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Contemporary Improvements in Postoperative Mortality After Major Cancer Surgery are Associated with Weakening of the Volume-Outcome Association

Nabil Wasif, MD, MPH[1,2], David Etzioni, MD, MS[2,3], Elizabeth B. Habermann, MPH, PhD[2], Amit Mathur, MD, MS[2,4], and Yu-Hui Chang, PhD[2,5]

[1]Department of Surgery, Division of Surgical Oncology, Mayo Clinic Arizona, Phoenix, AZ; [2]Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Surgical Outcomes Program, Mayo Clinic Rochester, Rochester; [3]Department of Surgery, Division of Colorectal Surgery, Mayo Clinic Arizona, Phoenix, AZ; [4]Department of Surgery, Division of Transplant Surgery, Mayo Clinic Arizona, Phoenix, AZ; [5]Department of Biostatistics, Mayo Clinic Arizona, Phoenix, AZ

ABSTRACT

Background. Regionalization of complex visceral surgery across the United States has followed identification of a volume-outcome association. However, improvements in postoperative mortality overall during the last decade may have weakened the strength of this association.

Methods. The National Cancer Database was used to identify patients undergoing colon, esophageal, liver, and pancreatic surgery from 2003 to 2011. Hospitals were divided into low-volume (< 33rd %tile), medium-volume (34–66th %tile), and high-volume (> 67th %tile) groups. Annual cancer-specific adjusted observed versus expected (O/E) ratios for 30- and 90-day mortality for each volume strata were calculated and plotted over time.

Results. In the year 2003, the O/E ratios decreased from low- to medium- to high-volume hospitals for all cancer surgeries for both 30- and 90-day mortality, indicating a strong volume-outcome relationship. For all volume strata, the O/E ratios trended downward from 2003 to 2011 for both 30- and 90-day mortality for all cancer surgeries. This trend was more pronounced for low- and medium-volume than for high-volume hospitals. Consequently, by 2011 the confidence intervals of the O/E ratios for the low-volume groups, and particularly for the medium-volume groups, overlapped those for the high-volume groups for most of the cancer surgeries studied.

Conclusions. The volume-outcome association for major cancer surgery is dynamic and has attenuated over time primarily due to improvements in postoperative mortality at low- and medium-volume hospitals.

The "Take-the-Volume Pledge" was issued by surgical thought leaders at three major academic teaching hospitals in 2015.[1] This initiative aims to encourage voluntary restriction of surgical procedures to hospitals and surgeons who meet a minimum threshold of average annual case volume for that particular procedure. The underpinning of this proposal is evidence accumulated during the last two decades that clearly demonstrates an association between higher surgical case volumes and lower postoperative mortality.[2,3] The procedures included have an established volume-outcome association, and thresholds in the pledge were set to weed out the very low-volume hospitals or "hobbyist" surgeons. The Leapfrog group, a consortium of health care purchasers and providers and a well-known promoter of volume-based referrals endorsed these recommendations.[4]

Although the motivation behind the pledge was sound, widespread adaptation in the surgical community was not seen. Several issues were raised, including discounting of past surgeon experience and fellowship training, disparities

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N. Wasif, MD, MPH
e-mail: wasif.nabil@mayo.edu

in access to high-volume centers, inability of regional centers to absorb all volume-based referrals, and potential fragmentation of care.[5–8] Other studies demonstrated that only 32% to 67% of the decline in postoperative mortality was associated with hospital volume and that most of the generalized decrease in mortality was secondary to improvements within, and not between, volume categories.[9] This suggests that other health care trends, primarily improvements in surgical quality and perioperative care, also were drivers of lower mortality rates.[10]

Work by our group used data from the National Inpatient Sample to show that the difference in adjusted in-hospital mortality rates between low-, medium-, and high-volume hospitals decreased for five of the six procedures studied from 2003 to 2011, suggesting "attenuation" of the volume-outcome relationship with time.[11]

What are the implications for the volume pledge if the volume-outcome associations underlying these thresholds are not fixed but dynamic? This study aimed to examine temporal trends in 30- and 90-day postoperative mortality and to determine how this influences the volume-outcome association with time. We hypothesized that declining postoperative mortality, especially in low- and medium-volume hospitals compared with high-volume hospitals, has weakened the volume-outcome association for the procedures studied.

