

ORIGINAL ARTICLE

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General characteristics and prognostic factors of lung cancer in women

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Abstract

Lung cancer has emerged as a major health problem among women, with smoking being the leading risk factor in both genders. This study aimed to evaluate the clinical and demographic characteristics of lung cancer in women and their impact on survival. A total of 110 female patients diagnosed and treated at the chest diseases clinic were retrospectively analyzed. Clinical features and their associations with survival were assessed. Among the cases, 72.7% (n=80) were diagnosed with non-small cell lung cancer (NSCLC) and 27.3% (n=30) with small cell lung cancer (SCLC). The mean age was 63.45±11.10 years for NSCLC and 60.57±9.42 years for SCLC patients. Smoking history was present in 40% of the cohort, and 98% were symptomatic at diagnosis. Performance status was determined according to the Eastern Cooperative Oncology Group (ECOG), with most patients initially categorized as ECOG 0. Distant metastases were observed in 78% of patients, and adenocarcinoma was the most frequent histopathological subtype (61.4%) among NSCLC cases. According to the TNM 7th staging system, 65% of NSCLC patients presented at stage IV. Multivariate analysis revealed that advanced age, smoking, advanced stage, leukocytosis, metastasis, and poor ECOG performance were independently associated with poor prognosis in NSCLC. Furthermore, thrombocytosis was also linked to unfavorable survival outcomes. In conclusion, in female patients with lung cancer, smoking, advanced age, late-stage presentation, poor performance status, and the presence of metastasis, leukocytosis, or thrombocytosis negatively affect survival.

Keywords: Lung cancer in women, survival, prognostic factors

Introduction

Lung cancer is one of the most common cancers worldwide and the most common cause of death. According to the World Health Organization (WHO) data, approximately 2.2 million new lung cancer cases were detected in 2020 [1]. In Türkiye; according to the Ministry of Health's 2018 cancer statistics, the lung cancer incidence rate is presented as 55 cases per 100 thousand people in men and 10 cases per 100 thousand people in women.

According to these data, lung cancer is the most common type of cancer seen in men. In women, it is the fourth most common type of cancer after breast, colorectal and thyroid cancers. Lung cancer has serious mortality rates all over the world and in our country [2].

There is still limited data on lung cancer in women in our country and in the world. Based on this lack of data, we examined female

patients who applied to Ankara University Faculty of Medicine Chest Diseases, were diagnosed with lung cancer and treated. We examined the demographic characteristics of female lung cancer patients, the relationship between smoking history and the disease, their complaints during the disease, laboratory findings at the time of application, the frequency of lung cancer pathological types, the stages of the patients at the time of diagnosis, the relationship between stage and histological type and the course of the disease, survival, and the factors affecting survival, and we present these with up-to-date literature information.

Material and Methods

The study between 2005 and 2009; 110 female patients who applied to the chest diseases clinic, were diagnosed with lung cancer and treated were included. The study was approved by

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the Ankara University Faculty of Medicine Clinical Research Ethics Committee (Number: 154-4898, Date: 29/06/2009). As our study was retrospective in nature and involved no direct contact with patients, the requirement for informed consent was waived by the ethics committee. The study was conducted retrospectively by scanning the patient files. The inclusion criteria for the study were determined as; lung cancer diagnosis was made histopathologically and the patients' survival time was determined. Most of the cases included in the study were diagnosed, treated and followed up in our clinic. We aimed to investigate the effects of factors such as biochemical and hematological parameters, age, symptoms on presentation, performance status, disease stage, cancer histopathology, whether or not the female patients received treatment, if received treatment type, metastasis status on survival and their prognostic importance determined before treatment. The criteria in the ECOG scale were applied to evaluate the patients' performance status. The WHO 2004 classification was taken as basis for histopathological classification. The treatment methods given were determined as chemotherapy, radiotherapy, surgery, chemoradiotherapy. Disease stage; The 1997 Mountain TNM staging system was used when they were diagnosed. The factors that may affect survival were the patient's age at diagnosis, smoking and asbestos exposure, complaints at presentation, histological type of lung cancer, stage of the disease, metastasis status, performance status at diagnosis, treatment received, hemoglobin level at diagnosis, white blood cell count, platelet count, erythrocyte sedimentation rate, serum calcium level, lactate dehydrogenase (LDH), aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP) levels.

