EFFICIENCY OF TREATMENT FOR FEMALE SUI (STRESS URINARY INCONTINENCE) USING THE TVT-O® (TENSION-FREE VAGINAL TAPE OBTURATOR) TECHNIQUE

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EFFICIENCY OF TREATMENT FOR FEMALE STRESS URINARY INCONTINENCE USING THE TENSION-FREE VAGINAL TAPE OBTURATOR TECHNIQUE (Abstract):

Aims: The modern Tension-Free Vaginal Tape Obturator (TVT-O®) technique is used worldwide to treat Stress Urinary Incontinence (SUI). The subject of the paper is timely and with a major practical potential. The paper presents an ample retrospective study on a series of patients hospitalized at the Second Clinic of Obstetrics-Gynecology of “Cuza-Vodă” Obstetrics and Gynecology Clinical Hospital from Iasi, for a period of 3 years. In the period January 2010–January 2012, 164 female patients were subjected to surgical procedures to treat type II SUI, inserting TVT-O® tapes.

Material and methods: Patients were selected based on anamnesis, clinical examination and positive Bonney’s test. When genital prolapse was associated with SUI, simultaneous with strip insertion, other interventions were practiced, too. Cases were followed in the immediate postoperative period, at 2 months, 6 months and 1 year, in order to analyze the efficiency of the method. 164 female patients aged between 38 and 65 were included in the study, of which 60 cases had isolated SUI and in 104 of the cases SUI was associated with genital prolapse.

Results: In 85% of the cases, the healing rate was satisfactory, and in 15% of the cases, it was partially satisfactory, keeping the percentage at 6 months and 1 year. In respect of complications at 16 female patients, SUI was improved, but persistent, in 14 cases the mictional necessity was described as absent before intervention; in these cases, we used oxybutynin, in 4 of them-tape sectioning and in 4 cases the exteriorization of the tape was relieved after 2 months, performing the secondary vaginal suture. The simple operatory technique, the reduced hospitalization period, the short convalescence and the immediate results support the TVT-O® procedure in the treatment of SUI. Postoperative complications are rare and do not compromise results. The main goal of “Sling” interventions is the creation of a reliable closure mechanism, supporting the passive urinary retention by urethral compression.

Conclusions: Our point of view with regard to the controversy of using TVT-O® tapes is that the technique does not have to be abandoned, being extremely efficient in academic centers with ultra-specialized staff.

Keywords: STRESS URINARY INCONTINENCE, TVT-O®, TAPE, MICTIONAL IMPERIOUSITY, DETRUSOR DYSSYNERGIA.
Urinary incontinence (UI) is a condition that seems to affect up to a quarter of the women over 45 years-old, causing discomfort or even a high level of severity.

Over time, UI was considered a consequence of the anatomic changes determined by births or great physical effort, being seen as a symptom of pelvic organ prolapse. UI is produced by the association of anatomic causes with a series of factors that determine disorders of the bladder and urethra. Thus, we can speak of an anatomic type of UI or a “functional” UI, and a mixed UI. In conclusion, we can distinguish SUI (stress urinary incontinence) caused by morpho-functional changes caused especially by parturition (“anatomic” UI) and “functional” UI based on the presence of involuntary contractions of the detrusor in the bladder filling phase. By definition, SUI is described as an involuntary urine loss generated by physical effort in the absence of the contraction of the detrusor muscle. It emerges during intra-abdominal pressure increase, when intra-bladder pressure increase and exceeds urethral closing pressure, having an intermittent character.

Though urinary incontinence does not endanger the patient’s life, it is a state that strongly affects physical, psychological and social wellbeing, thus affecting the quality of life.

Though using the TVT (tension-free vaginal tape) technique, the cure rates have been satisfactory, in 2001, Delorme et al. (1) proposed a trans obturator approach with the purpose of reducing significantly intraoperative complications.

Different surgical and non-surgical techniques have been adopted in the treatment of urinary incontinence for the past years, and the management principles have changed along with the introduction of new and less invasive techniques.

Starting 1913, when Howard Kelly et al. (2) described his first anterior plication stitch until today, several authors have proposed over 200 surgical approaches for the treatment of stress urinary incontinence. Although different treatment schemes have been proposed, the ones based on surgery remain the main treatment.

