Clinical Chemistry

P0396

A PREANALYTICAL CAUSE OF PSEUDOHYPERKALEMIA : A CASE REPORT

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BACKGROUND-AIM

Erroneous potassium results are common in routine laboratory tests. A pre-analytical cause must always be ruled out before confirming a diagnosis of dyskalemia.

METHODS

A 12-years-old diabetic child was admitted to the emergency department for abdominal pain, diarrhea, and vomiting. He was treated with a 5% glucose infusion, supplemented with potassium chloride (KCl) (1 g, or 13.4 mmol of KCl per 250 mL of glucose solution). A diagnostic workup was performed, including plasma electrolytes testing.

RESULTS

Electrolytes results revealed potassium concentration of 18.62 mmol/L, sodium concentration of 96 mmol/L and chloride concentration of 96 mmol/L. The plasma sample showed no evidence of hemolysis. Additionally, blood glucose measurement was obtained, which was 105.5 mmol/L. Given the markedly elevated potassium and glucose levels, which were not physiologically compatibles with life, sample contamination was immediately suspected. It was determined that the blood sample had likely been drawn from the same arm, in close proximity to the infusion site, which could explain the observed elevation in potassium and glucose levels, as well as the dilution of sodium. A subsequent blood sample was collected, and the results for both electrolytes and blood glucose were within the reference ranges.

CONCLUSIONS

Biologists must identify inaccurate potassium results. Constant communication between doctors and biologists is essential to prevent incorrect medical interventions.

Clinical Chemistry

P0397

ASSESSMENTS OF SERUM LEVEL VITAMIN D AND THYROID FUNCTION TESTS AMONG NEWLY DIAGNOSED FEMALE BREAST CANCER PATIENTS ATTENDING IN TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA

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BACKGROUND-AIM

Breast cancer (BC) is the most prevalent form of cancer among women and causes hundreds of thousands of deaths each year worldwide. There is a high correlation between an increased incidence of breast cancer and thyroid hormones abnormalities. However, there is limited evidence on the serum levels of thyroid hormone linked to BC among women diagnosed with the disease in Ethiopia. Thus, this study aimed to assess the serum levels of Thyroid hormone among females newly diagnosed with BC.

METHODS

A comparative cross-sectional study was conducted from January to March 2024 at Tikur Anbessa Specialty Hospital. A convenient sampling method was employed to recruit 69 newly diagnosed with BC as a case group and 69 samples from apparently healthy females as a control group. Blood samples were collected and sent to the Ethiopian Public Health Institute (EPHI) for Serum Thyroid Function Tests, by using a fully automated COBAS 6000 analyzer. The data was analyzed using SPSS version 20.0 software. Independent T-tests, Mann-Whitney U tests, and Logistic regression tests were used to analyze the data.

RESULTS

The mean values of Total Triiodothyronine (TT3) concentrations were significantly lower in the BC group (1.2 ± 0.28ng/mL) than in the healthy group (1.4 ± 0.19 ng/ml) at $p< 0.001$. The multivariate analysis also supported the role of TT3 as an independent risk factor, with lower TT3 levels significantly associated with an increased risk of BC (AOR=0.08, $p= 0.016$). This study also revealed a significant reduction in Free Triiodothyronine (FT3) levels ($p< 0.001$) among BC patients compared to controls although it did not support during the multivariate analysis. Nevertheless, no significant differences were found in Total Thyroxine (TT4), Free Thyroxine (FT4), and Thyroid Stimulating Hormone (TSH) levels between the two groups ($p>0.005$).

CONCLUSIONS

There is a significant difference in TT3 and FT3 among breast cancer patients and the control groups. Thus, this finding underscores the potential importance of TT3 and FT3 as a marker of disease state in BC patients.

Clinical Chemistry

P0398

UNMEASURABLE GLYCOSYLATED HEMOGLOBIN A1C DUE TO HEMOGLOBINOPATHY

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BACKGROUND-AIM

Glycosylated hemoglobin A1c (HbA1c) measurement is widely used for diagnosing diabetes and monitoring blood glucose control in diabetic patients. However, its accuracy can be compromised by various factors, including hemoglobinopathies.

METHODS

This study presents a case involving a patient who presented to our laboratory for biochemical and HbA1c analysis. The HbA1c test was conducted using a cation-exchange high-performance liquid chromatography (HPLC)-based Adams A1C HA-8180V® (Arkray) analyzer.

RESULTS

A 45-year-old woman attended her general practitioner for a routine checkup. During the HbA1c analysis, the instrument was unable to generate a value with a note of abnormal fraction. The hemogram showed Hb 7.8 g/dL, mean corpuscular volume 96.3 fl, mean corpuscular hemoglobin 35 pg, mean corpuscular hemoglobin concentration 34 %, and red cell distribution with 72.9%. Suspecting an hemoglobin variant, capillary electrophoresis of hemoglobin was performed on Minicap® Sebia analyzer which showed a large peak with area 81.4% in the S-window.

CONCLUSIONS

Visual inspection of chromatograms is important to detect non-separation of peaks or the presence of hemoglobin variants. In these cases, the biologist should complete with hemoglobin study and suggest other alternative tests for the patient to monitor blood glucose.

Clinical Chemistry

P0399

THE ASSESSMENT OF ANALYTICAL CHARACTERISTICS OF A NEW INTEGRATED CLINICAL CHEMISTRY ANALYZER DXC 500I (BECKMAN COULTER, USA)

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BACKGROUND-AIM

Tata Medical Center, Kolkata, India, a tertiary cancer care Institute, evaluated the performance of a new platform, the DxC 500i Clinical Analyzer, Beckman Coulter, USA. The investigation of the new instrument focused on thirty-one analytes (metabolic panel, several tumor markers, and procalcitonin), which are of primary importance for the metabolic management of cancer patients.

METHODS

The total imprecision figures were obtained (as per Clinical and Laboratory Standards Institute (CLSI) EP15-A3 guidelines) using bilevel internal quality controls (IQC) in a design with five runs spread over five nonconsecutive days. Patient samples for sixteen analytes were compared to an existing dry chemistry platform (Vitros XT 7600 Integrated System, QuidelOrtho, USA), and limit of blank was evaluated for three analytes according to CLSI EP09-A3 and EP17-A2 guidelines, respectively.

RESULTS

The total imprecision figures were lower than those recommended by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) for optimal (fourteen (56%)), desirable (twenty-one (84%)), and minimal (twenty-four (96%)) specification limits. EFLM lacked guidance for six analytes (19%). When compared with Ricos's database on biological variation, twenty-three (74%) at the low IQC level and twenty-seven (87.1%) of the analytes at the high IQC level were functioning at optimal precision requirements. Further, six (19.35%) and three (9.68%) analytes were at desirable imprecision specifications at lower and higher IQC concentrations, respectively. Serum sodium did not meet the requirements of both specifications but was acceptable as per Clinical Laboratory Improvement Amendments (CLIA) 2024 and the medical decision criteria. When comparing 16 analytes to the dry chemistry platform Vitros XT 7600 Integrated System, twelve analytes showed the Pearson's coefficient to be 0.99 and the remaining four above 0.96. The limit of blank evaluated for three analytes (thyroid stimulating hormone, ferritin, and procalcitonin) showed acceptable performance. It is important to note that all evaluations passed the manufacturer's claims.

CONCLUSIONS

In conclusion, the DxC 500i Clinical Analyzer is suitable for regular use in a tertiary cancer setup in a medium to large laboratory.

Clinical Chemistry

P0400

METHOD COMPARISON OF SIEMENS AND RADIOMETER BLOOD GAS ANALYZERS

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BACKGROUND-AIM

Blood gas analysis (BGA) is a widely ordered test especially in critical care settings such as emergency department, intensive care unit, operating rooms and pediatrics. BGA is of great importance as it reflects tissue perfusion, acid-base status, hemoglobin and electrolyte balance. Our aim in this study was to compare Siemens (RAPIDLAB 1265) and Radiometer (ABL 800) Blood Gas Analyzers.

METHODS

A prospective, randomized, observational, comparative study was performed at Department of Bicohemistry, Selcuk University Faculty of Medicine, Konya, Turkey in December 2024 with 50 randomly selected arterial and venous whole blood samples collected into 2.5 mL electrolyte balanced dry-lithium heparin (100 I.U) containing injectors.

RESULTS

Regression equations were Siemens PCO2 = 0.123273 + 0.920545 Radiometer PCO2; Siemens PO2 = 3.288113 + 1.002451 Radiometer PO2 and Siemens pH = -0.179641 + 1.025641 Radiometer pH. Correlation coefficients between two devices were 0.89, 0.97 and 0.94 for PCO2, PO2 and pH, respectively.

CONCLUSIONS

Siemens blood gas analyzer revealed satisfactory performance compared to Radiometer and is a good alternative in clinical laboratories.

Clinical Chemistry

P0401

HBA1C % LABORATORY MEASUREMENT: NEED FOR A STANDARDIZED NATIONAL METHOD

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BACKGROUND-AIM

Glycated hemoglobin (HBA1c) is a routine clinical test to monitor patients with type 2 diabetes. Two methods are mainly used to measure its blood levels: immunoassay and affinity chromatography. The two assays show different performance that is affected by conditions affecting red blood cell lifespan, e.g. anemia and hemolysis. In Oman, anemia and genetic hemolytic anemia are prevalent and different hospitals use different method. Therefore, we aimed to evaluate precision of the two methods for measurement of HbA1c and with oral glucose tolerance test (OGTT). We also aimed to Identify patient factors in cases of samples with discrepant values between the two methods.

METHODS

This cross-sectional method comparison study. We used HbA1c and OGTT data measured at Sultan Qaboos University Hospital (SQUH) and Armed forces hospital (AFH). Serum samples of 275 subjects were run in paired format between two methods. Patients' files were reviewed to discerntain those subjects who have hemoglobinopathies/ anemia. Block selection was performed to ensure gender and case matching.

RESULTS

Bland-Altman analysis showed 95.27% agreement of the patients analyzed by immunoassay and affinity chromatography. Disagreement of 13 patient (4.7 %) mainly when hba1c above 12% . we did not see significant differences between the two methods by conditions like haemoglobinopathy trait & low A2. Also, the performance between the two assays was not associated with mean hemoglobin and mean cell volume levels.

CONCLUSIONS

We did not see major difference between immunoassay and affinity chromatography, and this was not affected by conditions like haemoglobinopathy trait & low A2.The study recommends standardize national use of one assay to be more cost-effective.

Clinical Chemistry

P0402

REFERENCE VALUES FOR SERUM FOLATE AND VITAMIN B12 IN A SOUTHERN TUNISIAN POPULATION

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BACKGROUND-AIM

The interpretation of test results depends heavily on reference intervals (RI). It can be profoundly affected by variables including age, sex, lifestyle, ethnicity, developmental stage, diet, and other environmental factors. Thus, it is clear that RI needs to be established for every individual population.
The aim of this study is to establish reference intervals for folate and vitamin B12 in a southern Tunisian population.

METHODS

Healthy volunteers were recruited from medical and paramedical staff. Serum levels of vitamin B9 (folate) and vitamin B12 were measured using electrochemical immunoassay (ECLIA, COBAS e 601 Roche Diagnostics) in the clinical biochemistry laboratory. The reference intervals provided by the manufacturer are 3.89–26.8 ng/mL for folate and 197–771 pg/mL for vitamin B12. According to Clinical and Laboratory Standards Institute (CLSI) guidelines, we calculated the 95% reference interval including the 2.5th to 97.5th percentile. The data were analysed using SPSS version 26.

RESULTS

One hundred-thirty healthy individuals were included. The mean age of participants was 52.47 ± 11.78 years (18 - 65 years). The sex ratio was 0.8. Mean folate and vitamin B12 levels were 6.8 ±3.66 ng/ml and 405.28 ±135.17 pg/mL respectively. The reference interval for folate was 2.12-16.34 ng/ml (lower than claimed by the manufacturer). The reference interval for vitamin B12 was 218.55-779.62 pg/mL. There were no significant differences for vitamin B12 and folate levels according to gender subgroups.

CONCLUSIONS

The reference values obtained can help clinicians in the interpretation of folate and vitamin B12 status. The study highlights the importance of establishing local reference intervals for laboratory tests which depend on environmental factors and dietary habits.

Clinical Chemistry

P0403

WHAT TYPE OF CALCIUM SHOULD WE TAKE INTO CONSIDERATION?

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BACKGROUND-AIM

Hypocalcemia in hospitalized patients is common, and an effective method of detection is crucial. Although ionic calcium is the gold standard for diagnosis, this measurement is often not available in all hospitals, clinics or health centers. It is important to know the best way to estimate ionic calcium in the laboratory.

METHODS

A database was created with 2639 records of total calcium, albumin-corrected calcium, ionic calcium, creatinine, and pH corresponding to the year 2023. Total calcium was determined using the arsenazo III method, albumin using bromocresol green, creatinine using the Jaffe method with alkaline picrate (kinetic with blank correction), and pH using potentiometry with a Sanz electrode in blood gas analysis. Using R, descriptive statistics were performed to classify these data into categories of low, normal, or high according to calcium levels.

RESULTS

The reference ranges were 8.50-10.40 mg/dL for total and albumin-corrected calcium, 4.8 a 5.6 mg/dL for ionized calcium.
The number of patients obtained in each category of calcium levels in the studied population is:
Level Total Calcium Calcium Ionic Albumin-corrected calcium
Low 1482 2010 318
Normal 1106 580 2176
High 51 49 145
The results of the evaluation of the different regression models for predicting Ionic Calcium are as follows:
Model MSE R-squared
Model with Calcium corrected for Albumin 0,079 0,584
Model with only Total Calcium 0,067 0,634
Model with Total Calcium + pH 0,063 0,643
Model with Total Calcium + pH + Albumin 0,059 0,657
Model with Total Calcium + pH + Albumin + Creatinine 0,055 0,690

CONCLUSIONS

The findings of the descriptive statistical analysis provide valuable insight into the distribution of calcium levels among patients. Which shows us that patients with calcium within normal values is higher in the albumin- corrected calcium group demonstrating an overestimation of the results.
Based on these results, for predicting Ionic Calcium, the model that includes Total Calcium, pH, Albumin and Creatinine is the best in terms of accuracy and explanation of variability.

Clinical Chemistry

P0404

UROLITHIASIS IN DIABETIC PATIENTS

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BACKGROUND-AIM

The prevalence of urolithiasis is increasing globally, affecting around 10 to 20% of the population worlwide. Stone formation should be more common in patients with diabetes mellitus.
The aim of this study is to explore the composition of urinary calculi observed in diabetic patients.

METHODS

This is a retrospective study that was conducted at the clinical biochemistry laboratory, over a 13-year period from 2011 to 2024. We included patients with complete clinical informations. Calculi are analyzed on 2 stages: morphological analysis using a binocular optical miscoscope, and stones' composition using Fourier-transform infrared spectrophotometer

RESULTS

The study included 142 diabetic patients with urolithiasis. The sex ratio was 2.3 with a male predominance. The mean age of the patients was 59 years. Mean stone size was 11.7 mm (1 -50 mm). The most frequent type was calcium oxalate monohydrate (36.6% of stones), followed by uric acid stones (15.5% of stones) and calcium oxalate dihydrate (3% of stones). Combined structure of stones was also observed in 31% of cases. The most frequent association was calcium oxalate monohydrate and uric acid (15.5 %).

CONCLUSIONS

Calcium oxalate monohydrate was the most common type in diabetes with urolithiasis. The association with uric acid was also frequent. The evaluation of risk factors is primordial in this population (as hyperoxaluria, hyperuricuria, acid pH .....).

Clinical Chemistry

P0405

METHOD COMPARISON OF TWO DIFFERENT SEROLOGICAL ASSAYS FOR DETECTION OF ANTIBODIES AGAINST SARS-COV-2 IN VACCINATED INDIVIDUALS

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BACKGROUND-AIM

Public health has been greatly damaged by the worldwide Coronavirus Disease 2019 (COVID-19) outbreak, which was brought on by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Strong diagnostic instruments are now required in order to precisely identify and track immunity due to the pandemic

METHODS

From August 1, 2023, to January 31, 2024, a cross-sectional study was carried out at the Dow International Medical College in Karachi, in the Section of Chemical Pathology. Analysis was done on a convenience sample of 187 laboratory employees that was non-probability. Siemens Healthcare Atellica® IM SARS-CoV-2 IgG and Roche Elecsys® were used to evaluate blood samples. Software for SPSS and R was used to conduct statistical studies, which included Bland-Altman plots, bivariate regression analysis, descriptive statistics, Wilcoxon signed-rank test, and Passing-Bablok regression. There was a significance threshold of $p < 0.05$.

RESULTS

Among all participants, 48.7% and 51.3% were tested reactive for Siemens and Roche, respectively. Bivariate regression analyses showed weak correlations for age, gender, Covid-19 status, and vaccination status with both assays. The Bland-Altman plot demonstrated good concordance (red line at 0) between Siemens and Roche assays, though a few outliers were noted. Passing-Bablok regression analysis revealed a proportional relationship with Roche values generally higher than Siemens but with moderate correlation.

CONCLUSIONS

Both Siemens and Roche assays are reliable for detecting SARS-CoV-2 antibodies, with Roche showing slightly higher values. The findings highlightthe utility of serologicaltesting in complementing molecular diagnostics and monitoring immune responses in vaccinated individuals.

Clinical Chemistry

P0406

A CASE REPORT OF CONTASTE INTERFERENCE WITH PROTEIN ELECTROPHORESIS

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BACKGROUND-AIM

Detecting monoclonal immunoglobulin is crucial for diagnosing monoclonal gammopathy. Typically, in clinical settings, monoclonal proteins are identified and quantified using protein electrophoresis.
Certain exogenous substances, such as iodinated contrast agents, interfere with the interpretation of protein electrophoresis.

METHODS

Serum protein electrophoresis was performed using the Capillarys 2 Flex Piercing® capillary zone electrophoresis system.

RESULTS

We present the case of a 60-year-old female patient consulting the rheumatology department for bone pain.
we present the case of a 60-year-old female patient who consulted the rheumatology department for bone pain. Serum protein electrophoresis was requested. The result showed a protidemia of 66 g/L, hypoalbuminemia of 36.3 g/L and a similar appearance of an Alpha 2 peak. The patient was contacted and confirmed the CT scan injected the same day before the sample was taken. Contrast medium interference was suspected. A control protein electrophoresis was performed 15 days later, with no abnormalities.

CONCLUSIONS

Analytical interferences represent significant factors contributing to laboratory errors. It's crucial for laboratories to identify these interferences since they can lead to clinically significant outcomes such as improper treatment, both over and under, and misdiagnoses. There must be a 15-day delay between exposure to the contrast medium and the assessment.

Clinical Chemistry

P0407

A CASE REPORT OF CONTRAST INTERFERENCE WITH PROTEIN ELECTROPHORESIS

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BACKGROUND-AIM

Detecting monoclonal immunoglobulin is crucial for diagnosing monoclonal gammopathy. Typically, in clinical settings, monoclonal proteins are identified and quantified using protein electrophoresis.
Certain exogenous substances, such as iodinated contrast agents, interfere with the interpretation of protein electrophoresis

METHODS

Serum protein electrophoresis was performed using the Capillarys 2 Flex Piercing® capillary zone electrophoresis system.

RESULTS

We present the case of a 60-year-old female patient who consulted the rheumatology department for bone pain. Serum protein electrophoresis was requested. The result showed a protidemia of 66 g/L, hypoalbuminemia of 36.3 g/L and a similar appearance of an Alpha 2 peak. The patient was contacted and confirmed the computed tomography (CT) scan injected the same day before the sample was taken. Contrast medium interference was suspected. A control protein electrophoresis was performed 15 days later, with no abnormalities.

CONCLUSIONS

Analytical interferences represent significant factors contributing to laboratory errors. It's crucial for laboratories to identify these interferences since they can lead to clinically significant outcomes such as improper treatment, both over and under, and misdiagnoses. There must be a 15-day delay between exposure to the contrast medium and the assessment.

Clinical Chemistry

P0408

EXTRA PEAKS IN ALBUMIN ZONE REVEALED BY SERUM CAPILLARY ELECTROPHORESIS : A CASE REPORT

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BACKGROUND-AIM

Capillary electrophoresis is a high-resolution technique for separation serum proteins. Extra peaks in the albumin zone can be detected, which may arise from analytical interferences, genetic variants, or pathological conditions.

METHODS

This study reports the case of a patient hospitalized in the Hepato-Gastroenterology department. Serum protein electrophoresis was conducted using the capillary electrophoresis method with the Sebia Minicap®. The patient also underwent a lipid and liver function assessment.

RESULTS

We present the case of a 52-year-old patient who underwent serum protein electrophoresis, revealing two additional peaks in the albumin zone. Further investigations revealed mixed dyslipidemia with hypertriglyceridemia (3.35 mmol/L, normal range: 0.47–1.7 mmol/L) and hypercholesterolemia (12.96 mmol/L, normal range: 2.74–5.6 mmol/L). Jaundice was confirmed by elevated total and direct bilirubin levels (394 µmol/L and 193 µmol/L, respectively). Furthermore, the patient had not been treated with beta-lactams, excluding medication-related causes for these findings.
The observed additional peaks in the albumin fraction were ultimately attributed to interference caused by lipoproteins and bilirubin.

CONCLUSIONS

Extra peaks in the albumin zone could indicate an underlying pathological process. Biologist should comment them in the report. This can prompt the clinician to conduct further investigations and guide the management of the patient.

Clinical Chemistry

P0409

FACTITIOUS HYPERKALEMIA : A CASE REPORT

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BACKGROUND-AIM

Factitious hyperkalemia or pseudo-hyperkalemia refers to an artificial elevation in potassium levels (K+) in the blood. It is often associated with pre-analytical errors.

METHODS

This study presents the case of a nurse employed at pediatric departement who presented a blood sample to the biochemistry laboratory for a routine check up. The blood was collected using lithium heparin as anticoagulant. Blood electrolytes were tested on Beckman Coulter® AU DxC 700 analyzer (indirect potentiometry).

RESULTS

We report a case of a severe hyperkalemia, with a potassium level of 7 mmol/L, identified during a routine check up of a 34-years-old nurse with psychiatric disorders. False hyperkalemia was suspected due to the absence of clinical and electrocardiographic abnormalities (normal electrocardiogram). Renal function was normal. However, concomitant hyponatremia was noted (sodium (Na+) = 120 mmol/L) with a chlorid level(CL−) of 108.6 mmol/L . The plasma sample showed no evidence of hemolysis. Calcium level was normal excluding contamination by potassium salts of ethylene diamine tetra acetic acid (EDTA; hematology tubes). The patient was admitted to the endocrinology department. A follow-up electrolytes testing yielded normal results (K+ = 4.4 mmol/L ; Na+= 138 mmol/L and Cl− = 106 mmol/L). An addition of potassium chloride (KCl) to the blood sample by the patient was suspected leading to pseudohyperkalemia and pseudohyponatremia (dilution effect).

CONCLUSIONS

Factitious hyperkalemia is a relatively common phenomenon in medical laboratories. Identification of pre-analytical factors contributing to this false elevation is crucial to avoid unnecessary and potentially harmful treatments.

Clinical Chemistry

P0410

VITAMIN D AND SECONDARY HYPERPARATHYROIDISM IN CHRONIC KIDNEY DISEASE

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BACKGROUND-AIM

Chronic kidney disease (CKD) is commonly associated with a deficiency in 25-hydroxyvitamin D (25OHVD), which contributes to hypocalcemia and may trigger a compensatory increase in parathyroid hormone (PTH) levels.
This study aimed to evaluate the vitamin D status in patients with CKD and assess the potential occurrence of secondary hyperparathyroidism (sHPT).

METHODS

This descriptive study utilized retrospective data collection from patients with CKD who underwent simultaneous measurement of 25OHVD and PTH at the Biochemistry Laboratory of Hédi Chaker University Hospital in Sfax, over a period of two months (July and August 2024). According to the Institute of Medicine, vitamin D insufficiency was defined by serum concentrations between 20 and 30 ng/ml, while vitamin D deficiency was defined as a level below 20 ng/ml. A normal PTH level was considered to be between 12 and 88 pg/ml. 25OHVD and PTH levels were analyzed using an electrochemiluminescence assay on the Beckman DXI 600 analyzer.

RESULTS

A total of 115 patients were included in this study, including 65 men and 50 women. The mean 25OHVD level was 22.77 ± 18.8 ng/ml (range: 2.7 – 121.5 ng/ml). Of these, 64 patients (55.7%) had vitamin D insufficiency, 28 patients (24.3%) had vitamin D deficiency, and only 23 patients (20%) had normal 25OHVD levels. The mean PTH level was 297.3 pg/ml (range: 6 – 2309 pg/ml). A total of 80 subjects (69.6%) had hyperparathyroidism, 65 of whom also had vitamin D insufficiency or deficiency.

CONCLUSIONS

The vitamin imbalances observed in this study suggest the need for routine measurement of 25OHVD and parathyroid hormone levels as part of the biological assessment for all patients with chronic kidney disease, to ensure better patient management and prevent cardiovascular, bone complications and mortality.

Clinical Chemistry

P0411

THE INFLUENCE OF SEASONS ON VITAMIN D LEVELS IN A SOUTHERN TUNISIAN POPULATION

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BACKGROUND-AIM

25-hydroxyvitamin D (25OHVD), commonly known as the 'sunshine vitamin', is primarily synthesized endogenously in the skin under the influence of ultraviolet rays from the sun. The aim of this study was to assess vitamin D status and compare the results between the winter and summer periods.

METHODS

A retrospective descriptive study conducted in the Biochemistry Laboratory of the Hédi Chaker University Hospital in Sfax Tunisia, focusing on vitamin D requests. The study covered a period of 4 months, with 2 months in winter (January and February 2024) and 2 months in summer (July and August 2024). 25OHVD was analyzed using a chemiluminescence assay on the Beckman DXI 600 analyzer. According to the Institute of Medicine, vitamin D insufficiency was defined by serum concentrations between 20 and 30 ng/ml, and vitamin D deficiency was defined as a level below 20 ng/ml.

RESULTS

A total of 554 patients were included in the study, with 267 enrolled during the winter and 287 during the summer. The cohort consisted of 210 men and 344 women. The mean vitamin D level was 22.88 ± 20 ng/ml (range: <2 - 186 ng/ml). In winter, the average was 22.04 ng/ml, while in summer, it was slightly higher at 23.65 ng/ml. Normal vitamin D levels were observed in 20.6% of cases in winter and 24% of cases in summer. Vitamin D insufficiency was noted in 16.1% of patients in winter and 24.7% of patients in summer. However, vitamin D deficiency affected 63% of patients in winter and 51.2% in summer.

CONCLUSIONS

Vitamin D deficiency is prevalent in this population in southern Tunisia. A slight improvement in vitamin D status is observed during the summer months compared to winter. Public health measures such as vitamin D supplementation or dietary recommendations may be necessary to mitigate seasonal deficiencies.

Clinical Chemistry

P0412

ELECTROLYTES DISORDERS IN DIABETIC KETOACIDOSIS: A CASE REPORT

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BACKGROUND-AIM

Diabetic ketoacidosis patients present frequently electrolyte disorders. They may be related either to this metabolic complication or to the treatments administered.

METHODS

A 27-year-old pregnant woman with a 12-year history of type 1 diabetes presented with uncontrollable vomiting. A diabetic ketoacidosis was diagnosid. An insulin infusion via an electric syringe pump was instored.

RESULTS

Follow-up laboratory results showed potassium level of 3.13 mmol/L (normal range: 3.4–4.5), phosphate level of 0.25 mmol/L (normal range: 0.81–1.45), magnesium level of 0.61 mmol/L (normal range: 0.7–1.03), and calcium level of 2.37 mmol/L (normal range: 2.2–2.65).
Insulin reactivates anabolic pathways in metabolism leading to a massive intracellular influx of glucose and ions (potassium, phosphate, magnesium, and calcium) at the expense of the extracellular compartment. This explains hypophosphatemia, hypomagnesemia, and hypokalemia. On the other hand, acidosis induces the release of potassium and calcium, resulting in hyperkalemia and hypercalcemia. This explains why potassium levels are not significantly reduced in this case, and why calcium remains normal, in contrast to the other ions, which are severely depleted.

CONCLUSIONS

Systematic repeated determination of plasma electrolytes are necessary in monitoring diabetic ketoacidosis patients during treatment.

Clinical Chemistry

P0413

ASYMPTOMATIC HYPERCKEMIA: A CASE REPORT

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BACKGROUND-AIM

Elevated creatine kinase (CK) levels are indicator of muscle injury. However, elevated CK levels can be found incidentally in patients with mild or no muscle symptoms.

METHODS

A 41-year-old men presented to his endocrinologist with diffuse muscle pain, predominantly in the girdles. He had a previous history of hypertriglyceridemia treated with fenofibrate since three months. A routine panel, including creatine kinase measurement, was requested. The CK level was determined using a BECKMAN DXC AU 700 analyzer. The reference range for CK is between 49 and 171 IU/l.

RESULTS

CK testing revealed an elevated level of 1202 IU/l, which is 8 times higher than the normal range, prompting a reduction in the fibrate dosage. CK testing was repeated after a period of rest and interruption of fibrate treatment, and the levels remained elevated. They were consistently 1.5 fold higher than normal values.
No myalgias or other neurological symptoms were described. No family history for any neuromuscular disease and for any CK elevations. Physical examination showed no evidence of neuropathy. Further laboratory investigations including SGOT (Serum Glutamate Oxaloacetate Transaminase), SGPT (Serum Glutamate Pyruvate Transaminase), kidney function, thyroid and parathyroid hormone levels were within normal ranges. The search for macro-CK was negative. There were no signs of connective tissue disease or vasculitis (no arthralgia, skin signs, uveitis, proteinuria, or positive antinuclear antibodies). Viral serologies were negative. A neoplastic cause was unlikely (computed tomography of the thorax and abdomen revealed no abnormalities). The electromyogram of four limbs revealed normal findings.
Therefore, iatrogenic origin, the intake of fibrates, was the most suspect. Although it may be a contributing factor rather than the sole cause, as CK levels remained elevated one year after discontinuing fibrates. An idiopathic cause is suggested due to the lack of symptoms and a negative etiological investigations.

CONCLUSIONS

Idiopathic hyperCKemia, although typically benign, is a diagnostic dilemma for physicians. It is important to consider the various potential causes of elevated CK levels before labeling it as idiopathic.

Clinical Chemistry

P0414

COMPARATIVE EVALUATION OF PROCALCITONIN ASSAYS: INTERCHANGEABILITY BETWEEN TWO DIAGNOSTIC METHODS FOR BACTERIAL INFECTIONS

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BACKGROUND-AIM

Procalcitonin (PCT) has become a vital biomarker in laboratory diagnostics for bacterial infections. The ability of PCT to differentiate bacterial infections from other inflammatory conditions makes it an essential tool for clinicians in determining the need for antibiotic therapy. The aim of this study is to conduct a comparative study to evaluate the degree of agreement and interchangeability of procalcitonin results between two different analytical unit: VITROS® 5600 analytical unit (Quidelortho, San Diego, California, United States) and Cobas® e 801 analytical unit (Roche, Basel, Switzerland).

METHODS

Fifty-eight serum samples from different patients, representing a range of measurements, were simultaneously analysed with both analytical units. The samples were supplied by the Clinical Analyses Department from our hospital. All analyses were performed using R commander. The normality of data was evaluated using a Kolmogorov-Smirnov test. Descriptive data are cited as median and interquartile range in case of non-normal distribution for each of the variables were calculated. A Wilcoxon matched-pairs signed rank test was used to compare the results from both units. The Spearman's correlation coefficient (ρ) to determine potential correlation between the resultswas calculated. For absolute values of (ρ), 0-0.19 is regarded as very weak, 0.2-0.39 as weak, 0.40- 0.59 as moderate, 0.6-0.79 as strong and 0.8-1 as very strong correlation.

RESULTS

The values of PCT were 0.465 (0.15-1.07) and 0.377 (0.156-1.00) using VITROS® 5600 analytical unit and Cobas® e 801analytical unit, respectively. VITROS® 5600 analytical unit showed significantly higher results than Cobas® e801analytical unit (p-value<0.0001). Plotting the numbers from both units showed a very strong positive correlation (ρ = 0.9766304, p-value <0.0001).

CONCLUSIONS

In conclusion, VITROS® 5600 analytical unit showed higher PCT values than Cobas® e 801analytical unit, although the results given by both analytical units were highly correlated.

Clinical Chemistry

P0415

STABILITY OF CHOLESTEROL, TRIGLYCERIDES AND GGT ON THE GEL AFTER THREE DAYS

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BACKGROUND-AIM

For cholesterol (CHOL), triglycerides (TGL) and γ-glutamyl transferase (GGT) analisys manufacturer#s recommendation for storage of separated specimens are at 2-8°C up to two days. The aim of this study was to evaluate stability of CHOL, TGL and GGT in the serum on gel after storage at 2-8°C up to three days (72h).

METHODS

Samples of 37 patients were analyzed for CHOL, TGL and GGT on Dimension Xpand Plus (Siemens, Dublin, Ireland) biochemistry analyzer. Blood was collected for routine laboratory analysis in BD Vacutainer Rapid Serum Tube (RST) (REF 368774), with additive (Thrombin-based medical clotting agent) and gel separator. Analysis was performed upon arrival into laboratory after which samples were stored at 2-8°C for further analysis. Coefficient of variation (CV) of normal analytical quality control for CHOL was 0,97%, TGL was 0,00% and GGT was 0,00% and CV pathological control was 0,00%, 0,93% and 0,90% for CHOL, TGL and GGT. Statistical analysis was performed using MedCalc statistical software (Mariakerke, Belgium).

RESULTS

Results of measurement were compared using paired t-test where mean difference (MD) and standard deviation (SD) of MD were used for the difference assessment. MD were compared with CV of daily analytical quality controls. CHOL concentration expressed as mean±SD at 0h and 72h was 5,8±0,74 mmol/L and 5,9±0,76 mmol/L, MD±SD=0,10±0,02 (1,69%). TGL concentration expressed as mean±SD at 0h and 72h was 1,3±0,74 mmol/L and 1,3±0,74 mmol/L, MD ±SD=0,0±0,00 (0,00%). GGT concentration expressed as mean±SD at 0h and 72h was 32±21,53 U/L and 32±21,52 U/L, MD±SD=0±0,01 (0,00%).

CONCLUSIONS

Although mean difference between two measurements for CHOL (1,69%) is higher than both CV control (normal 0,97%; pathological 0,00%), for TGL (0,00%) and GGT (0,00%) is lower or same than both CV of quality controls for TGL and GGT. The result implies that serum on gel samples can be used for TGL and GGT analysis after prolonged storage if necessary.

Clinical Chemistry

P0416

SALINE SOLUTION INTERFERENCES WITH LABORATORY TEST RESULTS: A CASE STUDY

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BACKGROUND-AIM

Interference by exogenous substances with assays for clinical analytes is a common problem in Clinical Chemistry. One of the exogenous substances that can affect laboratory test results is saline solution.

METHODS

An 85-year-old male patient with severe dyspnea, atrial flutter, and a medical history of ischemic cardiomyopathy was hospitalized. The patient was treated with an ACE inhibitor, furosemide, and spironolactone. Our patient was treated at the Clinic for Heart Disease of our Clinic Centre, and laboratory investigation was done: glucose 2.42 mmol/L (3.3-6.1 mmol/L); urea 2.45 mmol/L (2.8-8.3 mmol/L); creatinine 44.2 µmol/L (63-109 µmol/L); sodium 151 mmol/L (136-145 mmol/L); potassium 3.1 mmol/L (3.6-5.2 mmol/L); and chloride 124 mmol/L (98-108 mmol/L). The laboratory tests were done using Alinity (ABBOTT).

RESULTS

The analysis showed a low glucose concentration of 2.66 mmol/L, which was lower than the reference range of 3.3 to 6.1 mmol/L. The other results had high sodium and chloride concentrations. After talking to the clinic, we knew that the patient had received a saline infusion, so a new blood sample was requested, which gave completely different results. In the second sample were glucose 3.99 mmol/L; urea 4.3 mmol/L; creatinine 70.7 µmol/L; sodium 142 mmol/L; potassium 4.5 mmol/L; and chloride 106 mmol/L. Glucose, urea, and creatinine were reduced in the first sample compared to the second sample. The values of sodium and chloride are significantly higher in the first sample than in the second.

CONCLUSIONS

The saline solution has interferences with potassium blood concentration. Sodium and chlorides are approximate in patients with values from saline solution and are falsely increased. The changed values are caused by the effect of the saline solution.

Clinical Chemistry

P0417

METHOD PERFORMANCE EVALUATION OF AUTOMATED ANALYZER FOR BIOCHEMICAL PARAMETERS THROUGH SIX SIGMA METRICS

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BACKGROUND-AIM

Accurate and precise measurement of biochemical parameters is critical for diagnosing and managing cardiovascular diseases in cardiac care settings. Automated analyzers offer reliable and rapid results, but performance evaluations for precision, accuracy, and compliance with regulatory guidelines are essential before implementation. This study evaluates the method performance of an Abbott Alinity ci analyzer, focusing on precision, accuracy, and Six Sigma metrics for routine and immunoassay parameters.

METHODS

After IRB approval, this prospective study was conducted in the Biochemistry Section, Department of Pathology and Laboratory Services at NICVD. Twelve parameters, including routine chemistries (ALT, Total Bilirubin, Calcium, Cholesterol, Creatinine, HbA1c, Sodium) and immunoassays (PCT, TSH, hs Troponin I, T3, T4), were analyzed. Precision was assessed over five days using internal quality controls, while accuracy was evaluated through instrument-to-instrument comparisons across two analyzer modules. Performance was further investigated using Six Sigma metrics. Statistical analyses were performed using EP Evaluator software, incorporating methods such as Bland-Altman and regression analyses.

RESULTS

Precision analysis demonstrated that most analytes exhibited excellent reproducibility, with CV values below the acceptable threshold of 5%. However, TSH at control level 1 exceeded its CV claim, requiring further evaluation. Accuracy analysis revealed strong correlations ($R \geq 0.968$) for all parameters, with results adhering to Total Error Allowable limits. Six Sigma metrics classified most analytes within the "Good" range ($\sigma \geq 3$ to < 6), with HbA1c nearing "World-class" performance ($\sigma = 5.31$). Calcium and Procalcitonin fell into the "Improvement needed" category ($\sigma < 3$).

CONCLUSIONS

The Abbott Alinity ci analyzer demonstrated strong performance for most biochemical parameters, aligning with industry standards. Precision and accuracy were robust for most analytes, though improvements are needed for TSH, Calcium, and Procalcitonin to achieve world-class performance. These findings emphasize the analyzer's reliability while identifying targeted areas for optimization, ensuring high-quality diagnostics in a cardiac care setting.

Clinical Chemistry

P0418

ZYMOGRAPHY METHOD SUITABLE FOR ANALYSIS OF URINARY PROTEASE ACTIVITY

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BACKGROUND-AIM

Urine contains many proteases, including cathepsin D; however, the exact mechanism related to protein degradation is unclear. In addition, in our laboratory, we found that albumin was degraded when added to healthy control urine and stored at 25°C and 37°C. Based on these results, we speculate that the degradation of albumin was caused by proteases. To date, most research on urinary proteases has focused on patients with kidney disease, and many factors regarding the types and levels of activity of urinary proteases in healthy individuals are unknown. Typically, zymography methods are used to study proteases. However, commercially available gels mainly contain gelatin and casein and are not suitable for urinary protease analysis. Therefore, this study aimed to examine the suitability of a zymography method developed in our laboratory for analyzing urinary protease activity.

METHODS

Urine samples from healthy controls were used in this study. Urinary protease activity was detected using zymography. A 12.5% polyacrylamide gel was used in the zymography method. Commercially available human serum albumin polymerized with 1-ethyl-3-(3-dimethylaminopropyl) carbodiimide hydrochloride (EDC) was added to the gel. In addition, a protease inhibitor (pepstatin A) was added to the samples to detect changes in protease activity.

RESULTS

In this zymography method, when human serum albumin was used as the substrate in the gel, one band was detected at 200 kDa, three at 70-80 kDa, and one at 30 kDa, confirming protease activity. Additionally, it revealed that albumin degradation was inhibited when pepstatin A was added.

CONCLUSIONS

Urine samples from healthy controls contain several proteases that degrade albumin. It was found that the zymography method used in our study was capable of detecting urinary proteases because albumin degradation was inhibited by the addition of pepstatin A.

Clinical Chemistry

P0419

CIRCULATING OXIDIZED LOW-DENSITY LIPOPROTEIN LEVELS IN AN EARLY STAGE OF ACUTE ISCHEMIC STROKE

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BACKGROUND-AIM

Atherosclerosis remains the most common cause of coronary artery disease (CAD) and cerebral or peripheral artery disease. At present, lipid peroxidation is considered one of the basic mechanisms involved in the initiation and progression of many diseases. An oxidative stress resulting in lipid peroxidation and protein modification is involved in the pathogenesis of atherosclerosis and cardiovascular diseases.
The aim of this study was to determine the circulating levels of oxidized low-density lipoprotein (ox-LDL) in patients with acute stages of ischemic stroke.

METHODS

Seventy-five patients with acute ischemic stroke (AIS) and ninety control subjects without cardiovascular risk factors were included in the study. Total cholesterol, triglycerides, HDL-cholesterol, and LDL-cholesterol were measured in patients as well as in control subjects by enzymatic methods on Roche C311 Cobas Analyzer. Ox-LDL was measured by the sandwich ELISA technique.

RESULTS

There was no significant difference in BMI, total cholesterol, triglycerides, HDLc, and LDL-c between the two groups. There was a significant difference between patients with AIS and the control group regarding ox-LDL concentrations ($p=0.03$). We did not find any significant correlation between plasma ox-LDL concentration and lipid parameters.

CONCLUSIONS

Levels of circulating ox-LDL were elevated in patients with acute ischemic stroke. Ox-LDL levels were not statistically correlated with major lipid risk factors for CVD. Therefore, ox-LDL levels may represent a novel risk marker of CVD.

Clinical Chemistry

P0420

GLYCAEMIC BALANCE AND LIPID PROFILE IN TYPE 2 DIABETIC PATIENTS IN A REGION OF SOUTHERN TUNISIA (TATAOUINE)

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BACKGROUND-AIM

The aim of our work is to evaluate the relationship between lipid profile variation and glycaemic control in type 2 diabetics.

METHODS

This is a retrospective study of 73 type 2 diabetic patients followed up at the outpatient clinic of the Tataouine Regional Hospital and the various basic health groups of the Tataouine region during the month of December 2024.
Glycaemia and lipid parameters were measured on the Beckman coulter AU480 automated system, HbA1C was measured by HPLC on the ADAMS A1C Lite HA-8380V automated system.

RESULTS

Our population had a classic type 2 diabetes profile with an average age of 60 and a predominance of women (sex ratio M/F=0.4%): 71.2% women compared with 28.8% men.
Patients were divided into two groups according to glycaemic control: 72.6% with unbalanced type 2 diabetes (Group 1: HbA1c>7%) versus 4% with balanced type 2 diabetes (Group 2: HbA1<=7%).
By comparing the lipid profile observed in unbalanced type 2 diabetics (Group 1) versus that observed in patients with controlled type 2 diabetes (Group 2), we find respectively: hypertriglyceridaemia (75% versus 73.6%), hypercholesterolaemia (60% versus 58.5%).
Of the 73 patients, 7 patients had their LDL determined and 7 had their HDL measured.
Two patients in group 1 had hypoHDLemia and hyper LDL, while one patient in group 2 had hyper LDL and two had hypoHDLemia.

CONCLUSIONS

Poorly controlled diabetes is one of the leading causes of death in developed countries. Lipid disorders remain significant in patients with type 2 diabetes. Good control of diabetes by raising patients' awareness of lifestyle and dietary changes, combined with regular monitoring, is essential to prevent cardiovascular complications and improve the quality of life of diabetics.

Clinical Chemistry

P0421

LIVER FUNCTION TESTS AND FASTING BLOOD GLUCOSE LEVELS OF ADULT MALE KHAT CHEWERS IN DILLA TOWN, SOUTHERN ETHIOPIA: A COMMUNITY BASED COMPARATIVE CROSS-SECTIONAL STUDY

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BACKGROUND-AIM

Khat is widely produced and consumed in Ethiopia. Studies showed that khat chewing has been associated with public health issues such as hepatic injury and diabetes. There are also contradictory findings, which call for further studies, regarding the levels of liver function tests and fasting blood glucose among khat chewers. Therefore, the purpose of this study was to determine liver function tests and fasting blood glucose levels of adult male khat chewers.

METHODS

A community-based comparative cross-sectional study was carried out from June to September 2023 in Dilla town, Southern Ethiopia. Two hundred apparently healthy adult male participants (100 khat chewers and 100 non-khat chewers) were selected with a convenient sampling technique. Structured, pretested and translated questionnaires were used to collect study participants' data. Levels of liver function tests and fasting blood glucose were analysed using Siemen dimension EXL200 automated clinical chemistry analyser. The data were coded and entered into Epi-data version 4.6 and then exported to SPSS version 27 for analysis. Mann-Whitney test, Kruskal Wallis test and Spearman's correlation were used for statistical analysis. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Khat chewers showed a statistically significant increase in the levels of transaminase enzymes (ALT and AST) and FBG than non-khat chewers ($P < 0.001$, $P = 0.007$, and $P = 0.002$), respectively. However, there was no statistically significant difference in the levels of ALP ($P = 0.098$), TP ($P = 0.113$), DBI ($P = 0.139$) and TBI ($p = 0.095$) among khat chewers compared to non-khat chewers. Duration and frequency of khat chewing showed a significant and positive association with ALT, AST, and FBG levels. Additionally, there was a significant and positive correlation of systolic blood pressure with AST and FBG levels. Age, diastolic blood pressure and bundle of khat had a significant and positive association with ALT levels.

CONCLUSIONS

The present finding concluded that higher LFTs and FBG are associated with khat chewing depending on the duration, frequency and amount of bundle used. We recommend further longitudinal studies to know the effect of khat chewing on the levels of liver function tests and blood glucose.

Clinical Chemistry

P0422

EVALUATION OF SERUM PROSTATE SPECIFIC ANTIGEN IN AGE- MATCHED MEN WITH TYPE 2 DIABETES

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BACKGROUND-AIM

Prostate-specific antigen (PSA) is an important marker for assessing prostate health, particularly in prostate cancer diagnosis. However, changes in men with type 2 diabetes may affect the accuracy of prostate cancer risk assessment. Although type 2 diabetes is associated with higher risk of cancer, including those of the pancreatic, liver and breast, there is evidence that men with diabetes have a lower incidence of prostate cancer. Studies on the association between type 2 diabetes and PSA level in Nepal are still limited.
Objective: This study aims to evaluate serum PSA levels in age-matched men with Type 2 diabetes and compare them to non-diabetic controls. Secondary objectives included correlating PSA levels with age, BMI, and other biochemical parameters in diabetic participants.

METHODS

Methods: A hospital-based, comparative, cross-sectional study was conducted in 100 male participants aged 40 years and above, divided into 50 diabetic and 50 non-diabetic subjects. Serum PSA and HbA1c concentration were measured using chemiluminescence immunoassay (CLIA) and immunoturbidimetry, respectively. Statistical analysis included independent t-test, Mann-Whitney U test, and Spearman correlation, with a significance of $p < 0.05$.

RESULTS

Results: Diabetic participants exhibited significantly lower median PSA levels (0.92 ng/mL) compared to non-diabetic participants (1.1 ng/mL; $p = 0.01$). HbA1c levels was higher in diabetic subjects (6.22 ± 1.25) than non-diabetics (4.66 ± 0.84; $p < 0.001$). Correlation analysis showed that PSA levels of subjects was positively correlated with age ($r = 0.31$, $p = 0.002$), while PSA was negatively correlated with HbA1c ($r = -0.27$, $p = 0.007$)

CONCLUSIONS

Conclusion: This study shows that men with Type 2 diabetes have lower serum PSA levels than men without diabetes. The findings suggest considering diabetes status when interpreting PSA results in prostate cancer screening. Further research could focus on improving PSA screening guidelines for diabetic populations to increase the accuracy of prostate cancer risk assessments.

Clinical Chemistry

P0423

PROGNOSTIC VALUE OF SOME HEMOSTASIS PAREMETERS, HOMOCYSTEINE, HIGH SENSITIVE CRP AND MULTIDETECTOR COMPUTED TOMOGRAPHY PARAMETERS IN PULMONARY EMBOLISM

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BACKGROUND-AIM

Nowadays, an arsenal of diagnostic methods is used in diagnosis of pulmonary embolism, which includes laboratory studies, x-ray, angiography, perfusion-ventilation scintigraphy, CT MRI and Doppler.
Purpose of our study was to evaluate the diagnostic significance of determination of some parameters of hemostasis - D-dimer, Soluble fibrinmonomer complexes(SFMC), fibrinogen, homocysteine, HS-CRP and computed tomography in suspected pulmonary artery thromboembolism(PATE).

