The use of spirometry testing prior to cardiac surgery may impact the Society of Thoracic Surgeons risk prediction score: A prospective study in a cohort of patients at high risk for chronic lung disease

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Objectives: Chronic lung disease is a significant comorbidity in patients undergoing cardiac surgery. Chronic lung disease is currently being classified and reported to the Society of Thoracic Surgeons database by using either clinical interview or spirometric testing. We sought to compare the chronic lung disease classification captured by the 2 methods.

Methods: We performed a prospectively designed study in which patients presenting for cardiac surgery, excluding emergent patients, were screened for a history of asthma, a history of 10 or more pack-years of smoking, a persistent cough, and the use of oxygen. Each selected patient underwent spirometry. The presence and severity of chronic lung disease was coded per Society of Thoracic Surgeons guidelines by using the 2 methods of clinical report and spirometric results. The chronic lung disease classifications were compared, and differences were determined by using concordance and discordance rates. The results were then used to construct Society of Thoracic Surgeons–predicted risk models.

Results: The discordant rate was 39.1%, with underestimation of the severity of chronic lung disease in 94% of misclassified patients. This affected the Society of Thoracic Surgeons–predicted risk models for prolonged ventilation, morbidity/mortality, and mortality by increasing the predicted risk when spirometry was used for morbidity/mortality by an average of 1.5 ± 1.2 percentage points ($P < .001$) and prolonged ventilation time by an average of 1.3 ± 1.4 percentage points ($P < .001$).

Conclusion: The use of patient history for symptoms, medication, and/or oxygen use as the only method to determine chronic lung disease for this subgroup of patients led to underreporting of chronic lung disease and underestimation of the risk for adverse outcomes. Therefore data submission to the Society of Thoracic Surgeons database should be designed to capture and correct for potential bias in the definition of chronic lung disease because the rate of spirometry in different centers in defining chronic lung disease is not regulated. (J Thorac Cardiovasc Surg 2010;139:686-91)

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality in the United States¹ and is often underdiagnosed not only in its early stages but also when there is severe impairment of lung function. The diagnosis of COPD or chronic lung disease (CLD) historically has depended on the presence of symptoms. Recent guidelines for the diagnosis of pulmonary disease use lung function measurements to diagnose and classify disease severity.²⁻⁴ Unfortunately, lung function measurements are infrequently performed by primary care physicians. During

the year 2000, an estimated 10 million adults in the United States reported “physician-diagnosed COPD.”^{4,5} A contemporaneous survey using lung function measurements resulted in a prevalence estimate of 23.6 million adults with COPD.^{6,7}

Because cigarette smoking is a shared risk for cardiovascular and pulmonary disease, cardiac surgery is often performed on subjects with lung disease. Several reports have determined that the incidence of CLD in patients undergoing coronary artery bypass grafting can range from 4% to 27%. More importantly, CLD is recognized as a significant risk factor for mortality and morbidity in patients undergoing cardiac surgery.⁸⁻¹¹ Data obtained from spirometry provide information beyond the diagnosis of CLD. A large population-based study found that even small decrements in lung function in a restrictive pattern can be associated with underlying heart disease and are associated with an increased risk of death (hazard ratio, 1.7; 95% confidence interval, 1.4–2.0).¹²

The Society of Thoracic Surgeons’ (STS) risk algorithms for determining 30-day operative mortality and morbidity risk and prolonged ventilation for patients undergoing cardiac surgery do not require spirometry to define the

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Abbreviations and Acronyms

ATS	= American Thoracic Society
CLD	= chronic lung disease
COPD	= chronic obstructive pulmonary disease
ERS	= European Respiratory Society
FEV ₁	= forced expiratory volume in 1 second
FVC	= forced vital capacity[0]
STS	= Society of Thoracic Surgeons

presence, severity, or both of CLD. In general, because there is a gross underuse of spirometry, it is likely that across centers submitting data to the STS on the rate and severity of CLD, their respective reports are based on different methods of assessment and use of spirometry. We found that before this study less than 2% of our patients underwent spirometric testing before surgical intervention, and we assume other centers reporting data to the STS will have similar findings. Therefore assessment of CLD is vital to accurately predict expected outcomes in patients undergoing cardiac surgery, especially in the new era in which the prediction models of outcomes are so thoroughly assessed by the different organizations.

