Tension-free vaginal tape and laparoscopic mesh colposuspension in the treatment of stress urinary incontinence: immediate outcome and complications – a randomized clinical trial

Antti Valpas, Arre Kivela, Jorma Penttinen, Minna Kauko, Erkki Kuusansuu, Elja Tomas, Mervi Haarala, Seija Meltomaa and Carl-Kustav Nilsson

Background. The purpose of the study was to evaluate the immediate outcome and complications of the tension-free vaginal tape (TVT) and laparoscopic mesh colposuspension (LC) procedures in the treatment of female stress urinary incontinence (SUI).

Methods. One hundred and twenty-eight patients suffering from urodynamically confirmed SUI were recruited to this multicenter, randomized clinical trial. After randomization there were seven drop-outs – 121 patients were operated upon: 70 patients in the TVT group and 51 in the LC group. The patients were evaluated according to the study protocol before operation and 6 weeks after it. The independent sample t-test and the Mann–Whitney U-test were used to calculate statistical differences between the study groups.

Results. Immediate cure rates, defined as negative stress test with 300 mL saline in the bladder, were similar (92.9% in the TVT group and 88.2% in the LC group; p = ns). Return to normal voiding was faster in the TVT group (9.2 h in the TVT group vs. 24.4 h in the LC group; p = 0.004). Fewer analgesics were used in the TVT group and hospital stay was shorter in this group. Complication rates associated with the procedures were similar and the number of complications was small.

Conclusions. The immediate outcome of both procedures is the same. The rates of complications were similar. However, the TVT procedure seems to be less invasive and requires fewer hospital resources than LC.

Key words: stress urinary incontinence; TVT procedure; laparoscopic colposuspension; complications of incontinence surgery

Submitted 23 May, 2002
Accepted 12 December, 2002
staples to avoid difficult suturing in the space of Retzius (4). By using an extraperitoneal approach as described by Hannah and Chin, the potential complications of pneumoperitoneum can be avoided (5). Using two sutures on each side of the urethrovesical junction, compared with a mesh and staples technique, gives equally good results for at least 1 year (6).

In 1990 Ulmsten and Petros published a new theory of female urinary incontinence (an integral theory) (7). Based on this theory, a new, minimally invasive procedure was developed (Intravaginal Slingplasty, IVS/Tension-free Vaginal Tape, TVT) (8–10). Under local anesthesia a polypropylene mesh tape (Prolene® Ethicon, Somerville, NJ, USA) is placed under the mid-urethra with special needle instrumentation. The tape gives support to the mid-urethra and is an inducer for the formation of new connective tissue.

The aim of the present prospective randomized clinical trial was to compare two modern surgical procedures in the treatment of female SUI: the TVT procedure and laparoscopic mesh colposuspension. The trial was carried out in four University Clinics and two Central Hospital Clinics in Finland. The immediate outcome and complications are reported in this study.

Materials and methods

The study was accepted by the local ethics committees of each participating hospital and each patient gave written informed consent. One hundred and twenty-eight women were recruited to the study: the inclusion criteria are shown in Table I. Randomization was carried out by means of a computer-generated randomization list that was kept in the randomization center. After the patient had given her consent to the study the investigator called the randomization center to enter the patient in the allocated group. Patients were randomized to the TVT group (group 1) or to the laparoscopic group (group 2). Block randomization (40 patients per center) was used for each participating hospital. After randomization seven patients dropped out: four patients refused operation; two patients did not accept the result of the randomization and one was operated upon in a smaller hospital that was not participating in the study. One hundred and twenty-one patients were operated upon: 70 patients in the TVT group and 51 in the LC group. Power calculation showed that if the cure rate is assumed to be 90%, for Type I error 5% is accepted and for the smallest noticeable difference 10% is assumed, and if for Type II error 20% is accepted, the sample size should be 180 patients. The exclusion criteria are shown in Table II. The characteristics of the study population are given in Table III.

Preoperative evaluation of the patients included clinical evaluation and a urodynamic investigation: medium-fill cystometry, rest and stress urethral pressure profiles and uroflowmetry in some centers. SUI was diagnosed if there was a stable bladder in cystometry and if the stress test was positive. The stress test was performed with 300 mL saline in the bladder in a supine position with repetitive maximal coughs (two to four coughs). Forty-eight-hour pad tests were performed. The Urinary Incontinence Severity Score (UISS) (11) and the Urge Score (US) (12) were assessed, and Visual Analogue Scale (VAS) and King’s College Quality of Life Questionnaires (13) were completed.

