Are the Effectiveness of Minimally Invasive Sacrocolpopexy Similar with Abdominal Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse?

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ABSTRACT Objective: The aim of this study was to present the outcomes of open abdominal sacro-colpopexy (ASC) and minimally invasive sacrocolpopexies (MISC). **Material and Methods:** A total of 41 women with a mean age of 59 (34-76) underwent sacrocolpopexy, with 21 ASC and 20 MISCs. Within the MISC group, 17 were laparoscopic (LSC) and 3 were robotic (RSC). The patients were presented with vaginal mass in 40 and bilateral lombar pain in 1. Statistical analyses were done using Mann-Whitney U test and Fisher's exact test with SPSS version 15.0. **Results:** The mean follow-up time was 61.3 (11-90) months. Mean estimated blood loss and length of hospitalization were significantly longer for ASC (p<0.001), whereas the operative time was significantly shorter (p<0.001). Recurrence was seen in 1 patient after MISC and repaired with ASC. Grade 2 prolapsus was seen in 4 at follow-up, however vaginal erosion was not. The success rates were; 90.0% for MISC and 90.4% for ASC. **Conclusion:** MISC led to shorter hospitalization, better hemostasis than ASC. MISC is as effective as ASC for the treatment of vaginal vault prolapse. Further prospective and randomized controlled studies including large series of patients are needed.

Key Words: Pelvic organ prolapse; laparoscopy; robotics

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he surgical repair of apical pelvic organ prolapse (POP) includes vaginal and abdominal approaches. The vaginal approaches are lessmorbid than abdominal approaches. However, abdominal approaches provides lower recurrence rates and less dysparenuia than vaginal approaches. Today, sacrocolpopexy is the gold standard procedure for apical POP repair. The procedure that can be performed by abdominally (ASC), or minimally invasively (MISC), provides excellent anatomical and functional outcomes.

Since vaginal vault prolapses occured more rarely, the number of studies including MISCs are rare.³ Herein we report our experience with abdominal and minimally invasive approaches of the sacrocolpopexy. In addition, we present the demographic, peri- and postoperative outcomes of abdominal and minimally invasive approaches.

MATERIAL AND METHODS

SUBJECTS

A total of 41 consecutive women who were diagnosed with POP and underwent a sacrocolpopexy operation (21 ASC, 20 MISC) were included in

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the study. We retrospectively reviewed the records. Within the MISC group, 17 were laparoscopic (LSC) and 3 were robotic (RSC). The mean age was 59 (34-76). Postoperative follow-up less than 6 months were the exclusion criteria in this study. Patients were divided into two groups according to open or minimally invasive surgeries. The demographic data were similar for both two groups (Table 1).

STUDY DESIGN

One of the women was presented with bilateral hydronephrosis, and the others were presented with vaginal masses. All women had Grade 3 or 4 prolapse according to Baden-Walker system.⁴ All women were evaluated with urodynamic investigation preoperatively. The urodynamic study consisted of uroflowmetry, meausurement of postvoid residual urine (PVR), cystometry and measurement of valsalva leak point pressure (VLPP). Most of the urodynamic investigations in this study were performed according to ICS "Good Urodynamic Practice" guidelines after it was published and the ICS terminology was used for all definitions.^{5,6} International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) was used to assess the continence.7

All patients underwent sacrocolpopexy as previously defined either via abdominal (ASC), laparoscopic (LSC) or robotic assisted laparoscopic (RSC) by experienced surgeons (BC, OD).⁸⁻¹⁰ All patients received intravenous antibiotic at the beginning of the operation. The operations were performed under general anesthesia. We used type 1 polypropylene mesh (monofilament, macrop-

TABLE 1: Preoperative datas.				
	ASC (N:21)	MISC (N:20)	P Value	
Age (year)				
Median+ SD	51.45±2.702	58.4±2.197	0.063	
Previous history of anti-incontinence or prolapse surgery				
No	5 (7.9%)	4 (92.1%)	0.534	
Yes	16 (6.3%)	16 (93.8%)		
Mean prolapse grade (Baden-Walker)	3.5	3.5	0.687	



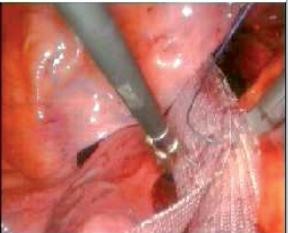


FIGURE 1: Polypropylene mesh was fashioned into a Y configuration (anterior part; between vagina and bladder, posterior part; between vagina and rectum, coupled part; to promontorium).