METHODS

Data Source

Data from the National Cancer Data Base (NCDB) were used in this study. The NCDB, a joint program of the Commission on Cancer of the American College of Surgeons and the American Cancer Society, is a nationwide oncology outcomes database for more than 1500 Commission on Cancer-accredited cancer programs in the United States and Puerto Rico. Approximately 70% of all cases comprising newly diagnosed cancer in the United States are captured at the institutional level and reported to the NCDB.

Variables in the database cover demographics, socioeconomic status, tumor stage, treatment received, and hospital characteristics. A Participant Use File (PUF) for the purpose of this study was approved by the NCDB personnel. The NCDB data contain no protected health information, so this study was deemed exempt from formal institutional review board review.

Inclusion and Exclusion Criteria

Patients undergoing colon, esophageal, liver, and pancreatic surgery from 2003 to 2011 were identified in the NCDB. These surgeries were selected primarily because a robust volume-outcome association has been demonstrated for each of these procedures. Patients with either clinical or pathologic metastatic disease and those who did not undergo curative intent surgery of the primary lesion were excluded. Variables with missing data are indicated in Table 1. Sensitivity analyses showed that this did not significantly alter any of the results because for all the variables included, the rate of missing data was lower than 6%.

Volume Calculation

Hospital volume was calculated according to the method proposed by Birkmeyer et al.[12] The hospitals were ranked in order of increasing average annual hospital volume, and then cutoffs for volume were established dividing the number of patients into three volume groups: low (< 33th %tile), medium (34–67th %tile), and high (> 68th %tile). All cutoffs were established a priori and chosen based on prior studies in the field. The cutoffs also were chosen to allow adequate power in each volume group for robust analyses. Only patients who had surgery at the reporting hospital were included to allow for appropriate volume calculations.

Due to an increase in the overall number of procedures performed during the time of the study, likely due to an aging population, volume thresholds could potentially change from year to year. To control for this possibility, the aforementioned cutoffs were calculated annually and not by averaging volume across the duration of the study. Consequently, even if a hospital increased the number of cases from one year to another, it would still be characterized as low-, medium-, or high-volume relative to the case volume of other hospitals in that particular year.

It is important to note that cancer-specific volume thresholds were calculated (i.e., for each hospital, different volume thresholds were applied for colon vs pancreatic cancer). This meant that a particular hospital could be high-volume for a particular type of surgical resection, (e.g., colon cancer), yet be classified as low-volume for another type (e.g., pancreatic resection). The cancer- and year-specific case number thresholds for low-, medium-, and high-volume hospitals are presented in Table S1.

Risk Adjustment

The observed (O) and expected (E) number of deaths 30 and 90 days after surgery were computed to generate O/E ratios for each hospital annually. The use of O/E ratios as a form of risk adjustment for quality measurement is endorsed by the Agency for Healthcare Research and Quality (AHRQ) and have been used extensively for the

