Pilot Test to Incorporate Patient Reported Outcomes into the STS Adult Cardiac Surgery Database

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PROs in STS Database Outline

• Rationale

• Update on preliminary work

• Description of pilot test

• Questions/discussion
Established in 1989
Gold standard clinical database
Adult Cardiac, General Thoracic, Congenital
95% data accuracy, externally audited
Predictive risk models for common procedures
Currently, thoracic surgery outcomes in the STS database are assessed by morbidity and mortality.
Patient-Reported Outcomes (PROs)

• Symptom management – a cornerstone of clinical practice

• Symptoms and quality of life are high priorities for patients and caregivers “How will I feel and function?”

• Patients are in the best position to report on their symptoms and quality of life

• PROs – measures of physical, mental and emotional well being obtained by patient self report
Increased Demand for PRO

• Organizations Promoting Use of PRO Measures:
  – Centers for Medicare and Medicaid Services
  – National Quality Forum
  – National Committee for Quality Assurance

• Medical specialty society guidelines
  – ACCP recommends that a validated HRQL instrument be administered to lung cancer surgery patients at baseline and subsequent follow-up (*CJt. Chest. 2013*)
The absence of PROs represents a critical gap in the STS Database and our current approach to quality measurement.
Pilot Study to Integrate Patient Reported Outcomes After Lung Cancer Operations Into The Society of Thoracic Surgeons Database

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Background. A critical gap in The Society of Thoracic Surgeons (STS) Database is the absence of patient-reported outcomes (PRO), which are of increasing importance in outcomes and performance measurement. Our aim was to demonstrate the feasibility of integrating PRO into the STS Database for patients undergoing lung cancer operations.

Methods. The National Institutes of Health Patient Reported Outcome Measurement Information System (PROMIS) includes reliable, precise measures of PRO. We used validated item banks within PROMIS to develop a survey for patients undergoing lung cancer resection. PRO data were prospectively collected electronically on tablet devices and merged with our institutional STS data. Patients were enrolled over 18 months (November 2014 to May 2016). The survey was administered preoperatively and at 1 and 6 months after lung cancer resection.

Results. The study included 127 patients. All patients completed the initial postoperative survey, and 108 reached the 6-month follow-up. The most common procedure was video-assisted thoracic lobectomy (55%). At the first postoperative visit, there was a significant increase in pain, fatigue, and sleep impairment and a decrease in physical function. By 6 months, these PRO measures had generally improved toward baseline.

Conclusions. Collecting PRO data from lung cancer surgical patients and integrating the results into an institutional database is feasible. This pilot serves as a model for widespread incorporation of PRO data into the STS Database. Future integration of such data will continue to position the STS National Database as the gold standard for clinical registries. This will be necessary for assessing overall patient responses to different surgical therapies.

Emory Pilot Study: Objectives

**Primary:** To demonstrate the feasibility of integrating PRO into our institutional STS database for patients undergoing lung cancer surgery.

**Secondary:** To describe the longitudinal pattern and variance of PRO following lung cancer surgery.
Methods

- Prospective, cohort study
  - Patients enrolled from Nov, 2014 through May, 2016

- Inclusion Criteria:
  - All patients who were candidates for resection of a known or presumed lung cancer
  - Patients with final path diagnosis other than primary lung cancer were excluded from subsequent analysis
Patient Reported Outcomes Measurement Information System (PROMIS)

• NIH funded initiative

• Comprehensive set of person-centered measures that evaluate physical, social, and emotional health

• PROMIS measures can be used with the general population and in patients with chronic conditions

• Specific to health domains rather than a specific disease
  – Created to be relevant across all conditions for the assessment of symptoms and functions
Customize a survey using PROMIS instruments for clinical relevance
Methods

Ten PROMIS instruments assessing several health domains were selected:

1. Physical Function
2. Pain Intensity
3. Pain interference
4. Depression
5. Anxiety
6. Sleep related impairment
7. Fatigue
8. Emotional support
9. Informational Support
10. Ability to participate in social roles and activities
Methods

• Assessment Center website used to administer survey, score and store PRO data

• Survey was administered via a tablet device in the clinic at 3 time points
  – preoperatively
  – initial postoperative visit
  – 6 months postop

• Linkage of the PRO data and STS-GTSD was accomplished with unique identifiers
Scoring PROMIS Instruments

• T-score (1-100):
  – Standardized score, like z-scores and IQ scores
  – Compared to a mean score representative of a reference population
  – Population mean is 50 for T-scores (SD ± 10)

• For many PROMIS measures, the reference population was the 2000 General US Census.

