Systematic Classification of Morbidity and Mortality After Thoracic Surgery

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Background. **Objective reporting of postoperative complications is the foundation of surgical quality assurance. We developed a system to identify both presence and severity of thoracic morbidity and mortality, and evaluated its feasibility and utility over the first two years of its implementation.**

Methods. **The system was based on the Clavien-Dindo classification, in which the severity of a complication is proportional to the effort to treat it. Definitions were developed by peer review and questionnaire. All patients undergoing thoracic surgery (January 2008 to December 2009) were prospectively evaluated.**

Results. **A total of 953 patients (mean age 61 years; range, 14 to 95) underwent thoracic surgery (total # cases 1260), of which 369 patients had at least one complication (29.3% procedures). Grades I and II include minor complications requiring no therapy or pharmacologic intervention only. Grades III and IV are major complications that require surgical intervention or life support. Grade V complications result in patient death. Grades I, II, III, and IV complications comprised 4.9%, 63.9%, 21.1%, and 7.8% of all complications; overall mortality rate (grade V) was 2.2%. The most common complications were prolonged air leak (18.8%) and atrial fibrillation (18.2%) after pulmonary resection, and atrial fibrillation (11.5%) after esophagectomy-gastrectomy. Prolonged air leak led to a major complication (13%), readmission (17%), or prolonged hospital stay (29%) to a greater extent than atrial fibrillation (3%, 2%, and 7%, respectively).**

Conclusions. **This standardized classification system for identifying presence and severity of thoracic surgical complications is feasible, facilitates objective comparison, identifies burden of illness of individual complications, and provides an effective method for continuous surgical quality assessment.**

(Ann Thorac Surg 2010;90:936–42)

Objective analysis and discussion of surgical morbidity and mortality (M&M) is the foundation of quality assurance. However, defining and measuring quality is a particularly difficult undertaking [1]. Mortality is well described in the medical literature and is a comparable surgical outcome, whereas morbidity rates have been poorly reported; thus limiting comparisons among surgeons, procedures, and centers, and within the same center over time [2–4]. To enable such comparisons, data on surgical outcomes must be acquired in a standardized and transparent format [2]. Short-term surgical outcomes, such as hospital length of stay (LOS), 30-day mortality rate, operating time, and approximate blood loss, are regularly reported in the data collected; yet, conclusive assessments of surgical procedures have remained limited by the lack of agreement on how to define and classify complications by severity [5].

Most surgeons depend on regular review of complications at M&M conferences to evaluate experience, analyze complications, and receive feedback regarding quality improvement measures undertaken to minimize risk [6]. However, data from M&M conferences are neither systematically collected nor stored in a standardized and reproducible fashion [7]. These shortcomings of traditional methods to quality assurance have partly encouraged a movement toward a new paradigm for improving surgical care quality [8].

In 1992, Clavien and colleagues [2] introduced an innovative system to grade complications by severity proportional to the effort required to treat the complications. This methodology was recently revised and a novel five-tiered classification system was developed with the intent of presenting an objective and reproducible method for reporting complications after general surgery [9]. This system, now known as the Clavien-Dindo classification system, has been validated in a large cohort of patients who underwent a number of general surgical procedures and has universal applicability [10–14]. However, we have found no published abstracts or papers applying the approach of standardizing surgical morbidity after noncardiac thoracic surgery.

Accepted for publication May 5, 2010.

Presented at the Forty-sixth Annual Meeting of The Society of Thoracic Surgeons, Fort Lauderdale, FL, Jan 25–27, 2010.

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Published by Elsevier Inc

0003-4975/$36.00
doi:10.1016/j.athoracsur.2010.05.014

Thus, our aims were to develop a classification system to grade presence and severity of thoracic morbidity and mortality (TM&M) which would enable us to compare surgical procedures and subgroups of patients, and simultaneously allow us to evaluate the feasibility of the system over the first two years of its implementation at the Ottawa Hospital, a high-volume, single academic thoracic surgery center. The Ottawa Hospital serves a population of 1.35 million people and thoracic surgical care is consolidated at one campus by five thoracic surgeons and one resident. We hypothesized that a standardized system for classifying thoracic-related postoperative complications would function as a basis to inform the individual surgeon regarding M&M rates after thoracic surgery.

Material and Methods

Ethical Concerns

Research on complex diseases raises ethical issues concerning informed consent, privacy, and patient confidentiality. The Ottawa Hospital Research Ethics Board approved the collection of thoracic morbidity and mortality data through waived consent.

