Han H C¹, Rajendra M², Lee L C¹, Tseng A¹, Wong H F¹

1. KK Women's & Children's Hospital, Singapore, 2. Selayang Hospital, Batu Caves, Malaysia

EFFECT OF VARYING BODY MASS INDEX (BMI) ON TENSION FREE VAGINAL TAPE OBTURATOR (TVTO) - OUTCOME AND COMPLICATIONS

Hypothesis / aims of study

High body mass index (BMI) has been associated with an increased risk of developing urinary incontinence. In the literature, studies comparing the Tension-free Vaginal Tape (TVT) with the more recently developed Trans-Obturator Tape (TOT) showed varied reports of the relationship between BMI and the success of surgery [1]. However there is a paucity of data on the relationship of BMI to the success of the TVTO midurethral sling procedure [2].

As midurethral slings are fast becoming the gold standard for the surgical treatment of Stress Urinary Incontinence (SUI), it would be useful to determine if there is a reduced success rate and increased complication rate associated with the use of these slings in women with an increased BMI. This would help to improve counselling as to the likely outcome of their surgery, and also to encourage weight loss prior to offering surgery in this group of women in the hope of improving surgical outcome. The aim of this study was to determine if varying BMI affects the outcome and complications of TVTO at 6 months.

Study design, materials and methods

All women who underwent TVTO between January 2004 and December 2006 were recruited into the study. Pre-operative evaluation consisted of history taking, documentation of BMI, abdominal and pelvic examination, cough stress test (CST) and urodynamic study (UDS). Post-operative evaluation consisted of history taking, abdominal and pelvic examination, CST and UDS at 6 months.

BMI was recorded as actual BMI and then divided into categories according to the Singapore BMI categorization revised in 2005 [3]. 3 groups of patients with varying BMI (the normal weight group (Group B), the overweight group (Group C) and the obese group (Group D) were compared to determine if varying BMI had an effect on TVT-O success and complication rates. BMI distribution at 6 months follow-up was also documented.

Patient demographics, operative characteristics and intra-operative complications were detailed for different BMI categories. Mean duration of surgery for isolated TVTO and TVTO with concomitant surgery, mean blood loss, intra-operative complications, mean duration of stay, mean number of catheterization days, incidence of voiding difficulty, pyrexia, groin and thigh pain were compared between the 3 BMI groups. Post-operatively, the presence of groin or thigh pain, vaginal tape erosion, voiding difficulty, need for tape loosening or division, and de novo urgency urinary incontinence was detailed at 6 months and compared between the 3 BMI groups.

Subjective cure, improved and failure rates; and objective cure and failure rates with CST and UDS were documented at 6 months follow-up and compared between the 3 BMI groups.

Results

There were a total of 422 TVTO patients. 3 patient case notes were unavailable for review and 5 patients did not have BMI documented. These 8 patients were excluded from the study. Out of the remaining 414 cases, 175(42.3%) had an isolated TVTO procedure and 239(57.7%) had TVTO with concomitant surgery. 328(79.2%) patients came for review at 6 months. The duration of surgery ranged from 5 to 51 minutes with mean 14.0 ± 7 mins for the isolated TVTO group; and 9 to 223 minutes with mean 57 ± 36.0 mins for the TVTO with concomitant surgery group.

The mean duration of surgery was shortest in Group B, followed by Group C and Group D. Operative blood loss ranged from less than 10ml to 1100 ml. Intra-operatively, 1(0.4%) patient had an estimated blood loss of ≥1L. This patient was from Group C and had concomitant hysterectomy. Bladder perforation occurred in 2(0.5%) out of 414 patients, with 1 patient each from Group B and Group C. The number of patient catheterization days post operatively ranged from 0 to 15 days. 47(11.4%) patients had voiding difficulty, with 15.3% from Group B, 11.0% from Group C and 7.2% from Group D. Tape loosening was required for 2(0.5%) patients, 1 each from Group B and Group C. The readmission rate was 4.5%, 2.2% and 1.8% in Group B, Group C and Group D respectively.

During the initial post-operative period, 40(9.7%) patients had a temperature >37.5°. 11(27.5%) had temperatures of at least 38.0° which did not extend beyond the second postoperative day; and the highest incidence of 3.6% being in Group D followed by 2.2% in Group C and 1.8% in Group B. Peri-operatively, 174(42.0%) patients had thigh or groin pain. 154(88.5%) had pain for less than 1 week with the lowest incidence of 33.3% being in Group B. 20(11.5%) had pain for 1-2 weeks with the highest incidence of 7.2% being in Group D.

Respectively for Group B, C and D at 6 months: 4(4.7%), 5(3.4%) and 2(2.3%) patients had pain; 2(2.3%), 3(2.1%) and 1(1.2%) patient(s) had erosion; 0, 2(1.4%) and 0 patient(s) had voiding difficulty; and 1(1.2%), 5(3.4%) and 1(1.2%) patient(s) developed de novo urge incontinence. No patients had any major life threatening complications.

Respectively for Group B, C and D at 6 months: the subjective cure rate was 96.5%, 94.5%, 84.9%; the subjective improvement rate at was 3.5%, 5.5%, 14.0%; the subjective failure rate was 0%, 0% and 1.1%; the objective cure rate by CST was 97.7%, 98.6% and 95.3%; and the objective cure rate by UDS was 95.1%, 94.8% and 93.8%.

Interpretation of results

There were minimal intra-operative complications with a 0.5% bladder perforation rate and a 0.4% operative blood loss rate of ≥1L. Peri-operatively, 47(11.4%) patients developed voiding difficulty with 17(15.3%) patients coming from Group B – possibly due to the tendency to overcorrect. The readmission rate was hence also highest in Group B due to voiding difficulty. In the immediate post-operative period, 27.5% had significant pyrexia of >38.0° which did not persist beyond the second postoperative day and the highest percentage of 3.6% came from Group D.

Peri-operatively, most patients (88.5%) had pain lasting <1 week, with the lowest incidence of pain coming from Group B. At 6 months, the highest tape erosion rate came from Group B at 2.3%. This may be due to the tape lying closer to the vaginal mucosa in thinner patients.

The subjective cure rate was lowest (84.9%) in Group D, p=0.013. The objective cure rates by CST and UDS were lowest at 95.3% and 93.8% respectively in Group D, p>0.05.

Concluding message

Post-operatively at 6 months follow-up for TVTO continence surgery, there is lower incidence of pain, erosion, voiding difficulty and readmission for women with increased BMI. Cure rate is also lower.

References

- 1. Stav K, Dwyer PL, Rosamilia A, Schierlitz L, Lim YN, Lee J. (2010) Risk factors of treatment failure of midurethral sling procedures for women with urinary stress incontinence. Int Urogynecol J 21:149-155
- 2. Chen HY, Yeh LS, Chang WC. (2007) Analysis of risk factors associated with surgical failure of inside-out transobturator vaginal tape for treating urodynamic stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 18:443–447
- 3. "Revision of Body Mass Index (BMI) Cut-Offs In Singapore". (http://www.hpb.gov.sg/hpb)

Specify source of funding or grant	NONE.
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Centralised Institutional Review Board (CIRB)
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes