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Original Research Article

Long Term Outcome of Laparoscopic Promontofixation for Pelvic Organ Prolapse. A Prospective Study of 240 Patients

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Objectives: **To evaluate the anatomical and functional outcomes of laparoscopic promontofixation using prolene prosthesis, in the cure of genital prolapse.** ***Study Design*****: This is a consecutive 8-year prospective observational study in which 240 patients presented with at least a stage 2 apical prolapse (Baden and Walker), with an anterior or a posterior vaginal wall prolapse, who underwent a double sacrocolpopexy. Two prolene prosthesis (Pro-swing® – Textile Hi-Tec™, Fr) were used for this technique. Pre- and post-operative data referring to prolapse quantitation, scores of quality of life and sexuality (French equivalent of the Pelvic Floor Distress Inventory (PFDI), Pelvic Floor Impact Questionnaire (PFIQ) and Pelvic organ prolapse-urinary Incontinence-Sexual Questionnaire (PISQ-12) were compared. Peri- and post-operative complications constituted the secondary outcome measures.** ***Results*****: At 5 years after surgery, 224 over 240 patients were evaluable. For these patients, the anatomical success rates (Stage 0 or 1) on the apical, anterior or posterior compartments were 100%, 97.5% and 89.3% respectively. On the functional level, all the scores of quality of life and sexuality were significantly improved except anorectal scores CRADI and CRAIQ that worsened.** ***Conclusions*****: This study confirms that laparoscopic promontofixation is an effective technique for the treatment of the urogenital prolapse. On the anatomical level, results are less good for the posterior compartment. On the functional level, our results do not plead in favor of an improvement of anorectal disorders.**

Keywords: Laparoscopy, Mesh, Prolapse, Promontofixation, Sacrocolpopexy.

INTRODUCTION

Currently, laparoscopic promontofixation is one of the most performed procedures for the treatment of genital prolapse in particular of the young woman [**1**]. It offers a better vision because of optical magnification and a net benefit to the dissection of sub-peritoneal spaces thanks to pneumoperitoneum. This greatly facilitates the implementation of prothesis, mainly the posterior one. The post-operative assessment of laparoscopic promontofixation must take into account both the anatomical and functional results by assessing the digestive, urinary and gynecological problems, it can decompensate or worsen.

The results reported in the literature show highly variable success rates mainly of the functional outcomes, some authors report even a tendency to worsening of symptoms related to the prolapse of the posterior compartment after repair [2,3]. However, these results have rarely been assessed using validated questionnaires. Also, most of the studies do not assess accurately, neither the repair stability over the time, nor the tolerance of the implanted prosthetic material in the longer term. The main objective of this study is to evaluate the long-term (5 years) anatomical and functional results of laparoscopic promontofixation. The secondary objective is to report the intra- and early and late post-operative complications of the procedure.

MATERIALS AND METHODS

Study settings

A prospective consecutive study was conducted in a center of gynecological surgery between January 2002 and December 2009. The hospital ethics committee approved this study.

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Study population

Women undergoing cure for urogenital prolapse (UGP) by laparoscopic promontofixation were included in the study during the outpatient consultation for urinary, pelvic-perineal or anorectal functional symptoms in connection with a UGP. Inclusion criteria were female patients with at least a stage 2 apical prolapse, functional symptoms induced by UGP and altering the quality of life, written consent for the surgical treatment and for anonymous data use of the patient's file. Patients were excluded from this study if they had a contra-indication for laparoscopy, history of pelvic irradiation, current immunosuppressive therapy which can cause the rejection of the prosthesis, or a history of genito-urinary neoplasia.

Study procedures

All patients had a pelvic exam to assess the stage of genital prolapse according to the Baden and Walker classification [4]. The maximum grade of prolapse was measured during a Valsalva maneuver. A testing of the levator muscles and assessment of anal sphincter were systematic. The maneuvers of Bonney and Ulmsten were done along with the clinical examination in case of stress urinary incontinence (SUI). All patients underwent pre-operative testings (cytobacteriological examination of the urine, pelvic ultrasound, pap smear, hysteroscopy with an endometrial biopsy and urodynamic assessment to search for urinary disorders).

