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Effect of Minimum-Volume Standards on Patient Outcomes and Surgical Practice Patterns for Hysterectomy

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Abstract

Objective—To model the effect of implementing minimum-volume standards for women who underwent hysterectomy on patient outcomes and surgeon practice patterns.

Methods—We conducted a retrospective cohort study using the New York Statewide Planning and Research Cooperative System (SPARCS) to capture all women who underwent hysterectomy from 2010 to 2014. We estimated the number of hysterectomies performed by each patient's physician during the prior year. Multivariable models were utilized to estimate the ratio of observed-to-expected (O/E) complications based on each surgeon's volume during the prior year. The mean O/E ratio of surgeons was then plotted by volume. The number of patients and surgeons that would be eliminated and the reduction in complications if minimum-volume standards (lowest 5th and 10th percentiles) were implemented were analyzed. Separate analyses were performed for each route of hysterectomy.

Results—We identified a total of 127,202 patients. For abdominal hysterectomy, increasing surgeon volume was associated with a decreasing rate of complications ($P<0.001$). Overall, 17.5% of surgeons ($n=1260$) had a prior year volume of 1 abdominal hysterectomy. The mean O/E ratio of surgeons with a prior year abdominal hysterectomy volume of 1 was 1.47 ($SD=2.71$). Within this group of surgeons, 31.4% had an O/E ratio of ≥ 1 indicating a higher than expected complication rate while 68.7% of the surgeons had an O/E ratio of <1 suggesting a lower complication rate than expected based on case mix. Selection of a prior year volume standard of 1

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would restrict 12.5% of surgeons performing robotic-assisted, 16.8% of those performing laparoscopic, and 27.6% of surgeons performing vaginal hysterectomy.

Conclusion—Implementing minimum-volume standards for hysterectomy, for even the lowest volume physicians, would restrict a significant number of gynecologic surgeons including many with outcomes that are better than predicted.

Precis

Implementing minimum-volume standards for hysterectomy will limit the practice of a large number of surgeons including many with good outcomes.

Introduction

A large body of literature has demonstrated the association between surgical volumes and outcomes; those patients operated on at higher volume hospitals and by higher volume surgeons have lower morbidity and mortality compared to patients treated by lower volume providers.¹⁻⁴ While the association between volume and outcomes has been shown for numerous procedures, the effect is most pronounced for operations associated with significant complication rates.^{5,6} Recognition of the volume-outcomes paradigm has led to changes in practice and resulted in the concentration of some operations to higher volume providers, which in turn has led to reduced mortality.^{7,8}

Despite the recognition of the volume phenomenon, a large number of patients are still treated by low volume providers. Quality improvement efforts have focused on either improving the quality of care rendered by low volume providers, or regionalizing care of some procedures to higher volume surgeons and centers.⁹ Recently, several institutions have proposed minimum-volume standards that hospitals and surgeons must achieve in order to continue to perform certain surgical procedures.¹⁰ Proponents of minimum-volume standards suggest that simple volume cut-offs can eliminate the lowest performing surgeons and hospitals and save lives.^{10,11} In contrast, others have argued that minimum-volume standards are often arbitrary, largely untested, and an over-simplification of a complex issue.¹²

In gynecology, changing practice patterns over the last decade have led to a large number of surgeons who perform a relatively small number of procedures annually. The effect of implementing minimum-volume standards for gynecologic surgery is largely unknown. We analyzed a large cohort of patients who underwent hysterectomy to model the effect of implementing minimum-volume standards on patient outcomes and surgeon practice patterns.

Materials and Methods

We performed a retrospective cohort study using the New York Statewide Planning and Research Cooperative System (SPARCS).¹³ SPARCS was established in 1979 as a state-wide comprehensive data reporting system that collects information on hospital discharges, inpatient surgeries, ambulatory surgeries, and emergency department admissions. Importantly, SPARCS allows identification of physicians across hospitals so that an accurate

volume assessment of surgeons can be obtained. Therefore, a specific surgeon's procedural volume and associated perioperative complications can be evaluated. The SPARCS database has been used in a large number of outcomes studies.^{14–16} This study used deidentified patient data and was deemed exempt by the Columbia University Institutional Review Board.

