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PATIENT REPORTED OUTCOME MEASURES (PROMS) EVALUATION FOLLOWING ELEVATE POSTERIOR™ REPAIR SYSTEM FOR APICAL AND OR POSTERIOR COMPARTMENT PROLAPSE

Hypothesis / aims of study

EQ-5D (1) is a standardised measure of health status developed by the EuroQoL Group in order to provide a simple, generic measure of health for clinical and economic appraisal. This contains 5 domains (Mobility, self-care, usual activities, Pain and anxiety) and a visual analogue scale (VAS). This questionnaire has been validated as a quality of life assessment for the patient reported outcome measures (PROMS) project. The PROMS includes EQ-5D and a disease-specific questionnaire –PISQ-12 (Pelvic organ prolapse/Urinary Incontinence Sexual function Questionnaire).

Because of the large dissections of transobturator and transgluteal passages and the use of large non absorbable meshes, transvaginal mesh repair has been thought to induce significant post operative sexual dysfunction. A recent Cochrane review (2) revealed that mesh repair in the posterior compartment has been proven to have a higher incidence of sexual dysfunction.

Therefore we aim to determine the efficacy and safety and also the PROMS following transvaginal mesh repair of posterior compartment and apical prolapse using the Elevate posterior™ system (American Medical Systems, Minnetonka, MN, USA).

Study design, materials and methods

Design: Single-arm, prospective, single-centre trial of women with POP-Q stage II or greater posterior compartment and apical prolapse implanted with Elevate Posterior™ device.

The study population is female subjects > 21 years of age who have been diagnosed with one or more clinically significant apical or posterior genital prolapse disorder(s) (symptomatic POP-Q stage II or higher) requiring surgical repair

The clinical data was analyzed by comparing post-treatment data with the baseline data, before the procedure with the subject acting as her own control. The primary endpoint is for 12 months after the procedure with objective and subjective assessments. All women underwent medical history, physical exam, before treatment (Baseline) and at 4 and 12 months after the procedure. At 4-months and 12-months' follow up, the impact of the procedure on PROMS as measured by EQ-5D and Pelvic Organ Prolapse/ Urinary Incontinence Sexual Questionnaire (PISQ-12) when compared with baseline before the procedure was done. Chi-Square test was used to determine the statistical significance by using SPSS release 16.0.

This project has been approved by the clinical effectiveness department.

Results

Forty five patients underwent the procedure. 26(57.7%) women were sexually active before procedure whereas 29 (64.4%) were sexually active after the procedure. One patient (2.2%) had buttock pain. 2 patients (4%) had mesh erosion needing removal. In one patient (2.2%) the mesh failed to rectify the prolapse. One patient (2.2%) had excessive bleeding over 500 ml, needing vaginal packing. 44(97.8%) had objective improvement at stage I or less at both 4 and 12 months' followup.

Demographic data
Age (61.15±10.4)
Parity (median 3 Range: 1-8)
BMI (32.5±11.18)

Tables 1 and 2 outline the results for the PISQ-12 and EQ-5D

Table1. Quality of Life analysis

Variable	Before the procedure	4 months after the procedure	12 months after the procedure	P value
PISQ-12	16.4±6.7	13.9±6.3	15.9±5.8	0.758
VAS	56.6±25.4	69.1±21.1	74.8±19.2	<0.05

VAS- Visual Analogue Scale included in EQ-5D

Table2. EQ-5D Assessment

EQ-5 Dimension	Problem	Before the procedure	4 months after the procedure	12 months after the procedure
Mobility	No	31(68.9%)	33(73.3%)	30 (66.7%)
	Yes	14(31.1%)	12 (26.7%)	15 (33.3%)

Self-care	No	39(86.7%)	42(93.3%)	39(86.7%)
	Yes	6(13.3%)	3 (6.7%)	6(13.3%)
Usual activities	No	27(60%)	26 (57.8%)	29 (64.4%)
	Yes	18(40%)	19(42.2%)	16 (35.6%)
Pain*	No	16 (35.6%)	24(53.3%)	21(46.7%)
	Yes	29(64.4%)	21 (46.7%)	24 (53.3%)
Anxiety€	No	28 (62.2%)	32 (71.1%)	30 (66.7%)
	Yes	17 (37.8%)	13 (28.9%)	15 (33.3%)

- *Statistically significant at 4 months p-0.003; at 12 months p-0.016
- € Statistically significant only at 4 months follow up p-0.002; However at 12 months p-0.258 not significant.

Interpretation of results

Overall VAS score on quality of life has significantly improved. In the VAS analysis for the state of the health, the women had significant improvement from 56.6±25.4 before the procedure to 69.1±21.1at 4- months and to 74.8±19.2 at 12 months of follow up ($P<0.05$). There was no deterioration in the sexual function following the procedure at 4 months and 12 months of follow up. When different aspects of EQ-5D are analysed the pain and anxiety showed a significant reduction ($P= 0.003$) and ($P= 0.002$) at 4 months respectively. Pain dimension continued to improve whereas anxiety dimension failed to show any significant variation at 12 months follow up.

Concluding message

Elevate Posterior™ system is safe and effective in the management of Posterior compartment prolapse repair. There is no deterioration in post operative sexual dysfunction. Our study also concludes that this repair system is associated with an overall improvement in the state of health.

References

1. The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.
2. Maher C, Baessler K, Glazener CM, Adams EJ, Hagen S. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2007 Jul 18;(3):CD004014. Review.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**This project has been approved by the clinical effectiveness department.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**