Clinical and urodynamic outcomes of tension – free vaginal tape procedure

The tension – free vaginal tape procedure (TVT) has been regarded as a safe, minimally invasive method for the treatment of female stress urinary incontinence. In a prospective multicenter study we evaluated safety and efficacy of TVT procedure for the treatment of female stress incontinence. From 1998 to 2003, a total of 42 patients, mean age 60 years (range 34-76) with urodynamically verified stress urinary incontinence underwent the TVT procedure. The mean follow-up period was 28 months (range 14 to 32). Intra- and postoperative complications were few, including bladder perforations (4.7%), vaginal hematoma (2.4%), complete urinary retention (2.4%), transient urinary retention (19%) and urinary tract infection (7.1%). Postoperatively, voiding time and functional urethral length significantly increased. The subjective and objective cure rates were 85.7% and 90.5%, respectively. We conclude that the TVT procedure is associated with high cure rate and low morbidity.

Key words: tension-free vaginal tape, stress urinary incontinence, intraoperative complications, postoperative complications, urodynamic parameters

INTRODUCTION

The tension free vaginal tape (TVT) technique in female stress urinary incontinence treatment has gained much popularity since it has been introduced by Ulmsten and Petros in 1995. To date, over 150,000 TVT procedures have been performed worldwide, with positive increasing trend. Available data continue to show a sustained trend of improved results in all indicators of outcomes in patients underwent this antiincontinence procedure.

Although the TVT technique is recent it has been demonstrated to be a safe and effective treatment for stress urinary incontinence, offering the benefits of a minimally invasive procedure, with good long-term results.

In the present study we evaluated the outcome of TVT procedure performed on 42 women, related to its safety and efficacy.

MATERIALS AND METHODS

The study is a prospective multicenter trial involving five Serbian hospitals. During the period between October 1998 and June 2003, a total of 42 female patients, mean age 60 years (34 to 76 years) with urodynamically verified stress urinary incontinence were operated using the TVT technique. Five of these 42 patients had already undergone surgery for incontinence: 2 Stamey procedures, 2 Burch and 1 Tanagho-Perin procedure. Clinically, the type of incontinence was defined as pure urinary incontinence in 18 patients (42.9%) and mixed urinary incontinence in 24 patients (57.1%). Associated SUI and genital prolapse was noted in 17 patients. Mean follow-up period was 28 months (from 14 to 32).

The pre- and postoperative protocol included the following:
- a detailed urogynecologic history,
- clinical study questionnaire,
- stress and urge score,
- objectivizing tests (Pad's test, Fluid-Bridge test, Nappy's test and Boney's test),
- standard urodynamic evaluation (uroflowmetry, cystometry, profilometry),
- special urodynamic evaluation by UEP-metry (the coefficient of urethral electrical conductivity profile in all three parts of the urethra, with the special regard to the urinary bladder neck),
- cystoscopy,
The TVT operation was performed according to Ulmsten’s original technique under spinal anesthesia in all cases. Preoperative prophylactic antibiotics were administered systematically. A urethral catheter was placed in all cases and left in place for 1-4 days (mean 1.7 days).

The postoperative evaluation also included data regarding the time required for surgery, intra- and postoperative complications, additional surgical procedures, length of hospital stay and analysis of outcomes. The outcome of the surgical procedure was estimated both subjectively and objectively. Objective cure was defined as no leakage of urine while performing the cough test with at least 250 ml of saline solution in the bladder, no need of pads, no chronic retention. Subjective cure was defined as no urine loss during stress.

Mean follow-up period was 26 months (range 12 to 42). Statistical analysis was estimated by Student’s t-test for independent groups and Fischer’s exact test.

RESULTS

The mean operative time for TVT implantation was 20 min (from 15 to 35). In cases of associated procedures, the operative time was 50 min (from 40 to 115). The average hospital stay was 4 days (from 2 to 11).

Associated surgical procedures combined with TVT included abdominal hysterectomy, anterior colporrhaphy and posterior colporrhaphy (Table 1).

