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## Original Article

# Laparoscopic promontofixation for pelvic organ prolapse: A 10-year single center experience in a series of 501 patients

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**Objectives:** To assess the long-term outcomes of laparoscopic promontofixation (LP) for the treatment of pelvic organ prolapse (POP).

**Methods:** A total of 501 consecutive patients with POP were included in this prospective study. The patients' mean age was 63.23 (36–90) years, their mean body mass index was 25.14 (15–36) and their mean number of deliveries was 3.3 (0–14). A POP grade  $\geq 3$  was diagnosed in 70.4% of the patients and 38.9% of them had a history of abdominal surgery. The patients underwent a Bonney test and urodynamic study. In cases of stress urinary incontinence (SUI), the patients underwent the simultaneous insertion of a tension-free vaginal tape. A prolapse quality of life questionnaire was sent to all patients.

**Results:** The mean operative time was 97.4 min (50–210) and there were 1.7% cases of intra-operative complications. The mean hospitalization time was 3.7 days (1–13 days). During the mean follow-up of 20.7 months (3–120), 91 (17.8%) complications were recorded, including constipation (5.5%), SUI (3.5%), vaginal erosion (2.4%), and urge incontinence (2%). Recurrences were recorded in 11.5% of the patients within an average time of 37.2 months. Risk factors for recurrence were the use of the polypropylene mesh compared with the polyester mesh ( $P < 0.0001$ ), an intra-operative hysterectomy ( $P = 0.02$ ), and bleeding ( $P = 0.049$ ). There was a statistical significant ( $P < 0.001$ ) improvement in most of the symptoms in the prolapse quality of life questionnaire.

**Conclusions:** LP is safe with effective long-term results, with low recurrence and morbidity rates, and a good quality of life.

**Key words:** pelvic organ, prolapse, laparoscopy, promontofixation.

## Introduction

Pelvic organ prolapse (POP) occurs in up to 50% of parous women and may be associated with a variety of urinary, bowel and sexual symptoms.<sup>1</sup> The prevalence of POP is currently increasing, and the lifetime risk of requiring surgery for POP is more than 10%.<sup>1</sup> The goal of surgical repair for POP is to return the pelvic organs to their original anatomical positions.<sup>2</sup> Ideally, there are four main goals: no anatomic prolapse, no functional symptoms, patient satisfaction, and avoidance of complications.<sup>2</sup>

Laparoscopic surgery allows a good view of the anterior and posterior compartments so that an overall approach for the prolapse is possible by the same surgical route.<sup>3</sup> Laparoscopic promontofixation (LP) was introduced to treat the three compartment defects, with the objectives of being less

invasive than open surgery, of easier access to the pelvis, of easier and magnified access to the pelvis, with less loss of blood and a shorter convalescence following surgery. However, there are only a few reports on the outcomes from LP and in the present study we assess the safety and efficacy of LP based on a 10-year, single center experience.

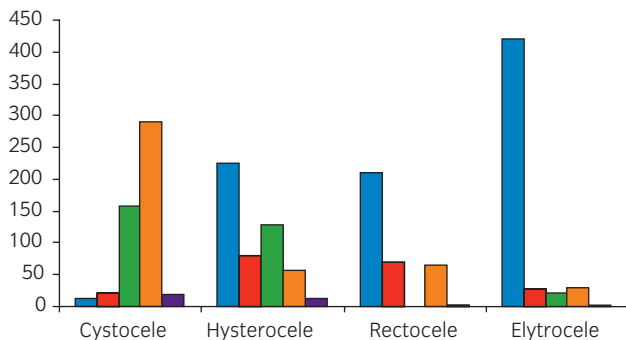
## Methods

### Patients' characteristics

After institutional approval, from January 2000 to December 2009, 501 consecutive patients with POP who had undergone LP were included in this prospective study. The mean age of the patients was 63.2 (36–90) years and their mean body mass index was 25.1 (15–36). Of the 501 patients, 195 (38.9%) had a history of abdominal surgery: 121 (24.1%) had a history of total hysterectomy (65 via the abdomen and 26 through the vaginal approach). Furthermore, 35 patients (6.9%) had a history of surgical treatment for stress urinary incontinence (SUI) and 58 patients (11.5%) had been treated for POP. The mean number of their

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**Fig. 1** The pelvic organ prolapse grade classification of prolapse for each stage. (■), grade 0; (■), grade 1; (■), grade 2; (■), grade 3; (■), grade 4.

deliveries was 3.3 (0–14), while 118 (23.5%) of the patients had at least one delivery with complications (e.g., uterine inversion and rupture, vaginal and cervical laceration).

