The volume–outcome relationship in lung cancer surgery: The impact of the social determinants of health care delivery

Sidra N. Bonner, MD, MPH,^a and Elliot Wakeam, MD, MPH^{b,c}

Feature Editor's Introduction—Most thoracic surgeons are familiar with the minimum number of annual procedures that are expected of them to maintain high-quality in the delivery of their surgical care. Fewer are familiar with the origin of these figures and the patient advocacy and quality improvement groups that promote them. The “take the volume pledge” was initiated by leaders at Dartmouth-Hitchcock Medical Center, The Johns Hopkins Hospital and Health System, and the University of Michigan Health System with the objective of reducing complications linked to insufficient practice by setting minimum volume thresholds on surgical procedures. These limits apply to surgeons and to hospitals. The use of volume and the use of the volume pledge as a surrogate for quality are controversial in lung cancer surgery. Recently in the *Journal of Clinical Oncology*, Farjah and colleagues reported the results of statistical models that compared outcomes of lung cancer resection across hospitals and surgeons who did and who did not meet volume pledge criteria (≥ 20 patients per year for surgeons and ≥ 40 patients per year for hospitals). Among 32,183 patients, 465 surgeons, and 209 hospitals, the authors reported no relationship of volume with operative mortality, complications, major morbidity, a major morbidity-mortality composite endpoint, or failure to rescue. These data add to an evolving body of surgical literature that highlight the challenges associated with the volume–outcome relationship and in the application of a “one size fits all” standard. In this Feature Expert Opinion article by Wakeam and colleagues, the study of Farjah and colleagues is showcased as a springboard for diving into the complexities of investigating the relationship between surgical volume and surgical quality. Similar to what has been seen in other specialties, in lung cancer surgery, this relationship is highly dependent on sociodemographic, race, and geographic variables, which are often limited for these kinds of analyses in the databases from which they are investigated. Taken together, the studies from Farjah and colleagues and Wakeam and colleagues provide a concise distillation of the field and its limitations for the

CENTRAL MESSAGE

Evaluation of volume minimum standards for lung cancer surgical resection must include measures of social determinants of health to assess the utility for all patients.

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practicing thoracic surgeon who desires to understand the origins and nuances of the minimal procedural requirements of the field.

Bryan M. Burt, MD

Lung cancer is the most common cause of cancer-related death in the United States, and surgical resection continues to play an important role in the treatment of early-stage and locally advanced lung cancers.^{1,2} Currently, lung cancer surgery is performed in a range of hospital settings and by general, cardiothoracic, and dedicated general thoracic surgeons, with notable differences in outcomes.³ Nearly one-third of lung cancer operations are performed by general surgeons, with a majority done in nonacademic settings.^{3,4} This heterogeneity creates an opportunity to improve outcomes through centralization of lung cancer surgery, with volume cutoffs to ensure adequate experience.^{5,6} The data show no clear relationship between using volume minimums and improved outcomes, however.⁶⁻⁹ Additionally,

From the ^aDepartment of Surgery and ^bSection of Thoracic Surgery, Department of Surgery, University of Michigan, Ann Arbor, Mich and ^cCenter for Healthcare Outcomes and Policy, Ann Arbor, Mich.

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Address for reprints: Elliot Wakeam, MD, MPH, Section of Thoracic Surgery, Department of Surgery, University of Michigan Health System, 1500 E Medical Center Drive, Ann Arbor, MI 48109 (E-mail: ewakeam@med.umich.edu).

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it is unclear in the literature whether surgeon or hospital volume is more important when assessing the role of volume outcomes on specific outcomes.⁷⁻⁹ Nevertheless, population-level efforts to centralize surgery have focused on volume in Europe and Canada, with improved outcomes reported.¹⁰

The 2015 “volume pledge” (VP), a voluntary minimum standard originally promoted by the Leap Frog Group, a patient advocacy and quality improvement group, and by 3 major academic hospitals (Dartmouth, Johns Hopkins, and the University of Michigan) set annual volume thresholds for lung cancer resection at 15 procedures per year for individual surgeons and 40 procedures per year for hospitals to improve outcomes.^{11,12} It is estimated that nationally, the proportion of hospitals meeting either the hospital volume or surgeon volume standards is between 20% and 25%, but only roughly 8% of hospitals that perform lung cancer resections meet both surgeon and hospital volume standards for lung cancer resection.^{6,12} Assessment of the validity of the VP for lung cancer has not yet been formally demonstrated, and it is possible that other minimums could be more accurate for assessing the volume minimum–outcome association depending on patient population, surgeon specialty or hospital type.

