The IASLC Lung Cancer Staging Project: The New Database to Inform the Eighth Edition of the TNM Classification of Lung Cancer

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Abstract: The analyses of the retrospective database of the International Association for the Study of Lung Cancer (IASLC), consisting of more than 81,000 evaluable patients diagnosed with lung cancer between 1990 and 2000, formed the basis of recommendations to the Union for International Cancer Control and the American Joint Committee on Cancer for the revision of the sixth edition of the tumor, node, and metastasis (TNM) classification of lung cancer. However, despite the large number of patients, not all descriptors could be validated. This prompted a new collection of retrospective and prospective data to overcome the limitations of the original retrospective database. The new IASLC database has information on 94,708 new patients diagnosed of lung cancer between 1999 and 2010. They originated from 35 sources in 16 countries, and 4,667 were submitted via the online electronic data capture system. Europe contributed 46,560 patients, Asia: 41,705, North America: 4,660, Australia: 1,593, and South America: 190. After exclusions, 77,156 (70,967 with nonsmall cell lung cancer and 6,189 with small cell lung cancer) remained for analysis. This database will be analyzed according to established objectives for the T, the N, and the M components to inform the eighth edition of the TNM classification of lung cancer due to be published in 2016. The IASLC hopes for the continuing contribution of our partners around the world to improve the classification of anatomical extent of disease, but also to create prognostic groups in a parallel project of the IASLC Staging and Prognostic Factors Committee.

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The call for action launched during the International Workshop on Intrathoracic Staging, that took place in London, United Kingdom, in October 1996[1] to revise and improve the tumor, node, and metastasis (TNM) classification of lung cancer, resulted in an unprecedented response from groups and institutions around the world. By 2005, data on 100,869 patients diagnosed of lung cancer between 1990 and 2000 were submitted to the International Association for the Study of Lung Cancer (IASLC) database at Cancer Research And Biostatistics (CRAB). These data originated from 46 different sources in 20 countries of Europe, North America, Asia, and Australia. After exclusions, 81,495 patients were available for analyses: 68,463 with nonsmall cell lung cancer (NSCLC) and 13,032 with small cell lung cancer (SCLC).[2] From the analyses of these data, a series of research articles on the T,[3] the N,[4] and the M[5] components of the TNM classification were peer-reviewed and published in the *Journal of Thoracic Oncology* for public discussion. In a similar manner, a revised stage grouping was proposed,[6] the new findings were internally and externally validated,[7] and the TNM classification was tested and validated for SCLC[8,9] and, for the first time in the history of the anatomical staging of malignant tumors, for broncho-pulmonary carcinoids.[10] In addition, a new lymph node map, resulting from an international and multidisciplinary consensus and reconciling the differences of the previous ones, was proposed for prospective validation;[11] and a new definition of visceral pleura invasion was agreed based on the published data.[12] The nonanatomic information included in the database was used to create prognostic groups before and after surgical treatment based on the combination of anatomic staging and very simple clinical variables, such as age, gender, and performance status.[13,14] The recommendations for changes in the TNM classification of lung cancer derived from the analyses of the IASLC database (Table 1) were submitted

to the Union for International Cancer Control (UICC) and the American Joint Committee on Cancer (AJCC), and were accepted and subsequently published in the seventh edition of their staging manuals.[15,16] At the same time, the IASLC produced the *Staging Handbook in Thoracic Oncology* and the *Staging Manual in Thoracic Oncology* including the TNM classifications of lung cancer and mesothelioma, the general rules of the TNM classification, site-specific rules for lung cancer and mesothelioma, and complementary chapters on survival analyses, prognostic factors, frequently asked questions and the history of the TNM classification since its inception by Pierre Denoix in the mid 20th century.[17,18] With this contribution, the IASLC became the primary source of database-based evidence to revise subsequent editions of the UICC and the AJCC TNM classifications of thoracic malignancies.