The purposes of the study were (1) to determine whether preoperative spirometric measures provide a better parameter in identifying the presence, severity, or both of CLD according to the STS definition compared with an assessment that is dependent on patient self-report for symptoms, medication, and/or home oxygen therapy; (2) to determine whether the use of spirometry in the identification of CLD has an effect on the STS-predicted risk models for prolonged ventilation, mortality, and morbidity; and (3) to determine whether our findings justify a review of the current method of capturing CLD data and a better control of the different methods used in identifying and classifying CLD and its respective potential bias on the STS risk score.

MATERIALS AND METHODS

Design

This was a prospective study. The intent was to “case find” patients who were at high risk for having lung disease; therefore each patient who presented for cardiac surgery, excluding emergent patients, were screened for a history of asthma, history of 10 pack-years or more of smoking, and/or a persistent cough (a cough lasting ≥ 4 weeks). The study was reviewed and approved by our institutional review board.

After a patient was identified as meeting the inclusion criteria, spirometry was performed before surgical intervention. The spirometric testing was administered under the American Thoracic Society (ATS) and European Respiratory Society (ERS) standard guidelines for spirometric testing.^{2,3,13,14} The spirometric results were reviewed by a board-certified pulmonologist after first coding patients based on their self-report of medication, oxygen use, or both. The pulmonologist then recoded the patient's CLD, if any, by using the spirometric results according to the STS guidelines. The data from each CLD classification were compared. Other patient variables collected included age, sex, type of operation, length of hospital and intensive

care unit stay, time to extubation, and postoperative complications. These were collected from the hospital's local inpatient STS database. In addition, patients were excluded from the analysis if their spirometric results were considered uninterruptible, as defined by the ATS/ERS task force.^{2,3,13,14}

Clinical Definitions

Spirometry is the most common, widely available, and reproducible pulmonary function test that measures the volume of air inhaled and exhaled from the lungs over time.^{2,3,13,14} Two machines were used to assess spirometric results before surgical intervention: inpatient (SpiroPro; SensorMedics, Yorba Linda, Calif) and outpatient (Puritan Bennett Renaissance II; Puritan Bennett, Boulder, Colo). Both machines met the ATS/ERS standards.^{2,3,13,14} Spirometric testing was performed within 2 weeks of surgical intervention (median, 2.0 days).

CLD according to the STS standards was staged on the following definitions: (1) none, no medications or forced expiratory volume in 1 second (FEV₁) greater than 75% of predicted value; (2) mild, patient taking chronic inhaled or oral bronchodilator therapy or FEV₁ 60% to 75% of percent predicted value; (3) moderate, patient taking chronic steroid therapy or FEV₁ 50% to 59% of percent predicted value; or (4) severe, home oxygen or room air Po₂ of less than 60 or room air pCO₂ of greater than 50 or FEV₁ less than 50% of percent predicted value.¹⁵⁻¹⁷

Sample Size

The total number of patients required for the study to have a nominal power of 80%, a test proposition of 20%, and an underlying undercoding prevalence of 10% was 294. However, a preliminary analysis demonstrated that the underreporting of CLD by using clinical definitions without spirometry was greater than 40%, which would require a sample size of 50 or more to retain a nominal power of 80%.

Statistical Analysis

Continuous data are presented as means $\pm$ standard deviations. Categorical data are presented as frequencies and percentages. Statistical comparisons were accomplished by means of 1-way analysis of variance, the χ^2 test, or the Fisher's exact test, where appropriate. The rate of misclassification was determined by using concordance and discordance rates (referent variant analysis). Lastly, after spirometric results were obtained, predicted STS risks models for prolonged ventilation, morbidity/mortality, and mortality for patients undergoing coronary artery bypass grafting surgery were subsequently recalculated with the new spirometry-designated classification. Both original STS-predicted risk models and recalculated models based on spirometric results were then compared and displayed. The STS risk model was developed and validated as a risk-adjustment methodology for the control of potential confounding variables.¹⁵⁻¹⁷ All analyses were conducted with SAS software (version 9.1; SAS Institute, Inc, Cary, NC).

RESULTS

From October 2007 to October 2008, 220 patients met the inclusion criteria for the study and represented 23.3% of the patients who were operated on by us using the heart-lung machine during this period. Patients were classified into groups based on their respective spirometric results. Table 1 displays the patients' demographics and clinical characteristics overall and by group. Regardless of classification, the average age was 64.9 (SD, 10.9) years, 78% of the patients were male, and 10% were current smokers. Patients in the severe group were significantly older (68 ± 10.1 years) and had a significant decrease in their FEV₁ percent predicted values ($45.0\% \pm 13.1\%$) when compared with the other groups.