The Marshall Krantz procedure and the Burch urethropexy were the first surgical techniques using suprapubic approaches to elevate the paraurethral tissues to the Cooper’s ligament or the pubic periosteum (3).

Though these techniques were considered in the past the golden standard, with high cure rates during the first postoperative year in comparison to the Kelly procedure, many physicians tried to bring a surplus to these techniques in order to reduce the hospitalization period, morbidity and postoperative complications (4).

Petros and Ulmstein, through the integral theory of female urinary incontinence by means of mid-urethral support stirred an actual medical revolution, with this theory leading to the TVT technique development towards the end of 1990, and a few years later Delorme E. proposed the TOT (transobturator tape) method.

The advantage of this procedure is the fact that it excludes the need for intraoperative cystoscopy and avoids the retro pubic area, thus excluding the risk of bowel perforation or vessel lesion.

The TVT procedure resembles the TOT, with a different technique to insert the tape, but no difference has been reported regarding the cure rate. The techniques can be compared as regards the patients’ satisfaction a year after surgery. Several studies reveal the fact that the TOT can reduce significant postoperative complications (5).
MATERIAL AND METHODS

The collection, processing and interpretation of the information necessary for the study led to knowledge on the particularities of the stress urinary incontinence cases hospitalized in the 2nd Clinic of Obstetrics and Gynecology of “Cuza-Vodă” Obstetrics and Gynecology Clinical Hospital from Iasi, between January 2010 and January 2013, by using the data recorded in the observation charts and the computerized system. This study is a retrospective analysis on all cases of operated stress urinary incontinence type II, in which TVT-O® tapes were inserted.

Between 2010 and 2013, 164 cases of SUI were diagnosed and investigated, and patients were selected based on their anamnesis, clinical examination and positive Bonney test (6).

Stress urinary incontinence was classified depending on the degree of stress causing it, namely: 1st degree – incontinence emerges only under high stress, 2nd degree – incontinence emerges under moderate stress, such as walking down and up the stairs, 3rd degree – incontinence emerges under low stress such as orthostatic, the patient being continent in clinostatism. The Bonney test is performed by the exploring physician with the middle finger and forefinger placed on either side of the urethra, ascending the urethra-bladder junction without compressing it. This test enables the differentiation between stress urinary incontinence and the detrusor dissinergy and it is positive when urine loss disappears during the test performance.

The data collected as a study material and considered refer to: the total number of cases of urinary incontinence type II investigated, diagnosed and operated, the annual distribution of the disease cases, the repartition of cases according to age groups, personal physiologic history (menstrual status, parity) and pathological history, the duration of the surgical intervention, the duration of hospitalization, the postoperative antibiotic treatment, postoperative complications.

The insertion of the TVT-O® (tension free vaginal tape obturator) tape was a sole operation or associated with other interventions for the correction of the associated genital prolapse. The efficiency of this technique was evaluated immediately after surgery, after 2 month, 6 months, and 12 months.

The study included operated patients with SUI type II who underwent the insertion of TVT-O® tape and who came for postoperative check-up after 2, 6, and 12 months, and excluded patients who did not come back for postoperative check-ups (31.7% of the total).

RESULTS

Following the processing and evaluation of the 164 cases of stress urinary incontinence operated, recorded in the 2nd Clinic of Obstetrics and Gynecology of “Cuza-Vodă” Obstetrics and Gynecology Clinical Hospital from Iasi, between 2010 and 2013, we should mention that from the point of view of the temporal variable, a maximum number of cases was in 2012, with 66 cases recorded (40.24% of the total), and the fewest were recorded in 2010.

Our study revealed that the average age of the patients diagnosed with SUI type II is 53 years, and the patients included in the study were between 38 and 65 years old.

Most hospitalizations (78.3% of the total) were persons over 50 years-old, which is associated with the “enrichment” of the morbid status with age.

The estrogens deficit generates a decrease in the capacity of proximal closure of the urethra, microbial colonization manifest-
ed clinically by dysuria, polakiuria, and urethral atrophy leads to the shortening of the urethra, the disappearance of the bladder-urethral angle and the emergence of an ectropion of the urethra mucous membrane, eventually favoring stress urinary incontinence. From the point of view of the menstrual status, 59.75% of the total women included in the study were menopausal and 40.24% of the total had genital activity.

