

Nationwide Inpatient Sample: Have Antireflux Procedures Undergone Regionalization?

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Introduction

The Nissen fundoplication was introduced in 1956 by Rudolph Nissen¹ and is a proven, effective treatment for gastroesophageal reflux disease (GERD).² The laparoscopic technique was first described in 1991 by Bernard Dallemagne³ and has also been shown to be safe and effective in treatment of GERD.⁴ From 1990 to 1997, antireflux surgery rates almost tripled⁵ and peaked in 1999,⁶ which was followed by a steady decline through 2006.⁷ The decline in surgical volume has been partially attributed to a question of the long-term effectiveness of antireflux surgery, where re-operation can often become required, and many patients require acid suppression medications post-operatively.^{8–11} The decline of operative intervention has also been attributed to the availability of over-the-counter proton pump inhibitors, new endoscopic therapies for treating GERD, and the rise of bariatric surgery.^{6, 7} Increasing outpatient antireflux procedures has also been examined as a potential cause for the decrease of

inpatient cases. However, analysis of outpatient data in several states has revealed that the decrease in inpatient procedures is not nearly matched by the volume of outpatient procedures.⁷

The effect of hospital volume on mortality has been demonstrated since the 1970s,¹² but the literature describing this effect rapidly increased in the late 1990s.^{13–17} This led to a call for regionalization of many procedures on a national level by the year 2000.¹⁸ Regionalization has been demonstrated for many complex procedures, oncologic and otherwise.^{19, 20} The timing of the national call for regionalization coincided closely with the peak of antireflux surgery. The purpose of this study is to examine trends in antireflux surgery to determine the extent of regionalization, if any at all, in the decade following the zenith of antireflux surgery.

Methods

A retrospective, population-based analysis was performed using the Nationwide Inpatient Sample (NIS)²¹ for the years 1998–1999 and 2008–2009. Using procedure codes from the International Classification of Disease Ninth Revision Clinical Modification (ICD-9 CM),²² antireflux procedures were identified (44.65, 44.66, and 44.67). Only patients with ICD-9 CM diagnosis codes for gastroesophageal reflux, esophagitis, esophageal ulcer, or hiatal hernia (530.10, 530.11, 530.19, 530.81, 530.20, and 533.3) were included in the study population. Unlike other antireflux studies emanating from billing data, the requirement of these diagnosis codes was applied for all three procedure codes, as opposed to 44.65 alone.^{5–7} Similar to the prior studies, patients with a diagnosis of achalasia, diagnoses of gangrenous or obstructing incarcerated diaphragmatic hernia, and those less than 18 years old were excluded.

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Nationwide Inpatient Sample

The Healthcare Cost and Utilization Project supports the NIS, which contains all-payer discharge information in a stratified sample of 20 % of non-federal US hospitals. In 2009, this contained 100 % of discharges from 1,050 hospitals in 44 states.²¹ The NIS-implemented weighting strategy²¹ was not used in this study; only the actual patient data contained in the database were used for analysis.

Hospitals were stratified by annual procedure volume. Using the total volume from 1998 to 1999 (T1), terciles were identified. This yielded high-volume centers (HVCs; 38 or more annual procedures), mid-volume centers (MVCs; 15–37 procedures), and low-volume centers (LVCs; 1–14 annual procedures).

NIS-contained sociodemographic factors were examined: age, gender, race, admission type, admission source, zip code median income, and primary payer. To measure the burden of comorbid disease between groups, ICD-9 CM coding was used to calculate the Charlson Comorbidity Index²³ (CCI) for each patient using the method of Quan.²⁴ The size of the patients' home county was also examined in T2.

ICD-9 CM coding was also utilized to detect complications. Similar to a previously described method for detecting surrogates of surgical complications,⁷ the frequencies of splenectomy, suturing of GI tract laceration, transfusion, total parenteral nutrition use, and infections were measured. The NIS data contain the following outcomes, which were included in analysis: length of stay (LOS), total charges, patient disposition, and inpatient mortality.

The NIS data contain the following outcomes, which were included in analysis: LOS, total charges, patient disposition, and inpatient mortality. The NIS does not contain patient identifying information, and therefore, IRB approval was not required for this study.

Statistical Analysis

All data were analyzed using SAS Software version 9.2 (SAS Institute, Inc., Cary, NC, USA). All group comparisons were unpaired. The incidence of pre-operative and intra-operative variables as well as unadjusted outcomes were compared using the Wilcoxon–Mann–Whitney *U* test for continuous and ordinal variables and Pearson's chi-square and Fisher's exact tests for categorical variables as appropriate. Frequencies of categorical variables are expressed as a percentage of the group of origin, and continuous variables are reported as means \pm standard deviation. Statistical significance was set at $P < 0.05$, and all reported *p* values are two-tailed.

