Comparative Effectiveness Issues in Lung Cancer

Thomas K. Varghese

Abstract

Lung cancer accounts for more cancer deaths than breast, prostate, colorectal and pancreatic cancer combined. With an aging population, greater intensity of cancer care, and the need for care of the growing number of cancer survivors, comparative effectiveness research opportunities will continue to emerge for this disease. In this chapter, we focus on CER opportunities in lung cancer surgery from the vantage point of those factors directly influenced by the surgeon, patient and the healthcare system.

Keywords

Lung neoplasms · Comparative effectiveness research · Thoracic surgery

Contents

T.K. Varghese (✉)
Division of Thoracic Surgery, Department of Surgery,
Harborview Medical Center, University of Washington, Seattle, WA, USA
e-mail: tkv@uw.edu

K.Y. Bilimoria et al. (eds.), *Comparative Effectiveness in Surgical Oncology*,
Cancer Treatment and Research 164, DOI 10.1007/978-3-319-12553-4_7

1 Introduction

Comparative effectiveness research (CER) aims to generate evidence on effectiveness of strategies for diagnosis, treating or preventing disease in the “real-world” compared to the existing “standard of care” so that informed decisions can be made to improve health care [1, 2]. CER studies thus often need to account for physician (surgeon), patient and system factors that affect outcomes observed when interventions are made in the real world, away from the controlled settings of a randomized clinical trial. As CER is by definition comparative, it can address questions on both clinical utility and added clinical value compared with standard of care. With an aging population, increasing cancer incidence, greater intensity of cancer care, and the need for continuing care of the growing number of cancer survivors, there is no doubt a growing economic burden associated with cancer and cancer treatment [3]. In this chapter, we will discuss CER issues for the surgeon with respect to the most common lethal malignancy—lung cancer. There are very few randomized clinical trials with respect to surgical interventions for lung cancer. Several factors have led to this situation including difficulties with accrual (including both provider and patient bias), and expense. With increasing need to answer questions on clinical care with respect to quality, outcomes and cost-effectiveness, opportunities for CER studies will emerge for this disease now and into the future. We will address 3 types of surgeon factors, patient factors and system factors that influence outcomes and can be the genesis of CER studies in the future.

In 1953, lung cancer became the most common cause of cancer death in men, while the same occurred for women in 1985. In 2012, there were 1.8 million patients with lung cancer globally, causing an estimated 1.6 million deaths [4]. In 2014, there will be an estimated 224,000 new cases of lung cancer and 159,000 deaths [5]. Lung cancer causes more deaths than the next three most lethal common cancers combined (colon, breast and pancreatic) [6].

There are several factors that can influence whether patients receive any type of treatment for lung cancer (Fig. 1). Evidence-based treatment options for lung cancer depend on histology, stage and patient specific factors (such as age, pulmonary function and comorbidities). Approximately 95 % of all lung cancers are classified as either small cell lung cancer (SCLC) or non-small cell lung cancer (NSCLC). SCLC is distinguished from NSCLC by its rapid doubling time, and early development of widespread metastases. In light of these factors, surgical intervention is not the standard of care for SCLC. Sadly, though SCLC is initially responsive to chemotherapy and radiation therapy, it typically relapses, with subsequent resistance to treatment modalities within a few months to a year. A two-stage classification is used for SCLC derived from the Veterans’ Affairs Lung Study Group (VALG) in the late 1950s [7]:

- Limited disease (Tumor confined to ipsilateral hemithorax and regional nodes)
- Extensive disease (Tumor beyond the borders of limited disease, including malignant pleural and pericardial effusions)

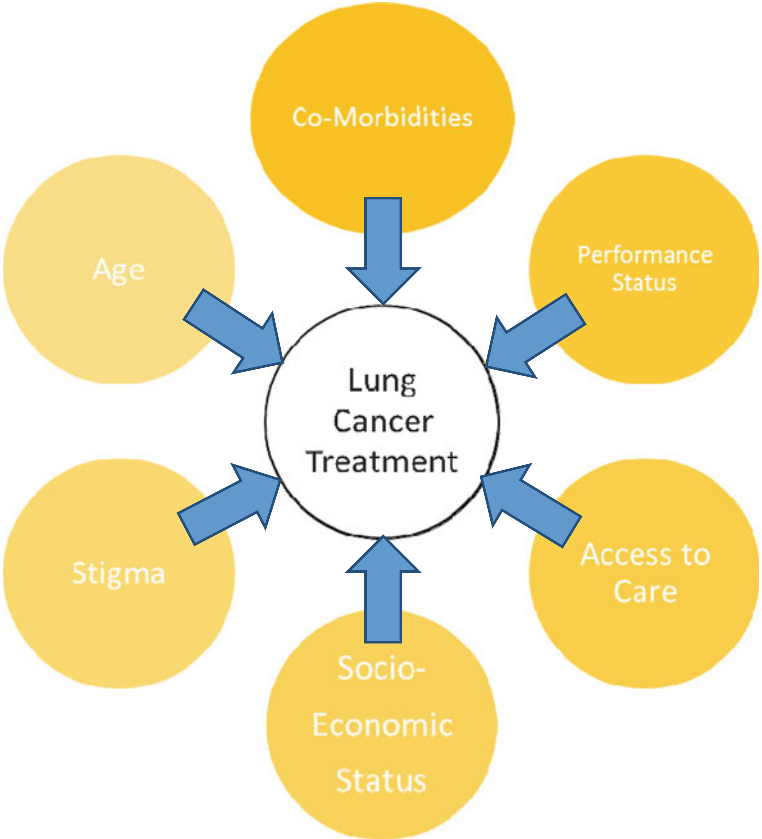

Fig. 1 Non-disease factors that influence receipt of lung cancer treatment

Limited disease is treated with chemotherapy and radiation therapy, while extensive disease is often treated with chemotherapy. Five-year survival rates for limited and extensive disease are poor (10–13 % vs. 1–2 %) with the median time of survival 15–20 months and 8–13 months respectively [8–10].

The remainder of this chapter will be focused on CER for NSCLC, where surgical intervention plays a role in early stage disease.

