

Defining the Volume–Quality Debate: Is It the Surgeon, the Center, or the Training?

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ABSTRACT

The quality movement in health care is ubiquitous in our society. The volume–quality debate is a central component of this that affects surgeons. In colorectal surgery and other fields, studies have demonstrated improved outcomes for patients having care provided at higher volume centers. What is unclear about this relationship however, is whether this improvement is related to the center, the surgeon, or the surgeon’s training and experience. Some studies have tried to better examine this relationship and have suggested that limitations in administrative data may exaggerate the impact of a high-volume center. The use of crude mortality as the primary outcome instead of more specific outcomes such as cancer recurrence, inadequate risk data, and the failure to account for clustering of cases are other important limitations.

Although higher volume likely equates to higher quality in some form, this may be more related to surgeon-specific factors rather than high-volume centers alone. The role of subspecialization, especially colorectal-trained surgeons with a high individual case volume may be the most important predictor of higher quality in colorectal surgery. This relationship may be especially important for the treatment of rectal cancer. The relationship of volume to outcomes is difficult to understand, and to appropriately answer these questions will require the collection and analysis of comprehensive, risk-adjusted data after adequate outcome measures are defined. This will only occur with significant institutional support, and a commitment to follow outcomes longitudinally and implement necessary changes to improve outcomes.

KEYWORDS: Colorectal surgery, volume-outcomes, surgical outcomes, subspecialization

Objectives: Upon completion of this article, the reader should be able to: (1) summarize the relevant data relating to the volume–outcomes quality debate in colorectal surgery; (2) discuss the limitations of these data as it relates to study design, patient selection, and interpretation of the data; and (3) understand how the practice of colorectal surgery may be affected by the volume–outcome debate.

THE "QUALITY" MOVEMENT

The quality movement in health care is ubiquitous in our society and it is quickly becoming one of the most important drivers of surgical care. These initiatives, reports, and standards arrive at our office doors from

payers, institutions, government, and even consumers. It is also becoming more pervasive because of the availability of “quality” related information on the Internet. Since the initial triad (structure, process, and outcome) was proposed,¹ new quality standards—some real, some

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imagined—that are held up for surgeons to meet and be judged by, are becoming more onerous everyday. No surgeon would argue that improving quality is not of paramount significance, and everyone agrees that attention to quality measures is important for our patients; however, defining the true measures of quality, and how they impact patient care and outcomes is much less clear, and often the subject of intense debate.²

For surgeons, central to this movement is the volume–quality debate. Large centers and higher volume surgeons champion the available data on this topic as evidence of the importance of superior performance at their institutions. There is an assumption that care for patients with certain diagnoses is “better” or outcomes are improved if certain procedures are performed at high-volume centers. This may seem intuitive; nevertheless, it is not necessarily true. Correctly understanding and interpreting the many studies that attempt to define the relationship of surgical volume and outcomes is difficult.

These studies have tremendous heterogeneity of patient populations, and include patients treated by a diverse array of surgeons with different training, expertise, and experience. Uniform and comprehensive risk-adjusted data collection is lacking, and frequently there is no standardized definition of what constitutes an appropriate “volume” to be considered a low or high center. Statistical methods are also often vague or inadequate to provide an appropriate analysis.

There is no paucity of studies examining the volume–outcome advantage in colorectal surgery as well as a variety of other disciplines. This review examines the relationship of volume outcomes in colorectal cancer operations, with particular emphasis on the challenges and discrepancies that these studies present.

To better understand the impact of volume and outcomes on colorectal surgery, it is helpful to briefly digress and review the history and impact that quality monitoring and outcomes analysis has had on coronary artery bypass graft surgery (CABG). Arguably, CABG surgery is the most thoroughly studied and best analyzed operation in the country. Much of this data comes from very large, regional databases that collect standardized comorbidity and outcomes data on thousands of CABG operations every year. Although not perfectly homogeneous, CABG operations are essentially uniform procedures, performed by similarly trained specialty surgeons, on a patient profile with similar comorbidities. Data from these centralized collection centers are analyzed by statisticians committed to only analyzing these data, and the process is transparent.

The best example of this system is the New York State Cardiac Reporting System. Once this system was implemented, outcomes for CABG surgery 4 years later demonstrated a marked improvement in overall mortality.^{3,4} Undeniably, the improvements seen in CABG outcomes in New York State are the direct result of the

reporting system. Although some of the improvements are related to quality monitoring of high-volume centers and surgeons, the public reporting of the data resulted in the closing of poorly performing centers and driving away surgeons with lower volumes and who were performing poorly. Two other important affects demonstrated were that outcomes could also be improved at high-volume centers, and that there is likely a volume threshold that smaller volume centers need to reach to achieve equal quality as a higher volume center. Surgeons practicing at a lower volume center with an appropriate case volume and the necessary infrastructure could meet a high standard of care.

