Surgical treatment of female stress urinary incontinence with the Gynecare TVT Secur™ System – preliminary report

Leczenie chirurgiczne wysiłkowego nietrzymania moczu za pomocą zestawu Gynecare TVT Secur™ System – doniesienie wstępne

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Summary

Introduction: Sling procedures were first introduced over 100 years ago in the treatment of stress urinary incontinence. Since then they have evolved to become less invasive and safer. The sling procedure using the Gynecare TVT Secur™ system is a new therapeutic option for women with stress urinary incontinence.

Objectives: To evaluate the efficacy and safety of Gynecare TVT Secur™ in the surgical treatment of stress urinary incontinence in women.

Material and methods: The study comprised consecutive female patients admitted to the Department of Gynaecology and Gynaecological Oncology of the Military Institute of Health Services in Warsaw, Poland, who had been qualified for surgical treatment of stress urinary incontinence on the basis of physical signs and symptoms and the findings of a urodynamic study. The procedure was performed using the Gynecare TVT Secur™ system with tapes introduced in an H- or U-shape mode.

Results: Between October 2006 and September 2009, 77 sling procedures using the Gynecare TVT Secur™ system were performed in women with stress urinary incontinence. Their mean age was 55.1 (30-76) years, mean BMI 28.5 (20.2-43.8) kg/m^2. Sixty-nine implants were positioned in H-shape mode, 8 in U-shape mode. Forty-nine women (63.6%) were menopausal, 14 (18.2%) previously had three or more natural deliveries, 13 (16.8%) had a history of gynaecological surgeries. Thirty-one procedures were performed under general anaesthesia and 46 under local anaesthesia. The mean duration of the surgery was 9 (4-42) minutes. It was possible to discharge fifty-seven (74%) women on the day of the surgery. Urine retention was observed only in 1 (1.7%) woman. No other complications were recorded.

Conclusions: The surgical treatment of urinary incontinence with sling procedures using the Gynecare TVT Secur™ system shows good immediate efficacy and safety. Considering this as well as the short duration of the procedure and its good tolerability under local anaesthesia, use of the Gynecare TVT Secur™ system in an outpatient setting can be advocated. Further studies with longer follow-up are necessary to establish the long-term efficacy of the procedure.

Key words: stress urinary incontinence, surgery, sling procedures, mini-invasive surgical procedure

Streszczenie

Wstęp: Operacja slingowa została przeprowadzona po raz pierwszy ponad 100 lat temu w celu leczenia wysiłkowego nietrzymania moczu. Od tego czasu metody ewoluują w kierunku technik mniej inwazyjnych i bardziej bezpiecznych. Najnowszą techniką leczenia operacyjnego kobiet z wysiłkowym nietrzymaniem moczu jest TVT Secur™.

Cel pracy: Ocena skuteczności i bezpieczeństwa stosowania systemu Gynecare TVT Secur™ w leczeniu operacyjnym wysiłkowego nietrzymania moczu u kobiet.

Materiał i metody: Badaniem objęto kolejne pacjentki przyjmowane do Kliniki, które na podstawie wywiadu, danych klinicznych i wyników badania urodynamicznego zostały zakwalifikowane do leczenia operacyjnego. Pacjentki poddano operacji zestawem Gynecare TVT Secur™ metodą *U-shape* lub *H-shape*.

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Wyniki: Od października 2006 r. do września 2009 r. u 77 pacjentek z wysiłkowym nietrzymaniem moczu wykonano procedurę Gynecare TVT Secur™. Średnia wieku wynosiła 55,1 (30–76) lat, średnie BMI 28,5 (20,2–43,8) kg/m^2. W pozycji *H-shape* umieszczono 69 implantów, w pozycji *U-shape* – 8. Czterdzieści dziewięć kobiet (63,6%) było po menopauzie, 14 (18,2%) przebyło 3 i więcej porodów siłami natury, 13 (16,8%) przebyło wcześniej operacje ginekologiczne. W znieczuleniu ogólnym wykonano 31 zabiegów, a 46 w znieczuleniu miejscowym. Średni czas trwania procedury wniósł 9 min (4–42). W dniu operacji wypisano do domu 57 pacjentek (74%). Przemijającą retencję obserwowano tylko u jednej pacjentki. Nie było żadnych powikłań śródoperacyjnych.

