Patient-Reported Outcomes in Thoracic Surgery

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KEYWORDS

• Patient-reported outcomes • Health-related quality of life • Outcomes research • Thoracic surgery

KEY POINTS

- Patient-reported outcomes (PROs) will be necessary for comparative effectiveness research and guideline development.
- Routine PRO data collection, along with inclusion in clinical trials and national clinical registries, is needed.
- PRO usage has been endorsed by numerous medical societies and national agencies, and has been endorsed as a possible future quality metric.

INTRODUCTION

Often in thoracic surgery, research efforts and analyses are focused on objective measurements of survival and major morbidity. There is the commonly accepted belief, particularly in regard to cancer treatment, that the best therapy provides the longest survival. Results of survival, perioperative mortality, and complication rates are objective and relatively easy to measure. However, patients undergoing major thoracic operations experience a myriad of postoperative symptoms that are not considered in these analyses and are forgotten in the concern for measuring 5-year cancer-free survival. Some are nonspecific, such as pain, fatigue, emotional distress, and anxiety. Others are specific to a disease or organ, for example, dyspnea, dysphagia, and gastrointestinal cramping. Regardless, all have some degree of subjectivity and can be patient-specific. Worries about health-related (HR) quality of life (QOL) are increasingly of greater concern to patients.

Ultimately, delivery of optimum patient-centered care (care focused on what is of greatest concern to patients) will require a greater focus on high-quality HR-QOL outcomes research (Fig. 1). The most accurate way to evaluate and measure these symptoms is by gathering these data directly from the patient, with no interpretation by medical providers. Such data are typically referred to as patient-reported outcomes (PROs). This article discusses the role for PRO research in thoracic surgery.

REASONS TO MEASURE PATIENT-REPORTED OUTCOMES

In the past, the subjective nature of research focused on HR-QOL has caused researchers concern regarding the validity of such studies. This is often due to methodological concerns, such as a lack of standardization in PRO measures making comparison of studies problematic, a perception of lack of sensitivity in PRO instruments to subtle changes in symptoms, and the procedural difficulties related to data measurement and administration of time-consuming surveys.[1] As a result, most studies in thoracic surgery,

Disclosures: This project was supported by grant from the American Association for Thoracic Surgery Graham Foundation Cardiothoracic Surgical Investigators Program.

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Thorac Surg Clin 27 (2017) 279–290
http://dx.doi.org/10.1016/j.thorsurg.2017.03.007
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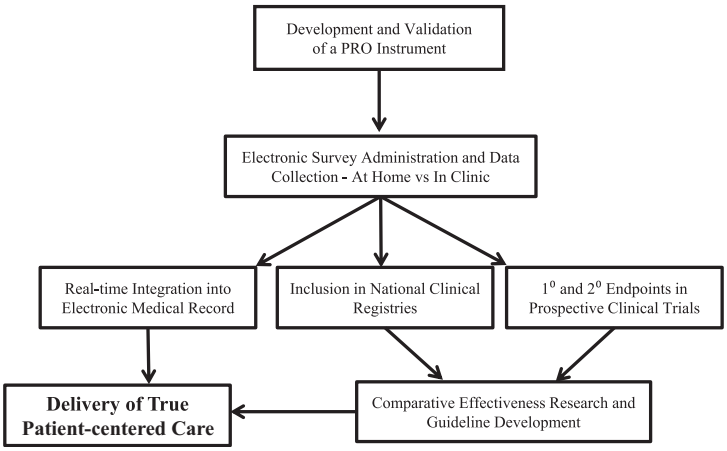

Fig. 1. Clinical integration of patient-reported outcomes research.

particularly those considered to be landmark papers, focus on more objective measures that are relatively straightforward to quantify, such as perioperative mortality, long-term survival, and rates of complications. Undoubtedly, these objective results are of vital importance because they form the basis of any treatment evaluation and, particularly in relation to oncologic care, they predominate research endeavors.