Forward, stepwise multivariate logistic regression was performed to calculate the adjusted odds-ratios for complications and routine discharge. All preoperative variables entered as covariates were selected a priori and were

considered potential confounders for the effect of volume center. The estimated odds of all outcomes were adjusted for all covariates. The statistical significance between eras and the adjusted outcomes was assessed using the Wald chi-square test. Adjusted odds-ratios are expressed as point estimates with associated 95 % confidence intervals. Multivariate logistic regression was also performed to determine the sociodemographic predictors of surgery at a LVC in each era.

Multivariate linear regression models were created to estimate the adjusted LOS and total costs for each volume designation. For each model, forward stepwise selection was performed in a similar manner as the logistic regression models and statistical significance was determined by the *F*-test. Each linear model generated parameter estimates for each covariate, reflecting the adjusted effect on LOS and total costs. Adjusted linear effects are expressed as point estimates with associated 95 % confidence intervals.

Results

The Effect of Time

A total of 11,803 antireflux procedures were identified in T1 and 8,855 in T2. Table 1 details differences between the two eras. Regionalization did not occur: HVCs experienced a decrease in market concentration with time, with 33.4 % of cases in T1 and only 25.3 % in T2 ($p < 0.0001$). There was, however, a decrease in proportion of procedures being performed at rural hospitals (19.1 % in T1 vs 10.3 % in T2, $p < 0.0001$). Both teaching and non-teaching urban hospitals increased their proportion of cases performed, but urban non-teaching hospitals had the largest gain (T1, 32.7 % vs T2, 38.7 %, $p < 0.0001$).

There was an increase in mean patient age between T1 and T2 (49.7 vs 56.8 years, $p < 0.0001$), with an increase in the proportion of medicare patients and a decrease in patients with private insurance ($p < 0.0001$). There was higher proportion of females undergoing antireflux procedures (56.6 % vs 68.9 %, $p < 0.0001$) and a decreasing frequency of Caucasians with time (91.3 % vs 84.9 %, $p < 0.0001$). The mean CCI score increased from T1 to T2 (0.28 vs 0.52, $p < 0.0001$), but emergent admissions did not vary with time. There was an increased prevalence of patients from the poorest zip codes and a decreased proportion from the wealthiest zip codes ($p < 0.0001$).

Comparisons by Annual Procedure Volume

Table 2 compares HVCs and LVCs in both eras. In T1, patients were slightly older in LVCs (50.6 vs 49.2 years in HVCs, $p = 0.001$), but there was no difference in T2. There was a higher prevalence of females in LVCs in T2 only (69.9 % vs 66.0 %, $p = 0.002$). There was a lower proportion

Table 1 1998–1999 versus 2008–2009

	1998–1999	2008–2009	<i>P</i> value
Procedures	11,803	8,855	
Volume center			<0.0001
Low	33.3 %	40.4 %	
Medium	33.3 %	34.4 %	
High	33.4 %	25.3 %	
Age (years)	49.7±14.4	56.8±15.1	<0.0001
Sex (% female)	56.6 %	68.9 %	<0.0001
Race ^a (% caucasian)	91.3 %	84.9 %	<0.0001
CCI score (weighted)	0.28±0.63	0.52±0.85	<0.0001
Primary payer ^a		Overall	<0.0001
Medicare	22.2 %	36.5 %	
Medicaid	6.5 %	6.4 %	
Private/HMO	67.4 %	52.2 %	
Self-pay	1.4 %	1.3 %	
No charge	0.03 %	0.2 %	
Other	2.5 %	3.4 %	
Patient zip code median income ^a			<0.0001
Bottom quartile	3.25 %	21.7 %	
Second quartile	32.5 %	30.6 %	
Third quartile	32.8 %	26.2 %	
Top quartile	31.5 %	21.6 %	
Procedures by hospital types			<0.0001
Rural	19.1 %	10.3 %	
Urban non-teaching	32.7 %	38.7 %	
Urban teaching	48.2 %	51.0 %	
Emergent admission ^a (any source)	3.9 %	4.0 %	0.614
Outcomes			
Inpatient mortality	0.41 %	0.34 %	0.433
Complications	3.7 %	5.8 %	<0.0001
LOS (days)	3.53±5.26	3.68±5.45	0.001
Total charges (\$1,000) ^a	16.02±20.67	40.26±50.69	<0.0001
Routine discharge (%)	95.4 %	91.6 %	<0.0001

^a Data not available for all states reporting to NIS in all years; analysis reflects reported values only

of Caucasians in LVCs in T1 (88.7 % vs 93.2 %, $p<0.0001$) but a higher proportion in T2 (85.4 % vs 81.1 %, $p<0.0001$). There was no difference in CCI scores between HVCs and LVCs in either era.

When examining the median income of a patient's home zip code, HVCs experienced a decrease in the relative proportion of patients from all quartiles but the largest decrease in patients from the poorest counties (36.0 % in T1 vs 20.4 % in T2, $p<0.0001$). Private insurance was more common in patients undergoing HVC antireflux surgery in T1 and T2, while emergent admissions were more common in LVCs in both eras.

