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INNOVATIVE SINGLE INCISION SLING VERSUS ESTABLISHED TRANS-OBTURATOR SLING IN WOMEN WITH STRESS URINARY INCONTINENCE: TWO YEAR RESULTS IN PROSPECTIVE RANDOMIZED COMPARISON

Hypothesis / aims of study
The aim was to compare the efficacy and safety of an innovative single-incision sling (SIS) with the inside-out transobturator sling (TOT) in the treatment of female stress urinary incontinence (SUI) [1,2].

Study design, materials and methods
A prospective randomized trial was performed in a tertiary referral urogynecology center from January 2012 to December 2013. The study included women with pure urodynamic SUI. Patients were randomized to either the SIS (Ophira, Promedon) or the TOT (Gynecare TVT Obturator, Ethicon) anti-incontinence procedure. Surgery duration, blood loss, and groin pain scores (visual analogue scale, VAS) were recorded for each patient. The 2-year follow-up visit included objective (negative cough stress test, CST) and subjective (Patient Global Impression of Improvement score, PGI-I) cure parameters, postoperative de novo urgency (Patient Perception of Intensity of Urgency Scale, PPIUS), complications and the impact on the patient's life quality (short International Consultation on Incontinence Questionnaire, ICIQ-SF). To provide consistency and transparency, our study protocol was approved and registered according to CONSORT guidelines on ClinicalTrials.gov (no. NCT02506309).

Results
Of 285 patients assessed for eligibility, a total of 93 patients (32.6 %) were randomized into TOT (n=48) and SIS groups (n=45). Mean operative time for the TOT group was 21.4±6.0 min, while the SIS group operative period was slightly shorter at 20.1±5.9 min. Average blood loss during surgery did not differ significantly between either group (72.9±32.2 vs. 68.9±28.5, p=0.602). There were statistically significant differences in groin pain VAS scores between the TOT and SIS group three hours postoperative (5.6±1.8 vs. 3.1±2.1, p<0.001) and also at the twelve hour postoperative period (3.8±1.7 vs. 2.1±1.7, p<0.001); (Table 1). Eighty four women (92.5 %) completed the two years observation (range 23.8 -26.7 months) with seven "lost to follow-up" patients; four in TOT and three in the SIS group. After two years post surgery (Table 2), there were no significant differences in objective cure rates (86.3 % vs. 88.1 %; p=0.675) or patient-reported success rates (90.9 % vs. 90.5 %; p=0.916). Postoperative de novo urgency incidence analysis did not show significant differences between the groups (0.7±1.6 vs. 0.8±1.8; p=0.422). Quality of life investigation two years after surgery showed no significant difference in ICIQ-SF scores between the TOT and SIS groups (3.7±2.4 vs. 3.8±2.8; p=0.743, respectively). Mean change in ICIQ-SF scores before and after surgery was 11.2±3.6 in the TOT group and 11.0±3.7 in the SIS group (p=0.891). No severe intraoperative or major postoperative complications occurred in either group.

Interpretation of results
There were no significant differences between the SIS and TOT patient's cohorts in age, body mass index, parity and pre-operative quality of life assessment between the two groups. A statistically significant difference between the two groups was found in groin pain scores three and 12 hours postoperatively. After two years, there were no significant differences between both groups in objective cure rates or patient reported success rates. Incidence of postoperative de novo urgency did not differ between TOT and SIS patients. Both groups registered a significant improvement in quality of life.

Concluding message
The Ophira SIS procedure has 2-year success rates comparable to standard TOT with significantly less groin pain in the early postoperative period. Both methods were safe and effective in terms of postoperative urgency and life quality improvement.

Tables

Table 1.
Pre-operative patient characteristics and operative data

Characteristic[1]	**TOT** (n=48)	**SIS** (n=45)	**p-value[2]**
Age (years)	64.3±10.6	62.3±10.3	0.313
Body mass index (kg/m2)	29.4±6.2	28.5±6.5	0.375
Parity	2.4±1.1	2.3±1.4	0.492
Pre-operative ICIQ-SF score	15.1±3.1	14.8±2.5	0.684
Operating time (minutes)	21.4±6.0	20.1±5.9	0.231
Blood loss (ml)	72.9±32.2	68.9±28.5	0.602
Groin pain VAS 3 hours post operation	5.6±1.8	3.1±2.1	**<0.001**
Groin pain VAS 12 hours post operation	3.8±1.7	2.1±1.7	**<0.001**

Table 2.
Objective and patient-reported outcomes two years after surgery

Characteristic[1]	**TOT** (n=44)	**SIS** (n=42)	**p-value**[2]
Mean follow-up (months, mean±SD)	25.3±1.4	24.5±0.7	0.324
Negative CST (%)	38 (86.3 %)	37 (88.1 %)	0.675
Patient-reported success on PGI-I (%)	40 (90.9 %)	38 (90.5 %)	0.916
PGI-I score	1.3±0.7	1.2±0.9	0.527
PPIUS score	0.7±1.6	0.8±1.8	0.422
Postoperative ICIQ-SF score	3.7±2.4	3.8±2.8	0.743
ICIQ-SF change pre/postoperative (mean±SD)	11.2±3.6	11.0±3.7	0.891
Postoperative complications	0	0	-

[1] Absolute and relative frequencies for categorical variables, mean ± standard deviation for continuous variables; [2] Fisher exact test for categorical variables and Mann–Whitney U test for continuous and nominal variables;

References
1. Ogah J, Cody DJ, Rogerson L (2011)Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. Neurourol Urodyn 30:284–291.
2. Nambiar A, Cody JD, Jeffery ST (2014) Single-incision sling operations for urinary incontinence in women. Cochrane Database Syst Rev 6:CD008709.

Disclosures
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