Of the 501 patients, 353 (70.4%) had a POP grade  $\geq 3$ .

Regarding the term of elythrocele, it is a herniation of the rectouterine pouch (cul-de-sac of Douglas) and depending on the contents, it can be an “enterocele” (small bowel), a “sigmoidecele” (sigmoid colon) or an “epiplocele” (omentum).

## Preoperative evaluation

Preoperatively, the type and degree of POP was determined according to the Baden and Walker classification (Fig. 1).<sup>4</sup> All the patients underwent a Bonney test and urodynamic study. In 476 patients (95%) the Bonney maneuver was positive. In 268 patients (53.4%) SUI was diagnosed through urodynamic studies.

If anti-incontinence treatment was indicated, the patients underwent the insertion of a tension-free vaginal tape (TVT) simultaneously with the LP. Urine analysis and a Papanicolaou smear test were routine in the preoperative evaluation. A pelvic ultrasound was performed in order to exclude uterus pathologies (e.g. fibroma) and, if indicated, to approach the patients for this consent to a simultaneous hysterectomy.

## Operative technique

The surgical technique has been described previously by the senior author.<sup>5</sup> The patient was positioned in a Trendelenburg lithotomy position with legs slightly bent. A 10-mm trocar was placed at the umbilicus, while two 5-mm trocars were positioned 2 cm above and medially to the anterior superior iliac spine and a third was positioned midway between the umbilicus and the pubic symphysis. The uterus and the sigmoid colon were fixed to the abdominal wall with the aid of a 0 absorbable suture on a straight needle inserted

through the skin. Initially, the opening of the posterior peritoneum took place on the sacral promontory and was extended under the right uterosacral ligament. The Douglas pouch was then opened and the rectovaginal plane was exposed. This maneuver was facilitated by the introduction and the relevant movements of a vaginal malleable valve.

Once the lateral dissection of the anus was performed the levator muscles were exposed. At this point the posterior mesh was fixed on the levator muscles with a 2/0 polyester suture on a tapered needle. The top of the wide portion of the posterior mesh was fixed on the uterosacral ligaments with two other sutures. Before releasing the uterus, a right and left window was created under each broad ligament in order to allow the passage of the two extensions of the anterior mesh. Thereafter, the anterior compartment was created by the dissecting the inter vesicovaginal space. Once the dissection was completed the anterior mesh was fixed on the anterior vaginal wall just before the trigone and at the isthmus of the uterus. There were usually five points of fixation (one medial and two on each lateral anterior vaginal wall). Eventually, both meshes were anchored on the sacral promontory using a 0 polyester suture on a 0.5 cm sharp needle. Full peritonization of the mesh was important in order to prevent intestinal adhesion. Therefore, after the promontofixation, wherever the peritoneum was opened it was closed with a 2–0 polyglactin running suture.

Until 2007 we used the polypropylene-dimethylsiloxane monofilament mesh (B. Braun, Boulogne Billancourt, France), while afterwards we used the polyester monofilament mesh (Sofradim, Trévoux, France) in an attempt to reduce the risk of vaginal erosion. Heavy polypropylene meshes have been reported to stimulate an inflammatory reaction that is responsible for mesh shrinkage and chronic pain due to scar tissue.<sup>6</sup> The novel polyester monofilament mesh that we used is made of a lightweight, large isoelastic pore knitted fabric that incorporates resorbable micro hooks that give the mesh self-gripping properties.<sup>2</sup>

## Post-operative assessment

The repair of POP was characterized as successful in the absence of POP or in the presence of grade 1 POP on physical examination. Recurrence of POP was assessed as grade  $\geq 2$  at follow-up visits scheduled at 6, 12, 24, 36, 48 and 60 months. In order to assess the long-term anatomical and functional results of LP, a French version of a prolapse quality of life questionnaire was sent by mail to all patients.<sup>7</sup> Variables evaluated in this questionnaire included urinary, bowel and sexual function as well as general satisfaction. All responses were compiled and analyzed statistically ( $\chi^2$  or Fisher’s exact test as appropriate), and the results were presented as percentages. A double-sided  $P$ -value  $<0.005$  was considered as statistically significant.

