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FOLLOW-UP AFTER TENSION FREE VAGINAL MESH (PROLIFT®): FIVE YEARS EXPERIENCE

Hypothesis / aims of study

This study is about evaluating complications and patient satisfaction after pelvic organ prolapse repair with vaginal mesh (Prolift®).

Study design, materials and methods

This is a prospective observational study performed in a tertiary referral center. Between January 2005 and December 2010, a total of 187 women with pelvic organ prolapse, Baden-Walker stage ≥3, underwent a transvaginal pelvic floor repair using a tension free vaginal mesh (Prolift®). All patients were interviewed and explored before intervention, and all they presented a confirmative urodynamics. After surgical intervention, we visited them at 1 and 6 months, and annually until 5 years. Then, we continued our study by telephonic interview annually so far. All our patients answered ICIQ-SF validated in Spanish and a subjective question: "How do you feel about surgery: cured-improved-equal or worse". We register this information in an Access® database, and we analyze it using SPSS® 18.0.

Results

Depending on the type of prolapse were placed 54.8% Prolift© total kit, 28.8% anterior and 16.4% posterior, with 43.2% concomitant hysterectomies and 32.3% incontinence surgery (tension free slings). There was previous surgery for prolapse in 34.2% of cases.

During the postoperative follow-up cystocele appeared in 5.5% of cases, uterine prolapse in 0.7%, vault prolapse in 4.8%, enterocele in 2.7% and rectocele in 2.7%, all of them, except uterine prolapse, usually due to involvement of an untreated compartment.

Subjective satisfaction rate described as: cure, improvement, unchanged and worse, was respectively 83%, 13%, 2% and 2% at one year follow up, 80%, 17%, 1% and 2% the second year, 81%, 15%, 2% and 2% the third year and 70%, 30%, 0% and 0% in the fourth year.

Complications were: bladder perforation 5.5%, vascular injury (Retzius) 1.2% -the 2 cases required blood transfusion and laparotomy one of them, vaginal vault hematoma 2.7%, acute urinary retention 4.8%, acute cystitis 3.4%, repeated cystitis 4.1%, mesh infection 2.7%, chronic pelvic pain 4.1% and mesh extrusion 21.2%. Mesh extrusion is significantly associated with the practice of concomitant hysterectomy (30.2% vs 14.5%, $p < 0.02$).

In general, 43.4% of patients were sexually active, and 16.3% were affected by previous dyspareunia. After surgery, 28.5% reported cure or improvement. The remaining patients, 22.2% reported dyspareunia de novo (50% mild, 37.5% moderate, 12.5% severe) with significant improvement after physiotherapy.

75.4% of patients had no urge incontinence; after surgery 10.9% had de novo urge incontinence. However, patients who previously suffered from urge incontinence improved by 48% of cases.

Interpretation of results

Prolift repair has a high anatomical success rate and also a high degree of patient satisfaction despite complications rate is not negligible, possibly due to the fact that many patients are not sexually active and the presence of extrusion, the most frequent trouble, not involve any disturbance. De novo urge incontinence is a complication to be considered, while in those patients who have previously urge incontinence may experience improvement.

It is very important to inform patients of potential risks and take into account their expectations.

Finally, we believe that we must be self-critical by the fact that the study population is not homogeneous, a problem that is otherwise common in the literature due to the complexity of this condition: we analyze patients with very different ages, as different levels of activity, with varying degrees of vaginal prolapse and affected compartments, carrying or not concomitant hysterectomy and incontinence surgery, repair of single or several compartments, previous history of prolapse surgery, etc. All these factors limit the value of the study.

Concluding message

This mesh system with anchorages is highly effective with anchors at the expense of a non-negligible complication rate.
Comparative studies are needed to evaluate different surgical techniques used in each patient profile.

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Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**