

Impact of Hysterectomy on Urethral Suspension with Transobturator Sling for Treatment of Stress Urinary Incontinence in Women

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ABSTRACT: Urinary stress incontinence is a condition that increases with age, influenced by many factors, mainly anatomical pathological ones, determined by changes of muscular pelvic floor, but also by hormonal and local neurological modifications. The aim of the study was an overview of the efficacy of stress urinary incontinence therapy with transobturator urethral sling suspension in patients with or without prior hysterectomy. Additionally, we evaluated the effectiveness and the rate of side effects of this method. The study group consisted of 100 patients and, within it, 32 patients (group A) underwent a hysterectomy. We noticed an improvement of symptoms, a reduced discomfort and an increase of quality of life, more prominent in group B (patients without previous hysterectomy) ($p=0,0012$, $p=0,17$ respectively, $p=0,03$). We consider that transobturator approach in treating stress urinary incontinence is a simple, rapid and effective procedure and, not lastly, modern technique that assures a significant improvement of symptoms and quality of life for the patients; positioning the sling along to the insufficient pubourethral ligaments reinforces the structures supporting the urethra; this approach is minimally-invasive with rapid recovery, reduced hospitalization, is cost effective and involves minimal risks of infection, bleeding, etc. moreover, the transobturator tension free sling has some advantages (no pain or tension). The rate of success of the treatment is significantly lower in patients with prior hysterectomy.

KEYWORDS: Stress urinary incontinence, hysterectomy, transobturator sling

Introduction

Stress (effort) urinary incontinence is characterized by urine leakage associated with activities that increase abdominal pressure (laughing, sneezing, coughing, weight lifting etc.). The prevalence of the condition is proportional with the age and it correlates with micturition and defecation disfunctions, obstetrical pathology, natural births, obesity and bariatric surgery etc. [1,2]. The severity of the urine leakage can vary from a few drops up to loss of important quantities that mostly have a critical impact on the patient's life quality [2].

Urinary incontinence is caused by many factors, mainly anatomical pathological ones, determined by changes of muscular pelvic floor but also by hormonal and local neurological modifications [1,3]. The treatment consists in lifting the middle of the urethra towards the pubic bone. Over the years, there were suggested

plenty of therapeutic options for urinary incontinence but only two have stood the test of time: abdominal colpo-suspension (Burch) and transobturator or pubovaginal ureteral suspension with homo-or heterotopic grafts [4,5]. During the last years, techniques using polypropylene sling with pubovaginal (tension-free vaginal tape, TVT) or transobturator approach (transobturator tape, TOT) were systemized.

Randomized studies were done in order to evaluate the efficacy of different therapies. There are, in some countries, recommendation regarding the indications and also the surgical techniques [1,6]. Our study focuses on a less common evaluated aspect such as to determine the influence of previous hysterectomy on the success of the treatment performing a transobturatory ureter suspension with intravaginal sling for effort urinary incontinence in women. In this field, a Chinese group

presented a study about outcomes of polypropylene mesh and sling exposure after reconstructive pelvic surgery [7]. From the very beginning, we must differentiate the effort urinary incontinence (stress urinary incontinence) from the mictional urgency (urge incontinence) that is also involuntary urine loss associated with a feeling of urgency that can no longer be inhibited. Our study evaluates the effort urinary incontinence being used very strict inclusion criteria.

Patients and methods

The primary objective of this prospective study was to appreciate, by comparison, the role of previous hysterectomy in the treatment of effort urinary incontinence with transobturator suspension of the urethra with intravaginal sling. Moreover, we evaluated the effectiveness and the rate of side effects of this method.

The study group consisted of 100 women over 18 years, with or without prior hysterectomy, with effort urinary incontinence evidenced with cough test and also excluding other pelvic pathology. The patients agreed this management of the disease by signing the informed consent. The study was conducted, during a period of 40 months, in accordance with the World Medical Association Declaration of Helsinki (1975) and approved by the Institutional Ethics Committee of the Medical Center Dr. Ianoși (No. 218/11.04.2015).