Statistical Method

Statistical Package for Social Sciences (SPSS, Inc. Chicago, IL, USA) 15.0 for Windows program was used for statistical data analysis. The research data were processed on the computer, statistical analyses were performed, and the results were organized in tables and graphs. The survival averages of the study groups were calculated using the Kaplan-Meier method. Survival times were expressed in months and Kaplan-Meier survival graphs were drawn. The differences between subgroups were tested using the log rank method. A p value of less than 0.05 was considered significant in the study.

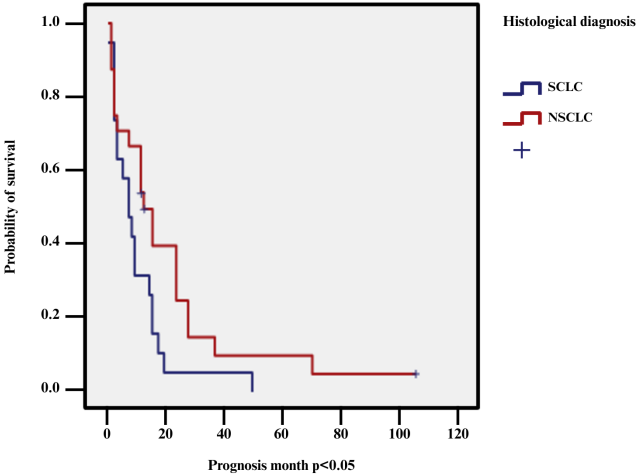
Results

The study included 80 patients diagnosed with non-small cell lung cancer (NSCLC) (72.7% of all patients) and 30 patients diagnosed with small cell lung cancer (SCLC) (27.3% of all patients). Three of the SCLC cases and seven of the NSCLC cases were alive when our study was completed. Therefore, 100 patients were used as the basis for survival analysis.

After obtaining the patient data; evaluations were made according to the pathological typing of NSCLC and SCLC. The mean survival time for 27 patients diagnosed with SCLC was 11.58±2.29 months, the median survival time was 8 months, and the mean survival time for 73 patients diagnosed with NSCLC was 16.73±2.33 months and the median survival time was 12 months. When the cell type was

taken into account, the survival time in NSCLC cases was found to be statistically significantly higher than in SCLC cases (p<0.05). When smoking history was examined, 60% (n=66) of the 110 patients had never smoked, 11.8% (n=13) had quit smoking and 28.2% (n=31) were actively smoking at the time of diagnosis. 66.6 % (n=20) of the cases diagnosed with SCLC had active smoking exposure. This rate was 30% (n=24) for NSCLC. The relationship between smoking and cell type was statistically significant in favor of SCLC (p=0.002).

The mean survival time in smokers with SCLC was 8±2.1 months and in smokers with NSCLC, the mean survival time was 13±3 months. The prognosis in smokers with SCLC was lower than in smokers with NSCLC. This finding was statistically significant (p=0.04) (Graph 1).



Graph 1. Survival status in smoking cases with SCLC and NSCLC

At the time of diagnosis, 98% of 110 patients were symptomatic. The most common symptoms were cough, shortness of breath, chest pain and weight loss (Figure 1). The most common method used for diagnosis in patients was bronchoscopic forceps biopsy (Figure 2). In metastasis screenings performed after diagnosis, distant organ metastasis was detected in 68.1% (n=75) of 110 patients. Distant organ metastasis was present in 73.3% (n=22) of SCLC cases and 66.3% (n=53) of NSCLC patients (Figure 3).