TABLE 1 Descriptive statistics

	Colon (n = 303,445) n (%)	Esophagus (n = 17,617) n (%)	Liver (n = 13,918) n (%)	Pancreas (n = 22,867) n (%)
30-Day mortality	10,012 (3.4)	740 (4.3)	612 (4.4)	816 (3.6)
90-Day mortality	16,560 (5.6)	1533 (8.9)	1051 (7.7)	1615 (7.2)
Volume				
Low	101,123 (33.3)	5898 (33.5)	4511 (32.4)	7705 (33.7)
Medium	101,214 (33.4)	5873 (33.3)	4788 (34.4)	7553 (33.0)
High	101,108 (33.3)	5846 (33.2)	4619 (33.2)	7609 (33.3)
Age (years)				
< 50	28,400 (9.4)	1922 (10.9)	2055 (14.8)	1826 (8.0)
50–64	85,361 (28.1)	8306 (47.1)	7860 (56.5)	8570 (37.5)
65–79	118,464 (39.0)	6766 (38.4)	3545 (25.5)	10493 (45.9)
80+	71,220 (23.5)	623 (3.5)	458 (3.3)	1978 (8.7)
Male	142,874 (47.1)	14,738 (83.7)	10,278 (73.8)	11,559 (50.5)
Race				
White	253,733 (83.6)	16,128 (91.5)	10,336 (74.3)	19,623 (85.8)
Black	36,268 (12.0)	893 (5.1)	1635 (11.7)	2221 (9.7)
Others	13,444 (4.4)	596 (3.4)	1947 (14.0)	1023 (4.5)
Charlson-Deyo score				
0	211,775 (69.8)	12,994 (73.8)	6252 (44.9)	15,673 (68.5)
1	67,307 (22.2)	3746 (21.3)	4149 (29.8)	5732 (25.1)
2+	24,363 (8.0)	87,7 (5.0)	3517 (25.3)	1462 (6.4)
Metro/urban/rural				
Missing	11,963	832	641	1224
Metro	244,182 (83.8)	13,019 (77.6)	11,269 (84.9)	17,576 (81.2)
Urban	41,188 (14.1)	3332 (19.9)	1811 (13.6)	3616 (16.7)
Rural	6112 (2.1)	434 (2.6)	197 (1.5)	451 (2.1)
Insurance				
Missing	5489	493	424	564
No insurance	8887 (3.0)	398 (2.3)	324 (2.4)	651 (2.9)
Private/managed care	105,980 (35.6)	8601 (50.2)	6850 (50.8)	9247 (41.5)
Medicaid	10,687 (3.6)	929 (5.4)	1443 (10.7)	1021 (4.6)
Medicare/other government	172,402 (57.9)	7196 (42.0)	4877 (36.1)	11,384 (51.0)
Income				
Missing	12,291	818	647	1274
< $30,000	41,046 (14.1)	2003 (11.9)	2012 (15.2)	2838 (13.1)
$30,000–$45,999	134,486 (46.2)	8228 (49.0)	5982 (45.1)	9841 (45.6)
$46,000+	115,622 (39.7)	6568 (39.1)	5277 (39.8)	8914 (41.3)
Education				
Missing	12,314	820	648	1274
29%+	50,776 (17.4)	2352 (14.0)	2640 (19.9)	3422 (15.8)
14 –28.9%	137,098 (47.1)	8396 (50.0)	6211 (46.8)	10,159 (47.0)
< 14%	103,257 (35.5)	6049 (36.0)	4419 (33.3)	8012 (37.1)
Facility type				
Community/comprehensive community cancer program	226,010 (74.5)	8217 (46.6)	3038 (21.8)	9635 (42.1)
Academic/research program	77,077 (25.4)	9370 (53.2)	10,879 (78.2)	13,199 (57.7)
Other types of cancer program	358 (0.1)	30 (0.2)	1 (0.0)	33 (0.1)

American College of Surgeons National Surgical Quality Improvement Program (NSQIP).[13] An O/E ratio higher than 1 suggests worse-than-expected and an A/E lower than 1 suggests better-than-expected outcomes.

The expected number of deaths were calculated using generalized estimating equations with age, sex, race, urban versus rural, modified Charlson comorbidity score, insurance status, zip code-level household median income, and zip code-level education level as independent variables.

In addition, the study also controlled for the relevant type of surgery (e.g., distal pancreatectomy vs pancreaticoduodenectomy). The study accounted for the clustering effect by the use of an exchangeable working correlation structure. An O/E ratio then was computed for each hospital. Bootstrapping was used to calculate mean annual O/E ratios with 95% confidence intervals for each volume strata: low-, medium-, and high-volume hospitals.