Development and Classification of Surgical Complications

The TM&M system was developed according to the Clavien-Dindo classification schema [9] of surgical adverse events (Table 1). Definitions of surgical adverse events were modified according to complications in patients after noncardiac thoracic surgery through peer review and questionnaire, and adjusted based on surgeons' experience. A complication was defined as any deviation from the normal postoperative course. For each of the following systems, pulmonary, pleural, cardiac, renal, gastrointestinal, neurologic, wound, and other, complications were described associated with the specific grading system (definitions are available upon request). The Common Terminology Criteria for Adverse Events (version 3.0) [15] was also used to refine some definitions.

Table 1. Classification of Complications After Thoracic Surgery

Grade	Definition
Complication	Any deviation from the normal postoperative course.
Minor	
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacologic treatment or minor intervention only.
Major	
Grade III	Any complication that requires surgical, radiologic, endoscopic intervention, or multitherapy.
Grade IIIa	Intervention does not require general anesthesia.
Grade IIIb	Intervention requires general anesthesia.
Grade IV	Any complication requiring intensive care unit management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Mortality	
Grade V	Any complication leading to the death of the patient.

Table 2. Demographics and Preoperative Diagnoses for Patients (n = 953)

Demographics and Diagnoses	No	% of Total Patients
Mean age (in years)	60.9	range, 14–95
Gender		
Males	520	54.5
Females	433	45.5
Preoperative diagnosis		
Lung		
Malignant	441	46.3
Benign	148	15.5
Esophagus		
Malignant	83	8.7
Benign	175	18.4
Other		
Malignant	68	7.1
Benign	38	4.0

Patients

The TM&M classification system was applied to a cohort of 953 consecutive patients undergoing noncardiac thoracic surgery at The Ottawa Hospital from January 1, 2008 to December 31, 2009. Demographics and indications for operation are shown in Table 2. There were 520 male (54.5%) and 433 female (45.5%) patients with a mean age of 61 years (range, 14 to 95 years). While 592 patients (62.1%) had a malignant disease, the remaining 361 patients (37.9%) had a range of benign lung, esophageal, and other thoracic-related diseases.

Data Collection

Daily data collection of M&M was carried out by a senior thoracic surgical resident and the thoracic surgery research coordinator using the TM&M form. Weekly lists of operative procedures along with related complications were compiled and further validated by attending staff. These complications were then discussed at monthly M&M conferences. A database for complication reporting was developed; data entered included gender, age, and preoperative diagnosis. Surgical details entered were type of operation, including whether it was a video-assisted or open operation. The grading of complications was prospectively applied to each patient according to severity and effort required to treat the complication (Table 1), but risk adjustment was not done at this time. Access to the database was protected by password and limited.

Statistical Analysis

Descriptive statistical analyses were performed to analyze surgical volume and M&M rates after noncardiac thoracic surgery. Incidence of complications in different subgroups was analyzed using the χ^2 test or Fisher exact test. Correlations between complication grade and hospital length of stay was analyzed using analysis of variance. A p value of less than 0.05 was considered significant. Data were analyzed using SAS version 9.2 software (SAS Inc, Cary, NC).

Results

Overall Grade and Severity of Thoracic Surgical Complications

During the study period, a total of 953 patients (mean age 61 years; range, 14 to 95) underwent a thoracic surgical procedure, of which 369 (29.3%) patients had at least one complication. As suggested by Clavien and colleagues [16], our goal was to record only the most severe complication pertaining to the affected system when those complications of a lower grade are a step in the process leading to the more serious outcome. Thus, grades I and II are minor complications and comprised 4.9% and 63.9% of all complications, respectively. Grades III and IV are considered major complications and comprised 21.1% and 7.8% of all complications, respectively. Overall mortality rate (grade V) was 2.2%. Distribution of complications by grade and by major surgical procedure is presented in Table 3. Of the 229 lobectomies performed, 96 (41.9%) were done by video-assisted thoracoscopic surgery.

Common Complications for Major Thoracic Procedures

The most common complications and their frequency are presented in Tables 3 and 4 for patients who underwent a lobectomy, pneumonectomy, or an esophagectomy-gastrectomy. The majority of all complications were Grade II morbidity for lobectomy (69.6%), pneumonectomy (54.8%), and esophagectomy/gastrectomy (55.8%).

