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ORIGINAL ARTICLE

Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: a prospective randomised study

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Abstract The management of an advanced multi-compartment prolapse requires a combination of techniques. The objective of this study was to report the anatomical outcomes of a prospective randomised trial comparing tension-free polypropylene mesh-reinforced anterior vaginal prolapse with anterior colporrhaphy at the time sacrospinous colpopexy and posterior fascial plication for the management of massive uterovaginal prolapse. A total of 116 patients with a stage III or IV (Pelvic Organ Prolapse Quantification System/International Continence Society) uterovaginal prolapse were randomised into two groups. The mesh group includes transvaginal cystocele repair using a tension-free polypropylene mesh, while the non-mesh group includes anterior colporrhaphy. All patients in the two groups underwent a sacrospinous colpopexy and posterior fascial plication. The primary outcome was objective success < stage 2 prolapse. The secondary outcomes were reoperation for recurrent prolapse, subjective success rates, patient satisfaction with the surgery and complications. The overall objective success rates (in all compartments) were 79 % (42/53) in the mesh group and 62 % (39/63) in the non-mesh group (p=0.043). The objective success rates in the anterior compartment were 85 % (45/53) in the mesh group and 62 % (39/63) in the non-mesh group (p=0.006). Three (6 %) patients in the mesh group and 12 (19 %) in the non-mesh group underwent repeat surgery for recurrent pelvic organ prolapse (p=0.03). The subjective success rates were 89 % (47/53) in the mesh group and 76 % (48/63) in the non-mesh group (p value=0.08). The mean patient satisfaction rates with the surgery were 84 % in the mesh group and 76 % in the non-mesh group (p=0.08). The development of a urinary tract infection, right-sided buttock pain (temporary sciatic neuralgia) and new-onset stress urinary incontinence were not significantly different between the two groups. The mesh exposure rate was 8 %. Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy and posterior fascial plication offers lower anatomic recurrence and less need for further prolapse surgery to correct recurrent pelvic floor defects than anterior colporrhaphy, sacrospinous colpopexy and posterior fascial plication.

Keywords Uterovaginal prolapse · Sacrospinous ligament fixation · Cystocele · Anterior vaginal wall repair · Mesh · Polypropylene

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Background

The management of multi-compartment advanced pelvic organ prolapse (POP) remains a major challenge for gynaecologists. It is estimated that a woman has an 11 % lifetime risk of undergoing a surgical procedure for the correction of pelvic floor dysfunction with almost one third of such women requiring a repeat operation either due to the failure of the first operation or due to the prolapse of another compartment [1]. Transvaginal sacrospinous ligament fixation is a widely used procedure for massive uterovaginal prolapse that is usually performed concomitantly with a

vaginal hysterectomy [2]. The procedure has a variable success rate but is known to lead to anterior vaginal wall prolapse [3].

Recent randomised controlled trials have demonstrated that the use of synthetic mesh at the anterior compartment is superior to anterior colporrhaphy in reducing the risk of recurrent anterior vaginal wall prolapse [4, 5]. de Tayrac et al. reported a low recurrence rate of anterior vaginal wall prolapse with the use of tension-free polypropylene mesh after 5 years of follow-up [6].

The combined use of anterior trans-obturator mesh (Perigee®, AMS) and sacrospinous ligament fixation for apical support and fascial repairs for posterior compartments in treating massive urogenital prolapse has been shown to effectively restore the anatomy and achieve favourable pelvic function 30 months postoperatively [7]. A combination of anterior vaginal mesh (Gynecare Prolift™), sacrospinous hysteropexy and posterior fascial plication has also been reported to effectively restore the anatomy and achieve favourable bladder, bowel and sexual function in a prospective study with a 12-month follow-up for women with anterior compartment-dominated uterovaginal prolapse [8].

To our knowledge, no prospective randomised trials have compared the use of native tissue repair versus the use of anterior vaginal wall tension-free polypropylene monofilament mesh at the time of sacrospinous colpopexy and posterior fascial placation to treat massive uterovaginal prolapse. The purpose of this study, therefore, was to evaluate the anatomical outcomes and reoperation rates following anterior vaginal wall mesh (Gynemesh™, PS) augmentation versus traditional anterior repair using native tissues with concomitant sacrospinous ligament fixation and posterior fascial plication in cases of massive uterovaginal prolapse.

