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EFFICACY OF OPHIRA MINI SLING SYSTEM FOR STRESS URINARY INCONTINENCE: MIDTERM FOLLOW UP OF 176 PATIENTS IN A MULTICENTRE INTERNATIONAL CLINICAL TRIAL

Hypothesis / aims of study

Ophira Mini Sling System is an innovative anatomical approach 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. It was developed in order to keep the optimal results of the transobturator sling through a 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 midterm follow up results of the use of Ophira Mini Sling System in an international multicentre prospective trial.

Study design, materials and methods

From February 2008 to February 2011, 176 female patients (mean age: 54.1 ± 9.9 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)

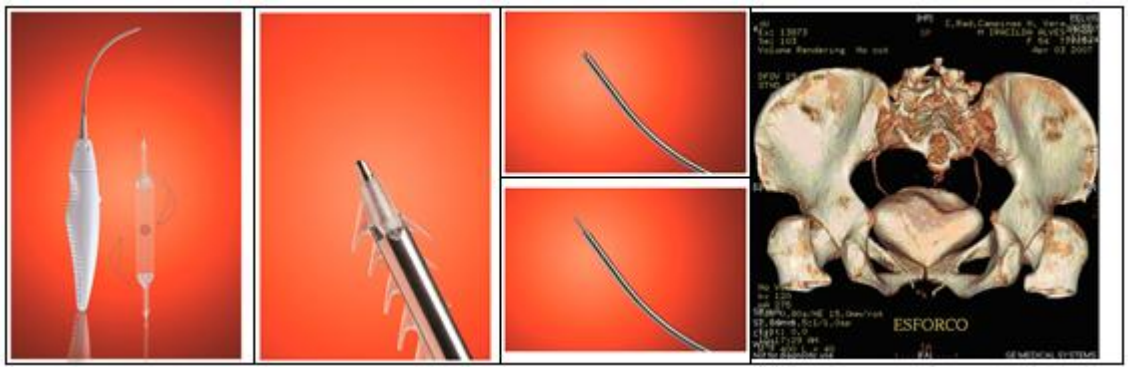

Figure 1. Surgical set. Detail of Ophira Mini sling system anti rotational tip and retractable insertion guided. Postoperative 3D CT showing sling fixation to obturator internus muscle.

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 (14%) or regional anesthesia (13%) 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. 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 18.11±7.3 minutes (in to out surgical room). 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 February 2011, 138 patients have more than 12 months follow up. Demographic data are summarized in Table 1 and Follow up data was presented in table 2.

Table 1. Demographic data

Previous gestation (mean ± SD)	3,03 ± 2.3

Post menopause (%)	62,5%
Previous anti-incontinence surgery (%)	35%
Body Mass Index (mean ± SD)	27.9 ± 4.4

Table 2. Follow up

	Pre	1 month	3months	6 months	1 year
N*	176	171	163	151	138
VLPP (cmH_2O)	79.2 ± 26.6	-	-	-	-
Pad-test (g)	12.1 ± 15.3	-	-	2.3 ± 7.2	2.1 ± 7.9
Post void residual (ml)	2.6 ± 6.8	5 ± 29.4	0.8 ± 3.5	0.8±6.26	1.0 ± 3.7
Positive stress test	97.7%	-	4.5%	6.8%	3.9%
ICIQ-SF score (0-21)	17.7 ± 2.8	3.2 ± 5.8	2.7 ± 5.5	3.6 ± 6.0	3.0± 5.2
UDI-6 score (0-18)	9.8 ± 2.9	2.3 ± 2.9	2 .0± 2.9	2.0± 2.8	2.2 ± 2.9

* 22 patients were lost to follow-up

Complications such as infection, severe bleeding or sexual dysfunction were not observed. Mesh exposure was observed in 13 patients (7.4%). All of them were less than 0.5 cm and were treated by ambulatory resection of the exposed area (8 patients) and local estrogen (5 patients). Seven patients have urinary retention, solved spontaneous (5 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 12 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 series 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.

Specify source of funding or grant	**The material used (sling Ophira) in surgery is donated by Promedon. But other resources are provided by the Unified Health System (SUS).**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Ethics Committee of the University of Campinas-UNICAMP: 019/08** **National Committee for Ethics in Research - CONEP: 0016.0.146.000-08**
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 Committee of the University of Campinas-UNICAMP and National Committee for Ethics in Research- CONEP**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**