Female Urology – Incontinence

Prospective Clinical Trial Comparing Obtape® and DUPS to TVT: One-Year Safety and Efficacy Results

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Abstract

Objectives: Obtape and DUPS are modifications of the original TVT procedure. To test these new products in terms of safety and efficacy, we designed a prospective clinical trial with a follow-up of at least 1 yr.

Methods: We randomized 190 consecutive females with SUI for this study. They were evaluated by history, ICIQ-SF, physical examination, cystoscopy, UDS, and the 1-h pad test. Patients were reevaluated at 1, 6, and 12 mo. The ICIQ-SF and pad test were repeated at 1-yr follow-up.

Results: There were 78, 32, and 80 patients in the Obtape, DUPS, TVT arms, respectively. An interim analysis after 32 patients in each arm indicated postoperative retention rates of 3 (9.4%), 6 (18.8%), and 4 (12.5%) patients in Obtape, DUPS, and TVT groups, respectively. Because of higher retention rate and suprapubic discomfort, DUPS was discontinued. At the end of the study, complete retention rates were 6 (7.8%), 6 (18.8%), and 6 (7.5%) in Obtape, DUPS, and TVT, respectively. TVT was the only procedure with bladder perforations at a rate of 14%. However, Obtape and DUPS were associated with more postoperative complications including complete retention, urethrolysis, hematoma, mesh erosion, UTI, and wound infection (13%, 28%, and 8%; \( p \leq 0.025 \)). At 1 yr, 83%, 94%, and 86% of patients in the Obtape, DUPS, and TVT groups were objectively cured (\( p > 0.05 \)).

Conclusions: TVT was the only procedure associated with bladder perforation, but there were more postoperative complications with Obtape and DUPS. No statistically significant differences in cure rates were observed at 1-yr follow-up. Longer follow-up is needed to confirm these results.

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1. Introduction

The prevalence of daily stress urinary incontinence episodes in women younger than 65 yr is in the range of 4–7%, and in women older than 65 yr, it is 4–14% [1]. In addition to its social implications, this condition costs $19.5 billion annually in the United States [2]. A variety of retropubic and transvaginal surgical techniques have been developed to restore support to the urethral sphincteric apparatus. However, there is no consensus about the best procedure [3]. Furthermore, morbidity and convalescence issues have stimulated a search for less invasive procedures.

Ten years ago, Ulmsten [4] developed tension-free vaginal tape (TVT), a minimally invasive procedure based on the “hammock hypothesis” of DeLancey [5]. TVT has become the most popular procedure since its inception [6–9]. Recent studies show that despite a high success rate of 80–90%, TVT is not without complications. These include bladder perforations at a rate of 6–25%, retropubic bleeding requiring surgery at a rate of 0.5%, and, rarely, bowel perforations [10–12]. Therefore, several modifications of the original TVT procedure have been developed. The SupraPubic ARCH sling (SPARC), transobturator tape (Obtape), and Distal Urethral Polypropylene Sling (DUPS) are three such modifications. In a recent study comparing TVT to SPARC, no difference in morbidity and subjective or objective cure rates were demonstrated [13].

In 2001, Delorme [14] described the transobturator approach in 40 patients with a 98% cure rate and one septic complication. The advantage of this modification of the original TVT procedure is that it reproduces the natural suspension of the pelvic floor without disrupting the retropubic space of Retzius, thus minimizing the risk of retropubic hemorrhage and infected hematomas. Furthermore, it decreases the risk of bowel and bladder perforation, and thus the need for cystoscopy.

DUPS was originally described by Raz [15] as an inexpensive approach to re-establish distal urethral support without the morbidity of harvesting autologous fascia nor the expense of using midurethral sling kits.

The aim of the present prospective, randomized, controlled clinical trial was to compare Obtape and DUPS to the original TVT procedure. We report our results with a follow-up of at least 1 yr.

2. Material and methods

2.1. Study end points

The 1-h pad test was chosen on the recommendation of the International Continence Society. Pad weight gain of up to 2 g may result from weighing errors, sweating, or vaginal discharge, and is considered continent [16]. Therefore, in this trial, a 1-h pad test of ≤2 g was considered an objective cure and was the primary study end point. To determine subjective cure rates as a secondary end point, we used the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), which is in a six-question format. The ICIQ-SF is shorter than the 30-question format of Shumaker's Incontinence Impact Questionnaire, which was used in previous studies [17,18]. ICIQ-SF has been found to have good correlations with the 24-h pad test and the 3-d frequency volume diary [19].

