Original article

Reducing mesh exposure in Posterior Intra-Vaginal Slingplasty (PIVS) for vaginal apex suspension

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Abstract: OBJECTIVES. Urogynecologists are constantly looking for simple, safe and effective ways to cure vaginal apex supportive defects. A novel surgical technique, Posterior Intra-vaginal Slingplasty (PIVS), was described recently to concomitantly achieve a high therapeutic efficiency with a low complication rate. Mesh exposure was reported to complicate up to 16% of the operations. This study evaluates surgical steps aimed to mesh exposure reduction in PIVS-operated patients. STUDY DESIGN. A total of 140 patients with vaginal apex prolapse were subjected to the PIVS operation in a daycare set-up by one of two surgeons: In the first surgeon's patients group (N=66) the surgical vaginal incisions were made as small as feasible, the para-rectal dissection was performed at the infra-fascial level, and the mucosal edges were not trimmed. These surgical procedures, assumed to have some anti-mesh exposure value, were not performed in the second group of patients (N=74), who were operated by a different surgeon. Preoperative demographics, operative details and postoperative follow-up data were prospectively collected for all patients. RESULTS. The demographics in both PIVS patient's groups were similar. A statistically non-significant improvement regarding the mesh exposure rate was observed in the patient's group where the three anti-mesh-exposure surgical steps had been applied. CONCLUSIONS. Reduction of vaginal mesh exposure rate following PIVS might be achieved by performing three simple anti-exposure surgical steps. However, more and long-term data is required for being able to draw solid conclusions concerning the superiority of the discussed operative techniques.

Key words: Mesh exposure; Vaginal apical defect; Posterior Intra-Vaginal Slingplasty.

INTRODUCTION

Pelvic organ prolapse is very common, and to some degree normal, especially among older women. Yet, up to 30% of all females suffer from pelvic floor relaxation advanced to a level, which has a negative impact upon their quality of life.[1] The affected women frequently require manual assistance to urinate and to defecate, and report urinary and fecal frequency, urgency and urge incontinence, as well as sex function-related symptoms.[2-4] The lifetime risk to undergo prolapse surgery is one in eleven, and up to 30% of those who underwent surgery will have repeat prolapse surgery.[5-8] There are two primary routes of access in reconstructive pelvic surgery: the abdominal (either by laparotomy or laparoscopy [9-10]) and the vaginal approach.[11-12] Vaginal sacrospinal fixation and abdominal sacrocolpopexy have remained the "gold-standard" for repair of vaginal apical suspension defects. Yet, being less invasive, the vaginal approach offers a safer option for the anatomical correction of this suspension defect.[13-21]

Though the best approach for restoration of vaginal apical support among the commonly utilized abdominal and vaginal routes remains controversial, the uterosacral ligament vault suspension is the most anatomical among the repairs. Hence, it is most unlikely that the uterosacral ligament support for the vaginal apical prolapse will create a predisposition to future anterior or posterior vaginal vault defects or compromise vaginal function.[22] Given that vaginal vault herniation is the result of separation of the pubocervical fascia from the recto-vaginal and paracolpion fascia, resulting in an apical enterocele, it should be corrected by meticulous herniorraphy including reattachment of the vaginal vault to the uterosacral ligaments.[23]

These considerations encouraged Petros to design an innovative procedure for the correction of the apical vaginal support defect, through replacement of the uterovaginal ligament encoding with a synthetic sling, positioned at the levator plate level space via vaginal approach to the pararectal area, performed in a daycare setting.[23-25] Mesh exposure has been described to complicate the postoperative course of these and similar procedures in up to 16% of the patients, necessitating additional operations.[26-29] The current study was conducted to evaluate the feasibility of reducing the vaginal mesh exposure rate by three simple surgical procedures: infra-fascial dissection, minimization of incisions and non-trimming of the vaginal incision edges. These procedural steps are intended at precluding mucosal mal-healing and hence to prevent vaginal mesh exposure.

