Volume and Process of Care in High-Risk Cancer Surgery

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BACKGROUND. Although relations between procedure volume and operative mortality are well established for high-risk cancer operations, differences in clinical practice between high-volume and low-volume centers are not well understood. The current study was conducted to examine relations between hospital volume, process of care, and operative mortality in cancer surgery.

METHODS. Using the Medicare claims database (2000-2002), we identified all patients undergoing major resections for lung, esophageal, gastric, liver, or pancreatic cancer (n=71,558). Preoperative, intraoperative, and postoperative processes of care potentially related to operative mortality were identified from inpatient, outpatient, and physician claims files using appropriate *International Classification of Diseases – Clinical Modification* (ICD-9) and Current Procedural Terminology (CPT) codes. We then assessed variation in the use of each process according to hospital volume, adjusting for patient characteristics and procedure type. Study Participants were US Medicare patients. The main outcome measure was specific processes of care.

RESULTS. Relative to those at low-volume centers (lowest 20th by volume), patients at high-volume hospitals (highest 20th) were significantly more likely to undergo stress tests (odds ratio [OR]: 1.51, 95% confidence interval [CI]: 1.21-1.87), but not other preoperative imaging tests. They were more likely to see medical or radiation oncologists (OR: 1.37, 95% CI: 1.16-1.62), but not other specialists, preoperatively. Although blood transfusions and use of epidural pain management did not vary significantly by volume, patients at high-volume hospitals had significantly longer operations and were more likely to receive perioperative invasive monitoring (OR: 2.56, 95% CI: 1.82-3.60). Differences in measurable processes of care did not explain volume-related differences in operative mortality to any significant degree.

CONCLUSIONS. Although high-volume and low-volume hospitals differ with regard to many aspects of perioperative care, mechanisms underlying volume–outcome relations in high-risk cancer surgery remain to be identified. *Cancer* **2006;106: 2476–81.** © *2006 American Cancer Society.*

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or many high-risk cancer procedures, it is well established that patients undergoing surgery at high-volume hospitals have lower risks of operative mortality than those at lower-volume centers. ¹⁻⁴ As a result, purchaser coalitions, patient advocacy groups, and the lay media are encouraging patients awaiting selected cancer procedures to seek care at high-volume centers. ^{5,6} Nonetheless, given geography, patient preferences, provider incentives, and other factors conspiring to maintain the status quo, ⁷⁻⁹ it is inevitable that a large number of

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these procedures will continue to be performed at low-volume hospitals.

It is not clear how best to improve outcomes in these settings. Hospital volume is no doubt a surrogate for numerous processes of care that directly influence patient outcomes, but such processes have not been well characterized. For some procedures, higher volume, particularly at the surgeon level, may translate directly to better clinical judgment and technical proficiency in the operative room—the "practice-makes-perfect" hypothesis. Such processes are difficult to measure and may be hard to transfer to lower-volume providers. On the other hand, high-volume and low-volume centers may also differ with regard to other processes of preoperative and postoperative care, which could be adopted by lower-volume centers.

To better understand potential mechanisms underlying volume–outcome relations in cancer surgery, we used data from the national Medicare population to study processes of care in patients undergoing high-risk cancer surgery. We focused on practices potentially related to risks of perioperative mortality with any high-risk procedure, including processes pertaining to preoperative risk stratification and perioperative care.

MATERIALS AND METHODS Subjects and Databases

Using national Medicare claims data, we identified all patients ages 65 to 99 undergoing major resection for 1 of 5 different cancers (lung, esophagus, stomach, liver, and pancreas) between 2000 and 2002. Patients were selected using the appropriate procedure codes from the International Classification of Diseases, v. 9 (ICD-9) from the inpatient file, which contain hospital discharge abstracts for fee-for-service acute care hospitalizations of all US Medicare beneficiaries. Patients undergoing resection were included only if there were accompanying diagnostic codes for 1 of the 5 cancers. The inpatient, outpatient, and physician claims files were used to identify relevant processes of care; the denominator file was used to assess patient vital status. The Institutional Review Board of the University of Michigan approved the study protocol.