## Results

The mean time taken by the operation was 97.4 min (50–210). There were nine cases (1.7%) of intra-operative complications: colonic puncture (one), vaginal perforation (one), impossible posterior dissection (five), and bleeding at the promontory bleeding (three). In five cases (1%) the laparoscopic operation was converted to an open one because of intra-operative complications. The mean hospitalization time was 3.7 days (1–13). The indwelling catheter remained for an average of 1.4 days (1–12) due to cases of post-operative urinary retention. There were 10 cases (2%) of acute urinary retention, which were managed with the reinsertion of the catheter and followed by successful trial without a catheter. Furthermore, there were three cases (0.6%) of urinary tract infection treated with oral antibiotics. In five patients (1%) an early (within 1 month) surgical intervention took place, consisting of the insertion of a TVT (three) because of post-operative SUI, hysterectomy (one) and the evacuation of pelvic hematoma (one) because of delayed bleeding.

The mean follow-up time was 20.74 months (3–120). During the follow-up 91 (17.8%) complications were recorded: constipation (5.5%), SUI (3.5%), vaginal erosion (2.4%) and urge incontinence (2%). There was one case of a pelvic abscess and one other case of a vesicovaginal fistula, treated surgically after the first month. The average time to the onset of a complication was 17.2 months (1–100). All but one the 28 cases of constipation were managed with long-term laxatives, while in the remaining patient surgical revision with a posterior section of the mesh was needed based on the findings of the colonoscopy. Of the 18 patients with SUI, nine were managed conservatively, in eight a TVT was inserted and in one patient an artificial urinary sphincter was eventually placed because of persistent SUI. All but one the 10 patients with urge incontinence were managed with anticholinergics, while in the remaining patient an S3 neuromodulation took place. Of the 12 patients with vaginal erosion, in one a re-operation took place to remove the mesh, in two cases vaginal repair was possible, while five patients were treated conservatively. In multivariate analysis, only the use of the polypropylene mesh (used until 2007) was a statistically significant risk factor for vaginal erosion in comparison with the polyester mesh ( $P < 0.0001$ ).

At the end of follow-up, 58 recurrences (11.5%) were recorded (7.2% grade  $\geq 3$ ). The average time to the onset of the relapse was 37.2 months (range 8–120). In 76% of the cases, the recurrence was a cystocele, in 13% it was a rectocele, in 5% it was a cystocele and hysterocele, in 3% a cystocele and rectocele and in 3% it was a cystocele, rectocele, and hysterocele. Risk factors for recurrence were: use of the initial polypropylene mesh in comparison with the polyester mesh ( $P < 0.0001$ ), intra-operative hysterectomy ( $P = 0.02$ ), and bleeding ( $P = 0.049$ ).

From the total of 501 patients, 347 (69.2%) filled and returned the questionnaires (Table 1). After the LP, there was a statistically significant ( $P < 0.001$ ) improvement in most of the symptoms: feeling pressure, discomfort or pain in the lower abdomen and genital area, not emptying the bladder, visible POP, urinary frequency, and urge and stress urinary incontinence. There was no statistical significant impact of the operation on the patients' bowel habits and sexual activity. Nearly, 65% of the patients reported a positive impact of LP in urination. Collectively, 86.4% of the patients reported a successful assessment for LP and 94.8% would prefer LP if there was an option to choose an operation for the treatment of POP again.

## Discussion

The wide variety of open and laparoscopic surgical approaches used to treat POP represented the complexity of managing this medical condition.<sup>3,8</sup> Irrespective of the route or repair chosen by the surgeon, a sound surgical judgment, complete understanding of the pelvic anatomy and the mechanisms involved in POP, and expertise in pelvic surgery are required if successful outcomes are to be expected.<sup>9</sup>

Recently, Cavadas *et al.* evaluated the way in which the quality of randomized controlled studies (RCT) for the treatment of POP has evolved.<sup>10</sup> The quality of reporting was assessed by applying the 2010 revised Consolidated Standards of Reporting Trials (CONSORT) statement. In all RCT were identified for review. Comparing the two periods 1997–2006 and 2007–2010, there was no improvement in the quality of reporting for any of the CONSORT criteria. Thus, RCT in POP are scarce, and the quality of reporting is suboptimal and has not improved in recent years. Therefore, the results of RCT between the different surgical procedures for treating POP are warranted.