Generalized Poisson mixed regression was used to model O/E ratios over time across each volume strata. For hospitals in low-, medium-, and high-volume groups, we computed the mean adjusted O/E over time and the mean differences compared with hospitals in the high-volume group in the adjusted O/E. The statistical inference for the mean difference was estimated using the delta method.[14] A p value lower than 0.05 was set as our threshold for statistical significance, and 95% confidence intervals were used unless otherwise indicated. The analysis was performed using SAS 9.4 (SAS, Cary, NC) and R 3.1.3 (The R Foundation).

RESULTS

Demographics (Table 1)

Our study population comprised 357,847 patients with colon (85%), esophageal (5%), liver (4%), and pancreatic (6%) cancer. The most common age was 65 to 79 years for the patients with colon and pancreatic cancer and 50 to 64 years for the patients with esophageal and liver cancer. The majority of the patients with esophageal (53%), liver (78%), and pancreatic (58%) cancer underwent surgery at a hospital classified by the Commission on Cancer (CoC) as having an academic/research program, whereas 75% of the patients with colon cancer had surgery in a community cancer program. The unadjusted 30-day mortality rate ranged from 3.4% for colon surgery to 4.4% for liver surgery, and the 90-day mortality rate ranged from 5.6% for colon surgery to 8.9% for esophagectomy.

30-Day Mortality

The adjusted O/E ratios with 95% confidence intervals for 30-day mortality in 2003 and 2011 for colon, esophageal, liver, and pancreatic resections are presented in Table 2. In general, two trends can be seen represented in this data. For both the years 2003 and 2011, the O/E ratio decreased from low- to medium- to high-volume hospitals for all cancer surgeries, indicating a volume-outcome relationship. Within each volume strata, a decrease in O/E ratios also is seen for each cancer surgery from 2003 to 2011, suggesting an improvement in outcomes over time.

90-Day Mortality

Adjusted O/E ratios with 95% confidence intervals for 90-day mortality in 2003 and 2011 for colon, esophageal, liver, and pancreatic resections are presented in Table 2. The associations seen with 90-day mortality are similar to those seen with 30 day mortality. Not only does the O/E ratio decrease from low- to medium- to high-volume hospitals, but it also decreases within each cancer-specific volume strata from 2003 to 2011.

Trends in O/E Ratios From 2003 to 2011

Figures 1 and 2 demonstrate trends in O/E ratios from 2003 to 2011 for all cancer surgeries stratified by low-, medium-, and high-volume hospital groups. Figure 1 shows trends by 30-day and Fig. 2 by 90-day mortality. In general, for all volume strata, the O/E ratios trend downward from 2003 to 2011 for both 30- and 90-day mortality for all cancer surgeries. This is more pronounced for the low- and medium-volume hospitals, as indicated by the red and green lines, respectively, compared with the high-volume hospitals, as indicated in blue. Consequently, by 2011, the confidence intervals of the O/E ratios for the medium-volume groups overlapped those for the high-volume groups for all of the cancer surgeries studied. More variability in trend also is seen in the low-volume versus the medium- and high-volume hospitals.

Differences in O/E Ratios From 2003 to 2011

For better representation of the attenuation in the volume-outcome relationship observed over time, the difference in the O/E ratios between low-, medium-, and high-volume hospital strata for each cancer surgery type was plotted from 2003 to 2011. As seen in Figs. S1 and S2, the adjusted differences in O/E ratios between low- and high-volume and particularly between medium- and high-volume hospitals attenuated during the period of the study. This is more apparent for esophageal, liver, and pancreatic surgery than for colon surgery.

