PERSPECTIVE ARTICLE

Challenges of Staging Lung Cancer with the New TNM Classification (9th edition)

Desafios do Estadiamento do Cancro do Pulmão com a Nova Classificação TNM (9ª Edição)

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Accurate staging of lung cancer is crucial in determining optimal treatment strategies and predicting patient outcomes. The staging process guides clinicians in making informed decisions regarding surgery, chemotherapy, radiotherapy, and the incorporation of emerging neoadjuvant or perioperative therapies.[1,2] The recent introduction of the 9th edition of the TNM (Tumor, Node, Metastasis) classification system brings significant changes, particularly in the nodal (N) classification, necessitating a reevaluation of current staging practices and methodologies.[1,2]

The TNM classification system, developed by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC), has been the highlight of cancer staging and has evolved to incorporate new medical knowledge and diagnostic tools.[1] For over three decades, the N classification within the TNM staging system remained unchanged since its 1987 edition.[1] However, the 9th edition introduces a critical subdivision of the N2 category into N2a and N2b, addressing limitations in the previous system that did not fully capture the tumor burden within the lymph nodes.[3,4] In the new classification, N2a indicates metastasis to a single ipsilateral mediastinal lymph node station, while N2b describes the involvement of multiple ipsilateral mediastinal lymph node stations.[3,4] Research has demonstrated that this distinction correlates with significant survival differences - approximately a 10% variation - in both clinical and pathological staging scenarios.[3,4] By subdividing N2, the classification system aims to reduce heterogeneity within the staging categories and provide a more precise prognostic tool[3] (Fig. 1).

However, the updated N classification also introduces complexities that challenge clinicians to adapt their staging practices. Accurately distinguishing between N2a and N2b disease mandates a more comprehensive and systematic

approach to mediastinal lymph node evaluation.[5-7] Firstly, clinicians must assess all accessible lymph node stations systematically rather than focusing solely on nodes that appear suspicious on imaging modalities.[5,8] This can be achieved by endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA), which has become a keystone of mediastinal staging, due to its minimally invasive nature and high diagnostic yield.[6,9] This technique allows real-time ultrasound-guided sampling of mediastinal stations 2R/2L, 3P, 4R/4L, 7, and broncho-hilar lymph nodes at 10 and 11 stations, facilitating a comprehensive and accurate staging[6] (Fig. 2). However, certain lymph node stations remain challenging to access via the tracheobronchial route. Stations 8 and 9, located in the paraesophageal and pulmonary ligament areas, cannot be sampled bronchoscopically and require endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) via the esophagus.[6,9] This may be achieved with the same scope used endobronchially, which has been called EUS-B.[10] The "SCORE" study demonstrated that combining EUS-B with systematic EBUS scanning improved the sensitivity of mediastinal lymph node staging in lung cancer patients by 9% when compared to a targeted approach by EBUS alone, guided by positron emission tomography/computed tomography (PET/CT) results.[10] In addition to lower paraesophageal stations, EUS also provides easy access to mediastinal lymph nodes at 2L, 3P, 4 L and 7 stations, complementing the endobronchial approach in difficult cases, and sometimes reaches station 5 at the aortopulmonary window.[11] This subaortic lymph node station, as the para-aortic station 6 and prevascular station 3A, all adjacent to major blood vessels, pose significant risks and difficulties when attempting access through either EBUS or EUS.[6,9] Although previous studies have shown that station 6 can be accessed using a transaortic approach,[12] this technique has not gained widespread adoption in clinical practice. As a result, they are often only accessible percutaneously, or through extended mediastinoscopy or video assisted thoracic surgery (VATS)[13] (Fig. 2). Thus, to ensure that all relevant nodes are assessed, a multimodal approach, combining EBUS-TBNA and EUS-FNA/EUS-B, in addition to interventional radiologists or thoracic surgeons, becomes increasingly vital to accurately separate N2a from N2b cases.[5,6,9]

Furthermore, while proficiency in both EBUS and EUS expands the pulmonologist's ability to access and sample a broader range of mediastinal lymph nodes, an accurate staging also requires good planning abilities, by meticulously reviewing computed tomography (CT) in axial, coronal, and sagittal planes, to avoid any misclassification.[6,9] Lymph node stations are defined based on anatomical landmarks rather than arbitrary lines, introducing variability in staging depending on individual patient variations.[6,9] For instance, the azygos vein serves as a boundary for differentiating between stations 4R and 10R,[9] and there is a risk of misclassifying a N2 case as N1, or vice versa, particularly when lymph node enlargement or anatomical variations obscure the precise location of the azygos vein, or the enlarged lymph node extends across the vein. This highlights the

