

A prospective randomized study comparing abdominal sacrocolpopexy and vaginal sacrospinous fixation for the management of vault prolapse

Abstract

Introduction: Pelvic organ prolapse is a common health problem, affecting up to 40% of parous women over 50 years old, with significant negative influence on quality of life.¹ Some degree of prolapse is common in most parous women, but treatment is required only for the symptomatic patients.

Purpose of the study: To compare between efficacy and feasibility of ASC and SSF in patient with POP.

Material and methods: This was a randomized prospective comparative study which included post hysterectomy women attending the Department of Obstetrics and Gynecology in Maternity Kuwait Hospital, Kuwait, who were referred with vault prolapse at least stage II between January 2008 and March 2012. The population study consisted of 74 women. Patients were divided into 2 groups. The first group (Group A) unilateral sacrospinous fixation; the second (Group B) underwent abdominal sacrocolpopexy. Data were normally distributed, which enabled the use of an independent samples t-test to assess the postoperative difference between the two groups and a paired Student's t-test to assess the same group before and after the surgery. The level of significance was 0.05.

Results: There was no significant statistical difference among the POP-Q measures between the groups pre-operatively. Sixty-nine women (93.2%) had an optimal anatomical result at first postoperative visit. The three patients with unsatisfied results two in SSF group (4.5%) and one in ASC group (3.33%). Six asymptomatic (stage I prolapse) were diagnosed 12 months after surgery, four patients from SSF group and two from ASC group. None of the six women required additional surgery. There was statistically significant difference between the POP-Q values of Aa, Ab, Pa, Pb,C before and after operation ($P < 0.001$) demonstrating that both techniques were able to improve anatomical parameters. The values of POP-Q, before and after operation ($n=74$) are seen in Table 3.

Conclusion: Sacrocolpopexy and sacrospinous fixation are both effective in the management of vault prolapse with less procedure and recovery time in sacrospinous fixation group making it more friendly. Further studies are indicated for the comparison between both procedures.

Keywords: pelvic organ prolapse, sacrocolpopexy, sacrospinous fixation, gynecologic surgery, POP Q

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Assem AM Elbiaa,¹ Magda Kmeikh,² AE Omu,³ Mohamed M Farghali¹

¹AinShams University, Egypt

²Kuwait University, Kuwait

³Department of Obstetrics and Gynecology, Kuwait University, Kuwait

Correspondence: Assem El-Biaa, Ain Shams University, Khalifa El-Maamon St, Abbasiya Sq., Cairo 11566, Egypt, Tel 0096597337143, Email assemelbiaa@gmail.com

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Abbreviations: SSF, sacrospinous ligament fixation; POP-Q, pelvic organ prolapse quantification

Introduction

Pelvic organ prolapse is a common health problem, affecting up to 40% of parous women over 50 years old, with significant negative influence on quality of life.¹ Some degree of prolapse is common in most parous women, but treatment is required only for the symptomatic patients.²

Surgery for prolapse is one of the most common operations Performed in gynecology. In women, the lifetime risk of needing surgery for prolapse by the age of 80 is around 11%. It is interesting to note that 25% of these operations are performed for recurrent prolapse, suggesting that success rates for initial operations are poor.³ The ideal procedure for vaginal apical support has yet to be determined. The past decade has seen several innovations in the treatment of prolapse due to greater understanding of pelvic anatomy and pathophysiology.²

Abdominal sacral colpopexy is the gold standard abdominal procedure used for apical prolapse. Success rates range from 78% to 100%. This is probably the only procedure in prolapse surgery where there is level I evidence to use synthetic mesh. Major complications from this procedure are rare but serious.⁴

Sacrospinous ligament fixation (SSF) is a vaginal procedure that is well established for POP repair. However, data are limited on the comparative efficacy of abdominal sacrocolpopexy and SSF.⁵

We conducted a randomized, non-inferiority trial to determine whether the efficacy of sacrospinous fixation is similar to abdominal sacrocolpopexy in women with symptomatic vault prolapse (POP-Q) stage 2 or higher.

