ORIGINAL ARTICLE

Assessment of the Quality of Life in Patients with Genuine Stress Urinary Incontinence Treated by Tension-free Vaginal Tape

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Abstract

Background and objective: To assess the impact on the quality of life in patients with genuine stress urinary incontinence (GSUI) following a tension-free vaginal tape (TVT) procedure.

Materials and methods: Twenty cases of GSUI managed surgically with TVT were assessed postoperatively at 1, 3, 6, and 12 months using two validated disease-specific quality of life questionnaires named incontinence impact questionnaire (IIQ-7) and urogenital distress inventory (UDI-6). The preoperative and postoperative scores were analyzed using the Wilcoxon signed ranks test.

Results: The results showed significant improvement in the median scores of both IIQ-7 and UDI-6 questionnaires. The median score of IIQ-7 improved to 10.00 at 12 months as compared to 71.00 preoperatively. Similarly, the median scores of UDI-6 improved to 16.00 at the end of 12 months as compared to 55.00 preoperatively. The improvement in both the scores was found to be statistically significant by applying the Wilcoxon signed ranks test with $p < 0.01$. Analyzing the stress and urge subscale of UDI-6 at 12 months, an improvement of 97.2% and 45.8 % was shown respectively.

Interpretations: The statistically significant decrease in the IIQ-7 and UDI-6 scores suggest definite improvement in the quality of life (QoL) of the patients at a medium-term follow up of 12 months.

Conclusion: Tension-free vaginal tape is an effective method for improving the QoL in patients with GSUI.

Keywords: Quality of life, Stress urinary incontinence, Tension-free vaginal tape.

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Introduction

Urinary incontinence (UI) is a very common condition that negatively affects the quality of life in women. There is under-reporting of the incidence as many women do not seek help due to associated embarrassment or acceptance of incontinence as a natural result of pregnancy or part of the aging process. Hannestad et al.,[1] in a study among more than 34,000 women, found that only 25% of incontinent women seek help, with the impact of urinary leakage on the patient's lifestyle being the most important reason to seek help.

Quality of life (QoL) as defined by Kelleher is an abstract concept, encompassing an individual's perceived level of physical, psychological, and social well being.[2] As such, it is influenced by personal experiences, disease processes, support structures, and treatment. The study of QoL becomes important because we as clinicians realize that the success of the procedure is not defined only by the clinical parameters, but also by the physical, mental, and social well being of the patient. Though objective clinical tests still clearly play a role in the postoperative assessment of the patients, the subjective concerns such as QoL are extremely important in determining the outcomes of various procedures.

The tension-free vaginal tape (TVT) technique that was first introduced by Ulmsten et al.[3] for the surgical management of stress UI in 1996 is a form of low-tension urethropexy. The rationale for the technology is grounded on the idea called the integral theory of female UI. This theory proposes that the cause of stress incontinence is connective tissue laxity in the vagina itself, or in its anterior and/or posterior supporting ligaments.[4] The pelvic floor muscles are unable to compensate for the laxity of the connective tissues sufficiently to maintain closure of the urethra. It is suggested that the tape simulates the support mechanism of the pubourethral ligament. According to the integral theory, the role of the pubourethral ligament and hence the tape is to provide a firm anchoring for the muscles associated with urethral closure.

The TVT is a minimally invasive procedure that avoids long operation, as well as achieves faster, easier and complete postoperative recovery when compared to other anti-incontinent procedures such as retropubic urethropexy (Burch colposuspension). The objective of this study is to assess whether this procedure improves the QoL in women with genuine stress urinary incontinence (GSUI).

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Materials and Methods

Women who presented with complaints of leakage of urine on coughing, laughing, lifting heavy weight or bending forwards at the Department of Obstetrics and Gynecology and Department of Urology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi were screened for the inclusion in the study. A total of twenty women with urodynamically confirmed GSUI requiring surgical management were included in this study. Associated conditions like uncontrolled diabetes mellitus, current urinary tract infection, other types of incontinence (urodynamically proved detrusor overactivity, mixed incontinence, overflow incontinence), neurogenic bladder, and pelvic organ prolapse were excluded in the study population. All the patients underwent a TVT procedure using the retropubic approach with Gynecare (Ethicon Inc.) synthetic polypropylene mesh as initially described by Ulmsten et al.[3] Sling surgery was not combined with any other surgery in this study.