LOW-VOLUME VERSUS HIGH-VOLUME INSTITUTIONS

Quality of Care

In colorectal surgery, there is a reported trend of improved outcomes for patients having their care provided in hospitals or practices that have higher volumes.^{5–9} Many of the studies demonstrate lower mortality, shortened length of stay, and in some cases even lower costs.^{5,6} Others have shown that older patients and those with higher risk related to comorbidity may also benefit from treatment at higher volume centers.¹⁰ These relationships, however, are not always clearly defined: None of these studies meet what should be considered the gold standard of uniform outcome monitoring and reporting provided by the CABG model. Whether the improvements seen in these studies are directly related to quantity of cases, quality of care, or something else is uncertain.

A study from the University of California Los Angeles raised the issue of whether other factors may be more important to improving outcomes rather than just volume alone.¹¹ They examined 22,000 patients undergoing colon resection from a national sample and identified baseline mortality at 12 of 1000 cases. If patients were treated at high-volume centers or by high-volume surgeons, this mortality decreased to 11 of 1000, or 10 of 1000, respectively. Other predictors of poor outcomes included age, gender, operation severity (elective versus emergency), and the presence of comorbid illness. The presence of certain comorbidities (liver disease) raised mortality to 44 out of 1000 patients. Volume had a marginal impact on outcomes; however, they found that other factors were more important. Others have confirmed the limitation of volume alone affecting quality.⁷

Comorbidities and Patient Profiles

These two studies highlight important limitations when examining a straight volume relationship at the

detriment of other factors such as comorbidities. Community hospitals are typically low-volume centers and may have patient populations with higher comorbidities. They may also see more emergent cases, which by their nature would lead to poorer outcomes. Patients at these lower volume centers may significantly influence the poorer outcomes experienced there. This finding is not new and may reflect an increasing risk of advanced cancer in low-volume centers.¹² Some of the trends favoring larger centers may be related to the selection of patients with lower comorbidities and earlier disease states and the availability of specialist surgeons—not necessarily just volume.

Some larger medical centers may attract higher income patients, more insured patients, and therefore healthier patients. In fact, patients may be drawn to these centers by “reputation” and therefore larger centers will achieve better outcomes because they are treating healthier patients with less-advanced disease. These issues have not been clearly examined and are important considerations when making judgments about quality at lower volume centers. The issue of whether the lower volume center or the higher volume center has patients with more comorbidity is unsettled, however, as tertiary care centers paradoxically are the target of referrals of sicker patients from smaller centers.

The Canadian experience offers an interesting examination of the quality-volume relationship. Urbach et al¹³ studied hospital mortality on patients undergoing major procedures in Ontario, Canada and carefully examined risk by adjusting for age, sex, and comorbidity. Of the 75% of patients treated for colorectal resections at low-volume centers, mortality would not have changed had they been treated at a high-volume center.¹³ His other work failed to demonstrate any clear relationship between volume and outcomes for colorectal cancer surgery. Another study by the same group did find improved care for certain procedures (esophagectomies) at higher volume hospitals, and also demonstrated additional improvement at centers that have a high volume of other procedures (esophagectomies at centers with a high volume of lung resections). This finding supports the importance of multidisciplinary management of similar diseases, and also likely demonstrates the clustering phenomenon of certain cases to a specific type of surgeon.¹⁴

Other studies from Canada have failed to demonstrate a specific volume relationship. Using the Ontario Cancer Registry, a group at McMaster University was unable to confirm the relationship between volume and outcomes for in-hospital mortality. There was however improved long-term survival in certain major cancer operations (breast, lung, and liver), but not for colon resection. They speculated that this change might represent an improvement in care coordination such as access to adjuvant therapy and not necessarily

surgical skill.¹⁵ The results did not specifically address the treatment of rectal cancer, but note that certain other more technically demanding procedures such as lung and liver surgery may benefit from referral to higher volume centers. Although one could argue that the Canadian experience does not correlate with medical care in the United States, the use of more regionalization of specialty care in Canada should afford improved outcomes at higher volume centers because of the concentration of specialists at those locations.