Categorization of Hospital Volume

For each of the 5 types of cancer resections, hospitals were given a percentile score according to their Medicare volumes during the 3-year study period. We then ranked hospitals according to the average of their 5 procedure-specific percentile scores and sorted them into 5 volume categories (quintiles), each containing a similar number of patients. We used this approach,

rather than simply summing the total number of all 5 procedures, to avoid skewing hospitals' volume rankings by lung resection, the most common of the 5 procedures.

Process Measures

For inclusion in this study, we focused on practices potentially related to operative mortality, including those related to preoperative risk stratification and patient selection, perioperative hemodynamic monitoring, and other aspects of postoperative care. We considered processes of care common to almost any high-risk procedure, but not practices specific to individual procedures. To identify potentially important process measures, we first consulted the literature, including 1 comprehensive review of hospital safety practices. 10 We considered additional variables based on the input of clinician experts. Once a candidate list had been developed, we consulted the ICD-9 and Current Procedural Terminology (CPT) coding manuals to determine the subset of these processes potentially reflected by inpatient and outpatient claims data and performed pilot analyses to develop and test coding algorithms.

Preoperative tests and specialist consultations were identified from the 6-month time period before the index operation. Anesthesiologist claims contain required fields documenting the total time for which bedside attendance from the anesthesiologist was required, which often includes the initial period after the patient is transferred to the recovery room. Although we used this variable to reflect operating time, it no doubt exceeds "skin-to-skin" time or room time. Blood transfusions, invasive hemodynamic monitoring, and epidural catheter use (for pain management) were determined from the day of the index procedure to hospital discharge or death.

Analysis

In examining relations between processes of care and hospital volume, receipt of each process of care was assessed at the individual level and exposure (volume) was measured at the hospital level and categorized into quintiles. We adjusted for both patient and hospital characteristics. Patient characteristics included age group (5-year intervals), sex, race (black, nonblack), cancer type, year of procedures, and admission acuity (elective, urgent/emergent). Patient comorbidities were identified using appropriate ICD-9 codes from the index admission and other inpatient and outpatient records within 6 months before surgery, excluding conditions likely to reflect either the primary surgical indication or postoperative complications. Comorbidities were incorporated into risk ad-

justment models using methods described by Elixhauser et al.¹¹ We used data from American Hospital Association files to ascertain and adjust for selected hospital characteristics, including ownership (not-for-profit and for-profit) and teaching status.

Next we examined the extent to which differences in processes of care between high- and low-volume hospitals accounted for volume-related differences in operative mortality. As in our previous work, operative mortality was defined as death occurring before hospital discharge or within 30 days of the index procedure. We assessed whether the volume effect was attenuated by running the models with and without inclusion of important groups of processes of care variables. The relative attenuation of the odds ratio (OR) was measured as (OR_H-OR_{HP})/(OR_H-1), where OR_H is the odds ratio of operative mortality for hospital volume ignoring processes of care, and OR_{HP} is the odds ratio for hospital volume after including processes of care, all models fully adjusted for patient and other hospital characteristics. This approach is more fully described in our earlier work assessing the contribution of surgeon volume to observed hospital volume-outcome associations.12 Some processes that may potentially reflect higher quality at the hospital level tend to be performed on sicker patients (e.g., perioperative invasive monitoring). For this reason, we evaluated processes of care at the hospital level to distinguish between more frequent use of the test as a marker of hospital practice patterns and illness sever-

Because patients at the same hospital may have correlated outcomes due to the similarity of the surgical environment and practice patterns, we used GEE logistic models, with patients clustered within hospital.¹³ Adjusted mortality rates were computed at the average value of the patient characteristics by backtransforming predicted mortality from the logistic model. All *P*-values are 2-tailed.

To further explore the possibility that our findings reflected unmeasured differences in patient case mix, we repeated our analysis using data from the linked Survival, Epidemiology, and End Results (SEER)-Medicare files (1992-1999), which contain detailed data pertaining to cancer stage and other characteristics. We found no evidence of significant case mix variation by hospital volume. Because results of these analyses were very similar, they are not presented herein.