The operations were performed by senior gynecologists, who had independently performed at least 20 of each procedure.

Tension-free vaginal tape (TVT) procedure

The TVT procedure was performed technically as described previously by Ulmsten and Petros (9).

Table I. Inclusion criteria

| History of stress urinary incontinence (SUI) |
| Operation indicated according to clinician’s standards |
| Urodynamically verified SUI (no bladder contractions over 15 cmH2O during cystometry, negative closure pressure during profilometry) |
| Positive stress test (300 mL saline in bladder) |

Table II. Exclusion criteria

| Age over 70 years |
| Previous incontinence operation (except previous anterior colporrhaphy) |
| More than three episodes of urinary infection within the past 2 years |
| Coincident other gynecologic procedures |
| Body Mass Index (BMI) > 32 |
| Contraindication for general anesthesia |
| Contraindication for laparoscopy |
| Unstable bladder in cystometry |
| Urethral closure pressure < 20 cmH2O |
| Residual volume > 100 mL in preoperative urodynamic investigation |

Table III. Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>TVT group</th>
<th>LC group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>50 (33–67)</td>
<td>48 (29–68)</td>
<td>ns</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25.7 (20–30)</td>
<td>24.7 (18–30)</td>
<td>ns</td>
</tr>
<tr>
<td>Duration of incontinence symptoms (years)</td>
<td>8.4 (1–33)</td>
<td>6.7 (1–23)</td>
<td>ns</td>
</tr>
<tr>
<td>48-h PAD test (g/48 h)</td>
<td>82.5 (7–614)</td>
<td>68.4 (0–253)</td>
<td>ns</td>
</tr>
<tr>
<td>VAS (0–10)</td>
<td>7.1 (4–10)</td>
<td>6.6 (3–10)</td>
<td>ns</td>
</tr>
</tbody>
</table>
A single intravenous dose of metronidazole 500 mg or cefuroxime 1.5 g was given during the operation as prophylaxis. No other antibiotics were administered. The bladder was emptied via a transurethral Foley catheter. First the abdominal skin was infiltrated at two spots about 5 cm apart just above the symphysis pubis with local anesthetics (prilocaine–epinephrine 0.25%). Using a 20-mL syringe, a long needle was inserted down the back of the pubic bone to the space of Retzius and the retropubic space was infiltrated on each side of the midline. Finally the vaginal wall was infiltrated sub- and paraurethrally. The amount of local anesthetics used on average was 93.2 mL (range 21–250 mL). Two 1-cm-long transverse skin incisions were made about two fingerwidths from the midline just above the superior rim of the pubic bone. A 1-cm-long incision was made in the midline of the suburethral vaginal wall starting about 0.5 cm from the outer urethral meatus. Laterally from this incision a blunt dissection around 1 cm deep was made with scissors just under the mucosa to each side of the urethra towards the inferior rim of the pubic bone. With a straight inserter introduced into the Foley catheter, the urethra and bladderneck were identified and moved to the side opposite the operation field. With a TVT needle (TVT Device, Gynecare, Johnsson & Johnsson, Somerville, NJ, USA) the urogenital diaphragm was perforated and the tip of the needle was brought up to one of the abdominal incisions. The procedure was then repeated on the other side. After each TVT needle pass cystoscopy was performed to confirm an intact bladder. With 300–400 mL saline in the bladder the patient was asked to cough in order to adjust the tightness of the tape: few drops should be leaking at this step of the operation during the cough. The bladder was then emptied and the incisions sutured with 4-0 Vicryl®. No catheter was left in place and 3–4 h later the spontaneous voiding residual volume was measured.

Laparoscopic colposuspension (LC)