TABLE 2 Adjusted mean 30- and 90-day observed vs expected (O/E) ratios for mortality

	Low volume		Medium volume		High volume	
	Mean	95% CI	Mean	95% CI	Mean	95% CI
30-Day						
Colon						
2003	1.25	1.13–1.36	1.01	0.90–1.12	1.10	0.98–1.22
2011	0.91	0.81–1.01	0.95	0.85–1.06	0.81	0.71–0.91
Esophagus						
2003	1.22	0.80–1.63	1.55	1.00–2.09	1.23	0.78–1.69
2011	0.95	0.56–1.35	0.99	0.58–1.40	0.75	0.46–1.04
Liver						
2003	2.41	1.59–3.22	1.71	0.91–2.51	1.17	0.60–1.74
2011	1.09	0.58–1.59	0.53	0.21–0.85	0.58	0.34–0.81
Pancreas						
2003	1.33	0.85–1.81	1.29	0.79–1.79	1.09	0.68–1.50
2011	1.01	0.62–1.40	0.79	0.46–1.09	0.65	0.42–0.87
90-Day						
Colon						
2003	1.23	1.14–1.33	1.08	0.99–1.17	1.10	1.00–1.19
2011	0.93	0.85–1.00	0.94	0.85–1.02	0.83	0.75–0.91
Esophagus						
2003	1.21	0.92–1.50	1.46	1.09–1.83	1.29	0.97–1.61
2011	1.04	0.75–1.33	0.92	0.65–1.20	0.83	0.61–1.04
Liver						
2003	1.87	1.31–2.42	1.53	0.95–2.11	1.36	0.88–1.84
2011	0.88	0.53–1.22	0.75	0.45–1.04	0.66	0.47–0.86
Pancreas						
2003	1.47	1.09–1.84	1.19	0.84–1.54	1.06	0.76–1.36
2011	0.81	0.55–1.06	0.86	0.62–1.09	0.70	0.53–0.87

CI confidence interval

Differences in Absolute Adjusted 30- and 90-Day Mortality Rates Stratified by Volume

The absolute differences in mean adjusted 30- and 90-day mortality rates for low- and medium-volume hospitals versus high-volume hospitals also were plotted over time (Fig. 3a, b). Several inferences can be drawn from these figures. For example, the mean mortality at low-, medium-, and high-volume hospitals for colon cancer differed little throughout the period of the study in terms of both 30- and 90-day mortality. In contrast, significant differences were seen for esophageal, liver, and pancreatic resections. These were more pronounced in 2003 and trended downward over time. This narrowing of absolute difference in mortality was more pronounced for low- versus high-volume compared with medium- versus high-volume hospitals.

DISCUSSION

The volume-outcome association for major cancer surgery is dynamic and has weakened over time primarily due to improvements in postoperative mortality at low- and medium-volume hospitals. This study built on previous work by our group using the National Inpatient Sample (NIS) that showed a similar phenomenon using in-hospital mortality as an end point.[11]

Although the NCDB includes only CoC-accredited hospitals, whereas the sampling frame of the NIS is broader and includes community and rural hospitals, the differential improvement in postoperative mortality in low- and medium-volume hospitals compared with high-volume hospitals was seen in both studies. This was observed for all the cancer types studied and for both 30- and 90-day mortality after surgery.

What are the underlying drivers of the temporal trends in lower postoperative mortality seen throughout the volume strata in our study? Although we are unable to

