



Investigation of the Necessity of Urodynamic Test in Patients with Urinary Stress Incontinence for TOT Surgery

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Abstract

Background and aims: Stress urinary incontinence is one of the most common diseases which can reduce the quality of life in women. Urodynamic test is a common method of diagnosis of this disease. This study is designed for investigating the necessity of urodynamic test in patients with urinary stress incontinence before transobturator tape (TOT) surgery. Urodynamic test before surgery can affect the quality of life in patients.

Methods: This study was a randomized clinical trial. The sample size was 48 patients divided into two groups of 24 women in January 2018. Women with urinary incontinence complaints were randomly divided into two groups. For the first group, the urodynamic test was done. Both groups were evaluated one month and six months after TOT surgery based on the results of the I-QOL questionnaire.

Results: The mean I-QOL score was 83.9 ± 3.3 in questionnaire group and 81.6 ± 4.6 in urodynamic group one month after surgery with no statistically significant ($P=0.052$) difference. The quality of life score after 6 months was 87.2 ± 4 in the questionnaire group and 85.4 ± 3 in the urodynamic group with no statistically significant differences with each other ($P=0.084$).

Conclusion: In this study, the urodynamic test only had additional information related to lower urinary tract symptoms and it did not have effects on improving the outcome of the surgery. The test only imposes economic burden. Therefore, the urodynamic test is not required before surgery in patients with urinary stress incontinence.

Keywords: Urodynamic test, Transobturator tape, Urinary stress incontinence, Incontinence quality of life

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Introduction

Stress urinary incontinence occurs during any activity that increases intra-abdominal pressure. The prevalence of urinary stress incontinence is about 4% to 35%.¹

It affects the quality of life and health of women, causing significant disability, social isolation, psychological stress, and economic hardship.²

The most important examination for urinary incontinence, especially in the bladder and urethra, is the urodynamic test. Differential diagnosis of urinary obstruction and diagnosis of various types of urinary incontinence can be done by physicians through this test.³ Transobturator tape (TOT) is a surgical method for the treatment of urinary incontinence, which is preferred due to its lower level of complications.⁴

Understanding the patient's acceptance in postoperative improvement is important to evaluate the results of

urinary incontinence surgery.⁵ By analyzing the quality of life (QOL) questionnaires, more data can be obtained over time and long-term follow-up of patients and the surgical outcomes can be evaluated more accurately.⁶ In this study, we tried to evaluate whether the urodynamic test is a necessary evaluation before TOT surgery.

Materials and Methods

This study was a randomized clinical trial with IRCT number (identifier: IRCT2016060618655N3 <https://www.irct.ir/trial/16855>) in January 2018 with the aim of determining the effect of preoperative urodynamic tests on surgical treatment outcomes in patients with stress urinary incontinence. According to a pilot study, a sample size of 20 subjects in each group was determined for comparing the total score of questionnaires between the first and the sixth month, considering $\beta = 0.2$, $\alpha = 0.05$, $S_d = 4.51$, and

$\mu_d = 2.8$ (SD and mean for paired difference). However, considering a possible dropout of 20%, the sample size was determined to be 24 cases in each group.

$$(n' = n \times \frac{1}{1-p}) = (z_{1-\alpha/2} + z_{1-\beta})^2 S_d^2 / \mu_d^2 = 20N$$

$$\alpha = .05, 1 - \beta = 0.8, z_{1-\alpha/2} = 1.96, z_{1-\beta} = 0.84$$

A total of 48 patients were included in the study and divided into two groups of 24 persons based on the randomization table. Patients with the complaint of urinary incontinence referred to Hazrat Zaynab Clinic affiliated to Shiraz University of Medical Sciences were entered the study. The questionnaire containing information such as having stress or urge incontinence, quality of urination (how to start urine, bladder emptying, hesitancy, and nocturnal dysfunction), the amount of fluid intake and urination, urine problems in intercourse, prolapse, gas or fecal incontinence, pelvic organ Quantification test, and vaginal length measurement was filled. Urinalysis, urine culture, and fasting blood glucose were also checked. In this study, urinary stress incontinence was detected based on history, having it less than 12 times a day, positive urinary incontinence test with sneezing, pelvic organ prolapse quantitation system (POP-Q), minimum bladder volume of 200 cc in the urodynamic test, the presence of urethral mobility, and the volume of urine remaining (PVR less than 150 cc).

Inclusion criteria were as follows: being 21 to 45 years of age, having urinary stress incontinence for at least 3 months, tendency towards surgery, negative urinalysis, and willingness to participate in the study.