Laparoscopic ICD-9 CM coding was not in use during T1, but there was a higher proportion of laparoscopic surgery in HVCs in T2 (80.0 % vs 75.5 %, $p<0.0001$).

Univariate Outcomes

Table 1 describes outcome differences between T1 and T2. There was no difference in inpatient mortality with time, while complication rates increased with time (3.7 % vs 5.8 %, $p<0.0001$). LOS increased with time (3.5 vs 3.7 days, $p=0.001$), as did total charges (\$16.0 k vs \$40.3 k, $p<0.0001$). The increase in total charges exceeded the rate of inflation, which was 32.1 % from 1998 to 2008.²⁵ The frequency of routine discharge also decreased with time (95.4 % vs 91.6 %, $p<0.0001$).

Table 2 compares outcomes between HVCs and LVCs. In T1, 5.4 % of LVC procedures were associated with at least one of the defined complications, compared with 2.7 % in HVCs ($p<0.0001$). Complication rates increased with time and remained more likely in LVCs in T2 (6.8 % vs 3.9 % in HVCs, $p<0.0001$). There was no difference in inpatient mortality rate between HVCs and LVCs in T1, but rates were higher in LVCs in T2 (0.45 % vs 0.04 %, $p=0.006$). LOS was longer in LVCs in both eras (T1, 4.1 vs 3.2 days; T2, 4.0 vs 3.1 days, all $p<0.0001$). Total charges were higher in LVCs in T1 (\$17.1 k vs \$16.5 k, $p<0.0001$) but lower in T2 (\$39.6 k vs \$42.4 k, $p=0.013$). Routine discharge was less common in LVCs in both eras (93.3 % vs 96.6 % in T1, 90.0 % vs 93.7 %, all $p<0.0001$).

Multivariate Outcome Analysis

To control for potential confounding variables, multivariate models were constructed. In a multivariate logistic regression model for complications (Table 3), LVCs were independently associated with increased complications in T1 (OR 1.8) and T2 (OR 1.9). Emergent admission, lack of private insurance, and increasing CCI score were independently associated with increased complication rates in T1 and T2. Increasing age was associated with increased complications in T1 only. There was no independent effect of hospital type, patient zip code, gender, or race on complication rates in either era.

In multivariate linear regression models for LOS (Table 3), surgery in a LVC was independently associated with a longer length of stay in T1 (0.82 days) and T2 (0.94 days). Emergent admission, lack of private insurance, increasing age, and increasing CCI score were all associated with increased LOS in both eras. Urban hospitals were associated with longer LOS in T1 versus rural hospitals, but urban teaching hospitals had longer LOS than urban nonteaching hospitals and rural hospitals in T2. Non-Caucasian race was associated with increased LOS in T1 only, and patients from the wealthiest zip codes had significantly shorter LOS than all three other

Table 2 Univariate comparison of HVC versus LVC

	T1 (1998–1999)			T2 (2008–2009)		
	HVC	LVC	<i>P</i> value	HVC	LVC	<i>P</i> value
Age (years)	49.2±14.1	50.6±14.9	0.001	56.5±15.3	56.6±15.0	0.854
Sex (% female)	55.6 %	57.7 %	0.058	66.0 %	69.9 %	0.002
Race (% Caucasian) ^a	93.2 %	88.7 %	<0.0001	81.1 %	85.4 %	<0.0001
Technique (% laparoscopic) ^b	N/A	N/A	N/A	80.0 %	75.5 %	<0.0001
CCI score (weighted)	0.28±0.62	0.30±0.67	0.255	0.49±0.84	0.52±0.84	0.060
Private insurance ^a	70.9 %	62.0 %	<0.0001	57.0 %	48.7 %	<0.0001
Patient zip code median income ^a			<0.0001			<0.0001
Bottom quartile	36.0 %	34.1 %		20.4 %	45.6 %	
Second quartile	30.2 %	35.6 %		28.3 %	42.7 %	
Third quartile	30.2 %	34.4 %		25.9 %	36.7 %	
Top quartile	39.6 %	30.0 %		25.4 %	35.9 %	
Procedures by hospital types			<0.0001			<0.0001
Rural	8.0 %	29.3 %		0.0 %	21.0 %	
Urban non-teaching	18.6 %	45.9 %		29.7 %	44.8 %	
Urban teaching	73.4 %	24.8 %		70.3 %	34.2 %	
Emergent admission ^a	1.6 %	6.1 %	<0.0001	2.5 %	5.2 %	<0.0001
Outcomes						
Inpatient mortality	0.38 %	0.53 %	0.313	<0.45 % ^c	0.45 %	0.006
Complications	2.7 %	5.4 %	<0.0001	3.9 %	6.8 %	<0.0001
LOS (days)	3.22±4.63	4.10±5.63	<0.0001	3.11±4.02	4.04±6.07	<0.0001
Total charges (\$1,000) ^a	16.5±23.0	17.1±18.7	<0.0001	42.4±49.3	39.6±50.3	0.013
Routine discharge (%)	96.6 %	93.3 %	<0.0001	93.7 %	90.0 %	<0.0001

^a Data not available for all States reporting to NIS in all years, analysis reflects reported values only

^b ICD-9 CM codes did not exist for laparoscopic antireflux procedures in 1998 or 1999

^c AHRQ does not permit identification of fields where the number of patients is less than ten. The <0.45 % corresponds to less than ten inpatient deaths in the T2 HVC group. This was statistically lower than the LVC mortality in T2

quartiles in T2 only. There was no independent effect on LOS by gender.

