【Title page】

Title: Outcome of modified laparoscopic sacrocolpopexy and its effect on voiding dysfunction

Running title: Voiding function after modified LSC

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1 【Abstract】

2 Background: Laparoscopic sacrocolpopexy (LSC) is an
3 increasingly popular treatment for pelvic organ prolapse (POP)
4 because of its low recurrence rate and safety. Although LSC may
5 improve the voiding function, it may also lead to *de novo* stress
6 urinary incontinence. The detailed impact of LSC on voiding
7 function and its mechanism remain unclear. Therefore, in this
8 study, we evaluated the impact of LSC on voiding function
9 prospectively by performing a pre- and post-operative urodynamic
10 study in patients with stage 3 or greater POP.

11 Methods: Urinary status was evaluated before and 3 months after
12 LSC. Pre- and post-operative evaluations included medical history,
13 clinical examination, urodynamic studies, chain cystography, and
14 residual urine volume measurement. Urinary symptoms were
15 assessed using the International Prostate Symptom Score (IPSS)
16 and the Overactive Bladder Symptom Score (OABSS).

17 Results: The non-recurrence rate at 3 months was 82.3%. All
18 recurrences involved bladder prolapse. Apart from the fact that

1 there was no significant change in the OABSS, the improvement
2 in IPSS suggests that subjective voiding symptoms have improved.
3 Although the maximum urinary flow rate did not change
4 significantly, the bladder volume at first sensation increased,
5 urinary storage function improved, and residual urine volume
6 decreased. There were no perioperative complications, and none of
7 the patients complained of post-operative difficulty in urination or
8 urinary retention. The retrovesical angle significantly decreased.

9 Conclusions: The modified LSC in women with POP provides good
10 functional outcomes in terms of IPSS, post void residual volume
11 (PVR), and urinary storage function.

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15 Keywords: Pelvic organ prolapse, Laparoscopic sacrocolpopexy,
16 voiding function, urodynamic study, retrovesical angle
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【Introduction】

Pelvic organ prolapse (POP) and urinary incontinence, although not fatal, are well known to reduce quality of life (QOL); surgery is the standard procedure for radical treatment. These conditions have a high morbidity with a lifetime risk of 10–20% in patients undergoing at least one surgery^{1,2}. Surgery for POP is also known to have a high rate of recurrence. The rate of reoperation is around 30%, and the time intervals between repeat procedures tend to decrease with each successive repair¹. Laparoscopic sacrocolpopexy (LSC) is a modified laparoscopic version of the conventional sacrocolpopexy and has gained popularity because of its low POP recurrence rate and safety. Although several studies have reported improvement in voiding function after LSC, there have also been reports of *de novo* stress urinary incontinence (SUI)³⁻⁵. The detailed impact of LSC on voiding function and its mechanism have not yet been elucidated.

Therefore, we conducted a study by performing a pre- and post-operative urodynamic study (UDS) and chain cystography in

patients with stage 3 or greater POP prospectively to evaluate the impact of LSC on voiding function and urethral hypermobility by measuring the retrovesical angle (RVA).

【Material and methods】

Study design and ethical consideration

This was the single-center hospital-based comparative study in consecutive patients who underwent LSC between April 2015 and March 2017. Ethical approval was obtained from the ethical committee of Nippon Medical School (No.26-03-430). All participants were provided written informed consents. Each patient consented to the operation and the pre- and post-operative urodynamic studies.

Patient inclusion and exclusion

Eligible patients were women younger than 80 years of age who opted for surgery for stage 3 or greater symptomatic bladder

prolapse. Excluded patients were women in whom general anesthesia was difficult to administer due to complications such as severe diabetes mellitus or those with a diagnosis of neurogenic bladder at UDS.

Pre- and post-operative evaluation

The staging of POP was recorded according to the POP-Q quantification system. The patients were examined in the Department of Urology at Nippon Medical School Hospital prior to surgery. The urinary statuses were evaluated both before and 3 months after surgery. Pre- and post-operative evaluations included medical history, clinical examination, UDS, chain cystography, and residual urine volume. Diagnosis of urinary symptoms was made by examining the clinical history according to the terminology guides of the International Urogynecological Association (IUGA) and the International Continence Society (ICS) ⁶. Urinary symptoms were assessed using the International Prostate Symptom Score (IPSS) and the Overactive Bladder

Symptom Score (OABSS). SUI and other symptoms were diagnosed through interviews. RVA was measured by chain cystography. In cases of SUI, it is known that the bladder neck is enlarged and RVA is enlarged in the lateral view. The normal value is 90–110°; however, in this study, $\leq 110^\circ$ degrees was considered normal. If post-operative SUI was present, information regarding pelvic floor muscle therapy, drug therapy, and surgical treatment was obtained. Using the OABSS questionnaire, overactive bladder (OAB) was diagnosed if the patient had a sudden desire to urinate that was difficult to defer and experienced either a day-time frequency of more than seven times or nocturia at least once.

