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ORIGINAL ARTICLE

Safety of laparoscopic sacrocolpopexy with concurrent rectopexy: peri-operative morbidity in a nationwide cohort

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Abstract

Introduction and hypothesis Rectopexy and sacrocolpopexy can be performed concurrently to treat rectal and vaginal prolapse. We hypothesized that concurrent procedures might be associated with more complications than rectopexy and sacrocolpopexy alone.

Methods Patients undergoing laparoscopic sacrocolpopexy or rectopexy, or concurrent laparoscopic sacrocolpopexy and rectopexy were identified in the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) database from 2013 to 2016. Preoperative characteristics, operative time, and 30-day post-operative complications were compared between groups. Complications were those defined by the ACS Risk Calculator. Descriptive tests and regression methods were utilized for group comparisons. Significance was set at $p < 0.05$.

Results We identified 7,232 laparoscopic sacrocolpopexy, 1,560 laparoscopic rectopexy, and 123 concurrent laparoscopic sacrocolpopexy and rectopexy cases. Patients undergoing concurrent procedures were more commonly white, non-Hispanic, non-diabetic, and smokers. Operative time was longest for concurrent procedures, followed by sacrocolpopexy and rectopexy ($p < 0.0001$). Patients undergoing isolated rectopexy were more commonly ≥ American Society of Anesthesiologists class 3 ($p < 0.0001$). Rates of any complication for colpopexy, rectopexy, and concurrent procedures did not differ (6.18%, 7.63%, 8.94%; $p = 0.058$). Serious complication rates for colpopexy, rectopexy, and concurrent procedures did not differ (5.52%, 6.35%, 8.13%; $p = 0.222$). Odds of experiencing any complication were higher comparing rectopexy with colpopexy alone (adjusted odds ratio = 1.252, 95% CI 1.002–1.565). Comparing all groups, rectopexy had the highest mortality, reoperation, and transfusion rates (all $p < 0.05$). Concurrent procedures had the highest surgical site and urinary tract infection rates (all $p < 0.05$).

Conclusions Complications were low for all three procedures. Concurrent repair may be appropriate in well-selected patients.

Keywords Laparoscopic sacrocolpopexy · Laparoscopic rectopexy · Complications · Surgery

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Introduction

Laparoscopic sacrocolpopexy is a commonly performed durable surgical repair for vaginal vault prolapse [1, 2]. Many women with significant pelvic floor dysfunction experience both vaginal and rectal prolapse [3]. Although laparoscopic sacrocolpopexy appears to have limited post-operative morbidity, evidence regarding the safety of combining this procedure with laparoscopic rectopexy is unclear [4]. Outcomes of minimally invasive sacrocolpopexy in 36 cases of concomitant sacrocolpopexy and rectopexy found that combined procedures were associated with increased risks of blood transfusion, cardiac complications, sepsis, and osteomyelitis when compared with minimally invasive sacrocolpopexy alone [5]. Abdominal sacrocolpopexy with sigmoid resection and

rectopexy compared with sigmoid resection and rectopexy alone revealed that post-operative ileus was more common in procedures that included sigmoid resection and rectopexy. Although there was a trend toward greater transfusion in the cohort with combined procedures, the study may have been underpowered to find a difference [6].

While previous studies raise important questions regarding whether or not concurrent rectopexy and colpopexy result in increased morbidity and mortality compared with the same procedures performed alone, they were small, single-institution studies that utilized differing surgical approaches. In the current study, we assessed post-operative morbidity among patients undergoing concomitant procedures for vaginal vault prolapse and rectal prolapse, utilizing a large, well-curated national dataset, and to compare complications and serious adverse events among women who underwent sacrocolpopexy with rectopexy or either procedure performed alone. We hypothesized that patients undergoing laparoscopic rectopexy at the time of laparoscopic sacrocolpopexy might have higher rates of 30-day post-operative morbidity than those patients undergoing laparoscopic sacrocolpopexy or rectopexy alone.