Despite the vastness of the IASLC database, not all descriptors of the T, the N, and the M components of the anatomical classification could be validated. The main reason was that many of the original datasets of the contributing databases had not been designed to study the TNM classification. The resulting lack of detailed data prevented the analyses of many descriptors. For the T component, only could tumor size, additional tumor nodule(s) and pleural effusion be analyzed reliably. For the N component, the present categories could be validated in the clinical and pathological staging. However, the

TABLE 1. Innovations Introduced in the seventh Edition of the Tumor, Node, and Metastases Classification of Lung Cancer

Descriptor/TNM	Category/Stage in the sixth Edition	Category/Stage in the seventh Edition
Tumor size ≤ 2 cm	T1	T1a
Tumor size > 2 cm but ≤ 3 cm	T1	T1b
Tumor size > 3 cm but ≤ 5 cm	T2	T2a
Tumor size > 5 cm but ≤ 7 cm	T2	T2b
Tumor size > 7 cm	T2	T3
Additional tumor nodule(s) in the same lobe of the primary tumor	T4	T3
Additional tumor nodule(s) in another ipsilateral lobe	M1	T4
Pleural dissemination (malignant pleural effusion and separated pleural nodules)	T4	M1a
Pericardial dissemination (malignant pericardial effusion and separated pericardial nodules)	N/A	M1a
Intrathoracic metastases	M1	M1a
Extrathoracic metastases	M1	M1b
T2b N0 M0	IB	IIA
T2a N1 M0	IIB	IIA
T4 N0-1 M0	IIIB	IIIA

TABLE 2. Number of Cases Submitted by Each Data Source, by Continent

Region	Data Source	EDC Source	N
Asia	EDC	Guangdong General Hospital, China	739
		Shanghai Lung Tumor Clinical Medical Center, China	51
	Japan 1999		13,344
	Japan 2002		14,695
	Japan 2004		10,889
	South Korea		1,987
Australia	EDC	Peter MacCallum Cancer Centre	4
	Prince Charles		229
	Sydney		1,360
Europe	Belgrade, Serbia		88
	Denmark		33,949
	EDC	Athens School of Medicine, Greece	39
		Clinical Center of Serbia, Serbia	40
		GCCB-S, Spain	2,362
		L'Institut Mutualiste Montsouris, France	120
		Military Medical Academy, Serbia	20
		Antwerp University Hospital, Multidisciplinary Oncological Centre Antwerp (MOCA), Belgium	195
		University Hospital Ghent, Belgium	85
		University of Torino, Italy	4
	Norway		2,354
	Turkey		7,304
North and South America	EDC	Alexander Fleming Institute, Argentina	6
		Clinica y Maternidad Suizo Argentina, Argentina	3
		Fundación Clínica Valle del Lili, Colombia	2
		Good Samaritan Hospital, USA	10
		Hospital Británico de Buenos Aires, Argentina	68
		Hospital Universitario Austral, Argentina	46
		Hospital Universitario-Fundación Favaloro, Argentina	36
		Hospital de Rehabilitación Respiratoria, Argentina	14
		Mayo Clinic Rochester, USA	47
		New York University Langone Medical Center and Cancer Center, USA	688
		Penrose Cancer Center, USA	73
		University of Sao Paulo Medical School, Brazil	15
	MDACC, USA		2,415
	MSKCC, USA		1,427
Global Total			94,708

GCCB-S, Grupo Cooperativo de Carcinoma Broncogénico de la Sociedad Española de Neumología y Cirugía Torácica; NYU, New York University; MDACC, M. D. Anderson Cancer Center; MSKCC, Memorial Sloan-Kettering Cancer Center.

TABLE 3. Number of Cases Submitted to the Database, With Exclusions and the Numbers Remaining for Analysis

Submitted	94,708
Excluded	17,552
Carcinoids	745
Other or unknown histology	5,986
Outside 1999–2010 timeframe	525
Incomplete survival data	938
Incomplete stage information	9,286
Multiple synchronous tumors	72
Included in initial analyses	77,156
NSCLC	70,967
SCLC	6,189

TABLE 4. Number of Cases Analyzed by Type of Data Source

	Other	EDC	Total
Data source type			
Consortium	41,548	2,089	43,637
Registry	26,122		26,122
Surgical series	5,373	592	5,965
Institutional series		1,185	1,185
Institutional registry	208		208
Unknown		39	39
Total	73,251	3,905	77,156

Consortium: group of institutions where all individuals diagnosed with lung cancer are registered. Registry: all individuals diagnosed with lung cancer in a defined region, including those diagnosed at death. Surgical series: all individuals diagnosed with lung cancer and treated by a particular surgeon or unit. Institutional series: same as consortium, but in a single institution; may be limited to a specific treatment specialty or specialties. Institutional registry: all individuals diagnosed with lung cancer and admitted to a particular institution are registered.