However, this approach can lead to an incomplete evaluation of treatment. Survival and complication rates alone do not provide a complete picture of the postoperative patient experience.[2] In many ways, HR-QOL measures are often of greater concern and relevance to patients, rather than minor differences in 5-year survival when comparing treatment options. Often, a patient may be willing to accept a treatment with potentially worse survival outcomes if they believe their postoperative QOL would be better. Despite this, currently, thoracic surgeons are unable to effectively counsel patients regarding the changes and differences in QOL that directly reflect a patient's experience. Further, objective measurements of survival are typically based on data gathered by the treating medical providers, who often ignore the postoperative effect on QOL. As such, the patient's voice is often lost when evaluating these life-changing therapies. In fact, prior study has confirmed that a patient's and a physician's assessments of the impact of any given treatment on postoperative QOL are drastically different.[3,4]

As greater emphasis is placed on the delivery of value-based, high-quality, patient-centered care, the importance of PROs has now become widely accepted. Patient-centered care, ultimately, is the delivery of treatment focused on what matters most to the patient. Measuring success in this effort through objective provider-driven measures would be inadequate. PROs are increasingly viewed as the optimal measurement for the quality of patient-centered care. As a result, several major national organizations are promoting PRO research and utilization, including the Center for Medicare and Medicaid Services, National Quality Forum, National Institutes of Health (NIH), National Cancer Institute, the US Food and Drug Administration (FDA), American College of Surgeons, and European Agency for Evaluation of Medical Products, among others.[5] As further evidence of this, the Affordable Care Act resulted in the creation of the Patient-Centered Outcomes Research Institute, with the primary objective of promoting and funding clinical effectiveness research through the use of PROs.[6]

To improve the quality of patient-centered care, it will be necessary to gather PROs as part of routine, standard practice. Because PRO measures are of greater concern to patients, it is critical for prospective studies of comparative effectiveness research (CER) to include these measures when comparing treatments and outcomes and in guideline development. No longer is overall survival a sufficient metric for comparison. As a result, the FDA has recommending incorporated PRO measures as primary and secondary endpoints in clinic trials and evaluation of new drugs and devices.[7] Similarly, the Center for Medical Technology Policy has recommended that PRO measures be included in all prospective clinical CER studies in adult oncology.[8]

The remainder of this article discusses how to best gather and use PRO data, the questions and types of studies PROs can be used for, and reviews some of the HR-QOL research using PROs that has already been completed in thoracic surgery.

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COLLECTION AND INTEGRATION OF PATIENT-REPORTED OUTCOMES INTO CLINICAL PRACTICE

Clearly, there is a need and an interest in PRO measurement and usage. Developing a generalizable system for clinical integration of PRO data gathering and usage for patient-centered care will necessarily require several steps (see **Fig. 1**). Routine survey administration at regular intervals would be the most efficient, accurate, and cost-effective method. The first, and in some ways, most significant step is developing a universal, standardized method for data collection that can be integrated into the existing clinical workflow and technical infrastructure, with minimal burden to the patient and the provider. This will require a robust, sensitive instrument or survey for gathering PROs, as well as a simple, efficient, and user-friendly method for survey administration.

The development of a PRO measurement instrument is a complex, deliberate process that requires multiple steps, patient and provider input, and careful validation.[5] The ideal PRO survey must be appropriate for the patient population and intervention, easy to understand and answer, sensitive to small changes in patient symptoms, and succinct enough to allow completion within 10 to 15 minutes to assure survey completion.[8] Several validated surveys and PRO questionnaires have been developed and studied in a diverse group of diseases, including those pertaining to thoracic surgery (**Box 1**). Two of the most commonly used surveys in thoracic surgical literature include the European Organization for Research and Treatment of Cancer (EORTC) Modules and the Medical Outcomes Study Short Form 36 (SF-36) because they are widely available and well-validated.

The survey must be applicable to the wide array of disease processes and organ systems treated by thoracic surgeons. Although some measurements will be universally applicable, such as physical function, pain, and fatigue, others will require greater specificity. For example, measurements regarding dysphagia and diet intake will be more applicable to the patient with esophageal cancer, whereas questions regarding postoperative dyspnea will be more useful in the patient with lung cancer or diaphragm paralysis. Thus, a single, universal survey may not be sufficient for general incorporation into a varied general thoracic surgery practice or a database such as the Society of Thoracic Surgeons (STS) General Thoracic Surgery Database (GTSD).