Multivariate linear regression was also performed to evaluate total charges. In T1, LVCs had higher total charges in univariate analysis; this held true in multivariate analysis as well (\$2.7 k more in LVCs). In T2, univariate analysis demonstrated lower charges in LVCs versus HVCs, however, after controlling for confounding variables, LVCs were associated with higher charges in multivariate analysis (\$3.2 k). Emergent admission, increasing age, and increasing CCI score were all associated with increased total charges in both T1 and T2. In both eras, urban teaching hospitals were associated with more charges than nonteaching hospitals.

Both were more expensive than rural hospitals in both eras as well. Lack of private insurance affected total charges in T1 only. There was no effect of gender, race, or zip code median income on total charges.

Multivariate logistic regression models were also created to control for confounding variables affecting routine discharge. Antireflux procedures performed in HVCs were independently associated with more frequent routine discharge in T1 (OR 2.0) and T2 (OR 1.8). Nonemergent admission, private insurance, surgery in an urban nonteaching hospital versus teaching hospitals, decreasing age, and decreasing CCI score were all associated with more frequent routine discharge in both eras. Male gender was only

Table 3 Adjusted odds ratios/for LVC versus HVC for outcomes

	Complication rates (OR, CI)	LOS (days, point estimate, CI)	Total charges (\$1,000, point estimate, CI)	Routine discharge (OR, CI)
T1	1.8 (CI 1.3–2.4)	0.82 (0.52–1.1)	2.7 (1.8–3.6)	2.0 (CI 1.4–2.8)
T2	1.9 (CI 1.3–2.6)	0.94 (0.65–1.2)	3.2 (0.73–5.8)	1.8 (CI 1.4–2.4)

associated with more frequent routine discharge in T2. Race and patient zip code did not effect routine discharge.

Due to very low rates of inpatient mortality, multivariate logistic regression was not performed for this outcome.

Hospital Analysis

There were 530 hospitals performing at least one antireflux procedure in 1998, 541 in 1999, 481 in 2008, and 456 in 2009. This reveals a decrease in hospital-years (some, but not all, of the hospitals in the 1998 sample are represented in the 1999, 2008, and/or 2009 sample, thus “T1 hospital-years” sums the hospitals in 1998 and 1999) from T1 to T2, 1,071 to 937. This pattern applied to LVCs (826 in T1 vs 773 in T2), MVCs (177 vs 131), and HVCs (68 vs 33). When combining all volume centers, the same trend was present for rural hospitals (308 vs 201), urban nonteaching hospitals (464 vs 431), and urban teaching hospitals (297 vs 293).

Figure 1a, b demonstrates the numbers and trends of rural, urban nonteaching, and urban teaching hospitals in T1 and T2 for LVCs and HVCs. There was a decrease in rural and nonteaching urban LVCs (Fig. 1a) and HVCs (Fig. 1b) with time. There was also a decrease in the number of urban teaching HVCs with time, but there was an increase in the number of urban teaching LVCs. There was a decrease in all classifications of MVCs with time (not demonstrated).

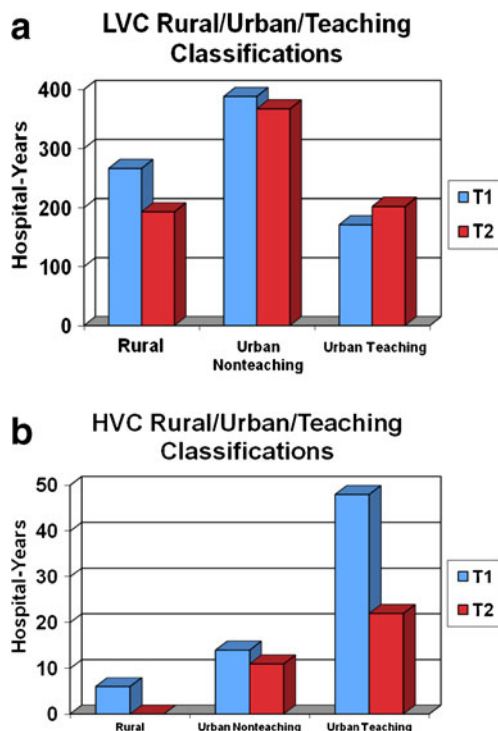


Fig. 1 a, b LVC and HVC rural/urban/teaching classifications. Numbers and trends of rural, urban nonteaching, and urban teaching hospital-years in T1 and T2 for **a** low-volume centers and **b** high-volume centers

