International Urogynecology Journal (2019) 30:545–555
https://doi.org/10.1007/s00192-018-3702-7

ORIGINAL ARTICLE

Anatomical outcomes 1 year after pelvic organ prolapse surgery in patients with and without a uterus at a high risk of recurrence: a randomised controlled trial comparing laparoscopic sacrocolpopexy/cervicopexy and anterior vaginal mesh

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Received: 7 February 2018 / Accepted: 13 June 2018 / Published online: 9 July 2018

Abstract

Introduction and hypothesis Few studies have compared the different approaches of mesh surgery in patients with severe pelvic organ prolapse (POP). In addition to laparoscopic sacrocolpopexy/cervicopexy (LSC-Cx), anterior vaginal mesh (AVM) may be an effective approach for correcting anterior vaginal wall associated with apical POP in women with advanced POP.

Methods A randomised controlled trial (RCT; January 2011 to March 2016) including 120 patients (60/group) with advanced symptomatic POP, with a predominant anterior vaginal wall descent stage III or greater in combination with a stage II or III apical defect (uterus or vaginal vault). Patients underwent four visits: baseline, 3, 6 and12 months after surgery. The main outcome was anatomical success defined as anterior and posterior vaginal wall not descending beyond the hymen and vaginal apex descent no more than one third into the vagina. Secondary variables: PFDI, ICIQ-UI-SF, intraoperative variables, postoperative morbidity and complications.

Results Anatomical success was achieved with LSC-Cx in 79% and with AVM in 76% (NS). No statistically significant differences were found among POP-Q anterior vaginal wall points between groups, whereas better results were obtained with LSC-Cx in posterior vaginal wall points and total vaginal length. Intraoperative outcomes were similar in the two groups, except for operating time (78.05 min LSC-Cx vs 44.28 min AVM). There were no statistically significant differences related to de novo stress urinary incontinence and dyspareunia. Worse results were found in the CRADI-8 in the LSC-Cx group, owing to constipation. Late postoperative complications and reinterventions were similar in the two groups.

Conclusions No differences were found in the anatomical correction of anterior and apical POP. The LSC-Cx group presented better correction of posterior vaginal wall defects and a longer total vaginal length.

Keywords Pelvic organ prolapse · Prolapse recurrence · Mesh surgery · Laparoscopic sacral colpopexy/cervicopexy · Anterior vaginal mesh

Introduction

Pelvic organ prolapse (POP) is one of the most prevalent gynaecological conditions requiring surgical treatment. The incidence of women undergoing POP surgery is 139 in 100,000 women [1]. Anterior POP surgery combined with apical correction is the most common procedure in most cases (50–80%) [2, 3]. POP vaginal repair using native tissue continues to be the first choice in treating primary POP [4]. However, both anatomical failure and recurrence of POP symptoms after surgery are common, requiring reoperation in 2.9 to 30% of patients [5, 6]. Recent publications have confirmed preoperative stage III or higher as a risk factor for POP recurrence after surgery with native tissues [7–9].

This study was presented as a podium oral presentation at the ICS 2017 Meeting (Florence) and EUGA 2017 Meeting (Barcelona)

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Sacrocolpopexy is considered the gold standard for the surgical treatment of apical vault POP, demonstrating higher cure rates than the vaginal route [10, 11]. Laparoscopic sacrocolpopexy or cervicopexy (LSC-Cx) was developed to reduce the short-term morbidity associated with the open abdominal approach [12], providing the same results. However, some patients present contraindications to the laparoscopic route or general anaesthesia, and this technique demands a steep learning curve [13].

In this context, vaginal wall repair with mesh reinforcement aroused great interest when the first publications suggested satisfactory anatomical results with lower morbidity using the vaginal approach. Nowadays, the use of meshes in vaginal wall repair is very controversial, with reports of a lower short-term risk of POP recurrence, albeit with new complications, such as postoperative vaginal or pelvic pain, mesh erosion or extrusion [9, 10, 14]. Therefore, mesh procedures result in lower rates of reoperation for recurrent POP, but higher reoperation rates for complications [14]. This additional risk suggests that vaginal meshes should only be used in the context of clinical trials, or in defined categories of high-risk women [3].

Few studies have compared laparoscopic abdominal procedures with vaginal mesh kits in a sub-group of patients with an advanced POP (stage III or greater). The aim of the present randomised controlled trial (RCT) was to describe anatomical modifications comparing LSC-Cx with anterior vaginal wall repair with a mesh kit (AVM) with bilateral fixation to the sacrospinous ligament (BFSL) in a group of women with a high risk of POP recurrence: patients with a predominant anterior vaginal wall descent stage III or greater in combination with a stage II or III apical defect (uterus or vaginal vault). Subjective and objective intraoperative and postoperative outcomes were also analysed.

Material and methods

An RCT was designed in a tertiary university hospital from January 2011 to March 2016. The inclusion criteria were: women requiring POP surgery with primary or recurrent symptomatic POP. We included patients with a predominant anterior vaginal wall descent (stage III or IV) and uterine or vaginal vault descent (stage II or III). All patients accepting an invitation to participate after evaluation by two expert urogynaecologists (ME, CR) and receiving an understandable explanation of the available alternatives to surgery and information about the risks and possible complications of surgery with meshes. The study protocol was approved by the Ethical Committee and written informed consent was obtained from all participants at enrolment. The patients were randomly allocated to the LSC-Cx or the AVM with BFSL group, using a computer-generated randomisation list by order of inclusion. Data were collected in a specific clinical data registry. The trial was registered at ClinicalTrials.gov (Identifier: NCT01097200).

