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Volume and outcomes relationship in laparoscopic diaphragmatic hernia repair

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Abstract
Background There is no published data regarding the relationship between hospital volume and outcomes in patients undergoing laparoscopic diaphragmatic hernia repair. We hypothesize that hospitals performing high case volume have improved outcomes compared to low-volume hospitals.
Materials and methods We reviewed the National Inpatient Sample (NIS) database between 2008 and 2012 for adults with the diagnosis of diaphragmatic hernia who underwent elective laparoscopic repair of diaphragmatic Hernia and/or Nissen fundoplication. Pediatric, emergent, and open cases were excluded. Main outcome measures included logistic regression analysis of factors predictive of in-hospital mortality and outcomes according to annual hospital case volume.
Results A total of 31,228 laparoscopic diaphragmatic hernia operations were analyzed. The overall in-hospital mortality was 0.14%. Risk factors for higher in-hospital mortality included renal failure (AOR: 6.26; 95% CI: 2.48–15.78; $p<0.001$), age>60 years (AOR: 5.06; 95% CI: 2.38–10.76; $p<0.001$), and CHF (AOR: 3.80; 95% CI: 1.39–10.38; $p=0.009$) while an incremental increase in volume of 10 cases/year (AOR: 0.89; 95% CI: 0.81–0.98; $p=0.019$) and diabetes (AOR: 0.34; 95% CI: 0.12–0.93; $p=0.036$) decreases mortality. There was a small but significant inverse relationship between hospital case volume and mortality with a 10% reduction in adjusted odds of in-hospital mortality for every increase in 10 cases per year. Using 10 cases per year as the volume threshold, low-volume hospitals (≤10 cases/year) had almost a twofold higher mortality compared to high-volume hospitals (0.23 vs. 0.12%, respectively, $p=0.02$).
Conclusions There was a small but significant inverse relationship between the hospitals' case volume and mortality in laparoscopic diaphragmatic hernia repair.

Keywords Laparoscopic hiatal hernia · Diaphragmatic hernia · Hospital volume · Outcomes

Diaphragmatic hernias represent a spectrum of disease from small asymptomatic sliding hiatal hernias to giant symptomatic paraesophageal hiatal hernias [1]. Traditionally, repair of these hernias was performed using an open approach either via a laparotomy or thoracotomy; however, laparoscopic repair has been shown to have improved perioperative outcomes and has thus become the preferred approach [1–5]. The laparoscopic approach provides superior visualization of the surgical field compared to the open technique but it is technically challenging and good outcomes are hinged on good surgical technique and the surgeon's experience [2, 6]. Morbidity and mortality rates associated with laparoscopic repair of paraesophageal hernias are relatively low, with previous studies reporting morbidity rates between 4 and 10% and a mortality rate from 0 to 1.7% [3, 4, 6–13].

There is much interest in the relationship between the provider or hospital surgical volume and outcomes for

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complex surgical operations. One of the first studies examining the relationship between hospital volume and surgical outcomes was published in 1979 by Luft et al. [14]. Since that time, there have been numerous studies published on the association between hospital volume and surgical outcomes for complex, high-risk operations [15–21]. The overwhelming majority of these studies have demonstrated that high-volume hospitals have improved outcomes, particularly for high-risk operations. A study by Varban et al. evaluating the effects of hospital volume on the outcomes of patients who underwent laparoscopic Nissen fundoplication for gastroesophageal reflux disease (GERD) found that patients who had surgery performed at low-volume hospitals had three times more accidental perforations than those performed at high-volume hospitals [22]. Another study by Wang et al. evaluated the volume–outcome relationship of laparoscopic Heller myotomy and found that higher volume hospitals had shorter length of stay and lower overall charges, but similar rates of in-hospital mortality [23]. There are currently no studies examining the relationship between hospital volume and outcomes in laparoscopic diaphragmatic hernia repair. Unlike laparoscopic antireflux surgery for GERD, laparoscopic diaphragmatic hernia repair is a higher complexity operation that can be associated with higher risk for morbidity. The aim of this study was to examine the effect of hospital volume on outcomes in patients who underwent laparoscopic diaphragmatic hernia repair using a large national database.