Materials and methods

Study design

This retrospective cohort study utilized a large national surgical quality database, the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP). The ACS designed the NSQIP database to measure risk-adjusted surgical outcomes following surgery, with the express purpose of improving surgical quality of care. This database contains prospectively collected 30-day post-operative surgical data from over 500 participating hospitals in the USA [7]. Participating hospitals are located in 49 out of 50 states and in 9 countries, and include a range of hospital sizes, from major academic institutions to small and rural facilities. Because this study utilizes existing de-identified case information, it was granted Institutional Review Board (IRB) Exempt status by the University of New Mexico Human Research Protections Office Human Research Review Committee. Any major surgical case determined by the Current Procedural Terminology (CPT®) code was eligible for inclusion within the NSQIP. Case exclusion criteria for NSQIP can be found in Supplemental Fig. 1; however, none of these would have applied to the patients assessed in this study.

The primary outcome of the current study was composite 30-day morbidity comparing laparoscopic sacrocolpopexy alone versus laparoscopic rectopexy alone, versus concurrent laparoscopic sacrocolpopexy and laparoscopic rectopexy. Outcomes used to assess morbidity were those designated by the ACS Risk Calculator. This tool utilizes 20 preoperative patient characteristics to estimate the likelihood of incurring any of 15 post-operative complications. Within the Risk Calculator, morbidity is further stratified into those defined as "any complication" and those defined as "serious complications" [8]. Because these outcome variables were defined a priori by the ACS and are compatible with the outcome variables assessed within the NSQIP Database, we chose to use these outcomes as the basis of our study.

Data collection

All data were collected by the NSQIP and made available to participating institutions. Data collection is carried out by trained surgical clinical reviewers with high inter-rater reliability [9]. Annual audits demonstrate an approximately 2% disagreement for all program-assessed variables [10]. Cases from participating hospitals are sampled every 8 days and patients are followed prospectively for 30 days following surgery. This method differs from other quality improvement program databases in that the information is collected directly from medical chart review rather than from insurance claims. The data from medical chart review were compared corroborated with operating room procedure logs to ensure accuracy. This method allows every day of the week to be sampled equally over the course of a year. Over 150 variables are collected, including preoperative risk factors, intra-operative occurrences, and 30-day post-operative outcomes for each patient undergoing surgery. Data collected by the surgical clinical reviewers is submitted through the NSQIP data collection website on a continuous basis. All data are compiled in participant use files (PUFs), which are published on a yearly basis and made available to NSQIP-participating institutions through an institutional data use agreement.

Data management

Participant use files from 2013 to 2016 were accessed in accordance with the data use agreement between the NSQIP and the University of New Mexico, and analyzed for the purposes of this study. SAS 9.4 (SAS Institute, Cary, NC, USA) was used to compile PUFs for all 4 years into a single repository. No duplicate cases were found. Male subjects were then excluded from the dataset. Cases of sacrocolpopexy and rectopexy (with and without sigmoid resection) were identified using CPT procedure codes for laparoscopic sacrocolpopexy (57425), abdominal sacrocolpopexy (57280), laparoscopic rectopexy (45400), laparoscopic rectopexy with sigmoid resection (45402), abdominal rectopexy (45540), and abdominal rectopexy with sigmoid resection (45550). For the purposes of this study, only laparoscopic cases were analyzed. To identify patients who underwent concurrent procedures, we aggregated cases into three mutually exclusive categories:

