

COMPARISON OF EFFICACY AND SAFETY OF VAGINAL MESH KITS (POSTERIOR INTRAVAGINAL SLINGPLASTY VS PROLIFT) IN THE TREATMENT OF PROLAPSE OF THE VAGINAL APEX

Hypothesis / aims of study

The aims of this study are to determine whether intravaginal mesh kits available now in Korea for restoring apical vaginal prolapse are acceptable, and to compare objective, anatomic outcomes.

Study design, materials and methods

We included 200 patients who had undergone pelvic organ prolapsed treatment with posterior intravaginal slingplasty (PIVS group; 100 cases, Tyco Healthcare, Norwalk, CT, USA) or Gynecare Prolift™ system (Prolift group; 100 cases, Ethicon Women's Health and Urology, Somerville, NJ, USA). The evaluation included a medical history, physical examination including Pelvic Organ Prolapse staging system (POP-Q), and urodynamic study. An anatomic cure after intervention was defined as stage 0 and an improvement was defined as stage I. Anatomic failures were defined as stage II or higher. The patients were monitored at 1, 3 and 12 months postoperatively, the mean follow up was 22.5 months.

Results

Preoperative prolapse stages were stage II in 47 (47%) vs 40 (40%), III in 35 (35%) vs 46 (46%), IV in 18 (18%) vs 14 (14%) for PIVS group vs Prolift group, respectively.

Among the patients operated on for apical vaginal prolapse, 83.0% (83/100) vs 90.0% (90/100) patients were cured, 13.0% (13/100) vs 10.0% (10/100) patients showed improvement, and 5.0% (5/100) vs 0% (0/100) patients showed failure for PIVS group vs Prolift group, respectively. The mean hospitalization was 3.5 vs 3.4 days, the mean operation time was 37.4 vs 44.0 minutes, and the mean bleeding volume was 95 vs 105 ml for PIVS group vs Prolift group, respectively.

The identified complications were mesh erosion in 11.0% (11/100) vs 4.0% (4/100), hemorrhage that needed transfusion in 4.0% (4/100) vs 4.0% (4/100) for PIVS group vs Prolift group, respectively.

Interpretation of results

Intravaginal mesh kits (posterior intravaginal slingplasty vs Prolift system) in restoring apical vaginal prolapse were both effective and safe.

Concluding message

Overall objective success rate was higher in Prolift™ system. However, because of an increasing number of women requiring surgical intervention for mesh related complication, close follow is necessary.

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	retrospective outcome analysis
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No