

A MULTICENTER PROSPECTIVE RANDOMIZED CLINICAL TRIAL COMPARING TENSION-FREE VAGINAL TAPE SURGERY AND NO TREATMENT FOR THE MANAGEMENT OF STRESS URINARY INCONTINENCE IN ELDERLY WOMEN

Hypothesis / aims of study

Stress urinary incontinence (SUI) is associated with aging and has greater repercussions on quality of life than on physical health. The aim of this study was to compare the quality of life of a group of elderly women suffering from SUI undergoing surgical treatment [TVT (Tension-Free Vaginal Tape)] versus a similar group of non treated incontinent women (control). Our primary hypothesis was that elderly women undergoing surgical treatment will have a better quality of life and satisfaction than non treated women as measured by the Incontinence Quality of life questionnaire (I-QoL), Patient Satisfaction questionnaire and Urinary Problems self-assessment tool.

Study design, materials and methods

This multicenter prospective randomized controlled trial was designed to compare a group of patients undergoing immediate TVT after randomization and a group where surgery was delayed by 6 months (control group). That study was approved by the 3 hospitals ethics committee. 69 enrolled women aged over 70 years initially consented to participate in the study. Parameters measured at every encounter (pre-randomization, 8-12 weeks and 6 months) consisted of a complete physical exam, uroflowmetry, cystometrogram, 24 hour pad test, cough stress test, three-day urinary diary, general health questionnaire, I-QoL questionnaire, Patient Satisfaction questionnaire and Urinary Problems self-assessment tool. The main outcomes measured were quality of life and patient satisfaction score (score correlates with degree of quality of life and patient satisfaction), urinary problems score (score correlates with degree of urinary problems) and peri-operative complications. The average value for the group was imputed when data was missing in the questionnaires. We used the Wilcoxon two sample test to compare the outcomes at 6 months because the data was not normally distributed.

Results

Patients were randomized to undergo immediate TVT surgery (n=35) or control (n=31). A total of 11 subjects were excluded from the analysis for the following reasons: three subjects were never randomized, three subjects were not followed at 6 months and five subjects did not complete the questionnaires required at each visit. This left 31 patients in the immediate surgery group and 27 subjects in the control group. The two groups had similar baseline characteristics in terms of age (76.5 vs. 75.4), I-QoL score (57.8 vs. 58.9), Patient Satisfaction score (2.5 vs. 2.9), and Urinary Problems score (11.1 vs. 12.4). The delayed surgery group had half as many subjects with an incontinence grade of only 1 (11.1% vs. 19.4%), but had no patients with Grade 3 incontinence (vs. 2 patients in the TVT surgery group). Peri-operative complications in the immediate surgery group were bladder perforation (22.6%), and estimated intra-operative blood loss was less than 50ml for 21 subjects and between 50-200ml for the remaining 10 subjects. Other major complications were post-operative urinary retention in four subjects (requiring a second procedure in three of them), urinary tract infection in one subject and constipation in one subject. The results at 6 months follow-up are shown in the table below (mean ± SD).

	TVT	Control	Mean difference (Control-TVT, 95%CI)	p-value
IQOL	96.5±15.5	61.6±19.8	-34.9 (-44.2, -25.6)	< 0.0001
Patient Satisfaction	8.0±2.7	2.0±2.4	-6.0 (-7.4, -4.7)	< 0.0001
Urinary Problems	4.5±4.3	11.6±3.5	7.2 (5.1, 9.2)	< 0.0001

The results were similar when we accounted for differences in baselines by using the change in score (6-month minus baseline) and are shown in the table below:

	TVT	Control	Mean difference (Control-TVT, 95%CI)	p-value
IQOL Change	38.7±22.4	2.7±16.4	-36.0 (-46.4, -25.5)	< 0.0001
Patient Satisfaction Change	5.5±3.5	-1.0±3.4	-6.4 (-8.2, -4.6)	< 0.0001
Urinary Problems Change	-6.6±3.9	-0.8±2.9	5.8 (3.9, 7.7)	< 0.0001

Interpretation of results

Despite an age-related higher risk for surgery, invasive treatment of stress urinary incontinence in elderly women is better than no treatment.

Concluding message

At 6 months post-randomization, the group of elderly women who underwent immediate TVT surgery had a significant improvement in quality of life, patient satisfaction and urinary problems compared to the group of women waiting for the same surgery.

FUNDING: NONE
DISCLOSURES: NONE

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the McGill University Health Center Ethics Committee, Sherbrooke University Ethics Committee, Laval University Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.