

## REVIEW OF LUNG CANCER PATIENT CHARACTERISTICS AND TREATMENT STRATEGIES IN THE PANDEMIC COVID-19 YEAR Treated at the University Clinic of Radiotherapy and Oncology in Skopje

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### ABSTRACT

**Introduction:** It is estimated that delays in diagnosis due to the COVID-19 pandemic in North Macedonia could result in significant reductions in the number of potentially curative stages in lung cancer patients.

**Purpose:** The aim of this study was to review patient characteristics and treatment strategies of lung cancer patients treated at the University Clinic of Radiotherapy and Oncology (UCRO), during the pre-pandemic year (from 1 of March 2019 to the end of February 2020) and the pandemic year (from 1 of March 2020 to the end of February 2021).

**Material:** We analyzed eligible patients in the course of these two years according to patient characteristics and treatment strategies.

**Results:** We have a record increasing in number of undefined lung cancer patients without any pathological or histological conformation (11% pandemic year compared to 7% in the previous year), and an increased number of stage III and IV NSCLC patients in the pandemic year 449 (87%), in comparison to the pre-pandemic year of 403 (74%) patients. We have found a decreasing number of stage II NSCLC patients in the pandemic year 82 (13%) compared to 141 (26%) patients in the pre-pandemic year. We also note a decreasing number of patients with NSCLC operated on from 218 to 123 in the pandemic group. Due to frequent check-ups for COVID-19, we report an increasing number of early stage IA and stage IB patients, treated only by surgery.

**Conclusions:** The strict screening and admittance criteria put in place by hospitals during the pandemic might have improved the oncology treatment course of lung cancer patients.

**Keywords:** COVID-19, lung cancer, pandemic year, pre-pandemic year s

### INTRODUCTION

The first Macedonian case of COVID-19 was reported in March 2020, and since then, COVID-19 has been responsible for >6,500 deaths in N. Macedonia. During the height of the pandemic, the National Health Service was transformed to provide services to those infected, whilst routine elective hospital care was put on hold [1]. Delivering lung cancer care during the current pandemic posed significant challenges, including the

potential overlap in symptoms between pneumonia secondary to COVID-19 and lung cancer (such as fatigue, cough and difficulty in breathing) making it difficult to differentiate them clinically; furthermore patients are at risk of exposure to infection whilst accessing healthcare for diagnostics and treatment including oncological therapies, all of which predispose them to the more harmful effects of COVID-19 infection. Patients with lung

cancer are also more likely to be of an older age, be current or ex-smokers and have higher number of comorbidities, thus increasing the risk of COVID infection [2, 3, 4]. High-risk patients are also more likely to be in ‘shielding’ categories, making healthcare access more challenging [5, 6, 7]. It is estimated that in N. Macedonia delays in diagnosis due to COVID-19 could result in significant reductions in the procurement of patients in their potentially curative stages of the disease. We shall now summarize the statistical reporting of lung cancer patients who commenced cancer treatment at the University Clinic of Radiotherapy and Oncology in Skopje during the pandemic year.

The aim of this study was to evaluate patient characteristics and treatment strategies of lung cancer patients treated at the University Clinic of Radiotherapy and Oncology in Skopje during the pre-pandemic year (from 1 of March 2019 to the end of February 2020) compared to those categories during the pandemic year (from 1 of March 2020 to the end of February 2021).

## MATERIAL AND METHODS

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This study is a retrospective analysis designed to review the difference in parameters of diagnosis and treatment strategies of patients with lung cancer at the University Clinic of Radiotherapy and Oncology (UKRO) during the pre-pandemic 1-year period and the pandemic 1-year period. The goal of this study was to analyze the parameters for each year separately and to show the impact of COVID-19 on these parameters in the pandemic 1-year period. Patients included in this study were lung cancer patients treated at the UKRO in Skopje during the pre-pandemic year (from 1 of March 2019 to the end of February 2020) and patients treated at UKRO during the pandemic year (from 1 of March 2020 to the end of February 2021).

