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Original research

Quality of life in women of non-reproductive age with transvaginal mesh repair for pelvic organ prolapse: A cohort study

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HIGHLIGHTS

- Global reoperation rate after transvaginal mesh repair was 6.1%.
- Mesh exposure with necessity of surgical excision occurred in 1.4%.
- Quality of life was comparable to asymptomatic women.
- Improvement was reported by 84.6% according the PGI-I.

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ABSTRACT

Background: Transvaginal mesh repair has been discredited due to high complications rates in the past years. Therefore, we evaluated the quality of life (QoL) and complication rates after transvaginal mesh (TVM) repair for pelvic organ prolapse (POP).

Methods: A total of 148 women who underwent TVM repair for symptomatic POP were retrospectively enrolled. Complication rates and functional outcomes were retrospectively assessed and validated, standardised questionnaires were used prospectively for evaluation of QoL. Univariate analysis by the chi^2-test as well as a multivariate Cox regression analysis was conducted to predict mesh exposure using various variables as predictors.

Results: Intraoperative complications with bowel or bladder injury appeared in 3.4%. Mesh exposure occurred in 2.7% whereas surgical revision was necessary only in 1.4%. No predictor for mesh exposure could be identified. Postoperative complications according to Clavien-Dindo classification $\geq$ III occurred in only 2.8%. An improvement of POP-symptoms was reported by 84.6% according the "patients' global impression of improvement" (PGI-I) and 88.2% women would repeat the surgery. The results of the "prolapse-quality of life"-questionnaire were comparable to asymptomatic women. Only 33% reported vaginal pain with a mean vaginal pain score of 0.6 according the international index of pain. Of sexually active women, 29% reported sexual impairments and mean score of sexual impairment was 1.52.

Conclusion: Low complication rates and a quality of life comparable to asymptomatic women following TVM repair could be achieved in our cohort. However, a high number of sexual impairments was identified although the impact of impairment was marginal.

Abbrevations: BMI, Body Mass Index; FDA, US Food and Drug Administration; ICIQ-VS, International Consultation on Incontinence Modular Questionnaire – Vaginal Symptoms; PGI-I, Patient Global Impression of Improvement; POP, Pelvic Organ Prolapse; POP-Q, Pelvic Organ Prolapse Quantification System; P-QoL, Prolaps Quality of Life questionnaire; TVM, TransVaginal Mesh; VRS, Verbal Rating Scale; QOL, Quality of Life.

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1. Introduction

Pelvic organ prolapse (POP) is defined as a downward descent of the pelvic organs that result in the protrusion of vagina, uterus, or both [1]. It is a common disease with a prevalence of approximately 30–40% and a lifetime risk of undergoing POP surgery of 10–20% [2]. If surgical management of the POP is necessary various operation techniques are available. Nowadays 80–90% of the POP repair is performed through a vaginal access in the USA [3] and a trend for the use of synthetic mesh increased up to 40% [4]. In 2008 and 2011, the US Food and Drug Administration (FDA) expressed concerns about the safety and effectiveness of transvaginal mesh usage for POP repair [2]. The most frequent reported complication is mesh exposure into the vagina with an incidence of 6–19%. In a recent review the overall exposure rate is reported with 10.3% [5]. Furthermore, mesh retraction with concomitant pain in 3–19% as well as dyspareunia in 14–24% are frequent complications [6]. This led to significant confusion for physicians, public and media [7]. In response, clinical trails are still necessary to declare the definite safety and effectiveness in POP repair.

We report a prospective study of quality of life after TVM repair since we are still lacking evidence for improved quality of life and patient satisfaction after mesh usage [8]. Furthermore, we evaluated retrospectively the peri- and postoperative complications of TVM in our cohort.