TABLE 1. Patient demographics and clinical characteristics by STS group (postspirometric classification)

	Total spirometry group (n = 220)	No CLD (n = 103)	Mild CLD (n = 62)	Moderate CLD (n = 21)	Severe CLD (n = 28)	P value
Age (y)	64.5 ± 10.9	62.1 ± 9.7	66.9 ± 12.1	66.0 ± 11.2	68.0 ± 10.1	.010
Ejection fraction (%)	51.6 ± 13.6	53.7 ± 12.4	48.9 ± 15.8	49.8 ± 14.7	50.3 ± 12.0	.145
Body mass index (kg/m ²)	29.2 ± 6.0	29.6 ± 6.3	28.4 ± 5.3	28.3 ± 4.5	29.4 ± 7.0	.564
FEV ₁ (%)	75.3 ± 24.5	88.2 ± 23.0	72.4 ± 25.0	54.1 ± 8.7	45.0 ± 13.1	<.001
FVC (%)	84.3 ± 46.4	96.3 ± 58.8	82.4 ± 32.3	61.3 ± 8.6	64.3 ± 20.9	.001
Male sex	171 (77.7)	86 (83.5)	47 (75.8)	15 (71.4)	20 (71.4)	.360
NYHA class (III or IV)	47 (21.4)	13 (12.6)	17 (27.4)	7 (33.3)	9 (32.1)	.914
Currently smoking	22 (10.0)	2 (1.9)	4 (6.4)	3 (14.3)	1 (3.6)	.086
Family history of CAD	138 (62.7)	65 (63.1)	36 (58.1)	15 (71.4)	18 (64.3)	.736
Diabetes	74 (33.8)	30 (29.1)	20 (32.2)	6 (28.6)	12 (42.8)	.572
History of renal failure	5 (2.3)	3 (2.9)	1 (1.6)	1 (4.8)	0 (0)	.686
CLD (severe)	28 (12.7)	0 (0)	0 (0)	0 (0)	28 (100)	<.001
CVA	16 (7.3)	3 (2.9)	5 (8.1)	5 (23.8)	3 (10.7)	.008
Myocardial infarction	15 (6.8)	6 (5.8)	5 (8.1)	3 (14.3)	1 (3.6)	.473
Hypercholesterolemia	21 (9.5)	7 (6.8)	8 (12.9)	4 (19.0)	2 (7.1)	.267
Hypertension	175 (79.5)	79 (76.7)	49 (79.0)	17 (80.9)	24 (85.7)	.772
Peripheral vascular disease	39 (17.7)	14 (13.6)	14 (22.6)	3 (14.3)	7 (25.0)	.339
Cerebrovascular disease	36 (16.4)	10 (9.7)	13 (21.0)	8 (38.1)	4 (14.3)	.008
Previous valve	2 (0.9)	0 (0)	0 (0)	1 (4.8)	1 (3.6)	.072
Previous CABG	4 (1.8)	2 (1.9)	0 (0)	1 (4.8)	1 (3.6)	.465
Elective	98 (44.5)	45 (43.7)	33 (53.2)	7 (33.3)	10 (35.7)	.278

Values are presented as means (standard deviations) and numbers (percentages), where shown. Six patients were missing values. STS, Society of Thoracic Surgeons; CLD, chronic lung disease; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; NYHA, New York Heart Association; CAD, coronary artery disease; CVA, cerebrovascular accident; CABG, coronary artery bypass grafting.

Perioperative Complications

The STS database guidebook definitions were used to determine perioperative complications.¹⁷ Twenty (9.1%) patients had a prolonged ventilation time, 8 (3.6%) patients had pneumonia, 68 (30.9%) patients had lengths of stay greater than 7 days, and 3 (1.4%) patients died within 30 days of surgical intervention. Statistically significant differences were noted for the following variables: transient stroke, prolonged ventilation time, pneumonia, length of stay greater than 7 days, 30-day mortality, and readmission at 30 days or less after the operation. However, the real clinical significance might need to be tested with a larger cohort of patients (Table 2).

Spirometric Findings

One hundred ninety-two patients had interpretable spirometric results. Seventy-five of the 192 patients were found to be misclassified/discordant, resulting in an overall discordant rate of 39.1%. The severity of CLD was underestimated in 71 (94.7%) of the 75 misclassified patients. Table 3 displays the number of patients misclassified for each category of CLD, as defined by the STS. More than 44% of the patients in the mild CLD category based on clinical evaluation were misclassified when the spirometric results were obtained.

