DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20221937

#### **Original Research Article**

### Selective allocation of patients with vaginal apical prolapse to either mesh augmented open abdominal repair or vaginal sacrospinous colpopexy improve functional and anatomical outcomes

#### Mahmoud F. Hassan<sup>1\*</sup>, Osama El-Tohamy<sup>1</sup>, Amr Helmy Yehia<sup>1</sup>, Salha A. Alghanimi<sup>2</sup>, Hessa Al-Enezi<sup>2</sup>, Mahmoud Moussa<sup>1,3</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University, Cairo, Egypt

<sup>2</sup>Department of Obstetrics and Gynecology, Air Base Hospital, Dhahran, Saudi Arabia <sup>3</sup>Department of Obstetrics and Gynecology, Great Western Hospital, Swindon, UK

Received: 11 June 2022 Accepted: 02 July 2022

#### \*Correspondence:

Dr. Mahmoud F. Hassan, E-mail: mahmoudfathy74 @yahoo.com

**Copyright:** <sup>©</sup> the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

#### ABSTRACT

**Background:** To evaluate the functional and anatomical outcomes after allocation of patients with apical vaginal prolapse to either mesh augmented abdominal repair or vaginal sacrospinous-colpopexy based on proposed selection criteria.

**Methods:** A non-randomized trial was conducted at Ain-Shams university maternity hospital on patients with apical vaginal prolapse stage  $\geq 2$  based on pelvic organ prolapse quantification system. Certain criteria were proposed for patient selection to either mesh augmented abdominal repair or vaginal sacrospinous-colpopexy. Seventy-eight patients were assigned for sacrospinous-colpopexy and 47-patients for abdominal repair. Primary outcomes were the functional outcome using urogenital distress inventory questionnaire and patient global impression of improvement (PGI-I). Both were measured at 1-year's follow-up. Secondary outcomes involved the anatomical success (defined as no apical prolapse  $\geq$ POP-Q stage 2), perioperative data and long-term complications.

**Results:** There was improvement in all UDI domains for sacrospinous-colpopexy and abdominal repair groups with genital prolapse domain of median (interquartile range) 0 (0-10), 0 (0-0) respectively. Eighty-nine percent of abdominal repair group and 85% of sacrospinous-colpopexy group reported scale of 1 or 2 on PGI-I scale at 1-year follow-up. PGI-I score and improvements in UDI domains were maintained till 5-year follow-up. The anatomic success rate at 1-year follow-up was 97.9% in abdominal repair group and 78.2% in the sacrospinous-colpopexy group. No long-term mesh complications were detected in mesh augmented abdominal repair over the whole follow-up periods.

**Conclusion:** The resulting meritorious functional and anatomical outcomes favor adoption of our proposed selection criteria in the initiation of guidelines and recommendations for managing vaginal apical prolapse.

Keywords: Abdominal sacrocolpopexy, Apical prolapse, Sacrospinous colpopexy, Vaginal vault prolapse

#### **INTRODUCTION**

It was estimated that pelvic organ prolapse affects about 40% of women aged 40 and older.<sup>1</sup> Apical prolapse is prolapse of vaginal apical structures (uterine or vaginal cuff after hysterectomy).<sup>2,3</sup> Conservative management of

apical prolapse includes pelvic muscle exercise or pessary, while surgical management includes transabdominal or transvaginal route using many procedures for each route.<sup>4,7</sup> As there are no clear guidelines to direct the surgeon to determine which approach to use, the decision is usually quite challenging.<sup>8</sup> Baseline factors that influenced the selection of different apical prolapse repair procedures for different patients were studied retrospectively.<sup>9</sup> Nevertheless, there are no prospective reports evaluating the effect of finite patients' selection criteria on different outcome measures. The present study aimed to prospectively evaluate and compare the functional and anatomical success when patients with apical prolapse were selectively allocated to either mesh augmented abdominal repair (sacrocolpopexy or sacrocervicopexy) (ASC) or vaginal sacrospinouscolpopexy (SSC) based on predetermined patients' selection criteria.

#### **METHODS**

This non-randomized prospective trial was performed at Ain-Shams university maternity hospital in Egypt from 2009 till 2014. All participants granted an informed written consent before involvement in the study. All procedures performed were in accordance with the Helsinki declaration. Initial assessment included history taking, clinical examination and staging of the prolapse according to pelvic organ prolapsed quantification System (POP-Q).<sup>10</sup> We selectively allocated symptomatic patients with an apical prolapse of at least stage two to either ASC or vaginal SSC. Treating surgeons properly counselled eligible patients regarding merits and demerits of both procedures. We aimed in the proposed selection criteria for improvement of the success rate in accordance with patients' needs, activity and sexual life.