Subjects and methods

The study group included women attending the Department of Obstetrics and Gynaecology at Jordan University Hospital (JUH), Amman, Jordan, for symptomatic uterovaginal prolapse or vaginal vault prolapse between January 2005 and January 2010.

All women with severe symptomatic pelvic organ prolapse (i.e. uterine or vaginal vault prolapse of stages III and IV according to the International Continence Society (ICS) grading system on maximum Valsalva manoeuvre) were eligible to take part in the study [9]. Women who had less than a stage III prolapse of any compartment or previous procedures with implants as a part of pelvic reconstructive surgery were excluded from the study. Other exclusion criteria included a known coagulation disorder, previous pelvic irradiation and women who wished to preserve their uterus. The study protocol was explained to the patients, and a written consent form was signed by all women before taking part in the study. Ethical approval was obtained from the local Ethics Committee at the JUH.

Prior to surgery, the pelvis was evaluated according to the recommendation of the ICS using the ordinal stages of pelvic organ prolapse (POP quantification (POP-Q)) system (grades 0–IV) as has been described [9]. A computer-generated randomisation list was made, and the patients were divided into two groups (mesh vs. non-mesh) as shown in Fig. 1.

Surgical technique

A midline longitudinal incision was made in the vaginal epithelium from the vaginal apex to 2.5 cm from the urethral meatus. This incision was preceded by a vaginal hysterectomy in patients with a uterine prolapse. In women who had previously undergone a hysterectomy, the procedure began with a transverse incision through the vaginal epithelium distal to the cuff. The anterior vaginal wall was sharply dissected from the underlying pubocervical fascia. The dissection was continued laterally in each direction to the pelvic side wall and distally to the level of the urethrovesical junction.

In the non-mesh group, the underlying pubocervical fascia was plicated in the midline with a delayed absorbable 2-0 polydioxanone suture (Ethicon, Somerville, NJ, USA). In the mesh group, the retropubic space was widened using sharp and blunt dissection before plication of the pubocervical fascia as mentioned, and a monofilament polypropylene Gynemesh™ PS (Gynecare, Ethicon Inc., Somerville, NJ, USA) was designed and tailored, leaving two tabs on each side. The mesh used was usually 15 cm long and 3 cm wide and was positioned by placing the tabs into the retropubic space in a tension-free fashion without sutures. The central part of the mesh was drawn down to the lowermost

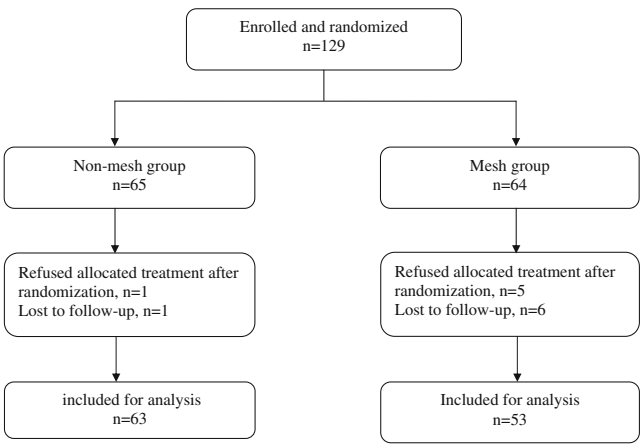

Fig. 1 Patient enrolment, randomisation and analysis

portion of the cystocele; excessive inlaying mesh was trimmed. The mesh was adjusted to avoid any folding and loosely fixed at four points using a 3-0 polyglactin absorbable suture (Vicryl; Ethicon, Somerville, NJ, USA) [10]. The vaginal incision was closed with a continuous 0 polyglactin absorbable suture (Vicryl; Ethicon, Somerville, NJ, USA) as shown in Fig. 2.