Taking into account an anatomical success rate for LSC of 77% [15] (considered the gold standard), the sample size necessary to demonstrate a non-inferiority anatomical success rate for the AVM kit with a non-inferiority margin of 20%, with a β error of 0.2 and an α error of 0.05, was 55 patients per arm. Considering an approximate drop-out rate of 10%, 120 patients were included (60/group). Patients refusing to participate after randomisation were replaced by the next consecutively selected patient.

Exclusion criteria included those younger than 21 years of age, having a comorbidity or being at a high anaesthetic risk requiring a particular approach, the inability to comprehend questionnaires or attend follow-up visits, previous colposacropexy or vaginal mesh procedure and a history of pelvic radiotherapy. The LSC-Cx interventions were carried out by FC, and the AVM techniques were performed by EB, both with lengthy experience in their respective standardised procedure (Dr Bataller had dealt with more than 200 patients with Elevate® Anterior and Apicals before the study, and Dr Carmona more than 300 patients undergoing LSC-Cx [16, 17].

Surgery procedures

Sacrocolpopexy/sacrocervicopexy technique

After establishing the pneumoperitoneum, four laparoscopic trocars were inserted (10 mm at the umbilicus, 10 mm above from the umbilicus, 5 mm in right Iliac fossae and a 5 mm in the left fossae). The posterior peritoneal layer was opened from the promontory down and medial to the right uterosacral ligament, to the cervix or vault, down to the vesicovaginal space until the level of the trigone, rectovaginal septum, and levator ani muscle. The dissection at the sacrum consists of opening the posterior peritoneum until the anterior longitudinal ligament is reached. A tunnel underneath the right parietal peritoneum is then laterally dissected using diathermy and scissors and extended caudally up to the rectum so that the pelvic floor muscles of both sides become visible. In this zone, the dissection is of around 1 cm [2] proximal to the right iliac artery. Two pieces of a polypropylene plus polyglactin mesh (Vypro II; Ethicon, Somerville, NJ, USA), the latter of which had a self-styled Y shape, were bilaterally sutured to the levator ani, anterior and posterior vagina, anterior and posterior cervix (when supracervical hysterectomy was also performed) and promontory with several polypropylene sutures (Prolene; Ethicon). The number of sutures depended on the length of the vagina. In general, four sutures were used to attach the anterior mesh arm and four sutures to attach the posterior mesh arm. We also used two additional sutures to attach the posterior mesh arm to the levator ani muscle. Finally, the meshes were

covered by closing the peritoneum with a 2–0 absorbable running suture (Vicryl; Ethicon) [16].

Anterior vaginal mesh kit with BFSL

After performing a total vaginal hysterectomy when indicated, the bladder was filled with 50 cm^3 of diluted blue dye. Hydrodissection with a total of 40 cm^3 vasoactive agent or saline facilitates dissection in the appropriate avascular plane (vesicovaginal and paravaginal space). The anterior vaginal wall was then laterally separated from the bladder up to both ischial spines. The self-fixating tip of the mesh kit (Elevate® Anterior and Apical; AMS, Minnetonka, MN, USA) with an attached polypropylene strip was inserted into sacrospinous ligaments on both sites. We pushed the mesh through the arms until reaching numbers 6–8 of the adjustment tool (white rule), so that the distance between the eyelets of the mesh and the SSL was around 2–3 cm. The distal arm of the graft was bilaterally attached to the obturator internus muscle. The midline of the mesh was attached to the endopelvic fascia overlying the bladder neck with delayed-absorbable sutures. The body of the graft was introduced into the mesh arms with the help of the adjustment tool up to the marks at 6 and 8 cm, always in a tension-free manner. Three previously placed apical PDS sutures were affixed to the apical tail. Afterwards, it was secured into position with the locking eyelets employing the adjustment tool. The polypropylene arms were trimmed such that at least 1 cm of mesh extended beyond the locking eyelets. The vaginal incision was closed with a quick absorbable running suture (Vicryl rapid; Ethicon). A vaginal packing moistened with antibiotic cream was placed into the vagina [17].

Primary and secondary outcomes

The primary outcome for surgery was anatomical success, defined as anterior and posterior vaginal wall descent not beyond the plane of the hymen and cervix or vaginal apex descent no more than one-third into the vaginal canal. The anatomical success was also analysed according to Maher, at POP-Q sites Aa, Ba, C, Bp and Ap defined as less than −1 cm individually and as a total [15]. Subjective success was considered with the absence of bothersome POP symptoms of vaginal bulging indicated by an affirmative response to either "Do you usually have a sensation of bulging or protrusion from the vaginal area?" or "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" in the Pelvic Floor Distress Inventory questionnaire (PFDI-20), and any response other than "not at all" to the question "How much does this bother you?" Finally, the combination of anatomical and subjective success, and no retreatment for POP by either surgery or pessary at 1 year, was considered as composite surgical success (following Barber et al.'s definition) [18].

Anatomical outcomes were analysed based on POP-Q points: Aa and Ba for the anterior vaginal wall; Ap and Bp for the posterior vaginal wall; an apical support was evaluated by measuring the total vaginal length (TVL), and POP-Q point C (or D if the cervix was present). We defined the prolapse stages according to the International Urogynecological Association/International Continence Society (IUGA-ICS) terminology [19].