METHODS

We have examined 54 patients -31 men and 23 women, aged 38 to 76 years, with characteristics of pulmonary embolism(Group I). Control group was with 59 healthy patients. Hemostasis parameteres studied on analyzer STA Compact Max(Diagnostica Stago). Homocysteine was studied on biochemical analyzer Cobas c 311(Roshe Diagnostics).

RESULTS

in Group I , measuring D-dimer was incresed up to 5.0±0.05 mkg/ml, fibrinogen
was 6.1±0.02g/l, SFMC also increased and was 12,0±0,03g/l, hyperhomocysteinemia increased up to 26,2±0,4 mkmol/l , with level of HS-CRP up to 20.3±0.04mg/l.

CONCLUSIONS

According to our data, multidetector computed tomography angiopulmonography , measuring D-dimer, fibrinogen, SFMC and related hyperhomocysteinemia with increased level of HS-CRP may serve as binding, diagnostically significant laboratory markers in the diagnosis and treatment efficacy of pulmonary thromboembolism.

Clinical Chemistry

P0424

EVALUATION OF ICTERIC INTERFERENCE IN CLINICAL BIOCHEMISTRY ASSAYS

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BACKGROUND-AIM

Icterus, elevated serum bilirubin, interferes with clinical biochemistry assays, causing inaccurate results. Automated systems block results above allowable bilirubin levels, leading to delays in diagnostics and compromised patient care. This study investigates the interference of elevated bilirubin on clinical biochemistry tests, evaluates whether the interference is instrument or method dependent, and establishes a dilution protocol to mitigate bilirubin interference.

METHODS

A laboratory experiment was conducted at the clinical biochemistry laboratories of Royal Hospital and Sultan Qaboos University Hospital. Six serum pools with varying creatinine concentrations were prepared, and bilirubin solutions were added to simulate icterus levels from 0 to 1026 μmol/L. Spectrophotometric measurements were obtained using two automated analyzers: Cobas 6000 C501 (Roche) and Atellica CH 930 (Siemens). Statistical analyses calculated percentage bias (i.e., interference) for each spiked sample. To minimize interference, a dilution protocol was designed where icteric samples with indices of 4, 5, and 6 were diluted at ratios of 3:4, 1:2, and 1:3, respectively, using serum pools with normal bilirubin levels. The diluted samples were reanalyzed to assess the protocol's effectiveness. Ethical approval was obtained per institutional guidelines.

RESULTS

Among the 20 analytes tested, bilirubin interference was observed in four analytes on the Siemens analyzer (creatinine, sodium, triglycerides, and total cholesterol) and six on the Roche analyzer (creatinine, total cholesterol, triglycerides, sodium, total protein, and gamma-glutamyl transferase). Interference became apparent at a bilirubin concentration of 470 μmol/L (spike 4). The dilution protocol, however, did not reduce interference but instead amplified it, a trend consistently observed across all analytes.

CONCLUSIONS

Bilirubin caused significant interference in spectrophotometric assays, with varying analytes affected across the Siemens and Roche instruments. Based on the study findings, tests not significantly impacted by high bilirubin levels can be confidently reported. However, for tests heavily impacted, the dilution protocol was ineffective, highlighting the need for alternative mitigation methods.

Clinical Chemistry

P0425

EVALUATION OF URINE PROTEIN QUANTIFICATION ACCURACY USING VARIABLE SULFOSALICYLIC ACID CONCENTRATIONS IN CLINICAL LABORATORIES

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BACKGROUND-AIM

The sulfosalicylic acid (SSA) coagulation method is widely used in clinical laboratories for detecting proteinuria. Despite the recommended 3% SSA concentration and a 3:1 SSA-to-urine ratio, variations in SSA concentrations are commonly practiced, potentially affecting accuracy and reliability. This study aimed to estimate and compare urine protein concentrations determined using different SSA concentrations (3%, 6%, 20%, and 30%) and the pyrogallol red molybdate dye-binding method. The study also evaluated the compatibility of dipstick strip test grading patterns with SSA-based methods.

METHODS

Urinary protein concentrations from 69 patient samples were analyzed using SSA precipitation methods with selected SSA concentrations, volume-corrected higher SSA concentrations, and the pyrogallol red molybdate dye-binding method. Dipstick strip test results were compared with SSA-based methods for protein grading and quantification. Statistical analysis was performed using SPSS (version 20), employing two-way ANOVA and correlation analysis.

RESULTS

Protein concentrations measured using 3% SSA strongly correlated with the pyrogallol red molybdate method (R^2=0.91, P<0.05). Higher SSA concentrations (>6%) significantly underestimated protein levels compared to 3% SSA unless volume-corrected. Dipstick strip test results aligned significantly with the 3% SSA method but demonstrated reduced reliability at higher protein concentrations. Results from human albumin calibration curves (57.9 ± 71.2) were significantly higher than those from bovine albumin (34.0 ± 36.4), with a mean difference of 23.8 ± 60.9 (P=0.000).

CONCLUSIONS

Quantitative analysis using SSA concentrations higher than 3% with the recommended 3:1 SSA-to-urine ratio yields inaccurate results, making them unsuitable for proteinuria detection. Volume correction improves accuracy for higher SSA concentrations. The dipstick strip test is only compatible with the 3% SSA method for reliable protein quantification. Adherence to recommended protocols is essential to ensure accurate and consistent detection of proteinuria.

Clinical Chemistry

P0426

UNVEILING THE DIAGNOSTIC POTENTIAL OF LNCRNAS IN NON-ALCOHOLIC FATTY LIVER DISEASE

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BACKGROUND-AIM

Non-alcoholic fatty liver disease (NAFLD) is a prevalent chronic liver disease with limited non-invasive diagnostic tools. Long non-coding RNAs (lncRNAs) have emerged as crucial regulators of gene expression in various diseases, including NAFLD. This study investigated the potential of HULC, NEAT1, and GAS5 lncRNAs as biomarkers for NAFLD.

METHODS

This case-control study included 50 healthy individuals and 50 patients diagnosed with NAFLD based on established clinical and imaging criteria. Serum samples were collected from all participants. RNA was extracted, and the expression levels of HULC, NEAT1, and GAS5 were measured using quantitative real-time PCR (qRT-PCR). Statistical analysis included Student's t-test and receiver operating characteristic (ROC) curve analysis.

RESULTS

Serum levels of HULC, NEAT1, and GAS5 were significantly elevated in NAFLD patients compared to the healthy controls ($P < .001$). ROC curve analysis revealed that these lncRNAs exhibited good sensitivity and specificity in discriminating NAFLD patients from healthy individuals.

CONCLUSIONS

Our findings suggest that HULC, NEAT1, and GAS5 lncRNAs hold promise as potential non-invasive biomarkers for the diagnosis of NAFLD. Further large-scale studies are warranted to validate these findings and explore their clinical utility.

Clinical Chemistry

P0427

COMPARISON OF NT-PROBNP MEASUREMENT ON ALINITY I AND IMMULITE® 2000 IMMUNOCHEMISTRY ANALYZERS

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BACKGROUND-AIM

This study aimed to compare NT-proBNP concentration results obtained from two immunochemistry analyzers: Alinity I (Abbott Laboratories, Abbott Park, IL) and Immulite® 2000 Immunoassay System (Siemens Healthineers, Erlangen, Germany). The Alinity i employed chemiluminescent microparticle immunoassay (CMIA) technology while the Immulite 2000 used a chemiluminescent enzyme immunoassay (CLEIA) technique.

METHODS

Serum samples from 65 patients were analyzed using both instruments. Statistical analyses were conducted with MedCalc version 23.1.1 (MedCalc Software Ltd). Correlation between the two methods was assessed using Spearman's correlation test, while assay comparisons were evaluated through Passing-Bablok regression analysis. Measurement differences were quantified by calculating bias with Bland-Altman plots.

RESULTS

NT-proBNP concentrations measured on the Alinity I system ranged from 22 to 35000 pg/mL, with a median value of 2168 pg/mL (95% CI: 940.624-3225.564). On the Immulite 2000 proBNP concentrations ranged from 26 to 35000 pg/mL, with a median of 2526 pg/mL (95% CI: 1137.818–4343.367). A strong correlation was observed between the two methods, as indicated by a Spearman's correlation coefficient of r = 0.979. Bland-Altman analysis revealed that over 95% of data points fell within ±1.96 SD of the mean, with limits of agreement between -1376.404 and -489.912 and a mean difference of -0.001. Passing-Bablok regression analysis showed an intercept of -0.7019 (95% CI:. 44.468- to 27.033) and a slope of 0.8463 (95% CI: 0.790 to 0.881) for the entire dataset.

CONCLUSIONS

The findings of this study demonstrated an acceptable level of agreement between NT-proBNP concentration measurements obtained from the Alinity I and Immulite 2000 platform. However, further evaluation in larger-scale studies is necessary to determine whether clinicians can reliably evaluate or initiate appropriate therapy based on consecutive results obtained from these two different analyzers.

Clinical Chemistry

P0428

OPTIMISING SERUM IMMUNOFIXATION ELECTROPHORESIS FOR MONOCLONAL PROTEIN IDENTIFICATION USING β-MERCAPTOETHANOL: A QUALITY IMPROVEMENT INITIATIVE.

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BACKGROUND-AIM

Investigation of monoclonal gammopathies (associated with malignant conditions such as multiple myeloma) involves the analysis of a patient's serum using agarose gel electrophoresis and immunofixation (serum IFE). This technique separates proteins based on their molecular weight and charge, producing distinct fractions. Monoclonal proteins appear as specific restricted bands, usually in the gamma fraction, and can be of any immunoglobulin (Ig) class (IgG, IgA, IgM, IgD, or IgE) or light chain type (kappa or lambda). Increases in the gamma globulin fraction with diffuse staining suggests polyclonal gammopathies linked to non-malignant conditions. Immunoglobulins can exist in various oligomeric forms and may form heterodimers, which may appear as overlapping restricted bands or diffuse bands, leading to potential misinterpretation of results. Beta-mercaptoethanol (BME) can reduce disulfide bonds within oligomeric structures and potentially improve the accuracy of result interpretation. However, literature on its use in serum IFE is limited and lacks consistent details on experimental conditions, including BME concentration, incubation time, and temperature. The present study aims to optimise the laboratory protocol for the use of BME to improve the resolution and quality of serum IFE results at a tertiary hospital in South Africa.

METHODS

Following serum IFE for specimens that were received at our laboratory for routine analysis (from January to December 2024), those that displayed poor resolution were used. Various BME concentrations (0.25%, 0.5%, 1%, 2%, and 5% v/v), incubation periods (5-, 15-, 20-, 30-, and 120-minutes), and incubation temperatures (room temperature, 37 ^{0}C, 100 ^{0}C/ boiling) were investigated. Results under various experimental conditions were visually assessed.

RESULTS

BME improved the resolution of serum IFE results in a dose-dependent manner and the best resolution was observed with 2% (v/v) BME. Superior serum IFE resolution was observed when incubating serum with BME at 37 ^{0}C compared to room temperature. A 30-minute incubation of serum with BME resulted in the best serum IFE resolution.

CONCLUSIONS

The optimal experimental protocol identified in this study was observed when serum was incubated with 2% (v/v) BME for 30 minutes at 37 ^{0}C.

Clinical Chemistry

P0429

CHOLESTEROL METABOLISM PROFILE IN PREGNANT WOMEN AFFECTED BY PREECLAMPSIA

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BACKGROUND-AIM

Numerous studies have indicated the link between dyslipidemia and pregnancy complications, particularly preeclampsia. Some studies have shown that non-cholesterol sterols could be more sensitive biomarkers of disbalance in cholesterol homeostasis. They can indicate early development of dyslipidemia and as such they are interesting for further investigation. The aim of this research was to investigate the longitudinal trajectory of changes in cholesterol synthesis precursors during high risk pregnancies and preeclampisa.

METHODS

This study analyzed cholesterol synthesis markers in 70 women with high-risk pregnancy without complications (HRG) and a group of 20 pregnant women who developed preeclampsia (PEE).We monitored Body mass index (BMI) and lipid parametrs such as tryglicerides (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C) and low-density lipoprotein cholesterol (LDL-C) in the first (T1), second (T2) and third (T3) trimester. Cholesterol synthesis is followed by the determination of synthesis precursors desmosterol, 7-dehydrocholesterol (7-DHC) and lathosterol.

RESULTS

The results have shown that TG, LDL-C and HDL-C were significantly higher in the PEE group in T2 and T3 compared with HRG ($p<0.05$). Desmosterol, 7-DHC and lathosterol were significantly higher in the high-risk group in T2 and T3 compared with T1 ($p<0.001$). The latosterol levels were higher in T1 in the preeclampsia group compared with the high-risk group ($p<0.05$).

CONCLUSIONS

In conclusion, the results of this study have shown significantly altered lipid parameters in PEE which main characteristic is proatherogenic lipid profile. There is an imbalance in the regulation of cholesterol synthesis in preeclampsia. Some of these parameters could be a further investigated as potential new biomarkers in early preeclampsia prediction.

Clinical Chemistry

P0430

ASSOCIATION BETWEEN URIC ACID LEVELS AND MULTIPLE SCLEROSIS SEVERITY

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BACKGROUND-AIM

Multiple sclerosis (MS) is characterized by inflammation and chronic neurodegeneration due to demyelination of the central nervous system. Oxidative stress plays an important role in its pathophysiology. Uric acid is characterized by its antioxidant capacity, acting as a natural scavenger of peroxynitrite. The aim of this study was to evaluate uric acid (UA) levels in MS patients and its correlation with the disease severity.

METHODS

This case-control study was conducted at the clinical biochemistry laboratory. We included 49 patients with relapsing-remitting MS and 49 age-sex matched healthy control population. For each participant, a blood sample was taken to measure UA levels. The degree of neurological disability for each patient was evaluated using the Expanded Disability Status Scale (EDSS) whose score varies from 0 to 10 depending on the disease severity.

RESULTS

The mean age of patients was 33.59 ± 10.18 years (19-55 years). The male-to-female sex ratio was 0.48. The distribution of patients according to their EDSS score ranged from 0 to 5, with predominance of score 1 and 2 (36.7% and 20.4% respectively). Mean UA concentration was lower in patients with MS than the control group (248.32 ± 67 mmol/L vs. 283.66 ± 38.8 mmol/L respectively, p=0.002). Uric acid concentrations were negatively correlated with EDSS scores ($p = 0.016$, $r = -0.3$).

CONCLUSIONS

Patients with MS showed lower serum UA levels when compared with healthy controls. Moreover, the UA concentrations decreased with high MS severity.

Clinical Chemistry

P0431

THE ASSOCIATION OF BODY MASS INDEX AND QUANTITATIVE 24-H URINE METABOLITES IN OBESE PATIENTS

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BACKGROUND-AIM

Obesity is a major risk factor for various metabolic, cardiovascular, and renal disorders. It is also associated with alterations in the biochemical composition of urine and can increase the risk of urolithiasis. This study aimed to analyze the biochemical composition of 24-hour urine in obese patients and evaluate the impact of body mass index (BMI) on urinary excretion of different metabolites.

METHODS

This was a cross-sectional study conducted on obese patients recruited from the Endocrinology Department. Patients with a history of urinary stones were excluded. The biochemical analysis of 24-hour urine was performed in the Clinical Biochemistry Laboratory. It included the quantification of magnesium, calcium, phosphorus, uric acid, and urinary electrolytes using validated techniques on the Cobas 6000 analyzer (Roche®).

RESULTS

The study included 79 patients (65 women and 14 men), with a sex ratio of 0.21. The median age of the patients was 55 years [21–71], and the median BMI was 38 kg/m² [31-59.1]. The mean urine collection was 1.4 L/24 hours. Hypercalciuria was present in 11.4% of patients and showed a positive correlation with BMI ($p = 0.019$). Other urinary abnormalities were observed included hyperuricosuria (31.6%), hyperphosphaturia (23%), hypomagnesuria (24.1%), and hypernatriuria (22.8%).

CONCLUSIONS

This study highlights the frequent occurrence of urinary metabolic abnormalities in obese patients, which increase the risk of lithogenesis. These findings underline the importance of regular assessment of urinary biochemical composition in this population with high risk of lithogenesis.

Clinical Chemistry

P0432

ALTERATIONS IN BLOOD GAS SAMPLES INDUCED BY A PNEUMATIC TUBE SYSTEM

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BACKGROUND-AIM

The pneumatic tube system (PTS) is an automated and efficient method of transportation of biological samples widely implemented in modern clinical laboratories to reduce transport time, thereby enhancing overall workflow and accelerating turnaround times. This is particularly beneficial for critical tests like Blood Gas Analysis (BGA), which requires quick results to make important clinical decisions.
However, while PTS can accelerate transport, it raises concerns about the integrity of samples, especially regarding sensitive blood gas parameters such as pH, pCO2, and pO2. This study aims to assess the effect of PTS on the accuracy and reliability of blood gas analysis (BGA) parameters.

METHODS

This was a prospective study involving BGA delivered by courier in accordance with standard protocols. An initial analysis was carried out immediately after receipt by the Siemens RAPID POINTe automated system, then the samples were run through the PTS before undergoing a second analysis. The whole procedure was carried out in less than 30 minutes, to respect the stability of the BGA. The analysis covered parameters including PH, pressure of CO2 and O2, lactates, Sodium, Potassium and ionized calcium. Data were analyzed using SPSS version 17 for windows, and the variation calculated were compared with SFBC standards of acceptability and validation of techniques.

RESULTS

Our study included 50 samples. Only PO2 increased after pneumatic transport and showed a statistically significant difference ($p<0.05$). For 26 samples (52%), the observed difference exceeded the SFBC acceptability limits. On the other hand, no values deviating from the thresholds were found for the rest of the parameters.

CONCLUSIONS

In conclusion, the PTS used in this study maintained the integrity of most of the blood gas parameters, except for PaO2. To minimize potential pre-analytical errors, further optimization of PTS settings is recommended, particularly to ensure accurate PaO2 measurements.

Clinical Chemistry

P0433

HOMOCYSTIENE: PERFORMANCE EVALUATION ELECTROCHEMILUMINESCENCE IMMUNOASSAYS

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BACKGROUND-AIM

Method standardization is essential for achieving result accuracy, which significantly influences patient outcomes. Regulatory organizations, such as the Clinical and Laboratory Standards Institute (CLSI), recommend method validation studies to quantitatively assess system performance, identify potential errors, and evaluate differences between methods. Therefore, this analytical study was undertaken to compare and evaluate two immunoassay methods: Chemiluminescence Immunoassay (CLIA) and the Electrochemiluminescence (ECL) enzymatic assay for measuring plasma homocysteine levels

METHODS

A method validation study was conducted in the Chemical Pathology section of the Department of Pathology & Laboratory Medicine at AKU. Plasma samples were analyzed simultaneously for plasma homocysteine levels to assess imprecision, linearity, and method comparison. The analyses were performed on the Cobas e503 analyzer (Roche, US) using the ECL enzymatic method and the Immulite 2000 xpi (Siemens Diagnostics, US) using the CLIA method. Statistical analysis was carried out using Microsoft Excel and EP Evaluator version 10.3.0.556 (Data Innovations, LLC).

RESULTS

The following studies were performed:
Precision: Precision was evaluated by analyzing two control levels—Low (L1) and High (L2)—20 times each. The coefficient of variation (CV) for L1 and L2 on the Cobas e503 analyzer was 3.7% and 3.4%, respectively.
Linearity and Analytical Measurement Range: To assess linearity and the analytical measurement range, four samples spanning the entire measurement range of the respective instruments were analyzed in triplicate.
Method Comparison: Fifty plasma samples from patients and five proficiency testing specimens provided by the College of American Pathologists were analyzed using both methods. The allowable systematic error was set at 15.0%, with a slope of 1.038, an intercept of 0.280, and a correlation coefficient of 0.9853.

CONCLUSIONS

The agreement between the two methods was satisfactory. Hence, the ECL method can effectively replace the older CLIA method without significantly affecting the clinical results for patients.

Clinical Chemistry

P0434

STUDY OF THE INTEREST OF HAEMATOLOGICAL INDICES IN THE DIAGNOSIS OF HAEMOGLOBINOPATHIES IN SUBJECTS FROM CENTRAL TUNISIA

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BACKGROUND-AIM

Iron deficiency anemia (IDA) and beta-thalassemia trait (ß-TT) share similar clinical and biological charasteristics, making their differential diagnosis complex. The objective of this study was to evaluate the performance of existing red blood cell indices and develop new diagnostic formulas based on hematological parameters.

METHODS

A total of 237 samples were included in the study. For each sample, hemoglobin elecrophoresis, a blood count (red blood cells (RBC), mean corpuscular volume (MCV), mean corpuscular hemoglobin concentration (MCHC), and red blood cell distribution width (RDW)), and ferritin levels were performed. The diagnostic performance (sensitivity, specificity, and area under the curve (AUC)) of 34 red blood cell indices was evaluated in 83 cases of ß-TT and 154 of IDA.

RESULTS

Significant variability in the diagnostic performance of the indexes was notes. The Sirachainan index (1.5 Hb - 0.05 MCV) and the Matos and Carvalho index (1.91 RBC + 0.44 MCHC) were the most effective, with AUCs of 0.801 and 0.847, respectively. In contrast, the Cruise index (MCHC + 0.603 RBC + 0.523 RDW) and the Wongrachum index ((MCV *RDW/ RBC) - 10 Hb) showed poor performance, with AUCs below 0.6. Unpublished indices showed moderate performance. Among the new regression formulas, the Y4 formula (RBC+MCHC+Hb) showed promising results, with an AUC of 0.673, a sentivity of 70%, and a specificity of 73%, outperforming existing indexes.

CONCLUSIONS

Further improvements are needed for clinical application. Future studies with larger multicenter cohorts and longitudinal models are needed to refine diagnostic thresholds and improve the applicability of these indexes.

Clinical Chemistry

P0435

HCG DOSAGE USING BLOOD STRIPS AS AN ALTERNATIVE TO QUANTITATIVE DOSAGE

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BACKGROUND-AIM

Given the increase in the number of requests from HCG contrasting with a low rate of positivity of results and for better speed of rendering of results with a lower cost, we proposed to study the effectiveness and reliability of the qualitative method of serum HCG determination.

METHODS

The prospective study included 50 patients presenting to the gynecology emergency room for suspected EP. A dry tube blood sample was taken from them. For each sample, the quantitative dosage of HCG was carried out on Architect (Abott) using Chemiluminescent Microparticle Immunoassay (CMIA) technology, as well as a qualitative dosage on an HCG test strip (Besure brand) using a chromatographic immunological technique. . The lower limits of detection for HCG measurement are 25 mlU/mL (Besure) and 1.2 mlU/mL (Abott), respectively.

RESULTS

Results:
All results were consistent for both techniques. Furthermore, for the 2 cases of HCG at 22 and 23 mlU/mL, the strips showed a slight positivity (very clear red line in the test region). According to this result, the higher the concentration of HCG, the more intense the color of the band. We did not encounter any false positives or false negatives.

CONCLUSIONS

Conclusion:
Our study clearly showed the reliability of HCG results using test strips. This will allow us to reduce the cost of this test by doing an initial screening using an HCG test strip for all requests and only keeping the quantitative dosage for positive tests.

Clinical Chemistry

P0436

EVALUATION OF IONIZED CALCIUM MEASURED AT CHU ANNABA

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BACKGROUND-AIM

Calcium is an alkaline-earth cation essential to the proper functioning of the body. It circulates in the blood in two forms : bound and free. The free form, also known as ionized calcium, represents the fraction that is regulated by systemic hormones and is physiologically active. Although its assay presents several constraints and interferences, notably the need to collect samples anaerobically, it best reflects the calcium status of the individual.
The aim of this study was to assess the concordance between serum ionized calcium measured without anaerobic collection, corrected ionized calcium and corrected total calcium.

METHODS

This retrospective, cross-sectional, analytical study was carried out in 2024 at CHU Annaba on a sample of 33 samples. Total calcium, albumin and ionized calcium assays were performed in the biochemistry department.
Total calcium and ionized calcium values were corrected for albumin and concomitant serum pH, respectively, using the Siggaard-Andersen equation.

RESULTS

The mean corrected total calcium level was 2.33 ± 0.19 mmol/L, the mean measured ionized calcium level was 1.23 ± 0.12 mmol/L, and the mean corrected ionized calcium level was 1.19 ± 0 .11 mmol/L.
Measured ionized calcium showed a strong and significant agreement with corrected ionized calcium (kappa = 0.868, $p < 0.001$) and a moderate but significant agreement with corrected total calcium (kappa = 0.439, $p < 0.001$).
Furthermore, measured ionized calcium was strongly and significantly correlated with corrected ionized calcium ($r = 0.90$, $p < 0.001$), as well as with moderately but significantly corrected total calcium ($r = 0.54$, $p < 0.001$).

CONCLUSIONS

This study demonstrated significant agreement between measurements of serum ionized calcium and its corrected values, as well as a moderate correlation with corrected total calcium. These results highlight the need for further research, involving a wider population and a variety of clinical contexts, to better understand the biochemical and pathophysiological factors influencing these measurements.

Clinical Chemistry

P0437

VERIFICATION OF THE HIL INTERFERENCES PROPOSED BY ABBOTT ON ALINITY CI SYSTEM

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BACKGROUND-AIM

Serum and plasma may contain some amount of hemoglobin derived from hemolysis (H), bilirubin due to liver failure (I) or may be lipemic (L). These 3 conditions may cause interference in clinical chemistry tests. Therefore, manufacturers must inform their customers what is the impact of these interfering substances on their methods. Manufacturer either considers a deviation of 10% to be clinically significant or only indicates the percentage deviation from the target value. We verified the HIL interferences proposed by the manufacturer using the CLSI EP07-A2 guidelines, and we validated our own interference thresholds.

METHODS

First, we prepared interfering solutions. Hemoglobin was obtained after lysis of red blood cells collected in heparinized tube without gel. Bilirubin was prepared from 97% pure bilirubin and lipids were prepared from 20% Intralipid*solution. Then, we selected at least 2 patient samples with different concentrations of 75 blood parameters measured on Alinity CI (Abbott). We spiked them with increasing concentrations of interfering solutions (ranging from 0% to 100%). Each of these serum was analyzed in triplicate for each parameters. We used the Reference Change Value (RCV) in % as a clinically significant difference between 2 results for the 75 biochemistry and hormonology tests available. We considered that each time a change was higher than the RCV was clinically significant.

RESULTS

For hemolysis, we demonstrated that some parameters were more or less strongly impacted : albumin, amylase, AST, ALT, LDH, iron, lactate, insulin, creatinine, magnesium, phosphorus, chloride, potassium, total protein and folates. For icterus, we showed that some parameters were more or less strongly impacted : GGT, triglycerides, sodium, ammoniac, Alpha-foetoprotein, vitamin B12, cholesterol, chloride, TBII. For lipemia, we demonstrated that some parameters were more or less strongly impacted : calcium, chloride, sodium, albumin, iron, cholesterol-LDL, total protein, potassium, ALT.

CONCLUSIONS

We defined our HIL thresholds and decided to systematically measure HIL index on each tube when measuring chemistry and hormology tests on Alinity CI. If the HIL index is above our newly defined limots, we replace the result obtained by the terms «hemolyzed», «icteric» or «lipemic» accordingly.

Clinical Chemistry

P0438

TYG INDEX AS A BIOMARKER OF STROKE IN DIABETIC PATIENTS IN NORTH INDIAN POPULATION: A PILOT STUDY

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BACKGROUND-AIM

Stroke is the most common cause of death after heart diseases globally. It causes significant physical & mental disability even amongst the survivors. The prevalence of stroke among diabetic patients is estimated to be between 17% and 25% (Stroke National Registry). The TyG index serves as a biomarker to indirectly identify Insulin Resistance, which has been associated with cardiovascular diseases. This study was conducted to assess the predictive capacity of the TyG index about risk of Ischemic stroke in Diabetic patients.

METHODS

A retrospective cross sectional study included 260 individuals (57% males, age: 43.1 ± 16.3 years) with acute ischemic stroke were divided into two groups, with diabetes (55%) and without diabetes. Demographic, anthropometric, clinical-laboratory, and lifestyle data were collected. The TyG index was determined using the formula Ln [fasting triglycerides (mg/dL) × fasting plasma glucose (mg (dL)/2].

RESULTS

Elevated TyG values (≥8.04) were positively associated with stroke risk factors (total cholesterol, LDL, VLDL, uric acid, alanine aminotransferase, aspartate aminotransferase, systolic blood pressure, smoking) in diabetic patients. After adjustment for confounding factors, individuals with high TyG showed an increase of 69% (RP = 1.69; 95%CI =1.03–2.78) in the risk of stroke, compared to those with low TyG in diabetes.

CONCLUSIONS

The results indicated the potential of using the TyG index for early identification of individuals at high risk for Ischemic stroke in Type 2 diabetes.

Clinical Chemistry

P0439

METHOD VERIFICATION OF FERRITIN ON ROCHE COBAS 8000 C7002 AND COMPARISON WITH ROCHE COBAS 8000 E801

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BACKGROUND-AIM

To perform a method verification of the immunoturbidimetric assay of Roche Cobas 8000 c702 for the determination of ferritin in plasma. This is followed by a comparison between this assay and the electrochemiluminescence assay of Roche Cobas 8000 e801.

METHODS

Retrospective data of 118 subjects was collected between November 2023 and January 2024 at UZ Brussel. Method verification of the Roche Cobas 8000 c702 was conducted by evaluating the imprecision (CLSI EP15-A3), the autodilution 1:50 (EP34) and the high-dose hook effect. The comparison with Roche Cobas 8000 e801 was conducted by performing a correlation using Passing-Bablok regression and by calculating the clinical performance.

RESULTS

The precision of the medium (mean: 122 µg/L) and the high control (mean: 249 µg/L) was within the optimal CV (3.2%), predetermined by EFLM.
The prozone-cut-off of 80000 µg/L mentioned in the instructions for use was verified for a sample with an original ferritin concentration of 77612 µg/L determined on Cobas 8000 e801. No false result without a “prozone flag” was observed.
The recovery of diluted samples with a ferritin concentration approaching the upper limit of quantification (1000 µg/L) was 101.9%, which is between the acceptable range of 92.8%-107.2%.
The overall Passing-Bablok regression analysis shows a good correlation between the two methods (y=1.09–1.11, r=1, range: 8–997 µg/L). Bland-Altman analysis showed that 95% of the samples are within the d% criterion of Sciensano (16%).
For the determination of the clinical performance, each sample was classified according to sex and whether the value was low (n=26), normal (n=59) or high (n=30) using the Roche Cobas 8000 e801 as the reference method. The sensitivity and specificity were between 95% and 100%.

CONCLUSIONS

Roche Cobas 8000 c702 meets the requirements of verification for the determination of ferritin and is comparable to Roche Cobas 8000 e801.

Clinical Chemistry

P0440

ASCORBIC ACID IN THE URINE OF CHILDREN AND ADULTS -OBSERVATION FROM THE ER, MORE THAN JUST A VITAMIN?

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BACKGROUND-AIM

Vitamin C (ASC) is an essential component of the human diet, found in a wide range of food products.
ASC is known as a mere supplement, but it is a substance with a broad effect on many systems and processes in the body, and it would not be a mistake to refer to this substance as a drug. ASC also is known by therapeutic role in conditions such as cancer, cardiovascular disease (CVD), and infectious disorders. In clinical laboratory ASC is known as significant interference and cause a disruption in results interpretation.
ASC causes falsely negative (FN) results for glucose, blood, nitrite and bilirubin using urine test strips. These FN results can cause a misdiagnosis of urinary tract inflammation or kidney disorders

METHODS

We reviewed results of 1398 general urine samples from pediatric and 7186 results from adult samples. ASC was measured by IRIS Analyzer, Beckman Coulter. We compared a percentage of expected negative results of ASC and the percentages of positive ASC results (at high and very high concentration of 20 and 40), in adult and pediatric ER urine screening

RESULTS

A high concentrations (20) of ASC were observed in 7.6% of adults and 14.4% of children. A very high concentrations (40) of ASC were observed in 6.54% of adults and 21.2% of children urine. The difference in ASC concentrations at both 20 and 40 levels between Pediatric and Internal ER is conclusively significant ($p<0.005$).

CONCLUSIONS

There is much more uncertainty and open questions about ASC effects. It is important to continue to investigate the significant source of difference in ASC concentrations in the urine of adults and children, as well as it the effect on the results of laboratory tests.

Clinical Chemistry

P0441

PROPOFOL-INDUCED LABORATORY INTERFERENCE

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BACKGROUND-AIM

A patient presented to the hospital with a new flare-up of ulcerative colitis following influenza infection, showing a good response to treatment with prednisone. During dose tapering, the patient reported clinical worsening, including frequent bloody stools.

METHODS

A colonoscopy (rectosigmoidoscopy), routine biochemical analysis, complete blood count (CBC) and coagulation panel were performed. Biochemical results revealed hyponatremia of 127 mEq/L. The hematology laboratory identified interference in the CBC, potentially due to hemolysis and lipemia. It was observed in the erythroblast channel, in the leukocyte histogram, where the neutrophil population was displaced toward the monocyte, eosinophil and basophil region, and in the scattergram, where large monocyte and neutrophil populations were detected.

RESULTS

Based on these findings and as the sample exhibited a lipemic index of 3, serum triglycerides were assessed.
Triglyceride determination was failed. We check the sample and the color of the serum was completely white. Then, we decided to do an ultracentrifugation to clarify the sample and repeat the affected parameters. Triglyceride levels were subsequently measured at 2059 mg/dL. Additionally, the CBC was repeated replacing 0.4 mL of serum with diluent to minimize the lipidic component, resulting in a successful analysis without interferences neither errors.
Once the interference was resolved, we contact the clinical service, confirming the administration of propofol during the diagnostic procedure, when the blood analysis was performed.

CONCLUSIONS

Propofol is an intravenous anesthetic agent, insoluble in water but highly lipid-soluble, which is presented in the form of a lipid emulsion. Therefore, the elevated triglyceride levels were attributed to the triglycerides and glycerol contained as excipients in the injectable solution of the drug, and would also explain the presence of hyponatremia due to a volume displacement phenomenon caused by the presence of said lipids in the sample.
The interference was confirmed after repeating the biochemical and hematological tests ten hours post-administration of the drug. The results showed 137 mEq/L of sodium, 75mg/dL of triglycerides and a normal CBC.

Clinical Chemistry

P0442

USE OF FALSE POSITIVE LIPEMIA INDEX FOR OPPORTUNISTIC DETECTION OF MONOCLONAL IMMUNOGLOBULINS

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BACKGROUND-AIM

We found several cases in our laboratory of high lipemia index where no turbidity or triglyceridemia was detected visually or analytically, so the interference of monoclonal immunoglobulins (IGs) with L-index was studied

METHODS

We retrospectively studied data of serum protein electrophoresis SPE and its paired lipemia assays, from April 2019 to December 2024 at Hospital Universitario Marques de Valdecilla
A search was made for all samples with a positive lipemia index ≥1 and M-protein peak detected by SPE confirmed by immunofixation or immunosubtraction. Cholesterol, total protein, triglyceride and immunoglobulin levels were collected when available
SPE and immunosubtraction was performed with a Capillarys 3 Tera instrument and immunofixation using Hydragel 4 system. IGs were measured in a BindingSite Optilite turbidimeter and the other analytes in an Atellica CH930 analyzer

RESULTS

85 samples had positive L-index and M-protein peak. Only 5 of them, 5.9% had high triglyceride levels, but significant M-protein was found in all samples. Only one sample with very high triglyceride level 1252mg/dl and a IgG peak seems truly lipemic
The M-protein was identified as IgM in 78 samples (91.8%). 4 samples (4.7%) had an IgG peak and 3 (3.5%) IgA. Out of 4326 samples with a M-protein peak detected in SPE 85 were identified by the L-index, a sensitivity of 2.0%
It is well-known that M-protein can cause interference by precipitation at neutral pH or other conditions, increasing turbidity that leads to a positive L-index. IgM is the most frequently involved, due to its pentameric structure that greatly generate aggregation. Other reports found IgG being involved in up to 30% of cases. This study confirms the tendency of IgM to precipitate: the involvement of IgG is not clear
The sensitivity found is relatively low compared with other studies, but there can be differences due to lack of standardization of L-index assay and the exact criteria used to select samples. Interestingly, the L-index detected M-protein even in samples with normal total protein values

CONCLUSIONS

The sensitivity of the L-index is too low to be a reliable screening method: but it could be used for opportunistic screening, for example by performing SPE and measuring calcium, proteins when L-index is elevated with normal triglyceride levels

Clinical Chemistry

P0443

IDENTIFICATION OF RENAL STONE COMPONENTS: CLINICAL CASE

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BACKGROUND-AIM

Renal lithiasis is a common condition that involves the formation of stones in the kidneys, which can have various components. The precise identification of these components is crucial for guiding treatment and preventing recurrence. Infrared spectroscopy (IR) has become an effective tool for characterizing renal stones, allowing for the simultaneous identification of various types of crystals.

METHODS

A 34-year-old male patient presented with recurrent renal colic and hematuria. Imaging studies revealed the presence of large renal stones, prompting surgical intervention for stone removal. The patient underwent a cistolitotomy and bilateral percutaneous nephrostomies. Postoperatively, he developed complications including hemoperitoneum and a vesical fistula, which required further surgical management. During the recovery phase, the patient showed signs of sepsis, confirmed by positive blood cultures for Klebsiella pneumoniae.
Infrared spectroscopy (IR) was performed to identify the composition of the renal stones, providing valuable insights for further treatment and prevention strategies.

RESULTS

The infrared spectroscopy (IR) analysis of the renal stones revealed the following composition:
40% Apatite (calcium phosphate)
30% Ammonium urate
30% Struvite (magnesium ammonium phosphate)
The IR spectra showed a high correlation (92.3%) with reference spectra, confirming the presence of these components in the stones.

CONCLUSIONS

Infrared spectroscopy proved to be an effective tool for the precise identification of renal stone components. In this clinical case, the stones were primarily composed of apatite, ammonium urate, and struvite. These findings are crucial for tailoring the patient's treatment plan and developing strategies to prevent further stone formation. The use of IR spectroscopy provides valuable insights into the metabolic profile of patients, contributing to personalized management of renal lithiasis.

Clinical Chemistry

P0444

PREANALYTICAL VARIABLES AND DERIVATIZATION STRATEGIES IN MALONDIALDEHYDE QUANTIFICATION VIA LIQUID CHROMATOGRAPHY: A REVIEW

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BACKGROUND-AIM

Accurate quantification of malondialdehyde (MDA)is essential for understanding its role in various physiological and pathological processes.The accuracy of liquid chromatography analysis is significantly influenced by preanalytical variables and derivatization strategies.This review aims to evaluate the impact of preanalytical variables and derivatization strategies on the accuracy and reliability of MDA quantification in biological samples using liquid chromatography.

METHODS

A literature review was conducted using the PubMed database to identify studies published in the last five years that focus on the preanalytical aspects of MDA measurement by liquid chromatography. The selected studies were evaluated for their approaches to sample collection, storage conditions, pretreatment protocols, and derivatization techniques.

RESULTS

Proper sample collection, sterile techniques, and storage at -80°C for long-term preservation are critical. Samples should be stored at -20°C or lower, protected from light to prevent photodegradation, and analyzed as soon as possible after collection. Preanalytical variables included the use of acid hydrolysis to break down protein-bound MDA and alkaline hydrolysis to release MDA from Schiff bases. Hydrolysis methods using trichloroacetic acid (TCA), sodium hydroxide (NaOH), perchloric, and metaphosphoric acids were found effective, with pH adjustments and centrifugation optimizing results. Extraction techniques included liquid-liquid with 1-butanol, toluene, cyclohexane, and solid-phase extraction. Antioxidants (BHT) and metal ion chelators (EDTA) were essential for preventing oxidation. Derivatization with TBA produced stable MDA-TBA adducts detectable by fluorescence, while dinitrophenylhydrazine (DNPH) formed hydrazones detectable by UV or mass spectrometry.

CONCLUSIONS

Optimizing preanalytical variables and derivatization strategies is essential for the accurate determination of MDA in biological samples using liquid chromatography. Standardizing sample collection, handling, storage, and derivatization procedures significantly enhances the reliability and reproducibility of MDA measurements, ultimately improving the assessment of oxidative stress in clinical and research settings.

Clinical Chemistry

P0445

MACROVITAMIN B12 IN HYPERVITAMINOSIS: A CASE REPORT

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BACKGROUND-AIM

The determination of vitamin B12 (VB12) is usually aimed at detecting deficiencies. However, on numerous occasions we have encountered patients with elevated VB12 levels, which have been associated with cobalamin supplementation and life-threatening pathologies. The presence of immunoglobulin complexes together with VB12 (macroB12) can interfere with immunoassays, leading to false elevations of VB12 and masking deficiencies. Treatment of samples with polyethylene glycol (PEG) is one method to detect sample interference. PEG acts as a dehydrating agent that reduces protein solubility and causes protein precipitation.

METHODS

A 28-year-old female patient referred to her specialised care physician for VB12 levels >2000 pg/mL (200 - 883 pg/mL) to rule out neoplastic process. Imaging and laboratory tests were performed, all of which were normal. In a subsequent analysis, the patient underwent another analytical control, where the VB12 level was 1800 pg/mL. In this case, we decided to carry out the macroB12 study. For the interference study, we treated the sample with a 25% PEG 6000 solution. We obtained values before and after treatment and calculated the percentage of recovery using the formula: (VB12 after PEG treatment x 2 / VB12 before PEG treatment) x 100. We considered: <40% presence of macroB12; 40-60% doubtful cases and >60%: no presence of macroB12.

RESULTS

The result of the patient's sample after PEG treatment was 162 pg/mL and the recovery percentage obtained was 21.60%, indicating that the VB12 elevations were due to the presence of macrovB12.

CONCLUSIONS

Although there are currently several analytical techniques designed to remove immunocomplexes from serum, the use of PEG has emerged as an rapid and simple method to detect the presence of these immunocomplexes.
The identification of macroB12 allows differentiation of patients among those with false elevations. Although it increases laboratory costs, it reduces the number of referrals to specialists and waiting lists for additional tests.

Clinical Chemistry

P0446

TOWARD PRECISION DIAGNOSTICS: UNVEILING MACROVITAMIN B12 IN HYPERVITAMINOSIS CASES

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BACKGROUND-AIM

Vitamin B12 (VB12) determination is used to detect deficiencies, although elevated levels are frequently observed. These hypervitaminoses are associated with cobalamin supplementation and severe pathologies such as myelodysplastic syndromes, neoplasms and increased mortality, leading to additional consultations and tests. Cobalamin levels, measured by immunoassays, may be affected by macroB12 (VB12 and immunoglobulin complexes), causing false elevations and masking deficiencies.

METHODS

Objective: To identify macroB12 in patients with hypervitaminosis B12.
90 samples from patients with VB12 ≥ 1000 pg/mL were studied. Medical records were reviewed, ruling out active supplementation. Samples were treated with 25% PEG to identify interference. Measurement of VB12 in the supernatant was performed by immunoassay on the Alinity analyser (Abbott). VB12 recovery was calculated ([VB12 after PEG×2/VB12 before PEG]×100). MacroB12 was considered present if the percentage recovery was ≤ 40%.

RESULTS

In 13/90 patients (14%), elevated macroB12 levels were detected. Among them, 7 were deficient after correction of interference. Data were collected and analysed with IBM-SPSS-Statistics version 26. The prevalence of macroB12 in our setting was 14%. ROC analysis (AUC 0.824; 95%CI 0.72-9.95) defined a cut-off point of 1500 pg/mL to investigate macroB12. Cases with recovery ≤ 40% were reported with the note: 'MacroB12 has been detected in this patient. The reported result corresponds to VB12 after precipitation of macroB12 with polyethylene glycol.

CONCLUSIONS

The association between hypervitaminosis B12 and severe disease highlights the need for accurate laboratory results. The determination of macroB12 allows the identification of false hypervitaminosis and the diagnosis of hidden deficiencies, improving clinical management.

Clinical Chemistry

P0447

A RARE CASE OF LIGHT CHAIN MYELOMA WITH ALPHA 1 MOBILITY ON SERUM PROTEIN ELECTROPHORESIS

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BACKGROUND-AIM

Light-chain multiple myeloma (LCMM) is a subtype of multiple myeloma (MM), which is less frequent accounting for 15% of MM cases. It is characterized by exclusive production of light chains and is known to be more aggressive with poorer prognosis.
Though serum protein electrophoresis (SPE) plays a major role in the diagnosis of MM, its role in LCMM is less significant as most of the cases present with absent M protein. Few M-proteins that are identified in LCMM are commonly present in either beta or gamma regions and very rarely found in alpha-1 region.

METHODS

A 76-year-old, diagnosed patient with chronic kidney disease and hypertension presented with persistent, non-traumatic nasal bleeding for 3 hours without a previous similar history. Salient investigation findings include pancytopenia, high ESR (126/hr), elevated total protein (96g/l), serum creatinine, C-reactive protein, corrected calcium, and positive urine Bence Jones proteins. He was further evaluated to find the etiology.

RESULTS

SPE revealed a small monoclonal band in the alfa-1 alfa-2 interphase region with a paraprotein level of 6.4 g/L. Serum immunofixation confirmed monoclonal production of Lambda-light chains. Serum free-light chain assay revealed kappa/lambda ratio of 0.0004 with Lambda-light-chain concentration of 158628 mg/L. Drastic elevation of lambda-light-chains with absent G, A,M heavy chains and M protein with alpha-1 mobility was suggestive of LCMM. Immunofixation for D,E heavy chains was not done as a cost-cutting measure. His bone marrow biopsy disclosed 84% of abnormal plasma cells.
Despite supportive treatment patient succumbed to death before definitive treatment was started.

CONCLUSIONS

Monoclonal band in the alpha-1 alpha-2 interphase in SPE, can be easily overlooked and mistaken for spikes that occur due to hemolysis, renal pathology, and acute inflammation. Thus, in the presence of suggestive clinical findings clinicians should be vigilant and further investigate such patients to exclude LCMM. As LCMM has a worse prognosis than other MM types, early diagnosis, and treatment will improve the patient outcome significantly.

Clinical Chemistry

P0448

NAVIGATING THE CHALLENGES OF CENTRAL NERVOUS SYSTEM GERMINOMA DETECTION; IMPACT OF IGNORING POLYURIA -CASE REPORT

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BACKGROUND-AIM

Central nervous system (CNS) germinomas are rare tumors that predominantly affect children and young adults. Intracranial germ cell tumors (GCTs) account for 3%-5% of all intracranial tumors and are further divided into two groups, germinomas and nongerminomatous GCTs.
Clinical presentation depends on the location and size of the lesion. Diabetes insipidus is the most common presentation followed by hypopituitarism, visual disturbances, features of intracranial hypertension, and Parinaud syndrome. Due to the variability of presentation, high index of suspicion is vital to accurately diagnose and plan appropriate laboratory investigations.

METHODS

An 11-years-old previously healthy child presented with blurring of vision, reduced visual acuity and double vision which progressively worsened during the last six months with associated loss of appetite, loss of weight, worsening headache and behavioral changes. On further inquiry, he has had polyuria, and polydipsia for three years duration for which he sought medical care and was reassured without further evaluation.

RESULTS

His hormonal workup was suggestive of panhypopituitarism with subnormal levels of cortisol (26nmol/ L), Thyroid Stimulating hormone (< 0.01mIU/L), free T4 (0.42 ng/dL), Follicular stimulating hormone (0.7IU/L), Luteinizing hormone (0.2IU/L) and elevated prolactin (1033mIU/L). His CSF analysis revealed elevated ß HCG (1827mIU/mL). MRI revealed four soft tissue mass lesions in the brain favoring diagnosis of multi focal germinoma. Though he was started on pituitary hormone replacement therapy and chemotherapy his condition deteriorated and succumbed to neutropenic sepsis

CONCLUSIONS

Diagnosis of CNS germinomas is challenging as different etiologies may present clinically and radiologically in a similar manner. If an accurate, timely diagnosis is made the prognosis of the disease is excellent as germinoma is radiosensitive. In our patient, the significant delay in diagnosis despite having long-term polyuria and polydipsia has resulted in poor treatment outcome. Thus, it emphasizes the importance of vigilant clinical evaluation and rational investigation in a patient presenting with polyuria and polydipsia.