Khullar and colleagues[9] recently completed a prospective cohort study in which all subjects undergoing surgery for primary lung cancer completed an HR-QOL survey at their preoperative visit, initial postoperative visit, and at the 6-month follow-up visit using the NIH-sponsored Patient-Reported Outcome Measurement Information System (PROMIS) (**Fig. 2**). PROMIS is a well-validated system of measures of PROs that include a variety of questionnaires that span multiple physical, mental, and social health domains.[1,8–12] By using a variety of short-form modules across all health domains, surveys can be customized to the patient population and disease process of interest. PROMIS questionnaires and instruments use item response theory and computer adaptive testing to adapt to the specific symptoms of a patient. Because of its versatility and advantages, it has been recommended by the Center for Medical Technology Policy as a preferred PRO measure for cancer clinical research and has been used in a variety of fields, including oncology, orthopedics, cardiothoracic surgery, transplantation, and pediatrics.[8,12]

Once an assessment tool has been selected, a method for survey administration and integration into the electronic medical records (EMRs) must be decided on. With the rapid improvement in accessibility and portability of technology, most patients will prefer an electronic survey method.

Box 1
Available patient-reported outcomes questionnaires

- Patient-Reported Outcomes Measurement Information System (PROMIS)
- European Organization for Research and Treatment of Cancer (EORTC) Modules
  - Quality of Life Questionnaire Core 30 (QLQ C-30)
  - QLQ Oesophagus Module 18 (OES18)
  - QLQ Lung Cancer Module 13 (LC13)
- Medical Outcomes Study Short Form 36 (SF-36)
- MD Anderson Symptom Inventory
- Functional Assessment of Cancer Therapy (FACT) Oncologic and Organ-Specific Modules
- Gastro-Esophageal Reflux Disease HRQL Questionnaire
- Gastrointestinal Quality of Life Index
- Rotterdam Symptom Checklist
- Depression, Anxiety, and Stress Scale 21 (DASS-21)
- Dyspnea Index

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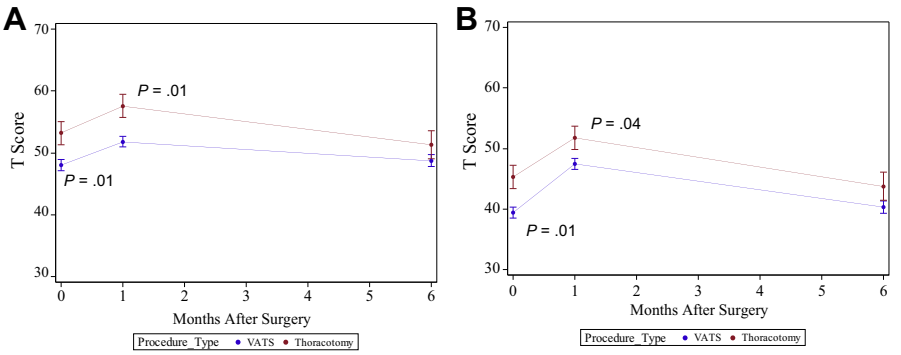

Fig. 2. PROMIS assessments of fatigue (*A*) and pain intensity (*B*) after surgical resection of lung cancer via video-assisted thoracoscopic surgery (VATS) and thoracotomy. (*Data from* Khullar OV, Rajaei MH, Force SD, et al. Pilot study to integrate patient reported outcomes after lung cancer operations into the Society of Thoracic Surgeons database. Ann Thorac Surg, in press.)

Such a survey would have multiple potential advantages. For example, a medical staff member would not be required to administer the survey and the results could potentially be directly integrated into the EMR, local institutional databases, and even national clinical registries. Additionally, electronic surveys can be adjusted and changed with relative ease. Finally, electronic surveys can be administered via a Web-based platform, as was used in Khullar and colleagues[9] study, which would be the ideal platform for survey administration. If administered through a secure, Web-based portal, such as the NIH-sponsored Assessment Center (for the PROMIS instrument) or other patient-portal, the survey can be accessed from anywhere, for example, the examination room, clinic waiting room, or even the patient's home.

