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Original Article

Comparative analysis of the 7th and 8th TNM staging with long-term outcomes in non-small cell lung cancer

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ABSTRACT

Objectives: This study aims to clinically validate 8th tumor, node, metastasis (TNM) staging for lung cancer on previously operated cases to evaluate its potential to achieve homogeneous patient groups and predict survival.

Patients and methods: Between January 2009 and December 2016, 425 patients (356 males, 69 females; mean age: 61.5±9.4 years; range, 14 to 83 years) with non-small cell lung cancer were included in the study. Statistical evaluation was made by staging the postoperative pathological TNM according to the 7th and 8th TNM staging and comparing these two groups. All cases were evaluated according to the pathological TNM data obtained after the operation. The cases were staged twice according to the pathology results reports, by the 7th and 8th TNM. The distribution of patients in these two groups according to T parameter, N parameter, and stage is given. When staging changed, distribution changes between patient groups were evaluated. The survival distribution between the 7th and 8th stage groups was evaluated with the 5-year survival data obtained during follow-up.

Results: No change was observed in any parameters or stages of 148 of 425 cases (34.8%) with the 8th staging classification. When classifying according to the 8th TNM in the T parameter, it was observed that there was a transition to advanced T between the groups. When the N parameter is examined; 63.5% (n=270) N0 cases, 27.5% (n=117) N1 cases, and 8.9% (n=38) N2 cases were detected. When the T parameter remained the same, the cases whose stage increased due to the nodal parameter were 9.4% (n=40), and the cases whose stage increased due to both the increase in the T parameter and the nodal parameter were found to be 6.8% (n=29). The cases whose stage increased because the T parameter had changed were 29.6% (n=126), and the cases whose stage did not change even though the T parameter increased in the 8th stage were 5.9% (n=25). When the general stage of the patients who underwent surgery is evaluated according to the 8th TNM, it is seen that a new case distribution emerges in the Stage IIIB group. It was determined that 14 (3.3%) cases passed from Stage IIIA to IIIB with 8th TNM, with a 5-year survival rate of 28.6%. Stage IIB group is the largest group with 125 (29.4%) cases, and when the subgroup differences between the two stagings are eliminated and the overall survival rates are compared, according to the 8th TNM, 17.9% (p=0.006) five-year survival increase were observed for Stage IIB cases.

Conclusion: The main changes that should be underlined in the 8th TNM staging, particularly for the patient group undergoing surgery, can be summarized as differentiation of survival expectancy in the early stage by increasing the tumor size subgroups in early-stage lung cancer without lymphatic metastasis, with tumor size becoming important in advancing the T parameter, emphasizing the need for systemic treatment by classifying N1 nodal metastasis as Stage IIB, being included in the T4 group, which is also known as the 'locally advanced' disease group, not only by anatomical invasion but also solely for the tumor size. It appears that the 8th TNM reveals the effects of tumor size on stage in a more effective distribution.

Keywords: Lung cancer, nonsmall cell, surgery, TNM staging.

While the seventh edition of tumor, node, metastasis (TNM) staging guide published by the International Association for the Study of Lung Cancer (IASLC) between 2009 and 2017 was used in the staging of non-small cell lung cancer (NSCLC), the 8th TNM staging guide published in 2017 was introduced with significant changes. With a correct staging, it is aimed to determine the need for additional treatment modalities that the patient needs and to have a prediction about the possible course of the disease. The main difference of the 8th TNM staging for the surgical patient group was the change in the T parameter, which evaluates the size and anatomical location of the primary tumor as seen in Table 1,[1] and the classification and distribution in general stages as seen in Table 2.[1]

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The main difference in the 8th staging was that the T1 group was divided into three groups a, b, and c, and since the tumor size was divided between the groups with 1 cm differences, the T2a and b groups also differentiated by decreasing their size. Groupings were created at 1 cm intervals, starting from less than 1 cm until larger than 5 cm in size. While tumors between 5-7 cm in size were in the T3 group, tumors over 7 cm in size were added to the T4 tumor group, which was previously independent of size. Main bronchus involvement without carina involvement was classified as T2, and atelectasis or obstructive pneumonia was also included in the T2 group regardless of how much lung area it affected. In addition, the diaphragmatic invasion was moved from the T3 group to T4, and the term 'mediastinal pleura invasion' was removed in the new staging.[2]

When the general stages are evaluated, the main differences in the 8th staging, which concerns cases that have undergone surgery, are the division of the Stage IA group into three in relation to the T parameter, the transfer of N1 nodal metastases from Stage IIA to Stage IIB in primary tumors up to T2a, and the transfer of T3N2 tumors from Stage IIIA to Stage IIIB. Oligometastatic disease is classified as Stage IVA.

