



Research Article

Long Term Quality of Life after Tension-Free Vaginal Tape-Obturator Procedure in Women with Stress Urinary Incontinence

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Abstract

Introduction: Stress urinary incontinence represents a common but strongly underestimated health problem that affects women of all ages and severely downgrades their health related quality of life. The transobturator vaginal tape (TVT-O) approach offers long term success rates, while minimizing complications. In this study, we examined quality of life of patients suffering by stress urinary incontinence and investigated whether TVT-O procedure offers considerable benefits in patient's quality of life after 5 years of placement.

Methods and results: Women with confirmed urodynamic stress urinary incontinence that underwent TVT-O procedure were included in this prospective study. Patient's quality of life was evaluated by using the Greek version of SF-36 preoperatively and 60 months postoperatively. The outcomes demonstrated that incontinence had significant adverse effect in patient's quality of life. However, TVT-O procedure offers a safe and efficient treatment, substantially improving both physical and mental dimension of women's health related quality of life ($P>0.05$).

Discussion: Stress urinary incontinence strongly impairs women's health related quality of life, limiting their physical activities, social function and causing emotionally imbalance. Insertion of tension free vaginal tape reverses symptoms and significantly improves all health indicators associated with patient's health related quality of life. In our study, we demonstrate that minimal invasive surgery, by using TVT-O procedure is highly effective, in long term, in improving quality of life of women with stress urinary incontinence.

Keywords: Urinary incontinence; Stress urinary incontinence; Transobturator vaginal tape; Quality of life; Physical health; Mental health

Abbreviations: HRQoL - Health related quality of life; SUI - Stress urinary incontinence; TVT-O - Tension-free vaginal tape-obturator; UI - Urinary incontinence

Introduction

Urinary incontinence (UI) represents an important problem which affects women of all ages [1,2]. However the prevalence increases considerably with age and it is estimated that half of all women above 60 years old have some form of UI [3,4]. The most common subtype of UI is Stress Urinary Incontinence (SUI) which accounts for up to 80% of all cases and is defined as the complaint of involuntary leakage during effort, exertion, sneezing, coughing, exercising, or any other condition that increases the intra-abdominal pressure [5]. SUI has great impact on women's quality of life and adversely affects their physical, mental and social wellbeing [6].

While pharmacological approach is associated with low cure rates, troublesome side effects and long term recurrences, surgery represents a feasible and high effective solution [7]. Over the last century, several techniques have been proposed and applied, with satisfactory treating rates [8]. However, introduction of tension-free vaginal tapes procedures since 1995 when it was first described by Ulmsten et al more than 20 years ago, constituted a revolution in the rapidly changing field of female incontinence treatment [9]. Nowadays, minimally invasive processes applying midurethral tension-free slings are regarded as a possibly new gold standard for treatment of SUI [10]. The use of transobturator route to apply tension-free vaginal tape (TVT-O) was first described by Delorme et al. In 2001 as a new method of inserting the tape which passes through the obturator foramen, thus theoretically avoiding some of the complications

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such as bladder perforation [11]. In the TVTO technique the needle is passed in a reverse route, in from vaginal incision and out through the obturator foramen (inside-out) and offers cure rates exceeding 90%, fewer severe and moderate complications, less operation time and less recurrent rates [12-16].

Health related quality of life (HRQoL) is a quantitative measurement of subjective perception of patients' health status, encompassing physical, functional, psychological, emotional and social aspects associated with their disease or its treatment [17]. The aim of our study was to evaluate the long term effect of TVT-O procedure on HRQoL in patients suffering by SUI.

Methods

In this prospective study were recruited women with urodynamic confirmed diagnosis of SUI that underwent TVT-O procedure. Exclusion criteria were pelvic organ prolapse, urogynecological malignancy, urinary tract infection, previous surgery for urinary incontinence and predominant urgency incontinence. Patients with major voiding dysfunction specified as an abnormal flow as maximum urinary flow rate <10 mL/s or residual urinary volume of >150 mL were also excluded. In all women HRQoL was evaluated preoperatively and 60 months postoperatively.

The validated Greek versions the Medical Outcomes Study 36-item Short Form Health Survey (SF-36), with statistically confirmed sensitivity and reliability were used was used to measure HRQoL [18]. All women were evaluated using SF-36 preoperatively and after 60 months postoperatively.

