistics with one difference: sCAL was statistically higher in PC group than in the HC group ($p<0.001$) although these subjects were no longer in the acute phase of inflammation.
sCAL showed a good positive correlation with CRP ($r=0.64$, $P<0.001$)

CONCLUSIONS

Our results showed that subjects with a severe course of the disease (IC and RC) had higher sCAL and CRP than subjects in postcovid or healthy group which defines sCAL as a useful biomarker that can predict the severity of COVID-19 disease. sCAL is also higher in postcovid group than in the healthy control group suggesting that the two tested markers do not follow the same dynamics in the acute inflammation that sCAL can be useful as a marker in the recovery period.

COVID-19

P0541

CELLULAR IMMUNITY AFTER BIVALENT COVID-19 VACCINE BOOSTER MEASURED WITH AN AUTOMATED SARS-COV-2 INTERFERON GAMMA RELEASE ASSAY (IGRA)

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BACKGROUND-AIM

An efficient antiviral response requires coordinated activities of both T and B lymphocytes. Several studies on the immune response after coronavirus disease 2019 (COVID-19) vaccination have focused on anti-SARS-CoV-2 serum antibodies, neglecting the role of T-cell immune response, which is instead crucial for providing cellular immunity and long-term immune protection against SARS-CoV-2. To date there are few tests for evaluating the immune response mediated by T lymphocytes. In this study we hence used an automated electrochemiluminescence Interferon Gamma Release Assay (IGRA) for monitoring T cell-mediated immune response against SARS-CoV-2 in human whole blood

METHODS

A total number of 51 healthcare workers (median age 43 years, 51% females) of Pederzoli Hospital (Peschiera del Garda, Verona, Italy) were studied. All received primary monovalent vaccination, monovalent homologous booster (3° dose) and a second bivalent booster (4° dose) >6 months afterwards with Pfizer/Biontech mRNA vaccines. Blood samples were taken before bivalent vaccine administration (T0) and 1 month afterwards (T1). An anamnestic survey was also administered. Cellular immunity was assayed with Roche Elecsys SARS-CoV-2 IGRA.

RESULTS

Overall, 29/51 (57%) subjects tested positive for SARS-CoV-2 at least once throughout the Pandemic. Seven (14%) subjects were SARS-CoV-2 IGRA non-reactive at T0. One month after bivalent COVID-19 vaccination (i.e., T1) 35/51 (69%) subjects displayed an increase of SARS-CoV-2 IGRA (“Responders”). At T1, only one subject (2%) remained SARS-CoV-2 IGRA “non-reactive” (p=0.027 for trend). No clear association emerged between reactogenicity and SARS-CoV-2 IGRA post-vaccine variation.

CONCLUSIONS

This study shows that SARS-CoV-2 IGRA values increase in the majority of subjects undergoing bivalent COVID-19 vaccine booster administration, with the percentage of those remaining IGRA non-responders decreasing by around 7-fold (i.e., from 14% to 2%), and thus ultimately confirming the importance of regular vaccine booster administration.

COVID-19

P0542

RELATIONSHIP BETWEEN SARS-COV-2 VIRAL LOAD, ANTIGEN POSITIVITY AND INFECTIOUS TITRE

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BACKGROUND-AIM

Performance of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) antigen tests is described relative to reverse transcriptase polymerase chain reaction (RT-PCR) cycle threshold (Ct) values. However, Ct values may not be consistent between tests from different manufacturers, or even between runs. Here we correlate the Roche Elecsys® SARS-CoV-2 Antigen assay results to a quantitative RT-PCR readout as a more reproducible measure of viral load. Additionally, we look at the relationship between the antigen test results, viral load and infectious titre.

METHODS

Longitudinal nasopharyngeal swab samples from patients (N=452) with severe Covid-19 pneumonia collected between 03 April and 28 May 2020 in a randomised, double-blind, placebo controlled, multicentre study to evaluate the safety and efficacy of Tocilizumab (COVACTA), were assessed for SARS-CoV-2 viral load (RNA copies/ mL) and a qualitative and semi-quantitative readout of Elecsys SARS-CoV-2 Antigen assay. Viral culture experiments were performed to determine the infectious titre (median tissue culture infectious dose [TCID50]/mL) in a subset of samples. Agreement analysis was performed to compare the results of the assays. Please note that the current intended use of Elecsys SARS-CoV-2 Antigen assay is the qualitative detection of SARS-CoV-2 antigen.

RESULTS

We observed high negative percent agreement between the Elecsys SARS-CoV-2 Antigen assay results and the RT-PCR results, while the positive percent agreement was only high in samples exceeding a certain viral load and at earlier time points from symptom onset.
Infectious titre values and both the antigen assay semi-quantitative readout and the quantitative RT-PCR results correlated well.
Positive percent agreement of RT-PCR and antigen results in relation to infectious titre was very high in both cases, while negative percent agreement was moderate to low.

CONCLUSIONS

These data show that in patients with high viral load the Elecsys SARS-CoV-2 Antigen assay correlates well qualitatively and quantitatively with the presence of SARS-CoV-2 RNA and infectious virus as determined by RT-PCR and viral culture, respectively.

COVID-19

P0543

EVALUATION OF THE KREBS VON DEN LUNGEN-6 (KL6) BIOMARKER IN COVID-19 PATIENTS.

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BACKGROUND-AIM

Krebs von den Lungen-6 (KL-6) is a high molecular weight (200 kDa) glycoprotein with a sialic acid chain that is mainly produced by damaged or regenerating Type II alveolar pneumocytes. The aim of our study was to evaluate the KL-6 biomarker in Covid-19 patients who developed more or less severe respiratory impairment with unfavorable outcomes in some cases.

METHODS

A total of 215 patients (144 male, 67%; 71 female, 33%) were evaluated, 72 of whom (33.5%) developed severe disease. The remaining 143 (66.5%) developed a mild/moderate form of the disease. To date, 29 patients of the total (13.5%) have undergone follow-up after 4-5 months. KL-6 was determined by fluorescence immunoenzymatic method (FEIA) on AIA 360 analyzer (TOSOH Biosciences).

RESULTS

The results highlighted: 1) High KL-6 values are associated with a worse hospital outcome (OR 23.33, $p<0.004$) with passage to intensive care or unfortunate outcome, regardless of age and gender. 2) The same elevated KL-6 values taken individually are not associated with "death" (OR 4.62, $p<0.113$) except in conjunction with metabolic comorbidities (diabetes, obesity) (OR 8.76, $p<0.047$). 3) The linear regression analysis does not show any evidence between KL-6 observed during recovery and total length of hospitalization ($p=0.417$) nor with that of recovery in sub-intensive care ($p=0.272$). 4) At follow-up, a significant reduction of KL6 was detected ($p=0.011$) in 13 out of 29 patients (44.8%) which, however, remains pathological in 6 patients who show a reduction of average degree of alveolar diffusion - capillary (DLCO) on spirometry. In the remaining 7 patients, in whom KL6 returned to normal, a slight reduction of DLCO was instead found. 15 out of 29 patients (51.7%) maintained constant KL6 values over time. For 11 (73.3%) of these KL6 remained normal with improvement in lung function at follow-up. In 3 (20%) patients KL6 remained pathological with marked reduction of DLCO at follow-up. Only one (0.7%) patient showed increasing KL6 with DLCO going from normal to mildly reduced.

CONCLUSIONS

The described results suggest the utility of KL-6 in predicting complex hospital course in Covid-19 patients. In the follow-up, a discrete relationship between KL6 and the alveolar-capillary diffusing capacity (DLCO) was noted.

COVID-19

P0544

ANALYSIS OF INFLAMMATORY MEDIATORS DEPENDING ON SERUM VITAMIN D IN COVID 19 PATIENTS

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BACKGROUND-AIM

Before the introduction of vaccination, vitamin D was an integral part of many protocols for the treatment of Covid-19 infection. Some scientific works have indicated that vitamin D levels in the serum before infection can be important for the prognosis and clinical outcome of covid-19 infection.

METHODS

In this work, the values of C reactive protein (CRP), procalcitonin (PCT) and interleukin 6 (IL-6) were analyzed and correlated depending on vitamin D in the serum of 134 people suffering from Covid-19. Vitamin D, CRP and IL-6 were analyzed in serum using standard kits with the help of a UniCel DCX-800 biochemical analyzer (Beckman Coulter) for clinical diagnostics. All patients had a confirmed diagnosis of viral infection using a rapid throat and nose swab test or a positive result using the polymerase chain reaction (PCR) test for SARS-Cov2 virus.

RESULTS

Results from the same test showed significant results for variables CRP and PCT ($p<0.001$; Spearman's rho correlation coefficient was 0.468). When we categorized IL-6 values according to the criteria of patients who had IL-6 values above 30 and those below 1.5, we found that patients with high IL-6 values had low serum vitamin D values compared to those with low values of visamine D. (Kruskal-Wallis Test).In addition, the data grouped and analyzed within the Heatmap test show that the low values of vitamin D for some patients were in the same cluster as the high values of IL-6.

CONCLUSIONS

These findings indicate that vitamin D levels may be important for the development of severe inflammation and that low vitamin D levels are associated with an increase in the pro-inflammatory marker IL-6.

COVID-19

P0545

MONITORING OF IMMUNOGLOBULIN VALUES DURING ONE YEAR AFTER RECEIVING THE SINOPHARM VACCINE

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BACKGROUND-AIM

The appearance of the corona virus has led to numerous problems in healthcare, but at the same time, with the help of modern technologies, several types of vaccines have been developed in the world. However, at the very beginning of the pandemic, it was a very big problem how to get the vaccine as soon as possible. One of the emergency vaccines approved by the WHO, applied since January 2021 in Serbia, was the Chinese Sinopharm BBIBP vaccine (Vero cells).

METHODS

Examination of the concentration of IgG immunoglobulin, IgA +M, was performed by Immunoenzymatic kit (EIA COVID-19, TestLine Clinical Diagnostics s.r.o.,Czech Republic) in serum, from a healthy male person, aged 52 years, without viral infections, without the presence of other chronic diseases and without previous exposure to SARS-CoV-2 virus. The first dose vaccine was administered in January 2021, among the first priority groups of health and education workers, the second dose after 14 days and the third dose after 6 months in August 2021.The tests were conducted before receiving the vaccine and after vaccination at intervals: 7, 14 and 21 days after each dose, and later at intervals of one month following up to a total of one year.

RESULTS

The dynamics of changes showed that after the application of the first dose, there was a slight increase in IgG +M antibodies with the highest values after 21 days (0.495). The second dose significantly increased the antibody concentration after 21 days as well. However, three months after the second dose, the antibody concentration was negative (7.74) but the IgA + IgM concentration was positive (0.742). All time without a positive antigen test or an RT-PCR test for SARS-CoV-2 virus. The adminsitration of third dose of the same vaccine led to an enormous increase in concenration IgG antibodies (12.82) and anti-S Covid-19 IgG 1000 U/ml, respectively, while IgA + IgM (1.021 IU/ml).

CONCLUSIONS

The results show that three doses of Sinopharm vaccine strongly increase the concentration antibodies and create good protection up to years (S-Covid-19 S IgG Ab; 66,5 U/ml), because during the year there were no infections and clinical signs of disease. However, respect for epidemiological measures and wearing a protective face mask was carried out all the time during contact at public area.

COVID-19

P0546

LIPID PROFILE IN THE PROGNOSIS OF HOSPITALIZED COVID19 PATIENTS.

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BACKGROUND-AIM

Anyone is susceptible to getting sick from COVID-19, but the data we have so far from the Ministry of Health show that the elderly, diabetics, cancer patients, immunocompromised patients, pregnant women, among others, have a higher risk of developing serious illness. by COVID-19. To this group we can add those people suffering from cardiovascular disease, so it is logical to think that increased lipid levels would be associated with a worse evolution and a poor prognosis.

METHODS

Descriptive cross-sectional study in a population of 294 patients who were admitted to our hospital due to SARS-Cov-2 infection between March 8, 2020 and March 1, 2022. We measured the following biochemical parameters: total cholesterol (TC), LDL cholesterol (LDL-c), HDL cholesterol (HDL-c) and triglycerides (TG) with the Roche Diagnostic analyzer, COBAS c701; as well as non-HDL cholesterol (NO-HDL-C), small, dense LDL-C particles, and various atherogenic ratios. To assess the lipid profile at survival, individual Cox regressions are calculated.

RESULTS

From the variables studied we can say that:
- TC ≤ 100 mg/dl is a poor prognostic factor. Patients with TC levels ≤ 100 have a 3.206 times higher risk of dying (Hazard Ratio (HR)= 3.206; p value <0.001).
- c-LDL ≤ 95.4 mg/dl manifest as a poor prognostic factor. Patients with c-LDL levels <=95.4 mg/dl present a 2.831 times higher risk of (HR=2.831; p_value=0.001).
- HDL-C ≤ 31 mg/dl manifest as a poor prognostic factor. Patients with HDL-C levels <=31 mg/dl have a 2.515 times higher risk of dying (HR= 2.515; p_value<0.001).
- c-NO HDL ≤ 86.9 mg/dl manifest as a poor prognostic factor. Patients with LDL-c levels <=86.9 mg/dl present a 2.259 times higher risk of dying (HR= 2.259; p_value=0.001).

CONCLUSIONS

Patients admitted to our hospital with COVID19 and who had a lipid profile below normal values had a higher mortality, so this lipid profile would be associated with a worse evolution and poor prognosis in the disease. The cause of this striking result remains to be elucidated. Some researchers suggest that cholesterol may play a role in viral replication and its cellular internalization. In addition, accelerated cholesterol catabolism is well known when there is an acute inflammatory process. Science is full of paradoxes and this is one of them.

COVID-19

P0547

EVALUATION OF THE IMMUNE RESPONSE OF MUCOSA-ASSOCIATED LYMPHOID TISSUE (MALT) IN PATIENTS AFTER VACCINATION AGAINST SARS-COV-2 AND/OR COVID-19

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BACKGROUND-AIM

An element of the acquired response is the production of antibodies in the IgA class, which play an important role in mucosal immunity. sIgA is responsible for inhibiting the adhesion of pathogens to the surface mucous membrane cells, as well as indirectly inhibiting the activation of the system genitive. Determination of specific antibody titers can also be used to monitor the immune response to the vaccine and/or COVID-19 infection. The aim of the study is to assess the immune response of mucous membranes in patients after vaccination with available vaccines and/or COVID-19 infection and the dynamics of concentration changes over time.

METHODS

Anti-SARS-CoV-2 ELISA (IgA) kit was used to determine sIgA antibodies Euroimmune (Lübeck, Germany). The control group consisted of 40 patients who were not infected with the SARS-CoV-2 virus and were not vaccinated. The study group consisted of a total of 320 (four groups of patients qualified depending on the vaccine used and without COVID-19 infection, 40 patients each, and four groups of patients after COVID-19 infection and vaccination 40 patients each.

RESULTS

The median titer of sIgA antibodies in the group of not vaccinated patients after COVID-19 infection was 1.111 COI (1.071;1.194). In patients vaccinated with Comiranty Pfitzer the titer was 1.281±0.147 COI vs COVID-19 and vaccination with Comiranty Pfitzer 1.317±0.023 COI ($p=0.0030$). After receiving Moderna vaccine, the titer was 0.902±0.238 COI vs. COVID-19 and Moderna vaccination 1.387±0.171 COI ($p=0.0320$), patients after vaccination with the Johnson&Johnson vaccine had an antibody titer of 0.803±0.140 COI, while after vaccination with this vaccine and infection with COVID-19 the titer was 1.149±0.153 COI. There was a statistically significant difference ($p<0.0001$) in antibody titers between control group 0.406 COI and all other study groups.

CONCLUSIONS

Increased titers of sIgA antibodies in non-infected patients may indicate the stimulation of the mucosal response and protect the patient against infection. COVID-19 infection and the use of the vaccine leads to a significant increase in the production of sIgA.

COVID-19

P0548

LOW INTERFERON-γ LEVELS IN CORD AND PERIPHERAL BLOOD OF SARS-COV-2-INFECTED PREGNANT WOMEN

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BACKGROUND-AIM

COVID-19 is characterized by the immune system's overreaction resulting in a 'cytokine storm', consisting in a massive release of cytokine into the bloodstream, leading to local and systemic inflammatory response. This clinical picture is further complicated in case of infection of patients with a peculiar immunological status, such as pregnancy. In this paper, we focused on Interferon-γ (IFN-γ), which plays a pivotal immunomodulatory role in normal pregnancy and fetal development, as well as in defense against pathogens.

METHODS

In this study, we compared the levels of IFN-γ and the Interferon- γ autoantibodies (IFN-γ auto-Ab) of the peripheral and cord blood of pregnant women with confirmed mild COVID-19 and healthy pregnant women, between February and June 2021.

RESULTS

The IFN-γ was significantly lower both in the peripheral and cord blood of SARS-CoV-2-positive mothers, suggesting that infection can affect the fetal microenvironment even without severe maternal symptoms. There was no significant difference in neonatal length, weight and head circumference between the two groups.

CONCLUSIONS

SARS-CoV-2 infection can affect the fetal microenvironment even without severe maternal symptoms, suggesting the need for long-term follow-up of newborns born from infected pregnant mothers. Further studies are needed to clarify both the molecular mechanism involved in the decrease in IFN-γ and IFN-γ auto-Ab and whether lower levels of IFN-γ due to SARS-CoV-2 infection affect the development or infection susceptibility of infants born to SARS-CoV-2-infected mothers.

COVID-19

P0549

EFFECT OF SARS-COV-2 NUCLEIC ACID DECONTAMINATION USING HYDROGEN PEROXIDE IN THE MOLECULAR DIAGNOSTIC LABORATORY

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BACKGROUND-AIM

False positive results due to nucleic acid contamination is a very important problem in the molecular diagnostic laboratory. Since the outbreak of COVID-19 (coronavirus disease 2019), the number of laboratories that perform SARS-CoV-2 (Severe acute respiratory syndrome coronavirus 2) PCR (polymerase chain reaction) tests has been markedly increasing, and quality management activities for preventing nucleic acid contamination have become more important. When nucleic acid contamination is found in several places or it is difficult to specify the contaminated space in laboratory, a space sterilizer using hydrogen peroxide can be useful as one of the tools for nucleic acid decontamination. In this study, we aimed to confirm the efficacy of the activated ionized hydrogen peroxide (AIHP) system space sterilizer for elimination of SARS-CoV-2 nucleic acid.

METHODS

Nucleic acid elution were extracted from samples of patients infected with COVID-19 and classified according to Ct (Cycle -Threshold) values (about 10, 20, and 30). Depending on the classified Ct value, RNA extract was applied to a sterilized petri dish and AIHP space sterilizer (MUGYUN, SUNGSAM, Korea) was used for sterilization. We performed COVID-19 PCR using swabs that wiped the surface of the disinfected petri dishes. Three tests were repeated in the same way, and petri dish under the same conditions except of sterilization was included in the control group for each validation.

RESULTS

As a result, all tests except for one petri dish with a Ct values of about 10 cycles showed negative results for SARS-CoV-2. And all samples of control group showed higher Ct values than the initial test results, and the control samples with initial Ct values of about 30 cycles showed negative results regardless of disinfection.

CONCLUSIONS

In conclusion, AIHP space sterilizer was effective for decontamination of nucleic acid in the molecular diagnostic laboratory, especially when extensive laboratory space needs to be disinfected at once.

COVID-19

P0550

CORRELATION ANALYSIS BETWEEN TRANSCRIPTOME EXPRESSION DIFFERENCES AND DISEASE SEVERITY IN THE FIRST WAVE OF THE COVID-19 PATIENTS

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BACKGROUND-AIM

The precise mechanism of the immune response caused by SARS-CoV-2 virus infection still needs further study. RNA sequencing technology is one of the important tools to study the intracellular signal transduction mechanism. The use of RNA-seq to clarify the transcriptomic changes in the interaction between pathogens and host cells after infection will provide a basis for further studies on the exact mechanism of SARS-CoV-2 infection. To clarify the differences in the expression of PBMC transcription in COVID-19 patients, and to provide scientific evidence for the mechanism of infection and severity in COVID-19 patients.

METHODS

Fifty COVID-19 patients admitted to the First Affiliated Hospital of Zhejiang University School of Medicine were included. PBMC samples were collected after admission, and Illumina high-throughput sequencing platform (HiSeq/ MiSeq) was used for sequencing to analyze transcriptome expression differences between infected patients and healthy control group, as well as, mild group and severe group.

RESULTS

Compared to the healthy group, there were 6,941 differentially expressed genes in the mild group and 8,779 differentially expressed genes in the severe group, respectively. There were 240 differentially expressed genes between the mild group and the severe group, among which 216 genes were up-regulated, while 24 genes were down- regulated. Compared to the healthy control group, there were significant differences in Rap1 signaling pathway, PI3K-Akt signaling pathway and cAMP signaling pathway in COVID-19 patients, while there were significant differences in herpes simplex, influenza A, inflammatory bowel disease and other pathways between the mild group and the severe group.

CONCLUSIONS

In this study, transcriptomics was used to analyze the pathogenesis and severity of COVID-19 from the RNA level. It is preliminarily revealed that RAP1 signaling pathway, PI3K-Akt signaling pathway, cAMP signaling pathway and herpes simplex virus infection signaling pathway may play a regulatory role in the pathogenesis and severity of SARS-CoV-2 infection, which laid a foundation for the in-depth understanding of the pathogenesis of SARS-CoV-2 infection.

COVID-19

P0551

THE LABORATORY PARAMETERS-DERIVED COLAB-SCORE AS AN INDICATOR OF THE HOST RESPONSE IN ICU COVID-19 PATIENTS DECREASES OVER TIME.

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BACKGROUND-AIM

The CoLab-score was originally developed and validated to rule out COVID-19 in suspected patients presenting at the emergency department. The CoLab-score includes the patient's age and ten blood parameters, reflecting the host response to SARS-CoV-2 infection. In the present study we investigated the CoLab-score over time in mechanically ventilated COVID-19 patients at the ICU. We hypothesized that the CoLab-score will decrease over time, independent of survival and disease severity. This would create the opportunity to monitor COVID-19 patients and potentially ruling out the need for isolation when the host response decreases and the infection is overcome.

METHODS

We used serial data of the Maastricht Intensive Care Covid (MaastrICCht) cohort of mechanically ventilated COVID-19 patients to investigate the association between time and daily CoLab-score using linear-mixed models. Crude models were adjusted for sex, APACHE II score, SOFA score, and stratified for mortality.

RESULTS

324 Patients (73% men), aged 64±12 years with 5,959 daily CoLab-scores, were included. The CoLab-score decreased with 0.26 (95%CI: -0.29 – -0.23) points per day. In patients with a higher SOFA-score, CoLab-score was higher at intubation and decreased to a greater extent over time. The CoLab-score slope was -0.23 (95%CI: -0.34 – -0.14) for survivors and -0.29 (95%CI: -0.34 – -0.25) for non-survivors. Adjustment for sex and APACHE II score were not significant.

CONCLUSIONS

The CoLab-score decreased over time in mechanically ventilated ICU COVID-19 patients, with a point reduction per four days. This suggests that the CoLab-score eventually decreases to a normal state. This decrease is still present in patient whom die during ICU stay and those with severe organ failure.

COVID-19

P0552

IN VITRO COMPATIBILITY OF THREE WHO APPROVED SARS-COV-2 RT-PCR ASSAYS PROTOCOLS ON CLINICAL SPECIMENS AND ITS PERFORMANCE FOR REAL LABORATORY PRACTICE

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BACKGROUND-AIM

Nasopharyngeal swabs RT-PCR testing is the gold standard in the diagnosis of COVID-19. WHO recommends using a sensitive and specific target of the SARS-CoV-2 genome. This study aimed to compare and evaluate three widely used SARS-CoV-2 RT-PCR testing protocols by WHO on real clinical specimens, to explain the reasons for the different results, and to suggest recommendations for selected target genomes.

METHODS

A total of 62 nasopharyngeal samples were randomly selected among the samples tested between the 1st and 31st of March 2020 in the Clinical Pathology Laboratory of Dr. Soetomo Hospital Surabaya, one of the referent laboratories of COVID-19 in Eastern Indonesia. All samples were tested by Abbott m2000® RealTime System (RNA-dependent RNA polymerase (RdRp) and nucleoprotein (N)), Cepheid Genexpert® Xpress SARS-CoV-2 (envelope (E) and nucleoprotein (N)), and Coyote® MINI 8 Plus RT-PCR System (Open reading frame-1ab (Orf1ab) and nucleoprotein (N)). The results were analyzed using Pearson's Correlation SPSS Ver 25.0.

RESULTS

Two samples were excluded because of invalid results. Among the 60 nasopharyngeal samples, 35(58%) were tested positive by Abbott m2000® and Cepheid Genexpert®, but only 27(45.0%) by Coyote®. Pearson's Chi-Square Abbott m2000® and Genexpert® analysis showed a significant result ($p<0.01$) with a Pearson's R coefficient of 1. Pearson's Chi-square Coyote® analysis with the other two tests also showed significant results ($p<0.01$), but Pearson's R coefficient was only 0.817. The CT-Value correlation coefficient on the gene targets in Abbott m2000®, Genexpert®, and Coyote® showed that RdRp/N, E/N2, and Orf1ab were significantly correlated ($p<0.01$), but the N gene targets in Coyote® showed insignificant ($p=0.287$).

CONCLUSIONS

While the two RT-PCR assays (Abbott m2000® and Genexpert®) displayed comparable diagnostic values, Coyote® remains usable with >80% sensitivity and 100% specificity. These results help regulate the apparent prevalence determined by the three RT-PCRs. Thus, they can support health center decisions to determine the selection of tools according to their respective abilities.

COVID-19

P0553

EVALUATION OF A NEW MOLECULAR TEST FOR THE DETECTION OF SARS-COV-2 NUCLEIC ACID IN SALIVARY SAMPLES

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BACKGROUND-AIM

Molecular testing of COVID-19 samples is considered the gold standard for the detection of SARS-CoV-2 infection. This study aimed to compare the performance of a new molecular metho for detecting SARS-CoV-2 in salivary samples, the 742 SARS-CoV-2 Nucleic Acid Multiplex Detection Kit (Technogenetics, Lodi, Italy), with respect to two CE-IVD methods, the 732HF Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit (Technogenetics, Lodi, Italy) and the TaqPath COVID-19 CE-IVD RT-PCR Kit (Thermo Fisher Scientific, USA).

METHODS

A total of 124 self-collected salivary samples were randomly selected from healthcare workers (HCW) who participated to the screening program at University-Hospital of Padua, Italy, from Oct to Nov 2022. RNA extraction was performed by Viral DNa and RNA Extraction Kit (Technogenetics, Lodi, Italy); then extracts were amplified by 742 (genes RdRp, N and E) and 732HF (genes ORF1ab and N). For TaqPath analyses (genes ORF1ab, N and S), RNA extraction was performed using MagNa Pure 96 DNA and Viral NA Small Volume Kit (Roche, Switzerland).

RESULTS

Ninety-four samples were positive for all genes at 742, while thirty were negative; for 732HF, ninety-six samples were positive, while twenty-eight were negative, with an overall agreement of 97.5% (Cohen's $\kappa = 0.930$, $p < 0.001$). TaqPath gave ninety-five positive samples for all genes, and twenty-nine negative results, with an overall agreement of 100% (Cohen's $\kappa = 1.0$, $p < 0.001$) with respect to 742, and 97.5% (Cohen's $\kappa = 0.931$, $p < 0.001$) with respect to 732HF. Moreover, comparing cycle threshold (Ct) between the 742 and 732HF, no statistical significant differences were found (p = n.s.).

CONCLUSIONS

For the two amplification methods under evaluation for the detection of SARS-CoV-2 RNA in salivary samples, the 742 method proved a better performance than 732HF, both having the same nucleic acid extraction procedure and the same amplification time. Moreover, the 742 method gave the same results obtained through the use of a second established method routinely used at University-Hospital of Padua, Italy.

COVID-19

P0554

A NATIONAL LABORATORY PERSPECTIVE: THE IMPACT OF THE COVID-19 PANDEMIC ON THE FOLLOW-UP OF PATIENTS WITH NONCOMMUNICABLE DISEASE IN SOUTH AFRICA

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BACKGROUND-AIM

After the World Health Organisation declared Coronavirus disease 2019 (COVID-19) a pandemic, the focus of healthcare in South Africa (SA) and across the globe shifted towards preventing the spread of the disease and treatment of infected patients. In response to this health crisis, routine healthcare services were de-escalated in SA. The aim of this study was to determine the impact of the COVID-19 pandemic on the routine care of patients followed-up at multiple public healthcare facilities across SA.

METHODS

A national multicentre retrospective audit of laboratory test requests received from hospital outpatient departments and primary healthcare facilities across SA was performed. Eight analytes were studied, namely glycated haemoglobin (HbA1c), lipids profiles, thyroid-stimulating hormone (TSH), thyroxine (fT4), triiodothyronine (fT3), serum protein electrophoresis (SPE), serum free light chains (SFLC) and prostate specific antigen (PSA); and used as a proxy of non-communicable disease follow-up. Requests received during the 3 waves of the pandemic (wave 1 (April – June 2020) (W1); wave 2 (December 2020 – February 2021)(W2); wave 3 (June – September 2021)(W3)) were compared to requests received the same period during 2017 - 2019.

RESULTS

During W1 requests for all analytes were reduced, with the biggest reduction observed for SPE (-37%); TSH (-29%); fT4 (-28%); and HbA1c (-25%). Requests received from urban facilities showed a larger decrease compared to those from rural facilities. An increase in requests was observed for all analytes during W3; the biggest increase observed for fT3 (21%) and HbA1c (18%).

CONCLUSIONS

The decrease in requests observed during W1 possibly resulted in delayed diagnosis and treatment adjustments of noncommunicable diseases. Increased requests during W3 could reflect the re-escalation of medical services and a more balanced approach as the pandemic progressed.

COVID-19

P0555

THE IMPACT OF THE COVID-19 PANDEMIC ON THE SCREENING, DIAGNOSIS, AND MONITORING OF DIABETES MELLITUS ACROSS SOUTH AFRICA

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BACKGROUND-AIM

Glycated haemoglobin (HbA1c) is an increasingly measured biomarker used for the screening and diagnosis of diabetes mellitus (DM). It is monitored 3 – 6 monthly to assess glycaemic control and to adjust treatment in people with DM. After the World Health Organisation declared the Coronavirus disease 2019 (COVID-19) a pandemic, routine healthcare services were de-escalated in South Africa (SA). The aim of this study was to determine the impact of the pandemic on the routine follow-up of diabetic patients across SA during the lockdown period.

METHODS

Geographically, South Africa consist of 9 provinces that are divided into 6 regions by the National Health Laboratory Services. The number of HbA1c requests received from outpatient departments and primary healthcare facilities across the 6 regions during March 2020 – December 2021 were compared to those requested during the same period in 2017 – 2019. Requests received during the first three waves of the pandemic were compared: wave 1 (April 2020 – June 2020) (W1); wave 2 (December 2020 – February 2021)(W2); wave 3 (June 2021 – September 2021)(W3).

RESULTS

During W1 there was an overall decrease of 25% in HbA1c requests across all provinces in SA. The two regions with the biggest reductions were the Western Cape and Northern Cape (-49%) and the Eastern Cape (-28%). There was no change observed in requests received from Limpopo and Mpumalanga. Overall, a bigger reduction was observed for requests received from urban facilities (-28%) compared to rural facilities (13%). During W2 the overall decrease in requests was 1%, however 2 regions observed an increase in requests. The Free State and North West region had a 14% increase and Gauteng region had a 15% increase. During W3 there was an overall increase of 18% nationally; the biggest increase observed in the Free State and North West region (40%).

CONCLUSIONS

Diagnostic and monitoring services for DM were likely restricted during W1 of the pandemic as reflected by the decrease in HbA1c requests received. The differences across the regions of SA reflects the diverse approaches of the provincial governments in response to the COVID-19 pandemic. The delay in diagnosis and the lack of follow-up to monitor glycaemic control could have serious future health implications for patients and the healthcare system.

COVID-19

P0556

DIFFUSION OF SARS-COV-2 OMICRON VARIANT IN CAMPANIA REGION BETWEEN NOVEMBER 2021 AND DECEMBER 2021

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BACKGROUND-AIM

SARS-CoV-2, like other RNA viruses, is prone to genetic evolution while adapting to their new human hosts with the development of mutations over time, resulting in the emergence of multiple variants that may have different characteristics. By sequencing viral RNA from SARS-CoV-2 positive samples we reconstructed the trend of Delta variant and Omicron variant in Campania region between November 2021 and January 2022.

METHODS

RNA was extracted from 246 nasopharyngeal positive swabs obtained in Campania region between 01/11/2021 and 04/01/2022. 72 samples were collected in November 2021; 95 samples were collected in December 2021; 79 samples were collected in January 2022. Sequencing was performed using the MGI DNB-Seq G400. The SARS-CoV-2 complete genomes were built using the pipeline MGI SARS-CoV-2 analysis pipeline for multiplex-PCR MPS (Massive Parallel Sequencing) data.

RESULTS

Out of 32 samples collected between 01/11/2021 and 10/11/2021, all the samples were Delta variant. Out of 26 samples collected between 11/11/2021 and 20/11/2021, 23 (88.5%) were Delta variant and 3 (11.5%) were other non-Omicron variants. Out of 14 samples collected between 21/11/2021 and 30/11/2021, 11 (78.6%) were Delta variant, 1 (7.1%) was Omicron variant and 2 (14.3%) were other non-Omicron variants. Out of 4 samples collected between 01/12/2021 and 10/12/2021, 3 (75%) were Delta variant and 1 (25%) was other non-Omicron variants. Out of 14 samples collected between 11/12/2021 and 20/12/2021, 10 (71.4%) were Delta variant, 2 (14.3%) were Omicron variant and 2 (14.3%) were other non-Omicron variants. Out of 77 samples collected between 21/12/2021 and 31/12/2021, 17 (22.1%) were Delta variant, 59 (76.6%) were Omicron variant and 1 (1.3%) was other non-Omicron variants. Out of 79 samples collected between 01/01/2022 and 04/01/2022, 7 (8.9%) were Delta variant, 71 (89.9%) were Omicron variant and 1 (1.3%) was other non-Omicron variants.

CONCLUSIONS

Our data show that between 01/11/2021 and 10/12/2021 there was a gradual decline in the cases of Delta variant in favor of Omicron variant. Starting from the 11/12/2021, the cases of Omicron variant quickly escalated until almost completely replacing the Delta variant from January 2022.

COVID-19

P0557

CIRCULATING COLLAGEN METABOLITES AND THE ENHANCED LIVER FIBROSIS (ELF) SCORE AS DISEASE SEVERITY MARKERS IN SARS-COV-2 INFECTION

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BACKGROUND-AIM

Serum markers for severity of SARS-CoV-2 infection remain limited. The Enhanced Liver Fibrosis (ELF) score is calculated combining the values of a collagen metabolites set including procollagen type III amino terminal propeptide (PIIINP), tissue inhibitor of metalloproteinases 1 (TIMP-1), and hyaluronic acid (HA). This study aimed to examine the association of the ELF score and its single analytes as surrogate outcome measures of severity of COVID19.

METHODS

Ninety COVID19 patients with the absence of chronic liver diseases were enrolled. Serum PIIINP, TIMP-1, HA, and the ELF score were measured and correlated with inflammatory indices and clinical variables. Patients were stratified for disease severity according to WHO criteria in two groups, based on the requirement of oxygen support.

RESULTS

Serum TIMP-1, but not PIIINP, HA and ELF score were significantly higher in patients with WHO score > 5 compared to patients with WHO score < 5 [PIIINP: 7.2 (5.4–9.5) vs. 7.1 (4.5–9.9), p = 0.782; TIMP-1: 297.7 (20.5–460) vs. 236.7 (28.5–452.8), p =0.029; HA: 117.1 (55.4–193.7) vs. 75.1 (36.9–141.8), p =0.258; ELF: 10.2(9.1–10.5) vs. 9.6 (8.7–10.4), p =0.266]. Even higher levels of PIIINP, TIMP-1, and ELF score were found in patients with SARS-CoV-2 infection than controls. TIMP-1 showed good correlation with PCR (r = .312, p =0.003) and with LDH (r=0.263, p=0.009). PCR and serum LDH were significantly higher in COVID patients with WHO score > 5 compared to the matched group of patients with WHO score <5 [15.8 (9–44.5) vs. 9.3 (3.4–33.8), p = 0.039 and 373 (282–465) vs. 289 (218–383), p = 0.013, respectively].

CONCLUSIONS

In patients with COVID19, circulating TIMP-1, but not ELF score, was associated with disease severity and with systemic inflammatory index as PCR. In the future, circulating collagen metabolites may potentially be used to select the patients for therapeutic approaches targeting matrix metalloproteases pathway.

COVID-19

P0558

THE STUDY OF GLYCATED HEMOGLOBIN AS A RISK FACTOR FOR ADVERSE OUTCOME IN COVID-19: A CROSS-SECTIONAL STUDY

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BACKGROUND-AIM

Although Random Blood Sugar (RBS) reflects the severity of diabetes mellitus and may predict the adverse outcome in COVID-19, but sometime levels of RBS varies. Glycated hemoglobin (HbA1c) has been considered as stable parameters in assessing the glycemic status and could be used as potential prognostic biomarker over RBS in predicting the mortality in COVID-19. Therefore, the aim of the present study is to establish HbA1c as a biomarker and its cut-off levels in predicting the mortality in COVID-19.

METHODS

The present study was hospital based retrospective cross-sectional study consisting of four hundred patients of COVID-19. Data regarding biomedical investigations and clinical outcome were obtained from medical record department.

RESULTS

The mean RBS and HbA1c were increasing as the severity increases from mild to moderate and moderate to severe COVID-19. The RBS and HbA1c were statistically positively correlated with hsCRP, ferritin, IL-6 and plasma D- dimer. ROC curve analysis predicted HbA1c was better marker than RBS and at a cut-off of 8.5 %, it predicted mortality with 94.4% sensitivity and 95.3% specificity. On regression analysis, HbA1c (Odd ratio=3.6, 95 % CI = 2.2-5.7, P< 0.01) showed significant predictability for mortality in COVID-19.

CONCLUSIONS

The present study revealed that raised RBS and HbA1c implying an increased risk of severe infection and mortality in COVID-19. Increased RBS and HbA1c, in combination with elevated serum hsCRP, ferritin, IL-6 and plasma D-dimer, may explain COVID-19 infected individuals are at an increased risk of adverse outcome in COVID-19. HbA1c screening for COVID-19 patients as a separate risk factor could be recommended for risk stratification in COVID-19.

COVID-19

P0559

URINARY [TIMP-2]*[IGFBP7] FOR EARLY DIAGNOSIS AND RISK STRATIFICATION OF ACUTE KIDNEY INJURY IN CRITICALLY ILL PATIENTS

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BACKGROUND-AIM

Acute kidney injury (AKI) is a common clinical complication in critically ill patients, associated with high morbidity and mortality. Thus, an early and accurate diagnosis of AKI is crucial to start therapeutic intervention to improve clinical outcomes promptly. However, the available diagnostic tool has some limitations. In this study, we evaluated insulin-like growth factor binding protein 7 (IGFBP7) and tissue inhibitor of metalloproteinases-2 (TIMP-2) as possible biomarkers for early detecting moderate to severe AKI in critically ill patients.