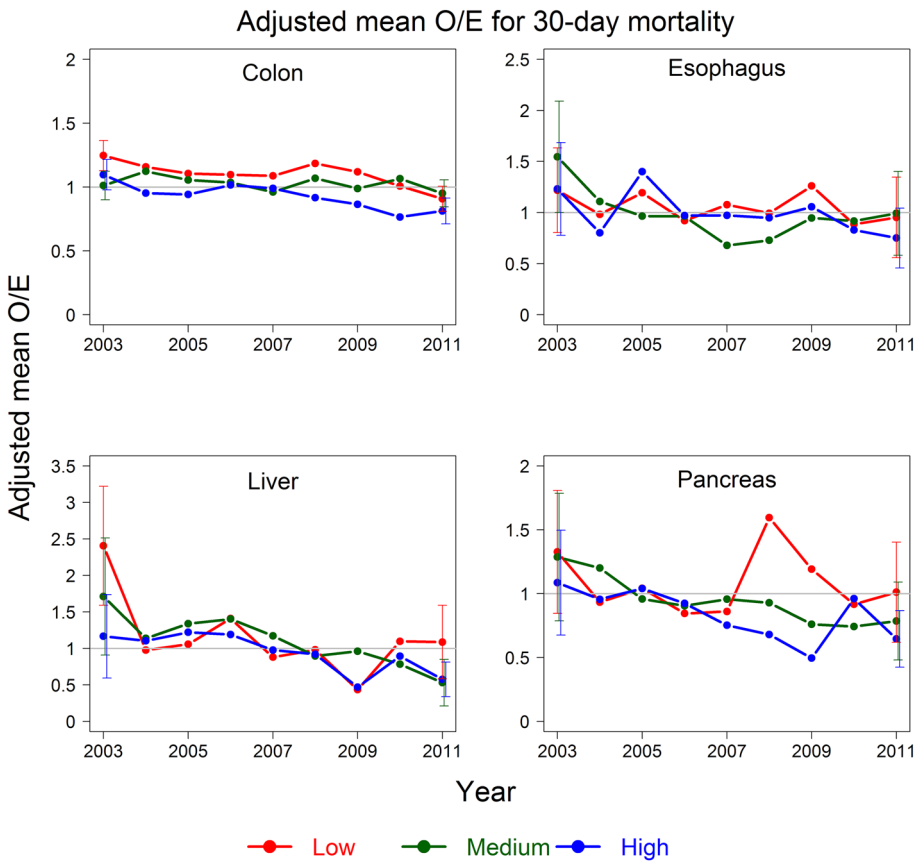

FIG. 1 Time trends of observed vs expected (O/E) ratios for 30-day mortality

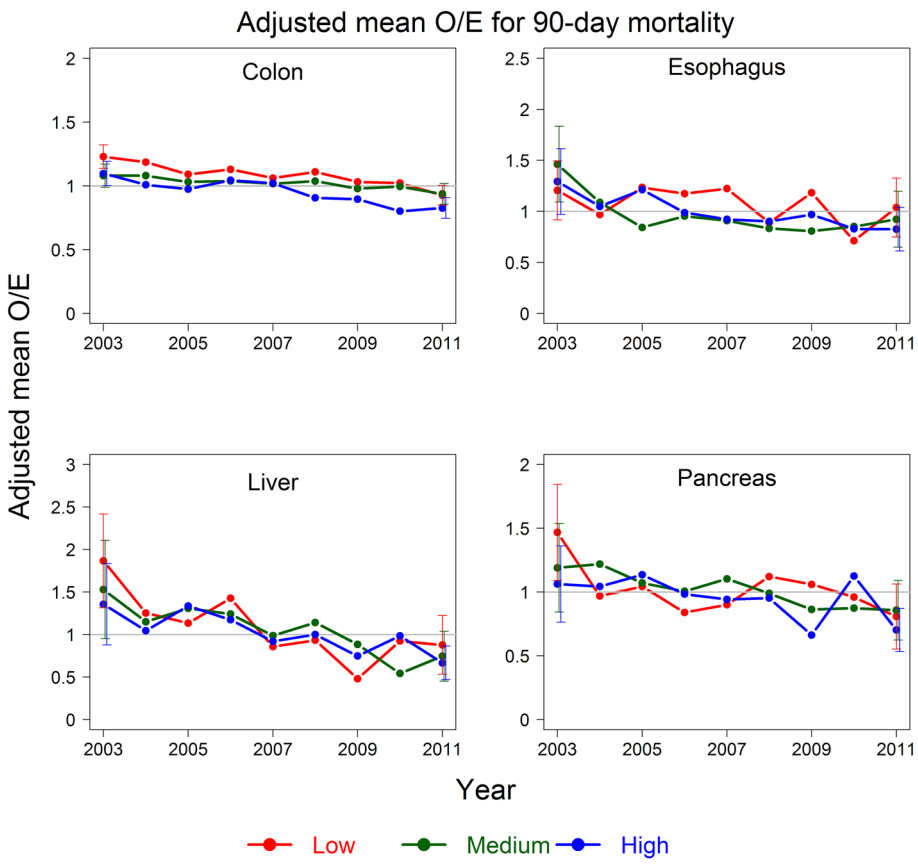

FIG. 2 Time trends of observed vs expected (O/E) ratios for 90-day mortality