Methods

Database

The National Inpatient Sample (NIS) database is the largest inpatient care database in the United States. Approximately, 1000 hospitals contribute data annually to the NIS, resulting in a database of information from nearly eight million hospital stays each year [24]. The NIS comprises a nationally representative sample of approximately 20% of U.S. hospital discharges, resulting in a sampling frame that comprises approximately 96% of all hospital discharges in the United States. Data elements within the NIS are drawn from hospital discharge abstracts that allow determination of all procedures performed during a given hospital admission. It also contains discharge information on inpatient hospital stay including patient characteristics, length of stay, specific post-operative morbidity, and in-hospital mortality. The NIS database has no information available on complications occurring after discharge. Approval for use of the NIS patient-level data in this study was obtained from the Human Research Protection (HRP) of the University of California, Irvine Medical Center and the NIS.

Selection and description of participants

The 2008–2012 NIS databases were retrospectively reviewed for adult patients with the diagnosis of diaphragmatic hernia (ICD-9 diagnosis code 5533) who underwent elective laparoscopic repair of a diaphragmatic hernia (ICD-9 Procedure Code 5371) and/or Nissen fundoplication (ICD-9 Procedure Code 4467). Pediatric, emergent, and open cases were excluded.

Demographics and outcome variables

Patient characteristics (age, gender, race, and payer type), hospital characteristics (teaching status, size, and location) and comorbidities (congestive heart failure, chronic lung disease, diabetes, hypertension, liver disease, peripheral vascular disease, and renal failure) were evaluated according to annual hospital case volume. Hospitals were considered high-volume if they performed more than ten diaphragmatic hernia repairs/Nissen fundoplications per year; this threshold is in line with a previously published study [22]. Primary endpoint was to examine factors predictive of in-hospital mortality using multiple logistic regression including age, gender, specific comorbidities, and incremental case volume increase of ten cases. Secondary endpoint was to examine the in-hospital mortality, serious morbidity and length of hospital stay according to annual hospital case volume. Serious morbidity was defined as a patient having one of the following postoperative inpatient complications: abscess, sepsis, leak/perforation, pneumonia, pulmonary abscess/empyema, respiratory failure, acute renal failure, cardiac complications, stroke/CVA, deep vein thrombosis (DVT), or bleeding.

Statistical analysis

All statistical analyses were conducted using the statistical analysis system (SAS), version 9.3 and the R Statistical Environment. Chi-square with Yate's correction (categorical variables) and t-test with unequal variance (continuous variables) were used for univariate analysis. Multivariate logistic regression was used to determine factors predictive of in-hospital mortality. Estimates of adjusted mean differences and adjusted odds ratios (OR) were obtained with 95% confidence intervals (CI). Statistical significant was defined when the p value was less than 0.05.

Results

A total of 31,228 cases were analyzed. The overall unadjusted in-hospital mortality rate was 0.14%. Using multivariate regression analyses, we identified risk factors

Table 1 Risk factors for in-hospital mortality in laparoscopic diaphragmatic hernia repair

Factors	AOR/95% CI	*p* value
Renal failure	6.257 (2.482–15.775)	<0.001
Age >60 years	5.058 (2.377–10.764)	<0.001
Congestive heart failure	3.795 (1.387–10.380)	0.009
Peripheral vascular disease	2.387 (0.632–9.013)	0.199
Chronic lung disease	1.597 (0.828–3.082)	0.163
Male gender	1.479 (0.784–2.790)	0.227
Hypertension	1.228 (0.642–2.351)	0.535
Incremental increase in volume per 10 cases	0.896 (0.818–0.982)	0.019
Liver disease	0.697 (0.092–5.299)	0.727
Diabetes	0.338 (0.122–0.933)	0.036

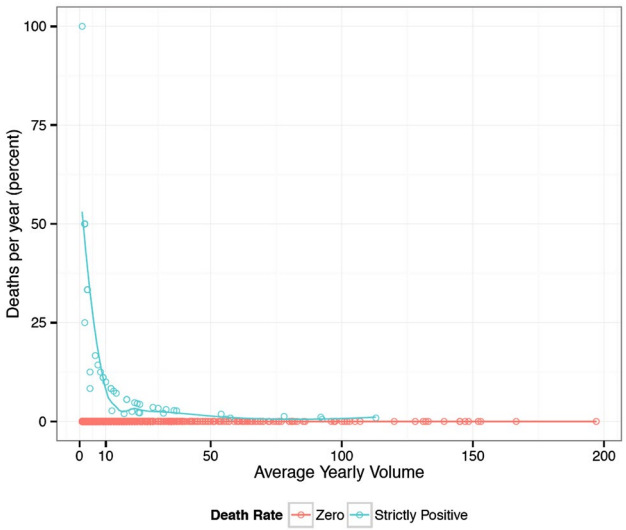


Fig. 1 Hospital deaths (percent) per year in laparoscopic diaphragmatic hernia repair according to average yearly hospital volume