METHODS

We enrolled 56 critically ill adult patients admitted to the intensive care unit of the University Hospital of Palermo, 42 men (75%) and 14 women (25%) with a median age of 67.5 years (IQR 49-78). The severity of illness was determined using the Simplified acute physiology score II (SAPSII) and the Sequential Organ Failure Assessment (SOFA) score. AKI was defined according to the Kidney Disease: Improving Global Outcomes (KDIGO) criteria. For each patient, urine samples were collected at admission (T0), after 4 (T4), 12 (T12), 24 (T24), and 36 hours (T36). TIMP-2 and IGFBP7 were measured by a clinical immunoassay (NephroCheck test, VITROS 5600®,Ortho Clinical Diagnostics). AKIRisk score is calculated as (TIMP-2)*(IGFPB7).

RESULTS

10 patients (18%) developed AKI during their hospital stay. In the AKI group, AKIRisk score was higher at T4 (1.11 vs 0.29 [(ng/ml)2/1000], p = 0.045) than at admission (0.96 vs 0.42 [(ng/ml)2/1000], p = 0.15) in comparation with the no AKI patients.

CONCLUSIONS

A cut-off of AKIRisk score >0.3 (ng/ml)2/1000, identify patients at high risk for developing moderate to severe AKI within 12 hours. Urine [TIMP-2]*[IGFBP7] is a promising candidate for early detection of AKI, especially in ruling-out AKI. However, the potential of this biomarker should be validated in large studies with a broader spectrum of clinical settings.

COVID-19

P0560

HEPCIDIN CONCENTRATIONS IN CORONAVIRUS DISEASE (COVID-19)

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BACKGROUND-AIM

Hepcidin (Hep), a peptide hormone predominantly synthesized by the liver, is a systematic iron (Fe) regulator. Fe metabolism disorders are in the pathogenesis of many diseases. Inflammatory cytokines such as interleukin-6 (IL-6) affect Fe metabolism by inducing the synthesis of Hep. Ferritin plays a critical role in COVID-19 as a predictor of a severe form of the disease. The aim of this study was to measure serum concentrations of Hep-25, Fe metabolism parameters, and inflammatory biomarkers in COVID-19.

METHODS

In this study, we analyzed 27 serum samples of COVID-19 patients admitted at the Osijek University Hospital Centre. All subjects were males over 18 years. Blood sampling was performed at admission into the anticoagulant-free tube. Fe, ferritin, and C-reactive protein (CRP) were measured using the Beckman Coulter AU480 analyzer (Beckman Coulter, Inc., Brea, USA) by spectrophotometric and turbidimetric methods, respectively; IL-6 by the electrochemiluminescent method (ECLIA) using the COBAS e411 analyzer (Roche Diagnostics, IN, USA) and Hep-25 by automatic enzyme-linked immunosorbent assay (ELISA) using the DRG Hybrid XL analyzer (DRG Instruments GmbH, Marburg, Germany). Data are presented as medians (M) and interquartile ranges (IQR) and compared with reference intervals (RI) provided by the manufacturer of the assays.

RESULTS

Hep-25 concentrations were significantly increased in COVID-19 (62.8 ng/mL; IQR 47.0-76.5; RI 0.2-34.1; M(age)=63 years (range 34-91)). Moreover, a significant serum concentration increase is observed for ferritin (1331 µg/L; IQR 753-1909; RI 30-300), IL-6 (57.6 ng/L; IQR 31.5-105.9; cut-off<7.0) and CRP (109.9 mg/L; IQR 80.5-139.3; cut-off<5), while Fe was decreased (6.7 µmol/L; IQR 4.7-8.6; RI 11-32).

CONCLUSIONS

A significant increase in Hep-25 concentration is observed in COVID-19. Fe concentration is low as a response to inflammation, while ferritin concentration is increased. Inflammatory markers (CRP and IL-6) are over-cut-off values. Hep-25 may be a potentially valuable marker in COVID-19 evaluation and monitoring. Further studies are needed to verify whether hepcidin-mediated iron metabolism may influence the outcome and therapeutic approach to the COVID-19 disease.

COVID-19

P0561

HISTONE-INDUCED ALTERATIONS IN HUMAN MONOCYTES: DOWN-REGULATION OF HYPER-INFLAMMATION BY AN HEPARINOID TREATMENT

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BACKGROUND-AIM

High circulating histone (HIS) levels have been described in several diseases with a critical inflammatory impact. Circulating histones act as Damage Associated Molecular Pattern proteins, activate pro-inflammatory reactions, and promote pro-coagulant conditions, representing a potent immuno-thrombotic trigger. Heparins have the potential to counteract the dangerous effect of histones by exploiting the interaction between the negatively charged glycosaminoglycans and the positive charges of histones to form complexes with less cytotoxicity. Here we investigated the ability of the heparinoid Danaparoid (DP) to counteract the cytotoxic and pro-inflammatory effect induced by HIS in human monocytes.

METHODS

Human monocytic THP-1 cells were treated for 24h in serum-free conditions with a histone mixture (0, 25, 50, and 100 µg/ml) in the presence or absence of DP (0.15, 0.3, 0.6, 1.2 U/mL). Monocytes were treated with either supernatant obtained from a histone-DP mixture previously incubated 60 min, RT, or directly added to cells. Trypan blue exclusion test was used to assess the cell viability (Luna II, Logos Biosystems). Bradford assay was used to explore the histone-DP binding, and a panel of 27 inflammatory cytokines was studied with Multiplex Immunoassay (Bio-Plex 200, Bio-Rad).

RESULTS

Histone treatment significantly reduced the cell viability in a dose- and time-dependent manner, and promoted a significantly increased release of most cytokines, mainly at the highest histone dose. At each time point, the use of DP restored the cell viability at control levels. DP down-regulated the release of most cytokines with a dose-dependent mechanism against HIS100 µg/ml, showing the strongest efficacy at doses 0.6-1.2 U/ml. The formation of HIS-DP complexes revealed that DP was both able to significantly reduce in a dose-dependent manner the % of free histones ($p<0.01$), and to revert the levels of almost all cytokines to those found in controls.

CONCLUSIONS

These findings sustain the ability of DP to bind circulating histones and counteract the inflammatory responses mounted by histone-activated monocytes, providing novel evidence on the anti-inflammatory and histone-neutralizing activity of heparinoid DP and finally its potential use in immuno-thrombotic clinical settings.

COVID-19

P0562

ONE-YEAR REPORT OF ANTI-COVID VACCINATION EFFICACY IN 117 INDIVIDUALS WITH OR WITHOUT PREVIOUS SARS-COV-2 INFECTION

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BACKGROUND-AIM

Studies on the dynamics of the post-vaccination antibody response are fundamental in estimating the efficacy of the COVID-19 vaccine.
From June 2021 to November 2021 we enrolled 117 patients to monitor the serum antibody titer up to one year after completing a full cycle of SARS-CoV-2 vaccination (96.6% of them received Comirnaty and 3.4% Moderna).

METHODS

At recruitment, we set patients in two separate groups, based on whether they had a previous SARS-CoV-2 infection (group 1) or not (group 2). People with previous SARS-CoV-2 infection received a single dose as first cycle of vaccination; people with no history of SARS-CoV-2 received two.
We recruited 71 women (61%) with a median age of 45 (IQR, 33-55) and 46 men (39%) with a median age of 44 (IQR, 33-55); 48 patients (41%) reported previous SARS-CoV-2 infection (52% of women). We collected samples before vaccination (T0), 10 days after the first dose (T1) in group 2, 15 (T2), 90 (T3), 180 (T4) and 360 (T5) days after the second or single dose of vaccination.
Samples were tested using Access SARS-CoV-2 IgG (1st IS) on Access UniCel DxI 800 (Beckman Coulter srl).

RESULTS

During our study, 75 (64%) patients received as booster dose either Comirnaty or Moderna after T3 and only 2 (2%) received it after T4. No significant differences between the two vaccines were observed.
Among 48 SARS-CoV-2 infections (41%) occurred after vaccination, specifically 2 of them after T2, 35 after T3 and 11 after T4.
At T0 and T3 the SARS-CoV-2 IgG concentration was higher in group 1, while at T2, T4 and T5 it was higher in group 2. Anyway, the comparison of IgG median concentrations between the two groups showed a statistically significant difference ($p<0.001$) at T0, T2 and T3, but not at T4 ($p=0.713$) and T5 ($p=0.069$). At T3 the antibody titer dropped in all patients, but the decrease was higher in group 1.

CONCLUSIONS

We confirm that the antibody titer immediately after vaccination is significantly associated with a previous SARS-CoV-2 infection, but not with age and sex, that the probability of contracting the infection after vaccination increases after three months from primary vaccination in both groups of patients, assessing the necessity of booster administrations to guarantee its long term efficacy.

COVID-19

P0563

EVALUATION OF COAGULATION STATUS IN COVID-19 PATIENTS: ASSOCIATION WITH THE DISEASE SEVERITY

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BACKGROUND-AIM

COVID-19, caused by the SARS-CoV-2 virus, has been associated with coagulopathy, a complication characterized by abnormal blood clotting. The aim of our study was to evaluate the coagulation status of COVID-19 patients using the most import biomarkers such as D-dimer, PT (Prothrombin Time), INR (International Normalized Ratio), APTT (Activated Partial Thromboplastin Time), platelet count and to investigate their association with disease severity.

METHODS

The study included 750 COVID-19 patients with different disease severity (“mild”, “moderate”, “severe” and “exitus letalis - EL”). Patients were recruited at the time of admission to the General Hospital Tešanj, Bosnia and Herzegovina, between January and July 2021. Biochemical markers of coagulation, including D-dimer, PT, INR, APTT, platelet count were analyzed in blood samples using standard IFCC procedures.

RESULTS

In our study, statistical analysis showed that D-dimer levels were highest in the group of patients with the moderate disease severity, while the lowest values were in the group of patients with the mild disease severity. The results showed a statistically significant difference in D-dimer levels between the mild and moderate ($p<0.001$), the mild and severe ($p<0.001$), and between mild and EL group of patients ($p<0.001$). Also, statistical analysis showed that PT values were highest in EL group of patients, while the lowest values were in the group of patients with mild disease severity. Our results show a statistically significant difference in PT values between the mild and EL group of patients ($p=0.021$). Also, our results demonstrated that platelet count was higher in moderate group while lower count was in EL group of patients. The results showed a statistically significant difference in platelet count between the mild and EL group of patients ($p=0.007$). On the other hand, APTT and INR didn’t show statistically significant difference between these 4 groups.

CONCLUSIONS

COVID-19 patients have an abnormal coagulation status as indicated by the results of biochemistry markers. Our results support the idea that coagulopathy may play a role in the development of severe COVID-19. Further studies are needed to investigate the underlying mechanisms of coagulopathy in COVID-19 patients.

COVID-19

P0564

MRNA VACCINE INDUCES SARS-COV-2 CELLULAR AND HUMORAL RESPONSES IN CHILDREN TREATED WITH OR WITHOUT IMMUNOMODULANT THERAPY OR PREVIOUS MIS-C

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BACKGROUND-AIM

mRNA vaccines elicit a durable cellular and humoral response to SARS-CoV-2 in adults, whereas evidence in children is lacking. This study evaluated antibody (Ab) levels and T cells immunoreactivity to SARS-CoV-2 S-proteins 6 months (mo) after vaccination, in children with or without immunomodulant therapy (IT) or previous multisystem inflammatory syndrome (MIS-C).

METHODS

A series of children were enrolled at Pediatric Departments at University of Padua, between Jun 2022 and Dec 2022, 6 mo after complete vaccination with BNT162b2. Whole blood (Li-He) and Serum samples were collected. Li-He was used to determine the T cell activation by bKIT dqTACT MS assay HYRIS bCUBE Real-time PCR System, by means of the 2^{-ddCt}[CXCL10 fold change (FC) of mRNA expression with respect to unstimulated cells]. Serum was used to determine anti-SARS-CoV-2 Abs by CLIA S-RBD IgG(S-RBD IgG) (Snibe, Shenzhen, China) and plaque reduction neutralization test ($PRTN_{50}$)(parental and Omicron BA.2 variant).

RESULTS

Fifty children were studied, 23(46%) were females, 27(54%) males and mean age(±SD) was 8.87±2.09. Thirty children were not in treatment (C), 10 were treated with immunosuppressant drugs (e.g. mycophenolate, tacrolimus, prednisone), while 10 had previous MIS-C. A total of 39(79.6%) had COVID-19 before vaccination. Gender and age didn't differ among groups. $PRTN_{50}$(parental strain) median values and interquartile ranges (IQR) were 113.1(20-320), 10(10-254.6) and 452.5(160-640) for C, IT and MIS-C, respectively(χ^2=4.2, p=0.128). $PRTN_{50}$(Omicron BA.2) median and IQR were: 10(10-56.6), 10(10-10) and 80(40-905.1) for C, IT and MIS-C, respectively (χ^2=7.81, p=0.01). S-RBD IgG median and IQR levels in kBAU/L were 331.9(196.5-627.6), 150.7(53.2-396.1) and 412.2(210.8-832.7) for C, IT and MIS-C, respectively(χ^2=3.51, p=0.173). The CXCL10 FC median values were 16.7(8.22-27.1), 6.1(2.9-18.1), 8.6(2.6-11.1) (χ^2=7.2, p=0.027). Except for CXCL10 FC, the other studied immunological parameters increased in individuals with previous COVID-19 infection(p<0.01).

CONCLUSIONS

Immune response 6 mo after mRNA vaccination was lower in IT children. mRNA vaccine increased humoral and cellular responses in C and MIS-C, providing insight into boosting immunity in children.

COVID-19

P0565

COMPARISON BETWEEN PANA9600S-GENTIER96E SYSTEM AND IPONATIC ANALYSER FOR THE DETECTION OF THE SARS-COV-2

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BACKGROUND-AIM

Coronaviruses are a large family of viruses which are known to cause a vast array of diseases, ranging from common cold to more serious conditions such as Severe Acute Respiratory Syndrome (SARS) and Middle Eastern Respiratory Syndrome (MERS). Since its first appearance in China in December 2019, the pandemic has spread rapidly throughout the world. To contain this pandemic, collaborative approach involving accurate diagnosis, epidemiology, surveillance, and prophylaxis is essential.
RT-qPCR assay is considered to be the gold standard for the early detection of virus. However, proper diagnosis using rapid technologies plays a crucial role for effective prevention and management of COVID-19 cases. Hence, in this study we compared Pana9600S®/Gentier96E® System (Xi'an TianLong Science and Technology, Xi'an, Shaanxi, China), analyzer used for the routine of swabs and POCT Real-Time PCR iPonatic®(Sansure Biotech Inc) for the detection of SARS-CoV-2.

METHODS

90 consecutive swabs were analyzed in both instruments for the detection of COVID-19. iPonatic® (4 modules) is a rapid molecular biology diagnostic system that integrates extraction, Real-Time PCR amplification and automatic result interpretation. iPonatic® allows for rapid sample lysis and nucleic acid release in 3 minutes with subsequent amplification in 40 minutes.
PANA 9600S is an automatic system for the extraction of nucleic acids by using magnetic beads from different biological matrices, from the primary tube. It is able to prepare the PCR master mix in automation and integrates the possibility of transferring the extracted sample into the PCR plates directly on board. GENTIER96E® is a user-friendly Real Time PCR that allows amplification monitoring in real time.

RESULTS

The results of this study showed a good overall percent agreement between the results obtained by Pana9600S-Gentier96E system and iPonatic (83%). The positive percent agreement has been of 100% while negative percent agreement of the 74%. Cohen's kappa concordance index showed substantial agreement between the two methods (k=0.67).

CONCLUSIONS

The data from our study showed that iPonatic® is a good tool for the rapid diagnosis and management of COVID-19 cases.

COVID-19

P0566

L-ARGININE PLUS VITAMIN C SUPPLEMENTATION IN LONG COVID PATIENTS: EVALUATION OF ARGININE METABOLISM USING AN UPLC-MS/MS METHOD

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BACKGROUND-AIM

Patients with COVID-19 have been reported to have altered arginine metabolism which, through nitric oxide synthesis, has been linked to immunological and vascular dysfunction. In the current study, we measured the serum levels of arginine, citrulline, ornithine, monomethylarginine (MMA), symmetric and asymmetric dimethylarginine (SDMA, ADMA) in adults with Long Covid at baseline and after 28 days of L-arginine plus vitamin C or placebo supplementation, compared to a group of adults without a previous Covid-19 diagnosis. Other arginine markers of nitric oxide (NO) bioavailability were also evaluated: arginine/ADMA, arginine/citrulline+ornithine, and arginine/ornithine.

METHODS

Long Covid patients enrolled for the study (46) were randomized into two groups: 23 treated with L-arginine plus vitamin C and 23 treated with placebo. The control group was composed by 11 subject.
An in-house validated Ultra Performance Liquid Chromatography Tandem Mass Spectrometry (UPLC-MS/MS) method was used to determine the metabolites concentration in serum samples. The chromatographic separation was performed with an ACQUITY UPLC I-Class System (Waters, Milford, MA, USA) using a hydrophilic interaction liquid chromatography (HILIC) column. Analytes detection was performed using a triple quadrupole Xevo-TQs Micro (Waters, Milford, MA, USA) equipped with an electrospray ion source operating in positive ion mode.
Mass spectrometric analytes detection was performed using multiple reaction monitoring (MRM) experiment.
Chemometric discriminant classification models were built using Partial least squares discriminant analysis (PLS–DA) to characterize arginine metabolism in patients and evaluate the effects of the supplementation.

RESULTS

PLS-DA allowed discrimination of Long Covid subjects at baseline from healthy controls with 80.2 ± 3.0% accuracy. Other parameters that express NO bioavailability were alterated in participants with Long Covid. After 28 days of L-arginine plus vitamin C supplementation, serum arginine concentration, and arginine/ADMA increased significantly compared with placebo.

CONCLUSIONS

In conclusion we assume that L-arginine plus vitamin C supplementation may be brought as a successful approach to contrast inhibition of NO synthesis in people with Long Covid.

COVID-19

P0567

DONOR SCREENING AND THERAPEUTIC MANUFACTURING OF SARS-COV-2 SPECIFIC T CELLS: FIRST EXPERIENCES

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BACKGROUND-AIM

Since 2015, our hospital is capable of producing Virus Specific T cells (VSTs) for therapeutic use. The widespread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) made us pursue the opportunity to produce VSTs against it for our patients. Our protocol makes us do a donor eligibility test in order to verify the response of donor's T cells to the stimulus. This way we can compare the quantity of VSTs in the donor's peripheral blood and of the end product and look for a way to predict the VST quantity for therapeutic use

METHODS

For the donor eligibility test, we use a functional flow cytometry test with a specially designed pool of peptides specific for SARS-CoV2.
First, we determine the VST percentages in the possible donor's blood, both within the CD4+ helper, and the CD8+ cytotoxic T cell subpopulations. Then we perform an immunomagnetic separation by CliniMACS Prodigy System and this gives us the target fraction to be administered to the patient.
We compared two datasets with the VST percentages of the donors: the percentages of VST cells in the CD4+ and CD8+ populations of the end product - called "purity" - and the exact number of CD4+ and CD8+ VSTs of the end product. The comparison is possible since we always use the same number of cells to start process.

RESULTS

Since April 2021, we have manufactured 7 cellular products, of which 6 was administered to patients. By applying the Spearman's correlation, we found moderate positive correlation between the CD4+ VST percentage in the donors' blood and the purity of the cellular products (r_s:0,61), and moderate positive correlation between the CD8+ VST percentage of donors' blood and both the purity (r_s:0,68) and the VST content of the cellular products (r_s:0,64). We manufactured more CD8+ VSTs than CD4+ ones for therapy, this may be the reason why we found only negligible correlation with the CD4+ end products.

CONCLUSIONS

Based on a small number of runs, our results suggest that there is a correlation between the VST content of the donor's unprocessed blood and the VST purity, and in case of the CD8+ cells, the VST content of the end product. We are planning to carry on monitoring the VST manufacturing processes, and with more data, we will get more elaborate results.

COVID-19

P0568

COVID-19 AND CRYOGLOBULINEMIC VASCULITIS. TWO-YEAR SURVEY STUDY ON THE IMPACT OF PANDEMIC AND VACCINATION.

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BACKGROUND-AIM

Cryoglobulinemic Vasculitis (CV) is a rare autoimmune-lymphoproliferative systemic disorder with multiple organ involvement. We aimed at investigating the prevalence and outcome of COVID-19, the safety and immunogenicity of COVID-19 vaccines in a wide CV cohort by a multicenter survey.

METHODS

CV subjects were consecutively recruited at 11 Italian referral centers. CV diagnosis, clinico-serological parameters, COVID-19 tests, and vaccination immunogenicity were carried out according to current methods.

RESULTS

Four-hundred-thirty unselected CV patients (130 M; mean age 70±10.96 years) were recruited from February 2020 to October 2021. COVID-19 prevalence was significantly higher in CV patients compared to the Italian general population ($p<0.005$); furthermore, we observed a higher mortality in CV subjects with COVID-19 compared to those without ($p<0.01$). An older age (≥60 years) correlated with a worse COVID-19 outcome. Vaccine was administered in 87% of patients, and 50% received a boostering dose. Disease flares/worsening following the vaccination were significantly less frequent than those associated to COVID-19 ($p=0.0012$). CV patients showed an impaired vaccination immunogenicity compared to controls ($p<0.05$), as well an increased no-response rate after the booster.

CONCLUSIONS

CV patients have a higher risk to develop COVID-19, as well of more severe disease manifestations. Vaccines had a good safety profile in CV patients and of note, the vaccine-related side effects/disease flares were significantly lower compared to those COVID-19-related. However, a quarter of vaccinated individuals do not show detectable seroconversion; this is a major challenge for clinicians. Overall, a close monitoring of these frail patients during the ongoing pandemic is particularly advisable.

COVID-19

P0569

CHARACTERIZATION OF CIRCULATING EXTRACELLULAR VESICLES FOR THE PROGNOSTIC STRATIFICATION OF COVID-19 PATIENTS

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BACKGROUND-AIM

COVID-19 is challenging since its clinical presentation ranges from an asymptomatic form to a critical one with lethal complications.
Extracellular vesicles (EVs), bioactive nanoparticles released by several cell types and found in most body fluids, could be appealing as non-invasive prognostic biomarkers. For this purpose, we assessed whether flow cytometry assays could have a diagnostic role in COVID-19 patients.

METHODS

We divided 97 COVID-19 patients in severe (n=47), and non-severe (n=50). Platelet poor plasma was collected at hospital admission (along with anamnestic and hematochemical parameters). Vesicles were then analyzed by flow cytometry to characterize particle size and to evaluate the expression of markers of endothelial, platelet, leukocyte, NK-cells, mural cell, and neural cell origin (i.e. CD31, CD34, CD42b, CD45, CD140b, CD56, and N-Cadherin). Last, we employed machine learning approaches to find a correlation between analyzed parameters and disease severity.

RESULTS

Patients with adverse outcome were significantly older and affected by several comorbidities. From a hematological point of view, 13 parameters were significantly different among the two groups (including C Reactive Protein, Proadrenomedullin, Procalcitonin, Lactate Dehydrogenase, N-terminal prohormone of brain natriuretic peptide, Troponin, Lymphocyte and Neutrophil counts). Moreover, the fraction of small EV expressing CD31, CD34, CD42b, CD45, CD140b, CD56, and N-Cadherin were significantly higher in patients with better outcome, while large EVs expressing CD34, CD45, CD140b, CD56, and N-Cadherin were higher in patients with severe outcome. Elastic net logistic regression analysis with cross-validation showed that LDH followed by the fraction of larger vesicles expressing 140b and CD56, IL6, proadrenomedullin and the fraction of larger vesicles expressing CD31 were the strongest predictors associated with disease severity. Conversely, smaller particles were predictors of a better outcome.

CONCLUSIONS

EVs and their size are independent predictors of COVID-19 severity. Data suggest that particle size, along its association with several markers of different cell origin might efficiently have a diagnostic role in the treatment care of COVID-19 infection.

COVID-19

P0570

MALDI-BASED SCREENING OF EXTRACELLULAR VESICLES BIOMARKERS APPLIED TO COVID-19 DIAGNOSTICS

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BACKGROUND-AIM

During COVID-19 pandemic, much effort has been employed in the assessment of multi-omic approaches for the identification of molecules that could be predictors of disease severity. In this setting, Matrix-Assisted Laser Desorption/Ionization – Time of Flight (MALDI-TOF) is being experimented to identify specific proteomic and lipidomic fingerprints of biological samples, that could be associated with disease outcome. Exosomes are small cell-derived vesicles (50-200 nm) increasingly recognized as a promising source of circulating biomarkers for non-invasive diagnostics from body fluids. For this reason, the aim of this work is to create a fingerprint of circulating extracellular vesicles associated with COVID-19 outcome.

METHODS

Platelet Poor Plasma of 20 COVID-19 patients, dichotomized based on disease severity, was processed for Exosomal Enrichment using SelectEV kit (Exosomics). Proteins were isolated using 2-D Clean-up kit (Biorad). Proteins, together with intact EVs, were desalted using C18-ZipTips and spotted directly on the MALDI plate in duplicate. We performed analysis using the MALDI-7090.

RESULTS

Protein extracts were analyzed by MALDI-MS in the range of m/z 2000-20000 and using mMass software for peak picking we identified: 82 peaks in non-severe patients' protein extracts, 90 peaks in severe patients' protein extracts, 67 peaks in non-severe patients' intact vesicles and 77 peaks in severe patients' intact vesicles. 38 of the peaks were shared among all the spectra, 26 were shared just in extracted vesicles and 17 were present only in the intact vesicles. Lastly, 23 peaks were exclusive of severe patients' protein extracts and 16 peaks exclusive of non-severe patients' while considering intact vesicles, 14 peaks were detected in severe patients' intact vesicles only as 4 peaks were only found in non-severe patients.

CONCLUSIONS

This work shows the potential of MALDI based technology for the identification of a specific proteic exosomal fingerprint to identify potential clinical biomarkers. More generally, MALDI could be promising to establish a high throughput screening platform for clinical purposes in several pathologies.

COVID-19

P0571

RESOLUTION OF BIOCHEMICAL PARAMETERS 6 MONTHS AFTER COVID-19 INFECTION

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BACKGROUND-AIM

Since the emergence of COVID-19 in 2019, numerous studies showed that COVID-19 is a multisystem disease which primarily affects lungs, but can also cause acute kidney, liver, neuronal and cardiovascular damage. Correspondingly, several routine laboratory parameters have been identified as significantly changed, depending on disease severity. However, much less attention has been given to parameters in recovering patients, which can provide important information on the disease resolution and could hint on the susceptibility of each individual based on their baseline parameters. Most laboratory parameters returned to normal from 2 weeks to several months after disease onset. However, several questions regarding resolution of COVID-19 infection still remain open.

METHODS

In this study, we analysed basic biochemical parameters in 75 non-vaccinated patients 5-6 months after disease onset. The measured parameters were correlated with demographic data and disease severity to assess the state of major organ systems 5-6 months after COVID-19 infection. The median age of the participants was 43 years (IQR, 35–54), and 60 (80 %) were women. There were 45 participants in the mild case group, 22 in the moderate cases group and 8 in the critical cases (CC) group.

RESULTS

We observed a statistically significant increase in age and in BMI with increasing severity of disease, but there was no difference in smoking history or reported comorbidities. Biochemical analysis showed that predictably, most measured parameters were within the reference range. Above the reference range were only measurements of sodium, chloride and cholesterol in CC. A statistically significant increase in CC was also detected for creatinine, ALP and ferritin. Markers of major organ system showed decreased kidney function (increased creatinine and serum urea in CC), slight liver stress (nonsignificant increase of bilirubin and ALT in CC) and slight cardiac stress (nonsignificant increase in AST and LDH in CC).

CONCLUSIONS

Our results thus suggest that COVID-19 can have long-term effects on the function of major organ systems especially in critical patients and that pre-infection state of the patient can affect disease severity. More studies should be performed to better understand these consequences.

COVID-19

P0572

STUDY THROUGH MOLECULAR TESTING OF COVID-19 INFECTION IN A GROUP OF ALBANIAN POPULATION

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BACKGROUND-AIM

The virus SARS-CoV-2, appeared even in a small country like Albania, with mass diffusion during the years 2020-2021. The INTERMEDICA clinic was involved in the identification, monitoring and study of population immunization. This study analyzes the infection during an eight-month frame from September 2020 until April 2021.
This paper aims to study the situation of infection with the SARS-CoV-2 virus through Real-Time PCR testing.

METHODS

The material was taken through the naso and oropharyngeal routes through a tampon. The genetic material was extracted through the QIAamp Mini Viral RNA Kit, then the preparation of the MasterMix, through the EURORealTime SARS COV 2 kit and reading in the cobas z 480 . After the measurements, the data was arranged in tables and subjected to statistical processing. The grouping and analysis of the data for the buffers was carried out using the SPSS program. Tampon data were grouped into two groups, according to age and gender. For each group, calculations were made for the mean, standard deviation, coefficient of variation, minimum and maximum value, quartiles Q1 and Q3 as well as the median. The frequency of positive cases was analyzed in each of the groups to identify the most affected age and gender groups. The time analysis of the spread of the virus was also carried out. Two types of statistical analyzes were used for the analysis of data: factorial and cluster analysis.

RESULTS

During the eight-month period, 56 385 individuals were tested, of which 7.45% were positive. From the study we can say that we have a higher number of men with a positive test result, 52.5% compared to the number of women 47.4%. In the case of age groups, a higher number of positive cases is represented by the 21-41 age group with 39.6%, followed by the 42-62 age group with 36.5% and over 62 years old with 20.4%. The age group 0-20 has a very low number of positive cases with 3.4%.

CONCLUSIONS

From the time analysis of the virus spread, we conclude that there were two peaks with the highest number of positive cases and these belong to the two months of November and February. The factors that have led to these two peaks have been: the opening of schools on September 14, the 2020 end-of-year holidays and low wind speed in the months September-October

COVID-19

P0573

SINGLE CENTER EXPERIENCE WITH LONG-TERM CLINICAL PERFORMANCE OF RAPID SARS-COV-2 ANTIGEN DETECTION TEST

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BACKGROUND-AIM

The COVID-19 pandemic in Korea has dynamically changed with occurrence of variants. A rapid, reliable diagnostic tool for detection of SARS-CoV-2 is needed. RT-PCR is currently the gold standard, but it is time-consuming and requires expert technicians. The rapid antigen detection test (RADT) was approved as a confirmatory test on March 2022 owing to dissemination of Omicron variant. The benefits of RADT are speed, simplicity, and point-of-care feasibility. The aim of our study is to evaluate the clinical performance of RADT for 15 months, fully covering the 'Variants of Concern (VOC)'.

METHODS

A total 14,194 cases that were simultaneously tested by RT-PCR and RADT from January 2021 to March 2022 in Gangnam Severance Hospital were retrospectively reviewed. PowerChek™ SARS-CoV-2, Influenza A&B Multiplex Real-time PCR Kit and STANDARD™ Q COVID-19 Ag Test were used. Positive rates, sensitivities, specificities, positive predictive values (PPV), and negative predictive values (NPV) were estimated for five periods(3 months/period). Receiver operator characteristic curve (ROC) analysis was performed and Spearman's rank test assessed the correlation between RT-PCR Ct values and semi-quantitative RADT results.

RESULTS

The overall positive rate of RT-PCR was 4.64%. The overall sensitivity and specificity were 0.577[95%CI, 0.539-0.614] and 0.991[95%CI, 0.989-0.993], respectively. ROC analysis resulted in an area under the curve of 0.786 ($P<0.0001$). The PCR positive rates were estimated as 0.11%, 0.71%, 4.51%, 2.02% and 13.72% in period 1, 2, 3, 4 and 5, respectively. PPV was estimated as 0.045, 0.421, 0.951, 0.720 and 0.798 in period 1, 2, 3, 4 and 5, respectively.

CONCLUSIONS

RADT exhibited good performances in specimens with low Ct values($Ct \leq 25.00$). The PPV was significantly higher in periods 3 and 5, which corresponds to dissemination of the Delta and Omicron variant. The high PPV implies that individuals with a positive RADT result are very likely infected and would require prompt quarantine, rather than additional RT-PCR. The sensitivity of 0.577 indicates that RADT should not replace RT-PCR. Nonetheless, given the high PPV and the ability to track infected persons through rapid results, our findings suggest that RADT could play a significant role in control strategies of further variants.

COVID-19

P0574

IMMUNOGENETIC IN THE MRNA-1273 VACCINE

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BACKGROUND-AIM

Vaccine-induced humoral response may be influenced by several immunogenetic factors. One of them is the human leukocyte antigen (HLA) molecules. These molecules are responsible for presenting peptides to follicular T-lymphocytes (TFH) to induce the differentiation of B-lymphocytes into antibody-producing plasma cells. HLA molecules present a high polymorphism, conditioning which peptides they present. Therefore, each allele will present different peptides and induce a different humoral response.

METHODS

The level of IgG antiprotein S antibodies was determined one month after the second dose of mRNA-1273 vaccine. We divided the degree of response based on the mean value (2700 BAU/mL) and +/- one standard deviation (1700 BAU/mL) into three groups: low responders (<1000 BAU/mL), medium responders (1000-4400 BAU/mL) and high responders (>4400 BAU/mL).
We then performed high-resolution class II HLA typing of 30 individuals from each group by NGS and compared allele frequencies.

RESULTS

Allele frequencies were compared between the different groups. There were no significant results with the group of half-responders. Our results show that the high responder group has a higher frequency of the HLA-DRB1*07:01 allele than low responders (P=0.0031).
Low responders have a higher frequency of the HLA-DRB1*01:01 allele compared to high responders, although not statistically significant.
In addition, individuals carrying the HLA-DRB1*07:01 allele had higher mean IgG Anti-S levels than non-carriers of this allele (P=0.002) and than carriers of the HLA-DRB1*01:01 allele (P=0.004).

CONCLUSIONS

The HLA-DRB1*07:01 allele is associated with increased antibody production in individuals vaccinated with mRNA-1273. One possible explanation is that the HLA-DRB1*07:01 allele is able to bind up to 16 protein S-derived peptides with high affinity, whereas the HLA-DRB1*01:01 allele is only able to bind 5 peptides with high affinity. This helps to explain why the frequency of the HLA-DRB1*07:01 allele increases in the high-responder group and the HLA-DRB1*01:01 allele is more frequent in the low-responder group. These results may help in the selection of immunodominant peptides that generate a better response in certain populations based on HLA class II allele frequencies.

COVID-19

P0575

AN EMPIRICAL APPROACH TO MODELLING THE ASSOCIATED FACTORS OF COVID-19

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BACKGROUND-AIM

The proposed empirical study uses a Romanian dataset to analyze the factors affecting the prevalence of COVID-19 and explore the inter-individual differences across the investigated subjects.

METHODS

In the spring of 2022, we have collected Covid related information corroborated with personal and work – related characteristics from 138 persons (86 medical students and 52 medical personnel). We determined the neutralizing IgG antibodies to SARS-CoV-2 in the blood using Siemens ADVIA Centaur® SARS-CoV-2 IgG assay. We have used a dichotomous logistic linear regression to estimate the probabilities of contracting COVID-19. Our main contribution is to propose a multi-level logistic model, first to identify the main contributors to developing AU/ml and, second, to model the severity of Covid.

RESULTS

Covid history does not statistically significant influence the concentration of neutralizing IgG antibodies to SARS-CoV-2. As the number of months between vaccination and antibodies testing increase, the titer concentration is likely to decrease. Probably most surprising result is that those who had allergies presented almost 3 times more chances to have higher concentration of neutralizing IgG antibodies to SARS-CoV-2 as compared with those without allergies. The odds of having Covid after vaccination are higher for men than for women. The existence of allergies is likely to increase the odds of contracting SARS-CoV-2 infection by 1.5 time. While date does not support a statistically significant relationship between doze 1 and 2 on the severity of Covid, doze 3 is shown to reduce the severity of Covid by almost 9 times. To the opposite, age is increasing the odds of a severe form of Covid (1.075).

CONCLUSIONS

Our research has highlighted the importance of allergies for developing higher antibodies titer and for preventing of SARS-CoV-2 infection, after vaccination. Analyzing the downsize of vaccination is thereby a major imperative of further studies in the field

COVID-19

P0576

TREND OF CHANGE IN SARS-COV-2 ANTIBODIES VALUES MEASURED BY FIVE DIFFERENT METHODS

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BACKGROUND-AIM

The aim of this study was to investigate the trend of change in SARS-CoV-2 antibodies values measured by five different immunoassay methods examined according to the months that have passed from the date of onset of symptoms to the date of blood sampling for analysis.

METHODS

The experiment included 84 serum samples for the determination of Beckman Coulter IgG (S protein); 84 serum samples for determining Abbott IgG (S protein); 53 serum samples for determining Abbott IgG (N protein); 80 serum samples for determining Roche total antibodies (IgG, IgA, IgM) and 21 serum samples for determination of Roche IgG (S protein). The period is divided into four categories: 1 - up to three months, 2 - from three to six months, 3 - from six to nine months and 4 - over nine months.

RESULTS

Only the results measured by the Abbott method for the determination of IgG (N protein) of the SARS-CoV-2 virus (P<0,001) and the Roche method for the determination of total antibodies (IgG, IgA, IgM) to the SARS-CoV-2 virus (P=0.016) showed a statistically significant trend of changes in antibody values. The Bonferroni posthoc test indicated that the statistically lowest antibody values were obtained in category 3, between the sixth and ninth month from the onset of symptoms. It is noted that there is a significant trend of decreasing antibody values from the sixth to the ninth month. In the last category, over nine months, slightly higher values of antibodies are obtained tested with these two methods. The determination of antibodies by other methods (Beckman Coulter IgG (S protein), Abbott IgG (S protein) and Roche IgG (S protein)) did not show a statistically significant trend of change in relation to the examined period.

CONCLUSIONS

The results of this study indicate that the choice of immunoassay method is important for monitoring SARS-CoV-2 antibody kinetics. It still remains unclear which of them are neutralising antibodies and work more effectively in the case of SARS-CoV-2 infection.

COVID-19

P0577

VERIFICATION OF A RAPID IMMUNOCHROMATOGRAPHIC TEST FOR ANTIBODIES TO SARS-COV-2

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BACKGROUND-AIM

The diagnostic accuracy of the immunochromatographic test (COVID-19 Sero NP/RBD, Coris BioConcept, Gembloux, Belgium) was assessed for the rapid qualitative determination of antibodies to the SARS-CoV-2 nucleocapsid protein (NP), and the receptor binding domain (RBD) in serum.

METHODS

A comparison was made between the chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of SARS-CoV-2 IgG antibodies to the NP, on the Architect i1000SR analyzer (Abbott, Abbott Park, Illinois, U.S.A.) with the qualitative immunochromatographic test. 50 serum samples in which antibodies to SARS-CoV-2 were routinely determined in the Clinical Department of Laboratory Diagnostics, University Hospital Dubrava, were tested for comparison. The accuracy assessment for the COVID-19 Sero NP/RBD immunochromatographic test was tested by the kappa statistic (inter-rater agreement (kappa)) with MedCalc (version 18.11.6.).

