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Lung Cancer Staging: An Overview of the New Staging System, and Implications for Radiographic Clinical Staging

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Introduction

The Cancer Commission of the League of Nations Health Organization established the Radiological Sub-Commission in 1929 with the primary mandate of creating a common cancer staging system in order to facilitate effective communication across institutions around the world. Shortly thereafter by Dr. Pierre Denoix developed the TNM system used in almost all solid cancer staging today, and he continued to broaden and refine his TNM based staging approach through a series of articles published in the 1940's and 50's.¹ Denoix's approach gained its first institutional endorsement when the 7th International Congress of Radiology adopted TNM staging for laryngeal and breast cancer in 1953. Subsequently, as chairman of the Union Contre Le Cancer (UICC) staging committee, Denoix oversaw the publication of a series of "fascicles" (brochures) released during the 1960's establishing standardized TNM staging for 23 solid organ cancers. A tradition of international consensus in cancer staging was established in 1969, when the American Joint Committee for Cancer Staging and End Results Reporting (renamed American Joint Committee on Cancer in 1980) and the UICC agreed that all subsequent staging recommendations by either body would be published in consultation with the other.²

Lung cancer staging was incorporated into the UICC TNM staging system in 1966. The first substantial revision of the lung cancer TNM staging was proposed by Dr. Mountain et al. in 1973 with the publication of "A Clinical Staging System for Lung Cancer". This work was based on the outcomes of 2,155 cases of lung cancer, 1,712 of which were non-small cell lung cancer. It further specified the T, N and M descriptors and introduced stage groupings for the first time.³ Over the next 25 years, the lung cancer TNM staging system underwent three major revisions, all based on Dr. Mountain's growing database, which had increased to 5,319 cases by 1996.⁴ It was at this point that the International Association for the Study of Lung Cancer (IASLC) initiated the IASLC Lung Cancer Staging Project.

The IASLC Lung Staging Project sought to revise lung cancer staging to by using a data set more powerful, current, and universal than any single institutional database. From 1997 until

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2009, this group developed a database incorporating patient data gathered from participating institutions around the world, collecting over 81,000 cases of lung cancer. The majority of cases were from Europe and the United States (58% and 21%, respectively), but a significant number of patients from Asia and Australia were included. Patients treated with all modalities were accepted into the database (including surgery, chemotherapy and radiation therapy) in order to better sample the true lung cancer population.²

The 7th edition of the lung cancer staging system thus represents the culmination of a remarkably comprehensive review process. Improvements in surgical, medical and radiation treatments, surveillance, radiographic staging, post-operative care and minimally invasive surgery have all changed lung cancer treatment and survival in the last decade. These new factors have not been accounted for in the previous staging schema and impact treatment decisions. Based on outcomes data from patients treated with these improved modalities, the TNM staging is more representative of current treatment patterns and helps better guide the clinician.

The IASLC Lung Cancer Staging Project set out to accomplish a series of goals:

1. Aid the clinician in planning treatment
2. Give some indication of prognosis for each stage
3. Assist in the evaluation of the results of treatment
4. Facilitate the exchange of information between centers across the globe
5. To contribute to the continuing investigation of human cancer.²

This article will review the AJCC 7th edition Cancer Staging for lung cancer and will compare it to the 6th edition, with emphasis on operable disease. Clinical staging, its strengths and weakness, along with minimally invasive staging supplements will be discussed to aid the clinician in the preoperative staging of lung cancer.

TNM STAGING CHANGES NEW TO THE 7TH EDITION

Overview of Changes

The 7th edition of the TNM Classification of Malignant Tumors contains the first revision to lung staging since the publication of the 5th edition in 1997. (The 6th edition carried no revisions for lung cancer.) These revisions were based entirely on the recommendations of the IASLC, and reflect outcomes data on 68,463 cases of NSCLC and 13,032 cases of SCLC gathered from around the world (with a numerical bias towards Europe).

The 7th edition introduces further subdivision of the T and M stages, dividing the T1, T2 and M1 into substages (Table 1). These changes were intended to better reflect an increased appreciation for the subtle prognostic differences associated with specific aspects of primary and metastatic disease progression.

