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Review of the Proposals in the Forthcoming 8th TNM Classification of Lung Cancer

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Abstract

Staging of lung cancer is a key factor for both prognostication and management of patients. Thus, there is a need for an accurate, uncomplicated, easily reproducible staging system. The database of the 8th TNM (T: Tumor, N: Node, M: Metastasis) classification is based on information gathered from 94,708 patients who received diagnoses of lung cancer between 1999 and 2010, originating from 35 sources in 16 countries. Data analysis was performed in 2013–2014 regarding proposals put forward for the 8th edition and was published in the Journal of Thoracic Oncology. It is thought that the 8th edition will be used in 2017. In this edition, tumor diameter is more important and each centimeter counts (T1a: ≤1 cm, T1b: >1 cm but ≤2 cm, T1c: >2 cm but ≤3 cm, T2a: >3 cm but ≤4 cm, T2b: >4 cm but ≤5 cm, T3: >5 cm but ≤7 cm, and T4: >7 cm). There are changes in some T descriptors such as main bronchus involvement (T2), total atelectasis/pneumonitis (T2), involvement of diaphragm (T4), and mediastinal pleural invasion (not used as T descriptor). Current N staging is still valid; however, there are clues for the importance of the abundance of nodal involvement. Three metastatic groups are defined: M1a (contralateral/bilateral tumor nodules, pleural/pericardial nodules or effusion), M1b (single metastatic lesion in one organ), and M1c (multiple metastasis in either single or multiple organs). More stage groupings demonstrating good prognostic categories are proposed. These changes do not have much implication on treatment. The proposed taxonomic changes do not affect therapeutic modalities. However, care should be taken to follow up for small pulmonary nodules.

Keywords: Lung cancer, TNM staging, tumor, 8th TNM

INTRODUCTION

Lung cancer remains the leading cause of cancer and cancer-related deaths worldwide (1). An accurate, uncomplicated, and easily reproducible lung cancer staging system is essential both for the appropriate management and prognostication of patients with lung cancer. Thus, regular review and updating of the staging system to incorporate changes in tumor characteristics, diagnostic techniques, and advances in therapeutic modalities is required.

Currently, the 7th edition of the TNM (T: Tumor, N: Node, M: Metastasis) classification in lung cancer has been used since it was first published by the International Association for the Study of Lung Cancer (IASLC) in *"Staging Manual in Thoracic Oncology"* at the end of 2009 (2).

The 7th edition of TNM classification was based on the most thorough data-based revision ever performed with substantial changes, based upon the largest database ever accrued, and global representation of cases treated by all modalities of care. However, there were some limitations and failings because of the retrospective nature of the data. Data collection was not designed for the primary purpose of TNM analysis; thus, there were shortcomings in the geographical accrual and unrepresentative dominance of surgically treated cases. Moreover, despite a large number of cases, quality control of the multilingustical data was limited. Positron emission tomography (PET) scanning was also not routinely used during the period of data collection (3). These limitations prompted the collection of new retrospective and prospective data instead of the original retrospective database, with contributions from centers worldwide. A prospective data set has been agreed upon and a web-

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based data collection system (EDC: Electronic data capture system) was developed and tested to make data submission easier. Data entry and analysis was proposed to be performed by Cancer Research and Biostatistics (CRAB) (4).

The database for the 8th edition of TNM classification was assembled between 2009 and 2013 and included patients diagnosed between 1999 and 2010. Data analysis was performed in 2013–2014. Subsequently, proposals for the revisions were published in the *Journal of Thoracic Oncology* (5-9). Finally, it is thought that the 8th edition of TNM classification will be adopted from 2017.

The database of the 8th edition of TNM classification has information on 94,708 patients diagnosed with lung cancer between 1999 and 2010, originating from 35 sources in 16 countries (Table 1). Most of the patients were from Europe (46,560 patients; 49%) and Asia (41,705 patients; 44%). Of interest, the contribution of Turkey was 7,304 patients. Although most of the patients from Europe were at advanced stages, the patients from Asia were at early stages. Contrary to expectations, only 4,667 cases (4.9%) were submitted via the online EDC system. The reasons for the exclusion of patients were carcinoids, multiple synchronous tumors, unknown or different histology, outside the 1999–2010 timeframe, incomplete survival data, or incomplete stage information. After exclusions, 77,156 patients; 70,967 with non-small cell lung cancer (NSCLC), and 6,189 with small cell lung cancer (SCLC) remained for analysis. In this database, surgical treatment, alone or combined with chemotherapy or radiotherapy, was performed in a high proportion of patients (nearly 85%) (10).