NSCLC accounts for the majority (approximately 85 %) of lung cancers. Localized disease is where the cancer is limited to one lobe of the lung, and does not involve the mediastinum. Stage I disease (small lesion, without involvement of any lymph nodes) and Stage II disease (larger lesion without lymph node involvement, involvement of structures that can be resected such as the chest wall or diaphragm, or involvement of hilar lymph nodes) makes up about a third of patients with NSCLC [11]. Although validation hasn't occurred with randomized clinical trials, good results and long-term survival data have established surgery as the treatment of choice for localized disease in those patients who are medically operable [12]. Surgical resection has also found a role for select patients with stage IIIA disease as well (involvement of ipsilateral mediastinal nodes).

2 Surgeon Factors

2.1 Extent of Resection

The surgical resection of a single lobe of the lung, or lobectomy, is the procedure of choice for early stage NSCLC. The lung cancer study group [13] conducted a prospective randomized clinical trial comparing limited resection (segmentectomy or wedge resection) versus lobectomy in the management of early stage (less than 3 cm, and absence of lymph node involvement) NSCLC. When the group first reported their results, of the 247 patients followed for a minimum of 4.5 years, patients undergoing limited resection had an observed 75 % increase in recurrence rates, 30 % increase in overall death rate, and an observed 50 % increase in death with cancer rate compared to patients undergoing lobectomy. Interestingly, errors in accounting for patients lost to follow-up were noted by Dr. Frank Lederle, and detailed in his letter to the journal [14]. This prompted a second review of the study that uncovered 12 additional recurrences and 3 additional deaths. Using the corrected data, there remained a survival benefit to the lobectomy group (5-year survival 73 % vs. 56 %), but a decrease in the rate of recurrence (5-year 63 % vs. 78 %). The rate of distant recurrences was the same in both groups, whereas limited resection patients experienced threefold higher rate of locoregional recurrence (5.4 % vs. 1.9 %). In the new multivariate analysis, weight loss replaced performance status as a significant predictor of overall survival. Though the numbers, graphs and multivariate findings changed slightly, the overall conclusions of the lung cancer study group study were not altered by the corrected data [15].

Lobectomy became the norm for those patients with adequate pulmonary reserve. Additional observational studies demonstrated improved survival in individuals with earlier stage disease who undergo resection (lobectomy) [16–18]. Most surgical series demonstrated five-year survival for stage I NSCLC in the range from 55 to 72 % [19, 20], with even more favorable results reported for those with small (less than 3 cm) peripheral lesions [21, 22]. In contrast, the 5-year survival of patients with Stage I lung cancer not treated surgically is reported to be from 4 to 14 % [23–25]. The role of surgery for Stage IIIA disease is limited. If previously unsuspected microscopic disease is found in the mediastinal nodes at the time of resection, then proceeding with lobectomy followed by adjuvant therapy is recommended [26]. In those patients where the mediastinal nodes are prospectively identified with sampling and imaging, then multimodality treatment is recommended, with concurrent chemotherapy and radiation therapy. Surgical resection can subsequently be an option in a subset of these patients after chemoradiation with low volume or microscopic mediastinal nodal disease involvement, where resection is technically feasible [26].

Proximal tumors with endobronchial involvement traditionally were treated with pneumonectomies. In the modern era, sleeve resection of the involved airway with lobectomy is preferred over pneumonectomy as a result of similar oncologic results, better preservation of pulmonary function, and avoidance of the complications associated with pneumonectomy [27].

There has been a renewed interest in the role of sublobar (limited) resection. Sublobar resection may be performed either as the removal of one or more anatomical segments (segmentectomy) or as a non-anatomical wedge resection. Sublobar resections can be an option for those patients with early stage disease who cannot tolerate a lobectomy due to decreased pulmonary reserve, or medical comorbidities. Several prospective studies have reported favorable outcomes in those patients undergoing segmentectomies or wedge resections for peripheral <2 cm in size, N0 lung cancers [28–30]. There are two ongoing clinical trials focusing on this issue. The Cancer and Leukemia Group B (CALGB) trial 140503 [31] has had a difficult time accruing patients since its launch in 2007, and aims to directly compare lobectomy versus limited resection among patients with peripheral tumors measuring <2 cm in size. In Japan, the nearly accrued JCOG 0802/WJOG 4607 L 1,100 trial is comparing the outcomes of peripheral invasive adenocarcinomas of less than or equal to 2 cm in size treated by lobectomy or segmentectomy. Another Japanese study (JCOG 0804/WJOG 4507L) has completed accrual evaluating the role of limited resections in the management of non-invasive adenocarcinomas. Results from these Japanese studies are awaited [32, 33]. Even after findings from these studies are released, CER opportunities will be present (Table 1).

Table 1 Surgeon factors—extent of resection

Dimension of care	Opportunities for CER study
Extent of lung resection for early stage lung cancer	• Can the findings from recent randomized clinical trials on lobectomy versus sublobar resection be replicated in real-world settings?
	• What is the cost-effectiveness of performing segmentectomies (which is not a direct focus of training in today's environment and thus require a learning curve) if indeed it is proven to be equivalent in outcomes to lobectomy?
	• What are the quality-of-life implications for patients with respect to lobectomy, segmentectomy, and wedge resections? Should quality of life be the driving factor in decisions in how much lung to resect in contrast to cancer survival times, and for which patient populations is this relevant?

2.2 Video-Assisted Thoracoscopic Surgery (VATS) Versus Open Lobectomy

VATS is a minimally invasive thoracic surgical procedure that can be utilized for the diagnosis and treatment of intra-thoracic diseases. Many procedures that historically were performed with an open thoracotomy are now performed as VATS. Absolute contraindications for VATS are the same as for a thoracotomy including the inability to perform a complete (R0) resection with suitable residual cardiopulmonary reserve, lymph node metastasis beyond regional lymph nodes, and widely metastatic disease [34, 35].

VATS procedures use ports that for the most part are <2 cm in length, except for one access or utility incision that ranges from 4 to 8 cm in length through which instruments can be inserted and allow for removal of the resected lung at the completion of the case. The important principle that is maintained during a VATS resection procedure is that a rib-spreader is not used. By avoiding muscle splitting, and rib-spreading with a retractor, VATS is believed to result in less pain, earlier ambulation, and fewer postoperative complications [36]. VATS lobectomy was first performed in 1992, and has been rapidly adopted in the surgical management of lung cancer. Several studies have shown lower rates of postoperative complications associated with VATS when compared with open lobectomy for early stage lung cancer [37–41]. Further studies have shown improved functional outcomes and equivalent oncologic efficacy as well [42–45].