EVALUATING THE VP AND LUNG CANCER

A recent analysis by Farjah and colleagues⁸ sought to identify the association of minimum volume standards for hospitals (40 cases) and surgeons (20 cases) with short-term outcomes using the Society of Thoracic Surgeons General Thoracic Surgery Database (STS-GTSD), a voluntary clinical registry. They performed a retrospective analysis of 32,183 patients with lung cancer who underwent any form of pulmonary resection over 3 years. Outcomes included operative mortality, complications, major morbidity, failure to rescue, and the STS major-morbidity composite endpoint.⁸ Descriptive results for the study population showed that 52% of patients received care by a hospital and surgeon that met the VP criteria. Additionally, there were significant differences in baseline characteristics between groups of patients who received care in a hospital and surgeon that met the minimum standards versus those that did not. Notably, race, extent of resection, operative approach, and American Society of Anesthesiologists score differed significantly. Associations between hospitals and surgeons meeting the VP criteria and short-term outcomes were evaluated using generalized estimating equations, a statistical technique commonly used in epidemiology and public health that allows for population-averaged interpretation and corrects for correlation between outcome measures.¹³

The authors found no significant difference in operative mortality, complications, or failure to rescue in patients treated at hospitals that met the VP cutoffs versus those

treated in hospitals that did not. They found no relationship between hospital volume and outcomes but did note a relationships between surgeon volume and short-term major morbidity, the STS composite endpoint, and length of stay. Further analysis of surgeon volume specifically demonstrated that an annual volume of >60 surgeries performed per year was associated with better outcomes.⁸

Farjah and colleagues should be commended for a well-done study of a topic of considerable policy and public health importance. The study highlights broader challenges in studying the volume–outcome relationship for lung cancer and using volume as a surrogate for quality. A great deal of attention has been paid in the literature to the methodological challenges inherent in studying the association of volume standards and outcomes for lung cancer surgery¹⁴; however, how the social determinants of lung cancer delivery create varied streams of access to and receipt of high-quality surgical care has received far less attention in the literature to date. Without the sociodemographic, racial, and geographic variables that allow us to analyze these issues, a “blind spot” may result whereby differential effects of volume standards on groups traditionally at risk for receipt of poor care are missed, as outlined in Figure 1. To contextualize the work by Farjah and associates, it is necessary to examine their findings in the context of both the population contained within the STS-GTSD and the way in which the demographic, racial, and socioeconomic variables in the STS-GTSD are used in the analysis.

INTEGRATING SOCIAL DETERMINANTS IN THE STS-GTSD AND VOLUME–OUTCOMES ANALYSIS

The STS-GTSD disproportionately selects for patients who receive their care at metropolitan academic centers, which are more likely to be higher-volume centers for lung cancer resection to begin with, and have been associated with better short- and long-term outcomes for lung cancer.⁴ For example, that national literature demonstrates that 8% of patients receive lung cancer surgical care at a facility meeting both hospital and surgeon standards, and yet 52% of the study population of Farjah and associates met these standards.^{8,12} The overrepresentation of patients from high-volume academic centers within the STS-GTSD ignores well documented income, geographic, racial/ethnic, and insurance disparities in terms of receipt of lung cancer surgery, as well as access to high-volume centers.¹⁵⁻¹⁹ For instance, the 1999 landmark study by Bach and associates¹⁷ showed a 12.7% lower rate of surgery for early-stage lung cancers in black patients compared with white patients even when adjusting for socioeconomic variables.¹⁷ In the last 20 years, similar findings of disparate receipt of surgical care have been demonstrated for Hispanic, American Indian, and Alaskan Native Americans.¹⁹ Furthermore, black, Hispanic, and Asian patients are 30% to 50% more likely to receive lung cancer resection at low-volume hospitals.¹⁶

The Social Determinants of Lung Cancer Surgical Delivery

FIGURE 1. The impact of social determinants of lung cancer surgical delivery and assessments of the volume pledge.