In both groups, a sacrospinous colpopexy was performed as previously described [11]. Briefly, a midline incision was performed in the posterior vaginal wall starting from the hymenal ring to the vault to expose the rectovaginal space. The vaginal skin was dissected laterally to expose the pararectal fat. Using the index finger, a window was created between the rectovaginal space and the ischial spine through the right rectal pillar to expose the sacrospinous ligament. A Miya hook ligature carrier was used to insert a triple No. 0 delayed absorbable polydioxanone suture (Ethicon, Somerville, NJ, USA) into the right sacrospinous ligament 2 cm medial to the ischial spine. The rectum was retracted medially using a Breisky–Navratil vaginal retractor, and the sutures were retrieved using a nerve hook. Pulley sutures were created using a no. 4 Mayo needle to ensure good contact between the vaginal skin and the sacrospinous ligament when the sutures were tied. The rectovaginal fascia was plicated in continuity with the perineum, and the vaginal incision was closed as previously described [12]. The PDS sutures were tied, pulling the vault to the sacrospinous ligament. A concomitant TVT-O™ (Ethicon, Somerville, NJ, USA) procedure was performed using a separate incision for patients with urodynamic stress urinary incontinence. Postoperatively, a vaginal pack was placed for 24 h, and a Foley catheter was kept in situ for 24 h. All participants received a preoperative intravenous antibiotic (cefuroxime 1 g) and low-molecular weight heparin as antithrombotic prophylaxis which we routinely give to all patients who underwent pelvic surgery according to the guidelines in our hospital. All procedures were performed under regional or general anaesthesia.

The patient demographics, previous surgeries, preoperative pelvic organ prolapse quantification (POP-Q) and perioperative information including operating time, blood loss, in-hospital stay, length of catheter use, time to return to activities of daily living and complications were collected. A postoperative evaluation occurred at 6 weeks and every 6 months thereafter and included a pelvic examination using the POP-Q grading system performed by an independent investigator. Patient satisfaction was recorded on a 0 to 100 visual analogue scale.

The primary outcome measure of this study was the objective success rate, defined as less than a stage II prolapse at the anterior vaginal wall and in all compartments. The secondary outcome measures included the need for repeat surgery to correct a recurrent prolapse, the subjective success rate (defined as no prolapse sensation), patient satisfaction and complication rates.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 15 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used for the patient demographics and peri-operative data. The continuous variables were compared with the paired t test, and the categorical variables were compared with the $\chi 2$ or McNemar test. A p value <0.05 was considered statistically significant for all comparisons.

The number of patients was calculated by a power analysis using the G-power programme, assuming the type I error to be 5 % and the power to be 80 %. The assumed rates of recurrent prolapse were estimated to be 10 % in the mesh group [6] and 35 % in the non-mesh group [15]. The effect size was estimated to be 0.25, and the dropout rate was estimated to be 10 %. Therefore, it was assumed that 57 patients were needed in each arm of the study.

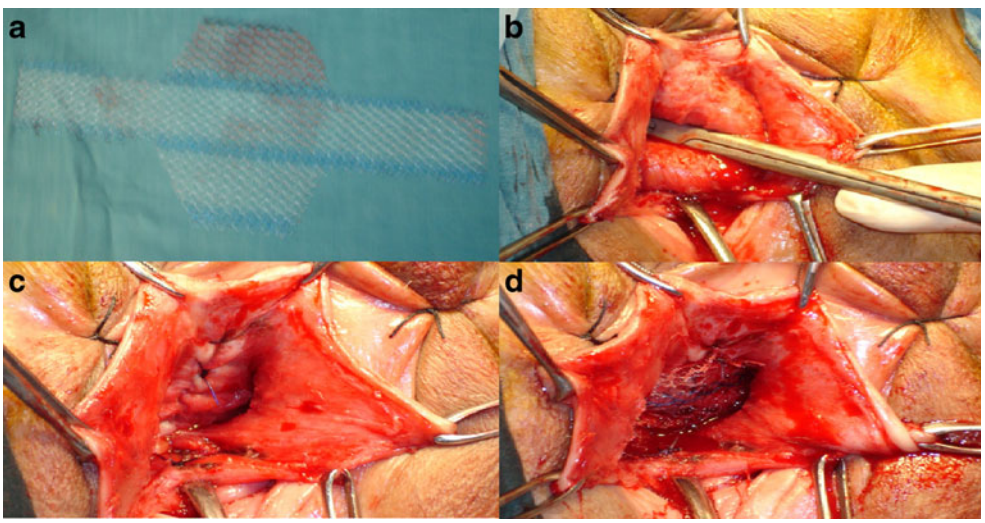

Fig. 2 Transvaginal cystocele repair using a tension-free polypropylene mesh. **a** A monofilament polypropylene mesh was designed and tailored, leaving two tabs on each side. **b** The retropubic space was widened using sharp and blunt dissection. **c** The underlying pubocervical fascia was plicated in the midline with a delayed absorbable 2-0 polydioxanone suture. **d** The mesh was positioned by placing the tabs into the retropubic space in a tension-free fashion

Findings

Overall, 129 patients were recruited into the study, and six dropped out on the day of surgery. Complete pre- and post-operative data were obtained for 116 patients. Seven patients were lost to follow-up. The clinical and demographic characteristics were similar in the two study groups (Table 1).