Multivariate Analysis of Predictors of LVC Surgery

Multivariate logistic regression was performed to identify factors independently associated with LVC antireflux surgery (vs HVC). Table 4 demonstrates the adjusted odds ratios for each significant covariate. Emergent admission was highly predictive of LVC surgery in T1 (OR 3.7) and T2 (OR 3.0). Lack of private insurance was also associated with LVC procedure, with an adjusted odds ratio of 1.3 for both eras. Non-Caucasian race was associated with LVC surgery in T1 (OR 1.8), but the opposite was true in T2, when Non-Caucasians were more likely to undergo HVC procedures (LVC OR 0.73). Patients from zip codes with median incomes in the second and third quartiles were more likely to undergo LVC operations in T1, but less likely in T2. There was no difference between the richest and poorest zip codes in T1, but the poorest zip codes were more likely to undergo LVC surgery in T2. Decreasing age (OR 1.1) and female gender (OR 1.2) were independently associated with LVC operations in T2 only. CCI score was not associated with increased likelihood of a LVC fundoplication in either era. Urban/rural and teaching hospital classification were not included in the models for LVC surgery, as they are not patient-specific factors.

Effect of Patients' Home County

Figure 2 demonstrates the rates of rural, urban nonteaching, and urban teaching hospital procedures in six county types in T2. The NIS data did not contain these county classifications in 1998–1999. The “central metropolitan” counties are defined as the central counties in metropolitan areas with population greater than one million. Over 65 % of procedures on patients from these counties were performed at urban teaching facilities. Patients from the “fringe metropolitan” counties, those surrounding the central metropolitan counties with population great than one million, continued to have surgery most frequently at urban teaching hospitals (53.8 %). Patients from counties with population ranging from 250,000 to one million had surgery most frequently in urban nonteaching hospitals (50.0 %). Rural hospitals (45.7 %) were the most common operative location for patients from counties with 10,000 to 50,000 citizens. In patients from the least populous counties (<10,000), rural hospitals remained popular with 32.7 % of the operative volume, but urban teaching hospitals were the most common with 40.3 % of the caseload.

Discussion

Consistent with prior publications describing national anti-reflux surgical trends,^{6, 7} there has been a decrease in operative volume, an increase in age of patients undergoing these procedures, and increased complications. Not only did

Table 4 Predictors of LVC surgery

	T1			T2		
	OR	95 % CI	P value	OR	95 % CI	P value
Non-Caucasian race	1.8	1.4–2.2	<0.0001	0.73	0.61–0.88	0.001
Emergent admission	3.7	2.6–5.3	<0.0001	3	2.0–4.6	<0.0001
Lack of private insurance	1.3	1.2–1.5	<0.0001	1.3	1.1–1.5	0.003
Poorest vs wealthiest zip codes			NS	1.2	1.0–1.5	<0.0001
Second quartile vs wealthiest zip codes	1.7	1.5–2.0	0.001	0.82	0.68–1.0	0.006
Third quartile vs wealthiest zip codes	1.6	1.3–1.8	0.033	0.81	0.66–1.0	0.006
Decreasing age (10-year difference)			NS	1.1	1.0–1.1	0.016
Female gender			NS	1.2	1.0–1.4	0.024

operative volume decrease with time, but the number of hospitals performing these procedures also decreased. Rural hospitals performing antireflux surgery decreased by 34.7 % with time, with a concurrent decrease in operative volume (19.1 % of all procedures in T1 vs 10.3 % in T2, Table 1). Both types of urban hospitals increased their relative caseload, despite slightly fewer numbers of nonteaching (7.2 % decrease) and teaching (1.3 % decrease) hospitals performing these procedures. Clearly, antireflux surgery became a more urban procedure between T1 and T2.

Despite this trend toward increased prevalence of antireflux surgery in urban centers, regionalization, defined as increased market concentration into HVCs, did not occur. In fact, LVCs had the largest gain in operative volume (33.3 % in T1 to 40.4 % in T2), despite the decreasing number of hospitals performing antireflux procedures.

Outcomes

In T1, complications were fewer at HVCs, LOS was shorter, total charges were lower, and routine discharge was more common. In multivariate analysis, all outcomes remained

improved in HVCs after controlling for confounding variables. There was no inpatient mortality difference in T1. In T2, univariate analysis revealed fewer complications, shorter LOS, lower inpatient mortality rates, and a more frequent routine discharge in HVCs. Complication rates, LOS, and frequency of routine discharge were also improved in HVCs in multivariate analysis. Notably, total charges were higher in HVCs in univariate analysis, but after confounding factors were controlled for with multivariate linear regression, HVCs were found to be independently associated with lower charges. Clearly, outcomes were superior at HVCs compared with LVCs in both eras.