PATIENTS AND METHODS

Patients suffering from an advanced vaginal apical supportive defect, diagnosed clinically according to the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POPQ) standard scoring system, were referred for a PIVS (Tyco healthcare) operation. Between 1/2003 and 6/2005, 140 PIVS procedures were performed according to Petros by two surgeons in daycare set-ups, after an informed consent form had been signed.[24-26] All patients were given one gram Monocef (Cefonicid, Beecham Healthcare) intravenously, one hour prior to surgery. Prior to the commencement of surgery, all patients were subjected to prophylactic antiseptic iodine vaginal wash. The mode of anesthesia depended upon the patient's request. Patients presenting with additional significant features of pelvic floor relaxation had anterior and posterior colporrhaphy, concomitant with the apical supportive surgery. Patients with uterine prolapse were asked to elect either vaginal hysterectomy or preservation of the uterus, while the uterine cervix was amputated if it dilated over more than half of the vaginal length.[30] The first patient's (study) group was subjected to three anti-mesh-exposure surgical procedures: 1) The initial incision at the posterior vaginal wall was minimized, ending more than 2 cm from the tape anchoring point at the vaginal apex. 2) The medial-to-lateral dissection developing the para-rectal space was made under the fascia rather then the traditional supra-fascial method of dissection. 3) The vaginal wall free edges were not trimmed prior to incision closure as usually is done with colporrhaphy. These 3 additional surgical procedures were not performed in the second (control) group of patients. Intra-operative and post-operative complications were prospectively recorded. The patients were interviewed in the first and sixth postoperative month

TABLE 1. – *Patients' demographics and personal details.*

Feature	*Study group (N=66)*	*Control group (N=74)*	*Statistical significance*
Age (Yrs): Av., (SD[1].)	62.5(8.9)	58.3(13.8)	NS[2]
Parity: Av., (SD)	3.0(1.5)	4.1(2.3)	NS
Chronic illness[3]: N (%)	34(51.5%)	30	NS
Previous hysterectomy: N (%)	37(56%)	19(25.7%)	NS
Previous anti-incontinence surgery: N (%)	1(1.5%)	0	NS
Pre-operative BOA[4]: N (%)	20 (30.0%)	70 (94.0 %)	P=0.022

[1] Standard Deviation; [2] Not significant; [3] D.M., Bronchial Asthma, Hypertension, etc.; [4] Bladder overactivity.

and yearly thereafter, with 6 to 24 months follow-up. Subjective data was prospectively recorded regarding urinal and fecal urgency, frequency, stress and urge incontinence, sexual function impairments, voiding habits and pelvic pain and bulging. Objective findings, including verification of urine and feces leakage, relaxation and prolapse of pelvic floor and organs, were also prospectively collected through a physical pelvic examination according to the ICS standards terminology. All statistical analyses were performed with SPSS 10.1.4 (SPSS Inc, Chicago, IL). Student's T test was used for the quantitative variants analysis, while Fisher's exact test and the Chi-square test were applied for the categorical variants. All statistical tests were evaluated at the 0.05 significance level.

RESULTS

One hundred and forty patients diagnosed with vaginal vault prolapse stage 3 or 4 according to the POPQ standard scoring system (D point 1 cm or more beyond the hymeneal ring) were enrolled into this study. All demographic and personal details are tabulated in Table 1. Fifty-eight (41.4%) patients were 0.5 to 25 years post hysterectomy (26 by abdominal and 32 by vaginal approach), 10 (7.1%) had undergone previous pelvic floor reconstructive surgery and 7 (5.0%) had undergone previous anti-incontinence surgery. One hundred thirty-seven (97.9%) of the patients presenting with significant features of pelvic floor relaxation underwent successful anterior and posterior colporrhaphy. Forty-four (31.4%) among those underwent vaginal hysterectomy and nine (6.4%) underwent cervical amputation concomitantly with PIVS. Thirty-five (25.0%) underwent anti-incontinence surgery (either TVT or TVT-Obturator) in addition to PIVS (Table 2). The only statistically significant difference in pre-operative details between the study and control patients groups found related to bladder over-activity, 30% versus 94%, respectively.

The patients were operated on by one of two surgeons: one performed the three anti-mesh-exposure surgical steps in the study group (N=66); these were omitted by the second surgeon who operated on the control group (N=74). When comparing the study and control patient groups, no significant differences regarding operative details or intra-operative complications were recorded with the exception of the mode of anesthesia, general or regional: 78% and 22% respectively for the study group, compared to 28% and 72% respectively for the control group. Two study group patients and four control group patients suffered early post-operative hematoma within the para-rectal fossa. These patients were treated orally with prophylactic broad-spectrum antibiotics and recovered spontaneously without need for infusion of blood products or bleeding control procedures.