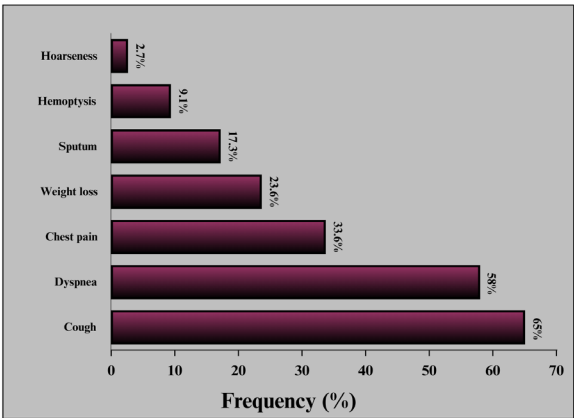


Figure 1. Symptoms seen at the time of diagnosis and their frequency

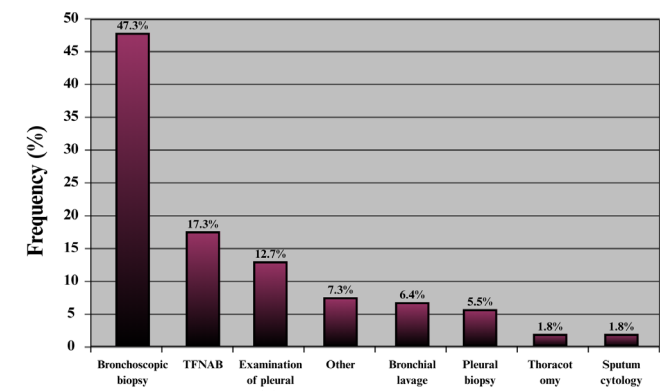


Figure 2. Diagnostic method used

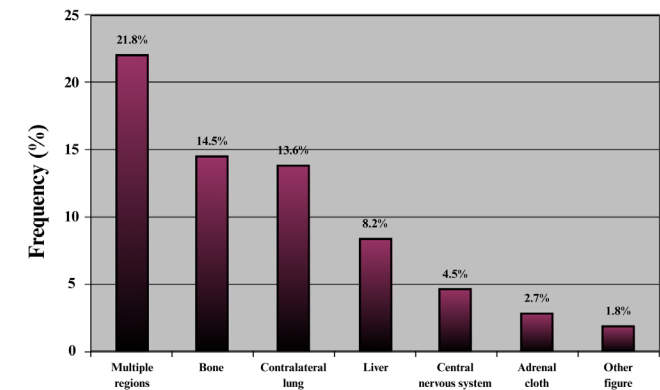
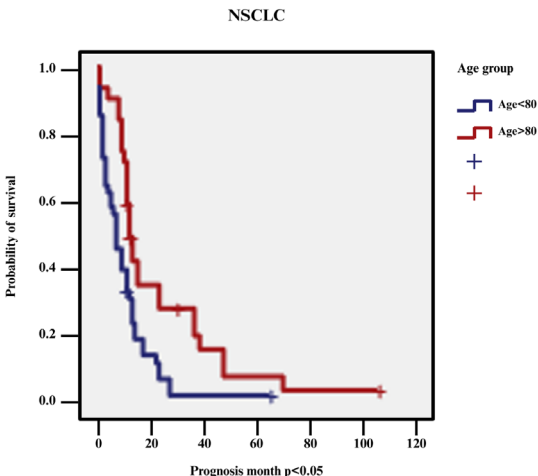


Figure 3. Metastasis status of patients at diagnosis

Survival analysis of the patients was performed according to histopathological cell type. 80 patients diagnosed with non-small cell lung cancer were included in the study. The mean age of the patients was calculated as 63.45 ± 11.10 years. When the effect of age on survival was examined, the average survival time was longer in patients under 60 years of age than in those over 60 years of age. The positive effect of the young age factor on survival in NSCLC cases was statistically significant ($p=0.002$). (Table 1, Graph 2).



Graph 2. Relationship between age and prognosis in patients with NSCLC

When smoking history was examined, it was determined that 70% ($n=56$) of NSCLC patients had never smoked, 22.5% ($n=18$) were active smokers, and 7.5% ($n=6$) had quit smoking

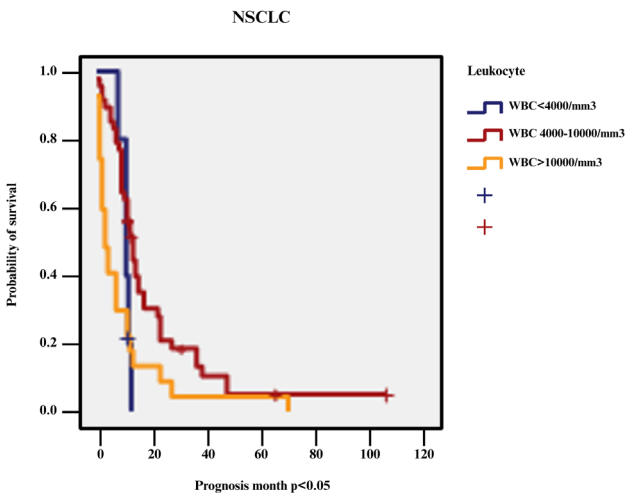
before diagnosis. No statistical significance was found in terms of survival between patients with a smoking history and those who had never smoked ($p=0.13$) (Table 1).

