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Bladder injury and success rates following retropubic mid-urethral sling: TVT EXACT™ vs. TVT™

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ABSTRACT

Objective: Although placement of a retropubic mid-urethral slings (MUS) is one of the gold standard surgical treatments for stress urinary incontinence, new devices are poorly evaluated before marketing. We compared TVT-EXACT™ (TVT-E), a new device expected to reduce bladder injuries, with the historically described bottom-to-top TVT™ (TVT).

Study design: This retrospective study compared TVT-E ($n = 49$) and TVT ($n = 49$). The main outcomes were the prevalence of complications (bladder injuries, immediate postoperative pain, perioperative complications, etc.) and the short-term success rate (no reported urinary leakage and negative cough test) of both MUSs.

Results: Minimum follow-up was 12 months. The characteristics of the two groups were comparable. The prevalence of bladder injury for TVT-E and TVT was 8% and 6%, respectively ($p = 1$). The intensity of immediate postoperative pain (VAS/100) was lower following TVT-E than after TVT (8.0 vs. 15.9, $p = 0.01$). The first post-void residual was increased in the TVT-E group (153.9 vs. 78.9 mL, $p = 0.045$), and there were more postoperative bladder outlet obstruction (BOO) symptoms in the TVT-E group (24% vs. 6%, $p = 0.02$). However, there was no difference when considering only de novo BOO (14% vs. 4%, $p = 0.16$). The prevalence of peri- and post-operative complications was equal in the two groups. The success rate was similar at 12 months of follow-up (80 vs. 82%, $p = 1$).

Conclusion: The prevalence of bladder injury was unchanged with TVT-EXACT™ compared with TVT™, but post-operative pain was decreased. The success rate of both retropubic MUSs was similar at 12 months of follow-up.

Introduction

Stress urinary incontinence (SUI) is a common symptom defined by the International Continence Society as a "complaint of involuntary loss of urine on effort or physical exertion" [1]. The prevalence of SUI in the general population is estimated to be as high as 25% [2]. After failure of conservative management (pelvic floor muscle training, weight loss, etc.), MUS surgery is considered to be the standard treatment. Retropubic (RP) sling placement is considered to be a fast and effective surgery associated with an average long-term subjective cure rate (over 5-year follow-up) of 84.3% [3–5]. Nevertheless, a recent meta-analysis [3] showed that RP slings were associated with the same perioperative complications as transobturator tape (TOT), except for major vascular injury such as retropubic hematoma or major visceral injury, which occurred more often with RP than TOT (RR 0.33, 95% CI 0.19–0.55). The TOT procedure is associated with a lower prevalence of bladder injury than the RP procedure (RR 0.13, 95% CI 0.08–0.20). Over the last decade, because SUI is a frequent disorder associated with a large economic burden, many new MUSs have been developed to decrease the morbidity of the RP procedure [6]. Top-to-bottom RP procedures (SPARC™) have been abandoned in favor of bottom-to-top slings, which are more effective and are associated with fewer

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complications (bladder injuries, vaginal tape erosion, voiding dysfunction). There are currently two different bottom-to-top RP slings, but no study has yet compared the two devices: TVT-EXACT™ (TVT-E) and TVT™ (TVT). The objective of the present study was to compare the efficacy and prevalence of complications associated with these two RP MUSs.

Methods

Study design

This was a retrospective comparative case–control study including all consecutive women who underwent a TVT-E or a TVT procedure in two care centers depending on the same university. The inclusion period extended from January 2011 to December 2014.

Population

A total of 144 patients underwent the RP sling procedure during the inclusion period. The following exclusion criteria were applied: concomitant surgery (hysterectomy, prolapse surgery), diabetes, previous prolapse surgery, and patients who were lost to follow-up before 12 months. 19.4% (28/144) of the patients were not eligible because of concomitant procedures. Of the remaining patients, 49 in each group had sufficient follow-up to be included for data analysis (see flow chart in Fig. 1). The choice of TVT or TVT-E was made according to the policy of the surgeons.

