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Lower urinary tract function improves after laparoscopic sacrocolpopexy for elderly patients with pelvic organ prolapse

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Running title: LSC is a valid option for elderly

20 **Conflicts of interest:**

21 Mio Togo: None declared, Takeya Kitta: None declared, Yukiko Kanno: None declared

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26

27

28 **Abstract**

29 **Objectives**

30 Pelvic organ prolapse (POP) is relatively common in the elderly population.
31 Laparoscopic sacrocolpopexy (LSC) has been reported by several studies to be a less
32 invasive treatment option as compared to open sacrocolpopexy. However, almost all
33 prior reports focused on the complications, or surgical obstacles. The present study was
34 designed to examine POP patients of all ages and assess lower urinary tract function
35 before and after LSC.

36 **Methods**

37 This retrospective study examined the results of LSC performed in POP patient.
38 Urodynamic studies were performed pre- and postoperatively in 50 patients, with the
39 subjects divided into two groups containing those less than and those older than 65
40 years of age. We performed a pressure-flow study. We examined bladder functions by
41 evaluating bladder capacity, detrusor pressure at maximum flow (PdetQmax), maximum
42 flow rate (Qmax), normal desire to void (NDV), strong desire to void, voided volume,
43 and post-void residual volume (PVR). Statistical analysis was performed using
44 Wilcoxon signed rank test. Values of $p < 0.05$ were considered significant.

45 **Results**

With regard to the pressure-flow study parameters, there was a significant increase in the NDV and bladder capacity only in the ≥ 65 age group. After the operation, there was a significant increase in the mean postoperative Qmax and voided volume, while there was a significant decrease in the PdetQmax and PVR as compared to the preoperative values only in the ≥ 65 age group.

Conclusions

Results show that in elderly patients with POP, LSC might be a valid option with regard to potentially regaining urinary tract function.

56 **Keywords:**

57 elderly; laparoscopic sacrocolpopexy (LSC); pelvic organ prolapse; urodynamic study

58

59 **Abbreviations:**

60 pelvic organ prolapse (POP)

61 stress urinary incontinence (SUI)

62 urgency urinary incontinence (UUI)

63 pressure flow study (PFS)

64 detrusor overactivity (DO)

65 maximal flow rate (Q_{max})

66 detrusor pressure at Q_{max} (P_{det} at Q_{max})

67 International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF)

68 Overactive Bladder Symptom Score (OABSS)

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Introduction

The number of people aged 65 and over has rapidly increased in countries worldwide in recent decades. The number of elderly patients with pelvic organ prolapse (POP) is also increasing, with a higher rate found in this group as compared to the general population.¹ Conservative treatments include pessary use and pelvic floor muscle training. However, surgical therapy is often a more effective option for patients with POP. Surgical procedures include native tissue repair, tension-free vaginal mesh, and laparoscopic sacrocolpopexy (LSC). These procedures can be carried out with or without the placement of a synthetic mesh. However, LSC is now the more favored treatment for POP due to the warnings issued by the U.S. Food and Drug Administration concerning the mesh-related complications that can follow transvaginal mesh surgeries. Furthermore, Richter et al. reported finding no significant difference in complication rates for abdominal sacrocolpopexy between women younger or older than 70.² LSC is now considered to be an effective option for women under 65 years of age by many surgeons, even though others are hesitant to suggest laparoscopic surgery in elderly women.³ However, studies have reported that the safety and complication rates are similar between younger and elderly women who undergo surgical treatment for POP.⁴ In addition, studies have also reported that LSC is an effective surgical procedure, with

the benefit of being less invasive than other open surgeries. However, these reports did not examine the lower urinary tract functional outcomes but instead primarily evaluated the recovery of vaginal function, postoperative complications, or surgical failure. Therefore, our current study was designed to compare lower urinary tract function before and after LSC for the treatment of POP in women under and over the age of 65 years.