Interestingly, cost effectiveness analyses have shown variable results. A study using the Surveillance, Epidemiology, and End-Results Medicare database found that VATS lobectomy was associated with a shorter length of stay (LOS) but not with differences in costs [36]. One explanation offered in the study was that payer reimbursement was linked to episodes of care rather than LOS. Other studies using the all-payer Nationwide Inpatient Sample [44, 45] described lower complication rates and LOS for VATS lobectomy, but no differences in costs. In contrast, an all-payer Premier Perspective database study [41] found that adjusted inpatients costs were $700 lower for VATS. A study from our group using the MarketScan database examined whether VATS lobectomy was associated with lower 90-day costs—thus assessing for costs and complications beyond the index hospitalization [46]. We found that the biggest driver of cost was prolonged LOS (PLOS) at the index hospitalization, VATS lobectomy was associated with lower rates of PLOS, and that the cost difference of the VATS approach extends only minimally into the period after discharge (i.e., health care use after discharge was only minimally different between the VATS and open thoracotomy groups). Outpatient use and readmissions accounted for approximately 16 % of the total 90-day costs of care after lobectomy. Emerging evidence suggests that the pressure to discharge patients earlier after lung resection may be driving readmission rates, independent of the surgical approach [47, 48].

Although use of VATS has increased over time, open thoracotomy is still the most widely used procedure for lobectomy with less than 50 % of lobectomies in the US performed using VATS [49]. Factors that have been proposed to explain this finding include insufficient training or experience, difficulty to achieve competency with minimally invasive approaches in low volume centers, and a belief that there remains an insufficient level of evidence for safety and efficacy. However, there are now two large institutional prospective cohort studies involving 1,100 and 500 patients respectively [50, 51], a randomized clinical trial [52] and two meta-analyses [53, 54] that have demonstrated safety and efficacy of the approach. The Cancer and Leukemia Group B (CALGB) 39802 trial [55] was a novel multi-institutional safety and feasibility study that not only standardized the definition of VATS lobectomy, but also standardized surgeon credentialing. The rigorous credentialing process had participating surgeons attend a course to review technique; submission of an unedited video tape, operative and pathology reports from a VATS lobectomy for central review; and participation in an animal laboratory. Surgeons were required to perform at least five VATS lobectomies before being credentialed. Eleven surgeons at six centers underwent credentialing, and the subsequent success rate, morbidity and mortality observed in the study achieved or surpassed prior levels cited in the literature. The study demonstrated a method for surgeons who had no prior experience with the technique to attain sufficient training and expertise in a supervised real-world environment.

Robotic-assisted thoracoscopic surgery (RATS) approaches for lobectomy have recently emerged as an alternative to traditional VATS. Initial results of robotic lobectomy have shown the same benefits achieved with VATS approaches as compared to open thoracotomy can be maintained [56–58]. Additionally, advocates for RATS cite benefits of improved ergonomics, three-dimensional optics, and wristed instrument motions. On the other hand, opponents of robotic surgery have cited increased costs and longer procedure times [59]. It is still to early to tell whether RATS is truly an advance in surgical technique, or as nay-sayers are fond of stating—a marketing gimmick. Cost analyses can be challenging for robotic programs as the cost of the robotic platform varies between institutions (purchase of a new robot versus incorporation of RATS into a facility with an existing platform), and that theoretic costs include the price of the robotic system divided by the total number of robotic cases (all specialties) performed. However, this shouldn't deter us from assessing the impact of RATS into practice, as similar issues are raised when assessing the introduction of any new surgical technology. Even if one is not convinced that RATS is a significant advance as compared to VATS lobectomy, there may be other reasons for surgeons to transition to robotic surgery, including the performance of other thoracic surgical procedures such as a thymectomy, robotic technology will continue to evolve, and more clearly delineated benefits of robotic surgery may become the reality in the future. What is missing till date is a standardized detailed credentialing process for RATS similar to that which was outlined in CALGB 39802. CER opportunities with respect to minimally invasive approaches are outlined in Table 2.

Table 2 Surgeon factors—type of surgical approach

Dimension of care	Opportunities for CER study
Minimally invasive lung surgery	• If PLOS at index hospitalization is the main driver of cost difference, are there evidence-based strategies to mitigate the frequency of PLOS that can be incorporated into systematic practice? Can these strategies be found from programs that incorporate VATS approaches as part of their practice?
	• VATS lobectomies are more commonly performed by high-volume surgeons working at high-volume or teaching hospitals. Are the lower 90-day costs only associated with VATS (i.e. more attributable to environment of practice) or directly attributable to VATS?
	• Can a standardized credentialing process be implemented for Robotic VATS lobectomy, accounting for feasibility, safety, efficacy and cost-effectiveness?
	• Can a prospective, pragmatic multi-institutional study be performed comparing robotic VATS, traditional VATS and open thoracotomy approaches for lobectomy for short-term outcomes, oncologic efficacy, and cost-effectiveness?

2.3 Specialty Training

The issue of who should provide care has led to considerable debate about access, and healthcare disparities. Surgeon specialty has been shown to be associated with better post-operative outcomes among high-risk operations [60–62]. In the United States, the majority of lung resections are performed by general surgeons [63]. However, there have been several studies demonstrating that board-certified thoracic surgeons have lower rates of operative mortality with lung resections compared to general surgeons [64–66]. In a study conducted by our group in the SEER-Medicare population [67], we extended the analysis to compare the results of board-certified general thoracic surgeons (GTS), board-certified cardiothoracic surgeons (CTS) (those who performed both cardiac and thoracic procedures as part of their practice), and those treated by general surgeons (GS). After adjustment for several well-known prognostic factors for survival, patients under the care of GTS had an 11 % lower risk of death compared with those treated by GS. General thoracic surgeons used preoperative and intraoperative staging procedures more often than GS or CTS, more often applied video-assisted thoracoscopic techniques, and less often performed bi-lobectomy (precision of resection).