Some patients, however, who are not comfortable with technology may have difficulty with such a platform and would be reluctant to complete a survey in this manner. Often, these will be older patients who are common to thoracic surgical practices. Alternate methods of survey administration would include telephone or paper survey administration. Although these methods may have higher completion rates, they require a significant labor investment with possibly added cost. Additionally, because they require manual input into electronic systems, there would be an inherent delay in data availability. In Khullar and colleagues[9] previously described study, surveys were administered electronically using handheld, tablet devices in the clinic waiting areas for most patients, with phone administration for the few of patients who missed their follow-up office visits. This system attained a completion rate of more than 90%.

Needless to say, there will be several difficulties with widespread use of PROs. For example, there will be additional cost associated with integration into the variety of EMR systems used and development of the infrastructure needed to electronically administer the surveys. Currently, a system does not exist for most of the commonly used EMR systems.[13] These leads to the second major challenge, which will be the logistics of survey administration in both the inpatient and outpatient clinic settings. To ensure adequate patient compliance with accurate completion, PRO surveys will need to be comprehensive, yet concise, to avoid missing data. With the availability and use of smarter and more portable technology, an Internet-based delivery system would be ideally situated to meet these technological needs (**Box 2**). Other technologic needs will include the hardware necessary for administration of a Web-based survey, such as computers and/or tablet devices, and a secure server for storage of PRO survey results, such as the Assessment Center Web site, which can store results from the NIH PROMIS system.[14] Assessment Center contains a library of PROMIS tools, as described previously, thereby allowing investigators to create a study-specific Web site with PROMIS instruments of their choosing. Additionally, it allows for near real-time scoring of PROMIS tools using a T score distribution normalized to responses from the general population, which can be used to track changes in an instrument of choice with an objective score.

With the widespread use and improvement of technology, most hospitals and surgical practices now rely on EMRs. To fully integrate PRO data into clinical practice, it will be necessary to view PRO data almost as a vital sign, such as the heart rate or blood pressure, and then to make these data readily available within the EMR system in real time. This would allow the treating clinician to not only report and identify changes in PROs in their

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Box 2
Technology needs for patient-reported outcome measurements

- Internet-based survey platform
- Electronic Medical Record (EMR)
- Hardware for survey administration and data collection
- Secure electronic system for PRO data storage, either within an EMR or off-site
- PRO integration into EMR and national registries or databases

documentation but also to incorporate these data into their evaluation, assessment, and treatment of the patient. For example, real-time identification of subtle changes in physical function, pain, or dysphagia could prompt further diagnostic testing or treatment interventions, such as physical therapy consults, further imaging testing, or procedural interventions, such as intercostal blocks and endoscopies. Thus, to fully embrace PROs, it will be necessary for the survey instrument to be either an integrated component of the EMR system or a free-standing electronic survey that can export normalized, interpretable PRO data directly into the EMR in real time.

PRIOR RESEARCH INTO PATIENT-REPORTED OUTCOMES AND HEALTH-RELATED QUALITY OF LIFE

Once a validated PRO measurement tool has been created and implemented, widespread collection of these data can be used for a wide spectrum of purposes ranging from large, registry-based comparisons of treatment algorithms and patient outcomes to granular use of PRO data in the individual patient to identify subtle changes in symptoms that may be a marker for a larger problem. There have been several studies that have assessed HR-QOL after a variety of thoracic surgical diseases, such as lung cancer, esophageal cancer, paraesophageal hernias, and diaphragm eventration or paralysis, to name a few.[9,15–43] Unfortunately, many of these studies had small sample sizes and used a variety of differing survey instruments (**Table 1**). Thus, they can be difficult to compare and are largely underpowered individually, limiting the studies that can be conducted and the conclusions that can be drawn. However, they do provide examples of the types of studies that can performed.