Methods

Study design

This retrospective study included 50 POP patients who underwent LSC between October 2013 and July 2016 in a single tertiary center. These urodynamic studies used a Laborie Delphis KT urodynamic system to evaluate the patients before and after LSC, with the patients divided into groups less than and older than 65 years of age. The terminology used in the current study follows the terminology guides of the International Urogynecological Association (IUGA) and the International Continence Society.⁵ Ethics approval was obtained (IRB number: 017-0184), and the study protocol followed the Declaration of Helsinki. Certain patients who took part in the current study have also participated in other studies that we previously reported.⁶

108

109 *Data collection*

110 Table 1 presents the patient characteristics. Previous clinical records were used for the
111 purpose of obtaining the current patient medical records. The data collected from these
112 records included the following: age at the time of surgery, basic characteristics of the
113 patients, body mass index (BMI) at the time of the preoperative appointment, estimated
114 blood loss, parity, operative time, and the pre- and postoperative pelvic organ prolapse
115 quantification (POP-Q) measurements. A simplified version of the scale of the
116 International Continence Society POP-Q was used to classify the stage of genital
117 prolapse. Since the outcome of patients who simultaneously underwent
118 anti-incontinence surgery could not reveal the impact of LSC on lower urinary tract
119 function, these subjects were excluded from our analysis. At 6 months after the surgery,
120 all patients underwent a follow-up, which examined the same areas as listed above. And,
121 symptom of patient's data were collected included the International Consultation on
122 Incontinence Questionnaire Short Form (ICIQ-SF) and Overactive Bladder Symptom
123 Score (OABSS). The validated Japanese versions of the ICIQ-SF and OABSS were
124 used in this study. Based on these questionnaires, stress urinary incontinence (SUI),
125 urgency urinary incontinence (UUI) was diagnosis.

126

127 *Surgical technique*

128 The LSC method has been previously reported in detail.⁶ For all patients, surgery was
129 performed by a single trained surgeon (JM). This surgeon performed posterior
130 (rectovaginal space) dissection to the level of the levator ani muscles bilaterally and the
131 perineal body in the middle, while the anterior (vesicovaginal space) dissection was
132 performed much deeper than that normally used for conventional LSC. This dissection
133 was performed to the bladder neck level. Two pieces of polypropylene mesh (Gynemesh,
134 Ethicon; Polyform, Boston Scientific) were stitched to three points of the anterior
135 vaginal wall. The two meshes were sutured together, attaching to the lateral edge of the
136 cervical stump and uterosacral ligaments bilaterally. The rectouterine pouch was
137 covered by the peritoneum. Subsequently, after determining there was an appropriate
138 level of suspension via a vaginal examination, the cranial end of the mesh was then
139 sutured to the anterior longitudinal ligament over the sacral promontory. Finally, closure
140 of the posterior parietal peritoneum was performed, which ensured there was coverage
141 of the entire length of the mesh.

142

143 *Urodynamic technique*

Multichannel urodynamic evaluations were performed for all 50 patients, and which included a urethral pressure profile, cystometry, and a pressure flow study.⁶ The preoperative pressure flow study was carried out with prolapse reduction using surgical gauze. Each patient underwent a urodynamic assessment before and at 6 months after the surgical procedure. With regard to the urethral sphincter function, functional profile length and maximum urethral closure pressure (MUCP) were evaluated. The parameters examined in order to evaluate the filling cystometry included the normal desire to void (NDV), strong desire to void, and bladder capacity. In addition, we also performed a pressure flow study that evaluated the maximum flow rate (Q_{max}), detrusor pressure at maximum flow (P_{det} at Q_{max}), voided volume, and post-void residual volume (PVR). Provocative maneuvers were carried out by cough and Valsalva after 200 ml of filling and a strong desire to void. Detrusor overactivity (DO) was diagnosed if involuntary detrusor contraction occurred during the filling cystometry, either spontaneously or provoked.