Multichannel urodynamic evaluation

The UDS was performed using Ellipse® (EDAP TMS, Tokyo, Japan), including pressure flow cystometry and uroflowmetry, by an independent urologist (A.G.). During cystometry, the bladder was filled with room temperature saline solution at a rate of 50

mL/min with the patient in a supine position. Organ prolapse reduction was performed with gauze packing.

Surgical procedure

LSC was performed by a single surgeon. The procedure was based on standard LSC, and in some cases, it included an additional technique in which the lateral compartment was supported by another mesh (hybrid-LSC). In our technique, mesh augmentation was used only for anterior vaginal wall, and posterior repair was accomplished by native tissue repair only. We refer to this technique as the modified LSC since our technique was a hybrid of two techniques. The hybrid-LSC procedure was performed according to Ichikawa et al.⁷. After dissecting between the anterior vaginal wall and the bladder, the lower end of the mesh for the anterior vaginal wall was fixed to the upper edge of the vagina and the upper edge was fixed to the cape angle. For the posterior wall, the upper part of the posterior vaginal wall was supported by continuous sutures on both sides of the rectovaginal fascia of the

posterior vaginal wall, and no mesh was used. In cases of hybrid-LSC, an inverted T-shaped mesh with a pair of arms was used for the anterior wall, and a portion of the mesh was fixed to the supravaginal and promontory angles, and then a pair of arms was implanted through the foramen magnum to support the paravaginal defect. The position of the puncture for the arm in cases of hybrid-LSC was in the midline between the first and second punctures in the transvaginal mesh surgery protocol, as described by Debodinance et al.⁸. No concomitant anti-incontinence surgery was performed.

Statistical analyses

All calculations were performed using JMP® 13 (SAS Institute Inc., Cary, NC, USA). Categorical data are presented in the form of absolute numbers and their corresponding percentage values. The Wilcoxon signed-rank test was used to compare pre and post-operative parameters. Statistical significance was set at $p \leq 0.05$.

【Results】

Of the 24 patients who enrolled for the study, 15 were available for evaluation. Five patients failed to visit the urologist postoperatively, one was diagnosed with underactive bladder and was excluded, one could not undergo UDS at the appropriate time due to mechanical failure, and two had incomplete data. The patients' background is shown in Table 1.

Table 1

Post-operative outcome

The non-recurrence rate (defined as stage 1 or better) at 3 months after surgery was 82.3%. All recurrences involved bladder prolapse. There were no perioperative complications, and none of the patients complained of post-operative difficulty in urination or urinary retention.

Pre- and post-operative evaluation

There were no perioperative complications. The IPSS and IPSS-QOL score decreased significantly postoperatively, especially in the IPSS irritative subscore. The OABSS did not change significantly pre- and postoperatively. Five patients had SUI preoperatively; of these, three patients had some improvement in symptoms, and two patients continued to complain of SUI postoperatively, which was similar to their preoperative rate. Three patients complained of *de novo* SUI, and two of whom opted for transobturator tape.

Three patients complained of preoperative urge urinary incontinence (UUI), but none of these patients complained of UUI postoperatively. One patient had *de novo* UUI, and requested no therapy. Data on pre- and post-operative urination are shown in Table 2. RVA significantly decreased and normalized postoperatively.

Table 2

UDS

The parameters for the UDS are shown in Table 3. Postoperatively, voided volume and volume at first sensation increased significantly. PVR was significantly reduced, and there were no significant differences between the pre- and post-operative volume at strong sensation, maximum urinary flow rate, and detrusor pressure at maximum flow.

Table 3

【Discussion】

At 3 months postoperatively, the non-recurrence rate was 82.3%, and the IPSS and IPSS irritative subscore improved, although there was no significant change in the OABSS. RVA significantly decreased and urethral hypermobility, a cause of SUI, normalized. Although Qmax did not change significantly, the bladder volume

at first sensation increased, urinary storage function improved, and residual urine volume decreased.

Because of its low recurrence rate of POP, LSC is becoming the gold standard treatment. Ganatra et al.⁹, Bacle et al.¹⁰, and Moriyama et al.¹¹ reported low recurrence rates of 8.0%, 11.5%, and 8.0%, respectively. Although we cannot compare our results with those of these studies because of the different follow-up periods, the recurrence rate remained low at 3 months after surgery in our study.

The purpose of our study was to prospectively evaluate voiding function before and after LSC. The results showed that there was a significant decrease in the IPSS postoperatively, while there was no significant difference in the OABSS. Nonetheless, preoperative UUI disappeared at follow-up after surgery in all three patients, and *de novo* UUI was observed in one patient who did not require treatment, suggesting that LSC may also improve urinary storage function. There was no change between the pre- and post-operative

OABSS; this could be because the mean score was originally as low as 3 points and therefore did not show a change.