Materials and methods

This was a randomized prospective comparative study which included post-hysterectomy women attending the Department of Obstetrics and Gynecology in Maternity Kuwait Hospital, Kuwait,

who were referred with vault prolapse at least stage II between January 2008 and March 2012. Subjects were excluded if they had vaginal or pelvic infections, any chronic disabling diseases, above 70 years old. The population study consisted of 74 women. Characteristics of the patients were shown in Table 1. Approval of ethical committee was conducted before collecting any of these data.

Table 1 Characteristics of the patients in 2 surgical groups

	Vaginal SSF	Abdominal SCP
Number of patients	37	37
Age (years)	57.8 (±12.3)	60.1(±10.5)
Parity	4.5(±2.5)	4.3(±2.6)
Body mass index (kg/m2)	29.6(±4.2)	28.2(±5.1)
History of prolapse surgery*	8 (21.62%)	8 (21.62%)
Anterior colporrhaphy	4	3
Anterior and posterior colporrhaphy	4	2
Vaginal Sacrospinous fixation	0	3
Cause of Hysterectomy		
Fibroid uterus	23	15
Adenomyosis	4	3
DUB	2	1
Endometrial carcinoma	2	2
Uterine prolapse at least stage II	9	6
Ovarian Pathology	4	3
Comorbidity**	31(83.7%)	29 (78.4%)
Hypertension	5	8
Diabetes mellitus	15	11
Hypercholesterolaemia	4	6
Hypothyroidism	3	2
Chronic obstructive pulmonary disease	2	1
Cardiovascular accidents	2	1
Prolapse stage pre-operative		
Stage 0	0	0
Stage I	0	0
Stage II	9 (24.3%)	9 (24.3%)
Stage III	13 (35.1%)	9 (24.3%)
Stage IV	15(40.5%)	12 (32.4%)
Performed surgical procedures		
Vaginal hysterectomy	37 (100%)	-
Sacro-colpopexy	-	37 (100%)
Anterior colporrhaphy	34 (83)	10 (27%)
Posterior colporrhaphy	35 (85)	10 (27%)
Colposuspension	-	22 (59.5)
Kelly's suture	25(67.6%)	-

All patients underwent a standardized Urogynecologic interview that included pelvic organ prolapse quantification (POP-Q) by the authors and a classification of the genital prolapse according to the recommendations of the ICS.

Preoperatively, the 2 groups were homogeneous with respect to age, body mass index, stage of apical prolapse. All eligible women who agreed to participate in the study and who provided written informed consent were enrolled (74 patients). The patients were allocated randomly to one of the two surgery groups. The first group (Group A) unilateral sacrospinous fixation; the second (Group B) underwent abdominal. All patients were consented for random selection for surgery.

All SSF were performed unilaterally to the right sacrospinous ligament. The posterior vaginal wall was incised and separated from the rectum and access to sacrospinous ligament was obtained through the pararectal space. The right ischial spine was localised digitally and the ligament was made visible through blunt dissection. One permanent suture (Prolene 1.0, Ethicon, Somerville, NJ, USA) and one delayed absorbable (Vicryl 1.0, Ethicon, Somerville, NJ, USA) were placed through the right sacrospinous ligament at least 2cm from the ischial spine. The sutures were placed through the vaginal apex. Two thirds of the posterior vaginal wall was closed with absorbable sutures (Vicryl 2, Ethicon, Somerville, NJ, USA). The suture was then tied, drawing the apex of the vaginal vault towards the sacrospinous ligament. The rest of posterior vaginal wall incision was then closed.

