The IASLC Lung Cancer Staging Project

Data Elements for the Prospective Project

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The International Association for the Study of Lung Cancer Retrospective Staging Project culminated in a series of recommendations to the International Union Against Cancer and to the American Joint Committee on Cancer regarding the seventh edition of the tumor, node, metastasis (TNM) classification for lung cancer. The International Staging Committee of the International Association for the Study of Lung Cancer now issues this call for participation in the Prospective Project designed to assess the validity of each component of T, N, and M, and other factors relevant to lung cancer staging and prognosis. In the Retrospective Project, the original data acquisition was typically motivated by interests other than staging. In contrast, the Prospective Project offers online data entry. Alternatively, participants may transfer existing data, provided core objectives are addressed. Cancer Research and Biostatistics will coordinate data management and analysis. The study population is newly diagnosed lung cancer patients. Data elements include patient characteristics, baseline laboratory values, first-line treatment, TNM plus supporting evidence, and survival. Pretreatment TNM will be collected for all cases; postsurgical TNM, if resection is attempted. T descriptors include size and degree of tumor extension, with further description of extent of visceral pleural invasion, venous invasion, carcinomatous lymphangitis, and pleural lavage cytology. M descriptors characterize the newly proposed M1a category and sites of distant metastases. Nodal station involvement is described by means of a newly proposed nodal map, facilitating international participation, and allowing further investigation of nodal zones. Successful collection and analysis of these data can be expected to yield unprecedented improvements in the utility and validity of lung cancer staging.

Key Words: IASLC Staging Committee, TNM classification of lung cancer, Lung cancer staging, International database.

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The objectives of the Lung Cancer Staging Project of the International Association for the Study of Lung Cancer (IASLC)[1] have been achieved with the submission of recommendations for the seventh edition of the tumor, node, metastasis (TNM) classification for lung cancer to the International Union Against Cancer and to the American Joint Committee on Cancer. These core recommendations and the methodology used in the analysis of the retrospective database have been published in this Journal,[2–6] as well as additional publications on small cell lung cancer, carcinoid tumors, and prognostic factors.[7–9]

The limitations of the analysis of the retrospective database derive from the fact that most databases that contributed cases to the international database were not designed to study the TNM classification of lung cancer. The most important consequence was that although the clinical or pathologic T status was recorded in most of the databases, few included the finer details, such as the specific anatomic sites of tumor extension. For this reason, most of the descriptors that define T3 and T4 tumors could not be validated in this retrospective study.[2] The same is true for the potential subdivision of the N1 and N2 nodal spread based on the number of involved nodes or nodal stations,[3] and for the differences in the various forms of M1 disease.[4]

In addition, subtle differences between nodal maps used in different parts of the world—e.g., the Mountain and Dresler[10] modification to the American Thoracic Society map and the Naruke-Japan Lung Cancer Society map—[11,12] complicated previous attempts to analyze international data on nodal involvement.

OBJECTIVES OF THE PROSPECTIVE PROJECT

To overcome the limitations of the Retrospective Project, the International Staging Committee (ISC) of the

IASLC is proposing a Prospective Project with the general objective to refine future editions of the TNM classification for lung cancer. This would imply the validation of all T-, N-, and M descriptors, with special attention to those that could not be validated with the analysis of the retrospective database, and the validation of descriptors that are not included in the present TNM classification. The specific primary objectives for each T, N, and M component, as well as for other factors, are outlined in Table 1.

These objectives would be achieved by collecting a large prospective international database. This would, as far as possible, correct the geographical omissions and disproportionate spread of treatment modalities, which were inevitable in the retrospective data base, and would include both nonsmall and small cell bronchogenic carcinomas at the time of the initial diagnosis. In addition, at a recent IASLC workshop in London, there was international support for the inclusion of specific neuroendocrine subsets into the prospective data set.[13] Pleural mesothelioma is to be covered in a separate data set at a later point.

DATA ELEMENTS

Based on the experience of the Retrospective Project, the ISC has defined the data required to address the objectives of the Prospective Project. Baseline data to be captured, at the time a decision is made as to first-line treatment of newly diagnosed lung cancer confirmed by histology or cytology, include patient characteristics, baseline laboratory values, treatment modalities, TNM stage, and all supporting evidence. Beyond that, all patients will be followed for survival. The complete set of data elements can be viewed online (http://www.iaslc.org/staging-project.asp).

Patient characteristics include birth date, race, sex, smoking history (never versus former versus current smoker), years since quitting, years smoked, weight loss in previous 6 months, performance status, height, weight, and the specific comorbid factors needed to calculate the Colinet score for each patient: tobacco consumption, renal insufficiency, respiratory comorbidity, cardiovascular comorbidity, neoplastic comorbidity, and alcoholism.

