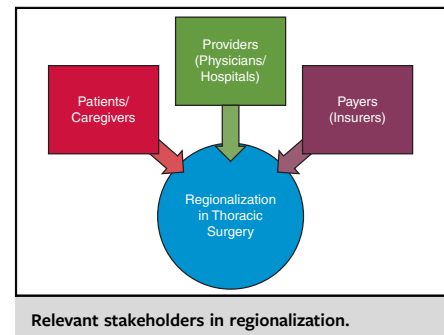


Regionalization for thoracic surgery: Economic implications of regionalization in the United States



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Feature Editor's Introduction—Regionalization of health care remains controversial and has been proposed as a way to improve outcomes in patients undergoing complex thoracic surgical procedures based on studies correlating hospital and surgeon volume to outcomes. In this month's Journal, we have an Invited Expert Opinion article written by a leading thoracic surgery health services research group led by Dr Varun Puri on the "Economic Implications of Regionalization in the United States." The authors provide an excellent overview of the potential benefits and consequences of volume-based regionalization of thoracic surgery care. They also describe a decision analytic model their group has developed that could be used to evaluate the cost-effectiveness of regionalization in the United States. Regionalization of care remains a complex and controversial topic of interest to thoracic surgeons, and the benefits must be carefully considered with the consequences and economic implications for key stakeholders before deciding whether regionalization can be applied more broadly in the United States.



CENTRAL MESSAGE

Volume-based referral strategies have been heavily discussed as a possible regionalization strategy for thoracic surgical procedures. However, consideration of the consequences to stakeholders and the cost-effectiveness of such policies must first take place.

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See Commentaries on pages 1710 and 1711.

Jules Lin, MD

Regionalization of care has long been discussed as a possible policy solution that can improve surgical outcomes for patients undergoing complex surgical procedures. The concept of centralizing complex surgical procedures was originally discussed by Luft and colleagues in their landmark study,¹ which documented the inverse relationship between hospital volume and surgical mortality rates. The debate was reinvigorated by publications by Birkmeyer and colleagues,^{2,3} who suggested that higher hospital and surgeon volume were associated with improved in-hospital mortality for high-risk surgical procedures. More recently, the Leapfrog Group has advocated for the use of minimum hospital and surgeon volume standards for select surgical procedures.⁴ In 2015, three high-profile hospital systems announced the "Take the Volume Pledge" initiative to regionalize the care of complex surgical procedures to higher-volume hospitals and surgeons within their

established healthcare network.⁵ These proposals represent the modern wave of volume-based regionalization efforts intended to improve quality of surgical care.

Although policies to regionalize thoracic surgical procedures have been implemented in other countries, there is no US federal mandate to encourage regionalization.^{6,7} The evidence in support of regionalization within thoracic surgery is heterogeneous, with the majority of studies focusing on implementation of volume-based thresholds. Existing studies comparing high-versus low-volume facilities focused on outcomes including in-hospital mortality, complications, and length of stay. Yet, relatively little attention has been given to the potential economic implications of regionalization policies for patients and their family, providers, payers, and the entire society/nation. Understanding the implications for these stakeholders and

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cost-effectiveness of regionalization policies is necessary to inform a thorough discussion of the merits and feasibility of regionalization of care.

REGIONALIZATION AND THE VOLUME-OUTCOME RELATIONSHIP

The majority of highly publicized regionalization policies for complex procedures are reliant on volume-based referral strategies. The volume-outcome relationship is largely predicated on 2 assumptions.¹ First, the “practice makes perfect” concept suggests surgeons in higher-volume facilities accumulate more experience, leading to improved patient outcomes. Second, this prevailing notion suggests that over time, referral patterns are influenced by surgeon and hospital reputation, leading to facilities with good surgical outcomes generating and maintaining high surgical volumes.

The volume-outcome relationship has been used as a cornerstone of policies developed by the Leapfrog Group and the Take the Volume pledge, and has been the focus of many studies investigating the potential effectiveness of regionalization in lung cancer resection, esophagectomy, and organ transplantation. However, the use of volume as a predictor of surgical quality has been criticized on multiple fronts. The volume-outcome relationship is nonlinear, yet several previous studies have failed to recognize this relationship when planning their methodology.^{8,9} Other strategies have attempted to use dichotomous cut points or quantiles to characterize volume. However, these strategies can be flawed, because they may not always represent the true inflection point(s) where a statistically significant change occurs.⁹ Some investigators have criticized the use of volume for regionalization policies citing inappropriate statistical methodology and inadequate risk adjustment in the volume-outcome evidence.¹⁰

