Original Article

Severity of Cystocele and Risk Factors of Postoperative Stress Urinary Incontinence after Laparoscopic Sacrocolpopexy for Pelvic Organ Prolapse

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Abstract

Objectives: Knowledge on the severity of cystocele and incidence of postoperative stress urinary incontinence (SUI) after prolapse repair is lacking. This study investigated the incidence and risk factors of postoperative SUI following laparoscopic sacrocolpopexy (LSC).

Materials and Methods: We retrospectively reviewed the charts of 83 women without occult SUI who underwent LSC for pelvic organ prolapse and developed SUI over 3 months postoperatively. We used Fisher's exact test, the Mann–Whitney U-test, and logistic regression for statistical data analyses.

Results: After 3 months, the incidences of postoperative SUI were 50% and 24% in those who did and did not report preoperative SUI, respectively. Eventually, postoperative SUI was reported by 39% and 9% of the women with and without preoperative SUI, respectively. Increased Ba (point of maximal anterior vaginal wall prolapse) measurement (odds ratio [OR], 1.44; 95% confidence interval [CI], 1.0–2.06; $P = 0.04$) and preoperative SUI (OR, 3.95; 95% CI, 1.14–13.7; $P = 0.03$) were the risk factors for postoperative SUI.

Conclusion: Our findings suggest that counseling regarding the risk of postoperative SUI should be conducted for women with preoperative advanced cystocele or bothersome SUI.

Keywords: Cystocele, pelvic organ prolapse, postoperative, sacrocolpopexy, urinary incontinence

INTRODUCTION

Pelvic organ prolapse (POP) affects millions of women worldwide and is a global burden on women's health.[1] In the United States, approximately 260,000 women undergo surgery for incontinence and 300,000 for prolapse annually.[2] Pelvic floor dysfunction is a major issue for older women, with an 11.1% lifetime risk of undergoing an operation for POP or urinary incontinence and a 30% reoperation rate.[3] Stress urinary incontinence (SUI), defined as involuntary urinary leakage on coughing, sneezing, or exertion,[4] coexists in 15%–80% of women with POP.[5] However, in cases of advanced POP, continence may be maintained due to urethral kinking caused by cystocele descent.[6] Herein, we define occult SUI as advanced POP with leaks upon provocation after the prolapse is reduced. Otherwise, the patient is simply considered to have overt SUI regardless of the prolapse reduction. If a patient anticipating POP repair does not complain of SUI, a preoperative prolapse reduction stress test (PRST) should be performed to rule out occult incontinence.[7] Lifting the cystocele too strongly during abdominal sacrocolpopexy (ASC) can flatten the

Access this article online	
Quick Response Code:	**Website:** www.e-gmit.com
	DOI: 10.4103/GMIT.GMIT_2_21

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How to cite this article: Sato H, Abe H, Ikeda A, Miyagawa T, Tsukada S. Severity of cystocele and risk factors of postoperative stress urinary incontinence after laparoscopic sacrocolpopexy for pelvic organ prolapse. Gynecol Minim Invasive Ther 2022;11:28-35.

urethrovesical angle and lead to postoperative SUI.[8] The incidence of postoperative SUI ranges between 7.5% and 23% after laparoscopic sacrocolpopexy (LSC),[9] although there are wide variations in the reported postoperative SUI rates (close to 40%–50%).[10,11] Limited data exist on the association between the increasing rates of cystocele and increasing rates of postoperative SUI in patients after ASC.[12] Thus, our primary objective was to analyze the incidence of postoperative SUI, such as *de novo* SUI and persistent SUI, for 3 months following LSC for POP in patients without occult SUI. The secondary objective was to analyze the risk factors associated with postoperative SUI. We hypothesized that advanced cystocele is positively associated with the development of postoperative SUI after LSC.

MATERIALS AND METHODS

Ethics

The institutional review board of our hospital approved the study, and the study was performed in accordance with the 1975 Helsinki Declaration, as revised in 2013 (approval number: 2019026). The need for informed consent was waived because of the retrospective study design.