Proposals for the Revisions of the T Descriptors

Tumor size: The 3-cm cut-off point is still valid to differentiate T1 from T2 tumors for both pathological and clinical staging. However, instead of classifying patients exclusively according to tumor size, T2 tumors also include tumors classified as T2 by other descriptors other than tumor size, i.e., main bronchus involvement (5). The survival analysis concerning 1-cm increments in tumor size (≤1 cm, >1–2 cm, >2–3 cm, >3–4 cm, >4–5 cm, >5–6 cm, >6–7 cm, and >7 cm) revealed progressive decreases in survival for each 1-cm cut-off. This was valid for patients with pT1-2 N0M0 (p: stage given by pathologic examination of surgical specimen) and R0 (R: residual tumor) tumors, patients with nodal involvement and incomplete resections, and in those with clinically staged tumors with or without nodal involvement (5).

Involvement of the main bronchus: In the 7th edition of TNM classification for lung cancer, although main bronchus involvement that was 2 cm or more distal to the carina was classified as T2, a tumor in the main bronchus less than 2 cm distal to the carina without invasion of the carina was classified as T3 (2). According to the analysis of the 8th edition database, main bronchus involvement 2 cm or more distal to the carina has similar survival patterns like other T2 descriptors. However, involvement of the main bronchus less than 2 cm distal to the carina, without invasion of the carina, has a better prognosis than other T3 descriptors in all studied populations. When the prognosis of patients with T2 and T3 tumors based on the level of main bronchus involvement was compared, the prognosis was similar. Moreover, it was found that patients with T3 tumors proximal to main bronchus involvement had better prognoses than patients with other T3 descriptors. In multivariate analyses, involvement of the main bronchus, regardless of distance to the carina, did not seem to increase the risk after adjusting for tumor size both in pathologically and clinically staged tumors. Based on these analyses, involvement of the main bronchus was classified as T2 unless invasion of the main carina existed (5).

Table 1. IASLC database for the 8th edition of TNM classification

Total patients submitted	94,708 (100)
Submitted via EDC	4,667 (4.9)
Other	90,041 (95.1)
Geographical origin	
Europe	46,560 (49)
Asia	41,705 (44)
North America	4,660 (5)
Australia	1,593 (1.7)
South America	190 (0.3)
Patients	
Excluded	17,552 (18)
Included	77,156 (82)
Patients included for analysis	
NSCLC	70,967 (92)
SCLC	6,189 (8)
Treatment modalities (%)	
Surgery alone	57.7
Chemotherapy + surgery	21.1
Radiotherapy + surgery	1.5
Trimodality therapy	4.4
Chemotherapy + radiotherapy	4.7
Radiotherapy alone	1.5

Data given as n (%) unless otherwise stated
EDC: Electronic data capture system; NSCLC: non-small cell lung cancer; SCLC: small cell lung cancer

Atelectasis/pneumonitis: In the analyses of the 8th edition database, survival of patients with T2 disease due to partial atelectasis/pneumonitis was similar to other patients with other T2 descriptors. However, total atelectasis/pneumonitis, a T3 descriptor in TNM 7, showed better prognoses than other T3 descriptors. The survival of patients with T3 disease due to total atelectasis/pneumonitis was similar to patients with T2 disease. Based on these findings, partial or total atelectasis/pneumonitis is proposed to be classified as T2 (5).

Visceral pleural invasion: Visceral pleural invasion (VPI) is a pathological staging descriptor. Use of elastin dyes for the evaluation of VPI is recommended. The extent of VPI is classified as PL0: tumor within the subpleural lung parenchyma or invades superficially into the pleural connective tissue beneath the elastic layer; PL1: tumor invades beyond the elastic layer of the visceral pleura; PL2: tumor invades to the visceral pleura surface; PL3: tumor invades into any

component of the parietal pleura (11). VPI is well positioned as a T2 descriptor and confers a worse prognosis even after adjustment for the current tumor size cutoff points (5). Further analysis revealed that pathologically staged tumors of greater than 3–4 cm with VPI has a similar prognosis to those greater than 4–5 cm; and that tumors of greater than 4–5 cm with VPI have similar prognosis to that of those greater than 5–7 cm. However, these differences are not so clear in the clinically staged patients, so VPI is still classified as T2.

Diaphragm invasion: In the 7th edition of the TNM classification for lung cancer, involvement of the diaphragm was classified as T3 (2). In the analyses of the 8th edition database, the survival of patients with tumors involving the diaphragm had a worse prognosis compared with that of patients with other T3 descriptors, both in the pathological and clinical settings. This was confirmed by multivariate analyses. Patients with pathologically classified T3 (pT3) tumors based on the diaphragm involvement had a worse prognosis compared with those with pT3 tumors based on other descriptors and even those with pT4 tumors. Clinically staged tumors with diaphragm involvement had similar prognoses to those clinically classified as T4 and T3. Based on these findings, diaphragm invasion is classified as a T4 descriptor (5).

