World Journal of Surgery and Surgical Research

Research Article
Published: 28 Mar, 2022

Functional Results and Quality of Life after Laparoscopic Promontofixation (LPF): A Multidisciplinary Approach

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Abstract

Aim of the Study: Our objective was to assess complications and mid-term functional outcomes of Laparoscopic Promontofixation (LPF) and to identify factors associated with patient dissatisfaction.

Patients and Methods: We included all women who underwent LPF for Pelvic Organ Prolapse (POP) in our hospital between 2013 and 2018. Each patient was invited to complete validated questionnaires of symptoms (PFDI 20, ICIQ, PISQ-12) and quality of life (PFQI-7) sent to their homes postoperatively. Complications were assessed using the Clavien-Dindo classification and patient satisfaction was assessed using the PGI-I questionnaire.

Results: Of the 201 women included, 103 (51.2%) had a posterior mesh alone, 22 (11.0%) an anterior mesh alone, and 76 (37.8%) had both anterior and posterior meshes. Eleven patients (5.5%) underwent concomitant procedures associated with the LPF. Eighty-three patients (41.3%) answered the questionnaires with an average follow-up time of 42.6 (± 18.7) months. The short-term complication rate was 6.5%. The anatomic recurrence rate was 16.9% according to the POP-Q classification. The reoperation rate was 15.4% within an average of 13 months. 57.8% of the patients reported being better or much better after surgery (PGI-I scores 1 and 2) and 81.9% would repeat the operation if necessary. Persistent urinary incontinence (p=0.03), constipation (p=0.02), and recurrence of prolapse during follow-up (p=0.03) were significantly associated with postoperative dissatisfaction.

Conclusion: LPF improves symptoms and patient satisfaction in the medium term. Persistence of urinary incontinence and constipation were significantly associated with lower postoperative satisfaction.

Keywords: Pelvic organ prolapse; Laparoscopy; Surgery; Quality of life; Satisfaction

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Received Date: *05 Feb 2022*
Accepted Date: *05 Mar 2022*
Published Date: *28 Mar 2022*

Citation:
Jamard E, Lebreton G, Tillou X, Alves A, Fauvet R, Pizzoferrato A-C. Functional Results and Quality of Life after Laparoscopic Promontofixation (LPF): A Multidisciplinary Approach. World J Surg Surgical Res. 2022; 5: 1370.

Introduction

Pelvic Organ Prolapse (POP) is a common pathology in women and is associated with a range of urinary, digestive and sexual disorders which significantly impact quality of life [1].

The prevalence of POP varies from 2.9% to 11.4% or from 31.8% to 97.7% depending on whether a questionnaire or a clinical examination respecting the POP-Q classification (Pelvic Organ Prolapse Quantification) is used. Furthermore, prevalence is on the increase due to the increase in life expectancy and obesity, and the cumulative incidence of surgery is as high as 11% in women over 70 years of age [2].

The most common symptom of POP is a sensation of vaginal bulge but other urinary, genito-sexual or anorectal symptoms may also lead a woman to consult [3]. This result in a diverse patient pathway involving all organ specialists dealing with pelvic-perineal functional disorders: Urologists, gynecologists and digestive surgeons.

Abdominal promontofixation is now recognized as the gold standard in the surgical management of apical POP. It is also considered an effective technique in the management of cystocele in several European countries and is indicated for the treatment of recto-elytroceles by dissecting

the rectovaginal septum on the anterior surface of the rectum [4]. In recent years, abdominal promontofixation is now usually performed by laparoscopy which is associated with similar anatomical results to the open abdominal approach but with lower morbidity [5].

While the anatomical results of Laparoscopic Promontofixation (LPF) are good in the medium term, few reports have evaluated functional results in the medium and long term, or pain and sexuality outcomes.

The main objective of this study was to evaluate the medium-term results of LPF by using validated self-administered questionnaires of symptoms and quality of life. The secondary objective was to identify predictive factors of postoperative dissatisfaction.