Study design, population, and procedures

This retrospective cohort study involved 83 consecutive women who underwent LSC for symptomatic prolapse (POP-Quantification [POP-Q] system stage ≥2) between August 2015 and July 2018 at our hospital. We diagnosed preoperative SUI with the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), question 4, "When does urine leak?" SUI was diagnosed if the patient had urinary leakage on coughing, sneezing, or physical activity/exercise. Subjects with and without preoperative SUI-related symptoms and whose PRST results were negative were included. The follow-up period was at least 1 year. The inclusion criteria comprised patients who underwent LSC using double mesh for POP and age >18 years. The exclusion criteria consisted of an absence of postoperative records, prior vaginal route surgery, a concomitant mid-urethral sling (MUS) procedure, or a positive PRST result. The optimal methods for distinctly defining occult SUI before POP correction have not been determined. We performed a cough stress test (CST) on every patient and a simple preoperative clinical test for negative CST patients, the PRST with gauze packing, to evaluate occult SUI. The gauze packing comprised a vaginal gauze roll (10 cm long) formed from one piece of an ordinary 40 cm ×20-cm gauze, similar to the methods used by Chang *et al*.[13] It was reported that this prolapse reduction method rarely caused bladder outlet obstruction and did not significantly influence the presence of detrusor overactivity.[14]

Preoperative cystoscopy was performed by injecting saline to the bladder until the patient could tolerate urination during cystoscopy. Then, the mean bladder volume was estimated at 300 ± 50 mL by calculating the saline volume of the individual patients. Therefore, we defined the range of the bladder volume as 300 mL. Furthermore, PRST was performed to investigate occult SUI using gauze packing prolapse reduction.[13,14] PRST involved instructing the subjects to cough with full force two times and recording the occurrence of urine loss. No leakage indicated a negative test result. We compared women with postoperative SUI at 3 months with those without postoperative SUI at 3 months. Postoperative SUI diagnosis was the same for all subjects; we diagnosed SUI using the ICIQ-SF question 4, which requires a yes/no answer [details of the questionnaire are provided in Appendix 1].

This study was performed at a single institution, and a single surgeon conducted all surgeries. We performed the double mesh procedure in all patients for prophylactic purposes. Briefly, the surgery was performed as follows: the GYNEMESH PS (Ethicon, Somerville, NJ, USA) was used during LSC. A two-part mesh set with precut anterior and posterior components was used. First, following subtotal hysterectomy, the peritoneum overlying sacral promontory was opened and dissected toward the pararectal and rectovaginal spaces to expose both the levator ani muscles and central perineal body. The posterior mesh was fixed over the levator ani and the distal posterior vaginal wall in the midline using nonabsorbable 2-0 sutures (Tefdesser II, KonoSeisakusyo, Chiba, Japan). Afterward, we dissected the space between the anterior vaginal wall and bladder to the level of the bladder trigone. The anterior mesh was sutured at the middle, right, and left sides of the distal end of the anterior vaginal wall with five-point fixation using nonabsorbable 3-0 sutures (Tefdesser II, KonoSeisakusyo). The anterior and posterior meshes were joined together at the isthmus level by suturing in the middle and right and left aspects with 2-0 nonabsorbable sutures (Tefdesser II, KonoSeisakusyo). Consequently, only one mesh limb was sutured, without tension, to the anterior longitudinal ligament over the sacral promontory. Finally, the peritoneum was closed over the meshes using a continuous nonlocking 2-0 absorbable suture (Monocryl®, Ethicon). In general, we treat SUI by performing a delayed (two-step) anti-incontinence procedure. Briefly, patients with bothersome postoperative SUI symptoms undergo MUS; a 2-cm anterior colpotomy is made at the mid-urethral site, and a standard "outside-in" transobturator tape procedure is performed. Details of the procedure are given elsewhere.[15]

Data collection

The following data were obtained retrospectively from the patients' medical records: age at the time of surgery;

parity; body mass index (BMI); medical comorbidities; history of hysterectomy; preoperative and postoperative simplified international continence society (ICS) POP-Q[16] and ICIQ-SF[17] data; and data related to preoperative and postoperative SUI, urgency urinary incontinence (UUI), mixed urinary incontinence (MUI), operative time, estimated blood loss, and concomitant surgical procedures. The most severe prolapse stage of the three vaginal compartments defined the general stage of POP.