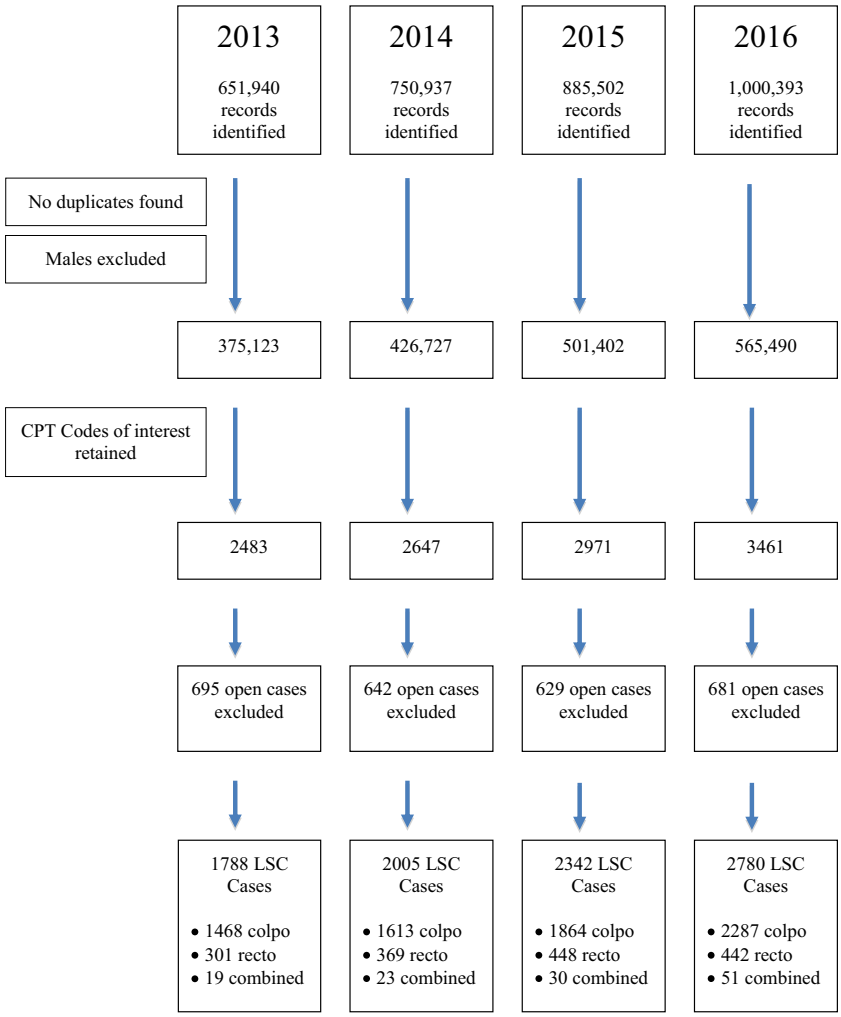

Fig. 1 Data flow diagram

colpopexy alone, rectopexy alone, and colpopexy combined with rectopexy, according to the CPT codes.

Data analysis

Means and standard deviations were used to describe numerical variables, whereas frequencies and relative frequencies were used to describe categorical variables. The Chi-squared test was used to assess any associations between categorical variables and the *F* test from the analysis of variance (ANOVA) was used to assess equality of means between groups. Linear logistic regression estimated the adjusted and unadjusted odds ratio of major complications or any complication for different groups. Although there were several preoperative characteristics that differed among the groups, we performed logistic regression to adjust for confounders that were most clinically significant, including smoking status, diabetes, race, operative time, weight, American Society of Anesthesiologists (ASA) class, and year of surgery, when comparing the cohorts' composite complications [11–13].

Results

Sample and participant characteristics

Analysis of the 2013–2016 NSQIP PUFs yielded a total of 11,562 cases of laparoscopic sacrocolpopexy, laparoscopic rectopexy (with and without sigmoid resection), open abdominal sacrocolpopexy, and open abdominal rectopexy (with and without sigmoid resection). For the purposes of this study, only the laparoscopic surgeries were analyzed, with a total of 8,915 cases identified. Among these cases, there were 7,232 cases of laparoscopic sacrocolpopexy, 1,560 cases of laparoscopic rectopexy, and 123 cases of laparoscopic sacrocolpopexy with concurrent rectopexy (Fig. 1).