Regardless, volume-based thresholds have been the most extensively studied when it comes to regionalization of complex surgeries. Multiple studies have used large administrative and clinical databases to evaluate the association between hospital or surgeon volume and lung resection outcomes. Wakeam and colleagues¹¹ used the National Inpatient Sample (NIS, 2007-2011) to assess the relationship between hospital volume and in-hospital mortality, complications, and hospitalization cost for patients receiving elective segmentectomy, lobectomy, and pneumonectomy.¹¹ They defined hospital volume by use of quartiles and ultimately divided patients into very low-volume (<21 cases/year), low-volume (21-40 cases/year), high-volume (40-78 cases/year), and very high-volume (>78 cases/year) groups. The authors observed a statistically significant (but clinically small) decrease in in-hospital mortality across quartiles: 1.9% in low-volume hospitals versus 1.1% in very high-volume hospitals. In stratified analysis by preoperative pulmonary risk (defined as history of

chronic obstructive pulmonary disease) and age, they demonstrated a widening volume-mortality effect, ultimately suggesting that older patients with greater preoperative pulmonary risk would more likely benefit from referral to higher-volume centers. Clark and colleagues¹² came to similar conclusions in patients with lung cancer who underwent an elective lobectomy or pneumonectomy, further stratified into “younger-healthier” (age 18-60 years, Elixhauser Comorbidity Index <1) and “older-sicker” cohorts (age >77 years, Elixhauser Comorbidity Index >3). They used the Healthcare Cost and Utilization Project Florida and New York State Inpatient Databases (2007-2013) to compare outcomes based on Leapfrog Group minimum hospital (>40 annual lung resections) and surgeon (>15 annual lung resections) volume criteria. The authors found that higher hospital and surgeon volume were overall associated with decreased in-hospital mortality and complications. When examining their subgroups specifically, the authors noted 2 interesting findings. First, patients treated by both low-volume surgeons and low-volume hospitals had higher risk of mortality, except for patients in the “younger-healthier” group. Additionally, “older-sicker” patients treated by high-volume surgeons had the highest mortality (12%). However, being treated at a high-volume hospital was protective. The authors ultimately concluded that policy should be directed by using hospital volume standards, and patients who are at advanced age or have higher preoperative risk would benefit the most from hospital minimum volume standards.

The volume-outcome relationship has been well demonstrated in esophageal cancer resection.^{7,13} Birkmeyer and colleagues² produced some of the earliest studies using Medicare data to suggest that there was a volume-outcome relationship. Analyzing volume by quintiles, they demonstrated an approximately 12% reduction in adjusted mortality rates between highest volume (>19 cases/year) and lowest volume hospitals (<2 cases/year). More recent analyses have echoed these findings. Using the NIS (2004-2013), Fuchs and colleagues¹⁴ found that adjusted odds of postoperative mortality were reduced by 46% when receiving an operation at high-volume (≥ 20 cases/year) compared with low-volume (<6 cases/year) and intermediate-volume (6-19 cases/year) centers.

The mortality and morbidity benefit associated with higher-volume hospitals is perhaps best demonstrated in lung transplantation. Mooney and colleagues¹⁵ linked Medicare administrative claims data to the Scientific Registry of Transplant Recipients to compare in-hospital mortality, hospital/intensive care unit length of stay, complications, 30-day readmission, and index hospitalization cost in 3128 lung transplant recipients who underwent transplantation at low-volume (<20 annual transplants), mid-volume (20-34 annual transplants), and high-volume (>34 annual transplants) centers.¹⁵ Notably, after adjusting

for recipient characteristics, patients who received transplantation at low-volume centers had a 41% increased risk of in-hospital mortality compared with high-volume centers. Additionally, these patients were observed to have longer intensive care unit admissions, longer hospital length of stays, and increased rates of postoperative respiratory and renal failure.

IS THE VOLUME-OUTCOMES RELATIONSHIP CAUSAL?

There has been controversy surrounding the use of volume-based referral strategies. Beyond criticisms of the statistical limitations on the estimated volume-outcome relationship, some have advocated that the use of volume is overly simplistic.¹⁶ More specific alternatives to volume have been proposed for thoracic cancer operations, including proportion of cases performed by a thoracic specialty-trained surgeon, presence of a dedicated cardiothoracic surgical intensive care unit, and proportion of cases performed using a minimally invasive approach.^{16,17}

Others have suggested that overall improvements in the perioperative care of thoracic surgical patients play a more influential role in determining surgical outcomes than volume. Sheetz and colleagues¹⁸ performed a longitudinal cohort study (2005-2016) using Medicare claims data. They observed significant decreases in mortality for patients who underwent esophagectomy and lung resection over the study time period. However, these findings were independent of hospital volume, and only 31% and 23% of hospitals met minimum Leapfrog esophagectomy and lung resection volume criteria by the end of the study period.