No additional subclassification was defined for the 8th staging in the N parameter that evaluates nodal metastasis, and the effect of nodal metastasis on the general stage was within the criteria mentioned above.

This study was designed for clinical validation of staging. It was planned to evaluate how these propositions, which we use in our current practice, change the current results and their ability to make

Table 1. Eighth TNM staging 'T' parameter changes

T1	The largest diameter of the tumor is 3 cm or less, it is completely surrounded by lung tissue or visceral pleura, and there is no invasion into the proximal lobar bronchus on bronchoscopic examination.
T1a mi	Minimally invasive adenocarcinoma
T1a	The tumor is 1 cm or less in greatest diameter
T1b	The tumor is larger than 1 cm in greatest diameter, but not larger than 2 cm
T1c	The tumor is larger than 2 cm in greatest diameter, but not larger than 3 cm
T2	The tumor is larger than 3 cm in greatest diameter, but not larger than 5 cm; or, • Main bronchus invasion is present regardless of its distance from the carina, but there is no carina involvement • Visceral pleura invasion • Atelectasis or obstructive pneumonia in part of the lung or the whole lung, extending to the hilar region
T2a	The tumor is larger than 3 cm in greatest diameter, but not larger than 4 cm
T2b	The tumor is larger than 4 cm in greatest diameter, but not larger than 5 cm
T3	The tumor is larger than 5 cm in greatest diameter, but not larger than 7 cm or there is direct invasion of one of the following structures; • Chest wall (including superior sulcus tumors) • Phrenic nerve • Direct invasion of any of the parietal pleura • Additional nodule in the same lobe as the tumor
T4	The largest diameter of the tumor is greater than 7 cm or there is direct invasion of one of the following; • Mediasten • Heart • Major veins • Trachea • Recurrent laryngeal nerve • Carina • Additional nodule in a separate lobe on the same side as the tumor • Esophagus • Vertebra • Diaphragm

Edited by quoting Detterbeck[1]; TNM: Tumor, node, metastasis.

Table 2. General stage changes in the 8th TNM staging

Occult carcinoma	Tx	N0	M0
Stage 0	Tis	N0	M0
Stage IA1	T1A mi	N0	M0
	T1a	N0	M0
Stage IA2	T1b	N0	M0
Stage IA3	T1c	N0	M0
Stage IB	T2a	N0	M0
Stage IIA	T2b	N0	M0
Stage IIB	T1a,b,c	N1	M0
	T2a	N1	M0
	T2b	N1	M0
	T3	N0	M0
	T1a,b,c - T2a,b	N2	M0
Stage IIIA	T3	N1	M0
	T4	N0, N1	M0
	T3, T4	N2	M0
Stage IIIB	T1a,b,c	N3	M0
	T2a,b	N3	M0
Stage IIIC	T3	N3	M0
	T4	N3	M0
Stage IVA	Any T	Any N	M1a
	AnyT	Any N	M1b
Stage IVB	Any T	Any N	M1c

Edited by quoting Detterbeck[11]; TNM: Tumor, node, metastasis; ** Changes in the 8th TNM compared to the 7th TNM are underlined.

the groups more homogeneous when evaluated on the previously operated patient group.

