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Is de novo stress incontinence after sacrocolpopexy related to anatomical changes and surgical approach?

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Abstract

Introduction and hypothesis The objective was to investigate the relationship between new onset postoperative stress urinary incontinence (SUI) after sacrocolpopexy (SCP) and anatomical change/surgical approach.

Methods We analyzed a retrospective cohort of patients with negative preoperative testing for SUI who underwent SCP from 2005 to 2012. Our primary outcome was new onset postoperative SUI. Logistic regression was used to examine the relationship among anatomical change, defined as Δ Aa, Δ Ba, Δ C, and Δ TVL, and surgical approach, categorized as abdominal (ASCP) for open cases and minimally invasive (MISCP) for laparoscopic and robot-assisted cases, and postoperative SUI.

Results Of 795 cases, 33 ASCP (43%) and 44 MISCP (57%) met the inclusion criteria for analysis. New onset SUI was demonstrated by 15 patients (45%) of the ASCP group and 7 patients (15%) of the MISCP group (p=0.005). New onset SUI was significantly associated with route of SCP and Δ Aa (p=0.006 and p=0.033 respectively). Controlling for Δ Aa, the odds of new onset SUI were 4.4 times higher in the ASCP group compared with the MISCP group (OR 4.37, 95% CI 1.42, 13.48). Controlling for route of SCP, the odds of new onset SUI were 2.2 times higher with moderate Δ Aa compared with low Δ Aa (OR 2.16 95% CI 1.07, 4.38). The odds of new onset SUI was 4.7 times higher in those with high Δ Aa than in those with low Δ Aa (OR 4.67 95% CI 1.14, 19.22). Δ Ba, Δ C, and Δ TVL were not associated with new onset SUI.

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Division Female Pelvic Medicine and Reconstructive Surgery, University of Oklahoma Health Sciences Center, 920 S. L. Young, 2430, Oklahoma City, OK 73104, USA e-mail: edgar.leclaire@gmail.com *Conclusions* Greater reduction in point Aa and abdominal surgical route are risk factors for new onset postoperative SUI after SCP.

Keywords Sacrocolpopexy · Stress urinary incontinence · Point Aa

Abbreviations

ASCP	Abdominal sacrocolpopexy
MISCP	Minimally-invasive sacrocolpopexy
POPQ	Pelvic organ prolapse quantification
SCP	Sacrocolpopexy
SUI	Stress urinary incontinence
TVL	Total vaginal length
ΔTVL	Difference between preoperative & postoperative
	total vaginal length
ΔAa	Difference in preoperative & postoperative POPQ
	point Aa
ΔBa	Difference in preoperative & postoperative POPQ
	point Ba
ΔC	Difference in preoperative & postoperative POPQ
	point C

Introduction

Symptomatic pelvic organ prolapse (POP) is a frequent indication for surgery with an annual incidence of 10 to 30 per 10,000 women [1]. Each year approximately 200,000 women undergo inpatient procedures to treat POP in the United States [2]. POP and associated pelvic floor disorders are expected to have an increasing impact on public health as the aging population grows.

Sacrocolpopexy (SCP), suspension of the anterior and posterior vagina to the anterior longitudinal ligament of the

sacrum using mesh, is a durable and effective treatment option for women with POP [3]. High anatomical success rates (78– 100%) and patient satisfaction rates (85–100%) have established SCP as a 'gold standard' to which all other surgical treatments for POP are compared [4].

Stress urinary incontinence (SUI), involuntary leakage of urine with exertion, often occurs as a result of vaginal support defects and commonly coexists with POP [5, 6]. As the degree of POP increases, SUI is more likely to be "masked" by kinking of the urethra [7-9]. Anterior vaginal tensioning intended to reduce bladder prolapse during SCP can result in flattening of the urethrovesical angle and lead to new onset SUI [10]. De novo SUI is a disappointing outcome for previously continent women who opt for surgical treatment of bothersome POP. Thus, preoperative urinary stress testing with prolapse reduced is used to identify patients who may benefit from incontinence surgery at the time of SCP. Unfortunately, bothersome SUI occurs after POP surgery even with negative preoperative testing. Reported rates of postoperative SUI following abdominal and laparoscopic SCP vary widely and range from 1.9 to 44% and 24% respectively [11, 12].

In this retrospective cohort study, we set out to investigate the relationship between de novo SUI and anatomical outcomes among women undergoing abdominal sacrocolpopexy (ASCP) and minimally invasive sacrocolpopexy (MISCP).

