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RETROSPECTIVE COMPARISON BETWEEN THE PROLIFT AND ELEVATE ANTERIOR VAGINAL MESH PROCEDURES.

Hypothesis / aims of study

The use of alloplastic material (e.g., polypropylene mesh) for transvaginal repair of pelvic organ prolapse (POP) has become a popular technique to improve outcomes of POP surgery. Transvaginal placement of surgical mesh (TVM) may provide an anatomical improvement as compared to the traditional POP repair without mesh, particularly in the anterior compartment.
The first generation external trocar-based kit (e.g. Prolift) and subsequently single-incision vaginal approach grafts (e.g. Elevate) have already been described. A typical placement of the Prolift anterior requires five incisions, i.e. one anterior vaginal incision and four cutaneous incisions for the passage of superficial straps. A typical placement of the Elevate mesh requires a single incision. In contrast to the Prolift, the Elevate system provides four-point fixation in the sacrospinous ligaments (SSLs) and the obturator internus muscles with plastic fixation tips. Given the above differences in the placement method certain differences in surgical and clinical outcomes may be expected between the Prolift and the Elevate mesh. It has been hypothesized that attachment of the Elevate to the SSLs may be associated with a better level I or apical support and less tissue dissection, and thus a lower risk of a nerve injury and postoperative pain [1]. Despite the clinical significance of the above hypotheses, there are insufficient data to guide treatment decisions, i.e. a choice between the first-generation (e.g. Prolift) and single-incision Elevate kits. The primary purpose of the present retrospective study was to compare a long-term (i.e. 18-month) operative success in patients who had undergone POP surgery with the Prolift or Elevate mesh procedures. Both subjective (bulge symptoms) and objective measures (absence of anterior or apical descent beyond the hymen, POP-Q anterior stage 0 or I, no-retreatment for POP) were used as the primary outcomes as recommended by the international guidelines. Rates of postoperative pain, dyspareunia, *de novo* overactive bladder (OAB), *de novo* stress urinary incontinence (SUI), and mesh exposures were used as secondary outcomes in statistical analyses.

Study design, materials and methods

The study groups included patients with symptomatic anterior compartment and/or apical prolapse, stages III and IV, based on the POP-Q system, who had undergone standardized implantation of the Prolift mesh or the Elevate anterior mesh. Women with a prior anterior POP surgery were excluded from the study, hence 114 out of 131 patients underwent further assessment. Medical records of women with an anterior vaginal wall prolapse operated between 2011 and 2012 were reviewed. The final database contained pre- and postoperative records of a total of 114 Caucasian women i.e. the Prolift (n=52) and the Elevate patients (n=62). For all the patients included in the database, a clinical follow-up assessment was performed at 18±2 months postoperatively. The vaginal bulge symptoms were assessed using a question selected from the Pelvic Floor Distress Inventory (“Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?”). Patients scoring ≥1 were considered as having bulge symptoms. Retreatment for POP was defined as any repeat surgery for a prolapse arising from the same site or the use of pessary for a recurrent anterior and/or apical descent.
The patients were interviewed about SUI symptoms using the Stamey Incontinence Score The patients with grade ≥ 1 or showing positive cough stress test were considered to have SUI. The OAB symptoms were assessed using questions selected from the Pelvic Floor Distress Inventory (“Do you usually experience frequent urination?“, “Do you usually experience a strong feeling of urgency to empty your bladder?”, “Do you usually experience urine leakage associated with feeling of urgency, that is, a strong sensation of needing to go to the bathroom?”). The patients who answered “yes” to any of the questions were considered to have OAB. The postoperative pain severity was estimated by the patient using a five-point scale based on the IUGA/ICS grading system for the assessment of mesh-related pain. Dyspareunia was assessed with the question “Do you have pain with intercourse?”

Results

There were no differences in the subjective (bulge symptoms) and objective measures of operative success (absence of anterior or apical descent beyond the hymen, POP-Q anterior stage 0 or I, no-retreatment for POP on the follow-up). In line with the above, the mean anterior POP-Q stage assessed on the follow-up evaluation did not differ between the groups (p values >0.05). The χ^2 test showed no between-group differences in the proportion of women reporting postoperative pelvic floor pain, dyspareunia, *de novo* SUI, and *de novo* OAB symptoms (p values >0.05). The proportion of patients with postoperative vaginal exposures was significantly higher in the Prolift (7.7%) as compared to the Elevate group (0.0%; p=0.02; Table 2).

Interpretation of results

Our study showed the high and comparable operative success rate in two groups of women following the POP surgery with the anterior Prolift or Elevate mesh. In general, the present results provide a further support for studies showing relatively high objective and subjective success rates following both anterior Elevate [1] and anterior Prolift mesh repair [2]. A closely similar conclusion has been drawn from a retrospective study by Larouche et al [3]. The latter authors have reported that trocar-guided Gynemesh and trocarless Polyform TVM systems resulted in comparable objective and subjective success rates and that the newer Polyform mesh led to significantly fewer mesh exposures.

Concluding message

Our results suggest that:
i) the single-incision Elevate mesh does not offer a clear-cut advantage in terms of objective and subjective postoperative success rates compared to the trocar-based Prolift mesh system,
ii) the Elevate mesh may offer a significant benefit regarding the risk of vaginal exposures,

iii) Further longitudinal studies on the first-generation external trocar-based kits and second-generation single-incision vaginal approach grafts are mandatory to validate the results of the present and previous studies.

References

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Disclosures

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.Sz., M.J., W.B.) and the Institute of Psychiatry and Neurology (P.B.), Warsaw, Poland. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Committee for Human Studies of the Military Institute of Medicine, Warsaw, Poland. **Helsinki:** Yes **Informed Consent:** Yes