Original article

Reconstruction of pelvic organ prolapse: the role of mesh implantation and the need for vaginal hysterectomy

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Abstract: Pelvic organ prolapse non-mesh reconstruction entails unacceptably high recurrence rate, thus mesh augmentation is indicated for long lasting prolapse cure and avoids the need for hysterectomy of the prolapsed uterus.

Key words: Mesh; Pelvic organ prolapse; Pelvic floor reconstruction.

GENERAL CONSIDERATIONS

The precise incidence of pelvic organ prolapse (POP) is unclear. POP encompasses many sub-groups such as vaginal wall relaxation, uterine prolapse, post-hysterectomy vaginal vault prolapse and others; POP occurs in up to 50% of parous women. Up to 30% of all females suffer from pelvic floor relaxation to a degree that has a negative impact upon their quality of life. The affected women occasionally require manual assistance to urinate and frequently report frequency, urgency and urge incontinence as well as sexual and bowel function-related symptoms. The lifetime risk of undergoing prolapse surgery is one in eleven; moreover up to 30% of those who do undergo surgery will eventually have repeat prolapse surgery, some of them following hysterectomy. Since POP is age-related it is assumed that its incidence will further increase with aging of the population. 1-3

The commonly performed non-mesh repairs for apical suspension in POP are the abdominal sacro-colpopexy and vaginaly approached sacro-spineous fixation (SSF) operation. Both requires a rather deep para-rectal pelvic dissection and are often associated with significant intra-operative bleeding. Reported complications following these procedures include post-operative dispareunia, buttock pain, urinary and fecal incontinence, cystocele and rectocele formation, altered defecation and constipation, bladder injuries, urinary retention and infections. However, the most worrying consequence of this operation is an unacceptably high prolapse recurrence rate, attributed to a large variety of pre-operative as wall as operative causative factors, among are obstetrical trauma, genetics, poor surgical technique ect. 4-6

Neither simple colporrhaphy, with or without plication of the utero-sacral ligaments and vaginal hysterectomy, nor sacro-spineous and sacral colpopexies, seem to be the ideal procedure for repairing vaginal prolapse. Some authors observed that these surgical modalities are associated with up to 58% recurrence rate, as determined by objective POP scoring and prolapse-related subjective symptoms, while others report a recurrent surgery rate for pelvic floor reconstruction of 30%. Quality of life improvement following these operations has never been properly addressed.⁷⁻¹⁴

There are sparse evidence-based data in the English literature regarding anatomical and functional long term outcomes of all the above mentioned non-mesh POP surgery. Nevertheless, vaginal hysterectomy, vaginal sacro-spinal fixation and abdominal sacro-colpopexy have remained the "gold-standard" for the repair of vaginal apical suspension defects.

As POP is, in fact, bulging of viscera through a weakened pelvic floor and weakened vaginal walls. Terms used to describe the pelvic organ prolapse can be replaced by simply stating the specific herniation process. Cystocele and urethrocele are herniation of the anterior compartment of the pelvic floor; uterine, uterine cervix and post-hysterectomy vaginal vault prolapse are all central pelvic floor herniation; while enterocele, rectocele and perineal body tear are herniation of the posterior compartment of the pelvic floor. Endorsement of this approach improves understanding of the underlying process and suggests what ought to be the appropriate therapeutic approach, based on knowledge accumulated from hernia repair in other regions of the body.

Being less invasive, the vaginal approach is safer and is associated with fewer side effects, however, it does not last as long as the repair of post-hysterectomy vaginal vault prolapse using the abdominal approach. Similarly, questions regarding the use of mesh, the preferred mesh type, size, shape and anchoring points for reinforcement of the pelvic floor compartment and for conservation of the prolapsed uterus remain unanswered for the time being. The decision as to which mesh to use – if at all, depends heavily on the individual surgeon's training and experience. This is obviously an insufficient basis for proper decision-making, which should clearly be evidence based.⁷⁻¹¹

A Cochrane review analyzing 22 trials with 2368 patients showed that abdominal sacro-colpopexy (SCP) result in lower POP recurrence rates and less dispareunia than does vaginal colpo-sacro spineous fixation (VCSSF). On the other hand, VCSSF has the advantage of a shorter operation time and recovery period. Mesh implants were found to reduce prolapse recurrence following anterior vaginal wall reconstruction, and the vaginal approach was found to be superior to the trans-anal for posterior compartment repair. 15-16

