Original article

Comparison to sacrospinous fixation versus infracoccygeal sacropexy in vaginal vault prolapse at 2-year follow-up

EDGARDO CASTILLO-PINO[1], CÉSAR CANESSA[2], WASHINGTON LAURÍA[3]

[1] *Urogynecology and Pelvic Floor Unit. Department of Obstetrics and Gynecology. University of the Republic. School of Medicine. Clinical Hospital Montevideo. Uruguay*
[2] *Department of Surgery. University of the Republic. School of Medicine. Clinical Hospital Montevideo. Uruguay.*
[3] *Department of Obstetrics and Gynecology. University of the Republic. School of Medicine. Clinical Hospital Montevideo. Uruguay.*

Abstract: Objective: The aim of this study was to compare the efficacy, outcomes and complications of sacrospinous ligament fixation (SSLF) with native tissue repair and infracoccygeal sacropexy with transvaginal mesh (TVM) in the management of vaginal vault prolapse. *Material and Methods:* We recruited 63 women with stage 3, or greater prolapse, according to the pelvic organ prolapse quantification (POP-Q) system, requiring surgical correction. They were randomized in two groups: SSLF (n = 31) and TVM (n = 32). The primary outcome was the absence of POP-Q stage ≥3 prolapse at 24 months, and secondary outcomes were perioperative events, complications and reoperations. The participants were followed for the next 2 years, with scheduled evaluation. *Results:* Clinical and demographic data did not differ significantly between the two treatment groups. Success in the TVM group was 84.3% (27/32) compared to 61% (19/31) in the SSLF group. Although there was not statistically significant differences between the groups, the prolapse recurrence trend was lower in the TVM group (RR 0.73). Recurrent prolapse occurred most frequently in the vaginal anterior wall (14.3%). The mesh exposure rate was 9.3%. Neither serious adverse events nor deaths occurred in either group. *Conclusion:* Our results showed that vaginal repair with mesh surgery was more successful in terms of reducing recurrent prolapse than the traditional sacrospinous colpopexy, 24 months after surgery.

Keywords: Native repair tissue; Pelvic organ prolapse; Sacrospinous fixation ligament; Surgical mesh; Vaginal vault suspension.

INTRODUCTION

Pelvic organ prolapse may occur in up to 50% of parous women[1]. The lifetime risk of undergoing stress urinary incontinence (SUI) or pelvic organ prolapse (POP) surgery by the age of 80 is 20%[2].

An increased prevalence of pelvic organ prolapse is estimated in the coming years. The result is more corrective surgeries and higher costs related to women's health care[3]. The precise incidence of vaginal vault prolapse after hysterectomy is difficult to define and was estimated to range from 0.2-43%[4,5].

The International Continence Society (ICS) defines apical vaginal prolapse as a descent of the vaginal cuff scar below a point that is 2cm less than the total vaginal length above the plane of the hymen[6].

Vaginal vault prolapse treatment is surgical and supports several approaches (abdominal, vaginal or laparoscopic) and different repair strategies, with synthetic mesh or with the patient's own tissues.

Sacrocolpopexy has proven an effective surgical treatment for apical vaginal prolapse, with 90% long-term success rates[7,8,9].

The safety and effectiveness of synthetic mid-urethral slings influenced the introduction of transvaginal mesh for pelvic organ prolapse. Transvaginal mesh placement kits using needles for bilateral fixation to ligaments sacrospinous were introduced in 2004 to create a hammock supporting the apex and anterior or posterior vaginal walls (depending on placement) and avoid abdominal surgery[10].

In July 2011, the U.S. Food and Drug Administration[11] issued a security statement noting that "serious complications associated with surgical mesh for vaginal repair of pelvic organ prolapse are not rare". They also add "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair"[12]. This has prompted responses and publications by many experts that transvaginal mesh can have some value because of the risk of recurrent prolapse after repairswith each patient's own local tissue[12,13,14].