Clinical Chemistry

P0449

A CASE REPORT OF SARCOIDOSIS, INCIDENTALLY DIAGNOSED AT ELABORATE HYPERCALCAEMIA WORKOUT

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BACKGROUND-AIM

Hypercalcaemia is a common abnormality with a majority of cases attributing to malignancy or hyperparathyroidism (majority primary). Sarcoidosis is a chronic granulomatous disease with idiopathic etiology and needs to be considered as a differential diagnosis, in an incidental finding of hypercalcaemia evaluation.

METHODS

A 54-year-old gentleman, diagnosed with hypertension, developed a sudden onset, progressive, double vision with no other neurological manifestations.He had excessive sweating, thirsty and weight loss for 3 months. There was no other significant finding in the history and examination.

RESULTS

His chest X ray, CT and MRI of brain were normal. Contrast enhanced CT revealed bilateral hilar, mediastinal and para aortic lymphadenopathy. Biochemical workup showed FPG -180 mg/dL, HbA1c-6.2% albumin corrected calcium-2.8 mmol/L.PTH was normal. He underwent video assisted thoracic surgery of a pre-tracheal node and it revealed non-caseating granulomatous lymphadenitis. His TB workout was normal. Serum angiotensin converting enzyme was elevated (112 U/L), making the diagnosis of Sarcoidosis.He was started on brief course of prednisolone and put on methotrexate later with improvement of serum calcium considering his diabetes history.He was followed throughout as an outpatient.

CONCLUSIONS

Diagnosis of Sarcoidosis can be challenging when hypercalcaemia is the presenting symptom and present in 10% of cases. The most common causes of hypercalcaemia include PTH-dependent hyperparathyroidism and malignancy which causes through PTHrP. Chronic granulomatous disease can cause a PTH- independent hypercalcaemia through enhanced conversion of 25- hydroxyvitamin D, to 1,25- hydroxyvitamin D. This disease is seen world-wide with an estimate prevalence of 20 to 60 per 100,000 population. Although sarcoidosis can affect any organ, the lung is involved in more than 90% of cases. Approximately 30% of patients have nonspecific extra pulmonary manifestations. Hilar or mediastinal lymphnodenopathy, arthritis, pancreatic, renal and ocular involvement are other manifestations.Treatment of hypercalcaemia in sarcoidosis consists mainly of corticosteroids.This case shows an uncommon presentation of Sarcoidosis, as acute hypercalcaemia and highlights the importance of including sarcoidosis in the differential diagnosis.

Clinical Chemistry

P0450

EFFECT OF JAFFE AND ENZYMATIC METHOD OF CREATININE ESTIMATION ON EGFR DISCORDANCE ASSOCIATED WITH MISCLASSIFICATION AT 60 ML/MIN/1.73 M2

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BACKGROUND-AIM

Serum creatinine estimation plays an important role in diagnosis and prognosis of renal disease. eGFR calculation is used as the preferred method to assess the Glomerular function for which serum creatinine, age, sex, and race are needed. The serum and urine creatinine can be estimated by two methods Jaffe and enzymatic method. The enzymatic method is more expensive than the Jaffe method hence majority of the laboratories use the Jaffe method for Creatinine estimation. However the Jaffe method of Creatinine estimation is prone to interferences, despite the standardization and harmonization achieved after creatinine standards traceable to the reference method. Hence this study was planned to compare the Creatinine value estimated using the Jaffe and Enzymatic method and its effect in eGFR calculation using the CKD EPI formula and its effect on misclassification at 60 ml/min/1.73m2.

METHODS

Serum creatinine was estimated in 477 outpatient samples in IGMCRI hospital by
Jaffe and Enzymatic method by the same analyser. eGFR was calculated using CKD EPI
formula using the creatinine value estimated by two different methods. The data was analysed using SPSS software.

RESULTS

A total of 477 samples were analysed. The mean value of creatinine estimated by Jaffe method was 1.50 mg/dl which is 0.06 mg/dl higher compared to the mean obtained by enzymatic method 1.44 mg/dl. Also the eGFR calculated using the creatinine value obtained by Jaffe was 79 ml/min/1.73 m2 which is lower compared to the value obtained by enzymatic method 85 ml/min/1.73 m2. 15%of all cases were different CKD stage when comparing the eGFR between both serum creatinine methods of which 8 % discordance is around the clinical decision limit of 60 ml/min/1.73 m2

CONCLUSIONS

The method of estimation of serum creatinine has its effect in calculation of eGFR and hence in subsequent staging of CKD. Hence, in spite of Jaffe method being cost effective it is better to use enzymatic method of serum creatinine estimation for appropriate staging of renal disease.

Clinical Chemistry

P0451

UTILITY OF INTACT PARATHYROID HORMONE AND VITAMIN D LEVEL AS A MARKER OF CHRONIC KIDNEY DISEASE

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BACKGROUND-AIM

Chronic kidney disease(CKD) is a major health problem in Nepal where the diagnosis of complications of CKD using invasive bone biopsy for bone turnover and mineralization is not convenient and difficult in developing country like ours. It is also important to quantify complications of CKD even before renal replacement therapy and during treatment. Hence, this study aims to estimate serum intact Parathyroid hormone(iPTH), Vitamin D to evaluate for the progression of CKD.

METHODS

This was a cross sectional study recruiting 80 CKD patients from OPD. Mean, median, standard deviation, percentage and frequency were used to describe demographic data. Chi square test was applied for analysis of categorical data and independent t test was applied for numerical data to compare the mean between two groups. Pearson's/ Spearman's correlation was used to correlate estimated Glomerular filtration rate (eGFR), iPTH, Vitamin D, Calcium and Phosphorus level. ANOVA was also be used to compare the variables between the groups (Stage 1-5). For Non parametric data Kruskal Wallis test was applied.

RESULTS

The present study showed the significant differences in the level of iPTH (155.400 (95.45, 389.27) across different stages of CKD. However, spearman's correlation analysis shows significant negative correlation between iPTH with vitamin D (r=-0.247, p=0.027), eGFR (r=-0.499; p=0.000) and calcium (r=-0.378; p=0.01) in CKD patients.

CONCLUSIONS

This study concludes that there was significant increase of iPTH with decrease in vitamin D, calcium and phosphorus level with declining eGFR. Therefore, iPTH can be suggested as a preliminary marker in CKD patients of different stages.

Clinical Chemistry

P0452

INNOVATIVE REDUCTION OF HISTAMINE LEVELS IN PICKLED PRODUCTS USING PLANT-DERIVED DIAMINE OXIDASE ENZYME

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BACKGROUND-AIM

Histamine-intolerance is seen in approximately 1-3% of the population. Diamine oxidase is an enzyme that oxidizes-diamines such as Histamine and primary monoamines. Since bacterial-enzymes increase histamine formation, foods treated with microbial production or fermentation, and foods with plenty of protein include a high amount of histamine. Persons who have low DAO activity might show cause intolerance reactions after consuming foods containing high amounts of Histamine.
Our aim is to enrich with DAO obtained from natural foods in order to reduce the amount of Histamine found in pickle products.

METHODS

Wheatgrass was obtained from Aegean Agricultural Research Directorate. DAO-enzyme that was purified by Ammonium-sulfate protein precipitation, dialysis, and column-chromatography steps, were added at the beginning of the fermentation process of pickles. Samples without DAO were used as controls. After 24 hour incubation period, Histamine levels of samples were determined by LCMS/MS.

RESULTS

The DAO enzyme was purified via ammonium sulfate precipitation and dialysis, increasing its specific activity from 10.18 U/mg to 207.6 U/mg. Histamine levels in sauerkraut samples were analyzed using the LC/MS-MS method after 3 weeks. Pickle samples without DAO showed the highest histamine levels at 6% salinity. Adding 25 U of commercial DAO reduced histamine in pickle juice by 92%, whereas 50 U and 100 U decreased it by 43% and 70%, respectively. Conversely, 25U of purified DAO reduced histamine by 87%, while 50U and 100U achieved reductions of 96% and 93%. Similarly, histamine in pickles decreased significantly with both enzyme types.

CONCLUSIONS

This innovative method which was applied for the first time by our group (Patent application no: 2021/010839) showed that the Histamine level of pickle was significantly reduced with DAO-enzyme sourced herbal nature. By spreading this innovative method to other foods, it will be possible for people with histamine intolerance to safely consume foods that cause intolerance.

Clinical Chemistry

P0453

HIGH-SPEED CENTRIFUGATION TO ALLEVIATE THE LIPEMIA INTERFERENCE ON CREATININE USING THE JAFFé METHOD

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BACKGROUND-AIM

Creatinine measurement is a cornerstone of renal function assessment in clinical laboratories. However, assays can be affected by interferences, such as lipemia. This study aimed to evaluate the impact of lipemia on two creatinine methods and assess high-speed centrifugation as a solution to mitigate this interference.

METHODS

A total of 115 anonymized samples with varying L-index levels were analyzed. Creatinine was measured using Jaffé (CREJ) and enzymatic (CREP) methods (cobas 503, Roche Diagnostics). All samples were centrifuged for 15 minutes at 13,400 rpm (Minispin, Eppendorf), and serum was manually separated from lipid residues. An allowable bias of 6.3% (EFLM BV Database) was used as the analytical goal.

RESULTS

The mean L-index decreased from 71.8 to 17.6 (-75.4%; $p<0.0001$) after centrifugation. Post-centrifugation, 29.6% (34/115) of CREJ samples and 0.9% (1/115) of CREP samples exhibited bias >6.3%. In samples with an L-index <50, no biases >6.3% were observed for either method. However, in high L-index samples, 42.0% (34/81) of CREJ results exceeded the allowable bias, whereas only 1.3% (1/79) of CREP results did. Pre-centrifuged CREJ results were significantly lower than post-centrifuged ones (mean bias 10.2%; $p<0.0001$), while post-centrifuged CREJ results were comparable to CREP (mean bias 2.2%; $p=0.26$).

CONCLUSIONS

CREP is robust against lipemia interference, while CREJ is sensitive from an L-index of 50, contrary to the manufacturer's claim of 800. High-speed centrifugation effectively mitigates lipemia interference in CREJ, aligning its results with CREP. This solution involves minimal additional workload, as L-index >50 samples constitute 0.98% of annual samples in our lab.

Clinical Chemistry

P0454

EVALUATION OF RENAL FUNCTION IN COVID-19 PATIENTS ADMITTED TO THE INTENSIVE CARE UNIT

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BACKGROUND-AIM

Renal complications are a common issue among patients hospitalized in intensive care for acute respiratory distress syndrome related to COVID-19. This deterioration of renal function can worsen the prognosis of patients and complicate their clinical management. The objective of this study is to assess renal function in a population of COVID-19 patients admitted to the intensive care unit.

METHODS

This prospective study included 43 patients diagnosed with SARS-CoV-2 infection, all of whom were admitted to the intensive care unit of our hospital between March and May 2021. Diagnosis was confirmed through a positive PCR test. For each patient, a detailed information sheet was completed, which included comorbidities and the prescribed biological parameters. Data was collected through the computerized medical system of our biochemistry laboratory.

RESULTS

This study involved 43 patients diagnosed with SARS-CoV-2, with an average age of 60 ± 25 years and a male-to-female ratio of 1:1. About 60.6% of the patients had comorbid conditions, including diabetes (30.8%), hypertension (16.2%), stroke (4.6%), hypothyroidism (4.6%), hemodialysis (2.3%), and myocardial infarction (2.1%).
The results showed that acute kidney injury (AKI) was present , with elevated plasma creatinine and urea levels in 18.6% and 62.8% of the patients, respectively. The average creatinine level was 191 µmol/L ± 90.46, and the mean urea level was 12.54 µmol/L ± 4.13. Furthermore, 44.2% of patients with elevated urea levels had isolated urea elevation, pointing to functional AKI.
AKI was found in 40% of diabetic patients and 56% of hypertensive patients. This complication was notably more frequent in patients aged 70 to 80 years, with 44.4% and 88.8% of those in this age group showing elevated plasma creatinine and urea levels, respectively.

CONCLUSIONS

Acute kidney injury in COVID-19 patients is a multifactorial condition, resulting from factors directly or indirectly related to the virus. Continuous assessment of renal function is essential for optimal management of these patients

Clinical Chemistry

P0455

ANALYSIS OF THE CLINICAL AND BIOLOGICAL CHARACTERISTICS OF INFERTILE COUPLES : INSIGHTS FROM A TUNISIAN UNIVERSITY HOSPITAL

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BACKGROUND-AIM

Infertility, described as a disease, affects up to 186 million people worldwide. Endocrine disorders, which account for 30% of the causes of female infertility, can be caused by various factors such as hyperprolactinemia, thyroid dysfunction, and reduced ovarian reserve (ROR), and have a negative impact on ovarian function and medically assisted procreation (MAP) results.
The aim of this study is to determine the incidence of endocrine disorders, to draw up hormonal profiles of infertile patients, and to assess the impact of these disorders on the results of MAP.

METHODS

This is a retrospective descriptive study conducted over a 15-month period from 1 July 2022 to 30 September 2023. Two subgroups, controls and cases, were selected for a possible correlation study.

RESULTS

A total of 100 cases and 100 controls were included in the study.Our study revealed that the causes of infertility were, in descending order, male, mixed, and finally female (60%, 32%, and 8%, respectively). We noted an incidence of endocrinopathies in 22.2% of the study population. The nature of these endocrinopathies was divided into hyperprolactinemia (14.8%), thyroid dysfunction (8.1%), and ROR (15%). Our results showed that the number of punctured oocytes was significantly lower ($p = 0.04$) in the case group compared with the control group. This finding could be attributed to the subgroup of patients with ROR, whose number of mature oocytes observed and those secondarily punctured were significantly lower than in the control group ($p = 0.01$ and $p = 0.03$, respectively). For the remaining results of MAP, no statistically significant difference was observed. This could be attributed to the good management of these disorders.

CONCLUSIONS

This study shows that balancing hormonal disorders before MAP can lead to similar results between pathological and control groups.

Clinical Chemistry

P0456

PREVALENCE OF HORMONAL DISORDERS AMONG INFERTILE WOMEN : A STUDY OF 450 PATIENTS

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BACKGROUND-AIM

Infertility is defined as the inability to achieve a clinical pregnancy after 12 months of regular, unprotected sexual intercourse. Endocrine disorders are one of the primary causes of female infertility, although their prevalence in Tunisia remains poorly documented.
This study aims to assess the prevalence of hormonal disorders among infertile patients in a Tunisian hospital setting.

METHODS

A retrospective descriptive study was conducted over 15 months, from July 1, 2022, to September 30, 2023. It included all infertile patients who sought care at the Department of Obstetrics and Gynecology of our hospital.

RESULTS

A total of 450 patients were initially analyzed, among whom 100 exhibited hormonal disorders. Hyperprolactinemia emerged as the most frequent hormonal disorder, affecting 14.8% of the cases. Abnormal FSH and LH concentrations were identified in 8.8% and 4.7% of patients, respectively. Elevated serum FSH levels were detected in 5.3% of patients, while 3.5% exhibited decreased levels. Elevated LH levels were noted in 1.5% of patients, whereas 3.2% showed decreased levels.
Thyroid dysfunction was present in 8.1% of patients, with hyperthyroidism observed in 1.6% and hypothyroidism in 6.5%. Among those with hypothyroidism, 23% reported irregular menstrual cycles.
Lastly, significantly reduced serum anti-Müllerian hormone levels were identified in 15% of patients.

CONCLUSIONS

Evaluating hormonal imbalances in infertility cases is essential, as improved care guarantees better outcomes for the couple.

Clinical Chemistry

P0457

INTERFERENCE OF SALIVARY AGGLUTININ (SAG) TO RAPID ANTIGENIC TESTS.

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BACKGROUND-AIM

Saliva has been widely used in recent pandemics as sample for rapid antigenic tests (RATs). Although the easy and non-invasive collection makes saliva a good alternative to nasopharingeal swab for the research of SARS-CoV-2 antigens, the low sensitivity of RATs limits its effective use. Saliva is a complex fluid composed of a plethora of innate immunity proteins including salivary agglutinin (SAG). It is known that SAG binds to bacteria, viruses, as well as to endogenous proteins such as immunoglobulins (Ig).
The aim of this study is to investigate if SAG represents an interference in RATs. For this purpose, the search for SARS-CoV-2 protein S by saliva RATs was used as model of investigation. The interaction between SAG and antibodies used for the revelation of protein S was also evaluated.

METHODS

The interaction between SAG and both protein S and anti-S monoclonal antibodies (mAbs) was evaluated by Enzyme linked immunosorbent assays (ELISA) appropriately developed to highlight the specific interactions. Three anti-S mAbs were tested (GTX635654; GTX632604; 40150-R007). Since carbohydrates are involved in the binding of proteins with SAG, ELISA assays were also performed using a deglycosilated anti-S mAb (GTX635654). Deglycosilation was obtained by the endoglycosidase S that specifically cleaves N-linked glycans. Each assay was repeated trice.

RESULTS

Performed experiments showed that SAG effectively binds to SARS-CoV-2 protein S (Abs450nm: 0.49±0.22 vs. 0.13±0.01 controls, p=0.049). Furthermore, an interaction between SAG and anti-S mAbs was also observed. In fact, the absorbance detected using GTX635654 and GTX632604 were significantly difference ($p< 0.0001$) from that of their respective control (0.75±0.24 vs. 0.13±0.017; 0.44±0.08 vs. 0.15±0.05). No interaction between SAG and 40150-R007 was revealed (0.16±0.02 vs. 0.13±0.017). Interestingly, a dramatic reduction of binding between SAG and deglycosylated mAb (dmAb) was observed (dmAb 0.57±0.08 vs. mAb 2.59±0.74; dmAb /mAb = 0.22).

CONCLUSIONS

This study highlights that SAG can interfere with diagnostic test by interacting with the antigen of interest but also with the mAb used in the test itself. Besides, this study suggests that a possible pre-treatment of capture mAb used in RATs could reduce the interference by SAG protein.

Clinical Chemistry

P0458

ADJUSTMENT OF THE CORRECTED CALCIUM FOR THE REFERENCE POPULATION

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BACKGROUND-AIM

Hypocalcemia is total serum calcium concentration <8.8 mg/dL in the presence of normal plasma protein concentrations or serum ionized calcium concentration <4.2mg/dL. Hypercalcemia is serum total calcium concentration >10.4 mg/dL or ionized calcium >5.2 mg/dL.
To assess the patient's calcemia, ionized calcium is used as the gold standard, total calcium and albumin-corrected calcium. Albumin-corrected calcium can be calculated on the basis of different equations, in many cases these do not reflect the analytical and population reality of the laboratory that applies them. Therefore, it is desirable to customize it in order to obtain more clinically useful results.
Develop an equation to find albumin-corrected calcium adjusted to our methodology and population.

METHODS

To calculate the equation, analytical results from our laboratory of patients with liver and kidney function in the normal range were used. Those requests that included total calcium, albumin and ionic calcium were selected. There were 1032 patients with normoalbuminemia and 207 with hypoalbuminemia.
Biochemical determinations were performed on a Cobas pro503 autoanalyzer. Ionic calcium was determined on a Radiometer ABL800 Flex analyzer.
Albumin-calcium regression equations were obtained for normo-and hypoalbuminemic patients and used to calculate equation-corrected calcium:
Corrected calcium = total calcium - albumin * slope + mean total calcium - ordinate at the origin

RESULTS

The calcium-albumin regression equations obtained were:
For normoalbuminemic patients: y=5.6470+0.9152x
For hypoalbuminemic patients: y=5.6927+0.8793x
The mean total calcium values for both groups of patients were 9.66mg/dL and 8.25mg/dL, respectively.
These values were used to adjust the corrected calcium equations for our laboratory:
For normoalbuminemic patients: Corrected calcium=Total calcium - Albumin*0.9152 + 3.99
For hypoalbuminemic patients: Corrected calcium=Total calcium - Albumin*0.8793 + 2.56

CONCLUSIONS

Laboratories should adapt the corrected calcium equations to their methodology and population.
Corrected calcium is a useful and inexpensive tool for assessing phospho-calcium metabolism and hypo- and hypercalcemic states in patients.

Clinical Chemistry

P0459

ASSESSMENT OF LIVER AND RENAL FUNCTION TEST AMONG PATIENTS WITH TYPHOID FEVER IN MOTTA GENERAL HOSPITAL, NORTHWEST ETHIOPIA: A COMPARATIVE CROSS-SECTIONAL STUDY.

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BACKGROUND-AIM

Background: Typhoid fever continues to be the key cause of morbidity and mortality in developing countries with poor hygienic practices and limited access to safe drinking water. It mostly affects the liver and kidney organs which leads to alteration of liver and renal function tests. This study aims to assess liver and renal function tests among typhoid fever patients in Motta General Hospital Northwest Ethiopia.

METHODS

Method: An institutional-based comparative cross-sectional study was conducted at Motta General Hospital among 90 typhoid fever patients and 90 control groups who were selected with a convenient sampling technique. After the collection of all clinical and laboratory data, the data was analyzed by SPSS version 26. A p-value < 0.05 was taken as statistically significant.

RESULTS

Result: The mean age of typhoid fever and control subjects were 32.23± 13.48 years and 32.62 ± 7.708 respectively. The values of serum aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, total bilirubin, direct bilirubin, and creatinine were significantly higher in typhoid fever patients than control groups, $p<0.05$.

CONCLUSIONS

Conclusion: The findings of this study showed that liver function tests (ALT, AST, ALP, TB, and DB) and renal function tests (creatinine) were significantly altered by typhoid fever as compared with the control groups. Abnormal liver and renal function tests in typhoid fever are seen more commonly in patients presenting in 2nd and 3rd week of illness.

Clinical Chemistry

P0460

RENAL FUNCTION TESTS AND LIPID PROFILES AMONG APPARENTLY HEALTHY ADULT MALE KHAT-CHEWERS AND NON-KHAT CHEWERS IN DILLA TOWN, SOUTHERN ETHIOPIA.

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BACKGROUND-AIM

Chewing khat, 'Catha edulis' is becoming more common in our society with increased harmful health repercussions, such as lipid metabolism disorder and impaired renal function. There is a scarcity of data and contradictory findings on this topic. Therefore, this study aimed to compare renal function tests and lipid profile levels among apparently healthy adult male khat chewers and non-khat chewers and to assess the associated risk factors.

METHODS

A cross-sectional study was conducted in Dilla Town using convenient sampling techniques. The levels of lipid and renal function tests were analyzed on apparently healthy adult male khat-chewers (n = 100) and non-khat chewers (n = 100) using the Siemens Dimension EXL 200 integrated system. Independent t tests and Pearson correlation statistical methods were applied using SPSS Version 27. A P-value < 0.05 was regarded as statistically significant.

RESULTS

Among khat chewers, the levels of HDL-C (mean ± SD) were significantly lower (34.0 ± 17 mg/dl) compared with non-khat chewers (39.5 ± 25 mg/dl) (P = 0.007). Additionally, khat chewers displayed significantly higher levels of TC/HDL ratio (3.81 ± 2.05 vs. 3.17 ± 1.29, P<0.001) and TG (95.5 ± 56 mg/dl vs. 80.5 ± 45 mg/dl, P = 0.005) than non-khat chewers (p<0.05). Long-term chewing, lasting more than 10 years, has been associated with a significant increase in creatinine and decreased eGFR levels compared with shorter durations, less than 10 years.

CONCLUSIONS

Khat chewing has a deleterious effect on HDL, triglyceride, and TC/HDL ratio levels and may be associated with chewing duration, frequency, bundle of khat, and time spent on chewing. Long-term chewing has been associated with kidney damage.

Clinical Chemistry

P0461

ARE B12 AND B9 DEFICIENCIES INDEPENDENTLY LINKED TO CARDIOVASCULAR BIOMARKERS? INSIGHTS FROM A CROSS-SECTIONAL ANALYSIS

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BACKGROUND-AIM

The effect of cobalamin and folate deficiency on cardiovascular disease is still unclear. We assessed the association of cobalamin and folate deficiency on lipidic and non-lipidic markers of cardiovascular disease in a large laboratory database.

METHODS

We conducted a cross-sectional study on a large database of a tertiary hospital's laboratory information system between 2017 and 2022. The study included laboratory data of Lebanese outpatients and cardiology inpatients. The following biological assays on serum were used: cobalamin, folate, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, creatinine, glycated hemoglobin, ferritin, C-reactive protein, fibrinogen, uric acid and homocysteine. Age, gender and a surrogate for cardiovascular disease were also used. Odds ratios adjusted for age, gender, inflammatory biomarkers and vitaminic status were derived using separate logistic regression models.

RESULTS

A total of 20,836 observations were included, of which 2.0% presented clinical cobalamin deficiency. The effect of cobalamin and folate deficiencies, while significantly affected cardiovascular biomarkers in univariate analyses, disappeared after adjusting on age, gender and inflammation biomarkers.

CONCLUSIONS

In this exploratory analysis, cobalamin and folate deficiencies were not significantly associated with abnormal lipid values and non-lipidic markers of cardiovascular disease.

Clinical Chemistry

P0462

INFLAMMATORY BIOMARKERS VARIATIONS IN AN ULTRA-ENDURANCE EVENT : A CASE STUDY OF THE TOR DES GéANTS

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BACKGROUND-AIM

Ultra-marathons represent extreme endurance events that impose significant physiological stress, particularly triggering systemic inflammation. Biomarkers such as high-sensitivity C-reactive protein (hs-CRP) and interleukin-6 (IL-6) are commonly used to assess inflammation levels. Hs-CRP, an acute-phase protein, reflects systemic inflammation and tissue damage, while IL-6, a myokine, is a sensitive biomarker for muscular activity who plays a dual role in both pro-inflammatory and anti-inflammatory responses. Studying these markers in ultra-marathon runners provides valuable insights into the body's inflammatory adaptations to prolonged physical effort. This study aims to analyze the temporal variations of hs-CRP and IL-6 in runners taking part in an elite ultramarathon.

METHODS

This study enrolled nineteen experienced runners (15 men and 4 women) participating in the Tor des Géants (330 km, D+ 24,000 m). Blood samples were collected at three key points: before the race (T0), at mid-race (T1), and after the race (T2). These samples were analyzed with an electrochemiluminescence immunoassay (Maglumi X3, Snibe®) to determine IL-6 and hs-CRP concentrations in runners. Wilcoxon testing was used for statistical analysis with MedCalc.

RESULTS

Hs-CRP levels increased dramatically by +7378% at mid-race ($p < 0.0001$) and remained elevated post-race with a +3769% rise ($p = 0.0002$). However, no significant difference was observed between T1 and T2 ($p = 0.6226$). Similarly, IL-6 increased significantly by +261% between T0 and T1 ($p = 0.0001$) and +317% between T0 and T2 ($p = 0.0003$), with no significant variation between T1 and T2 ($p = 0.4413$).

CONCLUSIONS

The study of inflammatory biomarkers hs-CRP and IL-6 in ultra-marathon runners highlights a marked and persistent inflammatory response during prolonged effort. These findings underscore the importance of monitoring these parameters to optimize recovery strategies and prevent athletes' long-term health. Furthermore, the elevated IL-6 levels are indicative not only of systemic inflammation but also of muscle damage resulting from sustained mechanical stress, emphasizing the necessity of targeted recovery protocols to facilitate tissue repair and minimize the risk of chronic musculoskeletal issues.

Clinical Chemistry

P0463

PROTEIN ELECTROPHORESIS: PRE-ANALYTIC NONCONFORMITY STUDY REPORT

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BACKGROUND-AIM

The pre-analytical phase of serum protein electrophoresis is very important for obtaining a reliable result.
Our objective is to determine non-conformities (NC) in serum protein electrophoresis.

METHODS

This is a retrospective study, carried out in the biochemistry laboratory of CHU Habib Bourguiba, Sfax, over 4 years, involving 2197 analysis requests. We collected NCs in the pre-analytical phase concerning: the request form, the sampling tube, sampling conditions and transport conditions.

RESULTS

Out of a total of 2197 requests, 317 NCs were identified. The NCs were: non-compliant tube in 41.3% of cases (n=131), followed by hemolyzed sample in 20.5% of cases (n=65). A discrepancy between the tube and the request form in 37 cases (11.7%). Insufficient quantity was noted in 33 cases (10.4%). Unlabelled tubes were detected in 8.8% of cases (n =28). The absence of clinical information, department or doctor's stamp was noted in 12 cases (3.6%), and request forms without tubes and samples in 6 cases each (1.8%).

CONCLUSIONS

The reliability of laboratory results depends not only on the analysis technique, but also on the pre-analytical phase, which underlines the importance of risk assessment and preventive measures to remedy NC. In addition, ongoing training of healthcare staff is necessary to ensure that this phase is respected.

Clinical Chemistry

P0464

DISORDER OF SEX DEVELOPMENT: CASE REPORT

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BACKGROUND-AIM

Ambiguous genitalia resulting from impaired androgen secretion or action can stem from various conditions associated with low, normal, or high levels of AMH.

METHODS

In disorders of sex development a first line and second line analysis were made according to clinical phenotype including: gonadotrophins, antimullerian hormone (AMH), testosterone, and estradiol on COBAS-6000-system (Roche Diagnostics, Penzberg, Germany); and 17 hydroxyprogesterone, androstenedione, and dehydroepiandrosterone-sulfate using ELISA kits (DRG, Germany).

RESULTS

We present the case of a 3-day-old newborn born to a 32-year-old mother, admitted to the neonatology department for sexual ambiguity with gonads palpated at the level of the 2 bursae with a single orifice. At pelvic ultrasound, there were 2 very thin gonads with testicular appearance and no uterus and no ovaries. The gonadotrophins, testosterone, and AMH levels were within normal range for male. The karyotype analysis showed 46, XY.

CONCLUSIONS

In this newborn with severely undervirilized genitalia, hormonal and karyotype analyses indicate a testosterone synthesis disorder. Additional laboratory tests are required to identify the definitive diagnosis. We highlight the biologist's position in the multidisciplinary management of these disorders.

Clinical Chemistry

P0465

ANGIOTENSIN CONVERTING ENZYME IN POLYCYSTIC OVARY SYNDROME

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BACKGROUND-AIM

Polycystic ovary syndrome (PCOS) is marked by an aberration in folliculogenesis. Angiotensin-converting enzyme (ACE), a ubiquitous enzyme, has been reported to influence folliculogenesis.
Objective: to evaluate circulating ACE levels in PCOS patients.

METHODS

A cross-sectional study was conducted. PCOS patients were diagnosed based on Rotterdam criteria. Gonadotrophins, testosterone, anti-mullerian hormone, sex hormone binding globulin, and ACE levels were measured using the Cobas-6000-system (Roche Diagnostics, Penzberg, Germany). 17 hydroxyprogesterone, androstenedione, and sulfate dehydroepiandrosterone were assayed with ELISA kits (DRG, Germany).

RESULTS

A total of 100 PCOS was enrolled. Their mean age were 25.7+/-5.6 years. The observed mean ACE levels were 39.7+/-13.9 UI/L. ACE levels were negatively correlated to LH/FSH ratio and 17-hydroxyprogesterone levels. No other significant correlations were noted.

CONCLUSIONS

ACE seems to be associated with PCOS steroïdogenesis and pathophysiology. Nevertheless, circulating levels of ACE in the bloodstream might not accurately mirror the intraovarian paracrine effects of ACE. Furthermore, ACE polymorphism could potentially introduce a confounding variable.

Clinical Chemistry

P0466

INVERSION OF BLOOD COLLECTION TUBES IS A SIGNIFICANT SOURCE OF BIAS IN MAGNESIUM TESTING

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BACKGROUND-AIM

This study was planned to establish whether inversion of Blood collection tubes(BCTs) is a significant source of bias in magnesium testing.

METHODS

Commercially available BCTs of ten brands were evaluated in this study. The serum samples of blood donors from the First Affiliated Hospital of Zhengzhou University were collected and mixed in the same container, and then allocated to different BCTs. Serum placed in tubes stored in 2-8°C in the upright position in each group for 1h, 2h, 4h, 8h and 24h served as control groups, while serum placed in tubes stored in 2-8°C upside down in each group for 1h, 2h, 4h, 8h and 24h served as experiment groups. Magnesium was then assessed in all tubes on a Cobas 8000 Analyzer using Roche Reagent.

RESULTS

The differences in the test results obtained from the samples in each BCTs group satisfied the allowable difference Ranges. However, the differences in magnesium measurement values between different BCTs under the same conditions were statistically significant. After being placed for different hours, a varying degree of elevation in magnesium values was found in all BCTs, especially in the “inverted” BCTs, the maximum difference was 0.125mmol/L in group J, which is more than allowed total error≤ 0.12 mmol/L (≤0.8 mmol/L) after 1h inversion.

CONCLUSIONS

Inversion of BCTs is a significant source of bias in magnesium testing. Prefilled BCTs should be kept in the upright position to reduce blood contact with the stopper.

Clinical Chemistry

P0467

PATIENT-BASED REAL-TIME QUALITY CONTROL FOR MONITORING SERUM SODIUM

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BACKGROUND-AIM

To develop patient-based real-time quality control (PBRTQC) system for serum sodium and compare it with multi-rule internal quality control charts.

METHODS

This study was conducted in a tertiary care centre in Western India.
De-identified serum sodium results were collected from laboratory patient results for 2 months. A target value, truncation limit, and control limit were derived from it and were used to develop a PBRTQC procedure. This PBRTQC procedure was then used prospectively to monitor daily quality control of serum sodium received. The error detected by the PBRTQC procedure was compared with the error detected in the multi-rule internal QC chart for the serum sodium, which was also being run parallelly for serum sodium for the day. This process was conducted for 5 months to compare the efficacy of PBRTQC with a multi-rule internal quality control chart.

RESULTS

Over 5 months, five cases of rule violation were raised by the PBRTQC procedure. In all five cases, the sample processing was stopped, and then the cause of the error was ascertained as per the guidelines set for corrective action and preventive action.
The patient sample was released only once the cause of the alarm was identified and rectified whenever needed. All those results that were released during this time were repeated from the back approach. Rules violated by 2:2S and 2:3S were 3 and 2 times. All the detailed investigation and corrective action was documented and kept for future reference. There is 100% agreement between the two modalities with a kappa coefficient of 1. PBRTQC procedure not only detected the error accurately but also detected the error even before it was picked by the traditional IQC technique.

CONCLUSIONS

Our study observed that the PBRTQC not only accurately detected the error but also helped in detecting it earlier as compared to the standard IQC technique; hence, implementing PBRTQC monitoring in clinical laboratories can significantly enhance quality assurance practices and ensure accurate and reliable test results in real time.

Clinical Chemistry

P0468

THE TRANSITION OF PROTEIN ELECTROPHORESIS REPORTS FROM NARRATIVE TO SYNOPTIC FORMAT: A SURVEY ON CLINICIAN SATISFACTION

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BACKGROUND-AIM

The synoptic report is a format that presents test results in a standardized structure and is widely utilized in pathology. While some guidelines recommend synoptic reports for protein electrophoresis (PEP), there is a lack of studies examining its practical implementation and impact.

METHODS

In November 2022, a survey was conducted with 61 clinicians who had prescribed S-PEP in the past six months, and 16 responses were obtained. The web-based survey designed to measure satisfaction with the former narrative-style reports using a 5-point Likert scale and identified additional requirements. On July 19, 2023, the report format was transitioned to a synoptic format. Six months later, a follow-up satisfaction survey on the revised report was conducted with 66 clinicians, and 13 responses were received.

RESULTS

Comparisons of Likert scale scores revealed slight differences in overall satisfaction, completeness, and readability between the pre-transition (median [Q1–Q3]: 4 [3–5], 4 [3–5], 4 [4–5]) and post-transition surveys (4 [4–5], 4 [4–5], 4 [4–5]), but the differences were not statistically significant (P = 0.592, 0.592, and 0.850, respectively, by Mann-Whitney U test). However, when directly comparing the two formats, the revised synoptic report was significantly preferred (n=11, P = 0.004, by one-sample Wilcoxon Test).

CONCLUSIONS

This study provides a practical example of the transition of PEP reports to a synoptic format and suggests that synoptic reporting may improve clinician satisfaction in PEP practice.

Clinical Chemistry

P0469

AGE AND SEASONAL VARIATION IN ALLERGEN SENSITIVITY AMONG CHILDREN: A COMPREHENSIVE ANALYSIS OF FOOD AND ENVIRONMENTAL ALLERGENS

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BACKGROUND-AIM

Allergic conditions, particularly food and environmental allergies, are increasingly affecting children worldwide. However, there is a lack of comprehensive data on the prevalence and seasonal trends of these allergies in Pakistan's pediatric population. This cross-sectional study aimed to assess the prevalence and seasonal variation of food and environmental allergens in the pediatric population of Pakistan.

METHODS

A total of 2796 participants (1676 males and 1120 females) under 18 years of age were included, categorized into four age groups: <1, 2-5, 6-10, and 11-18 years. Food allergens (peanut, milk, shrimp, soybean, egg white, beef) and environmental allergens (cat dander, dog epithelium, cockroach, Dermatophagoides pteronyssinus, Dermatophagoides farinae, Penicillium notatum, Aspergillus fumigatus, R. thistle) were analyzed using the IMMULITE® 2000 system with 3gAllergy® kits. Data were analyzed using chi-square and Kruskal-Wallis tests

RESULTS

Dermatophagoides farinae (52.5%) and Dermatophagoides pteronyssinus (52.1%) were the most common environmental allergens, while egg white (30.0%) and shrimp (28.7%) were the most common food allergens. Environmental allergens were most prevalent in the 2–5 year age group ($p < 0.001$), and food allergens were more common in the 11-18 year age group ($p < 0.001$). Male participants had higher allergen positivity rates than females. Significant seasonal variation was found, with higher allergen positivity rates in autumn and winter.

CONCLUSIONS

This study highlights the prevalence, seasonal variation, and demographic factors associated with food and environmental allergens in Pakistani children. The findings are crucial for enhancing allergy diagnosis and management in pediatric populations.

Clinical Chemistry

P0470

SWEAT TEST: VERIFICATION OF THE CF ∆ COLLECTION SYSTEM®

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BACKGROUND-AIM

Method verification is required for the accreditation of medical biology analyses in accordance with the standards of ISO 15189. The sweat test, a key examination in cystic fibrosis, consists of measuring the sweat chloride concentration. Our aim was to verify the analytical performances of the method for measuring chloride ions using the CF ∆ Collection System® (UCF 2011 Sweat Analysis Unit).

METHODS

Sweat chloride was determined by coulometry using the CF ∆ Collection System® analyser (UCF 2011 Sweat Analysis Unit). Validation of the methods, according to the ISO 15189 standard, requires verification of precision, accuracy, limits of detection and quantification and the linearity range (Scope A). Three levels of the manufacturer's CF ∆ ® quality control solution were used (level 1= 40 mmol/L, level 2= 70 mmol/L, level 3= 130 mmol/L). The recommended coefficient of variation (CV) is less than 5%.

RESULTS

The obtained results indicate acceptable repeatability for the low, medium, and high levels, with a coefficient of variation (CV) CV1#=#1.52%, CV2#=#1.43% and CV3#=#1.03%. Intermediate precision was satisfactory for levels 1, 2 and 3 with a respectively CV1#=#0.76%, CV2#=#0.87% and CV3#=#0.94%. The relative biases (%) at the 3 levels were respectively: 4.16; 3.72 and 2.7 without exceeding the acceptable accuracy limit (5%). The limit of detection was 0.45 mmol/L and the limit of quantification was 1.5 mmo/L. The linearity limit was 128 mmol/L.

CONCLUSIONS

The method for the determination of sweat chloride using the CF ∆ Collection System® is considered to be repeatable, reproducible and accurate.

Clinical Chemistry

P0471

HYPOPHOSPHATEMIA DUE TO TREATMENT WITH INTRAVENOUS IRON: A CASE REPORT.

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BACKGROUND-AIM

Hypophosphatemia is a rare ionic disorder in healthy population. It is generally caused by kidney disorders (chronic kidney disease or proximal tubulopathy), digestive disorders (malabsorptive syndromes) or endocrine disorders (vitamin D deficiency or hyperparathyroidism).
In a small percentage of cases it occurs due to less common causes such as an iron intake that makes its reabsorption difficult by the kidneys.

METHODS

We studied the case of a 39-year-old woman with a history of gastric bypass in 2013 with iron deficiency anemia of 6 years' duration who, due to poor tolerability of oral iron, was administered intravenous carboxymaltose iron. During this treatment, a biochemical study was performed, which revealed a phosphorus level of 0.7 mg/dl (2.5-4.5), and a phosphorus concentration in urine of 126.4 mg/dl (10-100). In addition, a measurement of vitamin D was requested, obtaining a result of 28.2 ng/ml (15-49.9) and PTH of 147.6 pg/ml (15-114.2), being suggestive of secondary hyperparathyroidism. Given the unknown origin of the condition, FGF-23 was measured.

RESULTS

The FGF-23 measurement was 248.1 pg/ml (23.2-95.4), confirming the renal origin of the condition. The patient required hospital admission for intravenous phosphate administration.

CONCLUSIONS

FGF-23 (also known as fibroblast growth factor) is a hormone derived from the bones that participates in the regulation of phosphatemia, as it increases renal excretion of phosphate (by decreasing the expression of the main Na+-dependent phosphate transporters of the proximal tubule) and hinders the hydroxylation of vitamin D by inhibiting the expression of renal cytochrome P450 27b1, a key enzyme for producing 1,25-OH vitamin D. All this leads to secondary hyperparathyroidism. FGF-23, which typically increases in chronic disease, has also been elevated by intravenous iron administration. This would be caused by a deficit in the cleavage of its active form when administered in the form of carboxymaltose, inducing hypophosphatemia associated with treatment of iron deficiency anemia.
Estimating the levels of this hormone can be helpful in the diagnosis of hypophosphatemia caused by iron treatment.

Clinical Chemistry

P0472

CHYLOTHORAX: A CASE REPORT.

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BACKGROUND-AIM

Chylothoraces are a rare cause of pleural effusion. Most of them are caused by an accident or surgery, and exceptionally by mediastinal tumors, tuberculosis or malformations of the thoracic duct. Its diagnosis requires biochemical analysis of the pleural fluid, with triglyceride values greater than 110 mg/dl, cholesterol less than 200 mg/dl, or the presence of chylomicrons.
Diffuse lymphatic malformation usually presents clinically as a chylothorax or chylopericardium. This is a type of lymphatic malformation (diseases that affect the lymphatic vessels, previously called lymphangiomatosis), characterized by an excessive and diffuse proliferation of these vessels, which can rupture and produce pleural or pericardial effusions. Due to its low prevalence, there are no clear criteria regarding its etiology and classification. Associated somatic mutations responsible for angiogenesis have been described; the greatest evidence is the PIK3CA gene mutation.

METHODS

We studied a 6-month-old male who was sent to our hospital because of respiratory distress, cough, and rhinorrhea for 48 hours. It was observed a pleural effusion on a chest x-ray which was obtained to do a biochemical analysis.

RESULTS

The pleural fluid showed characteristics of chylothorax. As part of the etiological study, tuberculosis was ruled out and it was decided to perform a lymphography, revealing a malformation of the thoracic duct. He was diagnosed of Diffuse Lymphatic Malformation. After performing a pleurodesis, the patient presented chylopericardium with cardiorespiratory arrest, secondary renal failure and secondary sepsis, from which he recovered. Although it was intended to do a genetic test, he died at 11 months of age due to multiple complications related to his pathology.

CONCLUSIONS

Biochemical analysis of pleural fluid by the laboratory is essential to make a clinical suspicion and initiate empirical treatment. Given that the most serious cases of this type of disease usually occurs in childhood, it could be considered to keep these entities in mind in the case of chylothorax at pediatric age.

Clinical Chemistry

P0473

INFLAMMATORY PROFILE AND CELLULAR DAMAGE IN MULTIPLE SCLEROSIS: EFFECTS OF 12-WEEK MELATONIN SUPPLEMENTATION

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BACKGROUND-AIM

Multiple sclerosis (MS) is a chronic autoimmune disease of the central nervous system, mediated by inflammatory reactions that induce demyelination and neurodegeneration. As part of MS treatment, melatonin has been shown to have a potent neuroprotective effect due to its anti-inflammatory proprieties. The aim of the present study was to investigate the effectiveness of 12-week melatonin supplementation on inflammatory profile and cellular damage in MS patients.

METHODS

Materials and methods: This randomized placebo-controlled study included 27 patients with relapsing-remitting MS (RRMS) who were assigned to either a melatonin group (n=15, 34.67 ±10.93 years old) or a placebo group (n=12, 36.83 ± 8.07 years old). Participants were asked to ingest the 3-mg supplement (melatonin/placebo) every night, 30 minutes before bedtime, for 12 weeks. Before and after the 12-week supplementation, blood sampling was conducted to measure the levels of immune inflammatory cells (complete blood count) as well as biomarkers of systemic inflammation (C-reactive protein) and cellular damage (creatine phosphokinase, lactate dehydrogenase, aspartate aminotransferase, alanine aminotransferase).

RESULTS

Results: Based on the pre-post supplementation change (∆), melatonin reduced the levels of leucocytes (32.42%, p=0.009, Hedges'g (g)=1.06), neutrophils (8,50%, p<0.001, g=1,74) and lymphocytes (11.37%, p=0.011, g=1.03) compared with placebo. No significant differences were found between both groups for C-reactive protein and cellular damage biomarkers.

CONCLUSIONS

This study revealed the repressive effect of 12-week melatonin supplementation on RRMS-induced inflammation. The anti-inflammatory and immunomodulatory properties of melatonin can be due to its receptors in the central nervous system and immune cells.

Clinical Chemistry

P0474

HYPOPARATHYROIDISM AS A RARE MANIFESTATION OF KEARNS-SAYRE SYNDROME: A CASE REPORT

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BACKGROUND-AIM

Kearns-Sayre Syndrome is a rare mitochondrial cytopathy caused by large-scale single deletions of mitochondrial DNA. It is characterized by progressive external ophthalmoplegia, cardiac conduction block, pigmentary retinal degeneration, and a variable number of red ragged fibers on muscle biopsy. The syndrome typically presents before the age of twenty. Kearns-Sayre syndrome can affect multiple organ systems, with additional features including myopathy, dystonia, bulbar symptoms such as dysarthria and nasal regurgitation, and bilateral facial weakness. It may also be associated with endocrinopathies, such as hypoparathyroidism and diabetes, which should be actively monitored to ensure optimal patient care.

METHODS

This study reports the case of a patient who sought care in the pediatric outpatient department. Calcium and phosphate levels were measured using a colorimetric method on the AU DXC 700® Beckman Coulter analyzer. The patient also underwent parathyroid hormone (PTH) analysis through the chemiluminescence technique on the DXI 600® Beckman Coulter analyzer.

RESULTS

We present the case of a 10-year-old patient, born to consanguineous parents, with a medical history that includes diabetes mellitus, keratoconjunctivitis sicca and school failure. Clinical examination revealed bilateral ptosis and myopathy, while brain imaging showed involvement of the central gray nuclei. Kearns-Sayre Syndrome has been mentioned. The biological assessment showed that calcium (2.46 mmol/L) and phosphate (1.34 mmol/L) levels were within normal ranges. However, the parathyroid hormone (PTH) concentration was 4 ng/mL (normal range: 15–50 ng/mL), confirming a diagnosis of hypoparathyroidism.

CONCLUSIONS

Hypoparathyroidism is a rare but significant manifestation of Kearns-Sayre Syndrome (KSS), adding to the complexity of its clinical presentation. This case underscores the necessity of maintaining a high index of suspicion for endocrine involvement in patients with KSS. A multidisciplinary approach is vital in addressing the diverse and multisystemic features of this rare mitochondrial disorder.

Clinical Chemistry

P0475

ANALYTICAL PERFORMANCE OF AN AUTOMATED LATEX IMMUNOTURBIDIMETRIC ASSAY FOR SERUM AMYLOID A

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BACKGROUND-AIM

Serum Amyloid A (SAA) is an important acute-phase reactive protein mainly produced by liver and the detection of SAA is more informative than the detection of C-reactive protein (CRP) in patients with viral infections. The objective of this study was to evaluate the analytical performance of the SAA protein assay (Beijing Strong Biotechnologies Inc., Beijing, China) on the Labospect 008AS analyzer (Hitachi High-Tech Co., Tokyo, Japan).

METHODS

Intra and inter-run precision were evaluated using a low and a high concentration quality control (QC) material. For inter-assay precision, single-use aliquots were analyzed in quintuplicate for 5 days, one run per day. Linearity was evaluated using 5 levels of pooled serum in duplicate. The reference interval (RI) was verified with 20 healthy Korean population that met the following inclusion criteria: (a) 24-75 years of age; (b) normal CRP; (c) routine biochemical analytes, such as hemoglobin, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyltransferase, creatinine, glucose, total cholesterol, triglyceride, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol, were within the normal RIs. Comparison with Cobas 8000 c702 (Cobas) was performed using residual de-identified patient specimens (n=20) spanning the analytical measuring interval, analyzed on the same day.