Additional research has found that lung cancer patients who are uninsured or have Medicaid are less likely to receive surgery compared with privately insured patients, and when they do receive surgery, the time from diagnosis to surgery is longer, the likelihood of prolonged delays to surgery is 1.5 to 1.6 times higher, and they are twice as likely to receive lung cancer resection at a low-volume hospital.^{16,20} The growing literature on surgical delivery for lung cancer patients suggests that individuals who are nonwhite, are on Medicaid, or are uninsured are concentrated in low-volume hospitals creating de facto segregation of lung cancer surgical care.¹⁶ The relegation of certain groups into low-volume hospitals has implications not only for short-term outcomes, but also for the overall quality of cancer care, with a subsequent impact on long-term survival. A seminal study evaluating short- and long-term outcomes following lung cancer resection demonstrated that the highest-volume hospitals had one-half the rate of postoperative complications and mortality at 30 days but also an 11% higher 5-year survival.²¹ If we conceptualize our health care system as segregated into high- and low-quality strata, it would be possible to find that those within the higher strata do not benefit from further regionalization, as the current study by Farjah and colleagues concludes. However, investigations that do not specifically address this reality of US health care cannot rule out the possibility that disadvantaged populations might in fact benefit from regionalization if barriers to access to high-volume centers were eliminated.^{22,23}

Beyond the impact on receipt of care, increasing evidence has demonstrated that nonclinical factors, including race, insurance, education, neighborhood characteristics, and income, are associated with perioperative complications and short-term mortality following lung cancer resection, even

when controlling for disease stage or comorbidities.^{8,16-21}

Large scale studies of disparities in postoperative complications following lung resection have demonstrated that patients without private insurance are 30% to 50% more likely to have a complication, and that individuals from low-income neighborhoods have a 12% higher incidence of complications.²⁴ Investigations of the role of race and ethnicity in postsurgical complications following lung cancer resection have yielded mixed findings on racial disparities when other nonclinical variables, such as insurance, income, and neighborhood characteristics, are controlled for in the analyses.²⁴⁻²⁷ These results suggest that any racial differences in postoperative complications on the population level are likely secondary to the conditions created by structural racism, that is, disproportionately higher rates of uninsured or public insurance status, neighborhood segregation and deprivation, and economic instability. In terms of postoperative mortality, a recent analysis found that whereas overall 30-day mortality declined for both white and black lung cancer patients over a decade, the disparity gap, higher postoperative mortality in black patients, has not narrowed.²⁷ Additionally, it has been found that individuals from neighborhoods with low median incomes and educational attainment are significantly more likely to die within 30 days of resection.²⁴ Whereas the STS-GTSD collects basic demographic information, such as self-reported race, ZIP code, and insurance payer information, additional data points such as income, education, or more granular geographic information, such as census tract or county, are not included. Nonetheless, the nonclinical factors of race, insurance status, and ZIP code included in the STS-GTSD were not included as covariates in the analysis by Farjah and colleagues in the assessment of VP and short-term outcomes. Without controlling for these socioeconomic variables, it is

impossible to know whether a so-called “blind spot” is introduced in the data as it relates to the outcomes studied.

Ultimately, by studying the minimum standards of the VP for lung cancer in patient populations that are already more likely to receive superior care, it is possible to underestimate the effect that minimum volume standards could have on populations known to receive poor quality surgical care. Additionally, the incomplete capture of socioeconomic variables included in the GTSD and absence of their inclusion in the analysis by Farjah and colleagues obscures the true value of the VP is for all lung cancer patients and whether select populations may benefit from hospitals and surgeons who meet VP standards.