Quality of life assessment was performed using the validated disease-specific incontinence impact questionnaire (IIQ-7) and urogenital distress inventory (UDI-6) questionnaire (Annexures 1 and 2). The average score of the items, which ranged from 0 to 3 was calculated and multiplied by 33 1/3, to put the scores on a scale of 0 to 100. A score of 0 suggested that the patient was not at all bothered by the symptom, whereas a score of 100 meant a severe degree of affection by the symptom. The subscales of UDI-6 were further evaluated to assess the irritative and stress symptoms of the patient. Quality of life questionnaires were filled preoperatively as well as at the end of 1 month, 3 months, 6 months, and 12 months after the surgical correction of GSUI by TVT.

Statistical analysis was performed using SPSS statistical software version 12.0. The pre- and postoperative scores were compared using the Wilcoxon signed ranks test, which is a nonparametric test to compare paired data.

Results

Patient Characteristics and Symptom Profile

Table 1 shows the demographic characteristics of the study population. The mean age of the group was 45.05 ± 2.53, with the range of 22–67 years. The mean parity was 3.1 ± 0.35.

The duration of incontinence ranged from 2 months to as long as 6 years. In the majority of the patients, the leakage amount and episodes had increased over the duration between onset and seeking medical care. All patients had a noticeably higher daytime affection with multiple leak episodes, compared to night, thus, interfering with their daily activities. Two patients in the study group used pads throughout the day for their symptoms. All these factors collectively had severe effects on the QoL of the patients. In the study group, 80% of patients had associated symptoms of sensory urgency with a urine holding time of less than 1 minute to a few minutes. However, motor urgency in the form of detrusor instability associated with the leaking of urine was not documented in any of them.

Surgery and Immediate Postoperative Period

All patients underwent sling surgery after informed consent. Operative time in minutes with a standard error of the mean was 25.00 ± 1.08 minutes, the range being 20–35 minutes (Table 2). No patient had excessive bleeding or hematoma formation during the surgery. In this series, there was one case of the bladder (5%) and urethral injury (5%) each. Bladder injury occurred during passage of the needle, which was removed, reinserted, and tract of needle reconfirmed using cystoscopy. Catheter was placed for 14 days postoperatively. Urethral injury was managed by primary repair with catheterization for 14 days, both the patients recovered, satisfactorily. Two patients required readmission due to retention. Hospitalization was required for a variable period of 7–14 days before and after the tape splitting procedure to relieve retention.

Table 1: Patient characteristics and symptom profile

Characteristic	*n*	*Mean ± standard error of mean/(%)/range*
Age	20	45.05 ± 2.53 years (22–67 years)
Parity	20	3.1 ± 0.35 (1–8)
Premenopausal	14	70%
Postmenopausal	6	30%
Occupation		
Housewife	17	85%
Outdoor	03	15%
Duration of incontinence	20	2.53 ± 0.48 years
Amount of urine leaked		
Small (slightly damp)	12	60%
Moderate (1–2 tsp)	07	35%
Large (>2 tsp)	01	05%
Previous treatment	03	15%
Hysterectomy with Kelly's	02	10%
Kegel's exercises	01	05%
Sensory urgency	16	80%
Motor urgency	00	00

Table 2: Surgery and postoperative period

	n/mean ± std error of mean	*Range/(%)*
Per operative time (minute)	25.00 ± 1.08	20–35 minutes
Per operative bleeding (mL)	24.00 ± 2.1	10–50 mL
Excessive bleeding (per operative/ immediate postoperative)	Nil	Nil
Bladder perforation	1	5%
Urethral laceration	1	5%
Catheter duration (days)	5.55 ± 2.4	1–21 days
Retention of urine	2	20%
Other voiding difficulty	3	15%
Hospital stay (days)	2.15 ± 0.69	1–14 days

Preoperative Quality of Life Score

Incontinence impact questionnaire-7 assessing the impact of the symptoms on the patient's life in terms of physical activity, travel, relationships, and emotional health showed high median scores of 71, signifying a detrimental effect on QoL. Urogenital distress inventory-6 questionnaire, which is further divided into stress, urge, and obstructive subscale also showed a high total score of 55.5. Stress and urge subscale of the UDI questionnaire, which was studied separately, also showed high mean scores suggesting a poor QoL due to these symptoms (Table 3).