Disease diagnosis descriptors include the date of clinical trial entry (if applicable), method of disease detection, whether diagnosis was based on cytology and/or histology and the dates of each, location of the primary, degree of tumor differentiation, and histologic type. For small cell lung cancer, the presence of paraneoplastic syndrome, such as the syndrome of inappropriate secretion of antidiuretic hormone or ectopic adrenocorticotrophic hormone, and myasthenic syndrome, will also be collected.

Baseline laboratory parameters include lactate dehydrogenase, hemoglobin, calcium, alkaline phosphatase, sodium, white cell count, neutrophil count, platelet count, and albumin, including the upper and lower limits of normal for each laboratory. Other prognostic factors of interest include the maximum standard uptake value for the primary tumor as well as for the nodes and pulmonary function test results of forced vital capacity and forced expiratory volume in 1 second.

TNM will be applied universally to nonsmall cell, small cell, and neuroendocrine lung tumors, in accordance in the seventh edition. The treatment section will first ask whether there was an attempt to remove the primary tumor. If resection was not attempted, a single set of TNM will be collected as representation of "evaluative" cTNM, and treatment information will include whether or not chemotherapy and radiation were given, with sites of radiation collected as well. The basis for pretreatment T, N, and M will be documented in terms of the use of history and physical examination, standard radiology, magnetic resonance imaging, computerized tomography, positron emission tomography, bronchoscopy, or more invasive surgical procedures not involving resection of the primary tumor.

If resection of the primary was attempted, two sets of TNM will be collected: pretreatment cTNM and postsurgical

TABLE 1. Study Objectives	
Component	**Objective**
T	Assess the prognostic impact of tumor size.
	Assess the classification capacity of each descriptor defining T-status.
	Study new conditions not included in the present T (e.g., differences between parietal pleura invasion and rib invasion).
N	Assess the prognostic impact of N-status.
	Explore the prognostic impact of involved lymph node "zones" within N1 and N2 categories.
	Assess the prognostic impact of:
	Nodal extent (single vs. multiple station involvement in N1 and N2 locations),
	Nodal size, i.e., the largest involved node within the relevant N category, and
	Individual nodes being involved in each nodal category.
	Assess the prognostic impact of extracapsular extension.
	Assess the prognostic impact of the N3 nodal location, i.e., contralateral mediastinum, ipsilateral or contralateral supraclavicular fossa.
M	Assess the prognostic impact of M-status, especially those descriptors now included within the new category of M1a proposed by the IASLC for the 7th edition.
	Assess the prognostic impact of:
	Single metastasis in a single organ
	Multiple metastases in a single organ, and
	Multiple metastases in several organs.
Other	Assess the prognostic impact of histologic type and grade.
	Assess the reliability of staging methods utilized in clinical staging (for those tumors with pretreatment and postsurgical classification).
	Assess the prognostic impact of complete, incomplete, and uncertain resections, according to the proposed definitions of the IASLC.
	Assess the prognostic impact of clinical factors, including co-morbidity and pulmonary function tests.
	Assess the prognostic impact of maximum standard uptake value (SUV max), at the primary site and in any positive nodal sites, for those patients with positron emission tomography (PET) scans in the pretreatment staging.

IASLC, International Association for the Study of Lung Cancer.

pTNM. The date of the resection attempt, extent, and completeness of resection, according to the proposed completeness of resection definitions of the IASLC,[14] will be recorded, with specification of sites of microscopic and macroscopic residual disease. Timing of chemotherapy and radiation to the primary tumor will be recorded relative to the resection attempt (i.e., before versus after versus both).

Pretreatment T-, N-, and M descriptors will be collected for all patients. Pretreatment T descriptors include clinical features and the size and degree of tumor extension. The presence of carcinomatous lymphangitis will also be described in the area of the primary tumor, elsewhere within the lobe of the primary, and involving other areas within the ipsilateral and/or contralateral lung. Nodal assessment by clinical or imaging studies will be recorded separately from biopsy or cytology, according to the IASLC 2009 nodal map.[15] Pretreatment N descriptors include the individual assessments of each nodal station as positive or negative for tumor— or alternatively, of each nodal zone. The size and location of the largest node will also be recorded.

A second, parallel set of postsurgical T-, N-, and M descriptors will be collected for patients undergoing resection. The postsurgical T section will also record the extent of visceral pleural invasion as proposed by Travis et al.,[16] venous invasion, status of the fissures, presence of lymphatic invasion, and pleural lavage cytology. The postsurgical M section will indicate which, if any, of the M-status findings changed as a result of the resection attempt. Optionally, the number of nodes explored, number of positive nodes, and presence of extracapsular involvement could be registered for N3, N2, and N1 regions.

For patients with multiple tumor nodules considered to be part of a single malignancy, extended data on the size, histology, and distance of additional nodules from the main mass will be collected, organized into three scenarios: the same lobe as the primary, ipsilateral lobes other than the lobe containing the primary tumor, and contralateral lobes.

For the uncommon patient with multiple synchronous primary tumors, staging data from each primary will be recorded separately.

Outcome variables to be collected will include the last date of contact, vital status, and the date of death. Data regarding the availability of tissue or results from molecular studies will also be briefly surveyed to identify potential resources for future collaborative research.