Table 1 summarizes the characteristics and operative times for the three cohorts. The majority of participants were white. Patients varied by weight, with those undergoing colpopexy being heaviest, followed by those undergoing combined procedures and those undergoing rectopexy. Diabetes requiring medication management or insulin was most common among patients undergoing sacrocolpopexy, followed by rectopexy,

Table 1 Patient characteristics and operative time

	Sacrocolpopexy, *n* (%)	Rectopexy, *ṅ* (%)	Concurrent, *n* (%)	*p* value
Ethnicity[a]				<0.0001
Hispanic	587 (8.69)	57 (3.94)	4 (3.36)	
Non-Hispanic	6,170 (91.4)	1,391 (96.1)	115 (96.6)	
Race[a]				<0.0001
White	6,114 (90.2)	1,344 (86.2)	117 (95.1)	
Black/African American	409 (6.04)	49 (3.14)	0 (0.00)	
Asian	208 (3.07)	19 (1.22)	0 (0.00)	
American Indian/Alaskan	26 (0.39)	15 (0.96)	2 (1.63)	
Hawaiian/Pacific Islands	19 (0.28)	1 (0.06)	0 (0.00)	
Unknown	456 (6.31)	132 (8.46)	4 (3.25)	
Age, mean (years)[b]	58.8 (11.7)	59.9 (16.7)	58.7 (14.0)	0.003
Weight, mean (lb)[b]	163 (35.3)	144 (34.6)	150 (33.9)	<0.0001
Diabetes requiring oral medications or insulin[a]	678 (9.38)	125 (8.01)	3 (2.44)	0.009
Smoking status[a]	669 (9.17)	275 (17.6)	23 (18.7)	<0.0001
Hypertension requiring medications[a]	2,681 (37.1)	609 (39.0)	37 (30.1)	0.086
Operative time, mean (min)[b]	192 (80.5)	171 (73.8)	240 (82.1)	<0.0001
Preoperative hematocrit, mean[b]	40.0 (3.40)	38.6 (4.21)	40.1 (3.11)	<0.0001
ASA class				<0.0001
1 – No disturbance	587 (8.12)	87 (5.59)	6 (4.88)	
2 – Mild disturbance	4,949 (68.5)	846 (54.3)	82 (66.7)	
3 – Severe disturbance	1,646 (22.8)	583 (37.4)	35 (28.5)	
4+ – Life-threatening	47 (0.65)	41 (2.63)	0 (0.00)	

[a] Chi-squared test was used to examine the association between two categorical variables. Reported results include the frequency *n* and the relative frequency (%)

[b] The *F* test from ANOVA was used to compare the means of three groups. Reported results include the sample mean ± the standard deviation

followed by concurrent procedures. Patients undergoing concurrent procedures were most likely to be smokers. Mean operative time was longest for concurrent procedures, followed by sacrocolpopexy and rectopexy ($p < 0.0001$). Most patients undergoing any procedure had an ASA physical status classification of 2, characterized as mild systemic disease. Patients undergoing rectopexy alone were most commonly ASA class 3 (a more severe ASA class) compared with the other cohorts.

Composite complication risk

The risk of a patient experiencing any complication did not differ between those women undergoing concurrent procedures, rectopexy alone, or colpopexy alone (Table 2). When comparing complications between two individual groups, rectopexy alone compared with colpopexy alone had higher odds of experiencing any complications (Table 3). This finding persisted following the adjusted logistic regression analysis (adjusted odds ratio [aO] = 1.252, 95% CI 1.002–1.565; Table 3). None of the other comparisons between two individual groups, including serious complications, differed (Table 3).

We performed an additional analysis to stratify composite post-operative outcomes by sigmoid resection. Patients who underwent sigmoid resection at the time of rectopexy did not have higher rates of serious post-operative complications or any post-operative complications. This was true among patients in the laparoscopic rectopexy alone group and among patients who underwent concurrent laparoscopic sacrocolpopexy and rectopexy group. Results are summarized in Table 2.