RECONSIDERING OUTCOMES MEASURES

The choice of outcome measure can also alter our perceptions of the value of volume cutoffs. Most studies of volume and outcome, including those of the VP, focus on short-term outcomes that are easily definable, such as mortality.³⁻⁸ Farjah and associates analyze 30-day mortality, complications, and failure to rescue (FTR). These outcomes are clearly important and have face validity in evaluating quality, but a total focus on these more easily measureable outcomes might not give a full picture of the value of a policy such as the VP.⁸ For example, the way the FTR metric is defined, as death among all patients experiencing a complication, might not reflect the complex clinical activity of patient rescue. Complications are known to “cascade” and can increase the risk for other subsequent events, and high-performing hospitals may be able to effectively arrest complication cascades to prevent other events, and yet this would not be reflected in the FTR rate in how it is defined by Farjah and colleagues.²⁸ Therefore, the clinical epidemiology of specific complications (eg, deep vein thrombosis) could offer a more granular assessment of short-term quality rather than solely using measures dependent on mortality rates. Furthermore, patient-centered outcomes, such as discharge location, also would not be reflected in performance measurement that focuses solely on complications or mortality. Finally, the quality of a cancer care is measured not only in short-term outcomes, but also in receipt of adjuvant therapy after resection, receipt of appropriate surveillance, and long-term survival, which are critical measures not addressed in the present study and are also mediated by social determinants.

FUTURE CONSIDERATIONS FOR CENTRALIZATION OF LUNG CANCER SURGERY

Attempts at large-scale regionalization have been limited overall in the United States, but the centralization of lung resection within Kaiser Permanente Northern California (KPNC) in 2014 demonstrated the feasibility of restructuring and was associated with significant reductions in morbidity, intensive care use, and complications.²⁹

Additional pressures toward centralization may occur with increased stereotactic ablative therapy (SABR) for stage IA and IB lung cancers. Predictive modeling suggests that increased uptake of SABR will decrease operative case-load for surgeons, necessitate changes to the cardiothoracic workforce, and require centralization of remaining high-risk surgeries for lung cancer to keep the profession viable and to meet minimum volume standards for competency.³⁰ Given the increased attention to the utility of centralizing lung cancer surgeries by health care system and insurance payers, assessments of the VP will serve as a key reference in decision making that will have large-scale implications for all patients and practitioners.

The inclusion of increased socioeconomic patient data within future analyses of minimum standards and outcomes is of utmost importance, so that decisions made by key stakeholders regarding centralization and use of the VP does not lead to unintended consequences. For instance, the absence of sociodemographic information in studies may lead policy makers to conclude that there is no value to centralization, even if there are subpopulations that may benefit. Alternatively, efforts to centralize care without an understanding of the socioeconomic demographics of patient populations may inadvertently increase barriers to care, ranging from transportation challenges to receive an operation to absent social support during hospitalization. Although centralization can be a tool for providing equitable care because it standardizes care delivery across populations, it assumes that all individuals will also have equal access to this care. Thus, any promotion of centralization of lung cancer must concurrently address long-standing disparities in access in the United States. The landmark study by Cykert and colleagues³¹ demonstrated that a systems-based intervention including integrating warnings in the electronic health record, feedback mechanisms to clinical teams about race-specific data, and a nurse navigator improved care for all patients and reduced racial disparities in the receipt of curative treatment for early-stage lung cancer.³¹ In Canada, where thoracic surgery is centralized, Ministry of Health travel grant programs fund travel and housing accommodations for patients who must travel more than 120 miles for specialty care.³² Thus, disparities-focused interventions aimed at improving the access and delivery of care for vulnerable populations must be a part of any comprehensive centralization plan implemented by payers or health care systems to ensure equitable access to lung cancer surgery composing “ethical centralization.”²²

Additionally, beyond traditional models of centralization, other models that use knowledge and resource sharing can be implemented. For instance, telemedicine could be leveraged such that a thoracic surgeon at a high-volume tertiary center can provide consulting services to a health system that does not have an in-network high-volume surgeon.³³

The use of volume, and in particular the “volume pledge” as a surrogate for quality, remains controversial for lung cancer surgery. Farjah and colleagues present a well conducted analysis of the STS-GTSD to evaluate whether the volume pledge is correlated with improved short-term outcomes, with implications for adoption nationwide. However, the STS-GTSD has certain sociodemographic “blind spots” that may skew the interpretation of the value of such regionalization efforts. Future studies must include study populations and hospitals that are truly representative of the broader population of lung cancer patients and should include granular data on socioeconomic, race, ethnicity, insurance, and geographic factors. This is essential to avoid the potential unintended consequence of finding no benefit of regionalization, when in fact groups traditionally at risk for receiving poor lung cancer care may benefit. Without an analysis of the social determinants of care delivery, it is difficult to judge the value of regionalization policy.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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