The main per-operative complications included uncomplicated bladder perforation in 2 cases and vaginal hematoma in 1 case (Table 2).

Bladder perforations were detected by cystoscopy immediately after retro pubic passing of TVT needle. In both cases TVT needle was withdrawn and reinserted. Bladder perforations had no longer-term implications. A vaginal hematoma was treated by surgical evacuation.

A total of 15 patients had some of postoperative complications.

Complete urinary retention occurred in 2 patients and they required intermittent catheterization for 3 to 7 days postoperatively.

There were a total of 8 patients with postoperative voiding difficulties, with residual urine more than 100 ml. Three of these patients had associated reconstructive surgery for genital prolapse. The only case lasting for 3 months was a woman who underwent TVT associated with total hysterectomy. In the rest of 7 patients it lasted from one week to 6 weeks. Of these, 2 patients recovered spontaneous miction after urethral dilatation, 4 patients spontaneously and 1 patient after suburethral tape sectioning. There were 3 cases of urinary tract infection, all treated by oral antibiotics. Two patients had postoperative pain in the region of gluteal muscle and thigh.

Comparing urodynamic parameters pre- and postoperatively we found slight increase in the maximal flow rate, average flow rate and maximal urethral closure pressure (p>0.05) and statistically significant increase in voiding time and functional urethral length (p<0.05). Urethral electrical conductivity profile showed postoperative decrease in the proximal urethra (p<0.05), also in the bladder neck and distal urethra (p>0.05) (Table 3).

According to the subjective outcome, the cure rate was 85.7% (36 patients), the improved rate 11.9% (5 patients) and the failure rate was 2.4% (1 patient). A total of 38 (90.5%) patients presented as cured, 3 (7.1%) as improved and 1 (2.4%) as failed on objective assessment by cough provocation test.

DISCUSSION

Since the beginning of the century, many surgical procedures for stress urinary incontinence in women have been described. It is still unclear which procedure among this variety of treatment methods is the most appropriate and effective. The tension free vaginal tape procedure represents very useful technique due to its simplicity, safety, efficacy and good tolerance of the biomaterial. This technique demonstrates a new concept in urethral support by dynamic urethral resistance restoration which does not compromise urethral function at rest and during voiding.

In our series morbidity was low, with few complications comparable with reported data.

The fact that female incontinence is often associated with coexisting genital prolapse, is well established. Therefore, the need for pelvic reconstructive surgery along with anti-incontinent surgery is frequently requested. In our study, 17 patients had genital prolapse associated

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No</th>
<th>%</th>
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<tbody>
<tr>
<td>Abdominal hysterectomy</td>
<td>2</td>
<td>11.8</td>
</tr>
<tr>
<td>Anterior colporrhaphy</td>
<td>8</td>
<td>48.0</td>
</tr>
<tr>
<td>Posterior colporrhaphy</td>
<td>4</td>
<td>23.6</td>
</tr>
<tr>
<td>Anterior+posterior colporrhaphy</td>
<td>3</td>
<td>17.6</td>
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<tr>
<td>Total</td>
<td>17</td>
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<table>
<thead>
<tr>
<th>Complication</th>
<th>No</th>
<th>%</th>
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<tbody>
<tr>
<td>Bladder perforation</td>
<td>2</td>
<td>11.1</td>
</tr>
<tr>
<td>Vaginal hematoma</td>
<td>1</td>
<td>5.6</td>
</tr>
<tr>
<td>Urinary retention</td>
<td>10</td>
<td>55.6</td>
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<tr>
<td>Urinary tract infection</td>
<td>3</td>
<td>16.6</td>
</tr>
<tr>
<td>Pain in the gluteal region</td>
<td>2</td>
<td>11.1</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>100</td>
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</table>
TABLE 3