Three (2.1%) patients, two of the study group and one of the control group, presented with operative failure, as the D point was found to be over 1 cm beyond the hymeneal ring. Four patients (2.9%) had a significant postoperative vaginal wall defect: three (of the control group) had cystocele and one (of the study group) had rectocele beyond the hymeneal ring, necessitating further corrective procedures. According to the POPQ measurements of the post-operative procedures, the cystocele, rectocele and vaginal vault prolapse corrections were satisfying in 93.9% of the study group patients and 95.9% of the control group patients (Table 3). One patient of the control group, who developed post-operative unilateral gluteal skin infection, was treated by surgical removal of the affected hemi-tape; the vaginal apex remained well suspended. Thirteen patients, four of the study group and nine of the control group, had vaginal mesh exposure. Ten of these patients underwent segmental tape resection at the outpatient clinic and three remained without treatment. Two patients (1.4%), one of each patient group, had complete spontaneous tape expulsion while the vaginal apex remained well suspended. One control group patient suffered post-operative fever of unknown origin,

TABLE 2. – *Operative details.*

Statistical significance	*Number(%) of patients per*		*Feature*
	Control group (N=74)	*Study group (N=66)*	
			Anesthesia
P=0.000	21(28%)	52(78%)	General
P=0.000	53(72%)	14(22%)	Regional
			Additive surgery
NS*	73(98.6%)	64(97.0%)	Colporrhaphy
NS	19(25.7%)	25(37.9%)	Vaginal hysterectomy
NS	16(21.6%)	19(28.8%)	Anti-incontinence surgery
NS	7(9.5%)	2(3.0%)	Cervical amputation

*Not significant

which recovered with oral antibiotics. All patients desiring sexual intercourse were able to do so, dyspareunia was not reported, and no de-novo post-operative urinary incontinence was recorded.

DISCUSSION

Pelvic organ prolapse (POP) may occur in up to 50% of parous women. It may cause a variety of urinary, bowel and sexual symptoms,[1-4] and is reported to necessitate surgical correction in 11% of the female population.[4] Previous hysterectomy, vaginal rather than abdominal, aggravates the risk for further vaginal prolapse. This probably is due to surgical damage as well as to pre-existing weakness of the pelvic floor.[7] Neither simple colporrhaphy, with or without plication of the uterosacral ligaments, nor sacrospinous and sacral colpopexies, seem to be the preferred procedures for repairing vaginal prolapse. Some authors observed that these procedures are associated with an up to 58% recurrence rate in terms of objective POPQ scoring and prolapse related subjective symptoms,[6] while others reported a recurrent surgery rate for pelvic floor reconstruction of 30%.[7-8] The use of mesh for fixing the vaginal apex to achieve sacral anchorage frequently resulted in vaginal mesh erosion and protrusion, complicating colposacral fixation.[15-18]

Sacro-spinous colpopexy, thought to be less invasive and safer than the abdominal route,[11] was reported to be complicated by post-operative dyspareunia, buttock pain, urinary and fecal incontinence, cystocele and rectocele formation,[17] altered defecation and constipation, bladder injuries, urinary retention and infections.[14] Laparoscopic sacral colpopexy necessitates meticulous and proper prior training [9-10] and, therefore, was unpopular.

Against this background, Petros was encouraged to develop the novel PIVS, entailing minimal invasiveness via a vaginal approach together with anatomical restoration of the uterosacral ligament suspension of the vaginal apex, performed in a daycare set-up.[24-26] Magnetic resonance imaging showed that significant improvements in the restoration of the vaginal configuration were achieved in patients who underwent PIVS.[21] The operative results in the current series of patients are in agreement with previously reported data regarding the safety and efficacy of the PIVS method for vaginal apex support.[24-26] The PIVS operation facilitates uterine conservation, even in the event of advanced uterine prolapse. The restoration of the uterosacral ligaments support enables the surgeon to re-suspend the uterine isthmus, hereby avoiding the necessity to perform vaginal hysterectomy for the treatment of uterine prolapse. In the current series of patients, the restoration of the uterosacral ligaments support along with uterine preservation was performed in 38 (27.1%) of the women according to their personal preferences. One of the repeatedly reported PIVS complications is post-operative vaginal mesh exposure.[29-33] This study was aimed at evaluating the introduction of three preventative surgical measures, namely infra-fascial undermining, minimization of the incision and non-trimming. The study and control group showed statistically significant differences regarding preoperative bladder over-activity (30% versus 94% respectively) and regarding the mode of anesthesia, being general or regional: 78% and 22% respectively in the study group versus 28% and 72% respectively in the control group. According to the POPQ measurements on the post-operative patients, the cystocele, rectocele and vaginal vault prolapse corrections were satisfactory in 133 (95%) of the patients, 93.9% in the study group and 95.9% in the control group. Bladder over-activity symptoms, preoperatively troublesome for 30% of the study group patients and for 94% of the control group patients were reduced post-operatively to 6.0% and 6.7% respectively. An explanation for this finding was offered earlier by Petros, suggesting that the well supported bladder tends to fire less neurological electrical activity than the poorly supported one.[26] The two patients groups are similar, except for the bladder over-activity and the mode of anesthesia. Those differences should not bias the study conclusions regarding the value of the three preventive steps to avoid tape protrusion, performed with the study group patients, but not with those in the control group. This included minimization of the incision at the posterior vaginal wall, making the para-rectal space dissection below the fascial level rather than the traditional supra-fascial method and not trimming the vaginal wall free edges. These steps, which seemingly improve mesh covering and mucosal healing, and might bring about some reduction of the tape exposure rate, do not seem to interfere with the well-proven efficacy and safety of the PIVS operation. The fact that the difference between the study and control group exposure rates (6.0% and 12.2% respectively) was not statistically significant might be attributed to the rather relatively small patient groups. It was retrospectively calculated that, for the above-reported exposure percentages, a sample size of 280 women per group would be required to prove a significant difference in mesh exposure rate between the two patient groups at a power of 80% (alpha=5%).

