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TRANSVAGINAL MESH REPAIR OF PELVIC ORGAN PROLAPSE: SHORT TERM OUTCOMES FROM A PROSPECTIVE MULTICENTER STUDY

Hypothesis / aims of study
This is the first report from an on-going international multicenter cohort study with the primary aim to describe short-term outcomes of pelvic organ prolapse repair using a standardized surgical kit with macroporous, monofilament polypropylene mesh placed through a transobturator or transgluteal approach (PROLIFT®, Ethicon, Somerville, NJ). We here present 2-month outcomes based on the interim safety analysis.
Study design, materials and methods
A prospective multicenter study throughout 28 clinics in Sweden, Denmark, Finland and Norway. The study aims for a three-year evaluation subsequent to pelvic organ prolapse surgery using transvaginal mesh, with comprehensive assessments scheduled at two months, one year and three years postoperatively. Clinical evaluation is performed using the pelvic organ prolapse quantification (POP-Q). Inclusion criteria stipulate that all patients have POP-Q stage ≥2 and symptoms attributed to pelvic organ prolapse including vaginal bulging, pelvic heaviness or vaginal protrusion. Subjective outcome is evaluated using the Urogenital Distress Inventory (UDI) and the short-form Incontinence Impact Questionnaire (IIQ-7). Statistical comparison was performed using the Wilcoxon test for dependent samples. The transvaginal mesh manufacturing company had no influence over study aim, study design, execution of the study or analysis and interpretation of data.
Results
The present evaluation includes 123 patients who completed their two-month follow-up before March 1, 2007. Mean age was 67.5± 8.7 (S.D), mean body mass index (BMI) was 31.0± 10.1 (S.D.), median parity was 2 (range, 1-5) and 110 patients (89%) were postmenopausal. Anterior repair was performed in 61 patients (59%), posterior repair in 32 patients (26%), combined anterior and posterior repair in 17 patients (14%) and total repair in 13 patients (11%). Pelvic organ perforation occurred in four cases (3.2 %): three bladder injuries detected intra-operatively, and one case of rectal perforation detected postoperatively. There were no cases of bleeding in excess of 500 ml but one patient was re-hospitalized and re-operated after a posterior repair due to a vaginal hematoma.
At the two-month follow-up, there was a significant improvement of anatomical support in all operated vaginal compartments ($p<0.001$ for all). In terms of anatomical cure, the postoperative prevalence of POP-Q stage 0-1 was: 87% after anterior repair, 91% after posterior repair and 88% after total repair. There were significant improvements in all quality of life aspects measured by the IIQ and considerable improvements in all urogenital complaints of the UDI. Symptoms of vaginal bulging, pelvic heaviness and need for manually assisted defecation decreased significantly ($p<0.001$). There were no cases of serious complications attributed to the polypropylene mesh two months after surgery.
Interpretation of results
The first report from our on-going prospective study suggest that transvaginal mesh surgery using the PROLIFT®-system is associated with satisfactory anatomical and functional outcomes with limited adverse events attributed to the polypropylene mesh within two months of surgery.
Concluding message
Newly introduced surgical procedures may be universally accepted when the magnitude of its benefits outweighs the risks. Caution is advised until further evaluations are available on several important long-term outcome measures including: sexual function, pelvic pain, in-vivo biocompatibility of large sized polypropylene mesh and sustainability of the achieved anatomical and functional results in comparison to traditional suture techniques.
References

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HUMAN SUBJECTS: This study was approved by the The Swedish Research Ethics Committee for Multicenter Studies at Karolinska Institutet and followed the Declaration of Helsinki Informed consent was obtained from the patients.