Complications have increased with time, in HVCs and LVCs. As the average patient undergoing antireflux surgery was older in T2, there is potential for comorbid disease to affect the defined complications in this study. Indeed, the mean CCI score was higher in T2 than T1, with 4.8 % of patients in T1 and 10.4 % in T2 having CCI scores of 2 or more. This is also reflected in the multivariate models for complications in each era, where increasing CCI score is independently associated with increased likelihood of complications.

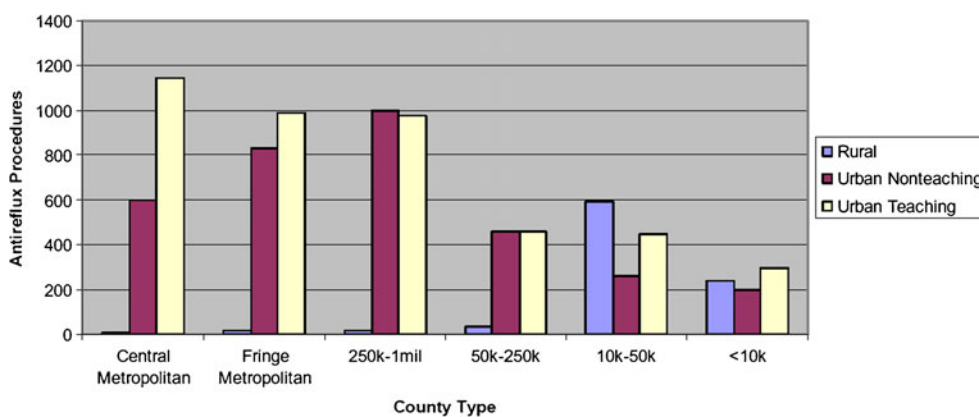


Fig. 2 Hospital classifications by patient county, 2008–2009. Number of antireflux procedures in patients from six county types, stratified by county population and proximity to metropolitan areas with population greater than 1,000,000. County type reflects the patients’ home county,

not the county of the hospital where the procedure was performed. The number of antireflux procedures is represented for three types of hospitals: rural, urban nonteaching, and urban teaching hospitals

Barriers to HVC Access

After demonstrating lack of regionalization despite improved outcomes at HVCs, sociodemographic variables were examined to identify factors that are associated with LVC surgery. Although it was not a frequent occurrence, emergent admission was associated with increased likelihood of an operation at a LVC in both T1 and T2. Patients without private insurance were more likely to undergo LVC surgery with an adjusted odds ratio of 1.3 in T1 and T2. Non-Caucasians were more likely have antireflux surgery in a LVC in T1 but more likely to visit a HVC in T2. Females and older patients were more likely to undergo LVC surgery in T2.

In T1, patients from the wealthiest zip codes were more likely to undergo antireflux surgery at a HVC compared with the second and third quartiles, but there was no difference compared with those from the poorest zip codes. This trend reversed in T2, where those from the wealthiest zip codes were more likely to undergo LVC surgery compared with the second and third quartiles, but more likely to undergo HVC surgery compared with patients from the poorest zip codes. This phenomenon may be due to the lack of rural HVCs in T2, as well as the increase in urban teaching LVCs.

Figure 2 demonstrates that patients from major metropolitan areas are more likely to undergo surgery in urban teaching hospitals, which is explained by the common presence of one or more large academic centers in large cities. The barrier to HVCs is evident in the smaller, rural counties. Patients from counties with population ranging from 50,000 to 250,000 are most likely to undergo antireflux surgery in a rural hospital, and there were no rural HVCs in T2. This may reflect unwillingness to travel or lack of referral by the rural hospitals. Interestingly, in the least populous counties with less than 10,000 citizens, patients are more likely to undergo surgery in an urban teaching hospital. This is possibly due to a lack of hospitals or surgical support in these rural counties.

Study Limitations

This study does have limitations. This cross-sectional analysis of the inpatient data does not afford follow-up examination of the patient outcomes, readmission, failed repair, or mortality after discharge. Because HVC procedures result in a shorter average hospital length of stay, the window of events captured in the NIS is, therefore, shorter. This is a potential source of systematic bias, which could result in artificially lower mortality, complications, and overall cost in HVCs. Breakdown of total charge data is also difficult in surgical patients, as operative time is not available and contributes significantly to total charges. There is also potential for coding errors in any administrative database, but the large sample size of this study will minimize any effect of coding errors. Additionally, there is no method for identifying redo

antireflux surgery, as there is no ICD-9 CM code for these procedures.

Conclusion

Despite improved results at HVCs, LVCs have increased their percentage of antireflux operations over time. The urban non-teaching hospitals have experienced the largest gains in caseload. Overall complication rates have increased with time, apparently due to an increased mean age and incidence of comorbidities in the patients seeking antireflux surgery. After controlling for confounding variables, complications are more likely in LVCs. Regionalization has not occurred over time but may improve outcomes if supported.