URODYNAMIC FINDINGS BEFORE AND AFTER TVT

<table>
<thead>
<tr>
<th>Urodynamic parameters</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>p</th>
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<tbody>
<tr>
<td>Maximal flow rate</td>
<td>22.4±5.1</td>
<td>20.2±5.2</td>
<td>p &gt; 0.05</td>
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<tr>
<td>Average flow rate</td>
<td>18.2±4.7</td>
<td>16.1±4.6</td>
<td>p &gt; 0.05</td>
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<tr>
<td>Voiding time</td>
<td>23.4±7.3</td>
<td>28.2±7.2</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>Functional urethral length</td>
<td>25.9±2.5</td>
<td>29.6±2.3</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>Maximal urethral closure pressure</td>
<td>29.2±2.7</td>
<td>33.1±2.5</td>
<td>p &gt; 0.05</td>
</tr>
</tbody>
</table>

with stress incontinence and had been underwent to some of pelvic reconstructive procedures combined with TVT. The per-operative complications included bladder perforation in 2 patients (4.7%) and vaginal hematoma in 1 patient (2.4%) which are comparable with previously reported data where bladder injury rate was reported to be up to 10%.

Two patients had complete urinary retention which resolved after prolonged intermittent catheterization for a few days.

Incomplete retention is observed in 8 cases. Three of them had suburethral sling over suspension which resolved after urethral dilatation in two, while 1 patient required extra procedure to enhance voiding (the sling was sectioned under the urethra). The rest of 5 patients achieved normal voiding pattern within the first 6 weeks after operation, but one patient who underwent total hysterectomy combined with TVT procedure who had achieved normal voiding pattern after 6 months. Reported data show transient urinary retention rate from 8 to 17.5%.

These complications could be avoided by adequate preoperative evaluation and absence of hypocontractile bladder on urodynamic testing, also by very slight suspension of the sub-urethral sling during the surgical procedure.

Patients with postoperative pain were treated by oral painkillers for only few days.

Urodynamic evaluation performed in this study before and after surgery showed significant increase in voiding time and functional urethral length and slight increase in maximal flow rate, average flow rate and maximal urethral closure pressure. It suggests an increase in urethral resistance supporting by TVT tape. Urethral electrical conductivity profile showed significant postoperative decrease in the proximal urethra which means that dynamic urethral resistance as a primary goal of the TVT technique was achieved.

Finally, the subjective and objective cure rates in our series (85.7% and 90.5%, respectively) are consistent with those reported by other authors.

The cure rates for TVT have been found to vary between 81% and 100%.

CONCLUSION

Based on the findings of the present study, TVT technique seems to fulfill the expectations of both surgeons and patients. Moreover, it can be combined with other types of reconstructive surgery offering satisfactory restoration of urinary continence in a variety of indications.

REZIME

Procedura sa beztenzionom vaginalnom trakom se smatra bezbednom, minimalno invazivnom metodom za lecenje stres urinarne inkontinencije kod žena. U prospektivnoj multicenternoj studiji ispitali smo bezbednost i uspešnost TVT procedure u lecenu stres urinarne inkontinencije kod žena. U periodu od 1998. do 2003., ukupno 42 pacijentkinje prošle starosti 60 godina (od 34 do 76) su urodisanski dokazanom stres urinarnom inkontinencijom su bile podvrgnute TVT proceduri. Prosječno vreme praćenja iznosilo je 28 meseci (od 14 do 32). Bilo je svega nekoliko intra- i postoperativnih komplikacija, uključujući perforacije mokraće bešike (4.7%), vaginalni hematomi (2.4%), komplet na retencija urina (2.4%), inkompletna retencija urina (19%) i infekcija urinarnog trakta (7%). Postoperativno, vreme mokrenja i funkcionalna dužina uretre su značajno povećani. Subjektivna stopa izlećenja iznosi 85.7%, dok objektivna iznosi 90.5%. Zaključujemo da je TVT procedura udružena sa visokom stopom izlećenja i niskim morbiditetom.

Ključne reči: beztenziona vaginalna traka, stres urinarne inkontinencije, intraoperativne komplikacije, postoperativne komplikacije, urodisanski parametri

REFERENCES