Materials and methods

This study protocol was approved by the Institutional Review Board at the University of Oklahoma Health Sciences Center. A retrospective cohort was sampled from all patients who underwent SCP at this institution between 2005 and 2012. Patients who did not report SUI symptoms and had negative testing preoperatively were included for analysis. Patients who underwent a concomitant incontinence procedure at the time of SCP or had prior surgery for POP or incontinence mesh were excluded.

All patients underwent preoperative cough stress testing with prolapse reduction. Reduction was performed with an intravaginal polycarbonate plastic sphere (ColpexinTM, Adamed, Warsaw, Poland). Cough stress test and Valsalva maneuvers were initiated when infused bladder volume reached 200 ml. If no leakage was observed, provocative maneuvers were repeated at 300 ml. No leakage indicated a negative test.

Our surgical technique for laparoscopic SCP is similar to that described by Frick and Paraiso for laparoscopic [13] and by Elliott et al. for robot-assisted SCP [14], with minor variations. Polytetrafluoroethylene suture (CV-2 GORE-TEX[®], Flagstaff, AZ, USA) was used for suturing graft to the vagina and sacrum during MISCP. Abdominal SCP was performed using techniques described by Addison and Timmons [15]. Polypropylene suture (Prolene[®]; Ethicon, Somerville, NJ, USA) was used to suture graft in the vagina and sacrum during ASCP. A Y-shaped polypropylene mesh graft, 10 cm in standard length and tailored to each patient's anatomical specifications during surgery, was used with all SCP procedures. If the uterus was present, a supracervical hysterectomy was performed at the time of SCP. All surgeries were performed by three fellowship trained faculty surgeons who interchangeably perform abdominal and laparoscopic or robotic SCP.

Our primary outcome was bothersome postoperative SUI after negative preoperative screening for occult SUI. To capture this outcome we considered a composite outcome that included:

- 1. A response ≥2 on item 3 of the Urogenital Distress Inventory (UDI-6)
- 2. A complaint of bothersome urinary leakage with coughing, laughing, or sneezing after surgery
- 3. A positive stress test during postoperative UDS

Our secondary outcome was reoperation for the treatment of de novo SUI.

Anatomical outcomes of interest included the difference between preoperative and postoperative measurements of total vaginal length (Δ TVL) and urethrovesical prolapse (Δ Aa) using the Pelvic Organ Prolapse Quantification (POPQ) system [16]. These outcomes were selected as surrogate markers for vaginal tensioning.

Eligible patients were identified through electronic medical record query of Current Procedural Terminology codes. All preoperative, operative, and postoperative documentation was reviewed. Only patients with postoperative follow-up and POPQ measurements were included in our final analysis.

Preoperative variables including age, race, parity, body mass index (kg/m²), menopausal status, medical comorbidities, and presenting stage of anterior prolapse were compared in ASCP and MISCP patients. Concomitant procedures at the of SCP were also compared. Continuous variables were compared using Student *t* tests, categorical variables were compared using Fisher's exact test, and ordinal variables were compared using Wilcoxon rank sum tests.

Logistic regression modeling was used to analyze the relationship between our primary outcome with the following predictor variables; change in total vaginal length (Δ TVL), change in point Aa (Δ Aa), change in point Ba (Δ Ba), change in point C (Δ C), and route of SCP (abdominal vs minimally invasive). Interactions between variables were assessed and, if significant, included in the model. Confounding variables were included in the model if point estimates changed by more than 20% with their inclusion. Anatomical change variables were assessed for linearity and converted to categorical variables as indicated by model fit statistics (concordance index, Deviance, Pearson, Hosmer–Lemeshow). Cochran–Armitage and goodness of linear fit tests were also used to evaluate for linear trends between anatomical changes and de novo SUI.

The resulting Δ TVL, Δ Ba, and Δ C variables were categorized as: increased (Δ >0), or reduced/no change (Δ ≤0). As reduction magnitude was categorized as low if less than or equal to 2 cm (Δ Aa≤2 cm), moderate if greater than 2 centimeters or less than or equal to 4 cm (4 cm≥ Δ Aa>2 cm), and high if greater than 4 cm and less than or equal to 6 cm (6 cm≥ Δ Aa>4 cm). For example, a preoperative point Aa of +3, which was reduced to -3 postoperatively would be categorized as a high reduction magnitude.

Abdominal route (ASCP) and smallest anatomical change were used as reference groups during analysis. An α level of 0.05 was considered statistically significant. Odds ratios were reported with 95% confidence intervals. All analyses were carried out using SAS[®] version 9.3 (SAS Institute, Cary, NC, USA).