Grade I complications accounted for 7.5% of all lobectomy complications with pneumothorax being the most common grade I complication. Grade II complications made up the majority of lobectomy complications with a total of 69.6%; prolonged air leak (22.4%) and atrial fibrillation (17.4%) were the most common grade II complications. Atrial fibrillation classified under grade II was defined as requiring medical therapy only (eg, beta-blockers) for heart rate control. Prolonged air leak classified under grade II was defined as persistent air leak beyond 5 days. Next, grade IIIa complications made up 13.0% of lobectomy complications with pneumothorax being the most common complication, requiring placement of an additional pleural tube. Postoperative bleeding requiring reexploration was the most common grade IIIb complication. Respiratory failure was the most common grade IVa complication. A total of 3 (2.4%) deaths occurred in patients undergoing a lobectomy due to respiratory failure, pneumonia, and gastrointestinal bleeding.

A similar trend in complication rates was noted for patients who underwent a pneumonectomy or an esophagectomy-gastrectomy, with grade II complications compromising the majority of complications. Atrial fibrillation (22.6%) was the most common grade II complication after pneumonectomy. There were 2 (6.5%) deaths in the pneumonectomy group due to pneumonia.

An array of grade II complications occurred in patients who underwent an esophagectomy-gastrectomy, among which atrial fibrillation (11.5%) was the most common. There were no deaths in this group.

Impact of Complication Grade on Readmission Rates and Prolonged Hospital Stay

Between May 1, 2009 and December 31, 2009, data were collected to evaluate the effect of complication grade on the risk of prolonged length of hospital stay and readmission to hospital for all cases. Patients with lower grade complications (ie, grade II) were less likely ($p = 0.0006$) to have prolonged hospital stay when compared with patients with higher grade (ie, III and IV) complications.

Table 3. Total Complications for all Cases and for Three Major Surgical Procedures

	Major Surgical Procedure			
Complication Grade	Lobectomy (n = 229)	Pneumonectomy (n = 33)	Esophagectomy/Gastrectomy (n = 51)	All Cases (n = 1,260)
Minor				
Grade I	12 (7.5)	0 (0)	2 (3.8)	22 (4.9)
Grade II	112 (69.6)	17 (54.8)	29 (55.8)	287 (63.9)
Major				
Grade IIIa	21 (13.0)	1 (3.2)	5 (9.6)	63 (14.0)
Grade IIIb	5 (3.1)	3 (9.7)	8 (15.4)	32 (7.1)
Grade IVa	7 (4.3)	8 (25.8)	8 (15.4)	30 (6.7)
Grade IVb	1 (0.6)	0 (0)	0 (0)	5 (1.1)
Mortality				
Grade V	3 (1.9)	2 (6.5)	0 (0)	10 (2.2)
Total complications	161	31	52	449
Total patients with complications	113 (49.3)	18 (54.6)	27 (60.8)	369 (29.3)

Table 4. Most Common Complications Resulting From a Major Thoracic Procedure

	Lobectomy (n = 161)			Pneumonectomy (n = 31)			Esophagectomy/Gastrectomy (n = 52)		
Grade	Complication	n	%	Complication	n	%	Complication	n	%
I	Pneumothorax	2	1.2	—			Elevated WBCs	1	1.9
	Delirium	2	1.2	—			Elevated platelets	1	1.9
	Social Issues	2	1.2	—			—		
	Other	6	3.7	—			—		
II	Prolonged air leak	36	22.4	Atrial fibrillation	7	22.6	Atrial fibrillation	6	11.5
	Atrial fibrillation	28	17.4	Pneumonia	2	6.5	UTI	4	7.7
	Delirium	7	4.3	Low hemoglobin	2	6.5	Wound infection	3	5.8
	Other	41	25.5	Other	6	19.4	Other	16	30.8
IIIa	Pneumothorax	6	3.7	UTI	1	3.2	Esophageal leak	1	1.9
	SubQ emphysema	3	1.9	—			Urine retention	1	1.9
	Prolonged air leak	1	0.6	—			UTI	1	1.9
	Other	11	6.8	—			Otter	2	3.8
IIIb	Postoperative Bleeding	2	1.2	Empyma	2	6.5	Anastomotic leak	5	9.6
	SubQ emphysema	1	0.6	Hiatus hernia	1	3.2	Ischemia	1	1.9
	Leak Anastomosis	1	0.6	—			Jejuno necrosis	1	1.9
	Other	1	0.6	—			Other	1	1.9
IVa	Respiratory failure	4	2.5	Respiratory failure	3	9.7	Myocardial infarction	2	3.8
	Prolonged air leak	1	0.6	Pulmonary edema	1	3.2	Anastomotic leak	1	1.9
	Myocardial infarction	1	0.6	Pneumonia	1	3.2	Respiratory failure	1	1.9
	Other	1	0.6	Other	3	9.7	Other	4	7.7
IVb	Renal failure	2	0.6	—			—		
V	Respiratory failure	1	0.6	Pneumonia	2	6.5	—		
	Pneumonia	1	0.6	—			—		
	GI bleeding	1	0.6	—			—		