Implementation of the above mentioned anti-exposure surgical procedures might ameliorate the patient's satisfaction and reduce the need for reparations after PIVS. This should be proved by additional studies before being adopted as proven preventive measures for vaginally implanted mesh exposure.

CONCLUSIONS

Three simple surgical steps, which are safe, effective and easy-to-perform procedures, might reduce mesh exposure after Posterior Intra-vaginal Slingplasty. If supported by additional and long-term data, this might be adopted for other vaginal mesh implants to cure pelvic floor supportive defects, to avoid one of the rather frequent complications of these operations.

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Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. *Porena M, Costantini E, Frea B et al. Eur Urol. 2007 Apr 27; epub.* Seventy three women were randomised to TVT and 75 to TOT: both procedures appear safe and effective with minimal complications at mean follow-up of 31 months.

Long-term results of perianal silicone injection for faecal incontinence. *Maeda Y, Vaizey CJ, Kamm MA. Colorectal Dis. 2007; 9:357.* This study is the first to determine the efficacy of silicone biomaterial (PTQ) injection in the long term for passive incontinence, in 6 patients followed up at 61 months: 1 patient had undergone a colostomy, in the score little was changed, but there was a substantial improvement in physical and social function on the SF-36 scores.

Biofeedback for fecal incontinence: short-term outcomes of 513 consecutive patients and predictors of successful treatment. *Byrne CM, Solomon MJ, Young JM et al. Dis Colon Rectum. 2007;50:417.* Little is known about factors that may be associated with biofeedback effectiveness. This retrospective study on 513 patients assessed short-term outcomes, predictors of patients who completed treatment, and predictors of treatment success. More than 70 percent of patients demonstrated improved short-term outcomes. Treatment success was more likely in those who completed six training sessions, were female, older, or had more severe incontinence.

7 – PAIN

Urethral pain syndrome and its management. *Kaur H, Arunkalaivanan AS. Obstet Gynecol Surv. 2007;62:348.* Persistent or recurrent episodic urethral pain usually on voiding with daytime frequency and nocturia, in the absence of proven infection or other obvious pathology is a condition of uncertain etiology. Treatment includes antibiotics, alpha-blockers, acupuncture, laser therapy and psychological support.

Chronic prostatitis/chronic pelvic pain syndrome and male interstitial cystitis: enigmas and opportunities. *Forrest JB, Nickel JC, Moldwin RM. Urology. 2007;69(4 Suppl):S60.*

Successful management of interstitial cystitis in clinical practice. *Forrest JB, Dell JR. Urology. 2007;69(4 Suppl):S82.*

The emerging presence of interstitial cystitis in gynecologic patients with chronic pelvic pain. *Stanford EJ, Dell JR, Parsons CL. Urology. 2007;69(4 Suppl):S53.* It is important to consider the bladder as a generator of symptoms early in the evaluation of the gynecologic patient with chronic pelvic pain. New tools have been developed to aid the gynecologist in ruling out interstitial cystitis in these patients, including a new IC symptom questionnaire and the Potassium Sensitivity Test (PST).

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