PROPERTY OF THE DATABASE AND PUBLICATION POLICY

Institutions approved by the IASLC Staging Committee for participation in this Prospective Project will preferably enter the data from an inception cohort online using a secure, web-based data entry; however, sites may alternatively petition the ISC to transfer data from an existing database. Access to the online data entry system will be available through the IASLC web site at http://www.iaslc.org, initially to limited institutions in China, Spain, and the United States which have agreed to pilot the system. Designed and administered by Cancer Research and Biostatistics (CRAB), the

system will incorporate extensive, between-field logic checks, and provide a query system enabling communication between CRAB and the institutions regarding the data. Transfer of existing, external data will initially be limited to selected partners from the retrospective project and centers that facilitate correction of geographical gaps identified in the retrospective data. Additional retrospective data may be required, however, stricter standards regarding data quality and completeness will be enforced than in the previous study. Each institution will retain full access and publishing rights to its own data; however, the collective database will be the property of the IASLC, and CRAB will be responsible for its management, storage, and analysis.

Publications related to the objectives of the Prospective Project of the IASLC Staging Committee (i.e., publications providing recommendations for changes in the TNM classification) will be planned, researched, analyzed, and written by the members of the respective Subcommittees, and will follow the same authorship pattern used for the publications on the retrospective data: Chairperson of the subcommittee, members of the subcommittee in alphabetical order, Chairman of the Staging Committee, on behalf of the IASLC Staging Committee, and participating institutions.

TIMELINE

Table 2 shows the timeline of the Prospective Project.

CALL FOR PARTICIPATION

The objectives of the Prospective Project of the ISC of the IASLC are well defined, and the prospective dataset has been designed to achieve the proposed objectives. The project's success will depend on both the extent of the international participation and the quality of the data. International representation is needed to ensure that the final staging system applies to genetically diverse populations, who may be subject to differing levels of investigations and care. The Retrospective Project showed that quality of the data is even more important than its size. It will, therefore, be pivotal to collect complete data, especially when registering the elements directly related to the pretreatment and postsurgical classification of lung cancer, the analysis of which is the main objective of this project.

TABLE 2. Timeline of the Prospective Project

Year	Activity
2009–2010	Data collection
2011–2012	Follow-up
2013	Data analysis
January 2014	Submission of recommendations to the UICC and AJCC
January–July 2014	Publication of the recommendations in the *Journal of Thoracic Oncology*
2016	Publication of 8th edition of the TNM classification by the UICC and AJCC

UICC, International Union Against Cancer; AJCC, American Joint Committee on Cancer; TNM, tumor, node, metastasis.

Useful information not related to the anatomic extension of the disease can also be derived from the prospectively registered data. The inclusion of the methods used in the clinical staging will allow us to explore their reliability in those patients undergoing lung resection, in whom the pretreatment and postsurgical classifications can be compared. The IASLC has published consensus guidelines on clinical staging based on the best evidence available in clinical practice.[17–19] With the information of the prospective database, the IASLC would be able to review those guidelines based on contemporary data specifically collected for the purpose of staging analysis.

One of the objectives of the TNM classification is to assign a prognosis based on the anatomic extent of the disease. However, there are other factors that influence prognosis of lung cancer that are not related to its anatomic extension. Sex, age and comorbidity,[20–22] biologic parameters,[23] and molecular and genetic factors are known to influence prognosis but have never been integrated into the TNM classification. Information on comorbidity and basic blood analyses is easily available from most patients. Because the study of molecular and genetic factors is not standardized or universally available, information on the accessibility of these data would be collected, rather than the actual end points. This could facilitate international collaborative research among contributing centers. The maximum standard uptake value, which has shown prognostic relevance,[24] will also be registered in those patients undergoing positron emission tomography scan in the pretreatment staging of their tumors.

The prospective registration of all these anatomic and nonanatomic parameters would allow us to address most of the issues that are expected from the ISC of the IASLC.[25] That said, the practical limitations of such an undertaking as a worldwide tumor registry must be understood. At current funding levels, the geographic expanse of the project and diversity of languages does not afford the ability to perform site audits or central pathology review or even to reimburse the expense of data collection. Consequently, the ISC will not be able to verify independently whether consecutive patients have been enrolled or to detect errors in the interpretation of source data. On the other hand, one can argue that these data reflect "real world" experience, and an international classification system must be reproducible in the diverse settings in which it is applied. Finally, access to the online registry and data retrieval is a service that has value to participants. Automated consistency checks comparing the assigned T, N, and M categories to the supportive data may actually improve the implementation of staging guidelines over time. We encourage the medical community involved in the diagnosis and treatment of patients with lung cancer to consider collecting data that are compatible with this data set and to contribute these data to the Prospective Project of the IASLC.

To obtain more information about the project, please send an email to information@crab.org with "IASLC Staging Project" in the subject line.

APPENDIX

IASLC International Staging Committee

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