NSCLC was divided into histopathological subtypes and 10% ($n=9$) were squamous cell, 61.4% ($n=48$) were adenocarcinoma, and in 28.4% ($n=23$) cases, the tumor type could not be determined histopathologically. The mean survival time in patients diagnosed with adenocarcinoma was 12 ± 1.2 months, and in the squamous cell and undetermined group, survival was 12 ± 2.1 months. Survival was not statistically significant between different histopathological types ($p=0.07$) (Table 1).

When the patient distribution according to stages was examined; almost 85% of NSCLC patients were detected as advanced stage (stage IIIB, IV) at the time of diagnosis. During the survival study, stages 0, I, II, IIIA were included in the same group because they were early stages. In patients classified as early stage (stage I, II, IIIA), the mean survival time was found to be statistically significantly longer than in cases of stage IIIB and stage IV ($p=0.011$) (Table 1).

In NSCLC cases; the effect of tumor size on survival was examined. Since the number of patients was not sufficient, T1 and T2 were included in the same group and grouping was performed. The number of patients in T1 and T2 groups was $n=22$ (27.5%), the number of patients in T3 was 17 (21.2%) and the number of patients in T4 was 41 (51.3%). When the mean survival time T determinant was considered, the short survival time in patients included in the T4 group in NSCLC was found to be statistically significantly longer than in the T1+T2 and T3 groups ($p=0.009$) (Table 1).

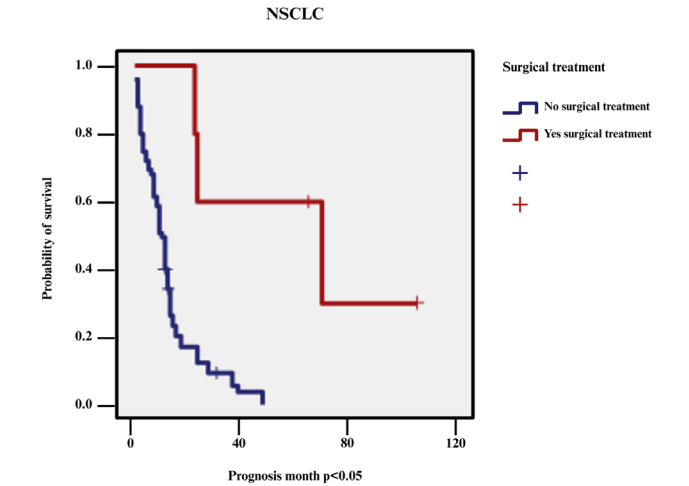
The laboratory tests performed at the time of diagnosis of all patients were examined. The effects of each of the blood hemoglobin, leukocyte, platelet, erythrocyte sedimentation rate, serum AST, ALT, LDH, and ALP values on prognosis were examined separately. Of these values, only the mean survival time in the patient group with high leukocyte count was found to be significantly lower than in patients with normal and low leukocyte counts ($p=0.003$) (Table 1, Graph 3).



Graph 3. The relationship between leukocytosis and prognosis in patients with NSCLC

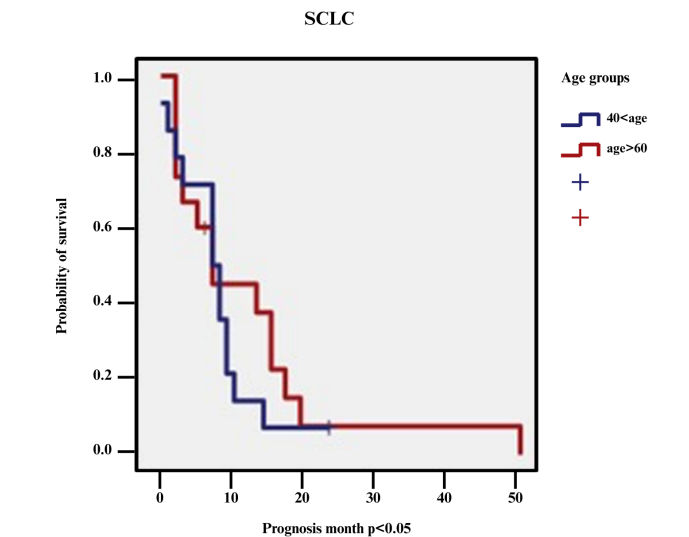
The effects of the ECOG performance status of the patients at the time of diagnosis and the metastasis status of the disease at the time of diagnosis on survival were examined. In patients with poor performance status 2 and above and patients with metastasis in any region at the time of diagnosis, short survival time was found to be statistically significant according to Long rank analysis ($p=0.000$, $p=0.021$) (Table 1).