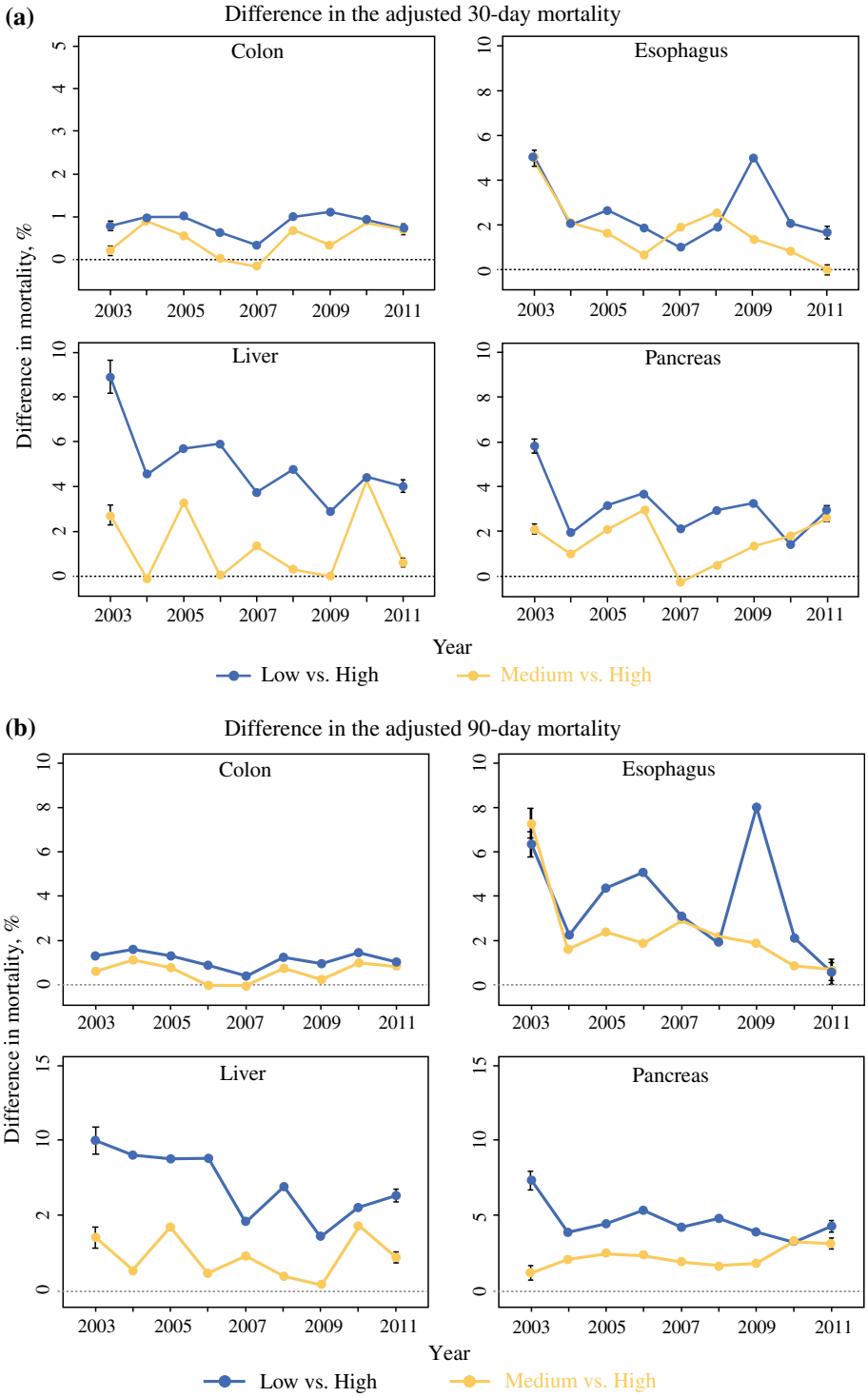

FIG. 3 **a** Difference in absolute adjusted 30-day mortality stratified by volume. **b** Difference in absolute adjusted 90-day mortality stratified by volume