General anesthesia was performed in all cases. A urinary catheter and uterine cannulation were placed on early intervention. Antibiotic prophylaxis (amoxicillin + clavulanic acid [Augmentin®]) was systematic in all patients at the beginning of intervention (2 g in intravenous). In case of allergy to beta-lactam, erythromycin was administered intravenously at a dose of 500 mg. Prophylaxis of thromboembolic disorders started the day before surgery with low molecular weight heparins. Initially, after insufflation, laparoscopic accessibility for the endoscope was done by periumbilical incision.

Three operating trocars were placed under direct vision, including two of 5 mm in iliac fossa and 15 mm in suprapubic median. After exploration of the abdominal cavity, the sigmoid loop was fixed in the left iliac fossa using a transparietal thread. The surgical technique used for promontofixation approached first the promontory by a median sagittal peritoneal incision. The peritoneum was open in the right sacral concavity and in the pouch of Douglas. The rectovaginal cleavage was carried to its lower third and at the lateral exposure of the levators.

The vesico-uterine peritoneum was then opened and the vesico-vaginal cleavage was carried to the junction upper two thirds-lower third of the vagina. The pars flaccida was fenestrated in the right lateral isthmus. Two prostheses of prolene cut from prosthesis plate 15 × 15 cm (Pro- swing® - Textile Hi-Tec ™, Fr) were then introduced. An inverted "Y" posterior prosthesis was fixed to the right and left levator muscles, then to the posterior vaginal wall with non-absorbable intracorporeal monofilament points.

The anterior prosthesis was attached to the anterior wall of the vagina and cervix, it went to the right side of the uterus, through the broad ligament, and sutured to the posterior prosthesis to the anterior ligament of the promontory. Finally, the visceral peritoneum was finalized. A cure for incontinence was done by suburethral tape and transobturator approach based on the results of the clinical examination and urodynamic assessment. The Foley catheter was kept until the morning of the first post-operative day.

Data collected and analyses of results

For each patient, the following data were recorded before surgery: age, parity, body mass index (BMI), obstetric history, previous pelvic surgery, menopause, and functional symptoms. The intra- and post-operative evaluation included: operative time (calculated from the incision for trocar insertion until skin closure), intra-operative complications, early (<1 month) and late (>1 month) post-operative complications, hospital stay (same criteria were to be met before terminating the hospital stay: resumption of a normal transit, no fever (<37°C), absence of urinary disorders, pain bearable without the use of painkillers).

All patients were reviewed and reexamined in consultation every six weeks during the first six months, then every six months for two years, and every year by the surgeon him/herself. The evaluation of anatomical results was made by a gynecological examination to assess the recurrence of prolapse and its quantification. An anatomic success was defined by a prolapse stage of 0 or 1 (post-operative stage 1 was considered physiological). The evaluation of functional results was done using a standardized questionnaire derived from the French translation (short version) by Tayrac [4] of PFDI-20 (Pelvic Floor Distress Inventory-20) which consists of 20 questions, PFIQ-7 (Pelvic Floor impact Questionnaire-7) with three sub questionnaires of 7 questions each and PISQ-12 (Pelvic organ prolapse urinary Incontinence Sexual Questionnaire-12) consisting of 12 questions. The anatomical and functional results were reported at 5 years of surgery.

Statistical analysis

Statistical analysis was performed using the chi-square test or Fisher's exact test for categorical variables, and Student's t test and Wilcoxon test for quantitative variables. A p value < 0.05 was considered significant.

RESULTS

Overall, 240 patients were included in the study. The preoperative characteristics of the patients are summarized in Table 1. The main functional signs reported were pelvic pain (51.2%), vaginal ball sensation (40%) and SUI (32.5 %) (Table 2). Preoperative characteristics of genital prolapse are summarized in Table 3. All patients had at least a stage 2 prolapse of the middle compartment. Cystocele of stage 2 or more was observed in 77.5 % of cases and a rectocele ≥ 2 in 15 % of cases.

