Relationship between Patient Safety and Hospital Surgical Volume

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Objective. To examine the relationship between hospital volume and in-hospital adverse events.

Data Sources. Patient safety indicator (PSI) was used to identify hospital-acquired adverse events in the Nationwide Inpatient Sample database in abdominal aortic aneurysm, coronary artery bypass graft, and Roux-en-Y gastric bypass from 2005 to 2008.

Study Design. In this observational study, volume thresholds were defined by mean year-specific terciles. PSI risk-adjusted rates were analyzed by volume tercile for each procedure.

Principal Findings. Overall, hospital volume was inversely related to preventable adverse events. High-volume hospitals had significantly lower risk-adjusted PSI rates compared to lower volume hospitals ($p < .05$).

Conclusion. These data support the relationship between hospital volume and quality health care delivery in select surgical cases. This study highlights differences between hospital volume and risk-adjusted PSI rates for three common surgical procedures and highlights areas of focus for future studies to identify pathways to reduce hospital-acquired events.

Key Words. Patient safety indicators, adverse events, hospital surgical volume

With the Institute of Medicine's 1999 landmark report, *To Err Is Human* (Kohn, Corrigan, and Donaldson 1999), patient safety became a key component of health care quality. Patient safety is measured by monitoring preventable adverse events (PAEs), which are injuries caused by medical management rather than by the underlying disease of the patient (Brennan et al. 2004). Numerous studies have shown an association between PAE and increased mortality, length of stay, and readmissions (Zhan and Miller 2003; Rivard et al. 2008; Friedman et al. 2009). To monitor PAE in hospitals, the Agency for Healthcare Research and Quality (AHRQ) established a set of

patient safety indicators (PSIs) to identify populations at risk and potential cases using administrative inpatient databases. Patient safety indicators are based on ICD-9-CM and codes and diagnosis-related groups (DRGs) and each PSI has specific inclusion and exclusion criteria (McDonald 2002; Romano et al. 2003; Agency for Healthcare Research and Quality 2003a). These data are used for hypothesis generation and give insight to areas in need of focused quality improvement efforts.

Hospitals performing higher numbers of certain surgical operations have demonstrated significantly lower operative mortality and morbidity, presumably through increased experience and selective referral patterns (Luft, Hunt, and Maerki 1987; Dudley et al. 2000; Birkmeyer et al. 2002). Specifically, evidence supports a sizable volume-outcomes relationship in abdominal aortic aneurysm (AAA) repair (Birkmeyer, Finlayson, and Birkmeyer 2001; Birkmeyer et al. 2002), coronary artery bypass graft (CABG) (Birkmeyer, Finlayson, and Birkmeyer 2001; Adogwa et al. 2009), and Roux-en-Y gastric bypass (RNYGB) (Nguyen et al. 2004; Alami et al. 2005). The Leapfrog Group, a consortium of health care purchasers and providers, estimates that performing all of these procedures at high-volume hospitals would save thousands of lives a year (Birkmeyer, Finlayson, and Birkmeyer 2001; Allareddy, Ward, and Konety 2010).

While the surgical volume-mortality association is well supported for certain high-risk procedures, little is known about the relationship between hospital volume and adverse events. The primary aim of this study is to examine the association between hospital volume and quality health care delivery, using surgical adverse events as a measure of quality.

METHODS

Data Source

Data were collected from the Nationwide Inpatient Sample (NIS) discharge database from 2005 through 2008, the years available for which PSI coding is

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valid. NIS is a nationally representative sample, the largest publicly available, all-payer, inpatient database in the United States (Healthcare Cost and Utilization Project [HCUP] 2007).

Study Sample

Abdominal aortic aneurysm, CABG, and RNYGB procedures were included in the analysis, as they have a sizable volume-outcomes relationship, established hospital volume standards from the Leapfrog Group, large enough cohorts to detect adverse events, and represent a variety of major surgical fields (Birkmeyer et al. 2002). Patients were identified using ICD-9-CM procedure codes indicating AAA (38.44, 39.71), CABG (36.10–36.16), or RNYGB (44.31, 44.39, 44.38). Patients under the age of 18 were excluded from the analyses. RNYGB patients were restricted to patients with an obesity diagnosis-related group (DRG) code 288 and excluded patients with malignant neoplasm of digestive organs or peritoneum (ICD-9-CM 150-159).