For example, 1 meta-analysis of 13 studies examining dyspnea after diaphragm plication found that improvement in subject-reported postoperative dyspnea scores ranged from 90% to 100%.[15] Several studies have assessed symptom improvement after laparoscopic repair of hiatal hernias and fundoplications for reflux disease.[16–22] In 1 of the largest series to date to examine PROs after laparoscopic hiatal hernia repair, Castelijns, and colleagues[16] examined 85 subjects retrospectively and found low rates of subject-reported dysphagia and heartburn on long-term follow-up. In another retrospective study, Koetje and colleagues[17] compared repair with and without mesh and found significant improvements in dysphagia and HR-QOL after surgery with no difference between the groups. A meta-analysis examining the same question confirmed these results, finding no difference between repair with or without mesh.[18] Finally, in 1 of the few randomized controlled trials examining laparoscopic hernia repair that included preoperative and postoperative PROs, using the SF-36 questionnaire, Oelschlager and colleagues[19] found no difference between repair with mesh or no mesh. Multiple prospective and retrospective studies, including PROs comparing Nissen fundoplication versus partial fundoplication for reflux have shown similar improvements in reflux and QOL between the 2 procedures, with possibly less dysphagia and gas-related symptoms after partial fundoplication.[20,21] These results provide examples of the valuable insights that can be gained with PROs, which would otherwise be overlooked in studies looking at only clinical outcomes such as hernia recurrence.

Several observational oncologic studies have been completed examining HR-QOL after surgery for esophageal cancer and lung cancer, typically using the EORTC Quality of Life Questionnaire (QLQ)-Core 30 (C30), QLQ-Oesophagus module 18 (OES18), and QLQ-Lung Cancer Module 13 (LC13) questionnaires (see **Box 1**).[23,24] In fact, 1 review examining which PRO measures were used most frequently in studies of surgical treatment of esophageal cancer identified a total of 58 studies, 41 prospective and 17 retrospective.[23] Similarly, a review of HR-QOL studies after surgical treatment of lung cancer identified 22 studies published in English.[24] Unfortunately, most of these studies are limited to observational studies with sample sizes ranging from 50 to 200 subjects; however, they do reveal valuable results.

A full review of the nearly 60 published studies on esophageal cancer is beyond the scope of this article. Most studies do have similar findings, showing that there is a considerable decline in HR-QOL immediately after surgery up to 1 month, which then begin to improve toward baseline

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Table 1
Summary of select HR-QOL studies in patients undergoing surgery for non-small cell lung cancer

Author, Year	Instrument Used	Number of Subjects	Time Frame Analyzed	Aim of Study	Select Findings
Li et al,[34] 2002	EORTC QLQ-C30, EORTC QLQ-LC13	51	Range 6–84 mo	Evaluate HR-QOL comparing VATS vs thoracotomy	No significant difference between the 2 groups in functioning and symptom scales
Kenny et al,[36] 2008	EORTC QLQ-C30, EORTC QLQ-LC13	173	Preoperatively to 2 y	Evaluate HR-QOL and survival in the 2 y after surgery	Half of subjects continue to experience symptoms and functional limitations 2 y after surgery Subjects with recurrence of cancer reported continued deterioration of HR-QOL, although most disease-free survivors experienced recovery
Balduyck et al,[37] 2008	EORTC QLQ-C30, EORTC QLQ-LC13	30	Preoperatively to 1 y	Evaluate HR-QOL after sleeve lobectomy and pneumonectomy	Subjects reported less impact on physical functioning, role functioning, cognitive functioning, and shoulder dysfunction after sleeve lobectomy, compared with pneumonectomy
Ferguson et al,[42] 2009	EORTC QLQ-C30, EORTC QLQ-LC13, DASS-21	124	Time from resection 2.6 $\pm$ 1.6 y	Compare HR-QOL, mood, and clinical factors in subjects < and $\geq$70 y	Subjects older than 70 y reported worse physical function, fatigue, and dyspnea (the differences were not statistically significant)
Sartipy,[35] 2009	SF-36	117	Preoperative to 6 mo	Compare HR-QOL in lobectomy vs pneumonectomy	Pneumonectomy had a larger impact on physical aspects of HR-QOL than lobectomy at 6 mo There was no difference in mental component scores

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Table 1
(*continued*)