Nodal substages were not revised, but the definitions of various nodal levels are clarified, resolving discrepancies between the various nodal maps in common use. Furthermore, though not applied to the current edition, the IASLC outlines a new system for grouping mediastinal lymph nodes into anatomic zones, with the recommendation that these zones be considered for future study.

Tumor Descriptor Changes

Tumor Size and Subdivision—Further stratification of tumor staging by size is one of the central changes found in the 7th edition. What were previously considered T1 and T2

tumors were further divided by size, creating subcategories T1a, T1b, T2a, and T2b. While all tumors smaller than 3cm in greatest dimension are still T1, they are further subdivided such that tumors < 2cm are now T1a, and those which are >2cm (up to 3cm) are considered T1b. Likewise, T2a is now used to designate tumors >3cm but <5cm in size, and T2b denotes tumors >3cm and up to 7cm. Furthermore, tumors larger than 7cm are now considered at least T3 by virtue of size alone. These specific size cut-off's were selected based on a log-rank analysis of 4,891 resected (RO) tumors with documented pathologic assessment of size, which identified 2cm, 3cm, 5cm, and 7cm as the optimal cut off points for segregating patients by survival (Tables 2 and 3).⁵

Multifocal Tumors—The seventh edition, also redefines the staging impact of multifocal disease, as the prognosis of patients with certain patterns of satellite lesions was found to be better than previously thought.⁶⁻⁹ Multiple tumors of similar histology in the same lobe are now T3 instead of T4 (provided that none of the individual lesions meets T4 criteria on its own). Likewise, patients with histologically similar tumor nodules found in separate lobes of the same (ipsilateral) lung are now staged as T4 (previously M1). Histologically similar nodules in the contralateral lung are still considered M1 disease (Tables 1 and 2).

Multifocal lesions or satellite nodules should not be confused with synchronous primary tumors. Multifocal disease is defined as such only when histology confirms the various lesions represent a single disease process. Two separate nodules showing distinct histopathologies are considered synchronous primaries—two separate disease processes that happen to be occurring in the same patient. As such, in cases of synchronous primaries, both primary tumors should be staged separately and the stage of the patient is the highest stage lesion.¹⁰

Pleural Invasions and Malignant Effusions—As in the previous system, invasion of visceral pleura conveys a minimum tumor stage of T2, and involvement of the mediastinal or parietal pleura qualifies as T3 disease. A clear pathologic definition of pleural invasion was provided, outlining the use of elastin stains.¹¹ The 7th edition also provides a new system of histologic grading of pleural invasion, but this “PL” sub-staging system is provided expressly for research purposes, and is not currently factored into staging.

Finally, due to remarkably poor prognosis of patients with positive cytology from pleural or pericardial fluid, malignant pleural and pericardial effusions now qualify as M1a disease.¹²

Nodal Descriptors

The 7th edition does not change the nodal staging criteria per se, but it does clarify precise definitions of the various nodal levels, and it proposes a new model for nodal zones to facilitate future study.

A New International Lymph Node Map—Though no changes were made to the lymph node descriptors in the seventh edition, a new lymph node map was created to resolve differences between the American Thoracic Society map (Mountain-Dresler's) and the Japan Lung Cancer Society map (Naruke's).¹³ These changes were minimal, but helped create a consistent nomenclature to be used, allowing easier comparison between different international centers (Figure 1).

Nodal Zones—In addition to consolidating the various nomenclatures for lymph node mapping, the 7th edition also introduces a new method of grouping the mediastinal nodes into five different zones (Table 4). These zones represent areas of similar nodal drainage and it is felt that defining nodal status by zones may allow for more prognostically precise nodal

staging.¹⁴⁻¹⁸ Though the committee falls short of incorporating the nodal zones into the subdivision of nodal metastasis (i.e. N1a or N1b), studies are underway to confirm their prognostic value, and they are expected to play an increased role in treatment decisions.

