Original article

Posterior intravaginal slingplasty: Feasibility and preliminary results in a prospective observational study of 108 cases

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Abstract: The Posterior Intravaginal Slingplasty has been evaluated in a continuous prospective series of 108 patients with an average follow up time of 19 months. Peri-operative and post-operative complications were recorded as well as an anatomical and functional assessment. The morbidity of the Posterior IVS procedure appears comparable if not lower than that of spinofixation in terms of dyspareunia and buttock pain. The technical feasibility is excellent. Insertion of the Posterior IVS tape is far easier to achieve than with the spinofixation technique, and it is quicker to perform than sacrocolpopexy. Follow-up of our patients at long term will reveal whether Posterior IVS will also offer the same advantages of durability or long term cure as shown by abdominal prosthetic repairs.

Key words: Genital prolapse; Mesh repair; Polypropylene; Posterior Intravaginal Sling.

INTRODUCTION

Adequate treatment of genital prolapse requires a defect specific approach. Repair of upper compartment prolapse (vaginal vault, hysterocoele, enterocoele) can involve abdominal or laparoscopic techniques such as sacrocolpopexy [1-10] the Kapandji type operation,[11, 12] combined abdominal/vaginal techniques [7, 12, 13] or techniques using the vaginal route, such as spinofixation [14-17] or MacCall type culdoplasty.[18] Peter Petros [19] described a new technique using a sling of polypropylene mesh for suspension of upper compartment organs which have prolapsed, called "Posterior Intra Vaginal Slingplasty" (PIVS), and for which a more detailed name would be "infracoccygeal translevatorial colpopexy".

The main aim of this study is the assessment of the feasibility, the morbidity and the anatomical results obtained with the Posterior Intra Vaginal Slingplasty (PIVS) technique for the treatment of severe uterine or vaginal vault prolapse by reporting the outcomes of a continuous series of 108 cases with an average follow-up of 19 months. The secondary aim is to use the same criteria to assess the treatment of any associated cystocoele and rectocoele by interposition of a prosthesis (Surgipro* Mesh - Tyco Healthcare, USA).

MATERIALS AND METHODS

A series of 108 consecutive patients, with a mean age of 60 years (range 36 and 82), who presented with genital prolapse giving rise to symptoms, were included between August 2001 and July 2003. To be eligible for inclusion, the prolapse had to include descent of upper compartment organs (vaginal vault, hysterocoele or enterocoele) with a point C > 0 cm according to the POP-Q classification.[20] Cystocoele and /or rectocoele, if associated, were given specific treatment.

In every patient, the clinical examination during consultation was re-assessed under anaesthesia. The first assessment served to include the patients, and the second was the basis for the final decision of treatment. All patients underwent PIVS; and in addition, those with an associated cystocoele or a rectocoele were treated with placement of a polypropylene mesh in the vesico-vaginal or recto-vaginal space respectfully. Hysterectomy was not performed to treat prolapse. Rather, hysterectomy was only performed for medical indications such as meno- or metrorrhagia with a polymyomatous uterus, symptomatic uterine hyperplasia or cervical dystrophy. In a case of isolated hypertrophic lengthening of the cervix, trachelectomy was carried out. When stress urinary incontinence was diagnosed at clinical examination with full bladder or when the closing pressure was less than 25 cm water, a sub-urethral tape was inserted using the Anterior Intravaginal slingpplasty (IVS) technique via a separate vaginal incision beneath the mid urethra.

This is a prospective, observational study. All patients were seen 6 weeks post operation, again after 6 months, and then every year by the surgeon or another gynaecologist in the department.

The main study criteria were patient morbidity (peri-operatively and immediately post-operatively, as well as long term morbidity), and also the anatomical and functional results at short term with respect to the PIVS.

The secondary study criteria were patient morbidity (perioperatively, immediately post-operatively as well as long term), together with the anatomical and functional results at short term with respect to the insertion of vesico-vaginal and recto-vaginal interposition prostheses.

In order to improve the morbidity study, three sub-groups were created: the first group included all patients who had had a hysterectomy (Group 1), the second group were the patients who had undergone a PIVS with or without a recto-vaginal prosthesis and/or a sub-urethral sling (Group 2) and the third group consisted of patients who underwent treatment for cystocoele by means of a vesico-vaginal interposition prosthesis (Group 3). (PIVS for vault prolapse also) The Krikal-Wallis test was used for statistical analysis of the duration of hospital stay and Pearson's chi-square test (exact p-value with SPSS Exact Tests module) for loss of haemoglobin.

