Original article

Apical pelvic floor prolapse surgical repair: comparison of anterior and posterior pelvic floor compartments vaginal mesh implants

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Abstract: Objectives: Urogynecologists are constantly looking for simple, safe and durable methods to cure apical pelvic floor prolapse (A-PFP). We used a well-known surgical technique utilizing either anterior or posterior pelvic floor compartment synthetic mesh (Prolift®, Gynecare, Somerville, NJ, USA) to reinforce the pelvic floor in cases of A-PFP with high risk of recurrence. The aim of this study was to analyze and compare cure rates as well as peri and post-operative related complications. Patients and methods: Patients with advanced A-PFP and being at risk for recurrence were enrolled into the study and underwent either anterior or posterior mesh implantation, according with the surgeon's decision. Previous Pelvic Organ Prolapse (POP) surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for A-PFP recurrence. Pre-operative demographic data, operative details immediate and long term postoperative follow-up data were prospectively collected for patients at the first post-operative month and year. Tele-interview was held at study conclusion by un-biased researchers who collected also the data from patient's charts and analyzed it. Results: A total of 57 A-PFP patients were subjected to the mesh operation in an overnight setting, at a university or privet hospitals, between October 2006 and May 2008. Twenty seven had an anterior compartment mesh and 30 patients had a posterior compartment mesh. Colporrhaphies and anti-incontinence mid-urethral synthetic sling operations (TVT-SECUR or TVT-Obturator®, Gynecare, Somerville, NJ, USA) were added upon indications. Peri and early post-operative complications included one event of bladder outlet obstruction which was conservatively treated. the operation failed and repeated surgery was needed with 3 patients, two of them had an anterior and one posterior mesh implant One patient of each group presented with an opposite side pelvic floor prolapse and 3 had recurrent USI. Conclusions: The mesh A-PFP reconstruction anterior and posterior mesh operation carries a low complication rate and high cure rate. The current study supports the previously reported favourable therapeutic outcome of this procedure and shows that the anterior and posterior meshes are similar regarding out-come. Thus, is the surgeon who allows to choose the mesh to be used as he finds anatomically and surgically appropriate.

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Key words: Apical Pelvic Floor Prolapse; Surgical Reconstruction; Mesh Implant.

INTRODUCTION

It is evident that pelvic organ prolapse (POP) occurs when the supporting pelvic floor becomes weakened or stretched, usually caused by childbirth, leading to descent of the pelvic organs to the vagina and beyond. POP might affect each of the 3 pelvic floor compartments or any combination of. This contributes to the impairment of pelvic organ function and a deterioration of patient quality of life. POP is estimated to severely affect approximately 11% of the female population. A-PFP, referring to the centro-apical prolapse of the pelvic floor, occurs in up to 20% of parous women. It might be related a variety of urinary, bowel and sexual symptoms. A-PFP is estimated to be surgically treated in 5% of the total female population. Furthermore, up to 30% of those who undergo traditional non-mesh surgery might eventually go through repeat prolapse surgery, some of them following hysterectomy.¹⁻⁴

Operation for A-PFP cure, such as vaginal hysterectomy, colporrhaphy, with or without plication of the utero-sacral ligaments, as well as sacro-spineous and sacral colposuspentions, are also associated with up to 30% recurrence rate, as determined by objective POP scoring and prolapse-related subjective symptoms. Previous POP surgical reconstruction, first degree relative with significant pelvic floor fascial defect and poor pelvic supportive tissue were regarded as risk factors for A-PFP recurrence.5-12

Experience with abdominal wall herniorrhaphy showed that the mesh implant concept had a low recurrence rate, and it was therefore subsequently implemented for pelvic floor herniation repair.

However, unlike abdominal wall hernia vertical mesh repair, the vaginally implanted horizontal meshes are subjected to relatively high levels of physical pressure, including sexual intercourse, thus should be well secured to solid pelvic structures such as the sacro-spineous ligaments (SSL), the pre-sacral fascia, the arcus tendinous fascia pelvis (ATFP) or the utero-sacral ligaments. The preferred anchoring method involves passing the mesh arms through the ligaments, since that probably results in longer lasting support than suture methods of mesh fixation.

Furthermore, just a thin and fragile mucosa layer covers the vaginal mesh, compared to the thick abdominal wall coverage of the abdominal hernia mesh; hence, mucosal erosion and vaginal mesh exposure are possible postoperative complications in the former. Steps should be taken to minimize mucosal erosion and the hazards of vaginal mesh protrusion.