We identified patients who underwent hysterectomy between 2010 and 2014. Patients with missing or invalid data of gender and surgeon and hospital identifiers were excluded. Hysterectomy was classified as abdominal, robotic-assisted, laparoscopic, or vaginal using ICD-9 and CPT codes (Appendix 1, available online at <http://links.lww.com/xxx>). Our primary estimate of volume relied on the given surgeon or hospital's procedural volume in the prior calendar year. Surgeon and hospital volume for each approach was calculated as the number of hysterectomies performed by a given patient's surgeon and hospital in the prior year. Patients with surgeons who had a prior year volume of zero were excluded.

We examined demographic characteristics including age (<30, 30–39, 40–49, 50–59, 60–69, 70 years), race (white, black, Hispanic, other, unknown), year of admission, insurance status (private, Medicare, Medicaid, other, none, unknown), and type of admission (elective, emergent/urgent, other/unknown). Comorbidity was measured using the Elixhauser comorbidity score and grouped as 0, 1, or 2 comorbid conditions.¹⁷ For each woman, we recorded concomitant procedures including lymphadenectomy (LND), anterior colporrhaphy, posterior colporrhaphy, incontinence repair, and sacral colpopexy. The following indications for surgery were also noted: leiomyoma, endometriosis, abnormal menstruation and bleeding, benign neoplasms and cysts, pelvic organ prolapse, endometrial hyperplasia, ovarian, fallopian tube, peritoneal cancer and other gynecological cancer (uterine or cervical).

The primary outcome of the analysis was perioperative morbidity. Using a previously described classification schema, we defined perioperative morbidity as the occurrence of any of the following complications: intraoperative injury (bladder injury, ureteral injury, intestinal injury, vascular injury, other operative injury), surgical site complications (hemorrhage, wound complication, abscess, gastrointestinal complication), and medical complications (vascular thrombosis, urinary complications, pulmonary complications, cardiovascular complications, neurologic complications, shock, infection).^{18–20} We also analyzed perioperative mortality; however, given that mortality was infrequent this outcome was not modeled in our primary analyses. The analysis of morbidity and mortality was limited to events that occurred during the index admission for surgery.

The demographic and clinical characteristics of patients were reported descriptively. Hospital and surgeon volumes are reported as medians and interquartile ranges. The primary analysis was to explore the association between a surgeon's perioperative morbidity rate and the prior year procedural volume. To examine the association between volume and perioperative morbidity, we calculated the observed-to-expected ratio (O/E) of morbidity for each surgeon each year. The expected morbidity rate was estimated as the mean predicted rate using a multivariable log-Poisson model adjusting for age, race, year of treatment, insurance, type of admission, comorbidity, concomitant procedures, indications for surgery

and hospital volume with spline effect. Concomitant lymphadenectomy was adjusted for in the abdominal, robotic-assisted, and laparoscopic hysterectomy cohorts, whereas concomitant anterior and posterior colporrhaphy, incontinence repair, and colpopexy were adjusted for in the vaginal hysterectomy cohort.

An O/E ratio of <1 indicates that the morbidity rate of a surgeon was lower than expected, while an O/E ratio of ≥ 1 indicates that the rate is the same as or higher than predicted. Separate O/E ratios were calculated for each surgeon annually and separately for each route of hysterectomy. After estimating the mean O/E ratios of all surgeons during a given year, the data was plotted based on a surgeon's prior year procedural volume.

To identify minimum-volume standards, we sought to select the lowest volume surgeons that should have had the highest O/E morbidity ratios. A priori, we defined the lowest 5th or 10th percentile by volume or surgeons with a volume of 3 standard deviations below the mean volume for this estimate. The number of surgeons below and above the volume cutoff and the descriptive statistics of their O/E ratios are reported. The association between O/E morbidity ratio and volume was examined using generalized estimating equation (GEE) with unstructured variance matrix to account for repeated O/E of the same surgeon across the years. Volume was included as restricted cubic spline with 5 knots placed at 5th, 27.5th, 50th, 72.5th, and 95th percentiles. P-values were estimated using robust score tests for curvature and overall significance. The number of patients and surgeons that would be eliminated and the reduction in complications if minimum-volume standards were to be implemented were analyzed. All analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, North Carolina). All statistical tests were two-sided. A P-value of <0.05 was considered statistically significant.