Materials and Methods

We conducted a retrospective, multidisciplinary, single-center study of women who had LPF for stage 2 or higher POP according to the POP-Q classification [6] between January 2013 and August 2018. Surgery could have been performed by digestive, gynecologic or urologic surgeons either jointly or independently.

A set of postoperative questionnaires was sent by mail to the women in November 2018 and re-emailed if no reply had arrived by February 2019. It included the PFID-20 (Pelvic Floor Distress Inventory) [7] and ICIQ-UI SF International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form) [8] questionnaires, as well as the Pelvic Floor Impact Questionnaire (PFIQ-7) about the impact of POP symptoms [7]. A sexual quality of life questionnaire, the POP Urinary Incontinence Sexual Questionnaire (PISQ-12), a sexual quality of life questionnaire [9], was also included.

The median total PFDI-20 score and the median score for each of its sub-questionnaires [Urinary Distress Inventory (UDI-6), Pelvic Organ Prolapses Distress Inventory (POPDI-6) and Colorectal-Anal Distress Inventory (CRADI-8)] were recorded. Patient satisfaction was assessed with the validated Patient Global Impression of Improvement (PGI-I) questionnaire [10], which asks patients to evaluate their condition now, compared to before starting treatment, on a scale of 1 (very much improved) to 7 (very much worse). Surgical complications were reported according to the Clavien-Dindo classification [11]. The other information collected were administrative and medical history, digestive, gynecologic and urinary symptoms, paraclinical exams, data concerning the surgical intervention, data concerning the immediate postoperative history, and data concerning short- and medium-term follow-up.

The analysis was descriptive for symptom and quality of life scores and satisfaction after LFP. To identify risk factors for postoperative dissatisfaction (PGI-I score <=2), a univariate analysis was performed using the student's t test or Chi^2 test when the variables were qualitative. Statistical analysis of this study was performed using STATA version 13 software.

The study was approved by the South Mediterranean Ethics Committee (Comité de Protection de Personne Sud Méditerranée 1, n°1886) on December 12th, 2018.

Results and Discussion

Results

Our study included 201 women who underwent an LPF between 2013 and 2018 in the gynecology, urology and digestive surgery departments of the Caen University Hospital. Among these patients, 83 (41.3%) returned the postoperative questionnaires (Flow chart, Figure 1) with an average follow-up time of 42.6 (± 18.7) months. Seventy-eight (93.9%) of these had a follow-up of more than 12 months.

Women responding to the questionnaires were not statistically different from those who did not in terms of general characteristics (Supplementary Table). The mean age of the study population at surgery was 62.4 years (± 11.8) and 79.1% were postmenopausal. The mean Body Mass Index (BMI) was 25.3 Kg/m^2 (± 4.8). Most of the women had an obstetric history (87.5%) and of these 82.1% had had two or more children.

In the total patient population, 80 patients (39.8%) presented with a stage 2 prolapse according to the POP-Q classification and 82 (40.8%) with a stage 3 or 4 prolapse (Table 1). Before surgery, 42 patients (20.9%) had already undergone pelvic floor muscle training, and 20 (10%) had already had a pessary fitted.

Overall, 103 women (51.2%) had a rectopexy, 22 (11%) a cystopexy, and 76 (37.8%) a double promontofixation. One patient required conversion to laparotomy due to difficulties encountered during laparoscopy. An associated surgical procedure was performed in 11 patients including a suburethral sling (n=6) and a concomitant subtotal hysterectomy (n=5) (Table 2).

Mortality was nil and overall morbidity 6.5%. Three women presented a grade 3b complication including two surgical revisions for small bowel volvulus and one surgery for postoperative sepsis. In addition, two women had acute urinary retention requiring indwelling urinary catheter placement and two had postoperative ileus requiring nasogastric catheter placement (grade 2).