Secondary outcomes included intraoperative data (Table 3), immediate and late postoperative complications and urinary, bowel and POP symptoms. Late postoperative complications included mesh exposure or extrusion, pain, de novo dyspareunia, de novo urinary incontinence (UI) and reoperation. Complications were defined and classified according to the IUGA-ICS terminology [20].

Pre- and postoperative dyspareunia was evaluated by question number 11 of the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire (PISQ-IR): "How often do you feel pain during sexual intercourse?" Dyspareunia was considered when patients answered sometimes, usually and always.

All women with urodynamic stress urinary incontinence (USUI) underwent concomitant suburethral sling (type transobturator or retropubic). Data related to reintervention were classified as: due to recurrence of POP symptoms, due to surgical complications, or related to urinary symptoms.

Urinary, bowel and POP symptoms were evaluated using the validated Spanish version of two questionnaires: the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI-SF), ranging from 0 to 21 points, and the Pelvic Floor Distress Inventory-20 (PFDI-20). The maximum score of the three subscales (the Pelvic Organ Prolapse Distress Inventory 6 [POPDI-6], the Colorectal Anal Distress Inventory 8 [CRADI-8] and the Urinary Distress Inventory 6 [UDI 6]) is 100, and the global score of the PFDI-20 ranges from 0 to 300. Patients with concomitant surgery for USUI were excluded from the analysis of UDI-6 and ICIQ-UI-SF improvement to evaluate the effect of the POP surgery on urinary symptoms. The questionnaires were self-administered by the patients.

After selection, inclusion and randomisation, the women were visited at baseline (presurgical evaluation) and at three follow-up visits (3 months, 6 months and 1 year after surgery) by the same two urogynaecologists (ME, CR) not related to surgery. Women were examined in the semi-lithotomy position at maximum Valsalva, and the quantification of the POP was measured using the POP-Q system [21].

Statistical analysis

The percentage of patients meeting the criteria for surgical success was used to describe the primary outcome. Comparison between groups was performed using Fisher's exact test. Each item of the surgical outcome was also

compared using Fisher's exact test. Mean and standard deviation were used to describe continuous variables of secondary outcomes. Student's *t* test was used to compare these variables between groups. Furthermore, frequency and percentages were used to describe categorical variables of the secondary outcomes, and Fisher's exact test was used to compare these frequencies between groups. Bonferroni correction was applied in POP-Q system measurements due to the multiple comparisons of data.

Results

A total of 128 out of 254 potentially eligible patients with an anterior vaginal wall descent stage III or IV and a uterus or a vaginal vault POP stage II or III (apical POP) were included (Fig. 1). The randomisation process was adequate, with no statistically significant differences between the two groups at baseline (Table 1). Patients with a history of prolapse-related hysterectomy presented a shorter TVL than patients without previous hysterectomy (7.5 ± 1.3 cm with previous hysterectomy and 8.2 ± 1.1 cm without previous hysterectomy; $p = 0.03$). Four women were lost to follow-up (3%), 2 from each group.

Considering the main outcome (Table 2), anatomical success was achieved in 79 and 76% of the patients with LSC-Cx and AVM kit respectively, when the plane of the hymen was considered to be the anatomical reference limit for success [18]. However, the anatomical success rate dropped to 53% in the LSC-Cx and 45% in AVM kit group, when the limit was POP-Q points less than −1 cm [15], without statistically significant differences between groups. Subjective success was greater, with similar 1-year reintervention rates. Therefore, the composite surgery success was also similar in the two groups (Table 2). Measurements of all the points of the POP-Q system were compared at baseline, and at 3, 6, and 12 months after surgery (Fig. 2). No statistically significant differences were found among POP-Q anterior vaginal wall points (Aa, Ba) between groups, whereas better results were obtained with LSC-Cx at posterior vaginal wall points (Ap, Bp) and TVL compared with the AVM group. The statistically significant differences observed in the study related to the TVL between LSC-Cx and the AVM kit were not seen on analysing the subgroup of patients with vaginal vault prolapse and a history of prolapse-related hysterectomy (6.8 ± 0.8 cm in the LSC-Cx group and 7.1 ± 1.4 cm in the AVM arm). However, this result has little statistical power because of the small sample size of these sub-groups (10 in LSC and 11 in AVM).

With regard to intraoperative outcomes, LSC-Cx surgery was 30 min longer than application of the AVM kit (78.05 min vs 44.28 min respectively; $p = 0.0001$; Table 3). Concomitant surgery included 50 hysterectomies and 26 suburethral slings for the LSC-Cx group, whereas 49 hysterectomies, 17 suburethral slings and 1 sling section were performed in the AVM kit group. No statistically significant differences were found between groups regarding the rest of the intraoperative outcomes. One bladder perforation (code 4A-T1) [20] occurred in each group and 1 vaginal perforation was observed in one woman during the LSC-Cx, preventing the placement of the vaginal mesh. The AVM group presented 1 case of vault haematoma (code 7A-T2-S2) [20], which did not require drainage, and 1 right ovarian tube abscess, which required laparoscopic bilateral salpingo-oophorectomy without removing the mesh. Two women required blood transfusion, one per study arm.