#### Criteria for selection

SSC group: essential criteria: older age (usually above 55 years), not liable to high impact activity, sexually inactive or seldom activity. Additional criterion: patients with increased surgical risks of laparotomy (previously known or expected to have dense abdominal adhesions). ASC group: essential criteria: younger age (usually below 50 years), liable for high impact activity, sexually active and would like pertain sexuality. Additional criteria: one or more of the following: short vaginal length (expected considerable tension upon approximation of the vaginal apex to the sacrospinous ligament), patients with multiply vaginal operations. Exclusion criteria encompassed old frail patients with elevated anesthetic risk, patients with cognitive dysfunction, massive ascites, prior failed apical repair, short vaginal length in conjunction with high surgical risk (iliococcygeal colpopexy was done) or patients who refused the allocated approach based on our selective criteria. Based on the above-mentioned criteria, we allocated most of patients to either procedure. However, we had two young sexually active patients with highly suspicious dense abdominal adhesions. Therefore, both patients were allocated to SSC after proper counselling. Assessment of participating patients incorporated an evaluation of urinary voiding disorder, stress urinary incontinence (SUI) and defecatory dysfunction. Burch colposuspension or trans-obturator tape (TOT) was used for treating SUI in ASC group and TOT was used in SSC group. Vaginal atrophy and trophic ulcers were managed by local conjugated estrogen cream for 2-weeks preoperatively.

#### Surgical intervention

As much as possible the two procedures were standardized, and all surgeons participated in the study were having salutary surgical experiences in both procedures. Prophylactic antibiotics and fractionated heparin were given according to the institutional protocols.

#### Vaginal sacrospinouscolpopexy (SSC)

A vaginal hysterectomy was done if the uterus was present followed by McCall culdoplasty for enterocele. Anterior segment prolapse was managed by anterior repair for midline defects and paravaginal repair for lateral defects. Sacrospinouscolpopexy (SSC) was done through a longitudinal incision in the posterior vaginal wall 2-cm below the level of the vaginal vault till the introitus. Surgeons dissected the vagina from the rectum and penetrated the pararectal fascia to expose the sacrospinous ligament. Two stitches passed through the ligament using Masson Luethy needle holder, the first was polyglactin suture 2-3 cm medial to the ischial spine and a second polypropylene suture passed medial to the first one.<sup>11</sup> The surgeons passed both sutures through the full thickness of the under surface (avoiding the vaginal epithelium) of the vaginal vault and held them by hemostats. Then, the posterior colpoperineorrhaphy was then started for posterior segment defect. The vaginal mucosa was closed till 3- cm above the hymen plane. Subsequently, surgeons tied the colpopexy sutures and completed the closure of vaginal mucosa.

#### Abdominal sacrocolpopexy/sacrocervicopexy (ASC)

Laparotomy through Pfannenstiel incision was performed under general anesthesia. Two pieces of polypropylene mesh (3-cm width, 15-cm length) were attached to anterior and posterior vaginal or cervical walls by 3-4 polypropylene stitches. Both pieces were attached together then the posterior one was sutured to the anterior longitudinal sacral ligament just below the promontory by 2-3 polypropylene stitches. Excess mesh was trimmed followed by closure of the peritoneum. Moschcowitz culdoplasty to treat enterocele was done. Afterwards, repair of SUI and associated vaginal prolapse were accomplished after evaluation of the effect of sacrocolpopexy. Patients in both groups were followed up post-operatively at 1-month and yearly till 5 years. The primary outcome measures were the patients global impression of improvement (PGI-I) (scale 1 to 7, 1 is very much better, 2 is much better and 7 very much worse) and the functional outcome using the validated urogenital distress inventory (UDI) questionnaire.12,13 Secondary outcomes included defecatory distress inventory (DDI) Questionnaire, enquiries regarding

sexual function, the anatomic success rate (defined as no apical prolapse  $\geq$ POP-Q stage 2), concomitant procedures, operative time, estimated blood loss, hospital stay, perioperative complications, long term mesh complications, and surgical re-interventions.<sup>14</sup>