Other T3 descriptors: Patients with T3 descriptors, such as parietal pericardium, mediastinal pleura, chest wall invasion, Pancoast tumors, parietal pleural invasion, and additional tumor nodules in the same lobe of the primary tumor had similar prognosis with patients with other T3 descriptors. Subgroup analysis revealed that survival rates were not significantly different between patients with tumors invading only parietal pleura and patients with more extensive chest wall involvement. This insignificance in survival difference was valid both for pathologically staged tumors with any N and any T and in clinically staged tumors with any N involvement. Based on these findings, chest wall invasion is still classified as T3 (5).

Mediastinal pleural involvement is a difficult criterion to define in clinical staging, and it is rarely described in pathological staging. In the analyses of the database, there were different prognostic data in both clinical and pathological settings. Therefore, mediastinal pleural involvement is not used as a T descriptor (5).

Other T4 descriptors: Because the proportion of patient data obtained via EDC was extremely low, there was limited data on T4 descriptors (10). A thorough analysis of the individual T4 descriptors was not possible because of the small number of patients in each group (5). However, although there was no significant survival difference between T3 and T4 stages in the 7th TNM classification (2), there was a significant survival difference between T3 and T4 stages, both in clinical and pathological settings. This difference is probably due to the reclassification of diaphragm invasion and tumor size larger than 7 cm as a T4 disease in the proposed 8th TNM classification.

The rearrangement of T descriptors in the 8th edition of the TNM classification in comparison with the 7th edition is summarized in Table 2. Proposed T descriptors for the 8th edition of the TNM classification for lung cancer are summarized in Table 3.

Table 2. The rearrangement of T descriptors in the 8th edition of the TNM classification and a comparison with the 7th edition of the TNM classification for lung cancer

Descriptor	7th TNM	8th TNM
≤1 cm	T1a	T1a
>1–2 cm		T1b
>2–3 cm	T1b	T1c
>3–4 cm	T2a	T2a
>4–5 cm		T2b
>5–7 cm	T2b	T3
>7 cm	T3	T4
Main bronchus involvement, <2 cm from the carina	T3	T2
Total atelectasis/ pneumonitis	T3	T2
Involvement of the diaphragm	T3	T4
Mediastinal pleural invasion	T3	-

TNM: Tumor, node, metastasis

Proposals for the Revisions of the N Descriptors

In the 7th edition of the TNM classification for lung cancer, there were important changes regarding the N status (2). Until 2009, there were two lymph node maps utilized worldwide: the Naruke map already introduced in 1978 and mainly used in Japan and Europe and the ATS-UICC (American Thoracic Society-Union Internationale Contre le Cancer) map published together with the 6th TNM classification and mainly used in North America (12, 13). These two maps have important differences regarding the precise delineation and enumeration of lymph node stations. The major difference is the classification of the number 10 lymph node (N1 disease) in the Naruke map as the number 7 lymph node (N2 disease) in the ATS-UICC map. These different nodal maps used for N staging did not allow revision of N classification in the 7th edition, but a new lymph node map was proposed to align the two maps. Accordingly, the oncological midline was proposed to be positioned at the left lateral side of the trachea because the lymphatic drainage of the right side predominantly goes to the right paratracheal and pretracheal lymph nodes and extends past the anatomical midline (14).

The current N staging only considers the anatomical involvement of a lymph node station. For example, a microscopic metastasis in the number 10 station is staged the same with an apparent metastasis with enlarged multiple lymph nodes as in station 10 and 11. Therefore, in the 8th classification, collection of data for the number of involved lymph nodes in each station was planned. But, because the number of cases collected via the EDC system was very low, it was not possible to study the number of metastatic lymph nodes. However, some subgroup analyses were performed in a limited number of patients. The survival of patients with multiple N1 diseases was found to be similar to a single N2 disease. In another subgroup analysis, five prognostic groups were formed among the pathologically staged patients: pN1a (single N1), pN1b (multiple N1), pN2a1 (single N2 without N1; i.e., skip metastasis), pN2a2 (single N2 with N1), and

Table 3. Proposed T descriptors for the 8th edition of the TNM classification for lung cancer (8)

