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WHAT IS THE BEST INDICATION FOR SINGLE INCISION MINI SLINGS? INSIGHTS FROM 2 YEAR FOLLOW-UP MULTICENTRIC INTERNATIONAL STUDY

Hypothesis / aims of study

The Ophira Mini Sling System (Figure 1) is an anatomical approach that involves placing a midurethral low-tension tape anchored to the obturador internus muscles bilaterally at the level of the tendinous arc (Figure 2). Success rates in different subsets of patients are still to be defined. Our hypothesis is that previous surgery and patient age can impact on the final results.

Study design, materials and methods

Analysis was based on a multicenter prospective study. Endpoints for analysis included objective measurements (1-hour Pad Weight Test and Cough Stress Test) and questionnaires (ICIQ-SF and UDI-6). Data was collected from 124 women included in this study who have completed at least the 1 year follow-up visit, out of which 95 (76.6%) complied with the 2 years visit. Demographic data are shown in Table 1.

Table 1: Demographic data of all women (n=124)

Age – mean (SD) [years]	54.8 (9.9)
Previous gestation – mean (SD)	3.0 (2.0)
Post menopause – n (%)	80 (64.5)
Previous anti-incontinence surgeries – n (%)	35 (28.2)[a]
Body Mass Index – mean (SD) [kg/cm^2]	27.9 (4.6)

[a]28 of those patients reached the 2 year follow-up, which is the number considered for further analysis for naïve and previously operated women.

Figure 1

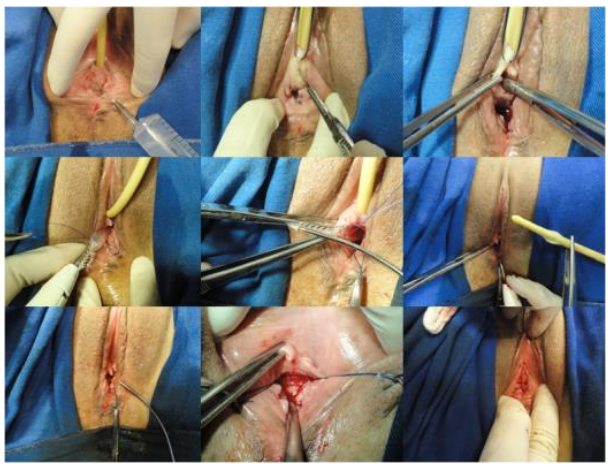

Figure 2

Figure 1 (A), (B), (C) Surgical set. Detail of Ophira Mini sling system anti rotational tip and retractable insertion guide.
Figure 2 (A) local anesthesia; (B) vaginal incision; (C) dissection laterally towards the ascending ramus of the ischiopubic bone; (D), (E) mesh insertion; (F) intraoperative stress test; (G) removal of the retractable insertion guide; (H) fine adjustment of the mesh ;(I) end of the procedure.

Results

A total of 124 female patients with SUI underwent treatment with Ophira MiniSling System. All patients completed the 1 year follow-up and 95 of them complied with the 2 years evaluation. Longitudinal analysis showed that there were not significant differences between results at 2 and 1 year. The 2 years overall objective results were 81 (85,3%) patients dry, 6 (6,3%) improved, and 8 (8,4%) incontinent (Table 2). In the previously operated group there were 67.9% dry and in the naïve group 89.6%. Within the group 60 years or higher, 80.6% women were dry compared to 87.5% among youngers. Two years after surgery women with previously failed surgery presented an objective cure rate of 69,7%, and naïve patients disclosed 89,6% of cure, resulting in an odds ratio for treatment failure of 4.0 [IC95%: 1.02-15.57] in patients with previous failed surgery and 1.2 [CI95%: 0.55-7.71] in women above 60 years (Table 3).

Table 2: Outcomes: objective measurements from non-segmented sample.

	Pre-operative (n=124)	1 year (n=124)	2 years (n=95)	*p-value (1 vs 2 years)*

1-h PWT[a,b]	Mean (SD)	12.5 (15.4)	1.4 (5.9)	2.2 (9.1)	*0.477*[c]
	Dry – n (%)	NA	103 (83.1)	81 (85.3)	
	Improvement – n (%)	NA	9 (7.3)	6 (6.3)	*0.368*[d]
	Failure – n (%)	NA	12 (9.7)	8 (8.4)	
CST[a]	Negative – n (%)	0 (0)	112 (90.3)	82 (86.3)	*0.508*[d]
	Positive – n (%)	124 (100)	12 (9.7)	13 (13.7)	

a. Post-operative records were compared with the pre-operative ones using a two tailed, dependent T-Student test for 1-h PWT and McNemar test for CST. All the comparisons resulted in a p<0.0005. b. In the 1 year and 2 years follow-up there were 4 and 3 missing data which were considered failed because last failure was carried forward. c. One and two year comparison with a two tailed independent T-Student test. d. One and two year comparison with a independent T-Student test (PWT) and McNemar-Bowker test (CST).

Table 3: Two years outcomes stratified by previous surgeries and age

	N	1-h PWT		Failure (PWT>1g)		Positive CST		ICIQ-SF		UDI-6	
		mean(SD)	*p*[a]	N (%)	*p*[b]	N (%)	*p*[b]	mean(SD)	*p*[a]	mean(SD)	*p*[a]
Previous surgery	28	4.2 (13.3)		5 (17.9)		7 (25.0)		4.4 (6.4)		2.5 (3.1)	
Naïve patients	67	0.8 (3.4)	*0.209*	3 (4.5)	***0.032***	6 (9.0)	***0.038***	0.8 (2.2)	***0.019***	1.4 (1.6)	*0.07*
>60 years	31	5.1 (15.1)		4 (12.9)		6 (19.4)		1.5 (4.3)		1.7 (2.1)	
<60 years	64	0.8 (2.2)	*0.205*	4 (6.3)	*0.274*	7 (11.0)	*0.263*	2.1 (4.3)	*0.631*	1.7 (2.3)	*0.94*

a. Independent T-Student test b. Chi-squared test.

Interpretation of results

To our knowledge, this is the first report about the results of mini slings in recurrent SUI. Besides our results are similar to those reported with TVT or TOT in this subset of patients (1,2,3), the ideal candidates for Ophira mini sling system are naïve patients.

Concluding message

Ophira MiniSling System is an effective option for the treatment of SUI with good lasting results in naïve and even for the elderly patients.

References

1. Verbrugghe A, De Ridder D, Van der Aa F. A repeat mid-urethral sling as valuable treatment for persistent or recurrent stress urinary incontinence. Int Urogynecol J. 2012 Oct 24. Epub ahead of print
2. Sabadell J, Poza JL, Esgueva A, Morales JC, Sánchez-Iglesias JL, Xercavins J. Usefulness of retropubic tape for recurrent stress incontinence after transobturator tape failure. Int Urogynecol J. 2011 Dec;22(12):1543-7.
3. de Landsheere L, Lucot JP, Foidart JM, Cosson M. Management of recurrent or persistent stress urinary incontinence after TVT-O by mesh readjustment. Int Urogynecol J. 2010 Nov;21(11):1347-51.

Disclosures

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