The results of urodynamic testing are reported in Table 4. We found during the same operation time: a bilateral oophorectomy in 21 patients, a vulvoperineoplasty in 12 patients and a cure for SUI by ureteral strips according to TOT technique in 42 patients (those with clinical examination that objectified SUI and urodynamic testing: ureteral hypermobility or pure intrinsic sphincter deficiency). Uterine preservation was the rule in all cases.

The average mean duration of the procedure, without accounting possible associated co-interventions, was 186 minutes (range 85-245 minutes). The main intra- and post-operative complications are summarized in Table 5. The rate of intra-operative surgical complications was 7.5% (18/240): bladder injury in 9 patients with a prior history of caesarean section, and 3 cases of intestinal wound during adhesiolysis to pelvic adhesions (all immediately identified and repaired laparoscopically during the same operation with favorable evolution.

Table 1. Pre-surgery characteristics of the patients

Parameter	Mean (extreme values), or n (%)
Age, years	59.2 (39 - 74)
BMI (kg/m2)	28.5 (18.8 - 35.4)
Gynecological and obstetric history	
Parity	3.4 (1 - 8)
Fetal macrosomia	44 (18.3%)
Instrumental delivery	26 (10.8%)
Ceasarean	31 (12.9%)
Menopause	183 (76.2%)
Hormone replacement therapy	0
Surgical history	
Hysterectomy	0
Cure for prolapse	0
Cure for stress urinary incontinence (TOT)	12 (5%)
Myomectomy	11 (4.5%)
Appendectomy	18 (7.5%)
Intraperitoneal cystectomy	24 (10%)

Abbreviations: TOT: Transobturator Tape

Table 2. Functional symptoms before and after surgery

Symptoms, n (%)	Before laparoscopic promontofixation N=240	5 years after laparoscopic promontofixation N=224	p-value*
Pain / pelvic heaviness	123 (51.2)	28 (12.5)	<0.05*
Vaginal ball sensation	96 (40)	21 (9.3)	<0.05*
Pollakiuria	45 (18.7)	6 (2.6)	<0.05*
Urge incontinence	39 (16.2)	27 (6 novo) (12)	NS
Dysuria	33 (13.7)	1 (0.4)	<0.05*
Stress urinary incontinence	78 (32.5)	17 (14 novo) (7.6)	<0.05*
Constipation	51 (21.2)	53 (27 novo) (23.6)	NS
Fecal incontinence	6 (2.5)	6 (2.7)	NS
Painful defecation	3 (1.2)	9 (6 novo) (4)	NS
Sexually active	216 (90)	201 (89.7)	-
Dyspareunia	57 (23.7)	12 (6 novo) (5.3)	<0.05*
Dyschezia (maneuvers)	42 (17.5)	6 (2.6)	<0.05*

Abbreviations: NS=not significant
* Significance level set at 5%.

Table 3. Prolapse staging before and after surgery

Etage et stade, n (%)	Before laparoscopic promontofixation N=240	5 years after laparoscopic promontofixation N=224
Anterior compartment	24 (10%)	184 (82.1%)
	30 (12,5%)	34 (15.2%)
Stage 0	156 (65%)	6 (2,7%) [a]
Stage 1	30 (12,5%)	0
Stage 2		
Stage 3		
Middle compartment		
	0	188 (83.9%)
Stage 0	0	36 (16.1%)
Stage 1	168 (70%)	0
Stage 2	72 (30%)	0
Stage 3		
Posterior compartment		
	120 (50%)	178 (79.5%)
Stage 0	84 (35%)	22 (9.8%)
Stage 1	12 (5%)	24 (10.7%) [b]
Stage 2	24 (10%)	0
Stage 3		

