361

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TRANSVAGINAL MESH REPAIR FOR PELVIC ORGAN PROLAPSE: LONG-TERM RESULTS AND QUALITY OF LIFE

Hypothesis / aims of study

The US Food and Drug Administration (FDA) expressed repeatedly concerns about the safety and effectiveness of transvaginal mesh (TVM) usage for pelvic organ prolapse (POP) repair.[1] The most frequent reported complication is mesh erosion into the vagina with an incidence of 6 – 19 followed by mesh retraction with concomitant pain in 3 – 19% as well as dyspareunia in 14 – 24%.[2] These complications can lead to multiple surgeries and continued sequelae. Nevertheless, evidence indicates that surgeons experience is probably of utmost importance for outcome in POP repair. Therefore, clinical trials are necessary to declare the definite safety and effectiveness in POP repair. Particularly long term outcomes are still lacking for a final evaluation for the safety of TVM repair. In this cohort study we investigated the long-term results of transvaginal mesh (TVM) repair and evaluated the quality of life of the patients by validated questionnaires.

Study design, materials and methods

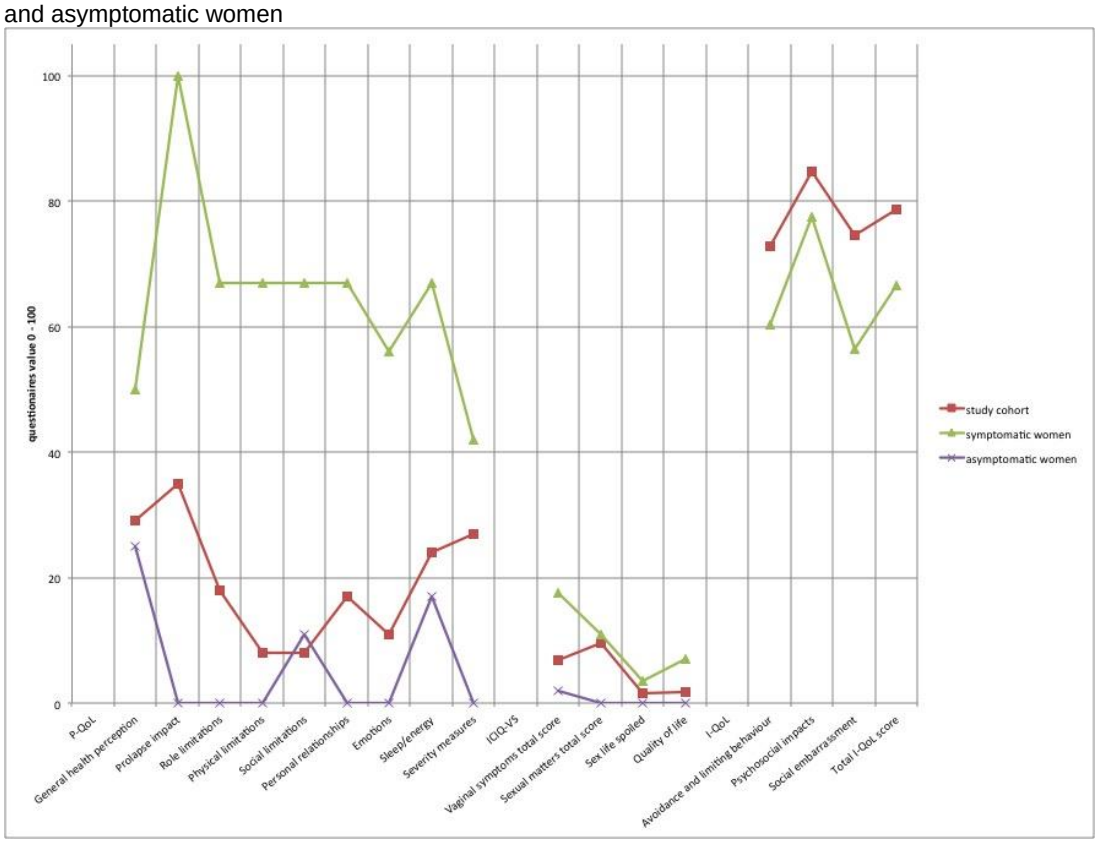
A total of 148 patients who underwent TVM repair for POP were retrospectively enrolled. Long-term complication rates and functional outcomes were retrospectively assessed. Additionally, standardised and validated questionnaires were used prospectively for evaluation of complication rates, physical complaints and quality of life. Descriptive statistic was performed for evaluation of complications and efficacy rates. Univariate analysis by the chi^2-test as well as a multivariate Cox regression analysis was conducted to predict recurrence of prolapse and mesh erosion using the variables prior hysterectomy, age, BMI, prolapse degree and anterior vs. combined mesh as predictor. A p-value < 0.05 was regarded statistically significant. Table 1 Postoperative complications according to Clavien-Dindo Classification

