

Patient-Reported Outcomes: Time to Integrate Into Outcomes Reporting?



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Historically, surgical outcomes research has focused on objective endpoints that are straightforward to measure and interpret using patient medical records, institutional databases, and national registries. In recent years, such data have been used to drive quality improvement, influence health-care reform, and impact reimbursement of healthcare spending. In order to continue improving outcomes and deliver high-quality patient-centered care, it is imperative that clinicians review not only objective morbidity and mortality data, but also subjective data regarding patients' experience. Patient-reported outcomes (PRO) are starting to drive patterns of healthcare delivery and influence surgical decision-making. The current article reviews the historical background of PRO, tools for integrating it into surgical outcomes research, current data reported within the literature, and future implications within thoracic surgery.

Semin Thoracic Surg 31:856–860 © 2019 Elsevier Inc. All rights reserved.

Keywords: Thoracic surgery, Surgical outcomes, Patient-reported outcomes

INTRODUCTION

Historically, surgical outcomes research has focused on objective endpoints that are straightforward to measure and interpret using patient medical records, institutional databases, and national registries. In recent years, such data have been used to drive quality improvement, influence healthcare reform, and impact reimbursement of healthcare spending. While these data are important for healthcare providers, administrators and payers, such information may not quite as valuable for patients. Someone newly diagnosed with an early stage lung cancer may care more about how specific treatment options impact their quality of life, in addition to their overall survival. These health-related quality of life (HR-QOL) concerns are of increasing concern to patients and providers alike.

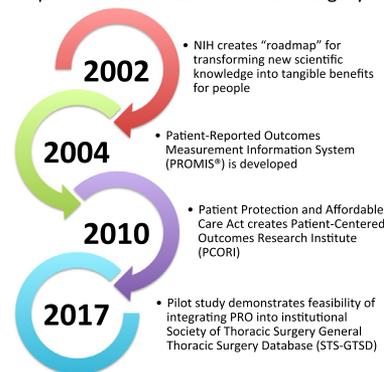
Individuals undergoing major thoracic operations often experience symptoms following surgery that are not captured by large databases or at most clinical visits, and thus not contained in data analysis. Some symptoms are nonspecific—pain, fatigue, physical function, anxiety; others are disease or organ specific—dyspnea, dysphagia, gastrointestinal cramping. The

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Disclosures: The authors have no financial disclosures.

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Patient Reported Outcomes in Thoracic Surgery



Historical timeline showing integration of patient-reported outcomes into thoracic surgery outcomes research.

Central Message

Future surgical outcomes research should include patient-reported outcomes alongside traditional morbidity and mortality data in order to ensure high-quality patient-centered surgical therapy.

most accurate way to evaluate and measure these symptoms is by gathering this data directly from the patient, without interpretation by medical providers.

In order to improve surgical outcomes and deliver patient-centered care, it is imperative that clinicians start reviewing subjective data regarding patients' experience alongside standard objective metrics contained within morbidity and mortality data. Such data, referred to as patient-reported outcomes (PRO), are starting to rapidly influence surgical outcomes research. The current article reviews the historical background of PRO, tools for integrating it into surgical outcomes research, current data reported within the literature, and future implications within thoracic surgery.

Background of PRO

In 2002, the National Institutes of Health (NIH) developed a roadmap for medical research within the 21st century with the goal of "catalyzing changes that are necessary for transforming new scientific knowledge into tangible benefits for people."¹ Two years later, the Patient-Reported Outcomes Measurement Information System (PROMIS) was developed and has since become a well-validated system of measuring PROs which

include a variety of questionnaires that span multiple realms of physical, mental, and social health.^{2,3} In 2010, the Patient Protection and Affordable Care Act created the Patient-Centered Outcomes Research Institute (PCORI), which has provided nearly \$2 billion of funding to promote high-quality clinical effectiveness research through the incorporation of PRO.⁴

Consequently, there has been a rapidly increasing demand for the integration of PRO into surgical outcomes research. Multiple national organizations, including the Center for Medicare and Medicaid Services, National Quality Forum, National Cancer Institute, the US Food and Drug Administration, and the American College of Surgeons advocate for integration of PRO into the measurement of patient outcomes and assessments of clinical performance.⁵ The American College of Chest Physicians has included PRO measures as part of their guidelines for lung cancer treatment, recommending the routine use of HR-QOL instruments in clinical care.⁶ The Center for Medical Technology Policy has advocated for the use of PRO in all prospective, adult oncology clinical effectiveness research studies.⁷ Consequently, there has been considerable interest recently in PRO research. For example, PubMed search of the phrases “patient reported outcomes” and “surgery,” limited to the last 10 years, results in over 20,000 citations.