Metastasis Descriptor Changes

The M descriptor was also subdivided in an effort to differentiate between distant and intrathoracic metastasis. Malignant pleural and pericardial effusions, previously considered T4 disease, are now designated M1a. Contralateral nodules are also placed in the M1a category and all distant metastatic disease is considered M1b (Table 1).¹⁹

Staging Changes

Overall, the greatest effects of the 7th edition revisions on overall stage are found in the earlier stages (Ia-IIb), where the subdivision of tumor descriptors has the largest impact. These changes have been outlined in Table 5.²⁰

CLINICAL STAGING

Assessment of Tumor Stage

CT scan continues to provide an excellent non-invasive and relatively inexpensive modality for assessing tumor size. The impact of pretreatment tumor-size measurements is greater than before as the new system emphasizes stage segregation based on tumor size, both in the creation of the T1a/b and T2a/b subdivisions, as well as in the fact that tumors can now be upstaged to T3 by size alone. Preoperative assessment of size is also helpful in anticipating nodal disease, as increased tumor size has been shown to increase the risk of nodal disease.¹⁵⁻¹⁸

When there is reason to suspect local invasion or critical anatomic risk factors (i.e. carinal proximity), supplemental imaging may be helpful. CT imaging is remarkably inconsistent in identifying chest wall invasion.^{21,22} While conventional MR imaging failed to outperform CT for detecting chest wall invasion,²³ small-scale trials have found both respiratory dynamic (RD) MRI and transthoracic ultrasonography achieved improved accuracy in assessing chest wall invasion. The best imaging modality to determine chest wall invasion remains in question, but as imaging technology and practice continues to evolve, it is likely that various modalities will soon offer precise and accurate noninvasive assessments to inform critical pre-treatment planning.

Local invasion of mediastinal structures can also be difficult to determine radiographically. While gross invasion can be obvious, CT images are unreliable for differentiating abutment from subtle invasion.^{23,24} Though the addition of endobronchial ultrasound and/or esophageal ultrasound (EBUS and/or EUS) can sometimes be helpful in questionable cases, in the setting of otherwise operable disease, anything short of obvious extensive local invasion must be confirmed intraoperatively.²⁵ Likewise, precise definition of an airway lesion's proximity to the carina and/or main bronchi requires bronchoscopic confirmation.

Though it may not provide a reliable evaluation of T-stage, high resolution CT remains an invaluable asset for providing the detailed anatomic information required for planning an operative approach and is the imaging modality of choice currently.

Assessment of Nodal Stage

By far, the most complicated and rapidly evolving aspect of clinical staging for NSCLC is the question of how to best assess nodal status. CT scan alone has long been recognized as ineffective as a stand-alone test for assessing mediastinal and hilar lymph nodes in NSCLC

patients, with false negative rates reported as high as 30%.²⁶ Though more sensitive than CT, FDG-PET scans have also been found to miss 6-20% of cases with nodal disease,²⁷⁻²⁹ particularly in the setting of larger primary tumors and in the assessment of hilar nodes.²⁸ Such false negatives are particularly concerning for patients being considered for definitive radiation therapy for early stage lung cancers; as failing to recognize nodal disease can result in inadequate treatment. Since a negative CT/PET scan does not obviate the need for tissue sampling, our bias is to confirm negative hilar nodal involvement with EBUS-TBNA (endobronchial ultrasound-transbronchial needle aspiration). Likewise, positive nodal disease suggested by CT/PET must be confirmed histologically due to the risk of false positive results. Beyond their immediate diagnostic role, these studies are remarkably helpful in planning tissue sampling procedures, likely augmenting their accuracy.

Nodal staging algorithms are currently in flux with the increasing use of endobronchial and esophageal ultrasound guided biopsy techniques (EUS-FNA). Quite recently, preoperative mediastinoscopy was the standard of care in the workup for most resection candidates; recently its role has diminished with the increasing availability of high quality CT/PET as well as the more widespread use of EBUS-TBNA/EUS-FNA capabilities. EBUS-TBNA/EUS-FNA provides a minimally invasive and remarkably sensitive modality for confirming nodal disease identified on CT/PET imaging.²⁵