Volume Measures

To assess variation in quality, each procedure cohort was divided into three groups: high-volume, mid-volume, or low-volume hospital. Procedure volume thresholds were based on the total number of each type of procedure performed at a given hospital (hospital volume) within a calendar year. Volume terciles were defined as the average terciles across the 4-year study period: AAA (<28, 28–61, >61), CABG (<245, 245–1,042, >1,042), and RNYGB (<89, 89–222, >222).

Patient Safety Indicators

The PSIs are a set of indicators providing information on potential inpatient PAEs following surgeries, medical procedures, and childbirth (Agency for Healthcare Research and Quality 2003a). The *PSI* software (version 4.1b, Bethesda, MD, USA) was used to analyze PAEs from 2005 to 2008 using Statistical Analysis Systems (*SAS*; SAS Institute Inc., Cary, NC, USA) software (Agency for Healthcare Research and Quality 2003b). New to this version of the *PSI* software are imputed present on admission (POA) data based on patient characteristics and secondary diagnoses, increasing the positive

predicted value for many PSIs, a problem previously noted in validation studies (Romano et al. 2009; Kaafarani et al. 2010). *PSI* software was run separately on each surgical cohort (AAA, CABG, RNYGB) for hospital volume terciles. PSI#2 (Death in Low Mortality DRG), PSI#5 (Foreign Body Left During Procedure), PSI#6 (Iatrogenic Pneumothorax), PSI#8 (Postoperative Hip Fracture), PSI#16 (Transfusion Reaction), and Obstetric PSIs (#18 and #19) were excluded from the analysis due to lack of data in our selected procedures (Appendix).

Statistical Analysis

Sample weights were applied to NIS data to produce nationally representative estimates. Patient and hospital characteristics were compared across hospital-volume strata using Rao-Scott chi-squared for categorical variables and Kruskal-Wallis Test for continuous variables. The Cochran-Armitage trend test was used to analyze outcomes by hospital volume. All point estimates, standard error estimates, and tests of significance accounted for the weighted nature of the data. As the NIS sampling frame changes over time, NIS Trends Supplement data were used to address the sampling changes over the time period (Healthcare Cost and Utilization Project 2008).

The AHRQ *PSI* software flags patient discharges with ICD-9-CM codes corresponding to each PSI, applies external cause of injury codes (e-codes), and calculates crude, estimated, and risk-adjusted incidence rates (Agency for Healthcare Research and Quality 2003b). For this study, we report risk-adjusted rates generated by the *PSI* software, which are adjusted for age, sex, age-sex interactions, DRG, and comorbidities as assessed using the Elixhauser Comorbidity Index (Elixhauser et al. 1998).

All models accounted for the clustered nature, admission within year-specific hospital cluster, of the study sample. Sensitivity analysis was performed to determine the degree our results were dependent on software imputed POA status. All other analyses were performed with *SAS* software 9.2 (SAS Institute Inc.).

RESULTS

Patient and Hospital Characteristics

Between 2005 and 2008, final weighted cohorts consisted of the following: AAA: 182,843; CABG: 1,093,825; and RNYGB: 354,478 discharges.

High-volume hospitals performed 26 percent of AAA, 16 percent of CABG, and 22 percent of RNYGB procedures (Table 1). High-volume patients were more likely to be younger, white, female, and privately insured compared to patients treated in lower volume hospitals, although these differences were negligible. More high-volume hospitals were teaching hospitals compared to low- and mid-volume hospitals. In all procedures, high-volume hospitals had lower risk-adjusted inpatient mortality rates, followed by mid-volume hospitals with low-volume hospitals having the highest risk-adjusted inpatient mortality rates (AAA: 4.39, 4.69, 8.22, $p < .0001$; CABG: 2.45, 2.98, 3.02, $p < .0001$; and RNYGB: 2.66, 0.53, 0.23, $p < .0001$) (Table 1).