References

1. Nissen R. [A simple operation for control of reflux esophagitis]. *Schweiz Med Wochenschr* 1956;86:590-2.
2. DeMeester TR, Bonavina L, Albertucci M. Nissen fundoplication for gastroesophageal reflux disease. Evaluation of primary repair in 100 consecutive patients. *Ann Surg* 1986;204:9-20.
3. Dallemagne B, Weerts JM, Jehaes C, Markiewicz S, Lombard R. Laparoscopic Nissen fundoplication: preliminary report. *Surg Laparosc Endosc* 1991;1:138-43.
4. Kelly JJ, Watson DI, Chin KF, Devitt PG, Game PA, Jamieson GG. Laparoscopic Nissen fundoplication: clinical outcomes at 10 years. *J Am Coll Surg* 2007;205:570-5.
5. Finlayson SR, Laycock WS, Birkmeyer JD. National trends in utilization and outcomes of antireflux surgery. *Surg Endosc* 2003;17:864-7.
6. Finks JF, Wei Y, Birkmeyer JD. The rise and fall of antireflux surgery in the United States. *Surg Endosc* 2006;20:1698-701.
7. Wang YR, Dempsey DT, Richter JE. Trends and perioperative outcomes of inpatient antireflux surgery in the United States, 1993-2006. *Dis Esophagus* 2011;24:215-23.
8. Kahrilas PJ. Laparoscopic antireflux surgery: silver bullet or the emperor's new clothes? *Am J Gastroenterol* 1999;94:1721-3.
9. Spechler SJ, Lee E, Ahnen D, Goyal RK, Hirano I, Ramirez F, Raufman JP, Sampliner R, Schnell T, Sontag S, Vlahcevic ZR, Young R, Williford W. Long-term outcome of medical and surgical therapies for gastroesophageal reflux disease: follow-up of a randomized controlled trial. *JAMA* 2001;285:2331-8.
10. Catarci M, Gentileschi P, Papi C, Carrara A, Marrese R, Gaspari AL, Grassi GB. Evidence-based appraisal of antireflux fundoplication. *Ann Surg* 2004;239:325-37.
11. Heniford BT, Matthews BD, Kercher KW, Pollinger H, Sing RF. Surgical experience in fifty-five consecutive reoperative fundoplications. *Am Surg* 2002;68:949-54; discussion 954.
12. Luft HS, Bunker JP, Enthoven AC. Should operations be regionalized? The empirical relation between surgical volume and mortality. *N Engl J Med* 1979;301:1364-9.
13. Gordon TA, Burleyson GP, Tielsch JM, Cameron JL. The effects of regionalization on cost and outcome for one general high-risk surgical procedure. *Ann Surg* 1995;221:43-9.
14. Lieberman MD, Kilburn H, Lindsey M, Brennan MF. Relation of perioperative deaths to hospital volume among patients undergoing pancreatic resection for malignancy. *Ann Surg* 1995;222:638-45.

15. Birkmeyer JD, Finlayson SR, Tosteson AN, Sharp SM, Warshaw AL, Fisher ES. Effect of hospital volume on in-hospital mortality with pancreaticoduodenectomy. *Surgery* 1999;125:250-6.
16. Begg CB, Cramer LD, Hoskins WJ, Brennan MF. Impact of hospital volume on operative mortality for major cancer surgery. *JAMA* 1998;280:1747-51.
17. Glasgow RE, Showstack JA, Katz PP, Corvera CU, Warren RS, Mulvihill SJ. The relationship between hospital volume and outcomes of hepatic resection for hepatocellular carcinoma. *Arch Surg* 1999;134:30-5.
18. Milstein A, Galvin RS, Delbanco SF, Salber P, Buck CR, Jr. Improving the safety of health care: the leapfrog initiative. *Eff Clin Pract* 2000;3:313-6.
19. Stützenberg KB, Meropol NJ. Trends in centralization of cancer surgery. *Ann Surg Oncol* 2010;17:2824-31.
20. Finks JF, Osborne NH, Birkmeyer JD. Trends in hospital volume and operative mortality for high-risk surgery. *N Engl J Med* 2011;364:2128-37.
21. HCUP Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). 1998-2009. Agency for Healthcare Research and Quality, Rockville, MD.
22. World Health Organization. International classification of diseases, 9th edn. Clinical modification. Salt Lake City: Medicode Publications; 2001.
23. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373-83.
24. Quan H, Sundararajan V, Halfon P, Fong A, Burnand B, Luthi JC, Saunders LD, Beck CA, Feasby TE, Ghali WA. Coding algorithms for defining comorbidities in ICD-9-CM and ICD-10 administrative data. *Med Care* 2005;43:1130-9.
25. Bureau of Labor Statistics. CPI inflation calculator. Bureau of Labor Statistics, United States Department of Labor, Washington, DC.