PATIENTS AND METHODS

Between January 2009 and December 2016, a total of 542 cases who underwent surgical resection due to the diagnosis of NSCLC in a single surgical clinic were evaluated retrospectively by scanning hospital records and pathological examination reports. A total of 88 cases were excluded from the study because the pathology reports of 48 cases could not be accessed, 21 cases were reported as benign pathology, three cases were diagnosed as small cell lung cancer, 11 cases were due to extrapulmonary organ metastasis, and five cases were reported to have necrosis after neoadjuvant treatment. Twenty-nine (6.4%) cases with three-month operative mortality were excluded from the oncological comparison evaluation between stagings. Statistical evaluation was made by staging the postoperative pathological TNMs of the remaining 425 patients (356 males, 69 females; mean age: 61.5±9.4 years; range, 14 to 83 years) according to the 7th and 8th TNM staging and comparing these two groups.

The age, sex, type of operation performed, and lung cancer cytology information of the

Table 3. Distribution of descriptive characteristics

	n	%	Mean±SD	Min-Max
Age (year)			61.5±9.4	14-83
≤70	352	82.8		
>70	73	17.2		
Sex				
Male	356	83.8		
Female	69	16.2		
Operation				
Pneumonectomy	80	18.8		
Lobectomy/bilobectomy	345	81.2		
Histology				
Adenocarcinoma	149	35.1		
Large cell	51	12.0		
Squamous cell	193	45.4		
Other	32	7.5		

SD: Standard deviation.

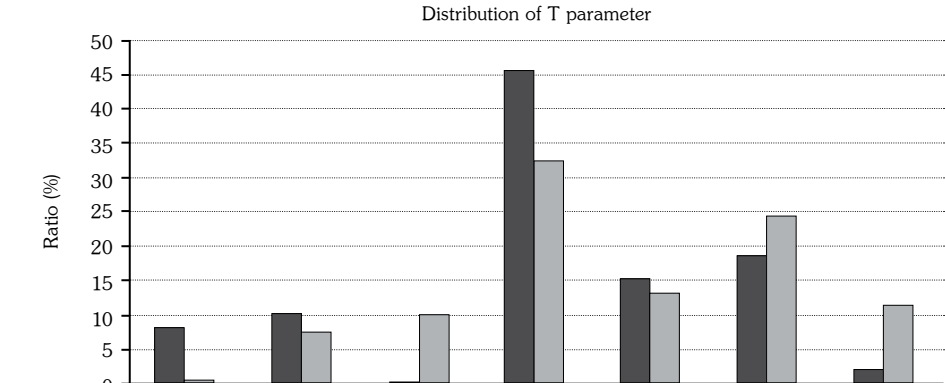


Figure 1. Case distribution according to T parameter.

cases were analyzed and the number and percentages of patients in the whole group were stated. In order to evaluate the effect of these case characteristics on survival, age was divided into two groups as over and under 70 years of age, sex was divided into male and female, operation type was divided into lobectomy/bilobectomy and pneumonectomy groups, and tumor cytology was divided into four; adenocarcinoma, squamous cell carcinoma, large cell carcinoma, and other cytology; and compared.

Table 4. Tumor size distributions according to T parameter in the 7th and 8th TNM

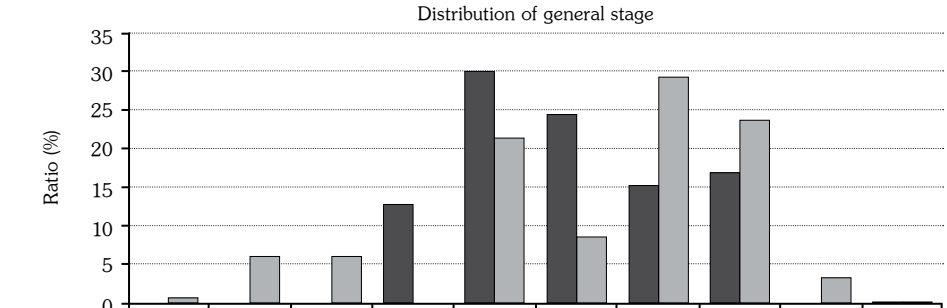
	Tumor size (mm)		
T parameter	Mean±SD	Median	Min-Max
7th TNM			
T1A	16.69±3.60	18	7-20
T1B	26.00±2.77	25	21-30
T2A	35.52±9.55	35	8-50
T2B	58.14±4.94	58	51-70
T3	69.91±27.88	71	25-160
T4	70.56±36.05	70	20-120
8th TNM			
T1A	9.00±1.73	10	7-10
T1B	17.76±3.10	18.5	11-25
T1C	26.12±2.76	25	21-30
T2A	31.22±7.80	32	8-40
T2B	46.09±2.89	45	40-50
T3	54.23±10.42	55	25-80
T4	87.69±24.73	85	20-160

TNM: Tumor, node, metastasis; SD: Standard deviation.