The preliminary results of the secondary follow-up outcomes were analysed later (Table 4). No statistically significant differences were found between groups on comparing the pain score and de novo stress UI. Two of the 7 patients with de novo USUI required reintervention with a suburethral sling. The remaining patients with mild symptoms of stress UI (with ICIQ-UI-SF <5) were referred for pelvic floor physiotherapy. Up to 7 of these patients (19%) were referred for de novo dyspareunia in the AVM kit group, compared with only 3 out of 43 (7%) in the LSC-Cx group. However, these differences were not statistically significant ($p = 0.09$, NS). Among 7 patients with dyspareunia at baseline, 2 out of 3 patients in the LSC-Cx group reported postoperative remission of dyspareunia compared with 2 out of 4 patients in the AVM kit group. Moreover, in 2 women in the AVM group, this symptom was maintained after surgery.

Statistically significant differences were found between LSC-Cx and the AVM kit regarding the global PFDI-20 and its three subscales. Nevertheless, on analysing improvement in the questionnaire score (Table 4), no differences were found between groups considering UDI-6 and POPDI-6. On the other hand, worse results were found in CRADI-8 improvement in the LSC-Cx, in relation to the question on constipation symptoms ("Do you feel the need to strain too hard to have a bowel movement?"). Up to 6 patients (10%) answered "moderately" or "quite a bit" in the LSC-Cx group, compared with only 1 (2%) in the AVM group ($p < 0.05$).

All patients expressed satisfaction with the surgery except for one woman in the LSC-Cx group (0.8%), who required a section of the sub-urethral sling for postoperative voiding dysfunction. In addition, she described pelvic pain apparently unrelated to POP surgery.

Finally, with regard to late postoperative complications, mesh exposure was observed in 3 women in the LSC-Cx group compared with 6 patients in the AVM kit group (NS). LSC-Cx mesh exposures were at the suture of the posterior mesh in the posterior vaginal wall, normally involving the threads of the suture. In contrast, AVM kit exposures occurred at the site of the colporrhaphy. No cases of mesh extrusion were detected at 1 year of follow-up in either group. Up to 4 reinterventions were performed in the LSC-Cx group: 1