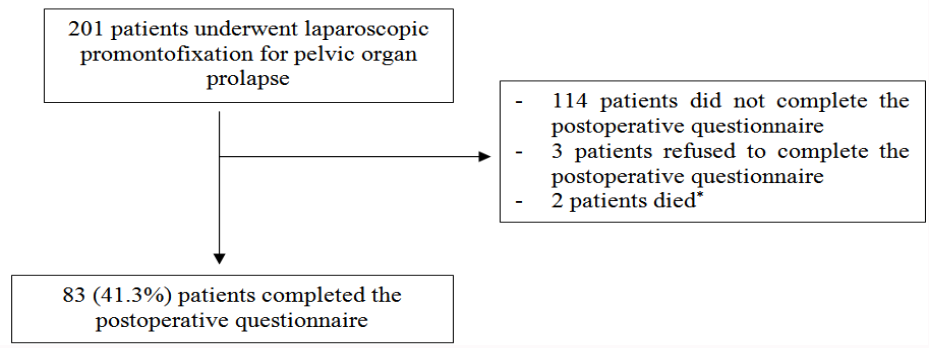

Figure 1: Study flow chart.

Table 1: Patient characteristics (n=201).

	N (%) Mean (± SD)
Age at surgery (years)	62.4 (11.8)
Body Mass Index (kg/m²)	25.3 (4.8)
Medical history	
Diabetes	13 (6.5)
Hypertension	68 (33.8)
Chronic cough	13 (6.5)
Neurologic disease	6 (3.0)
Functional colopathy	1 (0.5)
History of pelvic surgery	
Abdominal prolapse surgery	27 (13.4)
Vaginal prolapse surgery	26 (12.9)
Hysterectomy	68 (33.8)
Sub-urethral sling	26 (12.9)
Smoking	
No	137 (68.2)
Yes	27 (13.4)
Missing	37 (18.4)
Parity	
0	7 (3.5)
1	11 (5.4)
≥ 2	165 (82.1)
Missing	18 (9.0)
Menopausal status	
No	30 (14.9)
Yes	159 (79.1)
Missing	12 (6.0)
Pelvic organ prolapse stage (POPQ classification)	
Stage 2	80 (39.8)
Stage 3 or 4	82 (40.8)
Missing	39 (19.4)
Preoperative pessary testing	
No	181 (90.0)
Yes	20 (10.0)
Preoperative functional explorations	
Urodynamics	
No	93 (46.3)
Normal	60/108 (55.6)
Abnormal	48/108 (44.4)
Cystoscopy	
No	141 (70.1)
Normal	55/60 (91.7)
Abnormal	5/60 (8.3)
Pelvic sonography	
No	168 (83.6)
Normal	26/33 (78.8)
Uterine/ovarian abnormality	5/33 (15.1)
Bladder abnormality	2/33 (6.1)
Dynamic MRI	
No	60 (29.8)
Yes	141 (70.2)
Anorectal manometry	
No	121 (60.2)
Yes	100 (49.8)

Table 2: Perioperative characteristics (n=201).

	N (%) Mean (± SD)
Type of surgery	
Anterorior mesh placement alone	22 (11.0)
Posterior mesh placement alone	103 (51.2)
Anterior and posterior mesh placement	76 (37.8)
Operator	
Gynecologist alone	14 (7.0)
Urologist alone	19 (9.4)
Visceral surgeon alone	98 (48.8)
Gynecologist + visceral surgeon	23 (11.4)
Urologist + visceral surgeon	47 (23.4)
Concomitant suburethral sling	
No	195 (97.0)
Yes	6 (3.0)
Concomitant hysterectomy	
No	196 (97.5)
Yes	5 (2.5)
Operative time (mn)	141.9 (50.4)
Hospital stay (days)	
mean	5.4 (1.7)
01-2	52 (25.9)
3	68 (33.8)
04-7	74 (36.8)
08-11	7 (3.5)
Postoperative complications (Clavien-Dindo classification)	
No complication	188
Grade 1	6
Grade 2	4
Grade 3b	3

After the operation, the mean PFDI-20 score was 80.2 (0 to 262) and the POPDI-6, CRADI-8 and UDI-6 sub scores were 9.9 (0-100), 29.2 (0-93) and 30.7 (0-100), respectively. Bothersome constipation was the most frequent symptom found postoperatively for 44 of the 83 responding patients. Seven patients reported having de novo urinary incontinence (Table 3).