According to the ICS and the International Urogynecological Association guidelines,[18] SUI was defined as a complaint of bothersome urinary leakage while coughing, laughing, exercising, or sneezing (ICIQ-SF question 4: "When does urine leak?"). UUI was defined as a complaint of bothersome urinary leakage before reaching the toilet (ICIQ-SF question 4), and MUI was defined as a complaint of involuntary loss of urine associated with urgency, effort or physical exertion, or sneezing or coughing (ICIQ-SF question 4). We examined data on the patients' medical history and physical examinations at our unit at 1, 3, and 12 months postoperatively and every year thereafter. This included the patients' subjective assessment of SUI, UUI, and MUI based on the ICIQ-SF; POP-Q assessments, specifically point Ba and physical examination using a CST, were performed on every patient who complained of postoperative SUI in the lithotomy position. Similar to Davenport *et al.*,[12] we separated the range of Ba measurements into POP-Q stages to understand the association of point Ba, and specifically cystocele severity, with postoperative SUI (stage 2,−1–1 cm; early stage 3, >1 cm but ≤3 cm; and advanced stage 3 or stage 4, >3 cm). In a preliminary study by Leruth *et al.*,[19] 54.5% and 45.5% of the study population were in the postoperative
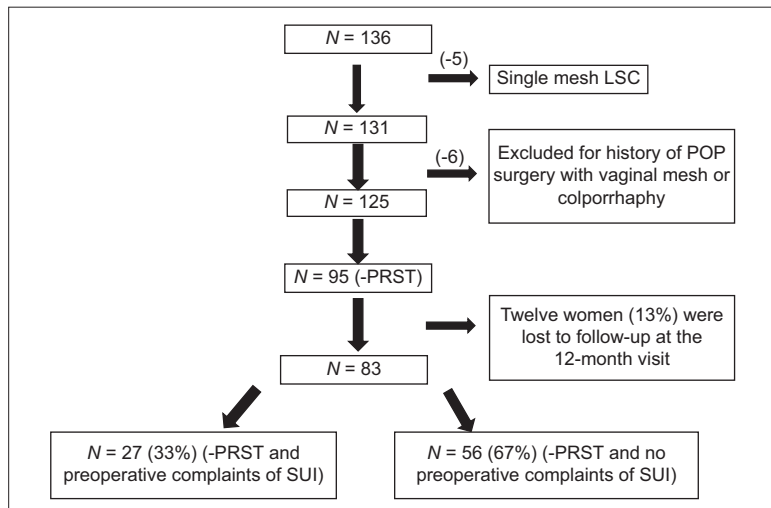