TABLE 5. Comparison of Basic Elements of the Two IASLC Databases Used for Informing the seventh Edition and the eighth Edition of the TNM Classification of Lung Cancer

Element	Database for the seventh Edition	Database for the eighth Edition
Period of diagnosis	1990 to 2000	1999 to 2010
Total patients submitted	100,869	94,708
Geographical origin		
Europe	58,701 (58%)	46,560 (49%)
North America	21,130 (21%)	4,660 (5%)
Asia	11,622 (11.5%)	41,705 (44%)
Australia	9,416 (9.3%)	1,593 (1.7%)
South America	0	190 (0.3%)
Patients excluded	19,374 (19%)	17,552 (18%)
Patients included for analyses	81,495	77,154
NSCLC	68,463 (84%)	70,967 (92%)
SCLC	13,032 (16%)	6,189 (8%)
Treatment modalities		
Surgery alone	41%	57.7%
Radiotherapy + surgery	5%	1.5%
Chemotherapy + surgery	4%	21.1%
Chemotherapy alone	23%	9.3%
Radiotherapy alone	11%	1.5%
Chemotherapy + radiotherapy	12%	4.7%
Trimodality	3%	4.4%

new information on the prognostic impact of nodal tumor burden represented by the number of involved nodal zones found at pathological staging could not be used to modify the N categories because it could not be validated at clinical staging, by geographical regions or by the different T categories. Finally, in the M component, although there was enough information to separate intrathoracic from extrathoracic metastases, nothing could be said about the prognostic impact of number and site of metastases.[19] These limitations prompted the IASLC Staging and Prognostic Factors Committee to launch a second phase of its Lung Cancer Staging Project with the objective to overcome the limitations of the initial project,[20] and to restructure its membership (Appendix 2).

THE NEW IASLC DATABASE

The new database, the analyses of which will inform the eighth edition of the TNM classification of lung cancer, consists of 94,708 patients diagnosed from 1999 to 2010. Their data originated from established databases (90,041 patients) or were submitted via the electronic data capture (EDC) system set by Cancer Research And Biostatistics (4,667 patients). The EDC allows the contributors to submit data online and retrieve their own data for their own studies at any time. Europe contributed 46,560 patients, Asia: 41,705, North America: 4,660, Australia: 1,593, and South America: 190. These new data came from 35 sources in 16 countries (Table 2). After excluding 17,552 patients, mainly because of unknown or different histology and incomplete stage information, 77,156 patients (70,967 with NSCLC and 6,189 with SCLC) remained for analyses (Table 3). The majority of these patients (99%) had been collected by consortia or registries. There were no patients from clinical trials (Table 4). Nearly 85% of the patients underwent surgical treatment either alone or in combination with chemotherapy or radiotherapy (Table 5). This is reflected in the stage distribution of NSCLC: except in Europe, where there is predominance of advanced stages, early stages are predominant, especially in Asia; for SCLC, advanced stages are predominant, as expected (Figure 1).

This new database is being analyzed according to concrete objectives for each of the T, the N, and the M components of the classification. In essence, the principal aims are to further explore and analyze the impact on prognosis of tumor size and of the different T descriptors; the prognostic significance of tumor burden in hilar and mediastinal lymph nodes; and the confirmation of the revised M1 categories (M1a and M1b) of the seventh edition of the classification along with the prognostic impact of number and anatomic location of metastases.[20] For this phase of the study, in addition to the data elements collected in the initial phase,[2] the descriptors