establish any causal associations in this study, several correlations can be made. The period of our study coincided with the quality movement in surgery, as manifested by the National Surgical Quality Improvement Program (NSQIP), public reporting of postoperative mortality rates, and surgical checklists.[10,15,16] Even for hospitals that do not actively participate in quality reporting, a downward trend in postoperative mortality is seen during this period.[17] This may be secondary to a "Hawthorne effect," in which the act of measuring performance itself results in behavior changes leading to immediate meaningful improvements. The differential improvements seen in low-

and medium-volume hospitals likely occur because these hospitals have more room to improve than high-volume hospitals.

Other explanations for the attenuation of the volume-outcome relationship over time may relate to the phenomenon of failure to rescue. Work by Ghaferi et al.[18] demonstrated that for gastric, pancreatic, and esophageal operations, very-low-volume hospitals had only slightly higher complication rates than high-volume hospitals (42.7% vs 38.9%), yet had a markedly higher rate of failure to rescue patients with a complication from mortality (30.3% vs 13.1%). Further work by the group demonstrated that structural hospital characteristics more commonly seen in the lowest-mortality hospitals, such as teaching status, increasing nurse-to-patient ratio, and presence of more than 20 intensive care unit (ICU) beds, were associated with lower failure-to-rescue rates.[19]

Focusing only on low-volume hospitals performing a median of 1 esophagectomy annually, Funk et al.[20] demonstrated that the presence of at least three in five characteristics of a hospital (high nurse ratios, lung transplantation service, complex medical oncology service, bariatric surgery service, and positron emission tomography scanner) was associated with a markedly lower mortality rate than exhibited by hospitals with none of these services (5% vs 12.5%). In aggregate, these studies suggest that low-volume hospitals could improve outcomes by adding structural support to rescue patients from complications that occur at rates similar to those for high-volume hospitals. However, hospital and patient characteristics taken together still explain only 12% to 57% of the variation in failure-to-rescue rates among hospitals, and other factors, such as hospital culture of safety, also are likely responsible.[19]

Our study had several limitations. Administrative data lack clinical granularity and are subject to misclassification bias. Although we used risk adjustment to account for differences in comorbidity (case-mix), surgery type, and socioeconomic factors between high- and low-volume hospitals, the possibility of residual confounding remains. Individual surgeon data are not available in the NCDB, so we were unable to study the influence of surgeon experience separately from institutional volume. The nature of the variables available in the NCDB limited our analyses to quantitative methods. Further research to identify specific hospital structural factors associated with excellent mortality outcomes independent of case volume is needed to isolate the true signal from statistical noise. The use of a qualitative or a mixed-methods approach likely would yield further insight into this topic.

CONCLUSIONS

We believe the reported data can help inform the debate on regionalization sparked by publication of the "Take-the-Volume Pledge" and also can have implications for the use of surgical volume as a stand-alone measure of surgical quality. A volume threshold that appropriately differentiated high- and low-volume hospitals a decade ago may be different today due to the dynamic nature of the volume-outcome relationship.

The pledge itself is based on sound empiric evidence and reasoning. The difficulty arises in knowing how to implement this as policy without restricting access to good-quality care. We believe our data suggest a path forward. Several medium-volume hospitals with lower volume thresholds currently have outcomes comparable with those of high-volume hospitals and also may serve as appropriate referral centers together with high-volume centers.

Setting lower volume thresholds without compromising postoperative outcomes could be the "Goldilocks policy," one that balances practicality with evidence. Further work should focus on defining these thresholds for different complex operations. A commitment to improving postoperative mortality, whether by increasing case volume and improving perioperative care or by establishing a culture of quality, is a pledge to which we all can sign.

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