Results

A total of 127,202 patients including 55,816 (43.9%) who underwent abdominal hysterectomy, 43,198 (34.0%) who underwent laparoscopic, 14,057 (11.1%) who underwent robotic-assisted, and 14,131 (11.1%) who had a vaginal hysterectomy were identified (Table 1, Figure 1). The demographic characteristics of the cohort are displayed in Table 1. The most common indications for surgery were leiomyoma for abdominal, laparoscopic and robotic-assisted hysterectomy and pelvic organ prolapse for vaginal hysterectomy. The overall morbidity rate was 15.9% for abdominal, 4.3% for laparoscopic, 6.8% for robotic-assisted and 5.1% for vaginal hysterectomy. Mortality was rare and ranged from 0.01–0.2% across the various routes of hysterectomy.

For abdominal hysterectomy, there were 7198 surgeons who performed the surgeries (Table 2). The number of surgeons performing procedures each year decreased over time, while the median prior year surgical volume declined from 5 cases (IQR, 2–10) in 2010 to 4 (IQR, 2–8) cases in 2014. The number of surgeons performing both laparoscopic and robotic-assisted hysterectomy each year increased over time. The median prior year case volume for laparoscopic hysterectomy was 5 (IQR, 2–10) in 2010 and 5 (IQR, 2–13) in 2014, while the corresponding median case volumes for robotic-assisted hysterectomy were 8 (IQR, 4–16) and 8 (IQR, 3–17), respectively. The number of surgeons performing vaginal hysterectomy

declined from 552 in 2010 to 421 by 2014, while the median prior year case volume remained constant at 3 (IQR, 1–6) in 2010 and 3 (IQR, 2–6) in 2014.

For abdominal hysterectomy, increasing surgeon volume was associated with a decreasing rate of complications ($P<0.001$) (Figures 2A, 3A). Overall, 17.5% of surgeons ($n=1260$) had a prior year volume of 1 abdominal hysterectomy. Thus, the a priori defined volume cut points of the lowest 5th and 10th percentiles of surgeons as well as a volume of 3 standard deviations below the mean would all be defined as a prior year volume of 1 (Table 3). The mean observed-to-expected morbidity ratio of surgeons with a prior year abdominal hysterectomy volume of 1 was 1.47 (SD=2.71). Within this group of surgeons, 31.4% had an O/E ratio of ≥ 1 indicating a higher than expected complication rate while 68.7% of the surgeons had a O/E ratio of <1 suggesting a lower complication rate than expected based on their case mix.

For robotic-assisted hysterectomy, there was a non-statistically significant decrease in complications with increasing prior year procedural volume ($P=0.12$) (Figures 2B, 3B). Overall, 12.5% of surgeons had a prior year volume of 1 ($n=118$) with a mean O/E ratio of 1.38 (SD=3.56). Within this group, 20.3% had an O/E ratio ≥ 1 while 79.7% had an O/E ratio of <1 . For laparoscopic hysterectomy, the complication rate (O/E ratio) rose slightly from a prior year volume of 1 case to 3 cases, and then declined ($P=0.03$) (Figures 2C, 3C). The lowest volume grouping of surgeons, those with a volume of 1, included 16.8% ($n=664$) of the physicians. Within this group, the mean O/E ratio was 0.86 (SD=3.55) suggesting a more favorable morbidity profile than predicted. For vaginal hysterectomy, the mean O/E ratio declined from a volume of 1 to a volume of 4 and then rose until 15 procedures and then declined again ($P=0.43$) (Figures 2D, 3D). A total of 27.6% ($n=676$) of surgeons had a prior year volume of 1 with a mean O/E ratio of 1.24 (SD=3.84).

Discussion

These data suggest that for hysterectomy, a relatively large number of surgeons perform a very low volume of procedures annually. Among this group of surgeons who perform only one procedure per year, outcomes are significantly worse than for higher volume surgeons for abdominal hysterectomy. However, even within this group of very low volume surgeons, a relatively large number of physicians have outcomes that are better than expected. Implementing minimum-volume standards for hysterectomy for even the lowest volume surgeons would restrict a significant number of gynecologic surgeons, including many with outcomes that are better than predicted.