We analyzed the eligible patients separately for each year, pre-pandemic and pandemic, according to stage at presentation, histology report, NSCLC subset, age, ECOG (Eastern Cooperative Oncology Group) status, biomarker status at presentation, patient’s EGFR status, patient’s ALK status, patient’s PDL-1 status, ROS testing status, first line therapy options, second line therapy options, neoadjuvant chemotherapy, adjuvant chemotherapy, concurrent chemoradiotherapy,

immunotherapy, curative radiotherapy, palliative radiotherapy options and, in the pandemic year, the number of COVID-19 positive patients. 725 patients in pre-pandemic year and 749 in the pandemic year were eligible and were stratified according to their age as follows: below 50, 50-60, 60-70 and above 70; Eastern Cooperative Oncology Group (ECOG) score of 1-2 and 3-4; histology differentiation to NSCLC, SCLC and undefined-unproven histology (without histology or cytology conformation) cases and determined lung cancer diagnoses with imaging only. According to the International Staging System for Lung Cancer, patients were stratified according to stage groups: I-II and III-IV for NSCLC and limited and extended disease for SCLC. Biomarker rendering status included EGFR, ALK, PDL-1, ROS-1 testing. Patients were then stratified into 3 groups: those with a histopathology report only, additionally referred patients for biomarker analysis by the oncologist, and biomarker analysis report at first appointment.

All lung cancer patients received treatment according to evidence-based treatment protocols. Before enrollment, the patients gave their full medical histories and underwent a clinical examination with assessment of performance status (PS).

We provided conformal radiotherapy with the use of LINACS and two-dimensional palliative radiotherapy with dose prescriptions. For 3D radiotherapy, CT was required to define the gross tumor volume (GTV). Each patient was positioned and immobilized with the use of wing-board in treatment position on a flat table. CT slices with at a 3mm thickness were obtained starting from the cricoid cartilage and extending inferiorly to the level of the L1 vertebral body. The GTV, clinical target volume (CTV), planning target volume (PTV), normal organs and organs at risk were all outlined on the CT slices. The normal tissues and organs at risk contoured included: both lungs (as the total lung volume), heart, spinal cord and esophagus. For NSCLC patients the GTV included visible tumor and enlarged lymph nodes  $\geq 1$  cm, and we defined CTV 44 as GTV plus a 0.5 cm margin plus elective nodal irradiation. We used elective nodal mediastinal irradiation due to a lack of mediastinoscopy biopsy and PET/CT during the treatment planning process in our country. The PTV included CTV plus an additional 0.5 cm margin. PTV44 was treated with parallel-opposed (anterior-posterior) fields and PTV60 was treated

with any combination of conformal fields, depending on the organ at risk constrains. The CTV 60 included GTV plus a 0.5 cm margin. For tumors situated in the inferior lung lobes, we used asymmetrical CTV margins and the longitudinal margins were 0.7-1.0 cm. The radiotherapy curative protocol for the treatment of microcellular lung cancer (limited disease) in our institution is based on a concurrent chemoradiotherapy approach or a sequential chemoradiotherapy approach.

We used platinum-based (with taxanes, pemetrexed, gemcitabine as a second cytostatic) first-line chemotherapy and a second-line monotherapy (docetaxel, gemcitabine pemetrexed), protocols conferring to the indication. Target therapies including erlotinib, crizotinib and second generation alectinib, as well as immunotherapy (first-line with chemotherapy, second-line, and monotherapy first line). These were all applied in selective lung cancer patients, per biomarker analyses results. Surgical treatments were performed at the University Clinic of Thoracic Surgery in Skopje, and we provided neoadjuvant, adjuvant chemotherapy, adjuvant radiotherapy and follow-up of these group of patients. Biomarker analyses were performed at the Institute of pathology (Medical faculty) in Skopje mostly at our request or at the request of a pulmonologist.

The statistical series were analyzed by determining the ratio of relations, proportions and ratios. Statistical significance between the detected differences was determined by the Chi-square test.