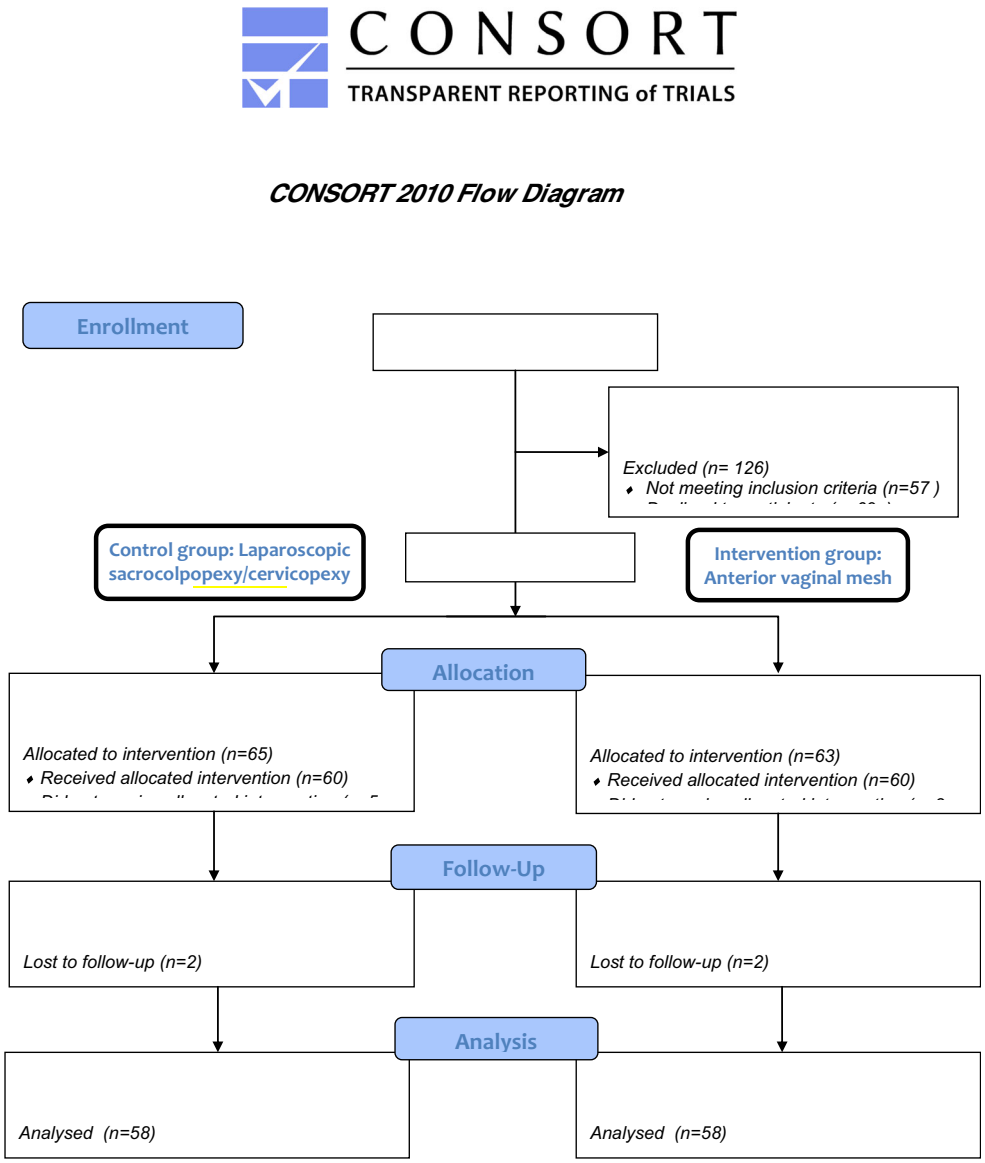

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram

patient with intraoperative vaginal perforation required one intervention due to evisceration and a second intervention with AVM to repair the POP. One patient required another laparoscopy to free a mesh with excessive tension and a bowel hernia. One posterior mesh was partially and successfully removed vaginally because of chronic pain. The remaining procedure was a sling section due to voiding dysfunction. In the AVM kit group, a total of 8 reinterventions were required (2 patients with two procedures): 1 patient with intraoperative haematoma required new surgery for mesh exposure, similar to 1 patient with a pelvic abscess; 2 more patients required covering mesh exposure, 1 with a posterior POP repair associated with the exposure (posterior native tissue repair), and another with a retropubic sling. One woman also required posterior repair because of a symptomatic stage III posterior vaginal wall prolapse (rectoenterocele). One mesh was released and a LSC-Cx was required afterwards. The 2 patients with severe de novo stress UI underwent a retropubic midurethral sling procedure.

Discussion

The main finding of this prospective RCT is that the anatomical success rate of the AVM kit with BFSL was not inferior to LSC-Cx in the treatment of patients with severe anterior compartment predominant POP associated with an apical POP (uterus or vaginal vault prolapse).

According to previous studies, women with preoperative POP stage III are at a significantly higher risk of recurrence after POP surgery than those with stage II, with an OR 2.7 (1.3–5.3) [7–9]. A Cochrane review [22] reported that women are less likely to have POP symptoms or measurable POP and fewer require repeat POP surgery after repairs with synthetic

Table 1 Demographic and baseline outcomes of the two study groups: laparoscopic sacrocolpopexy/cervicopexy (*LSC-Cx*) and anterior vaginal mesh (*AVM*) kit with bilateral fixation to sacrospinous ligament

	LSC-Cx ($n = 60$)	AVM ($n = 60$)
Demographic data		
Age at inclusion (± SD) in years	60.8 ± 7.4	63.3 ± 7.2
Body Mass Index (± SD) in kg/m^2	25.7 ± 3.2	26.9 ± 3.6
Number of vaginal deliveries (X ± SD)	2.3 ± 1.1	2.4 ± 1.0
Menopausal patients, *n* (%)	51 (85)	56 (93)
Age of menopause (± SD) in years	50.1 ± 3.7	49.7 ± 3.6
Patients sexually active at baseline, *n* (%)	43 (72)	37 (62)
Patients with dyspareunia at baseline	3 (7)	4 (10)
Patients with history of prolapse-related hysterectomy, *n* (%)	10 (17)	11 (18)
Questionnaire outcomes		
Prolapse pain score (0–10; ± SD)	1.3 ± 2.9	2.1 ± 3.4
PFDI-20 (0–300; ± SD)	90.1 ± 51.4	95.7 ± 55.1
UDI-6	37.9 ± 29.8	36.3 ± 26.7
CRADI-8	8.4 ± 11.5	9.8 ± 14.5
POPDI-6	43.9 ± 24.1	49.6 ± 25.4
ICIQ-SF (0–21; ± SD)	6.0 ± 6.4	4.8 ± 6.8
Urodynamics		
Patients with voiding dysfunction, *n* (%)	9 (15)	6 (10)
Patient with stress urinary incontinence, *n* (%)	26 (43)	19 (32)
Physical examination (POP-Q system)		
Anterior prolapse stage (± SD)	3.0 ± 0.0	3.0 ± 0.0
Apical prolapse stage (± SD)	2.2 ± 0.9	2.4 ± 1.0
Posterior prolapse stage (± SD)	1.2 ± 1.1	1.2 ± 1.3

No statistically significant differences were found in any parameter

SD standard deviation, *PFDI-20* Pelvic Floor Distress Inventory-20, *UDI-6* Urinary Distress Inventory 6, *CRADI-8* Colorectal Anal Distress Inventory 8, *POPDI-6* Pelvic Organ Prolapse Distress Inventory 6, *ICIQ-UI-SF* International Consultation on Incontinence Questionnaire-Short Form

non-absorbable mesh than after a native tissue repair. However, there was insufficient evidence to determine whether these women had a better quality of life. The authors concluded that meshes should only be used in the context of trials or in defined categories of high-risk women [3]. Although most of our patients with an indication of POP surgery undergo vaginal native tissue repair, we consider that meshes are necessary in patients with a high risk of recurrence, such as those included in the present study.

Results of anatomical outcomes are shown in this work and it is widely accepted that follow-up evaluations are performed 1 year after surgery. Nevertheless, this is an ongoing study, and the authors acknowledge that a longer follow-up is compulsory to evaluate complications related to mesh surgery.

The anatomical success rate of LSC-Cx and the AVM kit with BFSL was similar in the treatment of POP. Our results can be compared with five studies comparing meshes using the laparoscopic and vaginal approach: Maher's RCT for vault prolapse [15]; Sanses's retrospective review [23]; PROSPERE-RCT [24, 25]; Gutman et al.'s cohort study mesh hysteropexy [26]; and the recently published Australian retrospective cohort [27].