Figure 1: Study flowchart. Of the 136 patients who underwent LSC, 83 fulfilled the inclusion criteria. LSC: Laparoscopic sacrocolpopexy, POP: Pelvic organ prolapse, −PRST: Negative prolapse reduction stress test result, SUI: Stress urinary incontinence
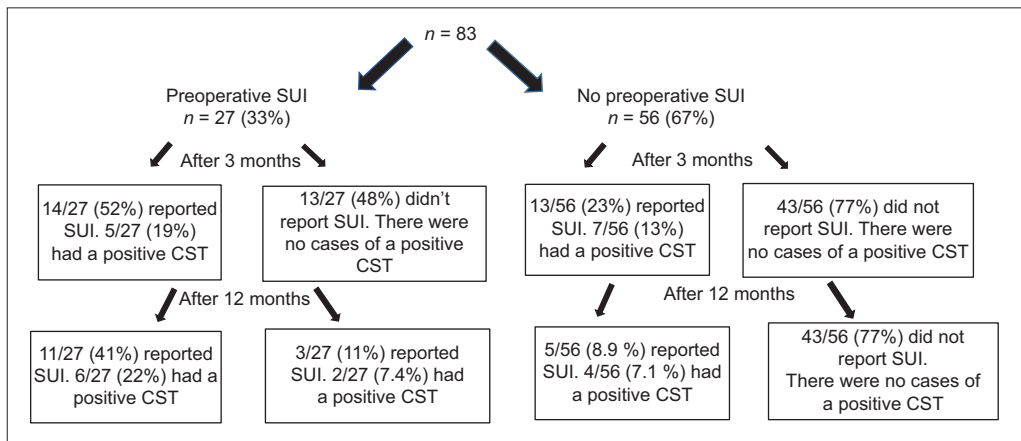
Figure 2: The number of patients with and without preoperative SUI. The study showed that 27 patients reported SUI and had a negative PRST preoperatively. There were 14 (52%) complaints of SUI symptoms after LSC surgery at 3 months; 11 (41%) reported SUI eventually after the study period. Moreover, 56 patients did not report SUI and had a negative PRST preoperatively. There were 13 (23%) complaints of SUI symptoms after LSC surgery at 3 months; 5 (8.9%) reported SUI after the study period. SUI: Stress urinary incontinence, LSC: Laparoscopic sacrocolpopexy, CST: Cough stress test

Table 1: Patient demographics

Variable	Total (*n*=83), *n* (%)
Follow-up time (months)	13 (12-24)
Age (years)	71 (66-75)
Parity	2 (2-3)
BMI (kg/m^2)	23.6 (22.0-25.1)
Diabetes	14 (16.8)
POP-Q stage 2	15 (18.1)
POP-Q stage 3	59 (71.1)
POP-Q stage 4	9 (10.8)
Cystocele only	33 (39.7)
Cystocele and VVP	17 (20.4)
Cystocele and uterine prolapse	22 (26.5)
Cystocele and rectocele	11 (13.2)
Baseline history	
Preoperative SUI	28 (33.7)
Preoperative UUI	13 (15.6)
Preoperative MUI	11 (13.2)

POP-Q: Pelvic Organ Prolapse Quantification, BMI: Body mass index, VVP: Vaginal vault prolapse, SUI: Stress urinary incontinence, UUI: Urgency urinary incontinence, MUI: Mixed urinary incontinence

Table 2: Concomitant surgical procedures

Concomitant surgical procedures	*n* (%)
STH	61 (73)
Uterine preservation	5 (6)
Lysis of adhesions	18 (22)
Salpingo-oophorectomy	36 (43)
Operating time (min), median	210 (178-240)
EBL (mL), median	10 (5-10)

EBL: Estimated blood loss, STH: Subtotal hysterectomy

SUI and no postoperative SUI groups, respectively, during the follow-up period. Based on this difference, a type I error rate of 5% and a type II error rate of 20% (80% power) for a sample size of 13 patients per treatment arm were calculated. The panel concluded that a 40% difference in the postoperative SUI rate would be clinically significant. Recognizing this minimum required sample size, we collected all available data to improve the statistical power to a feasible extent.

Statistical analysis

Data were analyzed using EZR, version 1.37 (Saitama Medical Center, Jichi Medical University, Saitama, Japan). Categorical variables were expressed as numbers and percentages, whereas continuous variables were expressed as medians (25th–75th percentile). Fisher's exact test and the Mann–Whitney's *U*-test were used to analyze categorical and continuous variables, respectively. Logistic regression was performed to assess the multivariate model of risk factors for postoperative SUI after LSC, and *P* < 0.05 was considered statistically significant. The variables included in the logistic regression were age, parity, BMI, diabetes, criterion complaints of urinary incontinence, and Ba.