Therefore, our study sought to compare, at a 2-year follow-up, the efficacy, outcomes and complications of two techniques for the treatment of vaginal vault prolapse: sacrospinous ligament fixation (SSLF) colpopexy with native tissue repair and infracoccygeal sacropexy with transvaginal mesh (TVM).

MATERIALS AND METHODS

This trial included women clinically diagnosed with vaginal vault prolapse stage 3 or greater -according to pelvic organ prolapse quantification (POP-Q)- who were candidates for reconstructive surgery for vaginal apical prolapse. The study was approved by the ethics committee and conducted at the Medical School of the University of the Republic, Montevideo, Uruguay, from October 2012 to October 2015.

The inclusion criteria were women with asymptomatic or symptomatic POP-Q stage ≥3 vault prolapse who had given their informed consent. Exclusion criteria included recurrent prolapse, vaginal or urinary infection in progress with diabetes, coagulopathies, anticoagulant therapy or vaginal length less than 6cm or more than 12cm, and patients who do not give their informed consent.

The allocation process was conducted by computer using a sample randomization the day before surgery. The participants were assigned to an SSLF or a TVM group and informed of their allocation before the procedure. Both procedures were performed by two surgeons from the surgical team with a previous learning curve.

All the patients were examined with the POP-Q system and underwent urodynamics with prolapse reduction. Participants with a positive stress test were considered as having occult stress urinary incontinence (OSUI).

We prefer to use a preoperative vaginal oestrogen cream for 4 weeks. Prophylactic antibiotics were given perioperatively (3g of intravenous ampicillin/sulbactam).

Anaesthesia was epidural, except in patients with contraindications or technique failure, in which case general anaesthesia was administered. Operating time was from colpotomy to cessation of colporrhaphy.

Unilateral sacrospinous colpopexy (SSLF) is suitable for restoration of a functional vagina[15,16]. A longitudinal inci-

sion is made in the posterior vaginal vault. Either the right or left rectal pillar, which separates the rectovaginal space from the pararectal space, is penetrated by blunt or sharp dissection. The opening in the rectal pillar is widened, exposing the superior surface of the pelvic diaphragm, including the coccygeus muscle, which contains the sacrospinous ligament.

A Breisky-Navratil retractor can be placed medially to mobilize and protect the rectum and expose the deeply located sacrospinous ligament. Any anchoring suture to the ligament should be performed 1-2cm medial to the ischial spine toavoid trauma to pudendal nerve and vessels. Weusually perform vaginal apical suspension unilaterally to the right sacrospinous ligament. Using a long needle holder with non-absorbable monofilaments sutures (Prolene ®) two threads are passed through the coccygeus muscle and the sacrospinous ligament at the predetermined point. The two sutures are placed in the vaginal wall avoiding catching the mucosa, and more than 1cm of the suture line.

After enterocele and rectocele repair and vaginal wall closure, the non-absorbable sutures fix the vaginal wall to the sacrospinous ligament. The previously placed sutures in the sacrospinous ligament are tied individually with the vaginal apex directed under finger guidance to the uppermost position.

Infracoccygeal sacropexy with mesh(TVM) was initially described as a minimally invasive surgical option to restore vaginal vault support[17,18]. A longitudinal incision is made in the posterior wall of the vagina. Make the pararectal dissection towards the ischiatic spine and palpate it with the index finger. Then, make a punctiform cutaneous incision in the gluteus, 3cm lateral and 3cm down from the anus, on both sides. Introduce the trocar through two small incisions into the ischiorectal fossa and through the levator ani muscles towards the 1-cm medial ischial spine.

Introduce a mesh tape onto the trocar tip and pull it back through the trocar's path. Perform a similar passage on the opposite side. Suture the intravaginal polypropylene mesh to the apex of the vagina with non-absorbable and fixed without tension. Pull the arms until the vagina is in anatomic position. Cut the mesh excess at perineal body level and cut the excess from the arms. The vaginal epithelium is closed. We used kit-Nazca R ® synthetic mesh (Promedon, Córdoba, Argentina). The kit includes one synthetic mesh (permanent implant involving polypropylene monofilament central mesh between two arms of the same material), and two posterior needles designed for use with the mesh implantation.