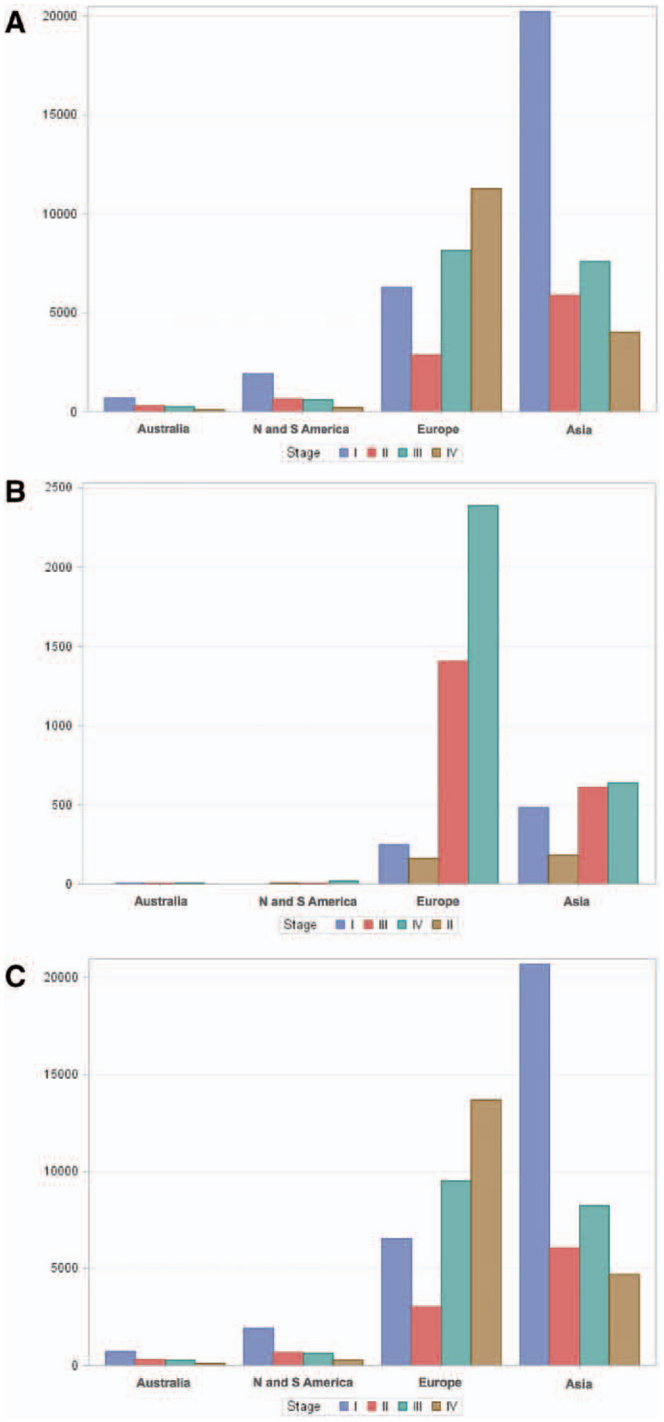

FIGURE 1. Histograms of stage (pathological stage, if provided; otherwise, clinical stage) distribution by region. (*A*) Nonsmall cell lung cancer; (B) small cell lung cancer; and (C) overall.

of the TNM classification were collected according to its seventh edition. Moreover, 23 nonanatomical elements were included in the data dictionary to prepare for the development of prognostic groups (Table 6). The combination of anatomic and nonanatomic elements in a combined prognostic index

TABLE 6. Nonanatomical Elements Collected in the New Phase of the IASLC Lung Cancer Staging Project

Patient-related elements	Age
	Sex
	Race
	Smoking history
	Weight loss
	Zubrod performance status
	Comorbidity index
	Laboratory analyses: LDH, hemoglobin, calcium, alkaline phosphatase, sodium, leukocyte count, neutrophil count, platelets, albumin
	Lung function tests: FVC and % of predicted; FEV1 and % of predicted
	Weight
	Height
Tumor-related elements	SUVmax for T and for N
	Lobar, bronchial location of primary tumor
	Differentiation grade
	Histological type
	Vascular invasion
	Lymphatic invasion
	Pleural lavage cytology
	Tumor markers in those centers that have the possibility to determine them
Environment-related elements	Method of detection: symptoms, screening, incidental
	Treatment
	Residual tumor after treatment
	Geographic area: continent, country of origin

LDH: lactate-dehydrogenase; FVC: forced vital capacity; FEV1: forced expiratory volume in 1 second; SUVmax: maximum standardized uptake value; T: primary tumor; N: lymph nodes

enhances the capacity to prognosticate beyond that of the TNM classification alone. These combined prognostic indexes will help personalize prognosis for a given patient.

