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CLINICAL EFFECTIVENESS OF RETROPUBIC (IVS-02) AND TRANSOBTURATOR (IVS-04) SLINGS IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE – A SEMI-RANDOMIZED TRIAL ON 398 PATIENTS

Hypothesis / aims of study

The aim of the study was to compare the clinical effectiveness of retropubic and transobturator tapes for surgical treatment of female genuine stress urinary incontinence (SUI).

Study design, materials and methods

Based on the data from our pilot study we calculated that each of the study group should count at least 180 patients assuming 75% power of the study. Therefore 537 women suffered from SUI were allocated into the study group. The criteria of enrolment to the study were: stress urinary incontinence as indicated by a full clinical examination, including a complete medical history, Gaudenz questionnaire, standard urodynamic evaluation, urinalysis, urine culture, a complete gynecologic examination, and cough provocation test in the supine and standing positions with a comfortably full bladder. Urodynamic tests were performed in seated position. A three channel vesical catheter 7Fr and rectal catheter was used. During cystometry, the bladder was filled at a constant rate of 40 - 50 ml per minute with 0,9% NaCl. Vesical and rectal pressures were recorded, as well as bladder sensation, detrusor stability and leak point pressures (LPP), during coughing and Valsalva maneuver. LPP was determined at 180 ml of bladder filling. If leakage was not observed it was repeated at every additional 100 ml of bladder filling. Urethral closure pressure (Pclos) and maximal urethral closure pressure (MUCP) were estimated during urethral pressure profile (UPP). The urodynamic tests were performed at a comfortably filled bladder, usually 150 ml. During the procedure the catheter was moved out at a rate of 1 mm per second.
The patients were divided into two study groups: I. retropubic sling IVS-02 and II. transobturator sling group – IVS-04. Both surgical techniques are already registered for the treatment of SUI and the Institutional Review Board approved the study design. The study group was free of any other gynecologic diseases, such as uterine myoma, ovarian cyst or severe uterine or vaginal prolapse (only patients in stage I and II according to the POP-Q classification were included in the study). Patients from both study groups did not differ according to demographic and urodynamic parameters – tab. 1.

Tab.1. Demographic and urodynamic parameters of patients in both study groups.

Parameter*	IVS-02	IVS-04	p-value (U Mann-Whitney test)
Age (years)	55.6±10.2	55.8±11.3	0.9
Parity (number)	2.6±1.2	2.6±1.1	0.9
PVR (ml)	13.3±22.9	13.2±22.7	0.9
VLPP (cm H_20)	67.9 ±23.1	69.8±24.8	0.6
MUCP (cm H_20)	50.3 ±19.2	52.4±20.5	0.4

*All parameters are given as mean ± SD.

The efficacy of the procedures was assessed by gynecologic examination and cough test in the supine and standing positions with a comfortably full bladder, which was done during check-up in the outpatient department in every woman. The follow-up visits were scheduled for 1, 4, 6, 12 and 18 months after surgery. 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 increases in intra-abdominal pressure, the cough test with a comfortably full bladder was positive, and the woman had to change her pads because of being wet during the day. In the improvement group the cough test was negative but patients still experienced stress urinary leakage (much less frequent than previously) and the pads were occasionally wet.
Statistical analysis was performed using U Mann-Whitney and chi square tests using Statistica package version 7.1 (StatSoft, Poland).

Results

After 18 months of follow up 398 patients were available for clinical check-up (201 – IVS-02 and 197 – IVS-04). We found out that there was no statistically significant difference in clinical efficacy between these two procedures (chi square = 1.88, p=0.39). In IVS-02 group 75.12% patients (n=151) remained dry (totally cured), 16.92% patients (n=34) reported significant improvement and 7.96 % patients (n=16) was considered as failure, whereas in IVS-04 group 74.11% patients (n=146) remained dry, 14.21% patients (n=28) reported significant improvement and 11.68% (n=23) patients was considered as failure.

Interpretation of results

On the basis of our work we concluded that both surgical techniques (retropubic and transobturator) are equally effective in the treatment of genuine female SUI. Most published data shows similar results clearly indicating that transobturator approach gives the same clinical effectiveness with much less intraoperative complications (mainly bladder perforation and no need for routine intraoperative cystoscopy).

Concluding message

On the basis of this clinical trial we can state that both procedures are equally effective in the treatment of SUI and since transobturator technique is much safer for the patients it should be the procedure of first choice in the treatment of female genuine SUI.

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Is this a clinical trial?	**Yes**

Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Comitee of Lublin Medical University**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**