Surgical technique

When vaginal hysterectomy is required, it is performed initially in the standard fashion. Treatment of cystocoele (if any) follows next with a sagittal anterior colpotomy. If a retropubic sub-urethral sling needs to be inserted for treatment of urinary stress incontinence, the colpotomy incision stops 4 centimetres from the urethral meatus and the tape is inserted via a separate incision. Vesico-vaginal and vesico-uterine dissection should be wide enough to reach the pelvic fascia laterally. Perforation is required each side of the bladder neck, opening a tunnel towards the Cave of Retzius.

The multifilament polypropylene material (Surgipro® Mesh TYCO Healthcare, USA) used for the vesico-vaginal anterior interposition prosthesis measures 4 centimetres in width, and 6 to 8 centimetres in length, and has two anterior tapered extensions or strips. It is cut from a 15 by 8 centimetre portion of mesh from which the posterior prosthesis can also be cut in order to be economical. It should cover the entire width of the bladder and reach the base of the vagina. The two anterior strips of the prosthesis are slipped through

the perforations in the pelvic fascia and laid flat against the posterior surface of the pubis using the forefinger and a dissection forceps with no grasping function. Adhesion to the pubis is sufficient to ensure reliable and sturdy anterior anchorage. The other end of the anterior prosthesis is fixed to the uterine isthmus using two stitches of resorbable suture. When there is no uterus, this end is fixed to the vaginal vault. A check is made that there are no sharp edges and that it is not placed under tension. Anterior colporrhaphy using rapid resorption suture material to close the entire thickness of the vagina (both mucosa and fascia) is carried out without colpectomy. Insertion of the PIVS mesh, and treatment of any existing rectocele requires standard sagittal posterior colpotomy, without incising the perineum in order to keep pain to a minimum. The top of the incision reaches the neck of the uterus or the vaginal vault when there has been a hysterectomy. The recto-vaginal plane and enterocoele pouch are dissected. The two para-rectal fossa are opened using the finger and blunt-tipped scissors. The landmarks on each side are the ischial spine, the sacrospinous ligament and the levator ani muscles (iliococcygeal fasciculus). Upwards, the uterine isthmus and its junction with the utero-sacral ligaments are visible. This classic dissection is carried out without any retractors. A 5 millimetre incision is made 3 centimetres lateral and inferior to the anal margin on each side. The IVS Tunneller® (Tyco Healthcare, USA) is inserted via this buttock incision in the ischio-rectal fossa, separated from the rectum by the levator ani muscles and the surgeon's finger which is inserted via the para-rectal fossa. This finger is used to keep a check on movement of the tunneller through the muscle layers. The blunt tip of the tunneller is maneuvered to a position where it is in contact with the sacrospinous ligament, and 2 centimetres medial to the ischial spine. The muscle is then perforated at this level by the blunt tip that comes into contact with the surgeon's finger. Thus covered and protected from any contact with the rectum, the blunt tip of the tunneller is taken out of the colpotomy area. The polypropylene tape is taken through the tunneller using the plastic stylette, and then the tunneller is removed. The tape is fixed to the utero-sacral ligaments, the uterine isthmus and the vaginal vault using two resorbable sutures. If there is a rectocele, a polypropylene recto-vaginal interposition prosthesis (Surgipro®, TYCO Healthcare, USA) measuring 8 centimetres long and 4 centimetres wide is used. Like the anterior prosthesis, its corners are rounded. The aim is to cover and reinforce the recto-vaginal septum in order to correct the rectocele. To the top it is fixed to the PIVS tape by two stitches of resorbable suture, and at the bottom, its point of fixation is to the central fibrous core of the perineum on each side of the anus, again using two stitches of resorbable suture. The prosthesis must lie flat against the rectum, with no large creases. It is pulled up into the sacral concavity at the same time as the vaginal vault or uterus, together with the vesico-vaginal prosthesis which acts integrally with the uterine isthmus or vaginal vault when the system is placed under tension. No colpectomy is used here either. The posterior colpotomy is closed with rapid resorption suture prior to pulling on the two external ends of the PIVS mesh. A vaginal pack is inserted into the vagina for 24 hours in order to ensure that the vaginal walls are properly in contact with the prostheses and the dissection planes. A bladder catheter is inserted for the same period of time.[21]

RESULTS

The PIVS operation was performed as planned in all 108 cases. Thirty three patients had a past history of hysterectomy or surgery for prolapse of the upper or posterior compartment (27 hysterectomies and 19 rectocoele repairs). From a functional point of view, all the patients had previously complained of a dragging sensation in the pelvis and the uncomfortable presence of a protruding mass. Twenty seven patients had also complained of stress urinary incontinence, 10 of stubborn constipation that worsened concomitant with the prolapse, 2 of anal pain at defecation and one of anal incontinence. All the prolapses included descent of upper compartment organs (vaginal vault, hysterocoele, enterocoele) with a point C > 0 cm according to the POP-Q classification.[20] Associated with this was a cystocoele (point Ba > 0 cm) in 73 cases, and a rectocoele (point Bp > 0 cm) in 87 cases. Nineteen hysterectomies, 22 amputations of the cervix and 49 urinary incontinence repairs using a sub-urethral sling (Anterior IVS) were carried out as detailed in the previous section.