RESULTS

Repeatability and within-laboratory imprecisions with 2 QC materials were lower than 2.02% and 1.57% for Labospect 008AS (Labo), and 1.51% and 1.95% for Cobas, respectively. Linearity was observed, with percent recoveries ranging from 99.0-100.0% on Labo and 98.5-100.0% on Cobas for SAA concentration in the performance ranges used (2.4-300 mg/L) for both analyzers. The transference of the RI in 20 healthy subjects was verified (10.0 mg/L) by using the Labo. There was a high concordance between the two systems: the equation of the Passing-Bablok line is YLabo = 0.492 + 0,972 XCobas with a correlation coefficient r=0.9993.

CONCLUSIONS

Acceptable analytical performance was observed for SAA protein assay on the Labo. Our study shows a high correlation of the SAA assay results between Labo and Cobas. It is suitable for application in routine clinical laboratories.

Clinical Chemistry

P0476

ANALYTICAL EVALUATION OF THE NORUDIA GLYCATED ALBUMIN ASSAY ON THE HITACHI LABOSPECT 008AS ANALYZER

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BACKGROUND-AIM

Glycated albumin (GA) is a reliable biomarker for the intermediate-term (previous 2-3 weeks) monitoring of glycemic control in patients with diabetes. Herein, we evaluated the analytical performance of Norudia GA assay (Sekisui Medical, Japan) on LABOSPECT 008AS platform (Hitachi High-Tech Co., Tokyo, Japan) and assay applicability on the clinical referral laboratory.

METHODS

Precision and linearity were evaluated following the guideline of Clinical and Laboratory Standards Institute (CLSI) EP15-A3 and EP06-A, respectively. The reference interval (RI) was verified following CLSI EP28-A3C. A comparison study was performed against the Lucica GA-L assay (Asahi Kasei Pharma Corporation, Tokyo, Japan) following CLSI EP09-A3 on LABOSPECT 008AS platform.

RESULTS

Repeatability and within-laboratory imprecisions using a low and a high concentration quality control materials were lower than 2.30%, 2.95%, and 2.86% for GA (μmol/L), albumin (μmol/L), and GA%, respectively. Linearity using 5 levels of pooled serum was observed for GA concentration in the performance ranges used (10.6–728.6 μmol/L). The transference of the RI in 24 healthy subjects without diabetes in the Korean population was verified (11.0-16.0%). In the comparison study with 40 patient samples, a Passing-Bablok regression analysis resulted in a slope of 1.00 (95% CI: 0.982-1.040) and an intercept of 0.00 (95% CI: -0.717 to 0.356) with a correlation coefficient r=0.9946.

CONCLUSIONS

The Norudia GA assay shows a reliable performance with fully automated LABOSPECT 008AS system, and could be used for glycemic control in diabetes patients on the referral clinical laboratory.

Clinical Chemistry

P0477

TRACE MINERAL ELEMENTS STATUS (COPPER AND MANGANESE) IN ALGERIAN TYPE 2 DIABETIC PATIENTS WITH ARTERIAL HYPERTENSION

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BACKGROUND-AIM

The relationship between trace mineral elements and high blood pressure (HBP) in type 2 diabetic patients is subtle and very complex. This relationship is mediated by endothelial dysfunction, insulin resistance, oxidative stress (OS), vascular inflammation and atherosclerosis. The aim of this work is to evaluate the serum status of trace mineral elements copper (Cu) and manganese (Mn) in Algerian subjects type 2 diabetic with arterial hypertension.

METHODS

This study involved 160 subjects, aged between 40 and 50 years, divided into 2 groups: hypertensive and type 2 diabetes (T2D) subjects (n=80) and control subjects (n=80). HTA was defined by systolic blood pressure (SBP) and diastolic blood pressure (DBP) > 140/90 mmHg. Trace elements (Cu and Mn) were measured by graphite furnace atomic absorption spectrometry on ICE 3300 from Thermo Fisher. In addition, ceruloplasmin and hs-CRP were measured as biomarkers of inflammation.

RESULTS

Low serum Mn levels are found in hypertensive T2D patients compared to controls (p<0,001), while serum Cu levels are increased (p<0,001). Furthermore, a strongly positive correlation is found between serum Cu and hs-CRP levels (r=0,644, p <0,001).

CONCLUSIONS

The imbalance of the trace mineral elements may be at the origin of the dysregulation of the pathophysiological mechanisms implicated in HBP through their involvement in oxidative stress and their relationship to inflammatory proteins. A balance of these minerals in parallel with nutritional and lifestyle recommendations could significantly contribute to reducing cases of high blood pressure in T2D patients.

Clinical Chemistry

P0478

PSEUDOHYPERNATREMIA WITH A NEGATIVE OSMOLAR GAP : A CASE REPORT

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BACKGROUND-AIM

Severe hypernatremia is a relatively rare condition among hospitalised patients. Confirmation of hypernatremia is essential prior to making clinical and therapeutic decisions.

METHODS

A 63-years-old woman underwent a plasma sodium test during a routine check-up of diabetes.
Plasma sodium (Na+) levels were measured using two different analyzers: the DXC AU 700, Beckman Coulter analyzer (indirect ion-selective electrode) and the ABL80, Radiometer analyzer (direct ion-selective electrode). Plasma osmolality was determined using a Fiske 210® freezing-point osmometer.

RESULTS

The patient had a high plasma sodium level of 168 mmol/L wich was not compatible with her clinical picture. The test was repeated on a direct ion selective electrode analyzer for confirmation. The Na+ appeared approximately normal (148 mmol/L). The lipid profile and total protein levels were within reference ranges. Sodium citrate contamination was suspected. Therefore, additional tests were carried including plasma calcium, chloride, and measured osmolality. Calcium and chloride levels were inappropriately low (1.85 mmol/L and 92 mmol/L respectively). The plasma osmolality was 304 mOsmol/kg while the calculated osmolality was 356 mOsmol/kg. A negative osmolar gap (-52) was noted. Repeated blood tests showed results within references ranges (Na+=138 mmol/L; chloride = 104 mmol/L and total calcium= 2.44 mmol/L).The falsely elevated Na+ was due to sample contamination with trisodium citrate a chelator of calcium, used in coagulation tubes. Chloride levels lowering due to a dilutionary effect.

CONCLUSIONS

Pseudohypernatraemia due to sodium citrate contamination should be recognised by biologists to avoid unnecessary clinical investigations and treatments.

Clinical Chemistry

P0479

PREDICTIVE FACTORS OF POOR PROGNOSIS IN BURN PATIENTS

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BACKGROUND-AIM

Severe burns, often accidental but sometimes intentional, result in major disruptions to vital functions.
the Aim is To identify predictive factors associated with poor prognosis in burn patients upon admission.

METHODS

This retrospective study analyzed 121 adult burn patients admitted between December 2023 and April 2024 to the specialized burn emergency unit. The study examined the cause of burns, the burned body surface area (BSA), biological parameters (complete blood count, blood glucose, urea, creatinine, albumin levels).
The leukocyte-to-lymphocyte and creatinine-to-serum albumin ratios were calculated, and the 28-day survival rate was estimated.

RESULTS

The study included 79 men and 42 women, with burns primarily caused by gasoline or gas flames (63%). Among patients with a BSA greater than 30% (26.4% of the study population), factors associated with poor prognosis included:
• Severe hypoalbuminemia (27%)
• Thrombocytopenia (27%)
• Severe thrombocytosis (13%)
• Hyperglycemia (47%)
• Leukocyte-to-lymphocyte ratio >4 in 90% of cases, with an average of 19.31.
The 28-day survival rate for burns with BSA >30% was 50%. The average creatinine-to-albumin and leukocyte-to-lymphocyte ratios were 2.17 µmol/g and 21.04, respectively

CONCLUSIONS

Severe burns lead to multi-organ failure and a high risk of mortality. Early clinical and biological evaluation upon admission is crucial to optimize management and reduce complications.

Clinical Chemistry

P0480

EVALUATION OF ANALYTICAL PERFORMANCE OF ROCHE COBAS PURE INTEGRATED SOLUTION ON 17 CLINICAL CHEMISTRY AND IMMUNOCHEMISTRY ANALYTES

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BACKGROUND-AIM

The growing need to optimize laboratory space and staffing has driven interest in automation and consolidation of analytical systems. The cobas® pure integrated solutions (Roche Diagnostics International Ltd, Rotkreuz) has been designed for low-to-medium throughput laboratories (up to 870 tests/hr) with a compact footprint, integrating a chemistry unit, cobas® c303, and an immunochemistry unit, cobas® e402. However, limited data exist on its analytical performance. This study evaluated the analytical performance of cobas® pure integrated solutions for clinical chemistry and immunochemistry analytes in serum and urine.

METHODS

Seventeen analytes were evaluated including apolipoprotein A, apolipoprotein B, ASO, C3, C4, estradiol, haptoglobin, human growth hormone, IgG, IgA, IgM, IgE, insulin-like growth factor 1 (IGF-1), Lp(a), urine microalbumin, rheumatoid factor, and transferrin. Evaluation included precision, linearity, carry-over, reference interval verification, and method comparison per CLSI guidelines. Method comparison was conducted on 40 clinical samples, against Hitachi 7180 chemistry analyzer (Hitachi. Ltd, Tokyo) and Liaison® XL analyzer (Diasorin, Saluggia).

RESULTS

Within-laboratory coefficients of variations (CVs) ranged from 0.43% to 5.07%, meeting the desirable specifications for imprecision from EFLM biological variation database or manufacture's claimed target. All analytes demonstrated acceptable linearity within their respective analytical measurement intervals. No carryover was observed, and reference intervals were verified. Coefficient of determination (R^2) exceeded 0.95 for all analytes except C3 (R^2=0.91). However, the 95% confidence interval of the slopes and intercepts of all analytes did not include 1 and 0, respectively, indicating significant differences. Bland-Altman analysis revealed biases ranging from 9.7% to 65.8%.

CONCLUSIONS

The cobas® pure integrated solutions showed excellent analytical performance for precision, linearity, and carry-over. However, significant differences between analyzers necessitate careful interpretation of results. Overall, this system is well suited for clinical testing, particularly in low-to-medium throughput laboratories with limited staffing.

Clinical Chemistry

P0481

THE RELATIONSHIP BETWEEN ACUTE PHASE PROTEIN AND CYTOKINES ON ALCOHOLIC LIVER DISEASE

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BACKGROUND-AIM

Chronic alcohol consumption may cause excessive cytokine production in the liver, leading to hepatocellular injury and inflammatory alcoholic liver disease. We evaluated the relationship between acute phase protein and cytokines on alcoholic liver disease.

METHODS

We have included 160 males divided in five groups: (1) no alcohol intake (< 20 g ethanol/d); (2) low alcohol intake (20-40 g ethanol/day); (3) high alcohol intake (> 40 g ethanol/d) without liver necrosis; (4) high alcohol intake with liver necrosis; (5) high alcohol intake and proven liver cirrhosis. Liver necrosis was based on transaminase levels. The patients were selected based on exclusion criteria (other relevant liver disease, nonalcoholic liver disease, uncontrolled diabetes, history of peptic ulcer, renal and cardiac failure, acute and chronic infection disease, tuberculosis, psychiatric disease.
To measure cytokines and hs-CRP we have used DPC IMMULITE 1000 based on chemiluminescent reaction. Statistical tests were performed using MedCalc® 12.6.1.0. All p-values <0.050 were considered statistical significant.

RESULTS

On the relationship between cytokines TNF alfa, IL 1 beta, IL 6 and acute phase proteins hs CRP, fibrinogen, there was positively significant related to hs CRP and no significant related to fibrinogen. The relationship remain non significant to fibrinogen even considered alcohol intake, respectively for TNF alfa ANCOVA GLM F=2.7 P=0.09 and for IL 1 beta ANCOVA GLM F=3.5 P=0.06. In a multivariate logistic regression, independent risk factors for liver necrosis are: TNF alfa, hs CRP, alcohol intake, while fibrinogen is protective factor liver necrosis (Hosmer & Lemeshow adapted test of model): Chi-squared = 9.77 P = 0.2.

CONCLUSIONS

TNF alfa, hs CRP, high alcohol intake, are considered as independent risk factors on liver necrosis while fibrinogen as a protective factor.

Clinical Chemistry

P0482

COMPARATIVE STUDY OF THE ANALYTICAL PERFORMANCE OF TWO TECHNIQUES FOR TESTING BLOOD IN STOOLS: IMMUNOCHROMATOGRAPHIC AND IMMUNOTURBIDIMETRIC METHODS.

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BACKGROUND-AIM

The aim of this study was to compare two methods for detecting blood in stools (screening techniques): the turbidimetric method, which is based on measuring the variation in turbidity in a solution containing stool samples, and the immunochromatographic technique, which uses a unique combination of monoclonal antibodies coupled to colloidal gold and polyclonal antibodies fixed on the solid phase to identify human haemoglobin.

METHODS

This was a prospective study carried out on a series of patients (48 patients) in a parasitology-mycology department of the university hospital centre.
The study compared these two approaches in terms of analytical sensitivity, specificity, detection and quantification limits, speed of execution, cost and ease of use.

RESULTS

Results: 48 samples were analysed simultaneously by the two techniques and by the same operator.
35 samples gave negative results with both techniques, while only one result was negative with the turbidimetric method alone, while the immunochroatographic method gave a result in the grey zone.
All 12 results were positive with both techniques.
In terms of sensitivity, the immunochromatographic method can detect concentrations close to 5 ng/ml (0.71 ug/g), in which case the result displayed will be <10 ng/ml (<1.43 ug/g), which is consistent with the results of our study, whereas the limit of detection corresponds to 2.5 ug of haemoglobin/g of stool and the limit of quantification is 9.5 ug of haemoglobin/g of stool for the immunoturbidimetric method.
The analysis time was 10 minutes for the immunochromatographic technique, whereas the immunoturbidimetric technique was faster, with a turnaround time of less than 5 minutes.

CONCLUSIONS

the results obtained show that the immunochromatographic technique offers better sensitivity and specificity, particularly for the detection of low haemoglobin concentrations. On the other hand, the turbidimetric method stands out for its simplicity, speed and relatively low cost, which may make it more accessible in certain contexts.
the choice of method depends on clinical objectives, economic constraints and available resources.

Clinical Chemistry

P0483

SERUM LEVEL OF VITAMIN D AMONG FEMALES NEWLY DIAGNOSED WITH BREAST CANCER IN TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA: A COMPARATIVE CROSS-SECTIONAL STUDY

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BACKGROUND-AIM

Breast cancer (BC) is the most common cancer among women and causes death among hundreds of thousands of people each year worldwide. There is a possibility of a high prevalence of vitamin D deficiency which could be associated with an increased incidence of breast cancer. However, there is limited evidence on the serum level of vitamin D and its link to breast cancer among females diagnosed with the disease in Ethiopia. Thus, this study aimed to assess the serum level of Vitamin D among females diagnosed with breast cancer.

METHODS

A facility-based comparative cross-sectional study was conducted from January to March 2024 in Tikur Anbessa Specialized Hospital, Addis Ababa. A total of 69 females with breast cancer (case) consecutively upon their diagnosis and equal among females without breast cancer (control) were included in the study. Serum 25 hydroxyvitamin D (25(HO) D) concentration test was measured by a fully automated COBAS 6000 analyzer. The data was analyzed by SPSS version 20.0. Descriptive statistics were used to compare the characteristics of cases and control participants and the p-value was calculated using the Chi-square test. Serum biochemical parameters were compared among cases and control groups using the Man Whitney U t-test. Logistic regression was used to determine the association factors for breast cancer.

RESULTS

There was a high prevalence of vitamin D deficiency in females with BC (85.5%) and without BC (72.4%). There was also a significant median difference in serum 25(OH) D concentrations between females with BC and those without BC (p= 0.012). Only 10(14.5%) females with BC and 19 (27.5%) females without BC had sufficient 25(OH) D concentrations. Severely low concentrations of 25(HO) D (<10 ng/mL) were significantly associated with an increased odds of BC by 6.6 folds with a 95% confidence level (1.7–26.1) with a p-value of 0.007.

CONCLUSIONS

There is a high prevalence of vitamin D deficiency in both females with BC and without BC However, there is a significantly increased odds of severe vitamin D deficiency (<10 ng/mL) among females with BC. Addressing severe vitamin D deficiency is vital to decrease the burden of BC.

Clinical Chemistry

P0484

SODIUM CITRATE CONTAMINATION

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BACKGROUND-AIM

Background
Contamination of blood samples with trisodium citrate (Na_3Cit) is a known cause of spurious hypernatraemia. Na_3Cit is used in solution in coagulation tubes and as Citra-Lock™ for venous catheter locking. Therefore, a dilutional effect is expected to accompany significant contamination. Calcium is likely decreased given that citrate works as an anticoagulant by binding free calcium. However, how Na_3Cit interferes with other biochemical tests is unknown.
Aim
To determine what clinical chemistry analytes suffer interference due to pre-analytical contamination with Na_3Cit.

METHODS

Surplus serum from samples was pooled. This was divided into two portions, one of which was spiked with crystalline trisodium citrate dihydrate. Another pool of surplus serum was created. 3.2 mL of serum from this pool was pipetted into a coagulation tube (Greiner-Bio-One Vacuette Sodium Citrate 3.2%). All four portions of serum were assayed for concentrations of citrate, sodium, total calcium, LDH, amylase, potassium, albumin, phosphate, AST, GGT, magnesium, uric acid, ALP, ALT, cholesterol, HDL, triglycerides, creatinine and iron.
The percentage change in results of the analytes was calculated.
All analytes, except citrate, were measured on the Abbott Alinity c platform (Abbott Laboratories, IL, USA) using its proprietary methods. Citrate was measured using a urinary and semen citrate kit (BioSystems, Spain) that had been validated for measurement in serum on the Abbott Alinity c platform.

RESULTS

Sodium expectedly increased in the contaminated serum. Calcium decreased in the presence of the large concentration of citrate from the experiment involving crystalline Na_3Cit but the decrease seen in the coagulation tube was not very different from the dilutional drop seen in most other analytes. Interestingly, magnesium did not experience dilutional decrease in the coagulation tube, introducing the question of magnesium contamination of the tube.

CONCLUSIONS

Na_3Cit contamination, in addition to causing spurious hypernatraemia, also causes a spurious hypocalcaemia. Additionally, there is a dilutional effect caused by the solution of Na_3Cit used.

Clinical Chemistry

P0485

ASSOCIATION OF TAC WITH SUPAR AND EGFR, IN RELATION TO URINE ALBUMIN LEVELS AND HBA1C

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BACKGROUND-AIM

Total antioxidant capacity (TAC) estimates all the antioxidant mechanisms that the body has to battle oxidative stress. Soluble urokinase plasminogen activation receptor (suPAR) is a marker of inflammation. Urine albumin to creatinine ratio (ACR) and CKD-EPI estimated glomerular filtration rate (eGFR) are used for the estimation of renal function. The present study aimed to evaluate inflammation and oxidation status markers in relation to renal function and glycemic status.

METHODS

In 75 participants (31 outpatients and 44 hospitalized), serum urea and creatinine levels, urine albumin and creatinine levels and plasma suPAR levels were determined by the use of an automated analyzer (Roche Diagnostics), with a photometric and an immunoturbidometric method, respectively, and we estimated ACR (mg/g Cr) and eGFR (mL/min/1.73m2). Serum TAC levels were measured manually, using a colorimetric method. The statistical analysis was performed with IBM SPSS Statistics v. 25.

RESULTS

Statistically significant difference was found only in suPAR and eGFR levels, between individuals with Hb1c<6.5% and with HbA1c ≥6.5%, p=0.024 and p=0.012, respectively. When patients were divided into three groups, according to urine ACR (<30 mg/g, 30-300 mg/g and >300 mg/g, respectively), statistically significant negative correlation between suPAR and eGFR was found in all three groups (rs=-0.569 p<0.001, rs=-0.436 p=0.033 and rs=-0.880 p<0.001, respectively). A statistically significant positive correlation between TAC and suPAR was observed in the first and second group (rs=0.336, p=0.05 and rs=0.574, p=0.003, respectively). A statistically significant negative correlation between TAC and eGFR, was found only in the first group (rs=-0.448, p=0.008). TAC levels did not differ significantly between the subgroups. In all three groups a statistically significant negative correlation between suPAR and eGFR was found, while there was a statistically significant negative correlation between eGFR and TAC only in the group with normal albumin urine excretion, regardless of HbA1c levels.

CONCLUSIONS

The combination of TAC with suPAR might be particularly helpful in monitoring CKD stage progression, but this needs further investigation.

Clinical Chemistry

P0486

COMPARISON OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) CONCENTRATIONS BY DIRECT MEASUREMENT AND BY FRIEDEWALD CALCULATION

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BACKGROUND-AIM

Low-density lipoprotein cholesterol (LDL-C) measurement is crucial for diagnosing and managing dyslipidemia and preventing cardiovascular diseases (CVD). The Friedewald formula (FF) is widely used due to its cost-effectiveness and convenience, but its accuracy may be compromised by elevated triglyceride (TG) levels, extreme LDL-C values, or variations in high-density lipoprotein cholesterol (HDL-C). Direct LDL-C measurement, though more accurate, is more expensive and less accessible.
This study aims to compare the LDL-C calculated by FF and LDL measured directly to evaluate their clinical utility and potential limitations.

METHODS

This cross-sectional study enrolled patients from the cardiology department at Habib Bourguiba Medenin Hospital who underwent a complete lipid profile assessment between July and November 2024. Patients with triglyceride levels> 3.4 g/L were excluded. LDL-C was calculated using the Friedewald formula: LDL-C (mg/dL) = Total Cholesterol − HDL-C − (Triglycerides/5). Direct LDL-C measurements were performed using enzymatic colorimetric assays on the Beckman Coulter AU480 analyzer. Comparative analyses of the two methods were conducted using Bland-Altman plots and spearman correlation coefficients.

RESULTS

This study included 67 patients. The median (interquartile range) LDL calculated by FF was 1.83 (1.36), while the direct measurement was 2.55 (1.19). Correlation coefficient (r) between measured LDL and FF calculated LDL was 0.805 ($p<0.01$). Bland-Altman analysis revealed a mean difference (bias) of 0.69, with limits of agreement ranging from -0.27 to 1.65. Most data points fell within these limits, suggesting acceptable agreement between the two methods.

CONCLUSIONS

The Friedewald formula shows strong correlation and reasonable agreement with direct LDL-C measurement, making it suitable for routine clinical use. However, its systematic underestimation and occasional discrepancies suggest that direct measurement should be prioritized for high-risk cardiovascular patients or research contexts where accuracy is critical.

Clinical Chemistry

P0487

PLACENTAL BED TROPHOBLASTIC TUMOR: A CASE REPORT

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BACKGROUND-AIM

Introduction:
Placental bed trophoblastic tumor is an exceptional tumor, with no more than 100 cases reported in the literature. It is a neoplastic disease of the intermediate trophoblast, with metastatic potential in a few cases. Unlike other trophoblastic tumors, a characteristic feature of this disease is the low production of human chorionic gonadotropin in relation to the tumor volume and its limited sensitivity to conventional chemotherapy.

METHODS

Clinical Case:
A 38-year-old woman with no significant medical history. Obstetric history includes 2 pregnancies and normal deliveries, and one spontaneous abortion with pharmacological treatment two months prior.
She presented to the emergency department with mild genital bleeding. Genital examination was normal, with minimal blood remnants and a closed cervix. Transvaginal ultrasound showed an anteverted uterus with a vascularized area measuring 18x21 mm, suggestive of a placental polyp. Ovaries were in rest, and no free fluid was observed. Based on these findings, a ß-HCG test was performed, with a result of 9.4 mUI/mL (<5).

RESULTS

Surgical resection of the irregular trophoblastic tissue was carried out, which in some areas was necrotic and very vascularized at the base with vascular tufts.
The directed biopsy was compatible with the diagnosis of placental bed trophoblastic tumor, and the staging study was negative, showing no signs of metastatic disease.

CONCLUSIONS

Discussion:
Although this tumor is extremely rare, it should be considered in the context of diagnosing trophoblastic disease, given its good prognosis following surgical treatment. On the other hand, careful follow-up will alert us to the persistence of the tumor or the development of metastatic disease.

Clinical Chemistry

P0488

THE EFFECTS OF DIFFERENT ANTIRETROVIRAL THERAPY REGIMENS ON LIVER AND RENAL FUNCTION IN HIV PATIENTS AT ELARD ALUMANDO DREAM CENTRE, MALAWI

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BACKGROUND-AIM

HIV/AIDS was first reported in Malawi in 1985, with an adult HIV prevalence of 8.9% in April 2022. While ART has significantly improved life expectancy, side effects such as liver and renal toxicity remain a concern. The effects of ART regimens on liver and renal function in Malawian patients, particularly with first-line ART options, are understudied. Monitoring liver (ALT, AST) and renal (creatinine) function is essential for effective HIV management. This study aims to assess the impact of ART regimens on liver and renal function in HIV-positive patients at Elard Alumando Dream Centre, Blantyre.
Understanding the effects of ART on liver and renal function is crucial for optimizing treatment and minimizing toxicity. ART-associated toxicity can affect adherence, and identifying regimens with minimal side effects can improve long-term outcomes. The primary objective is to investigate the effects of different ART regimens on liver and renal function, with a specific focus on the prevalence of liver and renal dysfunction in patients on ART.

METHODS

This retrospective cohort study will analyze records from HIV-positive patients aged 18–60 at Elard Alumando Dream Centre who have been on ART for at least one year and have liver and renal function test results. Data will be collected from EMRs for 2021–2022, including demographic details, ART regimen, and liver/renal function markers. Descriptive statistics and ANOVA will compare liver and renal function across ART regimens, and regression analysis will assess the influence of variables such as age and sex.

RESULTS

Out of 138 records, 60 met the criteria. Thirty patients were on first-line ART, and 30 on second-line ART. No significant relationship was found between ART regimen and liver (AST/ALT) or renal (creatinine) function. Renal dysfunction prevalence was higher than liver dysfunction at baseline and increased over time, remaining higher at one and two years. Our results align with studies from Tanzania and South Africa, showing minimal renal damage or improvement with tenofovir-based ART, and stable liver function.

CONCLUSIONS

This study shows minimal effects of ART regimens on liver and renal function in HIV-positive patients at Elard Alumando Dream Centre, supporting the continued use of current ART regimens in resource-limited settings like Malawi.

Clinical Chemistry

P0489

INFECTIOUS NEPHROLITHIASIS IN A PATIENT WITH PYELOURETERAL JUNCTION SYNDROME

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BACKGROUND-AIM

Infectious nephrolithiasis is viewed as a result of a urinary tract infection. These bacteria can produce urease, an enzyme that breaks down urinary urea, leading to an increase in urinary pH that promotes the precipitation and aggregation of crystals. Pyelo-ureteral junction syndrome is a malformation in the upper urinary tract characterized by a narrowing of the junction between the pelvis and the ureter. The increase in urinary pH due to infection and urinary stasis due to this syndrome leads to kidney stones formation.

METHODS

Case presentation: A 39-year-old woman is admitted for surgery to nephrolithotomy due to multiple stones. Medical history of pyeloureteral junction syndrome with recurrent urinary tract infections, renal colics and nephrolithiasis since childhood, with repeated extracorporeal lithotripsy treatments.

RESULTS

Diagnosis: Bilateral staghorn urinary lithiasis due to urinary tract infections. The first suspect was a metabolic alteration as a cause of repeated stone formation. This was ruled out when the complete metabolic study presented no alterations. A lithiasis study was conducted, involving a metabolic evaluation of kidney stone formation, a morpho-constitutional analysis of the formed calculi and performing a bacteriological analysis on the calculi. Sample received: fragment of calculus along with grit, fragile and white. surface is rough and crystalline, with a disorganized crystalline section. Morphological classification (M. Daudon): surface IVa1 + IVc. In conclusion, it corresponds to IVa1, indicating carbapatite composition, and IVc, indicating struvite. These was confirmed by infrared spectroscopy. Bacteriological analysis: Proteus mirabilis and Enterococcus faecalis.

CONCLUSIONS

Staghorn kidney stones are a type of large urinary calculus of the kidney. The causes considered were a metabolic disorder and the recurrence of urinary tract infections. Performing a complete metabolic study that resulted with no alterations ruled out metabolic disorder. Besides, a complete morphological, chemical and bacteriological analysis was performed, finding a consistency with kidney stones formed because of the presence of urease producer bacteria. To know the specific bacterial agent allows the application of the correct treatment.

Clinical Chemistry

P0490

SILENT THREAT: AN INCIDENTAL DISCOVERY OF PLASMA CELL MYELOMA DURING ROUTINE EVALUATION

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BACKGROUND-AIM

Plasma cell myeloma is a condition of malignant plasma cell proliferation in the bone marrow. These abnormal cells proliferate uncontrollably, producing excessive antibodies that can lead to bone damage, kidney dysfunction, and compromised immune function. Early detection and treatment are crucial to manage symptoms and improve patient outcomes. This case involves incidental finding of plasma cell myeloma following lower back pain.

METHODS

A 60-year-old man presented to the orthopedic department with complaints of lower back pain and progressive difficulty in walking for two months. He also reported generalized weakness and unintentional weight loss during this period. There was no significant past medical history or prior trauma.
On examination, both general and systemic findings were unremarkable. Routine biochemical tests revealed a total calcium level of 2.6 mmol/L (reference range: 2.2 – 2.6). Renal function tests and plasma hemoglobin were within normal limits.
However, a urine test for Bence Jones protein returned positive. Serum protein electrophoresis revealed an abnormal monoclonal band in the gamma region, and immunofixation identified immunoglobulin G (IgG) with kappa light chains. The kappa to lambda ratio was 6.5 (reference range: 0.27 – 1.65).
Despite a normal peripheral blood smear, bone marrow aspiration demonstrated plasma cell malignancy with a plasma cell count of 60%. Radiological imaging revealed a wedge fracture in the lumbar spine and multiple lytic lesions in the shaft of the right femur. The patient was commenced on antineoplastic therapy where he showed a drastic recovery.

RESULTS

Plasma cell myeloma, often diagnosed incidentally, presents a diagnostic challenge due to its non-specific symptoms. This case underscores the importance of comprehensive evaluation in patients with persistent back pain and generalized symptoms, even without overt systemic abnormalities. Early detection and prompt initiation of therapy significantly improved this patient's outcome.

CONCLUSIONS

This case highlights the critical role of detailed investigation and imaging in the timely diagnosis of plasma cell myeloma. The incidental findings underscore the need for vigilance in patients with seemingly non-specific musculoskeletal complaints.

Clinical Chemistry

P0491

SERUM AND EXOSOMAL MICRORNA-34A EXPRESSION CORRELATES WITH INFLAMMATORY AND METABOLIC BIOMARKERS IN SUBJECTS WITH INCREASED FAT MASS

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BACKGROUND-AIM

Adipose tissue (AT) is recognized as a key source of circulating extracellular vesicles (EVs), specifically adipocyte-derived extracellular vesicles (AdEVs), which play a critical role in intercellular communication. These EVs transport biological material, including microRNAs, between adipocytes, stromal cells within the AT, and other systemic cells. Among these microRNAs, the miR-34 family includes three members: miR-34a, miR-34b, and miR-34c. miR-34a is predominantly expressed in adipocytes and macrophages and regulates immune and metabolic functions within AT. This study evaluated the relative expression of miR-34a in serum and circulating exosomes from individuals with normal and high-fat percentages.

METHODS

Adults (n=142) were categorized by normal and high body fat percentage: Normal: men <25%, women <35%, High: men ≥25%, women ≥35%. Insulin resistance status, multimeric adiponectin, and chemerin were measured by ELISA, inflammation biomarkers, and lipid profile by immunoturbidimetric method. Exosomes were isolated by Total Exosomes Isolation kit (Invitrogen®) and characterized by cryo-TEM, miR-34a expression was quantified using qRT-PCR.

RESULTS

Serum miR-34a expression showed a negative correlation with C3, pCr, AdipoQ-H, Chemerin, CCL2, and LDLc, and a positive correlation with insulin resistance status indicators. In contrast, circulating exosomal miR-34a showed a negative correlation with lipid profile, fasting glucose, and QUICKI, while a positive correlation with AdipoQ-H and fasting insulin was shown. The expression levels of miR-34a were higher in serum than in EVs.

CONCLUSIONS

We suggest that increased relative expression of serum miR-34a is a promising biomarker for assessing the clinical manifestation of inflammation and insulin sensitivity within AT.

Clinical Chemistry

P0492

EVALUATION OF RENAL BIOMARKERS DURING CORONAVIRUS-2 INFECTION OF SEVERE ACUTE RESPIRATORY SYNDROME

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BACKGROUND-AIM

In December 2019, an outbreak of coronavirus disease 2019 (COVID-19) occurred in Wuhan, Hubei Province, China. It quickly spread to other parts of the world. Advances in the field of pathophysiology have shown that co-expression of angiotensin-converting enzyme 2 (ACE 2) receptors and TMPRSS proteases are required for virus entry into the host cell. Direct renal involvement of the virus was therefore strongly suspected due to the high concentration of these receptors at the renal level, particularly at the level of the proximal tubule.

METHODS

This was a prospective, descriptive and analytical study of patients infected with SARS-CoV2. For each patient, blood samples were taken on a heparin tube or dry tube for the determination of parameters (albumin, creatinine, urea, Na + K+) with the Abbott ARCHITECT ci4100.

RESULTS

Our study population consisted of 153 subjects with covid-19. The mean age was 55±19 years (15 and 93 years). The most representative age group was patients over 60 years of age (52.3%). Male sex accounted for 53.8% of the study population. 45.1% of patients had a severe form with 16.3% of deaths during hospitalization. The association of renal biomarkers with disease severity showed that the risk of severe disease was higher in patients with hypoalbuminemia (OR=5.3; p=0.001), hyperuraemia (OR=4.1; p=0.001), hypercreatinine (OR=3.6; p=0.001), hyponatremia (OR=2.8; p=0.008) and hyperkalemia (OR=2.7; p=0.003).

CONCLUSIONS

Disruptions of renal biomarkers during SARS-Cov2 infection increase the risk of severity and mortality. Our study suggests that clinicians should pay close attention to kidney biomarkers in hospitalized patients with COVID-19.

Clinical Chemistry

P0493

INFLUENCE OF PVP VISCOSITY ON RBC DEFORMABILITY MEASUREMENT

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BACKGROUND-AIM

The effect of polyvinylpyrrolidone (PVP) viscosity on Red Blood Cell (RBC) deformability regarding blood rheological properties remains unresolved despite its biocompatibility. RBC deformability is measured following application of shear stress with specific magnitude and duration of exposure. This deformability depends upon the medium viscosity of blood (25 μL) in biocompatible PVP solution (1mL) which is prepared according to general procedure of deformability measurement. We utilized PVP solutions with different molecular weights 360 kDa, 10 kDa and Elon ISO, which is commercially available, resulting in different viscosities. We facilitated comparison of RBC deformability measurements for these PVP solutions with different viscosities and the results were also tested with Raman spectroscopy.

METHODS

Shear stress measurement was performed for 300 s at nine different shear stress for blood samples taken from four individuals. Ektacytometry was used to quantify human RBC deformability using discrete samples. RBCs were smeared on cover slides and their rheological behavior in PVP solutions were also analyzed using Raman Spectroscopy.

RESULTS

PVP (360 kDa) and commercial PVP (Elon ISO) have similar viscosities and showed similar EI vs Shear Stress curves. PVP (360 kDa) has EImax(0.27), whereas EImax of PVP Elon ISO is around (0.30). After evaluating the sigmoidal curves, PVP (360 kDa) showed significantly decreased SS1/2:EImax which means impaired erythrocyte deformability higher than for the same blood sample measured with PVP (Elon ISO). The curve for blood in PVP (10 kDa) had a different trend than typical EI vs Shear Stress curve. In Raman spectroscopic measurements, PVP (10 kDa) could not allow blood to exert its blood fluidity characteristics, resulting in distinct Raman spectra compared to other high viscous PVP solutions.

CONCLUSIONS

Viscous PVP solution with larger molecular weight allowed us to measure erytrocyte mechanical response to shear stress whereas PVP (10 kDa) did not allow to measure RBC deformability which also monitored in Raman analysis.

Clinical Chemistry

P0494

A COMPARATIVE STUDY OF CAFFEINE INTAKE ON KIDNEY FUNCTION AND LIPID PROFILES OF STUDENTS IN TERTIARY INSTITUTIONS

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BACKGROUND-AIM

Introduction: A popular psychoactive drug among college students looking to improve their cognitive function is caffeine. Although its advantages for cognition are well known, little is known about how it affects lipid metabolism and kidney function. This study investigates the physiological effects of caffeine ingestion in order to fill up these information gaps.
Aim/Objective: This study investigates the comparative effects of caffeine intake on kidney function and lipid profiles among students at Lead City University and the University of Ibadan, Nigeria.

METHODS

A cross-sectional study was carried out with 100 subjects, 50 of them were caffeine drinkers and the other 50 were not. Structured questionnaires and biochemical assays were used to assess the participants, who were categorized according to their amounts of caffeine consumption. Assessments were made of lipid profiles (total cholesterol, HDL, LDL, and triglycerides) and renal indicators (creatinine, eGFR). Using IBM-SPSS version 20.0, statistical analysis was performed to find relationships and predictors using chi-square tests, independent t-tests, and linear regression.

RESULTS

Significant differences were observed in HDL levels (mean difference: 12.80 mg/dL, $p < 0.001$), creatinine (mean difference: 0.17 mg/dL, $p = 0.03$), and eGFR (mean difference: 18.50 mL/min/1.73 m^2, $p < 0.001$) between caffeine consumers and non-consumers. No significant differences were found in total cholesterol ($p = 0.77$), triglycerides ($p = 0.22$), or LDL levels ($p = 0.10$).

CONCLUSIONS

The study draws attention to the possible physiological effects of caffeine on students' lipid metabolism and kidney function. Caffeine users' elevated creatinine and decreased eGFR point to renal stress, while elevated HDL suggests a change in lipid metabolism. These results highlight the necessity of using caffeine in moderation and conducting additional research on its long-term consequences.

Clinical Chemistry

P0495

HBA1C FOR HEMOGLOBIN S PATIENTS: COMPARATIVE RESULTS FROM THREE ANALYZERS.

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BACKGROUND-AIM

HbA1c measurement is crucial for diagnosing and monitoring diabetes. However, this measurement can be challenging in patients with hemoglobinopathies, as these conditions can significantly affect HbA1c results, impacting their reliability and accuracy. In this study we aimed to analyze the correlation between three HbA1c measurement methods in patients with hemoglobin S (HbS).

METHODS

Our study included 34 samples from patients with sickle cell trait (Hb A/S). HbA1c was measured using three different analyzers: Capillarys- Sebia® (capillary electrophoresis), D10 Bio-Rad® (HPLC), and Cobas-Intégra® (immunoturbidimetry). Statistical analysis was performed using Excel to establish the correlation coefficient, regression curve, and Bland-Altman plot.

RESULTS

Our results show a strong correlation between the different methods. The correlation coefficients were close to 1: Capillarys-Integra r=0.97 (p=0.009), Capillarys-D10 r=0.99 (p<0.001), and D10-Integra r=0.99 (p<0.001). The regression curves were all linear with correlation functions: Capillarys-Integra: Y= 0.8018 x + 1.0646, Capillarys-D10: Y= 0.884 x + 1.0379, D10-Integra: Y= 0.896 x + 0.1727. The Bland-Altman plot showed a positive bias of 0.23% (95% CI [-0.81 to 1.27]) for Capillarys-Integra. For Capillarys-D10 and D10-Integra, the bias was negative: -0.3% (95% CI [-1.04 to 0.423]) and -0.53% (95% CI [-0.119 to 1.19]), respectively. We noted that discrepancies were higher for HbA1c values above 9%. Statistical analysis of our data showed excellent correlation between the different measurement techniques, indicating they are equivalent in patients with hemoglobin S. However, a bias was observed, indicating a slight overestimation of one method compared to another.

CONCLUSIONS

Our study demonstrated that the three HbA1c measurement methods are well correlated in patients with Hb S. However, discrepancies between these methods were observed for HbA1c values above 9%. Therefore, it is beneficial to monitor HbA1c values in the same patient using the same technique.

Clinical Chemistry

P0496

SERUM VITAMIN D AND CANCER RISK: RESULTS FROM A SMALL GREEK PROSPECTIVE COHORT STUDY

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BACKGROUND-AIM

Vitamin D has been studied for its potential role in reducing the risk of certain cancers, although the relationship is complex and not fully understood. Some research suggests that adequate vitamin D levels may reduce the risk of certain cancers such as colon, breast and prostate cancer. It is important to maintain healthy vitamin D levels through balanced sun exposure, a balanced diet and possibly supplements.

METHODS

In the present study, we analysed serum 25-hydroxyvitamin d in: a) 50 cancer patients, b) 50 patients critically ill with COVID-19 and c) 50 healthy donors. We collected the laboratory data from patients hospitalized in General Hospital of Athens "Georgios Gennimatas" during a six-month period (01/2024-06/2024). Vitamin D was measured by using Abbott Alinity c analyzer

RESULTS

Vitamin D levels were not influenced by age and gender. The vitamin D level was lower in the cancer group than in the healthy group with a p-value of 0.042, while there is no statistically significant change in vitamin D level between the healthy donors and the verified COVID patients. Finally, the correlation study of vitamin levels with the levels of established cancer biomarkers such as CA19 9, CEA, CA72 4, CA15 3 showed no statistically significant correlation.

CONCLUSIONS

More research is needed to fully comprehend and appreciate vitamin D's role in cancer biology and patient treatment.

Clinical Chemistry

P0497

A STEP INTO THE FUTURE: PERFORMANCE EVALUATION OF UNIQO®160 (EUROIMMUN®), A FULLY-AUTOMATED EQUIPMENT FOR THE DIAGNOSIS AND MONITORING OF AUTOIMMUNE DISEASES

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BACKGROUND-AIM

The aim of this study was to evaluate the semi-quantitative or qualitative in vitro detection of human immunoglobulin autoantibodies by IIF on UNIQO®160 (EuroImmun®) for the diagnosis and monitoring of autoimmune diseases.

METHODS

UNIQO®160 detects antibodies targeting cell nuclei (ANA) on Hep-20-10 cell substrates (HS), granulocyte cytoplasm (ANCA) on granulocyte substrates (GS), and tissue components on tissue substrates (TS). Specific antibodies bind to patient's antigens contained in sera and are detected using anti-human antibodies conjugated with fluorescein isothiocyanate by fluorescence microscopy, evaluated on a computer screen on EUROLabOffice® 4.0 software. Precision was evaluated using sera from positive patients tested three times daily over five days across the three types of substrates. For method comparison, 62 (HS), 26 (GS) and 34 (TS) patient sera were compared with manual microscopy (reference method). Results were correlated with immunodot analyses performed on the EUROBlotOne® and IgG antibody proteinase 3 (PR3) and myeloperoxidase (MPO) measurements in human serum, conducted by immunoenzymatic assay on the Chorus® platform. Accuracy was assesed through external quality control (EQC) analysis from Rerenzinstitut für Bioanalytik (RfB).

RESULTS

Intra- and inter-run results were identical in fluorescence images and antibody titers for all substrate types evaluated. Analytical concordance was achieved between the evaluated substrates on UNIQO®160 and the reference method. Few samples showed discrepancies, but correlation with immunodot results, IgG assays for PR3 and MPO, and clinical records largely supported the findings of the UNIQO®160. Antibody titers measured using the UNIQO®160 was slightly higher compared to manual microscopy, but clinically acceptable. EQC results demonstrated analytical concordance with methods results.

CONCLUSIONS

UNIQO®160 demonstrates reliable performance, yielding results comparable to those obtained through manual microscopy, with any differences observed lacking clinical significance and meeting the operational requirements of the laboratory.

Clinical Chemistry

P0498

REFERENCE INTERVALS FOR TOTAL SERUM MAGNESIUM IN SENIORS: RESULTS FROM THE PROSPECTIVE SENIORLAB STUDY

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BACKGROUND-AIM

Magnesium is one of the most abundant cations in the human body, playing a key role as a cofactor and allosteric activator for many enzymes (e.g., ATPase, alkaline phosphatase). Disorders in magnesium homeostasis are common in hospitalized and elderly individuals, potentially leading to clinical outcomes such as cardiac arrhythmias. The aim of this study was to determine the Reference Intervals (RI) for magnesium in Caucasian individuals aged 60 years and older.

METHODS

From 1467 study participants reporting subjective wellbeing at baseline examination in the SENIORLAB study, the following individuals were excluded: death at first follow-up for participants <80 years of age (mean follow-up time 3.7 +/- 0.7 years), survival of less than 3 years between age 80-84, less than 2 years between age 85-89, and less than 1 year for age 90 and older. Further exclusion criteria known to affect magnesium concentrations were: systemic inflammation (CRP>5 mg/L), decreased renal function (eGFR<40 ml/min/1.73m2), and polypharmacy. Additionally, patients with vitamins, mineral and trace element supplementation were also excluded. Magnesium was measured by colorimetric assay on a Cobas Integra 800. Effects of age and sex on magnesium levels were investigated. Double sided 99% RI together with the 90% Confidence Intervals (CI) were evaluated according to CLSI guideline EP28-3c.

RESULTS

A total of 617 study participants (311 males, 306 females, age range 60-96, median age 71 years) were included for RI calculation. No dependence of magnesium concentrations on age was observed. However, a significant median difference was observed between sexes (0.85 mmol/l males vs 0.87 mmol/l female, p=0.0002). An age independent robust RI for males (n=311) was 0.69, 90% CI [0.68,0.70] to 1.01, 90% CI [1.00,1.02] mmol/l. For females (n=306) was 0.73, 90% CI [0.72,0.74] to 1.01, 90% CI [1.00,1.02] mmol/l. RI did not change when using the robust method or a method based on normal distribution.

CONCLUSIONS

In this carefully selected senior population, the direct RI for magnesium concentrations showed an association with gender but not age. The lower limit of the RI was slightly lower in males than in females (0.04 mmol/l), whereas the upper limit was identical (1.01 mmol/l).

Clinical Chemistry

P0499

ROLE OF HYALURONIC ACID METABOLISM IN ENDOMETRIAL RECEPTIVITY: INSIGHTS FROM RNASEQ AND CELLULAR MODELS

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BACKGROUND-AIM

Despite long-term research, the percentage of successfully implanted embryos during in vitro fertilization (IVF) process stays low (ca. 30%) creating a significant number of patients with so called non-receptive endometrium pathological condition. The extracellular matrix (ECM) of the endometrium, the initial interface between the embryo and the endometrial lining, may play a crucial role in embryo implantation. This matrix contains various adhesive molecules that facilitate temporary adhesion, allowing subsequent biological processes to support implantation.

METHODS

Hyaluronic acid (HA), a key ECM component, has been identified as critical in this interaction. This study investigates the role of HA metabolism in endometrial receptivity by analyzing RNA sequencing (RNAseq) datasets from the GEO database. We utilized two endometrial epithelial cell lines as models of receptive and non-receptive endometria: RL95-2 cells, which are moderately differentiated and resemble luminal epithelium in a receptive state, and AN3CA cells, which are poorly differentiated and resemble glandular, thus non-receptive endometrium. Through PCR, proteomics, immunohistochemistry (IHC), and flow cytometry, we assessed differences in HA metabolism between these cell lines.

RESULTS

We compared datasets from GEO database of endometrial samples from healthy women with successful pregnancies to those with repeated IVF failures, revealing significant downregulation of HA metabolism in the latter group. The results from in vitro experiments indicated alterations in HA-related gene expression and protein levels, consistent with the differential HA gene expression observed in human endometrial samples.

CONCLUSIONS

These findings suggest that impaired HA metabolism may contribute to the non-receptive state of the endometrium, providing a potential target for enhancing implantation success in assisted reproduction techniques (ART).

This study was supported by a project VEGA 1/0747/24.

Clinical Chemistry

P0500

PREVALENCE AND FACTORS ASSOCIATED WITH POOR GLYCEMIC CONTROL IN TUNISIAN PATIENTS WITH TYPE 2 DIABETES

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BACKGROUND-AIM

Poor long-term glycemic control is a significant risk factor for the progression of complications related to type 2 diabetes (T2D). The aim of this study is to determine the prevalence and factors associated with poor glycemic control amongst patients with T2D.

