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CLINICAL ARTICLE

Sedation with local versus general anesthesia for the tension-free vaginal tape Secur hammock procedure

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ABSTRACT

Objective: To compare the intraoperative and immediate postoperative results achieved with the tension-free vaginal tape Secur (TVT-S) hammock procedure performed under local anesthesia (LA) versus general anesthesia (GA). *Methods:* Prospective randomized trial involving patients with symptomatic stress urinary incontinence grades 1 or 2 who underwent TVT-S under either LA or GA. Postoperative pain intensity, duration of hospitalization, rate of complications, duration of operating and recovery times, and number of additional procedures required were recorded. *Results:* Each group included 40 patients. The operative times were identical in the 2 groups, but the time spent in the recovery room was significantly longer in the GA group. Patients undergoing LA experienced less pain than did those undergoing GA. Most patients in the LA group had day surgery, whereas most patients in the GA group went home 1 day after the surgery. No significant differences were observed for the rates of complications. *Conclusion:* Performing the TVT-S hammock technique under LA rather than GA reduces postoperative pain and shortens the duration of hospitalization.

1. Introduction

Tension-free vaginal tape Secur (TVT-S; Gynecare TVT Secur System, Ethicon, Somerville, NJ, USA) is a 3rd-generation tension-free sling that provides support to the midurethra with the aim of resolving stress urinary incontinence (SUI). The device, consisting of a short sling with 2 absorbable tips, is fixed directly to the internal obturator muscle (hammock position). The TVT-S procedure is feasible, easy to perform, and safe, it produces low rates of thigh pain, bladder outlet obstruction, and visceral penetration [1–3], and it achieves good cure rates and patient satisfaction in the long term [1,2,4]. Although randomized studies with other midurethral slings have not been conducted, an experimental study showed that the pull-out forces of TVT-S were comparable to those of the original tension-free vaginal tape (TVT) [5]. Cornu et al. [6] reported high (93.5%) success rates with TVT-S in the short term, with the cure rate falling to 40% at 3 years of follow-up. However, this study included a small number of patients, some of whom also had pelvic organ prolapse or overactive bladder disease [6].

The TVT technique, when first introduced by Ulmsten et al. [7], was described as an ambulatory procedure carried out under local anesthesia (LA). Although its performance under LA is well proven and widely accepted, many clinical units now undertake the original TVT procedure under regional or general anesthesia (GA). The 3rd-generation tape devices were specifically developed with the intention of making sling procedures less invasive than their 1st- and 2nd-generation predecessors. In view of this trend toward reduced invasiveness, surgeons might be expected to have a preference for LA when placing the TVT-S. In fact, some authors have already reported performing this technique under LA [4]. The present study was conducted to compare the intraoperative and immediate postoperative results (especially postoperative pain control and length of hospitalization) achieved by TVT-S performed under sedation with LA versus TVT-S performed under sedation with GA.

2. Materials and methods

The results of the present prospective randomized trial are presented according to the Consolidated Standards of Reporting Trials (CONSORT) criteria [8]. The study was approved by the Ethics Committee of the

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University of Rome Tor Vergata, Rome, Italy, and informed consent was obtained from all participants. The study included women with symptomatic SUI grades 1 and 2 (Valsalva leak point pressure greater than 60 cm H_20), who were recruited during preoperative outpatient appointments. Exclusion criteria were SUI grade 3, an overactive bladder, an associated prolapse, a neurovegetative disorder, recurrent SUI, a history of previous vaginal surgery, and a history of rehabilitative or medical therapies for SUI (e.g. pelvic floor muscle training or duloxetine therapy). Two independent surgeons performed the TVT-S procedures. A 3rd surgeon who was not involved in the surgical procedures and a statistician analyzed the data at the end of the trial.

All patients who reported symptoms of urinary incontinence were investigated with the Q-tip test and urodynamics (measurement of residual volume and leak point pressure, subtracted cystometry, uroflowmetry, and pressure-flow study) in order to determine the type and severity of their incontinence. Stress urinary incontinence was classified according to the International Continence Society criteria. The volume of urine loss with coughing and the Valsalva maneuver was measured with a 24-hour pad test. Preoperative demographic and clinical data were also gathered during the preoperative evaluation.

If the inclusion criteria were met, 1 of the 2 surgeons explained the experimental nature of the study, confirmed the patient's willingness to participate in it, and obtained informed consent. Two identical closed envelopes were offered to the first patient to choose from in order to establish the group allocation; 1 envelop contained a note that read “LA” and the other a note that read “GA”. According to the first patient's choice, this patient was allocated to the “GA” group. The other patients were allocated in an alternating pattern. Both the patients and the surgeons were aware of the type of anesthesia used, but the 2 researchers who analyzed the data were not. Antibiotic prophylaxis consisted of a single preoperative dose of ceftriazone (2 g intravenously).