Overall, a stage II recurrence occurred in 19 % (10/53) of patients in the mesh group and in 24 % (15/63) of patients in the non-mesh group. Only one patient (2 %) developed a stage III prolapse in the mesh group, but 14 % (9/63) of patients developed a stage III prolapse in the non-mesh group. There were no stage IV recurrences in any group. The overall objective success rates (in all compartments) were 79 % (42/53) in the mesh group and 62 % (39/63) in the non-mesh group (p=0.043). A stage II anterior vaginal wall recurrence occurred in 13 % (7/53) of patients in the mesh group and in 24 % (15/63) of patients in the non-mesh group. Only one patient (2 %) in the mesh group developed a stage III anterior vaginal wall recurrence compared to 14 % (9/63) of patients in the non-mesh group. No stage IV anterior vaginal wall recurrences were noted in any of the two groups. The overall objective success rate in the anterior compartment was 85 % (45/53) in the mesh group and 62 % (39/63) in the non-mesh group (p=0.006). The postoperative POP-Q stages for all compartments are summarised in Table 2.

The preoperative POP-Q values were similar in both groups. The preoperative values for the anterior, vaginal cuff and posterior vaginal wall (point Ba, C and Bp) improved significantly after surgery in both groups. Between the study groups, the points Ba and C were significantly shifted proximally in the mesh group (Table 3).

The subjective success rates were 89 % (47/53) in the mesh group and 76 % (48/63) in the non-mesh group (p value=0.08). The mean patient satisfaction with the surgery was 84 % in the mesh group and 76 % in the non-mesh group (p=0.08).

The need for repeat surgery to correct a recurrent prolapse in any compartment during the follow-up period was significantly higher in the non-mesh group (Table 4). Only three (6 %) patients in the mesh group underwent repeat surgery for recurrent pelvic organ prolapse; two involved the anterior and apical compartments, and one involved an isolated rectocele. Conversely, 12 (19 %) patients in the non-mesh group underwent repeat surgery for the anterior and apical compartments; two of the patients also underwent rectocele repair (p=0.03).

The occurrence of a postoperative urinary tract infection and right-sided buttock pain (temporary sciatic neuralgia) which was resolved spontaneously after 2–3 weeks in all cases was not significantly different between the two groups (Table 4).

Mesh exposure was identified in four (8 %) patients and in all cases measured 1 cm or less in diameter and was asymptomatic. All mesh exposures were located under the suture line in the distal anterior vaginal wall. The initial management included topical oestrogen therapy and the

Table 1 Baseline demographic and clinical data of the two study groups

	No-mesh group (n=63)	Mesh group (n=53)	p value
Mean age ± SD (years)	56±10	57±7	0.58
Median (range) parity	6 (1–15)	6 (3–14)	0.69
Mean BMI ± SD (kg/m^2)	30±4	30±3	0.95
Postmenopausal	39 (62)	36 (68)	0.50
Postmenopausal with HRT	6 (10)	6 (11)	0.24
Prior pelvic surgery			
Abdominal hysterectomy	9 (14)	4 (8)	0.50
Vaginal hysterectomy	0 (0)	1 (2)	
Vaginal repair	11 (18)	12 (22)	
Vaginal repair > once	1 (2)	2 (4)	
Overall vaginal POP-Q stage			
Stage III	49 (78)	39 (74)	0.49
Stage IV	14 (22)	14 (26)	
Urodynamic stress urinary incontinence	10 (16)	9 (17)	0.87
Mean operating time ± SD (min)	89±26	88±19	0.85
Mean estimated blood loss ± SD (ml)	267±222	257±205	0.81
Median (range) hospitalisation length (days)	4 (2–9)	4 (2–9)	0.37
Median (range) catheter use (days)	2 (1–8)	2 (1–7)	0.15
Median (range) return to ADL (weeks)	6 (3–10)	6 (3–10)	0.14
Median (range) period of follow-up (months)	29 (6–60)	28 (10–60)	0.58

Data are n (%) unless otherwise specified

SD standard deviation, *BMI* body mass index, *HRT* hormone replacement therapy, *ADL* activities of daily living, *POP-Q* pelvic organ prolapse quantification