2. Material and methods

After approval of the local ethic committee (number 322/14) we retrospectively enrolled 148 women who underwent TVM repair for POP between 2011 and 2013 in a single center cohort study. All women gave their signed informed consent for participation in this study. The indication for POP repair were physical complains caused by the prolapse. Women in reproductive age, planning of pregnancy were excluded for mesh usage. Women with uterovaginal prolapse were recommended to concomitant hysterectomy. The decision for anterior or combined (anterior and posterior) TVM repair was made by localisation of POP. Prolapse in anterior compartment was repaired by anterior mesh. Prolapse of the middle compartment was mostly treated by a combined mesh. None of the women received concomitant sling placement for SUI. Surgery was performed by one senior surgeon experienced in TVM repair (RB). All women received antibiotic prophylaxis with cephalosporin and metronidazole as well as a vaginal pack and urethral catheter for 24 h. Furthermore, they received local oestrogens initiating at least three weeks before surgery and lasting until a minimum of three weeks postoperatively. Complication rates of POP repair were assessed through medical record of the local gynecological care provider. The complications were evaluated by vaginal inspection and palpation in follow-up by an experienced certified gynecologist (EO). The results were documented in the medical report. Prolapse recurrence was defined anatomically at any stage. In the absence of symptoms, no further surgical intervention was performed. Postoperative complications were classified due to Clavien-Dindo [9] as well as according the Joint International Urogynecology Association and International Continence Society System (IUAG/ICS) [10]. Validated, standardised questionnaires were used for prospective evaluation of quality of life and symptoms. The questionnaires "Global Impression of Improvement" [11] (PGI-I; range 1–7, very much better to very much worse), "Prolaps Quality of Life Questionnaire" [12] (P-QoL; scale 0–100; higher score represents higher negative impact of condition specific QoL), „International Consultation on Incontinence Modular Questionnaire - Vaginal Symptoms" [13] (ICIQ-VS; 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) and "Verbal Rating Scale" (VRS; scale 0–10, higher score represents more pain) of the International Index of Pain were used for prospective long-term evaluation. All questionnaires were standardised and validated for the german language [14,15].

2.1. Statistical analysis

The statistical analysis was conducted by IBM® SPSS® Statistics Version 22 for Mac. Figures were partially generated by Microsoft® Excel® Version 14.5.9 for Mac. Descriptive statistic was used for evaluation of complication rates and analysis of the questionnaires. Sample size calculation was based on the mesh exposure rates in literature and were calculated with a minimum of 120 women. Changes of incidence of SUI and urge symptoms before and after POP repair were calculated by the McNemar test. The chi^2-test was used to correlate complications with preoperative risk factors in univariate analysis. Controlling for the utilized mesh, correlations between the risk factors and complications were examined using the Mantel-Haenszel test. BMI was classified into four categories (Table 1). Cox regression was conducted to predict prolapse recurrence as well as mesh exposure using age, diabetic disease, nicotine consumption, anterior or combined mesh, prolapse degree, BMI, prior prolapse surgery, prior hysterectomy and concomitant hysterectomy at time of TVM repair as predictors. The *t*-test was utilized for comparison of the results of the questionnaires between the study cohort and results in literature. The Kruskal-Wallis test for continuous and the Chi^2-test for categorical variables was performed to identify heterogeneities in the questionnaires depending of the utilized mesh. A p value below 0.05 was considered statistically significant.

3. Results

The mean operation time was 58.8 (SD 15.4) minutes. A combined mesh was utilized in 64.2% (90.5% Prolift®, 9.5% Seratom®) and an anterior mesh in 35.8% (69.8% Prosima®, 30.2% Elevate®). The patients' baseline characteristics are presented in Table 1. There

Table 1
Patients' baseline characteristics.

Variable	Value
Mean age, *years ± SD (range)*	65.3 ± 11.0 (42–90)
Mean number of childbirths, *n ± SD (range)*	2.5 ± 1.5 (0–12)
Prior hysterectomy and colporrhaphy, *n (%)*	81 (54.7)
Prior surgery for POP and prior hysterectomy, *n (%)*	115 (77.7)
Diabetes mellitus, *n (%)*	16 (10.8)
Nicotine consumption, *n (%)*	5 (3.4)
Urge symptoms, *n (%)*	92 (62.2)
Stress urinary incontinence, *n (%)*	92 (62.2)
Mean BMI *kg/m^2 ± SD (range)*	28.9 ± 5.6 (20.2–49.4)
I: 15–25, *n (%)*	39 (28.5)
II: 25–30, *n (%)*	49 (35.8)
III: 30–35, *n (%)*	31 (22.6)
IV: >35, *n (%)*	18 (13.1)
Mean POP-Q grade, n ± *SD (range)*	2.9 ± 0.8 (1–4)
Grade I, *n (%)*	14 (9.5)
Grade II, *n (%)*	21 (14.2)
Grade III, *n (%)*	81 (54.7)
Grade VI, *n (%)*	32 (21.6)
Anatomical classification of prolapse	
Anterior vaginal wall (anterior compartment), *n (%)*	37 (25.0)
Apical vaginal wall (middle compartment), *n (%)*	111 (75.0)
Uterovaginal, *n (%)*	58 (39.2)
Vaginal Vault, *n (%)*	53 (35.8)

SD Standard deviation.