Patient-Reported Outcomes in Thoracic Surgery

Onkar V. Khullar, MD, Felix G. Fernandez, MD, MSc*

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,

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Section of General Thoracic Surgery, Emory University School of Medicine, 201 Dowman Drive, Atlanta, GA 30322, USA
* Corresponding author. The Emory Clinic, 1365 Clifton Road, Northeast, Suite A2214, Atlanta, GA 30322.
E-mail address: felix.fernandez@emoryhealthcare.org

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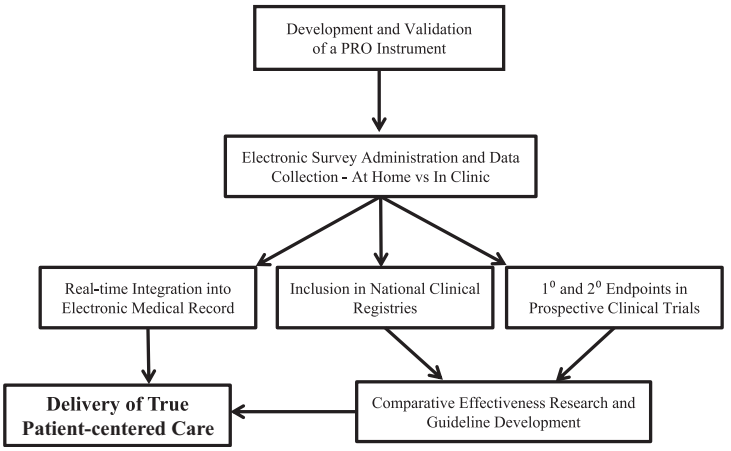

Fig. 1. Clinical integration of patient-reported outcomes research.

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.