8th Ed TNM Categories

T/M	Label	N0	N1	N2	N3
T1	T1a	IA1	IIB	IIIA	IIIB
	T1b	IA2	IIB	IIIA	IIIB
	T1c	IA3	IIB	IIIA	IIIB
T2	T2a Inv	IB	IIB	IIIA	IIIB
	T2a >3-4	IB	IIB	IIIA	IIIB
	T2b >4-5	IIA	IIB	IIIA	IIIB
T3	T3 >5-7	IIB	IIIA	IIIB	IIIC
	T3 Inv	IIB	IIIA	IIIB	IIIC
	T3 Same Lobe Nod	IIB	IIIA	IIIB	IIIC
T4	T4 >7	IIIA	IIIA	IIIB	IIIC
	T4 Inv	IIIA	IIIA	IIIB	IIIC
	T4 Ipsi Nod	IIIA	IIIA	IIIB	IIIC
M1	M1a Pl Dissem	IVA	IVA	IVA	IVA
	M1a Contr Nod	IVA	IVA	IVA	IVA
	M1b Single Les	IVA	IVA	IVA	IVA
	M1c Mult Les	IVB	IVB	IVB	IVB

Proposed 9th Ed TNM Categories

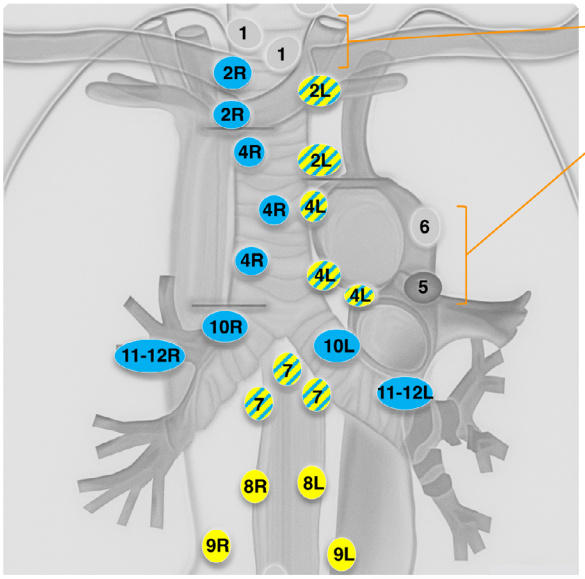
T/M	Description	N0	N1	N2		N3
				N2a	N2b	
T1	T1a ≤1 cm	IA1	IIA	IIB	IIIA	IIIB
	T1b >1 to ≤2 cm	IA2	IIA	IIB	IIIA	IIIB
	T1c >2 to ≤3 cm	IA3	IIA	IIB	IIIA	IIIB
T2	T2a Visceral pleura / central invasion	IB	IIB	IIIA	IIIB	IIIB
	T2a >3 to ≤4 cm	IB	IIB	IIIA	IIIB	IIIB
	T2b >4 to ≤5 cm	IIA	IIB	IIIA	IIIB	IIIB
T3	T3 >5 to ≤7 cm	IIB	IIIA	IIIA	IIIB	IIIC
	T3 Invasion	IIB	IIIA	IIIA	IIIB	IIIC
	T3 Same lobe tumor nodule	IIB	IIIA	IIIA	IIIB	IIIC
T4	T4 >7 cm	IIIA	IIIA	IIIB	IIIB	IIIC
	T4 Invasion	IIIA	IIIA	IIIB	IIIB	IIIC
	T4 Ipsilateral tumor nodule	IIIA	IIIA	IIIB	IIIB	IIIC
M1	M1a Pleural / pericardial dissemination	IVA	IVA	IVA	IVA	IVA
	M1a Contralateral tumor nodule	IVA	IVA	IVA	IVA	IVA
	M1b Single extrathoracic lesion	IVA	IVA	IVA	IVA	IVA
	M1c1 Multiple lesions, 1 organ system	IVB	IVB	IVB	IVB	IVB
	M1c2 Multiple lesions, >1 organ system	IVB	IVB	IVB	IVB	IVB

Downgrade:
- o T1 tumours with N1
- o T1 tumours with single--station N2 involvement
- o T3 tumours with single--station N2 involvement

Upgrade:
- o T2 tumours with multiple--station N2 involvement

IASLC INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER
Conquering Lung & Thoracic Cancers Worldwide in the 21st Century

Figure 1 Schematic representation of the 8th and the 9th TNM classification, with main changes highlighted.
Adapted, with permission from Elsevier, from Rami-Porta R, et al. The International Association for the Study of Lung Cancer Lung Cancer Staging Project: Proposals for Revision of the TNM Stage Groups in the Forthcoming (Ninth) Edition of the TNM Classification for Lung Cancer. J Thorac Oncol. 2024;19:1007-27.[17]