The Use of Administrative Data

Panageas reexamined the volume-quality relationship in three studies that demonstrated improved outcomes for patients undergoing surgery for colon, prostate, and rectal cancer.¹⁶ He specifically analyzed whether the effect of clustering of cases with certain surgeons would dilute the volume effect seen at high-volume institutions. He hypothesized that quality may be linked to providers and not institutions because of the individual style that a surgeon may use influences their outcomes. Adjusting for the clustering effect is important to prevent misinterpretation of the processes of care seen by individual surgeons or centers and he further advocates that whenever a volume outcome relationship is examined, statistical methods should be used to account for clustering. When the volume outcome data was reexamined using techniques to account for the effect of clustering, he found marked attenuation in the data supporting the effect of improved outcomes in high-volume centers. This important statistical limitation likely exaggerates the magnitude of the affect in studies demonstrating improved outcomes in higher volume centers.

The use of administrative data that is often based on payment claims is frequently used to determine comorbidity risk and outcomes in these studies. In the cardiac literature, this “proxy” data does not accurately detail a patient risk profile and fails to factor in other relevant data points considered important for risk adjusting cardiac outcome data.³ Studies using the SEER database also fail to accurately account for important relationships of risk and outcome. Other limitations of administrative data and the inability to explain important clinical relationships have been well reported.^{17–20}

Meyerhardt’s study reinforces the difficulty of defining exactly what accounts for improved care using administrative data.²¹ He points out that for colon cancer resection, recurrence free survival is an important data point not followed in administrative databases. Using prospective data obtained from a large, national clinical trial, he found recurrence rates to be identical at low- and high-volume hospitals. Overall long-term mortality was worse at lower volume hospitals, but this may have been a reflection of the higher comorbidities of

the patients encountered at those institutions demonstrating that surgical care may have been equivalent regardless of volume. The increase in mortality could not be explained by cancer recurrence, which can be a marker for individual surgeon skill. Absent from this analysis was an examination of surgical specialty or surgeon training, but intuitively there are less specialists at lower volume centers. It is possible that the differences seen with this study reflect successful discharge after surgery, but differences in processes of care such as the use of adjuvant treatment and follow-up.

Adjuvant Therapy and Patient Follow-Up

Adjustment for the use of adjuvant therapy was examined for later stage colon cancer (stage III). When this variable was controlled between smaller volume centers and larger volume centers, it failed to account for the improved survival seen at higher volume centers.⁹ Improvements seen with hospital volume alone may be a surrogate marker for the multidisciplinary management that takes place at higher volume centers.²²

Absolute mortality is a readily available data point in administrative databases, and is typically used as the primary outcome in studies employing this type of data. Meyerhardt's study and others have demonstrated that mortality is a crude measure of outcomes that has been inconsistently shown to predict quality of care.^{20,23,24}

Availability of Specialists

It is likely that specialty training and experience has an important and strong impact on outcomes for patients with colorectal problems. Hamman found that high-volume providers (threshold of 40 colectomies) had a more important impact on outcomes than high-volume centers.¹² Whether this is related to generalists with high volume or specialists with unique training is not determined.

Platell's group examined outcomes of patients with colorectal cancer treated by either general or colorectal surgeons at a community hospital.²⁵ There was a strong improvement in overall survival in those patients treated by the colorectal surgeons. The improvement in outcomes witnessed at the Department of Veterans Affairs (VA) medical centers may also be related to the accessibility of specialty care at larger VA centers.⁸

The treatment of colon cancer demonstrates marginal improvements in outcomes at higher volume centers,⁹ but more technical operations and complex diseases may show a stronger association. For colorectal surgeons, this disease may be rectal cancer. There is also conflicting evidence that rectal cancer patients need to be treated at high-volume hospitals alone, but there is more data supporting the treatment of rectal cancer by high-volume, specialty-trained, colorectal surgeons operating

in a center capable of providing multidisciplinary care. Schrag et al²⁶ examined patients with rectal cancer over 65, and found no volume-associated difference in 30-day mortality or the use of abdominoperineal resection (APR) versus sphincter-sparing procedures. There were improvements in 2-year survival in high-volume centers; however, once the investigators analyzed and controlled for surgeon-specific volume, the 2-year survival advantage at the higher volume centers was no longer present. They concluded that surgeon experience as defined by surgeon volume likely resulted in better outcomes.