Meyers et al found that adding mediastinoscopy to patients without evidence of mediastinal nodal disease on CT/PET scans lowered the false negative rate by only 1%, rendering its use not cost-effective.²⁸ Conversely, Herth et al found that a negative EBUS-TBNA result in patients with negative CT/PET imaging carried an NPV of 99%, using a technique which is both less invasive and less expensive than mediastinoscopy.³⁰ At our institution, a negative CT/PET is adequate for assessment of the mediastinum, except for patients who may require a pneumonectomy. Negative CT/PET for assessment of hilar disease, followed by a negative EBUS-TBNA, is considered adequate workup to proceed to surgical resection without neoadjuvant therapy. It is worth noting, though, that this is not to imply that negative findings on a CT/PET scan followed by a negative EBUS-TBNA can be taken as proof-positive confirmation of N0 status, but it is currently the best minimally invasive approach to stage these patients.

In years past, it was held by many that a negative EBUS-TBNA in the setting of positive CT/PET findings required confirmatory with mediastinoscopy.³¹ Recent studies have found that improved EBUS-TBNA sensitivity limit the marginal utility of such confirmatory mediastinoscopies. In a multi-center randomized control trial, Annema et al found that even in patients with suspicious CT/PET findings, performing mediastinoscopy after a negative EBUS/EUS-TBNA only detected nodal disease in 9% of those patients.³² This suggests 11 mediastinoscopies would be necessary to detect a single case of EBUS/EUS-occult nodal disease. As such, we do not routinely perform mediastinoscopies in patients who are CT/PET+ but EBUS- for nodal disease. In addition, avoiding a pretreatment mediastinoscopy has the added benefit of preserving the feasibility of mediastinoscopy for post-treatment restaging. However, as always, individual practices must be adjusted to reflect the technology and expertise of any treatment setting.

CONCLUSION

The 7th edition lung cancer TNM staging system's changes are significant for many reasons, including that this is the first time diverse international data was used. In addition, almost twenty times the number of patients was reviewed to make the recommendations for this edition, including patients who received a wide variety of treatment modalities. Specific changes to the T and M descriptors with stage shift are the major differences and reflect the

overall survival of these subgroups. The revisions made from the previous system were carefully selected to improve prognostic precision and accuracy of lung cancer staging.

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Figure 3: The International Association for the Study of Lung Cancer (IASLC) lymph node map, including the proposed grouping of lymph node stations into "zones" for the purposes of prognostic analyses. (Reprinted from Rusch VW, on Behalf of the Members of the IASLC Staging Committee. The IASLC lung cancer staging project: a proposal for a new international lymph node map in the forthcoming seventh edition of the TNM classification for lung cancer. *J Thorac Oncol*. 2009;4:568-577.)

Figure 1.
IASLC Nodal Chart

Table 1
T and M Descriptor: Summary of Changes from 6th Edition

This table lists all of the substages from the 6th edition effect by the 7th edition revisions, and summarizes the new or revised descriptors for classification.

Sixth Edition	Qualifying Descriptors	Seventh Edition
T1	Tumors ≤ 2 cm	T1a
	Tumors >2cm and ≤ 3 cm	T1b
T2	Tumors ≤ 5cm	T2a
	Tumors >5 cm - 7 cm	T2b
	Tumors > 7 cm	T3
[Any T3 tumor in 6 th Ed remains T3]		
T4	Separate nodule(s) in same lobe	T3
	Malignant pleural or pericardial effusion	M1a
M1	Satellite nodules in separate lobe of ipsilateral lung	T4
	Additional nodules in contralateral lung	M1a
	Pleural nodules	M1a
	Distant Metastases	M1b

Table 2
T Staging Changes Correlate with Survival

Subdivision of tumor based on size separated T1 and T2 into 2 subcategories each. T3 lesions represented large tumors or multiple nodules in the same lobe. Multiple nodules in the ipsilateral lung are now considered T4 and all malignant pleural or pericardial disease was upgraded to M1a.