RESULTS

Between 2000 and 2002, 71,558 Medicare patients underwent major resections for 1 of the 5 cancer types. As shown in Table 1, patients at lower-volume hospitals were older, more likely to be black, to be admitted

TABLE 1 Characteristics of U.S. Medicare patients Undergoing 1 of 5 Major Cancer Resections (2000-2002), According to Hospital Volume

	Но				
	Very low	Low	Medium	High	Very high
Number of patients	14300	14313	14343	14328	14274
Number of hospitals	1965	472	267	158	72
Patient characteristics					
Age* (% 75+ y)	45.3	43.1	41.5	41.6	38.2
Sex (% female)	44.2	43.4	43.1	43.4	43.4
Race* (% Black)	8.9	6.1	5.9	6.8	6.1
Admission acuity* (%					
urgent/emergent)	27.1	20.3	18.4	16.7	9.4
Comorbidity* (% 2+)	71.5	70.7	69.3	66.6	64.0
Cancer types*					
Esophagus (%)	5.0	7.3	8.1	9.9	14.7
Liver (%)	0.0	0.4	0.6	1.3	3.5
Lung (%)	68.8	72.8	72.5	70.6	59.6
Pancreas (%)	4.1	5.5	6.7	8.5	14.4
Stomach (%)	22.1	14.0	12.1	9.7	7.8
Hospital characteristics					
Not-for-profit* (%)	66.5	74.6	79.7	83.1	79.5
Teaching* (%)	32.7	40.3	45.7	60.7	77.8

^{*} P trend <.01

nonelectively, and had more comorbidities. Relative to higher-volume centers, low-volume hospitals performed proportionally more gastrectomies and lung resections, but fewer higher-risk resections for liver, esophageal, and pancreatic cancer. Lower-volume centers were more likely to be for-profit but less likely to be teaching hospitals.

After adjusting for differences in patient characteristics and cancer type, high-volume and low-volume hospitals differed with regard to several practices related to preoperative risk stratification and evaluation (Table 2). Relative to patients at low-volume hospitals (lowest 20th by volume), patients at high-volume hospitals (highest 20th) were over 50% more likely to undergo a stress test before surgery (adjusted OR: 1.51, 95% CI: 1.21-1.87), but not more likely to undergo echocardiograms and pulmonary function tests. Patients at high-volume hospitals were considerably more likely to see oncologists (OR: 1.37, 95% CI: 1.16-1.62), but not cardiologists, before surgery.

Aspects of intraoperative and postoperative care also varied according to hospital volume. After adjusting for patient characteristics and cancer type, patients at high-volume hospitals had longer operative times (5.3 vs. 4.6 hours at low-volume hospitals). They were more likely to receive invasive monitoring during or after surgery (OR: 2.56, 95% CI: 1.82-3.60), largely attributable to greater use of arterial lines. Conversely,

TABLE 2
Use of Various Processes of Care, According to Hospital Volume

	Hospital Volume Quintile						
	1 (low)	2	3	4	5 (high)	Odds ratio (high vs low) (95% CI)	
Risk stratification and evaluation*							
Echocardiogram (%)	17.0	17.2	16.4	16.5	17.5	1.04 (0.86-1.26)	
Stress test (%)	18.5	18.9	19.2	22.2	25.5	1.51^{\dagger} (1.21-1.87)	
Pulmonary function tests (%)	47.8	47.8	48.4	44.8	47.5	0.99 (0.83-1.18)	
Specialist consultation before surgery							
Cardiologist (%)	7.8	8.9	9.0	9.6	9.0	1.17 (0.94-1.45)	
Medical or radiation oncologist (%)	6.9	7.0	7.8	8.1	9.3	1.37^{\dagger} (1.16-1.62)	
Peri-operative care*							
OR time (hrs)	4.6	4.5	4.8	4.8	5.3		
Blood transfusion (%)	17.7	14.0	13.9	14.7	14.9	0.82 (0.57-1.18)	
Invasive monitoring							
Arterial line (%)	21.4	30.2	34.8	34.9	51.2	3.86^{\dagger} (2.65-5.62)	
Central venous line (%)	11.9	12.8	13.9	14.1	13.6	1.17 (0.82-1.66)	
Pulmonary artery catheter (%)	2.5	3.1	3.4	4.3	3.2	1.27 (0.91-1.78)	
Any (%)	31.9	40.5	44.1	43.5	54.5	2.56^{\dagger} (1.82-3.60)	
Epidural analgesia (%)	22.5	32.5	33.7	29.7	20.8	0.90 (0.38-2.17)	
Specialist consultation after surgery [‡]	34.1	35.2	32.3	28.7	18.2	0.43 (0.36-0.52)	