Colpopexy techniques were associated with anterior colporrhaphy in 33% and midurethral sling in 11% of the patients. All patients underwent perineorrhaphy. All participants had the indwelling urethral catheter removed 48 hours after surgery and the vagina is packed with moist gauze for 24 hours.

The participants were monitored for the next 2 years, with scheduled evaluations six weeks, then 3, 6, 12 and 24 months after surgery. At each evaluation, the women were interviewed regarding spontaneous micturition and lower urinary tract symptoms, defecation and bowel dysfunction pelvic pain, buttock pain and postoperative dyspareunia.

The outcomes measured were objective success rates at POP-Q point C defined as - 1cm and 0 postoperatively, frequency of complications and recurrent prolapse, and reoperations. Recurrent prolapse was defined as any POP-Q point C beyond the hymen 12 months after surgery, or any POP reoperation within 12 months after surgery.

We initially estimated 58 patients were required for an 80% chance -a significant 5% level- of detecting an increase in the primary outcome measure from 60% in the SSLF group[5,21] to 90% in the TVM group.

The statistical analysis was performed with SPSS 18.0 version (SPSS Chicago, IL USA) using Fisher's exact test, X2 test, relative risks (RRs) with 95% confidence intervals (CIs) and test for independent samples $P<0.05$ considering what was statistically significant.

RESULTS

Seven of 72 patients screened did not meet the inclusion criteria, 2 women refused to take part in the study and 63 patients consented and were randomized. Thirty-one underwent SSLF and 32 TVM and were followed up for 24 months. There was no loss to follow-up.

Both groups were similar in demographics and preoperative variables, as seen in Table 1.

The mean age was 58 years (range 47-72) in the SSLF group and 56 years (range 45-70) in the TVM. 74% and 68.75% of the SSLF and TVM groups respectively were in their menopause. Vaginal parity > 2 was 80% and 75% of the SSLF and TVM groups respectively.

All the patients had had a previous hysterectomy, 35% through vaginal and 65% through abdominal access. Posterior compartment defects were more frequent than anterior compartment (cystocele 33%, rectocele 46% and enterocele 54%).

There was no difference in age, parity, body mass index (BMI), menopause status, previous hysterectomy surgery, apical defects and follow-ups, or in preoperative scores for any urodynamic parameters between the groups.

Epidural anaesthesia was used in 93. 5% of the SSLF procedure and 90.6% of the TVM procedure, and general anaesthesia was used in 6.5% of SSLF cases and 9.4% of TVM cases.

Mean operating time was significantly shorter in the TVM group than in the SSLF group (23 minutes versus 45 minutes; $p< 0.01$). Hospital discharge occurred within 72 hours.

Perioperative complications for procedures are listed in Table 2.

Perioperative complications in the SSLF group included one bladder injury repaired intraoperatively without sequelae. Two patients in the SSLF group and one patient in the TVM group were transfused perioperatively, and 6 women

TABLE 1. Participant characteristics.

Variable	SSLF group (n= 31)	TVM group (n=32)	P value
Age (years)	58 (SD 7.54)	56 (SD 7.67)	0.571
Status menopause	23 (74)	22 (68,75)	0.836
BMI (kg/m^2)	27,79 (SD 2.67)	26,92 (SD 2.90)	0.219
Vaginal parity > 2	25/31 (80)	24/32 (75)	0.590
Prior hysterectomy vaginal	10/31(32.3)	12/32 (37.5)	0.663
Prior hysterectomy abdominal	21/31 (67.7)	20/32 (62.5)	0.663
Cystocele	11/31(35.4)	10/32 (31.3)	0.530
Rectocele	16/31 (51.6)	13/32 (40.6)	0.707
Enterocele	18/31 (58)	16/32 (50)	0.348
Occult SUI	4/31 (13)	3/32 (9,4)	0.656

Abbreviations: SUI, stress urinary incontinence; POP, pelvic organ prolapse; BMI, body mass index; SSLF, sacrospinous ligament fixation; TVM, transvaginal mesh.