Extrapерitoneal endoscopic bladderneck suspension was performed under general anesthesia using a tackler-mesh technique. The patients were in a semilithotomy position. A single dose of cefuroxime 1.5 g was given as prophylaxis. A Foley catheter was inserted into the bladder and the balloon was filled with 20 mL of saline. A 2–3-cm horizontal incision was made immediately inferior and lateral to the umbilicus. The fascia was identified and a 1.5-cm incision was made horizontally. The anterior rectus fascia was elevated and a preperitoneal balloon dilator (PDB®, Preperitoneal Distention Balloon System; Origin Medsystems, Inc., Menlo Park, CA, USA) was placed against the anterior rectus fascia and advanced into the retropubic space. The balloon was filled with air under direct observation through the laparoscope – approximately 30 pumps of the inflation bulb were adequate for the dissection. The inflated balloon was kept in place for 3–5 min to ensure hemostasis. The balloon was deflated and removed and replaced with a Structural Balloon Trocar and Inflation Bulb (Origin). Gas insufflation was introduced. Two to three 5-mm trocars were inserted under direct visualization into the retropubic space some 3–5 cm above the superior rim of the pubic bone, avoiding the large abdominal wall vessels. Cooper’s ligaments were dissected free, the surgeon’s left hand was placed in the vagina and with a finger placed 1.5 cm lateral to the vesicourethral junction the vaginal wall was elevated and dissected free. Two strips of precut polypropylene mesh 12 mm wide and 4 cm long were inserted into the operating cavity. The mesh was attached to the paraurethral tissue overlying the surgeon’s fingertip with two to four tackers (Origin Tacker™ System, Origin). The free end of the mesh was attached to Cooper’s ligament 3–4 cm lateral to the midline with three to four tackers while at the same time elevating the paraurethral tissue. An identical process was then repeated on the opposite side. A 2-cm space was left between the urethra and the pubic bone anteriorly.

In six (12.5%) operations the peritoneum was unintentionally opened. In these cases the procedure was completed by using an intraperitoneal technique (14). Two to three trocars were placed in the left and right lower quadrants of the abdomen. The bladder was filled with methylene blue solution. The dome of the bladder was identified and the peritoneum was incised about 2 cm above the dome transversely between the umbilical ligaments. The preparation of cavum Retzi was carried out using blunt and sharp dissection. The bladder was emptied and from this point the operation was continued in the same way as when using the extraperitoneal technique. Hemostasis was achieved, and the instruments were removed. Drainage was not needed. Skin incisions were sutured. The Foley catheter was left in place and removed next morning. Residual volume was measured after first spontaneous voiding after removing the catheter. Residuals were measured by catheterization.

The first postoperative visit took place 6 weeks after surgery. The evaluation consisted of clinical
examination, a stress test performed with 300 mL saline in the bladder, residual urine measurement, urinary sampling (dip-stick) and analysis of patient records. Other outcome measures used in the study are listed in Table IV.

For statistical analysis SPSS 8.0 for Windows software was used. The independent sample t-test and the Mann–Whitney U-test were used to calculate statistical differences between the study groups.

Results

The main results are presented in Table V. Immediate postoperative (6-weeks) cure rates, defined as a negative stress test with 300 mL saline in the bladder, were similar. The operation theatre time and operation time were shorter in the TVT group. Return to normal voiding, defined as residual volume <100 mL, was faster in the TVT group. Fewer analgesics were used in the TVT group. The hospital stay was shorter (0.7 vs. 1.8 days, \( p < 0.001 \)) in the TVT group and the return to work was faster (15 vs. 24 days, \( p < 0.001 \)) in the TVT group.

One patient in the TVT group reported an intense headache during the operation. One short injection needle snapped while inserting the local anesthesia into pararectal tissue. The broken needle was removed and the operation was completed without any further problems.

The complications are presented in Table VI. Average blood loss during operation was similar in both groups (34 mL in the TVT group vs. 30 mL in the LC group; \( p = 0.727 \)). Two cases of bladder perforation occurred, one in each group. This caused conversion of one LC to open laparotomy; in the TVT operation the needle was withdrawn and reinserted without problems. At the 6-week follow-up visit both patients had recovered normally. There were two patients in each group with retention (residual volume >100 mL). In the TVT group one patient had total retention. The tape was loosened next day under spinal anesthesia and recovery after that was uneventful. The second patient in the TVT group was managed by self-catheterization for 6 days. At the 6-week follow-up visit the residual urine volume was 35 mL and the patient reported no voiding problems. The two patients in the LC group with retention were managed by self-catheterization for 1 and 2 days, respectively; at the 6-week follow-up visit residual urine volumes were 27 and 50 mL. One case of mild wound infection occurred in the TVT group and was cured with oral antibiotics. In the LC group one case of port infection was treated and one abdominal wall hematoma was evacuated.

Discussion

To our knowledge this is the first randomized multicenter study where the TVT procedure and laparoscopic mesh colposuspension have been compared. We found that the two operations...
were equal in terms of complications and primary results, but the operation time in the TVT operation was shorter. Persson et al. compared the costs of the LC and TVT procedures. They used sutures instead of mesh in the laparoscopic procedure (15). They found that LC was less expensive than the TVT procedure. However, in our hands the operation time for TVT is shorter (29 vs. 45 min). They also states that the full attention of an anesthesiologist was needed and this had a major effect on the procedural costs. In Finland TVT is performed under local anesthesia and sedation supervised by an anesthesia nurse. These two factors – the operation time and the need for an anesthesiologist – might explain their findings.

