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Original Research

INTERVENTIONAL PULMONOLOGY

A Multicenter, Prospective, Advanced Diagnostic Bronchoscopy Outcomes Registry

Armin Ernst, MD, FCCP; Michael Simoff, MD, FCCP; David Ost, MD, FCCP; Gaetane Michaud, MD, FCCP; Divay Chandra, MD; and Felix J. F. Herth, MD, FCCP

Background: **Multiple new diagnostic bronchoscopic technologies are available, but little is known about their comparative performance and specific yield when adjusted for location of lesions, target size, and diagnosis. We present a multi-institutional prospective-outcomes database to assess diagnostic yields of advanced bronchoscopic procedures, as well as related morbidity and mortality.**

Methods: **Data were extracted and reviewed from an ongoing, paper-based, prospective, multi-institutional outcomes database for advanced diagnostic bronchoscopic procedures. All consecutive eligible patients are entered into this database, and information on demographics, procedure, and lesion characteristics as well as complications were documented. Descriptive statistical analyses were performed.**

Results: **A total of 310 diagnostic procedures were performed over a 1-year period in four institutions by 15 different clinicians. The majority of the patients were white (66%), male (56%), former smokers (55%), with a mean age of 61 ± 14 years. The average procedure time was 36 min, and the most common procedure was transbronchial needle aspiration (TBNA) (n = 198). Nodal tissue was obtained in 82.3% from TBNA sampling with a mean of three passes using endobronchial ultrasound guidance with a 22-gauge needle and mostly without on-site cytology. The overall diagnostic yield for all procedures was 75%. There were few complications, and none required a change in disposition.**

Conclusions: **Prospective and ongoing data analysis for bronchoscopic procedures is feasible and valuable. Lesion-adjusted diagnostic yields can be documented and potentially used for comparative assessment of different technologies and operators, as well as benchmarking and quality improvement initiatives. Extending the number of participating centers and web-based submission to minimize missing data components are the next, already-initiated steps.**

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Abbreviations: ACCP = American College of Chest Physicians; AQuIRE = ACCP Quality Improvement Registry, Evaluation, and Education; ASA = American Society of Anesthesiologists; EBUS = endobronchial ultrasound; ECOG = Eastern Cooperative Oncology Group; TBNA = transbronchial needle aspirates

The expense for medical care is increasing rapidly in the United States. New diagnostic and therapeutic technologies are frequently cited as a significant contributor to increasing health-care costs. New technologies are usually expensive and may be of either unproven benefit or of unclear improved efficacy as compared with existing conventional modalities.[1] It has therefore been proposed that devices undergo more rigorous comparative evaluation to better assess their use in order to justify reimbursement levels.[2] A good example of structured comparative effectiveness analysis exists in Great Britain, with the National Institute for Health and Clinical Excellence program.[3] This group reviews the available evidence for medical interventions, assesses the potential impact on the patients and health-care systems by calculating the price to be paid for a quality-adjusted life years, and then makes recommendations regarding coverage to the respective agency. Designing trials that enable proper comparative technology evaluation is complex and expensive and funding mechanisms at least for now are limited for this kind of important research. Also lacking are

bench marks for many technologies and for operator performances.

In the absence of formal effectiveness or research to develop bench marks, databases or registries can offer a reasonable alternative for valuable data accrual. Databases are used to collect information in a structured fashion and can be used in many different ways, all depending on the intended use of the collected information. Most frequently, data are collected on medical and surgical outcomes as well as adherence to guidelines and resource use.[4-8] Patient registries enable outcomes assessment from the natural progression of disease to assessing success (or lack thereof) of medical or device-based and surgical interventions. Registries are not clinical trials with fixed inclusion and exclusion criteria, and they do not have control groups. Well-designed registries facilitate population-based research and determination of best practices (best results with the use of the least resources necessary).[9] Participating in trials and outcomes databases is credited with decreasing morbidity and mortality after surgical procedures by identifying outliers and offering support for improving performance.[10,11]

We recently reported on a prospective, ongoing data registry to assess morbidity and mortality after therapeutic bronchoscopic interventions.[12] This effort showed that prospective data collection is feasible and valuable. Based on this effort, the American College of Chest Physicians (ACCP) has implemented a web-based pilot project for a multi-institutional database: the ACCP Quality Improvement Registry, Evaluation, and Education (AQuIRE) program.

Because most pulmonologists do not perform therapeutic interventions, but are more interested in diagnostic procedures, we also developed a prospective database tool for advanced diagnostic procedures. With the myriad of new technologies introduced, such as endobronchial ultrasound (EBUS) and electromagnetic navigation bronchoscopy, the time seems right to assess how these technologies fare in different institutions for a variety of indications. In this article, we describe a prospective, multicenter outcomes database that reports on procedure-specific morbidity, mortality, and diagnostic yield.