[a]recurrence of cystocele; [b]de *novo* rectocele

Table 4. Urodynamic testing before surgery

Parameters, n (%)	N=240
Ureteral hypermobility	66(27.5)
Sphincter deficiency	21 (8.7)
Bladder instability	42 (17.5)
Urethral instability	9 (3.7)
Bladder instability + urethral hypermobility	18 (7.5)
Bladder instability + sphincter deficiency	6 (2.5)
Dysuria	6(2.5)
Normal urodynamic testing	72 (30)

Table 5. Intra- and post-operative complications

Variables, n (%)	N=240
Intra-operative complications	9 (3.7)
	3(1.2)
Wound of the bladder	0
Intestinal wound	0
Vascular wound	0
Transfusion	6 (2.5)
Conversion	
Hypercapnia	
Early post-operative complications (<1 month)	
	6 (2.5)
Urinary retention	12 (5)
Back pain	24 (7.5)
Pelvic pain	0
Infection of the prosthesis	0
Recto-vaginal fistula	0
Urinary fistula	6 (2.5)
Urinary infection	1 (0.4)
Acute intestinal obstruction	1 (0.4)
Acute spondylitis	
Late post-operative complications (>1 month)	
	3 (1.2)
Another surgery (for erosion)	3 (1.2)
Mesh erosion	1 (0.4)
Vaginal pain caused by palpation of the prosthesis	

Table 6. Symptoms and quality of life, before and after surgery

	Before laparoscopic promontofixation N=240	5 years after laparoscopic promontofixation N=224	p-value*
PFDI-20	90.25 (± 51.18)	39.67 (±32.22)	<0.05*
POPDI-6	39.38 (±19.22)	973 (±13.33)	<0.05*
UDI-6	32.05 (±23.13)	16.01 (±17.13)	<0.05*
CRADI-8	18.82 (±18.89)	19.93 (±12.57)	NS
PFIQ-7	63.01 (±53.01)	15.79 (±37.01)	<0.05*
UIQ-7	28.24 (±20.27)	7.23 (±16.71)	<0.05*
POPIQ-7	22.42 (±24.15)	4.01 (±11.32)	<0.05*
CRAIQ-7	12.35 (±18.80)	10.55 (±11.32)	NS
PISQ-12[a]	31.62 (±6.3)	37.02 (±5.7)	<0.05*

Abbreviations: PFDI=pelvic floor distress inventory; POPDI= pelvic organ prolapse distress inventory; UDI=urinary distress inventory; CRADI=colorectal and anal distress inventory; PFIQ=pelvic floor impact questionnaire; UIQ=urinary impact questionnaire; POPIQ=pelvic organ prolapse impact questionnaire; CRAIQ=colorectal and anal impact questionnaire; PISQ=pelvic impact sexual questionnaire; NS=not significant. [a]Completed by 222 patients. * Significance level set a 5%.

Besides surgical complications, 6 hypercapnia (PCO_2> 50 mmHg) were observed requiring exsufflation repeatedly. The rate of post-operative complications was 23.7% (57/240). The average hospital stay of patients was 2.8 days (range 2-11 days). The main reported early post-operative complications were pelvic pain (24 cases), spinal pain (12 cases) which evolved favorably with analgesic and anti-inflammatory treatment, 6 transient urinary retention, which spontaneously resolve on anti-spasmodic treatment, and 6 urinary infections that responded well to antibiotics adapted to antibiogram. On

day 21, one patient had back pain associated with pain of both lower limbs with fever. MRI showed a lumbosacral spondylitis L5-S1; evolution was favorable under antibiotics (ciprofloxacin + Tazocilline) with strict decubitus for 4 weeks. Later, an exhibition of the previous prosthesis was objectified in 3 post-menopausal patients (1.2%) at 4, 6 and 8 months after surgery. We found a major vaginal atrophy at clinical examination in all these patients. A recovery of the vaginal prosthesis after partial excision of the material was performed in all cases associated with topical estrogen therapy and a favorable evolution. Finally, one patient presented vaginal pain 3 months after surgery. These pains were caused by deep palpation of the prosthesis without signs of erosion. The evolution was marked by the persistence of pain despite analgesic and anti-inflammatory treatment for a month; no other therapeutic sanction has been proposed.

