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ORIGINAL ARTICLE

Clinical and urodynamic assessment in patients with pelvic organ prolapse before and after laparoscopic sacrocolpopexy

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Abstract
Introduction and hypothesis We hypothesized that patient-reported urinary symptoms and urodynamic evaluation improve after laparoscopic sacrocolpopexy (LSC) despite deeper vesicovaginal space dissection.
Methods This was a retrospective study of women with pelvic organ prolapse who underwent LSC from January 2013 to January 2016 in a tertiary center. Urinary function was clinically evaluated using the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), the Overactive Bladder Symptom Score (OABSS) and the Pelvic Floor Distress Inventory Questionnaire- – Short Form 20 (PFDI-20). Urodynamic assessment was performed before and 6 months after surgery. The Wilcoxon signed-ranks test and the McNemar test were applied with $p < 0.05$ considered significant.
Results A total of 155 patients were included in the study. Of these, 46 had urodynamic assessment before and after LSC. There were significant improvements after LSC in urodynamic storage phase parameters (higher volume at first desire, higher volume at strong desire, and larger bladder capacity) and voiding phase parameters (higher Q_{max}, higher Q_{ave}, lower $P_{det}Q_{max}$, increased voided volume and reduced postvoid residual urine volume). Clinically, there was a significant increase after LSC in stress urinary incontinence and a significant reduction in urgency urinary incontinence, overactive bladder and voiding dysfunction.
Conclusions Apart from increased stress urinary incontinence, there was an improvement in overall urinary function in terms of patient-reported symptoms and urodynamics, despite deep vesicovaginal space dissection. Hence, LSC is a viable surgical option for pelvic organ prolapse, restoring both level 1 and level 2 support without detrimental effects on urinary function.

Keywords LSC · LUTS · POP

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Introduction

Pelvic organ prolapse (POP) is often associated with a variety of lower urinary tract symptoms including storage and voiding symptoms. Stress urinary incontinence (SUI) has been reported also to be present in 15–80% of women with POP [1, 2]. In many women SUI may persistent or develop de novo postoperatively, and this has led to a continuing debate on the need for concurrent antiincontinence surgery during prolapse repair. However, prolapse repair has been shown to improve symptoms of overactive bladder (OAB) [3, 4]. Voiding dysfunction (VD) is another common symptom in women with POP, with a rate reported to be as high as 87.2% in one study. However, it generally improves after prolapse repair [5].

Laparoscopic sacrocolpopexy (LSC) is a proven safe and effective surgical treatment for POP. As with other surgical interventions, LSC is also reported to carry an inherent risk of de novo urinary symptoms postoperatively. The reported prevalence of de novo SUI ranges from 7.5% to 23% [5–7] and of de novo OAB is 2.5% [5]. There are technical variations in the performance of LSC, potentially leading to different rates of urinary complications postoperatively. The conventional approach aims to provide only apical support and therefore involves less dissection. The modified LSC technique involves deeper dissection of the vesicovaginal space and rectovaginal space to allow mesh fixation at the levator ani muscle and perineal body posteriorly and at the distal end of the vesicovaginal junction anteriorly. The latter technique aims to provide level 2 support in addition to apical support. Therefore, it would be able to correct anterior and posterior compartment prolapse simultaneously.

However, there is concern as to whether the deeper anterior dissection negatively affects urinary function postoperatively. Therefore in this study we sought to determine the effects of deeper dissection during LSC on urinary function. Most previous studies have investigated urinary function after a native tissue repair and transvaginal prolapse surgery, and there are few studies of urinary function after LSC. The aim of this study was therefore to add to the information on urinary function after LSC. As well as assessment of urinary symptoms clinically using validated questionnaires, objective assessment of urinary function by urodynamic studies (UDS) was an essential part of this study to enable this concern to be addressed.

Hence, the primary objective of this study was to evaluate the patient-reported lower urinary tract symptoms which commonly coexist with POP before and after LSC. The secondary objective was to compare UDS parameters before and after LSC. We hypothesized that patient-reported urinary symptoms and UDS parameters would improve after LSC.