Results

An inclusion and exclusion diagram is shown in Fig. 1. During the study period, a total of 795 patients underwent SCP. Of these, 77 were eligible for inclusion in the final analysis: 33 ASCP and 44 MISCP patients.

Baseline characteristics and demographics of the study population are described in Table 1. The overall mean age of the population of interest was 62 (\pm 7.4) years, and 91% were white. There was no difference in parity, BMI or comorbidities between the groups. There was no statistical difference in preoperative variables between the ASCP and MISCP groups including presenting stage of anterior prolapse, and concomitant procedures. Median follow-up was 15 weeks (range 7– 99) for the ASCP group and 12 weeks (range 2–90) for the MISCP group (p=0.039). Although not statistically significant, there was a higher proportion of cystocele repairs in the MISCP group. We found no association between cystocele repair at the time of SCP and Δ Aa reduction magnitude, or postoperative SUI.

The overall rate of de novo SUI was 28.6% (22 out of 77). Table 2 demonstrates the association between surgical approach and anatomical outcomes with postoperative SUI in this cohort. New onset postoperative SUI was noted in 45.5% (15 out of 33) of the ASCP group and 15.9% (7 out of 44) of the MISCP group (p=0.004). De novo SUI occurred more frequently in the ASCP group than in the MISCP group (p=0.004). Δ TVL was not associated with new onset SUI in this study population (p=0.37). De novo SUI was noted among 10% (3 out of 30) of the low ΔAa group, 44% (12 out of 27) of the moderate ΔAa group, and 35% (7 out of 20) of the high ΔAa group. This positive trend was statistically significant (Chi-squared: p=0.012, Cochran–Armitage: p=0.03); however, this relationship was not linear (goodness of linear fit Chisquared: p=0.04). All patients demonstrated a positive ΔBa and no association with ΔC was noted (p=0.063). Overall and route-specific outcomes for the entire cohort are depicted in Fig. 2.

Postoperative anatomical outcomes themselves did not differ according to the route of SCP. Twenty-one ASCP patients (63.6%) and 27 MISCP patients (61.4%) had an increased TVL at postoperative follow-up (p=0.839). Average increase in TVL was 1.6 ± 0.9 cm. Otherwise, patients showed reduced or no change in TVL. Among ASCP patients, 11 (33.3%) had a low Δ Aa, 14 (42.4%) had a moderate Δ Aa, and 8 (24.2%) had a high Δ Aa. By comparison, of those who underwent MISCP, 19 (43.2%) had a low Δ Aa, 13 (29.6%) had a moderate Δ Aa, and 12 (27.3%) had a high Δ Aa. The differences in these outcomes were not statistically significant (p=0.49).

Results of the logistic regression analysis are listed in Table 3. Controlling for ΔAa , the odds of new onset SUI were 4.7 times higher in the ASCP group than in the MISCP group (OR 4.73, 95% CI 1.56, 14.34). Controlling for route of SCP, the odds of new onset SUI were 2.2 times higher with moderate ΔAa than with low ΔAa (OR 2.16 95% CI 1.07, 4.38). The odds of new onset SUI were 4.7 times higher in those with high ΔAa than in those with low ΔAa (OR 4.67 95% CI 1.14, 19.22).

Fig. 1 Inclusion and exclusion diagram. Of 795 sacrocolpopexy (SCP) patients, 77 met the inclusion criteria. POP pelvic organ prolapse, POPQ pelvic organ prolapse quantification, ASCP abdominal sacrocolpopexy, MISCP minimally invasive sacrocolpopexy