All participants received sedoanalgesia. Women in the LA group received midazolam 2–3 mg and intravenous fentanyl 50 μg, injected 5 and 2 minutes, respectively, before administration of the local anesthetic. LA was performed with lidocaine 1% 20 mL, with 2 mL being infiltrated under the urethra and 9 mL on either side of the periurethral space and into the internal foramen of the obturator canal. Patients undergoing GA received preanesthesia with midazolam 2–3 mg and induction with intravenous fentanyl 100 μg and propofol 2 mg/kg; after placement of a laryngeal mask, anesthetic maintenance was achieved with an inhaled mixture of oxygen, air, and sevoflurane.

During the TVT-S intervention, the patient was positioned in the dorsal lithotomic position. An accurate paraurethral dissection was carried out after incision of the anterior vaginal wall, 1 cm below the urethral meatus, for approximately 1.5 cm. Subsequently, the right side of the sling was introduced to the internal obturator muscle, with the tape edge being anchored by a needle holder instead of being passed through obturator foramen, muscle, and membrane, as is the case with the transobturator tape procedure. The left side of the sling was then introduced in the same way, creating a hammock-shaped sling. Finally, appropriate sling tension was achieved by pulling the 2 tips as close to the urethra as possible.

Postoperative analgesia was administered in the form of ketorolac (30 mg intramuscularly every 6 hours) during the course of the 1st postoperative day if requested by the patient. The urinary catheter was removed 1 hour postoperatively. If a postvoid residual volume of more than 100 cc was present, the woman performed intermittent catheterization. If she still failed to resume normal voiding after 2 postvoid measurements, intermittent catheterization was performed for a further 24 hours.

In the LA group, patients without complications were discharged 12 hours after the operation (day surgery). In the GA group, women free of complications were discharged 1 day postoperatively. Outpatient follow-up visits were planned for day 7 after surgery in order to identify any residual symptoms or postoperative complications that did not manifest during the initial recovery period.

The primary end point was the efficacy of the TVT-S technique in terms of reducing postoperative pain and the duration of hospitalization. Postoperative pain reduction was measured on a visual analog scale (VAS) at 1, 6, 12, and 24 hours after surgery [9] and by the requirement (yes/no) for postoperative analgesia. Women in the GA group were discharged from hospital when they recovered autonomic vasomotor tone, were able to self-mobilize safely, and could eat and drink without any nausea or vomiting, provided that no signs or symptoms of early complications were present. Women in the LA group were not required to meet the GA-specific criteria for discharge and were sent home after a few hours of observation, provided that no signs or symptoms of early postoperative complications were present. All discharged patients were contacted at home by telephone to discuss their progress.

Secondary endpoints of the study were any differences between the LA and GA groups in terms of the rate of complications (voiding difficulty/bladder perforation, vaginal bleeding, vaginal perforation), the length of the operating time (defined as the time required for anesthesia and surgery), the length of time spent in the recovery room, and the number of additional operations required.

In order to be able to detect a 50% reduction in the VAS score at 1 hour after surgery (assuming a significance level [α] of 0.05 and a power of 83%), 40 patients were enrolled per group. Data analysis was performed using SPSS version 13.0 (SPSS, Chicago, Illinois, USA). Descriptive statistics included the mean and standard deviation for continuous variables with parametric distribution, the median and range for continuous variables with nonparametric distribution, and the frequency for categoric variables. Normality assumptions were demonstrated with histograms and the Kolmogorov–Smirnov test. One-way analysis of variance (ANOVA) was used to compare the mean values of continuous parametric variables among groups. The χ^2 or Fisher exact tests were used as appropriate to compare categoric variables. The ANOVA test for repeated measures was used to calculate differences in the VAS score for pain over time and among groups. $P<0.05$ was considered statistically significant.

3. Results

The study began on January 1, 2008, and ended on December 31, 2009, with enrollment of the last patient (Fig. 1). Each group included 40 women. The groups were homogeneous for age, hypertension, body mass index, menopause status, hormone replacement therapy, and leak point pressure (Table 1). The Q-tip test was positive for all participants. The volume of urine loss with coughing and with the Valsalva maneuver was similar between the groups (Table 1).

The operating times in the 2 groups were identical ($P>0.05$). However, the time spent in the recovery room was significantly longer ($P<0.001$) in the GA group than in the LA group (Table 1). Analysis of the VAS results in the 2 groups showed that pain decreased significantly from 1 hour after surgery ($P<0.001$). Significant differences between the groups were observed at almost all time points, with patients in the LA group experiencing less pain than those who had undergone GA (Table 1). Analgesic and antiemetic drugs were requested 4 and 3 times more often, respectively, in the GA group than in the LA group (Table 1). However, this difference between the groups was not statistically significant. Most patients (n = 37 [92.5%]) in the LA group were discharged on the day of the surgery, whereas all patients in the GA group were discharged 1 day after surgery or later ($P<0.001$; Table 1). All patients were catheterized during the 1st postoperative hour only, with the exception of 1 (2.5%) patient in the LA group and 1 (2.5%) patient in the GA group who experienced postoperative voiding difficulties and required intermittent catheterization for 24 hours. These patients were both discharged 1 day after the surgery. Furthermore, 2 (5.0%) women in the LA group were