

Comparison of Posterior Intravaginal Slingplasty with Abdominal Sacrocolpopexy in Severe Uterovaginal or Vault Prolapse: a clinical trial

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Abstract

Objective: The abdominal sacrocolpopexy is the standard method of vaginal prolapse correction and posterior intravaginal slingplasty (PIVS) is a newer procedure with minimal invasiveness. This study compares the effectiveness and complications of these two surgical methods.

Materials and Methods: In this non randomized clinical trial study, which was conducted in Imam Khomeini Hospital, Tehran, 51 patients with severe uterovaginal or vaginal vault prolapse were evaluated. From 2001 to 2004 twenty six patients were operated by PIVS method and sacrocolpopexy was performed for the remainders. Data were primarily gathered from patients' folders and further information was achieved by two years follow-up and inviting patients to interview or exam.

Results: Eighty percent of women with abdominal sacrocolpopexy were cured compared to 96.2 percent with PIVS. Short-term surgical complications like hemorrhage, perforation, fever and abdominal distention were positive just in 36% of sacrocolpopexy group ($p=0.001$). Long-term complications like tape or mesh dysfunction were seen in 8% of PIVS group while none of sacrocolpopexy patients presented these complications.

Conclusion: According to shorter operating time, lower complications and efficient response to therapy in PIVS method, it can be an alternative procedure for prolapse surgeries. It is preferred in elderly patients with medical problems.

Key words: Posterior IVS, Abdominal Sacrocolpopexy, Vaginal Prolapse

Introduction

Physicians caring for women are likely to encounter pelvic organ prolapse (POP) with increasing frequency because the population is aging (1). The risk

of women who undergo surgery for the treatment of POP by the age of 80 is reported to exceed 10% (2). Most of the affected women are in their 5th or 6th decade, and the majorities suffer from other medical problems (2). The modern surgeon should be aware of those techniques that are well accepted, and those that have been abandoned because of lower efficacy or more complications (3). Various vaginal and abdominal procedures for correction of severe uterovaginal or vault prolapse have been described. The most co-

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Table 1: Patients characteristics and complaints

Characteristics	Abdominal sacrocolpopexy (n=25)	PIVS (n=26)	P-Value
Age (years)*	58 ± 7	65 ± 8	0.027
Number of children	5.7 ± 0.9	6.3 ± 1.1	0.550
Menopausal women	17 (68%)	24 (92%)	0.029
Previous pelvic surgery**	12 (52%)	16 (61%)	0.331
Stress incontinence	10 (40%)	15 (58%)	0.206
Urgency	10 (40%)	17 (65%)	0.095
Nocturia	7 (28%)	10 (38%)	0.985

* Data are presented as mean ± Standard deviation and p-values are computed with t-test.

** Data are presented as count (percentage) and p-values are computed with chi square test.

It must be noted that some patients had multiple urinary symptoms.

Common techniques are: sacrospinous ligament fixation, Mc Call Culdoplasty and abdominal or laparoscopic sacrocolpopexy. Recently, interest has focused on less invasive operative methods like as posterior intravaginal slingplasty (PIVS) (4). Few are known about the effect of various surgical techniques on the patient outcomes (3). This study aimed to compare the effectiveness and complications of abdominal sacrocolpopexy and PIVS methods in the management of severe uterovaginal or vaginal vault prolapse.

Materials and methods

From 2001 to 2004, fifty one patients with clinical evidence of severe uterovaginal or vaginal vault prolapse (grade 3 or 4 of the pelvic organ prolapse quantification [POP-Q system]) were evaluated in Imam Khomeini Hospital.

After approval of the ethical committee of Vali-Asr research center and chancellor for research of the TUMS, this clinical trial was conducted. A total of 26 PIVS operations and 25 abdominal sacrocolpopexy procedures were performed with informed written consents of all the participants.