Comparison between the RCT by Maher et al. and the present study should be interpreted with caution, because the study by Maher et al. only included patients with vault prolapse whereas the present study included more than 80% of patients with primary surgery with uterus. In addition, total vaginal mesh was performed in the vaginal mesh arm, whereas only an anterior mesh kit with BFSL was applied in the present study. Taking into account their stricter anatomical success criterion, our overall 53% anatomical success rate of the LSC-Cx was lower than the outcome of 77% reported by Maher et al. [15]. The omission of the paravaginal repair from our LSC-CS arm may explain these differences. Conversely, the 43% reported by Maher et al. for the vaginal mesh group is almost identical to the 45% in our study. Considering Barber et al.'s anatomical success criterion, our results are comparable with those of other mesh series [26, 28, 29]. The results of Gutman et al. were very similar to ours: laparoscopic and vaginal hysteropexy patients showed no differences in anatomical (77% vs 80% respectively), symptomatic (90% vs 95%) or composite (72% vs 74%) cure. The 85.8% composite success rate for LSC-Cx for primary POP surgery in the PROSPERE-RCT [24, 25] and 88.2% for vaginal mesh repair were higher

Table 2 Percentages of women with anatomical and subjective success at 1 year, comparing LSC-Cx and AVM kit surgical techniques, *n* (%). Data were analysed considering anatomical success defined as vaginal apex descent no more than one third into the vagina or anterior or posterior vaginal wall not beyond the hymen (column no. 1) and POP-Q sites Aa, Ba, C, Bp and Ap defined as less than −1 cm individually and as a total (column no. 2). Statistically non-significant differences were found between groups

	POP-Q sites = 0		POP-Q sites ≥1	
	LSC-CS ($n = 58$)[a]	AVM ($n = 58$)[a]	LSC-CS ($n = 58$)[a]	AVM ($n = 58$)[a]
Anatomical success, *n* (%)	46 (79)	44 (76)	31 (53)	26 (45)
Apical success, *n* (%)	57 (98)	55 (95)	57 (98)	55 (95)
Anterior success, *n* (%)	50 (86)	51 (88)	34 (58)	32 (55)
Posterior success, *n* (%)	56 (97)	50 (86)	52 (90)	46 (79)
Subjective success, *n* (%)	57 (98)	54 (93)	57 (98)	54 (93)
Reintervention for POP recurrence, *n* (%)	1 (2)	3 (5)	1 (2)	3 (5)
Composite surgery success, *n* (%)	46 (79)	44 (76)	31 (53)	26 (45)

[a] Two patients of each group were missing because of loss to follow-up

than in our study, probably due to the preoperatively more advanced POP stage of our patients (stage ≥III), while in the PROSPERE-RCT a considerable proportion of patients had stage II (24.6% in LSC and 19.7% in vaginal mesh group) [25]. Finally, the recent 97% objective cure rate reported by the Australian group [27] should also be interpreted with caution: the objective cure was defined as the absence of descent beyond the hymen in any compartment, whereas it was defined as vaginal apex descent no more than one third into the vagina in the present study. Additionally, up to 55% of patients with LSC-Cx and 26% of patients with Elevate® underwent a concomitant native tissue repair during the mesh surgery [27].

On analysing the data by compartments, correction of the anterior compartment was similar with both techniques. Abdominal sacrocolpopexy/hysteropexy has been reported to provide good apical support, but is associated with recurrent anterior POP (51–61%) [30, 31]. Our RCT was very successful in anterior compartment repair with both techniques. This is especially relevant when considering that we included only patients with stage III or greater anterior vaginal wall POP, whereas most studies also include women with stage II anterior compartment defects [22]. Therefore, our results of points Aa and Ba are not comparable with those of other studies.

The TVL was longer in the LSC-Cx than in the AVM kit group, similar to other studies [15, 23, 25–27]. The optimal correction of the apical compartment in the AVM group was of note, despite the shorter TVL.

The correction of the posterior compartment by AVM kit showed a trend towards being less successful than that by LSC-Cx. Nevertheless, these results for the posterior compartment are not comparable with those of the Australian retrospective study [27] because up to 66% of women underwent anterior and posterior vaginal mesh, or posterior native tissue repair, whereas only anterior vaginal mesh was used in the present study to determine the effect of both surgeries on the posterior compartment. We only had 4 patients with Ap and Bp >1 at baseline (3 in the LSC-Cx group and 1 in the AVM group). None of these patients required reoperation for posterior POP.

The high rate of subjective success and the low rate of prolapse-related reintervention of the present study confirm the need to consider a less strict criterion of success, according to the definition by Barber et al. [18].

There were no differences in the majority of intraoperative parameters, similar to previous studies [25–27]. However, a significantly longer procedure time was observed in the LCS-Cx compared with the AVM kit and also for the concomitant procedures. Nonetheless, the operating time was shorter than in previous studies [15, 26, 27], especially for the LSC-Cx procedure.

Validated questionnaires showed significant postoperative compared with preoperative improvement in symptom severity with both LSC-Cx and AVM, according to other studies [15, 25, 26]. Similar results in urinary function were found in both groups, in concordance with the RCT by Maher et al. The number of patients presenting de novo detrusor overactivity was higher in the LSC-Cx group (8 vs 2 patients in the AVM kit group). Nevertheless, 5 out of 8 women underwent a concomitant sub-urethral sling and symptoms could be associated with this sling.