Common themes in these studies were influence of provider volume on the overall effect, as well as more consistent process-of-care measures by specialty surgeons. As there is a trend towards increasing specialization amongst surgeons, other factors that may have influenced decision-making include training in the modern era, with inclusion of evidence-based protocols, and multi-disciplinary participation in tumor boards amongst specialists. The results however of all these studies are relevant to the overriding issue of how best to improve the quality of

Table 3 Surgeon factors—specialist care

Dimension of care	Opportunities for CER study
Surgeon specialty (general thoracic surgery [GTS] vs. cardiothoracic surgery [CTS] vs. general surgery [GS])	• What are the workforce implications if a policy was created to selectively refer patients with early-stage lung cancer to only board-certified GTS? For both GTS and CTS?
	• If the workforce implications were not practical, how can CTS or GS predominantly serving an underserved population gain additional expertise to mitigate against some of the factors leading to disparity in outcomes?
	• Should there be a central credentialing process for those surgeons who wish to perform surgical resections for lung cancer?

thoracic surgical care. One option might be to encourage referral of potentially resectable lung cancer patients to GTS. This of course would need to be accompanied by the addressing of issues such as barriers to access, especially amongst low-income patients and those that live in rural areas, as well as workforce issues. Attempting to improve outcomes by selective referral without addressing infrastructure and workforce issues could lead to vast segments of the population without access to surgical resection for an otherwise uniformly fatal disease. Opportunities for CER are detailed in Table 3.

3 Patient Factors

As overall outcomes for lung cancer treatment are poor, opportunities exist to explore the impact of treatment choices on the patient. When one traditionally thinks of patient factors, the focus has been on co-morbidities. In surgery, the decision-making process is often situational. Patient autonomy and participation can be influenced by medical condition, surgeon factors, patient educational level, and availability of evidence-based information on the particular condition. The degree of decisional authority assumed by patients can lead to three types of surgeon-patient relationships—the surgeon as agent, shared decision-making, and informed decision-making. Large-scale studies on decision-making have not been performed till date for lung cancer, but are anticipated to increase in the years ahead alongside the patient-centered movement.

The surgeon as agent occurs when the surgeon acts as an expert adviser who incorporates the values of the patient when making a treatment recommendation. In this model, the patient role is passive, as the surgeon assumes the values of the patient, and has total command over the decision-making process. Patients may be subjected to biased treatment if the surgeon only gives or delivers limited treatment options. In contrast, the informed decision-making model is one where the surgeon is recognized as the one who has technical expertise, but the patient plays an active role eliciting and understanding information about their treatment choices. The surgeon in this model doesn't volunteer their opinions, but rather presents the patient with various treatment options, allowing the patients to arrive at their own conclusions. In between these two extremes is shared decision-making. Here the surgeon and patient are equal partners, where each freely exchanges information and preferences about treatment options to arrive at a mutually acceptable decision. This works especially in those situations where there is ambiguity in treatment of choice, and helps to align the decision-making with patient's preferences and values.

Though surgeons may profess to always include patient-centered values in their discussions, there are plenty of opportunities for improvement. Some of these issues and opportunities for CER are detailed in Table 4.

4 Healthcare System Factors Related to Clinical Decision Making

4.1 Impact of Practice Environment

In principle, the Patient Protection and Affordable Care Act (ACA) signed into law in March 2010 seeks to improve health care delivery. The goal of ACA is to create a movement of payment reforms, in which private insurance companies would follow the lead of successful government payment reforms, such as bundled payments, and ultimately create system-wide changes for reimbursement [68]. Changing the reimbursement structure for providers will inevitably create new issues for surgeons who are making decisions for their patients. Payment reforms began in 2011 and 2012, and will continue through 2016. Two programs designed to restructure the way health care is delivered have been proposed under ACA, namely Patient-Centered Medical Homes (PCMHs) and Accountable Care Organizations (ACOs). These programs are designed to improve care coordination by encouraging use of electronic medical records, changing providers' financial incentives by including quality measures in reimbursement, and ultimately moving away from a fee-for-service to one where quality of care is valued [69].

The ACO movement has led to increased consolidation and integration in the medical marketplace. Hospitals are buying practices to keep their market share intact and to have access to electronic record systems and other infrastructure that are expensive to capitalize. Awareness emerges for surgeons that their medical decisions can potentially negatively influence their income. This is not necessarily unethical, as cost containment has been recognized as an important circumstance in

Table 4 Patient factors

Dimension of care	Patient perspective	Opportunities for study
Determination of patient's values, preferences and expressed needs	• Short-term and long-term goals of care	Can identification of health beliefs, practices and specific ethnic and cultural groups lead to better decision-making for the lung cancer patient population?
	• Level of involvement in decision making (surgeon as agent, shared decision-making, informed decision-making)	
	• Expectations of clinic visit and healthcare team	Can clinical interview protocols elicit patients' perceptions about their illness and their expectations of treatment?
Coordination of care and integration of services within a clinical setting	Coordination of delivery of care by a multidisciplinary team	Does the patient get consistent information from different clinicians?
		Do dedicated patient navigators have an impact on the delivery of care for lung cancer?
		How can one improve efficiencies in the diagnostic and staging work-up of a potentially resectable lung cancer patient?
		Are there evidence-based interventions that can be performed to optimize patients' health prior to elective surgical intervention?
		Can a set of processes of care be delivered as a guaranteed value bundle for each and every patient, all the time?
Communication between patient and providers	Dissemination of accurate, timely and appropriate information	Are treatment decisions aligned with patient-preferences and values at each point of contact with the health system?
	Education about the long-term implications of disease and illness	Will electronic medical records, and open access to records for patients lead to better communication for members of the healthcare team, referring providers and patients?
Cancer survivorship plans	Transition and continuity from one locus of care to another	What is the best method for delivery of a cancer survivorship plan for patients, family members and primary care providers that outline treatment summary, surveillance plans, any ongoing treatments, and health risks that are now in play as a result of past treatment?

good decision-making [70]. There will be the introduction penalties for lack of delivery of quality care, which could affect physician reimbursement. Adoption of rigid guidelines for the treatment of patients is anticipated in years to come, as well as expansion of care plans. All of these are attempts at decreasing variation in care, decreasing length of stay, and reducing use of resources.