Demographic information and medical history were asked. Exclusion criteria were diabetes, hypertension, renal dysfunction, neurologic disorders, musculoskeletal diseases and respiratory problems such as chronic bronchitis. Associated symptoms, including urgency, nocturia and pelvic pain were recorded using a standardized questionnaire. The surgery and the pre- postoperative assessments were performed or supervised by the same gynecologist. So this paper reports one surgeon's experience with these two procedures.

Abdominal sacrocolpopexy was carried out through an abdominal incision and the prolapsed vaginal vault

was suspended to the sacral promontory using a synthetic mesh (TV Co. Health care. USA) (5).

Posterior intravaginal slingplasty (PIVS) was performed for the first time in Iran. The PIVS creates a neo-uterosacral ligament using a polypropylene tape, thus helping to relocate the vaginal apex to its original level above the levator plate and to restore the normal vaginal axis (5). Under tension a transverse full-thickness incision approximately 4-5cm wide was made in the posterior vaginal wall, just 1.5 cm below the cervix or the hysterectomy scar line (4). Bilateral 0.8 cm perineal skin incisions were made 2 cm lateral and below the external anal sphincter at 4 and 8 o'clock. The PIVS Tunneller was placed into the ischiorectal fossa for a distance of 4 cm (4). At this point it was gently turned inwards and vaginal examination performed to determine the plane for passage through the rectovaginal fascia, so as to reach the transverse incision. Rectal examination was performed during and after tape insertion to ensure there was no rectal perforation. The procedure was repeated on the contra lateral side (4). Aseptic consideration were taken to minimize infection and other preventable complications.

Surgical outcomes including short term (hemorrhage and perforation) and long term complications (mesh dysfunction and prolapse recurrence), patient satisfaction (comparing with previous condition) were evaluated. All the patients were followed up for two years at 6, 12, 24 months intervals. To assess the results a questionnaire was filled for each patient and she was requested to strain while being examined in a semi-recumbent position (1). When the reduction in the frequency and severity of a symptom was found to be greater than 50%, the symptom was considered to be cured. For example, a reduction in nocturia

Table 2: Intra- and postoperative complications in patients

Outcome	Abdominal sacrocolpopexy (n=25)	PIVS (n=26)	P-Value
Fever and ileus *	9 (36%)	0	0.001
Blood loss > 500cc	1 (4%)	0	0.490
Tape rejection	0	2 (8%)	0.490
Operating time**	173 (90-300)	30 (20-40)	< 0.001

* Data are presented as count (percentage) and p-values are computed with chi square test.

** Data are presented as mean ± Standard deviation and p-values are computed with t-test.

from 4 to 2 events was recorded as cure (1).

Finally this nonrandomized study which was conducted for the first time in Iran, was not blind for the surgeon and the patient, but the statistician was blind. SPSS 11 (SPSS Inc. Chicago IL.) software was used for statistical analysis and P value less than 0.05 was considered as statistical significance. Analysis was performed by Chi-square and Mac-Nemar tests.

Results

Twenty five patients had undergone abdominal sacrocolpopexy and 26 had a PIVS. The main characteristics between the two groups were generally very similar except for their mean ages whereby women in the PIVS group were significantly older (Table 1). No patient had hormone replacement therapy.

There were no injuries to the great vessels and nerves in either group. In women undergoing PIVS, the symptomatic cure for urgency was 79%, for nocturia 90% and for pelvic pain 70%. In women undergoing abdominal sacrocolpopexy, the symptomatic cure was 70%, for urgency 86% for nocturia and 79% for pelvic pain. A significantly greater percentage of women who underwent abdominal sacrocolpopexy developed postoperative fever and ileus compared to women in the PIVS group ($P=0.001$) (Table 2).

Prolapse recurrence was not seen in abdominal sacrocolpopexy group, but 3 patients (12%) in PIVS group experienced prolapse again ($p=0.235$).

After two years, 20 patients (80%) in sacrocolpopexy considered themselves fully cured, whereas 2 patients (8%) felt considerable improvement and 3

patients (12%) felt no improvement. In 26 women who underwent PIVS, symptomatic cure was 96.2% (Table 3).