Exclusion criteria included urine obstruction, uterine prolapse, medical problem, previous pelvic surgery, and bladder capacity less than 200 cc.

The patients in the first group underwent urodynamic test. First, the drain schedule was given to the patient 24 hours before the surgery. Then, bladder sensation, capacity of the bladder, maximal bladder capacity, contractile force, nervous and muscle coordination between the muscles and the bladder valve and the function of the urethra were recorded in the urodynamic test.

The second group had operation based on the results of the I-QOL questionnaire. After TOT operation, both groups were evaluated one month and 6 months after surgery and compared with each other, based on the I-QOL questionnaire whose validity and reliability were assessed by Tehran University of Medical Sciences in Iran. Statistical analysis was performed using SPSS version 18.0 and $P < 0.05$ was considered to be statistically significant.

Results

In the present study, 48 patients with TOT surgery due to incontinence symptoms were followed. There was no

significant difference between the two groups in terms of age, body mass index (BMI), gravida, and incontinence duration (Table 1).

Both general (14%) and spinal anesthesia (86%) were used, all of which had posterior vaginal wall repair.

The duration of the TOT surgery was 10 to 20 minutes. The complications were divided into 3 categories of during operation, early, and late (after discharge and six months after surgery) (Table 2).

The rate of total perioperative complications was low. There were no cases of bladder, intestinal, and urethral damage. Cystoscopy was needed in two patients and no damage to the urethra or hematoma was detected. Moreover, 5 cases of urinary retention were reported which were resolved with catheter within 48 hours; however, none of the patients needed tape removing due to retention.

The average admission duration was one to two days after surgery, and no complication was observed in the

Table 1. Demographic Data of the Participants

Variables	
Age, mean \pm SD	37 \pm 6.46
Parity, mean \pm SD	3 \pm 2.4
BMI, mean \pm SD	28 \pm 2.3
Duration of symptoms (y)	
<1, No. (%)	2 (4.2)
1-5, No. (%)	25 (52)
>5, No. (%)	21 (43.8)

Table 2. Complications of the Surgery

Complications	No. (%)	
During operation	Bladder injury	0 (0)
	Ureter injury	0 (0)
	Bleeding >200 cc	2.1 (1)
	Perforation of the external vaginal wall	0 (0)
	Total	2.1 (1)
Late complication after discharge	Cellulitis	0 (0)
	Hematoma	0 (0)
	Urinary retention	10.41 (5)
	Pain leading to readmission	0 (0)
	Tearing of surgical tape	0 (0)
	Total	5 (10.41)
Late complication after 6 months	Recurrence of SUI	2.1 (1)
	Inguinal abscess	0 (0)
	Inguinal pain	0 (0)
	Tape removal	0 (0)
	Total	2.1 (1)

Table 3. Level of Satisfaction After 1 and 6 Months

	1 Month Post Operation			6 Months Post Operation		
	Urodynamic Test (n=24)	Questionnaire (n=24)	P Value	Urodynamic Test (n=24)	Questionnaire (n=24)	P Value
Urinary problems	60.6±2.9	61.8±2.7	0.14	62.8±1.6	63.8±3.6	0.22
Psychiatry	16.6±1.8	17.6±1.2	0.028	17.9±1.8	18.5±1.5	0.216
Social	25.1±2.0	25±1.7	0.852	25.2±1.6	25.3±1.8	0.839
Total score	102.4±4.5	104.5±3.2	0.069	106±2.9	107.7±3.8	0.088
Total score/100	81.6±4.6	83.9±3.3	0.053	85.4±3	87.2±4	0.084

longer follow-up period that was 6 months later. The QOL evaluation was performed one month and 6 months after surgery in both groups. The scores of quality of life questionnaires were significantly high after treatment in both groups. The difference between the two groups was not dependent on vaginal synchronous surgery, parity, age, and BMI

According to this questionnaire, patients' quality of life, one and six months after the operation, was evaluated in three dimensions in both groups and the satisfaction in each group one and six months post operation was finally compared with each other (Table 3 and 4).

Discussion

This study evaluated the outcome of TOT surgery by the I-QOL questionnaire. The outcome in groups of the study was acceptable and this did not have any relationship with the way of pre-operative urinary incontinence evaluation. Therefore, performing the urodynamic test is not necessary because of wasting time and imposing cost. This questionnaire included a short-term and long-term morbidity assessment of mental and social improvement and objective and subjective improvement with a focus on the quality of life assessment.