RESULTS

17 negative samples (< 50 AU/ml) and 33 positive samples (> 50 AU/ml) were tested. Samples with SARS-CoV-2 IgG antibody values < 21.0 to 14341.4 AU/ml were tested. The disproportion visible between the number of tested positive and negative samples is present due to the testing of samples with the limit values of the used method (about 50 AU/ml). A kappa coefficient of 0.827 was obtained, which represents a strong agreement.

CONCLUSIONS

The COVID-19 Sero NP/RBD test showed a strong concordance with the CMIA for the quantitative determination of IgG antibodies to SARS-CoV-2 (Architect i1000SR, Abbott). The CMIA (Abbott) detects the presence of IgG antibodies to a single SARS-CoV-2 antigen (NP), while the immunochromatographic test (COVID-19 Sero NP/RBD, Coris BioConcept) detects the presence of antibodies to NP and RBD antigens of SARS-CoV-2. The differences in the results are probably due to the detection of different types of antibodies to SARS-CoV-2 as well as the immunochemical methods themselves.
The immunochromatographic test is rapid and easy to use, however, the interpretation of the findings depends on the visual assessment of the technician performing the test. Given that immunochemical tests are not standardized, the findings should be interpreted with caution in the clinical context.

COVID-19

P0578

PREVALENCE OF MONOCLONAL COMPONENTS IN SARS-COV-2 HOSPITALIZED PATIENTS

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BACKGROUND-AIM

The protidology center of Clinical Pathology and Microbiology Division (L.Bonomo Hospital, Andria, BT) performs all electrophoresis (EF) and immunofixation of seroprotein ASL BT. During the pandemic period of SARS-Cov-2, many monoclonal immunoglobulins (CM) were observed in hospitalized patients with SARS-CoV-2 positive (COV+). The purpose of this document is to assess a potential correlation between viral infection and the presence of CM, using a retrospective study.

METHODS

510 EF from COV+ patients and 2244 EF from SARS-CoV-2 negative (COV-) patents were taken into account. Suspected CM were assessed by immunotyping or agarose gel immunofixation. Diagnostic classification of CM positive patients also requires a dose of sFLCκ and sFLCλ, sIgG, sIgA, sIgM and Beta2-Microglobulin, performed only for 59 CM positive samples.

RESULTS

CM was detected in 83 COV+ patients (17.3% of total), primarily characterized as IgG. The prevalence of CM in the COV+ group was higher than the prevalence in the COV- group (6.9%, 143 patients). In both groups predominantly monoclonal profiles were observed and the biclonal, triclonal and oligoclonal profiles were higher in the COV+ group than in the control group.
Monoclonal peak quantification was <11 g/L, but 21.9 g/L only in one case. In addition, 22.9% of cases reported a historical CM, 57.8% were previously negative for CM research, while 19.3% had never conducted an EF.

CONCLUSIONS

The presence of CM in the COV+ patient group was greater than in epidemiological studies.
In the population studied, there would seem to be a correlation between SARS-CoV-2 infection and the detection of a monoclonal peak, especially in the male and elderly population. It could be hypothesized that the immune stimulation in COV+ subjects could have determined a lymphocyte activation such as to induce the onset of a monoclonal gammopathy.
We propose the execution of the EF for all COV+ patients at admission and its repetition at discharge, with a contextual dose of sFLC at the first finding of CM.
Since age-related immune dysregulation and the presence of Monoclonal Gammopathy of Undetermined Significance (MGUS) could result in a non-optimal response to the SARS-CoV-2 vaccine, it would be useful to dose sIgG, sIgA and sIgM.

COVID-19

P0579

IMPROVING LABORATORY VITAMIN D STATUS IN PATIENTS DURING THE SECOND YEAR OF COVID-19 PANDEMIC COMPARED TO THE PRE-PANDEMIC PERIOD

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BACKGROUND-AIM

The COVID-19 pandemic led to search for all possible means that could protect people from the spreading infection, one of them was increase use of vitamin D. Based on the trend of a significant increase in the sale of over-the-counter vitamin D containing preparations (OTC-VIT D) in our public pharmacy, the main target of this study was to compare the status of vit D levels before (2019) and at the time of fully developed pandemic COVID-19 (2021) in a sample of patients visiting the hospital.

METHODS

Cross-sectional retrospective analysis on a hospital patients´ annual data of vit D levels in both years 2019 and 2021 was used. During the entire period, the same analytical procedure to determine vit D was used (Elecsys Vitamin D Total II, analyzer Cobas e411, Roche). At the same time, the whole both year´s quantities of dispensed OTC-VIT D from public pharmacy expressed in international units (IU) were compared.

RESULTS

In 2019, the average level of vit D examined on 3137 samples (m=491, f=2646) was 24.06 μg/l (median 23.55 μg/l), in 2021 - 3247 samples (m=738, f =2509) 29.55 μg/l (28.88 μg/l). From all measurements, in 2019 there were 24.83% of results with „normal" status of serum vit D (> 30 μg/l), in 2021 it was already 45.67%. The share of „deficient" vit D levels (< 20 μg/l) was 35.48% in 2019, but only 20.82% in 2021. When comparing the median levels of vit D according to the respective quarters (Q) of 2019 and 2021, observed levels were as follows: I.Q 2019 - 18.56 vs. I.Q 2021 - 22.96, II.Q - 23, 61 vs. 26.3, III.Q - 32.72 vs. 34.67, IV.Q - 22.62 vs.30.79 μg/l, all at $p < 0.00001$.Through a public pharmacy a total of 14,734,500 IU VIT-D in 2019, 38,125,000 IU (2020), 63,039,000 IU (2021) were dispensed.

CONCLUSIONS

Our analysis clearly confirms the trend of increase in vit D levels examined in 2021 compared to 2019 in average by 5.49 μg/l, in median by 5.33 μg/l, but also in all respective quarters of both years. It could also confirm the trend of a significant increase in the consumption of OTC-VIT D (more than 4.28-times higher amount of OTC-VIT D comparing both 2021 and 2019 years). We assume a mutual connection between these two observed trends. According to several studies, a higher status of vit D levels could be associated with less severe course of the COVID-19 infection

COVID-19

P0580

SELECTION AND IMPLEMENTATION OF POC RAPID COVID-19 ANTIGEN TEST: OVERCOMING CHALLENGES

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BACKGROUND-AIM

Qatar's success in overcoming three recurrent pandemic waves of coronavirus disease 2019 (COVID-19) is attributed to the collective efforts of public health measures and timely healthcare testing. As Qatar witnessed surge in COVID-19 cases, rapid antigen tests (RAT) were highly in demand for the virus detection. In this crucial timing, selection and procurement of available COVID-19 RAT following the World Health Organization (WHO) guidelines was a huge challenge for Point of Care testing (POCT) department. In this study, we highlighted the challenges in establishing COVID-19 testing system including validation, personnel training and building a compatible laboratory information system (LIS) upholding Hamad Medical Corporation (HMC) cyber security regulation.

METHODS

Three regulatory approved RATs were evaluated against real-time polymerase chain reaction (RT-PCR) and analytical performance were verified. Maintaining the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologist (CAP) standards for COVID-19 waived testing, POCT team initiated to conduct practical and educational training vastly through online platforms and face to face sessions. We utilized the Extendable LIS functionality for fast medical decisions in hospitals and enabled "reason of testing" feature in Qatar's COVID-19 tracking application.

RESULTS

Our performance verification showed 98.0% sensitivity and 100% specificity for PanbioTM COVID-19 RAT, 98.0% sensitivity and 100% specificity for Quidel SOFIA2 COVID-19 RAT and Roche COVID-19 RAT yielded a sensitivity of 97.0% and specificity of 100%. Total of 291 training sessions were conducted for 9710 clinical staffs across 17 HMC facilities and 185 private clinics. Using LIS and POC middleware features, obvious increment in RAT >509 tests/day has been reported in a single emergency unit and 5.5% decrement in incorrect patient identification data.

CONCLUSIONS

The methods established for the COVID-19 implementation showed acceptable performance fulfilling the elements of HMC product procurement specification and CAP Accreditation standards. Synergic actions of HMC-POCT with supportive laboratory management added efficiency to the public health control measures in Qatar optimizing efforts to pre-COVID normalcy.

COVID-19

P0581

FREE LIGHT CHAINS AS MARKERS FOR FOLLOW-UP IN COVID-19 PATIENTS

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BACKGROUND-AIM

COVID-19 infection produces during its recovery phase interleukin-6 (IL-6), circulating inflammatory monocytes, as well as IL18 and IL7 which promotes IL-2 secretion and, in turn, B-cell proliferation and antibody production. Immunoglobulin light chains (FLC) are produced in excess of the heavy chains. In pathological conditions, such as COVID-19 infection, FLC production will be increased.
The aim of this study is to evaluate the usefulness of serum FLC as a follow-up biomarker in patients with moderate to severe COVID-19 in the recovery phase.

METHODS

Prospective longitudinal study. The study cohort consisted of patients aged 18-85 years with moderate to severe COVID-19 admitted to the Intensive Care Unit (ICU) during the first and second wave of the pandemic.
They were followed from admission to final outcome, classified according to the need for invasive mechanical ventilation (IMV) and/or death (D).
Quantification of kappa (k) and lambda (λ) FLC levels will be performed by Turbidimetry (SPA PLUS from BindingSiteLtd). SPSS Statistics v.25 software was used (paired Wilcoxon test and non-parametric U-Mann Whitney test between independent groups).

RESULTS

The study included 80 patients, 52 required invasive mechanical ventilation (IMV) and 40 died during their ICU stay. The median age was 62 (interquartile range IQR, 17). There were a total of 19 women and 61 men.
Median CLLk was 19.66 (18.02), increasing to 35.07 (35.13) at week 3. Results according to VMI yes/no: 21.58/16.13 at admission and 36.32/13.0 at week 3 ($p<0.05$). According to D (yes/no): 21.01/17.91 at admission and 26.56/36.09 at week 3 ($p<0.05$).
Median CLLλ was 27.5 (16.69) at admission and 46.97 (40.76) at week 3. Results according to VMI yes/no: 28.78/21.84 at admission and 36.28/16.31 at week 3 ($p<0.05$). According to D (yes/no): 28.81/25.31 at admission and 40.74/54.10 at week 3 ($p<0.05$).

CONCLUSIONS

Patients in need of IMV had higher levels of FLC than those who did not. While patients who died during their stay had higher lambda FLC levels at week 1.
In summary, a continuous increase in FLC is associated with worse survival and a higher need for IMV, presenting itself as a biomarker for screening and monitoring the clinical course of the disease.

COVID-19

P0582

ASSOCIATION OF THE INFLAMMATORY CYTOKINES WITH THE COMORBIDITIES OF COVID-19 PATIENTS

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BACKGROUND-AIM

Pre-existing health conditions disturb the levels of cytokines, resulting in hyperinflammation and reduced interferon responses. These factors might predispose to severe COVID-19 disease.
The aim of our study was to evaluate how the comorbidities of the patients affect the concentrations of the cytokines in COVID-19.

METHODS

Hospitalized patients with polymerase chain reaction confirmed SARS-CoV-2 infection were enrolled in the study from December 2020 to February 2022. Quantitative bead-based multiplex assay was performed to determine cytokine concentrations in blood samples. Clinical and laboratory data were collected and analyzed using statistical methods.

RESULTS

106 patients were included in the study. Their mean age was 58.59 (SD=14.92) years. 38 (35.85%) were 65 years and older. 70 (66.04%) were males.
33 (31.13%) had mild-moderate, 27 (25.47%) severe, and 14 (13.21%) critical COVID-19. 17 (16.04%) did not survive COVID-19.
83 (78.3%) had at least one comorbidity. The most frequent ones were cardiovascular diseases (67.92%), diabetes mellitus (18.87%), onco-hematological and renal diseases (17.92% each), and respiratory diseases (15.09%).
No significant associations between COVID-19 severity or mortality and comorbidities were observed.
Patients with comorbidities had lower median concentrations of IL-6 (27 vs. 53 pg/ml, p=0.01) and IL-2 (98 vs. 102 pg/ml, p=0.049) compared to the ones without comorbidities. IL-6 median concentration was lower in patients with cardiovascular diseases (27 vs. 44 pg/ml, p=0.03). TNF-α (74 vs. 38 pg/ml, p=0.02) and lipocalin-2 (6004 vs. 4300 pg/ml, p<0.001) median concentrations were higher while IL-2 median concentration was lower (89.5 vs. 100 pg/ml, p=0.021) in patients with renal diseases. Patients aged 65 years and older, had higher median concentrations of IL-6 (31 vs. 27.5 pg/ml, p=0.059), TNF-α (41 vs. 34 pg/ml, p=0.024), and lipocalin-2 (4255 vs. 4593 pg/ml, p=0.005).

CONCLUSIONS

Patients with comorbidities had lower IL-6 and IL-2 concentrations compared to the ones without comorbidities. Patients with chronic cardiovascular diseases had lower IL-6 concentrations. Patients with renal diseases had lower IL-2 and higher TNF-α, as well as lipocalin-2 concentrations. Patients above 65 years had higher concentrations of IL-6, TNF-α, and lipocalin-2.

COVID-19

P0583

IMPACT OF COVID-19 PANDEMIC ON THE FRACTIONAL EXHALED NITRIC OXIDE, BLOOD COUNT PARAMETERS AND TOBACCO SMOKING IN THE GENERAL POPULATION.

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BACKGROUND-AIM

The coronavirus disease of 2019 pandemic outbreak has undeniably affected the current lifestyles and health of people all over the world. The aim of the study was to evaluate the impact of COVID-19 pandemic on exhaled nitric oxide concentration and blood count results in the general population. The scope of the study included the impact of the pandemic on tobacco smoking among population.

METHODS

The 2018-2022 survey was conducted on a group of Bialystok residents aged 20 to 79. The analyzed group was divided into two populations: before and during the COVID-19 pandemic. 713 probands were qualified to the group before the COVID-19 pandemic, and 509 probants were analyzed during the pandemic. All study participants underwent spirometry and measurement of nitric oxide in the exhaled air. From all patients, peripheral intravenous blood samples were collected for laboratory tests. Participants' lifestyle habits were collected from self-reported questionaries. The Fagerström Test for Nicotine Dependence was used to assess ordinal measure of nicotine dependence related to cigarette smoking.

RESULTS

Examination of the air exhaled from the respiratory tract and blood counts results showed a higher concentration of FeNO ($p<0.001$) and high-sensitivity C-reactive protein ($p=0.001$) in the population during the COVID-19 pandemic. In contrast high-density lipoprotein (0.002) and low-density lipoprotein (<0.001) concentration as well as white blood cells count (<0.001) were lower compared to the pre-pandemic group. No significant changes were observed in spirometry parameters. In the population during COVID-19 pandemic the number of cigarettes smoked during the day was lower ($p=0.005$) and the number of individuals planning to quit smoking in the next 6 months was higher ($p=0.049$), as reflected in the FTND results. In the population during the pandemic FTND score was statistically significantly lower ($p=0.007$) than in the population before the pandemic.

CONCLUSIONS

COVID-19 pandemic had an influence on the increase of hs-CRP and FeNO concentration. The impact of the pandemic on tobacco smoking habits is shown by reduced number of cigarettes smoked during the day and increased desire to quit smoking.

COVID-19

P0584

PREDICTIVE VALUE OF D-DIMER FOR THE SEVERITY OF COVID-19 DISEASE

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BACKGROUND-AIM

Virus infection and uncontrolled inflammation in patients with COVID-19, can cause damage to the microvascular system, destroying the integrity of the vascular barrier, which predisposes patients to a prothrombotic state. Hemostasis requires coordination between normal platelet function, coagulation, anticoagulation and fibrinolysis. An imbalance in any of these processes may result in coagulation dysfunction. The increase in the value of D-dimer is the most sensitive change in coagulation parameters in COVID-19 patients and indicates a greater risk for the development of thrombosis. In this study, we would like to evaluate the role of the D-dimer in determination of the severity of disease compared with inflammatory markers in ambulatory COVID-19 patients based in a retrospective study.

METHODS

In our study were included 145 ambulatory patients positive for SARS-CoV-2 PCR test. All patients were investigated for complete blood count, in SYSMEX XN-1500 hematology analyzer, for D-dimer in STA COMPACT MAX coagulometer, and c-reactive protein (CRP) in COBAS 6000 analyzer. All patients were divided in two groups. In the first group were included patients positive for COVID -19 with normal D-dimer value (d-dimer <0.5ug/ml), and in the second group patients positive for COVID-19 with elevated D-dimer value (d-dimer >0.5ug/ml). CRP and lymphocytes were evaluated in two groups.

RESULTS

There were 145 patients aged 20 to 80 years positive for COVID -19. In the first group with 42 patients (29.5% of patients), D-dimer value had a mean 0.28ug/ml, CRP 20.7 mg/l and lymphocytes 1.7x1000/UI. In the second group (severe group) with 103 patients (70.5% of patients), D-dimer had a mean 1.34 ug/ml, CRP 54ug/l and lymphocytes 0.9x1000ul. In the second group 15 (14.4%) patients have prolonged disease. There is a statistically significant difference in D-dimer, CRP and lymphocytes count between two groups ($p<0.001$). There is a strong correlation between D-dimer and CRP ($r=0.782$). Our results demonstrated association between D-dimer levels and the severity of disease (high CRP and low lymphocytes).

CONCLUSIONS

In COVID-19 severe diseases patients have a higher level of D-dimer than in patients with non-severe disease. D-dimer >0.5ug/ml predicts a severe infection.

COVID-19

P0585

THE ROLE OF MPV/PLT AND LCR VALUES AS PROGNOSTIC PREDICTOR IN COVID-19 DISEASE

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BACKGROUND-AIM

The rapid spread of COVID-19 disease and a great number of complications and mortality, has produced the need to identify indicators that can predict the severity of disease. These indicators can help to identify patients at high risk of developing severe diseases. The aim of our study was to determine the role, lymphocyte-to-CRP ratio (LCR), mean thrombocyte volume-to-platelet count ratio (MPV/PLT) as prognostic biomarkers of COVID-19, compared with routine parameters, absolute lymphocyte count, and C-reactive protein (CRP).

METHODS

We investigated retrospectively ambulatory patients positive for SARS-CoV-2 PCR test between March 2021 and March 2022. Routine blood tests were performed using SYSMEX XN-1500 hematology analyzer. CRP were performed in COBAS 6000 analyzer. The LCR index and MPV/PLT values were calculated based on laboratory parameters. The patients were divided into a non-severe group and severe diseases group.

RESULTS

Including in this study were 156 patients with confirmed COVID-19, 68 (43.5%) females and 88 (46.5%) males. The mean age was 54.02 +/-13.7 years. In the non-severe group were included 44 (28.2%) patients and in the severe group 112 (71.8%) patients. Our results demonstrated a positive correlation between CRP, and MPV/PLT index in two groups. In the non-severe group mean CRP=7.6mg/l versus 44.3 in the severe group, mean MPV/PLT=0.033 versus 0.065 in the severe group. LCR was higher in the non-severe group 21.1 versus 8.4 in the severe group. Absolute lymphocyte count was higher 1.5x1000/ul in the non-severe group versus 1.01x1000/ul in the severe group. There is a significant difference in LCR and MPV/PLT between the two groups ($p<0.001$).

CONCLUSIONS

In COVID-19 cases, LCR and MPV/PLT index correlate with disease severity and can be used as prognostic parameter. These index measurements are cost-effective and can predict the risk associated with infection.

COVID-19

P0586

VALIDATION OF THE PERFORMANCES OF AN IMMUNOASSAY FOR THE DETECTION OF ANTI-SARS-COV-2 N/S1 RBD IGG IN SALIVA SAMPLES

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BACKGROUND-AIM

Background and Aim: Saliva is a promising biological fluid to be used for measuring a number of analytes. Aim of this paper is to verify if salivary anti-SARS-CoV-2 antibodies determination could be suitable for monitoring the viral spread and vaccination efficacy during the COVID-19 epidemic.

METHODS

Methods: A total of 194 subjects (children and adults) were enrolled at the Padova University Hospital. All subjects collected a salivary sample, using Salivette (SARSTEDT AG & Co, Nümbrecht, Germany). For a series of 19 individuals, saliva was collected at three different times within the same day (8 am, 10:30 am, 2:30pm). A serum sample was also obtained for all individuals. Salivary COVID-19 N/S1 RBD (sal-IgG) and serum anti-SARS-CoV-2 S-RBD IgG Ab (ser-IgG) were used for determining anti SARS-CoV-2 antibodies.

RESULTS

Results: The population recruited is of 194 people (106 females (54.63%) and 88 males (45.36%)). The median (min – max) of age is 28.18 (3.09 – 56.87) and 12.16 (3.45 – 61.07), respectively for females and males. Negative sal-IgG were found in 37/194 (19.1%) samples. In serum samples, the negative for ser-IgG was found in 7/194 (3.6%). The K of Cohen value between ser-IgG and sal-IgG is 0.82. The sal-IgG median (25pct-75pct) levels are higher in female than male, being 44.92 (0.5-77.9) kAU/L in females and 9.85 (0.5- 92.77) kAU/L in males (p=NS). The ser-IgG median (25pct-75pct) levels are higher in females than males, being 1817.9 (519.1-3100.1) kBAU/L in females and 1248.7 (424.8- 3498.4) kBAU/L in males (p=NS). Spearman's correlation coefficient between ser-IgG and sal-IgG was r^2=0.57 , p<0.0001. The analytical imprecision (CV%) of sal-IgG assay was 13% at 1.97 kAU/L and 11.2% at 5.3 kAU/L. Evaluating the concentration of sal-IgG of samples collected at different time, no statistical significances (Fiedman test, p = 0.327) were found within the same day.

CONCLUSIONS

Conclusions: The measurement of sal-IgG agreed with the Ser-IgG, despite correlation was limited due to the assays differences (ELISA and CLIA). The times of sample collection do not influence sal-IgG results. For this reason, saliva could represent, above all in the pediatric population, an alternative matrix for the measurement of antibodies since its collection is non-invasive.

COVID-19

P0587

IN OUR BLOOD: COVID-19 AND COAGULATION ABNORMALITIES IN PREGNANCY

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BACKGROUND-AIM

The SARS-CoV-2 pandemic has been a defining event of our generation. Much research has focused on the topic, however certain aspects have been less well studied. The present research project aims to explore the area where COVID-19, coagulation and pregnancy meet.
Aim of the study was to measure whether coagulation parameters in pregnant women infected with SARS-CoV-2 are different from physiological values and whether said parameters are affected by infection severity. A second goal was to test for correlations between coagulation and inflammatory parameters in this subgroup.

METHODS

Data collection included coagulation and inflammatory parameters, as well as severity of SARS-CoV-2 infection and demographic and pregnancy details of 115 pregnant females admitted to the County Emergency Clinical Hospital in the city of Oradea, Romania, between 1st April 2020 and 1st April 2021. Additional parameters included the APGAR score of newborns born to SARS-CoV-2-infected pregnant females. Data analysis techniques included Student's t-test, ANOVA, chi-square, as well as normality tests (Kolmogorov-Smirnov), non-parametric tests (Kruskal-Wallis) and regression analysis.

RESULTS

The data were found to be normally distributed, with the exception of the APGAR scores. The overwhelming majority (86%) of the subjects were asymptomatic. Values for C-reactive protein (CRP) had missing data points. APTT and fibrinogen values had a statistically significant positive correlation with infection severity ($p=0.018$), while platelet levels were inversely correlated to infection severity. Platelet levels were shown to be positively correlated with levels of white blood cells (WBC), with a Pearson correlation coefficient $r=0.256$ and a p-value of 0.006. APTT levels had a statistically significant correlation with WBC levels (Pearson correlation coefficient $r=-0.432$), as did fribrinogen levels, $r=0.261$, with a p-value of 0.029.

CONCLUSIONS

APTT and fibrinogen levels showed a statistically significant correlation with infection severity. There was found to be a statistically significant correlations between platelet, fibrinogen and APTT levels and the inflammatory parameter WBC.

COVID-19

P0588

CIRCULATING HISTONES INDUCE PLATELET AGGREGATION AND TRIGGER INFLAMMATORY RESPONSES

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BACKGROUND-AIM

Circulating histones are involved in the alteration of the coagulative cascade foundseveral human diseases, including sepsis and COVID-19. Here we determined the role of circulating histones on thealteration of platelet (PLT) indices (count; mean platelet volume, MPV; platelet distribution width, PDW), and inflammatorycytokines released by blood cells.

METHODS

Peripheral whole blood was collected from healthy subjects and in vitro treated witincreasing doses of a histone mixture (0, 50, 100, and 200 μg/mL) to evaluate PLT index changes at 0, 30, 60, and 180 mi(UniCell DxH900, Beckman Coulter) and digital microscopy of blood smears (Sysmex System). Plasma samples obtainedafter 3h of treatment were used to quantify inflammatory cytokines with Multiplex Immunoassay (Bio-Plex 200, Bio-Rad).

RESULTS

PLT count in untreated controls remained within reference levels up-to 3h. Thetreatment with 50 μg\mL of histones reduced PLT count (x1000/μL) at 30 min (188±67; p<0.05), 60 min (182±63), and180 min (169±75; p<0.05) vs. controls. The dose of 100 μg\mL decreased PLT count at 30 min (109±44), 60 min(121±47), and 180 min (117±43) vs. controls (p<0.0001). Histone 200 μg\mL reduced PLT count at 30 min (37±22), 60min (39±27), and 180 min (34±28) vs. controls (p<0.0001). MPV and PDW increased of 10-13% (p<0.05) and 4-6%,respectively, in histone 50 μg\mL vs. controls. The dose of 100 μg\mL increased MPV of 15-20% (p<0.0001) and PDW of 69% vs. controls. These quantitative data were also supported by morphological changes highlighting PLT-PLT and PLT-WBCaggregates.
After 3h of treatment, we observed a significant dose-dependent increase of MIP-1α (18-, 32-, and 60-fold at 50, 100, and200 μg\mL), PDGFbb (9-, 12-, and 12-fold, respectively, p<0.001), RANTES (range 2-, 3-, and 4-fold, p<0.001), TGF-β1(range 3-, 4-, and 4-fold; p<0.01), TGF-β2 (range 1.4-, 1.4-, and 1.3-fold; p<0.01), and TGF-β3 (range 1.8-, 2.1-, and 2.fold; p<0.001).

CONCLUSIONS

These findings revealed that circulating histones may significantly contribute to thethrombocytopenia and cytokine storm observed in septic conditions (e.g. COVID-19 and classical sepsis).

COVID-19

P0589

EVALUATION OF THE ASSOCIATION BETWEEN SEVERITY OF ACUTE SARS-COV-2 INFECTION AND VACCINATION: A CROSS-SECTIONAL STUDY ON A GROUP OF PATIENTS ADMITTED TO A TERTIARY CARE HOSPITAL IN SRI LANKA

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BACKGROUND-AIM

A comprehensive understanding of the benefits of COVID-19 vaccination is critical in disease attenuation. The study aimed to compare clinical outcomes of acute SARS-CoV-2 infected patients with their vaccination status and the concentration of anti-covid IgG antibody specific to receptor-binding domain of S1 protein (RBD).

METHODS

A total of 115 COVID-19 patients admitted to the National Hospital of Sri Lanka during the month of August 2021 were enrolled. History and clinical findings were obtained using an interviewer-administered questionnaire. Blood samples for anti-COVID IgG antibody from each patient were collected at the time of admission and analyzed by a two-step chemiluminescent microparticle immunoassay in ADVIA Centaur XP fully automated analyzer. The association between vaccination status; unvaccinated (UV), partially vaccinated (PV), and fully vaccinated (FV) and disease severity; severe and non-severe was explored with logistic regression models. Correlations of anti-covid IgG antibody levels with each vaccination stage and clinical outcome were analyzed using the Kruskal-Wallis H test and the Wilcoxon rank sum test.

RESULTS

Out of the 115 participants, 71.55% were women and the mean age was 50.01 ± 18.73. The number (percentage) of UV, PV, and FV were 35 (30.43%), 31(26.96%), and 49(42.6%) respectively. Severe disease was seen in 24 (20.86%). Severe disease was significantly less among FV compared to UV (OR 0.23, 95% CI: 0.05–0.78 p-value 0.01). The relative risk estimate of progression to severe disease in FV, compared with UV was 0.28 (95% CI 0.09 – 0.83, p-value 0.01). Anti-covid IgG antibody levels were significantly increased with each vaccine dose (p-value <0.001). Association between clinical outcomes with anti-covid IgG antibody against RBD levels could not be demonstrated (Wilcoxon statistic 926, p-value=0.586).

CONCLUSIONS

These findings are consistent with risk reduction among the fully vaccinated group compared with the unvaccinated group. The antibody level on admission among vaccinated groups didn’t predict the clinical outcome.

COVID-19

P0590

PRACTICAL UTILITY OF LABORATORY DATA INCLUDING D-DIMERS IN COVID-19: A MULTIVARIATE REGRESSION MODEL TO PREDICT THE DISEASE SEVERITY.

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BACKGROUND-AIM

The chemical pathology laboratory at National Hospital of Sri Lanka performs D-dimer assay to be used as a marker of disease severity and prognosis in COVID-19. This study aimed to evaluate the correlation of D-dimer with other biochemical and haematological markers during COVID-19 and design a model comprising biochemical markers including D-dimer to predict the disease severity.

METHODS

Demographic, clinical and laboratory data of 178 COVID-19 patients admitted in August 2021 who underwent D-dimer assay were evaluated retrospectively. Pearson's correlation test was performed to evaluate the correlation of biochemical markers with D-dimer level. Multivariate logistic regression analysis using twelve continuous variables was conducted to design the model. A receiver operator characteristic (ROC) curve was constructed using unseen held-out data to calculate the optimum cut-off value to predict the severity.

RESULTS

Of the 178 participants, 74 were women and 83 were diagnosed with severe COVID-19 disease. The mean age was 58.9 (SD 14.8) years. D-dimer showed a significant positive correlation with lactate dehydrogenase, aspartate transaminase and counts of total white blood cells, neutrophils and platelets ($p < 0.05$). The multivariate logistic regression model developed including D-dimer and other markers to predict severe disease had a sensitivity of 95.83% (CI 87.5%-100%), a specificity of 71.43% (CI 53.6%-85.7%), a positive predictive value of 74.19% and a negative predictive value of 95.24% for the cut-off score of 67.5. The area under the curve of ROC curve was 0.870 (CI 77%-96%, p-value < 0.001). The AUC of ROC curve to predict the severe disease with D-dimers alone was 0.758 (CI 0.687-0.828, p-value <0.001)

CONCLUSIONS

Strong correlation of specific biochemical markers with D-dimer indicated that incorporating them in a predictive model would increase the predictive power of disease severity compared to models using D-dimer alone. Our model will aid clinicians in Sri Lanka in early prediction of clinical outcomes, better management and optimal usage of resources.

COVID-19

P0591

SARS-COV-2 SPECIFIC T CELL: CLINICAL VALIDATION OF A RAPID AND EASY TO USE METHOD BASED ON DIRECT REAL-TIME PCR AMPLIFICATION.

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BACKGROUND-AIM

T cells have a significant role in COVID-19 outcome and maintenance of SARS-CoV-2 immunity, even in the absence of humoral immune responses. In this study, we aimed to determine the expression of CXCL10 mRNA with a novel rapid direct real-time PCR (dRT-PCR) to evaluate the specific responses of T cells to SARS-CoV-2 in comparison with the time-consuming Quant-T-Cell SARS-CoV-2 ELISA assay (Euroimmun, Lubeck, Germany).

METHODS

Whole blood samples from 97 healthcare workers, with homologous (79/97, Pfizer/BioNTech) or heterologous (18/97, Pfizer/BioNTech and Vaxzevria or Moderna) COVID-19 vaccinations were stimulated with different SARS-CoV-2 spike peptides (S-peptide, PoolOne). Through dRT-PCR supplied by an artificial intelligence-based automatic result interpretation (bCube and bApp, Hyris srl, Lodi, Italy), we quantified CXCL10 mRNA related to antigen-specific T lymphocytes activation. Data were cross-checked with IFN-γ release by SARS-CoV-2-specific T cells assay (Quant-T-Cell SARS-CoV-2 ELISA) and with anti-SARS-CoV-2 S antibodies by CLIA S-RBD IgG (S-RBD IgG) (Snibe, Shenzhen, China).

RESULTS

Qualitatively, the two methods for measuring T cell immunity to SARS-CoV-2 agreed in 80/87 (91.9%) cases. Quantitatively, the levels of $2^{-\#\#Ct}$ PoolOne [CXCL10 fold change (FC) of mRNA expression to unstimulated cells], IFN-γ, and S-RBD IgG did not differ between males and females (χ^2 = 0.420, p = 0.517; χ^2 = 1.628, p = 0.202; χ^2 = 0.196, p = 0.657, respectively) and between individuals with homologous and heterologous vaccination (χ^2 = 0.159, p = 0.689; χ^2 = 0.257, p = 0.612; χ^2 = 1.455, p = 0.227, respectively). Overall, CXCL10 FC PoolOne was inversely correlated weakly with age (Spearman's r = -0.221, p = 0.03); when considering the gender, the correlation between CXCL10 FC PoolOne and age was significant only for females (Spearman's r = -0.462, p = 0.023). CXCL10 FC PoolOne significantly correlated with IFN-γ levels (Spearman's r = 0.302, p = 0.003), but not with anti-S-RBD IgG (Spearman's r = 0.101, p = 0.324).

CONCLUSIONS

Hyris dRT-PCR was found to be an accurate assay for determining the presence or absence of immunoreactivity of SARS-CoV-2 specific T cells after vaccination, especially when a rapid result notification is requested.

COVID-19

P0592

EVALUATION OF THE NUMBER OF SARS-COV-2 TESTS PERFORMED DURING 2020-2022 AT THE GALDAKAO HOSPITAL (NORTH OF SPAIN)

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BACKGROUND-AIM

SARS-CoV-2 was first described on December 2019 and rapidly expanded to cause a pandemic. Clinical laboratories had to adapt their workflows in order to be able to give all the results on time.
The aim of the study is to evaluate the number of SARS-CoV-2 tests performed during 2020-2022 at the Galdakao Hospital (north of Spain).

METHODS

Samples used for SARS-CoV-2 diagnosis were mostly nasopharyngeal swabs or saliva samples. The tests performed were viral antigen or RNA detection. Due to stock problems, different methods were used during these years.
For RNA detection methods, real-time rtPCR targeting at least two SARS-CoV-2 genes were used. In rtPCR, detection of two or more genes was considered positive.
For antigen detection, immunochromatographic tests were used, in which visualization of the antigen band was considered positive.

RESULTS

During 2020, 184.912 samples were analyzed, been 11.194 of them positive (6%). In 2021, 219.618 samples were analyzed, been 19.523 of them positive (9%) and in 2022, 158.057 samples were analyzed, been 17.958 of them positive (11%).
As already described in other studies, several waves were observed. In our case, the higher number of positive samples were detected between December 2021 and January 2022 (14.496 positive samples, 23% of the analyzed samples).

CONCLUSIONS

At the beginning of the pandemic, the laboratory had to rapidly adapt from using new techniques to performing thousands of test in brief periods of time.
Changes in protocol in 2022 have caused a decrease in the number of samples tested during this year.
All these data demonstrate the need of laboratories capable of performing different molecular tests, in order to be prepared for next pandemics.

COVID-19

P0593

ROLE OF VITAMIN D STATUS IN THE SUSCEPTIBILITY AND SEVERITY OF COVID-19

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BACKGROUND-AIM

COVID-19 is a potentially serious disease with high mortality. Therefore, a better understanding of its risk factors is needed. Evidence suggests that higher concentrations of vitamin D protect against this infection. Nevertheless, published studies have failed to consistently document a beneficial effect.
Our aim is to investigate the association between hypovitaminosis D and susceptibility to SARS-CoV-2 infection and to study the possible associations in the infected population between vitamin D status and clinical and biological features of the disease.

METHODS

A retrospective analytical study conducted at the Biochemistry Department at Sahloul University Hospital. Our study included two groups : patients who were hospitalized for SARS-CoV-2 infection at the Infectious Diseases Department on one hand, and health professionals, 85 of whom consulted the Occupational Medicine Department for a coronavirus infection confirmed by real-time RT-PCR on the other hand.

RESULTS

The first part of our study covered 204 health professionals in whom we compared the different characteristics including vitamin D status according to whether or not they were positive for SARS-CoV-2. Despite being at the limit of significance, our results suggest that vitamin D deficiency increases the risk of SARS-CoV-2 infection by a factor of 1.7. For our second objective, we included 117 COVID-19-positive subjects with a high prevalence of vitamin D deficiency (85.5%), considering a threshold of 30 ng/mL. The majority of our population (45%) developed a mild case of the infecion. The vitamin D averages were comparable for the different clinical forms of the disease. Our study did not show a significant association between the severity of COVID-19 and vitamin D deficiency (OR=1.9 ; p =0.489). Furthermore, no association was detected in our population between vitamin D deficiency and the necessity of hospitalization (OR=1,03 ; p=0,557), neither with the necessity of admission to an intensive care unit (OR=0,965 ; p=0,38) nor with the duration of hospitalization (p=0,187).

CONCLUSIONS

Our results do not support a significant association between vitamin D status and infectious risk and disease severity. Further and larger studies are needed to support these results.

COVID-19

P0594

EVALUATION OF THE INCIDENCE OF THE INFLUENZA A, B AND RSV DURING SARS-COV-2 PANDEMIA AT THE GALDAKAO HOSPITAL (NORTH OF SPAIN)

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BACKGROUND-AIM

Three years ago, due to the pandemic caused by SARS-CoV-2, new measures to stop transmission were implemented in the community. Hygiene and contact measures, such as use of masks, have been a great aid to slow transmission rates and have also decreased the transmission of other respiratory viruses.
The objective of this study is to evaluate the incidence of the Influenza A, B and RSV during 2020, 2021 and 2022 at the Galdakao Hospital (north of Spain), the years in which measures to prevent transmission or SARS-CoV-2 were being followed.

METHODS

Diagnosis of influenza A, B and RSV was achieved by amplification of nucleic acids. Different commercial platforms were used, all of which combined extraction and amplification of nucleic acids in the same cartridge. The commercial test used were LIAT cobas Influenza A/B & RSV (Roche, Switcherland), LIAT cobas SARS-CoV-2 & Influenza A/B or GeneXpert Xpress SARS-CoV-2/Flu/RSV (Cepheid, United States).

RESULTS

During 2020, there were 305 cases of influenza (80%A, 20%B) and 75 cases of RSV. In 2021, there were only 26 positive cases of influenza (100%A) and 24 cases of RSV. In 2022, there were 534 positive cases of influenza (99%A 1%B) and 149 cases of RSV.
In 2022, 297 cases of flu were diagnosed between August and October, 56% of the flu positives cases that year.