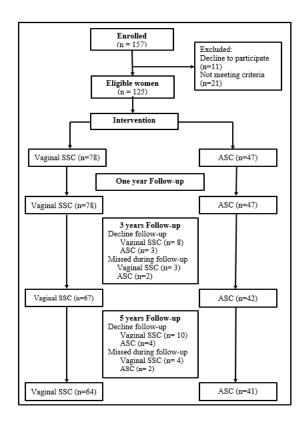
#### Statistical analysis

The required sample size was estimated by a priori emploving the powerandsamplesize.com analysis calculators (HyLown Consulting LLC, Atlanta, GA). We contemplated the score of the UDI genital prolapse domain as primary endpoint. As we had different selection criteria for each study group, the study was nonrandomized. We calculated the required sample size for each group in comparison to a gold standard reference value.<sup>15</sup> A mean difference of 10 points on the genital prolapse domain of the UDI 1-year after surgery was considered clinically relevant difference in relation to the standard reference. Assuming a standard deviation of the score on this domain of 20 points, we required 42 participants to show a statistically significant difference in the primary outcome (power of 90%,  $\alpha$  error 0.05). Considering 10% attrition, we included at least 47participants in each study arm. Statistical tests were made on The statistical package for social sciences, version-14.0 (SPSS Inc., Chicago, IL, USA), and GraphPad Prism, version-6 (GraphPad Software Inc., La Jolla, CA, USA). The normality of distribution of numerical data was tested using Shapiro Wilk test. Two tailed p<0.05 was considered statistically significant.

#### RESULTS

Between 2009 and 2014, we allocated 78-patients to SSC and 47-patients to ASC. Participants had a yearly followup till five years. Participants were contacted to ensure follow-up. However, many ladies declined follow up if they were improved (Figure 1). The baseline characteristics of the study population is depicted in (Table 1). In accordance with the predetermined selection criteria, the mean age of SSC group was statistically higher than ASC group; 62.56 (±5.25), 47.64 (±6.8); respectively, p=0.029; and, the premenopausal status was significantly higher at the ASC group (p=0.0001). Other baseline characteristics displayed no relevant differences between both groups. The clinical outcomes and complications after each procedure is depicted in (Table 2). No serious complications were noted in both procedures. We reported three cases in the SSC group who required retreatment for apical prolapse (one case with POP-Q stage 2 and 2-cases with stage 3). One patient treated with vaginal pessary. Second patient was treated with left SSC. Third patient refused any further management. On the other hand, two cases needing retreatment were recounted in the ASC group (one case with stage 2 and one case was reported at 3-year followup with stage 3). First case declined any further treatment, while the second one was treated with iliococcygeal colpopexy. Surgically treated patients in

both groups became POP-Q stage 1 during later follow-up.



#### Figure 1: Patients flow chart.

#### **Table 1: Baseline characteristics**

Parameters	Vaginal SSC (N=78)	ASC (N=47)	P value
Age	62.56 (±5.25)	47.64 (±6.8)	0.029*
BMI (kg/m <sup>2</sup> )	31.64 (±2.87)	31.19 (±2.64)	0.198*
Smokers	2 (2.6)	1 (2.1)	$1.0^{+}$
Parity	4 (3-5)	3 (3-4)	0.157‡
Previous hysterectomy	20 (25.6)	8 (17)	$0.376^{\dagger}$
Menopause status			
Premenopausal	4 (5.1)	29 (61.7)	$0.0001^{\dagger}$
Postmenopausal	74 (94.9)	18 (38.3)	-
Associated SUI	28 (35.9)	16 (34)	$0.85^{\dagger}$
Comorbidity			
Hypertension	15 (19.2)	6 (12.8)	0.461 <sup>†</sup>
<b>Diabetes mellitus</b>	11 (14.1)	4 (8.5)	$0.409^{\dagger}$
Hyperlipidemia	12 (15.4)	3 (6.4)	0.164†
Hypothyroidism	3 (3.8)	4 (8.5)	0.424†
Chronic obstructive pulmonary disease	1 (1.3)	0	1†

Data are presented as mean $\pm$ standard deviation, median (interquartile range), or number (%). \*Student t test was used; †Fisher exact test was used; ‡ Mann-Whitney U test was used; p<0.05 is significant. UDI and DDI scores and POP-Q staging before surgery and one, three and five years following surgery for the SSC group is depicted in (Table 3). All evaluated parameters were markedly improved after SSC (p<000.1).

