Abstract

Pelvic Organ Prolapse (POP) is characterized by the attenuation of endopelvic fascia and pelvic diaphragm. It reduces the quality of life (QOL) in almost 50% of women after menopause. Using meshes to reinforce endopelvic fascia and to obtain the reconstruction of pelvic floor anatomy and bladder sphincter support in women, begun with the Ulmsten's "Integral Theory" from 1996. FDA notification on high complications associated with transvaginal polypropylene (PP) meshes in pelvic reconstructive surgeries highlights "the need for new material" (1). The objective of this study is to examine the behavior of polyvinylidene fluoride (PVDF) meshes as a new material suggested for treatment of POP (2).

Methods and Materials

Between 2010-2018 and in 2 hospitals of the urology and urogynecology department of Isfahan University of Medical Sciences, women with symptomatic stage III or IV POP according to POP-Q classification. The presence of meshes erosion was evaluated using validated ICQI-FLUTS and ICQI-VS questionnaires; for urinary incontinence, patients underwent stress test while supine at maximum physiological bladder capacity. Finally, mesh edges are extracted by trocars for surgical management of pelvic organ prolapse.

Results

Polyvinylidene fluoride (DynaMesh PRF soft 07cm/9cm, PRG Textiltechnik, Aachen, Germany) were used with Double Trans Obturator technique. Sixty nine patients (77.5%) presented stage III and 20 patients (20%) stage IV of prolapse. The mean follow up was 22.9 months (ranged in 4-44 months). Eighty seven patients (97%) had complete resolution of the prolapse (stage 0 or 1 based on POP-Q) and 64 (75%) recovered from stress urinary incontinence (defined as no accidental release of urine after asking to cough). Four patients had vaginal mesh exposure; one after chemotherapy due to bladder cancer, one following vaginal bleeding 3 months after mesh insertion and the other two due to discontinuation of topical estrogen following vaginitis. Of these, 3 patients underwent surgical mesh removal and in 2 of them, symptoms recurred and outpatient treatment was performed. Five patients (5.6%) presented with the recurrence of prolapse after the symptoms were resolved. During the first week after surgery, 18 patients (20.2%) had urinary retention (defined as post-void residual volume (PVR<200ml) and received a urinary catheter. After a month of surgery, urinary retention sustained in only 5 patients (5.6%) needing surgical intervention to remove the obstruction and urinary retention.

Table 1. Patient’s baseline characteristics and perioperative data

<table>
<thead>
<tr>
<th>Age, years Mean ± SD (range)</th>
<th>Painy Mean ± SD (range)</th>
<th>Cesarean delivery no. (%)</th>
<th>BME Mean ± SD (range)</th>
<th>Menopause no. (%)</th>
<th>Risk factors (diabetes mellitus, smoking, UTSI, immunosuppression, chronic constipation, PVR&gt;100, hypothyroidism) no. (%)</th>
<th>Prior pelvic surgery no. (%)</th>
<th>Hystecestomy</th>
<th>Pelvic organ surgery (anti-incontinence surgery)</th>
<th>Concomitant procedures no. (%)</th>
<th>Levatoroplasty</th>
<th>Rectocele repair</th>
<th>Posterior wall repair to surgery no. (%)</th>
<th>POP transvaginal grade no. (%)</th>
<th>Grade IV</th>
<th>Grade III</th>
<th>Hospital stay Mean ± SD (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>63.5 ± 8.8 (41-86)</td>
<td>4.5 ± 2.3 (0-14)</td>
<td>8.1 (8.9)</td>
<td>27.9 ± 3.6 (18-37)</td>
<td>74.5 (63-84)</td>
<td>54 (60.5)</td>
<td>27 (30.5)</td>
<td>1 (1.1)</td>
<td>17 (19.1)</td>
<td>4 (4.5)</td>
<td>1 (1.1)</td>
<td>50 (56.2)</td>
<td>77 (85.5)</td>
<td>20 (22.3)</td>
<td>3 ± 0.9 (1-4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Discussion

Following the FDA notification of high complications associated with transvaginal polypropylene (PP) meshes, the need for a new material for the pelvic reconstructive surgeries is more than ever. Previous studies have shown the initial satisfactory result for the usage of PVDF rather than PP meshes. However, further studies in different populations and with longer follow ups are needed to confirm the biocompatibility and safety of PVDF meshes as a secure alternative for PP meshes. Our study suggests that in a mean of 2-year follow-up period, PVDF meshes have a low rate of complications and can effectively repair the pelvic organ prolapse.

Conclusions

In reaction to FDA warning on mesh associated complications, our study introduces PVDF mesh as an effective and biocompatible material for pelvic organ prolapse surgery.

References