Materials and methods

Study design

This was a retrospective study of women with POP who underwent LSC from January 2013 to January 2016 in the Urogynaecology Unit, Kameda Medical Center, Japan. These patients were from three urogynecology clinics (Kameda Clinic, Kyobashi Clinic, and Makuhari Clinic) run by the senior author (J.N.).

Sample size calculation and data sampling

Calculation of the sample size was based on the incidence of patient-reported symptoms of SUI before and after surgery in a study by Kummeling et al. [5]. Using a two-tailed hypothesis test with a type 1 error of 5% and 80% power, a sample size of 76 patients was required. However, we decided to double the sample size to 155 patients. A total of 46 patients underwent a UDS study before and after LSC during the study period, and all were included in the study. Only patients from the Kameda Clinic underwent routine UDS before and after LSC. Facilities for UDS were not available at the Kyobashi Clinic and Makuhari Clinic, and both are located far from the Kameda Clinic. Hence UDS was not routinely done in patients at these clinics.

A further 109 consecutive patients from the beginning of study period were also included in the study, apart from those who were already included. Those who underwent a simultaneous anti-incontinence procedure were excluded because the outcome in these patients would not represent the true impact of LSC on urinary function.

Data collection

The medical records of all the patients were retrieved. The data collected included the patients' basic characteristics, the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), the Overactive Bladder Symptom Score (OABSS) and the Pelvic Floor Distress Inventory Questionnaire – Short Form 20 questionnaire scores, and UDS findings before and 6 months after surgery. The validated Japanese versions of the ICIQ-SF, OABSS and PFDI-20 questionnaires were used in this study [8–10].

The clinical diagnosis of SUI, urgency urinary incontinence (UUI), mixed urinary incontinence (MUI), OAB and VD were based on the patients' responses to certain questions in the questionnaires. The definitions of the clinical diagnoses made in this study using the ICIQ-SF questionnaire (question 6: "When does urine leak?") were as follows 'SUI' was diagnosed if the patient had urinary leakage on coughing, sneezing or physically activity/exercise; 'UUI' was diagnosed if the patient had urinary leakage before she could get to the toilet; and 'MUI' was diagnosed if the patient had both SUI and UUI.

According to the terminology guides of the International Urogynecological Association (IUGA) and the International Continence Society (ICS), OAB is defined as urinary urgency, usually accompanied by frequency and nocturia, with or without UUI, in the absence of urinary tract infection or other obvious pathology [11]. Therefore in this study, OAB was diagnosed using the OABSS questionnaire. If the patient had a sudden desire to urinate that was difficult to defer and either day-time frequency more than seven times or nocturia at least once, OAB was diagnosed. Urinary tract infection was screened for and ruled out in all patients. IUGA and ICS define VD as abnormally slow and/or incomplete micturition demonstrated by repeated uroflowmetry and postvoid residual (PVR) urine volume measurement [11]. In this study, the diagnosis of VD was defined as any positive response to question 19 of the PFDI-20 questionnaire ("Do you usually experience difficulty emptying your bladder?") and either the presence of a maximum flow rate (Q_{max}) less than 15 mL/s or a PVR urine volume more than 50 mL.

In women who underwent a multichannel UDS evaluation, this involved urethral pressure profilometry, pressure flow cystometry, and uroflowmetry. In those with prolapse extruding from the vagina, the prolapse was reduced using surgical gauze during the UDS evaluation. Urodynamic stress incontinence was diagnosed as the occurrence of urine leakage during the increase in intraabdominal pressure from either a cough or the Valsalva maneuver. Detrusor overactivity (DO) is diagnosed if involuntary detrusor contraction occurs during filling cystometry, either spontaneously or provoked. PVR urine volume was measured using an in–out urinary catheter.