Group 1 comprised 19 patients who underwent hysterectomy during the same anaesthesia, whatever the other associated procedures (PIVS in every case, and sometimes correction of cystocoele or rectocoele). Group 2 comprised 31 patients with installation of PIVS and in some cases recto-vaginal prosthesis and/or a sub-urethral sling for stress incontinence (excluding any other procedure). Group 3 included 58 patients in whom a vesico-vaginal interposition prosthesis was installed (associated with any other procedure except hysterectomy).

The intra-operative complications (9 cases) were essentially bladder injuries (7 cases), either during dissection of the cystocoele (4 cases), or during passage of the sub-urethral sling insertion device (3 cases). One low rectal injury occurred during dissection of the rectocoele, and one case of bleeding from the Cave of Retzius during treatment of urinary incontinence was controlled by simple pressure (using a vaginal pack on the full bladder), for which the subsequent history was uncomplicated apart from anaemia at 9.5 g/dl. The post-operative complications consisted of anaemia (loss of more than 2 g/dl of haemoglobin) in 7 cases (6.5%), with a trend that did not reach significant level ($p = 0.14$) between the hysterectomy group 1 (3 cases or 15.8%) and the cystocoele (2 cases or 3.4%) and PIVS (2 cases or 6.4%) groups. Two cases of haematoma of the Cave of Retzius were observed, which had no further consequences for the patients. With respect to the cystocoele repair 2 vaginal erosions occurred at 2 and 18 months, that were resolved by simple excision of the exposed mesh under local anaesthesia. For the treatment of the upper and posterior compartments there were 2 infections of the prosthetic material which had to be completely removed, with one case occurring with a haematoma of the para-rectal fossa (on day 15) and the other on a vaginal erosion at 5 months. Finally, there were 6 cases of simple post-operative urinary infection and 5 cases of isolated fever, which resolved without complications in every case. The average hospital stay was 4.8 days (ranging from 2 to 10 days). No immediate re-operation was necessary. Note that the stays were significantly longer ($p < 0.001$) for Group 1 (hysterectomy) (5.4 days) and Group 3 (cystocoele) (4.9 days) compared with Group 2 (Posterior IVS) (4.1 days). The mean follow-up of the patients who were seen again was 19 months (ranging from 9 to 31 months). Six patients were lost to follow-up. They had had no intra-operative complication and their characteristics (age, past history, type of operation) were similar to those of the total cohort.

From an anatomical perspective, the presence of a prolapse at the first post-operative consultation at 6 weeks was considered as a failure, whilst if the same was found later, this was considered as a recurrence. With regard to correction of the upper and posterior compartments (assessment of

PIVS in 102 patients), there was one failure in the patient whose prosthesis was removed on day 15. There were 2 recurrences at 6 months, i.e. hysterocoele and cystocoele, one of which occurred in the patient who had an infection on the prosthesis at 5 months with, once again, complete removal of the mesh. With regard to repair of the anterior compartment (73 patients), there were 6 failures and 2 recurrences at 6 months.

From a functional point of view (in 102 patients) and with regard to PIVS and the posterior prosthesis, the results included 3 cases of moderate de novo constipation, 1 case of dyspareunia that resolved after section of one of the 2 PIVS side strips and also one case of urinary incontinence that previously was masked. However, in the 10 patients who presented with pre-operative dyschesia, 5 no longer have any symptoms and one has experienced considerable improvement. Concerning the anterior compartment, there were 8 cases of transient voiding obstruction, 6 cases of urinary incontinence that were unmasked, and 1 failure of the urinary incontinence treatment.