## RESULTS

Our study population consisted of 725 patients (562 men and 163 women) with lung cancer, treated between March 2019 until the end of February 2020 (pre-pandemic year) at the Lung Cancer Department, at the University Clinic of Radiotherapy and Oncology in Skopje. In the pandemic year, our study population consisted of 741 patients (545 men and 196 women) with lung cancer, treated between March 2020 and the end of February 2021 (pandemic year). We analyzed these two groups (pre-pandemic group and pandemic group) separately. In pre-pandemic group, 358 patients were between 60-70 years of age, 184 patients between 50-60 years, 142 above 70 years of age, and only 41 patients were under 50. The most common histology was non-small cell lung

cancer (NSCLC) which appeared in 544 (75%) patients and small-cell lung cancer (SCLC) in 130 (18%) patients, and undefined-unproven histology (without histology or cytology conformation) cases, where lung cancer diagnosis was determined with imaging methods only, were 51 (7%) patients. (Figure 1) Of all NSCLC patients, 50% had the adenocarcinoma subtype, 40% had squamous cell carcinoma, 2% were large cell carcinoma and 8% were NOS (not otherwise specified). According to the International Staging System for Lung Cancer, of the 544 NSCLC patients, 403 (74%) patients presented with stage III and IV (locally advanced and metastatic disease) and 141 (26%) patients with stage I and II (early stage disease). (Figure 2) We referred 181 patients (33%) from all NSCLC patients for biomarker analysis. In our study there were 12 patients proven with ALK positivity. Three patients from the ALK+ group did not receive any ALK TKIs.

Our pandemic lung cancer group consisted of 741 patients (545 men and 196 women) with lung cancer, treated between March 2020 until the end of February 2021 (pandemic group) at the Lung Cancer Department, at the University Clinic of Radiotherapy and Oncology in Skopje. In this COVID-19 year, 351 patients were between 60-70 years of age, 206 patients between 50-60 years, 132 above 70 years old, and only 52 patients were under 50. NSCLC tumors appeared in 531 (72%) of the patients, there were 129 SCLC patients (17%), and those with an undefined-unproven histology (without histology or cytology confirmation), where diagnosis was determined with imaging methods only, totaled 81 patients (11%) (Figure 3). The rate of undefined histology of lung cancer patients in the pandemic year was significantly different from pre-pandemic year (Chi-square = 43.722,  $p = 0.0003$ ). Of all SCLC patients, 65 were with limited disease and 64 were with extended disease. Of all NSCLC patients, 272 (51%) were of the adenocarcinoma subtype, 207 (39%) were squamous cell carcinoma, 15 (3%) large cell carcinoma and 37 (7%) were NOS (non-specified). Of the 531 NSCLC patients (according to the International Staging System for Lung Cancer), 449 (87%) patients presented with stage III and IV (locally advanced and metastatic disease) and 82 (13%) patients with stage I and II (early stage disease) (Figure 4). The rate of advanced stages for NSCLC patients in the pandemic year was significantly different from pre-pandemic year (Chi-square = 17.938,  $p < 0.05$ ). We focused on treatment strategies for lung cancer patients