In 2013, Basch et al defined PRO as “the concept of any report of the status of a patient’s health condition that comes directly from the patient (or in some cases a caregiver or surrogate), without interpretation of the patient’s response by a clinician or anyone else.”⁸ As a result, such data may provide a more reliable means of evaluating and comparing postoperative outcomes and effectiveness of various treatment options

than purely objective outcomes data. Furthermore, because PRO measure those outcomes that matter most to patients, they serve as the basis for improved patient-centered care and a reliable means for measuring HR-QOL.

Current Tools for PRO

In a 2015 international survey of 150 cardiothoracic surgeons, more than 50% reported that they never collect HR-QOL data during patient encounters.⁹ In order to advance patient-centered care, PRO must be gathered as a part of routine, standard practice. However, for providers to remain compliant, the ideal tool for data collection must be generalizable, efficient, user-friendly, accurate, and cost-effective. Furthermore, it should integrate into existing clinical workflow and technical infrastructure including the electronic medical record, with minimal burden to the patient and the provider (Fig. 1).¹⁰

Multiple potential PRO instruments exist for use in thoracic surgery patients (Table 1).¹¹⁻¹⁸ Our preferred instrument is the NIH-sponsored PROMIS. It utilizes a variety of short-form modules across multiple health domains. Surveys can be customized to the patient population and disease process of interest. Due to its versatility and advantages, it has been recommended by the Center for Medical Technology Policy as one of their preferred PRO measures for cancer clinical research and has been used in a variety of fields including oncology, orthopedics, cardiothoracic surgery, transplantation, and pediatrics.^{3,19} It is easily translated into a web-based, electronic interface and easily incorporates into several widely utilized electronic medical record systems. Most importantly, it is of no additional charge to providers or their patients.

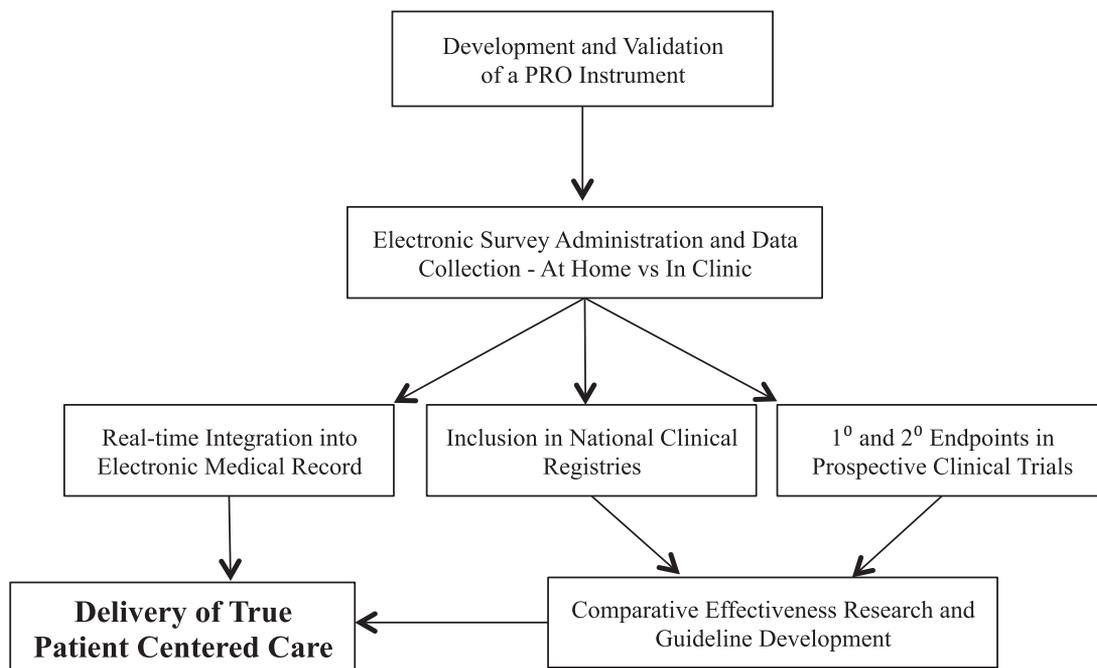


Figure 1. Overview of PROs. Reprinted with permission from ref.¹⁰

Table 1. Existing PRO Instruments for Thoracic Surgery Patients

Generic Questionnaires

- Patient-Reported Outcomes Measurement Information System (PROMIS)
- MD Anderson Symptom Inventory (MDASI)
- Patient Health Questionnaire (PHQ-2)
- RAND Medical Outcomes Study Short Form 36 (SF-36) and Short Form 12 (SF-12)
- World Health Organization Disability Assessment Schedule
- Quality of Recovery-15
- Rotterdam Symptom Checklist
- Depression, Anxiety and Stress Scale 21 (DASS-21)
- Rose Dyspnea Scale
- Nottingham Health Profile

