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Robotic-assisted Sacrocolpopexy with versus without Concomitant Midurethral Sling: A 2-year Follow-up of Urinary Symptoms and Quality of Life

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Abstract

Objective:

The objective of this study was to assess long-term postoperative urinary incontinence (UI) symptoms and quality of life (QOL) in patients after robotic-assisted sacrocolpopexy (RASC) with or without concomitant midurethral sling (MUS).

Materials and Methods:

This is a cross-sectional survey of patients comparing long-term postoperative urinary symptoms and QOL measurements in women who underwent RASC with or without MUS. We included all patients from 2011 to 2014 who had RASC with or without MUS. All patients had preoperative urodynamic testing (UDS). Patients who demonstrated stress UI on UDS underwent MUS at the time of RASC. Urinary symptoms and QOL were assessed through the validated Urinary Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7) patient questionnaires.

Results:

Sixty-eight patients met inclusion criteria, 46 patients completed follow-up questionnaires, and were included in the final analysis. Average length of time to follow-up from surgery was 24 months (range: 6–36 months). A statistically significant difference in UDI-6 scores between the two groups (RASC vs. RASC + MUS) was observed. Median (25th and 75th percentiles) scores for UDI-6 were 22.92 (8.33 and

32.29, respectively) for the RASC group and 4.17 (0 and 13.54, respectively) for the RASC + MUS group ($P = 0.0017$). Median scores for IIQ-7 were 0 (0 and 29.73 for the 25th and 75th percentiles, respectively) for the RASC group and 0 (0 and 0, respectively) for the RASC + MUS group ($P = 0.1691$).

Conclusion:

Patients who underwent RASC + MUS scored significantly lower on the UDI-6, indicating fewer urinary distress symptoms. Although not statistically significant, patients in the RASC + MUS group had lower IIQ-7 scores, indicating less negative impact on QOL, compared to the RASC-only group.

KEYWORDS: *Midurethral sling, robotic surgery, sacrocolpopexy, stress urinary incontinence*

INTRODUCTION

Pelvic organ prolapse (POP) rarely occurs in isolation. Two-thirds of women with POP have coexisting stress urinary incontinence (SUI).[1] Women without preoperative SUI have a 16%–51% chance of developing postoperative *de novo* SUI after surgical correction of POP.[2] Nygaard *et al.* established that 77% of patients without concomitant anti-incontinence procedure at the time of colpopexy developed SUI and 6.5% of those patients eventually underwent an anti-incontinence procedure.[3] Two previous studies demonstrated a 23% rate of *de novo* SUI after laparoscopic sacrocolpopexy, and a varied rate of subsequent anti-incontinence procedures ranging from 5% to 15%.[4,5]

A meta-analysis of randomized controlled trials comparing POP surgery with or without anti-incontinence surgery showed that the number needed to treat (NNT) to prevent one woman from developing SUI was two, three, and nine for patients who had co-existing SUI, occult SUI, and asymptomatic continent women, respectively. With regard to asymptomatic continent women, the NNT to prevent one woman from undergoing an anti-incontinence procedure was twenty. The only notable complication identified after concomitant surgery was prolonged catheterization, with persistent obstructive voiding found in 2% of patients.[6]

Large prospective trials have confirmed the benefit of an anti-incontinence procedure at the time of prolapse repair. The optimal angioplasty versus primary stenting (OPUS) trial demonstrated statistically lower rates of urinary incontinence (UI) in patients who received a midurethral sling (MUS) at the time of prolapse repair through a vaginal route.[7] In the CARE trial, patients who received a concomitant Burch urethropexy at the time of abdominal sacrocolpopexy had lower rates of SUI with long-term follow-up. When compared to Burch urethropexy, patients who received a MUS were shown to have similar continence rates, however they had better patient-centered outcomes.[8] MUS was also associated with shorter operative time, shorter hospital stay, and lower rate of voiding dysfunction.[9] Recently, more data have shown the benefits of MUS over other surgical treatments for SUI, including shorter operative time, shorter hospital stay, and lower rates of *de novo* urge incontinence.[9,10,11,12,13,14]

There are clear benefits to minimally invasive surgery (MIS) as compared to an open abdominal technique, such as decreased estimated blood loss, fewer intraoperative complications, shorter recovery time, and decreased postoperative pain.[15] As a result, rates of laparoscopic and robotic MIS are on the rise. Despite the increasing data on the benefits of MIS, there are no current studies evaluating the possible benefits of concomitant MUS at the time of robotic-assisted sacrocolpopexy (RASC).