Ultrasound-guided LN biopsy

Low cervical, supraclavicular and sternal notch LN (1)

Surgery / Percutaneous biopsy

Prevascular (3a), subaortic (5) and para-/preaortic (6)

EBUS (endobronchial route)

Paratracheal (2L/2R, 4L/4R), subcarinal (7), hilar (10L/10R) and inter-lobar (11L/12L)

EBUS/EUS

Left paratracheal (2L, 4L), retrotracheal (3P) and subcarinal (7)

EUS (esophageal route)

Paraesophageal (8L/8R) and pulmonary ligament (9L/9R)

Figure 2 International Association for the Study of Lung Cancer (IASLC) Lymph Node Map and description of sampling accessibility.

importance of integrating imaging findings with endoscopic or ultrasonographic anatomy, and maintaining a systematic approach during staging to minimize diagnostic errors that could affect treatment decisions. Consideration should be given to formal training programs and certification processes to standardize proficiency levels among clinicians performing these complex procedures.[6,9] In a previous study, the absence of expert bronchoscopy specialists showed a meaningful correlation with the inaccuracy of clinical staging.[14]

The utility of rapid on-site evaluation (ROSE) in the context of the new N classification also requires reconsideration. Traditionally, ROSE has been utilized to offer immediate cytological assessment during EBUS-TBNA, providing feedback on sample adequacy and allowing for adjustments during the procedure if necessary.[8,9] Obtaining a positive result at one single N2 lymph node station, for instance, the subcarinal, would typically allow the clinician to conclude the procedure without sampling additional nodes, thus saving time and enhancing patient comfort.[9] However, the need to assess multiple stations to distinguish between N2a and N2b disease reduces the time-saving advantage of ROSE.[8,9] On the other hand, ROSE can help guide decisions on needle change and prevent cross-contamination of samples when the first N2-positive station is sampled. Persistent oncocytological material is detectable in the fluid flushed through the EBUS needle after a metastatic lymph node has been sampled, raising concerns about tissue contamination and the potential for false declaration of multiple N2 infiltrates.[15] Each needle represents a significant expense, so immediate determination of the necessity for a new needle helps keep the procedure cost-effective.[8,9]

Despite the practical implications on treatment planning and patient management raised by the subdivision of the N2 category, emerging evidence from clinical trials supports the use of neoadjuvant and perioperative combined chemo-immunotherapy for patients with N2 disease, that requires further validation in light of the new TNM classification. For patients with T1 (≤3 cm) potentially resectable N2a disease - single-station involvement without bulky disease - upfront surgical resection may provide survival outcomes comparable to those achieved with neoadjuvant therapy followed by surgery[5,6,16] (Fig. 3). This was one of the major transformations with the new TNM classification, as every lung cancer with N2 involvement was previously categorized as at least stage IIIA disease in the 8th edition, but in the 9th edition, patients with a tumor diameter of ≤3 cm, single-level N2 disease (N2a), and no distant metastases are now downgraded as having stage IIB lung cancer[17] (Fig. 1). Another downgrade occurred for T3 tumors with N2a involvement, from stage IIIB to IIIA, which are now being considered for neoadjuvant and perioperative regimens[18] (Fig. 3), although in IIIA tumors with single station, non-bulky N2 disease, the benefit of surgical resection over chemoradiation therapy (CRT) remains uncertain.[19-22] On the other hand, T2 tumors with multiple N2 stations (N2b) involvement are upgraded from stage IIIA to IIIB, and these usually are not surgical candidates. Patients with unresectable stage III involving multiple lymph node stations or bulky mediastinal disease are typically considered for definitive CRT with the potential addition of consolidation immunotherapy based on recent trial data.[23]

Additionally, the importance of genetics and molecular testing in predicting patient outcomes and treatment responses cannot be overlooked.[7] Patients with NSCLC harboring certain actionable genomic alterations (AGAs), such as *EGFR* and *ALK* alterations, have a higher probability for treatment failure and

lower pathological regression following neoadjuvant chemo-immunotherapy regimens.[24] In the setting of T1 tumors (≤3 cm) with non-bulky lymph node involvement, where the disease is considered resectable and positive molecular testing results are already available, the distinction between N2a and N2b does not influence treatment decisions. This is because both subcategories are eligible for the same adjuvant targeted therapy in the postoperative setting for completely resected EGFR- or ALK-positive tumors.[7,25]