Risk-Adjusted PSI Rates

Patient safety indicator risk-adjusted rates per 1,000 admissions from 2005 to 2008 for low-volume terciles were compared across the three surgical procedures (Table 2). Overall, we saw a dose-response effect of volume of outcome. This effect was clear in AAA patients; high-volume hospital patients had lower rates compared to lower volume hospital patients for PSI#7: Central Venous Catheter-related Bloodstream Infections (3.50, 2.85, 1.65; $p < .0001$), PSI#12: Postoperative Deep Vein Thrombosis or Pulmonary Embolism (11.38, 9.75, 9.63; $p < .0001$), and PSI#13: Postoperative Sepsis (14.64, 13.62, 12.48; $p < .0001$). Similarly, there was dose-response effect on outcomes in CABG with high-volume hospital patients having significantly lower rates than lower volume hospitals for PSI#4: Death Among Surgical Inpatients (Failure to Rescue) (131.54, 131.15, 111.02; $p < .0001$), PSI#7: Central Venous Catheter-related Bloodstream Infections (1.57, 1.45, 0.95; $p < .0001$), PSI#9: Postoperative Hemorrhage or Hematoma (2.83, 2.49, 2.35; $p < .0001$), PSI#11: Postoperative Respiratory Failure (125.23, 76.09, 59.25; $p < .0001$), PSI#13: Postoperative Sepsis (9.41, 9.16, 6.55; $p = .0010$), and PSI#15: Accidental Puncture and Laceration (2.93, 2.65, 2.12; $p < .0001$). In RNYGB, all PSIs had statistically lower risk-adjusted rates in the high-volume hospitals compared to patients in lower volume hospitals with the exception of PSI#13: Postoperative Sepsis, where mid-volume hospitals had lower rates than patients at high-volume hospitals (19.43, 16.05, 17.75; $p < .0001$).

The importance of hospital volume on absolute differences of having any adverse event, as detected by the *PSI* software, varied according to type of procedure (Figure 1). In RNYGB patients, low-volume hospitals had four times more patients with an adverse events compared to high-volume

Table 1: Patient Characteristics by Procedure and Hospital Volume from 2005 to 2008

Volume	CABG				RNYGB				AAA			
	Low < 245	Mid 245–1,042	High > 1,042	p-Value	Low < 89	Mid 89–222	High > 222	p-Value	Low < 28	Mid 28–61	High > 61	p-Value
N(%)	491,428 (45%)	426,355 (39%)	176,042 (16%)		101,548 (29%)	174,830 (49%)	78,100 (22%)		53,642 (29%)	81,882 (45%)	47,319 (26%)	
Mean age (years)	66.08	66.16	65.67	<.0001	48.21	44.21	43.69	<.0001	72.11	72.39	72.12	.4597
Female (%)	28.18	28.85	28.91	.0016	73.29	79.43	80.13	<.0001	21.46	20.83	21.90	.1120
White* (%)	78.30	84.44	81.51	<.0001	74.63	73.29	76.10	<.0001	85.39	89.78	89.78	<.0001
Private insurance (%)	33.92	34.25	36.04	<.0001	62.23	71.10	77.95	<.0001	19.17	19.74	20.97	.0045
Teaching hospital (%)	45.29	64.04	79.94	<.0001	43.46	56.58	56.69	<.0001	34.21	60.93	78.37	<.0001
Risk-adjusted inpatient mortality (%)	3.02	2.98	2.45	<.0001	2.66	0.53	0.23	<.0001	8.22	4.69	4.39	<.0001
LOS (days)	9.93	10.10	10.07	.2096	7.66	3.58	2.84	<.0001	6.97	6.14	6.58	<.0001
Total charges (\$1,000)	129.98	110.84	101.07	<.0001	62.97	44.49	38.56	<.0001	93.83	87.91	93.85	<.0001

Notes. *The race variable is missing in ~25% of the patient records; inpatient mortality is adjusted for age, gender, race, payer, and patient comorbidity.
AAA, abdominal aortic aneurysm; CABG, coronary artery bypass graft; RNYGB, Roux-en-Y gastric bypass.