orous) which is fashioned into a Y configuration (Figure 1). Concomitant transobturator tape surgery was performed in 4 patients and sacrocolpopexy with uterus preservation was performed in 4. Intraoperative complications were grouped according to the Satava classification system (Grade I, incidents without consequences; Grade II, incidents repaired intraoperatively; Grade III, incidents requiring reoperation) and postoperative complications were grouped based on the modified Clavien system.^{11,12}

Success or failure was determined by physical examination. The presence of stage 2 prolapse or more at any anatomic site was considered as fail-

ure. Otherwise, women were classified as objectively cured. Women reporting no prolapsed symptoms and satisfied were classified as subjectively cured.

STATISTICAL ANALYSIS

Statistical analyses were done using Mann-Whitney U test and Fisher's exact test with SPSS version 15.0. A p value <0.05 was considered as statistically significant. The study was approved by Cerrahpasa School of Medicine Ethics Committee on 13.09.2013 (B.30.2.IST.0.30.90.00/32721).

RESULTS

The median follow-up time was 61.3 (11-90) months. The median estimated blood loss was significantly higher for ASC group (159.00±9.838 ml vs 66.50 ± 8.152 ml, p<0.001). The median ASC operative time was significantly shorter than for MISC (151±5.073 minutes vs 239 ± 10.511 minutes, p<0.001).

The median hospitalization time was greater in ASC than MISC group (4.0 ± 0.145 days vs 2.95 ± 0.387), however not statistically significant (p:0.052). The women who underwent concomitant transobturator tape surgery were continent after the procedure (Table 2). The median ICIQ-SF score was decreased from 12.5 to 0.2 after the operation.

TABLE 2: Per- and postoperative outcomes.				
	ASC (N:21)	MISC (N:20)	P Value	
Blood loss (cc)				
Median+ SD	159.00±9.838	66.50±8.152	< 0.001	
Operation time (mir	1)			
Median+ SD	151±5.073	239±10.511	< 0.001	
Concomittant TOT procedure				
No	19 (7.9%)	18 (92.1%)	0.678	
Yes	2 (6.3%)	2 (93.8%)		
Hospitalization time (day)				
Median+ SD	4.0±0.145	2.95±0.387	0.052	
Follow-up time (mo)			
Median+ SD	24.42±4.31	64.78±6.93	< 0.001	
Success (%)	19/21 (90.4%)	18/20 (90.0%)	0.678	
Satisfaction (%)	19/21 (90.4%)	17/20 (85.0%)	0.534	
I				

The median follow-up time was significantly longer for women undergoing MISC (64.78±6.93 months vs 24.42±4.31 months, p<0.001). The patient who had bilateral hydronephrosis due to the prolapse was improved after the operation and didn't have any symptoms. A total of 3 complications (15%) occurred in MISC group and 1 (4.7%) in ASC group. There were no intraoperative complications in both groups according to Satava. As postoperative complications, 3 Grade 2 (1 constipation and 2 de novo urgency) in MISC group, and 1 Grade 2 (de novo urgency) were observed in ASC group and classified according to the modified Clavien classification system.

The women who had de novo urgency were responded antimuscarinic drug treatment. There was not any other complication after the procedures.

The objective cure rates were similar for both ASC and MISC groups (90.4% vs 90.0%, p:0.678). Grade 2 prolapse was seen in 4 patients at followup (2 ASC, 2 MISC), however vaginal erosion was not. The subjective cure rates were also similar for both ASC and MISC groups (90.4% vs 85%, p:0.534).