All cases were evaluated according to the pathological TNM data obtained after the operation. The cases were staged twice according to the pathology results reports, in accordance with the 7th and 8th TNM. The distribution of the patients in these two groups were given according to T parameter, N parameter, and general stage. When staging changed, distribution changes between patient groups were evaluated. The survival distribution between the 7th and 8th Stage groups was evaluated with the five-year survival data obtained during follow-up.

Statistical analysis

Number Cruncher Statistical System (NCSS-Kaysville, Utah, USA) 2007 program was used for statistical analysis. Descriptive statistical methods (mean ± standard deviation [SD], median, frequency, ratio, minimum, maximum) were used when evaluating the study data. Kaplan-Meier survival analysis and log-rank test were used in survival studies. Pearson chi-square test and Fisher-Freeman-Halton test were used to compare qualitative data. Significance was evaluated at at least $p<0.05$.



	IA1	IA2	IA3	IA	IB	IIA	IIB	IIIA	IIIB	IV
7th TNM				12.9	30.2	24.5	15.3	16.9	0	0.2
8th TNM	0.7	6.1	6.1		21.6	8.7	29.4	23.8	3.3	0.2

Figure 2. Case distribution according to general stage.

RESULTS

Pneumonectomy was performed in 18.8% (n=80) of the cases, and lobectomy/bilobectomy was performed in 81.2% (n=345). Table 3 includes data of the cell type. The tumor cell type was adenocarcinoma in 35.1% (n=149), large cell carcinoma in 12% (n=51), squamous cell carcinoma in 45.4% (n=193), and 7.5% (n=32) of the cases were found to be carcinomas with other cell types. Among the cases, it was found that age (p=0.103), gender (p=0.060), and tumor histology (p=0.632) had no effect on survival, and the exitus rate in the pneumonectomy group was higher than the lobectomy and bilobectomy group (p=0.022).

The survival of 425 cases included in the statistical study was determined as 67.1%, and the average survival time was 46.75±0.96 months. With the 8th staging classification, no change was observed in any parameters or general stage of 148 of 425 cases (34.8%).

When classifying according to the 8th TNM in the T parameter, it was observed that there was a transition to advanced T between the groups. Case distribution is given in Figure 1. When the N parameter is examined; 63.5% (n=270) N0 cases, 27.5% (n=117) N1 cases, and 8.9% (n=38) N2 cases were detected. When the T parameter remained the same, the number of cases whose stage increased due to the nodal parameter was 9.4% (n=40), and the patients whose stage increased due to both the increase in the T parameter and the nodal parameter was 6.8% (n=29). The cases whose stage increased because the T parameter had

Table 5. Five-year survival distribution table according to stages

	5-year survival rate %	*p*
T parameter		
7th TNM		<0.001**
T1a	91.4	
T1b	69.8	
T2a	76.8	
T2b	58.5	
T3	41.8	
T4	33.3	
8th TNM		<0.001**
T1a	100	
T1b	90.6	
T1c	69.8	
T2a	80.4	
T2b	67.9	
T3	51.9	
T4	40.8	
N parameter		<0.001**
0	73.7	
1	55.6	
2	55.3	
General stage		
7th TNM		<0.001**
IA	87.3	
IB	78.9	
IIA	69.2	
IIB	47.7	
IIIA	44.4	
IV (n=1)*	100	
8th TNM		<0.001**
IA1	100	
IA2	88.5	
IA3	84.6	
IB	83.7	
IIA	67.6	
IIB	65.6	
IIIA	47.5	
IIIB	28.6	
IV (n=1)*	100	

TNM: Tumor, node, metastasis; * Since the number of people was insufficient, they were not included in the evaluation; ** p<0.01.