After diagnosis, 10.3% ($n=11$) of the patients with NSCLC did not accept any treatment method and were followed up without treatment. Only surgery was applied to 6.25% ($n=5$) of the cases, and 73.7% ($n=64$) of the cases were given a treatment protocol including KT and/or RT. The mean survival time in patients who received surgical treatment was found to be statistically significant ($p=0.001$) (Table 1, Graph 4).



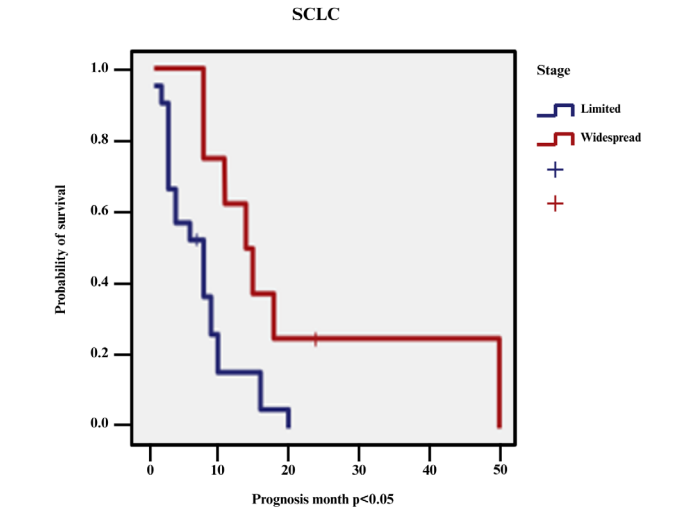
Graph 4. Surgical treatment-prognosis relationship in NSCLC

The findings in small cell lung cancer cases; the mean age of thirty patients was found to be 60.57 ± 9.42 years. The effect of age factor on survival was not significant ($p=0.44$) (Table 2, Graph 5).



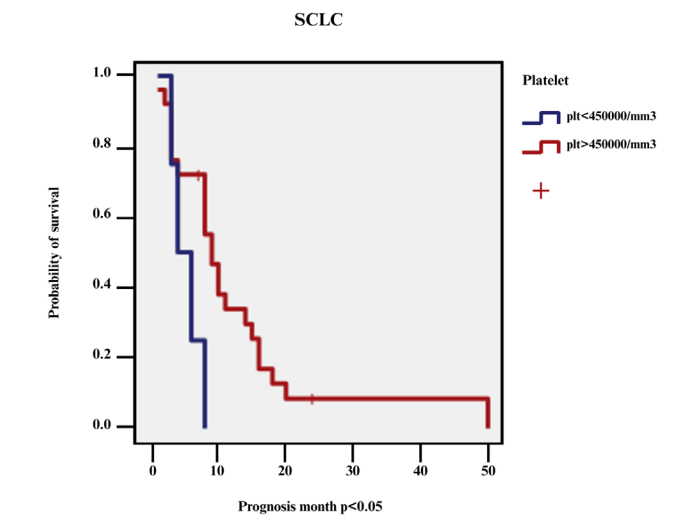
Graph 5. Relationship between age and prognosis in cases with SCLC

At the time of diagnosis, 23.3% ($n=7$) of the SCLC patients had limited disease and 76.7% ($n=23$) had extensive disease. Survival times were statistically significantly higher in the limited disease group ($p=0.014$) (Table 2, Graph 6).



Graph 6. Stage-prognosis relationship in cases with SCLC

From the laboratory examinations of the SCLC patients; the possible effects of blood hemoglobin, leukocyte, platelet, erythrocyte sedimentation rate, serum AST, ALT, LDH, ALP values on survival were examined. Only the presence of thrombocytosis had a negative effect on survival ($p=0.04$) (Table 2, Graph 7).



Graph 7. Relationship between thrombocytosis and prognosis in cases with SCLC

In SCLC, just like in NSCLC cases, low survival was statistically significant in those with ECOG performance status 2 and above ($p=0.000$) (Table 2).

23.3% ($n=7$) of SCLC cases were defined as limited disease and 76.7% ($n=23$) as metastatic disease. Survival time was observed to be low in cases with metastasis. This was statistically significant ($p=0.014$) (Table 2).