RESULTS

As shown in Figure 1, 136 subjects underwent LSC. Among the 95 (70%) subjects that had a negative PRST result, 12 patients (13%) were lost to follow-up at the 1-year visit, and thus, the study population comprised 83 (61%) patients. The demographic and operative characteristics of the entire cohort are described in Tables 1 and 2, respectively. All patients were diagnosed with a cystocele, including 17 with a vaginal vault prolapse, 22 with uterine prolapse, 11 with a rectocele, and 33 patients with other cystoceles. Thirty-three percent of women with stage 2 cystocele developed postoperative SUI compared to 15% of those with early-stage 3 cystocele and 57% of those with advanced-stage 3 or 4 cystocele. A comparison of the demographic characteristics between patients with and without postoperative SUI is presented in Table 3. There were no significant differences between patients with and without postoperative SUI in terms of demographic characteristics, such as age, BMI, parity, and prior hysterectomy. A significantly higher incidence of postoperative SUI was found among women with advanced-stage 3 or 4 cystocele than those with stage 2 and early-stage 3 cystocele. Significantly larger point Ba measurements and more complaints of preoperative SUI were reported among women with postoperative SUI compared to those without postoperative SUI.

Of the 83 patients, 27 patients had preoperative complaint of SUI. Of these 27 patients, 14 patients (52%) reported persisting complaint of SUI, and 5 patients (19%) had a positive CST in examination after 3 months.

Of these 83 patients, 56 patients had no preoperative complaint of SUI. Of these 56 patients, 13 patients (23%) reported complaint of SUI, and 7 patients (13%) had a positive CST in examination after 3 months.

Moreover, of these 27 patients, 11 patients (41%) reported persisting complaint of SUI, and 6 patients (22%) had a positive CST in examination after 12 months. Two of these 27 (7.4%) patients with preoperative complaints of SUI underwent a subsequent MUS procedure 8 months after the initial surgery and were continent at 1 year follow up. Moreover, 55 patients without preoperative SUI group eventually had SUI symptoms; Of these 56 patients without preoperative SUI group eventually had SUI symptoms; Of these 56 patients, 5 patients (9%) reported complaint of SUI, and 4 patients (7%) had a positive CST in examination after 12 months. A total of 16 out of 83 patients (19%) with a negative PRST result with and without preoperative SUI complaints reported postoperative SUI at 1-year follow-up, of whom 12% had a positive CST. Preoperative SUI (odds ratio [OR], 3.95; 95% confidence interval [CI], 1.14–13.7; *P* = 0.03) and increased Ba measurements (OR, 1.44; 95% CI, 1.00–2.06; *P* = 0.04) were identified as

Table 3: Comparison of the demographic characteristics between women without and with postoperative stress urinary incontinence

Variable	No postoperative SUI (*n*=56)	With postoperative SUI (*n*=27)	*P*
Age (years), median	70.5 (65.7-76.0)	71.0 (66.5-75.0)	0.87
BMI (kg/m^2), mean	23.8 (22.3-25.7)	23.5 (21.8-24.4)	0.29
Parity, mean	3 (2-3)	2 (2-3)	0.36
Prior hysterectomy, *n* (%)	9 (16.1)	8 (29.6)	0.16
POP stage (POP-Q), *n* (%)			
POP-Q 2	10 (17.9)	2 (7.4)	0.007*
POP-Q 3	44 (78.6)	18 (66.7)	
POP-Q 4	2 (3.6)	7 (25.9)	
Stage 2 cystocele (−1-1), *n* (%)	10 (17.9)	5 (18.5)	1
Early-stage 3 cystocele (>1 and≤3), *n* (%)	34 (60.7)	6 (22.2)	0.001*
Advanced-stage 3 or 4 cystocele (>3), *n* (%)	12 (21.4)	16 (59.3)	0.001*
Ba	2.5 (1.2-3.0)	3.2 (2.7-3.7)	0.004*
Bp	−2.0 (−3.0-−0.9)	−2 (−2.0-1.0)	0.07
C	−3.0 (−4.0-0.8)	−3.0 (−5.0-4.0)	0.65
TVL	8.0 (7.0-8.0)	7.0 (7.0-8.0)	0.13
Pre-SUI, *n* (%)	14 (25.0)	14 (51.9)	0.02*
Pre-UUI, *n* (%)	9 (16.1)	4 (14.8)	1
Pre-MUI, *n* (%)	8 (14.3)	3 (11.1)	1
Pre-ICIQ-SF	0 (0-4.2)	5 (3-6)	0.001*