Statistical analysis

The data were analyzed using JMP statistical software version 13.0 (SAS Institute Inc., Cary, NC, USA). Urodynamic and lower urinary tract symptoms pre- and postoperative

162 parameters for each group were compared using a Wilcoxon signed rank test. Values of
163 p less than 0.05 were considered significant.

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Results

A total of 50 patients were included in this study, 12 of whom were younger than 65 years and 38 were 65 years or older. Patients in the two groups had similar characteristics for BMI, estimated blood loss, operative time and parity ($p > 0.05$ for each; Table 2). The occurrence of perioperative complications did not differ significantly between the two groups (We have 3 patients' complications (>65 age group; 1) which were bladder injury, intestinal obstruction and bleeding in excess of 100 mL during operation. And no patient was reported to have a vaginal mesh exposure). With regard to urethral function, MUCP was significantly different between the groups ($p = 0.036$) (Table 3).

No significant changes in the urethral sphincter function were observed pre- and post-LSC in either group. Regarding the filling cystometry parameters, NDV and bladder capacity were significantly increased in only the ≥ 65 age group ($p = 0.008$ and 0.041 , respectively). For the voiding cystometry parameters, there was a significant increase in the mean postoperative Qmax and voided volume ($p = 0.0002$ and 0.003 , respectively) while there was a significant decrease in the Pdet at Qmax and PVR after the operation, as compared to the preoperative values only in the ≥ 65 age group ($p = 0.029$ and 0.003 , respectively). There were no significant changes observed in the

uroflowmetry parameters for either the pre- and post-LSC group (Table 4). Due to the small number of cases, the DO frequency was not statistically analyzed. After operation, there was a significant improvement in OABSS scores (from 4.0 ± 2.5 to 2.6 ± 2.6) but there was no significant difference in the ICIQ-SF scores in all patients. In each group, ICIQ-SF changed from 7.4 ± 2.1 to 6.6 ± 5.9 and from 7.3 ± 5.2 to 4.7 ± 5.6 for less than 65 and older than 65 years group, respectively. And, OABSS changed from 3.4 ± 2.3 to 1.4 ± 0.9 and from 4.2 ± 2.6 to 3.0 ± 2.8 for less than 65 and older than 65 years group, respectively. Of the 8 patients who had SUI preoperatively (>65 age group; 5), 7 patients had resolution of symptoms after LSC. De novo (occult) SUI occurred in 4 patients after LSC. 14 patients had UII before LSC (>65 age group; 10), 9 patients had resolution of symptoms after LSC. De novo UII occurred in 1 patient (>65 age) after LSC.

Discussion

Our findings suggest that LSC is a valid surgical option that can improve the POP in women ≥ 65 years old. There is a greater prevalence of POP in the elderly versus the younger populations. Previous reports have defined “elderly” as ranging between 60 and 80 years old. Conversely, in the epidemiological literature, “elderly” is frequently defined as being over 65 years old. In our current study, we defined “elderly patients” as those who were older than 65 years of age.

POP is a common, bothersome, and costly problem for women. Several treatment options are available, with individual patient’s circumstances dictating which option(s) are the most efficacious. In the majority of cases, it is suggested that patients undergo either pelvic floor muscle training or surgical treatment of POP. During the last decade, LSC has become widely recommended as a treatment for POP. It has been documented that exclusion of older patients from LSC is commonly done without any justification other than the subject’s age.³ Furthermore, laparoscopic hysteropexy and sacrocolpopexy are also avoided in elderly individuals without the presence of any specific reason.⁷ Unfortunately, many previous studies, especially those that have examined elderly populations, have only focused on major complications, without providing any information on the functional outcomes. In addition, after

urogynecological surgery in elderly women, there has been limited information provided on either the mortality and morbidity. The majority of these studies also did not include any calculation of the risks or account for any comorbidities.