Surgical technique

Surgery was performed by the senior author (J.N.) or urogynecology fellows under his direct supervision. Two pieces of type 1 polypropylene monofilament macroporous mesh (GYNEMESH, Ethicon; Polyform, Boston Scientific) were used during the LSC. Posterior (rectovaginal space) dissection was performed to the level of the levator ani muscles bilaterally and the perineal body in the middle. Anterior (vesicovaginal space) dissection was deeper than for conventional LSC. The dissection was performed to the bladder neck level. A separate mesh was sutured at the middle, right and left of the distal end of the anterior vaginal wall. This mesh was sutured at the apex of the cervical stump after ensuring it was laid without tension along the anterior vaginal wall. The anterior and posterior meshes were then sutured together attaching the mesh to the lateral edge of the cervical stump and uterosacral ligaments bilaterally. The peritoneum over the rectouterine pouch was closed. Subsequently, the cranial end of the mesh was sutured to the anterior longitudinal ligament over the sacral promontory after an appropriate level of suspension had been confirmed by vaginal examination. The posterior parietal peritoneum was then closed ensuring that the whole length of the mesh was covered. Surgery was modified accordingly in patients who had total hysterectomy, laparoscopically assisted vaginal hysterectomy (LAVH) or uterine preservation. However, the principles of the sacrocolpopexy technique were the same.

Statistical analysis

The data were entered and analyzed using SPSS version 20.0 (IBM Corp., Armonk, NY). The categorical data are presented in the form of absolute numbers and their corresponding percentage values. The Wilcoxon signed ranks test was used to compare preoperative and postoperative pressure flow cystometry parameters, uroflowmetry parameters and questionnaire scores. The McNemar test was used to compare the preoperative and postoperative prevalence of clinical and urodynamic diagnoses. Statistical significance was set at $p < 0.05$.

Ethical considerations

Ethical approval was obtained from the Kameda Medical Center Ethics Committee.

Results

A total of 155 patients were included in this study. The baseline characteristics and intraoperative details of the patients are presented in Table 1. The success rate at 6 months after surgery (defined as stage 1 or better) was 96.1%. The complication rate was 1.9% (3/155). The complications were bladder injury, intestinal obstruction and vaginal mesh exposure.

Of the 155 patients, 46 had UDS assessment before and after LSC. UDS parameters before and after LSC are shown in Table 2. After LSC the bladder volumes to reach ‘first desire’ and ‘strong desire’ were significantly higher and the bladder capacity was also higher. After LSC the voiding phase parameters, maximum flow rate (Q_{max}) and average flow rate (Q_{ave}) were significantly higher and pressure at maximum flow ($P_{det}Q_{max}$) was significantly lower. After LSC voided volume was significantly higher and PVR urine volume was significantly lower. However, there were no significant differences after LSC in functional profile length, maximum urethral closure pressure (MUCP), volume at first sensation and bladder compliance.

The clinical and urodynamic diagnoses before and after LSC are shown in Table 3. There were distinct differences between clinical and urodynamic diagnoses. After LSC there was a significant increase in the number of patients with SUI, and significant reductions in the numbers of patients with UUI, OAB and VD.After LSC there was a significant improvement in OABSS scores but there was no significant difference in the ICIQ-SF scores (Table 4). PFDI-20 scores were not compared because only question 19 was analyzed in this study.Differences in patient-reported symptoms of SUI, UUI, MUI, OAB and VD before and after LSC are shown in Table 5. The status of the patients was classified as ‘resolved’ if there were no symptoms postoperatively, ‘improved’ if the postoperative score was less than preoperative score, ‘similar severity’ if the postoperative score was the same as the preoperative score, or ‘worsened’ if the postoperative score was higher than the preoperative score.

Of the 37 patients who had SUI preoperatively, one did not complete the ICIQ-SF questionnaire after LSC. In 23 of the 36 patients, symptoms persisted after LSC. In 41 patients (26.6%) de novo SUI developed after LSC, and the ICIQ-SF scores in these patients ranged from 3 to 16. Whereas, in 28 of 34 patients (82.4%) with UUI before LSC, symptoms resolved after LSC. The ICIQ-SF scores in all six patients with persistent UUI were lower, indicating improvement in their symptoms. Only six patients