Other studies attempted to show that volume standards were not correlated to improved surgical outcomes. Harrison and colleagues¹⁹ used the Healthcare Cost and Utilization Project State Inpatient Database (California, Florida, and New York) to compare in-hospital mortality, major complication rates, and length of stay for patients whose hospitals did and did not meet Leapfrog volume criteria for lung (>40 resections/year) and esophageal (>20 esophagectomies/year) surgery. They performed a propensity-matched analysis of patients undergoing lobectomy/pneumonectomy and esophagectomy. Although limited by the lack of granularity associated with administrative data, the study ultimately found that there were no differences in in-hospital mortality or complications. Interestingly, they found that 62% of patients who underwent lung resection and 82% of patients who underwent esophagectomy received care at hospitals that were “low-volume.” They concluded that the use of highly publicized volume standards was an unsophisticated and crude way to capture surgical quality, and implementation of these volume standards could potentially have widespread negative effects on a significant portion of surgical patients.

THE VOLUME-OUTCOME RELATIONSHIP AND COST

An important consideration to the discussion of regionalization is cost. Unfortunately, the volume-outcome and cost relationship has not been extensively studied. It is possible that regionalization of care to high-volume centers can benefit from economies of scale. Higher-volume facilities may have more robust and efficient processes of care (ie, experienced perioperative care teams and postoperative enhanced recovery care pathways) that can drive down unit costs (costs per patient).²⁰ However, this has not been well demonstrated in the literature.

Few studies have attempted to examine hospitalization cost by surgical volume. Wakeam and colleagues¹¹ used the NIS to compare elective lung resection by volume quartile. On adjusted analysis, they observed similar hospitalization costs across all 4 volume strata (median cost \$24,836 in very low-volume hospitals vs median cost \$26,728 in very high-volume hospitals).¹¹ Kennedy and colleagues²¹ evaluated hospitalization costs by volume for patients undergoing esophagectomy. They used the NIS (2004-2013) to categorize patients by volume quartile (<7, 7-22, 23-87, and >87 cases/year). They observed significant mortality reductions by increasing hospital volume (lowest quartile 8.9% vs highest quartile 3.6%). They performed stratified analysis of costs by age and preoperative risk. Patients with higher preoperative risk accrued considerably higher costs compared with all other patients (\$92,017 vs \$54,874). However, very high-volume hospitals had similar costs compared with low-volume facilities (\$62,758 vs \$67,173). The authors used this similarity to suggest that higher-volume facilities could effectively manage high-risk patients, and that hospital networks would not be at risk of increasing costs by selectively referring high-risk patients to higher-volume centers within their network.

Meanwhile, a substantial cost savings has been reported with high-volume lung transplant centers. Mooney and colleagues¹⁵ used Medicare claims data to compare cost of lung transplantation admission among low-volume (<20 cases/year), intermediate-volume (20-34 cases/year), and high-volume (≥ 35 cases/year) centers. On adjusted analysis, they found that factors associated with increased cost included recipient pulmonary hypertension, preoperative use of extracorporeal membrane oxygenation, higher lung allocation score, and hospital volume. In fact, low-volume transplant centers were associated with an 11.7% increased hospitalization cost compared with high-volume centers. Accompanied by findings of decreased in-hospital mortality, reduced complication rates, and reduced hospitalization and intensive care unit length of stay, the authors concluded that higher-volume transplant centers offered high-quality and high-value care.

UNDERSTANDING THE STAKEHOLDER POSITION IN REGIONALIZATION

Going forward, evaluations of cost-effectiveness will be crucial to understand the potential feasibility of implementing a regionalization policy. Central to understanding cost-effectiveness is acknowledging that there are multiple stakeholders who stand to benefit or lose from volume-based referral strategies. Broadly speaking, these include payers, providers, and patients.