CONCLUSIONS

SARS-CoV-2 pandemic brought many changes in our lifestyle. Several hygiene protocols were implemented in order to contain the pandemic. Some of those measures have been followed for years and have had an impact on the incidence of other respiratory viruses.
Influenza is a seasonal virus in which the higher incidence happens between December and March. In 2021, thanks to the use of masks, hand hygiene and other measures that were established in order to fight SARS-CoV-2, there were almost no cases of flu or RSV. In 2022 some of the measures were abandoned (for example, the use of mask in open spaces was not compulsory), and that could explain the higher number of influenza and RSV cases observed, such as the atypical temporal pattern, showing a great number of cases on months such as April and September.

COVID-19

P0595

THE EFFECT OF COVID-19 VACCINATION ON THE SERUM LEVEL OF ANTI-SARS-COV-2 SPECIFIC ANTIBODIES

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BACKGROUND-AIM

The aim of this study was to evaluate the effect of vaccination against SARS-CoV-2 on the serum level of anti-SARS-CoV-2 specific antibodies.

METHODS

88 serum samples were analyzed. Serum samples were obtained from 22 patients vaccinated using Pfizer-BioNTech COVID-19 vaccine. Serum samples were taken one day before 1st dose of vaccination (0), 4 weeks after taken of 1st dose (A), 4 weeks after 2nd dose (B) and 6 months after 2nd dose (C). IgG antibodies to the receptor binding domain of the S1 subunit of the spike protein (S-RBD) and to the nucleocapsid protein (N) were measured using chemiluminescent method (CMIA) on the Alinity analyzer (Abbott). Results are presented as mean±SD.

RESULTS

The mean serum level of S-RBD IgG antibodies differ between tested groups (ANOVA rank Kurskal-Wallis test: P<0.001). Post-hoc analysis revealed that the serum levels of S-RBD IgG antibodies were higher in group B (18474.70±16455.31 AU/ml) in comparison to group 0 (685.88±1770.77 AU/ml), A (5446.15±13502.45 AU/ml) and C (2856.21±6373.92 AU/ml) (P<0.001, P=0.002, P=0.002, respectively). The levels of S-RBD IgG antibodies were also higher in group A and C in comparison to group 0 (P=0.008, P=0.013, respectively). The level of S-RBD antibodies was similar in group A and C (P=1.000). The mean serum level of N IgG antibodies did not differ between 0 (0.89±1.88), A (1.06±1.96), B (0.87±1.63), and C (0.43±0.73) groups (ANOVA rank Kurskal-Wallis test: P=0.353).

CONCLUSIONS

In conclusion, serum concentrations of S-RBD IgG antibodies increase after vaccination. On the other hand, a significant decline in antibody levels 6 months after vaccination was observed. These findings suggest the need for further booster vaccinations of patients to maintain the immunity against SARS-CoV-2.

COVID-19

P0596

CORRELATION OF TRACE ELEMENTS STATUS AND C REACTIVE PROTEIN IN COVID-19 PATIENTS WITH DIFFERENT DISEASE SEVERITY

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BACKGROUND-AIM

The emergence of the new coronavirus SARS-CoV-2 in late 2019 put the world under threat of a new pandemic. In humans, the virus causes the so-called coronavirus disease (COVID-19), whose most common symptoms are fever, chills and cough. A very important aspect related to the response to SARS-CoV-2 infection is the competence of the immune system, whose main role is to protect the individual from pathogenic microorganisms. Several minerals and trace elements (e.g., zinc, copper, selenium) are essential for an adequate immune response and have anti-inflammatory and antioxidant properties.

METHODS

In our study we evaluated the serum levels of Cu, Zn, Se and CRP in 210 patients with clinical conditions of different severity (“mild”, “moderate”, “severe” and “exitus letalis”). SARS-CoV-2 positive patients were recruited at the time of admission to the General Hospital Tesanj, Bosnia and Herzegovina. Serum samples were analyzed at the Laboratory of Applied Chemistry, Faculty of Pharmacy, University of Porto, Portugal, using duly validated inductively coupled plasma mass spectrometry (ICP-MS) analytical procedures.

RESULTS

In patients with mild disease severity, level of Cu and Cu/Zn ratio showed statistically significant positive correlation with CRP levels ($p<0.001$), whereas levels of Zn and Se showed statistically significant negative correlation with CRP ($p<0.001$, $p=0.002$). Also, Cu levels and Cu/Zn ratio showed statistically significant positive correlation with CRP levels ($p<0.001$) while Zn levels showed statistically significant negative correlation with CRP ($p<0.001$) in patients with moderate disease severity. Zn and Se levels in patients with severe clinical picture showed statistically significant negative correlation with CRP ($p=0.05$, $p=0.037$) while Cu/Zn ratio showed positive correlation ($p=0.008$). Cu/Zn ratio showed statistically significant positive correlation with CRP levels ($p=0.003$), while Zn and Se levels showed statistically significant negative correlation with CRP ($p<0.05$) in „exitus letalis“ patients.

CONCLUSIONS

Our results demonstrated that analyzed trace elements show a strong correlation with the CRP levels in COVID-19 patients with different disease severity. It is important for COVID-19 patients to maintain a healthy balanced diet and to take care of trace elements status.

COVID-19

P0597

THE CONTRIBUTION OF HOMOCYSTEINE MEASUREMENT IN POST COVID PATIENTS

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BACKGROUND-AIM

The clinical presentation of patients infected with SARS COV-2 can vary from asymptomatic to acute respiratory distress but can also affect the cardiovascular system. Symptoms of the infection may persist even after recovery. This leads to the description of the post-COVID syndrome, a syndrome encompassing a prolonged progression of symptoms that persist for more than 12 weeks without further explanation.
The objective of our work was to investigate an association between endothelial dysfunction and homocysteine levels in post-COVID patients.

METHODS

This is a prospective study that was carried out over a period of 4 months (January 2021-April 2021), in the cardiology department at the HediChaker University Hospital of Sfax in collaboration with the Biochemistry department at the HediChaker Hospital of Sfax, concerning 87 patients who had a SARS-COV-2 infection dated from 1 to 6 months confirmed by an antigenic test or RT-PCR test on a nasopharyngeal swab. For each patient, a blood sample was taken for homocysteine determination and a thermodigital monitoring technique using the E4 Diagnostics device was used to study endothelial function (Endothelial function being impaired if EQI endothelial quality index <2).
Statistical analysis was performed using the software: Statistical Package forSocial Science (SPSS) of Windows version 20.0.

RESULTS

The mean age of our patients was 47.87 ±11.9 years (2373), sex ratio at 0.52.
In our population,76 patients (87.4%) had post-COVID symptoms.
In our population,44 patients 50.57% had endothelial dysfunction with an EQI less than 2.
The prevalence of endothelial damage in patients with post-COVID syndrome was 52.6%.
Endothelial damage was statistically associated with homocysteine levels. Homocysteine averages were significantly higher in patients with endothelial dysfunction (p= 0.011).
Homocysteine was negatively correlated with the endothelial quality index EQI.

CONCLUSIONS

Homocysteine seems to be an important marker for the evaluation of endothelial damage. In fact, our study showed that its level is elevated in patients with endothelial dysfunction, which explains the interest of its measurement to detect thrombo-embolic disorders occurring in post-COVID patients.

COVID-19

P0598

COULD A COMBINATION OF BLOOD MARKERS BE USED IN PLACE OF SUPAR FOR ANAKINRA PRESCRIPTION IN COVID-19 PATIENTS?

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BACKGROUND-AIM

The SAVE-MORE study showed that the early start of treatment with the IL-1α/β inhibitor anakinra, guided by suPAR (Soluble Urokinase-Type Plasminogen Activator Receptor) ≥6 ng/mL, in patients with moderate or severe COVID-19, significantly reduced the risk of worse clinical outcome at day 28. With press release 665 of 28/09/2021, AIFA has approved the inclusion of anakinra in the 648/96 list for the treatment of hospitalized adults with COVID-19 and suPAR ≥6 ng/mL. However, suPAR methods are not widely available, which hinders the clinical use of anakinra. Aim of this study was to identify a panel of biochemical tests as a surrogate marker of suPAR positivity (≥6 ng/mL).

METHODS

The study included 456 (median age: 75 years (IQR 60-83); M:F 54:46%) hospitalized patients at the Infectious Disease Unit (n=124) and Medical ICU (n=332) of the Maggiore Policlinico Hospital of Milan with molecular diagnosis of COVID-19. suPAR was measured at admission by suPARnostic TurbiLatex kit (Vendor: ViroGates A/S, Denmark; Italian distributor: B.S.N. Srl) on Roche Cobas c702.

RESULTS

Median suPAR was 7.6 ng/mL (4.8-10.8), with 63% of patients displaying suPAR ≥6 ng/mL. At the univariate logistic regression analysis, suPAR was found to be associated with age (p<0.001), WBC (p=0.002), #NE (p<0.001), Hb (p<0.001), CREA (p<0.001), LDH (p=0.005), FERR (p=0.006), CRP (p<0.001), Fib (p=0.005), DD (p<0.001), but not with sex (p=0.943), #LY (p=0.444), #MO (p=0.233), PLT (p=0.064), ALT (p=0.238), TBIL (p=0.534), TnT (p=0.153) and TSH (p=0.970). However, at the multivariate analysis, only age (p<0.001), Hb (p=0.043), CREA (p<0.001), LDH (p=0.021), CRP (p=0.005) and DD (p=0.004) were found as independent predictors of suPAR positivity. Percentage of correct classification (< vs ≥ 6 ng/mL) and AUC of the multivariate model were 75.1% and 0.83 (95%CI 0.80-0.87).

CONCLUSIONS

suPAR is independently associated with age, Hb, CREA, LDH, CRP and DD. Due to the moderate % of correct classification of the multivariate model (75%), we conclude that this combination of blood markers cannot be used as a surrogate of suPAR for anakinra prescription. Further clinical validation is needed to assess a possible role of the model in predicting COVID-19 severity and mortality.

COVID-19

P0599

WHOLE GENOME SEQUENCING AND PHYLOGENETIC ANALYSIS OF SARS-COV-2 STRAINS IN AZERBAIJAN

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BACKGROUND-AIM

COVID-19, caused by the novel SARS-CoV-2 virus, started in China in late 2019, and soon became a global pandemic. Robust surveillance mechanisms should be implemented to control the ongoing pandemic such as a pressing clinical need, scalable diagnostics for detect infection, interrogate strain evolution, and identify novel patient biomarkers. Unlike RT-qPCR, SARS-CoV-2 whole genome sequencing has the added advantage of identifying viral cryptic origins and it has possible to track the evolution of the viral genome over time as it spread across the world. Here, we characterised the full-genome sequences of nine SARS-CoV-2 respectively isolated from nine patients diagnosed in the country during first wave.

METHODS

We performed shotgun transcriptome sequencing using RNA extracted from nasopharyngeal swabs of patients with COVID-19, to track virus origin we used multiple sequence alignment and phylogenetic tools to compare the assembled SARS-CoV-2 genomes to publicly available sequences.

RESULTS

Broadly, the sequences from Azerbaijan fall into GR/20B clade which is one of the lineages associated with the outbreak in Europe with a new global distribution. Of the sequences that fall into clade GR/20B, 8 sequences fall into a well-supported clade that is currently only observed in Azerbaijan. However, due to undersampling in the region (among the neighbouring countries of Azerbaijan, there are the following complete genomes currently in GISAID: Turkey, Russia, Iran, Georgia and Armenia) it is possible that this lineage is circulating more widely. Sequences most closely related to this cluster are from Western Europe. Eight sequences fall basal, and one sequence form a well supported apical clade. One viral strain presented a two previously unreported mutation in the ORF14 and nsp3 region, namely p.G50N and p.N1587Y.

CONCLUSIONS

SARS-CoV-2 whole genome sequencing is a highly feasible and powerful approach for tracking virus transmission. Genomic data can be used to determine the most appropriate public health decisions to control the pandemic. Epidemiologically-defined clusters displayed specific mutations, suggesting molecular signatures for strains coming from areas that were isolated during the lockdown.
Sequences are deposited in GISAID database, with accession numbers EPI ISL 882644 - EPI ISL 882637.

COVID-19

P0600

EVALUATION OF THE CORRELATION BETWEEN VITAMIN D, PHOSPHO-CALCIUM METABOLISM AND DEVELOPMENT OF THE ANTI-SARS-COV-2 IGG ANTIBODY RESPONSE AFTER THIRD DOSE OF THE VACCINE

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BACKGROUND-AIM

Vitamin D promotes the reabsorption of calcium in the kidney and phosphorus in the intestine1,2. The aim of our work is to verify the relationship between phosphocalcium metabolism, Vitamin D and development and maintenance of the anti-Sars-Cov-2 immune response.

METHODS

A monitoring of antibody response, calcium, phosphorus and vitamin D dosage was carried out in people subjected to the third dose of vaccine and in subjects of the some group who during the observation period were positive for Sars-CoV-2. 21 subjects were enrolled: 7 males and 14 females subjected to a third dose of mRNA vaccine, of which 9 positive for Sars-CoV-2 in itinere. Serum sampling was carried out at 15 days, 30 days, 45 days and 2-3-4-5-6 months, from the third dose and for positives 2 months after infection

RESULTS

The analysis of the data showed that the concentration of anti-RBD IgG after the third dose of vaccine decreases linearly in about four months after a peak that is observed between 15 and 20 days from administration. Only in two subjects, we observed a plateau observed that lasted up to three months after the third dose and then decreased linearly. The development of antibodies induced by natural infection appears superior to that induced by the vaccine dose. The concentration of calcium and phosphorus is linear and independent to immune response developed both following a vaccine and following a natural booster during monitoring.

CONCLUSIONS

The results related to Vitamin D do not present intra and inter-subject variations except in the seasonal period of greater exposure to UV rays and not in correlation with antibody concentrations. The trend of antibodies is indipendent to concentration of Vitamin D. In our monitoring, Vitamin D does not seem to be related to the course of anti-RBD IgG antibodies from vaccine or natural booster and above all seems to have no role in preventing reinfection4. The values of calcium and phosphorus are also constant. Our data are in line with those of the literature5,6,7. We observe that the infection occurs in the waning phase of the antibody concentration but is always independent of both Vitamin D and the titer of circulating antibodies3. A limitation of our study is the high heterogeneity of the group.

COVID-19

P0601

SARS-COV-2: EVALUATION OF THE DECAY OF THE ANTIBODY RESPONSE AFTER VACCINE AND AFTER INFECTION IN THE VACCINATED SUBJECTS

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BACKGROUND-AIM

The emergence of multiple variants that evade immunity and the high number of people who still continue to be infected has led scientific societies to deepen studies on the effectiveness and duration of natural and vaccine immunity and on the role of lymphocyte memory cells. Literature data showed development of a higher antibody concentration in the vaccinated subject. Aim of our work was to observe the extent of antibody decay in the vaccinated subject and in infected vaccinated subject, in health workers of the UOC Clinical Pathology and Microbiology ASL BT

METHODS

From January '21 to December '22 we monitored dosage of IgG ANTI S1/RBD antibodies (Ab) after mRNA vaccine in a group of 16 health workers (3 males and 13 females) heterogeneous by age. IgG anti RBD were measured with ABBOTT SARS-CoV-2 IgG II test. Serum sampling was carried out every one month after second dose,the third dose and the infection

RESULTS

Evaluation of the data allowed to register, in the group observed, 9 subjects contracted SARS-CoV-2 (56%),7 subjects not infected (44%); of the infected, 7(78%) contracted SARS-CoV-2 after third dose of vaccine,1(11%) after second dose, 1(11%) before the cycle. In vaccinated subjects, it is observed that Ab decay both after the peak following the second dose, and after the peak following the third dose. Was possible to evaluate a reduction of about 70% after 5 months from the peak to one month from third dose. Concentration of Ab in the infected subject undergoes a decay of about 50% at 5 months from the antibody peak after infection

CONCLUSIONS

Data show that contagion occurs when concentration of Ab is reduced:this condition makes the subject sensitive to variants of the virus capable of evading immune system at lower concentrations of Ab.It is observed that insubjects infected after vaccine the concentration of Ab is more stable than that developed after vaccination:can be attributable to the activity of lymphocyte memory cells and to direct action of virus. Immunological memory makes the subject ready for the development of immune defense:the infected vaccinated subjects have never developed the disease but were asymptomatic or paucisymptomatic. So the population need to undergo the vaccine and booster doses for the maintenance of an antibody concentration useful to avoid the onset of Covid-19.

COVID-19

P0602

GROWTH DIFFERENTIATION FACTOR-15 (GDF-15): BIOMARKER ASSOCIATED WITH POOR PROGNOSIS IN COVID

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BACKGROUND-AIM

COVID pandemics has led search for severity markers. We want to measure growth differentiation factor-15 (GDF-15), a marker of oxidative stress and inflammation, in COVID patients, to study its possible role as a severity biomarker and to compare it with other proposed biomarkers.

METHODS

115 COVID patients grouped as: severe, exitus or admission to ICU, sCOVID, n=39; non-severe, hospital admission <7 days, not ICU, nsCOVID, n=76; post-COVID, negative test post-COVID diagnosis and /or positive IgG and negative IgM Cov-2 serology, n=56; controls, negative test, n=74. GDF-15, proBNP and hsTnT were measured by CLIA (Roche Diagnostics International, Research Study FOC kits). Renal markers (creatinine and GFR), ferritin, CRP, IL-6, lymphocytes, and D-dimer (DD) were analyzed by standard laboratory techniques. Results are expressed as median(p25-p75). Statistical study: Kruskall-Wallis and post-hoc contrast with Bonferroni adjustment (K-W-B; significance 0.005). ROC curves (AUC; 95% CI) for GDF-15 (COVID vs. control and sCOVID vs. nsCOVID).

RESULTS

GDF-15 levels were increased in COVID patients:2061(1252-2582) in nsCOVID and 9944(6701-12657) in sCOVID vs. 658(481-759) pg/mL in controls, p<0.0001, K-W-B). In the post-COVID group, GDF-15 levels were comparable to controls (749(505-873), p=0.336, K-W-B). ROC curves for GDF-15: COVID vs. controls, AUC 0.977 (0.961-0.994); sCOVID vs, nsCOVID, AUC: 0.956 (0.90-1.00); 89% sensitivity and 96% specificity for an optimal empirical GDF-15 cut-off of 3967.5 pg/mL. A significant increase (p<0.001) in cardiac markers and DD levels in sCOVID vs. nsCOVID was observed: proBNP, 940 (206-6415) vs. 184 (102-184) pg/mL; hsTnT, 29 (11-68) vs. 6.6 (4.1-15) ng/L; DD, 1510 (1236-3207) vs. 700 (378-1350) ng/mL. sCOVID patients showed lower lymphocyte counts, 0.85 (0.4-1.2) vs. 1.2 (1-1.9) 103/μL in nsCOVID; p<0.001). Renal function, CRP, ferritin and IL6 were comparable in both COVID groups. The area under the curve (ROCAUCDeLong) of GDF15 for severity was higher (p<0.01) than those of hsTnT (0.880;0.69-0.90), proBNP (0.73;0.60-0.859), DD (0.78;0.68-0.88) and lymphocyte counts (0.73;0.62-0.84).

CONCLUSIONS

GDF-15 can be considered a prognostic biomarker of severity and fatal outcome in COVID, with better performance than proBNP, hsTnT, DD, and lymphocytes counts.

COVID-19

P0603

THE EVALUATION OF THROMBOCYTOPENIA IN PATIENTS WITH ACUTE INFECTION OF CORONAVIRUS DISEASE 2019.

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BACKGROUND-AIM

Coronavirus Disease 2019 (COVID-19) is a predominantly respiratory illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 is commonly associated with hematological abnormalities including in particular thrombocytopenia.
The aim of this study was to assess the correlation between thrombocytopenia and high SARS-CoV-2 Immunoglobulin M (IgM) antibody levels in patients with COVID 19.

METHODS

This observational study enrolled 100 patients of Genius Lab Clinic from January 2021 to May 2021. All patients were confirmed with positive real time polymerase chain reaction (RT-SARS-CoV-2 PCR) test and positive SARS-CoV-2 IgM antibody test. The serology was performed with chemiluminescence assay using Snibe Maglumi 4000 Plus analyzer and the complete blood count (CBC) was performed using Abacus 5 an automated hematology analyzer. All patient samples with low platelets numbers were confirmed microscopically with a peripheral blood smear. Thrombocytopenia was defined as a platelet count < 150 x 103cells/μL. Thrombocytopenia was graded as mild thrombocytopenia 100 x 103cells/μL -140 x 103cells/μL, moderate 50 x 103cells/μL -100 x 103cells/μL and severe thrombocytopenia <50 x 103cells/μL.

RESULTS

In 48% of patients was detected thrombocytopenia which is typically mild with an average value of 126 x 103cells/μL. 13% of patients had moderate thrombocytopenia with an average value of 68 x 103cells/μL, while 7% of patients had severe thrombocytopenia with an average value of 35 x 103cells/μL. 32% of patients did not have thrombocytopenia. It was observed that in patients with severe and moderate thrombocytopenia the SARS-CoV-2 IgM antibodies values were higher than mild or non-thrombocytopenic cases with an average above 100 AU/ml.

CONCLUSIONS

Higher SARS-CoV-2 IgM values are associated with lower platelet numbers, therefore platelets parameters are an important biomarker in COVID-19.

COVID-19

P0604

STUDY OF THE ACQUIRED IMMUNIZATION IN THE ALBANIAN POPULATION DURING THE MONTHS OF SEPTEMBER 2020-APRIL 2021 THROUGH THE TESTING OF IGG ANTI-SPIKE SARS-COV-2 ANTIBODIES CARRIED OUT AT THE INTERMEDICA CLINIC.

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BACKGROUND-AIM

In December 2019, the Covid-19 infection appeared suddenly, seriously threatening people's health due to the rate of its spread. The Albanian population, as the whole world, did not escape this infection. With the beginning of the pandemic, in addition to the identification of the SARS Cov-2 virus, to the monitoring of the situation in infected patients, attention was centered on the identification of the immunization situation of the population, in order to build vaccination policies. This paper aims to study the level of immunization against SARS-CoV-2 by measuring the antibody levels during the months.

METHODS

A total of 98,270 individuals were studied for the evaluation of the level of antibodies during these months. For each, serological testing was performed to identify IgG anti-Spike SARS-CoV-2 antibodies using the ELISA method (EUROIMMUN kit). Statistical analysis was performed to analyze the immunization situation.

RESULTS

From the statistical analysis, the values were not normal distributed, this is because the mean and the median are not similar. In order to carry out a survey on the level of immunization at the beginning and at the end of the study, the month of September and April were analyzed. The month of September represents a low level of immunization. Out of 5000 individuals, most of them have IgG antibody values close to 0.01 ratio. The end of the month represents a slight change in values and they undergo a slight increase and most of these studied individuals have values closer to 0.1 ratio than to 0.01 ratio.
The month of April, which represents the second extreme, has a large number of values for the antibody titer. The values of this month are presented rather around 50 ratio alongside a number of individuals with values above 100. So in these two months we have the transition from a period with a very low level of immunization to a period with a high level of immunization.

CONCLUSIONS

By analyzing the data throughout the months, out of 98,270 tests performed, 33,185 have been positive, this shows us that the level of immunization in the population for the studied months has been increasing and 33.76% of it has gained immunity.

COVID-19

P0605

ANALYTICAL EVALUATION AND CLINICAL PERFORMANCE OF THE SYMPHONY IL-6 NEAR-PATIENT TESTING (NPT) IN HOSPITALIZED COVID-19 PATIENTS

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BACKGROUND-AIM

Current EUA IL-6 assays that predict hyperinflammation require expensive laboratory-based auto-analyzers and skilled technicians, thus restricting accessibility. Here, we have evaluated a new and rapid Symphony IL-6 assay on a near-patient testing (NPT) diagnostic platform (Symphony IL-6, Bluejay Diagnostics).

METHODS

An IRB-approved protocol was followed for the analytical and clinical validation of the new NPT test using human whole blood and plasma EDTA samples. The analytic evaluation consisted of assessing precision, 6-point linearity, limit of quantitation (LOQ), method comparison, stability, and interference studies. IL-6 cut-off values for disease severity and clinical performance were determined using remnant COVID-19+ samples. Clinical correlation of IL-6 against CRP, lactate, admission disease severity, 28-day mortality rate, and overall length of stay were deduced. Interference was tested using 100 pg/mL of IL-6 and interferent concentrations up to 50,000 pg/mL. The statistical analysis was done using Graphpad Prism and EPA Evaluator.

RESULTS

The Symphony IL-6 assay showed 4-9.1% and 9.8-12.4% CV for within run and total 5-day imprecision, respectively. The assay was linear between 0-6000 pg/mL with a LOQ of 4 pg/mL. The IL-6 cut-off to rule out COVID-19 disease severity based on invasive mechanical ventilation (IMV) was found to be 35 pg/mL with a NPV of 98%. The Symphony platform exhibited a strong correlation with the EUA-approved Roche IL-6 assay (n=152; r=0.9490). IL-6 and CRP levels clearly exhibited a positive correlation with disease severity determined in terms of IMV. Length of stay and 28-day mortality rate were 6 and 3-fold higher in IMV relative to non-IMV patients, which correlated with IL-6 levels. This new assay exhibited acceptable cross-reactivity (<10%) against endogenous cytokines, growth factors, and special drugs.

CONCLUSIONS

The NPT Symphony IL-6 assay has comparable analytical and clinical performance to EUA-approved lab-based IL-6 assay. With its ability to test directly from whole blood, operational simplicity, reliability, portability, and fast turnaround time of <19 mins, the Symphony assay could be readily implemented for rapid identification of COVID-19 disease severity in ED and critical care setting.

COVID-19

P0606

GENETIC POLYMORPHISMS OF FOLATE CYCLE IN COVID-19 PATIENTS.

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BACKGROUND-AIM

Hyperhomocysteinemia is characterized for patients with COVID-19. Homocysteine has been estimated as a predictor of disease progression and death in patients with COVID-19. Genetic polymorphisms of folate cycle are associated with homocysteine level and thrombosis. To evaluate whether genetic polymorphisms are related to severity, thrombosis and laboratory markers in COVID-19 patients.

METHODS

The cross-sectional study included 42 patients (≥ 18 years) with PCR-confirmed COVID-19. We determined 4 polymorphisms in genes encoding cardiovascular risk factors: MTHFR C677T, MTHRF A1298C, MTR A2756G, MTRR A66G. We analyzed levels of homocysteine, folate, vitamin B12 and D-Dimer in all patients with different genotypes. We assessed association between these genetic polymorphisms with severity and thrombosis.

RESULTS

Homocysteine level were significantly elevated in patients with genotypes MTHFR 677 CT/ TT compared with MTHFR 677 CC (19,2 [16,3;24,5] mcmol/l vs 15,0[13,9;16,5] mcmol/l; p=0,012). Folate level were significantly lower in patients with genotypes MTHFR 1298 AA compared with MTHFR 1298 AC/CC (2,47 [1,17;5,17] ng/ml vs 6,50[3,48;11,13] ng/ml; p=0,033). Hyperhomocysteinemia was found in patients with genotypes MTR 2756 AA compared with MTR 2756 AC/CC (17,8 [16,4;23,4] mcmol/l vs 14,5[14,0;16,9] mcmol/l; p=0,046). There was no difference between genetic polymorphisms with severity and thrombosis.

CONCLUSIONS

Hyperhomocysteinemia is associated with MTHFR 677 CT/TT and MTR 2756 AA in patients with COVID-19. Folate deficiency is related to MTHFR 1298 AA genotype. Genetic polymorphisms are not likely to be affected severity and clinical outcomes such as thrombosis.

COVID-19

P0607

SEROPREVALENCE OF NEUTRALIZING ANTIBODIES AGAINST SARS-COV-2 IN RESPONSE TO CORONAVAC, CHADOX1 NCOV-19 AND BNT162B2 IN YOUNG ADULTS FROM NORTHERN MEXICO

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BACKGROUND-AIM

SARS-CoV-2 is the virus that causes COVID-19. In Mexico, the number of infections is underestimated. The Spike glycoprotein of SARS-CoV-2 is the primary vaccination target for the generation of neutralizing antibodies (Nabs), which are a key defense mechanism and highly predictive of protection against the disease. For the above reasons, this study aimed to determine the seroprevalence of neutralizing antibodies against SARS-CoV-2 in response to CoronaVac, ChAdOx1 nCoV-19 and BNT162b2 in young adults from Northern Mexico.

METHODS

A total of 120 vaccinated 21 days after the first dose, 46 vaccinated 21 days after the second dose of CoronaVac, ChAdOx1 nCoV-19 or BNT162b2 and 166 unvaccinated young adults aged 18-35 years from Sonora, Mexico were included in this study. A structured survey was conducted to identify previous COVID-19 infections. A qualitative determination of anti-SARS-CoV-2 antibodies in serum was performed by a lateral flow immunoassay (Certum IgG/IgM Rapid TestTM cassette kit). Nabs were also determined by the cPass™ SARS-CoV-2 Neutralization Antibody Detection Kit (GenScript, Piscataway, NJ, USA).

RESULTS

Of the total of unvaccinated individuals (n=166), 36 reported a history of COVID-19 infection and 130 reported not having had symptoms or being previously tested in any form for COVID-19. However, 57.2% (95/166) of the total of individuals were positive to the rapid antibody test and 56.6% (94/166) had Nabs.
We observed a significant increase in Nabs after the first dose of all the vaccines. For ChAdOx1 nCoV-19 and BNT162b2 we observed an increase in Nabs at the second respect to the first dose. However, we observed a decrease 21 days after the second dose for the CoronaVac vaccine.

CONCLUSIONS

Most of the young people who reported not having had the disease were seropositive for anti-SARS-CoV-2 antibodies. Consequently, asymptomatic cases not identified in a timely manner could still contribute to virus transmission. On the other hand, the efficacy of the BNT162b2 and ChAdOx1 nCoV-19 vaccine in inducing Nabs was higher with respect to the CoronaVac vaccine. At least two doses of CoronaVac vaccine are needed to induce protection against the virus. Vaccination is suggested regardless of sex and severity of disease identified during acute COVID-19 infection.

COVID-19

P0608

ASSOCIATION OF CT WITH PROGRESSION TO INVASIVE MECHANICAL VENTILATION IN MEXICAN PATIENTS HOSPITALIZED FOR COVID-19

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BACKGROUND-AIM

Coronavirus 2019 (COVID-19) is a respiratory infectious disease characterized by symptoms such as fever, pharyngodynia, fatigue, cough and dyspnea, and in severe cases acute respiratory distress and exacerbated inflammatory state, due to dysregulated immune response against the infectious agent SARS-CoV-2. The most efficient test for the detection of SARS-CoV-2 is the real-time RT-PCR (Reverse Transcriptase Polymerase Chain Reaction), which determines the product amplified by the cycle that crosses the threshold (Ct) and is inversely proportional to the patient's viral load. The aim of this study is to associate SARS-CoV-2 Ct values with progression to invasive mechanical ventilation (IMV) in patients hospitalized for COVID-19.

METHODS

SARS-CoV-2 Ct levels were evaluated in 76 patients hospitalized at the Civil Hospital of Guadalajara "Dr. Juan I. Menchaca", by RT-PCR with the kit DeCoV19 Triplex (Genes2Life), blood gasometry levels were determined and patients were followed to determine their hospital stay and progression to IMV.

RESULTS

Viral load was classified into high viral load (Ct: <25), medium (Ct: 25-30) and low (Ct: >30), significant differences were found in the percentage of $SatO_2$ between high viral load with medium viral load (High=84.5 %, 65-88 %; Medium=85 %, 77-86 %; p= 0.02) and low viral load (High=84.5 %, 65-88 %; Low=89 %, 88-93 %; p= 0.03), for hospital stay there is significant difference with a p= 0.008 between high and low viral load (High: 13 days , 9-25 days; Low: 6.5 days, 4-9 days), moreover the risk of being intubated is 5.73 times more in patients with high viral load than those with low viral load (95% CI= 1.42, 23.13). Ct values were negatively correlated with hospital stay (-0.45; p< 0.05) and stay in IMV (-046; p< 0.05); and for each unit increase in Ct, hospital stay decreased 0.99 days (R^2= 0.2135; p= <0.0001) and decreased 1.156 days in IMV (R^2= 0.20; p= 0.03).

CONCLUSIONS

Low Ct (high viral loads) are associated with lower $SatO_2$ and increased progression of patients to IMV, in addition to longer hospital stay and IMV stay, so it is proposed to use Ct as a possible biomarker of COVID-19 severity.

COVID-19

P0609

USING MULTIPLEX PCR RESPIRATORY PANEL TO INVESTIGATE THE ETIOLOGIES OF RESPIRATORY TRACT INFECTIONS DURING COVID-19 PANDEMIC IN A MEDICAL CENTER IN TAIWAN

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BACKGROUND-AIM

Clusters of unexplained pneumonia were discovered in Wuhan, Hubei, China in December 2019. Taiwan CDC announced that "severe special infectious pneumonia" (COVID-19) the fifth category of legal infectious disease on January 15, 2020. To meet the emergent treatment process needs for severe and special infectious pneumonia caused by COVID-19 and the immediate investigation of probable pathogens, a new molecular biology nucleic acid analysis and identification system, BioFire FilmArray Respiratory Panel, came into being for rapid detection of multiple respiratory pathogens. With this powerful platform, we collected nasopharyngeal swab specimens and analyzed the distribution of pathogens of upper respiratory infections from January 2020 to October 2022.

METHODS

We retrospectively study multiple respiratory pathogens from January 2020 to October 2022 by Biofire FilmArray platform. BioFire RP2.1 Plus is a multiplex nested, closed and autonomous PCR system, allowing simultaneous detection for four bacteria and 19 viruses, including SARS-CoV-2 and Middle East Respiratory Syndrome Coronavirus (MERS-CoV). BioFire RP2.1 (except for MERS-CoV) was launched for emergency use authorization (EUA) in Taiwan in May 2020 and introduced in the China Medical University Hospital, a 2,100-bed university-affiliated hospital located in Taichung, Taiwan, to replace the BioFire RP panel in February 2021.

RESULTS

From January 2020 to October 2022, 5,665 nasopharyngeal swab specimens from patients with respiratory tract infection or suspected COVID-19 were submitted for respiratory pathogen detection using the BioFire RP2.1 panel. The positive rate by BioFire FilmArray Respiratory Panel were collected and calculated retrospectively (Figure 1). Accordingly, 1,590 (28.07%) were found the target pathogens positive in the panel, and 455 specimens co-infected by two or more pathogen (Table 1).

CONCLUSIONS

During COVID-19 pandemic, BioFire Respiratory Panel is a rapid method to detect the pathogens of upper respiratory infections in children, which improves the rate of diagnosis between viral infection and COVID-19 infection and avoids the overuse of antibiotics.

COVID-19

P0610

IL-6 AS A BIOMARKER FOR OUTPATIENTS AND HOSPITALIZED PATIENTS FOR COVID-19 FROM WESTERN MEXICO

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BACKGROUND-AIM

Coronavirus 2019 (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus that can cause acute respiratory distress and an increase in proinflammatory cytokines (cytokine storm) that could lead to severe pneumonia and even death. IL-6 is a cytokine that regulates the immune response and has been proposed as a biomarker of COVID-19 due to the high concentrations reported in different studies and is considered to participate in the severity of the disease due to its proinflammatory response. The aim of this study was to determine IL-6 concentrations in outpatients and hospitalized COVID-19 patients infected with omicron and delta variants.

METHODS

The IL-6 were determined in 101 patients using the kit Human IL-6 High Sensitivity ELISA (Invitrogen), of which 57 were hospitalized patients at the Civil Hospital of Guadalajara "Dr. Juan I. Menchaca" and 44 were outpatients with positive RT-PCR test. SARS-CoV-2 variants were determined by sequencing with the kit AmpliSeq for Illumina SARS-CoV-2 Research Panel.

RESULTS

Significant differences were found between IL-6 concentrations in outpatients and hospitalized patients infected by the Delta variant for Delta hospitalized: 6.19 pg/mL, 0.08-43.22 pg/mL and Delta outpatient: 2.08 pg/mL, 0.40-13.38 pg/mL, p= 0.0073. Also, Omicron-infected patients have significance between hospitalized patients and outpatients in IL-6 levels for Omicron hospitalized: 7.14 pg/mL, 0.70-163.16 pg/mL and Omicron outpatient: 1.39 pg/mL, 0.18-14.79 pg/mL, p= <0.0001. In addition, ROC curve analysis showed that hospitalized patients have a cutoff point of IL-6 >2.945 pg/mL than outpatients (AUC=0.804, 95% CI=0.715-0.893, p= <0.0001).

CONCLUSIONS

Patients hospitalized with COVID-19 are associated with elevated IL-6 concentrations, regardless of which variant (Delta and Omicron) infected the patients. In addition, a possible cut-off concentration was found that would allow further observation of patients to reduce hospitalizations.

COVID-19

P0611

COVID-19 AND HIGHER LEVELS OF APTT IN THE GENERAL POPULATION

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BACKGROUND-AIM

Covid-19 infection may disrupt coagulation and heavy menstrual bleeding has been observed following vaccination with some covid-19 vaccines. In Denmark, the registered number of Covid-19 infections increased slightly in December 2020 and again more markedly in the fall of 2021 with a peak in February 2022. During the same periods, vaccination against covid-19 began. We aimed to test the hypothesis that levels of activated partial thromboplastin time (APTT) are higher in the general population after covid-19 infection and covid-19 vaccination.

METHODS

We conducted an observational study of 11,261 individuals from the Copenhagen General Population Study, Denmark, aged 20–100 years. In total, 4,492 individuals had measurements of both APTT and total SARS-CoV-2 antibodies performed on fresh samples collected from September 2020 to July 2022. APTT was measured on Sysmex CS-5100 Hemostasis System using Siemens Healthineers Dade Actin FS Activated PTT Reagent with a reference interval of 20-29 seconds in adult individuals. Total SARS-CoV-2 antibodies were measured using the Atellica IM SARS-CoV-2 Total on the Atellica IM Analyzer.

RESULTS

Mean levels of APTT increased in individuals examined in the fall of 2021 through to the beginning of 2022. From a stable mean of 24.7 seconds in the year 2020, the mean APTT increased 7.3% from 24.6 sec in January 2020 to 26.4 sec in February 2022 ($P<0.001$), followed by a decrease in mean APTT to 25.4 in July 2022. Individuals with a total SARS-CoV-2 antibodies level indicative of recent infection and/or vaccination had a mean APTT level of 25.5 seconds (interquartile range 24.0-27.0). In comparison, individuals with no detectable total SARS-CoV-2 antibodies had a mean APTT level of 25.0 seconds (interquartile range 23.0-26.0) ($P<0.001$).

CONCLUSIONS

Individuals from the general population with evidence of recent covid-19 infection and/or vaccination against covid-19 had higher levels of APTT though still within the reference interval.

COVID-19

P0612

PREALBUMIN AND THYROID DYSFUNCTION IN PATIENTS WITH COVID-19

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BACKGROUND-AIM

The aim of the study was to determine the frequency of changes in prealbumin and thyroid function in subjects with different stages of COVID-19 disease as well as to investigate the relationship between prealbumin, thyrotropin (TSH), free thyroxine (fT4) and free triiodothyronine (fT3) with the outcome of hospitalized patients.