# Table 2: Associated surgical procedures, clinicaloutcomes, complications and retreatment for apicalprolapse.

Parameters	Vaginal SSC (N=78)	ASC (N=47)					
Associated surgical procedures							
Vaginal hysterectomy	68 (87.1)	-					
Abdominal hysterectomy							
Total	-	13 (27.6)					
Subtotal	-	27 (57.4)					
Burch colposuspension	-	13 (27.7)					
TOT	15 (19.2)	3 (6.4)					
Anterior colporraphy	69 (88.5)	11 (23.4)					
Posterior colporraphy	45 (57.8)	9 (19.1)					
Vaginal McCall culdoplasty	13 (16.7)						
Moskcowitz culdoplasy	-	14 (29.8)					
Clinical outcomes							
Operative time (minutes)	119.1±17.96	117.23±13.63					
Estimated blood loss (ml)	274.36±84.0 3	323.4±77.21					
Hospital stay	2.13±0.34	2.98±0.61					
Complications	1 (1.3)	3 (6.3)					
Bladder injury	0	0					
Bowel injury	0	0					
Bleeding needing transfusion	1 (1.3)	1 (2.1)					
Ileus	0	1 (2.1)					
Wound complication	0	1 (2.1)					
Retreatment for apical prolapse	3	1					
Re-operation for apical prolapse	1	1					

Data are presented as mean±standard deviation, or number (%).

Besides, we reported a UDI score of 0.0 (IQR:0-10) for the domain "genital prolapse" at one, three and five years postoperatively, which was the primary outcome of the study. As well, (Table 3) discloses no significant changes in the UDI and DDI scores and POP-Q staging during the one year and five years follow-up. De novo incontinence developed in 16-participants in the SSC group (7-cases urge incontinence, 9-cases stress incontinence). All cases received conservative management, and none required further surgical intervention. Furthermore, the PGI-I score of "very much better" AND "much better" were 84.6% (66 out of 78), 84.4% (55 out of 67), and 82.6% (52 out of 64) for the SSC group at one, three and five years respectively with no significant difference. UDI and DDI scores, sexuality and POP-Q staging before surgery and one, three- and five-years following surgery for the ASC group (Table 4). All evaluated parameters were markedly improved after ASC (p<000.1). Furthermore, we reported a UDI score of 0.0 (IQR:0-0) for the domain "genital prolapse" at one, three and five years postoperatively. Moreover, table 4 discloses no significant changes in the UDI and DDI scores, sexuality and POP-Q staging during the one year and 5 years follow-up. De novo incontinence developed in 6participants in the ASC group (3-cases urge incontinence, 3-cases stress incontinence). Regarding sexuality, we didn't recount any case with de novo dyspareunia after ASC procedure. Additionally, the PGI-I score of "very much better" AND "much better" were 89.4% (42 out of 47), 90.2% (38 out of 42), and 87.8% (36 out of 41) for the ASC group at one, three and five years respectively with no significant difference.

#### DISCUSSION

Abdominal sacrocolpopexy/sacrocervicopexy (ASC) and vaginal sacrospinouscolpopexy (SSC) are the most performed procedures for treatment of apical prolapse in many medical institutes worldwide.9 We believe that both are not an alternative procedure to each other in many practical situations. Weighing benefits against risks is crucial during selection for either surgical procedure. Therefore, exposing an elderly sexually inactive woman to the risk of laparotomy and the potential complications of synthetic mesh is inappropriate. Conversely, performing a non-anatomical asymmetrical repair in a younger sexually active woman with high average remaining live expectancy is incongruous. Recently, a systematic review comparing mesh sacrocolpopexy with native tissue vaginal repair demonstrated only five randomized controlled trials. Last trial was published in 2004.8 This is consistent with our belief that randomization will allocate some women to a nonsuitable and less effective procedure with lower functional and anatomical success. There are no reported guidelines or recommendations for management of apical prolapse for patients with different baseline characteristics. Only few retrospective reports had evaluated factors influencing the selection of distinctive approaches.<sup>9</sup> This study was premeditated to evaluate the functional and anatomic success of both procedures over a relative long follow-up period. Patients were selectively allocated to either ASC or SSC procedures. In the selection criteria we tried to include most of the baseline factors that may alter the outcomes of surgical management for apical prolapse. The most vital factors in selection were women age, sexual activity and physical activity. As pelvic organ prolapse (POP) in women is related to ageing process and menopausal change in the collagen type, more patients were allocated to SSC than for ASC as expected.<sup>16,17</sup> Our study established marked improvement in all domains of the UDI and DDI Questionnaires in both procedures. Functional outcomes were comparable to or even higher than, those reported recently in ASC and in SCC without significant changes over the follow-up period which was extended up to 5-

years in many patients.18-24

## Table 3: Preoperative and postoperative Domain scores for disease-specific quality of life, POP-Q Stage and patient global impression of improvement for the sacrospinous colpopexy