METHODS

A descriptive cross-sectional study conducted over 5 months (september2023- january 2024) within the clinical biology laboratory of Mohamed Taher Maamouri hospital, Nabeul, Tunisia. A total of 140 patients with T2D attending the sampling room were included. The socio-demographic data and the clinical information were collected through a thorough interview. The following biochemical parameters were collected and analyzed using the Coobas 6000 ® analyzer: glycated hemoglobin (HbA1c), fasting blood glucose (FBG), total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C). Low-density lipoprotein cholesterol (LDL-C) was calculated using the Friedewald formula: TC - HDL-C- (TG/2,2). Glycemic control was assessed by HbA1c levels and poor glycemic control was defined as HbA1c ≥7%.

RESULTS

Of the total participants 65% had poor glycemic control. Bivariate analysis showed that duration of diabetes (p=0,013), TG (p=0,003), HDL-C (p<0,001) and the combination of oral antidiabetic agents with insulin (p=0,005) were significantly associated with HbA1c levels. Multiple logistic regression analyses revealed that only HDL-C (OR 6,803 [95% confidence interval {CI} 2,203–20,742], p=0.001) and combination of oral antidiabetic agents with insulin (OR 4,083 [95% CI 1,379–12,093], p=0.011) were independent factors of poor glycemic control.

CONCLUSIONS

More than half of Tunisian patients with T2D in this study did not achieve target levels of HbA1c. Identifying the factors associated with poor glycemic control is a crucial step to achieve diabetic balance and prevent future complications.

Clinical Chemistry

P0501

HEMATOLOGICAL INDICES AND THEIR CORRELATION WITH GLYCATED HEMOGLOBIN LEVELS IN PATIENTS WITH TYPE 2 DIABETES

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BACKGROUND-AIM

Chronic inflammation and hyperglycemia in diabetes type 2 (T2D) result in significant alterations in various parameters including hematological disturbances that lead to vascular complications. Therefore, this study aimed to evaluate the relationship between glycated hemoglobin (HbA1c) levels and hematologic inflammatory biomarkers, neutrophil-lymphocyte ratio (NLR), platelet-lymphocyte ratio (PLR) and monocyte-lymphocyte ratio (MLR) in predicting glycemic control in patients with T2D.

METHODS

A descriptive cross-sectional study was conducted over 5 months (september2023-january 2024) within the clinical laboratory of Mohamed Taher Maamouri hospital of Nabeul in Tunisia. A total of 140 patients with T2D attending the sampling room were included. The socio-demographic data and the clinical information were collected through a thorough interview. Completed blood cells count was determined using the Mindray BC780 analyzer. HbA1c and fasting blood glucose (FBG) were analyzed using the Cobas 6000 ® analyzer. Glycemic control was assessed by HbA1clevels, and poor glycemic control was defined as HbA1c ≥7%.

RESULTS

The average age of patients was 62,46±8,39 years old with a sex ratio (M/F) equal to 0,52. The average HbA1c and FBG levels were 8,13±1,87% and 8,97±3,74 mmol/L, respectively. 65% of the total participants had poor glycemic control. A significant positive correlation was found between HbA1c levels and platelet count (r=0,168; p=0,048), HbA1c levels and lymphocyte count (r=0,183; p=0,032) and HbA1c and FBG (r=0,691; p<0,001). We found significant difference in lymphocyte count (p=0,033) and FBG (p<0,001) between patients with HbA1c less than 7% and HbA1c more than or equal to 7%. HbA1c levels were not correlated with NLR (p=0,353), PLR (p=0,371) and MLR (p=0,072). There was no significant difference in NLR, PLR and MLR levels between controlled and uncontrolled diabetics patients (p=0,166; p=0,302 and p=0,294; respectively).

CONCLUSIONS

The findings of this current study showed statistically significant correlation between some hematological parameters and HbA1c levels in patients with type 2 diabetes. However, no significant association was found between the following inflammatory ratios: PLR, NLR and MLR and HbA1c levels therefore they can’t be used to assess glycemic control properly.

Clinical Chemistry

P0502

THE TRIGLYCERIDE GLUCOSE INDEX AND TRIGLYCERIDE/HDL-C RATIO AS PREDICTORS OF GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES

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BACKGROUND-AIM

Long-term poor glycemic control assessed by high levels of glycated hemoglobin (HbA1c) is a risk factor for the progression of cardiovascular complications in type 2 diabetes. The aim of our study was to evaluate the association between the Triglyceride-Glucose index (TyG) and Triglyceride/HDL-C ratio (TG/HDL-C) with HbA1c levels, and to investigate their ability to predict glycemic control in patients with type 2 diabetes (T2D).

METHODS

A descriptive cross-sectional study conducted over 5 months (september2023-january 2024) within the clinical biology laboratory of Mohamed Taher Maamouri hospital, Nabeul, Tunisia. A total of 140 patients with T2D attending the sampling room were included. The socio-demographic data and the clinical information were collected through a thorough interview. The following biochemical parameters were collected and analyzed using the Coobas 6000 ® analyzer: HbA1c, fasting blood glucose (FBG), total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C). Low-density lipoprotein cholesterol (LDL-C) was calculated using the Friedewald formula: TC - HDL-C- (TG/2,2). The TyG index was calculated using the following formula: Ln [TG (mg/dL) x FG (mg/dL) /2]. The TG/HDL-C ratio was calculated by dividing the plasma concentration of TG by that of HDL-C. Glycemic control was assessed by HbA1c levels and poor glycemic control was defined as HbA1c ≥7%.

RESULTS

The TG/HDL-C ratio and TyG index were significantly higher in T2D patients with HbA1c≥7% compared with T2D patients with HbA1c<7% (p<0.001; in both cases). In addition, the TG/HDL-C ratio and TyG index were positively correlated with HbA1c values (r=0.274; p=0.001; r=0.535; p<0.001; respectively). In multivariate analysis, TyG index was an independent factor of poor glycemic control (OR=74.066; 95% CI [13.315-411.991]; p<0.001). The sensitivity and specificity of the TyG index for glycemic control were 79% and 69% respectively, with a large area under the curve (0.80; 95% CI [0.727-0.873]; p<0.001) and a threshold value of 4.85.

CONCLUSIONS

Our results show that the TyG index might be a useful, simple and cost-effective marker of glycemic control in T2D patients when HbA1c is not available.

Clinical Chemistry

P0503

CLOZAPINE THERAPY MONITORING: AVAILABILITY OF A NEW AUTOMATED ASSAY ON DXC700AU

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BACKGROUND-AIM

Clozapine remains the gold standard for managing treatment-resistant schizophrenia, but its use is associated with a narrow therapeutic window and a risk of severe adverse effects, such as agranulocytosis and seizures. Therapeutic drug monitoring (TDM) is essential to optimize treatment efficacy minimizing toxicity. Aim of this study was to compare two clozapine assays: BC, the new Psychiatry Clozapine Assay Kit on Beckman Coulter DXC700AU platform (Beckman Coulter, Brea, CA, USA), based on homogeneous agglutination of two reactive nanoparticles detecting spectrophotometrically clozapine in human serum and plasma, and SC, the widely used clozapine gold standard assay on QTRAP 4500 LC-MS/MS system (Sciex, Framingham MA, USA).

METHODS

According to the CLSI EP09-A3 guideline 40 anonymized plasma samples were assayed. Values summary (mcg/L): minimum SC=56, BC=36; maximum SC=1292, BC=1548; mean SC=460, BC=456; median SC=400, BC=396; SD SC=284, BC=346.

RESULTS

Passing-Bablok regression analysis demonstrated good agreement between the BC and SC, with the regression equation: Clozapine-DXC700AU = -45.035 + (Clozapine-QTRAP 4500 × 1.008) (Intercept 95% CI: -143.45 to 5.67; Slope 95% CI: 0.93 to 1.34). Bland-Altman analysis showed a mean bias of 2.24% (95% CI: -0.20 to 15.34%). Additionally, method comparison revealed minimal variance around the regression line, with no significant differences in percentage or absolute values detected through Bland-Altman testing. These results show good concordance between the two methods, and the observed biases and limits of agreement fall within acceptable ranges.

CONCLUSIONS

The results of this preliminary study indicate that the Beckman Coulter Psychiatry Clozapine Assay the DXC700AU platform shows promising agreement with LC-MS/MS method (QTRAP 4500 system), which is considered the gold standard for TDM. The introduction of the new Beckman Coulter Psychiatry Clozapine Assay Kit provides a high-throughput viable alternative for routine TDM; results are available within ten minutes from instrument sample loading, a useful aspect in urgent situations or when it is necessary to report the data quickly. Further studies are necessary to validate its performance in diverse clinical scenarios and to establish its role as a TDM standard method.

Clinical Chemistry

P0504

LIPID PROFILE IN TYPE 2 DIABETES MELLITUS: FASTING VERSUS NONFASTING

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BACKGROUND-AIM

Lipid profile test consists of total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG) and low density lipoprotein cholesterol (LDL-C). Deranged lipid profile is seen in type 2 diabetes mellitus and it causes many cardiovascular diseases. Fasting blood samples are preferred for lipid profile testing. However, fasting blood testing requires visiting next day to give sample. It causes loss of time, energy and resources. This study aimed to compare the lipid profile parameters in fasting and non-fasting state in type 2 diabetes.

METHODS

This study is single centered, observational analytical cross-sectional study conducted in Department of Pathology and Laboratory Medicine, Patan Hospital, Patan Academy of Health Sciences. A total of 104 type 2 diabetic patients visiting collection center of central pathology laboratory of Patan Hospital were included in this study. TC, HDL-C, LDL-C and TG were measured at fasting and non-fasting state by chemistry analyzer. Paired t-test was used for TC, HDL-C and LDL-C whereas Wilcoxon signed ranks test was used for TG. Ethical clearance was obtained from institutional review committee.

RESULTS

A total of 48 male and 56 female were included with mean age of 58.7±12.0 and 55.6±13.8 years respectively. Out of 104, 58 were obese and 17 were overweight. Mean value of TC in fasting and non-fasting state were 155.6 mg/dL and 146.2 mg/dL respectively with the mean difference of 9.4 mg/dL. Similarly, mean value of HDL-C in fasting and non-fasting state were 41.9 mg/dL and 39.6 mg/dL respectively with the mean difference of 2.3 mg/dL. Likewise, there was mean difference of 5 mg/dL in LDL-C with the mean fasting and non-fasting mean value of 100 mg/dL and 95 mg/dL respectively. Meanwhile, median value of TG in fasting and non-fasting state were 150. 5 (103.0; 196.5) mg/dL and 180.0 (116.0; 247.0) mg/dL respectively with the median difference of 29.5 mg/dL. There were significant differences between the fasting and non-fasting state in all the lipid parameters.

CONCLUSIONS

Although there were statistical difference in the lipid test parameters between fasting and non-fasting state, clinically its significance is less except for triglycerides. Therefore, non-fasting sample can be considered for the lipid profile testing.

Clinical Chemistry

P0505

EXTENSION OF HEMOLYSIS INTERFERENCE TESTING WITH REAL PATIENT SAMPLES IN ENZYMATIC CREATININE DETERMINATION

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BACKGROUND-AIM

The enzymatic creatinine determination is significantly affected by hemolysis in our measurement system. The incidence of hemolytic samples in our laboratory is high (7.3%), therefore we are unable to provide a result in 65% of hemolytic samples. The previously performed interference study was conducted on spiked samples with two different creatinine concentrations (76 and 136 μmol/L), and hemolysis strengths of 0 and 2+, but we did not find the available information satisfactory. Therefore, we collected additional data to determine whether the degree of hemolysis or the creatinine level of the non-hemolytic sample has a greater impact on interference.

METHODS

The measurements were performed on an Abbott Architect c8000 automated chemistry analyzer using Diasys reagent (Creatinine PAP FS). The data pairs were collected between January and December 2024 from patients who had a resample sent within 6 hours of the first result not being issued due to hemolysis. The data pairs were divided into 3 groups according to the degree of hemolysis: 2+ (n: 150), 3+ (n: 211), and 4+ (n: 64) and we analyzed the magnitude of the increase in creatinine concentration due to hemolysis.

RESULTS

In 2+ samples, depending on the degree of hemolysis, creatinine levels below 100 μmol/L increased by 1.4-3.6-fold, between 100 and 200 μmol/L by 1.1-2.8-fold, while above 300 μmol/L the interfering effect of hemolysis was not clinically significant. In 3+ samples, creatinine levels below 100 μmol/L increased by 1.6-4.3-fold, and between 100 and 300 μmol/L by 1.3-2.4-fold, while above 500 μmol/L the interfering effect of hemolysis was minimal. In the 4+ samples, we saw a 2.8-9.6-fold increase in creatinine levels below 100 μmol/L and a 2.1-3.8-fold increase between 100 and 200 μmol/L. In contrast, our samples did not have a baseline creatinine level so high that the confounding effect of hemolysis would have been negligible.

CONCLUSIONS

The greatest interfering effect occurred in samples with creatinine levels below 100 μmol/L in all three groups. As the creatinine level increased, this interfering effect decreased exponentially, eventually becoming negligible.

Clinical Chemistry

P0506

EVALUATION OF THE BECKMAN-COULTER ACCESS PROCALCITONIN ASSAY ON A DXI-600 PLATFORM IN A PAEDIATRIC SETTING

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BACKGROUND-AIM

This study aims to evaluate the analytical performances of the BECKMAN COULTER ACCESS procalcitonin immunoassay (PCI-I) on a DxI-600 platform, as well as its diagnostic performance in paediatric samples for assessing the risk of progression to sepsis by comparing it with the BRAHMS KRYPTOR PCT (PCT-K) reference method.

METHODS

The evaluation of analytical performances focused on within and between-run imprecisions, at concentrations close to the decision thresholds, as well as on the linearity range. For the comparison study, the same volume of fifty-two blood samples (20 cords, 15 newborns and 20 infants) was analysed simultaneously by both methods. We studied the number of samples with insufficient volume and the concordance of the results at the threshold of 0,5 µg/L, associated with a risk of progression to sepsis using PCT-K as the reference.

RESULTS

Within-run imprecisions at concentrations of 0,56 and 2,29 µg/L were 4,8 and 2,6%, respectively. Between-run imprecisions at concentrations of 0,34 and 14,87 µg/L were 6,7 and 7,3%, respectively. The linearity in the range [0,09-80] µg/L was satisfactory. For the comparison study, seven samples (all from newborns) were found to be insufficient by PCT-I method, versus none by PCT-K method. The comparison performed in the range [0.04-45.75] µg/L was satisfactory (slope=1.46; R2 =0.98). The diagnostic agreement at the threshold of 0,5 µg/L was 98%.

CONCLUSIONS

This study suggests that the BECKMAN COULTER ACCESS PCT method has satisfactory analytical and clinical performances using currently used diagnostic thresholds with paediatric samples. An improvement on the minimum required volume is necessary, particularly in the neonatal context.

Clinical Chemistry

P0507

VITAMIN D STATUS IN TYPE 2 DIABETICS WITH NONALCOHOLIC FATTY LIVER DISEASE

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BACKGROUND-AIM

Vitamin D plays a crucial role in modulating insulin secretion and sensitivity, suggesting that it may influence the course of metabolic diseases, including type 2 diabetes and its liver complications such as non-alcoholic fatty liver (NAFLD). However, the interactions between vitamin D status and NAHS in type 2 diabetic patients remain poorly understood. The study aim was to analyze vitamin D status in type 2 diabetics (T2DM) with non-alcoholic fatty liver disease (NAFLD).

METHODS

This was a descriptive and analytical cross-sectional study, which included two groups of type 2 diabetic patients: group 1 with NAHS and group 2 without steatosis. All these patients underwent a dietary survey to determine their vitamin D intake and a 25 OH vitamin D assay.

RESULTS

We enrolled 41 patients with SHNA (group 1) and 40 patients without steatosis (group 2). Patients in group 1 had higher body mass index ($p = 0.001$), waist circumference ($p < 0.001$), triglyceride levels ($p = 0.02$) and transaminases ($p = 0.01$) than those in group 2 without steatosis. 25 OH-Vitamin D deficiency was identified in 23 patients (92%) in group 1 and in 19 patients (91%) in group 2 ($p=0.08$). The prevalences of 25 OH-Vitamin D deficiency and insufficiency were 57% (vs. 67% in group 2; $p=0.2$) and 44% (vs. 33% in group 2; $p=0.2$) respectively. No association was found between inadequate intake (OR=2.4; $p > 0.05$), 25 OH-Vitamin D deficiency (OR=0.65; $p > 0.05$) and hepatic steatosis.

CONCLUSIONS

The association between vitamin D status and SHNA has been well documented in several studies. Our findings do not concur with those of the literature, given the small number of patients. The benefits of vitamin D supplementation remain to be confirmed by further studies.

Clinical Chemistry

P0508

BIOLOGICAL PROFILE AND RISK FACTORS FOR NON-ALCOHOLIC FATTY LIVER DISEASE IN TYPE 2 DIABETIC PATIENTS

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BACKGROUND-AIM

Non-alcoholic fatty liver disease (NAFLD) is frequently associated with insulin resistance, type 2 diabetes (T2DM) and increased cardiovascular risk. It is most often discovered incidentally. The aims of our work were to study the biological profile of type 2 diabetic subjects with NAHS and to determine the biological risk factors associated with this pathology.

METHODS

This was a cross-sectional case-control study involving two groups of T2DM patients, with (group 1, n = 41) and without steatosis (group 2, n = 40). These patients underwent an interview and a metabolic and hepatic work-up. Risk factors for SHNA were determined by uni- and multivariate analyses with calculation of odds ratios (OR).

RESULTS

The mean age was 61.3 ± 1.4 years in group 1 and 60.1 ± 9.1 years in group 2 (p=0.567). A TG/high-density lipoprotein cholesterol (HDLc) ratio ≥ 2.5 was found in 92% of patients in group 1 versus 66% in group 2 (p=0.008). Patients with SHNA had significantly higher levels of AST and ALT than those without steatosis (p=0.005 and p=0.003 respectively). Female gender (OR = 2.353; p=0.047), a triglyceride/HDLc ratio ≥ 2.5 (OR = 5.5; p=0.008) and hepatic cytolysis (OR = 6.607; p=0.011) were positively associated with SHNA. Cytolysis (adjusted OR = 10.28; p=0.016) was independently associated with SHNA.

CONCLUSIONS

All T2DM patients with hepatic cytolysis should be systematically screened for SHNA, in order to reinforce hygienic-dietary measures in these patients and reduce insulin resistance.

Clinical Chemistry

P0509

HOMEOSTASIS MODEL OF INSULIN RESISTANCE (HOMA-IR): OPTIMAL CUT-OFF IN A TUNISIAN POPULATION

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BACKGROUND-AIM

The homeostasis model of insulin resistance (HOMA-IR) was developed to assess insulin resistance, an important mechanism in the pathophysiology of glucose metabolism disorders, notably T2DM. However, there is yet no universal threshold value for the HOMA index. The aim of our study was to estimate a reference threshold for Tunisian adult patients with T2DM.

METHODS

This is a case-control study of 98 T2DM patients and 95 healthy subjects. We collected clinical information and performed a fasting blood test, including blood glucose and insulin levels. Blood glucose levels were determined using the hexokinase enzymatic method on DXC 700 AU/AU 480 (Beckman Coulter ®), while insulin levels were determined using the sandwich-type electrochemiluminescence immunoassay (ECLIA) on Cobas e411 (Roche ®). The HOMA index was calculated using the formula: HOMA index =Fasting plasma glucose (mmol/L) *Fasting plasma insulin (mIU/mL)/22.5. To determine the optimal HOMA index threshold, a Receiver Operating Characterisitc (ROC) curve was used.

RESULTS

The mean age of the T2DM population was 55.67 ±9.48 years, with a sex ratio (male/female) of 0.69. The mean BMI of diabetic patients was 24.4 ±1.68 Kg/m2. That of control subjects was 22.84 ±2 Kg/m2. Mean blood glucose concentration was 10.45±4.92 mmol/L in T2DM patients and 4.78±0.67 mmol/L in the control population. Mean insulin levels were 13.19±11.27 μUI/mL and 6.89±4.06 μUI/mL in patients and controls respectively. T2DM was significantly correlated with blood glucose and insulin levels, with p values of 0.03 and 0.001 respectively. Analyzing the HOMA-IR index using the ROC curve, we obtained an area under the curve (AUC) of 0.85 (95% CI: 0.78-0.93), indicating a high discriminatory capacity of this index. The optimal threshold for the HOMA-IR index to distinguish diabetics from healthy subjects was set at 1.8, with a sensitivity of 82%, a specificity of 65%, a positive predictive value (PPV) of 80.4% and a negative predictive value (NPV) of 69.3%.

CONCLUSIONS

Our study suggests that the threshold of the HOMA-IR index in Tunisian diabetics was 1.8. The application of this index in clinical practice, with a reference threshold now defined and adapted to our population, could be useful in assessing insulin resistance and preventing T2DM.

Clinical Chemistry

P0510

STUDY OF THE RELATIONSHIP BETWEEN FRUCTOSAMINE AND LIPID PARAMETERS IN A TUNISIAN POPULATION

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BACKGROUND-AIM

Diabetes mellitus and dyslipidaemia are major metabolic pathologies. Fructosamines are ketoamines indicated for monitoring diabetes. However, they are subject to considerable variability.
The aim of this study was to evaluate the relationship between fructosaminemia (FRA) and the lipid profile in a Tunisian population.

METHODS

This work was carried out during a 6 month period on 349 non-diabetic patients from our institute. The mean age was 41.4±16.5 years and the sex ratio was 0.24. The following parameters were measured: FRA, proteinemia, albuminemia, total cholesterol (TC), HDL cholesterol (HDLc) and triglycerides (TG). The FRA/proteinemia (F/P), FRA/albuminemia ratios (F/A) and LDL-cholesterol (LDLc) were calculated. The statistical study was carried out on Medcalc®20.104, subdividing the population into 2 groups according to sex, G1 (men, n=67) and G2 (women, n=282).

RESULTS

In G2, FRA showed a weak negative correlation with TC and TG (r=-0.195, p=0.001 and r=-0.340, p<0.0001 respectively). F/P showed a weak negative correlation with TG (r=-0.182, p=0.0021). F/A showed a weak positive correlation with TC, HDLc and LDLc (r=0.140, p=0.0187, r=0.184, p=0.0019, r=0.127, p=0.033 respectively). No other correlations were significant for this group.
In G1, F/P showed a weak negative correlation with LDLc (r=-0.252, p=0.039). No other correlation was significant for this group.
The Mann-Whitney U test carried out for the total population then for each of the 2 groups showed that there was no significant difference between the FRA, F/P and F/A of patients with disturbed lipid profiles and those with normolipidaemia.
An analysis using the Chi-2 test confirmed the absence of a significant relationship between a pathological FRA and a disturbed lipid profile for the total population and each of the 2 groups.

CONCLUSIONS

The correlation between blood lipids and fructosaminemia is still unclear but sex appears to play a determining role in it. A study of the influence between lipoprotein profile and fructosaminemia could clarify this interaction.

Clinical Chemistry

P0511

FRUCTOSAMINEMIA, CORTISOLIEMIA AND THYROID, IS THERE A RELATIONSHIP?

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BACKGROUND-AIM

Thyroid hormones and cortisol are linked to protein metabolism. Fructosamines are serum ketoamines resulting from glycation and are indicated during the monitoring of diabetes mellitus. Their dosage is therefore influenced by protein metabolism.
The aim of our study is to evaluate the relationship between thyroid hormones, cortisol and fructosaminemia (FRA).

METHODS

the study was conducted over a 6-month period on 338 non-diabetic patients from our institute. The following assays were performed: FRA, thyroid-stimulating hormone (TSH), free thyroxine (FT4), cortisol, protein and albumin. The ratios of FRA to blood protein (F/P) and FRA to blood albumin (F/A) were calculated. The statistical study was carried out on Medcalc®20.104.

RESULTS

TSH did not correlate significantly with FRA, F/P and F/A.
There was a weak positive correlation between FT4, and FRA ($r=0.39$, $p<0.0001$), and F/P ratio ($r=0.117$, $p=0.0316$). However, the F/A ratio and FT4 showed a weak negative correlation ($r=-0.143$, $p=0.0086$).
Cortisolaemia correlated poorly with FRA ($r=-0.308$, $p<0.0001$) and F/A ratio ($r=0.201$, $p=0.0002$). The correlation with the F/P ratio was not significant.
The Mann-Whitney U test showed no significant difference between the FRA of patients with normal cortisolaemia and those with pathological cortisolaemia. The result was the same after correction for protein and albumin levels. However, the test showed more equivocal results when compared according to thyroid activity. The F/P and F/A ratios of euthyroid patients were not significantly different from those of patients with pathological FT4/TSH. However, there was a significant difference of 9 pmol/L between the medians of the FRA's ($p=0.047$) for the same comparison.

CONCLUSIONS

The relationship between fructosaminemia, cortisol and thyroid activity does not appear to be clearly quantifiable. The possible impact of thyroid activity on fructosaminemia needs to be verified in a multicentre study in coordination with hospital endocrinology departments.

Clinical Chemistry

P0512

MEASUREMENT OF AST AND ALT WITH PYRIDOXAL-5'-PHOSPHATE ACCORDING TO IFCC: A DECADES-LONG GAP SEEMS TO BE FILLED

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BACKGROUND-AIM

Pyridoxal-5'-Phosphate (PLP) is not always added to the reagents for the measurement of Aspartate Amino Transferase (AST) and Alanine Amino Transferase (ALT), although the International Federation of Clinical Chemistry (IFCC) recommends using it as a cofactor. This is particularly true for patients with decreased concentrations of Vitamin B6, the precursor of PLP. The aim of this study is to compare the methods for transaminase measurement with or without the presence of PLP.

METHODS

A total of 102 leftover LiHe samples were collected after transaminase measurement with Roche Cobas e702 (R; Roche, Switzerland) at University-Hospital of Padova (AOPD), already including PLP. The residual plasma was analyzed on the ILab Taurus instrumentation (Werfen, Spain) using Werfen reagents with (WP) and without (W) PLP. Vitamin B6 results were obtained on the respective residual K2-EDTA whole blood through HPLC coupled with mass spectrometry on the Acquity UPLC instrumentation (Waters, MA, USA) coupled with XEVO TQ-S micro (Waters, MA, USA). Qualitative and quantitative statistical analyses were performed for methods comparison.

RESULTS

Optimal agreement and comparability were found between R and WP (ALT R-WP slope (95%CI): 1.03 (1.02-1.05), intercept (95%CI): 3.64 (1.74-6.07); AST R-WP slope (95%CI): 1.05 (1.04-1.06), intercept (95%CI): 4.55 (3.35-5.92)). Adding PLP to the reagents is particularly beneficial for measuring ALT, showing an average percentage increase in ALT concentrations of 12%. In addition, patients were categorized for Vitamin B6 concentrations, considering a cut-off value of 100 nmol/L: the median value of WP-W for patients with lower Vitamin B6 is 34, while it is 18 for patients with higher Vitamin B6 ($p = 0.006$), demonstrating that ALT values are higher when measured with WP for patients with low Vitamin B6.

CONCLUSIONS

The addition of PLP to reagents has greater accuracy in the determination of transaminase, also promoting optimal comparability of the results between different methods, particularly in patients' samples with reduced Vitamin B6. Therefore, it is desirable that the users adapt their procedures to overcome the difficulties related to the lower stability of transaminase reagents containing PLP, respecting also the recommendations of international scientific societies.

Clinical Chemistry

P0513

PROLONGED NONCARDIAC TROPONIN ELEVATIONS IN RHABDOMYOLYSIS: A CASE REPORT

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BACKGROUND-AIM

Rhabdomyolysis is a recognized non-cardiac source of elevated troponin T and troponin I (hs-TnT, hs-TnI), with variable correlation to creatine kinase (CK) levels. Here, we report the case of a 59-year-old patient with severe muscle pain and fatigue three months after coronary artery bypass surgery. Blood testing revealed significant CK elevation and acute kidney injury, leading to the diagnosis of statin-induced rhabdomyolysis. Statin therapy (Suvezen®, containing rosuvastatin and ezetimibe) was discontinued, and intravenous fluids were initiated, leading to resolution of the rhabdomyolysis. Despite clinical improvement, the patient developed posture-dependent chest pain, accompanied by rising hs-TnT levels. To avoid invasive cardiac catheterization in this fragile patient, the laboratory was consulted to explore alternative diagnostic possibilities other than myocardial injury.

METHODS

Heparin plasma samples were analyzed for creatinine, CK, and hs-TnT using the e801 CobasPro (Roche Diagnostics), and for hs-TnI using the Alinity I (Abbott Laboratories). Analytical interference was evaluated with polyethylene glycol (PEG) precipitation, heterophile antibody-blocking reagents, and linear sample dilution.

RESULTS

At presentation, CK levels were markedly elevated at 23320 U/L (reference <190 U/L), $eGFR_{CKD\text{-}EPI}$ was 21.7 mL/min/1.73m². Initial hs-TnT was 200 ng/L, rising to 250 ng/L during chest pain and peaking at 450 ng/L (reference <14 ng/L) despite normalization of CK levels. Analytical interference (i.e. macrocomplexes and heterophile antibodies) was excluded. A literature review indicated that while hs-TnT and hs-TnI are strongly correlated in rhabdomyolysis-related increases, hs-TnT often remains elevated longer than hs-TnI and CK. Analysis of hs-TnI on samples collected 10 and 13 days post-presentation yielded normal results (6 ng/L and 5 ng/L, reference <34.20 ng/L), which excluded myocardial injury as the source of elevated hs-TnT. Unfortunately, due to the limited stability, hs-TnI was not analyzed on earlier samples.

CONCLUSIONS

This case highlights the different course of hs-TnT and hs-TnI in patients with rhabdomyolysis, demonstrating not only constant elevation of hs-TnT but even increasing concentrations in combination with low hs-TnI levels and decreasing CK levels.

Clinical Chemistry

P0514

ACCURATE CORRECTION MODEL OF BLOOD POTASSIUM CONCENTRATION IN HEMOLYTIC SPECIMENS

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BACKGROUND-AIM

The results of blood potassium can be seriously affected by specimen hemolysis which may interfere with clinicians' interpretation of test results. Redrawing blood and retesting may delay treatment time and it is not feasible for critically ill patients with difffculty in specimen collection. Therefore, it is signiffcant to establish a mathematical model that can quickly correct the blood potassium concentration of hemolytic specimens.

METHODS

The residual blood samples from 107 patients at Peking University Third Hospital were collected to establish potassium correction model. Samples with different hemolysis indexes were obtained by ultrasonic crushing method. Blood potassium correction models of hemolysis specimens were established by linear regression and curve fftting using SPSS and MATLAB, respectively. In addition, blood samples from another 85 patients were used to verify the accuracy of the models and determine the optimal model.

RESULTS

Variation of potassium (ΔK) was 0.003HI-0.03 (R2 = 0.9749) in linear regression model which had high correlation in ΔK and HI, and the correction formula was Kcorrection = Khemolysis-0.003 × HI + 0.03. Average rate of potassium change (αaverage) was 0.003 ± 0.0002 mmol/L in curve fftting model, and correction formula was Kcorrection = Khemolysis-0.003 × HI, and both men and women can use the same correction model. The accuracy of linear regression model was 96.5 %, and there was statistical difference between the veriffcation results and the measured values ($p < 0.05$), while the accuracy of curve fftting model was 100 %, and there was no statistical difference between the veriffcation results and the measured values ($p = 0.552$). The model was validated in an independent set of samples and all were within the TEa of 6 % and the accuracy of 100 %.

CONCLUSIONS

Both linear regression and curve fftting models of potassium correction had high accuracy, and can effectively correct the potassium concentration of hemolytic specimens, while the curve fftting model have superior accuracy.

Clinical Chemistry

P0515

SERUM PROTEIN ELECTROPHORESIS PROFILE IN DIFFUSE INFILTRATIVE PNEUMONIA

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BACKGROUND-AIM

The diagnostic approach to diffuse infiltrative pneumonia (DIP) is complex and multidisciplinary. Serum protein electrophoresis (SPEP) is one of the first biological tests requested in this context.
the aim of our cohort was To describe the serum protein profile in patients with DIP.

METHODS

A retrospective descriptive study was conducted between June 2023 and May 2024 at Mohamed Taher Maamouri Hospital, Nabeul, Tunisia . We collected the results of SPEP performed using the Sebia Minicap® capillary electrophoresis system, requested for patients with DIP.

RESULTS

A total of 52 patients were included. The mean age was 52 years (±16), with a male-to-female ratio of 1.6. A normal SPEP profile was found in only 23% of cases. An A/G ratio <1.2 was present in 58%. 61% of patients had a biological inflammatory syndrome, with 25% showing significant immune response, characterized by hypergammaglobulinemia >15 g/L. 37% had severe inflammatory profiles, defined by alpha1 >6 g/L and/or alpha2 >9 g/L. Isolated polyclonal hypergammaglobulinemia was found in 8%, compared to 4% with isolated hypogammaglobulinemia. Hypoalbuminemia was observed in 11.5%, with 66% of these cases being severe.

CONCLUSIONS

Our data, showing polyclonal hypergammaglobulinemia and a decreased A/G ratio, align with findings from Cattan et al. (2014), who reported that these profiles are common in autoimmune and infectious etiologies. Additionally, our observation of hypoalbuminemia in 11.5% of patients is consistent with McGarry et al. (2018), who noted that this anomaly is common in severe inflammatory states. However, the higher rate of severe hypoalbuminemia (66%) in our cohort compared to other studies may suggest more advanced forms of disease in our patients.
In conclusion ,The study of serum protein electrophoresis profiles in patients with DIP is a key tool for guiding clinicians towards autoimmune or infectious causes, in combination with other biological tests.

Clinical Chemistry

P0516

VITAMIN D STATUS AND THYROID FUNCTION

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BACKGROUND-AIM

Vitamin D, a fat-soluble vitamin, plays a key role in several physiological processes. Its receptors (VDR) are found in various tissues, including the thyroid gland, suggesting a potential influence on thyroid function.
This study aimed to investigate the relationship between vitamin D levels and thyroid function.

METHODS

We conducted a retrospective descriptive study over six months (January–June 2024) in the Medical Biology Department of Med Taher Maamouri Hospital, Nabeul. The following biological parameters were analyzed: 25 OH vitamin D (Vit D), thyroid-stimulating hormone (TSH), and free thyroxine (FT4) using the Cobas® pure analyzer. Patients with a history of thyroid dysfunction were excluded. Two groups were defined: Group A (Vit D < 30 ng/mL) and Group B (Vit D ≥ 30 ng/mL).

RESULTS

A total of 89 patients were included: 64 in Group A and 25 in Group B. The mean age was 48 ± 18 years, with a sex ratio (M/F) of 0.51. The mean Vit D level was 22.44 ± 12.67 ng/mL. The mean TSH level was 3.57 ± 2.61 µIU/mL in Group A and 2.31 ± 1.34 µIU/mL in Group B. Subclinical hypothyroidism was observed in 26% of Group A patients, with a mean TSH of 6.48 ± 2.37 µIU/mL. TSH levels were significantly higher in Group A compared to Group B ($p = 0.003$). Additionally, TSH was negatively correlated with Vit D levels ($r = -0.294$, $p = 0.006$).

CONCLUSIONS

This study highlights an association between vitamin D deficiency and elevated TSH levels, particularly in subclinical hypothyroidism. The findings are supported by a significant negative correlation ($r = -0.294$, $p = 0.006$), but the small sample size and retrospective design limit the conclusions. The absence of certain parameters, such as free T3 or thyroid antibodies, is a notable limitation. These results emphasize the importance of thyroid monitoring in vitamin D deficient patients, and further prospective studies are needed to confirm this relationship.
In conclusion, the results suggest that vitamin D deficiency may be a contributing factor in the alteration of thyroid function, particularly in the context of screening for subclinical hypothyroidism. Therefore, more rigorous monitoring of patients with vitamin D deficiency could be relevant to prevent or detect thyroid disorders at an early stage.

Clinical Chemistry

P0517

CHALLENGES IN HBA1C MEASUREMENT BY HPLC: INSIGHTS FROM FOUR CLINICAL CASES.

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BACKGROUND-AIM

HbA1c is the result of the slow, non-enzymatic, and irreversible attachment of glucose to the N-terminal valine of one or both β chains of hemoglobin A (Hb A).
Its semiological value as a retrospective and cumulative marker of glycemic control depends on normal hemoglobin synthesis (97-99% Hb A) and a normal lifespan of erythrocytes (120 days). If either of these parameters is altered, the balance between the synthesis/degradation reactions and the non-enzymatic glycation reactions is disturbed, leading to either an underestimation or overestimation of HbA1c levels or making its measurement impossible.
Through these clinical cases, we report the difficulties encountered during the measurement of HbA1c performed on the ADAMS HA-8180V ARKRAY® analyzer, using high-performance liquid chromatography (HPLC) with cation-exchange reverse phase technique.

METHODS

The HbA1c test on whole blood was performed using the ARKRAY ADAMS A1C HA-8180 analyzer, which utilizes high-performance liquid chromatography (HPLC) with cation-exchange reverse phase technique. Internal quality controls were conducted daily before the analysis was initiated, along with external quality evaluation monthly. Four situations were chosen, during which the interpretation of the HbA1c results and the chromatogram was impossible, excluding any analytical interference.

RESULTS

Case 1: HbA1c exceeds the linearity limit with HbA1c > 20% in a patient with an initial diabetic ketoacidosis (DKA) episode.
Case 2: HbA1c is below the detection limit with HbA1c < 3% in a patient with hemolytic anemia.
Case 3: HbA1c not detectable in a patient with homozygous sickle cell disease (S/S) (absence of HbA).
Case 4: HbA1c not detectable in a patient with heterozygous sickle cell trait (S/C) (absence of HbA).

CONCLUSIONS

Through these clinical cases, we identified various situations where the interpretation of HbA1c test results becomes challenging or even impossible. This highlights the need to raise awareness among laboratory professionals about the limitations of the HPLC method and the critical pitfalls that must be understood for accurate result interpretation, ultimately enabling better patient management.

Clinical Chemistry

P0518

BEYOND TRADITIONAL MARKERS: EXPLORING LNCRNAS IN SALIVA AND SERUM FOR BREAST CANCER DIAGNOSIS

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BACKGROUND-AIM

Given the need for non-invasive and accessible biomarkers for early breast cancer detection, this study aims to investigate the potential of long non-coding RNAs (lncRNAs) GAS5, MEG3, and HOTAIR as salivary and serum biomarkers for breast cancer and to assess the correlation between their levels in these two biological fluids.

METHODS

This case-control study enrolled 30 women diagnosed with breast cancer and 30 healthy women as a control group, matched for age and other relevant demographic factors. Saliva and blood samples were collected from all participants. Quantitative real-time PCR (qRT-PCR) was used to determine the expression levels of GAS5, MEG3, and HOTAIR in both serum and saliva samples. The Mann-Whitney U test was employed to compare lncRNA expression between the two groups, and Spearman correlation analysis was used to assess the relationship between serum and salivary lncRNA levels.

RESULTS

Our findings revealed a significant downregulation of GAS5 and MEG3 in both serum and saliva of breast cancer patients compared to the control group ($P < .05$). Conversely, HOTAIR expression was significantly upregulated in both serum and saliva of the breast cancer group ($P < .05$). Correlation analysis demonstrated a significant positive correlation between serum and salivary levels of GAS5 ($r = 0.65$, $P < 0.01$), MEG3 ($r = 0.72$, $P < 0.01$), and HOTAIR ($r = 0.71$, $P < 0.01$).

CONCLUSIONS

This study suggests that GAS5, MEG3, and HOTAIR lncRNAs hold promise as potential biomarkers for breast cancer. The altered expression of these lncRNAs in both serum and saliva may provide a valuable tool for early detection and diagnosis of breast cancer. Further large-scale studies are warranted to validate these findings and to explore their clinical utility.

Clinical Chemistry

P0519

NON-LINEAR RELATIONSHIP BETWEEN ACCELERATED AND REAL-TIME STABILITY OF SERUM BIOMARKERS

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BACKGROUND-AIM

The Arrhenius equation is widely used for shelf-life estimation of pharmaceutical products. This has been adapted for QC controls but some biomarkers in serum control materials may not follow this equation during handling and storage. This leads to a lack of correlation between predictive and real-time stability. However, accelerated stability tests can identify biomarkers sensitive to temperature changes during handling and transport. This study presents comparative assessment of accelerated stability vs real-time study on biomarkers in control materials.

METHODS

Accelerated stability studies on lyophilized clinical chemistry and immunoassay control materials with real-time shelf-life claims of 4 years and 2 years at 2-8°C, respectively, were conducted. Control materials were stored at elevated temperatures (+20, +30, +37°C) for 1-3 months. The recovery at each temperature and time point was measured, and the % degradation rate per month was extrapolated and compared to real-time stability data at normal storage conditions. Commonly used clinical chemistry and immunoassay instruments were used.

RESULTS

Eight biomarkers tested (ALAT, ALP, Amylase, Bilirubin direct, Bilirubin total, CK, Glucose, LDH) showed stability of less than 3 years compared to real-time stability.
In immunoassay control, the five biomarkers (BNP, CK, CRP, Digoxin, myoglobin) tested did not tolerate high temperatures at 20 and 30°C compared to real-time stability.
These are biomarkers whose mechanisms of folding/ unfolding/ refolding could be affected by storage at elevated temperature. The rate of autooxidation at elevated temperature may have also affected Bilirubin, CK, LDH and myoglobin recovery. CRP precipitated and had shown aggregation rather than formation of pentameric structure when tested in Sephadex 200.

CONCLUSIONS

Accelerated stability studies provide valuable insights into product weaknesses and potential issues early in development, allowing for timely adjustments in formulation, processing, and stability claims. It was useful to assess temperature excursions during transport. However, the complex folding mechanisms of some biomarkers, especially proteins and enzymes, may affect the linearity of accelerated tests, making shelf-life predictions less accurate.

Clinical Chemistry

P0520

LONG-TERM PROTON PUMP INHIBITOR AND IRON-DEFICIENCY ANEMIA

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BACKGROUND-AIM

Proton pump inhibitors (PPIs) have become one of the most commonly prescribed classes of drugs worldwide. However, their long-term use can lead to undesirable side effects including an increased risk of gastric cancer, chronic kidney disease, and iron-deficiency anemia. The aim of our study is to analyse the impact of long-term proton pump inhibitors on hemoglobin and ferritin concentrations in patients treated with long-term PPIs.

METHODS

This is a case-control study carried out at the clinical biochemistry laboratory including patients, from Gastroenterology department, using long-term proton pump inhibitor (>1 year) and age- and sex-matched controls. Both patients and controls underwent blood sampling for ferritin determination, and a complete blood count (CBC). Anemia was defined by hemoglobin level below 12g/dL in women and 13g/dL in men, and iron deficiency as ferritin below 15 ng/mL in women and 30 ng/mL in men.

RESULTS

A total of 65 patients and 130 controls were included. The mean period of PPIs treatment was 85,22 months (12 - 240months). The mean age of patients was 52.02 ± 11.72 years. The male-to-female ratio (M/F) was 0.8. No difference was found in mean hemoglobin and ferritin levels between patient group and the control group (p=0.54 and p=0.8 respectively). The prevalence of iron deficiency anaemia was 9.23% in the patient group and 4.76% in the control group, with no significant difference between the two groups (p= 0.25).

CONCLUSIONS

In the light of the results of this study, long-term treatment with PPIs for at least one year does not cause iron-deficiency anemia. There is no need to recommend screening for iron deficiency in these patients. Further studies on patients with longer treatment durations and on a larger population should be carried out to establish the association between iron-deficiency anemia and PPIs long term treatment.

Clinical Chemistry

P0521

PROCALCITONIN OR C-REACTIVE PROTEIN IN MONITORING INTENSIVE CARE UNIT'S PATIENTS?

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BACKGROUND-AIM

Procalcitonin (PCT) is frequently requested for monitoring patients hospitalized in intensive care units to evaluate treatment efficiency in various pathologies as infection, shock, extensive burns, postoperative period ...
The aim of our study is to evaluate the PCT prescriptions from intensive care unit.

METHODS

This study is a retrospective and descriptive study, carried out in the biochemistry laboratory including procalcitonin requests coming from the intensive care unit of the Hospital over a period of 3 months. PCT and C-reactive protein (CRP) determinations were performed on the Cobas 6000 automated system by electrochemiluminescence (ECLIA) and immunoturbidimetric method respectively.

RESULTS

A total of 143 requests for PCT determination were collected. In 96.5% of cases, we received a request to analyse both PCT and CRP. The major indication was "therapeutic follow-up to verify the efficacy of therapy and possibly adapt the choice and total duration of treatment" (38%), followed by "fever and rising CRP with biological inflammatory syndrome" (21%). Among these requirements of PCT analysis, only 59 % of requests were performed. In the remaining cases, the CRP kinetic was considered sufficient to judge the treatment efficiency.

CONCLUSIONS

PCT currently appears to be one of the best biological markers available, frequently requested in an intensive care unit. However, CRP alone can be sufficient to predict treatment efficacy and can reduce the cost of abusive PCT requests.

Clinical Chemistry

P0522

SEVERE HYPERCHOLESTEROLEMIA AND PSEUDOHYPONATREMIA DUE TO LIPOPROTEIN X IN DUCTOPENIC LIVER GVHD: A CASE REPORT

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BACKGROUND-AIM

Pseudohyponatremia is commonly associated with severe hypertriglyceridemia and hyperparaproteinemia, but its connection with severe hypercholesterolemia is less well recognized. This case discusses a 54-year-old female with B-cell acute lymphoblastic leukemia (B-ALL), who developed ductopenic liver graft-versus-host disease (GVHD) and severe dyslipidemia, presenting with chronic pseudohyponatremia, likely caused by Lipoprotein X (LpX).

METHODS

A 54-year-old female with B-ALL underwent stem cell transplantation (SCT) from an unrelated donor in November 2023. She developed both acute and chronic GVHD, affecting her skin and liver. A liver biopsy in April 2024 confirmed ductopenic liver disease. Her bilirubin was elevated (400 µmol/L), alkaline phosphatase (ALP) exceeded 3000 IU/L, and alanine aminotransferase (ALT) was 700 IU/L. The patient had frequent hospitalizations for chronic hyponatremia, with normoosmolar hyponatremia, raising suspicion for pseudohyponatremia. Sodium measurement by indirect ISE was 115 mmol/L and a direct ISE of 143 mmol/L confirmed pseudohyponatremia. Her lipid profile revealed significantly elevated total cholesterol (75.4 mmol/L) and triglycerides (6.2 mmol/L), though LDL-C was not calculated. She had a prior history of mildly elevated cholesterol, but no history of pancreatitis or cardiovascular disease. On examination, she had jaundice and abdominal obesity, but no signs of primary lipid disorders.

RESULTS

Further investigations showed Apolipoprotein B (Apo B) of 1.47 g/L (0.47-0.99), but lipoprotein electrophoresis did not confirm LpX. However, the combination of cholestasis, markedly elevated cholesterol, and an inappropriately low Apo B suggested LpX involvement, which explained the pseudohyponatremia.
Her GVHD treatment was escalated, resulting in gradual improvement of liver function. By discharge after 4 months, her total cholesterol decreased to 37.1 mmol/L, with LDL-C calculated at 32.2 mmol/L. Pseudohyponatremia gradually improved over time, although the patient did not fully recover due to persistent chronic liver GVHD.

CONCLUSIONS

Extreme hypercholesterolemia due to LpX in cholestasis is a rare cause of pseudohyponatremia. Direct potentiometry for serum sodium is critical in severe hypercholesterolemia to avoid mismanagement of hyponatremia.

Clinical Chemistry

P0523

SERUM HOMOCYSTEINE, FOLIC ACID AND VITAMIN B12 LEVELS AMONG YEMENI PREGNANT WOMEN WITH PRE-ECLAMPSIA

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BACKGROUND-AIM

Folic acid and vitamin B12 are essential for homocysteine metabolism. A deficiency in these nutrients can lead to elevated serum homocysteine levels during pregnancy, potentially resulting in complications such as pre-eclampsia. The aim of this study was to determine the levels of homocysteine, folic acid and vitamin B12 in pregnant women and the association of homocysteine with severity of pre-eclampsia.

METHODS

A case-control study of 118 pregnant women with and without pre-eclampsia, conducted in Mukalla Hospital for Maternity and Children from 1st January to 30th July 2024. Serum homocysteine, folic acid and B12 levels were measured by immunochemilumence assay (Cobase e411).

RESULTS

Serum levels of homocysteine were significantly higher in women with pre-eclampsia compared to the control group (P = 0.014). In contrast, folic acid levels were significantly higher in the control group than in those with pre-eclampsia (P = 0.010). Additionally, a positive correlation was found between serum homocysteine levels and several clinical parameters: diastolic blood pressure (r = 0.220; P = 0.018), proteinuria (r = 0.254; P = 0.006), urine creatinine (r = 0.188; P = 0.043), and the albumin-creatinine ratio (r = 0.216; P = 0.020). Conversely, serum folic acid levels were negatively correlated with proteinuria (r = -0.187; P = 0.045), microalbuminuria (r = -0.202; P = 0.030), and the albumin-creatinine ratio (r = -0.188; P = 0.044).

