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RANDOMISED TRIAL OF OPHIRA MINI-SLING SYSTEM AND UNITAPE FOR THE TREATMENT OF STRESS INCONTINENCE IN WOMEN. FIRST EXPERIENCES AFTER A FOLLOW-UP OF 6 MONTHS.

Hypothesis / aims of study

To compare the efficacy and safety of mini-sling system (Ophira, Promedon) and transobturator midurethral tape (Unitape, Promedon) as surgical treatment for stress urinary incontinence (SUI) in women.

Study design, materials and methods

Women with SUI and no prolapse >stage1 were randomized to have either Ophira or Unitape. Exclusion criteria were postvoid residual urine volume more than 100 ml, coagulation disorders, current urinary tract infection, sequelae of previous radiation therapy of the pelvis, anticoagulant therapy, vulvovaginitis, and anesthesia contraindication. The mini-sling Ophira procedure was carried out under local anesthesia according to published techniques. Cystoscopy was not mandatory, and no foley catheter was left in place. Two grams of cephalosporin and 500 mg of metronidazole were administered intravenously for infection prevention. The patients were discharged immediately after spontaneous voiding.
The transobturator sling Unitape was performed under regional anesthesia in an “outside-in” approach.
The primary outcome measure was objective cure rate 6 months after surgery, defined by a 1-hour pad-weighing test of <2 g and a negative stress test. Secondary outcome measure included quality of life and symptom severity scores (I-QOL and UDI-6 respectively) and rate of complications. Calculation of the sample size was performed based on a subjective cure rate for transobturator midurethral tape at our institution of 90%. Ethical committee approval was obtained and the study was registered in a public clinical trials. All patients provided written, informed consent.

Results

45 women had Ophira and 28 had Unitape. Results are summarized below.

Table 1. Baseline characteristics

	Ophira	Unitape	P value
Age (years)	52.9 (±9.5)	48.7 (±9.8)	0.07*
BMI (Kg/m2)	27.5 (±5.2)	28.5 (±4.9)	0.5*
Parity	3 (0-10)	3 (1-6)	0.2**
Previous surgery	8 (17.8%)	4 (14.3%)	1.0***
Postmenopausal	19 (42.2%)	10 (35.7%)	0.8***
Pre-op pad test (g)	24 (±26.5)	29.3 (±33.8)	0.5**
UDI-6 score	8.5(±2.5)	9.6(±2.4)	0.1**
Mean value pre-op VLPP (cmH2O)	72.3 (12-170)	74.9 (26-141)	0.7*

*Independent samples T test, **Mann-Whitney U test, ***Chi squared test

Table 2. Operative data/complications

	Ophira	Unitape	p value
Operating time (min)	27 (10-60)	29 (18-90)	0.6*
2 hr pain VAS (cm)	2 (0-10)	3 (0-10)	0.6*
1 week pain VAS (cm)	1.6 (0-8)	1.5 (0-6)	0.9*
Vaginal injury	0	0	
Urethral injury	0	1 (3.6%)	0.2**
Lydocaine intoxication	1 (2.2%)	0	0.4**

*Mann-Whitney U test, ** Fisher’s Exact test

At 6 months, data were available for 29 Ophira and 15 Unitape. Table 3 shows cure rate and problems experienced at 6 months.

Table 3. Six month cure rate/problems

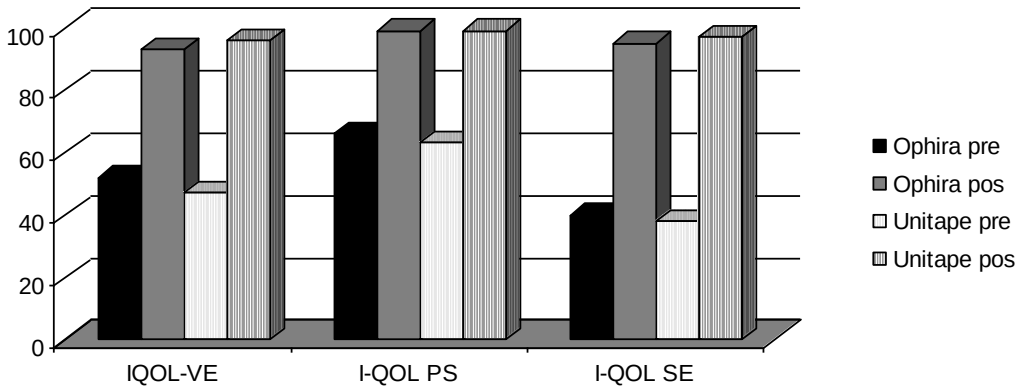
	Ophira	Unitape	p value
Objective cure (pad test <2g)	26 (90%)	15 (100%)	0.2*
Negative stress test	24 (82.8%)	15 (100%)	0.09*
Subjective cure “very much better”	25 (86.2%)	15 (100%)	0.1*
Pad test (g)	3.5 (0-56)	0.3 (0-2)	0.1***
Erosion	4 (16.8%)	1 (6.7%)	0.5**
De novo/worsening OAB	3 (10.3%)	0	0.2**
Retention	3 (10.3%)	0	0.2**
Hispareunia	1 (3.4%)	0	0.5**
Leg pain	0	4 (26.7%)	0.02**
UDI-6	2.0+2.5	0.1+0.5	0.01***

*Chi squared test, **Fisher’s Exact test, ***Mann-Whitney U test.

In the Ophira group four patients experienced mesh vaginal erosion less then 1,5 cm. From those, three patients underwent ambulatory mesh resection of the exposed area, and other 1 received treatment with local estrogen. One patient underwent half of the propylene column mesh resection due to partner dispareunia (hispareunia). Three patients had urinary retention, treated with mesh resection or cut, and one had spontaneous improvement. In the Unitape group one patient had mesh erosion, with ambulatory resection and four patients had leg pain. The symptom severity scores was statistically significant lower in the Unitape group.

Figure 1 shows I-QOL results. There was significant improvement in all domains and there was no statistically difference between the groups.

Figure1: I-QOL results.



Avoidance and limiting behavior (I-QOL-VE, p=0.18), psychosocial impact (I-QOL-PS, p=0.6), social embarrassment (I-QOL-SE, p=0.09).

Interpretation of results

The objective cure rate for Unitape and Ophira.was equivalent. Both methods improved the quality of life of women with stress urinary incontinence.

Concluding message

The efficacy of Mini Sling Ophira and Unitape is similar in early post-operatory follow-up. Subjects in this study will continue to be followed for twenty-four months.

References

1. Palma P, Riccetto C, Reges R, Fraga R, Miyaoka R, Hermann V, Marcondes T. Arcus to arcus microsling: technique and preliminary results. Int Urogynecol J Pelvic Floor Dysfunct. 2008;19(8):1133-6.
2. Jørgensen L, Lose G, Andersen JT. One-hour pad-weighing test for objective assessment of female urinary incontinence. Obstet Gynecol. 1987;69(1):39-42.
3. Moore PA, Hersh EV, Papas AS, Goodson JM, Yagiela JA, Rutherford B, Rogy S, Navalta L. Pharmacokinetics of lidocaine with epinephrine following local anesthesia reversal with phentolamine mesylate.Anesth Prog. 2008;55(2):40-8.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**NCT01094353**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Study was approved by UNIFESP Ethics Committee 0752/08**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**