Table 4 compares the STS-predicted risk models for prolonged ventilation, morbidity/mortality, and mortality with and without the use of spirometry. The predicted risk for

any one of the 3 modeled complications was significantly higher when calculated with spirometry rather than clinical assessment for the standard STS definition. The greatest effect was observed for composite morbidity/mortality, with an average increase in predicted risk of 1.5 ± 1.2 ($P < .001$) percentage points when spirometric information was used. Clinical diagnosis also underestimated the risk of prolonged ventilation time by an average of 1.3 ± 1.4 ($P < .001$) percentage points (Figure 1).

DISCUSSION

In this study we set out to determine whether the use of spirometric measures in a subset of patients undergoing cardiac surgery before the surgical intervention would provide a better parameter in determining the presence, severity, or both of CLD when compared with clinical classification based on STS definitions for CLD. Our findings suggest there is a significant underestimation of the prevalence and severity of CLD when using the STS definitions without spirometry. The greatest disparity was seen among patients who would have been classified as having either no or mild disease when, in fact, severe disease was detected in more than 12% of these patients.

In addition, the purpose of this study was to determine the effect, if any, on the STS-predicted risk models for prolonged ventilation, mortality, and morbidity. We did find that the use of spirometry affected the aforementioned STS risk models. This study determined that the use of

TABLE 2. Perioperative complication rates by STS group (postspirometric classification)

	Total spirometry group (n = 220)	No CLD (n = 103)	Mild CLD (n = 62)	Moderate CLD (n = 21)	Severe CLD (n = 28)	P value
Transient stroke	1 (0.5)	0 (0)	0 (0)	1 (4.8)	0 (0)	.026
Permanent stroke	4 (1.8)	2 (1.9)	1 (1.6)	0 (0)	0 (0)	.820
Septicemia	1 (0.5)	0 (0)	1 (1.6)	0 (0)	0 (0)	.487
Mediastinitis	1 (0.5)	0 (0)	0 (0)	0 (0)	1 (3.6)	.083
Cardiac tamponade	2 (0.9)	1 (1.0)	0 (0)	0 (0)	0 (0)	.785
Prolonged ventilator time	20 (9.1)	4 (3.9)	8 (12.9)	0 (0)	7 (25.0)	.001
Pneumonia	8 (3.6)	0 (0.0)	3 (4.8)	1 (4.8)	4 (14.3)	.004
Renal failure	15 (6.8)	5 (4.8)	6 (9.7)	1 (4.8)	2 (7.1)	.664
Dialysis required	3 (1.4)	1 (1.0)	1 (1.6)	0 (8)	1 (3.6)	.707
Reoperation for bleeding	2 (0.9)	0 (0)	1 (1.6)	1 (4.8)	0 (0)	.184
Atrial fibrillation	22 (10.0)	10 (9.7)	7 (11.3)	1 (4.8)	3 (10.7)	.856
Length of stay ≥7 d	68 (30.9)	18 (17.4)	21 (33.9)	10 (47.6)	17 (60.7)	<.001
30-d Mortality	3 (1.4)	0 (0)	1 (1.6)	0 (0)	2 (7.1)	.037
Readmission ≤30 d	15 (6.8)	7 (6.8)	2 (3.2)	0 (0)	6 (21.4)	.007

STS, Society of Thoracic Surgeons; CLD, chronic lung disease.

spirometry in the risk models created an underreporting of the expected number of adverse outcomes to include death by 2% to 25% depending on the degree of CLD severity identified.

This underreporting suggests that the current STS method of defining CLD might not be adequate. Having the option of using a clinical diagnosis versus spirometry might not be enough because the STS currently does not provide models that incorporate clinical diagnosis-only or spirometry-only models. Therefore it is apparent that the STS needs to address how best to capture CLD data or adjust for the method used to identify CLD so that the STS-predicted risk models can be correctly calculated, applied, and interpreted for a given patient population and across cardiac surgery centers.