• Higher score represents more of measured domain (i.e. more pain or better physical function)
Total Patients Enrolled
N=177

Completed Baseline and Initial Post Operative Surveys
N = 127
Reached 6 Months Postop
N = 108

Completed 6 Month Follow-up Survey
N = 97

Refused 6 Month Follow-Up Survey
N = 11

Total Excluded N=50
N =39 Non-lung cancer diagnoses
N = 9 Withdrew prior to surgery
N = 2 Mortalities prior to 30 days
**Overall Cohort**

<table>
<thead>
<tr>
<th>n = 127</th>
<th><strong>Pathologic Stage:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (SD)</td>
<td>66.3 (9.4)</td>
</tr>
<tr>
<td>Male (%)</td>
<td>50 (39.4%)</td>
</tr>
<tr>
<td>Race: White (%)</td>
<td>79 (62.2%)</td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>27.1 (5.9)</td>
</tr>
</tbody>
</table>

**Smoking Status:**
- Current smoker (%) | 24 (18.9%) |
- Former smoker* (%) | 81 (63.8%) |
- Non-smoker (%) | 22 (17.3%) |
- Zubrod Score=1 | 70 (55.1%) |

**Neoadjuvant Chemotherapy (%)** | 7 (5.5%) |
**Neoadjuvant Radiation (%)** | 11 (8.7%) |

**Pathologic Stage:**
- IA | 56 (44.1%) |
- IB | 29 (22.8%) |
- IIA | 16 (12.6%) |
- IIB | 15 (11.8%) |
- IIIA | 10 (7.9%) |
- IV | 1 (0.8%) |

**Surgery Performed**
- VATS: Wedge Resection | 18 (14.2%) |
- Lobectomy | 70 (55.1%) |
- Segmentectomy | 14 (11.0%) |
- Pneumonectomy | 1 (0.8%) |

**Thoracotomy: Lobectomy**
- Bilobectomy | 3 (2.4%) |
- Pneumonectomy | 8 (6.3%) |
### Survey Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Median Date of Survey (IQR)</th>
<th>Time to Complete Survey (IQR)</th>
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</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td>12 days prior to surgery (5-21)</td>
<td>13 minutes (10 - 16)</td>
</tr>
<tr>
<td><strong>1st Postoperative</strong></td>
<td>22 days after surgery (18-29)</td>
<td>14 minutes (11 - 20)</td>
</tr>
<tr>
<td><strong>6-Month F/U</strong></td>
<td>208 days after surgery (196-235)</td>
<td>15 minutes (12 - 19)</td>
</tr>
</tbody>
</table>
Patient Reported Outcomes

Graph showing trends in T-Score for "Ability to participate in social roles/activities" and "Physical function" over 6 months after surgery. Significant p-values are indicated for both outcomes, with p < 0.01 for both and p = 0.04 for the social roles/activities.
Patient Reported Outcomes

- Pain inference: $p < 0.01$
- Pain intensity: $p < 0.01$

![Graph showing patient reported outcomes over months after surgery](image)
Summary

1. Demonstrate the feasibility of collecting PRO data in a lung cancer surgery cohort.

2. The median time required for patients to complete the survey ranged from 13-15 minutes per encounter.

3. Pain and physical function worsened at 1 month, returning to near-baseline levels by 6 months.
Conclusions

• Serves as a model for widespread incorporation of PRO data into the STS National Database

• Generalizable and can be applied to other disease processes and procedures allowing for:
  – Improved risk stratification & performance measurement
  – Comparative analyses
  – Enhanced preoperative patient counseling

• Next step: measure PRO as routine clinic operations rather than as research
Pilot Test to Incorporate PRO Measurement into the STS Adult Cardiac Surgery Database
Incorporating PRO into STS ND

• 5-10 MSTCVS cardiac surgery programs

• Operations:
  – Coronary artery bypass grafting
  – Aortic valve replacement

• Data collection time points:
  – Pre-operative
  – 30 days post-operative (early recovery)
  – 6 months post-operative (late recovery)
Incorporating PRO into STS ND