The first innovative procedure for the correction of the apical vaginal support defect and used a vaginal approach was replacement of the utero-sacral ligament by a synthetic sling positioned at the levator plate level was the Posterior Intra-Vaginal Sling (PIVS). Restoration of the utero-sacral ligament support and re-suspend the uterine isthmus, making the addition of vaginal hysterectomy unnecessary.¹³⁻¹⁸ By not removing the uterus, the cervical ring, a solid central pelvic anchoring point is preserved. This provides extra stability for the pelvic floor by recruitment of the related web ligamentary architecture for the pelvic reconstruction and avoids potential iatrogenic weakening of the pelvic floor due to surgical impairment

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of innervation and blood supply. In contrary, adding hysterectomy to mesh pelvic floor reconstruction significantly increases (O.R. = 15 add confidence intervals) the risk of post-operative vaginal mesh exposure. Other occasional adverse outcomes of hysterectomy are vaginal shortening and psychological effects in terms of the woman's body image and self-esteem.¹⁹⁻²⁸

This study goal is to evaluate and compare the anterior and posterior meshes for A-PFP reconstruction, in terms of cure and failure rates as well as related complications rates, safety and durability of cure.

PATIENTS AND METHODS

The study was designed as a two patient's cohort study, comparing two surgical procedures for the treatment of A-PFP. The primary outcome measures were A-PFP mesh reconstruction safety, adverse effects and durability of cure at long term follow-up. Patients experiencing stage 3 or 4 vaginal apical supportive defects, diagnosed clinically in accordance with the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POPQ) standard scoring system, and who were at increased risk for recurrence of the POP, were referred for mesh implantation operation. Risk factors for recurrence included previous POP reconstruction surgery, first degree relative with a significant POP or poor pelvic floor tissue as assessed clinically.²⁹⁻³² Patients with mild POP and not at risk for recurrence were referred to conventional native tissue operations, Patients who had undergone previous pelvic irradiation, or with immune-depression, active infection, systemic steroid use or poorly controlled diabetes were excluded.

Thorough informed consent was obtained. All patients were given one gram Monocef (Cefonicid, Beecham Healthcare) intravenously prior to surgery. All patients were prepared by an iodine antiseptic vaginal wash prior to the commencement of surgery. Spinal or general anesthesia was elected upon patient's request.

Patients with an anterior vaginal wall defect, with or without an apical vaginal support defect had an anterior mesh implantation through a longitudinal median anterior wall incision and para-vesical lateral dissection. The mesh was spread from one pelvic side wall to the other, from the bladder neck to the uterine cervix or vaginal apex, so as to replace the whole anterior compartment endo-pelvic fascia. Proper mesh placement required a rather large para-vesical dissection, along the bony pelvis up to the iliac spines laterally and posteriorly and to the pubic bone anteriorly. The mesh arms were passed through the ATFP ligament to prevent weakening. The mesh was also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments so as to recruit the endo-pelvic ligaments for improved support. Mesh fixation to the para-urethral tissue was also done to ensure better stabilization of the construction.

For patients with posterior vaginal wall defect (recto-enterocele), with or without apical prolapse, a posterior mesh was implanted. This was carried out through a longitudinal median posterior wall incision, then freeing the vaginal wall from the rectum and the herniated peritoneal sac of the enterocele. A para-rectal dissection was then performed to the level of the SS ligaments. The mesh was spread from one pelvic side wall to the other, from the vaginal apex to the perineal body, to replace the whole posterior compartment pelvic endo-pelvic fascia. The mesh was also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments so as to recruit the endo-pelvic ligaments for improved support. Mesh was fixed to the perineal body to ensure better stabilization of the construction. Special surgical steps to prevent mesh exposure were undertaken. This included implying meticulous tension free technique with both, vaginal wall and mesh, refraining from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia, so as to preserve blood supply and nerve endings. This avoids ischemia, poor healing and tissue necrosis, which might potentially lead to vaginal mesh erosion. It is important to replace sufficient portions of the endopelvic fascia, beyond the borders of the herniating endopelvic fascia and pelvic floor herniation, with the mesh. This is best achieved by spreading the mesh from one pelvic side-wall to the other, from the urethra and bladder neck to the vaginal apex, through the posterior compartment all the way down to the perineal body.