We excluded the following patients:

- patients who underwent other intervention for correction of the pelvic static defects;
- immunosuppressed patients or the one with immunosuppressant drugs, also patients suffering from urinary, pulmonary and digestive conditions that could interfere with graft integration (chronic cough, constipation, dysuria, etc.);
- gynecological diseases that required concomitant or shortly after a corrective intervention;
- patients with local neurologic abnormalities associated with cognitive impairment or undergoing chronic treatment with sedatives;
- major blood dyscrasias with high risk of bleeding;
- cachectic patients or women that had a critical weight loss during the last year before surgery;
- patients treated with drugs used to stimulate diuresis, decrease urethral tonus (alfa-blockers), urine retention with overload incontinence

(antipsychotics, antihistamines, opiodes, antiparkinson drugs);

- pregnancy;
- lack of compliance or refuse to enter the study.

Obesity was not an exclusion criterion, even though they suffered from morbid obesity.

Patients underwent transobturator urethral suspension with polypropylene intravaginal mesh. From 100 patients, 44 had urinary incontinence without any other pelvic static defects and 56 had associated grade 1 cystocele. 32 patients had a previous hysterectomy (group A) and the rest of 68 (group B) were the control group.

Preoperative evaluation of the patients included a clinical examination and some laboratory investigations (complete blood count, blood clotting tests, glucose, urea, creatinine, liver functions test, urinalysis, uroculture). We also performed ultrasound pre and postmictional to evaluate post mictional residue. The anamnesis was useful to determine the type of urinary incontinence (stress, urgency) according to the symptoms, risk factors and life style. General examination revealed if there were conditions (digestive, cardio-respiratory, etc.) that met the exclusion criteria. The physical examination started with a urinary and gynecological consult with a full bladder to check for static pelvic defects. We tested perineal sensitivity to identify eventual neurological abnormalities and we performed cough test in order to objectify the stress urinary incontinence.

For an accurate evaluation of the treatment efficacy, each patient received a questionnaire used to estimate the severity of the symptoms, the discomfort produced by the incontinence and the impact on the quality of life. We compared the questionnaires with the data collected during the other visits. There are different types of questionnaires described in literature. We used CONTILIFE [1] type that is frequent and valid on a large scale, is easy to complete and includes all the urinary incontinence categories.

The questionnaire evaluates the quality of life according to urinary incontinence by following 3 aspects:

- evaluation of the symptoms due to urinary incontinence
- appreciation of the discomfort cause by this condition
- determination of satisfaction rate of the patients.

Every patient has to evaluate these three elements on a scale from 1 to 10 where 1 is the worst state and 10 maximum satisfaction.

The surgical technique consists of three small incisions, first vaginally immediately under the ureter meatus and the other two paravaginal, this approach allowing, by using a special forceps, to fixate transoburator the sling. Our approach was “out-in”, towards the vagina, blindly crossing the obturator fosa even though up to one point it was digitally guided.

We performed surgery under spinal anesthesia.

The operation lasted 26 minutes on average (15-40min), with the average hospitalization period of 3.2 days (1-7 days). The postoperative evaluation was done after 7, 30 and 60 days. Immediately preoperative and with each postop visit the patients filled out the CONTILIFE form.

Results

91 out of 100 patients came to all 3 postop follow up visits, the statistics being made only on these patients (30 from group A and 61 from group B). Demographic data showed no significant differences between the two study groups. Therefore, the mean age at intervention date was 59,29 in group A, respectively 59,97 years in group B, and the average period of incontinence (from the clinically evident onset up to the intervention date) was, also, similar (48,7 months in group A and 47,9 months in group B).

Among the risk factors mentioned in literature, we noticed previous multiple pregnancies, natural births, obesity and excessive physical effort, with a higher frequency (Table 1), still without a statistically important difference between the two study groups.

