ELSEVIER

JMIG The Journal of Minimally Invasive Gynecology

Original Article

Single-incision Mini-slings Versus Retropubic Tension-free Vaginal Tapes: A Multicenter Clinical Trial

Stefano Palomba, MD*, Rosamaria Oppedisano, MD, Angela Falbo, MD, PhD, Marco Torella, MD, Antonio Maiorana, MD, Caterina Materazzo, MD, Achille Tolino, MD, Pasquale Mastrantonio, MD, Giovanni B. La Sala, MD, Luigi Alio, MD, Nicola Colacurci, MD, and Fulvio Zullo, MD, The SIMS Italian Group

Obstetrics and Gynecology Unit, Department of Obstetrics, Gynecology and Pediatrics, Azienda Ospedaliera "Santa Maria Nuova," Istituto di Ricovero e Cura a Carattere Scientifico, University of Modena and Reggio Emilia, Reggio Emilia, Italy (Drs. Palomba, Falbo, and La Sala), Departments of Obstetrics and Gynecology, University "Magna Graecia" of Catanzaro, Catanzaro, Italy (Drs. Oppedisano, Materazzo, and Zullo), Departments of Obstetrics and Gynecology, Second University of Naples, Naples, Italy (Drs. Torella and Colacurci), Unit of Obstetrics and Gynecology, Hospital "Civico" of Palermo, Palermo, Italy (Drs. Maiorana and Alio), Department of Obstetrics and Gynecology, University "Federico II" of Naples, Naples, Italy (Dr. Tolino), and Department of Obstetrics and Gynecology, University of Molise, Molise, Italy (Dr. Mastrantonio).

ABSTRACT **Study Objective:** To compare single-incision mini-slings (SIMSs) and retropubic tension-free vaginal tape (r-TVT) in terms of the long-term efficacy and safety for the treatment of female stress (SUI) or mixed urinary incontinence (MUI).
Design: Prospective multicenter cohort trial (registration number NCT00751088) (Canadian Task Force II).
Settings: Department of Obstetrics and Gynecology, Italy.
Patients: Two hundred-forty women with SUI/MUI.
Interventions: SIMS or r-TVT.
Measurements and Main Results: The operative time and the use of analgesic tablets were significantly ($p < .001$) higher and lower, respectively, in the r-TVT group versus the SIMS group. After 24 months of follow-up, no difference between the study arms was observed in terms of the complication rate (30/120 [25%] vs 19/120 [15.8%] for the r-TVT and SIMS arms, respectively; relative risk = 1.58; 95% confidence interval, 0.94–2.65; $p = .083$), whereas the subjective cure rate was significantly lower in the SIMS arm than in the r-TVT arm (57/103 [55.3%] vs 89/106 [84.0%] for the r-TVT and SIMS arms, respectively; relative risk = 0.66; 95% confidence interval, 0.54–0.80]; $p < .001$). The proportion of retreated patients for SUI/MUI was significantly higher in the SIMS arm than in the r-TVT arm (37/103 [34.9%] vs 12/106 [11.3%] for SIMS and r-TVT arm, respectively; $p < .001$).
Conclusion: SIMS has no advantage in terms of safety over r-TVT and was found to be less effective than r-TVT. Thus, its use in the clinical practice should be questioned. Journal of Minimally Invasive Gynecology (2014) 21, 303–310 © 2014 AAGL. All rights reserved.

Keywords: Clinical trial; Incontinence; Mini-slings; Single-incision; Sling; Surgery

DISCUSS You can discuss this article with its authors and with other AAGL members at http://www.aagl.org/jmig-21-4-JMIG-D-13-00260

Use your Smartphone to scan this QR code and connect to the discussion forum for this article now*

* Download a free QR Code scanner by searching for "QR scanner" in your smartphone's app store or app marketplace.

Midurethral slings (MUSs) represent the current standard treatment for patients with stress urinary incontinence (SUI) [1,2]. Since the historic description of tension-free vaginal tape (TVT) by Ulmsten et al [3], these procedures have progressively become less invasive. In 2001, Delorme [4] proposed the transobturator access, and, more recently, many researchers have described the use of the third-generation MUS referred to as single-incision mini-slings (SIMSs) [5–15].

The authors declare that they have no conflict of interest.

Corresponding author: Stefano Palomba, MD, Unit of Obstetrics and Gynecology, Azienda Ospedaliera "Santa Maria Nuova," Via Risorgimento 80, 42123 Reggio Emilia, Italy.
E-mail: stefanopalomba@tin.it

Submitted May 1, 2013. Accepted for publication August 25, 2013.
Available at www.sciencedirect.com and www.jmig.org

1553-4650/$ - see front matter © 2014 AAGL. All rights reserved.
http://dx.doi.org/10.1016/j.jmig.2013.08.714

Several advantages of the SIMS over the standard MUS procedures (i.e., the retropubic tension-free vaginal tape [r-TVT] and transobturator [TOT]) have been reported during recent years. For example, SIMS is associated with a shorter operative time [5], the procedure can be performed under local anesthesia [6], and postoperative pain [7] and morbidity [8] are decreased. All these features would support the use of SIMS as an office procedure.