METHODS

The concentrations of prealbumin, TSH, fT4 and fT3 were determined in subjects with severe symptoms hospitalized in the intensive care unit (IC; N=45), subjects with moderate symptoms on oxygen therapy (RC; N=43), post-COVID patients monitored in the post-COVID clinic (PCDB; N=76) and healthy subjects (H; N=60). Kruskall-Wallis test and logistic regression were used for testing the differences between groups and the outcome study. MedCalc Statistical Software, version 14.8.1 (Ostend, Belgium) was used for statistical analysis.

RESULTS

The medians and IQR for prealbumin, TSH, fT4, and fT3 were: 0.21 (0.02-0.45) g/L; 1.02 (0.51-1.87) mIU/L; 13.34 (10.97-15.39) pmol/L and 3.28 (2.74-3.43) pmol/L respectively. Significant difference for prealbumin, TSH, fT3 and fT4 was obtained between the 4 study groups (P<0.0001). Post-hoc analysis revealed significantly lower (P<0.0001) prealbumin and TSH in the IC and RC groups compared to the PCDB and H groups. Significantly higher fT4 (P<0.0001) was found in the IC group compared to the RC, PCDB and H groups and RC compared to the PCDB and H group (P<0.0001). We found significantly lower fT3 (P<0.0001) in the IC group versus RC, PCDB and H groups and RC versus PCDB and H group (P<0.0001).
Logistic regression was significant only between fT3 and outcome (P=0.0058). Given fT3 <3.67 pmol/L, it was possible to classify mortality for 71.91% of hospitalized subjects.

CONCLUSIONS

The results indicate spontaneous recovery of prealbumin, TSH and thyroid hormone with recovery from COVID-19. The obtained significant difference is clinically significant only for TSH and for prealbumin but primarily as a negative acute phase reactant. This suggests the influence of the virus on the hypothalamic-pituitary axis without a secondary effect on the thyroid gland. Only fT3 showed significant association with the outcome, so it is worth investigating further as a useful outcome parameter for hospitalized patients.

COVID-19

P0613

EFFICACY OF THE MRNA-BASED BNT162B2 COVID-19 VACCINE AND ADDITIONAL BOOSTER DOSES IN PATIENTS WITH SOLID MALIGNANCIES TREATED WITH ANTI-NEOPLASTIC DRUGS

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BACKGROUND-AIM

Coronavirus disease 2019, caused by the Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2) infection.Patients with cancer are at increased risk for COVID-19,thus effective preventive measures for this population are urgently required.We have reported that cancer patients undergoing chemotherapy treatment had an impaired serological response to 2 doses of the mRNA SARS-CoV-2 vaccine.The aim of this study was to assess the response of cancer patients undergoing active anti neoplastic treatments to the mRNA vaccine

METHODS

This research was a collaboration between 2 Medical Center.The first part included 140 patients with tumors who were undergoing anti-cancer treatment when the vaccine was administered and 215 individuals without cancer.The second part was extended to cancer patients after the 3 and 4 booster doses.Blood samples were collected at least 7 days after the vaccine administration. IgG testing was performed using the SARS-CoV-2 S1 and S2 proteins and IgG against the Nucleocapsid protein

RESULTS

The humoral response in the cancer patient group was significantly lower than in the non-cancer group:seronegative 14.3% vs1.4%,median IgG levels 2231 AU/ml vs 4100 respectively.In the second part of the research, we follow vaccination in 76 patients who received 3 vaccine doses and in 25 patients with the fourth dose of the vaccine.The median SARS-CoV-2 IgG levels were significantly different $p< 0.001$ among the three groups:2231AU/ml following the second vaccine dose vs 4025 and 24465AU/ml after the 3 and 4 booster doses respectively.Only after the second vaccine there were significant differences in seropositivity and antibody levels between participants who received chemotherapy and those who did not $p<0.001$ After adjusting participants after 4 doses were at a higher probability to have antibodies titer compared to participants after 3 and 2 doses(odds ratio 6.9 , 20.7)

CONCLUSIONS

Cancer patients vaccinated while undergoing chemotherapy treatment had a reduced humoral response following two doses of the BNT162b2 vaccine.The impaired humoral response reported in these patients following two doses of the vaccine was not present after the third and fourth booster vaccine doses.COVID-19 vaccines should be prioritized for use in chemotherapy-treated cancer patients whenever possible

COVID-19

P0614

FIRST RESULTS FROM THE SARS-COV KIDDY MONITORING STUDY VIENNA USING AN INNOVATIVE SAMPLING COLLECTION SYSTEM

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BACKGROUND-AIM

During the COVID-19 pandemic regular monitoring of SARS-CoV-2 infections among infants exhibited limitations.

METHODS

In the present study an innovative sampling system has been used to monitor the prevalence of SARS-CoV-2 infections among young children. During a period of 68 weeks (September 2021 until December 2022) SARS-CoV-2 PCR testing was provided weekly to children (1-6 years) in 44 kindergartens of the 23 districts of Vienna. After informed consent parents were asked for electronic registration of children. Sample collection was done at home using an innovative self-sampling system. SARS-CoV-2-PCR analyses were accomplished using a pooling strategy.

RESULTS

A total of 1.262 children with a median age of 4.0 years were included in the study. The participation rate varied between 2,35% and 75,04%. The total number of samples collected was 24.415, with one feedback of an insufficient sample collection. Of 24.415 samples 251 tested PCR positive (median cycle-threshold (CT) 30,63; [minimum 17,95 – maximum 40,00]). The weekly percentage prevalence (unweighted), averaged over 68 weeks, was 0.92 [95% CI: 0.68; 1.17] among children and 2.41 [95% CI: 2.01;2.81] in the general population of Vienna. In 61 of 68 weeks the prevalence of SARS-CoV-2 infections among children was lower than that of the general population.

CONCLUSIONS

Our monitoring reveals low SARS-CoV-2 concentrations in the majority of kindergarten children and a mostly low prevalence of COVID-19 infections. Moreover, the innovative sampling system showed high acceptance.

COVID-19

P0615

COAGULOPATHY AND DIAGNOSTIC SIGNIFICANCE OF D-DIMER AND INFLAMMATORY INDICES IN MILD COVID-19 DISEASE

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BACKGROUND-AIM

Coagulopathy associated with Covid-19 disease represents a thromboinflammatory condition and is one of the important morbidity and mortality causes. The occurrence of coagulopathy correlates with the intensity of the inflammatory response to SARS CoV-2 virus infection. It is unclear whether, damage to the endothelium under the virus influence, inflammatory responses, platelet and the coagulation system activation in patients with a mild/ inconspicuous clinical picture represents a significant risk. The aim of this study was to analyze if there are significant changes in inflammatory indicies and D-dimer values in SARS-CoV-2 positive subjects with a mild, almost imperceptible clinical picture, compared to healthy controls.

METHODS

For the purposes of this research, we used data from 200 patients, 100 patients positive to COVID-19 disease, with mild symptoms without X-ray changes on lungs, and 100 apparently healthy controls negative for the COVID-19 disease. Among the laboratory parameters, the values of platelets, lymphocytes and neutrophils extracted from the complete blood count, D-dimer, and inflammatory indices were analyzed: neutrophil/lymphocyte ratio (NLR), platelet/ lymphocyte ratio (PLR) and systemic immune-inflammation index (SII). The data was analyzed retroactively from the medical history.

RESULTS

The results showed statistically significant differences in the lymphocyte count, D-dimer and values of inflammatory parameters, between Covid-19 patients with mild symptoms and healthy controls, at the level of $p < 0.001$. Covid-19 patients have significantly lower lymphocyte count, while significantly higher values of D-dimer, NLR, PLR and SII at the level of $p < 0.001$ when compared to healthy controls. Individually, neutrophil and platelet counts analysed in the complete blood count, did not show significant difference between the groups, $p=0.114$ and $p=0.884$, respectively.

CONCLUSIONS

COVID-19 is a state of hypercoagulation, and the risk of thromboembolic disease is increased even in patients with a milder and more favorable clinical picture. Their risk should not be overlooked. We believe that monitoring the increase in D-dimer and inflammatory indices provide a clearer picture of the patient's condition, prompting timely and appropriate treatment.

COVID-19

P0616

ASSOCIATION OF ANGIOTENSIN CONVERTING ENZYME 2 (ACE2) GENE POLYMORPHISMS WITH DISEASE SEVERITY IN INDIAN COVID-19 PATIENTS: A NEXT-GEN SEQUENCING APPROACH.

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BACKGROUND-AIM

The clinical picture of COVID-19 ranges from asymptomatic to mild, moderate or severe disease sometimes leading to death. Differences in the interaction between SARS-CoV-2 Spike (S) protein and angiotensin converting enzyme 2 (ACE2) protein may lead to differences in disease severity. We studied whether ACE2 polymorphisms are associated with disease severity and outcome.

METHODS

We recruited 114 patients between July 2020 - March 2022 confirmed positive by RT-PCR for COVID-19 with different degrees of severity (21 mild, 29 moderate, 34 severe, 30 death) and 30 controls (10 non vaccinated + 20 vaccinated) who were RT-PCR negative inspite of high-risk contact. Next-gen sequencing was done on MiSeq (Illumina) using amplicon-based targeted sequencing approach using a custom-designed panel to sequence all the exons of ACE2 gene. SPSS ver.26 was used for analysis.

RESULTS

The following ACE2 variants were identified on the Local Run Manager (LRM) software from Illumina:(i) rs2285666 (c.439+4G>A) splice region variant, in controls (60%) and Patients (45.8%),(ii)rs4646140 (c.802+24G>A) intronic variant in 4/114 patients and 1/30 controls, (iii)rs41303171(c.2158A>G) missense variant in 2/114 patients, (iv)rs536749578(c.2114+9T>C)intron variant, (v) rs763994205 (c.868A>C) missense variant and (vi)rs7595907(c.656G>A) missense variant in 1/114 patient each only. rs2285666 was observed in equal frequency(60%) in vaccinated and non-vaccinated controls. rs2285666 was observed amongst different severity groups: Mild(80.95%),Moderate(37.93%),Severe (44.11%),Death(56.67%). This suggested a high prevalence of the rs285666 variant in mild cases as compared to others ($p = 0.026$), which establishes that the presence of alternate allele A is associated with a protective role against SARS-CoV-2.

CONCLUSIONS

The result shows that there is a high prevalence of the rs285666 variant in mild cases as compared to others, and this association was statistically significant ($p = 0.026$). The results suggest that the alternate allele A in variant rs2285666 is associated with a lower infection rate as well as a lower CFR among the Indian population. Thus suggests a possibility of the SNV (rs2285666) being associated with a protective role against COVID-19. However, the results need to be confirmed in a larger cohort.

COVID-19

P0617

AFFINITY INVESTIGATION OF ANTI-SARS-COV-2 IMMUNOGLOBULINS IN MYOSITIS PATIENTS RECEIVING IMMUNOSUPPRESSANT THERAPY

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BACKGROUND-AIM

Serological tests detect immunoglobulins produced against the structural proteins of SARS-CoV-2 (e.g. spike protein). The quality of the immune response is determined not only by the amount of antibodies, but also by their potential neutralizing effect, which is manifested in the strength of binding to the relevant immunogenic structural proteins of the virus. According to previous surface plasmon resonance (SPR) performed at our institute, immunosuppressant therapy reduces the affinity of SARS-CoV-2 antibodies to the spike protein.
Our goal was to examine the effectiveness of the immune response against SARS-CoV-2 in several patients receiving immunomodulatory therapy. Our plan was to investigate the binding kinetics of anti-SARS-CoV-2 IgG (from myositis patients) to the spike structural protein.

METHODS

Anti-Spike and anti-NC determinations were performed using ECLIA method from serum samples taken 8 months apart from three myositis patients. On sensor chips immobilized with Spike protein, the most important kinetic parameters (ka, kd, KA, KD) were characterized by SPR.

RESULTS

Anti-Spike IgG was detected in high titers (>700 U/mL). The previous sample of patient I. can be characterized by a KD value of 9.56x10-9 M, while in the case of the new sample this value was 6.53x10-10 M. The previous KD value of patient II. was 1.94x10-10 M, while that of the new sample was 1.98x10-10 M. The III. patient, we obtained KD values of 5.49x10-9 M and 3.31x10-10 M for the previous and the new sample. The KD values of healthy subjects fell in the range of 10-8-10-10 M, depending on the vaccine. The values of kd were 10-3 1/sec, while the values of ka were in the range of 10+6 1/Ms (with the exception of one sample).

CONCLUSIONS

The examined patients developed an effective immune response against SARS-CoV-2 even with immunosuppressive therapy. In comparison with the data of healthy subjects, we can conclude that the immunosuppressant therapy did not increase the KD values, so it did not deteriorate the quality of the immune response. According to the parameters tested at the previous and new times, the new samples developed a bond almost an order of magnitude stronger. So, as time progresses, the anity of IgGs improves, which indicates a more effective immune response.

COVID-19

P0618

COMPARISON OF TWO METHODS FOR EVALUATION OF CELL-MEDIATED IMMUNITY AGAINST COVID-19.

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BACKGROUND-AIM

The aim of the study was to compare two methods for assessing cell-mediated immunity against COVID-19: ELISA (Quan-T-Cell, Euroimmun AG) and ELISPOT (T-SPOT.COVID, Oxford Immunotec Ltd). The latter test additionally differentiates between response to the nucleocapsid (N) or spike (S) SARS-CoV-2 antigen. ELISA measures interferon gamma (IFNγ) concentration in plasma, whereas ELISPOT enumerates cells producing this cytokine.

METHODS

The cohort comprised 27 patients who received a booster dose of Comirnaty (Pfizer-BioNTech). Blood samples were collected at two time points: point "0" (at the day of the booster dose) and point "30" (30 days after the booster dose). At both time points, cell-mediated immunity was tested with the above mentioned two methods. Additionally, the anti-S SARS-CoV-2 IgG concentration was measured with DiaSorin LIAISON® SARS-CoV-2 TrimericS IgG.

RESULTS

At point “0”, all 25 patients were positive in ELISA, but in ELISPOT 5 were negative in anti-S cellular response. Anti-S antibodies were detected in all 27 patients, but the median concentration was higher in patients positive in cellular anti-S (1828 BAU/mL vs 656 BAU/mL).
At point “30”, all patients were positive in both ELISA and ELISPOT assays, with higher values than at day “0”. Simultaneously, a rise in anti-S antibodies was noted.
The anti-N ELISPOT assay requires a separate discussion. At point “0”, 18 patients tested negative and 9 tested positive (suggesting natural contact with SARS-CoV-2). Negative patients had lower median antibody concentrations (1126 BAU/ml) than positive patients (2326 BAU/ml).
The anti-N ELISPOT results at point "30" are difficult to interpret. 6 out of 18 subjects negative at "0" turned positive, which could either imply a surprisingly high infection rate or a non-specific effect of the booster. 3 out of 9 positive participants turned negative, which may be attributed to the passage of time and the natural process of weakening of the acquired cellular immunity.

CONCLUSIONS

Our findings may lead to the conclusion that there is a correlation between cellular and humoral immunity, as well as between both methods of assessing cellular immunity, but the ELISA seems more sensitive (detects lower activity of the cellular response) than the ELISPOT.

COVID-19

P0619

VIRAL GENETIC SIGNATURES AND SERUM CYTOKINE PROFILING OF PEDIATRIC INPATIENT WITH COVID-19 WITH SEVERE NEUROLOGIC INVOLVEMENT

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BACKGROUND-AIM

In 2022 during the COVID-19 pandemic, severe neurologic involvement was common in children hospitalized in Taiwan for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)-related complications. The aim of the study is to elucidate both viral virulence and host factors that contributed to the severe neurologic complications.

METHODS

Forty-nine children hospitalized in Lin-Kou Chang-Gung Memorial Hospital (CGMH), Taoyuan, Taiwan for SARS-CoV-2 infection were enrolled in the study. Among these children, 28 with severe neurologic involvement, 21 showed mild disease. Respiratory specimens (nasal swabs) collected on the day of hospitalization were used for SARS-CoV-2 gene sequencing analysis. Bio-Plex suspension array were used for 47 cytokines analysis, serum specimens collected within 3 days after hospilization were analyzed.

RESULTS

α SARS-CoV-2 viral genetic sequence results showed that COVID19 variant strain Omicron BA5 was the major prevalent strain circulated in Taiwan, 2022; there were no differences among viral genetic sequences analyzed between severe cases or mild cases. The 47 cytokines results revealed that, 36 cytokines showed significant higher level in patients with neurologic complications; which includes IP10, and proinflammatory cytokines (IL-1ß, IL-8, TNFα, IL-17A), T-helper cytokines (IL-9, IL-10, IFNγ).

CONCLUSIONS

The results showed that children with severe neurologic complications were under severe cytokines storm; and there were no difference among the omicron BA5 viruses genetic signatures in severe or mild cases.

COVID-19

P0620

IMPACT OF COVID-19 PANDEMIC ON THE COLORECTAL CANCER SCREENING PROGRAM IN SPAIN: A MULTICENTER STUDY

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BACKGROUND-AIM

Colorectal cancer (CRC) is the second most common cancer in developed countries with an increasing incidence in recent decades. In Spain, it´s the most frequent cancer. Since 2014, in Spain, there is a CRC screening program with the following bases:
• Target population: men and women between the ages of 50 and 69.
• Screening test: fecal occult blood (FOB).
• Interval between examinations: 2 years.
The impact of the COVID-19 pandemic on healthcare has been enormous, with many countries suspending screening programmes, especially for CRC.
Objective: Evaluate the effect of the COVID-19 pandemic on the number of FOB tests requested during the year 2020 and the first semester of 2021.

METHODS

A descriptive, observational, retrospective, multicenter study was conducted in 7 clinical laboratories. Each laboratory collected monthly retrospective the number of tests performed for FOB for the study period (January 2019 -June 2021). Absolute and relative differences were calculated by taking the pre-pandemic period as a reference (January–December 2019). The percentage of change with respect to the 2019 mean was recorded and plotted. Statistically significant differences were analyzed using the non-parametric Wilcoxon test for paired samples. Data were analyzed using the statistical SPSS 25.0 software (IBM Corporation, USA).

RESULTS

In the March–December 2020 period, as compared to the same period of 2019, there was a 45.8% reduction ($p<0.001$) in the number of tests performed for FOB. This reduction was much more significant during the first wave of the pandemic (March–May 2020) (−65.5%, $p<0.001$).
The January–June 2021 period was compared to the same period of 2019, the number of tests for FOB (−3.4%) increased with respect to 2020, but did not reach 2019 values.

CONCLUSIONS

The dramatic decrease found in the requests for FOB tests from the start of the pandemic (virtually −100% some months), which remained the same throughout 2020 in several of the hospitals included, indicates a loss of undetected de novo cases in 2020. The recovery differed significantly as a function of the laboratory, so CRC screening programs were resumed later in some provinces/medical areas, with the corresponding delay in diagnosis.
Effective interventions are required in order to maintain the capacity of the CRC screening program.

COVID-19

P0621

POST-MARKET EVALUATION FOR SARS-COV-2 HOME ANTIGEN TESTS IN KOREA

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BACKGROUND-AIM

Respiratory infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has been a significant public health concern since 2020. Molecular diagnostic tests are considered the gold standard. However, rapid antigen tests for medical staff and self-collected home antigen tests (home tests) were widely performed in Korea after the omicron outbreak in February 2002. In the case of self-collecting tests, performance evaluation is required in real-world. We made the first post-market evaluation for home-test in Korea.

METHODS

The eleven home tests IVD certified by the Ministry of Food and Drug Safety (MFDS) from April 2021 to July 2022 were evaluated as the manufacturer's instructions. The limit of detection (LoD) and precision was tested with the serially diluted clinical pooled samples triplicate. The specificity was demonstrated with the eight commercialized respiratory virus isolates (Korea bank for pathogenic viruses, KBPV), eight typical respiratory track-related bacteria suspensions, and 14 clinical specimens with positive or negative PCR results of respiratory viruses triplicate. For precise and quantitative evaluation, each level of diluted samples was tested twice with real-time PCR methods and calculated for the number of viral copies. The AccuPlex SARS-CoV-2 Verification Panel (SeraCare) was used as standard material.

RESULTS

As a result of the LoD test, the sensitivity of the 11 home tests was in the range of 262 - 1,924 copies/uL, and the E gene Ct value in the range of 20.6 - 23.6. No cross-reactivity was detected with eight virus isolates, eight typical respiratory track-related bacteria suspensions, and 14 clinical specimens. Specificity results showed 100% results for all 11 home tests.

CONCLUSIONS

While home tests using a mainly nasal swab, the performance is compared with real-time PCR using a nasopharyngeal swab. Since the buffer volume (400ul) in the home test is smaller than the UTM (2,000ul), there is expected to be a difference in the concentration of the virus collected. If the home test is directly used with a self-collected nasal swab, up to 8 times higher virus concentration is likely to be contained in the swab. The LoD is expected to be showing Ct value 22-27. SARS-CoV-2 Home tests approved by MFDS are conducted to help diagnose COVID-19.

COVID-19

P0622

COMPARISON OF SARS-COV-2 NEUTRALIZING AND TOTAL SPIKE ANTIBODY RESPONSES FOLLOWING TWO DOSES OF MRNA, ADENOVIRAL VECTOR, AND INACTIVATED VIRUS VACCINATIONS IN COVID-19 NAïVE SUBJECTS

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BACKGROUND-AIM

Several studies have demonstrated the humoral response after various individual COVID-19 vaccines, however, only limited published data is available on the comparison of the three main types of COVID-19 vaccinations. Thus, we have evaluated the titer of SARS-CoV-2 neutralizing and total spike antibody following two doses of mRNA, adenoviral vector, and inactivated virus vaccines to compare the effectiveness of different immunizations.

METHODS

Age- and sex-matched participants were enrolled into three subgroups (n=50/cohort) who were tested 22-65 days (mean 45 days) after their second dose of mRNA (BNT162b2 or mRNA-1273), adenoviral vector (ChAdOx1 or Gam-COVID-Vac) and inactivated virus (BBIBP-CorV) vaccines, with no history or serologic evidence of prior SARS-CoV-2 infection. Total S1-RBD antibody (S-Ab) levels were assessed on the Roche Elecsys® e602, while neutralizing antibody (N-Ab) on the Snibe quantitative N-Ab assay (Maglumi® 800). Seropositivity was evaluated based on the manufacturer's N-Ab cut-off value of 0.3 μg/mL.

RESULTS

Within the mRNA vaccine group, most subjects became seropositive (88% vs 68% and 56%, respectively) by two doses of vaccine demonstrating significantly higher levels of SARS-CoV-2 N-Ab (mean value of 4.58 vs 1.95 and 1.83 μg/mL), and S-Ab (2272 vs 680 and 838 U/mL) compared to adenoviral vector and inactivated vaccinations under the same time interval ($p<0.0001$). The concentrations of N-Ab highly correlated with S-Ab levels ($r = 0.943$; $p<0.0001$) and were not affected by age and gender in any subgroups. Using N-Ab results, a new cut-off value of Roche S-Ab was calculated (166 U/mL) for discrimination of seropositivity following two doses of vaccines that showed a substantial AUC value of 0.974 ($p<0.0001$) with 95% sensitivity and 85% specificity. During the follow-up for 6 months after immunizations, only 8 participants were infected by SARS-CoV-2 in the entire group whose N-Ab levels remained low with a mean value of 0.33 μg/mL.

CONCLUSIONS

The mRNA COVID-19 vaccines generate more robust N-Ab and S-Ab levels than the adenovirus vector and inactivated virus vaccines, and these titers reliably correlate with each other.

COVID-19

P0623

EVALUATION OF CELLULAR AND HUMORAL RESPONSES AGAINST SARS-COV-2 AFTER 1 YEAR OF THE THIRD DOSE OF BNT162B2 MRNA HOMOLOGOUS VACCINATION IN HEALTHCARE WORKERS

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BACKGROUND-AIM

Several types of COVID-19 vaccine have been employed to immunize healthcare workers in Hungary. Immunogenicity of a third (booster) dose of COVID-19 vaccine has got in focus of the fight against SARS-CoV-2, but there is still a debate when the fourth dose of vaccine needs to be administered to those without any comorbidities. Here we have assessed T-cell responses after 1 year of the third dose of BNT162b2 mRNA vaccine in parallel to the analysis of SARS-CoV-2 neutralizing and total spike antibody titers.

METHODS

Forty participants were enrolled aged between 24-62 years who were tested 1 year (305-423 days) after their booster dose of BNT162b2 mRNA homologous vaccination with history of previous mild SARS-CoV-2 infection but no other chronic diseases. As controls, subjects (n=12) with different heterologous immunizations (BNT162b2 mRNA combined with BBIBP-CorV vaccines) were tested. T-cell responses were studied via IFN-γ levels using Elecsys® IGRA SARS-CoV-2 test, while neutralizing antibody (N-Ab) and total S1-RBD antibody (S-Ab) levels were determined on Snibe quantitative N-Ab assay (Maglumi® 800) and Roche Elecsys® e602, respectively. Cellular immunity was estimated according to manufacturer's algorithm of IGRA test, and seropositivity was evaluated based on N-Ab cut-off value of 0.3 μg/mL.

RESULTS

Except for two subjects in the BNT162b2 mRNA group, T-cell response was detectable showing the mean IFN-γ level of 1.66 IU/mL (0.16-10.54 IU/mL). These individuals demonstrated induced levels of SARS-CoV-2 N-Ab (mean value of 52.1 μg/mL) and S-Ab (18550 U/mL), while only one participant showed low N-Ab and S-Ab value (0.2 μg/mL and 90 BAU/mL, respectively) in the presence of 1.54 IU/mL IFN-γ. The concentrations of N-Ab correlated with S-Ab levels ($r = 0.879$; $p<0.0001$) and neither IFN-γ nor N-Ab were significantly affected by age. In terms of the efficacy of different vaccination strategies, there was no difference in IFN-γ ($p = 0.2008$) between homologous BNT162b2 mRNA and heterologous immunization cohorts. In contrast, significantly higher N-Ab titers ($p = 0.0010$) were found after three BNT162b2 mRNA vaccines.

CONCLUSIONS

The Roche® IGRA test is a suitable method to measure T-cell responses following different vaccination strategies.

COVID-19

P0624

PREDICTIVE VALUE OF SERUM TOTAL ANTIOXIDANT CAPACITY LEVELS IN COVID-19 PATIENTS

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BACKGROUND-AIM

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) causes an acute and potentially lethal disease with 2% mortality. There is no specific laboratory marker for the prediction and diagnosis of COVID-19, therefore a multiple marker approach is preferred. Since oxidative stress is one of the key factors in the pathogenesis of COVID-19, assessing its degree could be a potential marker of disease severity.
We aimed to quantify the non-enzymatic total antioxidant capacity (TAC) of the sera of COVID-19 patients and that of healthy controls by a previously validated enhanced chemiluminescence (ECL)-based TAC method and elucidated the predictive value of serum TAC in COVID-19 when comparing it with classical markers.

METHODS

We investigated 67 COVID-19 patients [n=40 ward, n=27 intensive care unit (ICU) patients] and 34 healthy controls. Admission serum TAC was measured by ECL microplate assay and was expressed in Trolox equivalent values (μmol/L). Routine clinical and laboratory data were collected from the hospital information system. For statistical calculations IBM SPSS Statistics 28 program was used.

RESULTS

Highest serum TAC levels were found in ICU patients (median: 386.76 μmol/L), compared to them, significantly lower TAC values were obtained in ward patients (315.44 μmol/L; $p<0.05$) and lowest values were found in controls (295.39 μmol/L; $p<0.01$). A newly introduced marker, TAC/lymphocyte ratio differentiated better COVID-19 patients (ICU vs. ward patients: 609.77 vs. 292.47 μmol/G; $p<0.05$) from controls (34.87 μmol/G; $p<0.001$) than TAC alone. Receiver operating characteristic (ROC) analyses revealed that, besides the classical parameters, both TAC [area under the curve (AUC)-ROC: 0.71; $p<0.05$] and TAC/lymphocyte ratio (AUC-ROC: 0.77; $p<0.01$) had predictive values regarding the severity of COVID-19. TAC/lymphocyte ratios were higher in non-survivors than in survivors (median: 481.29 vs. 277.78 μmol/G; $p<0.001$). Our data suggest that beside classical markers, TAC/lymphocyte ratio could also predict the mortality of patients (AUC: 0.79; $p=0.001$) and serum TAC and TAC/lymphocyte ratio are potential novel markers in COVID-19.

CONCLUSIONS

Our TAC microplate assay seems to be a promising method for assessment of antioxidant defence in severe inflammatory diseases.

COVID-19

P0625

DETECTION OF DELETION 69 AND 70 ON THE S GENE OF SARS-COV2 VIRUS BY COMMERCIAL ASSAY

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BACKGROUND-AIM

The SARS-CoV-2 virus spread rapidly throughout the world and caused a global pandemic in 2020. The virus is susceptible to numerous mutations that affect its properties in different ways. Some mutations can affect the results of the RT-PCR molecular analysis which are used to confirm virus infection. Deletion of amino acids H69 and V70 (Del 69/70) on the S gene is common mutation, and due to the lack of these amino acids, false negative results can be obtained when testing is performed with the RT-PCR assays that use S gene for detection of SARS-CoV-2 virus.
The aim of this study was to compare results of RT-PCR which uses ORF1ab, N and S genes for SARS-CoV2 detection with the NGS sequencing results of the same samples.

METHODS

The analysis was carried out on 30 nasopharyngeal squabs obtained from subjects referred to SARS-CoV-2 testing. MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit (Thermo Fisher Scientific, SAD) were used for viral RNA extraction. TaqPath™ COVID 19 CE IVD RT PCR Kit (Thermo Fisher Scientific, USA) was used for detection of SARS-CoV-2 in extracted samples on QuantStudio 5 (Thermo Fischer Scientific, USA). NGS sequencing of the studied samples was done by the courtesy of Eurofins Genomics Europe laboratory.

RESULTS

Out of 30 samples, positive result for S gene was obtained in 16 samples and negative in 14 samples when using RT-PCR method. Sequencing of same samples revealed the presence of a Del69/70 in all 14 samples in which S gene was not detected. In other 16 samples with positive S gene, presence of Del 69/70 was not confirmed by sequencing.

CONCLUSIONS

The results confirmed statements that S gene dropout is caused by del69/70. False-negative results for S gene do not indicate the absence of the virus because there are two other gens that still can be detected and indicate the presence of virus in the sample. On the other hand, dropout of S gene can be used for a fast detection of the presence of a new variant in population, especially if previously prevalent variant did not bear this mutation.

COVID-19

P0626

PREVALENCE OF ANTIBODIES TO SARS-COV-2 IN FOLLOWING WAVES OF THE PANDEMIC IN POLAND

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BACKGROUND-AIM

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) emerged in Poland in March 2020 and spread from then. Compared to other European countries, a relatively small number of confirmed cases of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections were reported in Poland during the first months of the COVID-19 pandemic. The objective was to estimate the seroprevalence of SARS-CoV-2 during the pandemic and subsequent waves of infection.

METHODS

To estimate the scale of the pandemic in Poland, we performed a serosurvey of antibodies against nucleocapsid (N) and spike (S) proteins of SARS-CoV-2. Within this study, we collected samples from 9 December 2020 to 30 September 2022. The study population was obtained from the Bialystok PLUS cohort study (N=543, aged 20 to 80 years). The ECLIA method was used to determine the presence of antibodies against the N protein using a Roche Cobas E411 analyzer. To assess antibodies against protein S, it was used the LIAISON SARS-CoV-2 TrimericS IgG serological test.

RESULTS

Overall, the percentage of samples positive at the end of September 2022 for antibodies against the N protein was 69.7% and against the S protein was 92.5%. The greatest increase in the presence of antibodies among the study population was observed between the delta and omicron variant waves. Anti-N antibodies have risen by 42.2% and anti-S by 10.1%.

CONCLUSIONS

Our findings indicated the presence of anti-SARS-CoV-2 antibodies in a significant group of respondents and a higher percentage from the third and fourth waves of COVID-19 in Poland, respectively. In fact, the majority of participants had no knowledge of COVID-19 infection, which may refer to asymptomatic infection or a mild course of the disease.

COVID-19

P0627

EVALUATION OF LABORATORY PARAMETERS AND THEIR PROGNOSTIC ROLE IN COVID-19 PATIENTS IN ALBANIA

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BACKGROUND-AIM

COVID-19 pandemic has challenged health care systems worldwide. This study aims to evaluate laboratory parameters at admission in COVID-19 patients and the role of routine tests at admission in predicting the need for Intensive Care during hospitalization.

METHODS

This is an observational prospective study. In this study are enrolled 150 adult patients admitted in Infective Emergency and hospitalized for COVID-19 from 15 November 2020 to 15 February 2021 in University Hospital Center 'Mother Theresa', Tirana, Albania. Data (age, gender and laboratory parameters at admission) were electronically collected from Laboratory information management system of Laboratory Networks, UHCMT, Tirana. Patients were categorized in two groups according to the need for Intensive Care during hospitalization and in subgroups after test results. Statistical analysis was performed using IBM SPSS Statistics 26. P-value<0.05 was considered statistically significant.

RESULTS

33% were females and 67% males. The average age was 61.94 ± 12.26 years. Inflammatory biomarkers (CRP, Ferritin, Fibrinogen, D-Dimer) are elevated at admission. Mean WBC and neutrophils count are elevated at admission. 68% of the patients had lymphocytopenia and 16.7% thrombcytopenia at admission. 23% of patients enrolled in this study needed Intesive Care during hospitalization. Ferritin, D-Dimer, SII, NLR, WBC, Neutrophils count, Monocytes count, Urea, LDH, CK-MB at admission were significantly higher among patient that needed Intensive Care. Lymphocytes count, LMR and PNR at admission are significantly lower among patients that didn't need Intesive Care treatment.

CONCLUSIONS

Biochemical and clinical laboratory tests play an essential role in the evaluation of inflammation and organ disfunction. Routine tests like CBC and biochemical parameters are a useful and cost-effective prognostic tool for the level of care COVID-19 patients will need during their hospitalization, potentially impacting clinical outcomes and management.

COVID-19

P0628

COMPARISON OF SUPAR LEVELS DETERMINED BY AN AUTOMATED ANALYZER AND A POINT-OF-CARE EQUIPMENT.

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BACKGROUND-AIM

soluble urokinase Plasminogen Activator Receptor (suPAR) is a marker of inflammation and its levels are found elevated in several infectious diseases. The determination of this marker helps in the clinical evaluation of a patient's condition and in the prevention of an unwanted outcome. The present study aimed to evaluate the sensitivity and specificity of the determination of suPAR in plasma by an automated analyzer and by a point-of-care equipment.

METHODS

Plasma samples of 161 COVID-19 hospitalized patients and 53 healthy volunteers (controls) were collected and suPAR levels were determined by the use of both an automated analyzer (ROCHE Diagnostics) with an immunoturbidometric method and the aLF point-of-care instrument (Qiagen) with lateral flow immunological method (suPARnosticQT). The statistical analysis was performed with IBM SPSS Statistics v. 25.

RESULTS

Median values (min-max) of suPAR levels determined with point-of-care in patients and controls were 5.6 (2-15) and 5.9 (2.0-13.9), respectively. Levels determined by an analyzer were 5.0 (2.1-27.4) and 3.6 (1.9-23.8), respectively. Mann-Whitney test revealed a statistically significant difference in values between the two methods only in controls. A significant positive correlation of suPAR values (Spearman's correlation) was observed in patients (r_s=0.763, $p<0.001$) and in controls (r_s=0.331, p=0.016). The ROC curve created by values of the analyzer (AUC=0,741) was better than that of the point-of-care equipment, with a sensitivity of 78% and specificity of 51% vs. 43% and 45%, respectively.

CONCLUSIONS

suPAR plasma levels determined by point-of-care equipment presented lower sensitivity and specificity and is a more time-consuming process. Therefore, the use of an analyzer for the determination of suPAR levels in a hospital clinical biochemistry laboratory with a high number of samples seems to be the method of choice.

COVID-19

P0629

ASSESSMENT OF THE IMPACT OF THE COVID-19 PANDEMIC ON LABORATORY DIAGNOSIS OF MYCOBACTERIUM TUBERCULOSIS INFECTION: A SINGLE-CENTER EXPERIENCE

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BACKGROUND-AIM

The coronavirus disease 2019 (COVID-19) pandemic has set back years of global progress in the combat against tuberculosis (TB). In many countries, human, financial, and other resources have been diverted to respond to COVID-19, limiting the availability of essential TB services. The study aimed to assess the impact of the COVID-19 pandemic on the number and types of samples sent for microscopy and culture of Mycobacterium tuberculosis compared to the period before the pandemic.

METHODS

The research was conducted on samples of suspected tuberculosis cases referred to the Hospital for Lung Diseases and Tuberculosis in Travnik, Bosnia & Herzegovina. The data were analyzed in two fifteen-month periods, pre-COVID-19, including 1st January 2019 to 30th March 2020, and COVID-19 from 1st April 2020 (emergence of SARS-CoV-2 in this area) to 30th June 2021. Acid-fast bacilli (AFB) smear microscopy and culture of M. tuberculosis on Löwenstein-Jensen medium were performed.

RESULTS

In the pre-COVID-19 period, 2109 samples were analyzed for M. tuberculosis, of which 41 cases (1.94%) were positive. During the COVID-19 period, although the number of tested samples decreased, M. tuberculosis was more often detected (33/753, 4.38%). The most common specimen sent for testing during the pre-COVID-19 period was sputum (1839/2109, 87.2%), urine (131/2109, 6.3%), bronchoalveolar lavage (BAL) (78/2109, 3.7%), pleural fluid (51/2109, 2.4%), and other samples (10/2019, 0.4%). Similar findings were observed in the COVID-19 period but in the significantly lower numbers $p < 0.001$. Positive sputum smears were obtained more often in the COVID-19 period (22/33, 66.7%) than during the pre-COVID-19 period (17/41, 41.5%), $p=0.031$. The difference in the frequency of positive M. tuberculosis culture results between the pre-COVID-19 (25/41, 61%) and COVID-19 (26/33, 78.8%) periods was not statistically significant ($p=0.09$).

CONCLUSIONS

During the COVID-19 period, although the number of analyzed samples decreased, positive sputum smears were more frequently recorded. Furthermore, the prevalence of positive M. tuberculosis cultures did not change significantly, regardless of the pandemic.

COVID-19

P0630

POTENTIAL ROLE OF NEUTROPHIL-TO-LYMPHOCYTE RATIO (NLR) AS A BIOMARKER FOR COVID-19 MORTALITY.

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BACKGROUND-AIM

As it is known, the SARS-CoV-2 virus is characterized by high infectivity, and in some patient's, it is accompanied by serious complications and high mortality. The aim of our study was to evaluate the diagnostic usefulness and prognostic value of neutrophil/lymphocyte ratio (NLR) in patients with COVID-19.

METHODS

We retrospectively analyzed data on 374 patients with COVID-19 (183 woman and 191 men, mean age 67 years) hospitalized at Temporary Hospital no 2 of Clinical Hospital in Bialystok (Poland) between November 2020 and November 2021. The severity of COVID-19 was defined on the basis of Modified Early Warning Score (MEWS) scale recommended by Polish Association of Epidemiologists and Infectiologists. NLR was calculated from CBC (complete blood count) by dividing the neutrophil count by the lymphocyte count.