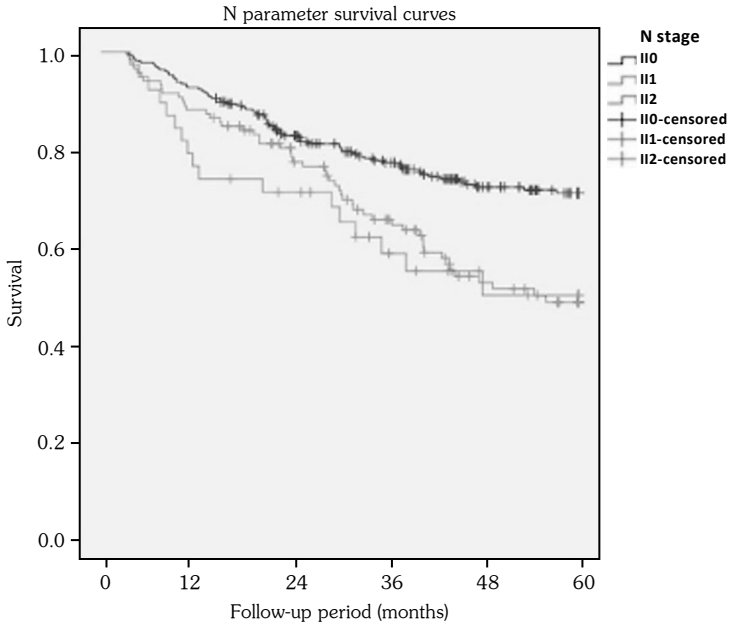


Figure 3. Survival curve of groups according to N parameter.

changed were found to be 29.6% (n=126), and the cases whose stage did not change even though the T parameter increased in the 8th stage were found to be 5.9% (n=25).

It was found that the median tumor size decreased in all T parameter stages except T4 as seen in Table 4, and there was an increase in tumor size in the T4 group.

Table 6. Comparison of five-year survival between general stages according to TNM staging 7th and 8th

TNM stage	5-year survival rate %	Average survival rate	95% CI Lower-Upper	*p*
IA				1.000
7th TNM	87.3	55.71±1.60	52.565-58.851	
8th TNM	87.3	55.71±1.60	52.565-58.851	
IB				0.375
7th TNM	78.9	51.24±1.53	48.239-54.241	
8th TNM	83.7	53.32±1.61	50.164-56.466	
IIA				0.777
7th TNM	69.2	48.78±1.77	45.304-52.261	
8th TNM	67.6	46.48±3.32	39.973-52.981	
IIB				**0.006***
7th TNM	47.7	37.49±2.78	32.033-42.942	
8th TNM	65.6	46.88±1.73	43.501-50.267	
III				0.972
7th TNM	44.4	37.31±2.61	32.190-42.424	
8th TNM	45.2	37.14±2.08	33.060-41.226	
IV				-
7th TNM	100.0	26.24±0	-	
8th TNM	100.0	26.24±0	-	

TNM: Tumor, node, metastasis; CI: Confidence interval; * Statistically significant.