Using a nationwide inpatient sample, Ludwig's group demonstrated that patients undergoing surgery for rectal cancer were 5 times more likely to have a sphincter-sparing procedure as opposed to an abdominoperineal procedure if they were treated by a high-volume surgeon.²⁷

In a study that looked at all patients newly diagnosed with rectal cancer ($n = 5021$) over a 3-year period in Denmark, patients were much less likely to have a colostomy if their surgery was performed at a higher volume center.²⁸ There was no difference in leak rate, 30-day, or 5-year mortality between centers by volume; there were wider fluctuations in long-term mortality between the higher volume centers and the lowest volume centers. Hodgson et al²⁹ found that patients undergoing surgery for rectal cancer were less likely to have a colostomy, had improved 30-day mortality and 2-year survival if undergoing surgery at a high-volume center. Of note is that they adjusted for comorbidity and the affect of clustering.

This raises an issue about who at a high-volume center is actually conducting the surgery. A low-volume surgeon at a high-volume center may have worse outcomes than a high-volume, or more-experienced surgeon, at a high-volume center. This relationship was examined by Harmon and colleagues³⁰ who demonstrated improved outcomes with surgeons of greater volume (> 10 cases per year) and operating at medium- to high-volume hospitals. They also found that surgeon-specific volume improved when low-volume surgeons operated at higher volume hospitals. Using the same data, they then examined the relationship between surgeon volume and hospital volume; although both were found to be independent and strong predictors of outcome, the hospital effect may have exerted a stronger influence, and raised the possibility that the difference was attributed to multidisciplinary management available at larger centers.

Another study that examined 309 consecutive colorectal resections involving 23 surgeons found that most of the cases (80%) were performed by four surgeons,³¹ 80% of the segmental colon resections were performed by general surgeons, and 70% of the rectal

resections were performed by colorectal surgeons. Defining the outcome performance of the other 19 surgeons is less helpful because of the clustering of the cases to a small number of surgeons. This further illustrates the importance of identifying surgeon training and experience and adjusting for clustering. The individual surgeon performance at higher-volume centers should be considered separately as well.

Patients with other colorectal diseases such as diverticular fistulas have also been shown to have improved outcomes when managed by colorectal-trained surgeons. There was less use of Hartman's procedures, fewer complications, and a shorter length of stay in this group as well.³²

The Process of Care

Providers and health care organizations with access to quality information and the ability to implement it in their practices will likely improve the delivery of care. Outcome reporting, monitoring, and coordination among surgeons performing colorectal procedures has been shown to improve processes of care, including compliance with antibiotic usage, shortened length of stay, and less use of specialty consultants.³¹

An organization that is able to examine their process of care and make improvements based on that examination could improve outcomes for certain operations.³³ Processes of care are transferable from large centers to smaller centers, and this transfer of care technology can be used to improve outcomes.³⁴ Senagore and colleagues³⁴ developed a care path for patients undergoing laparoscopic colorectal surgery at a large volume center and successfully applied the same methodology to a lower volume center and was able to achieve similar outcomes.

CONCLUSION

So how do we define, deliver, and ensure quality for our patients? Whereas defining this is no small measure, it likely involves two major components. The first part of the process is to ensure the collection of accurate, comprehensive comorbidity data, carefully define an appropriate outcome measure, and apply dedicated resources to use appropriate statistical methods for risk-adjustment and data analysis. This first component provides the necessary infrastructure.

The second component involves care providers. Subspecialization of surgeons, practicing in a "learning environment" where a continuous quality improvement process is used with comprehensive data, will drive practice patterns and likely ensure that standards of care are achieved and maintained. These two components will not happen in a vacuum and will likely only be supported in institutions that can devote resources

through a multidisciplinary approach for the management of complex colorectal problems.

There will need to be a mandatory, transparent, comprehensive reporting, and collection system that collects data longitudinally. It will need to be supported by leaders and institutions that are willing to make difficult decisions with the data to drive these improved outcomes. These are complex requirements and they will not be met easily. Nevertheless, to simply attribute high quality to high-volume without a deeper understanding of what defines and drives quality is superficial and ignores a true understanding of the process.

The treatment of complex gastrointestinal conditions is likely more difficult to standardize because of the inherent heterogeneity of the disease process; nevertheless, the CABG example demonstrates what is possible to achieve when a system is established.

The available data are difficult to clearly interpret. Case volume plays an important role in quality; it is unclear whether it is linked to centers, surgeons, or both. The only underlying variables consistently attributed to improving quality at both high-volume and low-volume centers, albeit weakly, is subspecialization and surgeon-specific volume. There is little doubt that an experienced, subspecialized surgeon performing a higher volume of the same types of cases will perform better than their lower volume, generalist colleague doing the occasional colorectal resection. As long as the specialist operating at a smaller center has access to volume and a multidisciplinary infrastructure to ensure the appropriate standard of care, patients will not need to be regionalized to a high-volume center to receive a higher quality of care.

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