To the best of our knowledge, the present study constitutes the largest series of such trials, including 501 patients. Our results have shown a repeat of the high success rates of open surgery. From the 347 patients who returned the questionnaires, 86.4% reported a successful assessment of the procedure, while the recurrence rate was 11.5%. Ganatra *et al.* reviewed 11 laparoscopic studies that included 1197 patients and reported a 10% recurrence rate for POP, which is similar to the present rate.<sup>11</sup> However, different definitions of POP recurrence have been used in these studies. The posterior mesh is of great importance for the support of intra-abdominal pressures and thus to avoid recurrences. POP recurrence could be attributed to inadequate healing inherent in the laparoscopic approach. In the same review by Ganatra *et al.* the mean incidence of vaginal erosion after LP was 2.7%; similar to the rate in the present study of 2.4%.<sup>11</sup> Our low incidence of complications with the mesh could be the result of tacking the posterior mesh to the levator anus

**Table 1** Results of the prolapse quality of life questionnaire (347 patients)

Section A	Yes (%)	No (%)	P	
1) Pressure in the lower abdomen			<0.001	
Pre-op	222 (64)	125 (36)		
Post-op	66 (19)	281 (81)		
2) Pressure in the genital area			<0.001	
Pre-op	235 (68)	112 (32)		
Post-op	55 (16)	292 (84)		
3) Pain/discomfort at lower abdomen/genital area			<0.001	
Pre-op	212 (61)	135 (39)		
Post-op	87 (25)	260 (75)		
4) Visible pelvic organ prolapse			<0.001	
Pre-op	273 (79)	74 (21)		
Post-op	47 (14)	299 (86)		
5) Pushing vaginal/anal area to pass stool			=0.231	
Pre-op	117 (34)	230 (66)		
Post-op	106 (30)	242 (70)		
6) Feeling the bladder has not been emptied			<0.001	
Pre-op	196 (57)	151 (43)		
Post-op	122 (35)	225 (65)		
7) Pushing at the vaginal area to urinate			<0.001	
Pre-op	90 (26)	257 (66)		
Post-op	10 (3)	337 (97)		
8) Fecal incontinence			=0.516	
Pre-op	58 (17)	289 (83)		
Post-op	53 (15)	294 (86)		
9) Discomfort with bowel movements			=0.1	
Pre-op	83 (24)	264 (76)		
Post-op	69 (20)	278 (80)		
10) Urinary frequency			<0.001	
Pre-op	247 (71)	100 (29)		
Post-op	127 (37)	220 (63)		
11) Urge urinary incontinence			<0.001	
Pre-op	216 (62)	131 (38)		
Post-op	128 (37)	219 (63)		
12) Stress urinary incontinence			<0.001	
Pre-op	242 (70)	105 (30)		
Post-op	130 (38)	217 (62)		
13) Constipation			=0.843	
Pre-op	173 (49)	174 (51)		
Post-op	174 (51)	173 (49)		
14) Sexual activity†			=0.458	
Pre-op	199 (64)	111 (36)		
Post-op	183 (59)	127 (41)		
Section B	Positive (%)	Nil (%)	Negative (%)	Not sure (%)
Impact on urination	224 (64.5)	96 (27.6)	25 (7.2)	2 (0.5)
Impact on bowel habits	74 (21.3)	249 (71.7)	22 (6.3)	2 (0.5)
Impact on sexual activity	72 (20.7)	202 (58.2)	25 (7.2)	48 (13.8)
Overall assessment	300 (86.4)	0	47 (13.5)	0
Choice of procedure	329 (94.8)	0	17 (4.8)	1 (0.3)

†37 did not answer.

musculature, avoiding posterior vaginal erosion and reperi-tonealization and thus preventing possible erosion in the surrounding tissues. Furthermore, in the present series there was no reported complication of dyspareunia, making LP an excellent option for young, sexually active patients with POP. The fact that the operation had no impact on sexual activity could be attributed to the minimally invasive feature of LP. The same could be true for the small number of post-operative bowel complications.

Sabbagh *et al.* performed a retrospective study of the 186 consecutive women who underwent LP for POP.<sup>12</sup> The median follow-up was 60 months. The success rate was 92.4% and eight patients were re-operated on because of recurrent POP. The long-term complication rate was 6% and five cases of vaginal mesh erosions were recorded. During the follow-up 91.1% of the responders were satisfied after their operation. The remaining patients were not satisfied because of POP recurrence (seven), lower urinary tract symptoms (five) and constipation (two). Rozet *et al.* performed LP with a polyester mesh on 363 women with POP. There were eight conversions due to anesthetic or surgical difficulties.<sup>13</sup> After a mean follow-up of 14.6 months, 96% of the patients were satisfied and there was a 4% recurrence rate. Furthermore, there were three vaginal erosions, two urinary retentions that required TVT section, one bowel incarceration, one spondylitis and two mesh infections.

