Assessment of Clinical Effectiveness and Economic Viability of the Obturator Tension Free Vaginal Tape Method for the Treatment of Stress Urinary Incontinence by Cost Benefit Analysis

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ABSTRACT

Stress urinary incontinence (SUI) is an important public health problem that significantly reduces quality of life. Today, there is a growing trend to change the current approach of surgical treatment of SUI in woman by using simple, effective and safe techniques that tend to significantly shorten the duration of hospitalization and reduce treatment cost with faster establishment of working capacity. According to that, the application of economic principles in healthcare has the task of comparison between the therapeutic methods that account their costs, benefit and health consequences. The aim of this study was to evaluate the clinical efficacy and economic viability of obturator tension free vaginal tape (TVT-O) method for treating SUI by using the cost - benefit analysis. The study was a retrospective-prospective study, which included 60 patients who were surgically treated after having a diagnosis of SUI in the period from January 2007 to August 2010 in the Regional Hospital in Bihać. The results identify TVT-O as a method of choice in the treatment of SUI, where the benefit of TVT-O method is up to 4.2 times higher in comparison to the vaginoplasty. Analyzing the clinical efficacy showed a shorter operative time, a shorter length of hospital stay and less complications by using TVT-O method. The outcome results showed that 83% of patients were considered to be cured and 17% had improved health status after TVT-O surgery. According to the parameters of quality of life, patients treated with TVT-O procedure showed a significantly faster return to their social activities and vitalities.

Key words: *Obturator tension free vaginal tape, stress urinary incontinence, cost-benefit analysis*

Obturator Tension-Free Vajinal Teyp Yönteminin Stres Üriner İnkontinens Tedavisinde Fayda-Maliyet Analizi İle Klinik Etki Ve Ekonomik Yaşayabilirliğinin

ÖZET

Stres üriner inkontinansı (SUI) yaşam kalitesini belirgin şekilde düşüren önemli bir halk sağlığı sorunudur.Günümüzde, kadın SUI cerrahi tedavisinde, hastanede yatış süresini kısaltan, çalışma kapasitesini daha hızlı kurarak tedavi maliyetleriniazaltan, basit, etkili ve güvenli teknikleri kullanılarak , güncel yaklaşımları değiştirmek için artan bir eğilim vardır.Sağlıkta ekonomik ilkeler uygulanmasının, tedavi yöntemlerinin, maliyet, yarar ve sonuç açısından karşılaştırma görevi vardır.Bu çalışmamanın amacı, SUI tedavisinde obturator tension-free vajinal teyp metodunun, klinik etkinliği ve ekonomik yaşayabilirliği, maliyet-fayda analizi kullanılarak değerlendirmektedir. Retrospektif-prospektif bu çalışma, Bihać Bölge Hastanesi'nde Ocak 2007-Ağustos 2010 döneminde SUI tanısı aldıktan sonra cerrahi olarak tedavi edilen 60 hastayı kapsadı. Sonuçlar SUI tedavisinde, TVT-O yönteminin tercih edildiğini, TVT_O'nun faydasının vajinoplasti ile karşılaştırıldığında 4.2 kat daha yüksek olduğunu tanımlamaktadır. Klinik etkinlik analizi TVT-O yöntemiyle, daha kısa ameliyat süresi,hastanede daha az kalış süresi ve daha az komplikasyon olduğunu gösterdi. TVT-O ameliyattan sonra hastaların % 83'inin tedavi olmuş kabul ettiğini ve % 17'sinin sağlık durumu düzeldiğini gösterdi. Yaşam kalitesi parametrelerine göre, TVT-O prosedürü ile tedavi edilen hastalar, sosyal etkinlikler ve çanlılıklarına belirgin ölçüde daha hızlı dönüş gösterdi.

Anahtar kelimeler: *Obturator tension-free vajinal teyp, stres üriner inkontinans, fayda-maliyet analizi*

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INTRODUCTION

Stress urinary incontinence (SUI) represents involuntarily leak of urine in the circumstances where the pressure in the urinary bladder exceeds that of the urethra, when the activation of the detrusor fails and it represents an important public health problem since it significantly reduces the quality of life. It is known that about 30% of women in older ages have the diagnoses of SUI, which occurs due to congenital or acquired defects of pelvic organs with loss of anatomic support (1). Today, there is a growing trend to change the current approach of surgical treatment of SUI in woman by using simple, effective and safe techniques that tend to significantly shorten the duration of hospitalization, reduce the treatment costs, faster establishment of working capacity with minimal damage to surrounding tissues and the local innervations, which decrease the number of postoperative complications and ensure the establishment of normal function (2).