Patients presenting with additional significant features of pelvic floor relaxation underwent anterior or posterior colporrhaphy, as well as anti-incontinence surgery when indicated, at the same time as the mesh operation.

Pre-operative demographic data, operative details and immediate postoperative follow-up data were prospectively collected for all patients. Intra-operative and post-operative complications of all patients were recorded prospectively. The patients were interviewed at the first postoperative month and 1 year after. Subjective data recording included symptoms as urgency, frequency, stress and urge incontinence of urine or feces, sexual function impairment, voiding habits and pelvic pain and bulging. The file data collection was carried out by non-involved researchers. Patients were tele-interviewed by these researchers at study conclusion, September 2011. The study was approved by the review board (Helsinki committee). The study patients were provided with detailed relevant information prior to their signing the consent form. All patients were given 1 gr Monocef® (Cefonicid, Beecham Healthcare) intravenously one hour prior to surgery. They all underwent an iodine antiseptic vaginal wash before the surgery. The mode of anesthesia depended on the patient's request. Urinary bladder catheterization or diagnostic cystoscopy was not routinely carried out. Patients presenting with opposite compartment prolapse and urinary stress incontinence had anterior and/or posterior colporrhaphies and anti-incontinence mid urethral sling operations respectively, concomitant with the mesh reconstructive surgery. All operations were carried out by a single surgeon (MN) at a university hospital and a private hospital. These study patients were reported earlier with a longitudinal large scale publication.33

All statistical analyses were performed using SPSS 18 (IBM Corporation, Somers, NY). The student T test was used for comparison of quantitative variables between groups, while the Chi-square test or Fisher's exact test were used to compare categorical variables between groups. The Mc-Nemar test was used for longitudinal data comparison. All statistical tests were evaluated at the P=0.05 level of significance.

RESULTS

Between October 2006 and May 2008, 58 A-PFP mesh operations were performed (Prolift[®], Gynecare, Somerville, NJ, USA). Of these 27 included anterior mesh implants and 30 had posterior mesh implants. Patients with USI had additive sub mid urethral sling (SMUS) anti-incontinence surgery (TVT SECUR[®] or TVT-Obturator[®], Gynecare, Summerville, NJ, USA) and patients with opposite pelvic floor relaxation had additive native tissue colporrhaphy. No significant intra-operative injuries were reported. One paApical pelvic floor prolapse surgical repair: comparison of anterior and posterior pelvic floor compartments vaginal mesh implants

tient had an early post-operative bladder outlet obstruction, treated conservatively. Dyspareunia occurred with 2 patients, one of each group. No tape exposures were recorded.

Three patients (2 of the anterior and 1 of the posterior group) presented with operative failure and had to be re-operated. Two patients, 1 of each group, had opposite side pelvic floor compartment prolapse. In 52 patients (91%) were the results satisfying, being both – free of complications and cured, as defined by the POPQ criteria. This includes patient's satisfaction with the anatomical results and cure of the debilitating introital lump related to the prolapse as well as proper function of the pelvic organs: the vagina, the bladder and the ano-rectum.

The patients' personal characteristics pre-operatively showed no statistical differences between the two groups. Age, parity, menopause, bladder over-activity, previous anti-incontinence surgery and the presence of chronic illnesses were similar for the two patient groups. There was no difference between the groups with regard to the operative details, including the length of the procedure and the need for concomitant colporrhaphy and SMUS operations. Operative injuries and cure rates as well as post-operative complication rates were similar in the two groups. Fifty percent of both groups presented for 1 year follow-up meeting, all were tele-interviewed at study conclusion.

DISCUSSION

Pelvic floor reconstructive surgeons, being aware to many hazards with pelvic mesh implants,29-40 are often facing the need to decide whether to implant an anterior or posterior mesh for assuring A-PFP long durability cure. Frequently, the decision is made according with the anatomical situation, namely - by verifying which of the pelvic floor compartments is prolapsed more - the anterior or the posterior. The surgeon has no data to predict if this decision entails the best reinforcement for the apico-central pelvic floor compartment. This rather small two armed cohort study looked at this particular issue. The two comparable patient's groups, who were operated each with an anterior or posterior mesh and followed-up for 3-5 years, shows no difference regarding the A-PFP correction. The mesh A-PFP reconstruction anterior and posterior mesh operation carries a low complication rate and high cure rate. The current study supports the previously reported favourable therapeutic outcome of this procedure and shows that the anterior and posterior meshes are similar regarding out-come. Thus, is the surgeon allowed to choose the mesh to be used as he finds anatomically and surgically appropriate.