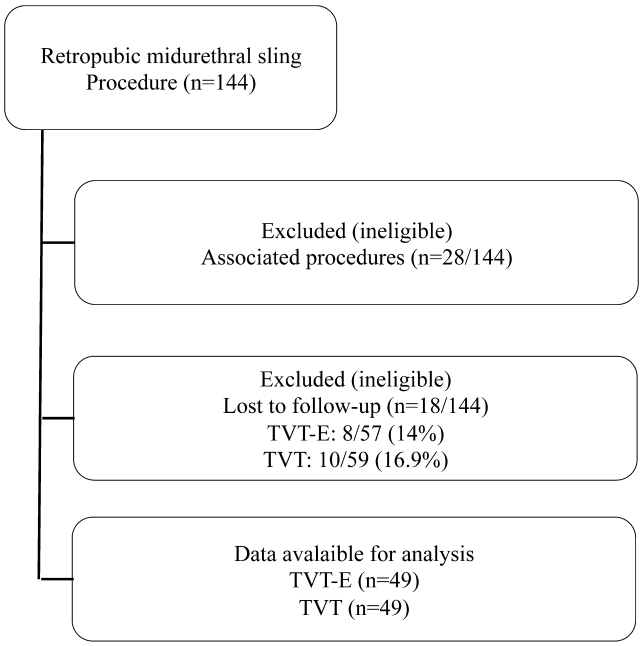

Fig. 1. Flow chart.

Surgical procedure

Both procedures were carried out under either general or spinal anesthesia, according to the patient's wishes. Surgical procedures were performed using the vaginal route, in accordance with the technique described by the manufacturer (Johnson and Johnson, Ethicon, Gynecare) and Ulmsten et al. [7]. The only difference between the TVT and TVT-E devices related to the type of trocar. In the TVT-E, the trocar consists of a non-sterile reusable instrument 3 mm in diameter with a single-use trocar handle that is more ergonomic than in the TVT device. In the TVT, the trocar handle is a stainless steel reusable instrument, whereas the other part of the trocar is non-sterile and reusable and measures 5 mm in diameter. Both procedures use the same Prolene™ polypropylene mesh (1.1 cm × 45 cm × 0.7 mm) (Fig. 2).

Data collection

Data were retrospectively gathered from medical records. Follow-up data were collected prospectively by means of postoperative follow-up and phone calls. Briefly, for all patients, preoperative data and follow-up data at 6 weeks were recorded. Each evaluation included questionnaires to evaluate satisfaction (visual analog scale (VAS) and Patient Global Impression of Improvement (PGI-I) [8]), quality of life and symptom severity (International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) [9]) and a physical exam. Follow-up at one year consisted of a phone call during which patients had to answer to all the latter questionnaires. Preoperative multichannel urodynamic testing data (uroflowmetry, cystometry, and urethral pressure profile) and perioperative data (surgical complications, postoperative pain, post-void residual volume (PVR), etc.) were also recorded. The primary outcome was the occurrence of bladder injury, which was diagnosed during surgery using a routine check by means of cystoscopy. Secondary outcomes were the clinical success rate (no reported SUI and absence of urine leakage in the cough test), and the prevalence of complications. Postoperative pain was also assessed using a visual analog scale (VAS from 0 to 100) on the day of surgery (3–5 h after the surgical procedure). The postoperative analgesic protocol was the same for each patient (paracetamol, ketoprofen and tramadol when the VAS exceeded 30/100). Immediately after surgery, PVR was measured by catheterization following the first postoperative void.

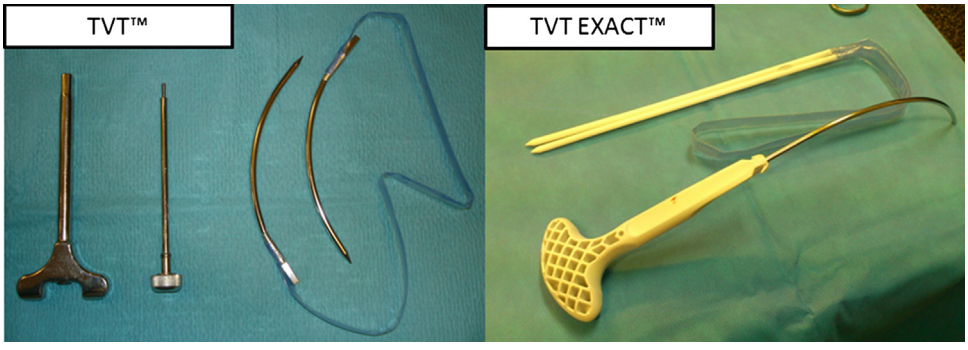

Fig. 2. TVT™ and TVT EXACT™ devices.