In the current study, perioperative complications for elderly patients were not significantly increased as compared to that for younger patients. In our previous study, we reported that LSC was an effective procedure in accordance with both the urodynamics (UDS) and subjective data in all age groups.⁶ In the current study, we focused on the factor of age when using the objective UDS data. Thus, this current study is one of the first reports in the urogynecological literature that has specifically examined patients before and after LSC. Since there have not been many studies that have performed objective tests of the lower urinary tract, our data will be of substantial benefit to both physicians and patients.

UDS is the general term for the study of the storage and voiding function/dysfunction of the lower urinary tract. UDS is the only objective diagnostic test that can clinically assess a patient's suffering with regard to lower urinary dysfunction. In the current study, we examine both storage and voiding symptoms. The parameters examined in order to evaluate the storage symptoms included the normal desire to void (NDV), strong desire to void (SDV), and bladder capacity. The voiding phase

parameters, maximum flow rate (Q_{max}) and average flow rate (Q_{ave}) and pressure at maximum flow (P_{det}Q_{max}) and voided volume (VV) and post-void residual urine (PVR) represent voiding symptoms. In addition, UDS can also be used to assess postoperative voiding function. In most cases, voiding function is usually recovered within a few weeks of surgery. However, this temporary voiding dysfunction is directly associated with the quality of life (QOL) of the patients. There are very few studies that have investigated the effect on the lower urinary tract function using UDS, even though there has been an increased awareness and effort in the urogynecological research field to identify the risk associated with POP surgery. At the present time, it still remains unknown as to the exact mechanisms that are responsible for these this temporary voiding dysfunction after surgery.

Kitta et al. attempted to evaluate preoperative and postoperative voiding function by PFS in addition to trying to assess the cause of postoperative voiding dysfunction.⁸ Lo et al. reported that some risk factors such as preoperative detrusor low pressure, concurrent midurethral sling insertion and diabetes mellitus were risk factors for postoperative voiding dysfunction.⁹ However, their findings showed that having an age ≥ 66 years was not a significant risk factor for postoperative voiding dysfunction. In the current study, in ≥ 65 years age group, after LSC the voiding phase parameters, Q_{max}

was significantly higher and Pdet at Qmax was significantly lower compared to pre-LSC. This means, even elderly patients ameliorate lower urinary tract function. In addition, in <65 years age group, both Qmax and Pdet at Qmax have a change in tendency pre and post LSC ($p= 0.058$ and 0.055 , respectively). It could be a case size matter. In our previous study ⁶, range of age was 49-88, after LSC the voiding phase parameters, Qmax was significantly higher and Pdet at Qmax was significantly lower pre-LSC. So, we did not consider elderly patients is more ameliorate lower urinary tract function, but even elderly patients could also ameliorate lower urinary tract function.

The second role of UDS is to evaluate DO following POP surgery. Lo et al.¹⁰ reported that having an age ≥ 66 years was an independent risk factor for developing postoperative DO following surgery for POP. Long et al.¹¹ found that women with POP who underwent repair using a tension-free vaginal mesh experienced improvement of their overactive bladder symptoms, and that the only significant predictor of symptom relief was the preoperative DO. POP can cause bladder outlet obstruction, which has been reported to be the cause of DO or overactive bladder in patients with POP.¹² In our study, the frequency of DO was not statistically analyzed due to the small number of cases. Finally, UDS can additionally be used to evaluate de novo stress urinary incontinence (SUI), with concomitant surgery then used to correct SUI. De novo SUI is

a known risk of POP surgery. However, previous studies revealed that concomitant SUI surgery for POP patients increases the risk of postoperative voiding dysfunction. However, this remains a complex and controversial issue.¹³ In the current study, since the outcome of patients who underwent a simultaneous anti-SUI surgery did not represent the true impact of the LSC on urinary function, we excluded these patients from our analyses. Even if the real usefulness of the preoperative UDS evaluation of women scheduled for POP repair has yet to be definitively determined, the current study does demonstrate that there is significant improvement of the lower urinary tract function in elderly women who undergo LSC treatment for POP.