Tension free vaginal tapes entered into the clinical practice in 1994 and since then, they are increasingly being applied around the world. The technique is significantly different from all previous actions and it is based on a series of experimental studies on the mechanism of closure of the urethra (4). The needle is drawn through the previously made stab wound and due to the fact that the TVT tape is carried out blindly, it is important that the surgeon knows the anatomical structures in the retropubic space, in order to prevent possible complications. Besides the possibility of damaging the urethra or the bladder, there is a possibility of violation of important vascular structures such as obturator vascular bundle. The biggest step in the evolution of the obturator approach was made by Leval in 2003 by using a specially constructed set of instruments of TVT-O tape in the direction "inside-out". With minimal vaginal dissection, the tape is placed under the mid urethra without elevation, without fixing the ends of the tape, just cutting it below the skin section (3).

Treatment success depends on the proper diagnosis and good choice of treatment method, because the modern diagnostic and therapeutic procedures achieve optimal therapeutic effects and ensure good quality of life of the patients. Studies that analyzed the effectiveness of the treatment of SUI took into account different ways of measuring the effectiveness of these procedures to define the proper method of treatment for SUI. The procedure for treating SUI has to be judged subjectively by patients, and objectively by clinical examination, which every patient must pass. It should be noticed that by applying the subjective evaluation, the success of a treatment can be measured by increased quality of life of the patients. In this sense, we can talk about activities that the patient can do now without fear of adverse consequences of unwilling urination. The objective assessment of cured patients must be made after the completion of clinical testing (4). Another way of deciding about the appropriate therapeutic method is the use of economic methods in determining the viability of the chosen method. The ultimate goal of such an analysis is to be helpful in selecting the most effective medical treatment for the lowest possible price (5).

The aim of this study was to analyze the clinical effectiveness and economic feasibility of the TVT-O method in the treatment of SUI in women compared with vaginoplasty.

MATERIALS AND METHODS

The study was a retrospective-prospective study, which included 60 patients who were surgically treated after having a diagnosis of SUI in the period from January 2007 to August 2010 in the Regional Hospital in Bihać. The subjects were divided into two groups. The first group comprised 30 patients having SUI and being treated with TVT-O method, while the second group of 30 patients had SUI treated with classical vaginoplasty by Kelly. We performed an economic and efficiency comparison of both methods. To assess the clinical efficacy, we used data from the medical records of the Department of Gynecology and Obstetrics in the Regional Hospital of Bihać, as duration of surgery, length of hospital stay, intra operative and early postoperative complications (30 days after surgery) and late postoperative complications (3 to 6 months after surgery). We evaluated the performed questionnaires and forms, we did the objectification of urinary incontinence, diagnostic ultrasound, gynecological and clinical examinations which were performed prior to surgery and the follow-ups in the first, third and sixth months after the surgery, and we evaluated the results of the investigation of complications and outcomes six months after treatment. The inclusion criteria were clinically and urodynamically diagnosed and surgically treated stress urinary incontinence, and the sample was determined randomly. The exclusion criteria were patients with other types of incontinence,

T*able 1. Consumption of materials during vaginoplasty*

Material type	*Amount*	*Price per piece (€)*	*Total price (€)*
Surgical gloves	*4*	*0.09*	*0.36*
Izosept 10%	*400 ml*	*9.95*	*3.98*
Izosept 7.5%	*400 ml*	*9.95*	*3.98*
Antiseptic	*300 ml*	*8.17*	*2.45*
Scalpel	*1*	*0.07*	*0.07*
Foley catheter	*1*	*0.35*	*0.35*
Syringe 200 cc	*1*	*0.06*	*0.06*
Urinary bag	*1*	*0.19*	*0.19*
Sticking plaster	*2 m*	*1.43*	*0.10*
Sewing supplies	*15*	*4.89*	*22.65*
Gaze	*13*	*0.33*	*2.42*
Total			*35.61*

and patients with previous reoperative or corrective surgery. The medical staff which performed the operations were same in both groups.