TABLE 2. Complications at 24 months following surgery.

Complication	SSLF group (n= 31)	TVM group (n=32)	P value*
Significant Hemorrhage	2 (6.45)	1 (3.12)	0.613
Urinary infection	3 (9.67)	3 (9.37)	1.000
Bladder injury	1 (3.22)	0	0.492
OAB "de novo"	3 (9,7)	3 (9,4)	1.000
SUI "de novo"	1 (3,2)	1 (3,1)	1.000
Postoperative ileus	2 (6.45)	1 (3.12)	0.613
Pelvic pain	2 (6.45)	1 (3.12)	0.613
Buttock pain	1 (3.22)	3 (9.37)	0.613
Dyspareunia "de novo"	2 (6.45)	4 (12.5)	0.672
Stenosis vaginal	2 (6.45)	1 (3.12)	0.613
Mesh exposure	0	3 (9.37)	0.238

Abbreviations: SSLF, sacrospinous ligament fixation; TVM, transvaginal mesh; OAB overactive bladder, SUI, stress urinary incontinence. * Test de Fisher.

with urinary tract infection were recorded, 3 in each group (Table 2). Subsequently demonstrated by a positive uroculture study. Escherichia Coli was the most commonly isolated germ (4 cases). All patients improved with antibiotics according to the sensitivity of the antibiogram.

Eight out of 63 patients presented urinary incontinence. Six of them were cases of "de novo" overactive bladder and 2 "de novo" stress urinary incontinence (SUI), understood as previously continent patients developing symptoms of stress incontinence after reparative prolapse surgery.

Only one patient in the SSLF group (1/31) presented buttock pain (3.2%) and three patients (3/32) in the TVM group (9.37%). Buttock pain was self-limited and never lasted over 4 weeks after intervention. All patients improved with oral analgesics.

Forty-six of the 63 cases were sexually active. "De novo" dyspareunia and hispareunia were reported in 2 of the SSLF group and 4 of the TVM group. Of 6 cases of dyspareunia, 3 required surgical correction. We observed vaginal stenosis in 2 out of 31 women in the SSLF group and 1 out of 32 in the TVM group. Two of the three vaginal stenosis cases required surgical correction.

The presence of vaginal stenosis and dyspareunia in our patients is attributed to excessive anterior or posterior vaginal wall tissue cutting. There were no vascular, bowel or ureteral injuries, fistulas or lesions to the sciatic nerve. There were three cases of mesh exposure in the TVM group (3/32).

All patients received local oestrogen administration and reoperation for treatment.

Follow-ups averaging two years demonstrated there was a significant reduction in the extent of prolapse according to the POP-Q including point C in both groups compared with preoperative assessment.

The objective success rate (with POP-Q stage 0 or 1 prolapse at all vaginal sites) was 27 of 32 in the TVM group, compared with 19 of 31 in the SSLF group. Prolapse recurrence was reduced in the TVM group (RR: 0.73).

In both groups, recurrent prolapse occurred most commonly in the anterior (10/63 or 15.8%), posterior (7/63 or 11.1%) and apical (4/63 or 6.35%) compartments. Of nine women with recurrences in the posterior compartment (posterior wall and apex), two had undergone open sacral colpopexy and another seven had undergone vaginal repair with mesh.

DISCUSSION

Our results showed that vaginal repair with mesh surgery was more successful in terms of reducing recurrent prolapse than traditional sacrospinous colpopexy 24 months after surgery.

A percentage of recurrence was found in our study with a 24-month follow-up. Distribution by segments: anterior 15.8%, posterior 11.1% and apical 6.35%. In apex vaginal prolapse surgery, reoccurrence is most frequent in the anterior wall. Additionally, 13 of the 31 patients treated by unilateral sacrospinous colpopexy presented recurrent prolapse (42%). One patient was recorded with recurrence in three compartments and another with recurrence in the anterior and posterior compartments. The transvaginal mesh group showed 5 of 32 patients with recurrent prolapse (15.6%).