CONCLUSIONS

Levels of serum folic acid and homocysteine showed significant alterations in pregnant women with pre-eclampsia compared to the control group. These findings provide further evidence that these biomarkers could indicate an increased risk of pre-eclampsia.

Clinical Chemistry

P0524

ARE SODIUM, POTASSIUM, AND CHLORIDE RESULTS ON BLOOD GAS ANALYSER COMPARABLE TO THOSE ON BIOCHEMISTRY AUTOANALYSER?

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BACKGROUND-AIM

Electrolytes are part of the standard test panel on the blood gas analysers (BGA) when analysing acid-base balance in the arterial blood sample. The turnaround time for a BGA analysis is shorter compared to a serum electrolyte analysis performed on an autoanalyser (AA). The purpose of this study was to determine whether the BGA (ABL90 flex, Radiometer, Denmark) measurements of sodium (Na), potassium (K), and chloride (Cl) are comparable with measurements using AA (Alinity c, Abbott, USA), and whether the results of the BGA can be used to guide clinical decisions before the availability of AA results.

METHODS

We obtained electrolyte results of 172 trauma patients, from whom both arterial and venous blood samples were collected simultaneously for analysis. Electrolyte concentrations were determined utilized two different methods, indirect on AA and direct potentiometric method on BGA. Obtained results were compared by Bland-Altman plot (BA) and Passing-Bablok regression analysis (PB) using MedCalc v11.5.1.0 (MedCalc Software, Ostend, Belgium). A clinically significant difference was assessed by comparing average bias with eligibility criteria (for Na 3%, K 6%, and Cl 4%).

RESULTS

The median values (interquartile range) in mmol/L for Na were 139 (137-141) using AA and 139 (136-142) using BGA (P=0.390), for K were 4.0 (3.8-4.3) using AA and 3.8 (3.6-4.1) using BGA (P<0.001), and for Cl were 105 (101-108) using AA and 104 (99-107) using BGA method (P<0.001). BA analysis showed a constant and proportional difference for K (0.21 (95%CI: 0.18 to 0.24) and 5.22 % (95%CI: 4.53 to 5.92), respectively), and for Cl (1.18 (95%CI: 0.96 to 1.40) and 1.16 % (95%CI: 0.95 to 1.38), respectively). By PB analysis, a complete agreement was obtained between methods for Na, whereas constant differences were observed for K (intercept -0.2; 95%CI: -0.2 to -0.2) and Cl (intercept -8.8; 95%CI: -14.4 to -1.0), without any clinical significance for either. The average bias between methods for K (-5%) and Cl (-1%) was within the eligibility criteria.

CONCLUSIONS

The findings of this study demonstrated that Na, K, and Cl measurements from serum samples using AA and from arterial whole blood samples using BGA are comparable, and can be used unambiguously to guide clinical decisions.

Clinical Chemistry

P0525

THE LIMITATIONS OF USING THE HEMOLYSIS INDEX TO SCREEN FOR INTRAVASCULAR HEMOLYSIS. CONSTRUCTION OF NEW BIOLOGICAL MARKERS - THE ACUTE INTRAVASCULAR HEMOLYSIS INDEX (AIVHI) TO MEET THIS CHALLENGE.

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BACKGROUND-AIM

The hemolysis index (HI) is inexpensive and rapid and is correlated with the free hemoglobin value. So could we use HI to screen for intravascular hemolysis? The preliminary results of two AIVHI scores (Acute IntraVascular Hemolysis Index) will be presented to assess whether they could be future tools for this screening.

METHODS

For one year, prescriptions with haptoglobin (serum) with an HI below 80 UA and LDH (plasma) were included. Plasma HI results were classified according to the category of the haptoglobin value (<0.1 “undetectable”; 0.1-0.29; >0.29 “normal”; g/L). The effectiveness of HI in detecting haptoglobin below 0.1 g/L was tested by ROC curve, with the point with the maximum likelihood ratio identified. Finally, two AIVHI scores, based on spectrophotometric algorithms designed at Rouen University Hospital, were measured on 100 randomly drawn samples for 4 HI classes (0-49; 50-149; 150-299; >300; UA). The 99th percentile of the groups was compared to the AIVHI scores of 6 patients with a finding of major intravascular hemolysis.

RESULTS

2090 prescriptions were included, with 193, 61 and 1836 HI values respectively for the different categories of haptoglobin values. A group effect was demonstrated (p<0.0001), with a higher HI value for the “ undetectable ” group compared with the “normal” haptoglobin group (p<0.0001). The ROC curve establishes the diagnostic power of HI for the presence of haptoglobin below 0.1g/L as poor, with a 95% confidence interval for the area under the curve of [0.55-0.64]. The likelihood ratio is highest (1.923) for an HI value greater than 35 UA. In our lab, 7.9% of samples had an HI greater than 35 UA, i.e. almost 27,000 samples per year. Finally, the AIVHI scores of the 6 patients with a major intravascular hemolysis are above the 99th percentiles of the reference populations, while 4 have an HI below 35 AU.

CONCLUSIONS

The results show that the use of IH alone does not appear to be suitable for detecting intravascular hemolysis. The AIVHI scores developed by the General Biochemistry Department of Rouen University Hospital appear to be a promising complement for detecting major intravascular hemolysis. The long-term objective is to be able to offer this type of score on automated platforms for rapid, low-cost detection of intravascular hemolysis.

Clinical Chemistry

P0526

IMPACT OF ENDOGENOUS BILIRUBIN ON SERUM HDL CHOLESTEROL CONCENTRATION MEASUREMENT

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BACKGROUND-AIM

Accurate analytical results are essential in clinical laboratories to ensure proper diagnosis and treatment. However, these results can be compromised by interferences from endogenous components like bilirubin, a byproduct of hemoglobin breakdown. Elevated serum bilirubin concentration (jaundice) can cause spectral and chemical interferences in assays, altering the measurements of quantities such as serum concentration of HDL cholesterol. This study evaluates whether bilirubin induces significant bias in these measurements, identifies interference thresholds, and examines differences between conjugated and unconjugated bilirubin.

METHODS

This study was conducted using a Cobas c702 analyzer (Roche Diagnostics). Serum samples with low jaundice indices were pooled into three categories based on HDL cholesterol concentration (low, medium, high). Conjugated and unconjugated bilirubin solutions were prepared and serially diluted into the serum pools to assess interference thresholds and directions (theoretical concentrations of bilirubin studied 50, 100, 200, 400, 600, 800, 1000 µmol/L). The percentage of interference was calculated for each dilution of the interferent. The analytical performance was compared to the maximum allowable systematic error, following the recommendations of the U.S. National Institutes of Health (5%).

RESULTS

Conjugated bilirubin caused significant decreases starting at bilirubin concentration of 600 µmol/L, not aligning with manufacturer thresholds (jaundice index of 1026 µmol/L). Unconjugated bilirubin showed no interference below bilirubin concentration of 1000 µmol/L.
The study confirmed bilirubin interference in specific assay for HDL cholesterol concentration measurement with variations in direction and magnitude depending on the bilirubin type. Notably, conjugated bilirubin exhibited more pronounced interference due to higher solubility and uniform distribution in serum.

CONCLUSIONS

This study highlights the necessity of tailored laboratory protocols to address specific interferences, ensuring accurate diagnostic outcomes. Future work should refine tolerance limits and integrate clinical relevance into interference criteria.

Clinical Chemistry

P0527

PERSISTENT INCREASE IN TROPONIN I – CAUSE FOR CONCERN ?

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BACKGROUND-AIM

A 29-year-old male with episodes of giddiness and a medical history that includes myocarditis (2021), ICD placement (2022), and ventricular tachycardia episodes leading to multiple hospital admissions in 2022 and 2023. The patient presented with an abnormal high Troponin I result, prompting suspicion of recurrent myocarditis. Normal Troponin T levels were noted concurrently. Our study aim was to investigate the cause of discrepancy between the two troponin assay results.

METHODS

Laboratory investigation for discordant Troponin results involved testing of patient serum sample on different platforms : high-sensitivity Troponin T on the Roche Cobas e411, Troponin I on the Beckman Coulter and Abbott Alinity i respectively. The Troponin I test was repeated on Abbott Alinity i Troponin I before and after treatment of serum with polyethylene glycol (PEG) solution. A negative control from patient of post myocardiac infarction with elevated Troponin I result is used to compare the recovery PEG. Data analysis was performed and reviewed for the potential cause of discordant troponin results.

RESULTS

Laboratory investigation shows that both Roche Troponin T and Beckman Coulter Troponin I results are in concordance. Discrepant cardiac Troponin result interpretation observed in Roche Cobas e411 (Troponin T:Normal,11.1 pg/mL), Beckman Coulter (Troponin I:Normal, 10.7 ng/L) and Abbott Alinity i (Troponin I:Abnormal high,133.0 ng/L). A pre-PEG Troponin I result of 133.0 ng/L (high) and post-PEG precipitation result of <10.0 ng/L on the Abbott Alinity i suggests the presence of macro troponin as the likely cause of falsely elevated Troponin I results. The findings supported the hypothesis of macro-troponins, a phenomenon triggered by prior myocardial injury. These complexes have prolonged circulation half-life (~3 weeks) and may cause assay specific false positive Troponin I result.

CONCLUSIONS

This information underscores the importance of ensuring accurate Troponin assays in patients, especially those with complex cardiac histories. The interference impact on Troponin I measurements can potentially lead to erroneous results and affect clinical decision making. The patient was educated about the assay specific nature of the Trop I elevation and advised to prioritise for future cardiac evaluations.

Clinical Chemistry

P0528

GULLO'S SYNDROME: A CASE REPORT

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BACKGROUND-AIM

Gullo's syndrome or benign pancreatic hyperenzyminaemia (BPH) is a condition where elevated pancreatic enzymes, lipase and amylase, are observed in the absence of any evidence of pancreatic disease. Characteristics:
- It occurs in healthy individuals.
- There is a large fluctuation and normalisation of enzymes.
- Enzyme elevation must be sustained over time (at least 1 year).
- 95% of cases there is elevation of amylase and lipase together.

BPH can occur sporadically or in families, so it is thought that there may be a genetic basis. However, the molecular mechanism of this syndrome is not known.

METHODS

A 61-year-old male patient with no past history of interest was referred to the Digestive Department for hyperamylasaemia of 391 IU/L (RV: 0 - 100 IU/L). No clinical history of interest. Normal physical examination. The patient was asymptomatic. The first suspected diagnosis was macroamylasaemia.

RESULTS

Digestive tract tests were requested to complete the study, highlighting amylase 128 IU/L, lipase 153 IU/L (RV: 1-60 IU/L) and amylase in isolated urine 775 (RV: <460 IU/L). The elevated urine amylase concentration allows ruling out macroamylasaemia.

Given the patient's clinical data, imaging tests were requested, all without pathological findings. Underlying pancreatic pathology was ruled out. The patient underwent successive analytical controls over time where amylase and lipase concentrations showed large fluctuations and normalisation of their values:
- 23/11/2017: Amylase 375, Lipase 391
- 05/04/2018: Amylase 133, Lipase 186
- 28/10/2019: Amylase 258, Lipase 632
- 01/10/2020: Amylase 437, Lipase 1275
- 21/10/2021: Amylase 98, Lipase 105
- 02/01/2023: Amylase 135, Lipase 215

Given the clinical characteristics of the patient and the analytical results, the patient was diagnosed with Gullo's syndrome.

CONCLUSIONS

Although the elevation of amylase and lipase are related to pancreatic pathologies, they can be elevated in other types of diseases. The importance of recognising Gullo syndrome lies in the fact that it is a benign process, and its diagnosis avoids the need for unnecessary tests and treatment for the patient.

Clinical Chemistry

P0529

COMPARATIVE ANALYSIS OF GFR ESTIMATION METHODS: COCKCROFT-GAULT, MDRD, AND CREATININE CLEARANCE IN AN ADULT POPULATION

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BACKGROUND-AIM

Accurate estimation of the GFR is crucial for the diagnosis and management of kidney diseases. Traditionally, GFR has been measured through direct techniques, such as inulin or radioisotope clearance, which are considered the gold standard. However, these methods are complex, and not widely available in clinical practice. Consequently, several indirect methods have been developed to estimate GFR based on serum creatinine levels. The most commonly utilised methods are Creatinine Clearance (CL-CR), Cockroft-Gault (CG) and Modification of Diet in Renal Disease (MDRD) formula. The aim of this study was to compare the performance and applicability of these three methods.

METHODS

a cross-sectional study was conducted on 75 adult patients within the Department of Internal Medicine at EPH Rouiba, Algiers.GFR was estimated using the CG,MDRD and Cl-Cr formulae. Subsequently, an analytical comparison was performed.

RESULTS

The study population had a mean age of 53.6±15.03 years and a female predominance (sex-ratio=0.63). Mean GFR was 68.2 mL/min ± 33.1 by creatinine clearance, 83.5 mL/min ± 42.4 by Cockcroft-Gault, and 73.8 mL/min ± 29.2 by MDRD. These differences were statistically significant ($p = 0.02$).
Moderate correlation was observed between Cl-Cr and CG ($r = 0.47$, $p < 0.01$), and weaker correlation between Cl-Cr and MDRD ($r = 0.31$, $p = 0.007$).
Compared to creatinine clearance, CG underestimated GFR by 15.3 mL/min (18.76%), while MDRD underestimated GFR by 5.6 mL/min (9.97%). Bland-Altman analysis showed that the agreement between Cl-Cr and both CG and MDRD varied across the range of eGFR values, with discrepancies exhibiting distinct patterns for each formula.

CONCLUSIONS

Substantial differences were observed between GFR estimated by CL-CR and two commonly used estimating equations, CG and MDRD. Both formulae underestimated GFR compared to Cl-Cr, with CG demonstrating a greater degree of underestimation (18.76%) than MDRD (9.97%). Bland-Altman analysis further revealed that the agreement between these methods varied across the range of GFR values.These findings highlight variability in GFR estimation methods and underscore the importance of careful consideration when selecting and interpreting GFR estimation tools in clinical practice.

Clinical Chemistry

P0530

" THE IMPACT OF AGE, GENDER AND SEASON ON VITAMIN D DEFICIENCY: INSIGHTS FROM COMPREHENSIVE ANALYSES"

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BACKGROUND-AIM

Vitamin D, produced when UVB sunlight converts 7-dehydro-cholesterol in the skin to Vitamin D3, is essential for immune functions and calcium absorption. Its active form, 1.25(OH)2D, activates over 200 genes. Vitamin D deficiency, affecting 1 billion people globally, is linked to bone disorders, cardiovascular diseases, and autoimmune conditions. This study in Arta, Greece, explores the effects of season, age, and gender on vitamin D levels to enhance public health strategies.

METHODS

The study involved 1858 participants from the General Hospital of Arta. Samples were grouped in five age categories and stratified by gender. Statistical analysis was performed with Jamovi and GraphPad. ANOVA and post-hoc comparisons assessed the effects of age, gender, and season on vitamin D levels, with a gnificance at $p<0.05$.

RESULTS

The study included 1858 participants with a median age of 53 years. The highest attendance for blood tests was in autumn, and the lowest was in summer. Median vitamin D levels were: Summer 25.5 ng/ml, Autumn 26.7 ng/ml, Winter 18.65 ng/ml, and Spring 18.30 ng/ml. Age group levels ranged from 25.20 ng/ml in 1-13 years to 18.75 ng/ml in 71+ years. Males had a slightly higher median of 23.15 ng/ml than females (22.30 ng/ml). ANOVA revealed significant effects of season and age ($p<0.001$), with seasonal variation confirmed ($p<0.001$). Seasonal differences were significant for Summer vs. Winter and Spring ($p<0.05$). The 71+ age group had the lowest vitamin D levels, and deficiency was most prevalent in Spring (22.8%) and Winter (21%), with lower rates in Summer (7.6%) and Autumn (6%). Age strongly influenced deficiency risk, with older adults (71+) showing the highest deficiency (26.9%). Autumn and Summer had the highest vitamin D adequacy rates, while Spring and Winter had the lowest. Gender did not significantly affect seasonal variation ($p=0.590$), but there were gender-age group interactions ($p<0.001$).

CONCLUSIONS

This study examined the effects of season, age, and gender on Vitamin D levels. Winter and spring show low levels, especially in older individuals (71+). Gender and age group interactions were significant, highlighting different trends. These findings stress the need for targeted interventions, particularly for the elderly, during low-sunlight months.

Clinical Chemistry

P0531

THE VALUE OF VITAMIN D IN CHRONIC KIDNEY DISEASE

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BACKGROUND-AIM

Vitamin D and parathyroid hormone (PTH) are among the most important regulators of calcium and phosphorus metabolism, both in patients with chronic kidney disease (CKD) and in healthy individuals.

METHODS

The study included 147 CKD patients of both sexes, aged 35 to 85 years, and 145 healthy individuals (control group). Serum aliquots were analyzed for 25 OH vitamin D concentration in CKD patients and the control group using the ALINITY (ABBOTT) analyzer via chemiluminescent microparticle immunoassay (CMIA). PTH levels were measured using electrochemiluminescence (ECLIA) on the COBAS 411 analyzer (ROCHE). Calcium and inorganic phosphate levels were determined using the ALINITY (ABBOTT) analyzer: calcium via a photometric color test (arsenazo III) and inorganic phosphate via a photometric UV test (phosphomolybdate).

RESULTS

The study revealed the following median values for CKD patients: 25 OH vitamin D: 12.96 ng/mL, and for the control group: 24.88 ng/mL. Vitamin D insufficiency was present in 80% of CKD patients and 35% of the control group (25 OH < 20 ng/mL), while deficiency was observed in 13% of CKD patients and 32% of the control group. Sufficient levels were present in 7% of CKD patients and 33% of the control group. Using the Mann-Whitney test to compare 25 OH vitamin D medians, a significant difference was found ($P < 0.05$) between CKD patients and the control group. PTH levels in CKD patients were 119.2 pg/mL, calcium 2.8 mmol/L, and phosphorus 1.36 mmol/L. An inverse correlation was found between 25 OH vitamin D and PTH levels in CKD patients, as well as a positive correlation between 25 OH vitamin D and calcium, and 25 OH vitamin D and inorganic phosphate.

CONCLUSIONS

In CKD patients studied at the University Clinical Center Kragujevac, Serbia (UCC), vitamin D insufficiency and deficiency were identified. Regular monitoring and supplementation of CKD patients are necessary to prevent complications such as hypertension and bone abnormalities. However, vitamin D supplementation should be conducted cautiously to avoid the development of hypercalcemia and complications such as vascular calcifications and nephrolithiasis.

Clinical Chemistry

P0532

IONIZED CALCIUM VS. TOTAL CALCIUM AND CORRECTED CALCIUMS: WHY PRIORITIZE IONIZED CALCIUM MEASUREMENT?

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BACKGROUND-AIM

Ionized calcium represents the biologically active form of circulating calcium. This parameter is rarely measured because its determination by direct potentiometry requires specific equipment and strict pre-analytical processing. Total calcium and its corrections for albumin and protein levels are often preferred but are suboptimal for evaluating phosphocalcic metabolism, which can lead to diagnostic errors, particularly in cases of primary hyperparathyroidism. The aim of this study is to demonstrate the relevance of ionized calcium compared to total calcium and corrected calcium levels in investigating abnormalities of phosphocalcic metabolism.

METHODS

We retrospectively collected clinical and biological data from 1,694 patients consulting in a rheumatology day care hospital for suspected phosphocalcic metabolism abnormalities. Among these patients, 256 were diagnosed with primary hyperparathyroidism (PHPT), confirmed by histopathological analysis of the parathyroid glands. The corrected formulas used were as follows:
With albumin (alb): Total calcemia+0.025×(40-alb)
With protein (prot): Total calcemia/(0.55+(prot/160))

RESULTS

In the cohort of 1,694 patients, the median (and interquartile values) ionized calcium (Cai) level was 1.29 mmol/L (1.26–1.33 mmol/L), total calcium (CaT) was 2.41 mmol/L (2.35–2.49 mmol/L), albumin was 45 g/L (43–47 g/L), and total protein was 69 g/L (67–72 g/L). The concordance between Cai and CaT was 33%, between Cai and albumin-corrected CaT 45%, and between Cai and protein-corrected CaT 30%.
Among the 256 patients with PHPT, 177 had elevated ionized calcium (threshold > 1.3 mmol/L), compared to only 48 patients based on total calcium (threshold > 2.60 mmol/L).
Applying the correction methods for albumin- and protein-adjusted CaT with a threshold of 2.60 mmol/L further reduced the number of identified hypercalcemic patients to 13 and 76, respectively. For patients with PHPT, the concordance between Cai and CaT was 49%, between Cai and albumin-corrected CaT 33%, and between Cai and protein-corrected CaT 58%.

CONCLUSIONS

Total calcium and corrected calcium formulas are not reliable for accurately diagnosing dyscalcemia. Ionized calcium measurement should be prioritized in cases of suspected phosphocalcic metabolism abnormalities.

Clinical Chemistry

P0533

S100B PROTEIN AS A SUPPLEMENTARY TOOL IN THE EVALUATION OF MILD TRAUMATIC BRAIN INJURIES

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BACKGROUND-AIM

Mild traumatic brain injuries(mTBI) are frequent and account for a large proportion of visits to emergency departments (EDs).However, cranial computed tomography(CCT) often shows no abnormalities. Recently, the serum protein S100B has emerged as a potential biomarker for traumatic brain injury(TBI).
This study aims to assess the clinical utility of S100B protein as a biomarker for detecting intracranial injuries in mTBI patients.

METHODS

This prospective study was conducted over four months (February 1–May 31, 2012). It included patients presenting to the ED with head trauma and a Glasgow Coma Scale (GCS) score of 13–15.Blood samples for S100B analysis were taken within 12 hours post-injury, with follow-up samples collected 3 hours later. All patients underwent CCT scans.

RESULTS

A total of 173 patients with mTBI were included in the study.The median age was 31 years (1-90) with a sex ratio (M/F) of 3.75.The most frequently reported clinical signs,were loss of consciousness(85.8%), amnesia(33.5%), vomiting(20%) and headaches (15.5%). A significant elevation in the concentration of the S100B protein was observed in cases of amnesia($p<0.0001$) and vomiting($p=0.015$).However, loss of consciousness, despite being the most frequent clinical sign, was not associated with a significant variation in the concentration of S100B protein ($p=0.084$).In our study, 33% of intracranial injuries were identified through CCT.The most common CCT findings included craniofacial fractures(15%), skull fractures(13.3%), meningeal hemorrhages(11%), cerebral contusions(11%), pneumocerebral conditions(5.8%), extradural edema(3.5%), acute subdural hematoma(2.9%) and cerebral edema(1.7%).The median concentration of the S100B protein was significantly higher in the group with CCT-detected lesions (median: 0.639 µg/L [0.108-12.320]) compared to the group without lesions (median: 0.145 µg/L [0.017-5.430]) ($p < 0.0001$). Furthermore, patients with cerebral edema exhibited the highest median concentrations of S100B protein (4.120 µg/L [0.810-12.320] ;$p<0.001$).

CONCLUSIONS

Serum S100B measurement offers valuable insights for managing mTBI. It can help reduce unnecessary CCT scans and radiation,but should always complement clinical judgment and imaging.Further research is needed to refine its use and establish standardized clinical thresholds.

Clinical Chemistry

P0534

CRYOACTIVATION OF PRORENINE IN PRIMARY HYPERALDOSTERONISM SCREENING

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BACKGROUND-AIM

Aldosterone to renin ratio is the screening tool for primary hyperaldosteronism (PHA). Rigorous pre-analytic conditions are essential to obtain precise laboratory results.
The aim of our study was to investigate the preparation of renin samples before analysis.

METHODS

We conducted a retrospective study on all samples received over a period of three months (from july 2024 to october) to check for PHA. Blood was collected in EDTA for renin analysis and in heparin for aldosterone analysis. Samples were handled at ambient temperature during transport to the laboratory, to be immediately centrifuged and stored at -20°C. Each renin sample was measured twice under two preparation conditions: 1) plasma incubated for one day at 37°C, and 2) plasma thawed just before analysis. Renin and aldosterone assays were made using ELISA kits (DRG, Germany). An aldosteron/renin ratio is considered increased if it is >37.83 according to the DRG Renin ELISA data sheet.

RESULTS

Au total of 74 patients were included, aged between 7 and 82 ans.
The sex ratio was 0.68 with a female predominance (44 women and 30 men).
A decrease in renin concentrations was observed in more than half of the samples stored at 37°C. The diagnosis of HAP was retained in 48% and 36%, respectively, when the first and second renin sample preparations were applied.
Comparison of renin values of the first condition with those of the second one ,showed a significant decrease (p=0.0001), which led to a significant increase in the aldosterone/renin ratio for samples incubated at 37°C (p=0.0002).

CONCLUSIONS

Preanalytical sample handling and storage for PHA screening are challenging. A reversible cryoactivation of prorenin could lead to false laboratory results. We suggest plasma incubation for one day at 37°C to enhance the PHA diagnosis.

Clinical Chemistry

P0535

ERYTHROPOIETIC STIMULATION-INDEPENDENT APPROACH IN GLUCOSE 6 PHOSPHATE DEHYDROGENASE (G6PD) DEFICIENCY SCREENING : REVISING THE WHO CLASSIFICATION

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BACKGROUND-AIM

Glucose 6-phosphate dehydrogenase (G6PD) deficiency is one of the most prevalent enzymopathies, and is characterized by increased erythrocyte sensitivity to oxidative stress. A classification of pathogenic variants was established by the World Health Organization (WHO) based on clinical symptoms: class A (formerly I, defined by chronic hemolysis) and class B (formerly II and III, defined by triggered hemolysis). Class B variants may lead to the absence of symptoms if carriers are not exposed to oxidative stress. While the identification of fully-deficient individuals (i.e.,hemizygous/homozygous/compound heterozygous for pathogenic variants) is straightforward, G6PD activity is variable in heterozygous individuals. Consequently, assessing a patient's hemolytic risk can be difficult because of multiple factors influencing G6PD activity (stimulation of erythropoiesis, iron deficiency…) and thus leading to a risk of therapeutic mismanagement. However, some intraerythrocytic enzymes like Pyruvate Kinase (PK) or Hexokinase (HK) can reflect the influence of external factors on erythropoiesis. In this work, we confirmed the obsolescence of the former WHO classification by adding PK and HK activity measurement in G6PD deficiency screening, ensuring the absence of confounding factors.

METHODS

We conducted a 6-year retrospective study (2015-2020) on a sample of patients addressed to our laboratory (biochemistry laboratory, Hôpital Henri-Mondor, Créteil, France) for G6PD deficiency screening. The study population included more than 1,000 individuals who underwent G6PD genotyping, with PK and HK activities systematically measured on a Kone 20XT analyzer.

RESULTS

We report large spreads and overlaps of G6PD/HK and G6PD/PK ratios between class II and class III variants in an erythropoietic stimulation-independent approach, as well as wide overlapping of G6PD/HK and G6PD/PK ratios between all WHO class variants solely in heterozygous patients.

CONCLUSIONS

Overall, our study demonstrates the inadequacy of the traditional WHO classification for G6PD deficiency. By incorporating PK and HK activity measurements, we offer a more reliable method for assessing hemolytic risk, particularly in heterozygous individuals, leading to better clinical management.

Clinical Chemistry

P0536

COMPREHENSIVE CLINICAL AND ANALYTICAL VALIDATION OF ALZPATH PLASMA PTAU217 AND LUMIPULSE PLASMA PTAU217 IMMUNOASSAYS FOR THE BIOLOGICAL DIAGNOSIS OF ALZHEIMER'S DISEASE IN TWO CLINICAL DIAGNOSTIC LABORATORIES

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BACKGROUND-AIM

Plasma pTau217 is a robust biomarker for the diagnosis and monitoring of AD. However, most pTau217 assays are not widely available for clinical testing. We assessed the analytical and clinical performance of two commercially available, laboratory-developed pTau217 immunoassays in a clinical diagnostic laboratory for the biological diagnosis of Alzheimer's disease.

METHODS

1100 plasma samples from top 5 USA memory clinic with confirmed amyloid PET, 363 plasma samples from healthy controls with negative amyloid PET from the Australian Imaging, Biomarker and Lifestyle (AIBL), 115 plasma samples from pathology-confirmed cases, and 55 matched plasma and CSF samples from patients referred to the UBC Clinic for Alzheimer's Disease and Related Disorders, were selected. Plasma pTau217 levels were measured at Neurocode USA, Bellingham, WA, USA and BC Neuroimmunology Lab., Vancouver, BC, Canada. using the ALZpath pTau217 assay on the Quanterix HD-X Simoa platform and the Lumipulse pTau217 assay on the Lumipulse G1200 platform. CSF Aβ42/40 ratio and p-tau181 levels were measured using the Lumipulse G1200 platform. The assays were validated based on CLSI guidelines.

RESULTS

All samples measured for pTau217 using the ALZpath assay were above the lower limit of quantification (0.032 pg/mL). However, for plasma pTau217 measured by the Fujirebio assay, 10 samples (6.5%) had values below the limit of quantification (0.06 pg/mL).
For the ALZpath assay, the coefficients were 10.4%, 10.4%, and 9.9%, respectively. For the Fujirebio assay, the coefficients were 12.1%, 12.2%, and 5.3%, respectively.
Sample stability and interference were similar between the two assays, although moderate heterophilic antibody interference and reduced frozen sample stability at -20°C were observed for the Fujirebio assay. Both assays demonstrated similar clinical performance and differentiated individuals with AD (ALZpath AUC = 0.94; Fujirebio AUC = 0.90).

CONCLUSIONS

The performance of the two pTau 217 assays was comparable. The reference range curve could be plotted with high certainty using the data from the about 400 AIBL samples. The clinical separation between the healthy controls and those with Amyloid pathology was nearly complete for both Alzpath and the Fujirebio assays.

Clinical Chemistry

P0537

HEMOLYSIS INTERFERENCE ON NORMAL AND PATHOLOGICAL VALUES IN CLINICAL BIOCHEMISTRY PARAMETERS

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BACKGROUND-AIM

Hemolysis is one of the most common interferences in clinical biochemistry. Measuring certain parameters on hemolyzed samples can lead to erroneous results, resulting in misinterpretation, misdiagnosis, and inappropriate patient management. The aim of this study is to evaluate the influence of varying degrees of hemolysis on twenty-two biochemical parameters performed on the Beckman Coulter DXC 700 AU analyzer.

METHODS

Two pools of healthy plasma composed of plasma from healthy donors and pathological plasma prepared from patients with pathological values, were overloaded with five increasing concentrations of hemolysate which was prepared by osmotic shock induced by distilled water to a pool of blood samples (lithium heparin tubes). The resulting hemolysis index (HI) and hemoglobin concentration were as follows: HI(+)=0.05 – 0.099 g/dL, HI(++)=0.1 – 0.199 g/dL, HI(+++)=0.2 – 0.299 g/dL, HI(++++)=0.3 – 0.5 g/dL, HI(+++++)> 0.5 g/dL. The limit of 10% variation was chosen to define the influence of hemolysis on the measurement. All analytes were tested on the Beckman Coulter DXC 700 AU® analyzer.

RESULTS

Clinically significant difference was exceeded for 13 analytes in the healthy pool of plasma: Potassium, Lactate dehydrogenase (LDH), Creatine kinase (CK), aspartate aminotransferase (AST) and total and conjugated bilirubin at HI(+), alanine aminotransferase (ALT), magnesium, phosphate and total cholesterol at HI(++), alkaline phosphatase at HI(+++), total protein and gamma glutamyl transferase at HI(++++). Clinically significant difference was exceeded for 9 analytes in the pathological pool of plasma: Potassium, LDH and total and conjugated bilirubin at HI(+), phosphate and total cholesterol at HI(++), AST, magnesium and total protein at HI(++++).

CONCLUSIONS

The use of both healthy and pathological plasma pools in this study enabled a thorough comprehensive evaluation of the differential impact of hemolysis on biochemical parameters. A higher degree of sensitivity to hemolysis was observed in the healthy pool. Such findings underline the necessity of considering both clinical context and hemolysis levels to ensure accurate result interpretation and reliable patient management.

Clinical Chemistry

P0538

SERUM HEPCIDIN LEVELS IN BOSNIA AND HERZEGOVINA HEMODIALYSIS PATIENTS

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BACKGROUND-AIM

Hepcidin is a hormone that regulates the body's iron metabolism and its bioactive circulating form is 25 amino acids in size, in which the N-terminal end is necessary for influencing iron metabolism. We investigate the role of serum hepcidin in hemodialysis (HD) patients with chronic kidney disease (CKD).

METHODS

Serum hepcidin concentration was determined using the DRG Hepcidin - 25 ELISA Kit, on the APE ELITE analyzer, which is based on the principle of competitive binding. Hepcidin levels were measured in serums obtained from 20 healthy subjects as control and 57 CKD patients undergoing regular hemodialysis at University Clinical Centre of Sarajevo.

RESULTS

The mean hepcidin value in patients treated with a chronic hemodialysis program was 82.49 ± 20.80 µg/L, ranging from 25.42 µg/L to 106.82 µg/L. The mean hepcidin value in the control group was 15.08 ± 10.88 µg/L, ranging from 1.56 µg/L to 35.74 µg/L. The inter-assay coefficient of variation (CV) for ELISA assay was 9.8% and 10.9% at 15.4 µg/L and 58.6 µg/L and the intra-assay CV was 3.5% and 4.0% at 15.4 µg/L and 21.9 µg/L, respectively.

CONCLUSIONS

The presented results performed by ELISA method for determination of human hepcidin in serum showed an acceptable precision. Serum hepcidin levels were specifically elevated in HD patients. Hepcidin may serve as a marker for better diagnosing and monitoring of anemia and iron metabolism disorders with CKD patients.

Clinical Chemistry

P0539

INFLUENCE OF DIABETES MELLITUS CONTROL ON ACUTE MYOCARDIAL INFARCTION

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BACKGROUND-AIM

Acute myocardial infarction (AMI) is one of the main causes of death in the Western world. Diabetes Mellitus (DM) has been described as one of the associated risk factors. HbA1C has been postulated as a measure of its control. We studied the effect of poor control of DM on AMI in a tertiary hospital.

METHODS

Descriptive and retrospective study of patients diagnosed with AMI between September 2022 and September 2023. We acceded to their Clinical History to check out if they had a previous diagnosis of Diabetes Mellitus. It was considered that those patients with a Glycosylated Hemoglobin level equal to or greater than 53 mmol/mol (20.00-42.00) had a poor glycemic control according to the therapeutic objective proposed by the ADA in 2022. Glucose data (measured on an Alinity c autoanalyzer (Abbott Diagnostics) and glycosylated hemoglobin (on a BIORAD D-100 autoanalyzer) were obtained from the LIS (OpenLab). SPSS (version 25) was used for statistical calculation, applying the Chi-square test and the U-Mann Whitney test.

RESULTS

A total of 237 patients diagnosed with AMI were obtained. Of these, 222 were diabetic (90% type II DM). Glucose results were obtained from 213 patients, with an average blood glucose value of 187.25 mg/dl (74-100 mg/dL), and Hb1Ac data from 212 patients with an average value of 58 mmol/mol (20.00-42.00). It was estimated that 51.4% had poor control of DM at the time of the infarction with an HbA1C greater than 53 mmol/mol. 2.10% presented diabetic debut. No statistically significant differences were found between diabetics with good control (110 patients) versus those with poor control (102 patients) in age (66.6 vs 69.3 years, respectively; p-value = 1.10) or sex (p-value = 0.92). We did find differences between blood glucose levels (159 vs 259 mg/dl; p-value = <0.001) and HbA1C (45 mmol/mol vs 69 mmol/mol; p-value <0.001).

CONCLUSIONS

Our results show how the diagnosis of DM is a risk factor for AMI. However, we did not find statistically significant differences in our population when classifying patients according to their diabetic control. This may lead us to consider the possibility that other risk factors may influence this. Detecting diabetic patients early could mean that they benefit from early treatment and management to avoid possible complications such as AMI.

Clinical Chemistry

P0540

RESOLVING A COMPLEX SERUM SAMPLE FROM A LYMPHOMA PATIENT BY MASS SPECTROMETRY

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BACKGROUND-AIM

A serum sample from a patient diagnosed with low grade lymphoma and confirmed MYD88 L265P mutation was previously measured by immunotyping and capillary zone electrophoresis (CZE). The sample was complex and not all paraproteins could be identified and quantified. The patient is currently monitored using their IgG paraprotein concentration. We hypothesised that mass spectrometry analysis of this sample would allow for a more specific understanding of the paraproteins present in the sample and facilitate more precise monitoring of the patient.

METHODS

The serum sample was measured using the EXENT® Immunoglobulin Isotype Assay (EXENT GAM Assay). In brief, serum was incubated with polyclonal antibodies targeted against IgG, IgA, IgM, total Kappa and total Lambda. Following immunoprecipitation, mass spectra were generated by matrix assisted laser desorption ionisation-time of flight mass spectrometry. Monoclonal immunoglobulins were quantified in conjunction with Optilite® measurement of total IgG, IgA, IgM.

RESULTS

The EXENT GAM assay results showed three paraproteins: 13.5 g/L IgM Kappa at 12126.8 m/z, 2.3 g/L IgG Kappa at 12110.5 m/z and 1.23 g/L IgG at 12097.6 m/z. The peaks from these were detected within a narrow mass range (30 m/z), and this was reflected in the visual representation of the peaks. The mass range could explain why immunotyping suggested IgG was the dominant clone and why only one paraprotein was quantifiable by CZE.

CONCLUSIONS

Using the EXENT GAM assay, we were able to identify and quantify all paraproteins. Mass spectrometry results identified that IgM Kappa is the dominant clone, and not IgG as suggested by conventional methods. Better understanding of the clones by mass spectrometry will aid with more precise monitoring of this patient.

Clinical Chemistry

P0541

RITUXIMAB-INDUCED HYPOGAMMAGLOBULINEMIA: A RETROSPECTIVE STUDY OF 40 CASES.

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BACKGROUND-AIM

Rituximab-induced hypogammaglobulinemia is a well-documented complication that occurs in certain patients treated with this anti-CD20 monoclonal antibody. Rituximab is widely used in the treatment of various conditions, including lymphomas, rheumatoid arthritis, and other autoimmune diseases.
This treatment leads to the depletion of B lymphocytes, which can disrupt immunoglobulin production and result in hypogammaglobulinemia (1).

METHODS

This is a retrospective study conducted over a period of three years, involving 40 cases recorded at the Biochemistry Laboratory of CHU Mohammed VI in Tangier. The method employed for serum protein electrophoresis (SPE) was agarose gel electrophoresis, performed on the Hydrasys® automated system from Sebia.
The patients included in this study were diagnosed with various conditions: 20 suffered from rheumatoid arthritis, 16 from chronic myeloid leukemia, 3 from Hodgkin lymphoma, and 1 from systemic lupus erythematosus.
Inclusion criteria included prior treatment with rituximab and an assessment of immunoglobulin levels.

RESULTS

Among the 40 patients, 13 (32.5%) developed hypogammaglobulinemia, while 27 (67.5%) did not show a significant decrease in immunoglobulin levels. The sex ratio was 116, and the average age was 59.05 years. The results indicate a notable incidence of hypogammaglobulinemia, particularly among patients with autoimmune diseases and lymphomas, who are often more susceptible to complications related to B lymphocyte depletion (2).

CONCLUSIONS

Rituximab-induced hypogammaglobulinemia represents a significant complication in patients treated for hematological and autoimmune diseases. In our study, 32.5% of patients developed this condition, highlighting the need for careful monitoring of immunoglobulin levels and proactive management of potential infections. Further research is necessary to better understand the mechanisms of this hypogammaglobulinemia and to establish appropriate follow-up protocols for at-risk patients (6).

Clinical Chemistry

P0542

INVOLVEMENT OF FOLATE AND VITAMIN B12 DEFICIENCY IN PATIENTS WITH NORMOCYTIC ANEMIA

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BACKGROUND-AIM

Folate and vitamin B12 deficiencies are generally associated with macrocytic anemia. However, their association with iron deficiency may be responsible for normocytic anemia. In recent years, there has been a notable overuse of testing for these vitamins. This study aims to assess the prevalence of folate and vitamin B12 deficiencies in patients with normocytic anemia.

METHODS

This is a retrospective descriptive study including 100 patients who sought consultation or were hospitalized in various clinical departments of our hospital. The mean age of the patients was 54 years [21 - 87 years]. The sex ratio was 0.66. Serum levels of ferritin, vitamin B12, and folate were measured using the chemiluminescence technique with the Beckman Coulter DxI 600® system.

RESULTS

A total of 100 patients with normocytic anemia were selected. The mean hemoglobin level was 10 g/dL [4–11.9 g/dL], and the mean corpuscular volume was 89.28 fl [80,1-99,7 fl]. Among these patients, 67% had vitamin B12 deficiency (<180 pg/mL), while 33% had folate deficiency (<24.8 ng/mL). A combined deficiency of vitamin B12 and folate, without ferritin deficiency, was observed in 19% of patients. Ferritin deficiency (< 11 ng/ml) was identified in 14 patients, of whom 9 exhibited vitamin B12 deficiency without folate deficiency. Simultaneous deficiencies of vitamin B12, folate, and ferritin were observed in only 3% of patients.

CONCLUSIONS

In the clinical setting, the measurement of Folate and B12 concentrations in patients with normocytic anemia may be useful. Replacement therapy may be a treatment option to consider in patients with low Folate and B12 concentrations. However, physicians need to pay attention to the presence of background diseases, and the mechanisms of this situation require further investigation.

Clinical Chemistry

P0543

EVALUATION OF SERUM COPPER AND ZINC STATUS IN ALGERIAN PATIENTS WITH PROSTATE CANCER

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BACKGROUND-AIM

Previous observations have shown that trace metals play various roles in human health. Certain metals such as copper and zinc are known to be associated with prostate cancer, but their involvement is currently unclear. The aim of this work is to study the serum status of copper and zinc in Algerian men with prostate cancer.

METHODS

45 prostate cancer patients aged between 55-65 years and 45 age-matched healthy men as a control group participated in this study. Serum copper and zinc were measured on the ICE 3300 atomic absorption spectrometer from Thermo Fisher, and PSA level was measured on Cobas e411 from Roche Diagnostic.

RESULTS

Significant increase in serum copper in patients with prostate cancer compared to controls ($p<0.001$) while serum zinc levels did not show significant differences ($P=0.46$). A strong positive correlation is observed between PSA levels and serum copper ($r=0.66$), this correlation is statistically significant ($p<0.001$). We also note that the copper/zinc ratio was higher in patients with prostate cancer than in controls ($p<0.0001$), this ratio was strongly and significantly correlated with PSA levels ($r=0\ .71$) ($p<0.001$).

CONCLUSIONS

This study showed a significant increase in the value of copper. The Cu/Zn ratio increases in proportion to increasing prostate-specific antigen levels in patients with prostate cancer. Further studies are needed to elucidate this complex relationship between trace elements (Cu and Zn) and prostate carcinogenesis with the aim of developing more effective diagnostic, preventive and therapeutic strategies.

Clinical Chemistry

P0544

THE RELATIONSHIP BETWEEN HEMATOLOGICAL RATIOS AND INFLAMMATION AND DISEASE SEVERITY IN CHRONIC KIDNEY DISEASE PATIENTS

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BACKGROUND-AIM

Patients with chronic kidney disease (CKD) are prone to complications such as hypertension, anemia, and metabolic acidosis. Cardiovascular dysfunctions and infections caused by impaired immune responses contribute significantly to increased morbidity and mortality. Inflammation and oxidative stress play critical roles in these processes. Hemogram-based inflammatory markers like the monocyte-to-lymphocyte ratio (MLR), platelet-to-lymphocyte ratio (PLR), neutrophil-to-lymphocyte ratio (NLR), systemic immune-inflammatory index (SII), and neutrophil-lymphocyte-platelet ratio (NLPR) are widely used, cost-effective, and accessible indicators for systemic inflammation

METHODS

This prospective study included 134 stage 2–4 CKD patients who visited Gazi University Nephrology Outpatient Clinic in the past year. Data such as age, sex, smoking status, medications, and comorbidities were collected. eGFR was calculated using the CKD-EPI formula. Inflammatory markers were derived from complete blood counts, including differential white blood cell and platelet counts: NLR (neutrophil/lymphocyte), PLR (platelet/lymphocyte), MLR (monocyte/lymphocyte), NLPR (N/L×P) and SII (N×P/L). Statistical analysis was performed using SPSS version 22. Spearman correlation was used to examine the relationship between NLR, MLR, PLR, SII, NLPR, and serum blood urea nitrogen (BUN), creatinine, and eGFR. Results were presented as p values and Spearman correlation coefficients.

RESULTS

Spearman correlation analysis revealed a moderate to strong significant negative correlation between NLR, MLR, NLPR, and SII with eGFR, and a moderate to strong significant positive correlation between these ratios and BUN and creatinine levels. PLR showed a weak to moderate negative correlation with eGFR and a weak to moderate positive correlation with BUN and creatinine. A strong positive correlation was observed between NLR and PLR.

CONCLUSIONS

The evaluation of hematological inflammation markers such as NLR, PLR and SII provides valuable insights into systemic inflammation and its impact on CKD progression. Their cost effectiveness and accessibility make them practical tools in clinical settings. The significant correlations with eGFR, BUN and creatinine highlight their potential as biomarkers for monitoring disease severity and prognosis

Clinical Chemistry

P0545

IMPACT OF FASTING ON PATIENTS WHO HAVE UNDERWENT PERCUTANEOUS CORONARY ANGIOPLASTY

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BACKGROUND-AIM

Percutaneous Coronary Angioplasty (PCA) is a major intervention with significant health implications. This study aims to evaluate the impact of Ramadan fasting on biochemical parameters in patients who underwent PCA prior to the fasting period.

METHODS

This is a prospective, observational, and analytical study conducted in the cardiology department of Sfax University Hospital, in collaboration with the Biochemistry laboratory. The study included patients who had undergone PCA during the 6 months prior to the Ramadan fasting period. A blood test was carried out 15 days before the fast, and within 15 days after. The test included parameters for glycemic control: fasting blood glucose and glycated hemoglobin (HbA1c), lipid profile: total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol calculation.These biochemical measurements were performed on a Beckman Coulter DXC 800 analyzer. Data were collected and analyzed using SPSS version 23.

RESULTS

A total of 85 patients who had undergone PCA decided to fast, but only 32 of them underwent a biological assessment.The average age was 60.45 years [range: 34 - 83 years], with a male-to-female ratio of 4.Statistically significant reductions were observed in cholesterol and triglyceride levels (P=0.021; P=0.05, respectively). Our patients had an average cholesterol level of 3.86 mmol/L before the fast, and 3.54 mmol/L after (normal values: < 5.7 mmol/L). The average triglyceride level was 1.25 mmol/L before the fast and 1.03 mmol/L after (normal values: < 1.7 mmol/L).However, there was no statistically significant change in LDL levels (P=0.129) or HDL levels (P=0.806).Additionally, a significant decrease in HbA1c levels was observed before and after fasting (P<0.001), with an average of 6.7% before the fast and 6.4% after.Meanwhile, the change in fasting blood glucose was not significant (P=0.33).

CONCLUSIONS

Fasting during Ramadan may improve lipid and glycemic profiles in coronary patients who have undergone PCA. Appropriate medical management can enable these patients to observe their religious practices while safeguarding cardiovascular health.

Clinical Chemistry

P0546

EFFECT OF RAMADAN FASTING ON ENDOTHELIAL FUNCTION AFTER PERCUTANEOUS CORONARY INTERVENTION

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BACKGROUND-AIM

The Ramadan fast (RF) is one of Islam's five pillars. While cardiologists often advise patients post-percutaneous coronary intervention (PCI) to avoid fasting, many still choose to fast. This study aimed to assess the impact of Ramadan fasting on endothelial function in PCI-treated patients.

METHODS

This is a prospective, analytical observational study conducted in the cardiology department in collaboration with the biochemistry laboratory at Hedi Chaker University Hospital in Sfax during the month of Ramadan in 2022.
The study included patients who had undergone PCI in the 6 months preceding Ramadan and who fasted during the month.
Endothelial function was biologically assessed by measuring homocysteine and insulin levels 15 days before and 15 days after Ramadan.
Insulin levels were measured using the electrochemiluminescence immunoassay (ECLIA) method, and homocysteine levels were measured using an enzymatic method on the Roche Cobas 6000 analyzer.
Endothelial function was evaluated 10 days before and 10 days after the Ramadan fast using thermodigital monitoring with the E4 Diagnoses device, calculating the Endothelium Quality Index (EQI). An EQI ≥ 2 indicates excellent endothelial function, while an EQI < 2 indicates impaired endothelial function.