Postoperative QoL Assessment

It was seen that the median scores on IIQ-7 improved from a preoperative score of 71–33, 23, 10, and 8 at a follow up of 1, 3, 6, and 12 months, respectively (Table 4). This improvement of the scores at all the follow-ups was highly significant with p value <0.001, suggesting a definite improvement in the postoperative QoL. Urogenital distress inventory scores also showed similar significant improvement of postoperative scores at 1, 3, and 12 months.

Stress and Urge Subscales of UDI-6

Consideration of these subscales is a useful way of critiquing a subject's status after the treatment. An incontinence operation may result in a good stress incontinence symptom score but result in a poor irritative symptom score. This subtlety can be overlooked if only the general UDI score is considered. An overall improvement of 97.3% was found in the stress subscale of UDI-6 at the end of 12 months after surgery when compared to preoperative and was statistically significant.

Analyzing the urge or irritative subscale of UDI (Table 5), it was found that the improvement was maximum (60%) at the end of 3 months with a decline of the scores at 12 months. This showed that in patients with persistent symptoms of urgency, there was an initial improvement of the symptom after the surgery, but with time the symptom of urgency gradually increased. This may be attributed to the irritative effect of the tape. However, the change at all the follow-ups as compared to preoperative was statistically significant.

Table 3: Preoperative quality of life questionnaire scores

	Mean ± std error of mean	*Median scores*
IIQ 7 score	68.85 ± 3.761	71.00
UDI-6 score	56.90 ± 2.670	55.50
Stress subscale	91.66 ± 12.3	
Urge subscale	88.3 ± 13.1	

IIQ, incontinence impact questionnaire; UDI, urogenital distress inventory

Table 4: Postoperative quality of life questionnaire scores

	Median score IIQ-7	*p*	*Median score UDI-6*	*p*
Preoperative	71.00		55.50	
1 month	33.00	$p = 0.000$ (<0.001)	28.00	$p < 0.001$
3 months	23.00	$p = 0.000$ (<0.001)	16.00	$p < 0.001$
6 months	10.00	$p = 0.003$ (<0.01)	16.00	$p = 0.003$ (<0.01)
12 months	8.00	$p = 0.002$ (<0.01)	10.00	$p < 0.001$

Discussion

The primary goal of this study was to assess the improvement in QoL of the patients after the TVT procedure. In the present study, 20 patients who underwent the procedure and followed up to 6 months showed a considerable improvement in median scores of IIQ-7 and UDI-6 questionnaires. The improvement in both the scores was found to be statistically significant, applying the Wilcoxon matched-pairs signed-ranks test with p values <0.01.

The short forms of IIQ and UDI-6 have been validated through correlations with long forms[5] and with clinical data, and a significant correlation with the 1-hour pad test has been reported.[6] It has been found that IIQ-7 and UDI-6 are sensitive to changes in clinical status after surgery for stress urinary incontinence or pelvic organ prolapse, but IIQ-7 is not responsive to objective change incontinence status.[7] The questionnaires include domain about physical health, travel, relationships, and emotional health, but a point of weakness of IIQ-7 is that it does not include the impact on sexual life that is an important aspect of incontinent woman's life.

