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Title:

“Surgical treatment of stress urinary incontinence in women with the use of urological tape Dallop®
NM.”

Key words:

polypropylene implants, TOT method, urogynaecology

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Abstract

Introduction. Stress urinary incontinence (SUI) in women is a common problem which worsens with age. Reliable assessment of disease epidemiology is difficult since a large group of patients does not seek medical help and hides the problem. A lot of SUI treatment methods have been described. Their efficacy and clinical application vary. Nonsurgical treatment (pharmacotherapy, physiotherapy, exercises) is applied in the initial stage and brings improvement in more moderate forms of the disease. Surgical treatment is applied in cases where nonsurgical treatment fails and in more severe examples of SUI. Among many described types of operational treatment, in the recent years the most popular became those with implantation of tension free polypropylene and polyester urological tapes keeping the urethra in the right position. Described treatment encompassed risk analysis of complications after the implantation of the tapes and their further influence on patients' lives.

Material and methods. Polypropylene urological tape Dallop® NM alongside with the system of multiple-use applicators were used in this work. The implantation was performed with the use of TOT method – via foramen obturatum of the pelvis. 20 patients with diagnosed SUI or mixed form of the disease (MUI) with a predominance of SUI were assessed.

Results. There were no intra- and postoperative complications that could have direct connection with the implanted tapes in none of the patients. All patients on the day of the discharge did not report stress urinary incontinence, the disease did not occur in the medical examination as well as during cough test. Positive effects of the treatment were observed during later check-ups after 1, 3 and 6 months after the surgery. In all patients the feeling of pain and discomfort in the postoperative wound was minor.

Conclusions. Based on clinical study from a six-month observation of 20 patients, it can be stated that urological tape Dallop® NM is an effective, convenient for doctors and patients treatment method of SUI.

Introduction

Urinary incontinence (UI), according to a report published in 2002 by the International Continence Society (ICS), is a subjective symptom involving uncontrolled leakage of urine (1). The incidence of the problem increases with age and affects approximately 10% of women aged 20 years, and it increases to about 35% in 50-year-old women (2,3). Urinary incontinence is one of the most intimate and embarrassing illness in women. According to estimates, only 20 - 25% of reported women affected by this problem seek medical help. This may be due to the fact that the patients themselves often initially deny this problem. Another barrier to start the treatment is the reluctance to communicate the problem to the environment and doctor. This disease significantly affects the quality of life, the functioning of women in society, the family, and in many cases leads to neurosis and depression. The US National Institute of Health in its report published in 2000 estimated UI to be the most costly disease of the urinary system with annual costs estimated at approx. 12.5 billion dollars.

The most frequent types of urinary incontinence are: stress urinary incontinence (SUI), urge incontinence due to overactive bladder (OAB - overactive bladder) and a mixed form in which involves the two mentioned types.

Stress urinary incontinence is involuntary loss of urine secondary to an increase in abdominal pressure, at the absence of detrusor contraction (4). Among all the forms of urinary incontinence in women, SUI is about 62%, another 12% is the mixed form.

The reasons for SUI may include events associated with damage to the pelvic structures. Past pregnancies are a significant risk factor for SUI.

Possible mechanisms related to pregnancy and childbirth are:

- damage to the ligament securing pelvic statics (births with significant tissue damage, ticks, vacuum-assisted deliveries, births of large foetuses),
- vascular damage caused by compression evoked by a foetus passing through the birth canal,
- damage to the nerves and muscles of the pelvic floor,
- direct damage to the urinary tract.

The development of the disease can be also significantly affected by congenital defects of connective tissue, hormone deficiencies, urinary tract surgeries, radiation therapy, heavy physical work, neurological disorders, smoking, obesity, urinary tract infections, and many other causes. SUI also occurs in approx. 5% of nulliparous (5).

The initial diagnosis of urinary incontinence includes history and physical examination. Some patients with symptoms of overactive bladder can be immediately diagnosed and prescribed pharmacological treatment. At failure of conservative treatment and at a planned surgery urodynamic study is recommended, whose components are: uroflowmetry (measurement of the flow rate of urine

through the urethra), cystometry (assessment of the pressure inside the bladder and abdominal pressure), urethral profilometry (measuring pressure at the urinary tract). The measurements are taken at gradual filling of the bladder at rest and at increased intra-abdominal pressure (Valsalva test).

There have many treatment methods of SUI described: conservative (drug therapy, physical therapy, exercise). A surgical procedure is considered in the event of failure of conservative treatment, in more severe cases of stress urinary incontinence and at coexisting static disorders of the pelvic organ.

Pre-treatment steps are:

- elimination of possible urinary tract infections,
- pelvic floor exercises,
- modification of lifestyle.

