

Can Pre-Operative Urodynamic Study Predict the Successful Outcome of Tension Free Vaginal Tape (TVT) Operation in Thai Women with Stress Urinary Incontinence?

Suvit Bunyavejchevin MD, MHS*

* Urogynecology Unit, Department of Obstetric and Gynecology,
Faculty of Medicine, Chulalongkorn University

Objective: To study the preoperative urodynamic parameters whether it can predict the outcome of TVT operation in Thai women with stress urinary incontinence (SUI).

Study design: Cohort study.

Material and Method: Twenty five Thai women undergone TVT from January to December 2004 at Bumrungrad Hospital were included in the present study. Urodynamic studies were done pre-operatively. The TVT operations were carried out with spinal anesthesia. The follow-ups at one, three, and six months were scheduled.

Results: At six months after the operation, the subjective cure rate was 72% (18/25) and 28% (7/25) had the improved symptoms. Multivariate regression analysis showed the valsava leak point pressure (VLPP) of less than 60 cm H₂O to be associated with the 0.6-fold (0.3-0.9) risk of having successful outcome (being cured). Anyhow, 7 cases of women not being cured still had improved symptoms and were satisfied with the operation.

Conclusion: The present results confirmed the usefulness of pre-operative urodynamic study in prediction of the outcome of TVT. Low VLPP (<60 cm. H₂O) was associated with poorer outcome of TVT operation in Thai women.

Keywords: Predicting factor, TVT, Stress incontinence

J Med Assoc Thai 2005; 88 (11): 1493-6

Full text. e-Journal: <http://www.medassocthai.org/journal>

Urinary incontinence is a highly prevalent condition affecting 14-25% of all women^(1,2). Stress urinary incontinence (SUI), the involuntary loss of urine during increased abdominal pressure in the absence of detrusor overactivity on urodynamic investigation, was diagnosed in > 50% of incontinent women^(1,3). Many surgical techniques have evolved for the treatment of SUI, with varying success rates⁽⁴⁾. Tension free vaginal tape operation is a minimally invasive operation⁽³⁾ that is now becoming one of the most commonly performed operations for stress urinary incontinence worldwide. Based on the integral theory⁽⁶⁾, the aim of this technique was to reinforce the pubourethral ligaments and the

suburethral vaginal hammock as well as the connections of the latter to the pubococcygeus muscles. The urethral support was restored by the synthetic sling at mid urethral level. There were reports of high success rates of 85-90%⁽⁷⁻¹⁰⁾. However, there are few reports of the predictive value of pre-operative urodynamic study in predicting the successful outcome. The aim of the present study was to study the predictive value of pre-operative urodynamic parameters whether they can predict the outcome of the TVT operation or not.

Material and Method

A cohort study in 25 Thai women with SUI from January to December 2004 was conducted at the urogynecology clinic, Bumrungrad Hospital, Bangkok, Thailand. Patients underwent a history and physical examination, urine culture, 3-day frequency-volume

Correspondance to : Bunyavejchevin S, Department of Obstetric & Gynaecology, Faculty of Medicine, Chulalongkorn University, Rama IV Rd, Bangkok 10330 Thailand. Phone: 0-2256-4241, Fax: 0-2254-9292, E-mail: suvit.b@chula.ac.th

chart, uroflowmetry, post void residual urine measurement, multichannel urodynamic study and valsalva leak point pressure (VLPP) measurement. Exclusion criteria included mixed or only urge incontinence. Urodynamic descriptions conformed to the standards of ICS⁽¹⁾. Pressure flow urodynamic studies were performed with a 7 fr urethral and a catheter in the rectum. Non-invasive urine flow and pressure flow studies were performed in the seated position. The Andromeda Ellipse Urodynamic system (Andromeda Medicine System GmbH, Freistat, Germany) was used for the urodynamic study. All studies were performed and reviewed by the author. Patients were considered totally cured when they were free of all stress urinary incontinence symptoms and cough tests in the supine and standing positions were negative. Moreover, the totally cured patients reported that the use of hygienic pads was not necessary. The operation was noted as a failure if the patient still reported urine leakage during increase in intra-abdominal pressure, the cough test with a comfortably full bladder was positive, and women who had to change their pads because of being wet during the day. In the "improvement group" the cough

test was negative but the patients still experienced stress urinary leakage (much less frequently than previously) and pads were occasionally wet.