Women who suffer from occult SUI after surgical correction of POP may be dissatisfied postoperatively. [16] It is unclear whether surgeons should consider having a discussion regarding a concomitant anti-incontinence procedure at the time of RASC.

Objective

The objective of this study was to compare symptoms and quality of life (QOL) in patients who have undergone RASC with or without concomitant MUS based on validated patient questionnaires. Secondary outcome measures include the subjective success of the procedure as well as the associated complications from the surgery. We hypothesized that patients undergoing concomitant MUS would have fewer urinary distress symptoms and an improved QOL.

MATERIALS AND METHODS

This is a cross-sectional survey of patients comparing long-term postoperative urinary symptoms in women who underwent RASC with or without concomitant MUS. Institutional Review Board approval was obtained (IRB # 14-582). A retrospective chart review was performed on all female patients over the age of 18, who underwent a RASC between 2011 and 2014 at North Shore University Hospital of Northwell Health System. All patients had urodynamic testing (UDS) as a component of routine preoperative evaluation. In patients with advanced POP, a rectal swab was used to reduce the prolapse and assess for urine leakage with cough or Valsalva. All patients who were diagnosed with SUI on UDS underwent MUS at the time of RASC. Patients were excluded from the study if they were diagnosed with SUI on UDS and declined concomitant MUS placement at the time of surgery. Demographic data, POP-Quantification (POP-Q), and Q-tip test scores were recorded.

Patients were dichotomized into groups based on preoperative UDS findings. The first group of patients were diagnosed with SUI on UDS and thus underwent RASC with concomitant MUS (RASC + MUS). The second group consisted of patients who were not diagnosed with SUI on UDS, and as such underwent RASC without a concomitant anti-incontinence procedure (RASC-only). All RASC procedures were performed by a single surgeon (HW) with robotic assistance from the da Vinci Si-HD[®] (Intuitive Surgical, Inc., Sunnyvale, CA, USA) at a single tertiary hospital. The type of sling was based on surgeon's and patient's preference after preoperative evaluation and counseling.

Two standard and validated questionnaires, the Urinary Distress Inventory-6 (UDI-6) and Incontinence Impact Questionnaire-7 (IIQ-7),^[17,18] were administered by telephone or mail to all patients who met the inclusion criteria. Questionnaires completed by telephone were administered by an obstetrics and gynecology resident and a urogynecology fellow. The UDI-6 is a 6-item questionnaire that addresses symptoms associated with lower urinary tract dysfunction such as urinary frequency and urgency, SUI, difficulty in urinating, pain, and discomfort due to leakage. The IIQ-7 is a 7-item questionnaire that focuses on QOL relating to UI. The UDI-6 and the IIQ-7 questionnaires were scored as described by the original developer: if more than two items were missing, a total score was not calculated. Higher scores indicate more symptom distress (UDI-6), or greater negative impact on daily life (IIQ-7).

This study added two QOL inquiries in addition to the UDI-6 and the IIQ-7 [\[Table 1\]](#). The first question asked the patient to subjectively rate her postoperative POP symptoms compared to her preoperative symptoms. The second question consisted of two parts that attempted to identify any complications as a result of the surgery, and if applicable, the severity of those complications.

Descriptive statistics (mean \pm standard deviation, median, 25th and 75th percentiles for continuous variables; frequencies and percentages for categorical variables) were calculated for the overall sample of patients ($n = 46$) who completed the questionnaires. Fisher's exact test was used to compare all the categorical variables and the Mann–Whitney test was used to compare all the continuous variables. $P < 0.05$ was considered statistically significant. All analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Sixty-eight patients met the inclusion criteria, 67.6% ($n = 46$) of which completed the follow-up questionnaires and were included in the final analysis. Of the 24 patients who did not complete the follow-up questionnaires, 12 were from the RASC + MUS group and 12 were from the RASC-only group. The median (25th and 75th percentiles) age, BMI, and parity of our patient population are 62.5 (59 and 69), 25.6 (23.7 and 28.0), and 3 (2 and 3), respectively. POP-Q stage was 28.3% ($n = 13$), 45.7% ($n = 21$), and 26.1% ($n = 12$) for stage 2, 3, and 4, respectively. Thirty-five patients (76.1%) had a supracervical hysterectomy at the time of RASC. Thirteen patients (28.3%) had a prior hysterectomy. Thirty patients were diagnosed with SUI on UDS, hence thirty patients were in the RASC + MUS group and 16 were in the RASC group. Preoperative positive cough stress test scores were significantly different between RASC + MUS and RASC-only groups, $P = 0.049$ (12 vs. 2, respectively). There were no significant differences between the above-mentioned groups with regard to the remainder of the demographic parameters, including urethral hypermobility [Table 2]. In the RASC + MUS group, 27 (90%) patients received a transobturator sling and three received a retropubic sling. The average follow-up time was 24 months, with a range of 6–36 months.