2.2. Sample size determinations and statistical analysis

Since the primary end point of the trial was an objective cure rate, as defined by the 1-h pad test of ≤2 g, the success rate of 90% for TVT was used. It was decided that a 20% difference in the success rate between TVT versus Obtape and between TVT versus DUPS would be clinically significant. Therefore, to detect a 20% difference, with an alpha value of 0.05 and power of 80%, at least 72 subjects were required in each group. This number was increased to 79 per group to account for 10% dropout during the follow-up period.

Sample size determination was performed with PS software, version 2.1.31 by Dupont and Plummer [20]. Student t test was used for continuous variables. Chi-square and Fisher exact tests were applied for proportions to compare Obtape with TVT and DUPS with TVT. Two-sided p values were calculated.

2.3. Inclusion and exclusion criteria

Women were eligible for the trial if they had SUI with or without pelvic organ prolapse. All preoperative parameters were recorded by either a urogynecologist (M.C.L.) or a female urologist (J.C.). Detailed history was obtained with patient age, menopausal status, parity, comorbid medical conditions, previous incontinence or pelvic surgery, number of pads per day, hormone replacement therapy, and incontinence history, including incontinence grade and quality-of-life assessment with the ICIQ-SF.

On physical examination, in addition to determining the type of incontinence, estimated by the degree of bladder-neck and urethral mobility, the presence of rectocele, enterocele, and pelvic organ prolapse was assessed. Multi-channel urodynamic studies (UDS) of each patient included: flowmetry, postvoid residual (PVR), cystometrogram, valsava leak point pressure, and the 1-h pad test. Women with previous failed anti-incontinence surgeries or bulking agent treatments were also eligible for study participation. Women with mixed urinary incontinence were not excluded as long as their cystometrogram showed normal capacity, compliance, and no uninhibited contractions. Exclusion criteria included...
obstruction, unstable bladder function, or neurogenic bladder. Urinary tract infection (UTI) was a temporary exclusion criterion.

### 2.4. Study design and follow-up

Originally, the study was designed to be a randomized clinical trial with three arms: Obtape, DUPS, and TVT. However, the randomization stopped accruing after 32 patients in each arm for reasons discussed in the Results section. After DUPS was discontinued, the patients were randomized for either TVT or Obtape and followed prospectively. Randomization was performed by an envelope method immediately before the start of surgery. The patients were blinded to the procedure. Perioperative information was obtained from preprinted operative reports filled by the surgeon immediately postoperatively. It included type of anesthesia, estimated blood loss (0–50 ml, 50–250 ml, and >250 ml) as well as bladder perforation (one or both sides). Information from anesthesia and nursing reports was also compiled.

Postoperatively, all patients were reevaluated by history and physical examination at 1, 6, and 12 mo. At the 12-mo visit, patients completed the ICIQ-SF and underwent the 1-h pad test conducted by the dedicated UDS nurse (B.S.D.), who was blinded to the procedure.

### 2.5. Surgical techniques

The TVT (Gynecare, Sommerville, NJ, USA) procedure was carried out as described by Ulmsten [4], with the exception of type of anesthesia. Obtape (Mentor Corp, Santa Barbara, CA, USA) was performed according to Delorme’s technique [14]. DUPS was undertaken according to the description of Rodriguez and Raz [15] and after formal training of the two surgeons by Dr Shlomo Raz. However, a suprapubic tube, suggested by these authors, was not inserted in our patients. Polypropylene mesh was supplied by Ethicon, Inc (Sommerville, NJ, USA).

Anterior and posterior colporrhaphy and vaginal hysterectomy were performed simultaneously when indicated in symptomatic women with pelvic organ prolapse. A 16F Foley catheter was left in situ until complete patient recovery from anesthesia. Patients were invited to urinate before leaving the hospital, and a bladder scan ensured that postvoid residual (PVR) was <150 ml. In cases of higher residual volumes or inability to void, an indwelling urethral catheter was reinserted and the patients followed at the clinic within 48 h for a voiding trial and PVR measurement. If they were unable to void 48 h later, they were taught clean intermittent catheterization (CIC) if they were physically capable, or an indwelling Foley catheter was reinserted and a repeat voiding trial conducted at a later time. If these measures failed, urethrolysis was performed.