The SF-36 represents a multi-purpose, health self-survey consisted of 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. Those scales represent vital parts patient's life, which are impaired by his health as are uniquely recognized and mentioned. Those health indications are: Physical Function (Pf), Role Physical (rp), Bodily Pain (bp), General Health (gh), Vitality (vt), Social Function (sf), Role Emotional (re) and Mental Health (mh) [19,20]. The eight scales form two distinct higher-ordered clusters due to the physical and mental health variance that they have in common [21]. On all scales, higher results indicate better subjective health. For each SF36 dimension, item scores were transformed on a 0-100 (worst to best possible health state) scale [22].

Chi-square analysis and independent-sample t test were used and P-value < .05 was considered statistically significant for all comparisons. Internal consistency both preoperatively and postoperatively for each scale was evaluated by using Cronbach's alpha. Statistical analysis was performed with SPSS Statistics 20 (IBM, Armonk, NY, USA). The study was approved by the local ethics committee.

Result

A total of 102 women that underwent TVT-O surgical

procedure for treatment of SUI and accepted to enroll in this study were included. Success rate of reversing SUI was 96% postoperatively, falling to 89% in 60 months. Compliance rate was as high as 91% in 5 years period. Complication rates were at 2,9%, as two women had urethra injury and another one had persistent pain, but didn't statistically affect outcome.

The mean age was 55.8 SD \pm 8.9 years, ranging from 37 to 81 years. 72% of the women were married and 28% were single. Seventy seven percent of patients had completed secondary education while thirty three percent of women had postsecondary education. Though, neither education level nor family status had a significant association with any individual scales in our study.

SUI had significant impact on all scales of SF-36, with the exception of bodily pain, as has been recorded preoperatively. Most impaired was physical function, recording the lowest score among physical health parameters (36,58), demonstrating limitations in physical activities because of incontinence. Among mental health's scales, highly impaired were social function and role emotional scales recording score 29,45 and 28,28 accordingly. No adverse effect of the disease was mentioned on bodily pain scale and high score was recorded (86,98). Moreover, as expected, no significant improvement was recorded in painful measurements postoperatively. Conversely, a statistically important improvement in all other health scales was recorded 60 months following TVT-O placement ($p < 0.05$). Highest scores after long term follow up were recorded in physical function, role emotional and vitality scales. The largest improvement among all health scales was recorded in physical function reaching to 79,2, followed by social function and role emotional [Figure 1].

Discussion

As SUI considerably affects women's daily activities, several surgical efforts had been made over the last 100 years in order to eliminate the problem, including but not limited to procedures such as Kelly plication, Pereyra, Marshall- Marchetti- Krantz, Burch colposuspension and urethropexy [23-25]. Those techniques despite their adequate success rates in reversing leakage, were associated with long learning curve, long operation times and high complication rates including high proportion of severe. Introduction of minimally invasive techniques with the application of tension-free vaginal tapes has largely replaced those surgical approaches [26]. Among tension-free vaginal tapes, TVT-O placement, through the obturator foramina, has the substantial advantage of avoiding the pelvis. In fact TVT-O has been proved a safe approach with high cure rate ranging from 80% to 100% and long-term success rate of 80% -95%, while offers low overall complication rates. Success rates in our study were in accordance with those data [27-30]. Most important complications that may reverse operation's benefits and patient's satisfaction, include injury to the structures of surrounding tissues such bladder, urethra or bowel, entrapment or damage of nerves, inability or urgency to void and persistent pain [31]. However, in our study, complication rates were too low to obtain statistically significant differences.