associated with in-hospital mortality (Table 1). Factors predictive of higher in-hospital mortality included renal failure (AOR: 6.26; 95% CI: 2.48–15.78; $p<0.001$), age>60 years (AOR: 5.06; 95% CI: 2.38–10.76; $p<0.001$), and CHF (AOR: 3.80; 95% CI: 1.39–10.38, $p=0.009$). Incremental increase in case volume of 10 cases (AOR: 0.89; 95% CI: 0.82–0.98; $p=0.019$) and a history of diabetes (AOR: 0.34; 95% CI: 0.12–0.93; $p=0.036$) were associated with a reduced risk of in-hospital mortality.

Figure 1 shows the relationship between annual hospital volume and in-hospital mortality rate per year. The majority of hospitals reported zero deaths. For hospitals with reported deaths, there was an inverse relationship between annual hospital volume and the annual mortality rate. From this graph, hospital volume of ten cases per year appears to be the threshold for improved mortality.

Using 10 cases of laparoscopic diaphragmatic hernia repair per year as the threshold, we compared the outcome of low-volume (≤10 cases/year) versus high-volume (>10 cases/year) hospitals (Table 2). The majority of cases (75%, $n=23{,}384$) were performed at high-volume hospitals with a mean hospital volume of 82.9 ± 112.1 cases per year while low-volume hospitals had a mean hospital volume of 5.2 ± 2.8 cases per year. High-volume hospitals tended to be large teaching hospitals in urban settings, where low-volume hospitals were large urban non-teaching facilities. Table 3 shows the comparison of the patient comorbidities by hospital volume. Patients at low-volume hospitals had higher rates of chronic pulmonary disease (20.4 vs. 18.9%, $p<0.05$), whereas patients at high-volume hospitals had higher rates of hypertension (47.7 vs. 50.0%, $p<0.05$), diabetes (13.3 vs. 18.7%, $p<0.05$), and chronic liver disease (2.9 vs. 7.0%, $p<0.05$). Table 4 lists the unadjusted outcomes for low vs. high-volume hospitals. The in-hospital mortality rate was significantly lower at high-volume hospitals compared to low-volume hospitals (0.12 vs. 0.23%, respectively, $p=0.02$). Low-volume hospitals had significantly higher rates of respiratory failure (1.26 vs. 0.69%, $p<0.001$), postoperative pneumonia (1.27 vs. 0.64%, $p<0.001$), and sepsis (0.40 vs. 0.26%, $p=0.049$) while high-volume hospitals had higher rates of gastrointestinal complications (2.84 vs. 1.52%, $p<0.001$). Overall length of stay was longer at low-volume hospitals (2.60 ± 3.28 vs. 2.22 ± 2.60 days, $p<0.001$).

Figure 2 shows the unadjusted probability of mortality and serious morbidity per thousand cases. An increase in volume of 50 cases resulted in the reduction of the probability of mortality from approximately 2 deaths per thousand to approximately 1 per thousand cases. There was also a small association between volume and serious morbidity that was detectable likely because of our large sample size.

Discussion

In this study, we examined the outcomes of patients who underwent laparoscopic diaphragmatic hernia repair and found an inverse relationship between an increase in-hospital case volume and in-hospital mortality. A graph examining the annual case volume vs. annual mortality rate appears to show a threshold of 10 cases per year for improved mortality. Using 10 cases as the threshold, high-volume hospitals (>10 cases/year) had an in-hospital mortality rate almost half that of low-volume hospitals (0.12 vs. 0.23%) but had similar rates of serious morbidity (6.6 vs. 6.6%). When evaluating the effects of increasing volume on a continuous basis, increasing increments of hospital

Table 2 Patient and hospital characteristics for laparoscopic diaphragmatic hernia repair at low-volume (≤10 cases/year) and high-volume (>10 cases/year) hospitals