are in bold

Table 1Comparison of baselinecharacteristics by surgicalapproach $(n=77)$	Variable	ASCP (<i>n</i> =33)	MISCP $(n=44)$	p value
	Age, mean (SD)	62.12 (7.12)	62.80 (7.67)	0.332
	BMI, mean (SD)	27.42 (4.19)	27.15 (4.48)	0.788
	Parity, median (range)	2.5 (2, 8)	2.5 (1, 7)	0.392
	Race, <i>n</i> (%)			0.597
	Caucasian	31 (93.9)	39 (88.6)	
	African–American	2 (6.1)	4 (9.1)	
	Asian	0 (0.0)	1 (2.3)	
	Menopausal, n (%)	31 (93.9)	40 (90.9)	0.695
	Smoker, n (%)	3 (9.1)	2 (5.0)	0.653
	Hypertension, n (%)	14 (42.4)	20 (45.5)	0.791
	Diabetes, n (%)	1 (3.0)	4 (9.1)	0.385
	COPD/chronic cough, n (%)	4 (12.1)	3 (6.8)	0.454
	Presenting stage of anterior prolapse, n (%	%)		0.408
	Stage 1	3 (9)	7 (16)	
	Stage 2	11 (33)	19 (43)	
	Stage 3	13 (40)	10 (23)	
	Stage 4	6 (18)	8 (18)	
	Concomitant procedures at SCP, n (%)			
	Hysterectomy	11 (33.3)	16 (36.4)	0.783
ASCD abdominal approach anour	Bilateral salpingo-oophorectomy	6 (18.2)	16 (36.4)	0.081
MISCP minimally invasive	Cystocele repair	1 (3.0)	8 (18.2)	0.069
sacrocolpopexy, COPD chronic	Rectocele repair	4 (12.1)	8 (18.2)	0.468
obstructive pulmonary disease	Perineorrhaphy	11 (33.3)	11 (25.0)	0.423
Statistically significant <i>p</i> -values are in hold	Weeks follow-up, median (range)	15 (7, 99)	12 (2, 90)	0.039

Variations in surgical route according to the primary surgeon were also evaluated for effect on the primary outcome. The proportions of ASCP among the three surgeons were 28%, 34%, and 38%. Statistical modeling showed no

association or interaction between postoperative SUI and primary surgeon (p=0.24).

Postoperative SUI was diagnosed by report of bothersome symptoms at a postoperative office visit in 94% (n=71), by

Table 2 Association between surgical approach and anatomical outcomes with postoperative stress urinary incontinence (SUI) in patients undergoing sacrocolpopexy (SCP; %)	Variable	SUI present ($n=22$)	SUI absent ($n=55$)	Chi-squared
	Surgical approach			0.005
	Abdominal	15 (68.2)	18 (32.7)	
	Minimally invasive	7 (31.8)	37 (67.3)	
	Change in vaginal length (Δ TVL)			0.372
	$\Delta TVL > 0$	12 (54.5)	36 (65.4)	
	$\Delta TVL \leq 0$	10 (45.5)	19 (34.6)	
	Point Aa reduction $(\Delta Aa)^*$			0.012
	Low ($\Delta Aa \leq 2 \text{ cm}$)	3 (13.6)	27 (49.1)	
	Moderate (4 cm $\geq \Delta Aa \geq 2$ cm)	12 (54.6)	15 (27.3)	
	High (6 cm $\geq \Delta Aa > 4$ cm)	7 (31.8)	13 (23.6)	
	Point Ba reduction (ΔBa)			
*Cochran–Armitage trend test	$\Delta Ba > 0$	22 (100)	55 (100)	_
p=0.029 (significant for positive trend), goodness of linear fit Chi-squared $p=0.042$ (nonlinear relationship)	$\Delta Ba \leq 0$	0 (0)	0 (0)	
	Point C reduction (Δ C)			
	$\Delta C > 0$	19 (86.3)	54 (98.2)	0.063
Statistically significant <i>p</i> -values are in bold	$\Delta C \leq 0$	3 (13.6)	1 (1.8)	



Fig. 2 Overall and route-specific percentage of de novo stress urinary incontinence (SUI) by ΔAa (*n*=77). The percentage of patients demonstrating de novo SUI after sacrocolpopexy (SCP) shows an increasing trend as ΔAa increases from ≤ 2 cm to > 2 cm. More women in the abdominal sacrocolpopexy (ASCP) group demonstrated de novo SUI

repeat stress testing in 4% (n=3), and by UDI-6 questionnaire in 3% (n=2). Overall, 7 patients (32%) were surgically treated for new onset SUI. Of these, 6 had undergone ASCP. Five patients underwent retropubic sling and 2 underwent urethral bulking. All patients had a satisfactory improvement in SUI symptoms.

Post hoc analysis revealed that our study had adequate power to detect a 34% difference in the proportions of de novo SUI between ASCP and MISCP groups. Most significantly, the 95% confidence interval for the difference in proportions did not include zero (0.29, 95% CI 0.09–0.49). Analysis of exclusion rates showed that 26 out of 59 (0.44) abdominal cases 18 out of 62 (0.29) minimally invasive cases had missing POPQs. The difference in the proportion of patients missing POPQ data between the two surgery types (0.15, 95% CI –0.03 to 0.32) was not statistically significant. Thus, there was no evidence to suggest that missing POPQ data might be related to surgery type.

