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PELVIC ORGAN PROLAPSE SURGERY WITH NON-ANCHORED MESH IMPLANTS AND VAGINAL SUPPORT DEVICE IN WOMEN WITH MODERATE SYMPTOMATIC PROLAPSE: PROSPECTIVE STUDY

Hypothesis / aims of study
Surgical treatment of pelvic organ prolapse (POP) is associated with high recurrence rates. Around 17-29% of surgically managed patients require re-operation. There is incerasing evidence that the tension-free vaginal insertion of prosthetic mesh in patients with symptomatic POP reduces the chance of anatomic failure. A troacar–guided mesh systems are more suitable for POP stage III or IV according to the Pelvic Organ Prolapse Quantification (POP-Q) classification. Approximately 54% of symptomatic POP patients have moderate (POP-Q Stage II) prolapse. The aim of this prospective study was to assess outcome of the system with non-anchored mesh technique to correct POP by the vaginal approach.
Study design, materials and methods
This is an open, prospective, observational study of patients operated with the Gynecare Prosima Pelvic Floor Repair System (Ethicon, Somerville, NJ) technique at one center between November 2009 and December 2010. A total of 49 women were included in the study (drop out 0 patients). Overall, 51% women had a prior hysterectomy and 64% had a previous POP surgery (1-5 previous POP surgeries). Women with symptomatic stage II prolapse by the POP-Q classification in anterior, posterior or both compartments were included in the study. Exclusion criteria were: 1) concomitant stress urinary incontinence procedure, 2) concomitant POP procedure, 3) previous POP mesh repair, 4) stage III or IV pelvic organ prolapse according to the POP-Q. In the group of women where the Prosima procedure was the primary surgery, severe morphological levator ani abnormalities where diagnosed (avulsion injury, hiatus area > 25 cm^2. Lower urinary tract symptoms (LUTS) before the procedure were present by 62% of women (13%-SUI, 27%-OAB, 22%-MUI). The pre-and postoperative evaluation (1 month, 3 months, 6 months and 1 year) comprised of a vaginal examination with the grading of the defect according to the POP-Q system of the ICS. Patients self-evaluated the severity of their POP symptoms with the use of a visual analog scale (VAS). Quality of life (QoL) assessment was performed using the QoL questionnaire: ICIQ-UI SF, PISQ 12, PFDI, PFIQ. The pre-and postoperative morphological evaluation was done with help of MRI and 3/4D ultrasound examination. The procedures were performed under general or regional anesthesia, antibiotic and venous thrombosis prophylaxis, digital rectal examination after posterior repairs and cystoscopy only in indicated cases. The mesh was inserted after hydro-dissection and full thickness vaginal wall incision. The vaginal support device was removed after 28 days.
Results
The mean age was 64.4±9.2 years (range 48-88), mean BMI 28.42±4.7 kg/m^2 (range 20.8-36.9), and mean parity was 2 (range 1-3). Mean follow-up 5.31 months (range 1-12). The surgical procedures were: Prosima Anterior - 20 (41%), Prosima Posterior - 19 (39%) and Prosima Combined - 9 (19%). Concurrent vaginal hysterectomy was performed in two patients. The mean operating time was 57.07 min. (range 20-120), and mean blood loss 59±89 ml (range 10-450). There were two (4.08%) major peroperative complications: one (2.04%) bladder perforation recognized during surgery (mesh was not inserted) and one (2.1%) severe bleeding episode (mesh was inserted). There were no other complications such as urethral, nerve or bowel injury. Early postoperative complications (day 0-7): a) febrile morbidity – 7.1%, b) VSD associated complications – 21.4%. There was no clinical hematoma or bleeding in the early postoperative period. Late postoperative complications (day 8-28): a) urinary tract infection – 12.8%, b) VSD associated complications – 42.0%, c) colpitis – 9.7%. The mesh exposure rate was 4.16%. The defect was localized in the anterior compartment. Mean time to exposure was 3 months. Levator avulsion was diagnosed (MRI, 4D ultrasound) in 45.2% patients (bilateral in 23.2%, unilateral in 21.4% cases).
Interpretation of results
There was a significant decrease in the mean VAS score from 5.31±2.77 to 3.0 ±2.27. The incidence of micturition problems after the surgery reflex the significant positive change in ICIQ-UI SF values from mean 7.05±5.41 to mean 4.51 ±5.11. Stress urinary incontinence by follow-up of 3 months was observed by 26% patients. Urgency by follow-up of 3 months was observed by 11% patients. We observed one (2.1%) case of POP recurrence after Prosima Combined insertion. In the anatomically cured group we found statistically significant changes in POP-Q points in treated compartment (Table 1). There was no significant change in the mean PISQ 12 score from 27.19±10.93 to 28.06±13.75 at 6month follow-up. Mean hospitality stay – 4.7 day.
Concluding message
Our findings suggest that the interposition of a monofilament polypropylene non-anchored mesh and VSD is safe and leads to improved vaginal support at short term follow up in women with symptomatic POP Q stage II prolapse but more studies are needed.

POP-Q	**Anterior Prosima**			**Posterior Prosima**		
Individual (cm)	**baseline**	**6m**	**stat.signif.**	**baseline**	**6m**	**stat.signif.**
Aa	-0.2	-1.1	s.s	-1.3	-1.7	n.s
Ba	0	-2.5	s.s	-2.2	-2.5	n.s
C	-2.7	-7.6	s.s	-2.7	-8.3	s.s
Ap	-1.3	-1.6	n.s	-0.4	-1.2	s.s
Bp	-2.3	-2.3	n.s	-0.7	-2.5	s.s
Gh	5.0	4.8	n.s	4.5	4.3	n.s
pb	4.0	4.3	n.s	3.7	3.8	n.s
TVL	6.4	7.8	s.s	6.3	8.0	s.s

Table 1: Pelvic organ prolapse data before and 6 months after surgery

Specify source of funding or grant	**NONE**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Local Ethics Committee of Institute for the care of mother and child**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**