A statistically significant difference in UDI-6 scores between the two groups (RASC vs. RASC + MUS) was observed. Median (25th and 75th percentiles) scores for UDI-6 were 22.92 (8.33 and 32.29) for the RASC group and 4.17 (0 and 13.54) for the RASC + MUS group ($P = 0.0017$), respectively. Median scores for IIQ-7 were 0 (0 and 29.73 for the 25th and 75th percentiles, respectively) for the RASC group and 0 (0 and 0, for the 25th and 75th percentiles, respectively) for the RASC + MUS group ($P = 0.1691$) [Table 3]. There were no statistically significant differences between the two groups for the three additional nonvalidated questions in reference to the success of the surgery (question 14) as well as complications from the surgery (question 15), $P < 0.7412$ and $P < 0.2227$, respectively.

The most common complication noted in the final question on the questionnaire was related to pain. Five patients noted intermittent lower abdominal pain, two of whom were in the RASC + MUS group and three were in the RASC-only group. Two patients in the RASC-only group specifically noted incontinence as a complication of surgery, neither of whom were diagnosed with detrusor overactivity on preoperative UDS. A cystotomy occurred in two patients, of note both were in the RASC-only group and both had a prior total vaginal hysterectomy. Three patients noted constipation, two of which were in the RASC + MUS group.

DISCUSSION

Similar studies comparing concomitant treatment of POP and SUI have been performed; however at this time, no such study exists that has investigated RASC with or without MUS. Significant differences were found in the composite UDI-6 scores between the two groups. Although not statistically significant, patients in the RASC-only group had higher IIQ-7 scores, indicating more of a negative impact on QOL. Although the two groups were not exactly equivalent, the findings of this study align with others that advocate for concomitant anti-incontinence procedures at the time of prolapse surgery.[7,9]

Limitations of this study are inherent with all retrospective studies. We were limited by the lack of preoperative UDI-6 and IIQ-7 results with which to compare the postoperative results. However, the greatest limitation of this study is the attempt to compare and draw conclusions from two similar groups with one crucial difference, the diagnosis of SUI. Sling type was determined by the surgeon in conjunction with patients based on their symptoms and concerns regarding possible complications and as such was not consistent throughout the RASC + MUS group. Another limitation is the lack of consistency with respect to the sling type. In addition, there was a relatively small sample size. Sample size was limited due to robotic surgery only becoming available to our department in 2011 and only one surgeon was performing RASC in our division during the study time frame. A single surgeon may be viewed positively or

negatively with respect to our findings. A single surgeon reduces possible confounders, such as variance in proficiency or techniques, and ensures that all surgeries were performed in a similar manner. However, the results of a single surgeon make our data less generalizable.

Placement of MUS at the time of RASC has been reported, with mixed results.[19,20] This is the first study to specifically look at the QOL factors after RASC with or without MUS. The RASC + MUS patients had significantly fewer SUI symptoms as well as significantly improved QOL. This could indicate that the patients in the RASC-only group, who were not diagnosed with SUI on preoperative UDS, may have benefited from a prophylactic MUS. It is interesting to note that patients who were not diagnosed with SUI had similar rates of urethral hypermobility as those who were diagnosed with SUI.

A strength of this study is the long-term follow-up. Despite a 2-year long-term follow-up, it is notable that none of the RASC-only patients returned for further surgical treatment of SUI despite being symptomatic. According to the CARE trial, 6.5% of patients in the abdominal sacrocolpopexy group without concomitant Burch colposuspension pursued surgical treatment for SUI.[3] This difference could be attributed to the route of colpopexy (laparotomy vs. laparoscopic), the type of anti-incontinence procedure (urethropexy vs. MUS), or surgical technique.

We were successful in retrieving a 67.6% response rate for our questionnaire. Although we had fewer responses than desired, this is above the average response rate of 60% for similar surveys published in medical journals.[21] In addition, this study focused on the subjective cure rates as well as on the QOL. In a survey of urogynecology patients, nurses, and medical staff, they ranked subjective cure rates and QOL as most important over several other factors.[22]

Previous studies noted that 6.3 MUS would have to be placed during vaginal prolapse surgery to prevent one patient from returning to the operating room for an anti-incontinence procedure.[7] It has also been shown that universally performing MUS at the time of ASC is more cost-effective than both preoperative UDS to determine whether or not to perform MUS and ASC alone (with the potential for subsequent MUS as needed for occult SUI).[23]

This study contributes to the literature by demonstrating the potential benefit of concomitant MUS at the time of RASC. Based on this study alone, it should not be inferred that all patients undergoing RASC should be recommended a concurrent MUS. Larger prospective trials are warranted. Future studies could randomize sling placement in patients without symptoms or the diagnosis of SUI and determine the improvement of QOL and urinary distress symptoms as well as the rates of adverse events in that population.

