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Volume, Process of Care, and Operative Mortality for Cystectomy for Bladder Cancer

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Abstract

Objectives—High volume hospitals have lower mortality rates for a wide range of surgical procedures, including cystectomy for bladder cancer. However, the processes of care that mediate this effect are unknown. We sought to identify the processes that underlie the volume-outcome relationship for cystectomy.

Methods—Within the SEER-Medicare dataset, we used ICD-9 procedure codes to identify 4,465 patients who underwent cystectomy for bladder cancer between 1992 and 1999. Pre- and peri-operative processes of care were abstracted from the inpatient, outpatient, and physician files using procedure and diagnosis codes available through 2002. Logistic models were used to assess the relationship between process and hospital volume, adjusting for differences in patient characteristics.

Results—There was substantial variation in the use of specific processes of care across hospital volume strata. High volume hospitals had higher rates of preoperative cardiac testing (OR 1.57, 95% CI 1.24-1.98), intraoperative arterial monitoring (OR 3.73, 95% CI 3.11-4.46), and the use of a continent diversion (OR 4.01, 95% CI 3.03-5.30), among many others. Patients treated at low volume hospitals were 48% more likely to die in the postoperative period (4.9% vs. 3.5%, adjusted OR 1.48, 95% CI 1.03-2.13). Differences in the use of processes of care explained 23% of this volume-mortality effect.

Conclusions—High volume and low volume hospitals differ with regard to many processes of care before, during and after radical cystectomy. Although these practices partly explain the volume-outcome relationships for cystectomy, the primary mechanisms underlying this effect remain unclear.

Keywords

Volume; Process of care; Quality of care; Mortality

Introduction

Radical cystectomy for bladder cancer is a high risk procedure, with morbidity and operative mortality rates ranging from 28-32%[1-3] and 3-6%,[4,5] respectively. Associations between hospital and/or surgeon volume and operative mortality have been demonstrated in several different patient populations.[4-7] By one estimate, patients undergoing radical cystectomy for

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bladder cancer at high volume hospitals were 54% less likely to die perioperatively compared to those treated at low volume hospitals.[4] The importance of hospital volume may also extend to other significant outcomes, including long-term mortality.[8,9]

However, the mechanisms underlying the hospital volume effect for cystectomy are not well understood. The persistence of hospital volume effects after accounting for case mix suggests true differences in hospital quality, but it is not clear by which processes of care better outcomes are achieved. Reasons could include processes related to patient selection, technical proficiency, or adherence to evidence-based perioperative care guidelines. Physicians at high volume hospitals may be better at identifying patients who are likely to survive the operation. These physicians may also have better technical skill, resulting in fewer downstream surgical complications and ultimately lower operative mortality. Finally, physicians at high volume hospitals may better adhere to recommended perioperative practices, including appropriate antibiotic and deep venous thrombosis prophylaxis.

We undertook a study to better understand the differences in processes of care between high volume and low volume hospitals. In addition to explaining which practices vary by hospital volume, we examined the extent to which measurable processes of care explained the association between volume and operative mortality.

Materials and Methods

Subjects

Incident bladder cancer cases diagnosed between 1992 and 1999 in patients between the ages of 65 and 99 were identified from the SEER-Medicare files. The demographic composition, as well as the cancer incidence and mortality trends, of the SEER registry is considered representative of the entire United States population.[10] For each Medicare patient within SEER, the SEER-Medicare linked files contain 100% of inpatient (Part A), outpatient and physician (Part B) claims. Thus, while SEER allows for accurate ascertainment of incident cases and disease severity (e.g., tumor stage), the linkage of Medicare files allows for the longitudinal evaluation of treatments received.

Among those with a bladder cancer diagnosis, 4,465 patients who underwent extirpative surgery were identified by *International Classification of Diseases, 9th Revision, Clinical Modification*, (ICD-9) procedure codes (partial cystectomy: ‘5759’-open excision of bladder lesion, and ‘576’-partial cystectomy; radical cystectomy: ‘5771’-radical cystectomy, ‘577’-total cystectomy, ‘5779’-other total cystectomy, and ‘688’-pelvic evisceration) and comprise our study population.