Rivoire *et al.* treated with LP 138 patients with POP.<sup>14</sup> The mean operating time was 190 min without any conversion to laparotomy. After a mean follow-up of 33.7 months the recurrence rate was 11%, while 98% of the patients were satisfied with the operation. Seven patients experienced vaginal erosion, and in some cases the mesh had to be removed because of infectious complications. However, the authors reported a high percentage (46%) of postoperative SUI (grade 1 or 2 in most cases). Similarly, there is a low risk of developing de novo urge incontinence after a laparoscopic sacral colpopexy and therefore patients should always be informed accordingly before agreeing to surgery. This could be attributed to the retraction and irritation of the bladder trigone following healing and scarring.<sup>15,16</sup> In our series, patients with concomitant SUI benefited from the TVT placement and this is recommended in proven cases of SUI.

White *et al.* treated 30 female patients with symptomatic POP with laparoscopic (10), robotic (10), or single-port laparoscopic (10) abdominal sacral colpopexy.<sup>17</sup> No significant difference was noted among the three groups with respect to operative time, blood loss, mean visual analogue pain score at discharge, or duration of hospitalization. The authors concluded that a single port laparoscopic abdominal sacral colpopexy offers comparable efficacy and superior cosmetic results compared to alternative laparoscopic and open approaches.

The use of a robotic system for sacral colpopexy facilitates the precise placement of intracorporeal sutures, with

decreased morbidity and improved appearance in comparison with the open procedure. Although the early experience is encouraging, long-term data are needed to confirm the efficacy of robotic-assisted sacral colpopexy. Xylinas *et al.* treated 12 women with symptomatic POP with robot-assisted sacral colpopexy.<sup>18</sup> The mean operative time was 144 min. At a mean follow-up of 19.1 month, no recurrence of the POP occurred. A major disadvantage of robotic-assisted sacral colpopexy is the high cost. It has been estimated that robot-assisted sacral colpopexy produces the highest estimated hospital charges of all surgical procedures and they are more expensive than simple laparoscopic and open sacral colpopexy.<sup>19</sup>

Recently, Maher *et al.* compared laparoscopic sacral colpopexy to total vaginal mesh placement for vaginal vault prolapse.<sup>20</sup> In this randomized study of 53 and 55 patients, respectively, the laparoscopic group had a shorter hospitalization period and a quicker return to work. At the 2-year review, the total objective success rate at all vaginal sites was 77% for laparoscopic sacral colpopexy as compared with 43% for total vaginal mesh ( $P < 0.001$ ). The re-operation rate was significantly higher after the vaginal mesh surgery (22%) as compared with laparoscopic sacral colpopexy (5%) ( $P = 0.006$ ). The authors concluded that the laparoscopic sacral colpopexy produced a higher satisfaction rate and objective success rate than the total vaginal mesh procedure with a lower peri-operative morbidity and re-operation rate.

Reviews by the Cochrane Group and others indicate that the abdominal sacrocolpopexy remains the gold standard for the surgical management of the apical compartment of POP.<sup>1-3</sup> For the time being, it is unclear whether LP duplicates the results of an abdominal sacrocolpopexy as well as the results of the vaginal approach with the use of a mesh.

Regarding the limitations of the present study, although this was the largest series on LP for the treatment of POP, the study was not randomized. It would be interesting to conduct a prospective and randomized study between LP and the open vaginal or abdominal approach for the treatment of POP. Another limitation of our study is that the self-applied questionnaire was not administered before surgery. Nevertheless, the response rate to the questionnaire was good at nearly 70% and the mean follow-up was 21 months.

In conclusion, the present study supports the use of laparoscopy for the treatment of POP. LP appears to be safe with a low complication rate and it does not represent a steep learning curve in surgeons who already practice laparoscopy. Nevertheless, longer term studies are needed to confirm these findings. While randomized prospective trials are greatly preferred; it is difficult for the laparoscopic surgeon to carry out such studies when most patients are referred specifically for the laparoscopic route.

## Conflict of interest

None declared.

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