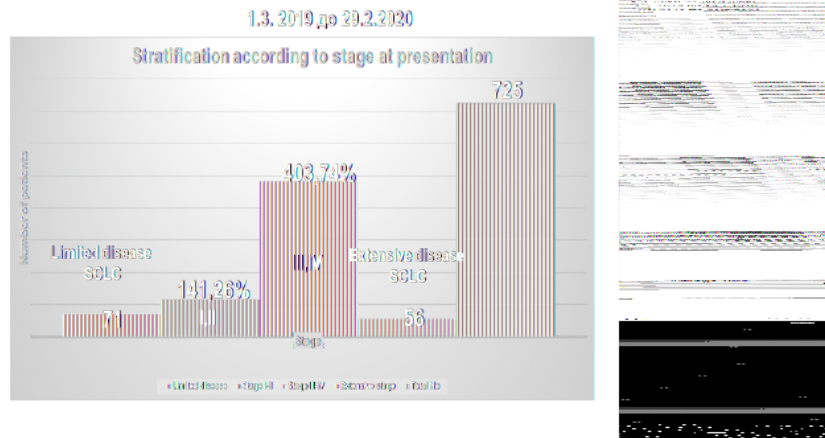


Figure 1. Histology segmentation for pre-pandemic lung cancer patients

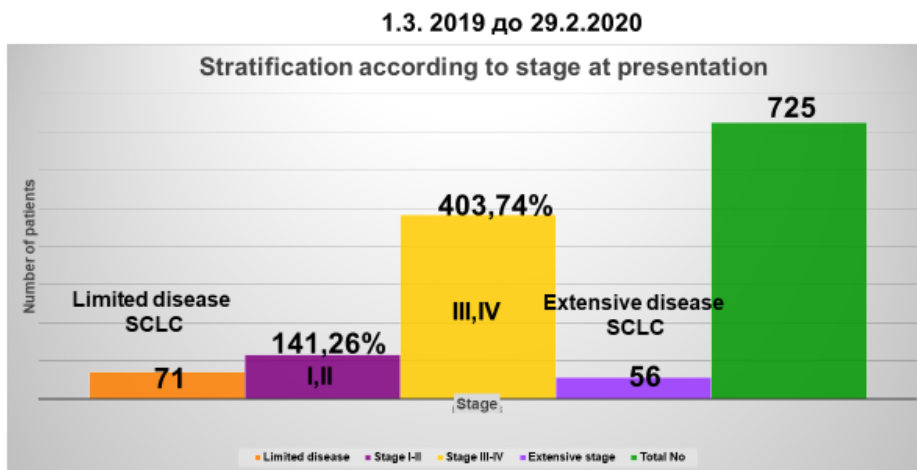


Figure 2. Stratification for lung cancer patients according the stage and presentation for pre-pre-pandemic year

Histology segmentation

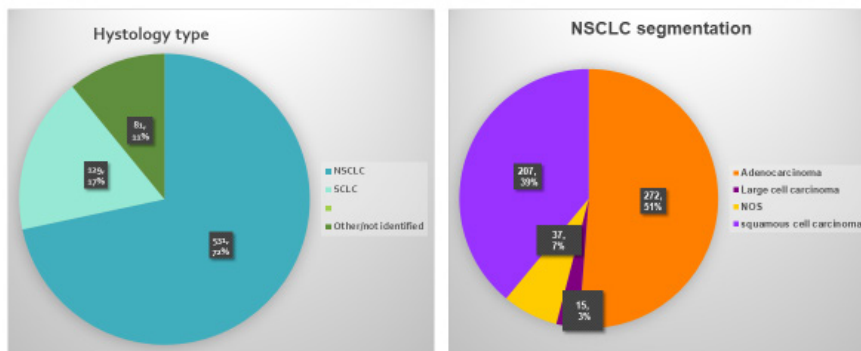
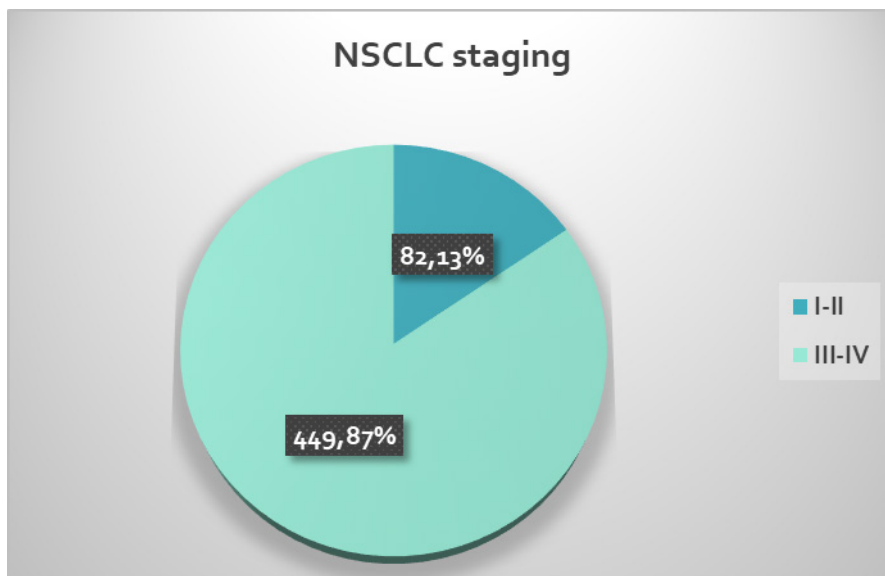
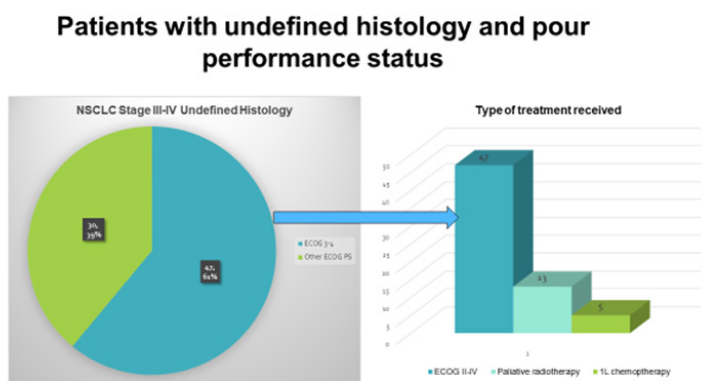