Follow up at 3, 6 months were scheduled. The effectiveness of the TVT operation were assessed at 6 month periods.

Statistical analysis

All statistical analyses were performed using the Statistical package for Social Sciences version 11.0 (SPSS 11.0, Chicago, IL) the unpaired t-test and the Fisher's Exact test were used for univariate analysis. Multiple logistic regression analysis were used for multivariate analysis. Statistical significance was determined at $p < 0.05$.

Results

There was no statistical difference in the patient's characteristics (Table 1). Among the pre-operative urodynamic parameters, only the number of cases with VLPP < 60 cm H₂O was different between the groups (Table 2). After multivariate analysis, the VLPP < 60 cm H₂O were associated with a 0.6 fold-risk

Table 1. Patient's Characteristics (n = 25)

	Patients with cure mean \pm SD (n = 18)	Patients with improvement mean \pm SD (n = 7)	p-value
Age (yrs)	52.1 \pm 12.6	53.0 \pm 5.3	NS
BW (kg)	62.4 \pm 8.5	66.8 \pm 11.9	NS
Height (cm)	159.1 \pm 7.9	157.2 \pm 6.8	NS
BMI (kg/cm ²)	26.9 \pm 4.2	24.6 \pm 2.7	NS
Duration of SUI (yrs)	3.2 \pm 2.0	4.5 \pm 1.3	NS

Table 2. Urodynamic parameter pre-operative (univariate analysis) (n = 25)

	Patients with cure (n = 18)	Patients with improvement (n = 7)	p-value
Free-flow uroflowmetry			
Q max (ml/s)	18.7 \pm 9.9	13.1 \pm 8.5	NS
Time to Q max (s)	8.9 \pm 6.9	4.6 \pm 1.7	NS
Flow time (s)	9.9 \pm 5.9	7.2 \pm 5.9	NS
Pressure-flow study			
Q max (ml/S)	2.2 \pm 9.9	10.4 \pm 4.3	NS
Pdet Qmax (cm H ₂ O)	3.6 \pm 48.4	32.5 \pm 8.9	NS
Pdet max (cm H ₂ O)	49.1 \pm 29.9	31.4 \pm 21.8	NS
First sensation (ml)	405.2 \pm 183.1	244.8 \pm 114.7	NS
Maximal bladder capacity (ml)	358.2 \pm 75.2	411.2 \pm 118.4	NS
Postvoid residual urine	30.5 \pm 48.35	25.7 \pm 15.1	NS
Valsava leak point pressure (VLPP) < 60 cm H ₂ O	7/18 (38.8%)	6/7 (85.7%)	< 0.05

Table 3. Multivariate analysis

Factors	Relative risk	95%CI	p-value
VLPP < 60 cm H ₂ O	0.6	(0.3-0.9)	<0.05

of having a successful outcome (Table 3). The success rate in women with VLPP < 60 cm H₂O was 7/13 (53.8%) while VLPP ≥ 60 cm H₂O was 11/12 (91.6%).

Discussion

In the present study, there was no case of voiding dysfunction as in other reports^(12,15). This may be due to the technique during the pulling of prolene mesh. The author used scissors to prevent too much tension and left a gap between the mesh and the mid urethra. So the author could not find the predictors for the voiding dysfunction problem. In order to detect the factors to this problem, additional studies, including a larger sample size were needed.