Given the association between volume and outcomes for many procedures, there is a strong rationale for minimum-volume standards.^{10,11} Restricting the practice of the lowest volume physicians and hospitals should eliminate providers with the worst outcomes and therefore improve the outcomes of patients.^{10,11} One analysis of the effects of using proposed minimum hospital volume standards for five procedures (coronary artery bypass grafting, aortic aneurysm repair, coronary angioplasty, esophagectomy, and carotid endarterectomy) estimated that such a program would save over 2500 lives per year.¹¹ In addition to public

reporting of procedural volume, some centers are now developing minimum-volume standards for both hospitals and physicians.^{10,21}

Despite the appeal of minimum-volume standards, our data demonstrate a number of practical limitations for the application of this strategy to hysterectomy. First, given that a large number of gynecologic surgeons now perform a low volume of procedures annually, even the lowest volume cut points would curtail the practice of a substantial number of surgeons. Using a volume threshold of only one case per year would restrict 18% of surgeons who perform abdominal hysterectomy and 28% of those who perform vaginal hysterectomy.

Limiting the practice of such a large number of providers has important practical implications. For patients, such a strategy may limit access to care and require increased travel to obtain treatment. Regionalization of care and selective referral is often unpopular among patients who are frequently unwilling to travel to receive care, even for procedures in which increased volume is associated with significant reductions in mortality.^{22–25} Given that the improved outcomes of high volume providers for hysterectomy are modest, restricting care by low volume physicians may be unpopular among patients. Further, efforts to regionalize surgical care often disproportionately affect minority and underserved patients and create a substantial burden for residents of rural areas.^{24,26} For physicians, limiting practice may disproportionately impact younger physicians who are building their practices and paradoxically further reduce the number of surgeons who meet minimum-volume standards.

Second, minimum-volume standards are problematic in that these criteria would restrict the practice of a large number of physicians who have better than expected outcomes.¹² In our analysis, while the mean observed-to-expected morbidity ratio for surgeons with a volume of 1 demonstrated a higher than expected complication rate, 69% of the physicians with a case volume of 1 actually had outcomes that were better than expected. Particularly among low volume surgeons there is likely significant random variation in outcomes. Using a strict minimum-volume standard does not allow distinction based on actual performance. As such, standards that use not only volume but also actual outcomes of surgeons may be more appropriate.

We recognize a number of important limitations. While the SPARCS dataset captures physician volume at all hospitals in New York State, it lacks data on operations performed in other states. However, any underestimation of volume is likely to be very small. There is some under capture of complications using administrative data. This analysis focused on only major complications likely to generate a code. Further, this classification schema has been used in a number of other studies and any under capture of complications should be balanced across the various volumes.^{27,28} We are unable to perform complete risk adjustment for some unmeasured confounding factors including uterine size, previous surgical procedures, and technical complexity of the procedure. Our analysis focused on the primary operating surgeon. We were unable to model the effect of volume gained by surgeons as assistants had on outcomes. As mortality and severe complications are relatively rare after hysterectomy, we analyzed a composite of significant complications. Finally, this

analysis was limited to a single state. Other regions of the U.S. may have different practice patterns and our data may not be generalizable to all areas of the country.

These data highlight the complexity of implementing minimum-volume standards in surgery. Although low-volume hysterectomy surgeons clearly have inferior outcomes, even using a very low volume cut-point would restrict privileges for a large number of surgeons, including many with acceptable outcomes. As policy makers contemplate minimum-volume standards, each procedure should be considered individually and any proposed standard should be based on objective data. Estimating how a chosen cut point reduces adverse outcomes should be weighed against the number of surgeons that would be affected and the potential downstream impact on patient access. Going forward, a more nuanced approach to surgical standards appears warranted. Other metrics such as prior outcomes, experience with the performance of other surgical procedures, and overall experience may also be useful and prove more meaningful for some procedures.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Flow diagram of cohort selection. *Patients in 2009 were included in the calculation of prior year volume.

Figure 2.

Observed-to-expected perioperative morbidity stratified by prior year surgeon volume for abdominal (A), robotic-assisted (B), laparoscopic (C), and vaginal hysterectomy (D).