De novo dyspareunia was more frequent, albeit not significantly, in the AVM kit than the LSC-Cx group (19% vs 7% respectively). These data are very similar to those of the PROSPERE study (19% vs 8%). Gutman et al.'s groups were not comparable in this respect because of the differences in age at baseline (non-RCT). The most painful points during the physical examination of patients after the AVM kit procedure were scarring of the colporrhaphy and the insertion of the harpoons into the sacrospinous ligament. However, some women who complained of pain at the harpoon site did not report de novo post-operative dyspareunia. Further studies

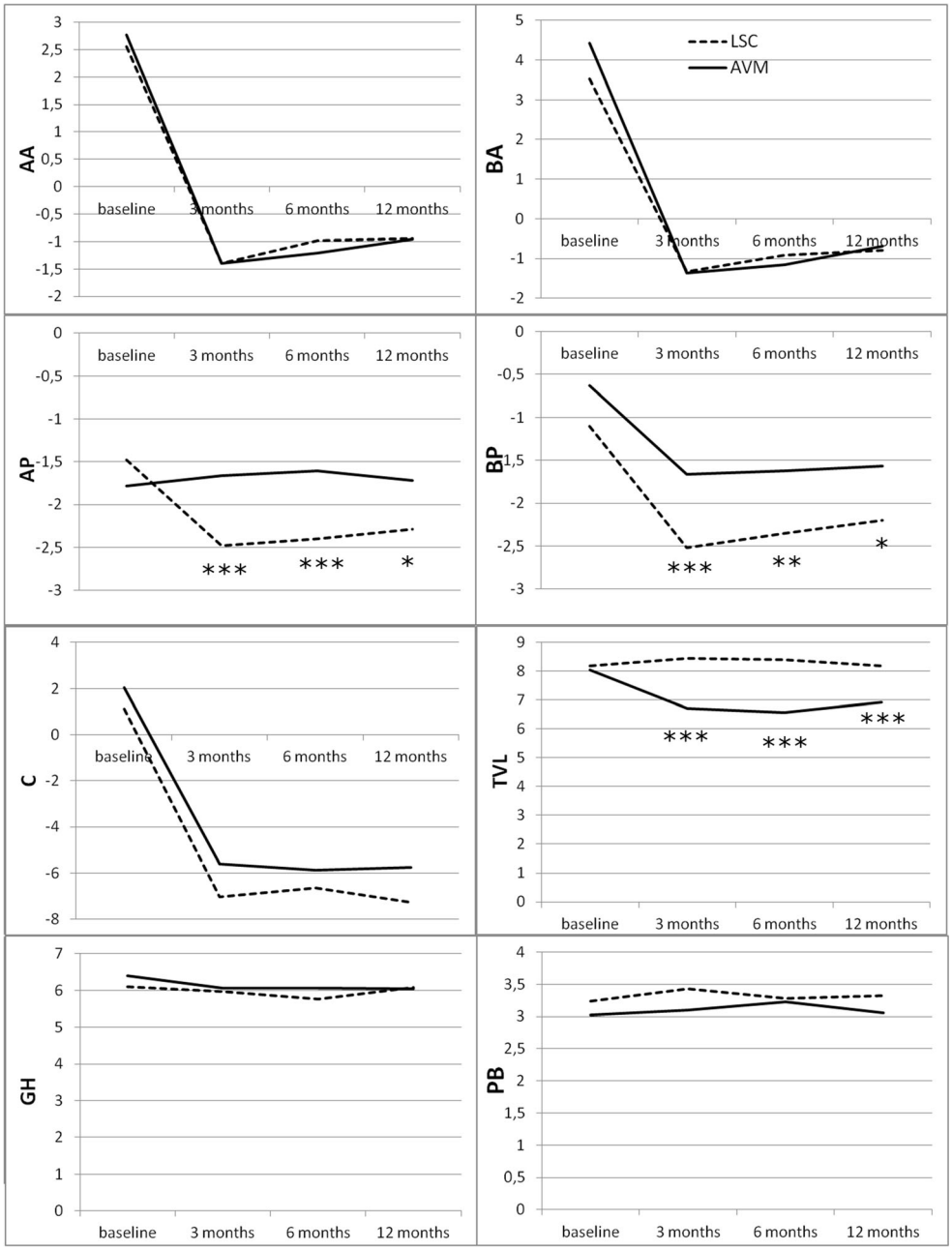

Fig. 2 Measurements of all the points of the POP-Q system were compared at baseline, and at 3, 6 and 12 months after surgery

with long-term follow-up and enough power to study this issue in depth are needed.

Pelvic floor symptoms evaluated using the PFDI-20 improved with both procedures, similar to other studies [15, 25, 26]. However, worse results were obtained in the global PFDI score in the LSC-Cx group, owing to constipation symptoms reported in the CRADI-8. The anchoring of the mesh to the levator ani muscles could likely explain CRADI-8 changes.

Preliminary results showed both groups to have a similar reintervention rate, classified in our analysis by POP recurrence, mesh complications or related to UI. The cases of mesh exposures were two-fold those in the AVM group (6 out of 60, 10%), but only 3 required reintervention (5%), with the remaining cases being very mild and asymptomatic. No reinterventions due to pain symptoms were needed. This 5% is in concordance with reported rates of mesh exposure (2–6.5%) [17, 26, 27], and lower than the results by Maher et al. with AVM, which required up to 22% reintervention [15]. The reintervention rate in the PROSPERE study (1% for LSC and 9% for AVM) [25] was also in concordance with our results owing to POP recurrence or mesh complications (5% for LSC-Cx and 10% for AVM).