REFERENCES

- DeLancey OJ. The hidden epidemic of pelvic floor dysfunction: achievable goals for improved prevention and treatment. Am J Obstet Gynecol 2005; 192: 1488-95.
- Nygaard I, Barber MD, Burgio KL et al. Prevalence of symptomatic floor disorders in US women JAMA 2008; 300: 1311-6
- 3. Dietz H.P.: The etiology of prolapse. Int Urogynecol J Pelvic Floor Dysfunc 2008; 19: 1323-9.
- Burger JW, Luijendijk RW Hop WC et al. Long-term followup of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg 2004; 240: 578-83.
- Flynn BJ, Webster GD. Surgical management of the apical vaginal defect. Curr Opin Urol 2002; 12: 353-8.
 Lovatsis D, Drutz H. Vaginal surgical approach to vaginal
- Lovatsis D, Drutz H. Vaginal surgical approach to vaginal vault prolapse: considerations of anatomic correction and safety. Curr Opin Obstet Gynecol 2003; 15: 435-7.

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- David Montefiore E, Garbin O, Hummel M, Nisand I. Sacrospinous ligament fixation peri-operative complication in 195 cases. Eur J Obstet Gynecol Reprod Biol 2004; 116: 71-8.
- Crafoord K, Sydsjo A, Johansson T. Factors associated with symptoms of pelvic floor dysfunction six years after operation for genital prolapse. Obstet Gynecol Scan 2008; 87: 910-5.
- Murphy M, Sternschuss G, Haff R et al. Quality of life and surgical satisfaction after vaginal reconstructive vs. obliteration surgery for the treatment of advanced pelvic organ prolapse. Am J Obstet Gynecol 2008; 198: 573e1-7.
- Silva-Filho AL, Santos-Filho AS, Figueiredo-Netto O, Triginelly SA. Uncommon complications of sacro-spineous fixation of vaginal vault prolapse. Arc Gynecol Obstet 2005; 271: 358-62.
- Morgan DM, Rogers MA, Huebner M et al. Heterogeity in anatomic outcome of sacro-spineous ligament fixation for prolapse: a systematic review. Obstet Gynecol 2007; 109: 1424-33.
- Deval B, Haab F. What's new in prolapse surgery? Curr Opin Urol 2003; 13: 315-23.
- Papa Petros PE. Vault prolapse: Restoration of dynamic vaginal support by infracoccygeal sacropexy, an axial day-care vaginal procedure. Int Urogynecol J Pelvic Floor Dysfunc 2001; 12: 296-303.
- Farnsworth BN. Posterior intravaginal slingoplasty (infracoccygeal sacropexy) for sever post hysterectomy vaginal vault prolapse – a preliminary report on efficacy and safety. Int Urogynecol Pelvic Floor Dysfunc 2001; 13: 4-8.
- Von Theobald P, Labbe E. Three-way prosthetic repair of the pelvic floor. J Gynecol Obstet Biol Reprod (Paris). 2003; 32: 562-70.
- Smadja S, Vanormelingen L, VandeWalle G et al. Trans levator posterior intra vaginal slingplasty: anatomical landmarks and safety margins. Int Urogynecol J Pelvic Floor Dysfunc 2005; 16: 364-8.
- Siegel AL, Kim M, Goldstein M et al. High incidence of vaginal mesh extrusion using the intravaginal slingoplasty sling. J Urol 2005; 174: 1308-11.
- Neuman M, Lavy Y. Posterior Intra-Vaginal Sling (PIVS) for the treatment of vaginal apex prolapse: medium term results of the 140 operations with a novel procedure. Eur J Obstet Gynecol Reprod Biol 2008; 140: 230-233.
- Maher CF, Cary MP, Slack MC, et al., Uterine preservation or hysterectomy at sacrospinous colpopexy for uterovaginal prolapse? Int Urogynecol J Pelvic Floor Dysfunct, 2001; 12: 381-4.
- Hefni M, El-Toukhy T, Bhaumik J, Katsimanis E. Sacrospinous cervico-colpopexy with uterine conservation for uterovaginal prolapse in elderly women: an evolving concept. Am J Obstet Gynecol, 2003. 188: 645-50.
- 21. Van Brummen HJ, van de Pol G, Aalders CI, et al. Sacrospinous hysteropexy compared to vaginal hysterectomy as primary surgical treatment for a descensus uteri: effects on urinary symptoms. Int Urogynecol J Pelvic Floor Dysfunc. 2003; 14:350-5.
- Diwan A, Rardin CR and Kohli N. Uterine preservation during surgery for uterovaginal prolapse: a review. Int Urogynecol J Pelvic Floor Dysfunc. 2004; 15: 286-92.
- 23. Constantini E, Mearini L, Bini V et al. Uterus preservation in surgical correction of urogenital prolapse. Eur Urol. 2005; 48: 642-9.
- Nicita G, Li Marzi V, Filocamo MT et al. Uterus-sparing vaginal surgery of genitourinary prolapse employing biocompatible material. Urol Int. 2005; 75: 314-8.
- 25. Diwan A, Rardin CR, Strohsnitter WC et al: Laparoscopic uterosacral ligament uterine suspension compared with vaginal hysterectomy with vaginal vault suspension for uterine prolapse. Int Urogynecol J Pelvic Floor Dysfunc 2006; 17: 79-83.
- 26. Neuman M, Lavy Y: Conservation of the prolapsed uterus is a valid option: Medium term results of a prospective comparative study with the posterior intra-vaginal slingoplasty operation. Int Urogynecol J Pelvic Floor Dysfunc, 2007; 18: 889-93.
- Rosen DM, Shukla A, Cario GM, Carlton MA, Chou D. Is Hysterectomy Necessary for Laparoscopic Pelvic Floor Repair? A Prospective Study. J Minim Invasive Gynecol. 2008; 15: 729-34.
- Stepanian AA, Miklos JR, Moore RD and Mattox TF. Risk of mesh extrusion and other mesh related complications after laparoscopic sacral colpopexy with or without concurrent la-