Discussion

Our primary aim was to investigate the role of prolapse reduction in the development of de novo SUI after SCP in

 Table 3
 Point estimates and 95% confidence limits for significant predictors of new-onset SUI after SCP in the logistic regression model

Covariate	Odds ratio	95% confidence intervals
ASCP vs MISCP	4.73	(1.56, 14.34)
Moderate ΔAa vs low ΔAa	2.16	(1.07, 4.38)
High ΔAa vs low ΔAa	4.67	(1.14, 19.22)

Logistic regression model fit statistics: concordance index = 0.774, deviation p=0.865, Pearson p=0.865, Hosmer–Lemeshow p=0.99 terms of surgical approach and anatomical change. We hypothesized that tensioning differences resulting from variations in tactile sensation between open and minimally invasive SCP might have an impact on SUI outcomes. Interestingly, postoperative SUI was observed more frequently after ASCP (45%), where tactile feedback is more accessible, compared with MISCP (16%).

We found no statistically significant difference in anatomical outcomes between ASCP and MISCP. This is consistent with findings from other studies comparing open and minimally invasive SCP [17, 18]. In a retrospective comparison, Siddiqui et al. found no significant difference in postoperative TVL between 70 robotic SCP patients and a cohort of 289 ASC patients from the CARE trial (median TVL=9 for both groups, p=0.06) [17]. In a randomized, non-inferiority trial comparing post-hysterectomy ASCP and laparoscopic SCP, Freeman et al. reported no statistically significant difference in point C at 1-year follow-up (-6.63 and -6.67 respectively) [18].

Total vaginal length, Aa, Ba, and C reduction magnitude were analyzed as surrogate markers for vaginal tensioning, which is thought to instigate de novo SUI [10]. In this study, only Aa reduction was associated with de novo SUI, regardless of surgical approach. Our analysis suggests that there might be a positive, nonlinear relationship between Aa reduction magnitude and postoperative SUI. Compared with women with low ΔAa , women with moderate ΔAa had double the odds of de novo SUI and women with high ΔAa had almost 5 times the odds of de novo SUI. Since ΔAa represents the anatomical repositioning of the urethrovesical junction, we feel that these findings provide empiric support to the theoretical mechanism of urethral "unkinking," which is thought to contribute to postoperative SUI.

In this study, 32% of patients with new onset postoperative SUI underwent reoperation. All except one of these patients had undergone ASCP. Published reoperation rates for SUI after ASCP range from 1.2% to 30.9%, while rates after laparoscopic SCP range from 11% to 16.4% [10, 12, 19, 20]. Our findings corroborate these results.

Screening for occult SUI using prolapse-reduced urodynamic (UDS) stress testing is commonly performed to identify patients who may benefit from an incontinence procedure at the time of corrective surgery for POP. However, reported SUI rates after negative testing are substantial. In a retrospective study that included abdominal and laparoscopic cases, Elser et al. report that 13% of subjects without demonstrable SUI at preoperative UDS developed urinary incontinence "of any type" postoperatively [21]. By comparison, Leruth et al. report a 55% postoperative SUI rate in a retrospective cohort of laparoscopic SCP patients who had negative reduction testing [20]. Both studies, however, included women with preoperative symptoms of SUI. The negative predictive value of reduction testing among continent women planning to SCP is limited. In the Colpopexy and Urinary Reduction Efforts (CARE) study, a randomized clinical trial to determine the effectiveness of routine colposuspension for the prevention of SUI among asymptomatic patients, Visco et al. report that 38% of control group subjects with negative testing developed new onset SUI after abdominal SCP [22]. Adequate counseling and optimal management of the continent, UDS-negative patient planning SCP requires further investigation of other risk factors for new-onset SUI. To this end, we focused on anatomical outcomes related to postoperative SUI.

Limitations of this study include its retrospective design and relatively small sample size. However, by analyzing a focused sample of asymptomatic patients, applying stringent inclusion criteria, and strictly defining relevant urinary outcomes we were able to mitigate confounders for postoperative urinary symptoms. The concordance index (c=0.774) indicates a strong, predictive fit between the data and our logistic regression model. To our knowledge, this is the first study to focus on analyzing specific anatomical outcomes as risk factors for postoperative SUI. Given our findings, a larger, randomized study can be planned to confirm the generalizability of our results, and to examine the predictive value of point Aa reduction magnitude in a urinary incontinence risk assessment model.

Based on this study, we conclude that a greater reduction in point Aa increases the risk of de novo SUI in previously continent patients undergoing SCP.

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Conflict of Interest None.

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