RESULTS

The study included 32 fasting patients. The mean age was 62.31 ± 7.9 years. The male-to-female ratio was 3.5. Statistical analysis revealed a significant increase in homocysteine levels after the fasting period ($p = 0.027$). However, insulin levels did not show a significant variation ($p = 0.516$). Before the Ramadan fast, 76.47% of patients had endothelial dysfunction with an EQI lower than 2. Endothelial function assessment after Ramadan showed an EQI of 0.817 ± 0.43, indicating impaired endothelial function ($p = 0.009$).

CONCLUSIONS

The increase in homocysteine during Ramadan fasting is likely due to dietary changes, leading to deficiencies in vitamin B6, B9, and B12, which are crucial for homocysteine metabolism.

Clinical Chemistry

P0547

EVALUATING THE COMMUTABILITY OF EXTERNAL QUALITY ASSESSMENT MATERIALS: A NEW APPROACH USING SMOOTHING SPLINES

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BACKGROUND-AIM

Traditional methods for assessing external quality assessment material (EQAM) commutability involve measuring differences in nonselectivity (DINS) between in vitro diagnostic medical devices (IVD-MDs) and using Deming regression prediction intervals to determine commutability. This method assumes a linear relationship, which may not always hold.
To address nonlinearity, we propose using smoothing splines—a flexible regression model that captures nonlinear relationships. This approach provides valid acceptance limits for commutability and a robust DINS measure, increasing the number of IVD-MD pairs eligible for evaluation.

METHODS

We defined a statistical model $y = f(x) + e$, where (x, y) are paired measurements from two IVD-MDs, and e are random errors. To estimate the function f, we used a smoothing spline g, a solution to a particular minimization problem. The smoothing parameter, which balances data fitting and function smoothness, was automatically selected to achieve an optimal balance.
Using g, we constructed prediction intervals serving as commutability acceptance limits. Moreover, a robust DINS measure for nonlinear IVD-MD relationships was constructed.

RESULTS

When f is nonlinear, the smoothing spline prediction intervals show higher statistical power to identify noncommutable EQAMs than Deming regression prediction intervals, which are too broad. Under linear f, both methods perform similarly with only minor differences.
In a CRP commutability experiment with 25 clinical samples, 4 EQAMs, and 5 IVD-MDs measured in triplicate, Deming regression excluded 8 out of 10 IVD-MD pairs due to excessive DINS. In contrast, the smoothing spline model permitted the evaluation of 7 pairs, demonstrating its robustness in nonlinear scenarios.

CONCLUSIONS

The smoothing spline approach excels in scenarios with nonlinear relationships between IVD-MDs, offering better statistical power and realistic commutability acceptance limits compared to Deming regression. Under linear conditions, both methods perform similarly, making smoothing splines beneficial only when nonlinearity is suspected. In the C-reactive protein commutability experiment, this model allowed more IVD-MD pairs to be evaluated, showcasing its robustness in nonlinear scenarios.

Clinical Chemistry

P0548

ANALYSIS OF TRANSTHYRETIN ISOFORMS USING ELECTROPHORETIC METHODS

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BACKGROUND-AIM

Transthyretin (TTR) is a protein having a molecular weight of 14,000 Da. It is classified as a rapid turnover protein. Owing to its wide range of fluctuations, TTR is used to assess nutritional status and to evaluate protein-binding capacity of the liver. In blood, it usually exists as a tetramer that binds to the retinol-binding protein (RBP) to transport retinol. Some studies have reported the existence of a complex in which a TTR tetramer binds to an RBP monomer (TTR-RBP complex), as well as dimeric and monomeric forms of TTR. However, the roles and characteristics of these isoforms remain largely unknown. Therefore, we aimed to analyze the molecular diversity of TTR isoforms by performing cellulose acetate membrane electrophoresis and SDS-polyacrylamide gel electrophoresis (SDS-PAGE).

METHODS

Serum sample obtained from a healthy individual was fractioned using cellulose acetate membrane electrophoresis. Next, TTR was purified from the sample using affinity chromatography, and the purified TTR was subjected to SDS-PAGE.

RESULTS

Following cellulose acetate membrane electrophoresis, the natural transfer method detected TTR in the α_2-globulin and prealbumin fractions. Analysis using ImageJ revealed that the α_2 fraction constituted 94.3% and the prealbumin fraction constituted 5.7% of TTR. Subsequent SDS-PAGE of the purified TTR samples revealed protein bands of approximately 18, 33, and 56 kDa, constituting 3.7, 43.0, and 4.2%, respectively. Additionally, when a ratio was calculated by dividing the band into 18 kDa and other bands , bands other than 18 kDa accounted for 96.3%, whereas the 18 kDa band constituted 3.7%.

CONCLUSIONS

The results of cellulose acetate membrane electrophoresis and SDS-PAGE suggested that the TTR monomer migrated in the prealbumin fraction, while other forms of TTR migrated in the α_2 fraction. This indicates that the charge state of TTR monomers differed from those of the other forms. The SDS-PAGE results further revealed the presence of monomeric, dimeric, and tetrameric forms of TTR in the blood. Because all the isoforms of TTR, i.e., monomer, dimer, and tetramer forms, react with antibodies, we will analyze these isoforms using the immunoturbidimetric method for measuring TTR in the future.

Clinical Chemistry

P0549

DEVELOPMENT OF A QUANTIFICATION METHOD FOR VASOPRESSIN AND OXYTOCIN USING LIQUID CHROMATOGRAPHY COUPLED WITH TANDEM MASS SPECTROMETRY

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BACKGROUND-AIM

Vasopressin and oxytocin are both neuropeptides, each consisting of 9 amino acids, produced by the hypothalamus and secreted by the posterior pituitary. Their respective roles include the regulation of plasma osmolarity through urinary volume modulation and the regulation of social behaviors or the initiation of uterine contractions. These two hormones are involved in pathologies such as diabetes insipidus for vasopressin while oxytocin is involved in autism, depression, and schizophrenia. The implication of these peptides in various disorders suggests that precise quantification could benefit patient care.
Currently, quantification of vasopressin and oxytocin is mainly performed through immunological methods but is still uncommon. These techniques face issues with specificity and can vary across laboratories. The development of a quantification method through a gold standard technique, such as liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS), is essential for harmonizing biological sample assays and standardizing vasopressin and oxytocin quantification.

METHODS

Based on earlier research, oxytocin quantification was adapted to set up a protocol for the combined quantification of both analytes. Plasma samples were prepared by solid-phase extraction (SPE HLB) before being analyzed by UPLC-MS/MS using a Waters Acquity™ UPLC H-Class Plus chromatographic system coupled with a Waters XEVO™ TQ-XS mass spectrometer.

RESULTS

Chromatographically, both analytes were successfully separated ensuring sufficient selectivity. The recovery and matrix effect were evaluated at more than 80% and 60%, respectively. Linearity was demonstrated for oxytocin but not for vasopressin. The lower limit of quantification was established at 1 pg/mL for vasopressin and 0,5 pg/mL for oxytocin.

CONCLUSIONS

In conclusion, a quantification method was successfully developed and pre-validated according to the recommendations of the Clinical and Laboratory Standards Institute (CLSI).

Clinical Chemistry

P0550

DISCORDANT THYROID FUNCTION TESTS DUE TO BIOTIN INTERFERENCE

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BACKGROUND-AIM

We present a case of a 64-year-old lady with discordant function tests (TFTs) due to assay interference from biotin supplementation. She presented with intracranial haemorrhage on the background of end-stage renal failure on dialysis. Routine TFTs showed a discordant pattern of elevated free thyroxine (fT4) and free triiodothyronine (fT3) with non-suppressed thyroid stimulating hormone (TSH).

METHODS

Initial TFTs were performed on a Beckman Coulter DxI 800 using Access TSH, Free T4 and Free T3 reagent. Subsequent testing was done on an Abbott Alinity using Alinity i TSH, Free T4 and Free T3 reagent kits (non-biotin-streptavidin assay design) and Roche cobas e602 using Elecsys TSH and FT4 IV reagent kits. Biotin depletion was achieved by incubating the plasma sample with recovered dried streptavidin paramagnetic particles from depleted Roche kits in an Eppendorf tube.

RESULTS

TFTs pre/post-biotin depletion were as follows: fT4 (pmol/L): Beckman 43/14, Abbott 12.9/13.2, Roche 16.6/15.4; fT3 (pmol/L): Beckman 8.0/2.9, Abbott 2.6/2.4, Roche not performed; TSH (mIU/L): Beckman 5.03/4.86, Abbott 4.58/4.42, Roche 5.43/5.44.

CONCLUSIONS

The most likely cause was biotin interference affecting the Beckman fT4 and fT3 assay causing false elevation in the results. This was not seen with the Abbott (non- biotin) and Roche (biotin-resistant) platforms. Following sample biotin depletion, all results were concordant. Further questioning revealed administration of multivitamin supplements containing 300 µg of biotin. This chronic dosing in the setting of end stage renal failure may have caused biotin accumulation, resulting in a higher plasma biotin concentration compared to people without renal failure.
This case demonstrates the importance of thorough examination of all medications in patients with discrepant thyroid function tests, particularly in patients with chronic renal impairment. Despite growing recognition of biotin interference by laboratorians and clinicians, and improvements in assay formulations, biotin interference continues to be a clinical concern for some assays. Clinicians and laboratorians should be aware that elevated fT4 and fT3 in patients taking biotin may be due to assay interference for test performed on the Beckman DxI immunoassay analyser.

Clinical Chemistry

P0551

IMMUNOTURBIDIMETRIC MEASUREMENT OF ALBUMIN EXACERBATES DISCREPANCIES BETWEEN CORRECTED AND IONIZED CALCEMIA DEPENDING ON ALBUMIN LEVELS

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BACKGROUND-AIM

Evaluating dyscalcemia in hypoalbuminemia (<35 g/L) remains challenging in clinical practice. Approximately 40% of plasmatic total calcium is bound to proteins, mainly albumin, but only free ionized calcium is metabolically active. Corrected total calcium levels are often calculated to estimate calcemia without hypoalbuminemia but discrepancies between the resulting corrected hypercalcemia and normal measured ionized calcium levels frequently arise with colorimetric albumin assay methods. However, such inaccuracies have not been investigated with immunoturbidimetric methods, which consistently yield lower albumin values compared to colorimetric methods, yet reference ranges have not been adjusted. This study aimed to evaluate the impact of transitioning from Roche® colorimetric to turbidimetric albumin assays on corrected total calcium calculations and its resulting concordance with measured ionized calcium in the assessment of dyscalcemia.

METHODS

Two time periods were analyzed: 7 months preceding and 14 months following the change in albumin assay method. For each period, the proportion of hypercalcemias resulting from albumin based correction, as well as the proportion of their discrepancy with measured ionized calcemia were assessed, depending on albumin levels.

RESULTS

Compared to the colorimetric method, the turbidimetric method for albumin resulted in a higher proportion of corrected hypercalcemias, increasing as albumin level decreased (17.8% vs 10.2% for albuminemia between 25 and 35 g/L, 34.1% vs 14.3% when <25 g/L; Fisher's test, P<0.0001). Similarly, the proportion of false hypercalcemia was greater with the turbidimetric method correction than with the colorimetric method (15.0% vs 9.3% when albuminemia comprised between 25 and 35 g/L, 41.8% vs 25.9% when <25 g/L, Fisher's test, P=0.0176 and 0.0003, respectively).

CONCLUSIONS

Payne formula calculating corrected calcemia has notable limitations, including its disregard for the albumin assay method. We demonstrate that transitioning from colorimetric to turbidimetric method exacerbates the bias between effective ionized calcemia and corrected total calcemia, risking patient clinical mismanagement. Whenever possible, ionized calcemia should be measured directly for the investigation of dyscalcemia in the setting of hypoalbuminemia.

Clinical Chemistry

P0552

ASSESSMENTS OF SERUM LEVEL THYROID FUNCTION TESTS AMONG NEWLY DIAGNOSED FEMALE BREAST CANCER PATIENTS ATTENDING IN TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA

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BACKGROUND-AIM

Breast cancer (BC) is the most prevalent form of cancer among women and causes hundreds of thousands of deaths each year worldwide. There is limited evidence on the serum levels of thyroid hormone linked to BC among women diagnosed with the disease in Ethiopia. Thus, this study aimed to assess the serum level of Vitamin D and Thyroid hormone among females newly diagnosed with BC.

METHODS

A comparative cross-sectional study was conducted from January to March 2024 in Tikur Anbessa Specialty Hospital. A convenient sampling method was employed to recruit 69 females newly diagnosed with BC as a case group and 69 samples from apparently healthy females as a control group. Blood samples were collected and sent to Ethiopian Public Health Institute (EPHI) for Serum Thyroid Function Tests, by using a fully automated COBAS 6000 analyzer. The data was analyzed using SPSS version 20.0 software. Independent T-tests, chi-square test, Mann Whitney U tests and Logistic regression test were used to analyze the data.

RESULTS

The mean values of Total Triiodothyronine (TT3) concentrations were significantly lower in the BC group (1.2 ± 0.28ng/mL) than in the healthy group (1.4 ± 0.19 ng/ml) at $p< 0.001$. The multivariate analysis also supported the role of TT3 as an independent risk factor, with lower TT3 levels significantly associated with an increased risk of BC (AOR=0.08, $p= 0.016$). This study also revealed a significant reduction in Free Triiodothyronine (FT3) levels ($p< 0.001$) among BC patients compared to controls although it did not support during the multivariate analysis. Nevertheless, no significant differences were found in Total Thyroxine (TT4), Free Thyroxine (FT4), and Thyroid Stimulating Hormone (TSH) levels between the two groups ($p>0.005$).

CONCLUSIONS

There is a significant difference in TT3 and FT3 among breast cancer patients and the control groups. Thus, this finding underscores the potential importance of TT3 and FT3 as a marker of disease state in BC patients.

Clinical Chemistry

P0553

DETECTION OF ATYPICAL CELLS IN ASCITIC FLUID

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BACKGROUND-AIM

Ascitic fluid, present in the abdominal cavity, lubricates the tissues that line the abdomen and internal organs. In certain pathologies, its formation or absorption is altered, leading to abnormal accumulation. Its cytological and biochemical analysis is crucial for quick diagnosis and proper patient management.
We present the case of a 77-year-old woman with abdominal pain of several months' duration. Due to elevated C-reactive protein (CRP), an imaging test was performed, revealing significant ascites and possible signs of peritoneal carcinomatosis. Paracentesis was carried out, obtaining ascitic fluid.

METHODS

A blood analysis was requested, which included renal function, liver profile, and levels of ions, calcium, and phosphorus. Additionally, glucose, proteins, albumin, and LDH were analyzed in the ascitic fluid. For the cytological study, the Beckman Coulter Unicel DxH 800/900 analyzer was used, which identifies cells based on the principle of impedance, complemented by cytocentrifugation and staining for microscopic observation. Various tumor markers were also evaluated, including CEA, Ca 125, Ca 19.9, Ca 72.4, SCC, and CYFRA 21.1.

RESULTS

A serum-ascitic albumin gradient (GASA) of less than 1.1 and an elevated fluid LDH (509 U/L) were noted, indicating that the ascites was not caused by portal hypertension. The scintigram showed an abnormal distribution of monocytes, suggesting non-leukocytic mononuclear cells associated with malignancy. Cytocentrifuge confirmed malignant cells typical of adenocarcinoma. Tumor markers showed elevated levels: Ca 125 (1408 U/mL), Ca 72.4 (1855 U/mL) and CYFRA 21.1 (14.80 ng/mL). The definitive diagnosis was ovarian adenocarcinoma. The clinical evolution was unfavorable due to the advanced deterioration of the patient, which prevented treatment.

CONCLUSIONS

The 5-year overall survival rate for ovarian cancer is 43.8%, and it is directly related to the stage at the time of diagnosis. In stage I, the survival rate is 90%, while in stages III and IV, it drops to 25%. The integration of cytological, biochemical, and tumor marker studies is essential for early diagnosis, improving survival prospects.

Clinical Chemistry

P0554

FINDING OF TUMOUR CELLS SYNCYTIA IN PERICARDIAL FLUID OF A PATIENT WITH METASTATIC BREAST CANCER

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BACKGROUND-AIM

Serous fluids are plasma-derived body liquids found in small volumes within the pleural, pericardial and peritoneal cavities. The accumulation of larger volumes constitutes an effusion, and the results of biochemical and cytological studies guide the clinical diagnosis. Regarding the differential cell count, it must include all types of nucleated cells: blood cells, serous macrophages, mesothelial cells and malignant neoplastic cells. Metastatic tumours are one of the most common causes of effusion due to obstruction of the draining lymphatic vessels because of lymph node metastases.

METHODS

The sample studied comes from a 74-year-old woman with a recurrence of HER2-positive infiltrating ductal carcinoma stage IV of the left breast with metastatic hepatic, lymph node, bone, pleuropulmonary and pericardial dissemination. She required emergency service attention due to dyspnoea at rest, orthopnoea, lower limbs oedema, oligoanuria, hypotension, tachycardia, tachypnoea and 92% oxygen saturation, in context of cardiogenic shock secondary to severe pericardial effusion. The laboratory received a pericardial fluid sample and carried out cytological and biochemical studies with DxH800 haematological counter (Beckman Coulter) and Cobas 8000 modular analyser (Roche).

RESULTS

The analysis showed the following results: macroscopically serohaematic; elevation of the tumour markers CEA (4227ng/mL), Ca15.3 (1015U/mL), Ca125 (1332U/mL) and CYFRA 21.1 (>1000ng/mL); glucose <2mg/dL, proteins of 4.2g/dL (3.1±0.6g/dL) and LDH of 1711U/L; and 7091 nucleated cells/µL. After performing cytocentrifugation, May Grünwald-Giemsa staining and microscopic examination, we reported that approximately 90% of the cells show the typical morphological characteristics of neoplastic cells. These features include large size, high nucleus/cytoplasm ratio, lax and immature chromatin, multinucleated with multiple and markedly visible nucleoli, intensely basophilic cytoplasm, abnormal mitosis, cannibalism between neoplastic cells and formation of syncytia.

CONCLUSIONS

The finding of neoplastic cells in pericardial fluid is less frequent than in pleural or ascitic fluids. The macroscopic, cytological and biochemical study, including tumour markers, constitute the most relevant parameters of pericardial fluid to guide the diagnosis.

Clinical Chemistry

P0555

ESTABLISHMENT AND VALIDATION OF A LC-MS/MS METHOD FOR DETECTING BLOOD METABOLITES AS BIOMARKERS IN COLORECTAL CANCER

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BACKGROUND-AIM

Colorectal cancer (CRC) has become an increasingly serious global challenge. Existing CRC detection markers, such as serum carcinoembryonic antigen (CEA), still exhibit limited sensitivity and specificity, highlighting the urgent need for a non-invasive and accurate CRC detection method. Gut microbiome-associated lipid metabolites (GMLMs) identified by metabolomics show potential as indicators for CRC. However, current methods for detecting blood metabolites rarely achieve absolute quantification, limiting their clinical application. Therefore, we aim to establish a quantitative LC-MS/MS method for GMLMs in serum and explore their clinical performance in CRC.

METHODS

Serum samples were extracted using protein precipitation. GMLMs were quantified and validated using the LC-MS/MS method according to Clinical and laboratory standards institute (CLSI) guidelines. The clinical utility of GMLMs for CRC was further evaluated.

RESULTS

We established a quantitative method for 22 GMLMs in human serum. The linear range, lower limit of quantification, intra-assay, and inter-assay precision of 22 GMLMs met acceptable criteria, and the recovery rates of 18 GMLMs met acceptable criteria according to CLSI guidelines. Among 18 GMLMs, the linoleic acid related metabolite 9,12,13-TriHOME (BN03), which owns a linear range of 1.25–125 ng/mL, had an area under the curve value of 0.930 (95% CI: 0.899–0.962) in distinguishing colorectal cancer and adenoma from healthy individuals. Furthermore, BN03 and CEA combination improved the sensitivity of CEA from 33.33% to 94.57%.

CONCLUSIONS

A LC-MS/MS method was established and validated for 22 GMLMs in serum, and the combination of BN03 and CEA improved detection sensitivity for colorectal cancer and adenoma.

Clinical Chemistry

P0556

EXPLORING AMMONIA AND LIVER FUNCTION TESTS AS PREDICTORS OF HEPATIC ENCEPHALOPATHY SEVERITY

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BACKGROUND-AIM

This study investigates the role of ammonia and liver function tests (LFTs) in predicting the severity of hepatic encephalopathy (HE). By examining their relationships with HE grades, the research highlights the potential of multi-marker approaches to enhance diagnostic precision and clinical management.

METHODS

A retrospective analysis of 59 patient samples was conducted to evaluate the relationships between ammonia levels, key LFTs (ALT, ALP, and bilirubin), and HE severity. Statistical analyses included multivariable regression to assess predictive contributions and correlation tests to examine marker associations with HE grades.

RESULTS

Ammonia levels showed a moderate positive correlation with HE severity, though not statistically significant. In contrast, bilirubin demonstrated a significant correlation with HE severity (Spearman's $r = 0.6039$, $p = 0.0080$; Pearson's $r = 0.5468$, $p = 0.0189$), suggesting its potential as a stronger predictor. Regression analysis explained 75.7% of the variance in ammonia levels ($R^2 = 0.757$, $p < 0.001$), with bilirubin, ALT, and ALP identified as significant contributors.

CONCLUSIONS

This study underscores the importance of integrating ammonia and bilirubin as complementary markers for assessing HE severity. While ammonia levels remain relevant, the significant association of bilirubin with HE grades highlights its role as a key marker in predictive models. A multi-marker diagnostic approach could improve patient stratification and management in HE. The findings support the utility of a combined approach using ammonia and LFTs, particularly bilirubin, in HE diagnosis. This approach has the potential to enhance diagnostic precision and guide timely interventions for HE patients.

Clinical Chemistry

P0557

DISCREPANCIES IN ELECTROLYTE MEASUREMENTS: A COMPARISON OF ARTERIAL AND VENOUS BLOOD SAMPLE ANALYSIS

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BACKGROUND-AIM

Electrolyte measurement is crucial in patient management, particularly in critical care. Blood gas analyzers (BGA) and automated biochemistry analyzers (AA) are widely used but differ in sample type and processing. While arterial samples are used for BGA, venous samples are preferred for AA. Variations in values between these methods can lead to clinical discrepancies.
This study aims to evaluate whether electrolyte levels measured by BGA and AA are equivalent and interchangeable.

METHODS

This retrospective study analyzed paired arterial and venous electrolyte samples collected at the laboratory of Habib Bourguiba Hospital, Medenine, between October and November 2024. Arterial samples, collected in heparinized syringes, were analyzed using an ST Core 200cc ABG analyzer, while serum electrolytes were measured with a Selectra analyzer following centrifugation. Correlation was assessed using Pearson's coefficient, agreement using Bland-Altman plots, and differences using paired t-tests ($p < 0.05$).

RESULTS

A total of 152 paired samples were analyzed. Mean sodium levels were 141.65 ± 7.64 mmol/L (arterial) and 139.88 ± 5.97 mmol/L (venous) ($p < 0.001$). Potassium levels were 3.35 ± 0.68 mmol/L (arterial) and 4.11 ± 0.63 mmol/L (venous) ($p < 0.001$). Chloride levels were 113.44 ± 6.6 mmol/L (arterial) and 103.98 ± 6.6 mmol/L (venous) ($p < 0.001$). Pearson's correlation showed strong and significant correlations for sodium ($r = 0.67$) and potassium ($r= 0.8$) ($p < 0.001$), but weak correlation for chloride ($r = 0.115$, $p = 0.165$). Bland-Altman analysis showed good agreement for sodium and potassium with mean biases of +1.77 mmol/L and -0.76 mmol/L, respectively, but poor agreement for chloride. The limits of agreement ranged from -14.64 to +9.6 mmol/L for sodium and -0.04 to +1.56 mmol/L for potassium, with variability at extreme values.

CONCLUSIONS

BGA and AA showed strong correlation and reasonable agreement for sodium and potassium, though differences may be clinically significant at critical thresholds. Chloride measurements showed poor agreement and cannot be used interchangeably. Clinical caution is advised before replacing serum electrolyte analysis with BGA measurements in clinical practice.

Clinical Chemistry

P0558

IGD LAMBDA /LAMBDA BICLONAL MULTIPLE MYELOMA WITH ACUTE RENAL FAILURE: A RARE CASE REPORT

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BACKGROUND-AIM

Immunoglobulin D (IgD) multiple myeloma (MM) is a very rare and aggressive form of myeloma affecting less than 1-2 % of all myeloma patients. The majority of MM are monoclonal; only precious few MM are biclonal, which almost all belong to the heavy chain type, such as IgG/IgA, IgG/IgM, and IgG/IgG. Thus, the infrequent type of light chain biclonal MM, and the IgD-Lambda/Lambda biclonal MM, are extremely rare. At present, only a few cases have been reported, it has a multiorgan involvement with renal failure being the key feature.

METHODS

Case description:
Mr B.J., 71 years old was hospitalized for deterioration of general condition.

Laboratory investigation showed hemoglobin 7.2 g/dL, platelet 51×10^9/L, Ca 2.6 mmol/L, LDH 560 U/L, Creatinin 300 μmol /L, uric acid 900 μmol/L with proteinuria at 6 g/24h. Serology was positive for serum free Lambda chain (CLL λ) with a level of 96800 mg/L and a free κ/λ ratio 0.00028. Protein electrophoresis showed two monoclonals peaks in beta-2 globulins and gamma zone. Immunotyping (IT) by capillary electrophoresis showed the presence monoclonal CLL λ. Thus, we highly suspected the possibility of type IgD or IgE protein component. Serum Immunofixation can confirm the presence monoclonal a band Ig D λ and CLL λ. Quantitative analysis of serum immunoglobulin D was 4 g/L (normal < 0.15). Urinary immunofixation was positive for Bence-Jones Lambda. Skeletal X ray survey showed multiple osteolytic lesions affecting all bone segments. At the myelogram, there were 21% dystrophic plasma cells.

RESULTS

The diagnosis of IgD Lambda multiple myeloma (ISS stage III), complicated by renal failure and hypercalcemia was retained. Treatment was an effective chemotherapy in the form of multidrug therapy, plus a correction of hypercalcemia.

CONCLUSIONS

This observation reminds us that it is important to consider this diagnosis and to test the IgD and IgE on agarose gel, in the case of the presence of Kappa or Lambda light chain without associated heavy chain IgG, IgA or IgM in the IT. IgD myeloma is more frequently associated with MM forms and renal damage: levels of patients have renal insufficiency at the time of diagnosis and more than half will have to resort to a dialysis.

Clinical Chemistry

P0559

THE EFFECTIVENESS OF SODIUM FLUORIDE, CITRATE AND ICE WATER SLURRY AS PRESERVATIVES OF BLOOD GLUCOSE IN THE DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS AT A TERTIARY HOSPITAL IN GAUTENG, SOUTH AFRICA

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BACKGROUND-AIM

Gestational Diabetes Mellitus (GDM) is defined as Impaired Glucose Tolerance (IGT) with onset or first recognition during pregnancy.Women with GDM and their children are at an increased risk of developing type 2 diabetes later in life. Glucose measurement is the mainstay for the screening and diagnosis of diabetes mellitus, precise and accurate glucose results are required.American Diabetes Association (ADA) recommends that for plasma glucose measurements, blood samples should be collected into sodium fluoride tubes and placed in an ice-water slurry immediately and centrifuged within 30 minutes of collection. This is to prevent glycolysis in the blood sample which can result in artificially lower glucose concentration. ADA also indorsed the use of citrate tube if a delay in centrifugation is expected, as citrate rapidly inhibits glycolysis.The aim of the study is to determine the effectiveness of sodium fluoride, sodium citrate and ice water slurry as preservatives of blood glucose in the diagnosis of gestational diabetes.

METHODS

Venous blood for glucose was collected in sodium fluoride and sodium citrate specimen tubes from women who were being screened for gestational diabetes.Each subject had twelve samples in total, six were placed on room temperature and the other six were placed in an ice-water slurry.The glucose concentration at room temperature and in an ice-water slurry were compared for both the sodium fluoride and the sodium citrate tubes.

RESULTS

Glucose concentrations measured in sodium citrate tubes and in sodium fluoride tubes placed in ice-water slurry, were similar with a strong correlation.Seven women were diagnosed with gestational diabetes according to WHO diagnostic criteria in tubes placed in on ice-water slurry and three women were missed when using sodium fluoride tubes placed at room temperature.

CONCLUSIONS

The findings shows that ice-water slurry is an effective glycolytic inhibitor irrespective of the tube used and more patients were found to have GDM when samples are collected in tubes placed on ice-water slurry.

Clinical Chemistry

P0560

IMPACT OF PLASMA PROTEIN LEVELS ON ELECTROLYTE MEASUREMENTS: A COMPARATIVE STUDY OF DIRECT AND INDIRECT ION-SELECTIVE ELECTRODE METHODS

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BACKGROUND-AIM

Accurate electrolyte measurement is critical for diagnosing and managing disorders of fluid and electrolyte balance. This study evaluates the effect of plasma protein levels on sodium (Na), potassium (K), and chloride (Cl) measurements using direct and indirect ion-selective electrode (ISE) methods, focusing on protein-induced matrix effects such as pseudohypernatremia and pseudohyponatremia.

METHODS

In leftover plasma samples (n=120, Li Hep), electrolyte (Na, K, Cl) concentrations were measured on the solite analyzer (MEON Medical Solutions) with integrated m|1 electrolyte module (EXIAS Medical) as well as on the Cobas 8000 analyzer (Roche Diagnostics). The m|1 electrolyte module uses direct ISE, while the Cobas 8000 uses indirect ISE. Additionally, total protein (TP) concentrations were determined for the same samples on the Cobas 8000.
Samples were classified into hypoproteinemic (<6.6 g/dL; 64.4%) and normoproteinemic (6.6–8.7 g/dL; 35.6%) groups based on TP levels. Systematic biases between methods were assessed using Bland-Altman analysis and linear regression modelling. A multifactorial linear model incorporating electrolyte concentration (Na, K, Cl), TP levels, and an intercept was used to quantify the impact of protein levels on electrolyte measurements.

RESULTS

Significant biases ($p<0.05$) were observed across all electrolytes. For every 1 g/dL increase in TP, indirect ISE underestimated Na by 0.77 mmol/L ($p<0.001$), K by 0.05 mmol/L ($p<0.001$) and Cl by 1.02 mmol/L ($p<0.001$) compared to direct ISE. Hence, indirect ISE overestimates Na levels (e.g. pseudohypernatremia) in hypoproteinemic specimens and underestimates Na levels (e.g. pseudohyponatremia) in hyperproteinemic specimens. Correcting for systematic differences confirmed that biases were exclusively attributable to TP levels.

CONCLUSIONS

Direct ISE methods provide more accurate measurements of Na, K, and Cl across varying protein levels (3.7–8.1 g/dL) compared to indirect ISE methods, which are prone to protein-induced matrix effects due to their reliance on a dilution step that assumes a typical plasma water-to-solids ratio. Selecting appropriate measurement techniques is critical in clinical settings to minimize errors in electrolyte assessment caused by plasma protein variations.

Clinical Chemistry

P0561

COMPARISON OF ORAL GLUCOSE TOLERANCE TEST PLASMA GLUCOSE CONCENTRATIONS FROM SODIUM FLUORIDE AND CITRATE BUFFER TUBES IN PREGNANT WOMEN. DOES PRESERVATION WITH CITRATE MAKE A DIFFERENCE?

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BACKGROUND-AIM

Accurate measurement of plasma glucose is vital for detection of gestational diabetes mellitus (GDM). The study aimed to compare the plasma glucose results obtained from sodium fluoride (NaF) and citrate buffer tubes post oral glucose tolerance test (OGTT) for screening of GDM.

METHODS

This prospective observational study was conducted at an antenatal unit at Charlotte Maxeke Johannesburg Academic Hospital, a tertiary teaching Centre in South Africa. Pregnant women > 18 years booked for OGTT were recruited into two cohorts. The first cohort compared plasma glucose in paired NaF and citrate buffer tubes (citrate/NaF) according to routine practice (samples sent to the lab at the end of OGTT) while the second cohort compared NaF and citrate following WHO protocol (centrifugation immediately post collection). All plasma glucose samples were analyzed using a hexokinase method. Passing Bablok and Bland Altman analysis were performed using MedCal software. Cohen kappa statistics were used for the assessment of the clinical impact of using NaF over citrate tubes.

RESULTS

Sixty-nine (69) and 57 patients were recruited for cohorts 1 and 2, respectively. There was good correlation between plasma glucose in both cohorts at all three time points of the OGTT with correlation coefficient of 0.941-0.992 ($p < 0.001$) and 0.982-0993 ($p < 0.001$) for cohort 1 and cohort 2, respectively. For cohort 1, the mean percentage difference (MPD) was -8.1%, -4.9%, and -4.5% at fasting, 1hr, and 2 hr. For cohort 2, the MPD was -2.9% at fasting glucose, and -2.5% at both 1hour and 2 hours. The MPD for both cohorts were outside the allowable bias desirable specification of 2.3 % set by the EFLM. Using NaF in cohort 1, classified 10.3% of the patients as GDM compared to 19% when citrate was used. In cohort 2, there was 100% concordance in classifying GDM.

CONCLUSIONS

The ineffectiveness of sodium fluoride (NaF) as a glycolytic inhibitor was significantly amplified in delayed sample processing, resulting in lower glucose levels compared to citrate-based tubes in both cohorts. These findings strongly support the recommendation for laboratories to transition to citrate/NaF tubes to ensure reliable glucose measurements and improve diagnostic accuracy.

Clinical Chemistry

P0562

EVALUATION OF THE PERFORMANCE OF BIOCHEMICAL RATIOS AND ALBUMIN'S GRADIENT IN THE ETIOLOGICAL EXPLORATION OF ASCITIC FLUID

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BACKGROUND-AIM

Biochemical exploration of effusion fluids plays a crucial role in the diagnosis of underlying pathologies. This study aims to evaluate the performance of biochemical ratios and the albumin gradients in the diagnostic process of ascetic fluids.

METHODS

This is a prospective study involving 56 samples from ascitic patients. For each patient, five biochemical parameters (glucose, protein, albumin, LDH, and total amylase) were performed in ascites and plasma samples. The Ascites/Plasma protein, LDH ratios, and serum-ascites albumin gradients, were calculated to evaluate their diagnostic relevance.

RESULTS

Were included in this study 28 adult patients presenting ascites, 18 women (64.28%) and 10 men (35.71%) with an M/F sex ratio of 0.55. The most efficient parameters to distinguish the transudate/exudate concept were: Ascitic proteins (p =0.01), Ascitic/plasma proteins (p =0.004), ascitic LDH (p =0.011), ascitic/plasma LDH ratio (p =0.013), ascitic albumin (p = 0.012), ascitic albumin/plasma ratio (p = 0.002) and ascitic glucose/plasma ratio (p = 0.02). A threshold of 14 g/L of Albumine had a better positive predictive value than a threshold set at 20 g/L (73 vs 46%). The sensitivity, specificity, diagnostic efficiency, and positive and negative predictive values for SAAG were 100%, 64%, 78%, 64%, and 100% respectively, and for the modified Light's criteria 78%, 86%, 82%, 80%, and 82% which had better diagnostic efficiency and specificity than the classic Light's criteria with the respective comparative value 82 vs 78% and 86 vs 57% but less sensitivity (78 vs 100%). The criteria H20-30, H25, and TAL had good diagnostic efficiency with 75%, 75%, and 78% respectively.

CONCLUSIONS

The integration of biochemical ratios and the Albumin's gradient significantly improves the differential diagnosis of ascites. It is essential to promote the use of these parameters in clinical practice to improve the treatment of patients with ascites.

Clinical Chemistry

P0563

MACRO-TROPONIN I: A DIAGNOSTIC CHALLENGE

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BACKGROUND-AIM

A 17-year-old patient was admitted to the emergency department due to vomiting and diarrhea for the past ten days. As part of the laboratory workup, troponin I (TnI) level was determined on a Dimension EXL analyser (Siemens, Germany), and a value of 1312 ng/L was obtained (normal values < 56 ng/L), due to which the patient was hospitalized.

METHODS

During a hospitalization, an electrocardiogram, echocardiogram, and CT angiography of the coronary arteries were performed, and all findings were normal. All laboratory tests performed, including creatine kinase, NT-proBNP, and myoglobin, were within the reference interval during hospitalization, except for TnI, which consistently had high values. TnI value was determined in serum on Dimension EXL and Atellica IM 1300 (Siemens, Germany) analysers. To determine interference from heterophilic antibodies, the sample was precipitated in Heterophilic Blocking Tube (Scantibodies Laboratory, USA) according to the manufacturer's recommendations, and TnI was determined on Dimension EXL analyser. To determine if there was a component of macro-troponin I, precipitation with polyethylene glycol (PEG) was performed. 200 μL of the sample and 200 μL of 25% PEG in buffered saline were mixed. It was vortexed for 20 seconds, centrifuged for 10 minutes at 4000 g, and TnI was determined in the supernatant on Dimension EXL analyser.

RESULTS

In the given sample, a value of 1371 ng/L was obtained on the Dimension EXL analyser, and the result was confirmed on the Atellica IM 1300, where the value was 1203 ng/L (normal values < 45 ng/L). The suspicion of the presence of HAMA antibodies was ruled out, since the TnI value after precipitation was 1306 ng/L. The TnI value in aliquot precipitated with PEG was 24 ng/L. Recovery was calculated according to the formula: (TnI post-PEG x 2 / TnI pre-PEG) x 100 and was 3.5%, indicating the presence of analytical interference (recovery <35%).

CONCLUSIONS

We proved the existence of interference and a component of macro-troponin in the sample with PEG precipitation. It is known that macro-troponin is excreted from the body more slowly than the free component of troponin, and elevated troponin values persist longer. Since the clinical significance of macro-troponin is not yet clear, we recommended to monitor the patient once a month.

Clinical Chemistry

P0564

SEASONAL FACTITIOUS DYSKALEMIA IN HOSPITAL DEPARTMENTS

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BACKGROUND-AIM

Many preanalytic factors leads to an artificially high or low potassium concentration such as heamolysis. We study the impact of ambient temperature variation on plasma potassium levels.

METHODS

We collected potassium results from all departments taken over a one year period (2023). The number of samples analysed during each month varied from 6590 to 8952 (mean of 8007 samples/month).These analyses were performed routinely on Beckman coulter Dxc 700 AU® analyser using an indirect ion selective electrode. The reference range of potassium is between 3.5 and 5.0 mmol/litre).

RESULTS

In cold winter months, approximately 8.8% to 9% of samples exceeded the reference range for serum potassium levels, indicating hyperkalemia. Contrastingly, during summer months, the percentage of samples above the reference range decreased to 6%. whereas, during colder seasons, only 14% to 15% of samples fell below the lower limit of the reference range, suggesting hypokalemia. However, during summer, this figure increased to 24 %, indicating a rise in hypokalemia cases as temperatures increased.

CONCLUSIONS

These findings suggest that fluctuations in ambient temperature during sample transportation to the laboratory impact plasma potassium concentrations and may lead to factitious dyskalemia.

Clinical Chemistry

P0565

ASSOCIATION BETWEEN GLYCATED HEMOGLOBIN AND LIPID PROFILE IN TUNISIAN PATIENTS WITH TYPE 2 DIABETES

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BACKGROUND-AIM

Poor glycemic control resulting in impaired lipid metabolism is a significant risk factor for the progression of cardiovascular complications in patients with type 2 diabetes. The aim of this study was to evaluate the relationship between HbA1c and dyslipidemia in Tunisian patients with type 2 diabetes (T2D).

METHODS

A descriptive cross-sectional study was conducted over 5 months (september2023-january 2024) within the clinical laboratory of Mohamed Taher Maamouri hospital of Nabeul in Tunisia. A total of 140 T2D patients attending the sampling room were included. The socio-demographic data and the clinical information were collected through a thorough interview. The following biochemical parameters were analyzed using the Cobas 6000 ® analyzer: HbA1c, total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C). Low-density lipoprotein cholesterol (LDL-C) was calculated using the Friedewald formula. Glycemic control was assessed by HbA1clevels, and poor glycemic control was defined as HbA1c ≥7%.

RESULTS

The average age of patients was 62,46±8,39 years old with a sex ratio (M/F) equal to 0,52. The average HbA1c levels 8,13±1,87%. 24,7% of the patients were on hypolipidemic treatment. An alteration in lipid profile was noted in 30,71% of cases. We found hypercholesterolemia and hypertriglyceridemia in 25,3% and 32,7% of patients, respectively. High levels of LDL-C and low levels of HDL-C were noted in 5,3% and 36,7% of cases, respectively. The perturbations of TC were significantly higher in female patients (p=0,004). We found a significant positive correlation between HbA1c levels and TG levels (r=0,193; p=0,023) and a significant negative correlation between HbA1c levels and HDL-C levels (r=-0,252; p=0,003). Patients with poor glycemic control had higher levels of TG (p=0,003) and lower levels of HDL-C (p<0,001) compared to patients with good glycemic control.

CONCLUSIONS

Our results highlighted the high prevalence of dyslipidemia in Tunisian patients with T2D and its close relationship with glycemic control. HbA1c can be a promising biomarker in predicting impaired TG and HDL-C levels in the context of diabetes.

Clinical Chemistry

P0566

VITAMIN B12 STATUS IN TUNISIAN PATIENTS WITH DIABETES TYPE 2 ON METFORMIN

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BACKGROUND-AIM

Metformin is the first-line treatment for type 2 diabetes. Recently, numerous studies have investigated the relationship between this drug and plasma vitamin B12 levels. The aim of our study was to assess the vitamin B12 status in type 2 diabetic patients on metformin and to study its association with the dose and duration of metformin intake, as well as various clinical and biological parameters.

METHODS

A descriptive cross-sectional study was conducted over 5 months (September 2023–January 2024). A total of 140 patients with type 2 diabetes (T2D) attending the blood sampling room of the Medical Biology Laboratory of Mohamed Taher Maamouri Hospital in Nabeul, Tunis, were included. Vitamin B12 levels were measured in all patients, and vitamin B12 deficiency was defined as a level <150 pmol/L. The patients were divided into two groups based on the presence or absence of vitamin B12 deficiency, and comparisons were made between the groups based on their clinical and biological characteristics. The cumulative dose was calculated using the following formula: daily dose of Metformin (gram)*duration of intake (months).

RESULTS

Sex ratio was 0,52 and mean age was 62,46±8,39 years old. Diabetes duration was 8,35±6,44 years. The mean daily dose of Metformin was 1618,96±640 mg/day. A vitamin B12 deficiency was noted in 6,4% of patients. Vitamin B12 levels were negatively correlated with the duration and dose of Metformin (r=-0,172; p=0,042 and r=-0,206; p=0,015 respectively). Vitamin B12 deficiency was significantly associated with diabetes duration (p=0,013), duration of Metformin use (p=0,016), daily dose of Metformin (p=0,036), cumulative dose of Metformin (p=0,003), hemoglobin levels (p=0,011) and peripheral neuropathy (Odds Ratio (OR)=4,20; p=0.043). Finally, in multivariate analysis, only the cumulative dose of Metformin was associated with vitamin B12 deficiency with an adjusted OR=1,005 and p=0,004.

CONCLUSIONS

Our results highlighted the association between vitamin B12 deficiency and the dose and duration of metformin intake in Tunisian patients with type 2 diabetes. An early screening for this deficiency should be implemented to avoid it’s neurological and hematological consequences.

Clinical Chemistry

P0567

LIPIDS, GLUCOSE AND HBA1C IN NEWLY DIAGNOSE PATIENTS WITH TYPE 2 DIABETES MELLITUS

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BACKGROUND-AIM

Type 2 diabetes mellitus (T2DM), lipid status, and CVD are closely related, as are risk factors for the development of diseases, like obesity, smoking, high blood pressure, and lifestyle. An earlier diagnosis of T2DM followed by appropriate management of diabetes will result in more cardiovascular event-free life years. One of the well-established causes of microvascular complications, and treatment of hyperglycemia reduces diabetic complications, is hyperglycemia.

METHODS

The study at the Medical Institute Bayer Tuzla included determination of HbA1c, glucose, cholesterol, triglycerides, HDL, and LDL. The patients (150) in the study were divided into two groups: newly diagnosed diabetics, aged 25–45 years, who were without prescribed therapy and were not hypertensive, and the second group was diabetics on therapy over 45 years old and hypertensive. The determination of HbA1c, glucose, cholesterol, HDL, and LDL was done at a Dimension biochemical analyzer.

RESULTS

The research showed that the mean values of the examined parameters were significantly higher in the group of newly diagnosed diabetics (HbA1c 11.34%, glucose 12.72 mmol/L, cholesterol 6.2 mmol/L, triglycerides 3.7 mmol/L, and LDL 3.5 mmol/L) compared to the other group of patients. Only HDL values in newly diagnosed diabetics showed significantly lower values (HDL 0.62 mmol/L) compared to the remaining groups. The Kruskal-Wallis test provided very strong evidence of a difference ($p < 0.001$) in the biochemical parameters of HbA1c, glucose, cholesterol, triglycerides, HDL, and LDL between the studied groups. The risk of developing cardiovascular diseases is significantly high. Smoking and high blood pressure have a significant impact on the development of CVD and T2DM.

CONCLUSIONS

Ultimately, significantly higher values of the analyzed biochemical parameters were recorded in the group of newly diagnosed diabetics, while only HDL values were much lower in comparison with the other group of diabetics on therapy. Blood glucose levels were positively associated with TG and LDL-C levels.

Clinical Chemistry

P0568

EVALUATION OF THE RELATIONSHIP BETWEEN ERYTHROCYTE G6PD ACTIVITY IN INFANTS WITH HYPOTHYROIDISM AND THE ROLE OF LEVOTHYROXINE TREATMENT

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BACKGROUND-AIM

Thyroid hormones including T3 and T4, play different metabolic roles and regulate the activity of enzymes such as glucose 6 phosphate dehydrogenase (G6PD), malic enzyme, and hexokinase. The glucose 6-phosphate dehydrogenase has an important role in the pentose phosphate pathway.

METHODS

120 infants including 30 hypothyroid infants with G6PD defective phenotype (group 1), 30 infants who were hypothyroid (group 2), 30 infants with G6PD deficiency (group 3), and 30 normal infants (group 4) participated in this study. After collecting blood samples from patients, the levels of G6PD enzyme, T4, and TSH hormones were measured.

RESULTS

In the present study, bi-weekly measurements of TSH in different groups showed an increase in the FSH level in infants with hypothyroidism compared to the normal group (p <0.001). Additionally, the highest value of FreeT4 belonged to the control group and the lowest to infants with hypothyroidism (p = 0.001). The lowest frequency of the G6PD enzyme belonged to infants with the G6PD deficiency phenotype. Moreover, the levels of this enzyme were lower in children with hypothyroidism compared to the normal group (p <0.001). Regarding the measurement of G6PD levels in 120 days in the group of infants with hypothyroidism, the amount of this enzyme decreased (p=0.001). Infants with hypothyroidism with glucose-6-phosphate dehydrogenase deficiency phenotype showed a significant decrease in TSH levels over 120 days compared to two weeks (p = 0.001). G6PD enzyme levels significantly increased in the same subjects after 4 months (p = 0.001). TSH, G6PD, and FreeT4 in groups 1 and 2 were examined in two weeks and 4 months. The difference was significant (p <001). However, the measurement of Free T4 at 4 months was significantly increased compared to the two-week measurement (p <001).

CONCLUSIONS

According to the findings of this study, treatment with levothyroxine (measured for 4 months) reduced the G6PD deficiency phenotype. Therefore, hypothyroidism can be considered a cause of the G6PD deficiency phenotype.

Clinical Chemistry

P0570

ANEMIA IN CROHN'S DISEASE: PREVALENCE, TYPES AND PREDICTIVE FACTORS

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BACKGROUND-AIM

Anemia is the most frequent systemic extra-intestinal manifestation in Crohn's disease. Its physiopathological mechanisms are multiple, dominated by iron deficiency and chronic inflammation. The mixed anemia is defined by the combination of iron deficiency and inflammation. The aim of our study was to identify the prevalence of anemia, its main causes and to look for its predictive factors.