Table 1 Baseline characteristics and intraoperative details of the 155 patients

Variable	Value
Age (years), median (range)	66 (49–88)
Body mass index (kg/m^2), mean (SD)	23.6 (16.6–32.9)
Parity, median (range)	2 (0–6)
Stage of POP (n,%)	
2	11 (7.1)
3	126 (81.3)
4	18 (11.6)
Type of laparoscopic sacrocolpopexy, *n* (%)	
Concurrent hysterectomy	127 (81.9)
Laparoscopic subtotal hysterectomy	125
Total laparoscopic hysterectomy	1
Laparoscopically assisted vaginal hysterectomy	1
Uterine preservation	16 (12.8)
Posthysterectomy/vault prolapse	13 (8.4)
Operating time (min), median (range)	231 (130–433)
Estimated blood loss (mL), median (range)	20 (5–360)

(3.9%) reported de novo UUI. A similar trend was observed in the incidence of OAB. Of patients who had OAB before LSC, 48% had resolution of symptoms after LSC. De novo OAB occurred in 17 patients (11.3%) after LSC. The majority (90%) of patients with VD also had resolution of symptoms with a very low incidence of de novo VD (1.4%). Of the 46 patients who had UDS before and after LSC, 14 had UUI before LSC. Only one patient had persistent UUI after LSC and her preoperative $P_{det}Q_{max}$ was much higher (48.0 cm H_2O) than the mean $P_{det}Q_{max}$ (32.9 cm H_2O, SD 15.9 cm H_2O). She did not have DO on either preoperative or postoperative UDS.

Table 3 Clinical diagnoses (based on ICIQ-SF and OABSS) and urodynamic diagnoses before and after surgery

Diagnosis	Preoperative (n,%)	Postoperative (n,%)	*p* value[a]
Clinical			
SUI[b]	37 (24.0)	65 (42.2)	<0.001*
UUI[b]	34 (22.1)	12 (7.8)	<0.001*
MUI[b]	30 (19.5)	20 (13.0)	0.099
OAB[c]	93 (62.0)	65 (43.3)	<0.001*
VD[d]	40 (27.6)	6 (4.1)	<0.001*
Urodynamic			
USI[e]	6 (13.6)	6 (13.6)	1.000
DO[f]	1 (2.2)	3 (6.7)	0.500

SUI stress urinary incontinence, *UUI* urgency urinary incontinence, *MUI* mixed urinary incontinence, *OAB* overactive bladder, *VD* voiding dysfunction, *USI* urodynamic stress incontinence, *DO* detrusor overactivity

*$p < 0.05$

[a] McNemar test

[b] $N = 154$, one patient did not complete the ICQ-SF questionnaire preoperatively

[c] $N = 150$, one patient did not complete the OABSS questionnaire preoperatively, and four patients did not complete the questionnaire postoperatively

[d] $N = 145$, ten patients were excluded because of incomplete data for one of the three assessments required to define voiding dysfunction

[e] $N = 44$, two patients were excluded, one due to inability to complete pressure flow cystometry preoperatively, and the other due to inability to perform the leak point pressure test preoperatively

[f] $N = 45$, one patient was excluded due to inability to complete pressure flow cystometry preoperatively

Table 2 Urethral pressure profilometry, pressure flow cystometry and uroflowmetry findings in the 46 patients who had UDS assessment before and after surgery

Parameter	Preoperative (median)	Postoperative (median)	*Z* value	*p* value[a]
Functional profile length (mm)	29	46	–0.561	0.574
Maximum urethral closure pressure (cm H_2O)	40	46	–0.268	0.789
Volume at first sensation (mL)	91	73	–0.518	0.605
Volume at first desire (mL)	137	156	–2.107	0.035*
Volume at strong desire (mL)	230	271	–2.300	0.021*
Bladder capacity (mL)	284	351	–2.527	0.012*
Bladder compliance (mL/cm H_2O)	47	63	–1.439	0.150
Q_{max} (mL/s)	11.9	18.0	–3.776	<0.001*
Q_{ave} (mL/s)	5.9	8.9	–3.668	<0.001*
$P_{det}Q_{max}$ (cm H_2O)	31.1	22.5	–2.961	0.003*
Voided volume (mL)	259	367.8	–3.599	<0.001*
Post void residual volume (mL)	30	17	–3.925	<0.001*

Q_{max} maximum flow rate, Q_{ave} average flow rate, $P_{det}Q_{max}$ pressure at maximum flow