Hospital Volume

Hospitals located within and adjacent to SEER regions often treat a variety of SEER and non-SEER patients. Thus, limiting hospital volume determination to data available in SEER-Medicare linked files has the potential to misclassify the volume status of some hospitals.[11] For example, a hospital located immediately outside of a SEER region might appear to have a low volume when restricting volume ascertainment to SEER-Medicare files despite treating a high volume of patients not living within a SEER registry. For this reason, we used the 100% sample of Medicare files to characterize hospital procedure volumes.[4] Hospitals were then ranked in order of increasing volume and thresholds were chosen to sort hospitals into three equal-sized patient groups (terciles). As a result, the average annual cystectomy volume performed at low, medium and high volume hospitals ranged from 0.26- 2.11, 2.12- 6.09 and 6.10-82.41 procedures annually.

Process Measures

Processes of care were ascertained from Medicare claims through 2002, from a window of six months prior to and six months after the index surgery. For the purpose of this study, we focused on two categories of process measures: 1) those potentially related to operative mortality with any high risk procedure; and, 2) those more specific to cystectomy. Potential process measures were selected from a review of the literature, including a comprehensive assessment of hospital safety practices.[12] We then identified the subset of these process measures that were ascertainable from ICD-9 and CPT codes. Pilot analyses were conducted to develop and test these coding algorithms. Processes of care were further divided into categories based upon their temporal relationship to the index procedures: preoperative (in the 6 months prior to cystectomy), and perioperative (during operative procedure and in the 6 months following cystectomy).

Statistical Analysis

The primary outcome for this study was the use of each process of care. Our secondary outcome was operative mortality, defined as death prior to hospital discharge or death within thirty days of cystectomy. Both outcomes were measured at the level of the patient. Separate logistic regression models were fit to examine the independent relationship of hospital volume and each process measure. Because the purpose of the study was to identify differences in processes of care as a function of hospital volume (and not necessarily other hospital attributes), we adjusted solely for differences in patient characteristics. For the purpose of parsimony, only patient characteristics with a marginal relationship ($p < 0.1$) to the process measure on bivariate analysis were included in the final models. Co-existing patient conditions were identified using ICD-9 diagnostic codes in the 6 month period prior to cystectomy, and were incorporated into the final models using the methodology described by Elixhauser and colleagues.[13] In addition, we adjusted for patient age group at the time of cystectomy (65-69 years, 70-74 years, 75-79 years, 80-84 years, and 85-99 years), modified American Joint Commission on Cancer stage (0 or 1, 2, 3, 4), cancer grade (low, high), gender, race (black, non-black), socioeconomic status (median household income measured at the zip code level), year of treatment, extent of resection (partial, radical) and admission acuity (elective, urgent or emergent).

For analyses of operative mortality, logistic models were fitted using generalized estimating equations to account for clustering of mortality outcomes within hospitals.[14] We sequentially adjusted for differences in patient characteristics and processes of care to determine whether the differential use of processes attenuated the volume-outcome relationship. For the purpose of parsimony, only process measures with at least a marginal relationship with operative mortality on bivariate analysis ($p < 0.1$) were included in this model. The relative attenuation of the odds ratio 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 modeling was carried out using computerized software (SAS, Cary, NC) and all P values were two-tailed. The study protocol was approved by the institutional review board at the University of Michigan.

Results

Between 1992 and 1999, 4,465 patients were treated with partial (n=1,375, 30.8%) or radical (n=3,090, 69.2%) cystectomy for bladder cancer within SEER-Medicare. Differences in patient characteristics for low, medium and high volume hospitals are illustrated in Table 1. In general, high volume hospitals treated a slightly younger patient population and a greater proportion of blacks. Although patients had a similar cancer stage distribution across hospital volume strata, those treated at high volume hospitals had higher grade bladder cancer and were substantially more likely to undergo a radical compared to a partial cystectomy. Patients treated at lower volume hospitals were considerably more likely to be admitted non-electively.