Complication	**Clavien Dindo**					
	Grade I	**Grade II**	**Grade IIIa**	**Grade IIIb**	**Grade IVa**	**Grad IVb**
Urinary tract infection, *n (%)*	-	20 (13.5)	-	-	-	-
Urinary retention, *n (%)*	-	2 (1.4)	-	-	-	-
Residual urine > 100 ml, *n (%)*	-	2 (1.4)	-	-	-	-
Haematoma, *n (%)*	8 (5.4)	-	-	-	-	-
Elevated infection parameter, *n* ***(%)***	-	3 (2.0)	-	-	-	-
Mesh erosion, *n* ***(%)***	-	2 (1.4)		2 (1.4)		
Loss of Prosima pessary, *n* ***(%)***	-	-	1 (0.7)	-	-	-
Renal failure, *n* ***(%)***	-	-	-	-	1 (0.7)	-
Total complication rates	8 (5.4)	27 (18.3)	1 (0.7)	2 (1.4)	1 (0.7)	0

Results

The mean follow-up time was 27.2 months. Intraoperative complications occurred in 3.4% including bowel and bladder injury. Mesh erosion occurred in 2.7% whereas surgical revision was necessary only in 1.4%. No predictor for mesh erosion could be identified. A recurrent prolapse was present in 6.8% whereas only 4.7% were in need of secondary prolapse repair. Postoperative complications according to Clavien-Dindo classification ≥ III occurred in 2.8% (Table 1). None of the patients developed painful mesh shrinking or fistula. An improvement of POP symptoms was reported by 84.6% according “Patient Global Impression of Improvement”. The mean postoperative vaginal pain score was 0.6 according the International Index of Pain. The questionnaires demonstrated similar results in comparison to asymptomatic patients (Figure 1). Of 44.4% sexually active patients, 71.0% reported no impairment of sexual intercourse postoperatively and 12.9% reported a very little or little impairment respectively. Only one patient (3.2%) reported major affection by vaginal discomfort and three (4.2%) were inactive due to vaginal discomforts. The mean score for sexual impairment was 1.52 (SD 2.4) according the ICIQ-VS.

Figure 1 Results of the postoperative P-QoL, ICIQ-VS and I-QoL questionaire of the study cohort in comparison to symptomatic and asymptomatic women



P-QoL: Prolaps Quality of Life Questionnaire (scale 0 – 100; higher score represents higher negative impact of condition specific QoL)
ICIQ-VS: International Consultation on Incontinence Modular Questionnaire - Vaginal Symptoms (total vaginal score 0 – 53 and total sexual score 0 – 58, higher score represents higher negative impact of symptoms. Quality of life and sex life scale 0 – 10, higher score represents worse impact)
I-QoL: Incontinence Quality of Life (scale 0 – 100; higher score indicates higher levels of condition specific QoL)

Interpretation of results

Our results support the findings that a correct surgical technique by experienced surgeons can significantly reduce the complication rates in TVM repair. Postoperative quality of life was comparable to asymptomatic women. Furthermore, overall complication rate was low and severe complications were rare.

Concluding message

Careful patient selection and experienced surgeons can diminish complication rates of mesh usage in transvaginal POP repair significantly. Hence emphasis should be put on adequate surgical training and patient selection.

References

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Disclosures

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