Payers

Payers, including public and private insurance agencies, have a vested interest in paying for facilities that can deliver high-value care. Payers (like the Leapfrog Group) have taken the lead in advocating for volume thresholds.⁴ Central to their argument is the belief that improved care processes and increased expertise will lead to delivery of quality care without excess healthcare use that can result from postoperative complications, prolonged length of stay, and readmissions.²²

Providers

For high-volume hospitals (and surgeons), volume-based referral strategies would lead to higher operative revenue. To be able to provide care for an additional influx in surgical referrals, high-volume hospitals may have to make an upfront additional investment in additional infrastructure (ie, operating rooms, surgical beds), which could result in increased costs in the short term.²³ In the long term, however, high-volume hospitals stand to benefit financially from volume-based referral strategies and economies of scale. This impact may be somewhat blunted if the lower-volume facilities refer only the highest risk patients (those expected to have higher use due to operative morbidity) to larger-volume centers.

Overall, however, lower-volume hospitals (and surgeons) may have more at stake. As previously described, a significant portion of thoracic surgical procedures take place in facilities that do not meet recommended volume criteria.¹⁸ The potential effect that regionalization based on volume-referral strategies could have on low-volume hospitals could be profound. It is well recognized that most hospitals derive a substantial proportion of their revenue from operations and procedures. The financial strain of losing case volumes may lead to the closure of lower-volume facilities resulting in severely reduced access to care. These effects may be profound for socioeconomically disadvantaged populations.

Patients and Their Caregivers

Although patients who live close to a high-volume facility may not experience many changes from a volume-based regionalization policy, those who live far away may suffer

many negative consequences. First, patients and their caregivers would require long-distance travel to receive care at a high-volume referral center. This could result in significant out-of-pocket costs for loss of productivity, travel, and lodging. This may not just be for the index hospitalization, but could affect postoperative and cancer surveillance visits. There are specific concerns that regionalization policies could result in barriers to care, especially for minority patients and those of lower socioeconomic status. Liu and colleagues²⁴ studied socioeconomic and racial disparities in patients receiving care at higher- and lower-volume hospitals. They performed a retrospective study of patients undergoing complex surgery (including lung resection) using California discharge data. They identified some alarming trends. Compared with white patients, minority patients (including Black, Asian, and Hispanic individuals) were 34% to 52% more likely to receive a lung resection at lower-volume hospitals. Additionally, compared with patients insured by Medicare, those who were insured by Medicaid or uninsured were 30% to 50% less likely to receive lung resection at a higher-volume hospital.

Resio and colleagues²⁵ performed a survey to identify motivators and barriers to receiving care at safer but more distant hospitals for complex cancer surgery. The authors presented survey respondents with a hypothetical option to travel more than 1 hour to a hospital specialized in complex cancer surgery. The authors identified that respondents with lower income and non-White race exhibited greater resistance to travel, with the most commonly cited barrier being financial (costs/insurance). For possible lung transplantation recipients, the additional impact on travel burden could be substantial. Depending on region, travel distances for lung transplant patients have been shown to range from 143 ± 189 miles (California/Southwest region) to 325 ± 420 miles (Pacific Northwest region).²⁶ Further regionalization of care could make patient travel distances and expenditures much greater.

Additionally, some studies have suggested that patients themselves may not inherently prioritize receiving care at higher-volume hospitals. Schwartz and colleagues²⁷ conducted a telephone survey of 510 patients insured by Medicare who underwent complex surgery (including 128 patients who underwent lung resection). They attempted to identify leading factors that weighed into their selection of a surgeon or hospital. Interestingly, hospital and surgeon reputations (determined mainly by the referring physician) were the most commonly cited factor in patient decision-making. Less than half (48%) of surveyed patients identified hospital volume as a key factor in the selection process.

THE NEED FOR COST-EFFECTIVENESS EVALUATIONS

Cost-effectiveness evaluations will be a crucial part of the discussion on regionalization because they can help

physicians, payers, patients, and policy-makers understand the potential consequences of implementation in terms of patient outcomes and resource use. In cost-effectiveness evaluations, the denominator becomes important. Whether it is assessing mortality risk, overall survival, or quality-adjusted life years, cost-effectiveness can allow investigators to select the outcome that is most meaningful and study the outcome relative to costs. Additionally, investigators can hypothetically vary model inputs representing a potential policy change and evaluate the impact of this change on cost, outcome, and cost relative to outcome.

The debate surrounding regionalization of care for thoracic surgical procedures is complex. Although volume-based referral strategies have been proposed, they have not received widespread national adoption. A more complete discussion that includes a consideration of the cost-effectiveness of volume thresholds in addition to surgeon outcomes and hospital-based quality metrics and their effects on relevant stakeholders will be necessary to assess the feasibility and appropriateness of regionalization in thoracic surgery.

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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