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Comparing effectiveness of combined transobturator tension-free vaginal mesh (Perigee) and transobturator tension-free vaginal tape (TVT-O) versus anterior colporrhaphy and TVT-O for associated cystocele and urodynamic stress incontinence

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ABSTRACT

Objective: To evaluate the efficacy and safety of transobturator tension-free vaginal mesh (Perigee) and concomitant transobturator tension-free vaginal tape (TVT-O) for treating cystocele with urodynamic stress incontinence (UDSI).

Study design: A retrospective study of 115 patients with symptomatic stages 2–3 cystocele and UDSI who were treated with a Perigee system (Group I, $n = 68$) plus TVT-O procedure or traditional anterior colporrhaphy (Group II, $n = 47$) plus TVT-O procedure. All patients were followed up for more than one year. Objective and subjective symptoms were evaluated at one year postoperatively. Statistical analysis was performed using SPSS software.

Results: The objective cure rates for cystocele at one year were significantly higher in Group I than in Group II (98.5% and 86.9%, $P = 0.018$), respectively. The cure rates for UDSI in the two groups were 91.0% vs. 91.3% ($P = 1.000$). Symptomatic improvement of frequency was better in Group I than Group II (87.7% vs. 70.0%, $P = 0.030$). There were no significant differences with regard to intraoperative and postoperative complications between the two groups.

Conclusions: The combination of the Perigee system and TVT-O offers a safe and effective treatment for cystocele with UDSI and may be performed as first-line treatment.

1. Introduction

The rate of coexisting stress urinary incontinence (SUI) in patients with pelvic organ prolapse is as high as 63–80%. Thus, the simultaneous treatment of SUI and cystocele using mesh is reasonable [1]. In recent years, tension-free midurethral sling techniques have been the most commonly used surgical treatment for SUI [2].

Anterior colporrhaphy represents one of the surgical treatments for cystocele, but repair of genital prolapse by traditional approaches has historically been associated with a recurrence rate as high as 30–40% [3,4]. Many different techniques performed with mesh repair have been used in cystocele and rectocele repair to reduce recurrence, as well as being used in the surgical repair of abdominal wall defects [5–7]. The use of transvaginal mesh as a first-line treatment was not recommended initially, however, due to complications such as erosion and formation of a sinus tract.

Cystocele repair can lead to de novo SUI or exacerbate pre-existing SUI [8]. The simultaneous treatment of UDSI is obviously an advantage to the patient because a second procedure can be avoided. In a recent study, Zullo et al. highlighted the efficacy and feasibility of concomitant anterior colporrhaphy and TVT-O to treat SUI and concomitant cystocele; 43 (91%) and 46 (92%) patients were objectively cured of cystocele and SUI, respectively [9]. In the recent literature, there has not been a direct comparison between the anterior transobturator mesh technique and concomitant TVT-O system and traditional anterior colporrhaphy and concomitant TVT-O as a treatment for female anterior vaginal wall prolapse with concomitant SUI. We sought to investigate the

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effectiveness and safety of a Perigee plus TVT-O for the treatment of both cystocele and UDSI.

2. Materials and methods

From April 2007 to January 2008, consecutive patients with symptomatic cystocele associated with UDSI who met the inclusion criteria were enrolled in the study. The institutional review board approved the study (IRB No: 98-03-42 A). Inclusion criteria included UDSI associated with cystocele greater than or equal to stage 2 and no contraindications for vaginal surgery, and signed informed consent was obtained.

Exclusion criteria were: uterine prolapse or rectocele greater than or equal to stage 2, overactive bladder, overactive bladder symptoms, intrinsic urethral sphincter deficiency, urinary retention, previous anti-incontinence and/or prolapse surgery, detrusor-sphincter dyssynergia, psychiatric disease, and a body mass index greater than 30. The preoperative evaluation consisted of a complete history, physical examination, 3-day voiding diary, and urodynamic testing. A total of 115 patients were enrolled in the study. Sixty-eight patients underwent the Perigee system (Group I) plus TVT-O and 47 patients received anterior colporrhaphy (Group II) plus TVT-O. All surgical procedures were performed by two gynecologists.