Specific complications

Table 4 notes the specific 30-day surgical morbidities/complications that occurred.

When analyzing risks of individual outcomes among procedures, individuals undergoing rectopexy alone had the highest risk of mortality, myocardial infarction, unplanned reoperation, systemic sepsis, and post-operative transfusion.

Table 2 The prevalence of serious complications or any complication within each surgical scheme

	Sacrocolpopexy, $n = 7,232$	Rectopexy, $n = 1,560$		Concurrent, $n = 123$		p value*
Serious complication	399 (5.52)	99 (6.35)		10 (8.13)		0.222
		Without resection,[a] $n = 971$	With resection,[a] $n = 586$			
		56 (5.77)	42 (7.17)			0.283
				Without resection,[a] $n = 103$	With resection,[a] $n = 20$	
				10 (9.71)	0 (0.00)	0.364
Any complication	447 (6.18)	119 (7.63)		11 (8.94)		0.058
		Without resection,[a] $n = 971$	With resection,[a] $n = 586$			
		68 (7.00)	50 (8.53)			0.278
				Without resection,[a] $n = 103$	With resection,[a] $n = 20$	
				11 (10.86)	0 (0.00)	0.209

*p values correspond to the Chi-squared test for examining the association between two categorical variables. Reported results include the frequency n and relative frequency (%)

[a] Resection refers to sigmoid resection at the time of rectopexy

Those individuals undergoing concurrent procedures were at the highest risk of superficial surgical site infection, organ space infection, wound disruption, and urinary tract infection.

No single complication occurred in more than 5% of cases. The three most common complications experienced by individuals undergoing sacrocolpopexy alone were urinary tract infection, unplanned reoperation, and post-operative transfusion. For those undergoing laparoscopic rectopexy alone, the three most common complications were unplanned reoperation, post-operative transfusion, and urinary tract infection. Patients undergoing concurrent procedures most commonly experienced urinary tract infection, organ space infection, and superficial surgical site infection For a detailed list of complications assessed and the stratification of any complication versus serious complication, see Table 5.

Discussion

Patients in this cohort undergoing concurrent laparoscopic sacrocolpopexy and rectopexy did not experience an increased risk of complications within the 30-day post-operative period when compared with women undergoing either procedure alone. In this retrospective cohort study using a national database, we found that laparoscopic surgeries for the treatment of vaginal and rectal prolapse have low rates of any complications and serious complications (less than 9%). These data suggest that, in appropriately selected patients, concurrent laparoscopic procedures can be performed for the correction of vaginal vault and rectal prolapse without significantly increasing morbidity.

Literature addressing the morbidity of concurrent sacrocolpopexy and rectopexy for the correction of pelvic

Table 3 The unadjusted and adjusted odds ratio of serious complications or any complication for different surgical schemes

	Unadjusted odds ratio OR (95% CI)	Adjusted odds ratio[a] (95% CI)
Any complication		
Both vs colpopexy	1.493 (0.798–2.793)	1.289 (0.692–2.401)
Both vs rectopexy	1.191 (0.624–2.273)	1.030 (0.541–1.960)
Rectopexy vs colpopexy	1.253 (1.016–1.546)*	1.252 (1.002–1.565)*
Serious complication		
Both vs colpopexy	1.516 (0.788–2.916)	1.325 (0.693–2.532)
Both vs rectopexy	1.306 (0.663–2.572)	1.168 (0.596–2.288)
Rectopexy vs colpopexy	1.160 (0.924–1.456)	1.134 (0.892–1.441)

[*] Confidence intervals (CIs) indicate statistical significance

[a] The odds ratios were adjusted for smoking status, diabetes, race, operative time, weight, American Society of Anesthesiologists (ASA) class, and year of surgery