Table 2 Overall and compartment-specific pelvic organ prolapse quantification stages at the last follow-up in the two study groups

POP-Q stage	Non-mesh group (n=63)	Mesh group (n=53)	p value
Overall			0.043
Stage 0–I	39 (62)	42 (79)	
Stage II	15 (24)	10 (19)	
Stage II	9 (14)	1 (2)	
Anterior			0.006
Stage 0–I	39 (62)	45 (85)	
Stage II	15 (24)	7 (13)	
Stage III	9 (14)	1 (2)	
Vaginal vault			0.11
Stage 0–I	52 (82)	49 (92)	
Stage II	8 (13)	3 (6)	
Stage III	3 (5)	1 (2)	
Posterior			0.51
Stage 0–I	56 (89)	49 (92)	
Stage II	6 (9)	4 (8)	
Stage III	1 (2)	0 (0)	

Data are number (n) and percentage (%)

mobilisation and excision of the exposed mesh with oversewing of the vaginal epithelium.

Stress urinary incontinence was cured in all patients in the two groups who underwent a TVT-O™ (Ethicon, Somerville, NJ, USA) procedure as a part of the surgery. Postoperative de novo stress urinary incontinence occurred in 5 % (2/44) of patients in the mesh group and in 4 % (2/53) of patients in the non-mesh group (Table 4).

Conclusion

We reported the results of two approaches for the management of multi-compartment vaginal prolapse with or without the use of mesh to support the anterior vaginal wall. To our knowledge, this study is unique in that it compared the outcome of two different techniques for the support of the anterior vaginal wall in conjunction with sacrospinous fixation; posterior fascial placation and vaginal hysterectomy were indicated. Our results suggest that the use of mesh is associated with a higher objective success rate on the anterior wall and in all compartments compared to native tissue repair (85 and 79 % with mesh and 62 and 62 % with native repair, respectively). This is not surprising given that the use of grafts has grown in pelvic reconstructive surgery under the rationale that a POP is similar to a hernia in its aetiology [13] and that reinforcement would most likely lower the recurrence rates, whereas putting stitches in already weakened tissue would not be the best way to achieve a long-lasting correction. A multi-compartment prolapse is more challenging to treat and achieve a favourable outcome than a single compartment prolapse, especially if an apical defect is involved.

Feiner et al. [8] reported a 1-year success rate of 87 % in the anterior compartment and a 75 % success rate in all compartments after the combination of anterior mesh repair (Gynecare Prolift™, Ethicon, Somerville, NJ, USA), sacrospinous hysteropexy and posterior fascial placation. Our results using mesh revealed a similar success rate, albeit with a longer follow-up period.

Previously, an objective cure rate of 91.8 % and an anterior compartment cure rate of 100 % were reported at

Table 4 Reoperation rates and postoperative complications in the two study groups

Complication	Non-mesh group (n=63)	Mesh group (n=53)	p value
Repeat surgery for recurrent prolapse	12 (19)	3 (6)	0.03
Temporary sciatic neuralgia	7 (11)	8 (15)	0.52
Urinary tract infection	9 (14)	11 (20)	0.35
Mesh exposure	NA	4 (8)	
New-onset stress urinary incontinence	2 (3)	2 (4)	0.86

Data are number (n) and percentage (%)

Table 3 POP-Q values at baseline and at the last follow-up in patients in the two study groups

POP-Q measurements (cm)	No-mesh group (n=63)			Mesh group (n=53)			p value
	Baseline	Follow-up	Difference	Baseline	Follow-up	Difference	
Point Ba	4.0±2.2	−1.0±1.9	−5.0±2.6	4.0±2.0	−2.2±1.3	−6.2±2.1	0.004
Point C	4.7±2.5	−4.8±2.8	−9.5±3.5	4.9±2.2	−6.0±2.2	−10.9±3.3	0.024
Point Bp	3.9±2.2	−1.8±1.1	−5.7±2.3	3.7±2.3	−2.4±0.6	−6.1±2.4	0.322

Data are mean ± SD. The POP-Q measurements are as recommended [9]. Point Ba is the anterior wall, most-dependent part (in centimetres); point C, cervix or vaginal cuff (in centimetres); point Bp, posterior wall, most-dependent part (in centimetres)

POP-Q pelvic organ prolapse quantification

a median follow-up of 30 months using a different technique of combined anterior vaginal wall mesh (Perigee® AMS) and conventional vaginal pelvic reconstructive surgery using sacrospinous ligament fixation [7].

