Hypothesis/aim of study

The aim of the study was to report peri-operative and immediate post-operative complications and anatomical outcome data following the surgical placement of transvaginal mesh, the Prolift procedure, in the treatment of pelvic organ prolapse.

Study design, materials and methods

In the retrospective study from April 2007 to October 2009, 70 women underwent vaginal repair with implantation of a soft mesh manufactured by Gynecare, Prolift (Ethicon, Sommerville, NJ, USA). Patients had undergone either an anterior, a posterior or anterior and posterior (total) Prolift. The mesh indication was reserved for recurrent vaginal prolapse and the cases with significant primary prolapse.

The stage of prolapse was assessed in the lithotomy position while the patient performed a Valsalva maneuver and prolapse was classified using POP-Q system of the ICS. A concomitant procedure was performed if necessary, including vaginal hysterectomy, sacrospinous fixation or TVT-O. Routine follow-up was performed after 4 weeks, 3 months and 6 months. Minimum follow-up was 3 months for all patients. Recurrent prolapse was defined as any descent of stage 3 or 4 even if patient had no symptoms.

Results

Average age was 67 (±7) years. Previously 31 (44.3%) had a vaginal surgery and 21 (30%) patients had abdominal hysterectomy for benign disease, usually most often fibroids. Ten patients (14.3%) had 2 or more pelvic operations. All patients had ≥ stage 2 symptomatic prolapse. An isolated anterior mesh was used in 38 patients (54.3%), an isolated posterior mesh in 24 patients (34.3%) and total mesh in 8 patients (11.4%). Prior hysterectomy had not been performed in 30 patients. Among these patients, the uterus was preserved in 70% of them (21 patients). Vaginal hysterectomy was performed in 9 patients for benign reasons or because it was a patient’s choice.

Associated procedures was sacrospinous uterine fixation in 3 (4.3%) patients, sacrospinous vaginal fixation in 12 (17.2%) patients, TVT-O in 16 (22.8%) patients. Intra-operative complications manifested as bladder injury in one (1.4%) patient. The bladder injury was recognized and sutured at surgery. There was no blood loss over 250ml and no rectal injury. Mean hospital stay was 4.5 days (range 3-12).

All patients were fully available for median follow-up of 14.4 months (range 3-32 months). Postoperative complications manifested as persistent perineal pain and painful intercourse in 1 (1.4%) case, the mesh exposure (vaginal erosion) in 8 (11.4%) patients (all in associated vaginal hysterectomy), the shrinkage of the mesh in 6 (8.5%) cases. Among 38 (54.3%) patients with anterior mesh placement, 3 (7.9%) had de novo stress urinary incontinence.

Failure rate after the procedure was 7.1% (5 patients). Three (4.2%) patients developed an asymptomatic stage 3 cystocele, 1 after posterior mesh and two after total mesh placed in one piece and didn’t required repeat surgery within a 6 months follow-up. One patient had asymptomatic rectocele stage 3 after anterior mesh and required father repair with posterior mesh placement. One patient had asymptomatic enterocele stage 3 after anterior mesh.

Interpretation of results

The patients developed prolapse in an uninvolved pelvic compartment. The choice between a complete vaginal reconstruction of all compartment and a specific repair of the defective areas only is much debates. The risk of a specific repair is to provide a de novo prolapse in a compartment that previously appeared well-supported. The anatomic outcome and the site of recurrence in our study suggest necessity to perform the correction of all anatomic defects.

Concomitant hysterectomy was an associated risk factor for mesh erosion in our study.

Concluding message

The transvaginal use of mesh according the Prolift technique is a safe procedure for definitive repair of pelvic organ prolapse. The procedure is minimally invasive, has low morbidity and is well tolerated by patients. We need a longer follow-up to confirm the effectiveness of procedure. Further evaluation into functional outcomes, including defecation and sexual function need to be explored.

References

| **Specify source of funding or grant** | none. |
| **Is this a clinical trial?** | No |
| **What were the subjects in the study?** | HUMAN |
| **Was this study approved by an ethics committee?** | No |
| **This study did not require ethics committee approval because** | Because it was retrospective design study. |
| **Was the Declaration of Helsinki followed?** | Yes |
| **Was informed consent obtained from the patients?** | Yes |