In this study, we assessed urethral function in addition to bladder function. Only a few studies have focused on the urethral function pre- and post-LSC, with almost all prior studies only focusing only on bladder function. However, continence mechanisms are composed of both bladder and urethral functions. When the bladder pressure exceeds the urethral pressure due to effort or exertion, or after sneezing or coughing, SUI occurs. SUI is dependent upon both the urethral closure function and the pressures to which it is subjected. Unfortunately, the specifics details on the closure mechanism of the urethra in women have yet to be definitively elucidated. Urethral pressure profilometry is used in the diagnosis of SUI. Currently, there is a lack of consensus

regarding urethral pressure profilometry as a diagnostic test, and thus it is mainly used in specialized centers as an adjunctive technique for clinical urodynamic assessment. Furthermore, there are still no clearly defined measurable criteria for the characterization of urethral function.¹⁴ In the current study, after we examined the functional profile length and MUCP, we determined that there were no significant differences for these factors before and after LSC. We only observed a significant difference between the two groups with regard to the preoperative MUCP, which was related to changes caused by aging. However, when patients with more severe forms of SUI, i.e., based on urodynamic testing, are compared to those exhibiting less severe forms, there has been no evidence to suggest that there will be any differences between the two groups after undergoing the most commonly offered surgical treatments. Although LSC did not alter the urethral static closure mechanisms in our current study, this does not mean that other urethral profiling methods should also be excluded. For example, urethral pressure examined at a high resolution could potentially shed more light on this issue. Moreover, not only the urethral static tests but also urethral dynamic tests should be able to provide information about the bladder neck or proximal urethra.

After LSC, there was a significant improvement in OABSS scores but there was no significant difference in the ICIQ-SF scores in all patients. These results correspond

with the results from our previous reports. However, in each less than 65 and older than 65 years group, there were no significant differences. It could be a case size matter. Nevertheless, we focused on the objective UDS data mainly in this study. Since there have not been many studies that have performed slightly invasive objective tests, our data will be of substantial benefit to understand aging affects the physiology of lower urinary tracts.

Although the original goal of LSC was to create a way to provide both a safe and effective surgical treatment for POP, the effect that LSC has on urinary function needs to be taken into consideration and should not be ignored. Our data indicated that the lower urinary tract function significantly improved in elderly women after undergoing LSC for POP. Our data could potentially provide support for the decision to consider a surgical option in older patients. The limitations of our current study included both the small number of patients treated and its retrospective design. Notably, we did not evaluate the QOL of the patients in each of the groups examined.

In conclusion, from the perspective of lower urinary tract function, LSC could be a valid option for elderly patients with POP.

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324 **Conflict of interest:** none declared

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Tables

Table 1

Baseline patient characteristics

Variable	Value
No. of patients	50
Age (years), median (range)	67.3 (50–88)
BMI (kg/m ²), mean $\pm$ SD	24.3 $\pm$ 3.1
Parity (n)	
1	5
2	32
3	10
4	2
unknown	1
Stage of POP (n)	
1	-
2	13
3	35
4	2
Operating time (min), median	230.7 $\pm$ 39.6
Estimated blood loss (ml), median	23.4 $\pm$ 50.7
Diabetes mellitus (n)	6

BMI: body mass index

Table 2

Baseline patient characteristics for the two groups examined

	<65 years of age group	≥65 years of age group
Variable	Value	Value
No. of patients	12	38
Age (years), median (range)	61.5 (50–64)	68.5 (65–88)
BMI (kg/m ²), mean ± SD	23.6 ± 3.7	24.5 ± 2.9
Parity (n)		
1	2	3
2	7	25
3	1	9
4	1	1
unknown	1	-
Stage of POP (n)		
1	-	-
2	3	10
3	9	26
4	-	2
Operating time (min), median ± SD	229.0 ± 42.4	234 ± 39.2
Estimated blood loss (ml), median, mean ± SD	20.0 ± 95.9	10.0 ± 15.8
Diabetes mellitus (n)	3	3