A method of performance with a powerful impact on outcomes is participation in large national or regional databases with inclusion of all patients and frequent provider feedback with comparisons to peer norms. Surgeons in the Veterans Administration hospital system have participated for more than a decade in a systematic data-gathering and feedback system of outcomes for major surgery [71]. The National Surgical Quality Improvement Project (NSQIP) works to decrease variation in clinical outcomes by demonstrating to surgeons when their center is an "outlier" in performance. This system allows hospitals to target QI activities that may influence components of care, and subsequently decision-making. The Society of Thoracic Surgeons (STS) in 1989 created a national voluntary cardiac surgery database as a means of supporting national quality improvement efforts. In 2003, a separate database was launched by the STS encompassing procedures specific to general thoracic surgery—the General Thoracic Surgery Database (GTSD) [72]. GTSD provides participants risk-adjusted benchmarks as well as data for research that can be used to improve patient care processes and clinical outcomes. On 30 July 2008, the National Quality Forum endorsed participation in a systematic national database for general thoracic surgery [73]. Unfortunately in 2012, only 8 % of all lung cancer resection cases in the US were accounted for in GTSD, with most of the participants high-volume centers with dedicated general thoracic surgeons [74].

4.2 Impact of Political Environment

The reporting of surgeon-specific outcome data is another example of the influence of the political environment. Outcome data were rarely reported prior to the mid-1980s [75]. The first release of hospital open heart surgery risk-adjusted mortality rates in December 1990 [76] and the first formal public report in December 1992 [77], marked the start of a new era. These performance reports, or physician report cards, have increased in recent years [78], and many believe will increase in frequency and across specialties in the years to come. Advocates believe that increased transparency of information on the quality of care help consumers, employers, and health plans to improve their decision-making and to stimulate quality improvement among providers. However, physicians are concerned that risk adjustment strategies in these reports are not adequate. Without this confidence, publication of procedural mortality rates may result in physicians withholding procedures in high-risk patients. Unintended consequence of scorecards might be to adversely affect healthcare decisions for especially high-risk patients. Scorecards may also impair the development of new treatments because of the more restrictive clinical practice environment.

In light of these drawbacks, many have proposed revamping the current system to facilitate rapid and accurate access to outcome data in the local practice environment. Adoption of these efforts is often embraced as this occurs on a voluntary basis rather than in response to punitive restrictions. Examples of such grass-roots initiatives on a state level that are surgeon-led include those in the states of Michigan [79] and Washington [80, 81]. On a national level, data from the STS database has been used for public reporting, and thus have an impact on risk-stratification and outcomes in cardiothoracic surgery [82, 83].

Regional quality improvement (QI) efforts have succeeded in cardiac surgery, and a regional QI initiative in thoracic surgery has been proposed in Washington State [84]. Fifteen thoracic surgeons from five institutions examined the landscape of care in the state, as well as to discuss standards for a regional QI effort in lung cancer surgery. Consensus standards endorsed in this initiative include:

- GTSD participation across all hospitals performing lung resection in the state
- Limited enhancements to data collection efforts to address local concerns and survey ongoing interventions
- Quarterly performance reports
- Surgeon-led QI interventions for addressing performance gaps, quality improvement and value optimization
- and leveraging existing QI infrastructure and relationships within Washington state to rapidly and successfully implement a regional QI effort for lung cancer surgery.

Success of the regional QI initiative will likely lead to performance of several CER studies, and can ultimately serve as a model for other regional and national efforts.

An example of a national effort to reduce unnecessary tests across specialties is the Choosing Wisely® campaign. The Choosing Wisely® initiative helps physicians and patients have important conversations necessary to ensure that timely and optimal care is delivered. Launched by the American Board of Internal Medicine (ABIM) Foundation, Choosing Wisely® enables physicians and patients to engage in conversation about the overuse of tests and procedures, and helps patients make smart and effective care choices [85]. The original campaign has evolved into a multi-year initiative where the ABIM Foundation has reached out to specialty societies to identify a list of five tests or procedures that may be overused or misused. Criteria for developing these lists include limiting to items that fall within the specialty; supported by evidence; documented and publicly available upon request; frequently ordered/costly; easy for a lay person to understand; and measurable/accountable. The STS participated in the February 2013 phase II release (Table 5) [86]. Two of the five proposed measures are directly applicable to lung cancer surgery. These specialty generated lists help to empower physician-patient

Table 5 Society of thoracic surgeons choosing Wisely® list

1. Patients who have no cardiac history and good functional status do not require preoperative stress testing before noncardiac thoracic surgery
2. Do not initiate routing evaluation of carotid artery disease before cardiac surgery in the absence of symptoms or other high-risk criteria
3. Do not perform routine predischarge echocardiogram after cardiac valve replacement surgery
4. Patients with suspected or biopsy proven Stage I non-small cell lung cancer do not require brain imaging before definitive care in the absence of neurologic symptoms
5. Before cardiac surgery there is no need for pulmonary function testing in the absence of respiratory symptoms

conversations and to avoid unnecessary procedures that may harm patients while driving up health care costs. 63 specialty societies have joined the campaign since its inception in 2012.

4.3 Lung-Cancer Screening

An example of how politics can influence standards of care recently arose with respect to lung cancer screening. A large prospective randomized clinical trial, the National Lung Screening Trial (NLST), demonstrated the potential of low-dose computed tomography (LDCT) to detect lung cancer at earlier stages, thereby decreasing mortality [87]. NLST demonstrated that annual lung cancer screening in a high-risk patient population for three years with LDCT resulted in 20 % fewer lung cancer deaths as a result of early detection and treatment. Using the strict NLST criteria, this translates to 8.6 million people eligible for screening in the US, and 12,000 averted lung cancer deaths if all those individuals are screened [88]. In light of these studies, a number of non-profit, professional and federal organizations have recommended evidence-based annual LDCT screening for lung cancer in high-risk patients, including the National Comprehensive Cancer Network (NCCN), the US Preventive Services Task Force (USPSTF), the STS, American Society of Clinical Oncology, and the American Cancer Society [89]. The USPSTF decision in the setting of the Affordable Care act resulted in a mandate for coverage by private insurers for lung cancer screening. However, controversy has arisen as despite the evidence, Medicare till date has not endorsed coverage for lung cancer screening [90]. The implications are especially pertinent as nearly 70 % of lung cancers occur in the Medicare population. Time will tell if the evidence and advocacy of several specialty societies and patient advocates will correct this, but the politics surrounding the issue are puzzling to say the least. CER opportunities will arise in the coming years assessing screening practices, access to LDCT, and impact of early referral for surgical interventions for cancers detected by LDCT.