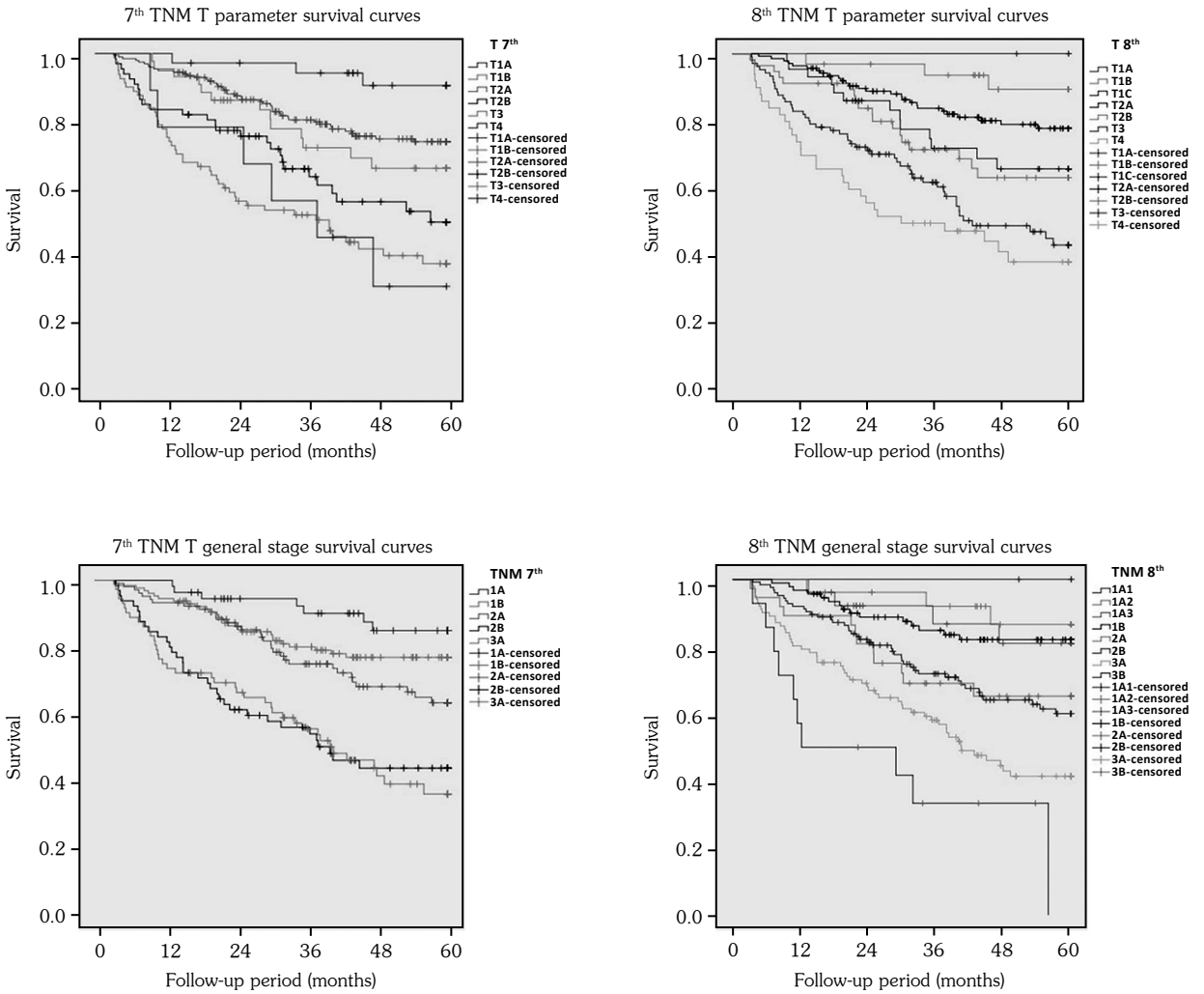


Figure 4. 7th and 8th TNM T parameter and overall stage survival comparison curves.
TNM: Tumor, node, metastasis.

When the general stage of the patients who underwent surgery is evaluated according to the 8th TNM, it is seen in Figure 2 that a new case distribution emerges in the IIIB group.

To summarize the main changes in the general stage: with the 8th TNM, it was determined that 14 (3.3%) cases passed from Stage IIIA to IIIB, with a five-year survival rate of 28.6% as given in Table 5 (Figure 2). In the survival distribution between groups, it was observed that survival decreased as the stage progressed in the T parameter, N parameter, and general stage, except for the T1b group in the 7th TNM and the T1c group in the 8th TNM ($p \leq 0.001$) (Table 5).

The survival rate in N0 cases was found to be higher than in N1 and N2 cases as seen in Figure 3 survival curves ($p<0.001$).

The Stage IIB group is the largest group with 125 (29.4%) cases, as demonstrated in Table 6, when the overall survival rates between the stages are compared by eliminating the subgroup differences between the two stagings, according to the 8th TNM, a 17.9% ($p=0.006$) five-year survival increase was observed for Stage IIB cases.

7th and 8th T parameter and general stage subgroups' survival comparison curves are given in Figure 4 to visualize distribution.

DISCUSSION

The most significant change in the 8th TNM staging is in the 'T' parameter, and it seems that tumor size is especially effective in the distribution of advanced stages. While T4 lesions were evaluated only by anatomical invasion, regardless of size, in the 7th TNM staging, with the changing size distribution in the 8th TNM, the patient pools of T2, T3, and T4 tumors have changed, and T1 lesions have been divided into three and grouped within themselves.