Characteristics	Low-volume hospitals ($N=7844$)	High-volume hospitals ($N=23,384$)
Age in years ± SD	56.25 ± 15.84	52.31 ± 14.95
Gender		
Male	2024 (26%)	5398 (23%)
Female	5805 (74%)	17,927 (77%)
Missing	15 (0.19%)	59 (0.25%)
Race		
White	5789 (74%)	16,169 (69%)
Black	411 (5.2%)	2024 (8.7%)
Hispanic	503 (6.4%)	1864 (8.0%)
Asian or Pacific Islander	38 (0.48%)	192 (0.82%)
Native American	39 (0.5%)	53 (0.23%)
Other	172 (2.2%)	622 (2.7%)
Missing	892 (11%)	2460 (11%)
Primary payer		
Medicare	2918 (37%)	6109 (26%)
Medicaid	542 (6.9%)	1203 (5.1%)
Private including HMO	3862 (49%)	14,401 (62%)
Self-pay	176 (2.2%)	791 (3.4%)
No charge	13 (0.17%)	23 (0.098%)
Other	303 (3.9%)	704 (3%)
Missing	30 (0.38%)	153 (0.65%)
Hospital type		
Non-teaching	4829 (62%)	9664 (41%)
Teaching	2961 (38%)	13,622 (58%)
Missing	54 (0.69%)	98 (0.42%)
Location		
Rural	1097 (14%)	1006 (4.3%)
Urban	6693 (85%)	22,280 (95%)
Missing	54 (0.69%)	98 (0.42%)
Bed size		
Small	1376 (18%)	4289 (18%)
Medium	2353 (30%)	5479 (23%)
Large	4061 (52%)	13,518 (58%)
Mean case volume per year (±SD)	5.27 ± 2.81	82.97 ± 112.16
Median case volume per year (IQR)	5.0 (3.0–8.0)	43.0 (22.0–96.0)

SD standard deviation, *HMO* health maintenance organization

Table 3 Patient comorbidities for laparoscopic diaphragmatic hernia repair at low-volume (≤10 cases/year) and high-volume (>10 cases/year) hospitals

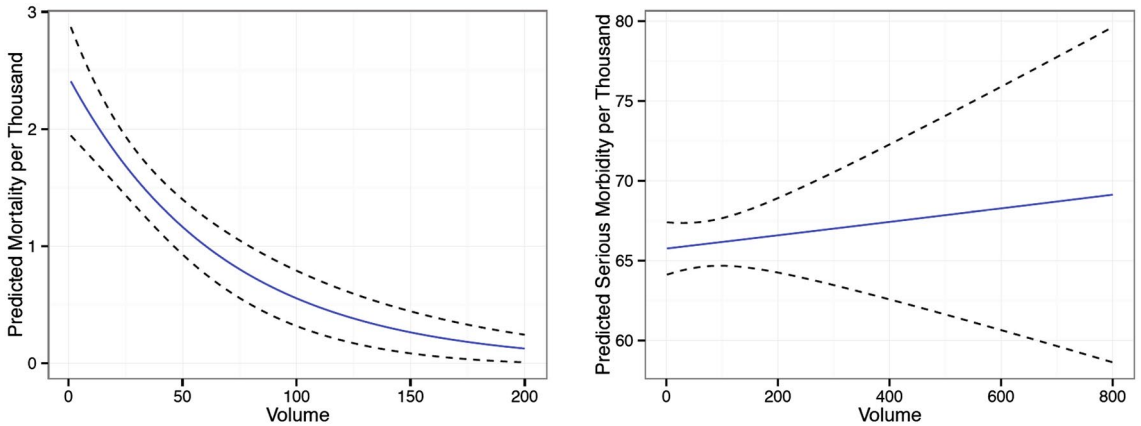
Comorbidity	Low-volume hospitals ($N=7844$)	High-volume hospitals ($N=23,384$)
Congestive heart failure	143 (1.82%)	368 (1.57%)
Chronic pulmonary disease	1572 (20.04%)*	4407 (18.85%)
Diabetes	1047 (13.35%)*	4385 (18.75%)
Hypertension	3744 (47.73%)*	11,691 (50.00%)
Liver disease	234 (2.98%)*	1636 (7.00%)
Peripheral vascular disease	90 (1.15%)	240 (1.03%)
Renal failure	134 (1.7%)	339 (1.4%)

*$p < 0.05$, compared to high-volume hospitals

Table 4 Unadjusted outcomes for laparoscopic diaphragmatic hernia repair at low-volume (≤10 cases/year) compared to high-volume (>10 cases/year) hospitals