DISCUSSION

In the present study, we present the outcomes of the minimally invasive approaches; MISC with traditional approach; ASC which needs an incision of laparotomy. The objective cure rates were similar in patients who underwent MISC and ASC for the treatment of POP (90.4% vs 90.0%, p:0.678). The median hospitalization time was greater in ASC than MISC group (4.0±0.145 days vs 2.95±0.387), however not statistically significant (p:0.052). Many authors have performed clinical studies comparing anatomical and subjective outcomes of ASC since Lane reported the sacrocolpopexy; abdominal approach in 1962.10 The transabdominal approach has been compared with transvaginal approaches for the treatment of vaginal vault prolapse in recent studies. 13-15 It appears from these studies that the transabdominal approach may be more effective. The success rates were found to be 80-94% for ASC and 69-80% for the vaginal approach.13-15 In a cochrane review, Maher et al reported clearly that sacral colpopexy has superior outcomes to a variety of vaginal procedures including sacrospinous colpopexy, uterosacral colpopexy and transvaginal mesh.¹⁶ Although the ASC has excellent objective and subjective cure rates in the surgical management of POP, ranged from 78 to 100% it has a longer recovery time. 2,13-15 A minimally invasive approach may overcome this limitation. Eventually, MISC has provided an excellent alternative to open sacrocolpopexy. Existing literature, MISC has less morbidity and faster recovering time when compared with the ASC. 16,17 Notwithstanding, there are few studies comparing advanced laparoscopic and robotic assisted laparoscopic approaches with traditional open sacrocolpopexy approaches. 18,19 The latter, the literature is limited regarding the long term efficiacy of MISC.²⁰ The disadvantages of MISC were longer operation time and learning curve. Nevertheless, the advantages of MISC provide; less postoperative pain, shorter hospital stay, better cosmesis and faster recovering time. Nezhat et al. reported a 100% success rate in 15 patients who underwent LSC for apical vault prolapse with a 3 to 40 months follow-up time.21 Claerhout et al. declared a 98% anatomic cure rate at a mean follow-up of 12.5 months.3 In this study, the outcomes of MISC were as sufficient as ASC (Table 2). The objective cure rates were 90.4% for ASC and 90.0% for MISC (p:0.678). The subjective cure rates were also similar for both ASC and MISC (90.4% vs 85%, p:0.534). The median follow-up time was 61.3 (11-90) months. However, the median follow-up time was significantly longer for women undergoing MISC (64.78±6.93 months vs 24.42±4.31 months, p < 0.001).

Complication and intervention rates after ASC and vaginal approaches has been also evaluated by Diwadker et al. in a systematic review and found to be a higher reoperation and complication rate among women undergoing vaginal approaches.²² In a Cochrane review of surgical operations for POP has been declared that ASC was better than vaginal approaches in terms of lower recurrent vault prolapse and less complication.² However, vaginal pro-

lapse repairs, are often faster and offer patients a shorter recovery time.²³ Minimally invasive approaches aim to bridge this gap and to provide the outcomes of ASC with less morbidity. Pantazis et al. compared open and MISC in the treatment of POP and the cure rates were similar for both groups at one year follow-up.²⁴ However, the mean blood loss was significantly greater in the open arm and the number of hospitalization was less in the MISC group.²⁴ In the present study, the median operative time for ASC was significantly shorter than for MISC (151±5.073 minutes vs 239±10.511 minutes, p<0.001). However, the median estimated blood loss was significantly higher for ASC group (159.00±9.838 mL vs 66.50±8.152 mL, p<0.001). In addition, the median hospitalization time was greater in ASC than MISC group (4.0±0.145 days vs 2.95±0.387), however not statistically significant (p:0.052). In a study similar to our own, Paraiso et al. observed a longer operative time but less blood loss and shorter hospitalization for women undergoing MISC.25

Maher et al. concluded that there was no difference in serious adverse events for ASC and MISC.2 In this study, postoperative constipation was seen in one case for MISC group. Although some studies suggest a high rate of postoperative bowel dysfunction, few data were reported about the effects of sacrocolpopexy on bowel function. In a review, Ganatra et al reported a rate of 9.8% bowel dysfunction in the postoperative periods after LSCs. 17,18,23 However, most of the bowel symptoms resolved within 6 mo. Further studies should investigate the bowel symptoms with preoperative and postoperative assessments in patients who underwent sacrocolpopexy to contribute literature especially for de novo constipation, fecal incontinence, perianal pain, etc.

Although there is no standard definition for prolapse recurrence, a prolapse extending beyond the hymen or the onset of new prolapse symptoms in any patient is regarded as a recurrence.²⁶ Maher et al. concluded a lower rate of recurrent vault prolapse on examination after the sacrocolpopexy operations than vaginal approaches.² Recurrent prolapse reported 0% to 13%.2 Ganatra et al found

the prolapse reoperation rate as 6.2% after LSCs.23 Hsiao et al. found no recurrent apical prolapse in their series of 25 patients whom underwent LSC.¹⁷ However, Antiphon et al found 33% re-operation rate in 104 patients.²⁷ In our study, a patient in MISC, who had prolapse recurrence on early follow-up, was underwent ASC and prolapse reoperation rate was found to be as 0% for ASC and 5% for MISC. Sacrocolpopexy with uterus preservation was performed in 4 patients according to their wishes and these patients were in MISC group. There were no any technical or surgical problems during the procedures.