5 Summary

Although the ideal is to practice evidence-based medicine at all times, there are many factors that influence the care that we provide. There is growing interest in assessing and improving the value of health care delivery, defined as health benefits per dollar spent. Value can be increased by improving clinical outcomes, decreasing costs, or ideally doing both. CER for surgical interventions in lung cancer should be viewed through this lens, and opportunities for health services researchers and surgeons in practice will continue to emerge in the years ahead.

References

1. Institute of Medicine (2009) Initial national priorities for comparative effectiveness research. National Academies Press, Washington
2. Rich EC (2009) The policy debate over public investment in comparative effectiveness research. J Gen Intern Med 24(6):752–757
3. Yabroff KR, Lund J, Kepka D et al (2011) Economic burden of cancer in the United States: estimates, projections, and future research. Cancer Epidemiol Biomarkers Prev 20:2006–2014
4. Brambilla E, Travis WD (2014) Lung cancer. In: Stewart BW, Wild CP (eds) World cancer report. World Health Organization, Lyon
5. Siegel R, Ma J, Jemal A (2014) Cancer statistics 2014. Cancer J Clin 64(1):9
6. American Cancer Society. Cancer facts and figures 2014. Accessed http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2014/index
7. Murray N (1997) Treatment of small cell lung cancer: the state of the art. Lung Cancer S1: S75–S89
8. Albain KS, Crowley JJ, Livingston RB (1991) Long-term survival and toxicity in small cell lung cancer. Expanded Southwest oncology group experience. Chest 99(6):1425
9. Lassen U, Osterling K, Hansen M, Domberneowsky P, Bergman B, Hansen HH (1995) Long-term survival in small-cell lung cancer: posttreatment characteristics in patients surviving 5 to 18+ years—an analysis of 1,714 consecutive patients. J Clin Oncol 13(5):1215
10. Tai P, Tonita J, Yu E, Skarsgard D (2003) Twenty-year follow-up study of long-term survival of limited-stage small-cell lung cancer and overview of prognostic and treatment factors. Int J Radiat Oncol Biol Phys 56(3):626
11. Dettterbeck FC, Boffa DJ, Tanoue LT (2009) The new lung cancer staging system. Chest 136 (1):260–271
12. National comprehensive cancer network guidelines—non-small cell lung cancer http://www.nccn.org/professionals/physician_gls/f_guidelines.asp Accessed on 19 March 2014
13. Ginsberg RJ, Rubinstein LV (1995) Randomized trial of lobectomy versus limited resection for T1N0 non-small cell lung cancer. Lung cancer study group. Ann Thorac Surg 60(3):615
14. Lederle F (1996) Lobectomy versus limited resection in T1 N0 lung cancer. Ann Thorac Surg 62(4):1249–1250
15. Detterbeck FC (2013) Lobectomy versus limited resection in T1N0 lung Cancer. Ann Thorac Surg 96(2):742–744
16. Jones DR, Detterbeck FC (2001) Surgery for stage I non-small cell lung cancer. In: Detterbeck FC, Rivera MP, Socinski MA, Rosenman JG (eds) Diagnosis and treatment of lung cancer: an evidence based guide. WB Saunders Company, Philadelphia, pp 177–190
17. Detterbeck FC, Egan TM (2001) Surgery for stage II non-small cell lung cancer. In: Detterbeck FC, Rivera MP, Socinski MA, Rosenman JG (eds) Diagnosis and treatment of lung cancer: an evidence based guide. WB Saunders Company, Philadelphia, pp 191–197