Wnioski: System Gynecare TVT Secur™ jest skuteczną i bezpieczną metodą chirurgicznego leczenia wysiłkowego nietrzymania moczu. Biorąc po uwagę krótki czas trwania zabiegu oraz dobrą tolerancję znieczulenia miejscowego, TVT Secur™ może być wykonywany z powodzeniem ambulatoryjnie. Aby określić długoterminową skuteczność tej procedury, konieczna jest dalsza obserwacja.

Słowa kluczowe: wysiłkowe nietrzymanie moczu, chirurgia, operacje slingowe, chirurgia małoinwazyjna

Introduction

The first sling procedure in the treatment of stress urinary incontinence (SUI) was performed over one hundred years ago. It was a Goebell-Stoeckel operation, during which pyramidal muscles were used to make the sling. In a slightly later, modified version of the procedure (Goebell-Frangenheim-Stoeckel operation) a fragment of the rectus abdominal muscle fascia was used as additional material to make the sling [1]. The first procedure, which was conceptually close to the sling procedures carried out nowadays for treating SUI, was an operation performed in 1942 by Aldrige, who made a sling using the rectus abdominal muscle. The disadvantages of Aldrige's method were its low long-term efficacy and a high perioperative complication rate [2]. In the following years, a sling was made from material deriving from the broad fascia, vaginal wall, dura mater, animal collagen, and such synthetic materials as polytetrafluoroethylene, polypropylene and silicone.

Simultaneously, there was a search for new surgical solutions, of which a breakthrough was an operation utilizing a monofilament polypropylene sling. The procedure was first performed in 1995 from a vaginal approach, retropubically, using special tunnelers [3]. The technique used was reflected in the name of the procedure, i.e. the tension-free vaginal tape (TVT) procedure. Since it was necessary to decrease the number of perioperative complications and adverse effects of the materials used to form a sling, a multifilament mesh and new (IVS) tunnelers were introduced.

The next step in improving the treatment of SUI was an *outside-in* transobturator procedure first introduced by Delorme in 2003 with the use of specially designed tunnelers [4]. Two years later, De Leval modified this technique by proposing an *inside-out* procedure [5].

Further searching for new therapeutic methods and materials which would decrease the number of complications resulted in designing an operating set which can be used both in retropubic and transobturator procedures. This has turned out to be the Gynecare TVT Secur system.

Objectives

To assess the efficacy and safety of the Gynecare TVT Secur™ system in treating female stress urinary incontinence surgically.

Material and methods

The study comprised consecutive patients admitted to the department, who had been diagnosed as having stress urinary incontinence based on history taken and clinical and urodynamic findings, and qualified for surgical treatment. The procedure was performed with the Gynecare TVT Secur™ system, which uses a monofilament polypropylene mesh (Prolene), the same as the one in the TVT set. The sling is 1.1 cm wide and only 8.0 cm long. The 2-centimetre tips of the sling are covered with *vicryl* (polyglactin) and PDS (polydioxanone) mesh, which is absorbed in 90 days; therefore the sling does not need any additional sutures or anchor during implantation. The tissue inflammatory reaction caused by polypropylene tape tips is minimal because connective tissue grows into the eyes of the mesh also in the tips. Polypropylene is neither absorbed nor weakened by the activity of tissue enzymes.

The sling was inserted beneath the middle part of the urethra with special tunnelers with a cutting edge at the end. The implant was placed in the *U-shape* (retropubically) or *H* (*Hammock*) position (towards the obturator foramen). The procedures were performed either under local or general anaesthesia. A 1.0-2.0 cm long incision was made 1.5-2.0 cm from the external opening of the urethra. Further preparatory procedures on the periurethral tissue were done with the tip of a scalpel, which diminished the trauma of the whole procedure. The direction in which the tissue was prepared depended on the technique applied. In the *U-shape* method, the tip of the tunneler was placed at a 45° angle to the sagittal midline towards the patient's shoulder and inserted until it touched the lower edge of the pubic bone. When the *Hammock* method was used, the tunneler was placed at a 45° angle to the midline in the

direction of the sciatic-pubic branch (the tip of the tunneler was approximately at the 9 or 3 o'clock position and was also inserted until it touched the lower edge of the pubic bone). In both the methods, initial positioning of the tunneler was facilitated by its markings. Constant physical contact of the tunneler tip with the pubic bone diminished the risk of damaging the vessels, organs or other anatomical structures. The position of the implant was adjusted by repositioning the tunnelers, and not by pulling the sling. Before the tunnelers were removed, the tape was checked to confirm that it was not tight under the mid-section of the urethra. The correct position and tension of the tape was checked by the cough test (in patients with local anaesthesia). Then the tunnelers were removed. When the *U-shape* method was used, cystoscopy was performed to make sure no harm to the urethra or urinary bladder had been done. This test was unnecessary in the case of the *Hammock* method because the risk of damaging the bladder is low then. After the procedure, a seton was left in the vagina until the next morning.