Five years after surgery, 224/240 patients could be evaluated. Anatomic success was observed in 97.5% of cases for the anterior compartment (6 recurrent cystoceles at the same stage 2: 2.5%), in 100% for the middle compartment and 89.3% for the posterior compartment (24 *de novo* rectocele stage 2: 10.7%) (Table 3). Functionally, significant improvement in symptoms related to UGP concerned the two subgroups of questions that assess urinary disorders (UDI) and the impact of prolapse (POPDI). No improvements concerned the group of questions assessing anorectal disorders which instead tended to worsen after surgery (CRADI: 18.82 ± 18.89 before surgery *versus* 19.93 ± 12.57 after surgery; NS).

Meanwhile, no improvement in the quality of life for this same subgroup was noticed (CRAIQ: 12.35 ± 18.80 before surgery *versus*10.55 ± 11.32 after surgery; NS). The outcome was favorable in all patients who underwent TOT (no SIU or other urinary symptoms have been reported). Two hundred four patients were still sexually active 5 years later, the average total score in PISQ-12 questionnaire rose from 31.62 to 37.02 ($p<0.05$) indicating an overall improvement of the couple's sexuality (Table 6).

DISCUSSION

It is surprising that the medical literature about the laparoscopic treatment of UGP reported in 1993 remains relatively poor compared to the cure of prolapse by vaginal approach or laparotomy [**5**]. In our experience, the mean operative time was 186 minutes (range 85-245 min). No laparotomy or early additional surgery was reported. Our overall rate of intra-operative complications was 7.5%, similar to those noted in several series ranging from 2.2% to 17.4% [6-11].

However, the post-operative complication rate was 23.7% and higher than those reported in the literature. This rate includes particularly back pain and pelvic pain which accounted for more than half of post-operative complications. Furthermore, a case of spondylitis treated with antibiotics was reported in a patient with a favorable evolution. Rozet [7] and Bui [2] reported two similar cases. In the published series, the rate of post-operative complications ranged from 2.7% to 15% [7,12-16] and early intervention rate varied from 0 to 3.9% [17]. Few series reported complications of laparoscopic promontofixation distance. Vaginal erosion because of the prosthesis was the most common specific complication, with a rate of 0 to 9% [17].

The average time to onset of vaginal erosion ranges between six and 36 months [7,8,18,19]. An exhibition of the anterior prosthesis was observed in three of our patients (1.25%) with all having major vaginal atrophy causing the renunciation of the prosthesis implantation in this situation. The exposure of the prosthesis is reported in 2.7% [17], highlighting that it is not a feature of the vaginal approach.

Laparoscopic promontofixationis a technique that proved its effectiveness in the anatomical repair of UGP in the short and medium term. In our series, the surgical success rate at 5 years was 100% for the middle compartment, 97.5% for the anterior compartment (6 recurrent cystoceles: 2.5%) and 89.2% for the posterior compartment (24 *de novo* rectoceles: 10.7%). Our data are consistent with the findings of meta-analysis made by Ganatra *et al*. [17], where the rates of laparoscopic promontofixation fluctuated between 75 and 100%, all stages of prolapse combined. The middle compartment is mostly spared from recurrence.

Some authors report a maximum of recurrence for the posterior compartment [6,15,20]. For others, cystocele is the most common form of recurrence [7,8,12,13]. The lack of a standardized definition of recidivism of UGP is certainly a source of bias and difficulty in the results' interpretation. Generally, recidivism is equivalent to UGP reappeared or to recurrence of the same initial symptoms after laparoscopic promontofixation. In a consecutive series of 132 laparoscopic promontofixations with anterior and posterior prostheses and a mean follow-up of 12.5 months, Claerhout observed an anatomical success rate of 98% for the apical compartment and 97% for the anterior compartment, but a failure rate of 18% for the posterior compartment [32].