T: Primary tumor		
Tx		Primary tumor cannot be assessed or tumor proven by the presence of malignant cells in sputum or bronchial washings but not visualized by imaging or bronchoscopy
T0		No evidence of primary tumor
Tis		Carcinoma in situ
T1		Tumor <3 cm in the greatest dimension surrounded by the lung or visceral pleura without bronchoscopic evidence of invasion more proximal than the lobar bronchus[1]
	T1a (mi)	Minimally invasive adenocarcinoma[2]
	T1a	Tumor ≤1 cm in the greatest dimension[1]
	T1b	Tumor >1 cm but ≤2 cm in the greatest dimension[1]
	T1c	Tumor >2 cm but ≤3 cm in the greatest dimension[1]
T2		Tumor >3 cm but ≤5 cm or tumor with any of the following features[3]:
		- Involves main bronchus regardless of distance from the carina but without involvement of the carina
		- Invades visceral pleura
		- Associated with atelectasis or obstructive pneumonitis that extends to the hilar region involving all or part of the lung
	T2a	Tumor >3 cm but ≤4 cm in the greatest dimension
	T2b	Tumor >4 cm but ≤5 cm in the greatest dimension
T3		Tumor >5 cm but ≤7 cm in the greatest dimension or associated with separate tumor nodule (s) in the same lobe as the primary tumor or directly invades any of the following structures: chest wall (including the parietal pleura and superior sulcus tumors), phrenic nerve, or parietal pericardium
T4		Tumor >7 cm in the greatest dimension or associated with separate tumor nodule (s) in a different ipsilateral lobe than that of the primary tumor or invades any of the following structures: diaphragm, mediastinum, heart, great vessels, trachea, recurrent laryngeal nerve, esophagus, vertebral body, or carina

[1]The uncommon superficial spreading tumor of any size with its invasive component limited to the bronchial wall, which may extend proximal to the main bronchus, is also classified as T1a
[2]Solitary adenocarcinoma, ≤3 cm with a predominately lepidic pattern and ≤5 mm invasion in any one focus
[3]T2 tumors with these features are classified as T2a if ≤4 cm in the greatest dimension or if the size cannot be determined and T2b if >4 cm but ≤5 cm in the greatest dimension
TNM: Tumor, node, metastasis

pN2b (multiple N2). The survival of patients with multiple N1 diseases (pN1b) was similar to patients with skip metastasis (pN2a1) (6).

In the 8th edition database, most of the data collected for the revision of N staging came from Japanese data collected using the Naruke map. Because it was impossible to correct all the data, the statistical analyses were performed according to the present data. The stage shift due to these two different lymph node maps is questionable. In the analyses, the patients clinically staged as N0, N1, N2, and N3 with any T and M0 disease demonstrated a significant progressive degradation of survival. This was also notable in patients pathologically staged as N0, N1, N2, and N3 with any T and M0 disease (6).

In conclusion, the analyses of the 8th TNM edition database indicated some important data about the number of involved lymph nodes or skip metastasis for prognosis, but the data were limited to changes in the N staging in the 8th edition. Proposed N descriptors for the 8th edition of the TNM classification for lung cancer are summarized in Table 4. It is difficult to count the number of lymph nodes radiologically in clinical staging. Collecting prospective data using the IASLC map in the following categories is suggested: pN1a for Single N1, pN1b for Multiple N1, pN2a1 for Single N2 without N1 (skip metastasis), pN2a2 for Single N2 with N1, pN2b for Multiple N2, and pN3 for N3 involvement.

Proposals for the revisions of the M descriptors

In the 7th edition of the TNM classification for lung cancer, the M1a (intrathoracic metastasis) and M1b (extrathoracic metastasis) categories separated tumors with different prognosis. The median survival in the M1a and M1b categories was 11.5 and 6 months, respectively (15). In the 8th edition database, there were 1,059 NSCLC cases avail-

Table 4. Proposed N descriptors for the 8th edition of the TNM classification for lung cancer (8)

Nx	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in ipsilateral peribronchial and/or ipsilateral hilar lymph nodes and intrapulmonary nodes, including involvement by direct extension
N2	Metastasis in ipsilateral mediastinal and/or subcarinal lymph node (s)
N3	Metastasis in contralateral mediastinal, contralateral hilar, ipsilateral or contralateral scalene, or supraclavicular lymph node (s)

TNM: Tumor, node, metastasis

Table 5. Proposed M descriptors for the 8th edition of the TNM classification for lung cancer (8)

M: Distant metastasis		
M0		No distant metastasis
M1		Distant metastasis present
	M1a	Separate tumor nodule (s) in a contralateral lobe; tumor with pleural or pericardial nodule (s) or malignant pleural or pericardial effusion[1]
	M1b	Single extrathoracic metastasis[2]
	M1c	Multiple extrathoracic metastases in one or more organs