Parameters	Before surgery (N=78)	1- year after surgery (N=78)	3-year after surgery (N=67)	5-year after surgery (N=64)	P value⁺*	P value <sup>‡*</sup>
UDI						
Overactive bladder	52 (37-62)	10 (10-20)	10 (10-22)	10 (0-24)	< 0.0001	0.261
Incontinence	13 (2-62)	0 (0-10)	10 (0-13)	10 (0-15)	< 0.0001	0.152
Obstructive micturition	10 (0-64)	10 (0-10)	10 (0-23)	10 (0-24)	< 0.0001	0.166
Pain/discomfort	50 (35-60)	5 (0-20)	10 (0-24)	10 (0-24)	< 0.0001	0.374
Genital prolapse	80 (65-90)	0 (0-10)	0 (0-10)	0 (0-10)	< 0.0001	0,509
Recurrent bladder i	infections (times	s/month)				
Never	0	52 (66.7)	43 (64.2)	41 (64)		
Once	41 (52.6)	26 (33.3)	23 (34.3)	22 (34.4)	< 0.0001	0.317
2-4	37 (47.4)	0	1 (1.5)	1 (1.6)		
>4	0	0	0	0	_	
Incontinence de nov	70					
Urge incontinence	-	7 (9)	-	-	-	-
Stress incontinence	-	9 (11.5)	-	-	-	-
DDI						
Constipation	50 (40-62.5)	10 (0-20)	10 (0-11)	10 (0-20)	< 0.0001	0.157
Obstructive defecation	40 (8-53)	10 (0-20)	0 (0-24)	0 (0-25)	< 0.0001	0.655
Pain/discomfort	40 (33-50)	10 (0-20)	10 (0-10)	10 (0-18)	< 0.0001	0.152
Incontinence	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-2.5)	< 0.0001	0.414
Incontinence flatus	30 (22-41)	0 (0-10)	10 (0-19)	10 (0-20)	< 0.0001	0.309
POP-Q stage	, , ,		, , ,	, , ,		
Anterior compartm	ent					
0	0	4 (5.1)	4 (6)	4 (6.3)		0.153
Ι	0	54 (69.2)	45 (67.2)	43 (67.2)		
II	35 (44.9)	20 (25.7)	17 (25.3)	16 (25)	< 0.0001	
III	37 (47.4)	0	1 (1.4)	1 (1.5)	_	
IV	6 (7.7)	0	0	0		
Apical compartmen	. ,					
0	0	16 (20.5)	13 (19.4)	12 (18.8)		
I	0	45 (57.7)	38 (56.7)	37 (57.8)	_	0.157
I	11 (14.1)	15 (19.2)	15 (22.4)	14 (21.9)	< 0.0001	
III	43 (55.1)	2 (2.6)	1 (1.5)	1 (1.5)	_	
IV	24 (30.8)	0	0	0		
Posterior compartm	. ,	~	<b>v</b>	~		
0	0	11 (14.1)	10 (14.9)	9 (14.1)		
I	5 (6.4)	54 (69.2)	45 (67.2)	43 (67.2)		0.316
I	24 (30.8)	13 (16.7)	11 (16.5)	11 (17.2)	< 0.0001	
III	44 (56.4)	0	1 (1.4)	1 (1.5)	-	
IV	5 (6.4)	0	0	0		
PGI-I	- ()					
Very much better		13 (16.7)	10 (15.2)	9 (14.3)	-	0.317
Much better		53 (67.9)	45 (68.2)	43 (68.3)	-	
			13 (00.2)	.5 (00.5)		

Data are presented as median (interquartile range), or number (%). <sup>†</sup>Significance of the difference between before surgery and 1-year, 3-year and 5-year after surgery. <sup>‡</sup>Significance of the difference between 1-year after surgery and 5-year after surgery. \* Wilcoxon Signed Ranks test was used, p<0.05 is significant.

## Table 4: Preoperative and postoperative domain scores for disease-specific quality of life, sexuality, POP-Q stage and patient global impression of improvement for the abdominal sacrocolpopexy/sacrocervicopexy.