To assess the economic viability, we analyzed the consumption of materials during TVT-O and vaginoplasty and the amount of ancillary charges (anesthesia, postoperative care, etc). We used the cost-benefit analysis, calculated by the total cost of treatment of SUI, following all the parameters that determine it (the costs associated with treatment and costs related to the disease before and after surgery), and the overall benefit for both treatments. Benefit is defined as gross national income (GNI) per day for a certain number of patients (GNI per capita per day= 3.95 €) (8). For the statistical analysis we used the standard methods of descriptive and inferential statistics and regression and correlation analysis. To test the statistical significance of the differences between the samples, we used the parameter

***Table 3**. Consumption of materials during TVT-O surgery*

Material type	*Amount*	*Price per piece*	*Total price*
TVT sling	*1*	*632.11*	*632.11*
Surgical gloves	*5*	*0.09*	*0.45*
Izosept 10%	*200*	*9.95*	*1.99*
Antiseptic	*200*	*8.17*	*1.63*
Scalpel	*1*	*0.07*	*0.07*
Foley catheter	*1*	*0.35*	*0.35*
Urinary bag	*1*	*0.19*	*0.19*
Syringe 20 cc	*1*	*0.06*	*0.06*
Circular tampon	*10*	*0.03*	*0.31*
Nylon cf 2-0	*1*	*1.19*	*1.19*
Saline	*60ccm*	*1.46*	*1.75*
Total			*639.99*

***Table 2**. Cost of services for vaginoplasty*

Service type	Amount	Price per day	Total price
Operation	1	99.90	99.90
Anesthesia	1	68.75	68.75
Intensive Care	2	74.00	148.00
Non intensive care	5	25.00	130.00
Total			446.65

tests, Student t test and chi-square test. Statistical hypotheses were tested at the level of significance of α= 0.05, and the differences among the samples were considered significant if the factor of significance p< 0.05. Statistical analysis was performed with SPSS (Statistical Package for Social Sciences) software (version 16.0) IBM.

RESULTS

As shown in the figure 1, most of the patients were in the range between 46 and 55 years (30% of the studied group). The total price of consumed materials during vaginoplasty was 35.61 €. The details are given in Table 1. The total cost of services performed during vaginoplasty was 446.65 € (Table 2). If we add the total price of consummated materials during vaginoplasty, we come to a total operation price for vaginoplasty which amounts 483.26 €. The total price of consummated materials during the TVT-O surgery was 639.99 €. The details are given in Table 3. The total cost of services performed during TVT-O surgery was 177.40 € (Table 4). If we add the total price of consumed materials during TVT-O surgery, we come to a total operation price for TVT-O surgery which amounts 817.39 €. Cost benefit ratio for vaginoplasty was calculated as C/B ratio = number of patients x cost of treatment/GNI per day for the total number of absences from work for x number of patients (4).

C / B = 30 x 483,26 / 3,95 x 10 x 30 = 12.2

***Table 4**. Cost of services for TVT-O surgery*

Service Type	*Amount*	*Price per day*	*Total price*
Price of operation	*1*	*99.90*	*99.90*
Local anesthesia	*1*	*3.50*	*3.50*
Intensive Care	*1*	*74.00*	*74.00*
Non intensive care	*0*	*0*	*0*
Total			*177.40*

***Table 5**. The data needed to determine the cost benefit ratio of both methods*

GNI per capita per day, €	*3.95*
The total cost of vaginoplasty, €	*483.26*
Total cost for the TVT-O, €	*817.39*
TVT-O patients, n	*30*
Vaginoplasty patients, n	*30*
The average absence from work for vaginoplasty	*10 days*
The average absence from work for the TVT-O	*4 days*

Cost benefit ratio for TVT-O was calculated as C / B ratio = number of patients x cost of treatment / GNI per day for the total number of absences from work for x number of patients C / B ratio = 30 x 817,39 / 3,95 x 4 x 30 = 51.7. The data needed to determine the cost benefit ratio of both methods are presented in Table 5.

The difference in the average duration of surgery between patients in group A (TVT-O) and group B (vaginoplasty) was statistically significant (chi-square= 60.001 p< 0.01, t= 160.507 p <0.01). The difference in the duration of hospitalization in patients treated with TVT-O method, and patients treated with vaginoplasty was statistically significant (chi-square = 60.001 p <0.01, t = 369.743 p <0.01). Overall comparison of complications (operative, early and late postoperative) was statistically significant in terms of a higher number of complications in the vaginoplasty group (Chi-square = 8.080, p= 0.0444, p< 0.05). The details are given in Table 6. Description of intra operative complications in both studied groups is shown in Table 7. Description of early postoperative complications in patients in both studied groups is shown in Table 8. Description of late postoperative complications in patients in both studied groups is shown in Table 9. Overall results of treatment after surgery expressed as cured, improved and not cured are shown in Table 10. There was statistically significant difference in total score between the observed treatment methods in terms of TVT-O method being more successful (x2=6,473;p=0,0393).