The exercises to strengthen the perineum muscles first described in 1948 by A. Kegel are still a recommended procedure in the initial treatment stages by many scientific societies (Polish Gynaecological Society, ICS). Their effectiveness depends on regularity, discipline and patient motivation. The exercise technique should be verified by physical examination or biofeedback.

Electrical stimulation of the pelvic floor muscles is a less popular procedure and less available. Another option in the conservative treatment is the use of various types of appropriately selected vaginal pessars correcting statics of the reproductive organs and strengthening muscles of the pelvic floor.

In many cases the improvement can be made by reducing excessive weight, giving up smoking, modifying lifestyle.

Additional help for the sick may bring specifically designed for this purpose, various types of liners, diapers and underpads with absorbent materials.

The pharmacological treatment in older women with symptoms of urogenital atrophy deals with hormone therapy (local or general oestrogen therapy). The oestrogen treatment also plays a big role in preparing patients for surgery.

Duloxetine - drug inhibiting reabsorption of norepinephrine and serotonin, despite promising preliminary research results so far has not been incorporated into clinical practice.

In the case of mixed ethology with an overactive bladder, conventional treatment with anticholinergic medicaments is used.

Surgical treatment of stress urinary incontinence includes many types of surgical treatment. The best-known treatment types are:

- suspension of the urethra by means of a tension-free tape implanted with vaginal access [e.g. Tension Free Vaginal Tape (TVT), Trans-Obturator Tape (TOT) and their later modifications to limit the scope of surgical interference such as TVT Secure];
- extraperitoneal bladder neck suspension (a Marshall-Marchetti-Krantz procedure or its modification a Burch colposuspension);
- urethral injections (usually with Teflon or collagen);
- loop operations using transplanted fascia lata slings;
- needle treatments (e.g. a Pereyra-Stamey's operation);
- implantation of an artificial sphincter (the highest degree of difficulty, this treatment is very rarely used, mainly in the treatment of urinary incontinence in men).

The TVT method first used by Ulmsten et al. in 1996 in Sweden revolutionised the surgical treatment of SUI, causing an increase in the efficacy of surgical procedures and decrease of complications. It is now widely believed that surgery should restore the damaged parts of pelvic connective tissues basing on the Integral Theory developed by Petros (6). Operations using polypropylene implants meet the objectives of this theory.

This work presents and discusses the results of clinical trials associated with the surgical treatment of urinary incontinence in women using an implant. The clinical study conducted at the Matopat Specialist Hospital in Toruń (Poland) in the period from 01.09.2010 to 01.09.2011 concerned Dallop® NM urological tapes. The implanted Dallop® NM urological tape, were produced by a Polish manufacturer of medical devices - Tricomed SA. The tape may be implanted both using a TVT (Tension Free Vaginal Tape) and a TOT (Trans obturator Tape) method. Along with the tape a set of reusable applicators was used. The aim of the study was to evaluate the efficacy and safety of the above-mentioned tape. The study also included an risk assessment of complications due to the implantation of the tapes and their subsequent effect on the quality of life in the patients.

Material and methods

Dallop® NM urological tape

The Dallop® NM urological tape by Tricomed was used for implantation. The Dallop® NM urological tapes are made of:

- monofilament polypropylene yarn with a thickness of 0.16 mm (185 dtex) – used to produce the main part of the tape;

- polypropylene yarn with a thickness of 0.3 mm (640 dtex) – used to make the handles allowing to fix the tape on a needle applicator.



Fig. 1. Dallop® NM urological tape

Both materials are made of 100% polypropylene homopolymer and are coated with preparations in an amount of not greater than 0.25%. Both yarns have a minimised elongation factor (up to 0.5% in water at $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) and corresponding tensile strength approx. 117N at requirements of 16N. Drains protecting the areas where the tape and the handles are connected, are made of medical PVC granulate and are used to protect the tape and the tape handles against separation when the tape is passed through anatomical structures (force needed to pull out the handles min. 35N). The handles are 25 - 30 cm long. Every connecting / bond place are secured with 3 cm heat shrinkable drains. The tape has a diverse pore size (alternating large and small). The average pore size is $4.1 \times 1.2 \text{ mm}$, with an average pore area of 0.38 mm^2 . The width of the tape is $1 \text{ cm} \pm 0.1$. The length of the tape with handles is 110 cm and without is 60 cm. The Dallop® NM tapes edges are delicate and do not require additional coating, because during the implantation there is no risk of tissue damage. The linear mass of the tape is 0.075 g/dm . The Dallop® NM tape is packaged in double gusseted paper-film medical packaging of BOM type suitable for EO sterilisation. The tape is adapted to both implantation methods (surgical techniques) - TOT and TVT. (7)

Applicators

For safe implantation of the Dallop® NM tapes special reusable applicators were designed (modified Emmet needles made of surgical stainless steel - of composition approved for the production of medical instruments). In this study, the modified Emmet needle was used (Fig. 2). The applicators were delivered in a non sterile form, and they were sterilised together with other instruments used for the procedure, which does not increase the costs of the operation, and eliminates disposal costs of disposable instruments.