Improving the quality of life of both groups after TOT surgery was not dependent on BMI and parietal cell number. In a study, Deval observed objective improvement (94%) in the groups, which is in line with the results of this study.⁷

Agarwal et al, with a sample size of 72 patients, reported better outcomes in the group which had pre-operative urodynamic test.⁸ Weber et al⁹ and Laurikainen & Kiilho¹⁰ showed that preoperative urodynamics did not improve the outcome of surgery in urinary incontinence patients treated with TOT. However, Patel and Chapple⁹ reported better outcomes in patients who had done this test.

Some medical diseases like diabetes lead to detrusor underactivity; in these patients, mid urethral slings like TOT predict postoperative voiding dysfunction. One of the causes of urinary frequency and incontinence which results in overflow bladder is low capacity.¹⁰ Since these patients could not enter this study due to exclusion criteria, the

Table 4. Comparison of the Level of Satisfaction (Total Score) Between 2 Groups

	Urodynamic test (n=24)	Questionnaire (n=24)	P Value
1 month post operation	81.6±4.6	83.9±3.3	0.052
6 months post operation	85.4±3	87.2±4	0.084

urodynamic test for patients with no significant prolapse and underlying disease was not necessary.

Conclusion

The present study focused on the specificity and sensitivity of patient complaints in questionnaires. The urodynamic test is merely a test that provides additional information about the symptoms of the lower urinary tract. It is not expected to play a role in improving the outcome of the surgery but imposes additional costs on the patients. It is not necessary to do the test before the TOT surgery in patients with urinary incontinence, but we should consider the point it is acceptable in women who do not have a medical disease in this screening. Considering the controversy in the results of studies, further studies with a larger sample size are recommended.

Ethical Approval

Written informed consent was obtained from all participants. The study protocol has been approved by the Ethics Committee of Shiraz University of Medical Sciences (IR.SUMS.MED.REC.1395.s13).

Conflict of Interest Disclosures

None.

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Authors' Contribution

All authors contributed to the study design, data collection, data analysis, data interpretation, and writing the manuscript.

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References

1. Serati M, Cattoni E, Siesto G, Braga A, Sorice P, Cantaluppi S, et al. Urodynamic evaluation: can it prevent the need for surgical intervention in women with apparent pure stress urinary incontinence? *BJU Int.* 2013;112(4):E344-50. doi: 10.1111/bju.12007.
2. Nager CW, Brubaker L, Litman HJ, Zyczynski HM, Varner RE, Amundsen C, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. *N Engl J Med.* 2012;366(21):1987-97. doi: 10.1056/NEJMoa1113595.
3. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology of lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. *Am J Obstet Gynecol.* 2002;187(1):116-26. doi: 10.1067/mob.2002.125704.
4. Digesu GA, Hendricken C, Fernando R, Khullar V. Do women with pure stress urinary incontinence need urodynamics? *Urology.* 2009;74(2):278-81. doi: 10.1016/j.urology.2009.01.089.
5. Weber AM, Taylor RJ, Wei JT, Lemack G, Piedmonte MR, Walters MD. The cost-effectiveness of preoperative testing (basic office assessment vs. urodynamics) for stress urinary incontinence in women. *BJU Int.* 2002;89(4):356-63. doi: 10.1046/j.1464-4096.2001.01687.x.
6. Laurikainen E, Kiilholma P. The tension-free vaginal tape procedure for female urinary incontinence without preoperative urodynamic evaluation. *J Am Coll Surg.* 2003;196(4):579-83. doi: 10.1016/s1072-7515(02)01904-x.
7. de Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. *Eur Urol.* 2003;44(6):724-30. doi: 10.1016/j.eururo.2003.09.003.
8. Agarwal A, Rathi S, Patnaik P, Shaw D, Jain M, Trivedi S, et al. Does preoperative urodynamic testing improve surgical outcomes in patients undergoing the transobturator tape procedure for stress urinary incontinence? a prospective randomized trial. *Korean J Urol.* 2014;55(12):821-7. doi: 10.4111/kju.2014.55.12.821.
9. Patel AK, Chapple CR. Urodynamics in the management of female stress incontinence-which test and when? *Curr Opin Urol.* 2008;18(4):359-64. doi: 10.1097/MOU.0b013e3283023c0e.
10. Natale F, Illiano E, Zucchi A, Balzarro M, La Penna C, Costantini E. Transobturator mid-urethral sling in females with stress urinary incontinence and detrusor underactivity: effect on voiding phase. *Int Urogynecol J.* 2019;30(9):1519-25. doi: 10.1007/s00192-019-03871-7.