Finally, it is important to point out that the data of this RCT are not extrapolatable to all vaginal mesh kits. The mesh design, volume, density, and anchoring technique of the AVM type

Table 3 Intraoperative outcomes of LSC-Cx vs AVM kit with bilateral fixation to the sacrospinous ligament

	LSC-Cx ($n = 60$)	AVM ($n = 60$)	p
Main surgery operating time[a] (± SD) min	78.1 ± 35.0	44.3 ± 18.4	< 0.001
Concomitant surgery operating time (± SD) in min	47.8 ± 24.9	31.4 ± 13.8	< 0.001
Hysterectomy operating time (± SD) in min	41.3 ± 24.8	27.3 ± 13.7	< 0.001
Suburethral sling operating time (± SD) in min	15.0 ± 0.9	14.5 ± 1.0	NS
Patients with concomitant suburethral sling for stress urinary incontinence, *n* (%)	26 (43%)	17 (28%)	NS
In-patient stay (± SD) in days	2.0 ± 0.6	2.2 ± 1.5	NS
Urethral catheterization days (± SD)	2.2 ± 4.1	2.2 ± 2.8	NS
Preoperative haemoglobin[b] values (± SD) in g/dl	13.3 ± 1.0	13.6 ± 1.0	NS
Postoperative haemoglobin[c] values (± SD) in g/dl	11.6 ± 1.1	12.0 ± 1.2	NS
Patients with intraoperative complications[d], *n* (%)	3 (5%)	4 (7%)	NS

SD standard deviation

[a] From knife to skin

[b] 1 month before surgery

[c] 24 h after surgery

[d] Intraoperative complications included: bladder or bowel injury, haemorrhage >400 ml, blood transfusion, urinary tract or surgical bound infection, urinary retention (need for bladder catheterisation >2 weeks after surgery), incision hernia, vaginal haematoma and readmission to the hospital within 30 postoperative days

Elevate® Anterior and Apical may account for the differences in anatomical results, mesh exposure rate or other complications published in the literature. Although Elevate® Anterior and Apical is no longer available, there are vaginal meshes with similar characteristics. Therefore, these results may be useful for surgeons using other types of mesh kits with BFSL.

As the present RCT was not a multicentre study, one of the main strengths of the study is that only two expert surgeons performed all the procedures with a well-standardised technique (one for each arm), with no relationship with either patient selection or follow-up. Although this could be a weakness in terms of its generalisability to the broader pool of surgeons, the authors considered that the complications and success of this type of surgery are highly related to the surgeon's experience and the technique used. Likewise, the two expert urogynecologists performing the selection and follow-up visits were not related to the interventions, avoiding examiner bias. Moreover, the loss of patients to follow-up (3%) was clearly lower than that expected in an RCT. Finally, another limitation could be that the sample size was based on sacral colpopexy data with a reference that only included vault instead of uterine POP. To our knowledge, this is the first RCT

Table 4 Questionnaire follow-up outcomes comparing the two surgical techniques: LSC-Cx and AVM

	LSC-Cx ($n = 58$; $n = 34$)	AVM ($n = 58$, $n = 43$)
Questionnaires outcomes		
POP pain score (0–10; ± SD)	0.5 ± 1.5	0.3 ± 1.3
PFDI-20 improvement (0–300; ± SD)	64.6 ± 54.6	82.4 ± 54.1
UDI-6 improvement	25.5 ± 30.6	29.6 ± 26.4
CRADI-8 improvement	−0.2 ± 13.8*	6.8 ± 13.4*
POPDI-6 improvement	39.5 ± 26.4	46.1 ± 26.1
ICIQ-SF (0–21; ± SD) improvement	2.6 ± 6.0	2.7 ± 7.0
De novo dyspareunia, *n* (% of sexually active at baseline)	3 (7)	7 (19)
Stress urinary incontinence de novo, *n* (%)	2 (3)	4 (7)
De novo detrusor overactivity, *n* (%)	8 (14)	2 (3)
Urinary function excluding patients with concomitant suburethral sling		
PFDI-20 (0–300; ± SD)	51.2 ± 52.6	72.8 ± 51.7
UDI-6	14.2 ± 25.3	21.0 ± 21.0
ICIQ-SF (0–21; ± SD)	0.3 ± 4.6	0.2 ± 4.6

* $p < 0.05$

POP pelvic organ prolapse,

to compare these two surgical techniques including only patients with combined anterior and apical defects (at least stage III for the anterior compartment and stage II for the uterine or vaginal vault prolapse), meaning that our study focused on a sub-group of patients with a high risk of recurrence.

The results of this study demonstrate that the benefits of mesh surgery should be evaluated in all patients with high-grade POP (primary surgery or recurrence), and the type of surgical approach should be tailored to the characteristics of the patients and their expectations and needs.

In conclusion, for patients with advanced anterior vaginal wall descent associated with an apical POP, anatomical correction using AVM kits with BFSL shows similar results to those of LSC-Cx, when evaluation is based on questionnaires or the POP-Q system. Better results are obtained with LSC-Cx in the posterior compartment. The apical compartment descent can be successfully corrected vaginally, although TVL and point C are higher in the LCS-Cx. These preliminary results demonstrate that the number of complications and reinterventions in both groups were similar, and none was life-threatening at 1-year follow-up.

Acknowledgements We would like to thank Dr Lluís Aragonès for his contribution to the statistical analyses.

Funding The Elevate® Anterior and Apical kits were donated by AMS as a grant for the study without any other support or supervision.

Compliance with ethical standards

Conflicts of interest Dr Bataller was a consultant for AMS (Astora, women's health). The remaining authors claim no conflicts of interest.

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