During labor, direct lesions are generated to the soft pelvic tissues and partial denervation of the pelvic floor. The dilacerations of the connections between vagina, urethra and bladder produced by excessive distension, together with the production of cortisol and progesterone during pregnancy lead to the laxity of the fascial supporting structures and therefore cause the decrease in intraurethral pressure and an increase in the mobility of the urethra. Our study did not include any nulliparous patients, 46 women (28.05%) of the cases were primarai and 118 women (71.95%) were multipartae. Obesity and the high body mass index represent a risk factor for SUI, and patients can improve incontinence by losing weight. A comparison was made between the TOT efficiency and safety from the weight point of view (weight excess and normal weight). Patients were divided depending on their body mass index into 3 batches: batch X with normal weight (BMI<25 kg/m²), batch Y with overweight (BMI 25-30 kg/m²) and batch Z with obesity (BMI>30 kg/m²). The study revealed a BMI between 19 and 48 kg/m², with an average of 28.5 kg/m². Of the 164 patients, batch X with BMI<25 kg/m² represents 26.8% of the total (44 patients), batch Y with BMI 25-30 kg/m² includes 79 patients (48.2% of the total), and batch Z includes women with BMI>30 kg/m², namely 41 patients (25%) (tab. I, fig.1).

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<td>Distribution in batches depending on the BMI</td>
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<tr>
<th>Batch</th>
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<tr>
<td>BMI (kg/m²)</td>
<td>&lt;25</td>
<td>25-30</td>
<td>&gt;30</td>
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<td>No. of patients</td>
<td>44</td>
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**Fig. 1.** Distribution of cases in the three batches: X, Y and Z
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From the point of view of the associated conditions, 48 patients (29.3% of the total number of patients included in the study) had associated pathology: 5 patients had angina pectoris, 12 suffered from high blood pressure, 22 had chronic venous insufficiency, 15 had dyslipidemia, 3 had hypothyroid and 2 had left renal lithiasis (fig. 2).

We found isolated SUI in 60 cases, genital prolapsed associated with UI in 63.41%. Of the 104 patients, rectocele was associated in 89 (85.58%), cystocele 11 (10.58%), and both cystocele and rectocele in 4 patients (3.84%) (fig. 3).

The duration of surgery varied between 20 minutes and 1 hour and 20 minutes, with an average of 35 minutes.

The insertion of the TVT-O® tape was a sole operation in 37.8% of the cases, namely in 62 patients, and in 62.2%, namely 102 patients, anterior colpoperineorrhaphy was associated with posterior colpoperineorrhaphy, myorrhaphy anal levators and right labial cystectomy (3 cases).

From the anesthetic point of view, general anesthesia was performed with orotracheal intubation in 25 (15.24%) patients’ general anesthesia using the larynx mask in 17 (10.37%) and rachianesthesia in 64 (74.4%) patients.

The average hospitalization time was 3.75 days, between 2 and 7 days.
In our study, the cure rate was 85% satisfactory and 15% partially satisfactory, after 2 months as well as after 6 months and 12 months.

52 (31.7%) of the 164 patients did not come for postoperative check-ups, therefore only 112 patients – 68.3% - were monitored immediately, after 2 months, 6 months and 12 months. As regards complications, 16 (14.28%) had improved but persistent SUI, 14 (12.5%) experienced previously inexistent imperious need to urinate (prosthesis positioned too tightly), which were treated with Oxybutynin or by sectioning the prosthesis in 4 cases, and in other 4 cases of prosthesis exteriorization in the check-up after 2 months after surgery, for which a secondary vaginal suture was performed.

The bladder voiding dysfunction after surgery for incontinence is a possible complication of all procedures treating SUI. The voiding dysfunction term indicates the term of obstructive uropathie until the full urinary retention and includes irritative symptoms such as hyperactivity of the detrusor or imperious need to urinate de novo.

The impossibility of storing urine is determined mainly by the hyperactivity of the detrusor muscle. There are basic theories of this hyper reactivity that include hypersensitivity acquired through the parasympathetic denervation produced by the obstruction of the urinary bladder, denervation produced by surgical dissection regardless of the voiding obstruction. The voiding impossibility is given mainly by the obstructive voiding of the urinary bladder determined by the increased pressure generated by urethral compression. The sutures placed too medially and therefore too close to the urethra can lead to urethral deviation or periurethral scars.