With a mean follow-up of 13.0 (± 12.4) months, the clinical recurrence and reoperation rates were 16.9% and 15.4%, respectively.

Concerning postoperative satisfaction, 57.8% of patients reported being better or much better after surgery (PGI-I score ≤ <=2), 77% would recommend surgery to a friend, and 81.9% would repeat the procedure if necessary (Table 3).

Table 3: Postoperative symptom scores and patient satisfaction (83 responses).

	Median (Min-Max) N (%)
PFDI-20 (/300)	80.2 (0-262)
POPDI-6 (/100)	19.9 (0-100)
CRADI-8 (/100)	29.2 (0-93)
UDI-6 (/100)	30.7 (0-100)
ICIQ-UI SF (/21)	6.3 (0-21)
PFIQ-7 (/300)	
UIQ-7 (/100)	19.1 (0-90)
CRAIQ-7 (/100)	18.8 (0-100)
POPIQ-7 (/100)	9.6 (0-90)
PISQ 12 (/48)	24.8 (0-53)
PGI-I	
Very much better	31 (37.5)
Much better	17 (20.5)
A littler better	12 (14.5)
No change	6 (7.2)
A little worse	0 (0.0)
Much worse	5 (6.0)
Very much worse	3 (3.6)
Missing	9 (10.8)
Global satisfaction (VAS. /10)	3.8 (2.7)
Would you recommend the procedure?	
No	14 (16.9)
Yes	64 (77.1)
Missing	5 (6.0)
Would you do the procedure again if necessary?	
No	12 (14.5)
Yes	68 (81.9)
Missing	3 (3.6)

There was no significant difference between the symptom scores (PFDI-20, ICIQ and PFIQ-7 and PISQ-12) or postoperative satisfaction (PGI-I ≤ 2: 87.5% after anterior mesh placement; 77.1% after anterior and posterior mesh placement; 83.9% after rectopexy) according to the type of intervention. However, patients who had rectopexy reported more digestive symptoms than the others.

In bivariate analysis, persistent urinary incontinence, constipation, and prolapse recurrence during follow-up were significantly associated with postoperative dissatisfaction (PGI score ≥ 2) ($p<0.05$) (Table 4). Postoperative symptoms scores were also inversely associated with dissatisfaction.

Synthesis of the results

This multidisciplinary retrospective cohort study suggests that LPF is associated with a low complication rate and a high satisfaction rate. Three years after surgery, 57.8% of the women overall had a PGI-I score of ≤ 2 and 83.9% of the women who had a posterior mesh. In addition, 77% of patients would recommend the procedure to a friend and 81.9% would repeat the procedure if necessary. However, the overall functional results based on the PFDI-20 questionnaire showed that urinary, anorectal and sexual symptoms were relatively frequent postoperatively.

Table 4: Factors associated with postoperative satisfaction based on the PGI-I score (bivariate analysis comparing patients with PGI ≤ 2 to others).

	PGI-I ≤ 2 group (n=48) Mean (± SD)/n (%)	PGI >2 group (n=26) Mean (± SD)/n (%)	p
Age (years)	61.1 (11.4)	61.1 (9.2)	0.99
Body Mass Index (Kg/m^2)	25.8 (4.4)	25.4 (4.8)	0.78
Menopausal status			
No	7 (15.2)	2 (8.0)	0.48
Yes	39 (84.8)	23 (92.0)	
Smoking			
No	35 (81.4)	19 (100.0)	0.09
Yes	8 (18.6)	0 (0.0)	
POP stage*			
2	14 (35.0)	11 (52.4)	0.27
03-4	26 (65.0)	10 (47.6)	
Digital maneuver before surgery			
No	39 (81.2)	18 (69.2)	0.24
Yes	9 (18.8)	8 (30.8)	
Overall discomfort associated with POP * before surgery (VAS**, /10)	7.1 (1.9)	6.9 (2.6)	0.74
Urinary incontinence before surgery			
No	19 (42.2)	10 (40.0)	0.9
Yes	26 (57.8)	15 (60.0)	
Urinary incontinence after surgery			
No	28 (62.2)	10 (40.0)	0.07
Yes	17 (37.8)	15 (60.0)	
Persistent urinary incontinence after surgery			
No			
Yes	32 (71.1)	11 (44.0)	0.03
	13 (28.9)	14 (56.0)	
Dysuria after surgery			
No	35 (81.4)	21 (84.0)	0.79
Yes	8 (18.6)	4 (16.0)	
Constipation			
No	23 (56.1)	7 (26.9)	0.02
Yes	18 (43.9)	19 (73.1)	
Dyspareunia after surgery			
No	23 (79.3)	9 (64.3)	0.29
Yes	6 (20.7)	5 (35.7)	
Anal incontinence			
No	36 (85.7)	18 (78.3)	0.44
Yes	6 (14.3)	5 (21.7)	
Pelvic pain			
No	33 (75.0)	13 (54.2)	0.07
Yes	11 (25.0)	11 (45.8)	
Clinical recurrence during follow-up			
No	40 (87.0)	17 (65.4)	0.03
Yes	6 (13.0)	9 (34.6)	

Second surgery during follow-up			
No	38 (82.6)	19 (73.1)	0.34
Yes	8 (17.4)	7 (26.9)	
Postoperative symptom scores			
POPDI-6	16.3 (15.6)	28.2 (24.1)	0.01
CRADI-8	22.8 (20.6)	40.5 (18.4)	0.001
UDI-6	25.3 (20.3)	39.7 (24.4)	0.01

Supplementary Table: Comparison of women who responded to the questionnaire and those who did not (n=201).

	Responding women (n=83) N (%) Mean (± SD)	Non-responding women (n=118) N (%) Mean (± SD)	p
Age at surgery (years)	60.9 (10.5)	63.7 (12.2)	0.1
Body Mass Index (kg/m²)	25.5 (4.5)	30.9 (41.1)	0.25
Smoking			
No	61 (88.4)	76 (80.0)	0.15
Yes	8 (11.6)	19 (20.0)	
Parity			
0	0 (0.0)	7 (6.6)	0.06
1	4 (5.2)	7 (6.6)	
≥ 2	73 (94.8)	92 (86.8)	
Menopausal status			
Non	11 (13.9)	19 (17.3)	0.53
Oui	68 (86.1)	91 (82.7)	
Preoperative POP* stage (POP-Q classification)			
Stage 2	28 (42.4)	52 (54.2)	0.14
Stage 3 or 4	38 (57.6)	44 (45.8)	

There was no significant difference between the symptom scores (PFDI-20, ICIQ and PFIQ-7 and PISQ-12) and postoperative satisfaction (PGI-I) according to the type of intervention (anterior mesh alone, anterior and posterior meshes, posterior mesh alone).

We identified several factors for postoperative dissatisfaction: persistent urinary incontinence (p=0.03), constipation (p=0.02), as well as recurrence of prolapse during the follow-up period (p=0.03). For women who had posterior mesh alone, the only parameter identified as being correlated with postoperative dissatisfaction was the presence of a higher stage prolapse (stage 3 to 4 according to the POP-Q classification) before surgery.

Interpretation of the results

The overall morbidity rate was 6.5% in our population: 188 women did not present any complications and only three underwent postoperative surgical revisions. This rate is low compared to those found in the literature [5,12] and may be explained by the surgical expertise of a multidisciplinary team.

Our recurrence rate determined by clinical diagnosis was 16.9%. This rate is extremely variable in the literature depending on the definition of recurrence used by the authors (symptomatic recurrence or anatomical recurrence). In 2016, Chevrot et al. [13] published a prospective single-center study analyzing the functional results of LPF in 82 patients. They reported anatomical recurrence rates of 12.8% for the posterior compartment, 5.1% for the anterior compartment, and 1.2% for the middle compartment.

In our population, 15.4% of women were reoperated which is higher than the rate reported in the literature review by Ganatra et al. [5]. This review explored the functional results of anterior LPF of more than 1000 patients in 11 studies. Their reoperation rate for recurrent prolapse was 6.2%, but their average follow-up time of 24.6 months was shorter than ours (42.6 months). The study by Chevrot et al. [13] found a rate of 4.9% for a follow-up period of 36 months.