Figure 3. Histology segmentation for lung cancer patients, and sub segmentation for NSCLC patient during pandemic year

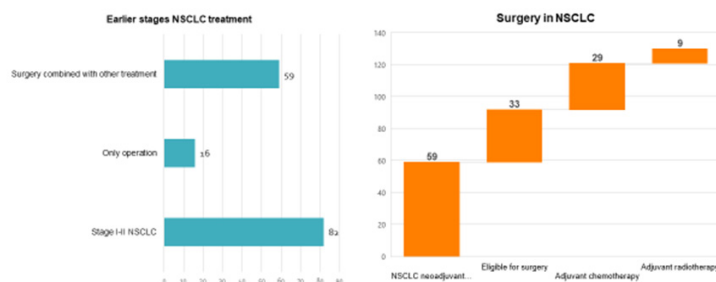


**Figure 4.** Stratification for lung cancer patients according the stage and presentation in the pre-pandemic year



**Figure 5.** Treatment options for lung cancer patients with undefined histology and poor performance status in pandemic year

**Surgery for NSCLC patients during pandemic year**



**Figure 6.** Treatment with surgery in lung cancer patients during pandemic year

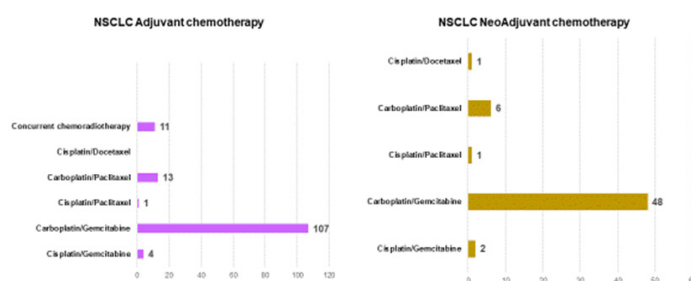
during the pandemic year. Patients with an undefined histology (Figure 5), mostly with an ECOG score 3-4, we treated with palliative radiotherapy and first-line palliative chemotherapy.

We referred 308 NSCLC patients (41.5%) for biomarker analysis in the pandemic year. We registered a statistically significant association between the rate of molecular testing in the pandemic year and pre-pandemic year. (Chi-square = 46.274,  $p = 0.00001$ ).

Considering the results of operated on patients in our study during the pandemic year, we can clearly distinguish the decreased total number of surgical cases. We have 123 (10%) patients treated with surgery in the pandemic year in comparison with pre-pandemic year, with total number of 218 (16%) surgically treated patients. We evaluated patients according to stage II-III and treatment and conducted with the use of neoadjuvant, adjuvant chemotherapy and adjuvant radiotherapy. The rate of curative surgery intervention in the pandemic year was significantly different from the pre-pandemic year (Chi-square = 40.714,  $p = 0.0001$ ).