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Affiliations: From the Division of Interventional Pulmonology and Thoracic Surgery (Drs Ernst, Michaud, and Chandra), Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; the Division of Pulmonary and Critical Care Medicine (Dr Simoff), Henry Ford Hospital, Detroit, MI; the Division of Pulmonary and Critical Medicine (Dr Ost), MD Anderson Cancer Center, Houston, TX; and Pulmonary and Critical Care Medicine (Dr Herth), Thoraxklinik Heidelberg, Heidelberg, Germany.
Correspondence to: Armin Ernst, MD, FCCP, Interventional Pulmonology, Beth Israel Deaconess Medical Center, Harvard Medical School, 1 Deaconess Rd, Deaconess 201A, Boston, MA 02215; e-mail: aernst@bidmc.harvard.edu

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Materials and Methods

The Interventional Pulmonology Programs at the participating institutions (Beth Israel Deaconess Medical Center, Boston, Massachusetts; Henry Ford Hospital, Detroit, Michigan; New York University Hospital, New York, New York; and Thoraxklinik Heidelberg, Germany) maintain an ongoing, common prospective database on both outcomes in therapeutic bronchoscopic interventions and diagnostic yield in advanced bronchoscopy. Both databases serve as the foundation of a multicenter pilot project by the ACCP for a web-based clinical database (AQuIRE). Here we report the results of the original effort to collect these data prospectively in four institutions.

The institutional review boards at the participating institutions approved the data collection. Informed consent was waived; all data were deidentified and no personal health information was collected. Data were collected prospectively and retrospectively reviewed. All data entry fields (such as location and size of lesions, specifics of the diagnostic procedures, comorbidities and complications, and diagnostic results), were predefined and agreed upon by the group (e-Appendix 1). Fields were selected based on a review of the literature in order to identify variables that might potentially affect diagnostic yield or complication rates. All potential data collection items were reviewed for relevance and inclusion and agreed upon by the group members. All submitted forms were controlled for completion before entering into the database to facilitate data accuracy and complete collection. No effort was made to cross-check the submitted data with the actual medical records at the participating institutions. All centers agreed to submission of all cases.

For this study, outcomes data from 310 patients who received care in four institutions over the period from August 2007 to August 2008 were analyzed. Data were extracted and reviewed from an ongoing, paper-based, prospective, multiinstitutional outcomes database for advanced diagnostic bronchoscopic procedures. All consecutive patients are entered into this database and information on demographics, procedure, and lesion characteristics as well as complications were documented. Demographics considered included age, sex, race, smoking status, Eastern Cooperative Oncology Group (ECOG) performance status, American Society of Anesthesiologists (ASA) score, and comorbid illnesses. Lesion characteristics included location and size, whereas the procedural information collected related to exact procedures performed, type of bronchoscopy (either flexible or rigid), route of intubation, and whether performed via an endotracheal tube. All procedures were entered into an Access database (Microsoft Office; Microsoft; Redmond, WA) by one individual only (D. C.).

Statistical Methods

Descriptive statistics were performed using STATA 10.0 (StataCorp; College Station, TX). Means, percentages, and ranges of values were calculated.

Results

A total of 310 diagnostic procedures were reported over a 1-year period in four institutions (133 Beth

Israel Deaconess Medical Center, 87 Henry Ford Hospital, 65 New York University, and 24 Thoraxklinik Heidelberg). Procedures were performed by one of 15 clinicians. Two hundred two procedures were performed by a trained interventional pulmonologist (66%), 103 by a pulmonologist (33%), and three by a cardiothoracic surgeon (1%) (data missing for two procedures). A fellow was the primary endoscopist in 205 bronchoscopies (66%).

Patient demographics and comorbidities are presented in Table 1. The mean patient age was 61.5 years and 44% were women. The majority were white (66%) and former smokers (55%). On average, the population smoked 44 ± 33 pack-years (range 0-240 pack-years). Nearly half of the patients were only limited with strenuous activity, having an ECOG performance status of 1 (47%, n = 133). Eighty-seven percent of patients suffered from either mild or severe systemic diseases that were not believed to be a constant threat to life (45% and 42% ASA score of 1 and 2, respectively). Comorbidities documented in the study population include hypertension (37%, n = 116), COPD (28%, n = 88), coronary artery disease (15%, n = 46), diabetes (14%, n = 42), congestive heart failure (8%, n = 25), asthma (6%, n = 18), chronic renal failure (3%, n = 10, five requiring hemodialysis), stroke (2%, n = 6), and hematologic malignancy (1%, n = 4).