The new database is almost as large as the one used for the seventh edition. As a matter of fact, some of the already established databases that have been submitted were not specifically designed to study the TNM classification and have the same limitations as the original IASLC database. However, the data contributed via the EDC contained all the necessary elements to do so. Although smaller in number of patients, it is much richer in details to allow refinements in the analyses of the different descriptors. Europe still is the leading contributing region, closely followed by Asia, thanks to the massive participation of Japan. In relation to the previous database, the cases from North America and Australia have dropped; and South America is represented by a few cases for the first time. Patients undergoing surgical treatment alone are predominant, as in the previous database. Owing to the nature of the data sources (no clinical trials), the number of patients treated with chemotherapy alone or in combination with radiotherapy has dropped. This database contains a similar number of patients with NSCLC, but the number of patients with SCLC has been reduced by 50% (Table 5).

The analyses of the new database and the findings suggesting recommendations for the revision of the seventh edition of the TNM classification of lung cancer will be submitted to the *Journal of Thoracic Oncology* to make them available to the worldwide oncology community. The suggested recommendations and their supportive data will also be submitted to the UICC and the AJCC for their assessment and inclusion in their new staging manuals, due to be published in 2016. The new edition of the classification will then be enacted in January 2017.

The contributing institutions are to be thanked for their touching generosity and enthusiasm. This is an ongoing project that will soon be complemented by a deeper study on prognostic factors, for which prospective data collection will be essential. We hope that this new project will be appealing to the international lung cancer community and will be supported again by our regular contributors and, hopefully, by new ones. Although there are several ways to contribute,[21] the best way to serve the objectives of the IASLC Lung Cancer Staging Project is to submit cases via the EDC. The online dataset contains the specific data elements needed to study the descriptors of the three components of the TNM classification and to refine prognosis. Your collaboration will be much welcome.