In the COVID-19 year, we saw an increased number of patients with early stage IA, IB disease who performed only surgery without any additional oncological treatment and were only followed-up at our Clinic. That group consisted of 16 patients (Figures 6, 7). We have almost the same number of patients with proven ALK positivity in the pre-pandemic and pandemic years, and we did not register any statistically significant association between ALK status between pre-pandemic and pandemic years (Chi-square = 3.873038,  $p = 0.14427$ ). In the pre-pandemic group, 14 patients from this subset of patients were men and 4 were women. According to the treatment strategy, we treated 5 ALK positive patients with alectinib as a first line therapy, and 10 patients with alectinib as a second line therapy. Three patients from the ALK+ group, did not receive any ALKIs. Patients with ALK positivity from the pandemic year are presented in (Table 1). Furthermore, we noticed an increased total number of patients treated with

**NSCLC Neo&Adjuvant Treatment Setting in operated patients stage III NSCLC during pandemic years**



**Figure 7.** Treatment with adjuvant, neoadjuvant chemotherapy and adjuvant radiotherapy in operated lung cancer patients during pandemic year

## Treatment strategy for ALK + patients in pandemic year

Treatment strategy   ALK +	Male	Female	Total No of patients
I line with Alectinib	4	2	6
II line with Alectinib	5	6	11
without ALK- inhibitors	1	1	2
<b>Total No of patients</b>	<b>10</b>	<b>9</b>	<b>19</b>

**Table 1.** Treatment strategy for ALK+ patients during pandemic year

immunotherapy during the pandemic year. The reason for this was that in the previous year, testing for PDL-1 was not possible for all of the concerned patients, and our clinic struggled with the restricted amounts of immunotherapy drugs. During the COVID-19 year, we managed to provide first-line immunotherapy concurrently with chemotherapy and maintenance immunotherapy thereafter; sec-

ond-line immunotherapy and have gained some experience with mono-immunotherapy for PDL-1 high positive patients (Figure 8). Currently, we have one ROS-1 positive patient on crizotinib. We used radiotherapy for NSCLC and SCLC patients at our Clinic on the (Figure 9).

During the pandemic year, 22 of our patients were COVID-19 positive, of which 2 have died.

### Immunotherapy regimen in pandemic year

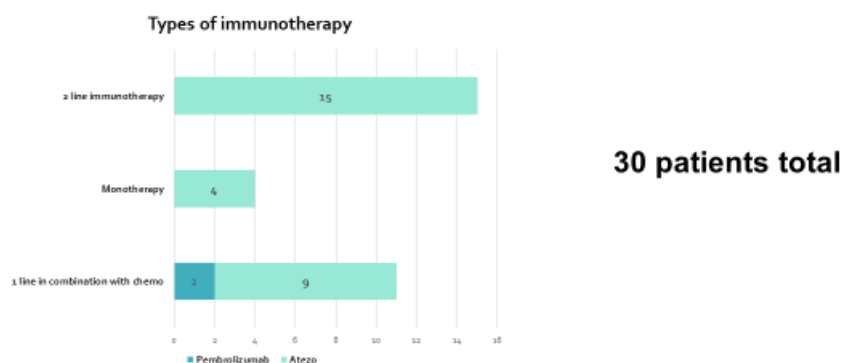


Figure 8. Immunotherapy regimen in lung cancer patients during pandemic year

### Radiotherapy regimen in pandemic COVID-19 year

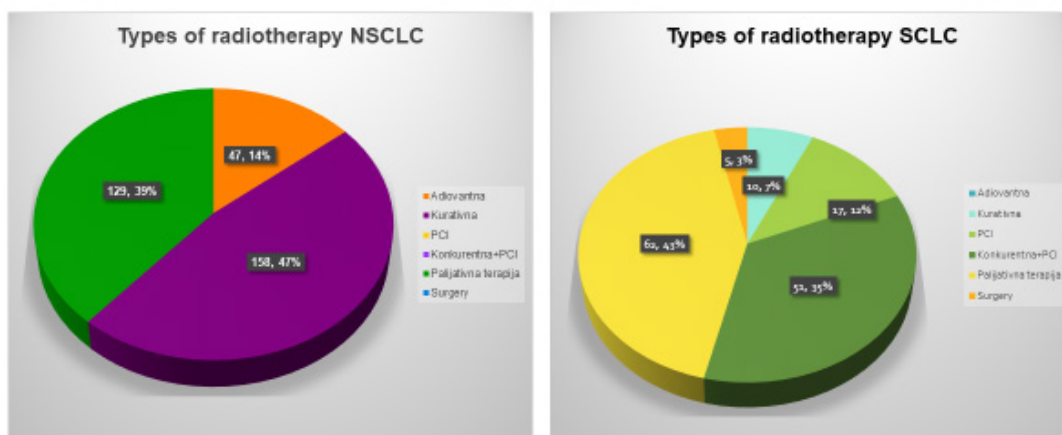


Figure 9. Radiotherapy regimen in pandemic year for NSCLC and SCLC patients during pandemic year