^{*} Adjusted for patient and hospital characteristics

patients at high-volume centers were much less likely to receive specialist consultations after surgery (OR: 0.43, 95% CI: 0.36-0.52). For both preoperative and postoperative processes of care, practice patterns at intermediate volume centers did not consistently fall within ranges established by low- and high-volume hospitals (Table 2). Overall, absolute differences in the proportions of patients receiving specific processes of care were relatively modest.

Accounting for patient characteristics, procedure mix, and hospital characteristics, patients at low-volume hospitals were twice as likely to experience operative mortality as their counterparts at higher-volume centers (8.0% vs. 4.3%, *P*<.0001, OR: 1.92, 95% CI: 1.65-2.24). Volume–outcome relations were not significantly mediated by either preoperative or postoperative processes of care. Adjusted ORs of mortality by volume were largely unaffected as process variables were added to the multivariable model (Table 3). To rule out confounding by differences in procedure mix, we repeated these analyses for each individual procedure. Although ORs of mortality by hospital volume varied by procedure (Table 3), none were not significantly attenuated by adjusting for measurable processes of care.

DISCUSSION

A growing body of literature documents relations between hospital volume and patient outcomes in cancer surgery, including operative mortality, nonfatal complications, and late survival. 1,2,14-17 Mechanisms underlying these volume-outcome relations have not been elucidated. Our previous work suggests that the hospital volume effect is mediated in part by surgeon volume, but little is known about direct determinants of outcomes. 12 In this national study of Medicare patients undergoing 1 of 5 high-risk cancer operations, high-volume and low-volume hospitals differed with regard to many aspects of both patient selection and perioperative care with high-risk cancer surgery. For example, patients at high-volume hospitals were more likely to undergo preoperative stress tests, to see oncologists preoperatively, to have longer operations, and to receive invasive monitoring after surgery.

Although our study may be the first study to focus specifically on volume-process relations in surgery, previous research has described differences in practice between high-volume and low-volume centers. For example, with acute myocardial infarction, patients treated at top-ranked (and higher volume) hospitals were more likely to be treated with beta-blockers and aspirin. With surgery for rectal cancer, patients at high-volume hospitals were more likely to avoid a permanent colostomy and to receive adjuvant radiation therapy. 19

Although this study documents volume-related differences in specific processes of care, these processes—individually or collectively—did not mediate

[†] P trend <.01.

[‡] Does not include operating surgeon.

TABLE 3
Association Between Hospital Volume and Operative Mortality, With and Without Adjustment for Patient Characteristics, Hospital Characteristics, and Processes of Care