The author found a lower success rate in patients with low VLPP (< 60 cm H₂O) than in patients without this factor. Patients with low VLPP (< 60 cm H₂O) tended to have a low urethral pressure profile and significantly worse stress leakage. There was a report of a better result in the sling operation than the colposuspension⁽¹⁶⁾. But the success rate was lower in women with low VLPP after TVT operation⁽¹⁷⁻¹⁹⁾. There are many reports of the association between low VLPP and the outcome of TVT^(18,19). But some studies could not find any association⁽²⁰⁾.

From the present study, the author found only low VLPP to be the factor associated with a poorer outcome. In the improved cases, the women were still satisfied with the results that were much better than before the treatment. The present study confirmed the usefulness of pre-operative urodynamic study before the TVT operation in predicting the success outcome and pre-operative counselling to the patients.

Conclusion

The low VLPP (< 60 cm H₂O) was associated with a poor outcome of the TVT operation in Thai women.

Acknowledgements

The author wishes to thank Prof. Sinn Anuras, MD., Group medical director, Sutat Kolkijkovin, MD., chief of Obstetrics and Gynecology Department, Bumrungrad Hospital for allowing access to the patients' database. The author also wishes to thank

Ms. Anothai Kingmanee, Ms. Korrawan Rakchanangam, Mr. Leigh Mummery, GLS company limited and the nursing staff of the Obstetrics and Gynecology Department for the assistance in the Urodynamic study setup.

References

1. Brocklehurst JC. Urinary incontinence in the community-analysis of a MORI poll. *BMJ* 1993; 306: 832-4.
2. Thomas MT, Plymat KR, Blannin J. Prevalence of urinary incontinence. *BMJ* 1980; 281: 1243-5.
3. Keane Dp, Eckford SD, shepherd AM, Abrams P. Referral patterns and diagnosis in women attending a urodynamic unit. *BMJ* 1992; 305: 808.
4. Black NA, Downs SH. The effectiveness of surgery for stress incontinence in women: a systematic review. *Br J Urol* 1996; 78: 497-510.
5. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J* 1996; 7: 81-5.
6. Petros PE, Ulmsten UI. An integral theory and its method for the diagnosis and management of female urinary incontinence. *Scand J Urol Nephrol Suppl* 1993; 153: 1-93.
7. Ulmsten U, Johnson P, Reazpour M. A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol* 1999; 106: 345-50.
8. Wang AC, Lo TS. Tension-free vaginal tape. A minimally invasive solution to stress urinary incontinence in women. *J Reprod Med* 1998; 43: 429-34.
9. Ulmsten U, Falconer C, Johnson P. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J* 1998; 9: 210-3.
10. Bunyavehchevin S, Santinagamkun S, Wisawasukmongchol W. The three years results of tension free vaginal tape (TVT) for the treatment of stress urinary incontinence in Thai women. *J Med Assoc Thai* 2005; 88: 5-8.
11. Abrams P, Blaivas JG, Stanton SL. The standardization of terminology of lower urinary tract function. The international continence society committee on standardization of terminology. *Scand J Urol Nephrol* 1988; 114[Suppl]: 5-19.
12. Karram MM, Segal JL, Vassallo BJ, Kleeman SD. Complications and untoward effects of the tension-free vaginal tape procedure. *Obstet Gynecol* 2003; 101: 929.

13. Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol* 2002; 81: 72-7.
14. Austin P, Spyopoulos E, Lotenfoe R, Helal M, Hoffman M, Lockhart JL. Urethral obstruction after anti-incontinence surgery in women: evaluation, methodology, and surgical results. *Urology* 1996; 47: 890-4.
15. Romanzi LJ, Balivas JG. Protracted urinary retention necessitating urethrolysis following tension-free vaginal tape surgery. *J Urol* 2002; 164: 2022-3.
16. Hsieh GC, Klutke JJ, Kobak WH. Low valsalva leak-point pressure and success of retropubic urethopexy. *Int Urogynecol J* 2001; 12: 46-50.
17. Abdel-Hady ES, Constantine G. Outcome of the use of tension-free vaginal tape in women with mixed urinary incontinence, previous failed surgery, or low valsalva pressure. *J Obstet Gynaecol Res* 2005; 1: 38-42.
18. Rezapour M, Falconer C, Ulmsten U. Tension-free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD): a long-term follow up. *Int urogynecol J* 2001; 12(Suppl 2): S12-4.
19. Haab F, Sananes S, Amarenco G, Ciofu C, Uzan S, Gattegno B, et al. Results of the tension-free vaginal tape procedure for the treatment of type II stress urinary incontinence at a minimum follow up of 1 year. *J Urol* 2001; 165: 159-62.
20. Cetinel B, Demirkesen O, Onal B, Akkus E, Alan C, Can G. Are there any factors predicting the cure and complication rates of tension-free vaginal tape? *Int Urogynecol J* 2004; 15: 188-93.

การตรวจวัดโรไดนามิกส์ก่อนทำการผ่าตัดในการทำนายผลลัพธ์หลังการผ่าตัด tension free vaginal tape (TVT) ในสตรีไทยที่เป็นโรคโอบซามปัสสาวะเล็ด

สุวิทย์ บุญยะเวชชีวิน

วัตถุประสงค์: เพื่อศึกษาค่าการตรวจวัดโรไดนามิกส์ ก่อนทำการผ่าตัดว่าจะสามารถทำนายถึงผลลัพธ์หลังการผ่าตัด TVT ในสตรีที่เป็นโรคโอบซามปัสสาวะเล็ด ได้หรือไม่

วิธีการศึกษา: เป็นการศึกษาชนิดไปข้างหน้า

วัสดุและวิธีการ: ทำการศึกษา สตรีไทย 25 คนที่ได้รับการทำผ่าตัด TVT ระหว่างเดือน มกราคม ถึง ธันวาคม พ.ศ.2547 ที่โรงพยาบาลบำรุงราษฎร์ ทุกรายจะได้รับการทำผ่าตัด TVT โดยการให้ยาสลบโดยวิธีฉีดยาเข้าช่องน้ำไขสันหลัง ทำการตรวจติดตามที่ตาม 1, 3 และ 6 เดือน

ผลการศึกษา: ที่เวลา 6 เดือนหลังผ่าตัด, โอกาสหายขาดของการผ่าตัด(ไม่มีอาการปัสสาวะเล็ดเวลา โอบซาม) คือ 72% (18/25) และ 28% (7/25 ราย) พบมีอาการดีขึ้น (ยังมีปัสสาวะเล็ดอยู่แต่อาการดีขึ้นกว่าก่อนผ่าตัด) จากการวิเคราะห์ข้อมูลโดย Multivariate analysis พบว่า ค่า Valsalva leak point pressure (VLPP) ต่ำกว่า 60 cm H₂O มีความสัมพันธ์ เป็น 0.6 เท่าของโอกาสที่จะหายขาดหลังการผ่าตัด (ไม่มีปัสสาวะเล็ดเวลาโอบซาม) อย่างไรก็ตาม ในรายที่มีปัสสาวะเล็ดอยู่หลังการผ่าตัดพบว่ามีอาการดีขึ้นกว่าก่อนผ่าตัดและพอใจกับผลการผ่าตัด

สรุป: จากการศึกษาพบว่า การตรวจวัดโรไดนามิกส์ ก่อนผ่าตัดมีประโยชน์ในการทำนายผลลัพธ์ของการผ่าตัด TVT ค่า VLPP < 60 cmH₂O มีความสัมพันธ์กับผลการผ่าตัดที่จะหายขาดน้อยกว่าในการผ่าตัด TVT ในสตรีไทย ที่มีภาวะโอบซามปัสสาวะเล็ด