	Before	1 after surgery	3-year after	5-year after	Р	
Parameters	surgery (N=47)	(N=47)	surgery (N=42)	surgery (N=41)	value <sup>†*</sup>	P value <sup>‡*</sup>
UDI						
Overactive bladder	42 (18-53)	10 (0-10)	10 (0-10)	10 (0-10)	< 0.0001	0.434
Incontinence	0 (0-60)	0 (0-10)	5 (0-10)	5 (0-10)	< 0.0001	0.234
Obstructive micturition	20 (0-20)	5 (0-10)	10 (0-10)	5 (0-10)	< 0.0001	0.122
Pain/discomfort	40 (30-60)	10 (0-10)	10 (0-20)	10 (0-20)	< 0.0001	0.547
Genital prolapse	80 (70-90)	0 (0-0)	0 (0-0)	0 (0-0)	< 0.0001	0.083
Recurrent bladder	infections (time	es/month)				
Never	3 (6.4)	30 (63.8)	29 (69)	26 (63.4)		0.739
Once	21 (44.7)	15 (31.9)	12 (28.6)	14 (34.2)	< 0.0001	
2-4	22 (46.8)	2 (4.3)	1 (2.4)	1 (2.4)		
>4	1 (2.1)	0	0	-		
Incontinence de nov	VO					
Urge incontinence	-	3 (6.4)	-	-	-	-
Stress incontinence	-	3 (6.4)	-	-	-	-
DDI						
Constipation	44 (32-50)	10 (0-10)	10 (0-10)	10 (0-10)	< 0.0001	0.459
Obstructive defecation	30 (23-44)	0 (0-0)	0 (0-20)	0 (0-20)	< 0.0001	0.815
Pain/discomfort	30 (20-30)	0 (0-10)	10 (0-10)	10 (0-12.5)	< 0.0001	0.066
Incontinence	0 (0-0)	0 (0-0)	0 (0-10)	0 (0-2.5)	< 0.0001	0.391
Incontinence flatus	30 (13-40)	10 (10-10)	10 (0-15)	10 (0-10)	< 0.0001	0.433
Sexuality						
Sexually active	47 (100)	47 (100)	42 (100)	41 (100)	-	-
Dyspareunia						
Not at all	2 (4.3)	37 (78.7)	34 (81)	33 (80.5)		
Moderate	33 (70.2)	2 (4.3)	2 (4.8)	1 (2.4)		
Somewhat	12 (25.5)	8 (17)	6 (14.2)	7 (17.1)	< 0.0001	0.317
Quite a bit	0	0	0	0		
Not applicable	0	0	0	0		
Frequency coitus						
Never	-	0	0	0	_	
<once month<="" td=""><td>30 (63.8)</td><td>3 (6.4)</td><td>2 (4.8)</td><td>1 (2.4)</td><td></td><td rowspan="2">0.564</td></once>	30 (63.8)	3 (6.4)	2 (4.8)	1 (2.4)		0.564
1-2 times/month	17 (36.2)	29 (61.7)	26 (61.8)	25 (61)	< 0.0001	
Once/week	-	15 (31.9)	13 (31)	14 (34.2)		
>Once/week	-	0	1 (2.4)	1 (2.4)		
POP-Q stage						
Anterior compartm	ent					
0	0	8 (17)	12 (28.5)	14 (34.2)		0.317
Ι	1 (2.1)	39 (83)	29 (69.1)	26 (63.4)	0.0001	
II	16 (34.1)	0	1 (2.4)	1 (2.4)	<0.0001	
III	19 (40.4)	0		0		
IV	11 (23.4)	0	0	0		
Apical compartmen	× /					
0	0	16 (20.5)	13 (19.4)	12 (18.8)		0.157
I	0	45 (57.7)	38 (56.7)	37 (57.8)	<0.0001	
I	11 (14.1)	15 (19.2)	15 (22.4)	14 (21.9)		
III	43 (55.1)	2 (2.6)	1 (1.5)	1 (1.5)		
IV	24 (30.8)	0	0	0		
	()					

Continued.

Parameters	Before surgery (N=47)	1 after surgery (N=47)	3-year after surgery (N=42)	5-year after surgery (N=41)	P value <sup>†*</sup>	P value <sup>‡*</sup>	
Posterior comparts	Posterior compartment						
0	0	12 (25.5)	12 (28.6)	11 (26.8)	< 0.0001		
Ι	6 (12.8)	28 (59.6)	25 (59.5)	25 (61)			
II	22 (46.8)	7 (14.9)	5 (11.9)	5 (12.2)		0.66	
III	9 (19.1)	0	0	0			
IV	10 (21.3)	0	0	0			
PGI-I							
Very much better	-	14 (29.8)	13 (30.7)	12 (29.3)	-	0.564	
Much better	-	28 (59.6)	25 (59.5)	24 (58.5)		0.564	

Data presented as median (interquartile range), or N (%). † Significance of difference between before surgery and 1, 3, 5 years after surgery. ‡ Significance of difference between 1 and 5 year after surgery. \* Wilcoxon Signed Ranks p<0.05 is significant.