Outcome	Low-volume hospitals ($N=7844$)	High-volume hospitals ($N=23{,}384$)	p value
Mean length of stay (days)	2.62 ± 3.28	2.22 ± 2.60	<0.001
Mortality (%)	18 (0.23%)	27 (0.12%)	0.02
Serious morbidity (%)	519 (6.62%)	1543 (6.60%)	NS
CVA	0 (0.00%)	4 (0.02%)	NS
Cardiac complications	73 (0.93%)	175 (0.75%)	NS
Respiratory failure	99 (1.26%)	161 (0.69%)	<0.001
Pneumonia	100 (1.27%)	150 (0.64%)	<0.001
Gastrointestinal complications	119 (1.52%)	665 (2.84%)	<0.001
Abscess	8 (0.10%)	18 (0.08%)	NS
Acute renal failure	145 (1.85%)	358 (1.53%)	NS
Post-operative bleeding	58 (0.74%)	157 (0.67%)	NS
DVT	7 (0.09%)	20 (0.09%)	NS
Sepsis	31 (0.40%)	60 (0.26%)	0.049
Bowel obstruction	7 (0.09%)	20 (0.09%)	NS

CVA cerebrovascular accident, *DVT* deep vein thrombosis



(a) In-hospital Mortality **(b)** Serious Morbidity

Fig. 2 Unadjusted probability of mortality and serious morbidity per thousand cases for laparoscopic diaphragmatic hernia repair with error bands represent plus and minus one standard error of the estimate

volume were associated with a small decrease of in-hospital mortality.

There is an association between increased hospital volumes with improved outcomes in a number of complex, high-risk operations [20, 22, 25]. The current study similarly identified a relationship between incremental annual increase of 10 case with improved outcomes. We also identified other factors predictive of increased in-hospital mortality including renal failure, age>60, and CHF. Advanced age was the most predictive for increased mortality with an adjusted odds ratio of >6. However, the association between advanced age and higher mortality after laparoscopic paraesophageal hernia repair is conflicting in the literature. Larusson et al. [9] reported an association of increased mortality with advanced age but other studies did not find this association [7, 13, 26]. Differences in results among these studies may be related to the definition threshold for advanced age. In this study, a threshold age of 60 years was used, while some study used 70 years [9], and others used 80 years [7, 13, 26]. Our finding of an association between annual case volume and outcome does bring into question any need for regionalization of care to high-volume hospitals. Many studies have found improved outcomes with regionalization of care for certain high-risk procedures [14, 27–30]. This has led to volume-based referral initiatives by organizations, such as the Leapfrog group, for selected high-risk procedures [31]. Regionalization of care for

complex surgeries such as esophagectomy and pancreaticoduodenectomy is now commonly being practice in the US. However, unlike these complex operations with associated high mortality [27], laparoscopic diaphragmatic hernia repair has an excellent safety profile with an overall in-hospital mortality rate of 0.14% as observed from this study. While there is an association between higher annual case volume and improved outcomes, the low overall rate for mortality in laparoscopic diaphragmatic hernia repair does not support the need for regionalization of care. However, it might be prudent to consider referral of complex diaphragmatic hernia cases such as total intrathoracic herniation or cases with incarceration to high-volume hospitals that are adept at performing more complex cases but also better at recognizing and managing complications when they occur.

There are several limitations to our study. First, this is a retrospective review of a database based from an administrative database, and as such, there is an inherent risk of coding errors for complications. Secondly, the NIS database only captures in-hospital morbidity and mortality. Any deaths or complications that developed after discharge will not be captured. Therefore, the reported overall in-hospital mortality likely is an underestimation of the true mortality rate. Additionally, the NIS does not provide the type and size of the hernias, which may be important variables for risk adjustment as larger, and true paraesophageal hernias are often more complex procedures. Lastly, we are not able to determine the surgeon volume within a particular center that might play a role in this complex relationship between volume and outcome. Despite these limitations, our study provides a large sample size that demonstrate a relationship between higher hospital volume and reduced mortality in laparoscopic repair of diaphragmatic hernias.

Conclusion

In this large, nationwide analysis on the outcomes of laparoscopic diaphragmatic hernia repair, we found a low overall in-hospital mortality of 0.14%. There is an inverse relationship between hospital volume and in-hospital mortality. An annual volume increase of 10 cases was associated with a 10% lower adjusted odds of in-hospital mortality. The reduced mortality in high-volume hospitals is likely due to a complex relationship of factors including surgeon and nursing expertise, and availability of structure and resources to detect and manage complications. Although the evidence in this study does not support a generalized regionalization of laparoscopic diaphragmatic hernia repair to high-volume hospitals, selective referral of high-risk patients may improve outcomes .

Compliance with ethical standards

Disclosures Matthew D. Whealon, Juan J. Blondet, John V. Gahagan, Michael J. Phelanand, and Ninh T. Nguyen declared that they have no conflicts of interest or financial ties to disclose.

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