### 3. Results

Of 207 eligible women with SUI, 190 agreed to participate and gave their informed consent for this study, which took place from February 6, 2003 to May 13, 2005. Seventeen patients declined to participate because they could not comply with the follow-up schedule because of travel plans during the winter months. Seventy-eight patients were randomized to Obtape, 32 patients to DUPS, and 80 patients to TVT. TVT patients were older than Obtape patients (61.1 yr vs. 56.2 yr, \( p < 0.01 \)). There was no statistically significant difference between the ages of TVT and DUPS patients (61.1 yr vs. 56.6 yr, \( p = 0.1 \)). Otherwise, the three groups were comparable in terms of grade and type of SUI, preoperative ICIQ-SF, the 1-h pad test, and previous anti-incontinence surgery (\( p = 0.21 \); Table 1). Most patients underwent spinal anesthesia (Table 2). An interim analysis was performed after 32 patients in each

### Table 1 – Distribution of patients according to grade and type of SUI

<table>
<thead>
<tr>
<th></th>
<th>Obtape</th>
<th>DUPS</th>
<th>TVT</th>
</tr>
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<tbody>
<tr>
<td>Patients</td>
<td>78</td>
<td>32</td>
<td>80</td>
</tr>
<tr>
<td>Mean age (range)</td>
<td>56.2 (21.7–85.7)</td>
<td>56.6 (34.6–83.7)</td>
<td>61.1 (35.4–94.6)</td>
</tr>
<tr>
<td>Grade</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3 (4%)</td>
<td>6 (18%)</td>
<td>13 (16%)</td>
</tr>
<tr>
<td>2</td>
<td>58 (74%)</td>
<td>16 (50%)</td>
<td>50 (62%)</td>
</tr>
<tr>
<td>3</td>
<td>17 (22%)</td>
<td>10 (32%)</td>
<td>17 (22%)</td>
</tr>
<tr>
<td>Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>IIa</td>
<td>62 (80%)</td>
<td>23 (72%)</td>
<td>67 (83%)</td>
</tr>
<tr>
<td>IIb</td>
<td>15 (19%)</td>
<td>9 (28%)</td>
<td>11 (14%)</td>
</tr>
<tr>
<td>III</td>
<td>1 (1%)</td>
<td>0</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>1-hour pad test, g (95% CI)</td>
<td>36.7 (28.1–45.3)</td>
<td>39.9 (24.8–55.0)</td>
<td>45.4 (34.0–56.8)</td>
</tr>
<tr>
<td>Preop ICIQ-SF (95% CI)</td>
<td>14.7 (13.4–16.0)</td>
<td>16.4 (14.8–18.0)</td>
<td>14.4 (13.0–15.8)</td>
</tr>
<tr>
<td>Previous surgeries for SUI</td>
<td>13 (17%)</td>
<td>1 (3%)</td>
<td>9 (11%)</td>
</tr>
</tbody>
</table>

DUPS = distal urethral polypropylene sling; TVT = tension-free vaginal tape; CI = confidence interval; preop = preoperative; ICIQ-SF = ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form; SUI = stress urinary incontinence.
arm indicated postoperative retention: 3 (9.4%), 6 (18.8%), and 4 (12.5%) patients in the Obtape, DUPS, and TVT groups, respectively. Because of a higher postoperative retention rate combined with several complaints of suprapubic abdominal discomfort on straining in the DUPS group, this procedure was discontinued. One patient in the Obtape group was found to have a urethral diverticulum, which was repaired, but the Obtape procedure was cancelled, leaving 77 patients in the Obtape group for the final analysis.

TVT was the only procedure associated with bladder perforation at a rate of 14% (Table 3). The risk of bladder perforation was higher in patients with previous anti-incontinence surgery (33% vs. 11%), but this risk was not statistically significant ($p = 0.1$). Median blood loss was higher in the DUPS group (75 ml) compared with Obtape and TVT (50 ml) ($p = 0.31$). Median hospital stay was 0 night (day surgery). Patients who required hospital admission had comorbidities, concomitant pelvic organ prolapse surgery, or complications. There were no statistically significant differences among the three groups in terms of postoperative analgesic requirements and concomitant pelvic prolapse surgery ($p = 0.1$; Table 3).

The postoperative complete retention rate at the end of the study was 6 (7.8%), 6 (18.8%), and 6 (7.5%) in Obtape, DUPS, and TVT, respectively ($p > 0.1$; Table 4). An indwelling catheter was reinserted, and patients underwent a repeat voiding trial 48 h later. One patient in each of the Obtape and DUPS groups required urethrolysis. The rest of the patients with postoperative retention resumed spontaneous, complete voiding within 48 h of the operation or after a period of CIC. In only the Obtape group, concomitant prolapse surgery was associated with postoperative retention (38% vs. 4%, $p < 0.001$). Two patients in the Obtape group developed vaginal bleeding and hematomas, which were managed conservatively. Two patients in the Obtape group developed vaginal mesh erosion that required resection of the mesh and closure of the vaginal wound. Overall, Obtape and DUPS were associated with more postoperative complications than TVT: 14%, 28%, and 8%, in Obtape, DUPS, and TVT, respectively ($p < 0.025$; Table 4). Two patients in the Obtape group and one patient in the DUPS group required repeat anti-incontinence surgery (Table 5). In these cases, TVT was used and led to a cure.