BMI: body mass index

Table 3

Urethral pressure profilometry, cystometry, and pressure flow study findings before surgery

	<65 years of age group	≥65 years of age group	
	pre-LSC	pre-LSC	<i>p</i> value
Urethral function			
FPL (mm)	26.4 ± 3.8	27.9 ± 4.6	0.411
MUCP (cm H ₂ O)	56.8 ± 22.0	43.8 ± 15.3	0.036
Bladder function			
NDV (ml)	175.3 ± 98.8	156.0 ± 77.5	0.615
SDV (ml)	267.6 ± 142.0	249.6 ± 122.2	0.905
Capacity (ml)	348.2 ± 145.6	324.2 ± 128.4	0.684
Q _{max} (ml/s)	16.9 ± 7.0	13.7 ± 8.9	0.108
P _{det} at Q _{max} (cm H ₂ O)	31.4 ± 14.7	30.5 ± 14.4	0.827
VV (ml)	319.5 ± 163.5	290.7 ± 143.7	0.703
PVR (ml)	42.7 ± 44.1	44.5 ± 41.7	0.537

Values are the mean ± SD. LSC: laparoscopic sacrocolpopexy, FPL: functional profile length, MUCP: maximum urethral closure pressure, NDV: normal desire to void, SDV: strong desire to void, VV: voided volume, PVR: post-void residual urine

Table 4

Urodynamic observations before and after surgery

	<65 years age group			≥65 years age group		
	pre-LSC	post-LSC	<i>p</i> value	pre-LSC	post-LSC	<i>p</i> value
Urethral function						
FPL (mm)	26.4 ± 3.8	25.9 ± 3.5	0.563	27.9 ± 4.6	28.0 ± 4.4	0.896
MUCP (cm H ₂ O)	56.8 ± 22.0	57.8 ± 28.0	0.789	43.8 ± 15.3	42.4 ± 12.2	0.427
Bladder function						
NDV (ml)	175.3 ± 98.8	215.0 ± 117.9	0.573	156.0 ± 77.5	194.4 ± 95.3	0.008*
SDV (ml)	267.6 ± 142.0	318.1 ± 102.1	0.684	249.6 ± 122.2	287.1 ± 115.2	0.118
Capacity (ml)	348.2 ± 145.6	405.0 ± 109.7	0.267	324.2 ± 128.4	364.5 ± 115.8	0.041*
Qmax (ml/s)	16.9 ± 7.0	22.1 ± 6.7	0.058	13.7 ± 8.9	20.8 ± 9.7	0.0002*
Pdet at Qmax (cm H ₂ O)	31.4 ± 14.7	23.9 ± 9.8	0.055	30.5 ± 14.4	23.9 ± 12.4	0.029*
VV (ml)	319.5 ± 163.5	431.5 ± 119.0	0.173	290.7 ± 143.7	398.1 ± 123.2	0.003*
PVR (ml)	42.7 ± 44.1	23.1 ± 26.9	0.202	44.5 ± 41.7	20.0 ± 22.8	0.003*
Uroflowmetry						
VV (ml)	377.9 ± 158.0	397.4 ± 117.1	0.519	291.4 ± 123.2	337.4 ± 94.9	0.030*
Qmax (ml/s)	22.5 ± 7.8	25.4 ± 6.7	0.233	19.3 ± 10.0	21.8 ± 9.3	0.027*
Qave (ml/s)	13.0 ± 5.1	15.3 ± 3.6	0.151	11.2 ± 6.1	13.2 ± 6.0	0.002*

Values are mean ± SD. **p* < 0.05, comparing pre- and post-LSC. LSC: laparoscopic sacrocolpopexy, FPL: functional profile length, MUCP: maximum urethral closure pressure, NDV: normal desire to void, SDV: strong desire to void, VV: voided volume, PVR: post-void residual urine