Discussion

There are several new treatments in addition to abdominal sacrocolpopexy and vaginal sacrospinous ligament fixation in the management of severe uterovaginal or vault prolapse. Petrus first described infracoccygeal sacropexy (posterior intravaginal sling-plasty) as a minimally invasive procedure for the treatment of vault prolapse (6). Surgeons should be familiar with the recent studies on efficacy and safety of intravaginal slingplasties. This new procedure is not yet used widely by gynecologists. Until data on the safety and efficacy of PIVS are available, these procedures cannot be routinely recommended. In this study, the success rate was defined as lack of recurrent prolapse and also included the level of patient satisfaction. When the definition of success is broadened to include lack of complications or undesired symptoms (new onset of incontinence, dyspareunia, pain, constipation, etc) subsequently after the procedure or need for additional surgical procedures, the success rate is more difficult to determine (3). In a review of literature, the success rate of abdominal sacrocolpopexy ranged from 78-100%, when defined as lack of apical prolapse postoperatively, and from 58-100% when defined as no postoperative prolapse (3). In Maher's study, mean patient satisfaction with abdominal sacrocolpopexy was 85%. In Farnsworth's study including 93 women with grade

Table 3: Patients 'satisfaction

Satisfaction	Abdominal sacrocolpopexy (n=25)	PIVS (n=26)	P-Value
Satisfactory	20 (80.0%)	25 (96.2%)	0.144
Relative satisfaction	2 (8.0%)	1 (3.8%)	
Unsatisfactory	3 (12.0%)	0 (0.0%)	

* Chi square test

2 or 3 vault prolapse, the symptomatic cure rate was 91% (4). Thakur's experience in 79 patients who underwent PIVS showed a symptomatic cure rate of 93% (5). Our results are in accordance with these similar studies. Three of 51 patients in the present study felt no improvement. All these patients belonged to the abdominal sacrocolpopexy group. This study, however, found no statistically significant difference in the success rate between the two surgical methods. In our study, PIVS appeared to be as effective as abdominal sacrocolpopexy in treating vault prolapse ($P=0.11$). The abdominal sacrocolpopexy is associated with a lower incidence of recurrent vault prolapse than the sacrospinous ligament fixation in treatment of severe uterovaginal or vaginal vault prolapse (7).

Many women who undergo abdominal sacrocolpopexy or PIVS have abnormal bladder function before surgery, including urinary stress incontinence, urgency and nocturia. Our study also confirmed Farnsworth's report of a high success rate of PIVS in relieving coexisting symptoms of urgency, nocturia and pelvic pain (4). Symptomatic cure of urgency, nocturia and pelvic pain was achieved in a significant number of patients in both groups. This supports the hypothesis that laxity in the pelvic support mechanism may cause such symptoms (4).

Sexual function before and after abdominal sacrocolpopexy and PIVS is an understudied area, and few published reports address this in detail (3). We did not assess this issue in the present study. Given the sparse literature in this area, and conflicting results, preoperative counseling for sexually active women is compromised until prospective studies using validated, disease-specific sexual function instruments are available.

An important question remains to be answered. The follow up period for pelvic floor reconstructive surgeries should be at least 5 years as the failure rate is directly proportional to the length of follow up (7). The present data will be reviewed after 5 years of follow up to obtain more certain success rates.

Abdominal sacrocolpopexy is technically more difficult and invasive as compared to PIVS, the former was associated with a significantly longer mean operating time. In the present study, abdominal sacrocolpopexy involved a higher risk of fever and postoperative ileus. In other studies abdominal sacrocolpopexy was associated with significant damage to

adjacent organs and caused febrile morbidity in up to 10% of patients (4). PIVS may be preferred in women with medical problems, as it is associated with lower intra- and postoperative morbidities. The abdominal scar may be associated with more postoperative pain in laparotomy cases, although this parameter was not assessed in the study.

In conclusion, further trials are warranted to determine not only the procedure with the most duration, but more importantly, which surgical approach is optimal for a given woman, bearing in mind considerations of effectiveness, complications and quality of life in various domains.

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There exists no conflict of interest to declare.

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