GI = gastrointestinal; SubQ = subcutaneous; UTI = urinary tract infection; WBCs = white blood cells.

Burden of Illness of Individual Complications

The TM&M classification system offers a comprehensive and objective evaluation of the impact of individual complications on patients. Atrial fibrillation (18.8%) and prolonged air leak (18.2%) compromised the majority of grade II complications after pulmonary resection, and thus require more careful attention. The majority of prolonged air leak complications after pulmonary resection were grade I or II (87%), grades IIIa and IIIb were 9% and 2%, respectively, and grade IV was 2%. Upon evaluation of all complications secondary to air leak after pulmonary resection, 97% of all atrial fibrillation was grade II with 1 patient (3%) experiencing a grade IVa complication (Table 5). In addition, since we began evaluating if complications led to prolonged hospital stay or readmission, we found air leak led to a 17% rate of readmission and 29% prolonged hospital stay, compared with 2% and 7% for atrial fibrillation. Thus, despite similar incidence after pulmonary resection, we identified air leak as having a significantly greater burden of illness than atrial fibrillation as defined by more severe complications, readmissions, and longer stay.

Complications by Grade and by System

Grade II complications accounted for the majority (63.9%) of complications in patients who underwent a

Table 5. Evaluation of the Burden of Illness of Individual Complications, January 2008–December 2009, and Readmission Rates and Prolonged Length of Stay for Patients (n = 41) who Underwent Pulmonary Resection, May 2009–December 2009

		Grade (%)							Readmission (%)		Prolonged LOS (%)	
Complication	Total (%)	I	II	IIIa	IIIb	IVa	IVb	V	Yes (%)	No (%)	Yes (%)	No (%)
Air leak	46 (100)	1 (2)	39 (85)	4 (9)	1 (2)	1 (2)	0 (0)	0 (0)	7 (17)	9 (22)	12 (29)	4 (10)
Atrial fibrillation	36 (100)	0 (0)	35 (97)	0 (0)	0 (0)	1 (3)	0 (0)	0 (0)	7 (17)	9 (22)	12 (29)	4 (10)
Pneumothorax	8 (100)	2 (2)	0 (0)	6 (8)	0 (0)	0 (0)	0 (0)	0 (0)	7 (17)	9 (22)	12 (29)	4 (10)
Myocardial infarction	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	7 (17)	9 (22)	12 (29)	4 (10)
Pneumonia	12 (100)	0 (0)	8 (67)	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	7 (17)	9 (22)	12 (29)	4 (10)

LOS = length of stay.

thoracic surgical procedure. When broken down by system, cardiac (27.5%), pleural (19.2%), and pulmonary (14.3%) complications accounted for the majority of grade II complications. A total of ten deaths occurred with an overall mortality rate of 2.2%. Of the ten patients who had a fatal outcome, six patients died from complications that were pulmonary in nature. An additional two patients died from cardiac complications. The remaining two patients died from other causes.

Impact of Complication Grade on LOS

The influence of complication grade on hospital LOS was analyzed for major thoracic procedures. Patients had a 30-day follow-up or until discharged from the hospital. For example, patients undergoing lobectomy are placed on a clinical pathway and their expected LOS is 5 days if no complications occur postoperatively. We found that LOS was significantly longer (analysis of variance, $p < 0.0001$) for patients with higher grade complications undergoing a lobectomy procedure. The median length of hospital stay in patients with grade I complications was 5.5 days (range, 5 to 11 days), with grade II 8 days (range, 3 to 42 days), with grade IIIa 8 days (range, 3 to 23 days), with grade IIIb 7.5 days (range, 5 to 14 days), with grade IVa 31 days (range, 19 to 114 days), and with grade IVb 43 days (1 patient). Postoperative mortality was defined as in-hospital mortality: 1 patient died of respiratory failure on postoperative day 32, 1 patient died of pneumonia on postoperative day 5, and 1 patient died of gastrointestinal bleeding on postoperative day 49.