In contrast to our data, the extended CARE trial displayed that the anatomic and functional outcomes and the durability of ASC were decreased significantly by time. It might be due to non-standardization of the surgical technique in that multicenter study. Besides, missing of a considerable number of patients during the follow-up might have a noteworthy role.<sup>25</sup>

Additionally, we conveyed anatomic success rate (no apical prolapse  $\geq$ POP-Q stage two) at 1-year follow-up of (78.2 %) in the SSC group and (97.9%) in the ASC group. Those data were comparable to the highest reported success rates in literatures.<sup>22,26</sup> As well, we demonstrated an admirable scale in the patient global impression of improvement (PGI-I) which was comparable in the two study groups (p=0.096). That lavish PGI-I scale exhibited the ability of our proposed selection criteria to individually direct the patients to her suitable procedure that suits her needs and baseline characteristics.

In addition, we recounted a significant improvement in all sexual parameters in ASC patients (p<0.0001) with the absence of de novo dyspareunia. It could be explained by the avoidance of extending the attachment of the used mesh down over the anterior and posterior vaginal walls. Additionally, during subtotal hysterectomy, the mesh was attached to the cervix. In agreement with our data, LO and Wang along with Maher et al showed significantly more de novo dyspareunia in patients who underwent SSC compared to ASC patients in some studies.<sup>6.26</sup>

Mesh complications principally erosions are fundamental issues during surgical selection for apical prolapse management.<sup>7</sup> After FDA issued a health statement on mesh use in treating POP, it was recommended to balance the need for optimal repair against the risk of mesh complications.<sup>25,27</sup> Mesh exposure was estimated to be as high as 10.5% after ASC.<sup>25</sup> Notwithstanding, we didn't detect any case of mesh exposure during the follow-up period which could be explained by attaching the mesh to the cervix in 57% of patients following subtotal hysterectomy, avoiding placing the mesh under tension and the younger age group with less degree of vaginal atrophy in ASC group.

#### **CONCLUSION**

Based on the results of our data, selectively allocating women with apical vaginal prolapse to either ASC or SSC resulted in functional and anatomical outcomes comparable to the most substantial success rates reported in recent literatures without any long-term mesh related complications.

Our innovative criteria of selection were constructed on the base of weighing risks against benefits of both procedures during patients' selection. The statistical similarity in PGI-I and the functional outcomes abolished the need of older sexually inactive patients with limited physical activity for ASC procedure. Nevertheless, the anatomic superiority and durability of ASC with absence of de novo dyspareunia in younger sexually and physically active women, justified the potential risks of long-term mesh complications.

After implementation of our proposed criteria on a more monumental scale with inclusion of other apical repair procedures as laparoscopic sacrocolpopexy, iliococcygeal colpopexy and obliterative operations, those criteria can be used as a preliminary step to initiate guidelines and recommendations to assist the gynecologists in the challenging situation of managing vaginal apical prolapse.

Funding: No funding sources Conflict of interest: None declared Ethical approval: The study was approved by the Institutional Ethics Committee

#### REFERENCES

- 1. Choi KH, Hong JY. Management of pelvic organ prolapse. Korean J Urol. 2014;55(11):693-702.
- DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. Am J Obstet Gynecol. 1992; 166(1):1717-28.

- Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An international urogynecological association (IUGA)/international continence society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J. 2010;21(1):5-26.
- Hagen S, Stark D, Glazener C, Sinclair L, Ramsay I. A randomized controlled trial of pelvic floor muscle training for stages I and II pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct. 2009;20(1):45-51.
- 5. Diwadkar GB, Barber MD, Feiner B, Maher C, Jelovsek JE. Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. Obstet Gynecol. 2009;113(1):367-73.
- 6. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2013;30(4):CD004014.
- Coolen AWM, Bui BN, Dietz V, Wang R, van Montfoort APA, Mol BWJ, et al. The treatment of post-hysterectomy vaginal vault prolapse: a systematic review and meta-analysis. Int Urogynecol J. 2017;28(12):1767-83.
- 8. Siddiqui NY, Grimes CL, Casiano ER, Abed HT, Jeppson PC, Olivera CK, et al. Mesh sacrocolpopexy compared with native tissue vaginal repair: a systematic review and meta-analysis. Obstet Gynecol. 2015;125(1):44-55.
- 9. Anand M, Weaver AL, Fruth KM, Gebhart JB. Factors influencing selection of vaginal, open abdominal, or robotic surgery to treat apical vaginal vault prolapse. Female Pelvic Med Reconstr Surg. 2016; 22(4):236-42.
- Bump RC, Mattiasson A, Bø K, Brubaker LP, DeLancey JO, Klarskov P, et al. The standardisation of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol. 1996; 175(1):10-7.
- 11. Ibrahim A, Eltohamy O, Ibrahim M, Ellaithy MI, Bahaa A, Elkady M, et al. Sacrospinous colpopexy using Masson luethy needle holder. Eur J Obstet Gynecol Reprod Biol. 2014;179:5-10.
- Srikrishna S, Robinson D, Cardozo L. Validation of the patient global impression of improvement (PGI-I) for urogenital prolapse. Int Urogynecol J. 2010; 21(5):523-8.
- 13. Van der Vaart CH, de Leeuw JR, Roovers JP, Heintz AP. Measuring health-related quality of life in women with urogenital dysfunction: the urogenital distress inventory and incontinence impact questionnaire revisited. Neurourol Urodyn. 2003; 22(2):97-104.
- 14. Roovers JP, van der Blom JG, van der Vaart CH. Hysterectomy does not cause constipation. Dis Colon Rectum. 2008;51(7):1068-72.
- 15. Roovers JP, van der Vaart CH, van der Bom JG, van Leeuwen JH, Scholten PC, Heintz AP. A randomised controlled trial comparing abdominal and vaginal prolapse surgery: effects on urogenital function. BJOG. 2004;111(1):50-6.