Shaded areas represent 95% CIs. Abdominal: $P < .001$; robotic-assisted: $P = .12$; laparoscopic: $P = .03$; vaginal: $P = .43$.

Figure 3.

Observed-to-expected perioperative morbidity stratified by prior year surgeon volume for abdominal (A), robotic-assisted (B), laparoscopic (C), and vaginal hysterectomy (D). For each surgeon in each year, the expected morbidity was calculated as the mean of the predicted morbidity from a multivariable log-Poisson model adjusting for age, race, year, insurance, type of admission, comorbidity, concomitant procedures, indications, and hospital volume, and then the observed-to-expected ratio was calculated. *Dotted lines* represent 5th and 95th percentiles of the observed-to-expected ratio for each value of prior year surgeon volume. The association between the observed-to-expected and prior year surgeon volume was examined using generalized estimating equations with prior year surgeon volume as a single predictor of the mean observed-to-expected and was plotted as the *solid lines*. *Shaded areas* represent 95% CIs from the generalized estimating equations. Abdominal: $P<.001$; robotic-assisted: $P=.12$; laparoscopic: $P=.03$; vaginal: $P=.43$.

Table 1.

Patient characteristics stratified by route of hysterectomy.

	Abdominal		Robotic		Laparoscopic		Vaginal	
	N	%	N	%	N	%	N	%
<i>Patients</i>	55,816	43.9	14,057	11.1	43,198	34.0	14,131	11.1
<i>Age (years)</i>								
<30	642	1.2	111	0.8	724	1.7	181	1.3
30-39	6,085	10.9	1,270	9.0	6,304	14.6	1,387	9.8
40-49	24,874	44.6	4,511	32.1	19,247	44.6	3,833	27.1
50-59	13,217	23.7	3,636	25.9	9,714	22.5	2,868	20.3
60-69	6,654	11.9	2,805	20.0	4,728	10.9	3,220	22.8
70	4,344	7.8	1,724	12.3	2,481	5.7	2,642	18.7
<i>Race</i>								
White	26,836	48.1	9,927	70.6	30,972	71.7	9,350	66.2
Black	14,446	25.9	1,617	11.5	4,294	9.9	1,283	9.1
Hispanic	6,787	12.2	1,126	8.0	3,677	8.5	1,961	13.9
Other	7,489	13.4	1,361	9.7	4,101	9.5	1,482	10.5
Unknown	258	0.5	26	0.2	154	0.4	55	0.4
<i>Year of admission</i>								
2010	14,114	25.3	1,631	11.6	7,659	17.7	3,363	23.8
2011	12,212	21.9	2,641	18.8	8,016	18.6	2,995	21.2
2012	10,434	18.7	3,227	23.0	8,817	20.4	2,726	19.3
2013	9,559	17.1	3,346	23.8	9,634	22.3	2,606	18.4
2014	9,497	17.0	3,212	22.9	9,072	21.0	2,441	17.3
<i>Insurance</i>								
Private	40,907	73.3	10,556	75.1	34,074	78.9	9,040	64.0
Medicare	7,215	12.9	2,394	17.0	4,923	11.4	3,605	25.5
Medicaid	5,286	9.5	709	5.0	2,891	6.7	949	6.7
Other	168	0.3	23	0.2	121	0.3	42	0.3
None	2,153	3.9	354	2.5	1,146	2.7	475	3.4
Unknown	87	0.2	21	0.2	43	0.1	20	0.1
<i>Type of admission</i>								
Elective	47,969	85.9	10,514	74.8	13,151	30.4	8,798	62.3
Emergent/urgent	7,028	12.6	1,268	9.0	2,176	5.0	1,004	7.1
Other/unknown	819	1.5	2,275	16.2	27,871	64.5	4,329	30.6
<i>Comorbidity</i>								
0	18,451	33.1	4,458	31.7	20,670	47.9	6,002	42.5
1	16,747	30.0	3,995	28.4	12,391	28.7	4,186	29.6
2	20,618	36.9	5,604	39.9	10,137	23.5	3,943	27.9
<i>Concomitant procedures</i>								
Lymphadenectomy	7,664	13.7	4,003	28.5	3,662	8.5	37	0.3
Anterior colporrhaphy	858	1.5	291	2.1	1,492	3.5	6,472	45.8