Change in Complications Over the 2-year Time Period

To determine whether the frequency of minor (grades I and II) and major (grades III and IV) complications have changed over time, we analyzed all patients who underwent a lobectomy, pneumonectomy, and an esophagectomy-gastrectomy between January 1, 2008 and December 31, 2009, in three-month intervals. The dispersion of minor and major complications for the three major procedures was not statistically significant. Despite this, the TM&M classification system has provided our department with an objective evaluation of thoracic surgical complications and has facilitated effective M&M review.

Incidence of Complications in Subgroups

Overall complication rate was not statistically different in patients undergoing a lobectomy or patients undergoing a pneumonectomy procedure (49.3% vs 57.6%; $p = 0.3766$). However, there was a significantly higher grade IVa complication rate in patients undergoing a pneumonectomy compared with those patients undergoing a lobectomy (24.2% vs 2.2%; $p < 0.0001$). Overall complication rate was not statistically different in patients undergoing video-assisted thoracoscopic surgery or patients undergoing an open lobectomy (53.1% vs 45.1%; $p = 0.2313$).

Regardless of type of procedure, there was a significantly higher complication rate in patients older than 71 years of age compared with those patients younger than 70 years of age (62.1% vs 40.1%; $p < 0.0001$). Particularly, patients older than 71 years of age experienced significantly more grade II complications (44.4% vs 23.4%; $p < 0.0001$) in comparison with patients younger than 70 years of age. No differences in major complications occurred between the two age groups.

Comment

An objective evaluation of surgical care quality is of utmost importance for patients, physicians, and hospitals. Evaluating the outcome of patient care is helpful in improving the quality of surgical care delivered. Thus, any system that is developed for this purpose must be simple, reproducible, and applicable to any surgical specialty at any medical institution. A uniform system would permit comparison of outcomes between surgical procedures and between different institutions, and allow for knowledge transfer for improvement in one's own institution. The implications are wide ranging as all disciplines would be empowered to work toward the same goal of improving surgical in-patient outcomes.

The development of the TM&M classification system and the accompanying TM&M database has facilitated systematic monitoring, reporting, and evaluation of postoperative complications across all thoracic surgical procedures performed at the Ottawa Hospital. To assess the validity and reproducibility of the modified classification, a 31-item, web-based questionnaire was sent to all active members of the Canadian Association of Thoracic Surgeons in August 2009. The first part of the questionnaire consisted of an introduction to the TM&M classification system along with definitions of the severity grades. The second part of the questionnaire showed 20 case-based examples along with postoperative adverse events to be classified in accordance to the proposed classification system. Last, respondents were assessed on their personal judgments about the classification system. A statistically significant degree of agreement was obtained among the survey respondents which will be reported separately.

The TM&M classification system is complementary to several ongoing, large-scale programs designed specifically to measure and improve surgical outcomes [17], such as the National Surgical Quality Improvement Program [18] and the Society for Thoracic Surgeons database [19], which provide hospitals and cardiac surgeons with information on their risk-adjusted M&M rates, respectively. These initiatives offer interinstitutional benchmarking. However, they are less applicable as a continuous quality improvement measure for an individual thoracic surgical program, as understanding and improving the delivery of a particular operation may require measures tailored to that operation [17], such as proper evaluation of the burden of illness of individual complications and subsequent patient impact. Incorporation of a standardized complication grading system, such as the TM&M, into large organizational databases would allow identification of areas for improvement for surgeons and institutions. It would provide a common denominator for the implementation of quality improvement programs to

reduce the incidence of complications after thoracic surgery.

By using the TM&M system as a continuous measure of quality, we have now embarked on several initiatives to further improve complication rates related to thoracic procedures. A comparison was performed at our institution to evaluate postoperative outcomes after lobectomy by video-assisted thoracoscopic surgery versus open thoracotomy performed on thoracic oncology patients. We further plan to utilize this continuous TM&M classification system as a backbone for prospective monitoring of essential surgical information upon which to add additional clinical data collection tools. While the use of a reliable and continuous system of evaluation of presence and severity of complications after thoracic surgery is necessary, it is not sufficient for a comprehensive evaluation of surgical quality. Monitoring of wait times, efficient resource utilization, patient experience, and satisfaction are all dimensions of surgical care quality improvement.