Discussant

Dr. Steven R. DeMeester (Los Angeles, CA): This is an important paper reconfirming a relationship between volume and outcome, but in contrast to evaluating complex procedures such as pancreatotomy or esophagectomy, the authors showed that volume is important even for laparoscopic antireflux operations. I have three questions.

1. There seems to be an increase in the number of patients presenting with paraesophageal hernias. Furthermore, the authors note that, since there is no code for redo procedures, the numbers of these could not be ascertained. Is it possible that higher numbers of patients undergoing PEH repair or a redo procedure explain the increase in complications and length of stay in T2 versus T1?

2. Also, if more of these complex procedures are being done in the high-volume centers, is it possible that the outcome differences that you showed would be even more dramatic if only first-time procedures were compared at low- versus high-volume centers?

3. What are the barriers to regionalization, and any insights on how big the difference needs to be before patients are willing to make sacrifices in terms of cost and/or convenience for their healthcare?

Closing Discussant

Dr. Paul D. Colavita: Thank you, Dr. DeMeester for your comments and questions. We are very pleased to have you review our manuscript. To address your first question, we did attempt to examine the rates of paraesophageal hernia repair. ICD-9 CM coding exists for diaphragmatic

hernia repair but not specifically paraesophageal hernia repair. Our study population was defined by patients undergoing antireflux procedures with a diagnosis of reflux or associated symptoms, but the patients that also had procedure codes for diaphragmatic hernia repair were available to us. We found that rates of a concurrent hernia repair did increase with time, from 9.7 % of all cases in 1998–99 to 23.6 % in 2008–2009. The complication rates and length of stay were indeed higher in the patients undergoing diaphragmatic hernia repair in both eras, which may certainly have contributed to the worsening of outcomes with time. In those undergoing diaphragmatic hernia repair, the mean hospital stay was 4.8 days in T1 and 4.4 days in T2, compared with 3.4 and 3.5 days for the rest of the study population in T1 and T2, respectively. Complication rates were 7.0 % in T1 and 8.2 % in T2 for those undergoing diaphragmatic hernia repair, while the patients without concurrent hernia repair had complication rates of 3.3 % in T1 and 5.1 % in T2. It is also important to note that we excluded patients with a diagnosis of gangrenous or incarcerated diaphragmatic hernia from this study.

As you stated, ICD-9 CM coding does not exist for re-operative antireflux procedures, and we are not able to analyze these procedures in the Nationwide Inpatient Sample. However, there is a potential to use surrogate codes, such as lysis of adhesions, to identify redo procedures, but the accuracy of such a surrogate is unknown.

Although the increased frequency of diaphragmatic hernia repairs contributed to the increased complication rate and length of stay, we believe that the increasing age and the increasing Charlson Comorbidity Index score in the patients undergoing these procedures was also responsible for the declining outcomes. Patients were, on average, 7 years older in T2 and 10.4 % had CCI scores of 2 or more, compared with 4.8 % in T1.

In regards to your second question, there was a higher percentage of concurrent diaphragmatic hernia repair in high volume centers in T2. Rates were similar in T1, with 10.5 % of all HVC antireflux procedures and 10.1 % of all LVC procedures involving hernia repair. However, in T2, 28.5 % of all HVC procedures involved hernia repair, compared with 20.2 % of all LVC procedures. Despite the higher frequency of concurrent hernia repair, outcomes were improved in HVCs. We would also like to state that regionalization did not occur for antireflux procedures involving diaphragmatic hernia repair, as 36.0 % occurred at HVCs in T1 compared with 30.5 % in T2, while LVCs had a stable rate of 34.7 % and 34.4 % with time. Again, we are unable to detect the true number of redo procedures, but a reliable method for identifying them would allow us to compare first-time procedures at HVCs and LVCs, as well as the rates and outcomes of re-operative procedures.

Finally, to address your third question, there are several barriers to regionalization. As we demonstrated in our graph comparing patients' home county and hospital location (Fig. 2), patients tend to have surgery near their home. The exception is patients in the least populous counties, those with less than 10,000 citizens, who may not have nearby hospitals or surgeons that perform antireflux procedures. As you stated in an editorial in the *Annals of Surgical Oncology* in 2009 regarding esophageal cancer surgery, patients may prefer surgery near their home due to familiarity, as well as proximity to family, friends, and ministers or other support group members. Another explanation for the lack of regionalization is that thousands of surgical residents were trained between 1998 and 2009, most of whom were likely taught antireflux procedures, especially laparoscopic Nissen funduplications. Many of these trainees became general surgeons and are now practicing in a variety of hospitals, both rural and urban. Regarding the necessary magnitude of outcome differences before patients take notice, we cannot reliably predict this. Compared with complex oncologic resections, antireflux procedures are considered a component of the general surgeon's armamentum; national recommendations for regionalization, from the insurance industry or otherwise, may be poorly received. A potential solution is to establish centers of excellence for antireflux procedures.

Thank you again for reviewing our manuscript.