RESULTS

Statistical analysis performed by Anova Kruskal-Walli's test revealed that values of NLR between four groups of patients divided according to MEWS classification differ statistically significant (p=0.0117). NLR value showed an upward tendency with the severity of the COVID-19 course, according to the MEWS scale (MEWS 1= 4.804, MEWS 2= 6.820, MEWS 3= 8.087, MEWS 4= 9.456). The statistically significant NLR value were between patients with MEWS 1 and MEWS 3 (p=0.042) and between MEWS 1 and MEWS 4 (p=0.045). ROC analysis demonstrated that NLR might be useful for differentiation severe or non-severe cases of COVID-19. The areas under the curve (AUC) of NLR was 0.589 and the optimal cut-off = 3.849. We also created ROC curves to determine whether the baseline of NLR could predictive mortality in patients with COVID-19. The AUC values of NLR was 0.656 and the optimal cut-of = 6.22. We performed COX regression analysis to explore the possible independent predictors of death during COVID-19 course. On admission, our analysis showed that increasing patients' age (HR 1.072, 95% CI 1.040-1.106), and NLR (HR 1.050, 95% CI 1.018-1.083) were identified as an independent factor associated with mortality according to multivariate analysis.

CONCLUSIONS

Our study indicates that NLR has got a clinical implication in severe COVID-19. NLR determined on admission to the hospital could quickly, and fast identify high-risk group patients and could be an independent risk factor of mortality during COVID-19.

COVID-19

P0631

THE ROLE OF BIOMARKERS IN RISK STRATIFICATION OF HOSPITALIZED COVID-19 PATIENTS IN A GREEK COHORT

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BACKGROUND-AIM

As the COVID-19 pandemic strains healthcare systems worldwide, finding predictive and prognostic markers of severe courses remains urgent. Most research so far was limited to selective questions hindering general assumptions for short- and long-term outcome. Here, we aimed to identify biomarkers of disease severity by measuring the serum levels of LDH, CPK, Ferritin and high-sensitive Troponin in a Greek cohort of COVID-19 patients and to evaluate their role in risk stratification.

METHODS

In total, 110 COVID-19 patients hospitalized in General Hospital of Athens "Georgios Gennimatas" were enrolled in this study. Disease severity was evaluated by clinical evaluation and laboratory tests. Data were collected at admission and at the endpoint. Patients were grouped in five groups: A. no need for oxygen, B. oxygen through Venturi mask, C. oxygen through high-flow mask, D. need for ICU and E. death. LDH, CPK, Ferritin and high-sensitive Troponin were measured by using Abbott Alinity c analyzer.

RESULTS

LDH levels were gradually increased between the five patient groups whereas CPK levels did not show any variation. Ferritin levels were highly increased in the three groups showing more severe manifestations. High-sensitive Troponin was significantly increased during admission to the hospital only in patient group 5. Comparing these parameters level between vaccinated and unvaccinated patients, only high-sensitive Troponin was found to be significantly higher in unvaccinated patients both in the first and the last day of hospitalization.

CONCLUSIONS

Ferritin, as many studies have shown, confirmed its prognostic role in hospitalized COVID-19 patients. Although, high-sensitive Troponin was significantly higher in patients that died, further evaluation of these patients age and underlying conditions is needed. Also, no differentiation was observed in vaccinated and unvaccinated patients in the markers studied.

COVID-19

P0632

WHAT WAS RHINOVIRUS UP TO DURING THE COVID-19 PANDEMIC?

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BACKGROUND-AIM

In March 2020, Estonia imposed a lockdown to contain the newly declared COVID-19 pandemic which was the beginning of a long battle with the SARS-CoV-2 virus. Numerous measures were taken to contain the spread of the virus, including mandatory face masks, hand disinfection, and limiting human contact. While the spotlight was on the new virus spreading around the world, the other respiratory viruses were left in its shadow as the measures led to a dramatic decrease in these viral infections with one exception.

METHODS

The study includes data from 50 898 respiratory samples from a total of 35 370 patients collected between 2018 and 2022. The samples were analyzed with one or more molecular diagnostic tests from the following list: Cepheid Xpert Xpress Flu/RSV, Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV, Roche cobas SARS-CoV-2 & Influenza A/B Assay and Seegene Allplex Respiratory Panels 1, 2, and 3.

RESULTS

With the emergence of SARS-CoV-2, almost all other respiratory viruses disappeared but rhinovirus managed to maintain its spread. Results from April 2020 to March 2021 were compared with the results from the same period in 2018 to 2022. During the first year of COVID-19, the number of positive samples with respiratory viruses such as influenza viruses, coronaviruses 229E and OC43, human metapneumovirus, parainfluenza viruses, and RSV were drastically reduced, a decrease of 94% in total. There were 0 cases of influenza A in samples analyzed during that period, however, rhinovirus remained, accounting for 86.3% of all positive results in the 2020/2021 season (excluding SARS-CoV-2), an increase from 29.6% in the previous season.

CONCLUSIONS

The spread of rhinoviruses even under pandemic restrictions was observed in many countries across the world, such as the United States, South Korea, Finland, Australia, Brazil, and several others. The same effect was seen in our results where rhinoviruses became the dominant respiratory viruses accounting for 86.3% of all positive respiratory viruses (except SARS-CoV-2). Rhinoviruses are known for their genomic diversity, stability on surfaces, and number of co-circulating strains. These could be the reasons rhinoviruses survived under pandemic conditions while other respiratory viruses such as influenza did not.

COVID-19

P0633

SUBACUTE THYROIDITIS ASSOCIATED (SAT) WITH COVID-19

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BACKGROUND-AIM

We will describe a case of a hospitalised patient with COVID-19 who developed subacute thyroiditis (SAT) in association with SARS-COV-2 infection.
The objective of this work is to alert physicians that SAT may be a manifestation of SARS-CoV-2 infection.

METHODS

Case report: A 34-year-old woman no medical history or known COVID-19 exposure presented to the emergency departmen with a 8-day history of fever, dry cough, headache and anosmia. On admission, she had a temperature of 38°C, blood pressure of 120/80mm Hg, heart rate of 85 beats/min, and an oxygen saturation (SpO2) of 96% on room air. An oropharyngeal swab and testing for COVID-19 was performed using reverse transcription real-time qualitative PCR. The test for SARS-CoV-2 was positive. Initial laboratory tests on admission to the hospital showed a normal white cell count (9.8×109/L), haemoglobin level (14.3g/dL) and platelet count (444000/mm3). C reactive protein (CRP) level was mildly elevated at 11.3mg/L, and lactate dehydrogenase (LDH) was within normal limits at 433 units/L. On examination of his neck, a diffuse asymmetric goitre was found that was hard and tender to palpation. There was no retrosternal extension or palpable bruit. Few cervical lymph nodes were palpable bilaterally.

RESULTS

Ultrasound of the neck showed an enlarged thyroid gland with heterogenous echotexture due to the presence of an hypoechoic nodule in the right lobe, but with clear and regular margins. A thyroid function test was done revealing FT3 (3,60pmol/L), FT4 (1,30pmol/L) and suppressed thyroid-stimulating hormone (TSH) (<0.04mU/L). Thyrotropin receptor antibody (TRAb) and thyroperoxidase antibody (TPOAb)were negative,Thyroglobulin 350ng/ml..After corticosteroid therapy the patient was asymptomatic and inflammatory markers had returned to normal range.

CONCLUSIONS

SAT may be an underestimated manifestation of COVID-19. Clinicians should keep in mind the possible occurrence of SAT during and after SARS-CoV-2 infectionThis case illustrates that subacute thyroiditis associated with viruses such as SARS-CoV-2 should be recognised as a complication of COVID-19 and considered as a differential diagnosis when infected patients present with tachycardia without evidence of progression of COVID-19 illness.

COVID-19

P0634

SERUM VITAMIN D LEVELS AND STRESS BIOMARKERS IN COVID-19 PATIENTS

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BACKGROUND-AIM

Early in the Coronavirus disease 2019 (COVID-19), vitamin D has been established as an immune-modulator that reduces pro-inflammatory damage which effectively diminish the severity of COVID-19. Vitamin D (Vit D) deficiency is highly prevalent worldwide and recently has been suggested to be associated with an increased risk of psychophysiological stress disorders. During the COVID-19 pandemic the mental health disorders and level of stress show a major increase compared before the pandemic. The aim of the study was to investigate levels of Vit D), salivary stress biomarkers such as a cortisol and alpha-amylase, and stress levels in patients with severe COVID-19 disease.

METHODS

The study included 100 COVID-19 patients with moderate (n=55) and severe (n=45) form of the disease and a control group (n=40) of healthy individuals. Serum Vit D (measured as 25(OH)D) concentrations were analyse by automated chemiluminescence enzyme immunoassay. Saliva cortisol (sCort), saliva alpha-amylase (sAA) were determined by ELISA assay. Symptoms of stress were measured with a Stress symptom checklist (SSCL).

RESULTS

The Vit D levels were significantly lower in the COVID-19 patients group compared with the values in the control group. Considering the disease severity, we found out significantly lower serum Vit D levels in the COVID-19 patients with severe disease (16.54±6.51ng/ml) than those with moderate disease (20.37±5.63 ng/ml) ($p<0.001$). The patient's group presented significantly higher levels of sCort and sAA compared with the control group. Based on their stress scores from SSCL the patients were associated with high stress level. In terms of the controls all the participants showed a low to moderate stress level. A negative correlation with statistical significance was observed between Vit D and sCort ($r = -0.882$, $p<0.001$), Vit D and sAA ($r = -0.741$ $p<0.001$). A strong positive correlation was found between sCort with sAA ($r = 0.934$, $p<0.001$).

CONCLUSIONS

Data from our study demonstrated that VitD and stress biomarkers may contribute to exploring negative impact of COVID-19 related stress.

COVID-19

P0635

PREDICTORS OF MORTALITY IN PATIENTS OF COVID-19

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BACKGROUND-AIM

Since the outbreak of the pandemic of COVID-19 in December 2019, India has observed three waves of the disease. Its pathophysiology points towards inflammation and cytokine storm. There has been varied results regarding the levels of biomarkers in survivors of this disease from different countries. The present study was thus planned to evaluate the levels of different serum biomarkers as predictors of mortality.

METHODS

An observational study (retrospective and prospective study) was carried out on 251 diagnosed cases of Covid-19 diseases admitted in the tertiary care hospital in Chandigarh, in whom all biomarkers could be done. A detailed demographic, clinical, lab results and co-morbid data was obtained from the patients record files for retrospective study while for prospective study, the same was obtained from the patients. Levels of Interleukin 6, procalcitonin, D-dimer, ferritin was analysed by chemiluminescence, C-reactive protein by immunoturbidimetry and lactate dehydrogenase by spectrophotometry at the time of admission. The levels of the serum biomarkers were compared in survivor vs non-survivor subjects of the study.

RESULTS

There were 45 non –survivors and 206 survivors. Mortality in the severe disease was found to be significantly higher (47.14%) than the mild(4.55%) and moderate(7.30%) disease. Median levels of serum biomarkers in non- survivor vs survivor were IL6 31pg/mL vs 11.05pg/mL ,CRP 86 mg/dL vs 73.5mg/dL,PCT 0.11ng/ml vs 0.05 ng/ml , D-dimer 0.5 ugFEU/mL vs 0.3 ugFEU/mL, ferritin 636 ng/mL vs 433.5ng/ml and LDH 1016 IU/L vs 839 IU/L.The levels were found to be significantly higher in non-survivors as compared to survivors.

CONCLUSIONS

The median levels of interleukin 6, PCT, d-dimer, and ferritin were found to predict mortality in patients of Covid-19 disease.

COVID-19

P0636

SERUM IL-6, CRP, PROCALCITONIN AND FERRITIN AS INDICATORS OF SEVERITY OF COVID-19

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BACKGROUND-AIM

The coronavirus 2019 disease (COVID-19) is characterised by a heterogeneous clinical presentation and viral mutation, a complex pathophysiology and a wide range of laboratory findings, depending on disease severity. It is still not well understood why some patients are asymptomatic or have mild influenza-like manifestation while others reveal a hyperinflammatory state ("cytokine storm") followed by an acute respiratory distress syndrome and even death. Scientists face challenges related to the management, prognosis and treatment of the infection and try to identify laboratory predictors for progression towards severe and fatal forms of this disease. We aimed to study some laboratory parameters, including serum IL-6, C-reactive protein (CRP), procalcitonin (PCT) and ferritin representing the inflammatory state and hospital mortality in COVID-19 patients.

METHODS

We analysed a total of 122 hospitalised patients with PCR proven symptomatic COVID-19 infection divided into two groups (50 with lethal outcome – 36 male and 14 female and 72 recovered patients – 56 male and 16 female). Serum IL-6, ferritin, PCT and CRP (Access 2, Olympus AU 480, Beckman Coulter) were measured. Collected data was analysed using SPSS software, version 19.0. Continuous variables were expressed as means and standard deviations (mean ± SD). Statistical differences were considered significant at $p<0.05$.

RESULTS

The mean age of the patients with lethal outcome was significantly higher than the recovered group (63.04 ± 2.23 yrs vs 55.22 ± 7.66 yrs, $p < 0.05$). On admission patients with lethal outcome exhibited significantly higher serum IL-6 (425.39 ± 215.48 pg/ml vs 32.89 ± 29.28 pg/ml, $p < 0.05$), CRP (204.53 ± 110.56 mg/l vs 91.73 ± 68.80 mg/l, $p < 0.0001$), PCT (7.14 ± 2.10 ng/ml vs 0.28 ± 0.15 ng/ml, $p < 0.05$) and ferritin (1417.75 ± 1288.33 ng/ml vs 811.76 ± 768.08 ng/ml, $p < 0.05$) than those in the recovered group.

CONCLUSIONS

Our results show that elevated serum IL-6, CRP, PCT and ferritin can predict the severity of the disease. They can be useful markers of risk scarification in COVID-19 and can be considered in combination with clinical details and other laboratory tests while designing the patient treatment.

COVID-19

P0637

THE SIGNIFICANCE OF ESTABLISHING NEUTROPHILS TO LYMPHOCYTES AND PLETELETS TO LYMHOCYTES RATIO IN ASSESSING THE DEVELOPMENT OF SYSTEMIC INFLAMMATION IN PATIENTS WITH COVID-19

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BACKGROUND-AIM

Regarding the fact that inflammation plays a key role in the development and progression of COVID-19, the goal of our research was to determine the importance of establishing NLR and PLR in patients with COVID-19, as well as their correlation with markers of systemic inflammation.

METHODS

The retrospective study included 152 subjects with confirmed COVID-19 infection, treated at the University Clinical Center of Kragujevac in the course of 2021. In all subjects, standard biochemical methods were used to establish: hematological markers, markers of inflammation (C-reactive protein (CRP), procalcitonin (PCT) and interleukin-6 (IL-6)), and the relation between the absolute number of neutrophils/platelets and the number of lymphocytes (NLR and PLR) in additional assessment of the degree of inflammation was calculated. A bivariate correlation test was used for the statistical analysis of the obtained data, to establish the relationship between the examined variables.

RESULTS

The research included 98 (64.5%) men and 54 (35.5%) women with an average age of 60.87 ± 12.81 years. The analysis of the obtained data (the relation between NLR and markers of systemic inflammation) showed a statistically significant positive correlation of NLR with: CRP concentration ($r=0.231$, $p=0.028$); PCT concentration ($r=0.643$, $p<0.001$) and IL-6 concentration ($r=0.179$, $p=0.028$). The relation between PLR and markers of systemic inflammation: CRP ($r = 0.046$, $p = 0.577$), PCT ($r = 0.034$, $p = 0.679$) and IL-6 ($r = 0.009$, $p = 0.912$) did not show statistical significance.

CONCLUSIONS

The assessment of the relation between neutrophils and lymphocytes (NLR) as well as biomarkers of systemic inflammation is important in controlling the pro-inflammatory response and is of particular importance in the diagnosis and monitoring the course of the disease in patients with COVID-19.

COVID-19

P0638

WHITE BLOOD CELLS SUBSETS AND THEIR ACTIVATION IN COVID-19 INFECTION: A COMPARISON BETWEEN DATA FROM 2020 VERSUS 2022

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BACKGROUND-AIM

In 2020, the WHO declared pandemic the infection by the novel Coronavirus SARS-CoV-2. After the first wave of naive infections, the Italian health system made many efforts to allow people vaccination. At the end of 2021, Italy administered 95,571,957 doses of COVID-19 vaccines, with an 84.5% coverage of fully vaccinated population over 12 years old and 87.3% with at least one dose.
In our work,we aimed to investigate the ability of white blood cell count (WBC) and their subsets to aid in the diagnosis of COVID-19 during the triage process at the Emergency department (COVID versus non-COVID patients).
Moreover, as future secondary endpoint, we will compare the different WBC subsets between people first exposed to the new virus and people who were supposed to receive at least one dose of vaccine or who probably got a natural infection.

METHODS

We therefore selected 92 patients with SARS-CoV-2 infection (COVID-19+/2020) and 252 patients with RT-PCR negative nasopharyngeal swab (non-COVID/2020) at their first admittance to the Careggi Emergency Department (ED) from April and May 2020 and 333 COVID-19+/2022 and 1052 negative patients (non-COVID/2022) at their admittance to the Careggi ED in January 2022, in order to compare the data.

RESULTS

The first wave results showed leukopenia and a significant difference between the parameters: high-fluorescent lymphocytes (HFLC), mean lymphocyte size (LY-Z), monocyte complexity and size (MO-X, MO-Z respectively), neutrophil complexity dispersion (NE-WX), lymphocyte fluorescence dispersion (LY-WY), secreting lymphocytes (AS-LYMPH) and neutrophil granularity intensity (NEUT-GI(SI)).
In particular, HFLC, AS-LYMPH and MO-X show a ROC curve with AUC > 0.7.
While the comparison with population from January 2022 is still ongoing.

CONCLUSIONS

Given the extreme ease with which the virus, as it mutates, evades the mechanisms of innate immunity and vaccine immunity, the results obtained intend to emphasise the importance of finding parameters that help the clinician to identify the infection at an early stage and to better understand the response of WBC subsets in COVID-19 positive patients who have been exposed to vaccination versus naive infections.

COVID-19

P0639

COMPARISON OF TWO COMMERCIAL KITS FOR SARS-COV-2 RNA DETECTION

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BACKGROUND-AIM

The quantitative real-time reverse transcription-polymerase chain reaction (QRT–PCR) assay is considered the gold standard for molecular diagnosis of SARS–CoV–2. The objective of this study was to compare the clinical performances of the two authorized tests — the Abbott Real Time SARS–CoV–2 (ACOV) assay (Abbott Molecular Inc., North Chicago, IL) and the BGI Real-Time Fluorescent RT-PCR (BGI) kit (BGI Biotechnology (Wuhan) Co., Ltd, Shenzhen, China) and to determine whether the selection of targeted genes has an impact on test's specificity.

METHODS

We have performed a prospective research from October 18th, 2022, through October 25th, 2022. Our study included 344 randomly selected nasopharyngeal and oropharyngeal swabs (NOS) previously tested by the ACOV and subsequently tested by the BGI for detecting SARS-CoV-2. Statistical analysis was performed using IBM® SPSS (version 20.0, IBM SPSS Inc., Armonk, NY, USA). Positive percent agreement, negative percent agreement, and 95% confidence intervals (CI) for the BGI assay were calculated using ACOV as the reference test. Cohen's Kappa of qualitative results (detected/non detected) between the BGI test and ACOV was also calculated with a 95% CI.

RESULTS

We found that the ACOV assay detects more cases of COVID–19 infection than the BGI assay. Also, we found that the BGI kit demonstrated a strong level of agreement with the ACOV assay. The positive percent agreement was 97.9% (95% CI: 95.4–99.7%), while Cohen's Kappa coefficient was 0.85 (95% CI: 0.82-0.92) between these two tests. The sensitivity of the BGI test compared to Abbott is 93.45% (95% CI: 85.74–95.71%), as is the specificity of the BGI test compared to Abbott. Our study found that 1.59% of the NOS specimens tested by ACOV were negative in the face of a positive result from the BGI Kit. Only 5.56% of ACOV positive but BGI negative cases had a median CT value of 24.69 (95% CI: 24.41–25.06).

CONCLUSIONS

We found that the ACOV assay detects more cases of COVID–19 infection than the BGI assay. As only 5.56% of cases were false negative using the BGI test to detect SARS–CoV–2, there was a strong agreement between the Abbott SARS–CoV–2 and the BGI assays. However, due to possible false negative results using the BGI test, we recommend complete testing with the ACOV test.

COVID-19

P0640

COVID-19 CONVALESCENCE MAY INFLUENCE DECISION ON BOOSTER VACCINATION.

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BACKGROUND-AIM

We aimed to investigate, whether the decision on accepting the booster shot was related to COVID-19 history, and if so – if the anti-spike SARS-CoV-2 IgG concentrations, measured with commercially available CLIA assay - LIAISON® SARS-CoV-2 TrimericS IgG (DiaSorin Inc.), were higher in COVID-19 convalescents.

METHODS

A cohort of 100 health care workers (HCW) has been followed continuously over a year after the first Comirnaty dose administration. Anti-spike (S) and anti-nucleocapsid (N) SARS-CoV-2 antibody concentrations were measured on day 10, 20, 30, 60, 90, 120, 240 and 360 after the first dose of the vaccine. During the study, recommendation on booster dose administration was released.

RESULTS

18 participants of our study had COVID-19 history, based on PCR and/or anti-N SARS-CoV-2 seropositivity. 83 subjects from our cohort decided to undergo boosting, which fell between study timepoints 240 and 360. We found that the percentage of COVID-19 convalescents was statistically lower among subjects who decided to get boosted (Chi2 test, p = 0,007), in comparison to those who opted out of the additional dose (14.5% vs 35.3%).
In line with this finding, the median concentration of anti-spike SARS-CoV-2 IgG antibodies prior to booster (on day 240 of the study) in the subgroup who decided against additional dose administration was higher than in the boosted individuals (666 BAU/ml vs 355 BAU/ml) and this difference was statistically significant (Mann-Whitney U test, p = 0,0100).
However, the percentage of individuals infected in the following period (between days 240 and 360) was statistically significantly (Chi square test with Yates correction, p = 0.0206) lower in the boosted (10%) than in the non-boosted (35.3%). Further, the anti-S SARS-CoV-2 antibody concentrations prior to the booster (day 240) didn't differ between the participants infected vs non-infected over the following 4 months (Mann-Whitney U test, p = 0,3397).

CONCLUSIONS

The history of COVID-19 influences the decision on booster acceptance. Our observations confirm the protective effect of the booster shot against infection but do not provide sound evidence for a relationship between antibody concentration and COVID-19 protection over the four months following blood testing.

COVID-19

P0641

HIGH SARS-COV-2 IGM AND IGG ANTIBODIES AMONG BLOOD DONORS DURING THE THIRD COVID-19 WAVE IN CAMEROON. WHAT OPPORTUNITIES FOR EPIDEMIOLOGICAL SURVEILLANCE IN LOW AND MIDDLE INCOME SETTINGS?

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BACKGROUND-AIM

As for many countries all over the world, Cameroon as paid a heavy burden of the COVID-19 pandemic since the first declared case in the country in 2020. Although many efforts were done both to reduce deaths, improve cases management and ensure prevention through massive immunization; many barriers including cultural and behavioral barriers are observed. In parallel, effective surveillance systems of the disease are mandatory for rapid interventions when need may be. As the third wave was officially declared in the country in May 2022, our study aimed to assess if data from blood donors could provide information about ongoing SARS-COV-2 evolution patterns.

METHODS

We performed a retrospective random screening for SARS-COV-2 IGM and IGG on eligible blood donor's plasma samples , which were collected during the month of May 2022 at the Yaounde General Hospital. Donor's information were obtained from individual information form, which all included consent for such additional lab assays. Data were analyzed with rstudio®.

RESULTS

In total,125 samples were screened, 93% being for males and 7% for females. The age group 20 to 30 years were the most represented (59%); More than half of all donors were university student whereas only 1% had no occupation. Donor's origin showed representativeness of all the regions of the country. None of the donor had reported to have received COVID-19 vaccine, despite free of charge available vaccine within the country. Despite absence of immunization, we observed 90% of positive SARS-COV-2 IGG antibodies and 63% with both SARS-COV-2 IGM and IGG antibodies. Only 10% of all donors had both negative IGM and IGG, whereas no donor had positive IGM antibodies only.

CONCLUSIONS

The findings highlighted important herd immunity for SARS-COV-2 among the assessed population of blood donors and low adherence to immunization programs. High prevalence of IGM/IGG in plasma was also observed in the absence of clinical symptoms, reflecting the ongoing wave which was declared in the country at that time. As there is a reported low adherence to voluntary COVID-19 testing in such settings due to several factors, adopting sentinel surveillance among blood donors, using accessible, accurate and rapid laboratory techniques could be an helpful tool for national surveillance system.

COVID-19

P0642

ROLE OF BLOOD TYPE IN COVID-19 INFECTION

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BACKGROUND-AIM

It has been suggested that blood group may influence evolution in COVID-19 patients disease, with group 0 displaying a protective effect in outcome when compare to other groups. There are also publications linking blood group 0 to the presence of iron deficiency.
Our study aims to determine whether there are differences in hematic iron reserves in a cohort of COVID-19 patients related to their blood group (A, B, AB or 0) and whether there are differences in morbidity according to these parameters.

METHODS

A cohort of 110 COVID-19 patients with anaemia was studied, recording their blood group and differentiating the type of anaemia into iron-deficiency or non-iron-deficiency based on mean corpuscular volume (MCV) levels. A Beckman Coulter DXH 900 autoanalyser was used for haemacytometry analysis.

RESULTS

A Chi-Square test was performed to study the presence or absence of iron deficiency according to blood group, obtaining significant differences (p=0.007). The percentage of iron deficiency was 57% for patients in group 0 (n=39) versus 31% in group A (n=51).
When we analysed the differences in outcome, no significant differences were found according to blood group (p=0.371) regarding admission to the ward, admission to intensive care unit (p=0.519), or death (p=0.512).
ANOVA for the variables days admitted, days at ICU, haemoglobin and MCV was significant only for MCV (p=0.04). The post-hoc test found differences in MCV values between groups A and 0 (p=0.017). Spearman's test was performed between MCV values, days of admission and days of ICU admission, obtaining significance correlation of $p<0.001$ and Rho= 0.339 for the pair MCV-days admitted and p=0.012 with Rho of 0.236 for the pair MCV-days at ICU.

CONCLUSIONS

In the anaemic patient with COVID-19, there are significant differences in haem iron levels in red blood cells according to blood group. No significant differences were found in the morbidity and mortality according to blood group. The MCV values of the patients showed correlation with days of admission and days at intensive care unit. It would be interesting to conduct a larger study evaluating the role of blood group in COVID-19 infection and the association between blood group, blood iron and COVID morbidity and mortality.

COVID-19

P0643

COVID 19 SEROLOGICAL PROFLIE IN A SMALL POPULATION OF BELO HORIZONTE IN BRAZIL

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BACKGROUND-AIM

COVID-19 has been a major public health issue in the last years given its highly contagious nature and potential clinical severity. Understanding the immunological response behind these cases may aid the comprehension of the most vulnerable groups and direct health policies to manage such risks. We aimed to analyze the serological profile IgG/IgM anti-SARS-CoV2 of a population from Belo Horizonte, Brazil, and correlate it to epidemiological data available in public health bulletins.

METHODS

This is an observational translational study in which a sample was extracted from the database of a private Clinical Laboratory and of COVID-19 related bulletins released by the Municipal Health Secretariat (MHS), comprehending patients who resided in Belo Horizonte and searched COVID-19 serological immunochromatographic testing, between May 20 and Jan 21, preceding the vaccination for Covid 19.The testing results were correlated to the variables sex, age, and health districts. The associations between categoric variables were analyzed by Qui-square test and the comparisons of media/medians by Kruskal-Wallis and Dunn tests.

RESULTS

3952 samples were used in the final analysis, including 49,8% females and 50,2% males. The medium age was 41,1±15,2 years,20-39(47,9%),40-59(33,8%).The age ($p<0,001$) and health region ($p=0,001$) had significant statistical correlation with the seroconversion (SC).The highest relative SC was observed in 60-79(18,9%)and ≥ 80(23,1%). Furthermore, a higher SC rate was observed in the West (18,5%) and Northeast (16,8%) health districts, 2 of the most densely populated and less social developed regions in the city.According to MHS, age ≥60 was the common factor identified in ARDS (acute respiratory distress syndrome) cases and deaths, suggesting that severe COVID-19 may induce a more robust immunological humoral response.Social inequities also appear to correlate to a higher exposure to the virus and unfavorable clinical evolution being, thus, linked to the SC rates.

CONCLUSIONS

Serological tests are valuable tools in the epidemiological-monitoring of infectious diseases and may lead to the identification of more vulnerable groups.Regarding COVID-19,current data suggest the elderly and those with social-economical vulnerabilities are among those and may require specific health policies.

COVID-19

P0644

CLINICAL AND LABORATORY FEATURES OF THE COURSE OF PULMONARY EMBOLISM IN PATIENTS WITH COVID-19 AND ABDOMINAL OBESITY

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BACKGROUND-AIM

High risk of pulmonary embolism (PE), severe COVID-19 in people with abdominal obesity (AO) and coronavirus infection (CVI) is actively discussed. The aim of our study is to determine the clinical and laboratory features of the PE in patients with abdominal obesity infected with SARS-CoV-2.

METHODS

The data of 11,056 patients with COVID-19 who were treated at the 4th State Clinical Hospital in Minsk at the period from 01.04.2020 to 31.05.2021 was analyzed.

RESULTS

The part of patients with PE is 3.68% (n=407). Other part of persons with AO (body mass index greater than or equal to 30 kg/m2, waist circumference more than 94 cm in men and 80 cm in women) - 11.38% (n=1259). The part of patients with PE among persons with CVI and AO (n=1259) is 7.15% (n=90); among persons with CVI without AO (n=9797) – 3.24% (n=317). Sample of 33 medical records of patients with COVID-19 and PE was formed. According to the AO level, two groups were formed: 1st - 25 patients with CVI and PE without AO, 2nd - 8 patients with CVI and PE with AO. Among patients with COVID-19 and PE with AO, in comparison with patients without AO, a higher proportion of persons with severe CVI was revealed: 62.5 (n = 5) % VS 20.0% (n = 5) ($\chi 2 = 5.18$; $p<0.05$), a higher level of fibrinogen and with C-reactive protein (CRP) : 6.97 (6.11 - 8.03) g/l VS 4.71 (4.02 - 5.59) g/l (U = 12.0, $p<0.01$) and 116.64 (80.38-134.08) mg/l VS 30.21 (15.11-57.21) mg/l (U = 36.04; $p<0.01$), respectively, higher values of CRP at the occurrence of PE 71.01 (50.59-105.06) mg/l VS 34.01 (18.85-60.81) mg/l (U = 49.00; $p<0.05$). In patients with CVI and PE, a direct moderate association was established between the presence of AO and the severe course of COVID-19 ($r = 0.41$; $p <0.05$), AO and an increase in fibrinogen levels ($r = 0.58$; $p <0.05$); a direct strong association between the presence of AO and an increase in serum CRP blood ($r = 0.76$; $p <0.01$), a direct moderate association between AO and the level of CRP determined during the development of PE ($r = 0.51$; $p <0.01$).

CONCLUSIONS

In patients with KIWI and AO, the proportion of patients with PE is higher, there is a more severe COVID-19 disease, which occurs against the background of increased markers of inflammation.

COVID-19

P0645

THE EVALUATION OF THROMBOCYTOPENIA IN PATIENTS WITH ACUTE INFECTION OF CORONAVIRUS DISEASE 2019.

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BACKGROUND-AIM

Coronavirus Disease 2019 (COVID-19) is a predominantly respiratory illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 is commonly associated with hematological abnormalities including in particular thrombocytopenia.
The aim of this study was to assess the correlation between thrombocytopenia and high SARS-CoV-2 Immunoglobulin M (IgM) antibody levels in patients with COVID 19.

METHODS

This observational study enrolled 100 patients of Genius Lab Clinic from January 2021 to May 2021. All patients were confirmed with positive real time polymerase chain reaction (RT-SARS-CoV-2 PCR) test and positive SARS-CoV-2 IgM antibody test. The serology was performed with chemiluminescence assay using Snibe Maglumi 4000 Plus analyzer and the complete blood count (CBC) was performed using Abacus 5 an automated hematology analyzer. All patient samples with low platelets numbers were confirmed microscopically with a peripheral blood smear. Thrombocytopenia was defined as a platelet count < 150 x 103cells/μL. Thrombocytopenia was graded as mild thrombocytopenia 100 x 103cells/μL -140 x 103cells/μL, moderate 50 x 103cells/μL -100 x 103cells/μL and severe thrombocytopenia <50 x 103cells/μL.

RESULTS

In 48% of patients was detected thrombocytopenia which is typically mild with an average value of 126 x 103cells/μL. 13% of patients had moderate thrombocytopenia with an average value of 68 x 103cells/μL, while 7% of patients had severe thrombocytopenia with an average value of 35 x 103cells/μL. 32% of patients did not have thrombocytopenia. It was observed that in patients with severe and moderate thrombocytopenia the SARS-CoV-2 IgM antibodies values were higher than mild or non-thrombocytopenic cases with an average above 100 AU/ml.

CONCLUSIONS

Higher SARS-CoV-2 IgM values are associated with lower platelet numbers, therefore platelets parameters are an important biomarker in COVID-19.

COVID-19

P0646

TRACE ELEMENTS ARE INVOLVED INTO RESPIRATORY DISTRESS SYNDROME DURING COVID-19

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BACKGROUND-AIM

To investigate the effects of zinc and selenium therapy on antioxidant status, inflammation and immune system responses, lung function, and health-related quality of life in patients with COVID-19 and acute respiratory distress syndrome.

METHODS

Twenty-three patients (mean age 55.2 ± 9 years; of which men 74%, and women 26%) with a positive PCR analysis for the presence of COVID-19 were included in the study. All patients had severe acute respiratory distress syndrome. The majority of patients (82%) had low levels of Se and Zn, along with elevated inflammatory parameters (CRP, PCT, and IL-6). The analysis of microelements was done by direct methods of determination: of zinc - flame atomic absorption spectrometry and of selenium - electrothermal atomic absorption spectrometry.

RESULTS

Se and Zn supplementation significantly increased Se ($p = 0.027$) and glutathione peroxidase 3 (GPx3) ($p = 0.021$) levels. Glutathione peroxidase showed an inverse correlation with markers of inflammation: CRP ($r=-0.795$), PCT ($r=-0.813$), and IL-6 ($r=-0.729$).

CONCLUSIONS

Se and Zn levels would have clinical relevance in assessing the immune response in patients with severe acute respiratory distress syndrome in COVID-19.

COVID-19

P0647

COVID-19 AND MENSTRUAL CIRCLE CHANGES

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BACKGROUND-AIM

Background: The menstrual cycle or menstruation is the periodic discharge of blood from uterus endometrium through the vagina caused from the rapid fall in ovarian production of estrogen and progesterone, which occurs in every cycle in the absence of pregnancy. Menstrual changes are defined as changes in the length of menses, in the number of days between two consecutive periods, changes in the amount of blood loss during the cycle or worsening of premenstrual syndrome.
Aim: The analysis of the impact of Covid-19 on the menstrual cycle in a group of subjects of 61 women, aged 18-25 years old.

METHODS

Method: This is an analytical type study with a specific direction. To carry out this study, two scientific methods are used: quantitative, which consists in reviewing the literature such as scientific articles, and qualitative method, which consists in drafting a questionnaire with 21 closed questions, where 61 subjects of the age group 18 - 25 years old, carried out for a period of 1 week from February 28 to February 22, 2022. The samples taken in the study are intentional, non-probabilistic.

RESULTS

Results: Based on the collected data of this study, we concluded that: the dominant age group is the 21year old group, with a median age of 22.02 years old. Post covid-19 menstrual changes as the loss of any cycle, the extension of the cycle over 35 days, the decrease in the duration and amount of bleeding, the presence of intermenstrual bleeding, the worsening of premenstrual syndrome or post-covid-19 blood clots are evident in quite high numbers in most of the subjects of the study.

CONCLUSIONS

Conclusions: Covid-19 has influenced the occurrence of menstrual changes in almost all subjects even though in a moderate and mild scale. Medicine today emphasizes that "Prevention is better than cure", for this reason nowadays the health promotion and education regarding the preventive methods of Covid-19 in the population must be priority.

COVID-19

P0648

ASYMPTOMATIC COVID-19 INFECTION IN A PATIENT WITH CONGENITAL ANALBUMINEMIA AND CORONARY ARTERY DISEASE

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BACKGROUND-AIM

Congenital analbuminemia (CAA) is a very rare autosomal recessive disorder that can be rarely associated with coronary artery disease. Our data describe the clinical features and laboratory results of an asymptomatic COVID patient with congenital analbuminemia (CAA) and coronary artery disease.

METHODS

A 34-year-old man, born out of a non-consanguineous marriage in northern Tunisia, with congenital analbuminemia was admitted to our hospital for SARS-CoV-2 RT-PCR test because of his contact history with his mother who developed a severe form of the disease. He had been hospitalized the last year for hypercholesterolemia and coronary artery disease.

RESULTS

To the best of our knowledge, it is the first case of recurrent acute coronary syndrome in a young adult with CAA. Moreover, COVID-19 has never been described among the 90 cases of CAA reported in the literature. Mild clinical manifestations observed in such CAA patients can be explained by the elevated biosynthesis of other plasma proteins, including serum globulins. Indeed, the high serum complements C3 and C4 resulted from CAA disease protect patient from the risk of intravascular coagulation and cell death during COVID-19 infection. On the other hand, the statin therapy of hypercholesterolemia which is mostly observed in CAA patient reduce the incidence of severe clinical manifestations and improve prognosis in COVID-19 patients by modulating the immune response to inflammation, improving endothelial function, inhibiting oxidative stress, and exerting direct antiviral effects.

CONCLUSIONS

Patients with multiple disorders appeared to be more predisposed to develop severe forms of this infection. Emerging data suggest a relatively high incidence of cardiovascular disease (CVD) in patients with severe COVID-19. In the present study, CAA protect patient from sever COVID-19 manifestations.

COVID-19

P0649

TO DETERMINE THE LABORATORY TESTS IN THE DIFFERENTIAL DIAGNOSIS OF COVID-19 PNEUMONIA WITH MACHINE LEARNING TECHNIQUES

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BACKGROUND-AIM

COVID pneumonia occurs when a COVID infection causes fluid to build up in the lungs. Not everyone with COVID will develop COVID pneumonia. The symptoms of COVID and pneumonia are very similar, but a radiological test such as an X-ray or CT scan can separate those. We aimed to evaluate the potential of laboratory findings in the differentiation of COVID pneumonia using machine learning (ML) models.