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paroscopic assisted vaginal hysterectomy: experience of 402 patients. J Minim Invasive Gynecol 2008; 15: 188-96.

- 29. Whiteside J, Weber a, Meyn L and Walters MD: Risk factors for prolapse recurrence after vaginal repair. Am J Obstet Gynecol 2004; 191: 1533-8.
- Dallenbach P, Kaelin-Gambirasio I, Dubuisson JB Boulvain M: Risk factors for pelvic organ prolapse repair after hysterectomy. 2007; Obstet Gynecol 110: 625-32.
- Alperin M, Sutkin G, Ellison R et al. Peri-operative outcome of the Prolift® pelvic floor repair system following introduction to an urogynecology teaching service. Int Urogynecol J Pelvic Floor Dysfunc 2008; 19: 1617-22.
- 32. J. Lucioni A, Rapp DE, Gong EM et al. The surgical technique and early post-operative complications of the Gynecare Prolift® pelvic floor repair system. Can J Urol 2008; 15: 4004-8.
- 33. 33. Neuman M, Sosnovski V, Tendler R and Bornstein J. Arguments for mesh implantation at the treatment of pelvic organ prolapse, enabling the benefit of uterine preservation: outcome in 459 procedures. Pelviperineology, 2009; 28: 92-6.
- 34. Gauruder-Burmester A, Koutouzidou P, Rohne J et al. Follow up after polypropylene mesh repair of anterior and posterior compartments in patients with recurrent prolapse. Int Urogynecol J Pelvic Floor Dysfunc 2007; 18: 1059-64.
- Maher C, Baessler K, Glazener CM et al. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2004; CD004014.

- 36. Silva WA and Karram MM. Scientific basis for use of grafts during vaginal reconstructive procedures. Curr Opin Obstet Gynecol 2005; 17: 519-29.
- Schultz DG: FDA public health notification: serious complications associated with trans-vaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence 2008.
- Wu MP. The use of prostheses in pelvic reconstructive surgery: joy or toy? Taiwan J Obstet Gynecol 2008; 47: 151-6.
- 39. De Ridder D. Should we use meshes in the management of vaginal prolapse? Curr Opin Urol 2008; 18: 377-82.
- Neuman M, Lavy Y. Reducing mesh exposure in Posterior Intra-Vaginal Slingplasty (PIVS) for vaginal apex suspension. Pelviperineology, 2007; 26: 117-21.

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