Patients were instructed to avoid intensive physical effort, hard physical work, and sexual intercourse for at least 3-4 weeks.

Results

Between October 2006 and September 2009, 77 women suffering from stress urinary incontinence underwent surgery using the Gynecare TVT Secur™ system at the Department of Gynaecology and Gynaecological Oncology of the Military Institute of the Health Services, Warsaw, Poland. The patients' mean age was 55.1 years (30-76), and their mean BMI was 28.5 (22-43.8) kg/m^2. Sixty-nine implants were applied in the *Hammock* position, 8 in the *U-shape* position. Forty-nine patients (63.6%) were menopausal, and 14 (18.2%) had had three or more natural deliveries. Thirteen (16.8%) patients had undergone gynaecological surgery before the TVT Secur procedure was performed [5 – hysterectomy with adnexectomy, 1 – adnexectomy, 4 – anterior vaginoplasty, 2 – radiotherapy for cervical carcinoma, 2 – sling procedure (in 1 it was complicated by erosion of the tape – finally the tape was removed)]. Intrinsic sphincter deficiency (ISD) signs were found in 7 patients (9.1%), and mixed urinary incontinence in 5 (8.7%). Thirty-one procedures were performed under general anaesthesia, 46 under local. The average duration of a procedure was 9 minutes (4-42). Two patients underwent simultaneous anterior vaginoplasty, 2 others conization of the cervix. Fifty-seven patients (74%) were discharged within 24 hours following the procedure (after the seton was removed and the first micturition was normal). In the postoperative period, 1 patient (1.7%) developed transient urine retention. Intraoperatively, no complications were encountered.

Discussion

The results of our study indicated that the TVT Secur™ system seems to be a safe and potentially easy to perform procedure in the treatment of SUI. It was designed to minimize the operative procedure as much as possible and to reduce the perioperative complications, i.e. thigh pain and bladder outlet obstruction, reported with use of the TVT-O [6, 7]. This was performed by tailoring the tape to only 8 cm long and changing the surgical technique, i.e. anchoring the tape edges into the internal obturator muscle, rather than passing it through the obturator foramen, therefore avoiding injury of the major vessels, nerves and bowel [8]. To ensure efficiency of the TVT Secur™ procedure we followed the surgical recommendation to place the tape close to the urethra with minimal extra tension, because the tape is less elastic than TVT-O [9].

Moreover, it did not require skin incision and the amount of synthetic material that remains in the body is smaller than in the case of the TVT-O procedure [10]. A further advantage was the possibility to insert the tape in the "hammock" shaped or the "U" shaped position regarding the urodynamic results.

The device was introduced to the internal obturator muscle – the "hammock" position, which imitates sub-mid-urethral slings provided with the TVT-O procedure, while no exit skin cuts are needed. The "U" shaped position approach appears to be a less invasive method imitating retropubic TVT with no need to pass the retropubic space and potentially effective in the ISD cases.

The advantages of this method also include the shortening of the duration of the operation. Moreover, the TVT Secur™ system may be performed under local anaesthesia in an outpatient service setting.

In conclusion, the surgical treatment of SUI using the Gynecare TVT Secur™ system is less invasive than TVT and TVT-O procedures and is associated with a minimal risk of intraoperative complications. Randomized comparative controlled trials with long-term follow-up are needed to compare TVT, TVT-O and TVT Secur™ procedures in terms of safety and effectiveness and to determine the place of TVT Secur™ among TVT approaches.

Conclusions

The surgical treatment of stress urinary incontinence using the Gynecare TVT Secur™ system is associated with a minimal risk of intraoperative complications. Owing to the short time of the procedure and the feasibility to perform it under local anaesthesia, the methods can be used on an outpatient basis. However, further studies are necessary to assess their long-term efficacy.

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