Functional results were rarely assessed using validated questionnaires. Based on the analysis of PFDI-20, our results show a significant improvement in symptoms related to UGP after laparoscopic promontofixation. This improvement is observed in both groups of questions that assess urinary disorders (UDI) and the impact of prolapse (PODI), but not in the subgroup of questions assessing anorectal disorders (CRADI). Our results are comparable to those of Bui [2] and Sergeant [3] which concluded that the improvement does not affect anorectal disorders which tend to worsen. In a series of 138 UGP patients with a mean follow-up of 43 months, Granese observed an aggravation of constipation and difficulty in defecation (7% and 1.4% before surgery respectively, and 13% and 5.8% after surgery) [21]. In opposite, Sarlos *et al.* [12] showed a significant improvement of symptoms with the 3 subgroups of questions (UDI, POPDI and CRADI).

As regards the quality of life of patients, it was reported improved with PFIQ-7 questionnaire,contrarily to the subgroup of questions assessing anorectal disorders (CRAIQ). These results are consistent with the evolution of symptoms after surgical treatment of prolapse, showing worsening or development of *de novo* clinical signs for digestive function (constipation: 21.2% *versus* 23.6% post-operatively; painful defecation: 1.2% *versus* 4% post-operatively).

The presence of anorectal disorders could be secondary to alterations in vascularization and innervation of the rectum with the dissection and/or excessive pull on the posterior strip [2]. In our series, *de novo* constipation was reported in 27 patients (12%), *de novo* painful defecation was reported in 6 patients (2.6%). The meta-analysis of Ganatra *et al.* [17] reported a rate of 9.8% (0-25%) of colorectal disorders, including constipation, anal pain and fecal incontinence. Most of these symptoms disappear spontaneously within six months post-operatively. Furthermore, *de novo* SUI is a common complication with a rate of up to 44% in the series of Rivoire *et al.* [8]. It is often unmasked by the UGP repair. In our series, the rate of *de novo* SUI was 6.2% (14/224).

In terms of quality of sexual life, our results demonstrate the positive impact of the prolapse cure. We noticed a significant improvement in PISQ12 after surgery, dyspareunia rate increased from 23.7% to 5.3%. Our results are comparable to those of Bui [2]. However, Altman *et al.* [22] found an impaired quality of sex life and explained their results by the deleterious effect of the posterior colpoperineorrhaphy.

In this study, *de novo* dyspareunia rate was 2.6%, significantly lower than those of Bui [2] who reported a rate of 15.7%. The incidence of *de novo*sexual dysfunction after promontofixation is very variable depending on the series (0-47%) with an average rate of 7.8% [17]. Indeed, sexual disorders induced by promontofixation are probably undervalued. However, promontofixation with uterine preservation is a surgical technique that has the advantage of preserving the integrity of the vaginal cavity, and consequently causes less sexual consequences than the surgery of prolapse by vaginal approach.

STUDY STRENGTHS AND LIMITATIONS

Our work is interesting because of the use of a standardized technique of promontofixation, a comprehensive evaluation of post-operative complications, including remote intervention, quality of life and sexuality of patients evaluated on long term. However, some limitations should be highlighted: the lack of a control group may affect the statistics; hence, randomized studies with larger samples are needed.

CONCLUSION

Vaginal prolapse is primarily a functional pathology which treatment should improve symptoms. The risk of aggravation and occurrence of secondary functional disorders should be considered in this type of treatment. Indeed, satisfactory but functionally imperfect post-operative anatomical result is a failure. Our results emphasize that the laparoscopic promontofixation is an effective technique in the treatment of urogenital prolapse.

Anatomically, the results are less good for the posterior compartment. In terms of function and quality of life, our results are not in favor of improved anorectal disorders. Further studies should be conducted to evaluate better the pre- and post-operative functional disorders, especially those related to the posterior compartment prolapse.

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