An objective cure rate of 89 % was reported by de Tayrac et al. [6] in his study of transvaginal cystocele repair using tension-free polypropylene mesh at a mean follow-up of 37 months. We performed a similar technique to de Tayrac, but our procedure was performed at the time of a sacrospinous colpopexy and posterior fascial plication for massive uterovaginal prolapse.

Nguyen [4] evaluated the outcome after anterior vaginal prolapse repair in a randomised controlled trial and demonstrated 55 % optimal and satisfactory anterior vaginal support after anterior colporrhaphy and 87 % optimal and satisfactory anterior vaginal support after anterior vaginal prolapse repair with polypropylene mesh reinforcement. In our control group, we observed a 38 % rate of recurrent anterior and apical prolapse, which is similar to the results of Maher's and Paraiso's trials. Maher reported a cumulative anterior and vault prolapse recurrence of 45 % at the time of sacrospinous colpopexy, and Paraiso reported a 37 % cystocele rate after sacrospinous colpopexy [14, 15].

In our study, only two patients (4 %) in the mesh group required surgical correction of a prolapse at the anterior and apical compartments during the follow-up period. In the control group, the need for surgical correction of a recurrent prolapse was required in 12 patients (19 %); all included apical and anterior vaginal wall defects. Cervigni et al. [16] reported a 24 % recurrence rate after 38 months of follow-up after repair using polypropylene mesh and only a 5 % occurrence of repeat surgery. The risk for a recurrent anterior vaginal wall prolapse using tension-free polypropylene mesh seems to increase over time, but no repeat procedures were required from 6 to 79 months of follow-up [17].

The concomitant sacrospinous suspension and the surgical technique we chose for (tension-free) mesh insertion may explain the number of cystocele recurrences (15 %) in the mesh group because of the lack of both lateral and apical support. The few cases of repeat surgery (6 %) may be explained by the elevated subjective success rate and higher patient satisfaction in the mesh group. However, these did not reach statistical significance, most likely due to the high number of withdrawals and the patients that were lost to follow-up in the mesh group.

The high cure rate in all patients with stress urinary incontinence can be attributed to the TVT-O™ procedure. New-onset stress urinary incontinence is low and similar in the two groups. The effect of anterior vaginal wall mesh on urinary incontinence is somewhat controversial, but our results show that mesh placement does not increase the risk of postoperative urinary incontinence, similar to the results reported by Nieminen et al. [5] and in accordance with results reported after trans-obturator mesh placement [7].

We reported 8 % asymptomatic mesh exposure during the follow-up period. Vaginal mesh exposure is the complication of greatest concern, and the rate of exposure using Gynemesh™ PS ranges from 3.8 to 20 % [6, 18–20], although the definition of exposure in these reports was usually absent or confusing. The avoidance of thinning of the vaginal epithelium, pre- and posttreatment with local oestrogen, placement of the mesh in a tension-free fashion and intraoperative coverage with antibiotics significantly reduce the serious exposure rates.

Urinary tract infection was the most common postoperative complication in both groups, and all cases responded to antibiotic therapy. This could be explained by the long catheter use time (2 days), which increases the risk of a urinary tract infection, but there was no difference between the two study groups. The relationship between urinary tract infection and vaginal mesh reconstructive surgery is not well reported in the literature.

We reported a 13 % occurrence of right-sided buttock pain with no difference between the two study groups; the pain was mild and disappeared after 2–3 weeks. Postoperative sciatic neuralgia was induced by the traction of the suture in the sacrospinous ligament. The incidence varied between 1 and 30 % [21–25], and the resulting pain was mild and could be controlled by simple analgesics with no need for suture removal.

The main limitation of this study was the lack of validated quality of life questionnaires as none are available in the Arabic language. Additionally, this was a single-centre study, and the sample size was not sufficient to assess complications.

In conclusion, anterior vaginal wall repair reinforced with tension-free polypropylene mesh with concomitant sacrospinous colpopexy and posterior fascial plication has significantly higher objective cure rates and less need for reoperation compared to pubocervical fascial plication with sacrospinous colpopexy and posterior fascial plication for women with massive uterovaginal prolapse at a median follow-up of 28 months with acceptable complication rates.

Declaration of interest The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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