	Hospital Volume Quintile						
	1 (low)	2	3	4	5 (high)	Odds ratio (low vs high) (95% CI)	
5 operations combined							
Unadjusted	9.5	8.4	7.4	7.2	5.2	1.92 (1.68-2.19)	
Adjusted for patient and hospital characteristics	8.0	7.3	6.6	6.3	4.3	1.92 (1.65-2.24)	
Adjusted for patient and hospital characteristics and							
preoperative processes of care	7.9	7.3	6.6	6.4	4.3	1.90 (1.62-2.22)	
Adjusted for patient and hospital characteristics and							
postoperative processes of care	7.8	7.2	6.5	6.2	4.4	1.84 (1.57-2.16)	
Adjusted for patient and hospital characteristics and all							
measurable processes of care	7.7	7.1	6.5	6.2	4.4	1.80 (1.53-2.11)	
Esophageal resection							
Adjusted for patient and hospital characteristics	15.5	15.2	11.6	9.9	6.8	2.52 (1.70-3.74)	
Adjusted for patient and hospital characteristics and all							
measurable processes of care	15.2	14.4	11.3	9.7	7.1	2.34 (1.58-3.46)	
Liver resection							
Adjusted for patient and hospital characteristics	16.8	18.3	7.9	7.8	7.9	2.33 (1.15-4.72)	
Adjusted for patient and hospital characteristics and all							
measurable processes of care	13.6	17.3	8.3	8.0	8.0	1.82 (0.83-3.98)	
Lung resection							
Adjusted for patient and hospital characteristics	6.2	5.2	5.0	5.1	5.1	1.24 (1.06-1.45)	
Adjusted for patient and hospital characteristics and all							
measurable processes of care	5.9	5.1	4.9	5.1	5.0	1.18 (1.00-1.38)	
Pancreatic resection							
Adjusted for patient and hospital characteristics	12.5	11.2	10.7	6.6	3.2	4.28 (2.93-6.27)	
Adjusted for patient and hospital characteristics and all							
measurable processes of care	11.8	10.8	10.1	6.6	3.2	3.98 (2.63-6.03)	
Gastric resection							
Adjusted for patient and hospital characteristics	10.1	9.5	9.8	9.2	7.3	1.43 (1.11-1.83)	
Adjusted for patient and hospital characteristics and all							
measurable processes of care	9.9	9.5	9.6	9.3	6.8	1.51 (1.16-1.97)	

to any significant degree relations between volume and operative mortality. It may be that these processes are simply not important. Thus, more intensive preoperative evaluation and perioperative monitoring may just reflect practice style at bigger hospitals with readier access to specialists, but these processes do not directly improve outcomes themselves. Alternatively, our findings may reflect the limited ability of claims data to capture these processes. Thus, claims may reliably determine whether preoperative stress tests are performed, but they contain no information about how information from these tests was incorporated in subsequent treatment decisions.

Claims data do not provide insights regarding many crucial aspects of care in patients undergoing high-risk cancer surgery. For example, they do not contain information regarding medication use (e.g., prophylactic beta-blocker use in patients at high risk of cardiac events perioperatively) or how the procedure itself was performed. Whether such information will be useful in understanding mechanisms underly-

ing volume–outcome relations in cancer surgery has yet to be established. However, studies exploring surgical performance in other contexts suggest that it might. For example, Hannan et al.²⁰ performed a prospective clinical study of patients undergoing carotid endarterectomy at 6 hospitals in New York State. In that study, vascular surgeons had substantially lower 30-day rates of operative stroke or death than did general surgeons or neurovascular surgeons. The investigators also found that intraarterial shunting, eversion endarterectomy techniques, patching of the arteriotomy, and protamine were associated with lower complication rates. These practices were more likely to be adopted by vascular surgeons, which explained in large part their better outcomes.

Many would question the adequacy of risk adjustment in this study. As with many earlier studies, patients at lower-volume hospitals tended to be older, have more comorbidities, and were more likely to be admitted nonelectively. Given the well-known limitations of Medicare claims data, it is possible that we did

not account fully for differences in patient case mix by hospital volume. However, this limitation does not explain our main findings. To the extent that lower-volume centers care for higher-risk patients, we would expect greater use of preoperative cardiopulmonary testing, cardiologist consultations, and postoperative invasive monitoring in these settings. Instead, lower-volume hospitals were generally less aggressive in these aspects of perioperative care.

To date, efforts to translate evidence about volume-outcome relations in surgery into quality improvement have focused on selective referral and encouraging more patients to seek care at high-volume hospitals. Although there is little doubt that such strategies could reduce patient risks with many procedures,3,21 payers and policy makers currently have limited opportunities for leveraging major changes in surgical referral patterns. As an alternative to volumebased referral, lower-volume hospitals and surgeons could improve by learning and adopting best practices from their higher-volume counterparts. Whether this goal is realistic will depend on mechanisms underlying volume-outcome relations in cancer surgery. Further studies based on detailed clinical data may yet implicate discrete processes of care that could be readily exportable to low-volume settings, as with beta-blocker use after acute myocardial infarction.¹⁸ However, to the extent that better surgical outcomes reflect unmeasurable aspects of clinical judgment and technical proficiency that only come with experience, goals of improving care at low-volume hospitals may not be easily realized with many high-risk cancer operations.

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