Considering the distribution differences of the T1 group between the two stages, a difference of 7.5% was detected between T1as and 2.7% between T1bs, and the newly added T1c group in the 8th TNM has 10.2% of the case pool and has replaced T1b. In the five-year survival evaluation of cases with T1 tumors, according to the 7th TNM, 91.4% survival was observed in T1a cases and 69.8% survival in T1b cases. According to the 8th TNM, survival was determined as 100% in T1a, 90.6% in T1b, and 69.8% in T1c. In the comparison between the two stages, a difference of 8.6% between T1as and 20.8% between T1bs was detected. By having T1b cases as T1c and by dividing T1a in the 7th TNM into two, in the 8th TNM, a 20.8% survival improvement was observed in the T1b group compared to the previous one. As a result, a survival difference of 9.4% between T1a and T1b and 20.8% between T1b and T1c was found (p=0.04).

When tumor sizes after T1 were evaluated as percentage differences between the two stagings, a distribution difference of 13.1% between T2as, 2.1% between T2bs, 5.9% between T3s, and 9.4% between T4s was detected. With the new tumor size classification in the 8th TNM, an increase was observed in the number of cases of advanced-stage T2b, T3, and T4 tumors, and a decrease was observed in the share of the case pool of other groups. In both TNM stagings, most cases were observed in T2a. In their study comparing the 7th and 8th TNM staging by Yang et al.[3] the pT parameters of 177,499 cases were evaluated. According to the 7th TNM, most cases were observed in T2a with 32.6%, and T4 cases were seen with 2.2%. In the 8th TNM, T2a, which is also the most common, showed a percentage decrease with a patient pool of 25.4%. Whereas T4 cases increased to 6.2%.

An average size difference of 17.13 mm was determined between the T4 groups in our study. In the 8th TNM, the tumor size of T2a, T2b, and T3 cases was observed to be smaller than in the 7th TNM, while larger tumor sizes were observed in T4 cases. In their study where Morgensztern et al.[4] evaluated the effect of tumor size on survival in 12,315 cases, they found that size was an independent factor affecting survival, and observed that patients with large tumor sizes in Stage IIIA and IIIB cases had a worse survival of approximately 10%.

When the survival between pT stages of the cases evaluated by Rami-Porta et al.[5] while preparing the 8th TNM staging of IASLC was compared, according to the 8th TNM, T1a, T1b, T1c, T2a, T2b, T3 and T4 cases were observed to have a five-year survival of 92%, 86%, 81%, 74%, 65%, 57% and 47%, respectively. According to the 7th TNM, these values were determined as 87%, 81%, 72%, 60%, 53% and 50% for T1a, T1b, T2a, T2b, T3 and T4, and as seen in our study, in the 8th TNM, a better five-year survival percentage distribution was achieved across all T stages.

As a nodal parameter, no additional recommendations were made in the 8th TNM compared to the previous staging. In our study, it was observed that N0 cases had better survival than cases with nodal metastasis, regardless of its level. In cases that underwent surgery, cases with single-station N2 metastases and cases with station-independent N1 metastases gave similar survival results. As stated by Osarogiagbon et al.[6] in their current IASLC project, no changes have been made in nodal parameters since the 4th TNM staging, and the effects of which station has lymph node metastasis or the number of lymph node stations with metastasis on survival are under evaluation. For the 9th TNM staging, it is planned to create subgroups such as N1a, N1b, N2a1, N2a2, and N2b in the N parameter.

With the increase in the number of tumors evaluated as T3 in the 8th TNM and the transfer of T3 N2 cases from Stage IIIA to Stage IIIB, Stage IIIB cases were detected among the operated cases when evaluated according to this staging. According to the 8th TNM, Stage IIA cases were 37 (8.7%), Stage IIB cases were 125 (29.4%), Stage IIIA cases were 101 (23.8%), and

Stage IIIB cases were 14 (3.3%). If we look at the comparison between the two stages, the difference is 15.8% in Stage IIA, 14.1% in Stage IIB, and 6.9% in Stage IIIA. When the 8th TNM was used instead of the 7th TNM, only stage progression was observed in the cases. All of the differences are due to the fact that some of the cases have been moved to the next stage group. In the 8th TNM, the distribution of cases in Stage IIA decreased, while it increased in Stage IIB and Stage III.