METHODS

It was a retrospective, descriptive and cross-sectional study successively enrolling from May 2015 to November 2015 all patients with Crohn's disease. Each patient benefited at the inclusion of a blood test including a complete blood count, a marital assessment (ferritin levels and serum iron), an inflammatory balance (C-reactive protein and erythrocyte sedimentation rate) and a vitamin balance (folic acid and vitamin B12). We divided our patients into two groups according to whether or not they had anemia, and we compared the two groups to identify the factors associated with anemia.

RESULTS

Eighty-eight patients were included with a median age of 42.45±13.81 years and a sex ratio of 0.87. Anemia was present in 53% of cases. The etiologies of anemia were as follows: iron deficiency in 34% of cases, anemia of chronic disease in 19% of cases, mixed anemia in 45% of cases and due to a vitamin B12 deficiency associated with a mixed anemia only in 2% of cases. The overall prevalence of iron deficiency was 78%. Twenty two percent of the population had vitamin B12 deficiency. In univariate analysis, anemia was associated with malnutrition (p=0.04), severe flare (p=0.01), hospitalization (p = 0.03), a history of corticosteroid therapy (p = 0.02) and high rates of erythrocyte sedimentation rate (p = 0.003). In multivariate analysis only severe flare and an erythrocyte sedimentation rate>35 were associated with anemia. Vitamin B12 deficiency was associated with extensive ileal resection (p=0.01) and both penetrating and stricturing behavior (p=0.002).

CONCLUSIONS

Our study showed the high prevalence of anemia in Crohn's disease, its main etiologic mechanisms dominated by both conditions iron deficiency and chronic inflammation and its main predictors highlighting the interest in its screening and treatment to improve the quality of life of patients.

Clinical Chemistry

P0571

UNLOCKING THE GENETIC LINK: ASSOCIATION OF KLF14 GENE POLYMORPHISM WITH TYPE 2 DIABETES IN A TUNISIAN POPULATION

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BACKGROUND-AIM

Type 2 diabetes is a multifactorial metabolic disease. The genetic component, in interaction with environmental factors, plays a fundamental role in predisposition to this pathology. The objectives of this study were to investigate the molecular variations of the KLF14 gene rs972283 polymorphism in a Tunisian population of type 2 diabetic subjects (T2DM subjects) and to investigate the association of this polymorphism with type 2 diabetes.

METHODS

This was a case-control study involving T2DM subjects and controls recruited from the outpatient department of the Institut National de Nutrition. Biochemical assays were performed in the clinical biology laboratory and the rs978322 polymorphism of the KLF14 gene was studied using molecular techniques: High Resolution Melt (HRM) and Sequencing.

RESULTS

We included 98 T2DM subjects and 95 control subjects who met the selection criteria. The GG genotype was the most frequent genotype in Type 2 diabetics. No statistically significant difference was observed in the genotypic distribution of the rs972283 polymorphism of the KLF14 gene between diabetics and controls (p=0.083). The G mutated allele was more frequent in T2DM subjects, with a significant difference between the two groups (p=0.02). We found a statistically significant association, according to the dominant model (GG vs AA+AG), between the GG genotype of the rs972283 polymorphism of the KLF14 gene and type 2 diabetes on the one hand (p=0.02 ; OR=1.9; 95% CI=[1.07 - 3.38]), and between the AG genotype and type 2 diabetes according to the codominant model (GG vs AG vs AA) with p=0.043 and OR=1.886 (95% CI=[1.886 - 3.505]), on the other hand. Mean blood glucose concentrations were significantly higher in GG genotype T2DM subjects than in those carrying the A allele (AA+AG) with p=0.012.

CONCLUSIONS

The G allele of the rs972283 polymorphism of the KLF14 gene appears to be associated with predisposition to type 2 diabetes in our population. Large-scale multicenter studies are needed to better elucidate the role of this polymorphism and other genetic factors in the development of this disease.

Clinical Chemistry

P0572

CONCENTRATION DEPENDENT IMPACT OF HEMOLYSIS ON LIPASE RESULT: DOES IT CLINICALLY MATTER?

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BACKGROUND-AIM

Roche Diagnostics recently lowered the hemolysis index (HI) interference threshold for lipase from 1000 (10 g/L) to 100 (1 g/L) hemoglobin, but there was limited supporting data communicated to support this change. This large threshold decrease significantly increases the sensitivity to interference for the lipase assay, potentially requiring result reporting changes that would slow laboratory workflow and impact result interpretation. To verify the new HI claim, we performed an interference study by targeting clinically relevant lipase concentrations.

METHODS

Five lipase concentrations of residual lithium heparin plasma samples (36-227 U/L, n=3-5) were spiked with increasing concentrations of hemoglobin prepared from lysed red blood cells (0, 0.5, 1, 2, 3, 4, 5, 8, 10, 12 g/L). Lipase was measured in triplicate and HI results were measured in singleton on a Roche Cobas Pro c503 instrument. Results are expressed as mean ± standard deviation. Interference was calculated as the absolute and percent differences from the 0 g/L control. Interference was compared against the allowable total error (ATE) from various sources: 1) 12 U/L if <60 U/L or 20% if ≥60 U/L (RCPA), 2) 12.9% (EFLM), 3) 30% (CAP), and 4) 8 U/L if <40 U/L or 20% if ≥40 U/L (IQMH).

RESULTS

At 1 g/L hemoglobin, the HI was 95±4, and yielded a 0.4-1.0% difference from baseline across all lipase concentrations. At the lowest lipase concentration group (38±2 U/L), results were falsely elevated starting at 3 g/L hemoglobin (HI=289 ± 18) when ELFM and IQMH ATE were used, while no difference was found when RCPA and CAP ATE were used up to 12 g/L hemoglobin (HI=1171±22). At other lipase concentrations, differences were all within ATE limits from all sources.

CONCLUSIONS

Hemolysis affected lipase results in a lipase concentration-dependent manner with an analytically significant impact found only when lipase concentration was <40 U/L. The clinical impact is minimal at this concentration as this is well within the normal reference interval for lipase. No changes to the hemolysis rules on the instrument were implemented. This study highlights the importance of verifying manufacturer claims and assessing change impact at a clinical level.

Clinical Chemistry

P0573

SERUM POTASSIUM MEASUREMENT: DEPENDENCE ON SEASONAL TEMPERATURE AND INDEPENDENCE FROM PRE-CENTRIFUGATION DELAYS ≤30 HOURS

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BACKGROUND-AIM

Hyperkalaemia is characterised by an elevation of serum potassium (K^+) above 5.5 mmol/L. Pseudohyperkalaemia, a false elevation in K^+, may result from pre-analytical errors, affecting clinical management. A common cause of pseudohyperkalaemia is delayed serum sample separation, with delays greater than 24 hours causing altered K^+ results. Seasonal temperature changes may impact K^+, but thorough investigation is limited. This study aims to analyse the effects of delay and seasonal temperature on K^+ measurement.

METHODS

Serum K^+ results from January to December 2023 were extracted from the laboratory information system, including 173023 patient samples from Groote Schuur and Red Cross War Memorial Children's Hospitals' National Health Laboratory Service (NHLS) laboratories in Cape Town, South Africa. Samples with a haemolysis >90 mg/dL and those lacking a collection time were excluded. The time between sample collection and registration in the lab was calculated as the pre-centrifugation delay. Cape Town monthly temperatures were retrieved from the World Weather website.

RESULTS

Data analysis showed similar average centrifugation delays across all months. The average K^+ levels in the warmer months (November to April) had statistically significant differences compared to cooler months (June to September), $p<0.05$. There was a significant negative linear relationship between temperature and K^+ ($R^2=0.909$, $p<0.0001$). The relationship between time and K^+ showed weak linear regression ($R^2=0.1733$, $p=0.178$). Of the 401 samples with a centrifugation delay ≥30 hours, only 76 (19%) had clinically significant K^+ values.

CONCLUSIONS

Serum K^+ samples remain stable for up to 30 hours without centrifugation. Seasonal temperature variations have a greater impact on K^+ levels than centrifugation delays. Clinicians and pathologists in South Africa should account for these seasonal fluctuations when interpreting K^+ results. The NHLS may need to reassess their rejection policy for serum K^+ samples between 24 and 30 hours, and take into account the influence of temperature fluctuations on K^+ measurement.

Clinical Chemistry

P0574

COMPARISON OF GLUCOSE STABILITY CONCENTRATION IN VACUETTE® SODIUM FLUORIDE/POTASSIUM OXALATE AND VACUETTE® FC MIX TUBES

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BACKGROUND-AIM

Sodium fluoride is currently mostly used additive for inhibiting glycolysis. Better inhibition of glycolysis can be achieved by acidifying the sample with citrate to pH value of 5.3-5.9. The aim of this study was to compare the stability of glucose sampled in tube with the anticoagulant Sodium Fluoride/Potassium Oxalate and in FC Mix tube with citrate buffer at room temperature. Our hypothesis is that there is statistically significant difference in glucose stability between these two tubes.

METHODS

Study included 42 patients referred to the Department of Clinical Chemistry, Sestre milosrdnice University Hospital Center, Zagreb for glucose measurement. Two tubes were sampled for each patient: VACUETTE® FX Sodium Fluoride/ Potassium Oxalate (NaF/Kox) and FC Mix (both Greiner Bio-One GmbH, Kremsmüster, Austria). Samples were centrifuged and analysed immediately after sampling at (0h) and after 1, 2, 3, 4 and 5 hours on analyser Abbott Alinity c (Abbott, Abbott Park, USA). PD% (percentage difference) between baseline value and a result measured at particular time point and instability equation were calculated for each hour using Microsoft Excel (Microsoft, Redmond, USA). Longest time with corresponding bias lower than acceptance criteria was considered as time of acceptable stability. Acceptance criteria for MPD (maximum permissible difference) was set to 1.20% according to the EFLM Biological Variation Database.

RESULTS

Instability equation for NaF/Kox and FC Mix tubes were: PD%= -0.002 x time (hours) and PD%= 0.0001 x time (hours), respectively. FC Mix tube showed comparable stability of glucose up to 5 hours (all MPD% values <1.2%). However, stability of glucose in NaF/Kox tube was shorter, up to 4 hours (MPD% -1,24% after 5 hours).

CONCLUSIONS

Better glucose stability was observed in Fc Mix tubes compared with NaF/Kox tubes at room temperature. Significant difference was observed for NaF/Kox tube after 5 hours with MPD%= -1.24%.

Clinical Chemistry

P0575

IMMUNOLOGICAL CHARACTERISTICS AND CLINICAL SIGNIFICANCE OF CIRCULATING TUMOR PLASMA CELLS IN MULTIPLE MYELOMA

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BACKGROUND-AIM

Multiple myeloma (MM) is a malignant hematological tumor. Circulating tumor plasma cells (CPC) refer to monoclonal plasma cells in the peripheral blood, which are related to the progression and dissemination of MM. The aim of this study is to explore the flow immunological characteristics of CPC in peripheral blood of MM patients and the clinical value of CPC detected by flow cytometry (FCM) in the diagnosis of MM.

METHODS

Cultured multiple myeloma cells were mixed with peripheral blood of healthy volunteers to prepare 5%, 1%, 0.5%, 0.1%, 0.01%, 0.001% concentrations. CPC was detected by 10-color flow cytometry, and the sensitivity of the method was analyzed. In terms of clinical samples, the peripheral blood CPC of 10 MM patients were detected, and the immunophenotypes of peripheral blood CPC and bone marrow tumor plasma cells were compared. The patients were divided into CPC positive group (CPC+) and CPC negative group (CPC-), and the differences in clinical stage and other clinical indicators between the two groups were compared. Clinical indicators included hemoglobin (Hb), β2-microglobulin (β2MG), serum calcium (Ga+), serum creatinine (Cr), serum albumin (ALB); At the same time, the correlation between the percentage of circulating tumor plasma cells (PBCPCs%) in peripheral blood and clinical stage and other clinical indicators in CPC+ group was analyzed.

RESULTS

Flow cytometry could detect 5%, 1%, 0.5%, and 0.1% CPC in peripheral blood, but could not detect 0.01% and 0.001% CPC. In the peripheral blood of 10 MM patients, there were 4 cases in CPC+ group with DS stage III, and 6 cases in CPC- group, including 2 cases in DS stage #, 1 case in DS stage #, and 3 cases in DS stage III. There was no significant difference in related clinical indicators between CPC+ group and CPC- group. The immunophenotype of CPC+ group was consistent with that of bone marrow tumor plasma cells. PBCPCs% was positively correlated with Hb, Ca+ and ALB, and negatively correlated with β2MG and Cr.

CONCLUSIONS

The level of CPCs in patients with multiple myeloma can reflect the burden of tumor cells in the bone marrow, and has a certain predictive value for DS stage III.

Clinical Chemistry

P0576

ANALYSIS OF CIRCADIAN VARIATION IN SUGAR CHAINS BOUND TO SALIVARY α-AMYLASE

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BACKGROUND-AIM

α-amylase is an endo-type enzyme that hydrolyzes α-1,4 glycosidic bonds within polysaccharides. Salivary α-amylase has three families: family C, which carries two bi-antennary complex-type sugar chains at the two potential glycosylation sites, family A, which carries one molecule of bi-antennary complex-type sugar chains, and family B, which carries no sugar chains. After salivary α-amylase is secreted by the salivary glands, the sugar chains are released by the action of an enzyme and becomes family B through family A. However, the mechanism by which the glycan is released has not yet been elucidated.
In this study, we analyzed the type of sugar chains bound to salivary α-amylase and its variation in saliva samples collected at specific times over three days. We also measured amylase activity and examined the relationship between amylase activity and sugar chains.

METHODS

Saliva samples collected at specific times (after waking up, before lunch, and before bedtime) for three days were analyzed by lectin blotting with eight types of lectins. Next, SDS-PAGE and western blotting were performed using Con A, LCA, PHA-E4 to focus on the lectins that react with α-amylase in saliva.

RESULTS

Lectin blotting revealed that PHA-E4 showed the highest reactivity, followed by Con A, WGA, and LCA. In contrast, PNA showed the lowest reactivity. When SDS-PAGE and western blotting were performed using PHA-E4, Con A, and LCA, a strong band was observed at approximately 62 kDa. Furthermore, a weak band was observed at approximately 66 kDa for PHA-E4.

CONCLUSIONS

The results of western blotting using lectin suggested that two bands at around 62 kDa and 66 kDa were observed for PHA-E4, corresponding to family A and family C, respectively. These bands were particularly clear in the sample with high amylase activity, so we anticipated that the proportion of amylase bound to sugar chains would increase when the amylase activity was relatively high.
For LCA and Con A, bands were observed at approximately 62 kDa, but no bands were observed at approximately 66 kDa. This suggests that bi-, tri-, or tetra-antennary complex- type sugar chains containing bisecting GlcNAc are cleaved first, followed by a bi-antennary complex-type sugar chain rich in mannose and fucose.

Clinical Chemistry

P0577

COMPARISON OF SURFACE-ENHANCED RAMAN SCATTERING PROPERTIES OF SERUM WITH ABNORMAL STATUES

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BACKGROUND-AIM

Qualified serum quality is a prerequisite for correct test results. In this research, we aim to use a variety of analytical methods to compare Surface-enhanced Raman scattering (SERS) spectra with the clinical serum index from distinct groups (Hemolysis group, Lipemia group, Icterus group, control group) and consequently to verify their feasibility as a potential routine rapid method for detecting the serum statues in clinical application.

METHODS

In our study, the SERS spectrum of serum samples of hemolysis (n=60), lipemia (n=41), icterus (n=58) and healthy control (n=48) group was acquired to compare the SERS characteristics between different groups by using silver nanoparticles (AgNPs).

RESULTS

Principal component analysis (PCA) results showed that SERS could significantly distinguish between hemolysis, lipemia, icterus and healthy control serums, and the area under the receiver operating characteristic (ROC) curve drawn with PC1 was 0.9802, 0.7983, and 0.9767 respectively. The main different peaks of all serums may be attributed to some known biochemical components related to all kinds of lipid, proteins, nucleic. Orthogonal Partial Least Squares-Discriminant Analysis (OPLS-DA) showed that SERS could significantly distinguish between mild and severe hemolysis, lipemia or icterus, and the area under ROC curve of the two groups was 0.804, 0.848, 0.912 respectively. However, no significant correlation was shown between PC1 and serum markers (serum index, triglycerides, bilirubin) attributing to the complexity of serum composition.

CONCLUSIONS

In conclusion, SERS method can be used to quickly and cheaply identify abnormal serum states such as hemolysis, lipemia, icterus. Further investigation needs to be conducted by expanding sample size and increasing methodological sensitivity.

Clinical Chemistry

P0578

THE IMPACT OF THE USE OF GLASS VIALS ON TRACE ELEMENT LEVELS IN QUALITY CONTROL MATERIALS

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BACKGROUND-AIM

Trace elements are found in minute amounts in the human body and can be acquired from food, water, or the environment. Some are essential for physiological functions, including growth, development, and maintenance of the endocrine and immune systems. Accumulation or deficiency can therefore significantly impact overall health. However, some trace elements can be harmful and lead to toxicity in excessive amounts. Hence, it is crucial to monitor trace elements using blood or urine tests. Quality control materials for these tests are produced from blood, urine, or serum samples, stored in plastic or glass vials, which may be potential contamination sources. Thorough testing of three different glass vials, including rubber stoppers and caps, has been conducted to determine suitable packaging materials for quality control materials for these trace elements.

METHODS

Leaching analyses were performed using two different concentrations of nitric acid (0.5 and 5%) on three different types of glass vials from various lots and producers. Additionally, 5% nitric acid was used to test the rubber stoppers and caps, which are a part of the packaging of the control materials. Concentrations of 71 different trace elements were measured using mass spectrometry.

RESULTS

The caps were generally found to be the most inert component of the packaging, but showed a minimal contribution to aluminium levels. In contrast, the stoppers were identified as potentially significant contributors to leaching of 12 trace elements, including aluminium, calcium, nickel and zinc. Glass vials were potential contributors to aluminium, boron, cobalt, lead and titanium levels. Further analysis also showed that the trace element contamination can vary between vial production batches, which may impact the final trace element levels in the control materials.

CONCLUSIONS

It is therefore critical to test the container of control materials to minimize the leaching of trace elements. It is also advisable to avoid the use of glass vials where possible and consider other alternatives such as plastic. This is essential to avoid inconsistent results, which could ultimately affect patient diagnosis and treatment.

Clinical Chemistry

P0579

IS SERUM A VIABLE MATRIX FOR P-TAU217 AS A BIOMARKER FOR ALZHEIMER'S DISEASE?

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BACKGROUND-AIM

Several studies have demonstrated the high accuracy of plasma p-tau217 assays in identifying individuals across the Alzheimer's disease (AD) continuum. While these assays are typically validated using EDTA plasma, clinical and bio-banked research settings often favor serum matrices due to established protocols for other biomarkers. However, the performance of p-tau217 assays in serum remains unclear. Furthermore, variations in anticoagulants in plasma tubes raise questions about their impact on assay performance.

METHODS

This study assessed six high-performing p-tau217 assays (Simoa ALZpath, Simoa Janssen, Nulisa Alamar, Lumipulse Fujirebio, MSD Lilly, and MSD S-plex) across plasma and serum, as well as different plasma tube types. Blood samples were collected from 100 participants with known amyloid PET status: 35 CU- (cognitively unimpaired, amyloid-negative), 15 CU+ (cognitively unimpaired, amyloid-positive), 15 MCI+ (mild cognitive impairment, amyloid-positive), 5 ADD (Alzheimer's disease dementia), and 30 MCI- (mild cognitive impairment, amyloid-negative) from the TRIAD cohort. Additional EDTA plasma, Na-citrate, lithium heparin, and serum samples were collected from 17 individuals without clinical data. All samples were analyzed in duplicate.

RESULTS

Plasma and serum p-tau217 quantifications showed strong correlation across assays, despite serum generally exhibiting a smaller dynamic range, except for Lumipulse. Serum p-tau217 effectively distinguished amyloid positivity, except with MSD Lilly. Quantifications from citrate and lithium-heparin plasma correlated well with EDTA plasma and had similar dynamic ranges. High CVs (>20%) were occasionally observed across assays and tube types, with no consistent pattern.

CONCLUSIONS

P-tau217 demonstrated high diagnostic performance in both serum and plasma across most platforms. Absolute plasma p-tau217 concentrations were generally higher than serum p-tau217, except with the Lumipulse assay. These differences suggest that plasma and serum can be used interchangeably if a correction factor or matrix-specific cut-offs are applied. Serum is a viable matrix for p-tau217 measurement, making it suitable for use in hospitals and research cohorts that prioritize serum over other blood matrices.

Clinical Chemistry

P0580

COMPARISON OF FRIEDEWALD-, SAMPSON- AND (EXTENDED) MARTIN-HOPKINS EQUATIONS FOR THE ESTIMATION OF LDL-CHOLESTEROL WITH MEASURED LDL-CHOLESTEROL IN PATIENTS WITH HYPERTRIGLYCERIDEMIA

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BACKGROUND-AIM

To compare the clinical performance and concordance of the Friedewald, Sampson, Martin-Hopkins and extended Martin-Hopkins equations with the direct LDL-cholesterol (LDL-C) in patients with hypertriglyceridemia.

METHODS

Retrospective data of 8388 subjects was collected between July 2020 and February 2023 at UZ Brussel. Triglycerides (TG), total cholesterol, HDL- and LDL-C concentrations were determined by enzymatic colorimetry on Cobas® 8000 c702 (Roche Diagnostics). The clinical performance (clinical cut-off=100 mg/dL LDL-C) and concordance between the direct LDL-C and the equations were compared in samples with hypertriglyceridemia (200-4414 mg/dL).

RESULTS

The correlation of direct LDL-C and LDL-C calculated by the different formulas was similar for TG between 200 and 799 mg/dL (r=0.87-0.96; n=8230). Best correlation was found for LDL-S (r=0.9; n=879) for samples with TG between 400 and 799 mg/dL. The correlation coefficient was lower than 0,5 for all formulas for TG higher than 799 mg/dL (n=159).
LDL-MH showed the lowest average bias (14%) for samples with TG between 200 and 799 mg/dL. Half of the samples in the subgroup of 400-799 mg/dL (n=879) had a bias higher than the desirable total error of EFLM (11.8%).
The clinical specificity was the highest for the LDL-F formula (98%), whereas the clinical sensitivity was the highest for the LDL-MH formula (94%) in the group of TG between 400 and 799 mg/dL.
Finally, the LDL-MH formula places the largest number of results in the same category as the measured LDL-C (76.3%). However, even in the group of TG between 200 and 399 mg/dL, LDL-MH resulted in a misclassification towards lower values in 21% of direct LDL-C results between 55 and 100 mg/dL.

CONCLUSIONS

The Martin-Hopkins formula is more concordant with direct LDL-cholesterol than the other formulas. To avoid underestimation in patients under cholesterol-lowering therapy direct LDL-C measurement is still an added value.

Clinical Chemistry

P0581

USE OF LABILE HBA1C AS A SCREENING TOOL TO MINIMIZE CLINICAL MISINTERPRATION OF HBA1C

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BACKGROUND-AIM

Hemoglobin A1c (HbA1c) is an established tool in the diagnosis and follow-up of patients with diabetes. However, in some patients the interpretation of HbA1c results faces challenges due to additional biological variation or non-steady-state conditions. This study aimed to demonstrate the value of the L-HbA1c/HbA1c-ratio as a tool to flag HbA1c results, which do not reflect average glycemia “as expected” in routine clinical practice.

METHODS

450 samples of unique patients were selected based on the L-HbA1c/HbA1c-ratio determined on a Tosoh G8 analyzer resulting in a group with a high ratio (≥0.50), a group with a low ratio (≤0.27) and a group with a normal ratio (0.27-0.50). The relationship between HbA1c and glycemic markers (fructosamine and random glucose) was established for all ratio groups.

RESULTS

The correlation between HbA1c and glycemia (random glucose and fructosamine) differs significantly between the ratio groups. For the same HbA1c level random glucose levels and protein-corrected fructosamine are higher in the high ratio group compared to the normal and low ratio groups, pointing to an underestimation of the glycemic status by HbA1c in patients with high L-HbA1c/HbA1c-ratios. The sensitivity of a high ratio to predict a glycation gap lower than -1.5 NGSP units is 82% and the specificity is 65%.

CONCLUSIONS

The results of this study reveal the usefulness of the L-HbA1c/HbA1c-ratio as an additional check in the interpretation of HbA1c results in order to detect HbA1c results not reflecting glycemia as expected.

Clinical Chemistry

P0582

A CASE OF SEVERE HYPERNATREMIA IN THE CONTEXT OF HOSPITALIZATION FOR PNEUMOCOCCAL PNEUMONIA.

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BACKGROUND-AIM

A 65-year-old patient was admitted to the emergency room for pneumococcal pneumonia. He exhibits an early-stage sepsis, and a severe hypernatremia (188 mmol/L), in a context of severe cachexia. Functional acute renal failure was diagnosed.
His medical history includes sequelae of strokes twenty years ago and significant loss of autonomy.
On Day 1, natremia decreased by 10 mmol/L but suddenly normalized to 138 mmol/L at 10:00 AM on Day 2, only to rise again to 176 mmol/L by 12:50 PM the same day.
We aimed to guide the interpretation of hypernatremia.

METHODS

Blood ionograms were obtained via indirect and direct potentiometry.
We used osmotic pressure (414 mOsm/kg), calculated plasma osmolality (412 mOsm/kg) and osmolar gap.

RESULTS

These abrupt variations in sodium levels required a critical evaluation. Severe hypovolemic hypernatremia leads to intracellular dehydration, which aligns with the patient's motor and neurological disturbances. However, in the context of pronounced hypernatremia combined with normoproteinemia (cachexia), potential measurement errors or dilutional effects must be considered.
The normal osmolar gap excluded analytical errors and supported the presence of excess endogenous osmoles and intracellular dehydration.
To exclude preanalytical error (contamination from sodium infusion), electrolytes were remeasured using direct potentiometry on a new sample. The results were consistent with those obtained by indirect potentiometry.
The recurrent hypernatremia, confirmed by direct potentiometry and a normal osmolar gap, validated true hypernatremia.
One explanation for the sudden normonatremia was dilution caused by rehydration infusion. This was confirmed by the medical team, with a sample collection from the infusion arm. After addressing this error, sodium levels were consistent with a more gradual correction (176 mmol/L on Day 2, 12:50 PM).

CONCLUSIONS

This case highlights the seriousness of severe hypernatremia and the critical need for careful monitoring during correction. The correction must be gradual to prevent cerebral oedema. Blood samples should be collected from the arm contralateral to the infusion site to avoid contamination. The rate of correction should align with the speed of hypernatremia onset, with a target sodium level of 145 mmol/L in this case.

Clinical Chemistry

P0583

DISCORDANCE BETWEEN CYSTATIN C AND CREATININE DETERMINATIONS IN A TERTIARY HOSPITAL

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BACKGROUND-AIM

The estimated glomerular filtration rate (eGFR) has been widely estimated through the measurement of the endogenous filtration marker creatinine (Crn). Nevertheless, KDIGO 2024 guidelines emphasise the importance of additional measurement of cystatin C (Cys) to add precision to eGFR clinical value. Currently, despite the recommendation to measure both Crn and Cys, most clinical laboratories calculate and report eGFRCrn and eGFRCys in mL/min/1.73m² separately. Notably, eGFR results from Cys and Crn measurements are frequently significantly different (eGFRdiff, eGFRCys minus eGFRCrn, in mL/min/1.73m²), causing challenges for clinical interpretation. Furthermore, the extent of eGFRdiff and its impact, particularly at borderline cut off values, is crucial for clinical reasoning.

METHODS

In this study, we collected matched eGFRCys and eGFRCrn data (n=18,777) from a heterogeneous population over 18 years of age, followed at a tertiary hospital in the north of Portugal, to analyse the real-world distribution and eGFRdiff. The eGFRs were calculated from Crn and Cys determinations in serum in 2024. The participants had a mean age of 60±16.4 years, and 43% were female. The eGFRCrn and eGFRCys were calculated using the 2021 and 2012 CKD-EPI equations, respectively. The central tendency measures were calculated for eGFRCys, eGFRCrn, and eGFRdiff, and stratified by gender.

RESULTS

Departure from normality revealed eGFRCrn and eGFRCys have non-parametric distribution. The Wilcoxon rank-sum test (Wt) indicated that eGFRCys and eGFRCrn are significantly dissimilar ($p<0.05$). Also, density plots also showed considerable discordance between eGFRCys and eGFRCrn. The eGFRCys was lower than eGFRCrn, with approximately 74.4% of measurements showing a negative eGFRdiff (mean = -10.8). This eGFRdiff was larger for males compared to females ((mean = -12.9 and -7.9, respectively, Wt $p<0.05$). The correlation between eGFRCys and eGFRCrn had a modest Spearman coefficient (rho=0.90, $p<0.05$). However, Cohen's effect size was small-to-medium (d=0.35).

CONCLUSIONS

This study highlights the inequality when using eGFRCrn or eGFRCys independently in clinical practice, underlining the importance of assessing Crn and Cys serum levels and reporting as combined eGFRCys-Crn.

Clinical Chemistry

P0584

OPTIMIZING MEDULLARY THYROID CARCINOMA DETECTION: COMBINED ASSESSMENT OF FNA-CALCITONIN AND SERUM CALCITONIN

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BACKGROUND-AIM

Medullary thyroid carcinoma (MTC), a neuroendocrine malignancy from thyroid parafollicular C cells, demands early diagnosis due to its aggressiveness and mortality impact. But current diagnostic tools like serum calcitonin (sCtn) assay and fine-needle aspiration (FNA) biopsy have flaws. This study evaluated FNA-Ctn's diagnostic efficacy against sCtn in detecting MTC in thyroid nodules and lymph nodes with suspected metastasis.

METHODS

From June 2022 to June 2024, patients suspected of MTC, who had FNA biopsy and calcitonin testing of washout fluid at West China Hospital, Sichuan University, were included. 91 thyroid nodules (25 MTC, 66 non-MTC) and 154 lymph nodes (26 MTC, 128 non-MTC metastatic) were analysed. Diagnostic performance of FNA-Ctn and sCtn was assessed via receiver operating characteristic (ROC) curves.

RESULTS

In suspected thyroid nodules, combined FNA-Ctn and sCtn assessment boosted MTC diagnostic efficacy. FNA-Ctn's ROC curve area under the curve (AUC) was 0.9733, with an optimal cut-off of 537.55 pg/mL. For suspected lymph nodes, FNA-Ctn outperformed sCtn in diagnosing MTC metastasis, having an AUC of 1.000 and cut-off of 71.36 pg/mL.

CONCLUSIONS

FNA-Ctn is a highly effective biomarker for MTC in thyroid nodules and lymph node metastasis. Combining it with sCtn enhances MTC diagnostic accuracy. This study provides evidence to support the incorporation of FNA-Ctn measurement into clinical practice for the diagnosis and management of MTC.

Clinical Chemistry

P0585

LEVELS OF HOMOCYSTEINE AND THYROID FUNCTION IN PATIENTS WITH SCHIZOPHRENIA SPECTRUM DISORDERS (SSD) AND MOOD DISORDER (MD)

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BACKGROUND-AIM

Homocysteine (Hcy) is a well-known marker of thrombosis and oxidative
stress. High Hcy (HHcy) levels have been associated with SSDs and MDs. It has been recently observed that in euthyroid subjects impaired sensitivity to thyroid hormones was associated with elevated Hcy levels. The aim of the present study was to investigate possible relation of homocysteine to thyroid function in patients with SSD and MD.

METHODS

We conducted a retrospective study on acutely admitted psychotic inpatients [total N=135, 51.9% males, mean age (SD)= 44.02(12.00) years, mean age-at-onset of psychiatric disorder (SD) = 26.46(10.55) years], either with a Schizophrenia Spectrum Disorders (SSD) (n=104, 55.8% males) or a Mood Disorder (MD) (n=31, 38.7% males), diagnosed according to DSM-V-TR. Vitamin B12, Hcy, folic acid, TSH, FT4 and FT3 were determined by electrochemiluminescence immunoassay (ECLIA) in automated biochemical-immunological analyzers (ROCHE Diagnostics). Parameters were compared between subgroups of the SSD and MD groups: subgroup 1 (SG1) with normal Hcy (≤15 umol/L) and subgroup 2 (SG2) with Hcy >15 umol/L. Statistical analysis was performed using IBM SPSS v.29. Level of significant difference was $p<0.05$.

RESULTS

Statistically significant differences between SSD and MD subgroups were found. In total the inverse relation of B12 and HHcy was confirmed. TSH and FT4 differed significantly between SG1 and SG2. In SSD patients, thyroid hormones did not differ significantly between SG1 and SG2, whereas in the MD group only FT4 had significant difference. In SSD, among the three subgroups of low, normal and high B12, FT4 and TSH levels had significant differences.

CONCLUSIONS

In conclusion, it seems that thyroid function and homocysteine metabolism in SSD and MD patients are interrelated in a way that is yet to be defined.

Clinical Chemistry

P0586

DEVELOPMENT OF A METHOD FOR PARATHYROID HORMONE FRAGMENTS QUANTITATION USING LIQUID CHROMATOGRAPHY COUPLED WITH TANDEM MASS SPECTROMETRY

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BACKGROUND-AIM

Parathyroid hormone (PTH 1-84) is a protein primarily synthesized by the parathyroid glands, which secrete it via exocytosis in response to low extracellular ionized calcium levels. PTH 1-84 plays a crucial role in maintaining calcium and phosphate homeostasis and regulating bone remodeling. Its effects on bones and kidneys are mediated through its receptor, PTHR1. PTH 1-84 metabolism results in the production of two types of fragments: N-terminal fragments, which are rapidly cleared by the liver, and C-terminal fragments, which are released into the bloodstream and then filtered by the kidneys. These fragments are not only byproducts of PTH 1-84 metabolism but can also be directly synthesized by the parathyroid glands.
Currently, the measurement of PTH 1-84 is primarily conducted using immunological methods, as no specific technique has yet been developed for quantifying its fragments. Kritmetapak and colleagues identified eight distinct PTH 1-84 fragments using LC-HRMS. However, tandem mass spectrometry (MS/MS) offers a more promising alternative due to its increasing availability and potential for use in clinical practice.

METHODS

The aim of this study was to develop a UPLC-MS/MS method for quantifying four specific parathyroid hormone (PTH 1-84) fragments—PTH 34-84, PTH 37-84, PTH 38-84, and PTH 38-77—in serum samples. The analysis was performed using a NEXERA X2 UPLC system (Shimadzu) coupled with an ACQUITY UPLC® Protein BEH C4 column and an AB SCIEX® QT-6500 mass spectrometer. Sample preparation utilized an SPE MAX cartridge (Waters). A low-PTH serum matrix (below 4 pg/mL) was used as a surrogate matrix for the analysis.

RESULTS

One LC-MS/MS method has been developped and a pre-validation was performed and gave promising results. Results on pools of patients ranked as a function of their glomerular filtration rate (GFR) gave similar trends as the one existing in the litterature.

CONCLUSIONS

The UPLC-MS/MS method can be applied to analyze patient samples, providing valuable insights into the role of PTH 1-84 fragments in PTH resistance observed in patients with chronic kidney disease (CKD). Ongoing efforts are focused on incorporating additional peptides, with future work aimed at expanding the study to larger patient cohorts.

Clinical Chemistry

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SELENIUM LEVEL AND CU/ZN RATIO IN PATIENTS WITH MONOCLONAL GAMMOPATHY ARE DEPENDENT ON THE IMMUNOTYPES

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BACKGROUND-AIM

Multiple myeloma (MM) is characterized by neoplastic plasma cell proliferation, the usual presence of monoclonal protein, and end-organ damage. Recent studies have shown that a high Cu/Zn ratio is associated with chronic inflammatory diseases, increased oxidative stress, and inflammation in hematologic malignancy and is associated with disease severity. We determined Selenium (Se) concentration, copper (Cu)/ zinc (Zn) ratio, kappa and lambda light chain, and kappa/lambda ratio in patients with monoclonal gammopathy.

METHODS

Serum samples were collected from patients with a history of MM or a history of MGUS. Subjects were grouped based on their free light chain immunotypes (kappa or lambda). The serum Zn, Cu, and Se levels were determined using a Triple quadrupole inductively coupled plasma mass spectrometer (Agilent 8900 ICP-QQQ) in collision/reaction cell (CRC) mode with oxygen gas for Se and helium gas for Zn and Cu. Free kappa and lambda light chain concentration were also determined using turbidimetry (Optilite, ThermoFisher). Unpaired t-tests, one-way ANOVA tests, and correlation studies were performed.

RESULTS

Eighty-four (84) patients had lambda light chain-related immunotypes, while 179 patients had kappa light immunotypes. Selenium levels in patients with kappa light chain immunotype were lower compared with patients with lambda light chain immunotype (129.2 ± 2.6 vs 134.3 ± 6.6 µg/L, $p<0.0001$). Cu and Zn were not significantly different in patients with kappa light chain immunotype compared with lambda immunotype (Cu (kappa vs. lambda) = 106.6 ± 1.8 vs. 108.6 ± 2.8 µg/dL; Zn (kappa vs. lambda) = (88.1 ± 2.0 vs. 90.04 ± 2.5µg/dL, $p<0.05$). However, the Cu/Zn ratio was higher in patients with kappa light chain immunotype compared with patients with lambda light chain (1.326 ± 0.04427 vs 1.272 ± 0.04366, $p<0.0001$).

CONCLUSIONS

The significantly lower serum Se concentrations and a higher Cu/Zn ratio in patients with kappa light chain immunotype suggest that trace metals may play a role in multiple myeloma pathophysiology. This may aid in understanding the role of selenium-containing proteins in the inflammatory response, severity of multiple myeloma, immunotyping, treatment, and prognosis, ultimately improving patient outcomes and informing future therapeutic interventions.

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UNLOCKING DIAGNOSTIC POTENTIAL IN OVARIAN CANCER: THE SUPERIORITY OF ROMA AND INSIGHTS FROM BIOMARKER ANALYSIS

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BACKGROUND-AIM

Ovarian cancer is the deadliest gynecological malignancy due to its slow progression and late diagnosis, with 70% of cases detected at advanced stages. Current diagnostic methods lack sufficient sensitivity and specificity, highlighting the need for improvement. This study evaluates the performance of the Risk Ovarian Malignancy Algorithm in assessing malignancy risk and examines the role of additional biomarkers in enhancing diagnostic accuracy.

METHODS

The study included 40 women who visited the General Hospital of Athens G.Gennimatas from June to November 2024. Among these, 21 had ovarian cysts (4 malignant), while 19 had no cysts. Serum samples were analyzed in the Biochemical Laboratory of the hospital to evaluate the diagnostic efficacy of ROMA, which integrates biomarkers HE4 and CA125 for malignancy risk assessment. A comparative analysis of additional biomarkers was conducted (CEA, Ca153, Ca19-9, Ca72-4, SCC, β-hCG, FSH, LH, Pg, E2, α-FP, CRP) to investigate their diagnostic value. The study aimed to assess the combined and individual contributions of these biomarkers in enhancing diagnostic accuracy and providing insights for clinical decision-making regarding ovarian mass evaluation

RESULTS

ROMA demonstrated excellent diagnostic performance, with an AUC of 0.971, showcasing superior sensitivity and specificity in malignancy risk prediction. However, 3 false-positive results highlighted areas for further refinement. Among the additional biomarkers analyzed, HE4, CA72-4, AFP, and β-hCG displayed higher values in malignant cases, while CA125 levels were unexpectedly lower in certain malignancies. Despite this variability, ROMA emerged as the most reliable diagnostic approach, supported by complementary biomarker insights.

CONCLUSIONS

This study highlights ROMA as a pivotal tool in ovarian cancer diagnostics. The analysis of additional biomarkers provides valuable context but underscores the necessity for ongoing refinement of diagnostic models. ROMA stands out as a cornerstone in advancing early and reliable ovarian cancer detection, with the potential for integrating further biomarker insights to optimize clinical outcomes.

Clinical Chemistry

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EXPLORING THE IMPACT OF PREOPERATIVE ANXIETY ON CORTISOL VARIATIONS IN WOMEN UNDERGOING CESAREAN DELIVERY WITH SPINAL ANESTHESIA

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BACKGROUND-AIM

Cesarean sections, a widely performed procedure in gynecology, have been steadily increasing in frequency. This intervention is often accompanied by significant preoperative anxiety, yet it remains frequently overlooked and underdiagnosed by healthcare professionals. The objective of this study is to assess the prevalence of preoperative anxiety and examine the correlation between anxiety, as assessed by the STAI (Y-1) scale, and cortisol levels in women undergoing cesarean section.

METHODS

This prospective study was conducted over a three-month period, from November 1, 2023, to February 4, 2024. The participants were women scheduled for cesarean delivery under spinal anesthesia. Anxiety was assessed upon admission to the operating room using the STAI (Y-1) scale. Cortisol levels were measured at two points: upon arrival in the operating room and after the procedure.

RESULTS

The study included 35 participants, with a mean age of 30.8 ± 5.3 years (range: 22 to 40 years). The prevalence of preoperative anxiety was 100%. Based on STAI (Y-1) scores, the patients were distributed into three groups:6 patients (17.1%) had moderate anxiety,28 patients (80%) had high anxiety,1 patient (2.9%) had very high anxiety.
Cortisol measurements revealed a slight but significant increase after the procedure. Before the intervention, the average cortisol level was 865.5 ± 420 ng/L. Post-intervention, it rose to 904.8 ± 411.8 ng/L. This modest increase was strongly correlated with preoperative anxiety levels, with a correlation coefficient of $r = 0.936$ ($p < 0.0001$).

CONCLUSIONS

This study highlights a high prevalence of preoperative anxiety among women scheduled for cesarean delivery under spinal anesthesia and a significant correlation between anxiety levels and cortisol variations. These findings underscore the importance of systematically assessing preoperative anxiety and the potential benefits of targeted interventions to enhance patient well-being.

Clinical Chemistry

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THE ROLE OF BIOCHEMICAL MARKERS AS ALTERNATIVES TO PET-CT IN ASSESSING ANGIOGENESIS AND METASTASIS IN GASTRIC CANCER TREATMENT: AN ANALYSIS OF VEGF, ENDOGLIN, MMP-4, AND LDH-A LEVELS

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BACKGROUND-AIM

Early diagnosis and effective treatment are crucial in the progression of gastric cancer. While chemotherapy is commonly employed in treating gastric cancer, disease progression is associated with angiogenesis and metastasis. Although PET-CT is the gold standard imaging modality for evaluating angiogenesis and metastasis in gastric cancer patients undergoing chemotherapy, the radiation exposure during this procedure can increase the risk of organ failure in patients with renal dysfunction. This study aims to investigate the potential of using alternative biomarkers to replace PET-CT, providing a safer and more effective assessment method. Specifically, the study examines the impact of Vascular Endothelial Growth Factor (VEGF), Endoglin, Matrix Metalloproteinase-4 (MMP-4), and Lactate Dehydrogenase A (LDH-A) levels in evaluating angiogenesis and metastasis, reflecting tumor cell activity.

METHODS

Blood samples were collected into gel-containing biochemistry tubes from 30 healthy volunteers, 30 newly diagnosed gastric cancer patients before chemotherapy, and 30 gastric cancer patients after chemotherapy. The samples were analyzed using BT LAB (Bioassay Technology Laboratory) ELISA kits.

RESULTS

In gastric cancer patients, a statistically significant decrease in VEGF, Endoglin, MMP-4, and LDH-A levels was observed in the post-treatment group compared to the pre-treatment group ($p<0.001$). When comparing the control group with the pre-treatment patient group, all parameters (VEGF, Endoglin, MMP-4, LDH-A) were significantly lower in the control group ($p<0.001$). No statistically significant differences were found between the control and post-treatment patient groups across all parameters (VEGF, Endoglin, MMP-4, LDH-A) ($p=0.767$, 0.024, 0.048, 0.107, respectively).

CONCLUSIONS

Assessing angiogenesis and metastasis in gastric cancer treatment may allow for the use of alternative biomarkers instead of PET-CT. VEGF, Endoglin, MMP-4, and LDH-A are considered to play significant roles in monitoring tumor-associated angiogenesis and metastasis, suggesting that these parameters could be beneficial in tracking the treatment of the disease.

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USP48 REGULATES RRNA 2'-O METHYLATION AND IRES-DEPENDENT TRANSLATION VIA DEUBIQUITINATION OF FBL IN BREAST CANCER

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BACKGROUND-AIM

Ubiquitin-specific protease 48 (USP48), a member of the deubiquitinating enzymes, has emerged as a key regulator of deubiquitination processes in various cancer types. However, its precise role in the initiation and progression of breast cancer (BC) remains incompletely understood.

METHODS

The expression level of USP48 in BC and its relationship with prognosis and survival were analyzed by tissue microarray. The biological function of USP48 in BC development and metastasis was evaluated by Gain- and loss of-function assays. The gene knockout technique was used to construct mammary gland specific USP48 knockout mice of BC spontaneous tumorigenesis, and to explore the effect of USP48 on the occurrence and metastasis of BC in vivo. The direct substrate of USP48 was identified by quantitative proteomics, ubiquiomics and interaction omics, and verified by subcellular localization, co-immunoprecipitation reaction (Co-IP) and mass spectrometry (MS). The role of USP48 regulatory substrate was investigated by western blot, rescue test and dual luciferase reporter test.

RESULTS

USP48 expression was significantly up-regulated in BC tissues, and high expression level was associated with the stage and poor prognosis of BC patients. In vivo experiments using the MMTV-PyMT mouse model of BC, we observed that depletion of USP48 suppresses BC tumorigenesis and lung metastasis. Through a comprehensive analysis involving proteomics, ubiquitinomics, and interactomics, we identified a wide range of potential substrates of USP48, with a particular focus on its involvement in protein translation, ribosome structure, and biogenesis. Notably, we discovered rRNA 2'-O-methyltransferase fibrillarin (FBL) is a direct substrate of USP48. Mechanistically, USP48 directly interacts with and deubiquitinates FBL to enhance its stability, thereby promoting rRNA 2'-O methylation and facilitating the internal ribosome entry site (IRES)-dependent translation initiation of crucial cancer-related genes such as c-Myc.

CONCLUSIONS

In conclusion, our study reveals the critical role of USP48 in the tumorigenesis and development of BC through stabilizing FBL and subsequent impact on cancer-associated translational regulation. This new insight sheds light on the potential of targeting USP48 as a therapeutic strategy for BC.

Clinical Chemistry

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DIAGNOSTIC ACCURACY STUDY OF SOLUBLE TRANSFERRIN RECEPTOR (STFR) OR STFR/LOG FERRITIN INDEX FOR THE DIAGNOSIS OF IRON DEFICIENCY ANEMIA

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BACKGROUND-AIM

This study aims to evaluate the diagnostic accuracy of serum soluble transferrin receptor (sTfR) for diagnosing iron deficiency anemia (IDA) in inflammatory conditions. Given the challenge of assessing iron status during inflammation using traditional markers affected by inflammatory processes, sTfR offers a promising alternative. The study focuses on determining sTfR's effectiveness in distinguishing between IDA and anemia of chronic disease (ACD), particularly in Oman, where its usage is not widespread.

METHODS

Conducted at the Medical City for Army and Security Services in Oman from 2021 to 2023. This retrospective study analyzed hospital records to evaluate sTfR's diagnostic utility. Data from patients with anemia and confirmed inflammatory conditions were compared to data from healthy controls. Key parameters included hemoglobin levels, mean corpuscular volume, ferritin, serum iron, transferrin saturation, and sTfR. Statistical analysis involved sensitivity, specificity, positive/negative predictive values, and receiver operating characteristic curve analysis. Exclusion criteria included patients on iron therapy or with recent blood transfusions, with active bleeding, and pregnant ladies. We collected additional parameters, including age, gender, reticulocyte counts, and C-reactive protein levels.

RESULTS

The study included 373 subjects divided into four groups: control (n =60, 16.1%), IDA (n =93, 24.9%), ACD (n =105, 28.2%), and IDA with ACD (n =115, 30.8%). Significant differences were observed in hemoglobin, mean cell volume, ferritin, and sTfR levels across groups ($p < 0.001$). The sTfR cut-off value of 4.7 mg/L demonstrated a sensitivity of 83% and specificity of 82% for distinguishing IDA from controls, with an area under the curve (AUC) of 81.5%. For differentiating IDA from ACD, a cut-off sTfR index of 3.0 showed high sensitivity (91.4%) and specificity (86.8%), with an AUC of 92.3%. These results suggest that sTfR is a reliable marker for diagnosing IDA, even in the presence of inflammation.

CONCLUSIONS

sTfR is an effective diagnostic tool for IDA in patients with inflammatory conditions, offering superior performance compared to traditional markers affected by inflammation, suggesting the potential for broader implementation of sTfR testing to improve anemia diagnosis accuracy.