At 1-yr follow-up, there was no statistically significant difference in the objective cure rates between Obtape, DUPS, and TVT (83%, 94% and 86%, respectively, $p > 0.05$; Table 6). Furthermore, no statistical difference was apparent in the subjective

<table>
<thead>
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<th>Table 2 – Type of anesthesia</th>
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<tr>
<td>Anesthesia</td>
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<tr>
<td>Local</td>
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<tr>
<td>Spinal (68%)</td>
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<td>General (35%)</td>
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DUPS = distal urethral polypropylene sling; TVT = tension-free vaginal tape.

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<th>Table 3 – Perioperative events</th>
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<tr>
<td>Eligible patients</td>
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<tr>
<td>Concomitant prolapse surgery</td>
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<tr>
<td>Bladder perforation</td>
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<tr>
<td>Median blood loss, ml (range)</td>
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<tr>
<td>Patients with &gt;250 ml blood loss</td>
</tr>
<tr>
<td>Analgesia</td>
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<tr>
<td>Median hospital stay (range)</td>
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<td>Complete retention (first 32 patients)</td>
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DUPS = distal urethral polypropylene sling; TVT = tension-free vaginal tape.

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<th>Table 4 – Postoperative complications</th>
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<tr>
<td>Complete retention (all patients)</td>
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<tr>
<td>Postop hematoma</td>
</tr>
<tr>
<td>Postop UTI</td>
</tr>
<tr>
<td>Mesh erosion</td>
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<tr>
<td>Superficial wound infection</td>
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<tr>
<td>Total postop complications</td>
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Postop = postoperative; UTI = urinary tract infection.

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<th>Table 5 – Subsequent procedures</th>
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<td></td>
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<tr>
<td>Urethrolysis</td>
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<tr>
<td>Mesh excision for erosion</td>
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<tr>
<td>Redo anti-incontinence surgery</td>
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<tr>
<th>Table 6 – Objective cure rates</th>
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<tbody>
<tr>
<td>Obtape</td>
</tr>
<tr>
<td>83%</td>
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cure rates, as determined by postoperative mean ICIQ-SF scores (5.2 vs. 2.5 vs. 3.7, p > 0.05). When compared with preoperative ICIQ-SF scores, the postoperative scores were significantly better (p < 0.01). There was no statistically significant differences among the three groups in terms of persistent or de novo urgency (p ≤ 1; Table 6).

4. Discussion

This is the first prospective trial comparing Obtape and DUPS to TVT. In contrast to the original paper by Ulmsten [4], most patients in the present study received regional anesthesia (Table 2). In our experience, regional anesthesia reduces operative time and is better tolerated by patients. An RCT comparing local and regional anesthesia for TVT showed that subjective and objective success rates did not differ significantly in the two groups, but women in the regional anesthesia had significantly greater evidence of urinary obstruction [21–24]. Regional anesthesia may have contributed to the high retention rate.

In the present study, TVT was the only procedure associated with bladder perforation at a rate of 14%. This finding is comparable to the reported rates of 0.7–24% [9,12,13,25–28]. Previous surgeries for SUI and learning curve have been previously associated with increased risk of bladder perforation [9,27,29,30]. Another possible explanation for the higher perforation rate might be the use of regional anesthesia. Since perivesical tissue hydrodissection is a feature of local anesthesia, this procedure may decrease the perforation rate. We agree with Niknejad et al [9] that bladder perforation, “when recognized intraoperatively, it is without sequelae” and should not be called a complication. In our practice, when bladder perforation occurs, a prolonged indwelling catheter is not used. In the present study, similar to the original article, no bladder perforation occurred in the DUPS group [15]. The most likely reason for this is that Stamey/Raz needles are finger-guided in the retropubic space. Similarly, no bladder perforations occurred in the Obtape group. These findings confirm the theoretical basis for the procedure’s invention. One advantage of transobturator approach is that cystoscopy could be avoided.