Table 4 Thirty-day surgical morbidity

	Sacrocolpopexy, $n = 7,232$ (%)	Rectopexy, $n = 1,560$ (%)	Concurrent, $n = 123$ (%)	p value
Death	4 (0.06)	3 (0.32)	0 (0.00)	0.011
Cardiac arrest	4 (0.06)	1 (0.06)	0 (0.00)	0.957
Myocardial Infarction	6 (0.08)	6 (0.38)	0 (0.00)	0.012
Pneumonia	15 (0.21)	8 (0.51)	0 (0.00)	0.083
Renal insufficiency	5 (0.07)	1 (0.06)	0 (0.00)	0.957
Renal failure	4 (0.06)	2 (0.13)	0 (0.00)	0.578
Pulmonary embolism	13 (0.18)	3 (0.19)	0 (0.00)	0.889
DVT or thrombophlebitis	11 (0.15)	1 (0.06)	0 (0.00)	0.635
Unplanned reoperation	104 (1.44)	51 (3.27)	1 (0.81)	<.0001
Superficial surgical site infection	53 (0.73)	23 (1.47)	2 (1.63)	0.011
Deep incisional infection	13 (0.18)	5 (0.32)	0 (0.00)	0.469
Organ space infection	33 (0.46)	19 (1.22)	3 (2.44)	<.0001
Systemic sepsis	18 (0.25)	15 (0.96)	1 (0.81)	<.001
Septic shock	10 (0.14)	5 (0.32)	0 (0.00)	0.253
Ventilator dependence for 48 h	6 (0.08)	3 (0.19)	0 (0.00)	0.439
Unplanned re-intubation	10 (0.14)	5 (0.32)	0 (0.00)	0.253
Wound disruption	4 (0.06)	3 (0.19)	1 (0.81)	0.007
CNS deficit or cerebrovascular accident	3 (0.04)	2 (0.13)	0 (0.00)	0.408
Urinary tract infection	235 (3.25)	31 (1.99)	6 (4.88)	0.016
Post-operative transfusion	55 (0.76)	39 (2.50)	1 (0.81)	<.0001

DVT deep vein thrombosis, *CNS* central nervous system

organ prolapse is limited. Regarding postoperative morbidity for concurrent procedures, our findings differ from those reported elsewhere in the literature. In a retrospective case series of 36 patients undergoing minimally invasive concurrent rectopexy and sacrocolpopexy, women who had concurrent procedures more commonly received a blood transfusion, suffered cardiac complications, sepsis, and experienced osteomyelitis [5]. A retrospective cohort study assessing 34 patients undergoing concurrent abdominal sacrocolpopexy with sigmoid-resection suture rectopexy also noted a trend toward an increased risk of transfusion in patients undergoing concurrent abdominal procedures relative to those undergoing isolated sacrocolpopexy or rectopexy [6]. Although our present study did not assess osteomyelitis, it did not substantiate the occurrence of the other complications noted previously.

This study adds to the discussion regarding the safety of performing sigmoid resection at the time of rectopexy with concurrent laparoscopic sacrocolpopexy. Although laparoscopic resection rectopexy has been associated with an increased risk of post-operative complications when compared with laparoscopic ventral rectopexy (without sigmoid resection) in patients undergoing colorectal procedures alone, this was not the case in the present study [14]. We did not find any significant difference in rates of serious complications or any

Table 5 ACS risk calculator stratification of complications

Complication type	Examples
Serious complication	Death, cardiac arrest, myocardial infarction, pneumonia, progressive renal insufficiency, acute renal failure, PE, DVT, return to the operating room, deep incisional SSI, organ space SSI, systemic sepsis, unplanned intubation, UTI, wound disruption
Any complication	Superficial incisional SSI, deep incisional SSI, organ space SSI, wound disruption, pneumonia, unplanned intubation, PE, ventilator >48 h, progressive renal insufficiency, acute renal failure, UTI, stroke, cardiac arrest, myocardial infarction, DVT, systemic sepsis

PE pulmonary embolism, *SSI* surgical site infection, *UTI* urinary tract infection

complications when comparing 971 cases of laparoscopic rectopexy without resection with 586 cases of laparoscopic resection rectopexy. In the retrospective study by Unger et al. of cases performed at Cleveland Clinic, although only 8% of rectopexy operations included concomitant sigmoid resection, there was no association with infectious perioperative complications [5]. In the present study, 16% of concurrent laparoscopic sacrocolpopexy and rectopexy cases included sigmoid resection. These cases were not associated with an increased risk of serious complications or any complications. Further prospective trials are necessary to further clarify these relationships.