18. Scott WJ, Howington J, Feigenberg S, Movsas B, Pisters K (2007) Treatment of non-small cell lung cancer stage I and stage II: ACCP evidence based clinical practice guidelines (2nd Edition). Chest 132:234S–242S
19. Nesbitt JC, Putman JB, Walsh GL, Roth JA, Mountain CF (1995) Survival in early stage non-small cell lung cancer. Ann Thorac Surg 60:466–472
20. Thomas P, Doddoli C, Thirion X et al (2002) Stage I non-small cell lung cancer: a pragmatic approach to prognosis after complete resection. Ann Thorac Surg 73:1065–1070
21. Reif MS, Socinski MA, Rivera MP (2000) Evidence-based medicine in the treatment of non-small cell lung cancer. Clin Chest Med 21(1):107–120
22. Ost D, Goldberg J, Ronitzky L, Rom WN (2008) Survival after surgery in stage IA and IB non-small cell lung cancer. Am J Resp Crit Care Med 177:516–523
23. Flehinger BJ, Kimmel M, Melamed MR (1992) The effect of surgical treatment on survival from early lung cancer: implications for screening. Chest 101:1013–1018
24. Sobue T, Suzuki T, Matsuda M et al (1992) Survival for clinical stage I lung cancer not surgically treated: comparison between screen-detected and symptom-detected cases. Cancer 69:685–692
25. Rowell NP, Williams C (2001) Radical radiotherapy for stage I/II non-small cell lung cancer in patients not sufficiently fit for or declining surgery (medically inoperable). Cochrane Database Syst Rev 56(1):628–638
26. Robinson LA, Ruckdeschel JC, Wanger H Jr, Stevens W (2007) Treatment of non-small cell lung cancer stage IIIA: ACCP evidence-based clinical practice guidelines (2nd edition). Chest 123(3 Suppl):243S–265S
27. Ferguson MK, Lehman AG (2003) Sleeve lobectomy or pneumonectomy: optimal strategy using decision analytic techniques. Ann Thorac Surg 76(6):1782
28. El-Sherif A, Gooding WE, Santos R et al (2006) Outcomes of sublobar resection versus lobectomy for stage I non-small cell lung cancer: a 13-year analysis. Ann Thorac Surg 82 (2):408
29. Kodama K, Doi O, Higashiyama M, Yokouchi H (1997) Intentional limited resection for selected patients with T1N0M0 non-small cell lung cancer: a single-institution study. J Thorac Cardiovasc Surg 114(3):347
30. Lee W, Daly BD, DiPetrillo TA et al (2003) Limited resection for non-small cell lung cancer: observed local control with implantation of I-125 brachytherapy seeds. Ann Thorac Surg 75 (1):237
31. CALGB NCT00499330—comparison of different types of surgery in treating patients with stage IA non-small cell lung cancer. Clinicaltrials.gov http://www.clinicaltrials.gov.offcampus.lib.washington.edu/ct2/show/NCT00499330?term=nct00499330&rank=1 Accessed 15 May 2014
32. Asamura H. Role of limited sublobar resection for early-stage lung cancer: steady progress. J Clin Oncol 2014 Jun 30 (Epub ahead of print)
33. De Ruysscher D, Nakagawa K, Asamura H (2014) Surgical and nonsurgical approaches to small-size nonsmall cell lung cancer. Eur Respir J 44(2):483–494
34. Demmy TL, James TA, Swanson SJ et al (2005) Trouble-shooting video-assisted thoracic surgery lobectomy. Ann Thorac Surg 79(5):1744–1752 discussion 1753
35. Berry MF, D'Amico TA (2007) Complications of thoracoscopic pulmonary resection. Semin Thorac Cardiovasc Surg 19(4):350–354
36. Farjah F, Wood DE, Mulligan MS et al (2009) Safety and efficacy of video-assisted versus conventional lung resection for lung cancer. J Thorac Cardiovasc Surg 137(6):1415–1421
37. Cattaneo SM, Park BJ, Wilton AS et al (2008) Use of video-assisted thoracic surgery for lobectomy in the elderly results in fewer complications. Ann Thorac Surg 85:231–236
38. Kirby TJ, Rice TW (1993) Thoracoscopic lobectomy. Ann Thorac Surg 56:784–786
39. Whitson BA, Andrade RS, Boettcher A et al (2007) Video-assisted thoracoscopic surgery is more favorable than thoracotomy that resection of clinical stage I non-small cell lung cancer. Ann Thorac Surg 83:1965–1970

40. Paul S, Altorki NK, Sheng S et al (2010) Thoracoscopic lobectomy is associated with lower morbidity than open lobectomy: a propensity-matched analysis from the STS database. J Thorac Cardiovasc Surg 139:366–378
41. Swanson SJ, Meyers BF, Gunnarsson CL et al (2012) Video-assisted thoracoscopic lobectomy is less costly and morbid than open lobectomy: a retrospective multiinstitutional database analysis. Ann Thorac Surg 93:372–379
42. Handy JR Jr, Asaph JW, Douville EC et al (2010) Does video-assisted thoracoscopic lobectomy for lung cancer provide improved functional outcomes compared with open lobectomy? Eur J Cardiothorac Surg 37:451–455
43. Scott WJ, Allen MS, Darling G et al (2010) Video-assisted thoracic surgery versus open lobectomy for lung cancer: a secondary analysis of data from the American College of Surgeons Oncology Group Z0030 randomized clinical trial. J Thorac Cardiovasc Surg 139:976–981
44. Park HS, Deterbeck FC, Boffa DJ, Kim AW (2012) Impact of hospital volume of thoracoscopic lobectomy on primary lung cancer outcomes. Ann Thorac Surg 93:372–379
45. Gopaldas RR, Bakeen FG, Dao TK et al (2010) Video-assisted thoracoscopic versus open thoracotomy lobectomy in a cohort of 13,619 patients. Ann Thorac Surg 89:1563–1570
46. Farjah F, Backhus LM, Varghese TK et al (2014) Ninety-day costs of video-assisted thoracic surgery versus open lobectomy for lung cancer. Ann Thorac Surg 98:191–196
47. Farjah F, Wood DE, Varghese TK et al (2009) Health care use among surgically treated medicare beneficiaries with lung cancer. Ann Thorac Surg 88:1749–1756
48. Freeman RK, Dilts JR, Ascioti AJ et al (2013) A comparison of length of stay, readmission rate and facility reimbursement after lobectomy of the lung. Ann Thorac Surg 96:1740–1745
49. Boffa DJ, Asslen MS, Grab JD et al (2008) Data from the society of thoracic surgeons general thoracic surgery database: the surgical management of primary lung tumors. J Thorac Cardiovasc Surg 135:247–254
50. McKenna RJ Jr, Houck W, Fuller CB (2006) Video-assisted thoracic surgery lobectomy: experience with 1,100 cases. Ann Thorac Surg 9:421–425
51. Onaitis MW, Petersen RP, Balderson SS et al (2006) Thoracoscopic lobectomy is a safe and versatile procedure: experience with 500 consecutive patients. Ann Surg 9:420–425
52. Shigemura N, Akashi A, Nakagiri T et al (2004) Complete versus assisted thoracosocpic approach: a prospective randomized trial comparing. Surg Endosc Other Intervent Tech 18:1492–1497
53. Whilston BA, Groth SS, Dival SJ et al (2008) Surgery for early-stage non-small cell lung cancer: a systematic review of the video-assisted thoracoscopic surgery versus thoracotomy approaches to lobectomy. Ann Thorac Surg 9:2008–2018
54. Yan TD, Black D, Bannon PG, McCaughan BC (2009) Systematic review and meta-analysis of randomized and nonrandomized trials on safety and efficacy of video-assisted thoracic surgery lobectomy for early-stage non-small cell lung cancer. J Clin Oncol 9:2553–2562
55. Swanson SJ, Herndon JE 2nd, D'Amico TA et al (2007) Video-assisted thoracic surgery lobectomy: report of CALGB 39802- a prospective, multi-institution feasibility study. J Clin Oncol 9:4993–4997
56. Park BJ, Melfi F, Mussi A et al (2012) Robotic lobectomy for non-small cell lung cancer (NSCLC): long-term oncologic results. J Thoracic Cardiovasc Surg 143:383–389
57. Louie BE, Farivar AS, Aye RW, Vallieres E (2012) Early experience with robotic lung resection results in similar operative outcomes and morbidity when compared with matched video-assisted thoracoscopic surgery cases. Ann Thorac Surg 93:1598–1604
58. Cerfolio RJ, Bryant AS, Skylizard L, Minnich DJ (2011) Initial consecutive experience of completely portal robotic pulmonary resection with 4 arms. J Thorac Cardiovasc Surg 142:740–746
59. Flored RM, Alam N (2008) Video-assisted thoracic surgery lobectomy (VATS), open thoracotomy, and the robot for lung cancer. Ann Thoracic Surg 85:S710–S715