Many authors acknowledge that the paucity of relevant data regarding the operation of choice for POP does not provide adequate information to guide practice. At the same time it is recognized that non-mesh POP reconstructive surgery carries an unacceptably high rate of POP recurrence. Thus, and in spite of the relative lack of evidence-based information regarding long term efficacy and safety, the use of grafts for POP vaginal reconstruction is growing rapidly. It is widely agreed that mesh implantation should be further investigated prior to the retraction of recommendations regarding their usage. Mesh implantation must be considered carefully for each potential candidate, taking into account that the ultimate goal must be the patient's quality of life improvement, by correcting both the anatomical and functional derangements. At present there are no any data-

based guidelines for proper patient and surgery selection, peri-operative management or surgical training. There is also considerable debate regarding the place of vaginal hysterectomy in POP surgery.¹⁷⁻²⁶

The feasibility and safety of the mesh procedures does not appear to be inferior to previously reported operative techniques, and may in fact have less intra-operative and post-operative complications. The long-term effectiveness of this mesh pelvic floor reconstruction, with uterine suspension or after hysterectomy, has yet to be demonstrated by long term prospective studies.

Given that the recurrence rate following traditional non mesh vaginal apex re-suspension is unacceptably high, and that underlying genetic, traumatic and surgical co-factors contribute to progressive weakening of the endo-pelvic fascia, a surgical method with a low recurrence rate should be encouraged. Experience with abdominal wall hernior-rhaphy showed that the mesh implant concept had a low recurrence rate, and it was subsequently implemented for pelvic floor herniation repair as well.²⁷

However, unlike abdominal wall hernia vertical mesh repair, the vaginally implanted horizontal meshes are subjected to relatively high levels of physical pressure. This makes the vaginally implanted meshes prone to further prolapse unless they are well secured to solid pelvic structures.

The vaginally implanted meshes are covered by a thin, fragile layer of mucosa, compared to the thick abdominal wall coverage of the abdominal hernia mesh; hence erosion and mesh exposure are possible post-operative complications in the former. 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. In that way the pelvic organs are no longer supported by the defected endo-pelvic fascia that caused in fact the herniation, but rather with the synthetic fascial substitution. Wide dissection is generally required to achieve proper repair and to ensure adequate support.

With vaginal surgery one cannot achieve the degree of pre-operative sterilization of the surgical field that one can with abdominal operations. At best the level of sterility will not exceed the level of "clean-contaminated" sterilization, due to our inability to totally disinfect the vagina. Hence, mesh materials that are designed to be anti-infectious are needed. Thes new macro-porous and mono-filament meshes discourage bacterial growth and colonization, and are preferred for use in vaginal pelvic floor reconstruction.

The SS and ATFP suspensions are the most anatomical of the repairs, hence, it is most unlikely that these ligament supports will result in future anterior or posterior vaginal vault defects. Yet, the SS ligaments provides a unique evel 1 anchoring point.¹ for the vaginal apex, thus many prefer using this rather then to suspemd the apex to the ATFP.

The results of early attempts to reduce the prolapse recurrence rate in POP surgery by means of the standard simple mesh implantation method as used in abdominal wall herniorraphy were disappointing. Failure rates and mesh exposure rates were extremely high and this method fell into disrepute. The reasons for failure were better understood later, as the intra-abdominal forces directed to the mesh implanted in the pelvic floor and the need for proper support as well as the need for whole full thickness vaginal wall mesh coverage was appreciated. 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.²⁸⁻²⁹ The first operation to follow these principals is the Posterior Intra-Vaginal Sling (PIVS). This involves a vaginal approach, together

with anatomical restoration of the uterosacral ligament suspension of the vaginal apex, and can be performed in a daycare setting. Magnetic resonance imaging showed that significant improvement in the restoration of the vaginal configuration was achieved in patients who underwent PIVS. The restoration of the uterosacral ligament support enables the surgeon to re-suspend the uterine isthmus, thereby avoiding the need for vaginal hysterectomy, even in the event of advanced uterine prolapse. ³⁰⁻³² Currently, a large variety of pre-cut meshes are manufactured and offered for curing POP, each attached to certain safety, cure rate and specific complications. ³³⁻⁵⁰