The improvement in QoL is mainly contributed to the correction of symptoms of stress and urge after the procedure. In the present study, the improvement of stress subscale on UDI-6 was constant, significant, and maintained at all the follow-ups. Though the urge subscale showed an initial improvement of up to 60%, which declined at 12 months follow up, the improvement was significant and did not negatively affect the final QoL score. The decline in urge subscale can be attributed to the development of de novo symptoms of urgency or the irritative effect of the tape per se. Obstructive subscale did not matter to have much effect on the overall outcome. Similar outcomes in the improvement of stress and urge subscale have been cited by other authors.[8,9]

After the introduction of the procedure by Ulmsten et al. in 1996,[3] many short-term follow-ups have been published[10–12] claiming the technique to be safe and effective for the treatment of stress urinary incontinence. Although validated questionnaires were not used, but the studies showed a definite improvement in the QoL of the treated patients. Our study has also revealed noteworthy short to midterm outcomes. Postoperative development of troublesome symptoms related to the procedure may also decline the QoL and affect the subjective outcome. The follow up in the present study cases did not reveal any significant bothersome symptoms, and documented complications are comparable with the published literature.[13–16]

Acceptance of any procedure on large scale depends more on the long-term outcomes when compared to short-term benefits. Our study was limited to a short- to mid-term follow up, but widely published data is available on the long-term success of the procedure.[17–20] These long-term follow-ups show that the improvements in measures of QoL after TVT surgery are dramatic and persist for years. These promising results are encouraging enough to accept it as a standard procedure for stress urinary incontinence.

Table 5: Stress and urge subscales of UDI-6

	Stress subscale			*Urge subscale*		
	Mean ± std error of mean	*Improvement (%)*	*p value*	*Mean ± std error of mean*	*Improvement (%)*	*p value*
Preoperative	91.66 ± 12.3			88.3 ± 13.1		
1 month	28.33 ± 15.0	67.5	$p = 0.000$ (<0.001)	40.0 ± 17.2	52.5	$p = 0.000$ (<0.001)
3 months	6.6 ± 0.9	92.5	$p = 0.000$ (<0.001)	30 ± 20.4	60.0	$p = 0.000$ (<0.001)
6 months ($n = 12$)	2.6 ± 0.8	97.2	$p = 0.002$ (<0.01)	36 ± 33.6	45.8	$p = 0.016$ (<0.01)
12 months	2.4 ± 0.6	97.3	$p = 0.002$ (<0.01)	37 ± 32.5	44.6	$p = 0.018$ (<0.01)

Conclusion

Quality of life assessment at a follow up of up to 12 months using the validated IIQ-7 and UDI-6 questionnaires showed a significant improvement in the majority of patients, with 97.3% improvement of symptoms of stress and 44.6% improvement in the urge symptoms. Thus, TVT procedure can be recommended as an effective surgical procedure to improve the QoL in women with GSUI.

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Annexure 1: Incontinence Impact Questionnaire (IIQ-7)

For each question, the response that best describes the affect on activities, relationships, and feelings of the patient due to urine leakage is encircled.

Has urine leakage affected your…

	Not at all	*Slightly*	*Moderately*	*Greatly*
1. Ability to do household chores (cooking, housecleaning, laundry)?	0	1	2	3
2. Physical recreation such as walking (swimming or other exercise)?	0	1	2	3
3. Entertainment activities (movies, concerts, etc.)?	0	1	2	3
4. Ability to travel by car or bus more than 30 minutes from home?	0	1	2	3
5. Participation in social activities outside your home?	0	1	2	3
6. Emotional health (nervousness, depression, etc.)?	0	1	2	3
7. Feeling frustrated?	0	1	2	3

Items 1 and 2 = physical activity
Items 3 and 4 = travel
Item 5 = social/relationships
Items 6 and 7 = emotional health

Annexure 2: Urogenital Distress Inventory–SF (UDI-6)

Do you experience, and, if so, how much are you bothered by:

	Not at all	*Slightly*	*Moderately*	*Greatly*
1. Frequent urination? (I)	0	1	2	3
2. Urine leakage related to a feeling of urgency? (I)	0	1	2	3
3. Urine leakage related to physical activity, coughing or sneezing? (S)	0	1	2	3
4. Small amounts of urine leakage? (S)	0	1	2	3
5. Difficulty in emptying your bladder? (OD)	0	1	2	3
6. Pain or discomfort in the lower abdominal or genital area? (OD)	0	1	2	3

I = Irritative symptoms
S = Stress symptoms
OD = Obstructive/discomfort symptoms
Scoring: The average score of items responded is calculated, which ranges from 0–3 and then multiplied by 33 1/3 to put scores on a scale of 0–100