- Tinelli A, Malvasi A, Rahimi S, Negro R, Vergara D, Martignago R, et al. Age-related pelvic floor modifications and prolapse risk factors in postmenopausal women. Menopause. 2010;17(1): 204-12.
- 17. Swift S, Woodman P, O'Boyle A, Kahn M, Valley M, Bland D, et al. Pelvic organ support study (POSST) the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. Am J Obstet Gynecol. 2005;192(3):795-806.
- Coolen ALWM, van Oudheusden AMJ, Mol BWJ, van Eijndhoven HWF, Roovers JWR, Bongers MY. Laparoscopic sacrocolpopexy compared with open abdominal sacrocolpopexy for vault prolapse repair: a randomised controlled trial. Int Urogynecol J. 2017;28(10):1469-79.
- Illiano E, Giannitsas K, Zucchi A, Di Biase M, Del Zingaro M, Bini V, Costantini E. Sacrocolpopexy for posthysterectomy vaginal vault prolapse: long-term follow-up. Int Urogynecol J. 2016;27(10):1563-9.
- 20. Freeman RM, Pantazis K, Omson A, Frappell J, Bombieri L, Moran P, et al. A randomised controlled trial of abdominal versus laparoscopic sacrocolpopexy for the treatment of posthysterectomy vaginal vault prolapse: LAS study. Int Urogynecol J. 2013;24(3):377-84.
- Culligan PJ, Blackwell L, Goldsmith LJ, Graham CA, Rogers A, Heit MH. A randomized controlled trial comparing fascia lata and synthetic mesh for sacral colpopexy. Obstet Gynecol. 2005;106(1):29-37.
- 22. Maher CF, Qatawneh AM, Dwyer PL, Carey MP, Cornish A, Schluter PJ. Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. Am J Obstet Gynecol. 2004;190(1):20-6.
- 23. Halaska M, Maxova K, Sottner O, Svabik K, Mlcoch M, Kolarik D, et al. A multicenter, randomized , prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. Am J Obstet Gynecol. 2012;207(4):301.e1-7.
- 24. Svabik K, Martan A, Masata J, El-Haddad R, Hubka P. Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. Ultrasound Obstet Gynecol. 2014; 43(4):365-71.
- 25. Nygaard I, Brubaker L, Zyczynski HM, Cundiff G, Richter H, Gantz M, et al. Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. JAMA 2013;309(19):2016-24.
- Lo TS, Wang AC. Abdominal colposacropexy and sacrospinous ligament suspension for severe uterovaginal prolapse: A comparison. J Gynecol Surg. 1998;14(2):59-64.
- 27. Serious complications associated with transvaginal placement of surgical mesh for pelvic organ

prolapse: FDA Safety Communication. Available at: https://www.burgsimpson.com/wp-content/uploads/ 2018/03/FDA-safety-communication-pelvic-mesh. pdf. Accessed on 12 March 2018.

**Cite this article as:** Hassan MF, El-Tohamy O, Yehia AH, Alghanimi SA, Al-Enezi H, Moussa M. Selective allocation of patients with vaginal apical prolapse to either mesh augmented open abdominal repair or vaginal sacrospinous colpopexy improve functional and anatomical outcomes. Int J Reprod Contracept Obstet Gynecol 2022;11:2199-207.