There is a need within gynecologic surgery to develop minimally invasive procedures in order to achieve shorter hospital stays and shorter convalescence periods. Patients will continue to seek minimally invasive surgical procedures with reliable and durable outcomes. However, many of these new techniques have been adopted in clinical practice without controlled clinical trials. For example, the long-term results of so called needle suspension proved to be disappointing despite good results reached in initial uncontrolled trials (16–18). Only a few randomized clinical trials involving modern incontinence operations have been published (14). Buller and Cundiff (19) list three such studies (20–22) in their review article. Recently, El-Toukhy and Davies published the results of a randomized study where they compared open Burch colposuspension (OC) with laparoscopic mesh colposuspension (23). They reported an objective cure rate of 62% for LC and 79% for OC after 2.5 years of follow-up. An optimal way of evaluating a new technique is to compare it with a ‘gold standard’, that is with OC (24). The results of most randomized studies in which open and laparoscopic colposuspensions have been compared suggest that the outcome of LC is inferior to that of OC.

In Finland it was not feasible to conduct a study involving an open technique; it was rapidly abandoned because the patients found it unacceptable. During the study, advances in the TVT procedure also made it difficult to recruit patients to any other operation. For this reason the number of patients originally planned to be enrolled (180) could not be achieved and randomization could not be completed in the intended way. This produced different numbers of patients in the two study groups even though the randomization process was strictly adhered to. Nevertheless, the groups are still comparable and there is no systematic selection bias. This in turn leads to the fact that only differences larger than intended in patient outcome measures can be detected. As the sample size goes down the possibility of missing a true difference grows. With this sample size and with these assumptions it can be calculated that the Type II error is 45% in the present study.

The reported cure rates after incontinence surgery depend strongly on the method and on the definition of cure used in the study. There is a great difference between the objective and subjective cure rates, as has recently been demonstrated by Ward and Hilton in their study comparing TVT with open colposuspension (25). We used a negative stress test as the primary objective outcome measure for cure. However, it is possible that a patient has SUI and at the same time the stress test is negative, but as a positive stress test was one of the inclusion criteria in our study it is logical to regard a negative stress test as an indicator for cure. Cure rates after the TVT procedure look promising, as the objective cure rate after a mean follow-up time of 17.5 months has been reported to be 87.3% and the rate of significant improvement 8.8% (26). LC has also been shown to have good results, at least in the short term (23). However, it is only possible to compare results reliably in randomized studies.

The immediate results of this work show that the operations were performed technically in an adequate way. The results of the TVT procedure have been shown to be stable for up to 5 years (27), but the results after Burch colposuspension show a trend towards continuous decline in the course of time (21,28,29). These findings may be explained by the fact that TVT creates a new hammock under the mid-urethra and the tape is invaded by fibroblasts during the course of time, thereby stabilizing its position.

The most common complication reported with LC is bladder injury (3.7–17%) (14). In our series there was only one case of bladder perforation in the LC group. It was repaired in open laparotomy, because the tackers placed through the
bladder wall were very difficult to remove laparoscopically and it was judged that the best way of suturing the bladder was in open operation. In the TVT procedure the bladder complication rate has been reported to be 5.4% on average (26), but in our series in only one case did the TVT needle cause bladder perforation.

Blood loss was similar in both groups (Table VI). There was one case of gate infection and one patient had sepsis in the LC group. One hematoma was evacuated from the abdominal wall. In the TVT group one patient had a wound infection. The rate of urinary tract infection in the TVT group was 4.2% and in the LC group it was 2.0%. It can be concluded that the complication rates were similar in both study groups and that the number of complications was small. From this point of view both procedures seem to be equally usable.

The operation theatre time and operation time were significantly shorter in the TVT group (Table V). It has been routine in Finland that after LC the catheter is kept in overnight. After removing the catheter the recovery of spontaneous voiding was slower in the LC group than in the TVT group. The amount of analgesics needed after laparoscopy than after the TVT procedure. The immediate results of both of the studied groups and that the number of complications was small. From this point of view both procedures seem to be equally usable.

In conclusion, the present study indicates that the immediate results of both of the studied groups and that the number of complications was small. From this point of view both procedures seem to be equally usable.

References


Address for correspondence:
Antti Valpas
Department of Obstetrics and Gynecology
Central-Ostrobothnian Central Hospital
Mariankatu 16-20
FIN-67200 Kokkola
Finland
e-mail: antti.valpas@kolumbus.fi