CONCLUSION

Surgical treatment strategies should be tailored to each individual. In this study, patients who underwent combined RASC and MUS had significantly fewer urinary symptoms. The results of this study align with the findings of the CARE and the OPUS trials and thus patients should be counseled appropriately about the potential benefits of a concomitant anti-incontinence procedure, regardless of UDS diagnosis, at the time of RASC.

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Conflicts of interest

Dr. Winkler, consultant, Kimberly-Clark, and consultant, Boston Scientific, receives personal fees, however unrelated to this research study.

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Figures and Tables

Table 1

Post-operative quality of life questionnaires

UDI-6

1. Do you experience, and, if so, how much are you bothered by frequent urination?
2. Do you experience, and, if so, how much are you bothered by urine leakage related to the feeling of urgency?
3. Do you experience, and, if so, how much are you bothered by urine leakage related to physical activity, coughing, or sneezing?
4. Do you experience, and, if so, how much are you bothered by small amounts of urine leakage (drops)?
5. Do you experience, and, if so, how much are you bothered by difficulty emptying your bladder?
6. Do you experience, and, if so, how much are you bothered by pain or discomfort in the lower abdominal or genital area?

IIQ-7

7. Has urine leakage affected your ability to do household chores (cooking, cleaning, laundry, etc.)?
 8. Has urine leakage affected your physical recreation such as walking, swimming, or other exercise?
 9. Has urine leakage affected your entertainment activities (movies, concerts, etc.)?
 10. Has urine leakage affected your ability to travel by car or bus more than 30 min from home?
 11. Has urine leakage affected your participation in social activities outside your house?
 12. Has urine leakage affected your emotional health (nervousness, depression, etc.)?
 13. Has urine leakage affected your feeling frustrated?
 14. Rate your symptoms of prolapse/bulge at this time on a scale from 0 to 10 (0: significantly worse than prior to surgery, 5: unchanged from prior to surgery, 10: significantly better than prior to surgery)
 15. Rate your complications as a result of the surgery (0: no complications; 1: minor/inconsequential complications; 2: moderate complications; 3: significant complications)
 16. If you answered 1, 2, or 3 on question 15, note the complications you experienced
-
- For the first 13 questions, please enter the corresponding number in the blank box (0: not at all, 1: slightly, 3: moderately, 4: greatly).
UDI: Urinary Distress Inventory, IIQ: Incontinence Impact Questionnaire

Table 2

Patient demographics

	RASC-only group (n=16)	RASC + MUS group (n=30)	P
Age (mean)	63.5	62.7	0.963
Parity (median)	3	3	0.814
BMI (mean)	25.9	26.1	0.981
POP-Q stage (n)			
Stage 2	4	9	0.244
Stage 3	6	15	
Stage 4	7	5	
Positive preoperative cough stress test (n)	2	12	0.049*
Urethral hypermobility (n)	16	25	1.000
Degree of urethral mobility (mean)	49.0	45.6	0.414
Lowest urethral profile pressure (mean)	76.8	72.3	0.475
Preoperative diagnosis of detrusor overactivity on UDS (n)	1	6	0.222
Concomitant SCH at the time of RASC (n)	13	22	1.000

*Statistically significant. BMI: Body mass index, POP-Q: Pelvic organ prolapse-Quantification, RASC: Robotic-assisted sacrocolpopexy, MUS: Midurethral sling, UDS: Urodynamic testing, SCH: Supracervical hysterectomy

Table 3

Comparison of Urinary Distress Inventory-6 and Incontinence Impact Questionnaire-7 scores

Questionnaire	Treatment group	Median	25 th , 75 th quartiles	P
UDI-6	RASC	22.92	8.33, 32.29	0.0017*
	RASC + MUS	4.17	0, 13.54	
IIQ-7	RASC	0	0, 29.73	0.1691
	RASC + MUS	0	0, 0	

*Statistically significant. UDI: Urinary Distress Inventory, IIQ: Incontinence Impact Questionnaire, RASC: Robotic-assisted sacrocolpopexy, MUS: Midurethral sling

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