MESH CHOICE

Accurate diagnosis of all the prolapse features and site specific support requirements identification are mandatory for proper mesh choice. Isolated apical supportive defect at the central pelvic floor compartment might be present, with anterior or posterior compartments prolapse, or any combination of these. This determines the requested mesh shape. It is the coexistence of urinary stress incontinence that indicates the need for additional mid-urethral support. The elected mesh or combination of meshes should be providing support for all the prolapsed pelvic floor sites. One must beer in mind that some commercially available anterior compartment meshes are designed for cystocele repair only, while others provides the possibility to suspend the vagina, apical prolapse or the prolapsed uterus, by cervical ring attachment. Other meshes provide support the mid urethra, concomitantly with anterior compartment reconstruction, hence un-necessitating the need for an additional tape to support the mid-urethra separately. Other meshes are designed for posterior compartment reinforcement, some of provides the possibility to support the prolapsed uterus or vaginal apex at the same time. Whenever there is a need to treat several sites of pelvic supportive defects more than one mesh might be needed. The mesh texture need to be as soft and light as possible, none shrinking, small in dimensions, yet sufficient for comprehensive replacement of all defected areas of the endo-pelvic fascia, causing pelvic floor herniation. Thorough defected endo-pelvic fascia substitution with the artificial fascia is crucial for insuring long lasting support. Host against graft and graft against host reaction formation should be ruled out according with any particular mesh prior to usage, so should any mesh related bacteria nesting or harboring. This is generally the case with type 1 mono-filament macro-porous knitted meshes, not interfering with macrophages migration. Long lasting anchoring method were reported to involve ligament through passing mesh arms, thus the particular mesh attachments to the pelvic chosen supportive points should be proved before hands for long lasting support, preferably with mesh arms through ATFP or the evel 1 providing SS ligaments anchoring. Mesh and arm delivery systems for mesh individually prepared or pre-cut kits should be proven to yield the desired correct mesh and arms placement at the pelvic floor. Some pre-cut meshes might be too small to provide the necessary complete coverage of the whole fascial defects, thus easier to place because less dissection is required. Others might provide relatively easy arm placing devices, but at the price of improper arm passage at the deep ligaments of the pelvis for appropriate high support. These meshes might be prone to operative failure and recurrent prolapse. One should not be tempted for these easy to apply kits but rather go for the highly curative ones. Bio meshes where not proven to yield any advantage over the synthetic ones and one should not endanger his patients with bio-hazards. Smilingly, the absorbable meshes where not reported to entail any superiority and one should ask himself is there any potential benefit of a vanishing mesh in herniation repair at all. The list of available commercially manufactured products expends fast and the existing ones are regularly re-shaped, thus there is no point in referring to any particular currently available mesh. With this atmosphere of many newly designed meshes popping up almost monthly, one must be extra couches when choosing his own mesh. Of huge importance is solid clinical data, proving high cure rate and low rate of complications of mild nature.

SURGICAL ASPECTS

A comprehensive pelvic floor anatomic-functional reconstruction should be based upon firm, long-lasting suspension of the vaginal walls and apex to well establish fixed pelvic structures. These anchoring structures include the arcus tendineus fascia pelvis (ATFP) and the sacro-spineous (SS) ligament. The former lies along the lateral border of the Levator ani muscles, from the inferior pubic ramus and the obturator membrane anteriorly to the iscial spine posteriorly, while the latter connects the iscial spine to the sacrum. Another potential anchoring option is the pre-sacral fascia, which covers the sacral vertebrae longitudinally and provides a solid structure that can serve as a suspensory point to which to secure the vaginal apex. The two last mentioned providing probably superior true level 1 ¹ apical support. Attaching the vaginal apex to one of these ligaments will presumably yield long lasting apical support, permitting restoration of the weakened pelvic floor and pelvic organ function. Since the ATFP is relatively easily accessible via the vagina, it is favored by some vaginal surgeons, while others prefer the SS ligament, since it is both: the most stable pelvic structure and offers the opportunity to establish a level 1 high fixation for the uterus and the vaginal vault. Hence, this provides the best long term support. However, access to the SS requires wider and deeper pelvic dissection than requested to reach the ATFP.