Table 1. Characteristics of female cases with non-small cell lung cancer

Characteristics of patients		Number of patients	Percentage (%)	Median survival time (months)	p
Age	<60 age	32	40	13.00±1.05	0.002*
	>60 age	48	60	8.00±1.29	
Histology	Adeno	49	61.25	12.00±1.24	0.076
	Other	31	38.75	12.00±2.19	
Stage	1. (EI+EIH+EIHA)	11	13.9	24.00±0.48	0.011*
	2. (EIIIB)	17	21.3	12.00±2.95	
	3. (EIV)	52	65.0	10.00±1.02	
Tumor size	T1+T2	22	27.6	13.00±280	0.009*
	T3	17	21.3	13.00±3.17	
	T4	41	51.3	8.00±2.56	
Metastasis	Yes	53	66.2	10.00±1.03	0.021*
	None	27	33.8	14.00±1.60	
WBC	≤4000/mm ³	5	6.2	12.00±1.60	0.003*
	4000-10000/mm ³	48	60	14.00±1.26	
	>10000/mm ³	27	33.8	4.00±1.03	
Hemoglobin	≤12 g/dl	35	43.8	9.00±1.10	0.095
	>12 g/dl	45	56.3	13.00±0.80	
Platelet	≤450000 /mm ³	63	78.8	12.00±1.10	0.35
	450000/mm ³	17	21.3	10.00±1.11	
AST	≤40 U/l	70	87.5	12.00±1.09	0.84
	40 U/l	10	12.5	6.00±3.95	
ALT	≤40 U/l	70	87.5	12.00±0.95	0.60
	>40 U/l	10	12.5	9.00±4.74	
ALP	≤115 U/l	48	60	12.00±1.28	0.50
	115 U/l	32	40	10.00±2.24	
LDH	≤200 U/l	16	20	12.00±1.98	0.99
	>200 U/l	64	80	12.00±1.08	
Sedimentation	Normal	20	25	12.00±2.87	0.37
	High	60	75	11.00±1.16	
Performance status	Good	73	91.2	12.00±0.75	0.00*
	Bad	7	8.8	2.00±0.65	
Chemotherapy treatment	Taken	62	77.5	6.00±3.12	0.60
	Not taken	18	22.5	12.00±0.77	
Radiotherapy treatment	Taken	15	18.3	8.00±3.22	0.18
	Not taken	65	81.3	12.00±0.77	
Surgical treatment	Taken	5	6.3	70.00±36.60	0.001*
	Not taken	75	93.8	11.00±0.92	

*p<0.05, WBC: white blood cell, AST: aspartat amino transferase, ALT: alanine aminotransferase, ALP: alkaline phosphatase, LDH: lactate dehydrogenase

Table 2. Characteristics of female cases with small cell lung cancer

Characteristics of patients		Number of patients	Percentage (%)	Median survival time	P
Age	<60 age	15	50	8.00±1.76	0.44
	>60 age	15	50	8.00±1.80	
Stage	Limited	7	23.3	14.00±2.82	0.014*
	Prevalent	23	76.7	8.00±2.10	
Metastasis	Yes	23	76.7	8.00 ±2.10	0.01*
	No	7	23.3	14.00 ±2.82	
Hemoglobin	≤12 g/dl	11	36.7	6.00±2.20	0.74
	>12 g/dl	19	63.3	8.00±1.69	
Platelet	≤450000/mm ³	26	86.7	9.00±1.20	0.04*
	>450000/mm ³	4	13.3	4.00±1.50	
AST	≤40 U/l	22	73.3	10.00±1.44	0.24
	>40 U/l	8	26.7	3.00±0.00	
ALT	≤40 U/l	22	73.3	10.00±1.44	0.24
	>40 U/l	8	26.7	3.00±0.00	
ALP	≤115 U/l	20	66.7	8.00±1.23	0.23
	>115 U/l	10	33.7	8.00±3.95	
LDH	≤200 U/l	7	23.3	8.00±3.20	0.96
	>200 U/l	23	76.7	8.00±1.32	
Sedimentation	Normal	9	30	8.00±1.60	0.27
	High	21	70	9.00±1.06	
Performance status	Early	24	80	10.00±1.14	0.000*
	Late	6	20	3.00 ±0.00	
Radiotherapy treatment	Take	6	20	8.00±0.00	0.89
	No take	24	80	8.00±1.6	

*p<0.05, AST: aspartat amino transferase, ALT: alanine aminotransferase, ALP: alkaline phosphatase, LDH: lactate dehydrogenase

Discussion

Lung cancer; while it was a rare disease until the beginning of the twentieth century, it has become an important health problem with an increasing frequency today [3]. When the incidence of the disease is examined from a historical perspective; it is known that it is more common in men than in women. With the increase in the smoking rate in women, the male/female ratio in the incidence of the disease has decreased over time. Although the prevalence of smoking has decreased from 40% in the second half of the 20th century to 12% in the 21st century, smoking is still the most important cause of lung cancer [4].