Table 1. Risk factors in study groups

Risk factors	Group A	Group B
Age over 60 years	16	32
Over 3 pregnancies	26	54
Over 3 natural births	24	52
Obstetrical traumas	12	25
Obesity	18	36
Intense physical activity	21	39
Constipation	12	24
Chronic bronchitis	4	8
Diabetes	3	7
TOTAL	30 patients	61 patients

There was no mortality rate in our study while the morbidity was extremely reduced.

Moreover, just 3 patients from group A (10%) and 7 patients from group B (11,47%) had urinary tract infection (p=NS), complication associated with urinary catheter and resolved with antibiotherapy. 3 patients from group A (10%) and 6 patients from group B (9,84%) experienced postoperative prolonged pelvic pain (p=NS) but symptoms was slight and was ameliorated with pain killers. Postoperative, none of the patients received non-steroids anti-inflammatory drugs. Also, one patient from group A presented dysuria and we re-implanted the urinary catheter and kept it for 72 hours.

Usually, the postoperative hemorrhage is small and subsides spontaneously. In our group we had no lesions of the urinary bladder or of the urethra, important hemorrhages with development of huge hematomas, suppuration, etc.

Patients assessed from 1 to 10 (1 is the worst situation while 10 is the best, meaning the lack of the disease), each of the parameters of the CONTILIFE questionnaire at every visit (preop and at 7, 30 and 60 days after the intervention). All the data were introduced in Excel and we used the descriptive statistical method. It was calculated variant analysis of the 2 groups and the parameters of interest (One way Anova) in order to compare their statistical averages.

The evaluation of satisfaction of the women index is showed in Fig.1.

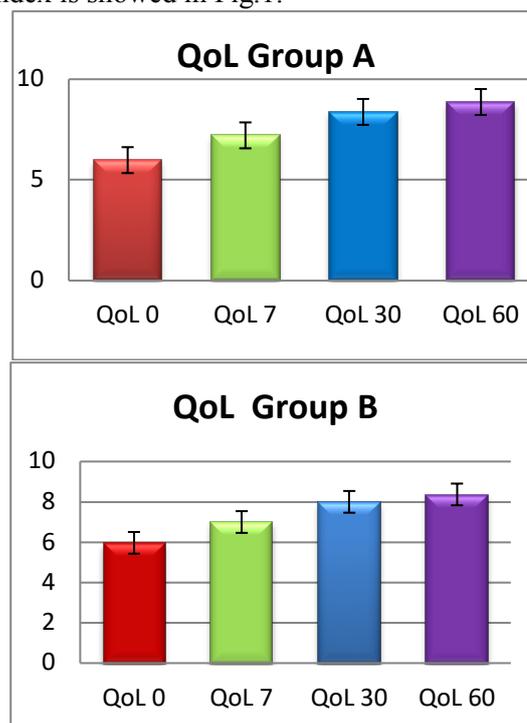


Fig.1. The evolution of the satisfaction index from 0 to 60 days

It was observed an increased grade given by the patients for their well being, for both groups A and B, but the satisfaction index ascends faster and higher in group B, in patients without a previous hysterectomy. The result is $p=0.03$ for both groups at 60 days, statistically important, so it represents a mathematical proof of the clinical notes that show a more pronounced improvement of the life's quality in women with uterus in comparison with the ones that suffered a hysterectomy.

Symptom quantification showed a critical statistically improvement from (mean: 8.69; stdev=0.9) at 30 days to (mean: 9.09; stdev=0.87) after 60 days postoperative for group A and for group B (mean=8.16; stdev=0.833) at 30days and (mean=8.43; stdev=0.77) at 60 days postoperative as we presented in Fig.2. The obtained value ($p=0.0012$) is statistically significant comparing group B to A.