SUI has been strongly associated with lower quality of life

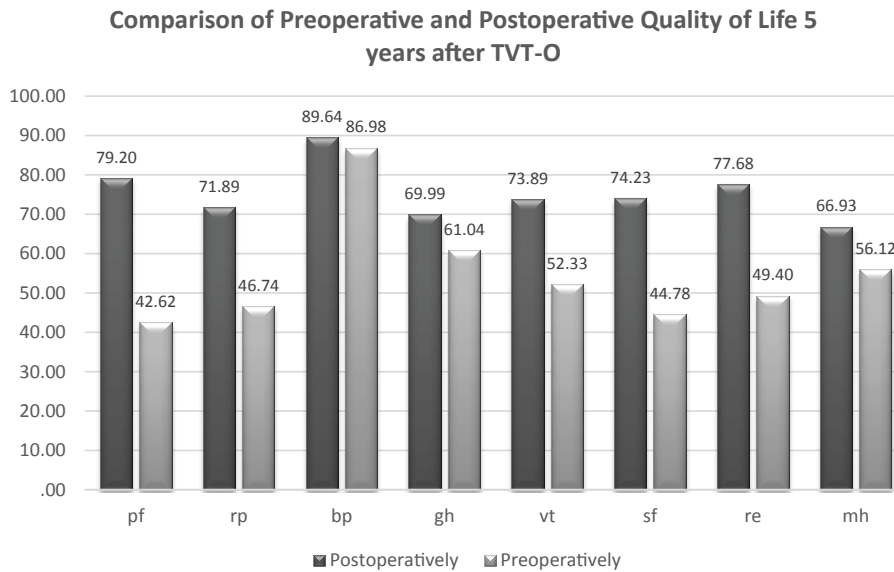


Figure 1: Preoperative and postoperative (60 months) comparison of patient's quality of life (sf-36). Pf: Physical Function, rp: Role Physical, bp: Bodily Pain, gh: General Health, vt: Vitality, sf: Social Function, re: Role Emotional, mh: Mental Health.

[32,33]. In fact women try to reduce their physical activities in order to avoid any situation that could increase intra-abdominal pressure and create urine leakage. This has impact on their daily activities and work. Moreover, due to the unpredictable and embarrassing symptomatology of SUI, women tend to isolate themselves and avoid socializing. As a consequence of their physical problems and limitations, women's mental health is noteworthy impaired, usually complicated by depression and all those factors lead to limitations in women's usual role in family, working and social life [34]. In fact, in our study both physical and mental health dimensions were remarkably impaired by SUI's symptoms in consistence with previous studies [35].

TVT-O procedure has been demonstrated to improve SUI and as incontinence is reversed and symptomatology is eliminated, there is a significant improvement in women's HRQoL [36-38]. However, there are several restrictions in evaluating the effect of TVT-O in women's quality of life. Several short term (6 months to 1 year) evaluations have been performed and demonstrated significant improvement in HRQoL [39, 40]. Nevertheless, there are only limited data regarding long term quality of life evaluation following TVT-O procedure [41,42]. In addition we used the SF-36 to evaluate multilevel effects in HRQoL and benefit of its applicability to patients over a range of ages and with varying types and severities of SUI.

In physical dimension of health, the most noteworthy improvement was in patient's physical function, as women eradicate their self-forced limitations in their physical activities. In addition, they feel capable of regaining their role as vital part of their family, work and society that were previously starkly impaired because of their inconsistency. Partially but definitely not worthless, previous beneficial effect on patient's role, is due to women's higher energy level and less fatigue demonstrated. The only health indicator,

in which no significant alterations were recorder, was body pain. This is totally expectable as SUI is not associated with any painful symptomatology.

In mental dimension of women's health, improvement was as significant important as was in physical health. Actually, the improvement was almost equal in both physical and mental dimensions, demonstrating the multilevel impairment that SUI brings and respectively how capable TVT-O procedure is in reversing those problems. Depression, anxiety and emotional distress affect women's quality of life. However postoperatively women are more optimistic regarding their health status and emotionally and mentally more balanced. Women recover their unique roles in family, work and society. In fact regaining their social role is of significant importance as has been confirmed by our study.

Social function recorded the lowest score among mental scales and the second in total demonstrating SUI adverse effect in women's social quality of life. Women's anxiety and fear of involuntary leakage even during laughing, makes them either avoiding social contacts and events, or adopting behavioral changes. However, this way their social life is severely downgraded. Nevertheless, minimal invasive techniques such implication of TVT-O, eliminates those multiple negative effects. In fact, in our study after surgery social function was restored recording one of the highest scores. Moreover, in this health indicator was recorded the second largest difference, before and after surgery, demonstrating the important role that social function has in women's quality of life.

In summary, our study demonstrates that all health indicators of both physical and mental health are significantly improved by using TVT-O procedure, especially remarkably in the domains of physical and social functioning and benefits are present after 60 months.



Conclusion

Stress urinary incontinence significantly downgrades health-related quality of life, adversely affecting women's physical and mental health and impairing their personal and social life. TVT-O procedure represents minimal invasive techniques which reverse incontinence and is highly effective in considerably improving quality of life at long term.

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