Fig. 2. TOT needle applicator (modified Emmet needle)

20 female patients with diagnosed with stress urinary incontinence or a mixed type of this disorder with a predominantly stress component took part in the assessment. Each patient had one Dallop® NM tape implanted; the surgical procedures were performed in the period 13.09.2010 – 08.03.2011. There were three doctors involved - specialists of obstetrics and gynaecology. Each of those doctors qualifying the patients for surgery was both the operator and the person collecting the clinical data from the intra- and post-operative period.

All the tapes was implanted with trans-obturator access (TOT). This access is now preferred by most medical centres dealing with surgical treatment of stress urinary incontinence, as giving less complications, shortening the procedure time and eliminating the need for intraoperative cystoscopy - in comparison with the vaginal access (TVT).

Characteristics of the study group:

20 female patients with stress urinary incontinence, 4 of them before the surgery additionally had urinary urgency. Patients aged 35 – 74 years, (average age 52 years), BMI between 19 – 41 (average 27).

All the patients in the preoperative period and during the qualification for the surgery had their medical history collected, and an gynaecological examination with ultrasound performed. In all the patients the test result was positive. Before the surgery urine cultures were performed in order to exclude an urinary tract infection, the urodynamic test confirmed the presence of stress urinary incontinence.

Risk factors:

Two patients did not give birth vaginally, one patient gave 7 with vaginal births, the average number of births for the group - 2. One patient reported doing sports exercises, two - performing heavy physical work before the surgery. One patient with asthma. Smoking - 1. After menopause - 10 patients receiving hormone replacement therapy - 3, after unilateral oophorectomy - 3, state hysterectomy - 3. Diabetes mellitus treated with insulin - 1. Hormonal contraception - 1.

Surgical technique:

The surgeons participating in the study prefer the TOT access for the reasons described above. According to literature data the TOT procedure is less frequently followed with urinary urgency compared with the TVT procedure. Also the risk of hematoma in the surgical site is lower. After preparing the operating field a 1.5 cm longitudinal incision in the vaginal wall was performed; the vaginal wall was dissected from the urethra; tunnels were created to the sides towards the obturator foramens. Through incisions on both of the groin folds sides an Emmet needle was passed directing it then through the obturator foramens to the previously prepared tunnels (Fig. 3, 4). The handles of the Dallop® NM tape connected to the ends of the tape were passed through the hole in the needle applicator, and the ends of the tape were led „inside-out” by withdrawing the needle (Fig. 5). The tape was laid without tension under the urethra (Fig. 6), under the urethra Kelly stitches were placed, then the vaginal wall was sewn back. A vaginal compression tampon was applied for a day, after the surgery the catheter was removed from the bladder, the patients urinated on their own. In one patient also a vaginoplasty procedure the two vaginal walls was performed using an implant supporting the front wall of the vagina (Perigee), in the second patient vaginal hysterectomy was performed due to excessive uterine bleeding caused by uterine fibroids.

Eighteen operations were carried out under general anaesthesia. In two cases regional (spinal) anaesthesia was used. The type of anaesthesia was chosen by the anaesthesiologist in consultation with the patient.

The research protocol took into account the data collected after 30 minutes from the surgery, at the discharge from the hospital, and within a period of one, three and six months after the surgery.



Fig. 3. Passage of an Emmet needle towards the obturator foramen. The operator's finger inserted into the left pre-formed tunnel towards the obturator foramen, behind the pubic bone.



Fig. 4. Needle passed through the obturator foramen and the formed tunnel. Tip of the needle under the urethra.



Fig. 5. Taking out the tape on the left.



Fig. 6. The Dallop® NM tape after the implantation before the final placement under the urethra and before cutting off the ends in the groin folds.

Results

Intraoperative data.

The total time of the 18 TOT operations took 10 – 30 minutes (average 19 minutes). Two operations connected with additional procedures lasted 60 minutes; the average time for all the 20 patients: 23 min.

Convenience assessment of the tape used during the surgery (0-5), (0 – cumbersome and difficult to use, 1 – very complicated application, 2 – complicated application, 3 – high degree of difficulty, 4 – small degree of difficulty, 5 – easy to handle).

In two cases the operators rated the tape at 4, in the other cases – 5 (average 4.9).

Incidents during the operations (such as urethral perforations, breaking of the tape, twisting of the tape, pulling out of the handles): in one case the handles got broke on one side while passing the tape with a needle through the tunnel formed in the tissues. The tape was implanted.

No other intraoperative incidents were reported.

Postoperative data – after 30 minutes.