With respect to the procedures, 95% (n = 296) were performed with a flexible bronchoscope, whereas the other 14 were carried out via the rigid bronchoscope (Table 2). Two flexible cases required endotracheal intubation. All rigid bronchoscopy patients underwent general anesthesia, whereas 275 (92% overall) flexible cases were performed under moderate sedation (eight deep-sedation cases). The average length of the procedure (insertion to removal of the bronchoscope) was 36 min (range 5-97 min). The bronchoscope was passed via the nasal route in 55% (n = 171).

One hundred ninety-eight transbronchial needle aspirates (TBNA), 93 transbronchial biopsies, 61 cytology brushes, 99 BAL, and 96 bronchial washes were performed over the course of study. A firm diagnosis was established in 154 patients with an overall yield of 75% for all procedures performed.

Table 1—*Demographics and Underlying Comorbidities, Including Risk Assessment and Performance Scores*

Variable	Value
Age, y	61.5 ± 14 (range 17-88)
Sex, female	135 (44)
Race	
White	205 (66)
Black	52 (17)
Other	44 (14)
No race specified	9 (3)
Smoking status	
Current	39 (13)
Former	172 (55)
Pack-years	44 ± 33 (range 0-240)
ECOG performance status	
0	35 (12)
1	133 (47)
2	90 (31)
3	18 (6)
4	9 (3)
5	1 (< 1)
ASA score	
1	29 (10)
2	133 (45)
3	123 (42)
4	6 (2)
5	2 (1)
Comorbidities	
Hypertension	116 (37)
COPD	88 (28)
CAD	46 (15)
Diabetes	42 (14)
CHF	25 (8)
Asthma	18 (6)
CRF	10 (3)
CVA	6 (2)
Hemodialysis	5 (2)
Hematologic malignancy	4 (1)

Values given as mean ± SD or No. (%). ASA = American Society of Anesthesiologists; CAD = coronary artery disease; CHF = congestive heart failure; CRF = chronic renal failure; CVA = cerebrovascular accident; ECOG = Eastern Cooperative Oncology Group.

Table 2—*Specifics of Performed Procedures and Sedation Used in All Patients*

Variable	Value
Procedure performed	
TBNA	198
Blind	19
EBUS-guided	173
TBBx	93
Brush	61
BAL	99
Wash	96
Overall	154
Total procedure time, min (range)	36 (5-97)
Type of bronchoscopy	
Flexible	296 (95)
Rigid	14 (5)
Route of bronchoscopy	
Oral	139 (45)
Nasal	171 (55)
Type of sedation	
Moderate	275 (92)
Deep	8 (3)
General	14 (5)
ETT for procedure	
No ETT	294 (95)
ETT	16 (5)

N = 310. Some patients had more than one procedure performed; therefore, the total number exceeds 310. Values given as No. or No. (%) unless otherwise indicated. EBUS = endobronchial ultrasound; ETT = endotracheal intubation; TBBx = transbronchial biopsies; TBNA = transbronchial needle aspirates.

Of the 198 TBNA cases, 173 were documented as performed with EBUS guidance, whereas 19 were without guidance (four cases both EBUS and conventional TBNA). No data regarding guidance for TBNA were available in the remaining cases. Nodal tissue or diagnostic material was obtained in 164 out of 198 patients (82.3%); however, a firm diagnosis was only established in 43% based on the TBNA results.

The primary lesions met size criteria for mass in 54 (17 peripheral and 37 central) and 37 were nodules (27 peripheral and 10 central) (Table 3). The mass involved the hilum in 19 and the mediastinum in another 10 cases. An airway adjacent to the lesion was identified on computed tomography in 42 lesions. Procedure characteristics are tabulated in Table 2.

All lymph nodes accessible by the airway were sampled over the course of study with the most common nodal stations accessed being level 4, 7, and 11. Frequency of sampling of nodal stations is presented in Table 3. The mean number of passes per lymph node was 3 (median 5, range 1-10 passes). Rapid onsite cytology was used in 20 of the 173 patients who underwent TBNA (12%). Because the majority of cases were performed with EBUS guidance, a dedicated 22-gauge EBUS needle was used in 167 cases.

Table 3—*Descriptive Characteristics of Sampled Nodal Stations and Peripheral Lesions*

Variable	Value
Lymph nodes, No. (%)	
Nodal station	
1	1 (0.5)
2	13 (7)
3	2 (1)
4	84 (44)
7	57 (30)
10	9 (5)
11	23 (12)
12	1 (0.5)
No. of passes	
1	5 (3)
2	53 (27)
3	61 (32)
4	41 (21)
5	22 (11)
6	7 (4)
8	1 (0.5)
9	2 (1)
10	1 (0.5)
Peripheral lesion characteristics, No.	
Peripheral mass	17
Central mass	37
Adjacent airway	42
Hilar involvement	19
Mediastinal involvement	10
Peripheral nodule	27
Central nodule	10

Values given as No. or No. (%).

Other needles used included 18 gauge, 19 gauge, and 21 gauge (n = 1, 14, and 19, respectively, with more than one type of needle being used in three cases). Data on the short-axis dimension were available in 190 nodes sampled and the frequency was as follows: 34 (18%) 1 to 10 mm, 103 (54%) 11 to 20 mm, 31 (16%) 21 to 30 mm, and 22 (12%) >30 mm.

Few complications were reported in the data set (Table 4). There were six pneumothoraces, only one of which required placement of a chest drain. Of note, there were no cases of hemoptysis post-procedure. A single case required mechanical ventilation following the intervention. There were seven reports of increased level of care following the procedure; however, none of these resulted in an actual change in disposition (ie, all patients returned to where they originated).

Discussion

This report constitutes the largest effort reported for a multi-institutional outcomes database for advanced diagnostic bronchoscopy. We deliberately did not include basic bronchoscopy as the primary procedure, such as BAL or brushings, because complications would have been exceedingly low and lesion/indication description was deemed to be potentially too vague to be useful for statistical analysis. Similar to the prior report on therapeutic outcomes, we found the data collection for diagnostic bronchoscopy to be feasible and not to be associated with significant inconvenience.

We introduced a new concept of lesion-adjusted yield. It describes the yield of a specific procedure for a specific set of lesion characteristics; this would allow comparisons of different diagnostic approaches after adjusting for lesion size, location, and other factors of the targeted lesion, basically ensuring that we are comparing apples with apples. In the absence of comparative trials, this approach could then, for example, support or disprove the usefulness of electromagnetic guidance for transbronchial biopsy of peripheral lung lesions or clarify the situations in which it would be justified. Another application of this concept is in the setting of bench marks. Evaluating the average yield of EBUS-guided TBNA for lymph nodes of certain

Table 4—*Complications Reported in This Series*

Complication	Number
Pneumothorax	6
Hemoptysis	0
Postintervention mechanical ventilation	1
Increased level of care[a]	7

[a]Increased level of care was considered a complication of the performed procedure.

sizes in certain locations would be possible and avoid establishing generic yield data. Even though our database created many data points, the number of procedures performed did not yet allow for this level of detailed analysis.

We believe the data obtained in such a registry can be used for multiple additional purposes. For one, it would allow for much better determination of resource use for bronchoscopy and a more rational assessment of work and time requirements. It can be used to assess best practices for diagnostic outcomes, meaning the use of the least amount of resources to reach a defined goal and formulation of practice recommendations.

The usefulness of adding supportive technology, such as EBUS and electromagnetic navigation bronchoscopy, to existing conventional procedures can be more precisely measured and better recommendations on technology performance and use can be made. Maybe even more importantly, these efforts can be used for quality control and improvement initiatives. If an individual knows how he or she performs against bench marks, support can be initiated if needed to improve patient care. Such participation in databases could also be used to demonstrate continued competence and efficiency.

Obviously another significant issue associated with assessment of technology performance and operator performance is the topic of reimbursement—be that technical or professional. For the most part pay-for-performance is already a process that is well underway in many areas of medicine.[13,14] Establishing databases with data fields that the medical community truly considers relevant is an important initiative, and as we have shown here, it is "doable" and valuable. Allocating resources to this initiative in order to make ongoing measurement sustainable will be an important future consideration if pay-for-performance is to be a reality.

Our work has shortcomings. We did not independently cross-check the data field entries with medical records and we did not have a mechanism in place to ensure that all procedures were submitted. We accepted this as unavoidable in a pilot trial and realize that we most likely underreported. Additionally, not all fields were completely filled out, another shortcoming of any paper-based system. Last, we did not collect enough procedures to be able to create comparative lesion-adjusted yields for all applications and clinical circumstances.

All of these issues are being addressed with the next generation of data collection efforts spearheaded by the ACCP with the AQuIRE project. Consecutive patient data similar to the ones presented here are being collected through a web-based process, improving speed and enforcing completeness of the data submitted. The number of centers has been increased and therefore sample size and scenario analysis should be more robust.

In conclusion, an outcomes database for advanced diagnostic procedures is feasible and valuable. The data can be used for quality improvement, for bench marking, and potentially for resource allocation and diagnostic algorithms.

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Dr Michaud: contributed to performing statistical analysis and review, had access to the full data set, and participated in drafting the document.
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Dr Herth: contributed to conceiving the study, had access to the full data set, and participated in drafting the document.
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Additional information: The e-Appendix can be found in the Online Supplement at http://chestjournal.chestpubs.org/content/138/1/165/suppl/DC1

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