Post-operative voiding functions such as the maximum flow rate and Pdet (Qmax) were comparable to the preoperative values. There was no decrease in voiding function due to surgery because of the improvement in residual urine volume. Hence, the urodynamic parameters were unchanged or improved similar to that reported by Abdullah et al., who reported 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 Qmax, higher Qave, lower Pdet [Qmax]), as well as increased voided volume and reduced postvoid residual urine volume¹².

Abdullah et al.¹² also reported that preoperative SUI was 24%, 82.4% of which disappeared postoperatively, and *de novo* SUI was 26.6%. In our study, the preoperative SUI complication rate, post-operative improvement rate, post-operative exacerbation rate, and *de novo* SUI rate were 33.3%, 60.0%, 0%, and 20.0%, respectively;

in comparison, Narushima et al.¹³ reported these rates as 67.3%, 61.7%, 14.5%, and 37.8%, respectively, after LSC without surgery for urinary incontinence. In our study, the post-operative improvement rate was similar, but the *de novo* rate was lower than that reported elsewhere. Because the population was limited to 15 cases, this may have resulted in a population with a small predisposition to SUI. Also, the timing of the evaluation was different in these other studies. Nomura et al.¹⁴ reported that 63% of the patients with *de novo* SUI had improved by the 1-year evaluation, suggesting that the timing of post-operative SUI improvement may vary depending on the surgical technique and whether anti-incontinence surgery is performed at the same time. Despite its predisposition because of compression of the urethra by the prolapsed organ, SUI might not exist preoperatively. POP surgery aims to improve activities of daily living but it sometimes causes *de novo* SUI, which appears suddenly after surgery and can greatly impair the patient's QOL. Preoperative identification of patients at high risk of developing *de novo* SUI would be beneficial.

Some studies have focused on the maximum urethral closing pressure as a risk factor for *de novo* SUI, but Abdullah et al. reported that there was no significant difference in maximum urethral closure pressure before and after surgery¹². Therefore, the risk factors for *de novo* SUI have not yet been identified.

Causes of SUI include urethral hypermobility and intrinsic urethral sphincter deficiency, and are diagnosed by either urodynamic study or findings of RVA enlargement and open bladder neck on chain cystography and ultrasonography. In our study, all patients underwent chain cystography before and after surgery; those with *de novo* SUI had no preoperative bladder neck open sign, and the post-operative RVA normalized in all but one case. Thus, the patients with post-operative SUI in our study may have had causes other than urethral hypermobility and urethral sphincter insufficiency. Nomura et al. reported that the SUI observed at 6 months postoperatively disappeared or improved at 1 year postoperatively; this is because the *de novo* SUI that appeared due to the release of urethral flexion by surgery may

have improved during the follow-up period as the anatomical position improved and the urethral function improved, resulting in improvement of SUI at 1 year postoperatively¹⁴. This suggests that the improvement in anatomical position and urethral function may be delayed, and some other factor may be responsible for this delay; however, this requires investigation in a further study.

Our study had several limitations such as the small number of cases and the inclusion of cases of hybrid-LSC among the cases of LSC. Hybrid-LSC is a technique that was performed in addition to regular LSC to provide better support for paravaginal defects, and it is unlikely to have a positive effect on voiding function because it is a slightly more invasive procedure. In order to verify our results, similar studies should be conducted in a larger number of patients with normal LSC only.

In conclusion, the modified LSC in women with POP provides good functional outcomes in terms of IPSS, PVR, and urinary storage function.

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Conflicts of interest: None

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Table1 Baseline characteristics of the study population

Variable	value
Age(years),median(range)	64(39-78)
Body mass index(kg/m ²), median(range)	24.3 (21.8-37.1)
Stage of POP (n,%)	
	3 14(93.3)
	4 1(6.6)
Type of operation (n,%)	
hybrid LSC	1(11.7)
LSC	14(88.2)
operating time(min) median(range)	274(176-361)

Table 2 Symptoms score and retrovesical angle before and after surgery

Parameter	Preoperative median (range)	Postoperative median (range)	p value
OABSS	3(1-7)	2(1-8)	0.414
IPSS	8(2-21)	2(0-20)	0.0002
IPSS			
the voiding score	3(0-10)	1(0-13)	0.1099
the irritative score	5(2-16)	2(0-8)	<0.0001
IPSS QOL	4(2-6)	2(1-5)	0.0129
retrovesical angle	254.9(138-314)	104.2(91.3-126.3)	<0.001

Table 3 Pre- and postoperative urodynamic parameters

Parameter	Preoperative median (range)	Postoperative median (range)	p value
Volume at first sensation (mL)	169(45-500)	216(61-429)	0.049
Volume at strong sensation (mL)	230(110-600)	368(166-483)	0.057
Voided volume(mL)	242.7(46-404)	319.6(140-737)	0.05
Post void residual volume (mL)	65(3-325)	7.5(2-106)	0.012
Q _{max} (mL/s)	19.05(4.5-31.4)	22.6 (8-38.6)	0.528
P _{det} Q _{max} (cm H ₂ O)	27.1(5-60)	21.85(4.1-59.4)	0.231