Our functional results 42.6 (± 18.7) months after the surgery are consistent with those found in the literature [13-15] and show that patients still frequently present urinary, digestive or sexual symptoms after LPF. Patient satisfaction and quality of life have been the primary outcome measures of promontofixation efficacy for a long time now and for many authors [16]. Barber et al. [17] team compared patient satisfaction outcomes based on 19 definitions of surgical success after promontofixation. They demonstrated that the success rate of surgery based on the absence of anatomical recurrence was poorer than the functional success rate based on the symptoms experienced by the patient. In particular, the absence of vaginal bulge was significantly associated with overall patient satisfaction while the anatomical criteria were not.

Identification of factors of postoperative dissatisfaction – persistent urinary incontinence, constipation, and recurrence of prolapse during follow-up – can help improve the quality of information given to patients in preoperative consultation and select those who will benefit most from surgical management. Two of these factors, prolapse recurrence and postoperative constipation, have already been identified as being associated with patient dissatisfaction in a study published in 2019 [15]. The recurrence of prolapse during follow-up was also identified as a factor for postoperative dissatisfaction by Barber et al. [17]. In their study, factors associated with the success of the surgery were "the absence of vaginal ball" and "no new surgical treatment".

Concerning the specific results of rectopexy, literature analysis is difficult due to the heterogeneity of the surgical techniques and approaches described. Of our 201 patients, 103 (51.2%) had a posterior mesh alone. The functional results for this population are not different from those for the overall cohort. Analysis of the CRADI-8 questionnaire (from the PFDI-20) showed that constipation was the most common postoperative symptom (52.7% among the 36 responding patients) as found in other studies. However, outcomes have clearly improved with the D'Hoore technique compared to the Orr-Loygue technique [18,19]. The D'Hoore technique, which has been used in our hospital since its introduction in 2004, preserves innervation of the rectum through minimal dissection and thus reduces postoperative constipation [20]. We also observed a high postoperative satisfaction in this group since 19 of the patients (52.7%) declared to be better or much better after the surgery, 80.6% would recommend the surgery, and 83.3% would do it again if necessary. The study by Wong et al. found an 88% satisfaction rate with an average follow-up of 29 months [21]. The recurrence rate determined by clinical diagnosis in our study was 20.4%, which is higher than in the studies of Samaranayake [22] (3.4%) and Boons et al. [20] (5%); however, these authors only studied exteriorized rectal prolapse.

The consensual indication for rectopexy is currently symptomatic exteriorized prolapse of the rectum [22,23]. This is still poorly evaluated in the management of rectoceles and elytroceles. Grandjean et al. [24] found a rectocele recurrence rate of 2.8% at 58 months postoperatively after promontofixation carried out by laparotomy or

by laparoscopy.

Strengths and limits of the study

The present study has several limitations. The study design was retrospective which explains the lack of a preoperative questionnaire. Furthermore, fewer than half of the patients (41.3%) responded to the questionnaires although responders and non-responders were not statistically different according to the general characteristics.

The originality of the study lies in its multidisciplinary design with homogeneous surgical techniques: All the anterior meshes were fixed to the vagina and the uterine isthmus, and all the posterior meshes were fixed to the anterior face of the rectum according to the technique described by D'Hoore and Penninckx in 2006 [23]. The main strength of the study is the use of validated questionnaires to assess functional outcomes and quality of life.

Conclusion

Middle-term postoperative satisfaction in women who have undergone LPF is good. While urinary, digestive and sexual symptoms are relatively common after surgery, they do not affect women's quality of life.

We identified several factors of postoperative dissatisfaction: Persistent urinary incontinence, constipation, and recurrence of prolapse during follow-up. These factors can add to the quality of patient information delivered during the preoperative consultation and help select patients who will most benefit from this surgery.

These findings should encourage multidisciplinary evaluation of postoperative of LPF. More studies are needed to evaluate the results of laparoscopic rectopexy in case of rectoceles.

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