## DISCUSSION

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We would like to indicate that the regular treatment and follow-up of cancer patients during the new pandemic period has been affected [8]. The impact of the stress placed on the availability of medical resources and hospitals have reduced clinical admissions to most other departments, including oncology departments. Consequently, the benefits some cancer patients could have received have been compromised due to treatment delay. Systemic anticancer treatment has significantly changed as a result of the pandemic [9]. Our Clinic opted for continuous work without any reduction. We did not reduce inpatient and outpatient treatment, as seen from the results in this retrospective study. The total number of lung cancer patients at our department in the pre-pandemic year was 725, from a total number of 830 patient treated in the pre-pandemic year, and in the pandemic year, lung cancer patients were 741, from total number of 849 cancer patients with other thoracic malignancies. In the face of the pandemic, primary care in N. Macedonia, as was worldwide, adapted rapidly. This included a significant digital transformation to remote consultations with significantly less face-to-face contact. Whilst there are many positives to these changes, there are concerns that remote consultations may increase health inequalities, and impact on doctor–patient relationships, and continuity of care, especially for lung cancer patients [10]. Patients may be reluctant to disclose some health problems by phone or online, including symptoms of serious disease, such as lung cancer. Whilst urgent referrals are still operating, many patients with potential cancer symptoms do not meet referral thresholds, and for those with vague symptoms, routine secondary care referrals have been significantly impacted. The observed reductions and potential delays in screening, urgent and routine referrals are likely to lead to significant additional lung cancer patients in locally advanced and metastatic stages [11]. Lung function, bronchoscopy procedures and image-guided biopsies are the cornerstone of lung cancer diagnostics. In our country, these procedures were significant casualties of the COVID-19 pandemic with all but the most essential procedures stopping in some centers. Only the University Clinic of Pulmonology con-

tinues without any stoppage. As services reopen, the demand for these tests will increase, but the capacity will remain reduced. Rigorous infection control procedures are being implemented that require both pre-procedure COVID-19 testing and fewer procedures completed per session [12]. This is likely to lead to longer diagnostic pathways and may negatively impact early diagnosis in the curable stages of the disease. In our study, we confirmed this problem of delay with the increased number of undefined lung cancer patients without any pathological or histological confirmation (11% this year compared to 7% in the previous year). These groups of patients had poor performance status and were not suitable for any oncological treatment. The large number of unproven histological or cytological, but otherwise obvious, cases of lung cancer patients seen through imaging methods is mainly due to the COVID-19 lockdown period, non-acceptance of patients by the services and their disorganization, lack of information from family doctors whose services work, and where patients go for diagnosis. At the same time, the disease was so widespread in these patients that they were not able to undergo invasive diagnostic procedures. For most of them, their families came to our Clinic alone, bringing the results of the imaging examinations and informing us about the severity of the symptoms of their loved ones, requesting only supportive and symptomatic therapy.

We also confirmed delays in the managing pathways for lung cancer diagnosis. We found an increased number of stage III and IV NSCLC patients in the pandemic year, namely 449 (87%) patients who presented with (locally advanced and metastatic disease) of NSCLC. This stands in comparison to the pre-pandemic year, when we treated 403 (74%) with stage III and IV [13, 14]. We also noticed a decreasing number of stage II NSCLC patients in the pandemic year, at 82 (13%) compared to 141 (26%) patients in pre-pandemic year. Throughout the course of the pandemic, thoracic surgical units in our country sought to maintain appropriate elective and emergency activity. However, the recognition of thoracic surgery as being involved with the induction of anesthesia through to and beyond extubation has had a significant impact on the reduction of surgical activities for lung cancer patients. We proved this finding in our study by reporting a decreasing number of operated on patients with NSCLC: from 218 in the pre-pandemic year to the 123 in the pandemic year. But



we also report an increasing number of early stage IA and stage IB numbers, 16, treated by surgery without need for any additional oncological treatment. This group of patients explains the accidental diagnosis of lung cancer disease during routine COVID-19 examinations. This group of patients have benefitted from the pandemic year [15]. We think that the reason for the large number of operated on patients with early stage IA and IB lung cancer in the pandemic year is due to the more frequent radiographic examinations when there is little suspicion of COVID-19 symptoms or contact with a COVID patients. In these early stages in our country, sublobar resection or lobectomy is applied while stereotactic radiotherapy is not applied yet.