Subsequently, debate arose regarding the issue of mesh versus slings: the question revolving around the adequacy of replacing the specific ruptured endo-pelvic ligaments with a synthetic sling. Some felt that the whole endo-pelvic fascia should be replaced with large mesh, similar to the way mesh implants are used with abdominal wall herniation repair. This obviously entails the use of large meshes. Others thought that replacing the thorn pelvic ligament by synthetic tapes is sufficient; hence the total mesh mass and related adverse outcome might be reduced. Another point of controversy with POP vaginal mesh implantation involves the preferred pelvic fixation methods. Some feel very strongly that the only long lasting fixation method is to pass wide mesh arms through the ligaments; others sutured the mesh to ligament, or used various stapling devices.³²⁻³⁷

The mesh should be secured to the vaginal walls and apex at one edge and to the elected supportive structure – the SS, utero-sacral, pre-sacral or the ATFP ligaments – along the other edge. It should take the place of the herniated weakened fascia and ligaments that led to prolapse of the central, anterior or posterior pelvic floor compartments. Thus, the post-hysterectomy vaginal vault prolapse, as well as the frequently co-existing cystocele and/or entero-rectocele, are corrected simultaneously. It is important to flatten the mesh meticulously before assembling the cut vaginal edges, to avoid post-operative infra-mucosal folding of the mesh, which can result in pain, including dispareunia. Securing the mesh in position, either by passing ligament mesh arms or by suturing, should ensure that the mesh is properly spread to replace the entire herniation that caused the endo-pelvic fascia defect.

Steps should be taken to minimize mucosal erosion and the hazards of vaginal mesh protrusion. These anti-erosive measures involve established, conventional tension-free surgical principles for herniation repair, applied to both vaginal wall tissue and the mesh. This also includes refraining from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia, so as to preserve blood supply and nerve endings. Thus, ischemia, poor healing and tissue necrosis are avoided and likelihood of mesh exposure is reduced.⁴⁵

THE ISSUE OF REMOVAL OR PRESERVATION OF THE PROLAPSED UTERUS

Hysterectomy can result in damage to the integrity and blood supply of the endo-pelvic fascia as well as to the innervation of the pelvic floor musculature, which might potentially contribute to the manifestation of later POP, vaginal wall un-healing and later mesh exposure. As there are no data regarding the effect of hysterectomy on the pathogenesis of POP, there is considerable debate as to whether vaginal hysterectomy improves or worsens the long term outcome of surgical reconstruction of POP and the necessity for repeat prolapse surgery. The natural history of the status of the pelvic floor post-hysterectomy has never been studied in depth to determine whether the prolapsed uterus should be removed or preserved in order to achieve long-term POP cure and minimize adverse effects. By the same token, the peri-operative complications and general improvement in quality of life, including the impact of hysterectomy on the female body image and sexuality, have not been studied in terms of comparing vaginal hysterectomy to preservation of the prolapsed uterus or uterine cervix

The cervico sacral, cardinal and cervico-pubic ligaments provide the spared cervical ring extra stability for the pelvic floor, by recruitment of these web architecture structures for the pelvic reconstruction. This perspective challenges the widely endorsed practice of routine vaginal hysterectomy with any uterine prolapse, a POP reconstructive operation which currently not well supported with solid data regarding safety and cure rates. Nevertheless, some level 2 evidence supports the preservation of the prolapsed uterus, or at least the uterine cervix. This may herald a change in the policy of almost automatic reference for vaginal hysterectomy whenever POP is present. Performing hysterectomy at the time of mesh pelvic floor reconstruction significantly increases the risk of post-operative vaginal mesh exposure, with the subsequent need for further operative intervention to deal with it. Vaginal shortening is also a not infrequent complication of hysterectomy, sometimes occurring to a degree that interferes with sexual intercourse. Apart from the negative effects on pelvic floor structure and function, vaginal hysterectomy carries operation-related complications, some of which can be health or life threatening. In addition, the psychological effects in terms of the woman's body image and self esteem must not be underestimated. Novel minimally invasive operative methods as well as increasing public awareness against unnecessary hysterectomies and permit preservation of the prolapsed uterus even with formerly accepted indication for hysterectomy, other then uterine prolapse as menorrhagia, endometrial polyps and uterine myomas. 17-26