Use of preoperative and perioperative processes of care was highly variable across hospital volume strata. High volume hospitals had higher rates of almost all of the preoperative processes of care assessed in this study. The largest differences were observed for preoperative cancer staging (abdominal and chest imaging, transurethral resection) and cardiac stress testing (Table 2). Similarly, high volume hospitals had higher rates of invasive monitoring (central venous and pulmonary artery catheters) and other interventions, including frozen section. High volume hospitals more commonly performed lymphadenectomy and continent urinary diversion (Table 3).

Overall, operative mortality following radical cystectomy was 4.5%. Unadjusted operative mortality was variable across hospital volume strata: low—4.9%, medium—5.0%, and high —3.5%. Patients treated at low volume hospitals were 46% more likely to die postoperatively compared to those at high volume hospitals (unadjusted OR 1.46, 95% CI 1.04-2.04). After adjusting for differences in patient characteristics, those treated at low volume hospitals were 48% more likely to die in the perioperative period compared to patients treated at high volume hospitals (adjusted OR_H 1.48, 95% CI 1.03-2.13).

To measure the contribution of differential process use according to hospital volume, those measures with a marginal relationship ($p < 0.1$) with operative mortality were incorporated into the adjusted model as a group. These processes of care included preoperative cancer staging evaluations (chest imaging and transurethral resection within 2 months prior to cystectomy), preoperative pulmonary function testing, use of invasive monitoring (arterial line, central venous catheter, pulmonary artery catheter), partial cystectomy, epidural anesthesia, gastric tube placement, perioperative hemodialysis and perioperative consultations (critical care and other physician services). Adjusting for these processes had a modest effect in reducing the odds ratio of mortality associated with volume (adjusted OR_{HP} 1.39, 95% CI 0.93-2.09). Thus, the percent attenuation of the volume-mortality effect by the process measures was 23%.

Comment

After adjusting for differences in health status and disease severity, patients treated at low volume hospitals were nearly 50% more likely to die in the postoperative period. We observed substantial disparities in the use of processes of care by hospital volume for all phases of patient care. With regard to most processes, high volume hospitals had substantially higher rates of utilization, exhibiting a more intensive practice style overall. Cumulatively, these processes had a moderate effect in attenuating the volume-mortality effect among those undergoing cystectomy, accounting for 23% of the variation in operative mortality.

The processes of care that varied most by volume included those related to the extent of the resection (e.g., lymphadenectomy) and invasive monitoring (e.g., central venous catheter). The beneficial effect of some of these processes is supported in the literature. For example, extensive pelvic lymphadenectomy at the time of radical cystectomy improves long-term survival.[8] Preoperative urinary diversion (among patients with acute renal failure) and epidural anesthesia (at the time of cystectomy) appear to reduce postoperative morbidity.[15] Thus, the more frequent use of these processes at high volume hospitals may reflect better quality of patient care. While other processes characteristic of high volume hospitals lack high level evidence supporting their effectiveness, many have face validity in elderly patients undergoing high risk surgery. These include processes related to preoperative risk stratification (e.g., cardiac stress testing), and perioperative invasive monitoring (e.g., pulmonary artery catheter).

However, it is unclear whether the observed differences in process are part of the causal pathway for the volume-outcome relationship or are merely proxies for factors that more directly improve patient outcomes. Under the former scenario, exportation of some processes of care to lower volume hospitals could lead to downstream improvements in operative mortality. If the latter scenario holds and the greater use of invasive monitoring simply reflects, for instance, more “careful” physicians, then disseminating these processes of care would not likely translate into quality improvement.

