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SAFETY AND EFFICACY OF OPHIRA MINI SLING SYSTEM IN AN OUTPATIENT BASIS: ONE-YEAR FOLLOW UP OF A MULTICENTRE INTERNATIONAL CLINICAL TRIAL

Hypothesis / aims of study

Ophira Mini Sling System is an innovative anatomical approach(1) that involves placing a midurethral low-tension tape anchored to the obturator internus muscles bilaterally at the level of tendineous arc by a single vaginal incision.
Its rationale have evolved from the transobturator tape, which has proved to be as efficient as retropubic sling for the restoration of the pubourethral ligaments and urethropelvic fascia support (2). It was developed in order to keep the optimal results of the transobturator sling through a multipoint fixation arm which confers a stable primary fixation to the tissue, adding safety and minimizing the surgical and recovery time.
The aim of this presentation is to report up to one year 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 March 2010, 149 female patients (mean age: 53.9 ± 9.5 years old) with stress urinary incontinence (SUI) underwent treatment with Ophira Mini Sling System.
Ophira Mini Sling System has a Type 1 polypropylene monofilament mesh held between two self-anchoring polypropylene arms with a multi point fixation design
which are connected to disposable retractable insertion guide during the procedure (Figure 1).

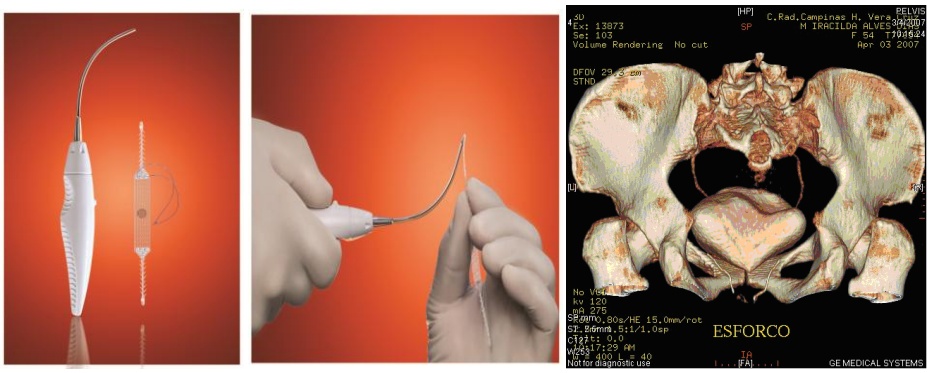

Figure 1. (A) Ophira Mini Sling. (B) multipoint fixation arms and the retractable insertion guide. (C) 3D CT showing sling fixation to obturator internus muscle.

The work-up included history, physical examination, stress test, standardized 1-h pad test, and pre-operative urodynamic study. Also, patients were evaluated with three validated questionnaires: International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) and Urogenital Distress Inventory (UDI-6). During the follow-up, patients were reviewed at 1, 3, 6 and 12 months.
The procedure was carried under local anesthesia in 73% of the patients, using 10 ml of 2% lydocaine solution, injected at the midurethra towards the vaginal fornix, advancing 2 cm in the obturator internus muscles. Eventually, general (18%) or regional anesthesia (9%) was used, according to the anesthesiologist decision. A vertical 1-cm lenght vaginal incision was performed at 1 cm from the urethral meatus. Minimal dissection was performed laterally towards the ascending ramus of the ischiopubic bone, preserving the endopelvic fascia. For insertion of the implant, first, the retractable insertion guide is connected to the multipoint fixation arm and is introduced towards the obturator internus muscle, one centimeter above the vaginal fornix, guided by surgeon's index finger. When the centering mark of the implant is slightly underneath the right flap of the vaginal incision, the trigger at the handle is deploid to release in place the fixation arm. The multipoint fixation arms design provides strong and stable primary fixation(3). The same maneuvers were repeated on the other side.

After the fine adjusts of the mesh, the retractable insertion guide is removed and the vaginal wall was closed in the usual manner. Cystoscopy was not mandatory. No Foley catheter was left in place. The patients were discharged immediately after spontaneous voiding.

Results

The mean operative time was 12.6 ±7.4 minutes. Three patients presented lydocaine overdose symptoms which were treated conservatively. Among the patients which performed the procedure under local anesthesia, one referred severe intraoperative pain and need intravenous sedation. Severe bleeding and technical problems of the device were not observed.

Until March 2010, 91 patients have more than 12 months follow up (mean follow-up was 9 months). Demographic data are summarized in Table 1 and Follow up data was presented in table 2.

Table 1. Demographic data

Previous gestation (mean ± SD)	2.9 ± 2.2
Post menopause (%)	63%
Previous anti-incontinence surgery (%)	32.1%
Body Mass Index (mean ± SD)	27.9 ± 4.4

Table 2. Follow up

	Pre	1 month	3months	6 months	1 year
N*	149	8	28	18	91
VLPP (cmH_2O)	78.2 ± 27.1	-	-	-	-
Pad-test (g)	13.1 ± 16.7	-	-	2.7 ± 7.9	2.3 ± 8.7
Post void residual (ml)	3.0 ± 7.3	6.3 ± 32.9	1.0 ± 4.0	0.9 ± 7.0	1.4 ± 4.2
Positive stress test	96,5%	0.0%	7.8%	12.5%	9,8%
ICIQ-SF score (0-21)	17.0 ± 2.7	3.2 ± 5.9	2.7 ± 5.3	4.3 ± 6.4	2.9 ± 4.8
UDI-6 score (0-18)	9.4 ± 2.9	2.3 ± 2.8	2.0 ± 2.6	2.2 ± 2.7	2.5 ± 3.0

* Four patients were lost to follow-up

Complications such as infection, severe bleeding or sexual dysfunction were not observed. Mesh exposure was observed in 3 patients. All of them were less than 0.5 cm and were treated by ambulatory resection of the exposed area (1 patient) and local estrogen (2 patients). 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). Urinary tract infection (UTI) was present in 8 patients, and de novo urge in 7 patients.

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.

References

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Specify source of funding or grant	**Promedon - Argentine**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Commitee - University of Campinas School of Medicine - Sao Paulo - Brazil**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**