SURGEON TRAINING

Pelvic floor mesh reconstruction operations involve extensive deep pelvic dissection. Hence, it is mandatory that surgeons be thoroughly familiar with the anatomy, with accurate surgical technique, potential hazards and preventive measures, and management of complications before

embarking on the implantation of such meshes. It is suggested that surgeons undergo a meticulous training program with an expert prior to undertaking this procedure.⁵¹ One should seek for proper training before adopting any new operation and maintain his skills with frequent operation performance.⁴⁹⁻⁵⁰

CONCLUSIONS

The mesh operations, designed to prevent POP recurrence, provides a safe and feasible surgical technique. However, this rather new procedure, for either post-hysterectomy POP or for advanced uterine prolapse with or without uterine preservation, needs to be proved effective in the long run. POP reconstructions with anterior and or posterior meshes were reported to successfully achieve POP cure, with a reasonable rate and severity of complications in comparison to older operative techniques. Mesh implantation with POP reconstructive surgery permits the preservation on vaginal hysterectomy, whose adverse outcome is well established, yet true contribution for POP cure it widely questionable.

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Triple therapy in refractory detrusor overactivity: a preliminary study. *Natalin R, Reis LO, Alpendre C et al. World Journal of Urology. EPUB: 2009-03-18.* To prospectively evaluate the impact of the "three-drug therapy" (antimuscarinic, alpha-blocker and tricyclic antidepressants) on the treatment of refractory detrusor overactivity, data from 27 consented patients were collected through a daily urinary chart and an urodynamic evaluation before and 60 days after treatment with a mean follow-up of 15 months. There was a significant increase on bladder capacity and decreases on urgency, urge-incontinence and frequency. Main side effects comprised dry mouth and constipation (40%). More studies are necessary to achieve more consistent data on the matter.

7 – PAIN

Treatment of endometriosis of uterosacral ligament and rectum through the vagina: description of a modified technique. *Camara O, Herrmann J, Egbe A et al. Human Reprod. EPUB: 2009-02-19*. The optimum way to diagnose endometriosis is by direct visualization of the implants. Four patients with a uterosacral ligament and rectal endometriosis, average tumour diameter 3.5 cm, complaining of rectal bleeding and lower abdominal pain in relation to their menstrual cycle were successfully treated with combined laparoscopic-transvaginal resection.

Adequate relief in a treatment trial with ibs patients: a prospective assessment. Passos MC, Lembo AJ, Conboy LA, Drossman DA et al. *Am J Gastroenterol.* EPUB: 2009-03-19. Adequate relief of irritable bowel syndrome symptoms as an end point in randomized controlled trials is inversely related to baseline symptom severity. However, if patients who report adequate relief at screening are excluded from study participation, baseline symptom severity is no longer confounded with a report of adequate relief at the study end point.

8 - FISTULAE

Fournier's gangrene: population based epidemiology and outcomes. *Sorensen MD, Krieger JN, Rivara FP et al. J Urol. EPUB: 2009-03-17.* A national database was used to investigate the epidemiology of Fournier's gangrene. Inpatients diagnosed with Fournier's gangrene who underwent genital/perineal débridement or died in the hospital were identified in 1,641 males and 39 females the cases representing less than 0.02% of hospital admissions. The overall incidence was 1.6/100,000 males, which peaked in males 50 to 79 years old with an overall case fatality rate of 7.5%.

Hidradenitis suppurativa. *Buimer MG*, *Wobbes T*, *Klinkenbijl JH. Br J Surg. EPUB: 2009-03-14*. is a. Despite its incidence, optimal medical or surgical treatment hidradenitis suppurativa remains unclear. On the basis of histological findings, this chronic, recurrent, suppurative cutaneous disease is considered inflammatory and originating from the hair follicle; therefore it is called also acne inversa. but Smoking seems to be a major triggering factor though the exact aetiology remains obscure. Treatment should be individualized according to the site and extent of the disease. Absolute cessation of smoking is essential. Management with antibiotics or other medications may relieve early symptoms, but radical surgery may be necessary for control and to prevent recurrence.

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