In order to detect other pathologies related to the bladder, uterus or appendages, and to ensure that the appropriate procedure was performed, women were evaluated preoperatively by history, clinical examination, ultrasound and urodynamic study. The stage of the prolapse was assessed in the lithotomy position while the patient performed a Valsalva maneuver. Stage 1 prolapse was defined as when the presenting part descended up to 1 cm inside the introitus, stage 2 as when the presenting part descended from 1 cm inside to 1 cm outside the introitus, and stage 3 as when the presenting part protruded more than 1 cm outside the introitus, according to the Pelvic Organ Prolapse Quantification (POP-Q) system [10]. The urethral axis and urethrovesical junction mobility were assessed by the Q-Tip test, using a cotton bud placed into the urethra, and measuring the angle made by clinical examination from rest to Valsalva maneuver. Urethral hypermobility was defined as a maximal straining angle of more than 30°. The urodynamic examination was performed after the repositioning of the prolapse following the criteria established by the International Continence Society. All patients underwent a full urodynamic evaluation using the Lectromed 6000 system (Lectromed K Ltd., Herts, UK), which included provocative twin-channel (7F double lumen catheter) subtracted cystometry at a filling rate of 50 mL/min and pressure flow studies. The definition of occult UDSI is positive UDSI evaluation after the prolapse was repositioned using a pessary. Intrinsic sphincter deficiency was defined as a maximum urethral closure pressure (MUCP) <20 cm H_2O at rest profilometry.

A short-term antibiotic prophylaxis with Cefazolin (1 g) was performed 1 h before surgery in both groups. The standard plicating technique of anterior colporrhaphy was used for cystocele repair, in which the ultralateral anterior colporrhaphy started with a midline anterior vaginal incision; the dissection was performed laterally to the limits of the pubic rami on each side. Afterwards, the paravaginal connective tissue (pubo-cervical fascia) was plicated under tension at the midline with 3 cross-interrupted stitches of No. 0 polydioxanone sutures. A detailed description of the anterior transobturator mesh procedure (Perigee system) is given in the literature [11]. We fixed the mesh paraurethrally and to the vaginal cuff with absorbable sutures to stabilize the mesh longitudinally and to avoid folds. After anterior colporrhaphy or the Perigee, the patients were placed with their thighs in hyperflexion, and the TVT-O procedure was performed through a separate vaginal incision. The TVT-O was placed suburethrally to treat USI. The inside-out technique permits the reproducible insertion of the tape after a minimal dissection; the tape is passed from underneath the urethra, through the obturator foramina and towards the thigh folds.

The vagina was packed with a strip of disinfecting gauze for 24 h to avoid hematomas and to press the mesh tightly against the vaginal wall. An indwelling catheter was emplaced for 24 h for Group I and 72 h for Group II. If the postoperative post-void residual was greater than 100 mL after removing the catheter, the patient then carried out intermittent self-catheterization until a post-void residual less than 100 mL on two consecutive measurements was obtained.

Operating time, blood loss, and length of hospital stay were all noted. A clinical examination was performed every 3 months. Cure of SUI was defined by urodynamic study after 1 year. Recurrent prolapse was defined as any descent of stage 2 (cystocele or vault prolapse), even if the patient had no symptoms. Outcome measures included intra- and post-operative complications, healing abnormalities, dyspareunia, transitory urinary retention and the efficacy of symptomatic improvement of conditions such as protruding vaginal mass, urinary incontinence, frequency and nocturia at the 1-year follow-up. The definition of dyspareunia is persistent or recurrent pain with attempted or complete vaginal entry and/or penile vaginal intercourse. The definition of transitory urinary retention is prolonged postoperative urinary retention, defined as an inability to void greater than or equal to 30 days postoperatively necessitating an indwelling catheter or intermittent self-catheterization.

Statistical analysis was performed using software (SPSS 17: SPSS, Chicago, IL) The *t*-test was used for continuous data or the χ^2-test for categorical data. Differences between two independent proportions were calculated by *z*-test. $P < 0.05$ was considered to be statistically significant. The data are summarized as the mean ± SD or the percentage according to the variables. Expecting that the objective cure rates for prolapse at one year may be increased from 70% to 95% by the Perigee system (based on literature review [6]), we determined a

Table 1
Patients' baseline characteristics.

Patients characteristics	Group I ($n=68$)	Group II ($n=47$)	*p* value	95% CI
Age	62.07 ± 12.50 [35–89]	57.0 ± 12.68 [34–82]	0.036	5.074 (0.346,9.801)
Parity	3.24 ± 1.51 [0–8]	3.1 ± 1.76 [0–8]	0.778	0.086 (−0.520,0.693)
Menopausal status	60 (88.2%)	31 (66.0%)	0.004	0.258 (0.100,0.670)
Hypertension	21 (28.8%)	11 (23.4%)	0.379	0.684 (0.293,1.598)
Diabetes mellitus	14 (19.2%)	10 (21.3%)	0.929	1.042 (0.418,2.598)
Previous hysterectomy	13 (19.1%)	5 (10.6%)	0.219	0.504 (0.167,1.523)

Group I: Perigee system + TVT-O.
Group II: A-repair + TVT-O.
t-test: mean difference (95% CI).
Chi square: odds ratio (95% CI).