The COVID-19 protocol at our Clinic has been implemented as to not avoid chemotherapy and not to minimize the need to attend hospital for inpatient and outpatient purposes. Non-curative chemotherapy-based treatments and palliative radiotherapy with a lower chance of palliation or tumor control (e.g., relapsed non-small cell lung cancer - NSCLC) did not cease [16] and were not delayed. Chemo-immunotherapy regimens for first-line NSCLC for patients with PD-L1 positivity and maintenance treatments have continued at the same pace [17]. We noticed an increased total number of patients treated with immunotherapy during the pandemic year. The reason for this was that in the previous year, testing for PDL-1 was not possible for all of the concerned patients, and with our Clinic struggled with the restricted amounts of immunotherapy drugs. During the COVID-19 year we managed to provide first-line immunotherapy concurrently with chemotherapy and with maintenance immunotherapy thereafter; second-line immunotherapy. We have also gained some experience with mono-immunotherapy for PDL-1 high positive patients. We referred 308 NSCLC patients (41.5%) for biomarker analysis in the pandemic year, which provided us the ability to perform better personalized therapy for lung cancer patients in our country. In the pre-pandemic year, we admitted only 181 (25%) patients for molecular testing.

Radiotherapy fractionation schedules and post-treatment follow-up protocols have not changed [18, 19, 20, 21].

## CONCLUSIONS

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We faced diagnostic problems presented by an increase in the number of patients with advanced stages and undefined cases of lung cancer in the pandemic year as well as a decrease in the number of operated on cases.

The strict screening and admittance criteria put in place by hospitals during the pandemic might have improved the oncology treatment course of lung cancer patients. Once the routine treatment process is interrupted, the tumor can progress, which increases mortality rate in lung cancer patients.

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## Резиме

### ПРЕГЛЕД НА КАРАКТЕРИСТИКИТЕ И ТРЕТМАНОТ НА БОЛНИТЕ СО БЕЛОДРОБЕН КАРЦИНОМ ВО ТЕК НА ГОДИНАТА СО КОВИД-19 Третирани на Универзитетската клиника за радиотерапија и онкологија во Скопје

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Целта на студијата беше да ги прикаже карактеристиките на болните со белодробен карцином и третманската стратегија на овие болни лекувани на Универзитетската клиника за радиотерапија и онкологија во текот на препандемиската и пандемиската година со Ковид-19.

Забележавме зголемување на бројот на недефинирани случаи со белодробен карцином, односно случаи без хистолошка потврда во пандемиската година (11 % во пандемиската година споредбено со 7 % во претходната година), и зголемување на бројот на болни со напреднати стадиуми на болест, стадиум III и IV NSCLC, во пандемиската година 449 (87 %) болни со NSCLC, во споредба со 403 (74 %) во препандемиската година. Воедно, регистриравме намален број болни со стадиум II на NSCLC во пандемиската година 82 (13 %) во компарација со 141 (26 %) болни во препандемиската година. Вкупниот број оперирани болни во пандемиската година се намали од 218 на 123 во пандемиската година. Меѓутоа, бројот на оперирани болни со многу рани стадиуми, стадиум IA и стадиум IB беа зголемени, како резултат на случајни наоди при прегледи за Ковид-19.

**Заклучок:** Во текот на пандемиската година со Ковид-19 се судривме со зголемување на бројот на болни со напреднати стадиуми на белодробен карцином и со недефинирани хистолошки случаи, а намален вкупен број оперирани болни со оваа болест. Строгите критериуми за скрининг и прием во болниците за време на пандемија можат да го подобрат онколошкиот третман на болните со белодробен карцином.

**Клучни зборови:** Ковид-19, белодробен карцином, препандемиска година, пандемиска година