Tumor Descriptors	Seventh Edition	5 Year Survival¹
Tumors ≤ 2 cm	T1a	77%
Tumors ≤ 3 cm	T1b	71%
Tumors ≤ 5cm	T2a	58%
Tumors >5 cm - 7 cm	T2b	49%
Tumors > 7 cm	T3	35%
Same lobe nodules	T3	28%
Separate nodule(s) in ipsilateral lung	T4	22%
Malignant pleural or pericardial effusion	M1a	2%

Table 3
T Descriptors Overview

TX	Primary tumor confirmed, but stage cannot be determined (eg tumor undetectable on imaging and diagnostics despite positive sputum cytology)
T0	No evidence of a primary tumor
Tis	Carcinoma in situ
T1	Tumor is less than 3cm in greatest dimension and meets the following criteria: <ul style="list-style-type: none"> +Tumor is surrounded by lung or visceral pleura + There is no evidence main bronchus invasion, <p>T1a Tumor $\leq$ 2cm</p> <p>T1b 2cm < Tumor $\leq$ 3cm</p>
T2	3cm $\leq$ Tumor $\leq$ 7cm OR meets any of the following criteria <ul style="list-style-type: none"> +Tumor involves main bronchus (at least 2cm from carina) +Tumor invades visceral pleura, but no further +Tumor associated with atelectasis or obstructive pneumonitis extending to hilar region, but not involving the entire lung <p>T2a 3cm < tumor $\leq$ 5cm</p> <p>T2b 5cm < tumor $\leq$ 7cm</p>
T3	Tumor is more than 7cm in greatest dimension OR meets any of the following criteria <ul style="list-style-type: none"> +Directly invades chest wall, diaphragm, pnic nerve, mediastinal pleura or parietal pericardium +Tumor involves main bronchus less than 2cm from (but not into) carina +Associated with atelectasis or obstructive pneumonitis of entire lung +Associated with satellite nodule or nodules that are all limited to the same lobe as main tumor
T4	Tumor of any size that meets any of the following criteria <ul style="list-style-type: none"> +Invades mediastinum, heart, great vessels, trachea, recurrent laryngeal nerve, esophagus, vertebral body +Involves the carina +Associated with satellite nodule or nodules in an ipsilateral lobe separate from that containing the primary

Table 4**Nodal Zones**

Nodal draining basins are the basis for this grouping of the nodal stations and will require future validation to assess prognostic significance.

Nodal Zone	Descriptor	Nodal Station
Supraclavicular Zone	Low cervical, supraclavicular and sternal notch	1R and 1L
Upper Zone	Upper paratracheal	2R and 2L
	Prevascular/Retrotracheal	3a and 3p
	Lower Paratracheal	4R and 4L
AP Zone	Subaortic/Para-aortic	5 and 6
Subcarinal Zone	Subcarinal	7
Lower Zone	Paraesophageal	8R and 8L
	Pulmonary Ligament	9R and 9L
Hilar/Interlobar Zone	Hilar	10R and 10L
	Interlobar	11R and 11L
Peripheral Zone	Lobar	12R and 12L
	Segmental	13R and 13L
	Subsegmental	14R and 14L

Stage Groups bolded are the changes seen between the 6th and 7th editions. Larger tumors were upstaged, multiple nodules in same lung and ipsilateral lung were downstaged and all malignant effusions were upstaged.

Table 5

Changes from the 6th Edition Staging Group

6 th Edition	7 th Edition	N0	N1	N2	N3
T1 (=2cm)	T1a	IA	IIA	IIIA	IIIB
T1 (>2 cm =3 cm)	T1b	IA	IIA	IIIA	IIIB
T2 (>3 cm =5 cm)	T2a	IB	IIA	IIIA	IIIB
T2 (>5 cm = 7 cm)	T2b	IIA	IIIB	IIIA	IIIB
T2 (> 7 cm)	T3	IIIB	IIIA	IIIA	IIIB
T3 (direct invasion)		IIIB	IIIA	IIIA	IIIB
T4 (same lobe nodules)		IIIB	IIIA	IIIA	IIIB
T4 (extension)	T4	IIIA	IIIA	IIIB	IIIB
M1 (ipsilateral nodules)		IIIA	IIIA	IIIB	IIIB
T4 (pleural effusion)	M1a	IV	IV	IV	IV
M1 (contralateral nodules)		IV	IV	IV	IV
M1 (distant)	M1b	IV	IV	IV	IV