De novo stress and/or urge urinary incontinence after sacrocolpopexy is a well-known complication for the surgeons.2 In the reviews of Cochrane's database, conflicting data are mentioned about the prophylactic surgery for concurrent incontinence during the repair of apical prolapse.² Urge incontinence after sacrocolpopexy can ocur in up to 33% of patients after ASC.2 However, its etiology is not well understood. In our study, all patients had urodynamic investigations preoperatively. We simultaneously inserted TOT in 4 patients who was found to have urodynamic SUI, preoperatively. None of these patients developed per- or postoperative additional complications. TOT was satisfied in all patients. The mean ICIQ-SF value was declined to 0.2 postoperatively which was 12.5 preoperatively. De novo urgency was seen in 1 of ASC (4.7%) and 2 of MISC (10%) groups on the postoperative period. These women were responsed from antimuscarinic drug treatment. There was not any other urinary symptoms after the procedures.

Mesh erosion is a compliacation after ASC and reported 3-12% of patients. A higher erosion rate is seen in vaginal approaches placed meshes (up to 40%). Ganatra et al reported the erosion rate in LSC as 2.7% with a 24.6 mo follow-up period. Mesh extrusion was not seen in the present study. However, there are several studies showed the complications including mesh extrusions. 16,27

Robotic sacrocolpopexy has been used at some instutions using the da VinciTM system. 18,19 The

operation time and learning curve was higher in LSC than ASC. It is not certain if the advantages of robotic surgery will overcome this problem. However, early experience from the Mayo Clinic with RSC showed excellent outcomes and low complication rates.³⁰ We performed RALSC on 3 women in this limited study. The applications of robotic surgery continue to expand and will be used further in the future.

Although, this study is benefit for the literature of the outcomes of ASC and MISC techniques, our study has several limitations. The data were collected longitudinally and verified retrospectively, which could have introduced error. Another limitation of our study is the lack of validated preand postoperative questionnaire data for symptoms of pelvic floor dysfunction. However we used ICIQ-SF to assess the continence. Hence, the cure rates might have been overestimated since pre- and postoperative prolapse status was not assessed with validated questionnaire in our study. Nevertheless, we used Baden-Walker grading system in this study. Last, we added our 3 robotic cases in LSC group. This might affect the results. However, our results are similar existing literature. Despite these limitations, our results suggest that MISC is as safe and effective treatment as ASC for the management of POP surgery in women. Future studies comparing ASC and MISC should be prospectively designed to overcome existing limitations.

In summary, MISC seems to be as effective as ASC for the treatment of POP surgery in women. Shorter hospital stays, less blood loss are the advantages of MISC. However, longer operation time is the main disadvantage of MISC. Further prospective and randomized controlled studies including large series of patients are needed.

Conflict of Interest

Authors declared no conflict of interest or financial support.

Authorship Contributions

Idea/Concept: Constructing the hypothesis or idea of research and/or article: Sinharib Çitgez, Oktay Demirkesen, Bülent Çetinel; Design: Planning methodology to reach the conclusions: Sinharib Çitgez, Çetin Demirdağ, Bülent Önal; Con-

trol/Supervision: Organizing, supervising the course of progress and taking the responsibility of the research/study: Sinharib Çitgez, Bülent Çetinel; Data Collection and/or Processing: Taking responsibility in patient follow-up, collection of relevant biological materials, data management and reporting, execution of the experiments: Çetin Demirdağ, Fethi Ahmet Türegün, Oktay Demirkesen; Analysis and/or Interpretation: Taking responsibility in logical interpretation and conclusion of the results: Sinharib Çitgez, Fethi Ahmet Türegün, Bülent Önal; Literature Review: Taking responsibility in necessary lit-

erature review for the study: Çetin Demirdağ, Fethi Ahmet Türegün, Bülent Önal; Writing the Article: Taking responsibility in the writing of the whole or important parts of the study: Sinharib Çitgez, Çetin Demirdağ, Bülent Önal; Critical Review: Reviewing the article before submission scientifically besides spelling and grammar: Oktay Demirkesen, Bülent Çetinel; References and Fundings: Providing personnel, environment, financial support tools that are vital for the study: None; Materials: Biological materials, taking responsibility of the referred patients: None.

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