The postoperative retention rate at the end of the present study was 6 (7.8%), 6 (18.8%), and 6 (7.5%) in Obtape, DUPS, and TVT, respectively (p < 0.10). One patient in each of the Obtape and DUPS groups required urethrolysis after 6 wk of CIC. DUPS patients had the highest rate of postoperative retention and suprapubic abdominal discomfort on straining. Whereas the original paper described the insertion of a suprapubic catheter for at least 7 d to allow healing of the tract, in our study, we omitted the catheter to attempt to standardize postoperative care in the three arms of the study [15]. Rodriguez and Raz [15] reported 0.66% suprapubic pain and 3 (1%) patients requiring intermittent catheterization for 3 mo. In general, with the transobturator procedures, the reported urinary retention rate varies between 0% and 13.3% [14,31–35]. Therefore, the urinary retention rate of 7.8% in the Obtape group observed in this study is comparable to published results. The complete retention rate of 7.5% in the TVT group is within the published range of 4–10% in the literature [6–10,26]. Abouassaly et al [12] and Klutke et al [36] have advocated tape release under local anesthesia within 48–72 h from the operation to allow mobilization of the tape before it becomes fixed in place.

In the present study, there was no statistical difference in median estimated blood loss or the number of patients with >250 ml blood loss (p > 0.05; Table 3). However, two patients in the Obtape group developed hematomas and vaginal bleeding. Both were treated conservatively. With the transobturator approach, obturator hematoma has been reported at a rate of 3.3% [32]. In the DUPS group, one patient developed a superficial wound infection, which was treated with oral antibiotics. DUPS patients may be more likely to have wound infections since the suprapubic incision is larger than TVT or SPARC. In the original series, no wound infection occurred [37].

Obtape was the only procedure associated with mesh erosion, necessitating partial tape excision because of failure of vaginal epithelialization after conservative therapy. In our series, it was noted in 2.6% of Obtape patients. This complication has been reported in 2.5–20% [34,35,38]. Furthermore, Obtape
has been associated with ischiorectal abscess and necrotizing fasciitis [39,40], possibly because of differences in the type of mesh used. TVT and DUPS use the same polypropylene woven macropore (>75 μm) mesh, whereas Obtape uses thermally bonded micropore (50 μm) mesh. These micropores may allow bacteria to get in but not macrophages and fibroblasts, thus increasing the chances of mesh extrusion [38,41–44]. Kobashi and Govier [40,44] have recommended conservative management of macropore meshes for 3 mo, but this does not apply to micropore meshes in the Obtape kit.

In the current study the objective cure rate with TVT was 86%, which is comparable to previously published findings (63–92%) [9,13,45,46]. The objective cure rate with Obtape was 83%, which was comparable to 89.9% reported by Deval et al [35]. Others have found similar subjective cure rates of 80% and 85.5% at 1 yr [47,48]. The DUPS group had a higher, although statistically insignificant, objective cure rate of 94% compared with TVT and Obtape. The higher cure rate together with the higher retention rate and suprapubic pain in the DUPS group may indicate that the DUPS tape may have been placed tighter than TVT or Obtape. An objective cure rate of 92% and a 5-yr subjective cure of 88% have been reported [37,49]. Whereas there was no statistically significant difference among the three groups in postoperative ICIQ-SF scores, they were statistically lower than preoperative ICIQ-SF scores (14.7 vs. 5.2 for Obtape, 16.4 vs. 2.5 for DUPS, and 14.4 vs. 3.7 for TVT, \( p < 0.01 \)). Therefore, patients were satisfied.

5. Conclusions

TVT was the only procedure associated with bladder perforation, but there were more postoperative complications with Obtape and DUPS. At 1-yr follow-up, no statistically significant differences in cure rates were evident. Longer follow-up is needed to confirm these results. The cost-benefit ratio for DUPS must be analyzed for each health care system in view of the risks and benefits of this technique.

Conflicts of interest

There are no conflicts of interest.

References


Editorial Comment on: Prospective Clinical Trial Comparing Obtape® and DUPS to TVT: One-year Safety and Efficacy Results
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Suburethral sling procedures are specifically designed to address both urethral hypermobility and intrinsic sphincteric deficiency components of stress urinary incontinence (SUI) in women. Although further studies are needed to establish their long-term efficacy and safety, these procedures seem more efficient than the ones adopted in the era before the development of tension-free procedures and found that at a mean follow-up of 24 mo the outcome after TVT seems slightly worse in patients with MUI. “Urgency remains a postoperative problem especially in the TVT group” [6].

I believe that multicentre RCTs with longer follow-up are needed to establish which suburethral sling procedure in the treatment of MUI or recurrent SUI is better. In addition, comparative RCTs are needed to determine whether POP surgery and the retropubic or trans-obturator anti-incontinence procedure should be performed simultaneously or not.

References


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