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EFFICACY OF OPHIRA MINI SLING SYSTEM FOR STRESS URINARY INCONTINENCE: MIDTERM FOLLOW UP OF 124 PATIENTS IN A MULTICENTRE INTERNATIONAL CLINICAL TRIAL

Hypothesis / aims of study

Sling procedures have been around for decades in the management of female stress urinary incontinence (SUI), but only in the past decade they have become the preferred technique. The Ophira Mini Sling System is an anatomical approach that involves placing a midurethral low-tension tape anchored to the obturator internus muscles bilaterally at the level of the tendinous arc.
The aim of this presentation is to report up to two years follow up results of the use of Ophira Mini Sling System in an open international multicentre prospective trial.

Study design, materials and methods

From February 2008 to February 2011, 124 female patients, mean age = 54.7 years old (SD±9.9) with S UI, underwent treatment with Ophira Mini Sling System. 95/124 patients were followed for 24 months and 29/124 for at least 12 months.
The work-up included history, physical examination, stress test, standardized 1-h pad test, and preoperative urodynamic study. Also, patients were evaluated with two validated questionnaires: International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) and Urogenital Distress Inventory (UDI-6).
A minisling (Ophira Mini Sling System - Promedon), made of polypropylene monofilament mesh, held between two self-anchoring polypropylene columns in a fishbone design connected to two delivering needles was used.
The procedure was carried under local anesthesia in 87 (73.1%) patients, using 20 ml of 2% lydocaine solution, injected at the midurethra towards the vaginal fornix, advancing 2 cm in the obturator internus muscles. Eventually, general in 21 (17.6%) or regional anesthesia 11 (9.2%) patients was used, according to the anesthesiologist decision.
During the follow-up, patients were reviewed at 12 and 24 months as to urinary incontinence, lower urinary tract symptoms, and dyspareunia.
The objective evaluation included 1 hour pad test and stress test. For comparative purposes it was considered pad test: cure (<1g), improvement (loss of <50% of preoperative) and failure (loss> 50% of preoperative).
This study was approved by the ethical committee, and all patients signed a written consent.

Results

Until February 2011, 124 patients complete at least 12 months follow-up and 95 of those patients have more than 24 months of follow-up. Demographic data are: previous gestation 2.99 (SD ±2.0); post menopause 64.5%; previous anti-incontinence surgery 27.4%; Body Mass Index 27.9 (SD ±4.4); stress test was positive in 100% of the cases, VLPP preoperative 79.2 cmH_2O (SD ±26.6). The demographic data of all patients is presented in Table 1.

Table 1. Demographic data

Previous gestation (mean ± SD)	2.99 ± 2.0
Post menopause (%)	64.5%
Previous anti-incontinence surgery (%)	27.4%
Body Mass Index (mean ± SD)	27.9 ± 4.4

The mean pad test ranged from 12.5 g (SD ± 16.4) to 2.2 (SD ± 9) preoperatively and after 24 months of follow up respectively (*p <0.0005*). The scores of the ICIQ-UI SF ranged from 15.8 (SD ± 3.8) to 1.9 (SD ± 4.3) (*p<0.0005*) and UDI-6 ranged from 9.2 (SD ± 3.1) to 1.7 (SD ± 2.2) (*p<0.0005*). The mean operative time was 17.0 (SD ± 7.1) minutes (in to out surgical room).
Complications such as infection, severe bleeding or sexual dysfunction were not observed. Three patients presented lydocaine overdose symptoms which were treated conservatively.
Mesh exposure was observed in 4 patients (3.2%). All of them were less than 0.5 cm and they were treated by ambulatory resection of exposed area, of which two patients had been treated with local estrogen. Four patients have urinary retention, solved spontaneous (2 patients), treated with mesh excision (1 patient) and solved within the first week by sling loosening (1 patient). Nine patients (7.3%) have de novo urge incontinence, all treated with anti-cholinergic.
Using the pad test to objectively evaluate the patients after 24 months 81 (85.3%) patients were dry, 6 (6.3%) improved, and 8 (8.4%) was incontinent.

Table 2: Follow up

		Pre-op	12 months***	24 months***
N (N° patients)		124	124	95
Lost to follow-up – N (%)		N/A	1 (0,8)	6 (5,9)
PAD WEIGHT TEST 1 h (g)	**Mean (SD)**	12,54 (15,36)	1,44 (5,86)	2,23 (9,07)
	*p-value**	N/A	<0,0005	<0,0005
	Dry - N (%)	N/A N/A	103 (84,4)	81 (85,3)
	Improvement - N (%)	N/A N/A	9 (7,4)	6 (6,3)
	Failure - N (%)	N/A N/A	10 (8,2)	8 (8,4)
ICIQ (0-21)	**Mean (SD)**	15,75 (3,86)	3,04 (5,14)	1,92 (4,30)
	*p-value**	N/A	<0,0005	<0,0005
	Max	21,00	18,00	16,00
	Mín	5,00	0,00	0,00
UDI6 (0 a 18)	**Mean (SD)**	9,15 (3,11)	2,31 (2,99)	1,72 (2,22)
	*p-value**	N/A	<0,0005	<0,0005
	Max	18,00	12,00	8,00
	Min	3,00	0,00	0,00
COUGH STRESS TEST *p-value**<0,0005*	**Negative -** N (%)	0 (0,0)	110 (90,9)	82 (86,3)
	Positive - N (%)	90 (100,0)	11 (9,1)	13 (13,7)
RESIDUAL VOLUME	**Mean (SD)**	3,15 (7,77)	0,90 (3,47)	0,95 (4,09)

* Compared to Pre-op records – t-Student. ** Compared to Pre-op records – McNemar. *** No significant difference was found between the results at 12 or 24 months for PAD TEST WEIGHT, ICIQ, UDI-6 (ANOVA - $p = 0.05$) or CST (McNemar - $p = 0.05$).

Interpretation of results

The results let us to assume that the multipoint fixation arms provided primary and stable fixation of the sling over the time. The comparison of this serie with published data related to the transobturator tapes (2) suggests that the efficacy of Ophira Mini Sling System is quite similar. Otherwise, the most severe adverse events related to the transobturator route, such as infection and post-operative persistent pain were not observed. This can lead us to suppose possible advantages in the clinical setting. Future randomized studies would verify this hypothesis.

Concluding message

Ophira Mini Sling System is an effective option for the treatment of SUI, offering reliable fixation and stability of the device and represents a real advance towards an in office procedure.

Disclosures

Funding: Promedon provides material and statistics. **Clinical Trial:** Yes **Public Registry:** Yes **Registration Number:** SISNEP, 0016.0.146.000-08 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** CEP - Ethics and Research Committee of the State University of Campinas **Helsinki:** Yes **Informed Consent:** Yes