Thoracic Specific

- European Organisation for Research and Treatment of Cancer (EORTC) Modules
 - Quality of Life Questionnaire Core 30 (QLQ C-30)
 - QLQ Oesophagus Module (OES-18)
 - QLQ Lung Cancer Module (LC13)
- Lung Cancer Symptom Scale (LCSS)
- Functional Assessment of Cancer Therapy (FACT) Oncologic and Organ-Specific Modules
- Gastroesophageal Reflux Disease-Health-Related Quality of Life Questionnaire (GERD-HRQL)
- Gastrointestinal Quality of Life Index

PRO in Thoracic Surgery: Current Data

A variety of both retrospective and prospective series have examined PRO and HR-QOL after surgery for non-small cell lung cancer. While most are relatively small, single center, observational studies, they report interesting findings. Two different series have investigated the impact of minimally invasive vs open operative approach on PRO: one (Li et al) found no statistically significant difference between the 2 groups with regards to function and symptom scales, while the other (Zhao et al) reported that patients' bodily pain, energy, and physical role scores were better following VATS compared to thoracotomy.^{20,21}

Our team recently published the initial results of a pilot study investigating the feasibility of integrating PRO into the institutional Society of Thoracic Surgery General Thoracic Surgery Database (STS-GTSD).²² In this prospective cohort study, 127 patients undergoing lung cancer surgery completed HR-QOL surveys using PROMIS software at their preoperative, initial postoperative, and 6-month follow-up clinic appointments. Similar to other studies, there was a significant increase in pain, fatigue, sleep impairment, and decrease in physical function reported at the first postoperative visit. By 6 months, however, these PRO measures generally improved toward baseline (Fig. 2). Additionally, we found that patient-reported physical function was significantly worse after thoracotomy, compared to VATS, at the initial postoperative visit, but did

not identify a significant difference at 6 months. Most importantly, survey completion rates were over 90%.

Three additional studies have examined PRO with respect to type of surgical resection. In a series of 30 patients, Balduyck et al revealed that patients reported less impact on physical, role and cognitive functioning as well as shoulder dysfunction following sleeve lobectomy compared to pneumonectomy.²³ Similarly, Sartipy et al report a series of 117 patients and conclude that pneumonectomy had a larger impact on physical aspects of HR-QOL than lobectomy at 6 months postoperatively, but there was no difference in mental component scores.²⁴ Last, Fernando et al observed 212 high-risk patients undergoing sublobar resection and found that patients reported worse dyspnea scores with segmentectomy (compared to wedge) and thoracotomy (compared to VATS).²⁵

Additional series have investigated PRO with regards to survival, patient age, and timeline of postoperative recovery. Kenny et al followed 173 patients for up to 2 years following their operation and found that one half of patients continued to experience functional limitations.²⁶ Interestingly, however, those patients with disease recurrence reported continued deterioration of HR-QOL, while those who remained disease-free experienced recovery. A larger series by Yun et al contained 809 patients and found that physical function, dyspnea, personal strength, and anxiety were independent predictors of survival following surgery for lung cancer.²⁷ Ferguson et al compared HR-QOL, mood, and clinical factors in 124 patients based on age.²⁸ While not statistically significant, they found that individuals older than 70 years reported worse physical function, fatigue, and dyspnea than younger patients. Last, Fagundes et al performed longitudinal PRO assessments on 60 patients to define symptom recovery trajectory.¹¹ They conclude that fatigue, pain, shortness of breath, disturbed sleep, and drowsiness severity peaked 3–5 days after surgery with recovery by 3 months.

Future Implications of PRO

It is readily apparent that incorporation of PRO into thoracic surgery outcomes research is necessary. The importance is not only emphasized on a national level with the creation of tools such as PROMIS and research funding through PCORI, but it is meaningful within local healthcare systems to help deliver high-quality and patient-centered healthcare. We have demonstrated that integrating PRO into institutional STS data is feasible, but the next step remains integrating such data on a national level. Consequently, the STS is planning a multi-institutional pilot study of PRO measures likely utilizing the PROMIS platform.²⁹

Widespread incorporation of the PRO into the STS-GTSD will be critical for quality assessment, performance measurement, guideline development, and research. Such data will ultimately be necessary for future comparative analyses of treatment effectiveness and can be used with any number of avenues within thoracic surgery. For example, similar analyses are needed when comparing minimally invasive techniques with open techniques, such as with esophagectomy and valve