APPENDIX 1. IASLC Staging and Prognostic Factors Committee

Peter Goldstraw, Past Chair, Royal Brompton Hospital and Imperial College, London, United Kingdom; Ramón Rami-Porta, Chair, Hospital Universitari Mutua Terrassa, Terrassa, Spain; Hisao Asamura, Chair Elect, National Cancer Center, Tokyo, Japan; David Ball, Peter MacCallum Cancer Centre, Melbourne, Australia; David Beer, University of Michigan, Ann Arbor, MI, USA; Ricardo Beyruti, University of Sao Paulo, Brazil; Vanessa Bolejack, Cancer Research And Biostatistics, Seattle, WA, USA; Kari Chansky, Cancer Research And Biostatistics, Seattle, WA, USA; John Crowley, Cancer Research And Biostatistics, Seattle, WA, USA; Frank Detterbeck, Yale University, New Haven, CT, USA; Wilfried Ernst Erich Eberhardt, West German Cancer Centre, University Hospital, Ruhrlandklinik, University Duisburg-Essen, Essen, Germany; John Edwards, Northern General Hospital, Sheffield, United Kingdom; Françoise Galateau-Sallé, Centre Hospitalier Universitaire, Caen, France; Dorothy Giroux, Cancer Research And Biostatistics, Seattle, WA, USA; Fergus Gleeson, Churchill Hospital, Oxford, United Kingdom; Patti Groome, Queen's Cancer Research Institute, Kingston, Ontario, Canada; James Huang, Memorial Sloan-Kettering Cancer Center, New York, NY, USA; Catherine Kennedy, University of Sydney, Sydney, Australia; Jhingook Kim, Samsung Medical Center, Seoul, Korea; Young Tae Kim, Seoul National University, Seoul, South Korea; Laura Kingsbury, Cancer Research And Biostatistics, Seattle, WA, USA; Haruhiko Kondo, Kyorin University Hospital, Tokyo, Japan; Mark Krasnik, Gentofte Hospital, Copenhagen, Denmark; Kaoru Kubota, Nippon Medical School Hospital, Tokyo, Japan; Antoon Lerut, University Hospitals, Leuven, Belgium; Gustavo Lyons, British Hospital, Buenos Aires, Argentina; Mirella Marino, Regina Elena National Cancer Institute, Rome, Italy; Edith M. Marom, MD Anderson Cancer Center, Houston, TX, USA; Jan van Meerbeeck, Antwerp University Hospital, Edegem (Antwerp), Belgium; Alan Mitchell, Cancer Research And Biostatistics, Seattle, WA, USA; Takashi Nakano, Hyogo College of Medicine, Hyogo, Japan; Andrew G. Nicholson, Royal Brompton and Harefield NHS Foundation Trust and Imperial College, London, United Kingdom; Anna Nowak, University of Western Australia, Perth, Australia; Michael Peake, Glenfield Hospital, Leicester, United Kingdom; Thomas Rice, Cleveland Clinic, Cleveland, OH, USA; Kenneth Rosenzweig, Mount Sinai Hospital, New York, NY, USA; Enrico Ruffini, University of Torino, Torino, Italy; Valerie Rusch, Memorial Sloan-Kettering Cancer Center, New York, NY, USA; Nagahiro Saijo, National Cancer Center Hospital East, Chiba, Japan; Paul Van Schil, Antwerp University Hospital, Edegem (Antwerp), Belgium; Jean-Paul Sculier, Institut Jules Bordet, Brussels, Belgium; Lynn Shemanski, Cancer Research And Biostatistics, Seattle, WA, USA; Kelly Stratton, Cancer Research And Biostatistics, Seattle, WA, USA; Kenji Suzuki, Juntendo University, Tokyo, Japan; Yuji Tachimori, National Cancer Center, Tokyo, Japan; Charles F. Thomas Jr, Mayo Clinic, Rochester, MN, USA; William Travis, Memorial Sloan-Kettering Cancer Center, New York, NY, USA; Ming S. Tsao, The Princess Margaret Cancer Centre, Toronto, Ontario, Canada; Andrew Turrisi, Sinai Grace Hospital, Detroit, MI, USA; Johan Vansteenkiste, University Hospitals, Leuven, Belgium; Hirokazu Watanabe, National Cancer Center Hospital, Tokyo, Japan; Yi-Long Wu, Guangdong Provincial Peoples Hospital, Guangzhou, People's Republic of China.

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APPENDIX 2. Chairpersons And Members Of The Subcommittees Of The Lung Cancer Domain Of The IASLC Staging And Prognostic Factors Committee

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N subcommittee: Chairperson: Hisao Asamura. Members: David Ball, Kari Chansky, John Crowley, Peter Goldstraw, Valerie Rusch, Paul Van Schil, Johan Vansteenkiste, Hirokazu Watanabe, Yi-Long Wu and Marcin Zielinski.

M subcommittee: Chairperson: Wilfried Ernst Erich Eberhardt. Members: John Crowley, Young Tae Kim, Haruhiko Kondo, Alan Mitchell and Andrew Turrisi.

Validation and Methodology subcommittee: Chairperson: Patti Groome. Members: Vanessa Bolejack, Kari Chansky, John Crowley, Frank Detterbeck, Catherine Kennedy, Mark Krasnik and Michael Peake.

Small Cell Carcinoma subcommittee: Chairperson: Andrew G. Nicholson. Members: Ricardo Beyruti, Kari Chansky, John Crowley, Kaoru Kubota and Andrew Turrisi.

Prognostic Factors subcommittee: Chairperson: Jean-Paul Sculier. Members: Kari Chansky, John Crowley, Fergus Gleeson, Jan van Meerbeeck, Alan Mitchell and Lynn Shemanski.

Neuroendocrine Tumors subcommittee: Chairperson: William Travis. Members: Hisao Asamura, Kari Chansky and John Crowley.

Biological Factors subcommittee: Chairperson: Ming S. Tsao. Members: David Beer, John Crowley and Yi-Long Wu.

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