In abdominal sacrocolpopexy, the abdomen was entered via a transverse incision. The bladder and rectum wall dissected as needed. A transverse incision was made in the peritoneum overlying the vault to expose the pubocervical and rectovaginal fasciae. A longitudinal incision was made over the anterior surface of sacrum one to expose the anterior longitudinal ligament. The posterior wall peritoneum was reflected and bisected, starting from the anterior surface of the sacrum to the transverse incision over the vault, taking care to avoid injury to the presacral vessels, the right common iliac vessels, ureters, and the sigmoid colon. Mersiline tape was attached to the vaginal vault and to the anterior longitudinal ligament overlying the sacrum, without being too tight, to help maintain a horizontal rather than an upright direction of the upper vagina on standing. The bisected posterior peritoneum was sutured with vicryl 2/0.

All surgeries were performed by experienced gynecologists who were familiar with both techniques. The patients were seen 4-6 weeks after surgery, and then at 6, 12 and 24 months. There were no drop-outs in the follow-up. The preoperative assessments and the postoperative follow-ups were conducted by the authors at alternating visits.

All numerical data were expressed as the means±standard deviations. To detect preoperative intergroup differences, we used a Mann-Whitney U test for continuous variables and a chi-square test for categorical variables. Data were normally distributed, which enabled the use of an independent samples t-test to assess the postoperative difference between the two groups and a paired Student's t-test to assess the same group before and after the surgery. The level of significance was 0.05.

Results

Operations were performed under general anesthesia in 12.1 % (9) or epidural anesthesia 87.8 % (65) of cases. The mean operating time was 44±16min for sacrospinous group and 65±18min for abdominal sacrocolpopexy group. The presence of an associated cystocele was

noted in 34 (83%) cases which were corrected by anterior repair, and 35 (85%) cases had rectocele corrected by posterior repair and in VSSF group. While 10 (27%) patients had anterior repair and 10 (27%) had posterior repair in the ASC group. 25 (67.6%) patients of SSF group had Kelly's suture due to stress urinary incontinence and 22 (59.5%) patients had Burchcolpo suspension in ASC group.

In sacrospinous group, the overall perioperative complication rate was 35.1%. Two patients (5.4%) had intraoperative complications One patient had injury to the inferior gluteal vein on passing the suture needle through the sacrospinous ligament. Blood loss was about 200 ml, and bleeding was controlled by compression and vaginal pack was left for 24 hours. Bladder injury occurred in one patient during anterior repair. The injury was noted during surgery and sutured immediately, with simple stitches with foley's catheter left for 7 days postoperative. Early complications occurred in 6 cases (13.6%). Hematoma of the para-rectal fossa occurred in 2 cases. This hematoma resolved spontaneously within a few days without surgical intervention. Acute urinary retention occurred in 2 cases. In one patient retention resolved after 3 days of bladder drainage with a Foley catheter, the other patient was treated medically with alpha-blockers. For this patient, the mean duration of hospitalization was 14 days. Paralyticileus occurred in one woman and resolved on day 5. Gluteal pain or right groin pain occurred in another woman and was treated with non-steroidal anti-inflammatory drugs. Late complications occurred in 5 cases (11.3%), with high vaginal swabs revealing candidiasis, they were successfully treated with antifungals. The mean length of hospital stay was 1±2 days for SSF groups and 2±2 for ASC group.

In ASC group there were 12 complications, 3 patients had bleeding during surgery due to dissection and injury to venous presacralplexus and compression of the plexus was enough in 2 of the patients while 3rd one received blood transfusion. Estimated loss 200ml while in the 3rd one it was 500 ml. four patients had wound infection and received antibiotic according to culture and sensitivity result.

Five patients had paralytic ileus and recovered spontaneously on the 3rd day postoperative (Table 2). In SSF group 34 (83%) patients had an anterior repair and 35(85%) patients had a posterior repair. while in the ASC group 10(27%) patients had an anterior repair and 10 (27%) patients had a posterior repair. In ACC group 22 patients had colposuspension for stress urinary incontinence while in SSF group 25 patients had Kelly's suture.

