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

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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 POP-Q stage 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 women1. 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 care1. The precise incidence of vaginal vault prolapse after hysterectomy is difficult to define and was estimated to range from 0.2-43%3,4.

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 hymen4.

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 rates5,6,7.

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 surgery8.

In July 2011, the U.S. Food and Drug Administration9 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”10,11. This has prompted responses and publications by many experts that transvaginal mesh can have some value because of the risk of recurrent prolapse after repairs with each patient’s own local tissue10,12,13.

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 vagina13,14. A longitudinal inci-
Comparison to sacrospinous fixation versus infracoccygeal sacropexy in vaginal vault prolapse at 2-year follow-up.

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.

<table>
<thead>
<tr>
<th>Variable</th>
<th>SSLF group (n=31)</th>
<th>TVM group (n=32)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58 (SD 7.54)</td>
<td>56 (SD 7.67)</td>
<td>0.571</td>
</tr>
<tr>
<td>Status menopause</td>
<td>23 (74)</td>
<td>22 (68.75)</td>
<td>0.836</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.79 (SD 2.67)</td>
<td>26.92 (SD 2.90)</td>
<td>0.219</td>
</tr>
<tr>
<td>Vaginal parity &gt; 2</td>
<td>25/31 (80)</td>
<td>24/32 (75)</td>
<td>0.590</td>
</tr>
<tr>
<td>Prior hysterectomy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>10/31(32.3)</td>
<td>12/32 (37.5)</td>
<td>0.663</td>
</tr>
<tr>
<td>Enterocele</td>
<td>21/31 (67.7)</td>
<td>20/32 (62.5)</td>
<td>0.663</td>
</tr>
<tr>
<td>Rectocele</td>
<td>11/31(35.4)</td>
<td>10/32 (31.3)</td>
<td>0.530</td>
</tr>
<tr>
<td>Cystocele</td>
<td>16/31 (51.6)</td>
<td>13/32 (40.6)</td>
<td>0.707</td>
</tr>
<tr>
<td>Occult SUI</td>
<td>18/31 (58)</td>
<td>16/32 (50)</td>
<td>0.348</td>
</tr>
</tbody>
</table>

### Abbreviations: SUI, stress urinary incontinence; POP, pelvic organ prolapse; BMI, body mass index; SSLF, sacrospinous ligament fixation; TVM, transvaginal mesh.
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 6.3%) 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.

Complications arising from mesh insertion are well described. In our study, the prevalence of vaginal mesh exposure (9.37%) is similar to rates reported for vaginal surgery. 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 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, sacrocolpopexy 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.

Another matched case-control study comparing iliococcygeus suspension and sacrospinous colpopexy for vaginal vault prolapse reported results equally effective with similar complication rates. 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.

There have been many studies on SSLF, which have revealed a recurrence rate of 2.4% to 19%.

Withagen et al 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.

**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, recollection 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%).

**Table 2. Complications at 24 months following surgery.**

<table>
<thead>
<tr>
<th>Complication</th>
<th>SSLF group (n=31)</th>
<th>TVM group (n=32)</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Hemorrhage</td>
<td>2 (6.45)</td>
<td>1 (3.12)</td>
<td>0.613</td>
</tr>
<tr>
<td>Urinary infection</td>
<td>3 (9.67)</td>
<td>3 (9.37)</td>
<td>1.000</td>
</tr>
<tr>
<td>Bladder injury</td>
<td>1 (3.22)</td>
<td>0</td>
<td>0.492</td>
</tr>
<tr>
<td>OAB “de novo”</td>
<td>3 (9.7)</td>
<td>3 (9.4)</td>
<td>1.000</td>
</tr>
<tr>
<td>SUI “de novo”</td>
<td>1 (3.2)</td>
<td>1 (3.1)</td>
<td>1.000</td>
</tr>
<tr>
<td>Postoperative ileus</td>
<td>2 (6.45)</td>
<td>1 (3.12)</td>
<td>0.613</td>
</tr>
<tr>
<td>Pelvic pain</td>
<td>2 (6.45)</td>
<td>1 (3.12)</td>
<td>0.613</td>
</tr>
<tr>
<td>Buttlock pain</td>
<td>1 (3.22)</td>
<td>1 (3.97)</td>
<td>0.613</td>
</tr>
<tr>
<td>Dyspareunia “de novo”</td>
<td>2 (6.45)</td>
<td>4 (12.5)</td>
<td>0.672</td>
</tr>
<tr>
<td>Stenosis vaginal</td>
<td>2 (6.45)</td>
<td>1 (3.12)</td>
<td>0.613</td>
</tr>
<tr>
<td>Mesh exposure</td>
<td>0</td>
<td>3 (9.37)</td>
<td>0.238</td>
</tr>
</tbody>
</table>

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 antibiotic.

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 buttlock 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 (9.37%). Buttock pain (3.2%) and three patients (3/32) in the TVM group had mesh exposure through vaginal epithelium (Point C ≥ -1).

**Table 3. Participant characteristics.**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>SSLF group (n=31)</th>
<th>TVM group (n=32)</th>
<th>RR (95% IC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective success (POP-Q stage 0-1)</td>
<td>19 (61)</td>
<td>27 (84.3)</td>
<td>0.73 (0.53-1.00)</td>
</tr>
<tr>
<td>Anatomic recurrence of anterior vaginal wall</td>
<td>7 (22.58)</td>
<td>3 (9.37)</td>
<td>2.41 (0.68-8.48)</td>
</tr>
<tr>
<td>Anatomic recurrence of posterior vaginal wall</td>
<td>6 (19.35)</td>
<td>1 (3.12)</td>
<td>6.16 (0.79-48.53)</td>
</tr>
<tr>
<td>Anatomic recurrence of apical vaginal (Point C ≥ -1)</td>
<td>3 (9.67)</td>
<td>1 (3.12)</td>
<td>3.10 (0.34-28.39)</td>
</tr>
</tbody>
</table>

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)\(^9\). The 2016 Cochrane review found limited evidence in the use of transvaginal mesh compared to native repair tissue for apical vaginal prolapse\(^9\).

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.

**REFERENCES**


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