Author, Year	Instrument Used	Number of Subjects	Time Frame Analyzed	Aim of Study	Select Findings
Fagundes et al,[33] 2015	MD Anderson Symptom Inventory	60	Preoperative to 3 mo	Longitudinal PRO assessments to define symptom recovery trajectory	Fatigue, pain, shortness of breath, disturbed sleep, drowsiness severity peaked 3–5 d after surgery with recovery by 3 mo
Fernando et al,[40] 2015	SF-36, SOBQ	212	Preoperative to 2 y	Evaluate HR-QOL in high-risk subjects undergoing sublobar resection	Subjects reported worse dyspnea scores with segmentectomy (compared with wedge) and thoracotomy (compared with VATS) Poor baseline QOL scores was not associated with survival
Zhao et al,[41] 2015	SF-36	217	Postoperatively 1 mo to 1 y	Evaluate QOL following lobectomy, comparing VATS with thoracotomy	Bodily pain, energy, and physical role scores were better after VATS, compared with thoracotomy
Yun et al,[32] 2016	EORTC QLQ-C30, QLQ-LC13, HADS, PTGI	809	Single survey in 1 y survivors only	Evaluate prognostic value of QOL for predicting survival	Physical functioning, dyspnea, personal strength, and anxiety were independent predictors of survival
Khullar et al,[9] 2017	PROMIS	127	Preoperatively to 6 mo	Integrate PROs into the STS-GTSD and to describe pattern of PROs after surgery	Physical function, pain, fatigue and sleep impairment are significantly worse than preoperatively at 30 d after surgery (recovery toward baseline over 6 mo)

Abbreviations: DASS-21, Depression Anxiety Stress Scale; HADS, Hospital Anxiety and Depression Scale; PTGI, Post-Traumatic Growth Inventory; QLQ-C30, Quality of Life Questionnaire Core 30; QLQ-LC13, Quality Of Life Questionnaire Lung Cancer Module; SOBQ, San Diego Shortness of Breath Questionnaire; VATS, video-assisted thoracic surgery.
Data from Refs.[9,32–37,40–42]

levels.[25–31] However, it is clear in these studies that symptoms can persist for several months to years after esophagectomy. For example, Lagergren and colleagues[26] administered the QLQ-C30 and QLQ–OES18 questionnaires to 90 subjects undergoing esophagectomy, finding that physical function, breathlessness, diarrhea, and reflux were significantly worse than baseline 1 month after surgery, after which they continued to improve until 6 months. However, all 4 symptoms remained

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significantly worse than baseline even after 3 years. In 1 of the few randomized studies of esophageal cancer including PROs, de Boer and colleagues[27] randomized nearly 200 subjects to either transhiatal or transthoracic esophagectomy and surveyed subjects at periodic intervals from baseline preoperative to 3 years postoperatively. Results of their analyses showed declines in physical function, activity, and QOL after surgery, with return to baseline within 1 year. Subjects in the transhiatal group reported fewer physical symptoms and better activity levels at 3 months. However, there were no differences identified at any time afterward.

Several studies have attempted to compare PROs after surgical therapy versus definitive chemoradiotherapy. In an observational study comparing 132 subjects undergoing chemoradiotherapy or combination treatment, including surgery in stage II or III subjects, Avery and colleagues[28] found that surgery was associated with a greater reduction in HR-QOL than chemotherapy. Perhaps not surprisingly, in a recent meta-analysis of 8 prospective, randomized trials comparing surgical and nonsurgical treatment of esophageal cancer, Best and colleagues[30] found the overall quality of evidence to be low and that only a single trial examined postoperative HR-QOL. In this single study, a significant decline in HR-QOL scores, determined using the Spitzer QOL Index, was noted in the surgical arm at 3 months after surgery. However, no difference was found between the surgical and nonsurgical arms in long-term follow-up as far as 2 years after treatment.[31]