[1]Most pleural (pericardial) effusions with lung cancer are due to tumor. In a few patients, however, multiple microscopic examinations of pleural (pericardial) fluid are negative for the tumor and the fluid is non-bloody and not an exudate. When these elements and clinical judgment dictate that the effusion is not related to the tumor, the effusion should be excluded as a staging descriptor
[2]Involvement of a single distant (nonregional) lymph node is included in this category
TNM: Tumor, node, metastasis

able for a detailed analysis of the clinical M status (7). M1 categories were reclassified as M1a (contralateral/bilateral tumor nodules and pleural/pericardial nodules or effusion), M1b (single metastatic lesion in one organ), and M1c (multiple metastasis in single or multiple organs) (Table 5). In the survival analysis, patients with contralateral/bilateral tumor nodules, pleural/pericardial nodules or effusion, or multiple M1a descriptors had a similar prognosis. Patients with a single metastatic lesion in one extrathoracic organ site (M1b) showed a prognosis similar to that of patients with M1a disease with a median survival of 11.4 months. Patients with single extrathoracic metastasis (M1b) had a better prognosis than those with multiple extrathoracic metastasis in one or multiple organs (M1c) (7).

Proposed TNM stage groupings for the 8th edition of the TNM classification for lung cancer is summarized in Table 6. In the 7th edition, there were seven stage groupings with different prognoses (2). In the

Table 6. Proposed TNM stage groupings in the 8th edition of the TNM classification for lung cancer

	N01	N12	N23	N34	M1a Any N	M1b Any N	M1c Any N
T1a	IA1	IIB	IIIA	IIIB	IVA	IVA	IVB
T1b	IA2	IIB	IIIA	IIIB	IVA	IVA	IVB
T1c	IA3	IIB	IIIA	IIIB	IVA	IVA	IVB
T2a	IB	IIB	IIIA	IIIB	IVA	IVA	IVB
T2b	IIA	IIB	IIIA	IIIB	IVA	IVA	IVB
T3	IIB	IIIA	IIIB	IIIC	IVA	IVA	IVB
T4	IIIA	IIIA	IIIB	IIIC	IVA	IVA	IVB

[1]N0 disease is staged according to T descriptors as seen in the first column
[2]N1 disease is staged as IIB, unless T descriptor is T3 or T4
[3]N2 disease is staged as IIIA, unless T descriptor is T3 or T4
[4]N3 disease is staged as IIIB, unless T descriptor is T3 or T4
Intrathoracic metastasis or single extrathoracic metastasis is staged as IVA
Multiple extrathoracic metastasis in one or more organ is staged as IVB
TNM: Tumor, node, metastasis

Table 7. Overall survival rates of patients by clinical stage according to the proposed 8th edition of the TNM classification for lung cancer

Stage	24-month survival	60-month survival
IA1	97	92
IA2	94	83
IA3	90	77
IB	87	68
IIA	79	60
IIB	72	53
IIIA	55	36
IIIB	44	26
IIIC	24	13
IVA	23	10
IVB	10	0

Data given as %
TNM: Tumor, node, metastasis

8th edition, 11 stage groupings are proposed. In the survival analyses, these groups demonstrated a progressive degradation of survival (8). Two and five-year overall survival of patients by clinical stage according to the proposed 8th edition is seen in Table 7 (8). Despite there being a statistically significant survival difference, it is important to note that the survival of patients with stage IIIC and IVA are very close.

In the 8th edition database, there were 5002 retrospective cases with SCLC, of which 4,848 were clinically staged, 582 were pathologically

staged, and 428 were both clinically and pathologically staged. The analyses of the database confirmed the prognostic value of clinical and pathological TNM staging in patients with SCLC. The continued usage of TNM staging in relation to proposed changes to T categories for NSCLC in the 8th edition is recommended for staging of SCLC (9).

In conclusion, in the 8th edition of the TNM classification for lung cancer, tumor diameter is more important and each centimeter counts. There are changes in some T descriptors such as main bronchus involvement, total atelectasis/pneumonitis, involvement of the diaphragm, and mediastinal pleural invasion. The current N staging is still valid; however, there are clues for the importance of abundance of nodal involvement. Three metastatic groups are defined. More stage groupings demonstrating good prognostic categories are proposed. The implication of these changes to treatment is minimal. Proposed taxonomic changes do not affect therapeutic modalities. However, it is important to follow up on small pulmonary nodules more carefully. The prognosis of locally advanced diseases (T3–4N3, stage IIIC) is as poor as stage IVA. An oligometastatic disease definition can be derived as "single metastasis in a single organ".

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