Table 2: Risk-Adjusted PSI Rates per 1,000 Admissions from 2005 to 2008 for High-Volume and Low-Volume Hospitals in AAA, CABG, and RNYGB Patients

Procedure		PSI	Low Volume	Mid Volume	High Volume	p-Value
AAA	3: Pressure Ulcer		12.18	8.56	12.26	.3103
	4: Failure to Rescue		118.46	121.61	120.86	.1181
	7: Blood-stream Infections		3.50	2.85	1.65	<.0001
	9: PO Hemorrhage or Hematoma		3.32	3.41	3.59	.2573
	11: PO Respiratory Failure		45.47	22.67	40.06	.0600
	12: PO PE/DVT		11.38	9.75	9.63	.0006
	13: PO Sepsis		14.64	13.62	12.48	.0010
	14: PO Wound Dehiscence		5.09	3.13	3.14	<.0001
	15: Accidental Puncture or Laceration		3.54	3.96	3.66	.0233
CABG	3: Pressure Ulcer		9.62	8.16	12.23	.0150
	4: Failure to Rescue		131.54	131.15	111.02	.0405
	7: Blood-stream Infections		1.57	1.45	0.95	<.0001
	9: PO Hemorrhage or Hematoma		2.83	2.49	2.35	.0157
	11: PO Respiratory Failure		125.23	76.09	59.25	<.0001
	12: PO PE/DVT		8.35	9.48	9.40	<.0001
	13: PO Sepsis		9.41	9.16	6.55	<.0001
	14: PO Wound Dehiscence		0.94	3.51	2.91	<.0001
	15: Accidental Puncture or Laceration		2.93	2.65	2.12	<.0001
RNYGB	3: Pressure Ulcer		15.12	14.20	7.92	<.0001
	4: Failure to Rescue		160.41	118.78	101.70	<.0001
	7: Blood-stream Infections		2.88	0.74	0.34	<.0001
	9: PO Hemorrhage or Hematoma		2.93	2.67	1.69	<.0001
	11: PO Respiratory Failure		11.51	9.60	3.81	<.0001
	12: PO PE/DVT		14.35	9.27	7.87	<.0001
	13: PO Sepsis		19.43	16.05	17.75	.0875
	14: PO Wound Dehiscence		2.06	1.66	0.49	<.0001
	15: Accidental Puncture or Laceration		4.40	3.76	3.36	<.0001

Notes. Bold indicates statistical significance at $p < .05$.
 AAA, abdominal aortic aneurysm; CABG, coronary artery bypass graft; DVT, deep vein thrombosis; PE, pulmonary embolism; PO, postoperative; PSI, patient safety information; RNYGB, Roux-en-Y gastric bypass.

hospitals (6.1 percent versus 2.1 percent). Relatively large differences in the number of patients with adverse events by hospital volume also existed for AAA patients (8.8 versus 7.2). Although present, this difference was less pronounced for CABG patients (4.4 versus 4.1) (Figure 1).

Results did not change significantly on sensitivity analysis, when the *PSI* software was run without the imputation of POA. While the overall numbers of identified events did increase for those PSIs that use POA

Figure 1: Percentage of Patients with One or More Patient Safety Indicator (PSI) (2005–2008), According to Tercile of Total Hospital Volume for Abdominal Aortic Aneurysm (AAA), Roux-en-Y Gastric Bypass (RNYGB), and Coronary Artery Bypass Graft (CABG)

Notes. $p < .0001$ for all procedures. Values above the bars are the percent of patients with one or more PSI.

information, the dose–response effect of volume on outcome did not change for these PSIs.

DISCUSSION

Our analysis of hospital volume confirms previous findings (Birkmeyer, Finlayson, and Birkmeyer 2001; Birkmeyer et al. 2002) and provides further evidence that high-volume hospitals have superior risk-adjusted in-patient mortality rates and less resource utilization on the basis of length of stay (LOS) and total charges. The superior outcomes demonstrated with high-volume hospitals for high-risk procedures have led to a Leapfrog Initiative for Evidence-Based Hospital Referral (Dudley et al. 2000; Halm, Lee, and Chassin 2002; Birkmeyer and Dimick 2004). The current study provides the first evidence for the relationship between quality indicators and hospital volume.

Surgically related PSI events were analyzed from 2005 to 2008 in AAA, CABG, and RNYGB patients between high-, mid-, and low-volume hospitals to study the effect of hospital volume on the incidence of PAE measured through AHRQ's PSIs. Our dataset is large and generalizable,

allowing us to examine the association of adverse events and hospital volume. Evidence-based quality indicators, such as AHRQ's PSIs, have become a standard way to measure potential lapses of quality in health care systems and are one of the most widely used surgical quality-benchmarking tools (Agency for Healthcare Research and Quality 2003a). Screening administrative and clinical data using the *PSI* software for potentially PAE is a universally replicable method of identifying likely lapses in patient safety (Quan et al. 2008; Drosler et al. 2009). PSIs are used in local dashboards and at the national level, including the federal government's annual report on hospital performance, *The National Healthcare Quality Report* (Agency for Healthcare Research and Quality 2007). The Center for Medicare and Medicaid Services (CMS) uses PSIs in their Hospital Compare Program and the National Quality Forum endorses PSIs for benchmarking measures (Agency for Healthcare Research and Quality 2007; National Quality Forum 2010).

