

THE CLINICAL EFFECTIVENESS OF TRANSOBTURATOR MIDURETHRAL SLING (T-SLING) WITH ADDITIONAL 2-POINT TAPE FIXATION PERFORMED ON INPATIENT AND OUTPATIENT BASIS.

Hypothesis / aims of study

Nowadays midurethral sling unconsidered a gold standard for stress urinary incontinence. Traditionally, this technology has been followed by hospitalization and inpatient convalescence. From both patient and physician perspective, this technique became increasingly popular due to accompanying by very high clinical effectiveness, fast recovery, no need of painful incisions or overnight hospital stays.

The aim of the study was to compare the efficacy and safety of transobturator monofilament sling (T-sling-Hernia Mesh, Italy) with additional 2-point tape fixation in the treatment of stress urinary incontinence in women operated on inpatient and outpatient basis.

Study design, materials and methods

Two hundred womens with stress urinary incontinence were included into the study. Patients randomly allocated to inpatient or outpatient group at a ratio of 1:1. All patients underwent clinical and urodynamic evaluation before surgical treatment, had a positive cough stress test and post-void residual urine was less than 10 ml. Excluded criteria as follow: previous urogynecological surgery, no detrusor overactivity on urodynamics, patients with advanced urogenital prolapse (pelvic organ prolapse-quantification scale [POP-Q] scale grade ≥ 2). In both groups 2 absorbable sutures parallel to the urethra were added to fix the tape and prevent displacement during tape tensioning. Surgery was done by 2 (TR;AW) surgeons. Using identical surgical technique, all patients had a monofilament tape inserted at the midurethra. Patients were discharged home after the first urination (outpatient group) or 2 days (inpatient group) postoperatively. Final clinical effectiveness was assess after 12 months follow up. Success was defined as lack of any leakage during coughing, a negative cough stress test. The subjective cure rate was determined by Sandvik test after 12 months.

Statistical analysis was performed using the Statistica 7.1 pl. The Shapiro-Wilk test was used to examine compatibility distribution. The Mann-Whitney U test was applied for statistical comparison of the results between outpatient and outpatient group. The χ^2 test was used to compare the results in Sandvik severity index. The results are shown as follows: the arithmetic means and standard deviation (SD). At the significance level of $p \leq 0.05$ was taken as the results statistically significant.

Results

There were no differences in patients' parity, rate of postmenopausal status, pelvic floor defects, preoperative bladder neck mobility and mean Valsalva leak point pressure in the preoperative urodynamic study. A comparison of the peri- and postoperative results comprising complications and symptoms of voiding function revealed no significant differences between the two groups. Operation time, change in hematocrit, spontaneous voiding time and urinary infection were also not different. There was no significant difference between the two groups in terms of the cure rate ($\chi^2=4,039$, $p=0,133$) [Tab.I]. The only difference referred to body mass index (mean $26,6\pm 3,9$ vs $28,67\pm 3,99$; $p<0,001$) and age ($50,48\pm 9,71$ vs $61,7\pm 9,2$; $p<0,001$) [Tab.II] in the inpatient versus outpatient group, respectively.

Interpretation of results

The main factor that determines the effectiveness of surgical treatment of stress urinary incontinence is proper surgical technique but not the time of hospitalisation. Tape fixation is a simple surgical maneuver that seems to improve transobturator sling effectiveness and does not markedly increase procedure duration or cost of the treatment.

Concluding message

Outpatient surgery for stress urinary incontinence using midurethral sling ensure the same cure and satisfaction rates as outpatient one, allow to reduce costs of treatment without compromising clinical efectivness

Tab.I. Subjective clinical effectiveness of T-sling between study groups.

Outpatients group n=99	Inpatients group n=93	Sandvik scale	Chi ²	p
87(87,88%)	75(80,65%)	slight	4,0386	0,13274
8 (8,08%)	7 (7,53%)	moderate		
4 (4,04%)	11(11,83%)	severe		

Tab.II.Demographical data of study groups.

	Age(years) Mean±SD	BMI(kg/m ²) Mean±SD	Parity(n) Mean±SD
Inpatient	61,7±9,2	28,67±3,99	2,65±1,21
Outpatient	50,48±9,71	26,6±3,9	2,37±1,2
Test Mann-Whitney	-6,92	-3,44	-1,88
P	0,0000001	0,00056	0,0588

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Committee Medical Univeristy of Lublin **Helsinki:** Yes **Informed Consent:** Yes