Complications arising from mesh insertion are well described[1,5]. In our study, the prevalence of vaginal mesh exposure (9.37%) is similar to rates reported for vaginal surgery[1,5]. These cases were resolved by releasing the mesh and vaginal closure. Mesh exposure through vaginal epithelium has been one of the most serious complications reported, with a global frequency of 10%.

The 2013 Cochrane review[1] observed that abdominal sacrocolpopexy was superior to a variety of vaginal procedures with a decreased rate of recurrent vault prolapse. The vaginal approach facilitates pelvic floor relaxation repair, especially colporrhaphy and perineorrhaphy. Nevertheless, sacrospinous colpopexy was shorter to perform and less expensive, with the advantage of early return to daily activities. Early cohort studies of sacrospinous colpopexy show the operations are effective for vaginal apex support[1]. In 243 patients who underwent sacrospinous colpopexy and vaginal repairs, with a 73-month follow-up, showed prolapse recurrence of anterior, posterior, and apical segments was 37.4%, 13.6% and 8.2% respectively[19].

Another matched case-control study comparing iliococcygeus suspension and sacrospinous colpopexy for vaginal vault prolapse reported results equally effective with similar complication rates[20]. The same author found, at 2-year follow-up, in a randomized trial comparing abdominal sacrocolpopexy and vaginal sacrospinous fixation that there was no difference in objective cure rates between the groups[7].

There have been many studies on SSLF, which have revealed a recurrence rate of 2.4% to 19%[5,21]. The advantage of bilateral SSFL is the symmetry of the procedure, which restores anatomy closer to normality with low morbidity and good anatomic and functional subjective results[22].

Withagen et al[23] compared mesh and conventional repair in patients with recurrent prolapse. The failure rate at 1-year follow-up was 45% in the conventional repair group and 10% in the mesh group.

TABLE 3. Participant characteristics.

Outcomes	SSLF group (n= 31)	TVM group (n=32)	RR (95% IC)
Objective success (POP-Q stage ≤l 1)	19 (61)	27 (84,3)	0.73 (0.53-1.00)
Anatomic recurrence of anterior vaginal wall	7 (22.58)	3 (9.37)	2.41 (0.68-8.48)
Anatomic recurrence of posterior vaginal wall	6 (19.35)	1 (3.12)	6.16 (0.79-48.53)
Anatomic recurrence of apical vaginal (Point C ≥ - 1)	3 (9.67)	1 (3.12)	3.10 (0.34-28.19)

Abbreviations: SSLF, sacrospinous ligament fixation; TVM, transvaginal mesh; POP-Q, pelvic organ prolapse quantification.

In a meta-analysis of clinical trials and observational studies evaluating apical prolapse repair, the authors reviewed 3425 patients from 24 studies employing vaginal mesh kits and reported a lower operation rate for recurrent POP (1,3% at 17 months)[24]. The 2016 Cochrane review found limited evidence in the use of transvaginal mesh compared to native repair tissue for apical vaginal prolapse[25].

The strength of our study is that the surgical interventions were performed by only two skilled surgeons. Although our study was implemented as a randomized trial, it may have some limitations. One limitation is that the sample size was not enough to detect the difference that we initially expected. Nevertheless, our data may be considered in future systematic reviews.

In conclusion, our study showed improvements in objective outcomes at 2 years, following transvaginal surgery with mesh augmentation in the apical vault compared to sacrospinous fixation with native tissue repair. The transvaginal mesh had an objective success rate with lower complications and reoperation rate. However, the risk of mesh exposure remains an issue for consideration and evaluation in future. More randomized controlled studies are needed to assess the effectiveness and safety of surgery for vaginal repair with mesh and long-term outcomes.

DISCLOSURE STATEMENTS

The authors have no conflict of interest, informed patient consent was obtained, and the study was approved by the local ethical committee. The authors declared that this study has received no financial support.

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Correspondence to:

Edgardo Castillo Pino - Avenida Italia s/n - Montevideo 11600 Montevideo - Uruguay
E-mail: castillopino@gmail.com