60. Halm EA, Lee C, Chassin MR (2002) Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. Ann Intern Med 137:511–520
61. Dudley RA, Johansen KL, Brand R et al (2000) Selective referral to high-volume hospitals: estimating potentially avoidable deaths. JAMA 283:1159–1166
62. Birkmeyer JD, Siewers AE, Finlayson EV et al (2002) Hospital volume and surgical mortality in the United States. N Engl J Med 346:1128–1137
63. Schipper PH, Diggs BS, Ungerleifer RM, Welke KF (2009) The influence of surgeon specialty on outcomes in general thoracic surgery: a national sample 1996 to 2005. Ann Thorac Surg 88:1566–1573
64. Goodney PP, Lucas FL, Stukel TA et al (2005) Surgeon specialty and operative mortality with lung resection. Ann Surg 241:179–184
65. Luchtenborg M, Riaz SP, Coupland VH, Lim E, Jakobsen E, Kransik M, Page R, Lind MJ, Peake MD, Moller H (2013) High procedure volume is strongly associated with improved survival after lung cancer surgery. J Clin Oncol 31(25):3141–3146
66. Freeman RK, Dilts JR, Ascioti AJ et al (2013) A comparision of quality and cost indicators by surgical specialty for lobectomy of the lung. J Thorac Cardiovasc Surg 145(1):68–73 discussion 73–74
67. Farjah F, Flum DR, Varghese TK Jr et al (2009) Surgeon specialty and long-term survival after pulmonary resection for lung cancer. Ann Thorac Surg 87:995–1006
68. Lee PV, Berenson RA, Tooker J (2010) Payment reform—the need to harmonize approaches in Medicare and the private sector. N Engl J Med 362:3–5
69. Ein D, Jefferson A (2014) The patient protection and affordable care act: causes and effects. Ann Allergy Asthma Immunol 112:6–8
70. Devettere RJ (2000) Making health care decisions. In: Devettere RJ (ed) Practical decision making in health care ethics. Georgetown University Press, Washington DC, p 94
71. Itani KM (2009) Fifteen years of the national surgical quality improvement program in review. Am J Surg 198(5 Suppl):S9–S18
72. Magee MJ, Wright CD, McDonald D et al (2013) External validation of the society of thoracic surgeons general thoracic surgery database. Ann Thorac Surg 96(5):1734–1739
73. National Quality Forum endorses national consensus standards promoting accountability and public reporting—National Quality Forum Endorsed Measure #0456 http://www.qualityforum.org Accessed 15 May, 2014
74. LaPar DJ, Bhamidipati CM, Lau CL et al (2012) The society of thoracic surgeons general thoracic surgery database: establishing generalizability to national lung cancer resection outcomes. Ann Thorac Surg 94:216–221
75. Topol EJ, Califf RM (1994) Scorecard cardiovascular medicine. its impact and future directions. Ann Intern Med 120:65–70
76. Hannan EL, Kilburn H Jr, O'Donnell JF et al (1990) Adult open heart surgery in New York state. An analysis of risk factors and hospital mortality rate. JAMA 264:2768–2774
77. Epstein A (1995) Performance reports on quality—prototypes, problems and prospects. N Engl J Med 333:57–61
78. Schneider EC, Epstein AM (1998) Use of public performance reports: a survey of patients undergoing cardiac surgery. JAMA 279:1638–1642
79. Prager RL, Armenti FR, Bassett JS et al (2009) Cardiac surgeons and the quality movement: the Michigan experience. Semin Thorac Cardiovasc Surg 21:20–27
80. Flum DR, Fisher N, Thompson J et al (2005) Washington state's approach to variability in surgical processes/outcomes: surgical clinical outcomes assessment program (SCOAP). Surgery 138:821–828
81. Aldea GS, Mokadam NA, Melford R et al (2009) Changing volumes, risk profiles, and outcomes of coronary artery bypass grafting and percutaneous coronary interventions. Ann Thorac Surg 87:1828–1838
82. Clark RE, The STS (1995) Cardiac surgery national database: an update. Ann Thorac Surg 59:1376–1381

83. Wright CD, Gaissert HA, Grab JD et al (2008) Predictors of prolonged length of stay after lobectomy for lung cancer: a society of thoracic surgeons general thoracic database risk-adjustment model. Ann Thorac Surg 85:1857–1865
84. Farjah F, Varghese TK, Costas K et al (2014) Lung resection outcomes and costs in Washington state: a case for regional quality improvement. Ann Thorac Surg 98(1):175–182
85. Cassel CK, Guest JA (2012) Choosing wisely: helping physicians and patients make smart decisions about their care. JAMA 307:1801–1802
86. Wood DE, Mitchell JD, Schmitz DS et al (2013) Choosing wisely: cardiothoracic surgeons partnering with patients to make good health care decisions. Ann Thorac Surg 95(3):1130–1135
87. The national lung screening trial research team (2011) Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med 365:395–409
88. Qiu R, Eberth JM, Porter N et al (2013) Annual number of lung cancer deaths potentially avertable by screening in the United States. Cancer 119(7):1381–1385
89. Eberth JM, Qiu R, Adams SA et al. Lung cancer screening using low-dose CT: the current national landscape. Lung Cancer 2014 Jul 21 (Epub ahead of print)
90. Wood DE, Kazerooni EA Medicare's puzzling refusal to cover lung-cancer screening. Wall Street J 2014 June 17. http://online.wsj.com/articles/douglas-wood-andella-kazerooni-medicares-puzzling-refusal-to-cover-lung-cancer-screening-1403046693. Accessed 20 June 2014