DISCUSSION

There were few intra-operative complications encountered with this technique (9 cases, 8.5%). None of these can be specifically attributed to the installation of the PIVS, since they all occurred during dissection of the level 2 or level 3 defect and not during the dissection for level 1 (PIVS) attachment. When examined in detail, of the 4 bladder injuries that occurred during dissection of the cystocoele (including one in a patient with a past history of hysterectomy), suturing was uncomplicated in every case and in only one case the proximity of the bladder trigone required double J catheters to be inserted as a precaution. The subsequent history for these 4 patients was uncomplicated. The only case of rectal injury occurred during rectal dissection immediately above the anus; a simple suture closure was inserted together with myorrhaphy of the levator ani muscles and perineorrhaphy. It was possible to implant the PIVS normally, as it lay some distance away from the rectal suture. The subsequent history was uncomplicated, with a follow-up of 12 months. Immediate post-operative complications consisted essentially of anaemia that was encountered three times more often when hysterectomy took place. Other authors, such as Hefni,[22] argue as we do, that the uterus should be preserved in order to reduce morbidity. The 3 cases of vaginal erosion (2.7%) opposite the prosthesis material (twice with a vesico-vaginal prosthesis, once with a recto-vaginal prosthesis) are consistent with the results found in the literature, and which vary considerably between 0 and 40% (Tab. 1). However there are few series and the number of cases is low or concern repair of a cystocoele alone. Many different types of mesh have been used by the vaginal, abdominal or combined approach without any clear relationship appearing between the type of prosthesis, the route of approach and the rate of erosion. It should be noted that regardless of the approach for inserting the prostheses, those for which there is no erosion and those which have a very high rate of erosion are the shortest series, and thus those with the least experience. This latter factor, namely technique or experience therefore appears to be the determining factor. Our good results encourage us to continue with the same materials and the same longitudinal incisions. The same prosthetic material made of multifilament polypropylene (Surgipro® Mesh, Tyco Healthcare, USA) has been used in our department since 1993 for laparoscopic promontofixation (5) and laparoscopic colposuspension using tapes [36] in over 400 patients with an erosion rate of less than 2%. In addition, it should be highlighted that if it is necessary to remove a multifilament prosthesis, this is achieved far more easily than for a monofilament prosthesis that tends to "unravel" and presents an important risk of leaving filaments behind that will prolong the infection. However, as was perfectly expressed by Michel Cosson:[37] "the ideal prosthesis does not exist yet".

No erosion occurred on the PIVS mesh. The 2 cases of infection of the prosthesis were in patients who had undergone several operations. In one case, the infection was secondary to a vaginal erosion that occurred on the recto-vaginal prosthesis at 5 months and required removal of the PIVS tape together with the posterior mesh prosthesis, but the cystocoele repair was not involved. Myorrhaphy of the levator ani muscles was carried out and the subsequent history was uncomplicated. The vault prolapse nevertheless recurred. In this case, the patient was obese and had a past history of a Richter spinofixation and myorrhaphy. In the other case the infection occurred on day 15 following a post-operative haematoma in a patient treated by PIVS alone, and this patient had a past history of promontofixation then hysterectomy and Richter spinofixation, with rejection of the polypropylene suture material after the latter operation. A new PIVS was installed 6 months later and the subsequent history was uncomplicated, with a follow-up of 12 months.

The rate of post-operative complications appears to us to be linked with the technique. A number of steps are mandatory to avoid infection. For example, meticulous asepsis must be observed, the anus must be covered with a transparent adhesive drape at the beginning of the operation, the prosthesis inner packages must be opened at the very last moment prior to insertion of the tape, and gloves must be changed every time the prosthetic material is handled. In order to avoid erosion, the prosthesis must be placed deep down between the viscera and the fascia, and not between the fascia and the mucosa. Placement of the prosthesis must be done without tension and without any anchoring stitch transfixing the mucosa. Excision of the vaginal mucosa must also be avoided, or at least there should be no excessive colpectomy. Indeed, just as observed after abdominal sacrocolpopexy, once the organ hernia has been reduced the vagina retracts rapidly in a few days, and if there is no tension it is able to recover adequate thickness to cover the prosthesis and avoid erosion.

With regard to the anatomical results following the PIVS procedure, only one case was disappointing (because it occurred without removal of the PIVS): this was the recurrence after 6 months of a hysterocoele associated with cystocoele. The patient in question weighed 140 kg and suffered from bronchitis and constipation. Re-operation was possible without problems, with the installation of an anterior transobturator prosthesis associated with spinofixation and retensioning of the PIVS. The subsequent history was uncomplicated, with a follow-up of 18 months.

