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RANDOMIZED TRIAL TO COMPARE THE EFFICACY OF TVT-O AND SINGLE INCISION TAPE AJUST IN THE TREATMENT OF STRESS URINARY INCONTINENT WOMEN – TWO-YEAR FOLLOW-UP.

Hypothesis / aims of study
Tape surgical methods are at present considered the gold standard for surgical treatment of stress urinary incontinence, but there are some complications associated with them. In an attempt to reduce further the invasive nature of the procedure and the rate of complications, a new generation of tension-free vaginal tapes has been introduced, known as minitapes or single incision tapes. Unfortunately, the first generation of single incision tapes had lower efficacy compared to standard methods. This was explained with reference to the fixed length of the tape and the type of tape introducer, which was not suitable for all patients. The problem was solved in the third generation of single incision tapes, which have adjustable length and a special anchoring mechanism (Ajust). This tape is available on the market and is regularly used for the treatment of stress urinary incontinence worldwide. It is important to establish whether these new, less invasive surgical procedures really do minimize the unfavourable impact of surgical procedures on patients while achieving a comparable curative effect.
The aim of this study was to compare the efficacy of the use of tension-free vaginal tape - obturator (TVT-O) - and single incision tension-free vaginal tape - Ajust - in the treatment of urodynamic stress urinary incontinence (USI) at two-year follow up.

Study design, materials and methods
Between May 2010 and May 2012 100 women with proven urodynamic stress urinary incontinence were included in this randomized trial. For randomization the envelope technique was used. Before enrolment in the study all patients signed to indicate their informed consent. The patients were randomized into a TVT-O group (50) and an Ajust group (50). Based on pre-study statistical calculations it was indicated that the required sample size in each group was 45 patients.
All patients underwent a complete urogynecological investigation before the procedure (clinical examination, urodynamics, ultrasound examination), and they filled in the ICIQ and iQol questionnaires; after surgery, to evaluate their satisfaction with the procedure, VAS and Likert scales were added. Surgery was only offered if conservative therapy had been unsuccessful. Exclusion criteria were: predominant urge incontinence, urodynamic detrusor instability, previously failed anti-incontinence surgery, previous radiotherapy, postvoid residual volume (PVR) greater than 100 ml, bladder capacity less than 300 ml, stage III or IV pelvic organ prolapse according to the International Continence Society pelvic organ prolapse quantification system, planned concomitant surgery, age < 18.
The peri-operative complications were monitored. The intensity and length of postoperative pain was monitored using the visual analogue scale. The patients underwent an examination 3 months and one year after surgery.
Postoperative follow-up was terminated if the result of surgery was evaluated as a failure, and reoperation was then offered

Results
There were no significant differences in age, body mass index, parity, or history of surgery for gynecological disorders among the study participants. Preoperative urodynamic and QoL parameters were also not significantly different (Tab. 1).
There were no serious perioperative complications in either of the two groups. In the Ajust group there was a significantly lower intensity and shorter duration of postoperative pain compared to the TVT-O group.
At two-year follow up 48 patients were evaluated in the TVT-O group and 50 in the Ajust group. No differences in subjective cure rates and objective cure rates were observed (Tab. 2); the rates for no subjective stress leakage rates were 83.3% in the Ajust group and 82% in the TVT-O group, while the figure for negative stress test was 88% in the Ajust group and 87.5 in the TVT-O group (Tab. 2). In each group one failure and no tape protrusion was observed. In the Ajust group two patients mentioned de novo pain during intercourse (clinical examination revealed palpable painful anchor in the obturator membrane: one patient required surgical removal of the anchor).

Interpretation of results
The mid-term follow-up revealed the same objective cure rates in both groups, with lower intensity and shorter duration of postoperative pain in the Ajust group. Compared to the first generation of single incision tape TVT-S, we did not observe any decline in the cure rate over the time. Different anchoring mechanism, different insertion technique and the adjustable length of Ajust tape may increase the efficacy of this procedure. The major weakness of our study is that it was a single centre study on a selected patient population: larger multicentre studies are necessary to verify the results.
Concluding message
At two -year follow-up we did not find any statistical difference between subjective and objective outcome for single incision tape Ajust and TVT-O. In the Ajust group lower intensity and shorter duration of postoperative pain were observed.

Tab. 1 Pre-operative patient characteristics

	TVT-o	Ajust
N	50	50
Age, years	58.9±12.4	55.8±10.2
BMI , kg/m2	27.9±4.4	27.3±4.8
Parity	2±0.6	2.0±0.9
Prior Hysterectomy n%	17 (34%)	16 (32%)
Prior Vaginal wall repair	9 (18%)	6 (12%)
Mixed UI n/%	23 (46%)	22 (44%)
Urgency n/%	31 (62%)	27 (54%)
Sexually active	28 (56%)	34 (68%)
MUCP cm H20	54.0±20.8	55.5±22.5
Maximum Flow rate mL/s	26.8±13.8	23.5±11.7
ICIQ	14.6±2.5	14.7±2.5
iQoL	41.0±17.8	38.5±18.4

Values are given as mean ±SD or number of patient/%
MUCP – Maximal Urethral Closure Pressure
ICIQ- International Consultation on Incontinence Questionnaire

Tab.2 Two year subjective and objective follow up, Quality of life

	TVT-o	Ajust	p
Length of follow-up days	773.2±200.0	784.0±123.8	NS[a]
N	48	50	
Cured (5)	42 (87.5%)	42 (84%)	
Improved (4)	4 (8.3%)	7 (14%)	
No change (3)	2 (4.2%)	0	NS[a]
Worsened (1+2)	0 (0%)	1 (2.0%)	
ICIQ	3±3.89	2.2±3.2	NS[a]
Subjective stress negative	40 (83.3%)	41 (82%)	NS
iQoL	90.0±12.8	89.6±12.9	NS[a]
Urgency	22 (45.8%)	18 (36%)	NS[b]
Urgency Cured	12 (25%)	15 (30%)	NS[b]
De novo Urgency	4 (8.3%)	6 (12%)	NS[b]
VAS	93.7±16.3	93.2±16.2	NS[a]
Sexually active	22 (45.8%)	30 (60%)	NS
De novo dyspareunia	0	2 (6.7%)	NS[b]
Objective cure rates			
Stress test negative	42 (87.5%)	44 (88%)	NS[b]
Failure	1	1	NS[b]
Reoperation for SUI	1	0	NA[b]
Tape erosion	0	0	NA[b]

a Mann-Whitney test, bFisher test

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