Furthermore, the correct calculation of the risk models carries significance beyond the immediate postoperative period of time. In this era of tying compensation to outcome, there is increased accountability for the health professional. Having correctly calculated predicted risk models can be imperative to the success of a cardiac surgery program.^{18,19}

Another relevant concern we had in the design of our study was the increased cost associated with additional testing before surgical intervention, even a relatively small one. This was one reason why we designed the study to “case find” patients with a higher risk for CLD who most likely would benefit from early intervention, especially patients with severe disease. The true effect of early intervention on patients identified with a certain level of impairment

TABLE 3. Cross-tabulation of clinical versus spirometric assessment (n = 192)*

		Spirometric assessment				
		No CLD	Mild CLD	Moderate CLD	Severe CLD	Total
Clinical assessment	No CLD	96	33	11	12	152
	Mild CLD	2	20	5	9	36
	Moderate CLD	1	0	0	1	2
	Severe CLD	0	1	0	1	2
	Total	99	54	16	23	192 *

Concordance rate: 60.9%, (117/192)

Discordance rate: 39.1%, (75/192)

Underestimation by STS definition: 94.6% (71/75)

Overestimation by STS definition: 5.4% (4/75)

Misclassification rate by prespirometric STS class

No CLD	56/152	(36.8%)
Mild CLD	16/36	(44.4%)
Moderate CLD	2/2	(100.0%)
Severe CLD	1/2	(50.0%)

*Twenty-eight patients were given diagnoses of “unknown” based on American Thoracic Society guidelines. CLD, Chronic lung disease; STS, Society of Thoracic Surgeons.

TABLE 4. Average values for STS-predicted risk models with and without spirometry

		Total spirometry group (n = 192)	
Prolonged ventilation time	STS without spirometry	5.5 ± 4.4	—
	STS with spirometry	6.8 ± 5.8	$P < .001$
Mortality	STS without spirometry	1.1 ± 1.3	—
	STS with spirometry	1.3 ± 1.8	$P < .001$
Morbidity/mortality	STS without spirometry	8.9 ± 6.1	—
	STS with spirometry	10.4 ± 7.3	$P < .001$

STS, Society of Thoracic Surgeons.

requires a long-term clinical study, which was beyond the scope of this study. However, we did show that the use of spirometry is important when determining CLD in a subset of patients so that more in-depth assessment can take place.

A further area of exploration should focus on the consideration of using the ATS/ERS guidelines in determining CLD rather than the current definitions. A strength of the ATS/ERS guidelines is that they provide for 2 different types of ventilatory defects: obstructive and restrictive abnormalities. An obstructive abnormality is defined as an FEV₁/forced vital capacity (FVC) of less than the fifth percentile of the predicted value. A restrictive abnormality is defined as an FVC reduction to less than the fifth percentile of the predicted value and a normal FEV₁/FVC ratio.¹⁴ Perhaps thought should be given to incorporating both FEV₁ and FVC, if not the diffusion capacity of the lung for carbon monoxide, when determining CLD.^{2,3,13,14}

Limitations of the Current Study and Analysis

Spirometry was only performed in subjects with a history of asthma, a 10 pack-year or greater smoking history, or a chronic cough. By focusing only on this cohort of patients, we might have missed some patients with abnormal spirometric results. Also, restriction on the use of spirometry only might represent factors other than intrinsic pulmonary disease, such as neuromuscular weakness, congestive heart failure, pleural effusions, and obesity.

In addition, the study design (preselecting patients at a higher risk for CLD) might have a potential for work-up bias. Work-up bias was originally described by Ransohoff and Feinstein²⁰ in the late 1970s, when they wrote about inherent biases in diagnostic testing. More recently, Blackstone and Lauer,²¹ in their 2004 editorial for the *Journal of Thoracic and Cardiovascular Surgery*, discussed the treachery of work-up bias and the generalizability of investigators' findings. They described work-up bias as "...occurs whenever a test is performed and a gold standard (reference) validation is not performed for each patient, and accuracy of the test is reported for only patients with reference validation." We did not correct for any bias that might be introduced in our findings.

CONCLUSION

The findings of this study suggest that the presence and severity of CLD might be significantly underreported in a cohort of patients (≥ 10 pack-year smoking history, asthma, or a persistent cough) when using only the STS definitions without spirometry. The underreporting/misclassification

FIGURE 1. Clinical and spirometric comparison of the Society of Thoracic Surgeons–predicted risk models for prolonged ventilation time, mortality and morbidity, and operative mortality.

led to a perceived decrease in the risk for adverse outcomes. This study found that when the STS definitions with spirometry were used to determine CLD, the predicted risk models for prolonged ventilation, morbidity/mortality, and mortality were significantly adversely changed. This adverse change can have a significant effect on composite risk stratification scoring for cardiac surgery programs. Consideration should be given to using spirometric testing when determining CLD in a cohort of patients. Further study should be undertaken to determine whether all patients presenting for cardiac surgery should undergo spirometry and how the STS should define, adjust for, or both the method used to identify CLD.

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