Our analyses found an overall inverse relationship between hospital-volume and patient safety events, where higher volume resulted in lower adverse events as measured by PSIs for three major surgical procedure cohorts. These results indicate that the volume-outcome relationship is dose dependent for both RNYGB and AAA. The same volume-outcome relationship is not as clearly shown for CABG. Both RNYGB and AAA are incorporating new technologies (laparoscopy and endovascular stenting) where volume experience may be best demonstrated. CABG represents a well-established procedure with a long history of quality improvement efforts in this field. The maturation of both the CABG procedure and quality improvement efforts in cardio-thoracic surgery may blunt the volume-outcome effect more clearly seen in RNYGB and AAA. Adoption and dissemination of new technology will better reveal a volume-outcome effect. In addition, the strongest relationship, found in RNYGB patients, might be the result of the Centers of Excellence (COE) movement as mandated by the Centers for Medicare and Medicaid Services, which is based on volume. COE have demonstrated improved patient outcomes and increased laparoscopic approach, which is known to decrease adverse events (Nguyen et al. 2004; Hollenbeak et al. 2008). As shown in previous studies (Billingsley et al. 2007; Smith et al. 2007), our data did not show a relationship between Death Among Surgical Inpatients (Failure to Rescue) and hospital volume for AAA and CABG. However, we saw a strong relationship between hospital volume and Death Among Surgical Inpatients (Failure to Rescue) in RNYGB

patients, possibly due to COE. These findings have broad implications for public policy and warrant further investigation into the causality of these relationships.

Limitations

This study has several limitations. First, we identified adverse events using administrative data, which results in some miscoded events and incomplete risk adjustment due to ICD-9 coding limitations and completeness for secondary diagnoses (Iezzoni et al. 1994; Romano et al. 2003, 2009). Although principal diagnosis is frequently accurately coded in administrative data, secondary or comorbid diagnoses are often underreported. Using administrative data, we are unable to control for the increasing number of ICD-9-CM diagnosis per patient due to potentially increased rates of reporting. However, this is indirectly controlled for in the software using the Elixhauser method of comorbidity adjustment.

Another concern is over-reporting of PAE due to the possibility of including POA conditions (Bahl et al. 2008). Certain PSIs are greatly influenced by the inclusion of POA information and the validity of these rates is questionable in the absence of POA codes (Houchens, Elixhauser, and Romano 2008; Henderson et al. 2009; Romano et al. 2009). However, *PSI* software now imputes POA data and therefore false-positives should be less of a concern. Despite these limitations, PSIs are used for safety monitoring across the nation.

While surgical volume is only a surrogate marker for structures and processes that lead to better health care quality and patient safety, it remains a valuable starting point for surgical quality improvement. Lower mortality and adverse events at high-volume hospitals is likely dependent on a multitude of factors, including patient selection, technical skill, anesthesia support, and postoperative care. The quality of care rendered on the basis of volume is likely a continuum and not simply a threshold number (Christian et al. 2003). More research in the nascent field of quality improvement and patient safety is required for better understanding of the specific drivers of the volume-outcome relationship.

CONCLUSIONS

Further examination of structural and process differences between outcomes and hospital volume will help identify means of closing the quality gap.

Research in this area will elucidate specific areas for improvement in low-volume hospitals with the ultimate goal of improving mortality, morbidity, and overall health care quality associated with high-risk surgical procedures. Further research is needed to better understand the underlying mechanisms resulting in comparatively higher rates of adverse events at hospitals performing at lower volumes.

ACKNOWLEDGMENTS

Joint Acknowledgment/Disclosure Statement: Tina Hernandez-Boussard was supported by grant number K01HS018558 from the Agency for Healthcare Research and Quality. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

Disclosures: None.

Disclaimers: None.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Appendix: AHRQ's PSI Definitions Used for Analysis (Agency for Healthcare Research and Quality 2003a).

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