***Table 7**. Description of intra operative complications*

Intra operative complications	*TVT - O*	*Vaginoplasty*
Bladder injury	*0*	*1*
Urethra injury	*0*	*0*
Intra operative bleeding	*0*	*1*
Vessel injury	*0*	*0*
Total	*0*	*2*

***Table 6**. General comparisons between the TVT-O and vaginoplasty*

	TVT - O	*Vaginoplasty*
Average operating time (min)	*12.2*	*28.2*
Range of operating time (min)	*<10-20*	*20-30 >*
Length of hospitalization(days)	*3.03*	*8.3*
Intra operative complications	*0*	*2*
Early postoperative complications	*1*	*4*
Late postoperative complications	*0*	*3*

DISCUSSION

The basis for the decision on the selection of operative technique is certainly clinically proven efficacy of the tested methods as well as their economic viability. Taking into account the incidence of diseases such as stress urinary incontinence, it is an important aspect to find a method that will have a shorter operative time and shorter hospital stay, fewer complications, and certainly a greater rate of cure (6).

Analyzing the clinical efficacy of both methods has led to the data that the mean operative time for TVT-O group was 12.2 while the vaginoplasty lasted about 28.2 minutes. The average length of hospitalization for TVT-O group was 3.03 days, while the average hospital stay in patients treated with vaginoplasty was 8.3 days. Looking at the complications of the TVT-O group, there was one early postoperative complication, and not a single operative and late postoperative complication. In patients treated with vaginoplasty, two intra operative, four early postoperative and three late postoperative complications occurred.

The analysis of objective methods and subjective statements about the outcome of the operation showed that in the TVT-O group, 25 patients (83%) were considered to be cured, 5 patients (17%) had improvement after

***Table 8**. Description of early postoperative complications*

Early postoperative complications	*TVT - O*	*Vaginoplasty*
Infection	*0*	*1*
Pain	*0*	*0*
Hematoma	*0*	*1*
Urine retention	*1*	*2*
Vaginal erosion	*0*	*0*
Compression of urethra	*0*	*0*
Edema	*0*	*0*
Total	*1*	*4*

***Table 9**. Description of late postoperative complications*

Late postoperative complications	*TVT - O*	*Vaginoplasty*
Abscess	*0*	*0*
Late urine retention	*0*	*2*
Pain	*0*	*0*
De novo instability	*0*	*1*
Total	*0*	*3*

***Table 10**. Overall results of treatment*

	TVT-O		*Vaginoplasty*	
Outcome	*n*	*%*	*n*	*%*
Cured	*25*	*83.0*	*18*	*60.0*
Improved	*5*	*17.0*	*7*	*23.0*
Uncured	*0*	*0.0*	*5*	*17.0*
Total	*30*	*100.0*	*30*	*100.0*

surgery, while there was no uncured patients. In patients treated with vaginoplasty, 18 (60%) was cured, 7 patients (23%) showed improvement after surgery, and 5 patients (17%) had no improvement.

The overall results of 38 clinical studies, particularly done to assess the clinical performance and safety of TVT-O method in the treatment of stress urinary incontinence in women revealed that .the full cure rate was roughly 87% with an improvement occurring in 9% of the cases. The failure rate was 4% .Operation length had an average of 14,8 minutes (± 4.3 minutes), while the length of hospital stay averaged 1.2 days (± 1.3 days). Postoperative complications occurred in approximately 2% of the cases, mainly as the retention of urine in the first three days after surgery. Clinical studies indicate a significantly higher success rate by treating SUI with TVT-O procedure which has become the gold standard for surgical treatment of SUI (7). Economic analysis obtained showed that the cost of the TVT-O method is higher and amounts 817,39 € in comparison to the conventional method that costs 483,26 €. However, postoperative care of the conventional method is more expensive and longer. So, by looking at the fact that a longer recovery means a longer absence from the work, TVT-O method seems to be more advantageous. By analyzing the ratio of cost benefit of both methods, taking the gross national income as a parameter, we have found that the benefit of TVT-O method is up to 4.2 times greater than the benefit of conventional vaginoplasty (8).

Conducted research confirmed the advantage of TVT-O method in the treatment of stress urinary incontinence compared to the vaginoplasty by Kelly. The advantage of TVT-O lies primarily in being an easier and more efficient treatment of stress urinary incontinence. The results showed a shorter duration of surgery and hospital stay, lower hospital costs, fewer operative, early and late postoperative complications for TVT-O method. These allowed the patient a greater comfort while solving the problems of stress urinary incontinence easily with a higher cure rate.

Based on the results and analysis of existing studies, we believe that with the introduction of TVT-O surgical technique as a new standard for the treatment of SUI in the Federation BIH, the cure rate of SUI and the quality of life of patients may be increased. Furthermore, this might lead to greater efficiency in allocating resources within the health budget.

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