The pain strength felt by the patients after the surgery was assessed according to the visual analogue scale (VAS) with a scale from 0 – no pain to 9 – severe pain. The pain ranged 2 – 4, average of 2.3.

All the patients were administrated Ketonal intravenously at a dose of 1 amp. every 8 hours; 9 patients additionally were given Morphine 1 amp. every 6 hours, 5 were given Tramal intravenously 1 amp.

Perceptible discomfort on a scale 0-5 (0 – pain, I want to remove the tape, 1 – huge discomfort, 2 – big discomfort, 3 – moderate discomfort, 4 – slight discomfort; 5 – no discomfort) ranged from 4 – 5, average of 4.4.

Postoperative data - at discharge from the hospital.

The cough stress test result for all the patients was negative, the patients did not report any episodes of stress urinary incontinence. The pain strength according to VAS was 0 to 2, on average 0.6.

7 patients were administrated Ketonal for oral use, 5 paracetamol for oral use, 3 required no painkillers.

Hospitalisation time took 1 – 3 days (on average 1.95).

Perceptible discomfort (scale 0-5) – three patients reported mild discomfort, the rest no discomfort (on average 4.85).

Postoperative complications (such as hematoma, urinary retention, need to remove the tape, temperature above 37.5°C, infection symptoms) were not observed in any of the cases. One of the patients at discharge reported occurrence of „de novo” urinary urgency.

All patients reported to a check-up after a month from the surgery. None of them reported any incidents of stress urinary incontinence. The patient who experienced postoperative urgency, was treated conservatively with uroflow and estrogens. Since she reported no improvement but the intensification of symptoms, she was directed for urological consult (cystoscopy). Two other patients with a mixed type of incontinence, reported persistence of urinary urgency similar to those in the preoperative period, continued treatment with anticholinergics.

Gynaecological examination - in all the patients the course of post-operative wound healing was correct, there was no erosion, haematoma, need to remove the tape, etc.

Cough stress test – negative in 100% of the patients.

Perceptible VAS pain – one patient estimated at “1”, while others at “0”.

Perceptible discomfort (0-5 scale): one patient “2”, one “4”, the rest “5”, average of 4.8.

3 months after the surgery no case of stress incontinence occurred in any of the patient in the entire study group. The patient after urological consultation – where a cystoscopy examination revealed diffuse bladder leukoplakia, state after resection and coagulation of leukoplakia lesions (a condition not causally related to the implantation of the tape), reported subjective improvement and reduction of urinary urgency. In the other two patients treated with anticholinergics, in one urinary urgency entirely stopped, in the other it significantly decreased compared with the preoperative period. The time needed to return to full active pre-operative life ranged from 1 - 8 weeks, the average of 2.9 weeks. Patients assessed that their health has improved.

Gynaecological examination - in all the patients the condition was correct.

Cough stress test – negative in 100% of the patients.

Perceptible VAS pain – “0” all the patients.

Perceptible discomfort: two patient “4” – slight discomfort, the rest “5” – no discomfort, average of 4.9.

6 months after the surgery again all the patients reported for a check-up. In none there was worsening of health condition, there were no problems that could be associated with the history of the surgery, there was no stress incontinence. None of the patients agreed to a proposed urodynamic examination.

The most common justification for refusing to undergo the examination was that the treatment was completed and there was no relapse.

Gynaecological examination: in all the patients the state was correct, cough stress test was negative. The VAS pain was estimated at "0" and the discomfort at "5" - 100%.

Discussion

In the study group of 20 patients with stress urinary incontinence or with mixed type, within 6 months after the implantation of the Dallop® NM urological tape with the TOT method, there were no significant intra- and postoperative complications related to the implanted tape. The tape was evaluated by three operators involved in the study as handy, convenient to use and safe. The time to implant the Dallop® NM tape with the TOT access was short (on average approx. 20 min.). The pain and discomfort associated with the history of the surgery in the operated patients was short-lived and mild. Most patients returned to active life within 2 - 3 weeks, and within a period of 6 months all the patients assessed their health condition as better comparing to the preoperative period. The efficacy in the treatment of SUI in the study group was assessed as 100% in terms of subjective (interviews collected from patients) and objective (gynaecological examination with a cough stress test) opinion.

Conclusions

Based on the results obtained from the 6 month observation of the operated twenty female patients, the Dallop® NM urological tape can be considered as an effective, convenient for doctors and patients, and safe method of treatment of stress urinary incontinence in women.

In the study group, all the patients achieved good results of the surgical treatment and there were no complications associated with the history of the surgeries and the implanted tape.

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DESCRIPTION OF THE FIGURES:

Fig. 1. Dallop® NM urological tape

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Fig. 3. Passage of an Emmet needle towards the obturator foramen. The operator's finger inserted into the left pre-formed tunnel towards the obturator foramen, behind the pubic bone.

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