METHODS

Patients with positive RT-PCR results were divided into two groups according to the chest CT findings, the group with COVID-19 (n=95) and the group with COVID-19 pneumonia (n=79), respectively. We randomly selected the patients among those who sought our hospital within the first seven days of symptoms with no prior hospital admissions or treatment. Simultaneous chest CT results, CBC, and routine biochemistry tests were evaluated in all patients. ML models were analyzed in Jupyter Notebook 6.4.0 software using Python Pandas, Numpy, and Scikit-learn libraries. Logistic regression, linear discriminant analysis, K-nearest neighbor, decision tree, random forest (RFC), gaussian Naive Bayes (NB), and support vector machine learning models were created and the model performances of the classifiers were evaluated with accuracy percentages. ROC and permutation importance analysis were also performed.

RESULTS

The mean age of the COVID-19 pneumonia group was statistically significantly higher (46.5±15.6 years) (p=0.001). No significant difference was found in gender distribution between the groups. The accuracy performances of the models in the test set were determined as 63, 62, 56, 60, 62, 63, and 38%, respectively. The area under curve (AUC) values of the RFC and NB, were determined as 75 and 77%. Permutation_importance analysis showed that elevated CRP, lower MLR, and WBC levels had influenced the NB model's explainability.

CONCLUSIONS

Although three years have passed since the beginning of the COVID-19 pandemic, the early diagnosis of COVID-19 pneumonia is still crucial. In addition to radiological tests, laboratory tests may contribute to the fight against the disease by providing early diagnosis of covid pneumonia. Explainable ML models can help determine the appropriate markers for this purpose.

COVID-19

P0650

EVALUATING SARS-COV-2 ANTIBODY REACTIVITY TO NATURAL EXPOSURE AND INACTIVATED VACCINATION WITH PEPTIDE MICROARRAYS

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BACKGROUND-AIM

Vaccination is an effective tool for preventing and controlling SARS-CoV-2 infections, and inactivated vaccines are the most widely used type of vaccine. In order to identify antibody-binding peptide epitopes that can distinguish between individuals who have been vaccinated and those who have been infected, this study aimed to compare the immune responses of vaccinated and infected individuals.

METHODS

SARS-CoV-2 peptide microarrays were used to assess the differences between 44 volunteers inoculated with the inactivated virus vaccine BBIBP-CorV and 61 patients who were infected with SARS-CoV-2. Clustered heatmaps were used to identify differences between the two groups in antibody responses to peptides such as M1, N24, S15, S64, S82, S104, and S115. Receiver operating characteristic curve analysis was used to determine whether a combined diagnosis with S15, S64, and S104 could effectively distinguish infected patients from vaccinated individuals.

RESULTS

Our findings showed that the specific antibody responses against S15, S64, and S104 peptides were stronger in vaccinators than in infected persons, while responses to M1, N24, S82, and S115 were weaker in asymptomatic patients than in symptomatic patients. Additionally, two peptides (N24 and S115) were found to correlate with the levels of neutralizing antibodies.

CONCLUSIONS

Our results suggest that antibody profiles specific to SARS-CoV-2 can be used to distinguish between vaccinated individuals and those who are infected. The combined diagnosis with S15, S64, and S104 was found to be more effective in distinguishing infected patients from those who have been vaccinated than the diagnosis using individual peptides. Moreover, the specific antibody responses against the N24 and S115 peptides were found to be consistent with the changing trend of neutralizing antibodies.

COVID-19

P0651

THE IMPACT OF COVID-19 ON ALLERGY PATIENTS

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BACKGROUND-AIM

The novel SARS CoV-2 virus is the cause of acute viral respiratory disease. The symptoms it causes are different, from a common cold and headache, to massive pneumonia and death. In the course of dealing with its spread, measures were implemented to protect the population from the spread of the virus, and one of those measures was the definition of chronic diseases that are a risk for patients if they become infected with SARS CoV-2.Working in the largest Covid-19 Center in Macedonia during the Covid-19 pandemic, I singled out groups of patients, with allergic diseases who were expected to be considered patients with higher risk and comorbidities. But practice has shown that these patients are somehow more protected than other patients.

METHODS

65 allergy patients with covid-19 and 65 patients with other comorbidities also with covid-19 were inspected in this study with analysis of their peripheral blood samples. In this study was used automatic analyzer Immulite 2000 xpi to present the results for concentration on serum levels of Interleukin-6 as inflammatory factor of first response and Immunoglobulin E as secondary inflammatory factor. Allergy patients had asthma, allergic rhinitis and atopic dermatitis.Patients with other comorbidities had heart failure, thrombophlebitis and obesity. Internal Hospital system was used to detect reported deaths.

RESULTS

The statistical processing showed no statistically significant difference in relation to the level of Interleukin 6 (IL-6) in the two studied groups. But Covid patients with allergic disease had significantly higher Immunoglobulin E (IgE) values than other covid patients. None of the patients with allergic diseases were resulted with death 0% (0n/65n), and very dramatically 23% (15n/65n) of the patients with other comorbidities were reported dead.

CONCLUSIONS

Patients who have allergic diseases already have increased levels of Immunoglobulin E formed towards an allergen, and when these same patients are infected with SARS CoV-2 they have already activated secondary defenses which is supposed to be the reason why there are no deaths in the group of patients with allergies. Further research is needed to substantiate these assumptions which give a very important and new meaning for Immunoglobulin E and the importance of their testing.

COVID-19

P0652

THE DIAGNOSTIC AND PROGNOSTIC ROLE OF URINARY PROTEIN MARKERS IN PATIENTS WITH SARS-COV-2 INFECTION

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BACKGROUND-AIM

The SARS-CoV-2 infection related coronavirus disease 2019 (COVID-19) is characterized by an extremely diverse manifestation causing a challenge in diagnostics and treatment. In COVID-19 a dysregulated immune response can occur which may lead to progression and organ failures. To identify novel laboratory markers that can help assess disease severity, predict progression and guide therapeutic decision-making would be highly beneficial. Our aim was to investigate whether urinary levels of orosomucoid (u-ORM), cystatin-C (u-CYSC) and neutrophil gelatinase-associated lipocalin (u-NGAL) have diagnostic and prognostic value in relation to COVID-19.

METHODS

244 adult individuals with confirmed SARS-CoV-2 infection visiting the Emergency Care Unit of University of Pécs were recruited in this retrospective study. Patients were classified based on different clinical outcomes recorded in the patient care documentation. Blood and urine samples of each participant were taken for routine laboratory testing at the time of admission. U-ORM, u-CYSC and u-NGAL were measured from urine samples stored at -80°C by automated immune turbidimetric assays and results of routine blood analysis were obtained from the medical information system.

RESULTS

Elevated u-ORM levels indicated the need for intensive care and the need for artificial ventilation with high performance (AUC ROC: 0.864 and 0.834 respectively, $p<0.001$). Higher levels of u-ORM were observed in non-survivals (medians: 275.9 vs. 68.8 mg/L, $p<0.001$) and in those who showed disease progression (191.9 vs. 60.4 mg/L, $p<0.001$) as well. Strong correlation was found between u-ORM and the conventional inflammatory markers (hs-CRP, ferritin, IL-6; $p<0.001$). U-CYSC and u-NGAL were predictive of RRT ($p=0.002$, $p=0.023$) and u-NGAL was also predictive of the development of oligo/anuria ($p=0.003$). Significant but weak correlations were demonstrated between u-CYSC and u-NGAL vs. plasma creatinine and GFR.

CONCLUSIONS

Based on our findings u-ORM as an inflammatory marker seems to be a valuable additional approach in predicting outcomes of COVID-19. Besides creatinine and GFR, u-CYSC and u-NGAL as tubular markers may provide further information on renal function.

COVID-19

P0653

LYMPHOCYTE SUBSETS IN HOSPITALIZED COVID-19 PATIENTS: A SINGLE-CENTER RETROSPECTIVE OBSERVATIONAL STUDY

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BACKGROUND-AIM

In this retrospective study we analysed the changes in lymphocyte subsets of COVID-19 hospitalized patients. The aim of the study was to understand the role of lymphocyte subset counts as COVID-19 outcome markers.

METHODS

We enrolled 107 COVID-19 patients older than 18 years of age, admitted to Alessandria Hospital with a confirmed diagnosis of SARS-CoV-2 infection by RT-PCR of a nasopharyngeal swab, who performed analysis of lymphocyte subsets between 2020 March 01 and 2021 May 31. Patients have been splitted into two groups, based on clinical manifestations: group 1 non-severe disease (n=44) and group 2 severe disease (n=63). For the comparison between the two groups of patients, statistical significance was tested with the Mann-Whitney and the Chi-Square test.

RESULTS

Among the 107 patients examined, 57 were male and 50 were female. Patients with non-severe disease (n=44) showed typical signs of COVID-19 disease without pneumonia and/or respiratory complications. Patients with severe disease (n=63) were affected by respiratory distress, acute respiratory distress syndrome and signs of sepsis or septic shock. In the group of patients with severe disease the blood cells analysis showed a significant reduction in the counts of total lymphocytes (p 0.004) and absolute CD3 lymphocytes (p 0.012) and CD8 lymphocytes (p 0.019) as well as a significant reduction in monocyte percent (p 0.010) and very significant increase in neutrophil counts (p 0.001).

CONCLUSIONS

This study evaluated the clinical characteristics and the prognostic factors of COVID-19 hospitalized patients. From the results obtained it can be stated that lymphocytopenia is associated with progression of the disease and increased mortality, as previously demonstrated. Our results show a significant decrease of the CD3 and CD8 lymphocyte in blood of patients with severe disease. Our study also identified a reduction in CD4 T lymphocytes, even if at the limit of statistical significance (p 0.055) probably due to the small number of patients that could be selected. Prospective studies on larger samples will be needed to overcome these limitations.

COVID-19

P0654

ASSESSMENT OF HUMORAL AND CELLULAR IMMUNITY AFTER BIVALENT BNT162B2 VACCINATION AND POTENTIAL ASSOCIATION WITH REACTOGENICITY

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BACKGROUND-AIM

This study investigated the feasibility and clinical value of using a novel, automated and high-throughput SARS-CoV-2 Interferon Gamma Release Assay (IGRA), combined with total anti-SARS-CoV-2 antibodies assessment, for evaluating the immune response after bivalent BNT162b2 vaccination.

METHODS

A cohort of healthcare workers, who already underwent primary vaccination and boosting with monovalent BNT162b2 vaccine, received a booster dose of the new BNT162b2 bivalent formulation. Blood samples were taken immediately before vaccination (T0) and 1 month afterwards (T1). Humoral and cellular immunity were assayed with Roche Elecsys Anti-SARS-CoV-2 and Roche Elecsys IGRA SARS-CoV-2, respectively.

RESULTS

The study population consisted of 51 subjects (median age: 43 years; 51% females). Total anti-SARS-CoV-2 antibodies and IGRA SARS-CoV-2 values increased at T1 from 9050 to 25000 BAU/mL ($p<0.001$), and from 0.44 to 0.78 IU/mL ($p=0.385$), accounting for median increase of 2.0 and 1.6 folds, respectively. Increased T1 values of total anti-SARS-CoV-2 antibodies and IGRA SARS-CoV-2 were recorded in 100% and 68.6% subjects, respectively. In those with baseline values below the median, post-vaccine levels displayed larger increases of 3.3 and 5.1 folds for anti-SARS-CoV-2 total antibodies and IGRA SARS-CoV-2, respectively. The variation of total anti-SARS-CoV-2 antibodies was inversely associated with their T0 values ($r= -0.97$; $p<0.001$), whilst that of IGRA SARS-CoV-2 was inversely associated with its T0 value ($r= -0.58$; $p<0.001$). No other associations were found with demographical or clinical variables, including side effects.

CONCLUSIONS

The bivalent BNT162b2 vaccine booster enhance humoral and cellular immunity against SARS-CoV-2, especially in recipients with a lower baseline biological protection.

COVID-19

P0655

EVALUATION AND MONITORING THE HUMORAL IMMUNE RESPONSE AGAINST SARS-COV-2 IN VACCINATED HEMODYALISIS PATIENTS

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BACKGROUND-AIM

Patients with advanced chronic kidney disease (CKD) who receive hemodialysis (HD) treatment have a higher risk of mortality from COVID19. Thus, vaccination of this population was considered a priority. However, experts had many doubts about whether immunization was going to be effective since the immune system of CKD patients is altered due to the accumulated toxins and the chronic inflammatory state. The objectives of the study were:
- To monitoring the response to the vaccine by performing SARS-CoV-2 (S) antibodies.
- To estimate the rate of reinfection by determining SARS-CoV-2 (N) antibodies.

METHODS

We carried out an analytical observational and retrospective study with longitudinal follow-up during 2022. Seven analytical controls were performed prior to the HD session.
The vaccination period was february-april 2021 with an additional dose in december 2021 and a 4th dose in april 2022. Total SARS-CoV-2 nucleocapsid (N) and spike (S) antibodies were measured in serum by ECLIA (Roche Diagnostics®).

RESULTS

59 blood samples (24 female, 35 male) were collected. Median age was 75±10,3 years. All patients developed humoral immunity against SARS-CoV-2 (S) after vaccination. Before the study, 34% of the patients had passed COVID19 infection and at the end of the study, 41% more patients were infected. All of them with mild symptoms. The remaining 15% were not infected.
Median concentration of SARS-CoV-2 (N) antibodies remains stable throughout the year. A peak concentration in SARS-CoV-2 (S) antibodies is observed at the third point that coincides with the fourth dose, then the median concentration of SARS-CoV-2 (S) antibodies began to decrease. The results of median concentration of SARS-CoV-2 (N) and SARS-CoV-2 (S) antibodies were:
- January: 21,0±47,1 and 37716,7±88779,7
- March: 32,8±55,9 and 48767,3±139361,7
- May: 28,9±51,7 and 31615,2±40708,8
- August: 30,3±51,2 and 49338,9±84151,5
- October: 26,5±44,7 and 38227,6±64671,4
- November: 23,9±39,3 and 35898,4±52853,2
- December: 28,4±46,2 and 27017,7±32778,1

CONCLUSIONS

All HD patients generated SARS-CoV-2 (S) antibodies but humoral inmune response begins to decrease from the eighth month. Nevertheless, these antibodies are useful to avoid the development of severe cases of COVID19 in our study population.

COVID-19

P0656

SEROPREVALENCE OF SARS-COV-2 ANTIBODIES AMONG VACCINATED AND NON-VACCINATED ADULTS IN ALBANIA

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BACKGROUND-AIM

Seroprevalence studies provide an accurate measure of SARS-COV-2 spread at a population level and the number of undiagnosed individuals.
The aim of this study is to assess the seroprevalence rate among a random sample and among those who were not vaccinated and not diagnosed. The study was able to assess the prevalence of asymptomatic cases.

METHODS

This study involved 2183 participants. The samples was randomly selected. Serological tests were performed using Anti-SARS-CoV-2 S1-spike IgG ELISA (Euroimmun).

RESULTS

Study findings indicate that as of August 2022 there was a seroprevalence rate of 91.7% (22.7% due to infection with SARS-COV-2 and 69.2% due to vaccination). The results indicate that the prevalence of antibodies among those who are unvaccinated and undiagnosed was 28.3%. The average age of participants was 45.8 years old. A total of 59.9% were females and 40.1% were males. In relation to SARS-COV-2 infected, 45.4% reported getting infected without difference between males (22.8%) and females (22.6%). In terms of vaccination 71.7% reported getting vaccinated with an important difference between females 44.3% and males 27.3%.

CONCLUSIONS

Our findings reveal a drastic rise in seroprevalence of SARS-COV-2 antibodies due to infection and vaccination.Special attention should be given to encouraging people to get vaccinated especially males.

COVID-19

P0657

KINETICS OF NEUTRALIZING ANTIBODY FOR EVALUATION OF INACTIVATED VACCINE DURABILITY IN HEALTHCARE WORKERS : COMPARISON STUDY OF COMERCIALLY CHEMILUMINESCENCE ASSAYS

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BACKGROUND-AIM

Monitoring humoral immune response post vaccination is considered as an essential tool for estimating vaccine effectivity. Different methods may influence the result of antibody levels. However, estimating antibody response using Plaque Reduction Neutralization Test (PRNT) method was still difficult to perform for routine monitoring purposes. Commercial SARS-CoV-2 serological assays that detect antibodies specific to these viral proteins have become available but still require further evaluation. This study was aimed to compare the level of quantitative neutralization antibody following SARS-CoV-2 vaccination using commercially available Chemiluminescence method.

METHODS

This observational study was conducted among 50 healthcare workers in Dr. Soetomo Hospital, Surabaya. Blood samples were obtained 5 times from each participant. The first sample was obtained before the first dose of inactivated coronavac vaccine. The second, third, fourth and fifth sample was obtained 14 days, 28 days, 90 days and 180 days later after second of coronavac vaccine. Neutralizing antibody (NAb) were measured using the chemiluminescent immunoassays Autolummo A1000 (Autobio, China) and Maglumi 800 (SNIBE, China).

RESULTS

Both NAb level of Snibe and Autobio reach the peak on 14 days and started to decline in 28 days after second dose of vaccination. Median NAb level pre vaccination, 14 days, 28 days, 90 days and 180 days using snibe were 18.630, 166.658, 116.640, 49.208 and 41.715 AU/mL. While NAb level using Autobio were 8.177, 209.563, 140.591, 48.118 and 25.406 IU/mL Agreement between NAb Snibe and Autobio on 14 days, 28 days, 90 days and 180 days after second dose of vaccination was good (Kappa 0.680, 0.760, 0.600, and 0.760).

CONCLUSIONS

Kinetics level of NAb showed peak in 14 days after second dose and started to decline 28 days after second dose vaccine, emphasizing the need of a booster administration. Agreement between the two commercially methods of NAb was good.

COVID-19

P0658

ARE ANTI-SARS-COV-2 S/N IGG ANTIBODIES ALWAYS PREDICTIVE OF PREVIOUS SARS-COV-2 INFECTION?

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BACKGROUND-AIM

We planned this study to verify whether an immunoassay for quantifying anti-SARS-CoV-2 antibodies against both spike (S) and nucleocapsid (N) proteins may be used for identifying previous SARS-CoV-2 infections.

METHODS

The study population consisted of a cohort of fully-vaccinated healthcare workers from the Pederzoli Hospital (Peschiera del Garda, Verona, Italy), undergoing administration of Pfizer/Biontech mRNA BNT162b2 bivalent vaccine between November and December 2022. All study subjects underwent regular medical visits and molecular testing for diagnosing SARS-CoV-2 infections every 2-4 weeks since 2020. Venous blood was drawn before bivalent vaccine administration, for measuring anti-SARS-CoV-2 antibodies with MAGLUMI 2019-nCoV IgG/IgM CLIA Assays (SNIBE; Shenzhen, China). The test claims to detect the presence of antibodies directed against both SARS-CoV-2 S and N proteins (i.e., S/N). Test results ≥1.1 (absorbance of sample/absorbance of calibrator) are considered reactive

RESULTS

Overall, 31 (58.5%) subjects had tested positive for SARS-CoV-2 by RT-PCR throughout the study (24 once, 7 twice). No positive correlation was found between anti-SARS-CoV-2 S/N IgM antibodies and molecular test result. In univariate regression analysis, both a positive molecular test result (r=0.33; 95%CI, 0.07-0.55; p=0.015) and the number of positive molecular test results (r=0.43; 95%CI, 0.18-0.63; p=0.001), but not vaccine doses (r= -0.12; 95%CI, -0.38 to 0.16; p=0.392), were significantly correlated with anti-SARS-CoV-2 S/N IgG antibodies. These two associations remained significant in multiple linear regression analysis (p=0.029 and p<0.001, respectively) after adjusting for sex, age, body mass index, and vaccine doses. In ROC curve analysis, anti-SARS-CoV-2 S/N IgG antibodies significantly predicted molecular test positivity (AUC, 0.69; 95%CI; 0.55-0.84; p=0.004), with the best cut-off of 0.05 AU/mL displaying 67.9% (95%CI, 53.7-80.1%) accuracy, 0.97 (95%CI, 0.93-1.00) sensitivity, and 0.27 (95%CI, 0.11-0.50) specificity.

CONCLUSIONS

Although anti-SARS-CoV-2 S/N IgG antibodies provides helpful information for identifying previous SARS-CoV-2 infections, a lower cutoff than that of sample reactivity should be used. Anti-SARS-CoV-2 S/N IgM antibodies seem useless for this purpose.

COVID-19

P0659

VIRUS LEVELS IN BLOOD IS DETERMINING DEGREE OF SEVERITY IN COVID-19 INFECTION

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BACKGROUND-AIM

Whether the virus itself in Covid-19 versus the accompanying inflammation is the noxious factor causing cell lysis and hypoxemia is still being discussed.
To elucidate this we monitored 84 patients admitted to hospital with different degrees and severity of disease using all available biomarkers.

METHODS

We measured N-Antigen concentration by Simoa technology, RNA by digital PCR (dd PCR), IL-6, CRP and antibody levels in blood.

RESULTS

Statistical analysis by logistic regression showed that the degree of viremia measured as quantitative N-Antigen and Covid-19 RNA predicted risk of death, severity of disease and probability for need of artificial ventilation.
Viremia levels preceded antibody response and inflammation response by several days. Cytokine Storm evidenced by IL-6 concentration is a secondary phenomenon.

CONCLUSIONS

Virus level in blood is the determining factor for severity of disease, and degree of inflammation response.
Treatment should be focused on reducing production of virus using anti-viral drugs.
The effect of antiviral drugs should be followed and documented by daily measurement of N-Antigen levels in the blood and/or quantitative Covid-19 RNA by dd PCR.

COVID-19

P0660

LIMIT OF DETECTION (LOD) OF SARS-COV-2 USING RT-QPCR WITH A COMMERCIAL KIT – RETESTING NEEDED OR NOT?

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BACKGROUND-AIM

Real-time reverse transcriptase- polymerase chain reaction (RT-qPCR) is current the gold standard for qualitative detection of SARS-CoV-2 in nasopharyngeal (NP) and/or oropharyngeal (OP) swabs. Aim of the study was to determine proper limit of detection (LoD) and base treshold value (Ct value) to correctly distinguish positive from negative SARS-CoV-2 results.

METHODS

In 2022 RT-qPCR (SARS-CoV-2 kit Sacace/ABI 7500 Real Time), accredited according ISO15189 standard, was performed after RNA isolation (ExiPrep 96 Viral DNA/RNA Kit/ExiPrep96 Lite, Bioneer) from 17240 NP/OP swabs. Manufacturers LoD (10 copies/PCR; 50 µl eluate) with Ct value 32,0 for all determinated (E-like/ E/ N) genes was confirmed by manufacturers positive sample dilution (1:100, unknown RNA copy number), while determinated LoD (750 copies/mL) with genes Ct values 32,4 (E-like), 32,7 (E) and 32,6 (N) was proven by positive sample dilution (1:1000/AmpliRUN RNA CTRL, Vircell/15000 copies/µl) with NP/OP negative samples and detection rate > 0.95%. SARS-CoV-2 results were considered positive (all Ct values < 32,4), negative (all Ct values > 32,7) or marginal (at least one 32,4 < Ct value < 32,7).

RESULTS

From 17240 NP/OP swabs, 6135 were positive (35,6%) and 11049 negative (64,1%). 56 patients (0,3%) with marginal SARS-CoV-2 results were counseled to retest after 24/48 hours because of the Ct value(s) at the determinated LoD (Ct 32-33). 37 patients did not retest (66%), 19 retested (34%) and 10 of 19 retested (53%) considered SARS-CoV-2 positive (Ct 15-32).

CONCLUSIONS

As shown, marginal SARS-CoV-2 results can be considered presumptive positive SARS-CoV-2 results. Retesting may be helpful if early stage disease is present and viral RNA levels are still low. Proper determination of LoD is a key criteria for routine qualitative detection of SARS-CoV-2, small number of retested samples and correct distinction positive from negative SARS-CoV-2 results.

COVID-19

P0661

GENOMIC SEQUENCING AND SEROLOGICAL ANALYSIS IN HEALTHCARE WORKERS OF RAGUSA AREA HOSPITALS

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BACKGROUND-AIM

The COVID-19 post pandemic evolution is correlated to the development of new variants. Viral genomic and immune response monitoring are fundamental to the surveillance of SARS-CoV-2 infection. Healthcare workers (HCWs) are at high risk of SARS-CoV-2 infection due to direct exposure to infected patients.

METHODS

Since January 01th to July 31th 2022, we monitored the SARS-CoV-2 variants trend in Ragusa area sequencing n.600 samples by NGS technology: N.300 were of HCWs of ASP Ragusa. The evaluation of anti-N, anti-RBD, anti-S1 and anti-S2 IgG levels in 300 exposed vs 300 unexposed HCWs to SARS-CoV-2 was performed. The effects of infection on the immune response and clinic symptoms related to the different variants were investigated.

RESULTS

The SARS-CoV-2 variants trend of Ragusa area were the same of the rest of Sicily region. BA.1 and BA.2 were the most representative variants, whereas the diffusion of BA.3 and BA.4 affected some places of the region. Although no correlation was found between variants and clinic manifestations, anti-N and anti-S2 levels seem correlate with the symptoms number increase.
SARS-CoV-2 infection induced an enhancement statistically significant of antibody titers rather than ones produced by SARS-CoV-2 vaccine administration.

CONCLUSIONS

We demonstrated that the SARS-CoV-2 infection dynamics of our area reproduce the same dynamics of the rest of Sicily region. In the first 6 months of 2022, Omicron BA.1 and BA.2 have been the most representative variants both in our area and in the rest of region. Our findings demonstrated that SARS-CoV-2 infection induced an enhancement statistically significant of antibody titers rather than ones produced by only SARS-CoV-2 vaccine administration.
In addition, considering the temporal dynamics a significant negative correlation was found for anti-N, anti-RBD, anti S1 and anti-S2 between SARS-CoV-2 infection and serological analysis.
Instead, anti-N IgG and anti-S2 IgG levels were positively correlated with the enhancement of symptoms number.
Overall, the evaluated antibodies wane over time than it is necessary to find a durable antibody marker to assure a more accurate epidemiological estimate.

COVID-19

P0662

ANALYTICAL PERFORMANCES OF A NEW RAPID ANTIGEN ASSAY FOR THE DETECTION OF SARS-COV-2 VIRUS

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BACKGROUND-AIM

The rapid diagnosis of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is essential to reduce the disease spread. Despite nucleic acid detection is the gold standard, SARS-CoV-2 antigen detection offers a trade–off among clinical performance, speed and accessibility. Aim of our study was to evaluate performance characteristics of a new rapid antigen assay for the detection of SARS-CoV-2: IVD Capsule COVID-19 (Abionic SA, Switzerland).

METHODS

IVD Capsule COVID-19 Abionic SARS-CoV-2 rapid antigen detection test (Abionic-Ag RDT) performed on abioSCOPE device (Abionic SA, Switzerland) was compared to in house Real Time PCR (RT-PCR) test [ELITe MGB® Kit (ELITechGroup, France) performed on CFX96™ RT-PCR Detection System (Bio-Rad Laboratories, USA)] and to in house antigen detection assay [Standard Q COVID-Q 19 Ag test performed on SD-Biosensor, RELAB I (Republic of Korea)]. 413 consecutive nasopharyngeal swabs from COVID-19 suspected sickness individuals including pre-operative patients or direct contact subjects were evaluated between October 2022 and January 2023 at Mauriziano Hospital, Turin, Italy.

RESULTS

Of the 413 respiratory samples 78 (18.9%) were found to be positive by RT-PCR and 49 (11.9%) were found to be positive by Abionic-Ag RDT. Detection Abionic test's sensitivity, specificity, positive and negative predictive values were 62.8%, 100.0%, 100.0% and 92.0% respectively. 29 false negative and no false positive results were observed with this new rapid antigenic assay. A good concordance between Abionic-Ag RDT and RT-PCR (Cohen's k = 0.73, 95% CI:0.64-0.82) and between Abionic-Ag RDT and in house SD-Biosensor antigen assay (Cohen's k = 0.65, 95% CI:0.55-0.75) was observed.
Abionic-Ag RDT analytical performances were excellent in individuals with significant viral excretion (Ct values ≤25 by reference RT-PCR): sensitivity, specificity, positive and negative predictive values were 93.9%, 100.0%, 100.0% and 99.4% respectively

CONCLUSIONS

The Abionic-Ag RDT presents almost perfect analytical performances for viral loads ≤ 25 Ct, classically corresponding to situations of symptomatic COVID-19 and/or proven contagiousness and very good analytical performances if subjects with low or very low viral shedding are included (Ct≤ 40).

COVID-19

P0663

RELEVANT INFLAMMATORY BIOMARKERS IN THE PATHOGENESIS OF CORONAVIRUS SARS-COV-2 (COVID-19). PRE AND POST VACCINATION EVALUATION

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BACKGROUND-AIM

During the COVID-19 pandemic prior to vaccination, many patients experienced critical symptoms caused by the release of cytokines, called cytokine storm, with fatal outcomes in many cases. The laboratory has contributed to identify patients at increased risk of developing the most severe complications from COVID 19.
The aim of this study is to compare different biomarkers at different times of the pandemic (pre and post vaccination).

METHODS

Prospective study of diagnostic testing in our hospital (2020-2022) based on a protocol with Ethics Committee approval.
Inflammatory biomarker data from patients with high severity (HS) and low severity (LS) during the pre-vaccination phase (1st and 2nd waves of the pandemic) and during the post-vaccination phase (6th wave of the Omicron variant) were compared.
Inclusion criteria: patients admitted with a request for determination of IL 6 levels and suspicion of SARS CoV2 infection.
Biomarkers analyzed: Interleukin-6, D-dimer, Ferritin, Neutrophils/Lymphocytes, ALT, C-Reactive Protein.

RESULTS

265 patients (age 55-83) were studied.
2020 pre-vaccination variables
HS (36) LS (109) p value
IL-6 75.1(33–187,1) 28.6(11.4–58.4) p<0.001
D-dimer 1240.0 (867–3584) 825 (471– 1444) p 0.008
Ferritin 747 p 0.439
Neutrophils 6650 (4125-8900) 4400 (2750–7500) p 0.015
Lymphocytes 500 p 0.119
CRP 66.7 p 0.140
ALT 35 p 0.903
N/L Index 12.4 (7.7– 19.3) 6.05 (3.1 – 11.3) p<0.001
2022 6th wave (n=60 25 HS/35 LS)
IL-6 44.4 p 0.237
Ferritin 610 p 0.885
Neutrophils 6400 p 0.197
Lymphocytes 500 p 0.379
PCR 60.0 p 0.968
ALT 36 p 0.998
N/L Index 9.2 (3.7–22.8) 5.0 (2.6–6.2) p 0.033
Values expressed in medians and interquartile ranges; p values calculated with Mann-Whitney U test.

CONCLUSIONS

Prior to vaccination, IL-6 is significantly higher in HS patients.
After vaccination, there is no significant difference in IL-6 levels between HS and LS patients, probably due to decreased uncontrolled reactions of the immune system in patients with COVID-19.
The difference in neutrophilia between HS and LS patients is more pronounced in the pre-vaccination phase and the N/L index is significantly related to severity in both phases.
Other inflammatory parameters such as ferritin, ALT or CRP show no significant differences between the 1st and 6th waves.

COVID-19

P0664

CROSS-SECTIONAL EVALUATION OF ANTI-SARS-COV-2 ANTIBODY RESPONSE TO AZD1222 RECOMBINANT VACCINE DEPLOYMENT IN THE BONO REGION, GHANA

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BACKGROUND-AIM

Preliminary data across the globe shows that the AZD1222 recombinant vaccine was highly effective in preventing not only the symptoms but also the transmission of the SARS-CoV-2 virus. In Ghana, data on the immune response generated by different vaccination doses is lacking. The present study aimed to compare the anti-SARS-CoV-2 antibody response among single and double-vaccinated versus unvaccinated individuals.

METHODS

A case-control design was employed for this study. Seventy-nine participants (35 vaccinated, 44 unvaccinated) were recruited from the Sunyani West Municipality and screened for the presence of SARS-CoV-2 specific IgG and IgM antibodies in plasma samples using a Standard COVID IgG and IgM Combo FIA test. Data analysis was carried out with STATA (Version 21).

RESULTS

The current study showed that mean IgG levels among vaccine groups (Group 1: Not vaccinated, Group 2: 1 dose, Group 3: 2 doses) differed significantly ($F_{2, 76}=11.457$, $p<.001$) between Group 1 and Group 3; and between Group 2 and Group 3. Participants in Group 2 and Group 3 were 4.1 and 12.5 times more likely to develop more antibody responses compared to their counterparts in Group 1 respectively.

CONCLUSIONS

This baseline study demonstrates that in the short term, taking one or two doses of the AZD1222 recombinant vaccine generates a significant protective antibody response over not taking the vaccine at all. It remains to be seen how long the generated immune response will last in this population and whether a booster shot could be a useful strategy.

COVID-19

P0665

A TWO YEAR RETROSPECTIVE STUDY OF MULTI DRUG-RESISTANT BACTERIAL RESPIRATORY INFECTIONS IN A SOUTH ITALY HOSPITAL DURING PRE-COVID-19 OMICRON ERA

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BACKGROUND-AIM

Healthcare was changed by Coronavirus disease 2019 (COVID-19) all over the world. A rapid spread of Multi-Drug Resistant (MDR) organisms was observed in the last years, although the predominant bacterial species in SARS-CoV-2 co-infections are still under investigation. Here, we report data of a mono-centric retrospective study on the occurrence of bacterial respiratory superinfections in pneumonia patients with and without COVID-19 admitted to our hospital from April 2020 to December 2021.

METHODS

We collected bronchoalveolar lavages/bronchial aspirates from 36 COVID-19 positive patients [28 males, mean age(SD): 66(9); 8 females, 68(7)] and 212 COVID-19 negative patients [143 males, 60(19); 69 females, 61(18)] diagnosed with pneumonia. Microbiological tests were performed by molecular (Pneumonia Panel Plus, Biofire Filmarrey) and cultural identifications with antibiogram examination (Vitek 2, Biomerieux – Sensititre, Thermofisher) of both bacterial and fungal species. Bacteria that resist treatment with three or more antibiotic classes were considered MDR organisms.

RESULTS

Among COVID-19 positive patients, MDR organisms-related respiratory infections accounted for 81% and 72% in 2020 and 2021, respectively. Lower percentages (54% and 62%) were observed in COVID-19 negative patients. As for MDR bacterial species, the following percentages were detected in COVID-19 positive pneumonia (2020-2021): Acinetobacter baumanni(76-40%), Klebsiella pneumoniae(16-13%), Staphylococcus aureus(8-20%), Enterococcus faecium(0-20%) and Stenotrophomonas maltophilia(0-7%). The following percentages were instead observed in COVID-19 negative pneumonia (2020-2021): Acinetobacter baumanni(50-55%), Klebsiella pneumoniae(18-12%), Staphylococcus aureus(12-11%), Pseudomonas aeruginosa(3-6%), Enterococcus faecium(3-3%), Escherichia coli(9-2%), Stenotrophomonas maltophilia(5-7%) and other species(0-4%). Interestingly, co-infections of MDR bacteria and Candida albicans were twice in COVID-19 positive patients compared to those observed in COVID-19 negative patients: 43% and 20%, respectively.

CONCLUSIONS

Overall, we observed an increase in the percentage of MDR bacterial gram negative and positive species along with fungal co-infections in COVID-19 positive pneumonia, regardless of the pandemic year.

COVID-19

P0666

SARS-COV-2 INFECTION: FOCUS ON LONG-COVID AMONG HEALTHCARE PROFESSIONALS OF THE CLINICAL PATHOLOGY AND MICROBIOLOGY UNIT OF A HOSPITAL ASL BT

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BACKGROUND-AIM

Long COVID is the persistence of symptoms after the acute phase of Sars-CoV-2 infection. The aim of work is to evaluate the incidence and occupational health consequences of Long Covid in healthcare professionals of the Clinical Pathology and Microbiology Unit ASL BT

METHODS

A questionnaire was distributed to 32 healthcare professionals: aged 23 to 65, 23 females and 9 males. The subjects positive to Sars-Cov-2 were grouped into 3 age classes: group 1 (0-30 years), group 2 (31-60 years) and group 3 (> = 61 years)

RESULTS

Of the 32 operators, 18 (58%) tested positive to Sars-CoV-2. 17 positive subjects showed symptoms in the following percentage: fever 47%, asthenia 41%, sore throat 30%, cough/musculoskeletal pain/headache 23%, hoarseness 18%, retrosternal pain/dysgeusia/dysosmia 12%, conjunctivitis/dyspnea/abdominal pain/hair loss 6%. After resolution of the infection, 14 of the symptomatic people had asthenia 50%, sleep disturbances 33%, myalgia/breathlessness 28%, arthralgia 22%, gastrointestinal manifestations 17%. In group 1, all presented asthenia, widespread pain, headache, nausea and cough. In group 2, they showed asthenia 54%, widespread pain/sleep disturbances 31%, myalgia/arthralgia/sore throat/memory problems/dyspnoea 23%, abdominal pain/tachycardia/anxiety/dysgeusia/dysosmia 8%-15%. In group 3 they had asthenia/dyspnea/sleep disturbances/myalgia 67% and tachycardia/abdominal pain 33%. Long Covid was more common among women than men

CONCLUSIONS

Asthenia was the most reported symptom. Subjects of group 1 had fewer organ-specific symptoms; people of the second group had non-specific and specific disorders; subject of the last group presented physical and mental symptoms; extent and persistence of symptoms were directly proportional to age. The symptoms following the infection coincided with manifestations physiologically related age but they were highlighted earlier with greater intensity and persistence over time. It useful to implement supportive measures to improve the quality of life of those affected. In our operating unit, the awareness of the serious health moment did not determine conditions of disservice

COVID-19

P0667

EVALUATION OF NEW LEUKEMIA DIAGNOSES IN THREE YEARS 2020-2022: THE ROLE OF CLINICAL PATHOLOGY UNIT-ASL BT, DURING PANDEMIC CAUSED BY SARS-COV-2

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BACKGROUND-AIM

The COVID-19 pandemic has become the most serious economic, health and social crises of the last millenium. During the emergency, many medical visits were suspended. These measures had reduced the spread of the virus but have delayed the diagnosis and had decreased the proper follow-up of haematogical diseases.
The purpose of this work is to evaluate whether the COVID-19 outbreak had an impact on identification of new haematological disordes in patients coming from emergency room (ER) and the blood sampling center of our hospital.

METHODS

Using the data archive of our management system (DIANOEMA), we conducted a retrospective analysis, blood counts and blood smears were collected from January 1, 2020 to September 30, 2022. We compared the results with data of pre-pandemic period (1.1.2019-31.12.2019).
Blood counts were performed up to May 2020 on Sismex analyzer and from June 2020 on Yumizen H2500-Horib, blood smears were supported by Yumizen SPS-Horiba.