A significant question still arises regarding the necessity of invasive mediastinal staging in patients with small, peripheral lung tumors. Proceeding directly to surgical resection without prior invasive staging may be accepted in certain cases, according to the latest societal guidelines,[26] particularly when the surgical risk is low and the potential for occult mediastinal disease is minimal.[5,7] However, studies have shown that even tumors staged as T1, with PET and CT-negative mediastinal involvement, may contain occult N2/N3 mediastinal metastases in over 10% of the cases, which can significantly alter treatment options and prognosis.[5,7,27] Nevertheless, similar rates of incidental N2 disease have been shown in the MEDIASTrial, the first multicenter randomized controlled trial investigating the added value of mediastinoscopy after negative EBUS results. The unforeseen N2 disease rate was 8.8% in those who underwent immediate resection after EBUS, which was not significantly lower than the rate of 7.7% in those with confirmatory mediastinoscopy assessment.[28] Therefore, the decision to undergo invasive staging should always be personalized to each patient's unique circumstances to balance the benefits of comprehensive staging against the risks and costs of invasive procedures.[5-7]

The complexity of clinical decisions in such cases demands in-depth analysis within the frame of multidisciplinary discussions. The updated lung cancer staging system brings both opportunities and challenges. Standardized protocols for lymph node assessment and biopsy are essential to minimize inconsistencies and ensure reliability.[6,9] This includes consensus on criteria for suspicious lymph nodes and uniform biopsy techniques.[6,9] The accuracy of mediastinal staging relies significantly on the proficiency of the clinician performing the procedure.[6,9] As such, enhancing clinician training is vital to ensure consistent and accurate implementation of the new TNM classification across different healthcare settings.[6,9] The detailed N classification may also strain healthcare resources by requiring multiple biopsy needles and ROSE assessment.[6,9] Moreover, proper staging demands, more than ever, collaboration across specialties – surgeons, pulmonologists, radiologists, and pathologists united in patient care.[6,7,9] The evolving landscape of treatment also underscores the need for ongoing research and adaptation of clinical practices.[1,5,6] Future directions will involve refinement of staging protocols by integrating molecular markers and advanced imaging techniques to enhance accuracy and predictive value.[7]

In conclusion, the introduction of the 9th edition TNM classification marks a substantial step forward in lung cancer staging, offering a more detailed and clinically applicable framework for evaluating nodal involvement.[1,2] The subdivision of the N2 category into N2a and N2b addresses the prognostic variability inherent in the previous grouping system, thereby improving the accuracy of staging and informing more personalized therapeutic approaches.[3,4] By embracing the challenges presented, investing in clinician expertise, and encouraging multidisciplinary collaboration, the medical community can enhance the accuracy of lung cancer staging and optimize therapeutic strategies, ultimately improving survival rates and quality of life for patients facing this complex disease.[1,5,6]

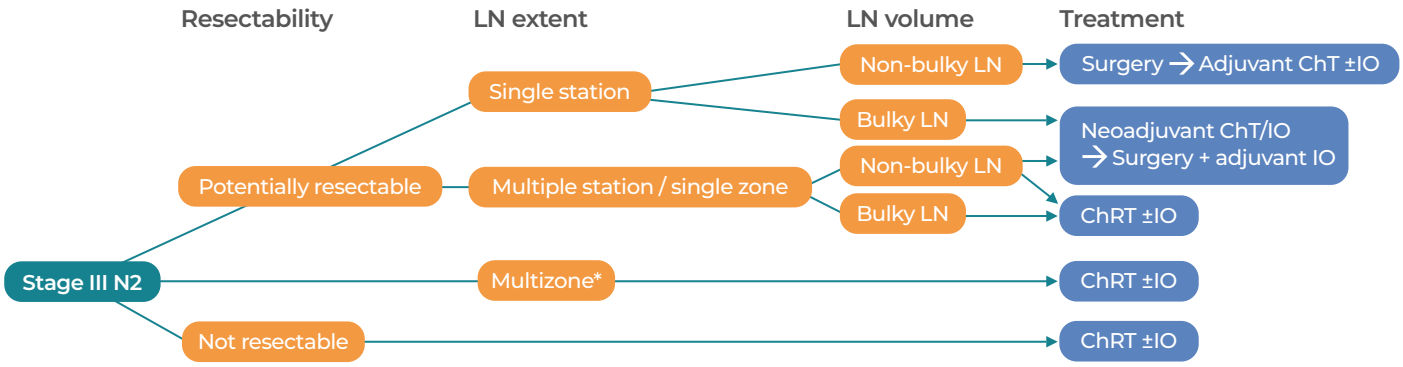


Figure 3 Management algorithm proposal based for stage III N2 tumors, considering the N2 division in subcategories. Lymph node zones*: superior (2-4), AP (5-6), subcarinal (7), lower (8-9). Adapted from Rei J [16]; Faivre-Finn C [23]; Bousema JE [28]
ChT – chemotherapy; ChRT – chemoradiation therapy; IO – immunotherapy; LN – lymph nodes.

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