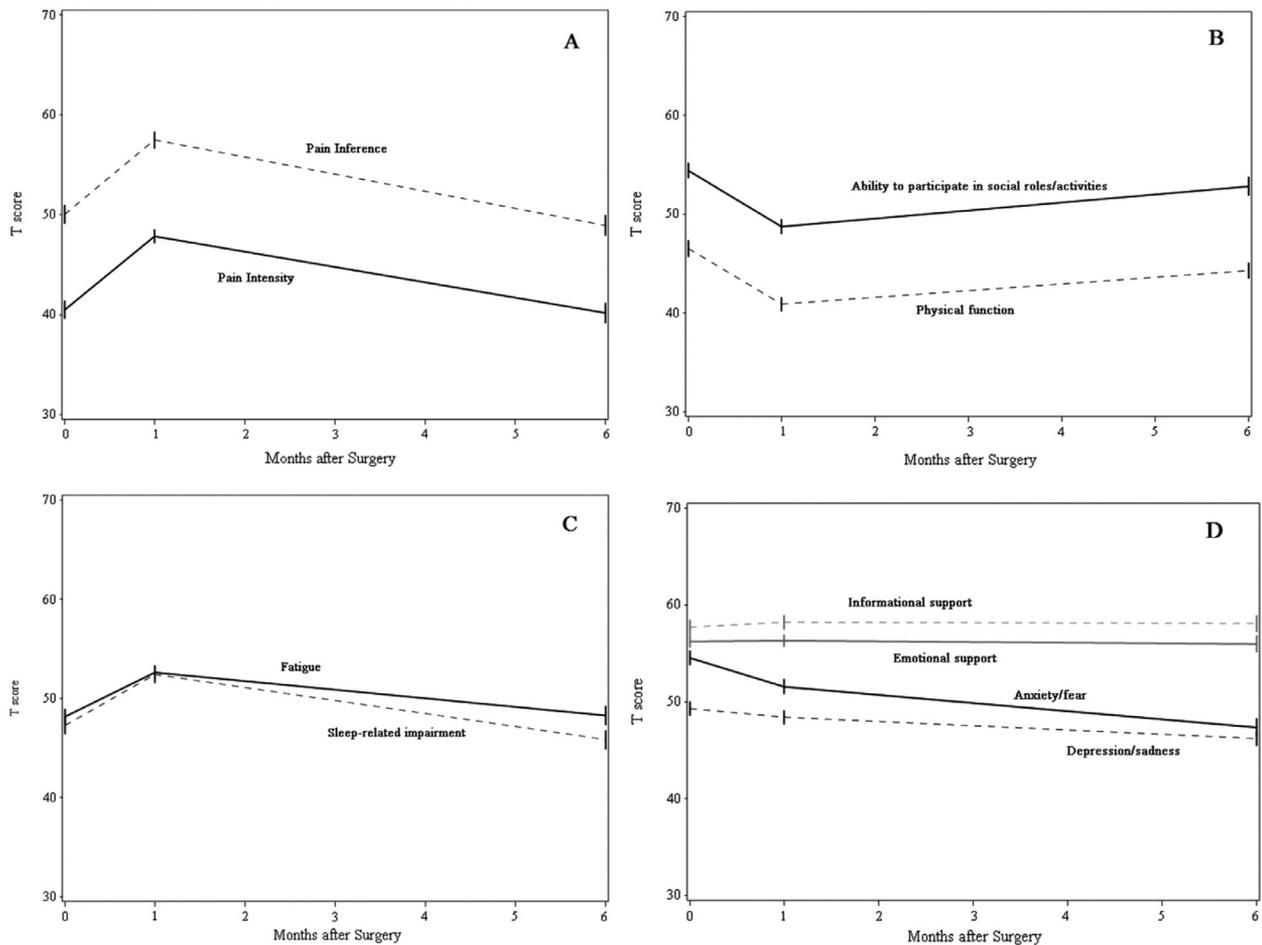


Figure 2. PRO following lung surgery. Postoperative PROMIS scores in patients who underwent lung cancer resection: (A) pain intensity and interference, (B) physical function, fatigue, and sleep-related impairment, (C) anxiety/fear and depression/sadness, and (D) ability to participate in social activities, emotional support, and informational support. Reprinted with permission from ref.²²

replacement techniques; when determining optimal treatment strategies for high-risk patients, such as sublobar resection and stereotactic body radiotherapy; and when determining treatment cost effectiveness. Most critical, though, is that such PRO data are vital in order to appropriately counsel patients regarding the postoperative outcomes most relevant to them.

CONCLUSIONS

Quality-focused, cost-effective, patient-centered care is at the forefront of current healthcare reform. The incorporation of PRO data into clinical outcomes registries is not only feasible but also necessary to ensure that the care we deliver meets the needs of patients and stakeholders alike. Future studies reporting on surgical outcomes need to report upon PROs alongside traditional morbidity and mortality data in order to ensure optimal surgical therapy that matters most to our patients.

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