These findings should be interpreted with a few caveats. First, this study involved Medicare patients only, and the generalizability of our findings to a younger population is uncertain. However, bladder cancer is generally a geriatric disease, with approximately three-quarters of cases occurring within the U.S. Medicare population.[16] Our recent analysis of data from the Nationwide Inpatient Sample suggests that Medicare patients represent approximately half of U.S. patients undergoing cystectomy (unpublished data). Second, because we estimate hospital volume status using Medicare data instead of all-payer data, our classification of hospital volume may be imprecise.[11] However, our previous work has demonstrated that volume estimates based on Medicare and all-payer data are highly correlated for most procedures. Further, since errors in volume categorization are likely random, any misclassification would likely bias our findings toward the null hypothesis.

The third and perhaps most important limitation of this study relates to the ability of administrative data to adequately adjust for differences in case-mix.[17] To address this limitation, we used well-described methods to account for differences in comorbidity[13] and controlled for other important predictors of survival after cancer surgery, including age, race, gender, socioeconomic status, cancer stage and grade, and admission acuity. While more detailed measures of patients’ health status and demographics may improve our ability to risk adjust, such would require a large cohort study or clinical trial which is not possible for practical reasons (e.g., cost, sample size). At this time, the direction of the bias related to imperfect risk adjustment is unclear in the bladder cancer population.

Although the processes of care measured in this study play a moderate role in explaining the hospital volume effect among patients undergoing cystectomy for bladder cancer, a considerable component remains undefined. Differences in operative mortality are likely explained by processes of care not readily captured by administrative data. These may include those related to surgeon proficiency and expertise, above and beyond that measured by volume.[5] In addition, other aspects of perioperative care not reflected in administrative data, such as the use of beta blockers or other medications, may play a role as well. For this reason, efforts dedicated to measuring what happens in the operating room and those focused on widening the scope of the measured clinical data would be of considerable utility.

Conclusions

This study is among the first to suggest differences in processes of care according to hospital volume. These differences explain some, but not all, of the volume-mortality effect among patients undergoing cystectomy for bladder cancer. Ultimately, the exportation of processes of care identified at high volume to low volume hospitals may provide the most practical means of reducing variation in mortality rates across hospitals.

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Table 1

Differences in patient characteristics treated by hospital cystectomy volume.

Patient Characteristic		Low Volume (%)	Medium Volume (%)	High Volume (%)	p-value
Age	*65-69*	355 (23.6)	348 (23.3)	383 (26.2)	0.0016
	70-74	423 (28.1)	415 (27.7)	426 (29.1)	
	75-79	370 (24.6)	397 (26.5)	404 (27.6)	
	80-84	242 (16.0)	230 (15.4)	179 (12.2)	
	85-99	116 (7.7)	106 (7.1)	71 (4.9)	
Race	*Black*	103 (6.8)	28 (1.9)	84 (5.7)	<0.0001
Gender	*Female*	482 (32.0)	468 (31.3)	408 (27.9)	0.0343
Socioeconomic Status	*Low*	271 (18.9)	250 (17.7)	266 (19.3)	0.1278
	Intermediate	848 (59.1)	812 (57.4)	761 (55.1)	
	High	316 (22.0)	352 (24.9)	353 (25.6)	
Cancer Stage	*0 or 1*	439 (34.8)	493 (37.8)	468 (36.2)	0.2137
	2	271 (21.5)	246 (18.8)	281 (21.7)	
	3	293 (23.2)	311 (23.8)	270 (20.9)	
	4	260 (20.5)	256 (19.6)	274 (21.2)	
Cancer Grade	*High*	940 (76.8)	959 (75.6)	1012 (80.6)	0.0063
Admission Acuity	*Urgent/emergent*	412 (27.4)	275 (18.4)	249 (17.0)	<0.0001
Extent of resection	*Partial cystectomy*	645 (42.8)	501 (33.5)	229 (15.7)	<0.0001

Table 2

Differences in general process of care use across hospital volume strata occurring before, during and after cystectomy for bladder cancer.