*$p < 0.05$

[a] Wilcoxon signed ranks test

Table 4 Symptoms score before and after surgery

Questionnaire	Preoperative, median (range)	Postoperative, median (range)	*Z* value	*p* value[a]
ICIQ-SF	4 (0–19)	4 (0–17)	–1.721	0.085
OABSS	4 (0–13)	3 (0–13)	–3.206	0.001*

ICIQ-SF International Consultation on Incontinence Questionnaire – Short Form, *OABSS* Overactive Bladder Symptom Score

*$p < 0.05$

[a] Wilcoxon signed ranks test

Discussion

Overall, there were significant improvements after LSC in urodynamic storage phase parameters (higher volume at first desire, higher volume at strong desire, and larger bladder capacity) and voiding phase parameters (higher Q_{max}, higher Q_{ave}, lower $P_{det}Q_{max}$, increased voided volume and reduced postvoid residual urine volume). Despite these remarkable improvements, correlations between UDS parameters and patient symptoms clinically was crucial. The incidence of SUI after LSC was 42.2%, of which 26.6% was de novo SUI. This is in agreement with the previously reported high incidence of SUI after sacrocolpopexy that ranges from 23.6% to 57.4% [7, 12]. However, the effect of concurrent antiincontinence procedures remains controversial [12–15]. It is crucial to highlight that in this study the diagnosis of SUI was based on patient-reported symptoms. Therefore, those with occult SUI were not identified preoperatively. Hence the high incidence of SUI after LSC could be partly explained by some patients having occult SUI preoperatively.

MUCP has been consistently reported to be lower in women with SUI [16, 17], and hence, it is believed to be one of the important etiological factors in SUI. However, it is interesting to note that there was no significant difference in MUCP before and after LSC in this study, despite a significant increase in the incidence of SUI after LSC. A previous study has shown that there is no difference in MUCP even after bladder neck suspension [17]. Therefore, the etiology of SUI can be considered to be multifactorial. MUCP may only contribute minimally. The anatomical changes after repair affecting the bladder neck may be a better explanation for the development of SUI.

OAB is known to be more prevalent in patients with POP than in those without POP, regardless of stage and the compartments involved [3]. The lack of correlation between symptoms of OAB and UUI and the UDS finding of DO found in this study has also been found in previous studies [18, 19]. This has led to the suggestion that urge-related symptoms may often be due to anatomical distortion of the lower urinary tract and the presence of bladder outlet obstruction rather than DO [4]. The lack of correlation is also in accordance with the findings of previous studies showing that OAB symptoms generally improve to various extents after all treatments for POP, including pessaries and reconstructive and obliterative surgical repair [3, 15, 18, 20], given that a certain degree of lower urinary tract anatomy is restored.

Table 5 Patient-reported symptoms of stress incontinence, urgency incontinence, and overactive bladder before and after surgery

	Stress urinary incontinence, *n* (%)[a]	Urgency urinary incontinence, *n* (%)[a]	Mixed urinary incontinence, *n* (%)[a]	Overactive bladder, *n* (%)[b]	Voiding dysfunction, *n* (%)[c]
Before surgery	37 (24.0)	34 (22.1)	30 (19.5)	93 (62.0)	40 (27.6)
After surgery					
Resolved	13 (36.1)[d]	28 (82.4)	20 (69.0)[e]	45 (48.4)	36 (90.0)
Improved	9 (25.0)[d]	6 (17.6)	3 (10.3)[e]	23 (24.7)	1 (2.5)
Similar severity	1 (2.8)[d]	–	1 (3.5)[e]	7 (7.5)	3 (7.5)
Worsened	13 (36.1)[d]	–	5 (17.2)[e]	18 (19.4)	–
De novo symptoms	41 (26.6)	6 (3.9)	10 (6.5)	17 (11.3)	2 (1.4)

[a] Incidence based on ICIQ-SF questionnaire responses in 154 patients

[b] Incidence based on OABSS questionnaire responses in 150 patients

[c] Incidence based on responses to question 19 of the PFDI-20 questionnaire, Q_{max} values and PVR volumes, with complete data in 145 patients