When comparing the two stagings using a five-year survival assessment, with the 8th TNM distribution, the five-year survival increase was observed as 1.6% among Stage IIAs, 17.9% among Stage IIBs, and 3.1% among Stage IIIAs. In all stages except Stage IIA, higher survival was observed compared to the 8th TNM, and the survival was seen in cases that increased from IIIA to IIIB with the 8th TNM was observed to be 15.8% lower compared to the previous percentages in the 7th TNM. In the study conducted by Chansky et al.[7] to determine the stage groups in the 8th TNM staging of IASLC, 182,616 cases were staged with pathological TNM. The five-year survival of the stages according to the 8th TNM was observed as 90%, 85%, 80%, 73%, 65%, 56%, 41%, and 24% for stages IA1, IA2, IA3, IB, IIA, IIB, IIIA and IIIB, respectively. In the general stage evaluation of Goldstraw et al.[8] in the same patient pool, the five-year survival rates according to the stages in the 7th TNM as pathological TNM are given as 83%, 71%, 57%, 49%, 36%, and 23% for Stage IA, IB, IIA, IIB, IIIA and IIIB, respectively. In percentage terms, better survival is observed in all stages compared to the 8th TNM distribution.

Nonetheless, the current study has several limitations. The surgically operated oligometastatic disease (M1a) Stage IV case in the case group was not included in the comparison between numbers and survival but was included in the tables representing the Stage IV group. The lack of more cases of oligometastatic disease is one of the weaknesses of the study. Cases of Stage IIIC with N3 lymph node metastasis and Stage IVB with multiple metastatic diseases in the 8th TNM, which have no place in the treatment of surgery, are not included in the study. No evaluation could be made for these groups. In survival comparisons of T1 groups, due to the high percentage of nodal metastases in the cases in the T1c (old T1b) group and the limited number of cases, this group remained below the expected percentage and fell behind the next group in terms of survival.

In conclusion, main changes that should be underlined in the 8th TNM staging, particularly for the patient group undergoing surgery, can be summarized as differentiation of survival expectation in the early stage by increasing the tumor size subgroups in early-stage lung cancer without lymphatic metastasis, however, tumor size gaining importance in advancing the T parameter, N1 nodal metastasis being taken to Stage IIB and emphasis on the need for systemic treatment, being included in the T4 group, which is also known as the 'locally advanced' disease group, not only by anatomical invasion but also solely for the tumor size. It appears that the 8th TNM reveals the effects of tumor size on stage in a more effective distribution. Although significant differences were detected observationally, we needed data to say that "the 8th TNM staging is more effective in staging cases diagnosed with NSCLC." To achieve this, the cases were distributed by combining the stage groups in the 8th TNM into subgroups equivalent to the 7th TNM. Statistical significance was found in Stage IIB in five-year survival comparisons between these groups. It was observed that the five-year survival value of Stage IIB, which was 47.7% in the 7th TNM, increased to 65.6% in the 8th TNM (p=0.006). The reason why we consider this an important result is that Stage IIB is seen as perhaps the last 'comfort zone' for the surgeon in surgical practices. The large tumor size that occurs after Stage IIB, invasion of mediastinal structures and chest wall, mediastinal lymph node positivity, N2 cases, and all the controversies that arise with them in academic studies make the period after Stage IIB 'gray areas' in terms of surgery. Finding that the five-year survival in Stage IIB at this threshold is similar to the average survival of all cases in our study is important in terms of surgical decision and patient follow-up mechanism. It is possible to see the 8th TNM staging as more decisive in predicting the survival of cases, as it shows that we will gradually fall below the average in advanced stages.

Ethics Committee Approval: The study protocol was approved by the Dr. Siyami Ersek Research and Training Hospital Ethics Committee Ethics Committee (date: 20.06.2017, no: 28001928-051.99). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from the patients and/or parents of the patients.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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