There was no significant statistical difference among the POP-Q measures between the groups pre-operatively. Sixty-nine women (93.2%) had an optimal anatomical result at first postoperative visit. The three patients with unsatisfied results two in SSF group (4.5%) and one in ASC group (3.33%). Six asymptomatic (stage I prolapse) were diagnosed 12 months after surgery, four patients from SSF group and two from ASC group. None of the six women required additional surgery. There was statistically significant difference between the POP-Q values of Aa, Ab, Pa, Pb,C before and after operation (P<0.001) demonstrating that both techniques were able to improve anatomical parameters. The values of POP-Q, before and after operation (n=74) are seen in Table 3.

Table 2 Shows complications in both groups

	Group ASC		Group SSF		3 month	1 year	2 years
	Range	Mean	Range	Mean			
Age	55-60	53	54-60	52			
BMI	20-24	22	21-24	21			
Parity	P6-11	P7	P5-P9	P6			
Time of procedure		44min±16		65±18min			
Blood transfusion	1		No				
Postoperative recovery	2 days		1 day				
Complications	12 (32.4%)		13 (35.1%)		-VE	-VE	-VE
Bleeding	3		1		-	-	-
Infection	4 wound infections		5 vaginitis		-VE	-VE	-VE
Urine retention			2				
Injury to bladder	NO		1		-	-	-
Injury to rectum	NO		NO		-	-	-
Gluteal pain	NO		1		-VE	-VE	-VE
Hematoma of pararectal fossa	NO		2		-VE	-VE	-VE
Paralytic ileus	5		1		-VE	-VE	-VE

Table 3 POP-Q in sacrospinous (Group A) and abdominal sacro-colpopexy (Group B) groups' pre-operative and 4 weeks' post-operative

	Group SSF	Group ASC	pa
Aa			
Pre-operative	1.23 (1.52)	1.97 (1.18)	0.679
Post-operative	-0.95 (0.61)	-0.87 (0.41)	0.974
pb	<0.01	<0.01	
Ba			
Pre-operative	3.24 (1.67)	2.93 (1.81)	0.901
Post-operative	-0.56 (0.31)	-0.88 (0.79)	0.891
pb	<0.01	<0.01	
C			
Pre-operative	-0.07 (4.22)	-0.96 (4.10)	0.938
Post-operative	-0.41 (2.50)	-0.16 (2.67)	0.954
pb	<0.01	<0.01	
Bp			
Pre-operative	0.64 (2.96)	0.51 (3.17)	0.904
Post-operative	-0.27 (1.15)	-0.88 (1.58)	0.84
pb	<0.01	<0.01	
Ap			
Pre-operative	+2.3(1.35)	+2.1 (1.61)	0.982
Post-operative	-2.1(2.25)	-2.4(1.99)	0.985
pb	<0.01	<0.01	
GH			
Pre-operative	4.79 (0.67)	4.81 (0.92)	0.995
Post-operative	2.76 (0.55)	2.46 (0.48)	0.896
pb	0.46	0.383	
PB			
Pre-operative	2.39 (0.83)	2.81 (0.67)	0.854
Post-operative	-2.5 (0.82)	-2.6 (1.13)	0.972
pb	0.472	0.614	
TVL			
Pre-operative	7.45 (0.99)	7.17 (1.32)	0.942
Post-operative	9.89 (0.75)	10.17 (0.47)	0.947
pb	0.722	0.621	

Discussion

Genital prolapse is a common condition whose incidence is increasing representing a major public health issue. Hysterectomy for pelvic organ prolapse appears to be a particular risk factor. The risk of prolapse repair after hysterectomy was 4.7 times higher in women whose initial hysterectomy was indicated for pelvic organ prolapse and 8 times higher if preoperative prolapse grade 2 or more was present.⁶

The lack of standardized definitions for surgical success following pelvic organ prolapse (POP) surgery has resulted in highly variable estimates of success. Studies with the lowest success rates defined success using more stringent anatomic support while those with the highest success rates generally used subjective outcomes such as satisfaction and resolution of POP symptoms. Barber et al.⁷ stated that More than a hundred surgical techniques have been proposed, but the choice is not unique because no therapeutic has demonstrated its superiority.