Stage 2 = 0.32, Stage 3 = 0.286, Stage 4 = 0.00455*. BMI: Body mass index, POP-Q: Pelvic Organ Prolapse Quantification, Ba: The most prolapsed portion of the anterior vaginal wall, Bp: The most prolapsed portion of the posterior vaginal wall, C: Leading edge of the cervix or vaginal cuff, TVL: Maximum depth of the vagina with prolapse reduced, ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form, SUI: Stress urinary incontinence, UUI: Urgency urinary incontinence, MUI: Mixed urinary incontinence

Table 4: Multivariate logistic regression analysis of the risk of subjective stress urinary incontinence after laparoscopic sacrocolpopexy

Subjective risk factor	OR	95% CI	*P*
Age	0.99	0.922-1.08	0.92
BMI	0.85	0.66-1.09	0.20
Parity	0.77	0.36-1.67	0.51
Diabetes	2.06	0.52-8.15	0.30
Pre-SUI	3.95	1.14-13.7	0.03*
Pre-UUI	0.53	0.11-2.64	0.43
Ba	1.44	1.00-2.06	0.04*

*$P<0.05$, median (25th-75th percentile). BMI: Body mass index, SUI: Stress urinary incontinence, UUI: Urgency urinary incontinence, Ba: The most prolapsed portion of the anterior vaginal wall, OR: Odds ratio, CI: Confidence interval

significant risk factors for predicting postoperative SUI complaints [Table 4].

DISCUSSION

In this study, we aimed to assess the incidence and risk factors for postoperative SUI following LSC. After 3 months, the incidences of postoperative SUI were 52% and 23% in those who did and did not report SUI preoperatively, respectively. Increased Ba measurement and preoperative SUI were the risk factors for postoperative SUI. We demonstrated that postoperative SUI was relatively rare in the study population. In a previous retrospective study,[19]

wherein women underwent LSC without a concomitant incontinence procedure after negative preoperative urodynamic studies (UDS) with prolapse reduction, 54.5% of the patients developed postoperative SUI, reflecting that a history of SUI preoperatively was an inclusion criterion in their study. In contrast, Alas *et al*.[20] evaluated postoperative SUI in women with no evidence of occult SUI while comparing suspension and nonsuspension procedures and observed that 9.9% of the patients experienced postoperative SUI. According to their findings, this incidence was only 4.4% in patients without preoperative SUI complaints. The reported incidence of postoperative SUI following reconstructive surgery for POP ranges widely in the continent and incontinent subjects in previous studies, which is likely due to differences in the methodology used. The CARE[10] and OPUS[11] trials are the most cited studies for *de novo* SUI where women without occult SUI were randomly assigned to groups of POP surgery with and without concomitant anti-incontinence procedures. Both studies concluded that a prophylactic anti-incontinence procedure should be performed in POP surgery, as the incidence of *de novo* SUI is likely to be as high as 49.4%. These studies included patients with negative occult stress tests, similar to our present study participants. We confirmed that 52% of the incidence of postoperative SUI was similar to their study outcome, particularly in patients with preoperative complaints of SUI. However, the total incidence in subjects with an endpoint of

postoperative SUI at 12 month follow up was lowered to 41%, and 22% underwent CST. In addition, only 7% of the subjects underwent an additional incontinence surgery 8 months after the initial surgery. Finally, CST-positive subjects did not need an MUS. However, we did not objectively demonstrate urine leakage in all patients. Therefore, the true incidence of *de novo* SUI could be less. This could be the reason why only a few patients required additional anti-incontinence procedures.