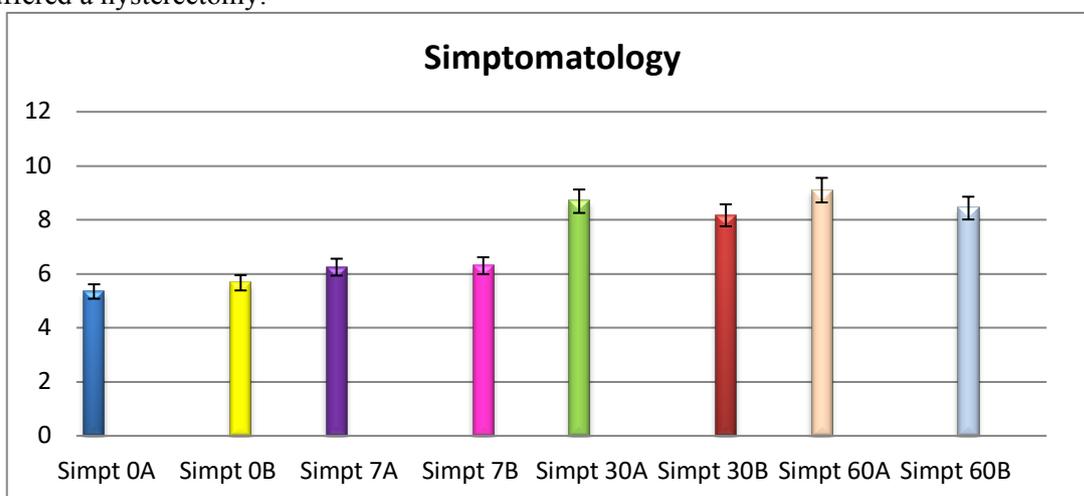


Fig.2. Evolution of the symptoms from 0 to 60 days

We also noticed a slight improvement of the life quality at 7 days postop but we considered it as placebo effect due to lack of total fixation of the polypropylene tape.

Furthermore, the discomfort due to urinary incontinence, evaluated by the patients, decreased from (mean=5,86; stdev=0.95) at first visit, to (mean=6.93; stdev=1.18) at 7 days, (mean=8.24; stdev=1.07) at 30 days, respectively (mean=8.85; stdev=1.04) at 60 days postop for group A and from (mean=6.00; stdev=1.26) at the first consult to (mean=6.96;

stdev=1.32) at 7 days, (mean=7,86; stdev=1.19) at 30 days, respectively (mean=8.46; stdev=0.97) at 60 days postop for group B as showed in Fig.3.

We considered this symptom, discomfort, as a result of the above mentioned parameters, this being also decreased at 30 days (mean=8.12; stdev=1.12) and respectively after 60 days postop (mean=8.72; stdev=1.03) for the entire study group, its value being also statistically relevant ($p=0.17$).