Notwithstanding these considerations, some doubts remain in terms of the safety and efficacy of SIMSs, especially at the long-term follow-up. In fact, during the last 2 years, clinical studies regarding the objective and subjective cure of patients treated with SIMS have been published, showing different results from previous publications [9–15]. Based on these considerations, the present study aimed to evaluate the long-term efficacy and safety of the SIMS and r-TVT approaches for treating female urinary incontinence (UI).

Materials and Methods

The current study was a multicenter prospective cohort clinical trial. The primary outcome was the subjective cure rate at the 24-month follow-up. The secondary outcomes were the objective cure rate at the 24-month follow-up, safety, feasibility under local anesthesia, and quality of life.

The procedures used in the study protocol were in accordance with the Helsinki Declaration on human experimentation guidelines. The trial was registered on the Web site (www.clinicaltrial.gov) with the registration number NCT00751088, and it was approved by the Ethical Committee of the Department of Obstetrics and Gynecology of the University "Magna Graecia," Catanzaro, Italy.

Between September 2008 and November 2010, 282 women with SUI or mixed urinary incontinence (MUI) referring to 5 Italian departments of obstetrics and gynecology at the University "Magna Graecia" of Catanzaro, the University "Federico II" of Naples, the Second University of Naples, the Hospital "Civico" of Palermo, and the University of Molise were checked for inclusion/exclusion criteria. Specifically, SUI was defined as the involuntary leakage of urine with effort or physical exertion or upon sneezing or coughing, whereas MUI was defined as SUI associated with urgency. In all cases, the diagnosis was confirmed by urodynamic assessment (uroflowmetry, cystometry, abdominal leak point pressure assessment, and a pressure flow voiding study). Only patients who were incontinent after conservative management (i.e., pelvic floor muscle training) and, in the presence of MUI, only patients with persistent, clinically significant SUI under oral antimuscarinic therapy were enrolled.

The exclusion criteria were postvoidal residual (PVR) urine >100 mL, intrinsic sphincteric insufficiency (maximal urethral closure pressure <20 cm H_2O and Valsalva leak point pressure <60 cm H_2O), detrusor instability score (DIS) >7 [16], history of previous incontinence surgery, lower urinary tract anomaly, current urinary tract infection (UTI) or more than 3 UTI episodes in the last year, Baden-Walker pelvic organ prolapse $\geq$second degree [17], body mass index >35, neurogenic disease and/or drugs affecting bladder function, desired future childbearing, pregnancy, <12 months postpartum, concurrent genitourinary disease, previous pelvic surgery or radiotherapy, previous or active malignancies, contraindications for surgery, unable to understand the purpose of the trial, sexually inactive, or immobility.

The eligible patients were extensively counseled about the risk-to-benefit ratio of the r-TVT or SIMS, and the treatment allocation was based on the patient's choice. The data assessors were masked to the SIMS or r-TVT procedure (single-blind design).

At baseline, the cohort of patients underwent a standardized evaluation, including urogynecologic history and an anthropometric, gynecologic, and neurologic evaluation. Pelvic prolapse was graded using the Baden scale [17], and it was assessed with the patient in the standing position under maximal straining. The stress test and the Q-tip test were performed according to International Urogynecological Association guidelines [18], and the neurologic integrity of S2–S4 was also evaluated. All women also underwent a standard ultrasonographic gynecologic evaluation, bacterial culture of a midstream urine specimen, and urodynamic assessment (uroflowmetry and PVR urine, multichannel cystometry, pressure flow study, urethral pressure profilometry, and leak pressures).

The severity of UI was assessed by a 24-hour pad test and a 3-day "frequency-volume chart" voiding diary [18]. The DIS [16] was calculated for each patient to detect and measure the urge component.

The Short-Form Healthy Survey-36 (SF-36) [19] was used to study the patients' quality of life, whereas the King's Health Questionnaire (KHQ) [20] and the Patient Global Impression of Severity (PGI-S) [21] were used to study the disease-specific impact of UI on the quality of life. Finally, the Female Sexual Function Index (FSFI) [22] was administered to assess the sexual function of the patients. For each questionnaire, the Italian version was used.

For each center, 1 experienced operator skilled in both surgical approaches performed the surgeries under local anesthesia with light conscious sedation [14]. The operator was considered an expert if he had performed more than 20 r-TVT and more than 20 surgeries in the previous year for each type of SIMS procedure. All the procedures were technically performed as suggested by the manufacturers. Just before the surgery, the same intravenous prophylactic antibiotic therapy (1.5 mg cefuroxime or, in the case of a documented allergy to cephalosporins, 500 mg metronidazole) was administered for each procedure. In the SIMS groups, after local anesthetic injection (into the vaginal wall sub- and periurethrally, under the bonny edge, horizontally up to the inferior pubic arm, and into the internal obturator muscle), a 15-mm vaginal incision was made starting