	Abdominal		Robotic		Laparoscopic		Vaginal	
	N	%	N	%	N	%	N	%
Posterior colporrhaphy	631	1.1	252	1.8	985	2.3	5,174	36.6
Incontinence repair	1,672	3.0	797	5.7	1,986	4.6	4,330	30.6
Sacral colpopexy	2,745	4.9	1,090	7.8	2,403	5.6	4,193	29.7
<i>Indication for surgery</i>								
Leiomyoma	34,571	61.9	5,338	38.0	24,199	56.0	4,477	31.7
Endometriosis	9,812	17.6	2,381	16.9	14,224	32.9	2,219	15.7
Abnormal menstruation and bleeding	21,580	38.7	4,411	31.4	20,114	46.6	4,095	29.0
Benign neoplasms and cysts	12,615	22.6	2,603	18.5	12,060	27.9	1,609	11.4
Pelvic organ prolapse	3,221	5.8	1,420	10.1	5,298	12.3	9,943	70.4
Endometrial hyperplasia	1,750	3.1	1,153	8.2	3,475	8.0	473	3.4
Ovarian, fallopian tube, peritoneal cancer	4,656	8.3	389	2.8	526	1.2	14	0.1
Other gyn cancer (uterine, cervical cancer)	6,677	12.0	4,636	33.0	5,498	12.7	252	1.8
<i>Hospital prior year volume (median, IQR)</i>	147	(80—246)	82	(42—230)	109	(62—251)	40	(22—73)
<i>Outcomes</i>								
Morbidity	8,855	15.9	962	6.8	1,851	4.3	721	5.1
Mortality	126	0.2	6	0.04	9	0.02	2	0.01

Table 2.

Descriptive statistics of prior year surgical volume by route of hysterectomy.

	No. surgeons	Median	(IQR)
<i>Abdominal</i>	7198	5	(2—9)
2010	1604	5	(2—10)
2011	1542	5	(2—10)
2012	1428	4	(2—9)
2013	1328	4	(2—9)
2014	1296	4	(2—8)
<i>Robotic</i>	945	8	(3—19)
2010	98	8	(4—16)
2011	150	7	(2—19)
2012	207	8	(3—21)
2013	245	9	(3—19)
2014	245	8	(3—17)
<i>Laparoscopic</i>	3965	5	(2—11)
2010	733	5	(2—10)
2011	785	5	(2—10)
2012	804	5	(2—11)
2013	822	5	(2—11)
2014	821	5	(2—13)
<i>Vaginal</i>	2446	3	(1—6)
2010	552	3	(1—6)
2011	530	3	(1—7)
2012	491	3	(1—6)
2013	452	3	(1—6)
2014	421	3	(2—6)

Data represent number of surgeons performing the given type of hysterectomy each year with the median volume and interquartile ranges of procedures performed by these surgeons during the prior calendar year.

Table 3.

Theoretic minimum-volume standards and observed-to-expected ratio of perioperative morbidity stratified by route of hysterectomy.

	Abdominal	Robotic	Laparoscopic	Vaginal
<i>Volume</i>				
5th percentile	1	1	1	1
10th percentile	1	1	1	1
<i>Volume cutoff</i>	1	1	1	1
<i>Below volume cutoff</i>				
Mean O/E morbidity ratio (SD)	1.47 (2.71)	1.38 (3.56)	0.86 (3.55)	1.24 (3.84)
N (%) surgeons	1,260 (17.5%)	118 (12.5%)	664 (16.8%)	676 (27.6%)
O/E <1	865 (68.7%)	94 (79.7%)	594 (89.5%)	584 (86.4%)
O/E = 1	395 (31.4%)	24 (20.3%)	70 (10.5%)	92 (13.6%)
<i>Above volume cutoff</i>				
Mean O/E morbidity ratio (SD)	1.03 (1.79)	1.20 (2.22)	1.11 (2.71)	1.05 (3.22)
N (%) surgeons	5,938 (82.5%)	827 (87.5%)	3,301 (83.3%)	1,770 (72.4%)

O/E: observed-to-expected ratio of perioperative morbidity.