Smoking is the most important cause of lung cancer in both sexes. While smoking is responsible for 85% of lung cancer cases in men, this rate is 75% in women [5]. In developed countries such as the USA, the smoking rate has decreased since the beginning of the 21st century. In proportion to this, the lung cancer rate has

also decreased by 10%. Between 2011 and 2015, lung cancer incidence rates decreased by 3% per year in men and 1.5% per year in women [6]. In Türkiye, the smoking rate is 41.3% in men and 15.5% in women, but it has been observed that the smoking rate in women has increased in the last 10 years. While the lung cancer rate in men has decreased in the last 10 years, it continues to increase in women [2,7]. It is thought that this increase is significantly related to the increase in tobacco use in women. In our study, the smoking rate in women was 40%, which was found to be quite high compared to the rates in our country.

Whether women are more sensitive to the carcinogenic effects of smoking than men is still a matter of debate. Although some studies have reported increased sensitivity against women, a large meta-analysis has been presented on this subject. According to the results of this study, it has been stated that smoking is associated with lung cancer at similar rates in women and men

[1,8]. The reason for this is that the CYP1A1 enzyme, which can cause mutations on DNA, is detected more in women who smoke compared to men [9]. In addition, the mutation-causing activity of the glutathione S-transferase M1 enzyme has been detected twice as much in women as in men [10]. Other causes of lung cancer in women may be; air pollution in open and closed environments, passive smoking, radon and asbestos exposure. The fact that most cases with lung cancer who are not exposed to tobacco are women and especially Asian indicates that there is an intersection between tobacco, gender and race [11].

The risk of lung cancer increases with increasing age in both sexes. Diagnosis at an older age is associated with a shorter life expectancy [4]. Lung cancer is thought to occur at an older age in women than in men [12,13]. There may be many reasons for this situation. The fact that women start smoking at an older age than men can be listed as histological subtype differences, environmental exposures, problems accessing the health system and hormonal factors [14,15]. Two separate studies conducted in our country on this subject support the fact that lung cancer occurs at a later age in women than in men [16,17].

In our study, the mean age of the patients at the time of diagnosis was found to be 62, and 57.3% of the cases were found to be over 60 years of age, and the survival rates of older patients were observed to be low.

Lung cancer is histopathologically divided into two large groups as non-small cell lung carcinoma (NSCLC) and small cell lung carcinoma (SCLC). NSCLC; It constitutes 80-85% of lung cancers. Approximately 40% of these are adenocarcinomas [18]. Adenocarcinoma type; It is the most common type among women who do not smoke, smoke less or are passive smokers. It is also the cancer type whose relationship with the estrogen hormone is more clearly understood [19,20]. While squamous cell carcinoma was the most common type in both genders until the end of the 20th century, it has been replaced by adenocarcinoma in the last 30 years. The change in histological types is thought to be largely related to the type of filtered cigarette used [20,21]. In our study, histopathological typing was found to be 72.77% non-small cell lung cancer and 27.3% small cell lung cancer, which is consistent with the literature. In addition, 51.8% of patients diagnosed with NSCLC had adenocarcinoma and the smoking rate was found to be low at 22% in this histopathological type, which is consistent with the literature. It is known that laboratory values are effective in showing the course of lung cancer and predicting the response to treatment. In particular, high LDH, an indicator of high tumor burden at the time of diagnosis, and serum albumin levels associated with poor nutrition-poor performance scores were found to be compatible with short survival times [22]. In a comprehensive meta-analysis conducted in 2020, it was found that high platelet levels at the time of diagnosis in lung cancer cases were associated with short survival [23]. In another study, patients with high leukocyte values at the time of diagnosis; It has been determined that they are in advanced stages and have poor ECOG performance status, which is associated with poor

prognosis [24]. In our study, high leukocyte count at the time of diagnosis in NSCLC cases and high platelet count in SCLC cases were found to be compatible with lower survival.

In lung cancer, more than 90% of cases are symptomatic at the time of diagnosis due to local, regional, metastatic or systemic effects of the tumor. The most common symptoms are cough, dyspnea, weight loss and chest pain [25,26]. In our study, 98% of patients were symptomatic at the time of diagnosis and the most common symptom was cough.