[d] The progress of SUI was based on responses in 36 patients because one patient did not answer one question of the postoperative ICIQ-SF so that the total score and the progress of symptoms in this patient could not be determined

[e] The progress of MUI was based on responses in 29 patients because one patient did not answer one question of the preoperative ICIQ-SF so that the total score and the progress of symptoms in this patient could not be determined

However, it is also interesting to highlight the finding of higher preoperative $P_{det}Q_{max}$ (48 cm H_2O) in the only patient with persistent UUI after LSC (among those who had UDS performed before and after LSC) compared with the mean preoperative $P_{det}Q_{max}$ of 32.9 cm H_2O (SD 15.9 cm H_2O). Fletcher et al. [21] found that persistent UUI after anterior vaginal repair was significantly related to a higher preoperative $P_{det}Q_{max}$. These authors suggested that bladder outlet obstruction caused by the prolapse may contribute to alterations in detrusor function that leads to persistent OAB symptoms [21]. Therefore, despite the anatomical correction, some patients might show persistent UUI.

The findings of significant improvements in first desire, strong desire and bladder capacity in this study provide objective evidence of improvement, which then directly translated into less irritative and storage symptoms. Similar to the findings of this study, Kummeling et al. [5] also found improvements in first desire and bladder capacity, and a reduction in OAB symptoms. However, in their LSC procedure, Kummeling et al. purposely avoided extensive dissection and disruption of the bladder base, in contrast to the procedure in this study. This demonstrates that extensive dissection anteriorly as far as the bladder base with the aim of enhancing level 2 support is not associated with a detrimental effect on bladder function.

VD and findings of bladder outlet obstruction clinically and on UDS have been reported to be common in advanced POP [22–24]. Remarkable improvement in voiding function demonstrated by UDS in this study corresponded with significant improvement in patient-reported symptoms of VD. Even those with persistent VD (four women, 10%) reported no worsening in its severity.

LSC has been proven to be effective for the treatment of POP and was found to be comparable to open sacrocolpopexy [25–27]. However, there are a variety of LSC techniques and in a survey involving 189 surgeons who practiced LSC, only 25% placed sutures down to the level of the trigone anteriorly [28]. To the best of our knowledge, this was the first study evaluating urinary function objectively with urethral profilometry, pressure flow cystometry, and uroflowmetry before and after LSC which involved deep vesicovaginal space dissection, supplementing the subjective assessment by the use of questionnaires.

This study had several limitations. Because it was a retrospective study, some incomplete data were unavoidable. We acknowledge the general limitations of UDS, for example, it was not done in a natural setting, it did not represent normal bladder filling, the fluid was nonphysiological, and the presence of pressure catheters might itself have affected the patients' responses. However, it remains the best objective method available for assessing lower urinary tract function. Prolapse reduction performed during UDS might potentially compress the urethra which might affect the UDS findings. However, efforts were made to ensure that no excessive pressure was applied during prolapse reduction. The diagnosis of SUI in this study was based only on the ICIQ-SF questionnaire. Therefore, patients with occult SUI were not identified as having SUI.

Although the aim of LSC is to provide a safe and effective surgical treatment for POP, its effect on urinary function should not be ignored. Deeper dissection of the vesicovaginal space anteriorly and rectovaginal space posteriorly is able to enhance level 2 support, hence allowing the surgeon to correct the anterior and posterior vaginal prolapse in the same setting. Therefore a randomized controlled trial is needed to evaluate the efficacy and safety further, particularly to compare urinary function outcomes between LSC that only provides apical support and LSC that provides both apical and level 2 support. Further research to compare urinary function outcomes between LSC and other surgical options for POP is also vital.

Conclusions

Apart from increased SUI, which occurs in all types of surgical repair for POP, there was an improvement in overall urinary function as demonstrated by the UDS findings and patient-reported symptoms, despite the deep vesicovaginal space dissection. Hence, LSC is a viable surgical option for the treatment of POP, restoring both level 1 and level 2 support, without a detrimental effect on urinary function.

Compliance with ethical standards

Conflicts of interest None.

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