In Barber et al.⁷ study, success after POP surgery included subjective criteria as the absence of bulge symptoms in addition to anatomic criteria (using the hymen as a threshold for anatomic success) and no need for re-surgery.

In several retrospective and prospective studies it has been shown that sacrospinous fixation in case of uterine or vaginal vault prolapse is a safe and effective treatment.^{8,9} In our study, Seventy-one women (95.94%) had an optimal anatomical result at first postoperative visit. The success rate of SSF group and ASC group are (95.5%) and (96.66%) respectively. Six asymptomatic (stage I prolapse) were diagnosed 12 months after surgery, none of the six women required additional surgery. There was a significant statistical difference between the POP-Q of Aa, Ba, Ap, Bp, and D before and after the operation (P<0.001).

In published literature reviews, the average mean follow-up after SSLP is 13.8 months to 4.8 years. Benson et al.¹⁰ and Maher¹¹ followed up cases for 1 year unlike our study where follow up was 24 months. The success rate of SSLF was 84.7%-97%. Recurrences usually happened within six months post operation.^{12,13}

Sacrocolpopexy is an effective option for the correction of advanced POP. The major advantages of sacrocolpopexy are excellent ten-year success rates, and for the sexually active patient provide the longest possible vaginal length. In our study total vaginal length postoperative in ASC 10.17 compared to in 9.89 in SSF group however this not statically significant (p 0.947).

Many studies have shown that sacrospinous fixation is effective for vaginal vault repair.¹⁴ The advantages of the vaginal were supported by Maher et al.¹⁰ in a meta-analysis: the shorter operative time, less complications, faster recovery and costless.

In the study of Abeera Choudhry et al.¹⁵ they conclude that SSF is a patient friendly operation (shorter procedure and quicker recovery) with little short-term morbidity and excellent functional results, which are equivalent to sacrocolpopexy. To settle the war between abdominal VS vaginal route we need to design bigger and longer-term high quality clinical trials.

In the study of Aigmueller et al.¹⁶ 99 women (mean 66 years) underwent vaginal SSF for vault prolapse. He contacted all patients 2-15 years after surgery for examination (POP-Q, survey). Sixteen out of 55 (29%) patients, who completed follow-up, presented with cystocele, three patients with rectocele, and four patients had a recurrent vault prolapse. As for quality of life, 42/55 (76%) patients reported lower urinary tract symptoms, but only 9/55 (16%) felt a sensation of prolapse. Ten out of 24 patients, who were still sexually active, reported symptoms of sexual dysfunction. There was no correlation between lengths of follow-up and anatomical or functional results. Vaginal sacrospinous fixation resulted in excellent vault suspension but 29% of the patients developed cystocele formation. Only 16% of patients reported symptoms of descent.

There are only two randomized controlled trials that compare the vaginal and abdominal routes for vault prolapse surgery. Surprisingly these trials report on only 175 cases. One trial was done in by Benson et al and the other in by Maher et al.¹⁵

Conclusion

Sacrocolpopexy and sacrospinous fixation are both effective in the management of vault prolapse with less procedure and recovery time in sacrospinous fixation group making it more friendly. Further studies are indicated for the comparison between both procedures.

Authors contributions

Assem AM Elbiaa: did the procedure, collected and analyzed the data and wrote the manuscript

MAI-Azemi: did the procedure, collected data and critically reviewed the manuscript.

Mohamed M Farhali: did the procedure, critically reviewed the manuscript.

AE Omu: did the procedure collected data and critically reviewed the manuscript.

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None.

Conflict of interest

The authors declare that there is no conflict of interest.

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