• PRO will be collected from patients in a variety of clinical settings:
  – Pre-operative clinic visit
  – Acute inpatient consultation (preoperative)
  – Post-operative clinic visit
  – Hospital readmission
  – Longitudinal follow-up clinic visit
  – Email or phone call?
  – Web based portal
Incorporating PRO into STS ND

• Patients can be provided access to PRO surveys by the following individuals:
  – Clinic front desk staff
  – Clinic medical assistant
  – Clinic/hospital midlevel provider
  – Clinical practice care coordinator

• We do not want to pay a study coordinator to facilitate PRO collection because that is not representative of clinical practice
Incorporating PRO into STS ND

• PRO survey based on PROMIS instruments will be created in Assessment Center

• Suggested domains for PRO measurement:
  – Global health measure v1.2
  – Physical function measure (CAT) v2.0
  – Pain interference measure (CAT) v1.1
  – Dyspnea severity measure (CAT) v1.0

• <5 minutes to complete
Assessment Center

• Online data collection tool that enables creation of study-specific websites for capturing PRO data securely online.

• Assessment Center enables:
  – Customization of items or instruments
  – Real-time scoring of instruments
  – Storage of PHI in a separate, secure database
  – Automated accrual reports
  – Real-time data export
Incorporating PRO into STS ND

• Assessment Center account license to be obtained from Northwestern University

• Participating sites will have administrative access to Assessment Center Account

• PRO surveys administered on electronic tablets with internet access or hospital/clinic computers
  – 1-2 tablets provided to each site
Incorporating PRO into STS ND

• At registration, patients enter name and date of birth
  – Used to link patient PRO data to STS data by site data manager

• Institutional IRBs have uniformly approved waiver of all elements of informed consent and complete waiver of HIPAA authorization for patients to have their data entered into the STS database
WHAT IS ASSESSMENT CENTER™

Assessment Center™ is an online data collection tool that enables researchers to create study-specific websites for capturing participant data securely online.

Studies can include measures within the Assessment Center library as well as custom instruments entered by the researcher. The instrument library includes self- and proxy-report short forms, computerized adaptive tests (CATs), and batteries or profiles from:

- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Quality of Life in Neurological Diseases (Neuro-Qol)
- NIH Toolbox
- Health iTT

Among other important features, Assessment Center also enables:

- Downloading library instruments for administration on paper
- Customization of items or instruments (e.g., format, randomization, skip patterns)
- Real-time scoring of CATs and short forms
- Storage of protected health information (PHI) in a separate, secure database
- Automated accrual reports
- Real-time data export
- Ability to capture endorsement of online consent forms

ANNOUNCEMENTS

Learn how to use the Assessment Center Scoring Service in this brief tutorial.
Short cut to URL can be created that appears on desktop of tablet or computer
Welcome to the AATS Graham Patient Reported Outcomes Survey

If you already have a Login and Password, please enter them in the boxes.

Login
Password

If you are a first time user, click Start below.

Start

If you have any questions or problems, please contact scott@mailserver.edu.
If you would like to bookmark this page, click this Add to Favorites link.
Name and DOB (or other identifier) entered by patient at time of registration
Click the button below to begin the survey. Your participation in the study is appreciated. Below is your password for the study. Please write down this login and password for your records.

Your Login (22144) and Password (yxj)

Begin

Remembering password will be a challenge. Individuals with administrative access to Assessment Center site can retrieve password.
Computer Adaptive Test (CAT)
Retrieve login and password

Customize login/password

Access patient specific URL

Download patient data
Challenges

• Integrating PRO measurement into clinical workflow
• Capturing PRO on inpatient consults scheduled for surgery the next day
• Longitudinal follow-up
  – Change in normal follow-up pattern (6 months is not standard)
  – Lost login/password
  – Patients missing follow-up may not be missing at random
• Merging PRO data into STS data records
Future Directions

• Integration of PRO into EMR
  – Limited availability in Epic and Allscripts
  – 10 most common instruments

• Automated emails to patients at pre-specified time points

• Bar codes or QR codes to facilitate login process
Next steps

• Identification of pilot test sites

• Contracting with STS

• Obtain Assessment Center license and set up survey