Similarly, several PRO-based studies have been conducted on surgical treatment of lung cancer.[9,32–42] A selected number are described in **Table 1**. The findings of these studies in total describe a common decrease in physical function, dyspnea, and QOL scores after surgery. Most studies describe a return to baseline within 6 months to a year. Similar to the studies for esophageal cancer, most of these studies are either retrospective or prospective observational studies of limited sample size. However, in 1 of the few studies with a large enough sample size to perform an adjusted analysis, Yun and colleagues[32] conducted surveys of more than 800 subjects undergoing lung cancer surgery using the EORTC QLQ-C30 and QLQ–LC13 questionnaires, examining the relationship between PROs and long-term survival. After adjusting for independent demographic and clinical predictors of survival, they found QOL measures for postoperative physical function, dyspnea, personal strength, and anxiety were all independent predictors of long-term survival. In another recently published series including 60 subjects evaluated with the MD Anderson Symptom Inventory, Fagundes and colleagues[33] administered the survey to subjects daily for the first week after surgery followed by weekly for 3 months. The investigators found fatigue, pain, shortness of breath, disturbed sleep, and drowsiness to be the postoperative symptoms to be most significantly affected. Symptom severity peaked 3 to 5 days after surgery. By 3 months, all of these symptoms had returned to preoperative levels. To date, this represents the only study to survey in-hospital subjects immediately after surgery, providing valuable information regarding the immediate postoperative impact on HR-QOL.

The study by Khullar and colleagues[9] developed a PRO survey using validated PROMIS instruments and prospectively assessed 127 subjects undergoing lung cancer surgery. These results were merged with an institutional STS-GTSD to correlate PROs with clinical data and outcomes. Subjects reported significant worsening in pain, fatigue, sleep deprivation, and physical function; at 6 months these symptoms had all returned to baseline levels. Most interestingly, subjects treated with minimally invasive thoracoscopy (n = 103), when compared with thoracotomy (n = 24), reported less pain and fatigue, along with better physical function and social functioning at the preoperative baseline assessment and 1-month postoperative assessment. At the 6-month postoperative assessment, no difference was identified (see **Table 1**).[9] Perhaps the most important finding of the study was that PRO data can be successfully linked with clinical registry data, allowing for more robust CER. Similar to these findings, results from analysis of QOL in the American College of Surgeons Oncology Group Z4032 study cohort showed significantly worse scores in regard to postoperative shortness of breath with thoracotomy.[40] Similarly, in a prospective observational study using the SF-36 questionnaire, Zhao and colleagues[41] found pain, energy, and physical role functioning all to be worse after thoracotomy.

Not surprisingly, it does seem that a greater extent of pulmonary resection, particularly pneumonectomy, can have a significantly detrimental impact on postoperative HR-QOL. Sartipy[35] performed a prospective comparison of subjects undergoing lobectomy (n = 101) versus pneumonectomy (n = 16) using the SF-36 questionnaire. Results from this analysis found a significantly greater decrease in physical function scores after pneumonectomy. Balduyck and colleagues[37] found similar results when comparing sleeve lobectomy with pneumonectomy. Physical functioning, role functioning, cognitive functioning,

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and shoulder dysfunction were all significantly worse than sleeve lobectomy. On the other hand, the analysis by Khullar and colleagues[9] compared video-assisted thoracoscopic surgery (VATS) sublobar resection with lobectomy and, interestingly, found no difference in any parameter after surgery, including pain, physical function, fatigue, and social functioning.

These numerous studies provide examples of studies that can be completed and valuable results that can be obtained with PROs. Unfortunately, even the prospective studies described here are limited to relatively small studies with sample sizes ranging from 50 to 200 subjects with few exceptions. This is often related to the limitations and costs associated with randomized studies and paper-based, mailed surveys. Meta-analyses attempt to solve this problem by combining data from numerous studies, particularly for oncologic studies. However, these results are limited by low-quality data, lack of granularity in regard to clinical outcome data, and difficulties with comparing PRO data due to differing surveys used. Thus, each of these studies is ultimately flawed and unable to fully answer the questions posed.