Among postoperative complications, there were three cases of allergic reaction to Ciprinol, in which the antibiotic was replaced with Gentamicin based on prior testing, and 1 case of urine loss upon suppression of the urinary probe, which was corrected with Oxybutynin (Driptane) the second postoperative day.

**DISCUSSION**

In order to establish the individual statistical risk for every woman of developing SUI, a rigorous evaluation of all health problems that she can have (or has) is necessary. Other factors, such as obesity, parity, hormonal status, can be risk factors for SUI.

A large number of long-term studies are necessary to establish the efficacy of the transobturator tape in comparison to the TVT technique. Trying to define the cure rates of this surgical procedure, Novara et al. say in a systematic analysis of literature that patients treated by the TOT technique had slightly lower rates of complications than the ones treated by the TVT method, with a significantly low risk of vagina perforations.

Our study revealed that the TVT-O® technique was as safe and efficient in treating SUI, regardless of the body mass index. After surgery, life quality improved the same way for each patient, regardless of the batch to which she belonged, depending on weight. There were no significant differences as regards complications. Our study revealed a BMI between 19 and 48 kg/m², with an average of 28.5 kg/m². The 164 patients were divided into 3 batches, X, Y and Z, respectively, with normal weight, overweight and obese, with the highest percentage in batch Y, with a BMI
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between 25 and 30 kg/m², representing overweight.

Most hospitalizations were of persons over 50, which is associated with the “enrichment” of the morbid status that comes with age. Our study revealed that the average age of patients diagnosed with SUI type II is 53 years-old.

56.76% of the 164 women included in the study were menopausal and 40.24% cases had genital activity.

Adding the TVT-O® intervention during the anterior prolapse correction seems to convey higher durability to the correction resulting in the long run in a lower rate of the urinary symptoms and a better life quality in comparison to isolated anterior colporraphy. Isolated SUI was found in 60 cases, genital prolapsed associated to SUI in 63.41% of the total number of patients.

Moreover, in subsequent postoperative consultations, no patient had increased body mass index and no patient was susceptible of recurrent SUI, which contradicted the literature results of studies on incontinence surgery in obese patients (7).

In comparison to the literature data, patients were monitored for 29 months and the cure rate was 78.8%, in what concerns our study, the cure rate is slightly higher—85%—but the monitoring period in our study was 12 months.

The absence of intraoperative complications is in accordance with the literature data. As for postoperative complications, specialized literature reports 11.2%, and in our study postoperative complications were 25% (8).

Abdel-Fattah et al. (9) did a secondary analysis, in a randomized study on women who had any type of surgical intervention for SUI and showed that TOT had a good success rate (he referred to a success rate and a cure rate of 69.6 and 76.5% respectively, but there were no significant differences in the cure rates for the insertion of the tape through the obturator hole from the outside to inside and from the inside to outside).

Based on their report regarding the data available in the two randomized clinical studies, Novara et al. (10) could not demonstrate any significant difference between TVT-O and TOT.

In a randomized multi-centric study done in 2007, Porena et al. (11): 148 women, of which 73 underwent TVT and 75 underwent TOT, concluding that both surgical approaches were as safe, without significant ongoing differences of the intra- and postoperative complications during the 2-year monitoring period.

Another element to be discussed is the urodynamic tests. As regards our study, preoperative urodynamic exploration was not performed, which is a disadvantage, because this exploration could help in selecting cases more efficiently and in increasing the patients’ satisfaction degree.

CONCLUSIONS

Our study data demonstrate that the TVT-O® procedure is safe and effective and that the body mass index did not influence the result during 12 month (in which the patients included in the study were monitored) and does not have contraindications for continent surgery.

The treatment for SUI has undergone revolutionary improvement for the past 15 years. The transobturator techniques either from the inside to outside or from the outside to inside have been proposed this past decade precisely to minimize complications.

As regards the cure rate, both proce-
dures –TOT and TVT-O®– improved women’s quality of life and have almost equal cure rates.

The TVT-O® surgical technique is a minimally invasive procedure characterized by simplicity, reduced hospitalization, short convalescence period, and immediate results. Intraoperative complications are absent and postoperative complications are few and solving them does not compromise the continence results.

The main purpose of the “Sling” intervention is to create a certain closing mechanism helping in the passive retention of urine by compressing the urethra.

Important randomized clinical studies with a longer monitoring period related to the said techniques are necessary to establish exactly the efficacy and safety of the said minimally invasive technique.

REFERENCES