620

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PELVIC ORGAN PROLAPSE TREATMENT BY THE VAGINAL ROUTE USING A VYPRO® COMPOSITE MESH: PRELIMINARY RESULTS ABOUT 106 CASES.

Hypothesis / aims of study

Pelvic organ prolapse may recur after classical procedures in up to 40%, mainly concerning anterior vaginal wall.
Mesh reinforcement decreases the recurrence rate but exposes to problems of tolerance.
Vypro® is a mixed fibre mesh composed of half of absorbable (polyglactin 910) and half of non-absorbable (polypropylene) fibres. It was supposed to provide lower problems of tolerance than a non-absorbable mesh.
The aim of this study was to evaluate recurrence rate and tolerance of this mesh used in the treatment of pelvic organ prolapse by the vaginal route.

Study design, materials and methods

Continuous retrospective study of 106 women treated for pelvic organ prolapse by the vaginal route using Vypro® mesh. This study set up in a University Hospital in France between June 2000 and June 2002.
Pre operative evaluation included evaluation of pelvic organ prolapse related symptoms, lower urinary tract symptoms, clinical examination and urodynamic study. Details of surgical procedures were notified. Post operative events were recorded and late results were evaluated by clinical examination. Particular attention was laid on cicatrisation, erosion, retraction and rigidity phenomena.

Results

106 women were concerned. Population characteristics were: mean age of 63 years, previous hysterectomy in 32%, previous surgical procedure for pelvic organ prolapse in 26%, 93% of the women described at least one of the pelvic organ prolapse related symptoms, 96% of the women were concerned by a prolapse to or below the distal third of the vaginal length, 100% of the women completed at least one of the two last critters, 64, 2% of the women described urinary incontinence.
Surgical procedures used a mesh for anterior vaginal wall prolapse in 86%, for posterior vaginal wall prolapse in 32%, and association of both in 18%. Hysterectomy was performed in 55% of the cases and surgical procedure for urinary incontinence in 65% of the cases (62% by the TVT® procedure).
Mean follow-up was 7, 9 month (2 to 22 month). One patient was lost for follow-up.
Tolerance:
- 9, 5% of the women required removal of small part of the mesh during post operative physical examination without any anaesthesia and 30% of them cicatrised properly, 40% required additional surgical procedure and 30% had persistent defect of cicatrisation for more than 4 month.
- 10, 4% of the women required surgical removal of a part of the mesh and vaginal suture under general anaesthesia.
- 2, 8% of the women had persistent defect of cicatrisation for more than 4 month.
- 17% of the women underwent at least one of the 3 previous events.
- 9, 5% of the women had an unusually retracted mesh at the last physical examination.
- 4% of the women had an unusually rigid mesh or vagina at the last physical examination.

Recurrence of prolapse to the distal third of the vagina or below, or requiring surgical procedure occurred in 10, 4% of the women and in 7% of the procedures for anterior vaginal wall prolapse.
Recurrence (using the same critters) on a mesh-repaired compartment occurred in 7% of the all the women and in 6, 6% of the procedures with mesh for anterior vaginal wall.
At the last physical examination, 49, 5% of the women had anatomical descent at the mid third of the vagina.
At the last follow-up 71, 5% of the women described no urinary incontinence.

Interpretation of results

In this study, tolerance of the Vypro® mesh is very poor. High rates of erosion and problems of cicatrisation have been observed and may either be explained by the mesh itself or by surgical technical details.

Not well known complications of retraction and rigidity have been observed frequently with clinical severe consequences.

The use of a half absorbable mesh does not seem to reduce the inflammation and could even accentuate it.

Good results of the TVT® procedure does not seem to be much modified by the additional procedure for prolapse.

Concluding message

Vypro® mesh did offer disappointing results of tolerance.

Longer follow-up is necessary to evaluate the impression of improvement on recurrence rate.

All these results lay emphasis on the importance of clinical evaluation of biomaterials.

The results of the ongoing prospective study on Vypro® are expected to confirm or not these preliminary results.