The technique used in our series differs from that described by Peter Petros[19] and Bruce Farnsworth [38] and the differences concern the sagittal incision perpendicular to the long side of the prostheses; the complete dissection of the para-rectal fossae; the anchorage point for the PIVS which in our series is located very high up beneath the sacro-sciatic ligament; the use of meshes to repair the associated cystocoele and rectocoele; and the absence of colpectomy. These differences explain why there is no rectal injury in our series, and no erosion on the PIVS tape that occurred in 5.3% of cases in the Petros series. The other complications and the anatomical and functional results are very similar.

With respect to the functional results obtained with the PIVS procedure, only 3 cases of de novo constipation were observed. Therefore, this technique does not present the

TABLE 1. – *Erosion rate according to technique and mesh. (SCP = sacrocolpopexy).*

Author	*Procedure*	*Mesh*	*Patients*	*Follow-up (months)*	*Erosion rate*
Fox SD (1)	SCP	?	39	14	0 %
Gadonneix P (2)	SCP	?	46	?	0 %
Leron E (3)	SCP	Teflon	13	16	0 %
Brizzolara S (4)	SCP	Prolene	124	35	0.8 %
Von Theobald P (5)	SCP	Surgipro	100	53	2 %
Lindeque BG (6)	SCP	PTFE	262	16	3.8 %
Visco AG (7)	SCP	?	243	?	4.1 %
Sullivan ES (8)	SCP	Marlex	205	?	5 %
Marinkovic SP (9)	SCP	PTFE	12	39	16.6 %
Kohli N (10)	SCP	Mersilene PTFE	57	20	12 %
Average			***1101***		***3.9 %***
Visco AG (7)	combined	Mersilene PTFE	30	?	26.6 %
Montironi PL (14)	combined	Polypropylene	35	14.6	2.8 %
Average			***65***		***16.2 %***
Sergent F (23)	vaginal	Surgipro Parietex	26	12	0 %
Canepa G (24)	vaginal	Marlex	16	20	0 %
Migliari R (25)	vaginal	Mixed fiber ?	15	23.4	0 %
Migliari R (26)	vaginal	Polypropylene	12	20.5	0 %
Nicita G (27)	vaginal	?	44	13.9	0 %
Shah DK (28)	vaginal	?	29	25	0 %
Flood CG (29)	vaginal	Marlex	142	38.4	2.1 %
Our series	vaginal	Surgipro	108	19	2.7 %
Borrell Palanca A (30)	vaginal	Polypropylene	31	23.5	3.2 %
Adhoute F (31)	vaginal	Prolene	52	27	3.8 %
Bader G (32)	vaginal	Gynemesh	40	16.4	7.5 %
De Tayrac R (33)	vaginal	Gynemesh	48	18	8.3 %
Dwyer PL (34)	vaginal	Atrium	47	29	17 %
Julian TM (35)	vaginal	Marlex	12	24	25 %
Average			***562***		***4.6 %***

classic disadvantages of promontofixation: 9 to 14 % de novo constipation.[1, 5] On the contrary, greater than one out of two cases of pre-operative dyschesia were improved or cured thanks to the repositioning of the rectum within the sacral concavity, as proven by post-operative defecography. The same effect on supra levator rectocoeles and rectal intussusception was demonstrated with the bilateral spinofixation technique.[17, 18, 24]

No pain in the area covered by the pudendal nerve was observed, unlike spinofixation in which pain in the buttocks is likely to occur in 6.1 to 19.2% of cases.[39-42] The only case of post-operative dyspareunia is explained by excessive tension and seemed to be caused by one of the PIVS side strips secondary to fibrosis. The pain disappeared after the tape was divided. In the spinofixation series the rate of dyspareunia varied between 2.3 % and 9 %.[15-17]

With regard to the vesico-vaginal prosthesis, there were 6 failures and two recurrences out of 73 patients. Our failure rate is poor at 11% and we consider this too high. The failures involve lateral detachment of the anterior vaginal wall and we have concluded that this technique does not seem to adequately correct "lateral defects".[39] Subsequent to this assessment, we have decided to modify the anterior prosthesis and add a lateral anchorage point to the arcus tendineus via a transobturator route.

CONCLUSIONS

This is a prospective observational study of a continuous series of 108 cases with an average 19 months follow-up. PIVS appears to be a feasible technique involving a low rate of morbidity and satisfactory results at 19 months. Randomised comparative studies against sacrospinous fixation including questionnaires of quality of life and sexuality are under way.

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Editor's Note: The authors wish to inform the reader that a paper analysing this data has previously been published in the French language journal Gynecologie, Obstetrique et Fertilite.[43] The paper presented in Pelviperineology has been rewritten for publication in the English language. The editors of Pelviperineology encourage authors who have published work in their native language to consider submission to Pelviperineology in English.

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