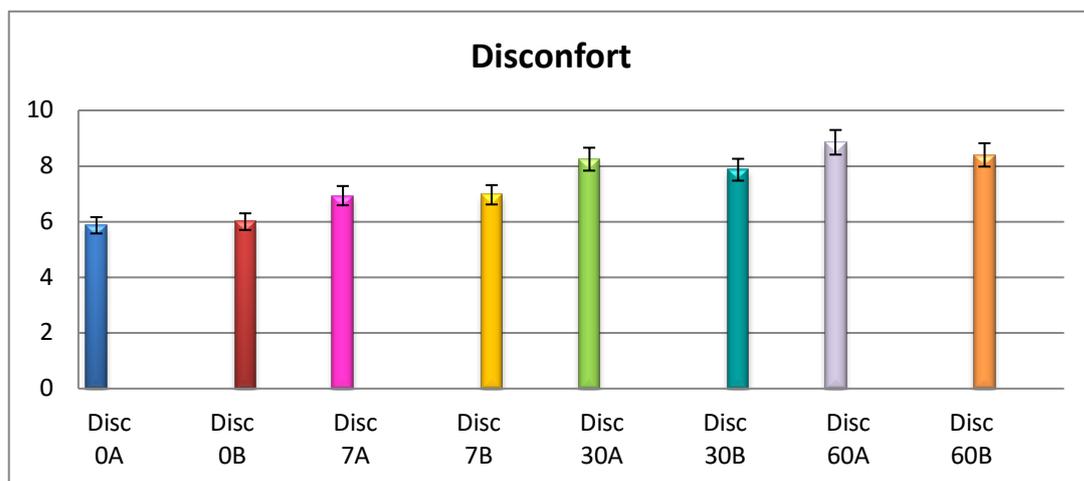


Fig.3. Evolution of discomfort during evaluation

Discussions

The prevalence of the disease is high, being estimated between 10-53%, depending on demographic aspects but also on the inclusion/exclusion criteria used by the authors [3,8,9].

We must consider that for many patients, this topic is taboo and it translates into embarrassment and a delay of the diagnosis.

The risk factors, as described in literature, are: advanced age, previous natural births (more than three), gynecological and obstetrical traumas (usage of forceps, even episiotomy, as showed by studies), previous hysterectomy, obesity and intense physical activities [3,10].

In our study, obesity and morbid obesity was not an exclusion criterion. Furthermore, we performed ureter suspension in a patient with BMI=61,7 with good outcome.

The voiding diary, with variable timetable, from 1 day to 1-2 weeks, are used to evaluate uncontrolled or controlled loss of urine, its frequency and represents an objective tool of diagnosis. There are several variants described in literature [11].

We used one-week voiding diary immediately preoperative, considering the time period diagnostically relevant. Moreover, we asked the women to keep a similar voiding diary for the follow up visits at 30 and 60 days postoperative in order to have a better evaluation of the treatment efficacy. Still, the results were estimative due to decrease compliance of the patients proportionally with the extend of the time.

It is known the concept of suburethral and subcervical support in the urinary incontinence's therapy. It represented the foundation of the first surgical techniques, among the most representative being the Burch maneuver. At the beginning of the 90's, due to the development of prosthetic materials, was introduced a new concept, "mid-urethral support". Based on it, it was performed for the first time retropubic ureter suspension (tension-free vaginal tape, TVT) and nowadays TVT and other derivated techniques represent the gold standard in treatment of effort urinary incontinence in women [12,13].

The transobturator approach in treatment of effort urinary incontinence was first described by Nickel in Netherlands in 1998 but it was first used in France, by Delorme in 2001 [11].

During this short period there was over 1 million intervention around the world [13].

Unlike the retopic approach, the transobturator ureter suspension is more rapid and safer (some studies show that it is more effective) [14].

The intervention has a reduced risk of vascular lesions with important bleeding or lesion of the urinary bladder or intestinal. More, it does not require abdominal incisions and it allows a better anatomical fixation of the sling compared with the retropubic approach [15].

All the above mentioned represents strong arguments in usage of the transobturator approach in treatment of the effort urinary incontinence.

Studies regarding the anatomy of the ureteral and urinary bladder junction revealed the pubo-urethral ligament and adjacent connective tissue in supporting the urethra and the bladder neck [16].

This ligament is functionally tied to the muscular pelvic floor. Its tension allows a normal interaction between the muscular structures of the pelvic floor and vagina. Therefore, the contraction of the pubococcygeus muscle (anteriorly disposed) or levator anal muscle (posterior) ensures closure of the urethra or the bladder neck. (hammock theory). According to this theory, the treatment of the effort urinary incontinence does not need lifting of the urethra or the bladder neck (like older surgical techniques) just an adequate support of those [17].

So, only the reinforcement of the insufficient pubo-urethral ligament will allow the proper local functionality with an improvement of the urinary incontinence [12].

The structure of the pelvic floor and the vectors that act on it are modified by hysterectomy. These anatomical changes add to limitation of the surgical treatment of the incontinence, fact also noticed in our study, but there are hormonal factors that play a role [17].

Several materials (natural or synthetic), different fixation points and adjustment methods were suggested for the bandelet [11,13].