In all histopathological types of lung cancer; the stage of the disease at the time of diagnosis and the patient's performance status are the most important prognostic factors. As the stage increases and the performance status worsens, the expected survival decreases. The 5-year relative survival rate for NSCLC is 90% for stage 1A1, while this rate drops below 10% for stage 4. Among patients with SCLC, the 5-year relative survival rates are approximately 30% for limited disease and below 10% for extensive disease [26]. Studies have reported that NSCLC metastasis is more common in female patients. The reason for this; the most common histopathological type is adenocarcinoma. Adenocarcinoma is often located in the peripheral region and therefore the symptoms related to the disease appear at a more advanced stage, that is, metastatic [27]. In our study, 80% of NSCLC cases were found to be advanced stage and 73% of SCLC cases were found to have disseminated disease at the time of diagnosis. Metastatic sites; The most common sites of metastasis in SCLC are bone and liver, and in NSCLC, liver, adrenal and brain involvement [28,29]. In our study, the most common sites of metastasis were liver for SCLC and bone for NSCLC.

In women, the treatment of lung cancer is determined by histological subtypes, stage of disease, genetic mutations and patient performance status. Treatment for small cell lung cancer is surgery and adjuvant platinum-based chemotherapy for early-stage disease. Concurrent platinum-based chemotherapy is recommended for locally advanced disease. Patients with metastatic disease are treated with systemic chemotherapy with or without immunotherapy [30]. Treatment for non-small cell lung cancer is related to the stage of the disease, its molecular profile and the patient's performance status [31]. NSCLC is generally associated with poor outcomes due to late diagnosis and limited treatment options [32]. In recent years, targeted therapies, advances in immunotherapy and opportunities for earlier-stage diagnosis have prolonged survival [33]. The standard treatment for patients with NSCLC is surgery for Stage I and II. Stage III is a heterogeneous group and surgical outcomes are poor for N2 and multinodal disease. Stage IIIB and Stage IV are not suitable for resection. After surgery for stage I NSCLC, mortality rates are lower in women and 5-year overall survival is thought to be higher in women than in men [34]. In NSCLC, only a minority of patients are eligible for curative lung resection because of early metastasis. These cases require adjuvant platinum-etoposide chemotherapy.

Therefore, most patients are currently treated with chemoradiotherapy with or without immunotherapy. In those with disease limited to the thorax, standard treatment includes thoracic radiotherapy and concurrent platinum-etoposide chemotherapy. Cases with metastatic disease are treated with a combination of immunotherapy with anti-programmed death ligand 1 monoclonal antibody and platinum-etoposide chemotherapy [29].

Conclusion

Lung cancer continues to be a significant health problem, with its incidence increasing especially in people over the age of 60. Age stands out as an important variable to be considered in treatment planning.

Smoking continues to play a central role in lung cancer etiology. The relatively high smoking rate (approximately 40%) among our female patients—compared to the national average—highlights an urgent need for targeted smoking cessation programs.

Adenocarcinoma was the most common histological subtype in our study, consistent with global trends in female lung cancer populations. Our results also demonstrate that clinical factors such as leukocytosis, thrombocytosis, and poor performance status (ECOG $\geq$ 3) are associated with worse survival, emphasizing their importance in prognostic assessment.

The data clearly indicate that early diagnosis and surgical eligibility in NSCLC cases significantly prolong survival. Similarly, limited-stage SCLC cases showed better outcomes than those with extensive-stage disease, further supporting the value of early detection and staging.

Clinical implications of our findings suggest that more aggressive screening and prevention strategies—particularly for women with risk factors like smoking, are warranted. Individualized treatment plans considering age, performance status, and laboratory markers may improve outcomes.

Limitations of our study include its retrospective design and the limited sample size from a single center, which may restrict the generalizability of the findings. Additionally, molecular and genetic data were not analyzed, which could have provided further insights into prognosis and targeted therapy responses.

Future prospective studies with broader datasets are needed to validate these associations and to explore personalized treatment approaches based on clinicopathological and molecular characteristics.

Conflict of Interests

The authors declare that there is no conflict of interest in the study.

Financial Disclosure

The authors declare that they have received no financial support for the study.

Ethical Approval

The study was approved by the Ankara University Faculty of Medicine Clinical Research Ethics Committee (Number: 154-4898, Date: 29/06/2009).

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