USES FOR PATIENT-REPORTED OUTCOMES

As previously discussed, PROs are the most direct measurement of patient-centered care that goes beyond simply examining survival or cancer recurrence. Once a tool for data gathering and method of implementation has been established, PROs can then be incorporated into research endeavors, as well as routine surgical practice. By measuring patient satisfaction, symptoms, and QOL directly from the patient with the previously described instruments can obtain objective measurements of outcomes of greater immediate relevance to patients. With routine measurement and use, surgeons can emphasize the delivery of quality care with a focus on what matters most to the patient: true patient-centered care (see **Fig. 1**).

For example, longitudinally collected PRO data can be used for a variety of studies, including CER and guideline development. As treatment options continue to improve and less invasive options become more widely available, comparisons will need to go beyond simply comparing survival and major morbidities. This is especially true when survival is similar. For example, PROs can be used to compare:

- Lobectomy versus sublobar resection
- Sublobar resection versus stereotactic body radiotherapy
- Transthoracic versus transhiatal versus minimally invasive esophagectomy
- VATS versus thoracotomy for a variety of thoracic procedures
- Nissen versus Toupet fundoplication, with or without mesh.

The previous research on HR-QOL has, most often, been observational studies focused on describing longitudinal patterns and variance in postoperative QOL. The few studies that do aim to perform CER using PROs typically do so in an observational manner. Inclusion of PROs as primary and secondary endpoints in prospective, randomized studies with the aim of answering questions, such as those previously described, will provide valuable direction and insights into optimal surgical treatment.

When combined with clinical data from a robust patient registry, such as the STS-GTSD, these data can be further used to compare subsets of patient populations, such as by age, gender, and risk status, and not just by treatment modality. For example, a comparison of PROs, such as postoperative dyspnea and physical function in high-risk versus low risk-patients, after treatment of lung cancer would have immense value. By using large data registries, such as the STS-GTSD or the American College of Surgeons National Quality Improvement Program, large numbers of patients can be compared using techniques such as propensity matching to compare groups and treatments when randomized studies cannot be performed. Linking PRO data to large registries would also provide the clinical data necessary to risk adjust PROs, which will be necessary for accurate CER.[43] Such results could then be used for patient counseling; prediction algorithms; and, perhaps most importantly, treatment guideline development.

There are several advantages to routine PRO collection at the individual level. Subtle changes in physical function, dysphagia, or dyspnea may be early warning signs of clinical problems. Early recognition of this through routine checks at postoperative visits can lead to early interventions, such as cardiopulmonary rehabilitation, diagnostic imaging, endoscopy, or additional physical therapy. Further, thorough prospective objective measurement of PROs will provide surgeons and patients with a roadmap for postoperative changes in QOL symptoms. This will allow for more accurate preoperative counseling for patient expectations, which is currently limited to surgeon anecdotal experience and limited data from small observational studies. Additionally, these studies would facilitate early detection of problems when patients are not following the expected

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postoperative course. Changes in QOL scores have already been shown to be an independent predictor of survival in patients with lung cancer.[32] Such symptoms are easily dismissed during routine clinic visits but with readily available QOL scores obtained directly from the patient as objective measures, subtle changes can more readily be identified.[44]

Given these multiple benefits, numerous national societies have endorsed the routine use of PROs as previously mentioned. The American College of Chest Physicians has gone so far as to recommend that a validated HR-QOL instrument be used to evaluate all patients with lung cancer undergoing curative-intent surgery at baseline and at follow-up visits.[45] Similarly, the FDA has endorsed the inclusion of PROs as endpoints in clinical trials.[7] CMS has endorsed the routine gathering of PROs, with future plans to possibly require them for Medicare reimbursement, as well as to include them as quality and performance measures.

SUMMARY

With increasing focus on the delivery of high-quality patient-centered care, PROs have been increasingly endorsed and recommended by numerous societies and agencies. There are numerous advantages to using PROs. Although several studies within the existing thoracic surgery literature have included PRO instruments and measures, these have been typically limited to small, observational studies. Unfortunately, at the moment, PROs are not typically included in routine patient care. Further, the lack of inclusion of PRO measurements in the STS National Database is a critical gap in current practice. PROs can be successfully integrated with an institutional STS National Database and used to gather valuable insight into the postoperative patient experience. Routine inclusion of PRO measurements in patient care will continue to allow thoracic surgeons to deliver optimal, patient-centered care.

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