Although few studies have reported specifically on composite morbidity, the rates of isolated outcomes reported here for colpopexy alone are similar to those reported in previous NSQIP studies of pelvic organ prolapse surgery, indicating high reliability of the data [4, 15]. Our results also found lower rates of complications with laparoscopic sacrocolpopexy than the 22% reported in an analysis of 176 Medicare patients, although this sample was much older than the patients included in the present study [16].

Strengths of this study include its utilization of a national cohort of patients who underwent surgical procedures in a diversity of hospitals, likely representing the breadth of practice throughout the USA. Because cases were identified by CPT code, we were able to compare patients who received the same surgical approach rather than comparing patients who underwent open or robotic approaches. Although there have recently been several studies using the NSQIP to examine outcomes of pelvic reconstructive surgery, this study is unique in that it uses this database to specifically assess concurrent colpopexy and rectopexy. Previous studies assessed single-outcome variables, whereas the present study uses composite outcomes pre-specified by the ACS Risk Calculator to compare overall morbidity risk and includes data from 2016, the most up-to-date reporting on female pelvic floor surgery within the NSQIP sample [4, 15, 17]. Additionally, the present study represents the largest reported cohort of patients who have undergone laparoscopic sacrocolpopexy.

Limitations of this study include the inherent biases associated with any retrospective review. Because our analyses were limited to the 30 days following surgery, we cannot comment on complications more remote from surgery including mesh erosion or osteomyelitis. The sample size of patients undergoing concurrent procedures remained low compared with sacrocolpopexy or rectopexy alone. And, although crude risks of complications were not statistically different, there was a trend toward a higher complication rate for those undergoing concurrent procedures. A larger sample size of these patients may have the power to detect a significant difference. Finally, the NSQIP does not collect data regarding certain technical differences in the sacrocolpopexy cases (e.g., the shape of mesh used, and the location of mesh fixation) nor did we extract specific indications regarding reasons for unplanned reoperation. Therefore, we are unable to assess the impacts of these variations in technique on perioperative outcomes nor are we able to comment upon the specifics of unplanned reoperation.

In summary, this study represents analysis of a large national cohort and reports short-term post-operative morbidity for patients undergoing laparoscopic sacrocolpopexy and laparoscopic rectopexy. The extensive NSQIP database afforded the opportunity to effectively characterize the patient population and allowed a standardized approach to classifying complications based on the NSQIP calculator. Although a direct comparison of laparoscopic rectopexy alone with colpopexy alone found rectopexy 30-day complications to be higher, overall 30-day complication rates for all three surgical cohorts were low, including performance of concomitant rectopexy and colpopexy.

Compliance with ethical standards

Conflicts of interest Rebecca Rogers receives royalties from Uptodate, and served as the DSMB chair for the TRANSFORM trial sponsored by American Medical Systems, she receives travel and a stipend as a member of the American Board of Obstetrics and Gynecology, and she receives a stipend and travel from the IUGA for work on the *International Urogynecology Journal*. Yuko Komesu receives research support for grant 1R01AT007171, National Center Complementary and Integrative Health, NIH. Biostatistical support for this project was made possible by the CTSC Biostatistics Core, which is supported by the National Center for Research Resources and the National Center for Advancing Translational Sciences of the National Institutes of Health through grant number 8UL1TR000041. The remaining authors claim that they have no conflicts of interest.

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