RESULTS

In 2020, 19469 blood counts were performed (12835 ER, 6634 external); in 2021 were 26124, (16840 ER, 9284 external); in the first 9 months of 2022 were 19959, (12414 ER, 7545 external). In the first 9 months of 2019 15,935 blood counts were performed (10,473 ER, 5,462 external) became 21753 at the end of 2019 (14119 PS, 7634 external). There were no smears in the archive for the year 2019 while 4 smears were performed in 2020, 48 in 2021 and 92 in the first 9 months of 2022.
With particular reference to leukemia cases, we observed 4 suspected leukocytoses in 2020; 1 promyelocytic leukemia and 5 cases of chronic lymphocytic leukemia in 2021; 1 case of myeloid leukemia type 1, 4 cases of chronic lymphocytic leukemia, 4 cases of acute myeloid leukemia and 1 case of pediatric acute lymphoblastic leukemia in 2022.

CONCLUSIONS

According to previous finding, our study confirmed an increase of the blood counts and blood smears from ER and external patients of our hospital, in the three years. The reduction observed in 2020 was secondary to the measures that have reduced access to the hospital.
From our results, we observed a possible correlation between the SARS-CoV-2 virus and/or vaccine and the onset of clonal haematogical disease. This consideration required further study and consideration.

COVID-19

P0668

TRANSLATING POPULATION RISK INTO PERSONAL UTILITY USING A MOBILE PHONE APP FOR APPLICATION OF GENOMIC MEDICINE INTEGRATING SERVICE AND RESEARCH IN THE COVID-19 ERA

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BACKGROUND-AIM

Emergence of the coronavirus disease in 2019 (COVID-19) limited in-person interactions during lock-down, leading to an increase in the migration from paper-based to digital healthcare. The dissolving distinction between research and clinical care furthermore underscored the value of a pathology-supported genetic testing (PSGT) service used in translational research projects through community engagement in P4 medicine: Participatory, predictive, personalised and preventative. Identification of risk factors associated with post-COVID conditions is important for prevention.

METHODS

A database of multiple sclerosis (MS) patients and control individuals referred before 2020 for PSGT of the iron-metabolism pathway was used to select potential study participants for a health check after emergence of COVID-19. To date, 14 cases were invited to give feedback on their COVID-19 and vaccination status via a mobile phone app (Gknowmix™). All potential study participants were informed that a weblink will be sent to their email address that will take them to an online survey questionnaire that needs to be filled in within 7 days to avoid the link from expiring.

RESULTS

Six of the 14 MS patients invited to participate completed the online health questionnaire, with two pending. Age at diagnosis of MS ranged between 21 and 48 years. None of the patients were obese; one was overweight with a body mass index of 28.1kg/m2. Of the six patients who completed the survey online, three reported a previous COVID-19 diagnosis and two patients remained unvaccinated. In an illustrative case with relapsing remitting MS, followed over more than 10 years due to severe iron deficiency, magnetic resonance imaging after SARS-CoV-2 infection revealed an active punctate focus of demyelination in the posterior left frontal white matter, in addition to previously reported non-enhancing white matter lesions. PSGT incorporating whole exome sequencing revealed multiple genetic variants in the iron metabolism pathway, including homozygosity for TMPRSS6 2207 C>T, A736V.

CONCLUSIONS

The new mobile phone app facilitated online informed consent and patient follow-up in accordance with the requirements of the Protection of Personal Information Act (POPIA) of South Africa.

COVID-19

P0669

ANTI-SARS-COV-2 HUMORAL IMMUNE RESPONSE AFTER HETEROLOGOUS BOOSTING VACCINATION WITH CHADOX1 VACCINE: A COMPARISON BETWEEN TWO IMMUNIZATION SCHEDULES

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BACKGROUND-AIM

Coronavirus disease (COVID-19) caused by SARS-CoV-2 was declared as a public health emergency in 2020. The administration of inactivated and mRNA vaccines has been one of the most effective strategies for worldwide immunization, showing a higher 95% efficacy. Nevertheless, emergent virus mutants and delays in fulfillment of vaccination programs have produced an increase of re-infection cases. The administration of booster shots has become a recommendation to reduce the incidence of COVID-19. However, there are still many questions about the safety and effectiveness of heterologous boosting with a different primary vaccination schedule. The aim of this study was to analyze the production of anti-SARS-CoV-2 IgM and IgG levels after the administration of ChAdOx1 vaccine booster between two immunization schedules.

METHODS

Blood samples were obtained from volunteers with and without history of COVID-19 infection, who had completed a two-dose vaccination schedule with BNT162b2 (Pfizer-BioNTech) (n=25) or mRNA-1273 vaccine (Moderna) (n=15), before and 20-30 days after the administration of one booster with ChAdOx1 vaccine (AstraZeneca). Serum levels of IgM and IgG antibodies against SARS-CoV-2 were measured by an indirect ELISA method.

RESULTS

Volunteers with no previous COVID-19 infection and Pfizer BioNTech scheme showed a greater increment of IgM concentration (48.66 ± 8.81 vs 63.04 ± 17.51 U/mL, N.S.). Levels of IgG increased after heterologous boosting (Pfizer-BioNTech 44.27 ± 9.26 vs 67.59 ± 14.06 U/mL, p=0.0020; Moderna 58.48 ± 14.05 vs 89.74 ± 19.78 U/mL, p=0.0151). Also, elevation of IgG antibodies was found in both previously uninfected and infected Pfizer-BioNTech immunized volunteers (47.06 ± 20.85 vs 62.52 ± 20.06 U/mL, p=0.0371; 42.40 ± 7.61 vs 70.97 ± 19.77 U/mL, p=0.0353). Correlations were found between IgM levels and days after booster administration in the Moderna vaccinated group (r=0.565, p=0.028), and IgM with IgG concentrations in Pfizer-BioNTech immunized individuals (r= 0.515, p=0.008).

CONCLUSIONS

The administration of ChAdOx1 booster leads an adequate humoral immune response when individuals were previously immunized with mRNA vaccines. Heterologous boosting vaccination is an effective strategy that will play an important global approach in the current COVID-19 pandemic.

COVID-19

P0670

TWO-YEAR EXPERIENCE OF LIVING WITH SARS-COV-2 VIRUS

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BACKGROUND-AIM

More than two years since first cases were reported, COVID-19 pandemic remains an acute global emergency. During two years of COVID-19 outbreak, we have learned a lot about routine infection prevention and control practices and the value of laboratory testing strategies. Preventing nosocomial outbreaks is essential for the operation of Laboratories, especially after the prevalence of highly transmissible Omicron variant that can escape the immune response. This study aims to evaluate the two years experience of living with SARS-CoV-2 virus.

METHODS

A structured questionnaire concerning the history of illness and vaccination was administered to 41 Health Care Workers(HCWs) of Biopathology Laboratory of Ippokration General Hospital of Thessaloniki Greece, during 2020-2022 outbreak. All of them were fully vaccinated with three doses of the BNT162b2(Pfizer-BioNTech) vaccine. Specific SARS-CoV2 IgG RBD antibodies were measured using Quantitative SARS-CoV-2 IgGII assay in Architect i2000 and Alinity-i systems.

RESULTS

35 HCWs were infected with SARS-CoV-2. 32 were infected once(3 by strains of Delta variant and 29 by Omicron subvariants), while 3 were infected twice by strains of both Delta and Omicron variant. 8 HCWs were infected before the third dose of vaccination, 26 after the third, 1 after the fourth. IgG antibody titers remained in high level after the third dose of vaccination. In our review 1 HCW was infected for a second time, after the third dose, meanwhile SARS-CoV-2 IgG titers was 64000AU/ml. Three HCWs were vaccinated with a fourth booster, one of them was infected. No one was vaccinated with the updated bivalent booster vaccine.

CONCLUSIONS

The majority of HCWs were infected by strains of subvariants of Omicron variant, after the third dose of vaccination. High IgG antibody titers did not protect them from infection by Omicron subvariants. Throughout the pandemic, there was not noticed any nosocomial spread of COVID-19 in the Laboratory due to the application of strict personal protective measures. Creating a culture of personal protection must be a priority in every workplace.

COVID-19

P0671

LATERAL FLOW IMMUNOCHROMATOGRAPHY ASSAY FOR DETECTION OF SARS-COV-2. EVALUATION AND CLINICAL UTILITY OF ABBOTT, ROCHE AND MENARINI ANTIGEN RAPID TEST DEVICE.

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BACKGROUND-AIM

The detection of active Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is mainly based: a) amplification techniques of viral RNA, the most extended is RT-PCR (Reverse transcription polymerase chain reaction). Provided high sensitivity and specificity. b) antigen rapid tests. Provided simplicity and fast results, but lower performance than RT-PCR.
Our goal was to evaluate the diagnostic performance of three antigen rapid tests device, stratified by RT-PCR cycle threshold (Ct), to discern the capacity diagnosis, screening effectiveness and follow-up utility of patients.

METHODS

286 samples obtained by nasopharyngeal exudate were analyzed. We compared the results of the lateral flow immunochromatographic tests device provided by Abbott, Roche and Menarini diagnostics. For the RT-PCR analisys (detection of viral RNA-Gen N) we used the NX48S extractor and thermocycler Biorad CFX96. MedCalc software was used for data analysis.

RESULTS

Agreement analysis:
Cohen´s Kappa Coefficient: Abbott-Menarini (0.916; 95%CI:0.869-0.963) / Abbott-Roche (0.923; 95%CI:0.878-0.968) / Roche-Menarini (0.895; 95%CI:0.843-0.947).
Diagnostic performance:
Abbott: Sensitivity 56.79% (95%CI:50.31-63.11%) / Specifity 100% (95%CI:91.78-100%) / PPV 100% (95%CI:83.14-100%) / NPV 94.29% (95%CI:90.78-96.75%).
Roche: Sensitivity 56.38% (95%CI:49.89-62.71%) / Specifity 100% (95%CI:91.78-100%) / PPV 100% (95%CI:83.03-100%) / NPV 94.23% (95%CI:90.72-96.71%).
Menarini: Sensitivity 56.38% (95%CI:49.89-62.71%) / Specifity 97.67% (95%CI:87.71-99.94) / PPV 77.27% (95%CI:56.58-91.32%) / NPV 94.51% (95%CI:90.51-96.64%).
The evaluation of sensitivity stratified by RT-PCR Ct values for all tests revealed values of 100% for Ct<20 and higher than 90% for Cts≤25. Above this threshold, the sensitivity is less than 60%.

CONCLUSIONS

1.- The concordance between the results provided by the three antigen rapid tests assayed is very good (0.81-1.00).
2.- The sensitivity of the rapid antigen test is only suitable in patients with RT-PCR Cts≤25. Therefore, there is a detection window in which patients with high viral load presents Negative results in antigen test. A clinical and epidemiological evaluation of the patients are needed in order to an adequate selection of test and a proper interpretation of the results.

COVID-19

P0672

A COMBINATION OF INFLAMMATORY AND HEMATOLOGICAL MARKERS IS STRONGLY ASSOCIATED WITH RISK OF DEATH IN BOTH MILD AND SEVERE INITIAL DISEASE IN UNVACCINATED INDIVIDUALS WITH COVID-19 INFECTION

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BACKGROUND-AIM

Inflammatory and hematological markers were used extensively for early prognostication and monitoring in COVID-19. We aimed to determine whether routinely prescribed laboratory markers can predict adverse outcome at presentation in COVID-19.

METHODS

This retrospective observational study was performed on 401 samples collected between July to December 2020 from COVID-19 positive subjects, admitted at All India Institute of Medical Sciences, Delhi, India. Clinical details and laboratory investigations within 3 days of COVID-19 positivity and outcomes were noted from patient medical records, till discharge or death. Complete blood count (CBC), C-Reactive Protein (CRP), ferritin, Lactate Dehydrogenase (LDH), Creatine Kinase-MB (CKMB) and Interleukin-6 (IL-6) were analyzed. Neutrophil-Lymphocyte Ratio (NLR), Platelet-Lymphocyte Ratio (PLR) and Lymphocyte-CRP Ratio (LCR) were calculated using absolute neutrophil and lymphocyte counts. Receiver operating characteristics (ROC) curve analysis was carried out to assess the discriminative ability of various laboratory parameters between survival and death in both, severe and non-severe disease. Further, with a sensitivity of 80% the cut-offs for four parameters which had maximum AUC in the ROC analysis were decided. A likelihood of death for patients presenting with any three or all four out of the four inflammatory markers elevated beyond the designated cut-offs and clinical severity was calculated using univariate and multivariate logistic regression models.

RESULTS

TLC, ANC, NLR, CRP, IL-6, LDH, Ferritin and LCR were significantly altered at presentation in severe COVID-19 as compared to non-severe cases; and, also in those who died due to COVID-19 compared to those who survived. The combination of four markers, CRP (≥3.9mg/dL); IL-6 (≥45.37pg/ml); Ferritin (≥373ng/mL); 1/LCR ≥0.405 was found to strongly predict mortality in cases with non-severe presentation as also in severe cases.

CONCLUSIONS

The combination of routinely used markers, CRP, IL-6, Ferritin and 1/LCR can be used to predict adverse outcomes, even in those presenting with mild to moderate disease. This would identify subset of patients who would benefit from closer monitoring than usual for non-severe disease.

COVID-19

P0673

THE IMPACT OF SECONDARY INFECTIONS IN ICU PATIENTS AFFECTED BY COVID-19.

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BACKGROUND-AIM

COVID-19 can range from asymptomatic to symptomatic disease with severe pneumonia, inflammation, and death. The outcome depends on various factors, including microbial secondary infections which can contribute to an increase in the risk of mortality, particularly in patients with severe diseases. Laboratory data are fundamental to support clinicians. Thus, in this study, we collected and evaluated the clinical, laboratory and microbiological data of COVID-19 critical ill patients needing intensive care (ICU) to assess the significance and the prognostic value of these parameters.

METHODS

178 ICU patients with severe COVID-19, hospitalized at the S. Francesco Hospital of Nuoro (Italy) in the period from March 2020 to May 2021, were enrolled in this study. Clinical data and microbiological results were collected. Blood chemistry parameters, relative to three different time points, were analyzed through multivariate and univariate statistical approaches.

RESULTS

74% of the ICU COVID-19 patients had a negative outcome. A correlation between the laboratory parameters and days of hospitalization of the patients was observed with significant differences between the two groups (negative and positive outcomes). In deceased patients, there was a significant increase in the indices of inflammation, neutrophils, creatinine, sodium, and potassium, and a significant reduction in hemoglobin and lymphocytes, probably due to the organism's failure to counteract infections and consequent organ damage. Moreover, Staphylococcus aureus, Enterococcus faecalis, Candida spp, Pseudomonas aeruginosa, and Klebsiella pneumonia were the most frequently isolated microorganisms from all clinical specimens.

CONCLUSIONS

The analysis of the blood chemistry parameters was found essential in monitoring the progression of COVID-19. The trend of the laboratory and microbiological data reflected the different outcomes of the patients. Secondary infections seemed to play an important role in the clinical outcome

COVID-19

P0674

COMPARING LABORATORY TESTS OF HOSPITALIZED COVID-19 PATIENTS AGED 1 DAY TO 98 YEARS: THE LABORATORY EXPERIENCE IN NORTHERN GREECE

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BACKGROUND-AIM

Most studies regarding SARS-CoV2 concern adults. However, many children are affected, mostly during the Omicron pandemic wave and the winter school period. They become source of infection for the elderly. The majority of children has indolent disease or is asymptomatic and less likely to be hospitalized. Consequently, children's laboratory tests differ compared to adults. Nevertheless, severe disease and Multisystem Inflammatory Syndrome have been described regarding children. We compared inflammatory markers: ferritin, fibrinogen and fibrin degradation products: D-Dimers, between COVID-19 hospitalized adults and children.

METHODS

We studied 1004 adults, median age 67(16-98)years and 202 children median age 3years(1 day-15 years) with COVID-19 disease, hospitalized between 1/9/2021-15/6/2022. Pregnant women, patients with renal failure, thalassemia, cancer or transplantation were excluded. Ferritin was determined on UniCell DXI800 Access Immunoassay System(Beckman-Coulter) by enhanced chemiluminescence-CMIA, Fibrinogen and D-Dimers on BCS®XP(Siemens). Mann-Whitney test compared laboratory tests between adults and children upon admission. Chi-square compared adults and children admitted to Intensive Care Unit (ICU).

RESULTS

Ferritin was determined in 204 adults and 10 children, median 458.6(13.6-5258)ng/ml and 87(10-5450)ng/ml, respectively. Fibrinogen was determined in 942 adults and 196 children, median 497.3(20-1560)mg/dl and 305.1(106.6-947.8)mg/dl, respectively. D-Dimers were determined in 876 adults and 189 children, median 931(175-32518)ng/ml and 684(174-21143)ng/ml. Ferritin, fibrinogen and D-Dimers levels upon admission were statistically significant lower in children compared to adults with COVID-19 ($p<0.05$). Children were less likely to be hospitalized or admitted to ICU ($p<0.05$).

CONCLUSIONS

Despite clinical differences, viral load appears to be the same between children and adults, even regarding asymptomatic children. However, COVID-19 disease is milder in children, probably due to less comorbidities, ACE-2 receptors and smoking. Consequently, children have lower ferritin, fibrinogen and D-Dimers levels. Nevertheless, children with COVID-19 disease get hospitalized, need monitoring, are contagious and play a key role in SARS-CoV2 transmission.

COVID-19

P0675

JUXTAPOSING LABORATORY TEST RESULTS BETWEEN PATIENTS WITH DELTA AND OMICRON SARS-COV-2 VARIANTS

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BACKGROUND-AIM

SARS-CoV-2 Omicron variant causes indolent disease. Hospitalized patients are less likely to suffer pneumonia or hyperinflammation syndrome. Consequently, laboratory tests differ compared to previous pandemic waves. Their study is challenging. We compared inflammatory marker procalcitonin(PCT), acute phase proteins, ferritin fibrinogen and fibrinolysis products, D-Dimers in COVID-19 patients, hospitalized during Delta and Omicron variant pandemic waves.

METHODS

1004 COVID-19 patients, admitted to a tertiary Greek hospital were studied, 530(52.74%) male, median age 67(16-98)years. 554(55.18%) hospitalized during Delta variant wave, 450(44.82%) during Omicron. Patients with renal and/or cardiac failure were excluded. Ferritin and PCT were determined on UniCell DXI800 Access Immunoassay System(BECKMAN-COULTER) by enhanced chemiluminescence(CMIA), Fibrinogen and D-Dimers on BCS®XP(Siemens) modified Clauss method and immunoturbidity (INNOVANCE® D-DIMERS reagent), respectively. Mood's median compared laboratory tests between Delta and Omicron variant waves.

RESULTS

Ferritin was determined in 204 patients, 133 during Delta variant wave, median 649.5(31.4-5258)ng/ml, 71 during Omicron, median 214.2(13.6-4457)ng/ml. PCT was determined in 418 patients, 238 during Delta, median 0.09(0.01-34.11)ng/ml, 180 during Omicron, median 0.09(0.02-15.33)ng/ml. Fibrinogen was determined in 942 patients, 515 during Delta, median 548.3(42.3-1560)mg/dl, 427 during Omicron, median 437.3(20-1042.5)mg/dl. D-Dimers were determined in 876 patients, 484 during Delta, median 886(177-32518)ng/ml, 392 during Omicron, median 1039(175-30461)ng/ml. Ferritin and fibrinogen levels upon admission were statistically significant lower, regarding patients admitted during the Omicron variant pandemic wave($p<0.05$).

CONCLUSIONS

SARS-CoV-2 Omicron variant is more contagious, evades vaccination and causes mild disease. Delta pandemic wave, 9/21-12/21 was shorter than Omicron, 1/22-6/22 but hospitalized patients were less during the Omicron. Patients with the Omicron variant have lower ferritin and fibrinogen levels. This may be a reason to reduce laboratory tests for patients' initial evaluation. Vaccination may reduce the incidence of severe illness. Nevertheless, people with underlying diseases remain vulnerable.

COVID-19

P0676

A CRUCIAL BIOMARKER TO ASSESS MULTISYSTEM INFLAMMATORY SYNDROME (MIS-C) IN CHILDREN WITH COVID-19 DISEASE

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BACKGROUND-AIM

The disease COVID-19 shows great clinical heterogeneity and mainly affects adults. Children account for approximately, 19% of COVID-19 cases. They are asymptomatic or have indolent disease. Nevertheless, some children can be severely ill. A serious complication in children is the Multisystem Inflammatory Syndrome (MIS-C) with fever, multisystem and cardiovascular manifestations. 50-80% require ICU hospitalization. Elevated CRP, troponin and low platelets and lymphocytes are reported. B-natriuretic peptide (BNP) is a biomarker for heart failure diagnosis and monitoring. Currently, its role in MIS-C is being evaluated. We aimed for BNP levels determination in children with COVID-19 and in children with MIS-C. Also, we evaluated the possibility that BNP may discriminate children at increased risk of developing MIS-C.

METHODS

60 children were admitted to a tertiary care hospital in Northern Greece, between 1/2/2020-5/12/2022, with COVID-19 disease up to 60 days before or during hospitalization. Their median age was 9 years (3 months-16 years) and 37 (61.67%) were boys. 21 (35%) of them were diagnosed with MIS-C, according to the current diagnostic criteria. BNP was determined on the UniCell DXI800 Access Immunoassay System (Beckman Coulter) by enhanced chemiluminescence (CMIA). Mood's median test compared BNP levels between non-MIS-C and MIS-C children with COVID-19 disease.

RESULTS

The median BNP value regarding the 39 children with COVID-19 was 29 (4-199) pg/ml, regarding the 21 children with COVID-19 and MIS-C, median BNP value was 216 (55-4161) pg/ml. BNP levels were statistically significantly higher in children with MIS-C ($p<0.001$).

CONCLUSIONS

MIS-C is a life-threatening complication of COVID-19 in children. Main manifestations are cardiovascular complications resulting in increased BNP levels. Clinical and laboratory monitoring of critically ill admitted children, including determination of BNP levels, is essential for early diagnosis and management of MIS-C.

COVID-19

P0677

C-REACTIVE PROTEIN (CRP), A PREDICTIVE FACTOR OF MORTALITY IN DIABETICS WITH COVID-19

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BACKGROUND-AIM

The aim of our work is to evaluate the variation of blood glucose and its relationship with the inflammatory state of moderate and severe forms of Covid-19 in type 2 diabetics.

METHODS

This is a prospective study that included 64 type 2 diabetic patients with Covid-19 admitted to the University Hospital of Constantine from November 1 to December 31, 2021. The main clinical data as well as the biological parameters were recorded daily during the whole period of hospitalization of the patients. At the end of the study, we subdivided the patients into two groups: cured patients (54) and deceased patients (10). Clinical data and biological parameters (fasting blood glucose, glycated hemoglobin (HbA1c), transaminases, CRP, and GFR) were compared between the two groups. Statistical analysis was performed on Excel software and statistical significance was defined for a p value <0.05.

RESULTS

The mean age of the patients was 66 ±10 years (56 to 76 years) with a sex ratio of 1.56. The mean duration of diabetes was 10 ± 4 years. Patients who died had a significantly higher mean age than those who recovered (67 ± 11 years vs. 60 ± 5 years; p= 0.002*). Renal status as well as glycemic control over the last 3 months were equivalent in the 2 groups (GFR: 73 ± 35 ml/min vs 79 ± 30 ml/min; p= 0.56 and HbA1c: 8.5 ± 2.68% vs. 7.69 ± 2.03%; p= 0.10), whereas fasting blood glucose, estimated during the period of viral infection, was found to be significantly higher in patients with a poor prognosis compared to those with a favorable outcome (2.33 ± 0 .83 vs. 2.16 ± 0.98 g/l; p=0.02*). Similarly, CRP levels were significantly higher in patients who died compared to those with moderate disease (70 ± 20 mg/l vs 20 ± 10; p= 0.001*). The transaminase profile was significantly normal and comparable in the 2 groups (p>0.05).

CONCLUSIONS

The impact of SARS-COV2 virus on the increase of glycemia in type 2 diabetic patients would be related to the simultaneous presence of a severe inflammatory state and an advanced age. The association of these two criteria seems to be an indicator of a poor prognosis of the disease in these patients. These data remain to be confirmed and should be completed by larger scale studies

COVID-19

P0678

EVOLUTION OF BINDING ANTIBODIES AFTER THE ADMINISTRATION OF THE SECOND BOOSTER OF PFIZER-BIONTECH BOOSTER VACCINE.

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BACKGROUND-AIM

The COVID-19 sanitary crisis has been going on for several years now. Different tests have been developed, notably serological tests that are able the measure the presence of anti-SARS-CoV-2 antibodies in case of infection and/or vaccination. Methods measuring antibodies against the nucleocapsid (N) and the spike (S) protein have been developed.

METHODS

Anti-S antibodies levels of 41 healthy participants were measured after the administration of a second homologous Pfizer-BioNTech booster (36 received the BA.1 adapted vaccine and 5 the BA.4/5 adapted vaccine). Participants were aged between 26 and 65 years old. Twenty-nine were females and 12 were males. Anti-S and anti-N antibodies were measured with the assays from Roche Diagnostics. Antibodies were measured at different times points: before the booster administration, and after 14, 28 and 90 days. The normality of the population was assessed using a D'Agostino-Pearson test, with or without log-transformation. The difference between time points was evaluated using a non-parametric ANOVA multiple comparison test.

RESULTS

Before the administration of the second booster, 34 participants had detectable levels of anti-N antibodies, meaning that they all developed the infection in the past.
The levels of anti-S antibodies were all significantly different ($p<0.05$) considering all timepoints, except between day 14 and day 28. Mean antibody levels at days 0, 14, 28, and 90 were 14,266, 23,674, 22,871 and 19,732 BAU/mL, respectively. There was a significant increase from day 0 to day 14 ($p<0.001$), demonstrating that vaccination was efficient in boosting the adaptive humoral immunity. The significant decrease ($p<0.05$) between days 28 and 90 demonstrates that the humoral response weakens over time. However, the average antibody level at day 90 remained significantly higher than at day 0 ($p<0.01$), showing a perduring humoral response over time.

CONCLUSIONS

The administration of a fourth dose of vaccine boosts the humoral immune response. The peak of the anti-SARS-CoV-2 S antibodies level occurred between days 14 and 28 and then decreased slowly until day 90.

COVID-19

P0679

BIOPATHOLOGIST'S PERSPECTIVE REGARDING THE INVESTIGATION OF BIOMARKERS IN CHILDREN WITH COVID-19 DISEASE

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BACKGROUND-AIM

Children account for approximately 19% of COVID-19 cases. Usually, they are asymptomatic or have mild disease and are less likely to become seriously ill and hospitalized. However, severe disease and sudden death are reported. In the effort to optimally manage sick children, laboratory tests such as CRP, D-Dimers, fibrinogen, ferritin were used. B-natriuretic peptide (BNP) is a biomarker for heart failure diagnosis and monitoring. In ICU patients BNP predicts the occurrence of Acute Respiratory Distress Syndrome (ARDS). BNP levels determination in children with COVID-19 disease compared to children with other febrile infection.

METHODS

Between 1/2/2020-5/12/2022, 60 children were hospitalized in a hospital in Northern Greece with COVID-19, (Group A), median age 9 years (3 months-16 years), 37 (61.67%). 30 children were hospitalized with another febrile infection (Group B), median age 6.5 years (3 months-15 years), 15 (50%) boys. Children with cardiovascular disease were excluded. BNP was determined in UniCell DXI800 Access Immunoassay System (Beckman Coulter) by enhanced chemiluminescence (CMIA). Mood's median test compared BNP levels between the two groups.

RESULTS

In Group A, the median BNP value was 57 (4-4161) pg/ml, while in Group B, median BNP value was 39.5 (2-409) pg/ml. No statistically significant difference in BNP levels was found between the two groups (p=0.180).

CONCLUSIONS

Recent studies in adults with COVID-19 disease have shown that activation of inflammation is associated with increased levels of BNP. A correlation with disease severity was also depicted. Similar studies in children are few. In our groups of children, BNP could not be associated with COVID-19 disease. The reason is probably the retrospective nature of the study, the hospitalization of only serious cases and the determination of BNP only in seriously ill children.

COVID-19

P0680

SARS-COV-2 OMICRON BA.4 AND BA.5 LINEAGES LABORATORY TESTS COMPARED TO DELTA AND OMICRON VARIANTS: EXPERIENCE IN NORTHERN GREECE

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BACKGROUND-AIM

The Omicron SARS-CoV-2 variant of concern(VOC) was first detected in South Africa. Nowadays, BA.4 and BA.5 Omicron lineages are dominating in Greece and are responsible for the sixth pandemic wave. The majority of patients has indolent disease and is not hospitalized. We determined and assessed laboratory tests of patients infected with SARS-C0V-2 Omicron BA.4 and BA.5 lineages. We also compared them with findings from Delta and Omicron pandemic waves.

METHODS

426 patients with COVID-19 disease were studied. 275 during the prevalence of subvariants BA.4-BA.5(Group A) 15/7/2022-5/11/2022. 82 when the Delta mutation prevailed 1/9/2021-24/12/2021(Group B). 69 when Omicron prevailed 25/12/2021-15/6/2022(Group C). Patients with anemia, renal failure, transplantation, cancer and pregnant women were excluded. Complete blood count was performed on the UniCell DXH800(Beckman-Coulter), ferritin, procalcitonin(PCT), TSH, FT4, FT3, B-Natriuretic-peptide(BNP) on the UniCell DXI800 Access Immunoassay System(CMIA)(Beckman-Coulter), Fibrinogen and D-Dimers on BCS®XP (Siemens). Kruskal-Wallis and chi-square statistical tests were used. Statistical significance threshold $p<0.05$.

RESULTS

Patients in Group A were older ($p<0.001$). In Group B patients had higher fibrinogen levels ($p<0.001$), D-Dimers ($p<0.05$), lymphopenia ($p<0.05$) and more hospitalizations ($p<0.05$). No statistically significant difference was found regarding gender ($p=0.861$), WBC($p=0.817$), PLT($p=0.175$). Also, no statistically significant difference was found regarding ferritin($p=0.066$), TSH($p=0.465$), FT4($p=0.536$), FT3($p=0.835$), PCT($p=0.533$), BNP($p=0.641$), perhaps due to the small number of tests.

CONCLUSIONS

Patients with BA.4 and BA.5 subvariants present with mild disease, probably due to vaccination. Although they are older, they have better laboratory results, compared to patients of previous pandemic waves. However, laboratory tests are often abnormal and some patients require hospitalization. COVID-19 pandemic is still here, especially for patients with comorbidities. The best strategy for disease management is always prevention.

COVID-19

P0681

ASSESSMENT OF THE NEUTRALIZING ANTIBODY RESPONSE IN OMICRON BREAKTHROUGH CASES IN HEALTHCARE WORKERS WHO RECEIVED THE BNT162B2 BOOSTER

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BACKGROUND-AIM

With the emergence of this variant, questions of vaccine efficacy against it emerged. The aim of this study is to compare anti-receptor binding domain (RBD) total antibodies and the neutralizing antibody response in breakthrough case in healthcare workers who received the BNT162b2 booster with a control group using a binding assay and a pseudo virus neutralization test (pVNT).

METHODS

The breakthrough group was compared to a 1:1 matched control group. They were matched on sex and age. All serum samples were analyzed on cobas e801 for the quantification of anti-SARS-CoV-2 total antibodies and on a pVNT technique using Omicron B.1.1.529 variant pseudovirus to assess the neutralizing antibody response post booster dose. Antibodies titers were interpolated based on an individual kinetic curve 10 days prior to the positive RT-qPCR test results Descriptive statistics were computed. Differences between groups were computed using parametric T-test.

RESULTS

Twenty-four patients had a breakthrough infection after the booster dose. The median breakthrough time is 105 days (IQR: 75 - 133 days) post booster dose. In the breakthrough cases, the neutralizing antibodies titers 10 days before the positive RT-qPCR were significantly lower than in the control group (26.52 vs 59.19; p=0.0109). The difference between the two groups is marked before D87 (46.93 vs 348.80; p=0.0065) after this day there is no more significant difference between the two groups (21.14 vs 27.71; p=0.3381). Concerning RBD total Abs titers 10 days before the positive RT-qPCR, they were significantly lower in breakthrough cases than in the control group (6950 vs 11395 BAU/mL; p=0.0236).

CONCLUSIONS

Our results suggest that there is a clear difference between the pre-infection NAbs titers in breakthrough infected individuals and those in matched controls. As the neutralizing antibodies correlate with the level of protection against re-infection, this suggests that about 3 months (90 days) after the booster, the effectiveness of this protection strongly decreases. The probability of having a breakthrough infection after 90 days would therefore depend more on the prevalence of the disease, on the variant in circulation and on the application of sanitary measures

COVID-19

P0682

EFFECTIVENESS OF ANTI-COVID-19 VACCINES APPLIED IN ALBANIA

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BACKGROUND-AIM

COVID-19 vaccines have proven to be safe, effective and life-saving. Vaccination has been used to control the COVID-19 pandemic. Four vaccines have been applied in Albania: Pfizer-Biontec, Astrazeneca, Coronavac and Sputnik.
The purpose of the study was to investigate the types and doses of vaccines applied to the general population in our country, as well as to evaluate their immunogenicity and effectiveness in all individuals. Also, we determined and compared the quantitative level of anti-S1(spike) antibodies for three vaccines Pfizer-Biontec, AstraZeneca and CoronaVac.

METHODS

In this study we carried out on vaccination and the effectiveness of vaccines in the general population, 2142 individuals from 2021 and 2183 individuals from 2022 were included. The samples were randomly selected. Serological tests were performed using anti-SARS-COV-2 S1-Spike IgG Quantivac by ELISA (Euroimmun).

RESULTS

27% (579) of all individuals studied have applied 2 doses of the vaccine in 2021 and 53% (1157) of them in 2022. Regarding the third dose, 31.2% (361) of the individuals have applied this dose until on August 2022. In all individuals who received 2 doses, in 2021, CoronaVac vaccine was the most applied 43.9% compared to the year 2022 where the Pfizer vaccine was 59% the most applied. The average quantitative level of anti-S1spike antibodies was evaluated for three vaccines and resulted: Pfizer (2502 BAU/ml), Astrazeneca (1612.7 BAU/ml) and Coronavac (825.1 BAU/ml). The seroprevalence of anti-S1-spike antibodies in all individuals resulted 71.9% in 2021 and 92% in 2022.

CONCLUSIONS

The results of our study showed a lower level of vaccination in third dose. So we should encourage people to get vaccinated. Different vaccines applied in Albania were associated with a favorable effevtiveness again SARS-COV-2 infection. Vaccination indicated in high prevalence of SARS-COV-2. Vaccination could be the best strategy to prevent the severe form of the disease.

COVID-19

P0683

THE STRUCTURE OF MICROORGANISMS FROM THE BLOOD AND PANDEMIA COVID-19: DATA FROM THE MINSK (BELARUS, 2018-2021)

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BACKGROUND-AIM

The structure of microorganisms from the blood was studied in patients hospitalized in the intensive care unit (ICU) in the hospitals of Minsk from 01.07.2018 to 31.12.2021 and a comparative analysis of the etiological agents for 2 periods was carried out.

METHODS

The structure of microorganisms isolated from the blood by the classical bacteriological method was analyzed.

RESULTS

The number of blood samples examined during the pandemic increased by 2,6 times; during this period, blood cultures from 11,551 patients were examined, while the number of blood samples with detected growth of cultures significantly increased - 5,518 (47,86 ± 0,5% ; P<0,05).
A significant part of the positive samples (79,8±1,0% in the 1st period and 84,6±0,5% in the 2nd (P<0,05)) were epidemically significant bacterial isolates. The leading groups were: staphylococci – 54,4±1,4% before the pandemic and 43,1±0,7% in COVID-19 (P<0,05); enterococci – 9,0±0,8% and 5,2±0,3% (P<0,05); non-fermenting gram-negative bacteria – 12,1±0,9% and 29,0±0,7% (P<0.05) and enterobacteria – 27,2±1,3% and 23,1±0,6% (P <0.05).
In the 1st period B.cepacia was not isolated and only 6 isolates S.maltophilia were found, while during the pandemic, the number of S.maltophilia isolates was 173, and B.cepacia - 223. In addition, from 10,6±0,9% in the 1st period to 18,9±0,6% in the 2nd (1,8 times) the frequency of occurrence of A.baumannii increased.

K.pneumoniae isolates before and during the pandemic remained consistently leading ($P^{>}0.05$), amounting to 20,2±1,2% and 19,9±0,6%, respectively. Also, there were no differences in the detection rate of P.aeruginosa, E.faecalis,E.faecium, P.mirabilis and S.hominis. A decrease in the frequency of occurrence in the structure during a pandemic was reliably established for S.aureus - from 8,8±0,8% to 3,0±0,2%, S.epidermidis - from 22,1± 1,2% to 18,3±0,6%, S.haemolyticus – 11,9±0,% to 9,4±0,4% and E.coli - from 5,5±0,7% and 1,6±0,2%.

CONCLUSIONS

Thus, there has been a significant increase in blood sampling from ICU patients during the COVID-19 pandemic. The main etiological agent in the structure of bloodstream infections both before and during the pandemic is Klebsiella pneumoniae ss. pneumoniae.

COVID-19

P0684

INITIAL HEMATOLOGIC INDICES IN COVID-19 PATIENTS WITH INVASIVE MECHANICAL VENTILATION

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BACKGROUND-AIM

Invasive mechanical ventilation (IMV) is frequently needed intervention in patients with severe COVID19. There are attempts to identify biomarkers that could be helpful in determining the best moment to intubate these patients. It is known that cost-effective hematological indices, easily calculated from a routine complete blood count (CBC), are useful in determining patient's inflammatory response to COVID-19. The aim of this study was to examine the hematologic indices value in patients with and without the need for IMV and a control group.

METHODS

A total of 274 COVID-19 patients (178 males/96 females, median age 65), hospitalized in temporary COVID-19 hospital in Clinic for Pulmonology Diseases, University Clinical Centre of Serbia in Belgrade between November 18, 2020 to January 15, 2021, were stratified as IMV (Group 1) (n = 24) or did not require invasive mechanical ventilation (Group 2) (n = 250). The control group was consisted of 274 healthy individuals. CBC was determined at hospital admission using Sysmex XN-1000 (Sysmex Corporation, Kobe, Japan). Few hematologic indices were calculated, the neutrophil-to-lymphocyte ratio (NLR), the derived NLR (d-NLR), the neutrophil-to-platelet ratio (NPR), the platelet-to-lymphocyte ratio (PLR), the lymphocyte-to-monocyte ratio (LMR), and systemic immune-inflammation index (SII).

RESULTS

There was significant differences ($p<0.001$) in all hematological ratios between COVID-19 patients and the control group. Patients in Group 1 had significantly higher values of NLR (7.1 (3.3-15.7) vs 4.3 (2.4-8.1), $p = 0.011$), dNLR (4.4 (2.5-8.3) vs 2.8 (1.7-5.1), $p = 0.013$), NPR (0.03 (0.02-0.05) vs 0.02 (0.01-0.03), $p = 0.001$), compared to those in group 2. Conversely, the Group 1 had markedly decreased LMR (1.9 (1.1-3.3) vs 2.5 (1.8-3.7), $p = 0.043$), compared to the Group 2. There was no significant difference in PLR and SII between these two groups ($p >0.05$).

CONCLUSIONS

Our study suggests that admission value of hematological indices NLR, dNLR, NPR have potential for use as auxiliaries in clinical decision-making regarding the need for IMV in COVID-19 patients.