					High vs. Low Odds Ratio (95% confidence Interval)	
Timing of Process	**Process of Care**	**Low Volume (%)**	**Medium Volume (%)**	**High Volume (%)**	**Unadjusted**	**Adjusted for Patient**
Preoperative	Abdominal imaging (within 2 months)	58.5	66.2	73.1	1.90 (1.61-2.25)	1.66 (1.38-2.00)
	Chest imaging (within 2 months)	71.9	76.3	84.8	2.21 (1.82-2.69)	2.07 (1.69-2.56)
	Systemic Chemotherapy	4.3	7.0	7.0	1.47 (1.04-2.08)	1.24 (0.87-1.77)
	Radiation therapy	2.7	2.9	4.2	1.33 (0.85-2.09)	1.48 (0.93-2.35)
	Cardiac stress test	11.8	16.7	20.4	1.97 (1.60-2.44)	1.57 (1.24-1.98)
	Pulmonary function test	16.4	20.5	20.7	1.35 (1.10-1.64)	1.23 (0.99-1.52)
	Physician consultation (other than surgeon)	87.4	95.3	96.6	4.30 (3.02-6.13)	4.66 (3.22-6.76)
Perioperative	Arterial line	25.8	39.7	62.1	4.50 (3.81-5.33)	3.73 (3.11-4.46)
	Central venous catheter	28.4	36.8	48.9	2.39 (2.03-2.81)	1.77 (1.48-2.12)
	Pulmonary artery catheter	7.3	9.8	12.9	1.84 (1.41-2.39)	1.73 (1.31-2.30)
	Epidural anesthesia	22.2	30.9	40.9	2.40 (2.03-2.85)	1.85 (1.55-2.21)
	Frozen section	48.3	62.7	74.2	3.02 (2.55-3.57)	2.30 (1.91-2.77)
	G-tube placement	6.4	6.9	17.6	3.18 (2.46-4.13)	2.46 (1.86-3.26)
	Total parenteral nutrition	3.7	4.9	4.4	1.25 (0.84-1.86)	0.84 (0.56-1.27)
	Transfusion	24.1	23.1	21.8	0.86 (0.71-1.03)	0.73 (0.60-0.88)
	Critical care consult	10.9	10.3	12.9	1.20 (0.94-1.52)	1.00 (0.78-1.23)
	Consult (other than critical care)	52.5	57.2	59.9	1.37 (1.17-1.60)	1.27 (1.07-1.51)

Table 3

Differences in cystectomy-specific process of care use across hospital volume strata occurring before, during and after cystectomy for bladder cancer.

					High vs. Low Odds Ratio (95% confidence Interval)	
Timing of Process	**Process of Care**	**Low Volume (%)**	**Medium Volume (%)**	**High Volume (%)**	**Unadjusted**	**Adjusted for Patient**
Preoperative	Transurethral resection (within 2 months)	50.3	59.6	60.2	1.36 (1.16-1.59)	1.23 (1.03-1.47)
	Intravesical Chemotherapy	8.3	9.6	10.1	1.14 (0.88-1.47)	0.87 (0.66-1.16)
	Urinary diversion (ureteral stent)	6.6	6.6	9.6	1.46 (1.11-1.94)	1.33 (0.99-1.79)
Perioperative	Partial cystectomy	34.3	28.5	12.0	0.23 (0.18-0.29)	0.72 (0.46-1.13)
	Lymphadenectomy	46.8	56.1	68.4	2.35 (2.00-2.77)	1.55 (1.28 -1.87)
	Continent diversion	5.6	9.5	23.7	5.02 (3.88-6.49)	4.01 (3.03-5.30)
	Hemodialysis	1.6	0.9	1.5	0.68 (0.36-1.29)	0.77 (0.40-1.48)
	Urinary diversion (ureteral stent)	7.2	7.8	16.1	2.37 (1.84-3.05)	2.00 (1.54-2.59)