We recognize several important limitations to this type of classification system. Reported morbidity bears little importance without an understanding of the medical impact of that morbidity [20]. It is as important to precisely document the complication as it is to analyze it and relate it to preexisting risk factors, intraoperative difficulties, and lack of hospital resources. While it is important to recognize the financial implications for prolonged length of stay in the hospital, it is equally important to determine the exact reason for such occurrence. Similarly, for all complications seen in the thoracic surgical population the cause must be identified, the severity of the complication assessed, and the steps necessary to rectify quickly should be undertaken. The attribution of cause of morbidity is an additional dimension of morbidity reporting that we have not endeavored to record systematically as it is based on judgment, and customarily requires peer discussion during M&M conferences. Our results indicate that atrial fibrillation and prolonged air leak have a different burden in different patients, but risk adjustment, to account for the different case-mix was not performed at this time. Thus, future modifications to the TM&M classification system are planned, including a measure of the etiology of complications which may be useful for attributing cause as knowledge about risk factors is fundamental to compare outcomes among risk-adjusted populations.

Whereas complications may reflect both patient and health care factors, the ability to save patients once complications arise is much more closely related to the quality of health care [21]. A failure-to-rescue rate may not be correlated with postoperative adverse events but represents a limitation of the TM&M classification system to counter the occurrence and progression of complications.

Indeed, collecting TM&M data is inherently a collegial activity. It requires participation of the senior residents on a daily basis, weekly confirmation by attending staff, and monthly discussion at M&M conferences. The presence and grade of a complication is not always clear and frank collegial discussion enhances the validity of the data. Our experience has been that M&M conferences have greatly been enhanced by improved quality of statistical reporting of all complications while maintaining individual patient case presentations.

We conclude that a prospectively collected, standardized classification system for accurately identifying and grading thoracic surgical complications in all cases is feasible to implement, facilitates objective comparison between surgical procedures and patients, and between surgeons and centers, identifies burden of illness of individual complications, and thus provides an effective tool for continuous surgical quality assessment.

The authors would like to gratefully acknowledge funding from the Department of Surgery at the Ottawa Hospital, Dr. Lorenzo Ferri (McGill University) for his suggestion to initially explore the Clavien-Dindo classification system, and to Dr. Jack Kitts, president and CEO of The Ottawa Hospital for his encouragement of this project.

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DISCUSSION

DR SCOTT J. SWANSON (Boston, MA): Who pays for the research nurse? Is that a hospital-based person?

DR SEELY: No. It's out of our research budget, which is from our own internal and external grants. We did receive some competitive grant funding from the Department of Surgery to support this, but there is no formal institutional funding.

DR DAVID H. HARPOLE (Durham, NC): These are excellent data. This is exactly what we need to do. We need to quantify these things and really learn from them. You're just beginning to collect your data, and hopefully we can figure out how to transcend your institution and generalize things like this across North America. It would be very helpful for us to learn from these.

DR SEELY: Thank you.

DR MARK I. BLOCK (Hollywood, FL): I really enjoyed that. I fully agree with David. I think this is a fantastic contribution. It's like the STS [Society of Thoracic Surgeons] database an order of magnitude advanced.

My first question was already answered. I guess you have one coordinator who enters all the data, collects all the data, and that is obviously the biggest hurdle. My second question is, now that you have this data, you have this wonderful tool, have you started to make any changes in your practice by looking at that data? What are you thinking about? Have you done any of that?

DR SEELY: One of the important findings really was uncovering the impact that air leak has on our patients. It's something that we had all realized, but statistically it really struck us from evaluating the data. So we are embarking on new ways to try to reduce air leak. We have limited the pressures exerted on the airway at the end of the pulmonary resection cases. We have tried additional techniques to limit air leak. We are trying to reduce those numbers as a continuous quality improvement project. We are also entertaining the use of sealing products. So I guess that's just one example, but we're just starting to get into it at this time.

DR BLOCK: It reminded me of the other question. Grade II complications are pharmacologic intervention only.

DR SEELY: Precisely.

DR BLOCK: What's an air leak grade II complication?

DR SEELY: One of the findings was that it wasn't always obvious how to define a complication. So that's a perfect example. We defined an air leak greater than 5 days as a grade II complication even though it may not require additional pharmacologic therapy. We also defined an intervention that requires an additional chest tube or pigtail catheter as being a grade IIIa complication. Whereas some might consider that a minor intervention, we felt it was important enough to consider that a major intervention. So these were the kind of collegial discussions we had to have to define these grades of severity.