Treatment for SUI may include consistent training of the pelvic floor muscles or physiotherapy and drug treatment. These results were worse than those reported by Hafidh *et al.*[21] who investigated *de novo* SUI after vaginal repair for POP with a 1-year follow-up. They observed subjective SUI in 13.5% of the patients, whereas objective SUI was present in 2% of the patients 1 year after the index surgery. This difference in the outcome might be due to a difference in the specific surgical approach. Therefore, prophylactic sling procedures should not be proposed as a standard treatment because of an increased risk of mesh complications, prospective surgeries, and voiding dysfunction.[22] As mentioned earlier, postoperative SUI resolves naturally; therefore, we recommend staged MUS procedures.

This study demonstrated the detection of occult SUI using a simple, useful, brief, and noninvasive clinical test instead of the previously used UDS. Visco *et al.*[23] reported that all five reduction methods in the CARE trial had positive (50%–79%) and negative (51%–66%) predictive values. We observed that the rigor of cystocele was significantly associated with postoperative SUI. Davenport *et al.*[12] reported a secondary analysis of the CARE trial, wherein increasing degrees of cystocele were associated with an increased incidence of *de novo* SUI in women undergoing POP correction. Point Ba was observed to be significantly related to *de novo* SUI in univariate (OR, 1.17; $P = 0.015$) and multivariate analyses (OR, 1.16; $P = 0.04$). In addition, LeClaire *et al.*[24] identified a composite endpoint using anatomical and questionnaire findings in their analyses. They observed that a greater reduction in the Aa and an abdominal approach were risk factors for new-onset postoperative *de novo* SUI after ASC and LSC. Point Ba and/or Aa is potentially related to an increased incidence of postoperative SUI. Similar to our analysis, Jelovsek *et al.*[25] reported that questionnaire data were used to identify bothersome symptoms, which were then used to build a prediction model. Although the best predictive method remains debatable, these questionnaire-based methods can help counsel continent subjects before prolapse surgery on the chances of developing postoperative SUI.

This study had a few limitations. One was the small sample size; a larger sample may reveal other significant risk factors, and randomized controlled trials may be necessary to corroborate our findings. Similarly, the retrospective

design may be associated with missing or incomplete data, and insufficient symptom severity assessments before and after subjective SUI complaints might have affected the true morbidity rates of postoperative SUI. In addition, a urodynamic evaluation was not performed to objectify functional outcomes; however, clinical tests and UDS are equivalent and concordant to demonstrate occult SUI.[26]

CONCLUSION

The postoperative SUI incidence after LSC increases with the severity of preoperative cystocele and the presence of a preoperative history of SUI symptoms. This essential observation should provide an elementary instrument for counseling continent or incontinent patients before LSC on the risk of developing SUI. Furthermore, given that the incidence of postoperative SUI after LSC in women without preoperative occult SUI is relatively low, we would not recommend concomitant incontinence procedures in these patients. With appropriate training of the pelvic floor muscles or physiotherapy and drug treatment, postoperative SUI resolves naturally; therefore, we recommend counseling and staged MUS procedures if necessary.

Conflicts of interest
There are no conflicts of interest.

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Appendix 1

Items in the ICIQ.

1. How often do you leak urine? (*Trick one box*)

0 □ Never

1 □ About once a week or less often

2 □ Two or three times a week

3 □ About once a day

4 □ Several times a day

5 □ All the time

2. How much urine do you usually leak (whether you wear protection or not)?

(*Trick one box*)

0 □ None

2 □ A small amount

4 □ A moderate amount

6 □ A large amount

3. Overall, how much does leaking urine interfere with your everyday life?

Please ring a number between 0 (not at all) and 10 (a great deal)

0   1   2   3   4   5   6   7   8   9   10

Not at all   a great deal

ICIQ score: sum scores 1 + 2 + 3□ □

4. When does urine leak? (*Please tick all that apply to you*)

□ Never – urine does not leak

□ Leaks before you can get to the toilet

□ Leaks when you cough or sneeze

□ Leaks when you are asleep

□ Leaks when you are physically active/exercising

□ Leaks when you have finished urinating and are dressed

□ Leaks for no obvious reason

□ Leaks all the time