The approach can be done under general anesthesia, rachianesthesia and local anesthesia. Transobturator bandelet is fixed and kept in position due to the contact between the graft and the tissue tunneller formed by passage of the needle. The natural cicatrization determines the fixation of the tape and prevent its migration. It represents a "tension-free" approach, the bandelet not anchored in position and it is a minimally-invasive therapeutic method with speed recovery and rapid return to work.

An intense debated problem is the risk of obturator nerve injury while passing through obturator foramen. Performed as originally described, the needle passes the medial margin of the foramen obturatoris and the risk of injury is null due to its passage laterally and superior to the obturator vessels towards the ischiopubic ramus. More, to prevent a lesion of the urinary bladder or the urethra, the needle is guided by the contralateral index finger into the vaginal incision. The intravaginal tape, fixated this way, will form a hammock for the urethra, following the natural disposition of the pubo-urethral ligament. In our group there was no such complication.

There is a series of tests called urodynamic tests that are useful to etiologically differentiate urinary incontinence from some neurological or mictional (dysuria) dysfunctions.

These are: cystomanometry, cystography, sphincter electromyography, uroflowmetry and determination of the urethral stress profile. Nowadays, there is no unanimous agreement regarding the mandatory usage of these tests: some authors consider that there are mandatory in patients with urge incontinence or with previous intervention at this anatomical level [3,18,19], while others do not consider them mandatory. In a randomised prospective study on 110 patients with stress urinary incontinence [20], urethral hypermobility accounted for 42% of the cases while intrinsic sphincter deficiency was responsible for 58% of the cases. In our study group, usually we did not perform urodynamic tests but we insisted on thorough selection of the women that underwent the intervention. Based on that, our results, despite of the not very numerous study group, represents a solid argument.

As mentioned in the introduction, the prevalence of this condition is up to 50% of the female population and it has a intense negative effect on quality of life. In our study we identified several risk factors (Table 1). Among these, the most frequently associated to stress urinary incontinence are: age over 60, previous multiple pregnancies, natural births, obesity and excessive physical effort. Adding, there are other conditions that worsen the disease like: recurrent lower urinary tract infections, atrophic vaginitis, constipation, different causes of polyuria (diabetes insipidus, diuretics intake, diabetes mellitus, etc.) or chronic cough (chronic bronchitis, bronchial asthma, etc.), different neurological and cognitive conditions. These data are according with literature observations.

Moreover, a French group [21] published a study on a large number of cases that showed as worsening factors, along the above mentioned, recurrent urinary infections, atrophic vaginitis, edema due to cardiac insufficiency or chronic venous insufficiency and any factor that reduced the patient's mobility. The neuronal lesions resulted from hysterectomy or radical surgery of the rectum can determine dysfunctions of the urinary bladder or urethral sphincter [3,22] that can become irreversible. The treatment of stress urinary incontinence with transobturator sling can be efficient when urinary bladder compliance is good but the internal sphincter is altered [18].

Most of the studies showed a 90% efficacy of this method and a reduce with 12% of the novo urge incontinence [11,23].

The good outcomes had a positive impact on the patient's life quality. Still, in mixed incontinence or an intrinsic sphincter deficiency the successful results dropped to 60% efficiency at 4 years and 30% at 8 years postoperative [11].

Conclusions

The transobturator approach in treating urinary (stress) incontinence is a simple, rapid and effective procedure and, not lastly, modern technique that assures a significant improvement of symptoms, of quality of life to the patients; positioning the sling along the insufficient pubourethral ligaments reinforces the structures supporting the urethra/the normal anatomy of the region; this approach is minimally-invasive with rapid recovery, reduced hospitalization, is cost effective and minimize risks of infection, bleeding, etc. Moreover, the transobturator tension free sling has some advantages (no pain or tension at the graft).

The efficacy of the treatment, as showed in our study, is significantly lower in patients with prior hysterectomy.

Least but not last, the intervention is simple to perform and to be studied so it can be done by the surgeon, gynecologist or urologist even without continue hospitalization.

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