SINGLE INCISION MONOPROSTHESIS FOR THE TREATMENT OF ANTERIOR PROLAPSE, STRESS URINARY INCONTINENCE AND LEVEL ONE APICAL PROLAPSE REPAIR –A MIDTERM OUTCOMES

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OBJECTIVE

The main objective of this study is to assess midterm clinical effectiveness of an implantable device (Calistar A – Promedon) for the simultaneous treatment of anterior and apical Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI) (Figure 1).

BACKGROUND

The use of mesh augmentation for transvaginal treatment of pelvic organ prolapses is being strictly observed . Several studies, the Public Health Notification in 2008 and communication done by FDA in last year alert regarding the safety and efficacy of the use of mesh for POP treatment.

The IUGA round table documents held in 2011 shows that the criterious use of these surgical techniques have their indications. In an attempt to both benefits from the advantages of mesh augmentation in the anterior vaginal prolapses and also decrease some of the associated risks seens in techniques who needle through the groins and obsturator space a new single incicsion vavinal approach was developed. The purpose of this study is to report the midterm outcomes of patients that underwent this procedure for treatment of symptomatic stage 3 anterior compartment and/or apical prolapse and results in SUI.

METHODS

From January 2010 to January 2012 women with Pelvic Organ Prolapse Quantification System (POP-Q) stage 3 anterior vaginal wall prolapsed were included in this multicentric study. The work-up included history, physical examination, standardized 1-h pad test, stress test and International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) and POP-Q. Follow up was performed at 3, 6, 12 and 24 months post implantation.

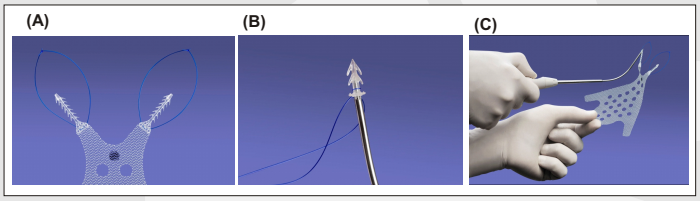

Figure 1. (A) Polypropylene mesh and multipoint fixation arms (B) Tissue anchoring system and trocar. (C) Surgical set.

RESULTS

Sixty-eight women underwent the surgical procedure (mean age 60.8±8.9 years old) under spinal anaesthesia. Baseline information is summarized in Table 1. Concomitant SUI was determined in 29 (42.6%) patients (mean ICIQ-SF score of 13.3±5.1). There were no significant intraoperative nor immediate postoperative complications such as severe bleeding, organ perforation or neurovascular damage. After implantation SUI was resolved in 26/29 cases (89.7%). 58 (84.1%) women were considered prolapsed cured (POP-Q stage 0 or 1) and 9 (13.2%) got an improvement of one level POP-Q stage (from 3 to 2) (Table 2)

Table 1. Baseline information

Age (Mean ± SD)	60.9 ± 9.0
Menopause (%)	89.7
Body Mass Index (Mean ± SD)	27.3 ± 4.2
Pregnancies (Mean ± SD)	4.3 ± 3.4
Previous anti-incontinence surgeries (%)	16.2
Histerectomy (%)	16.2

One woman (1.5%) could not improve her preoperative POP-Q stage 3 along her follow-up. In the immediate postoperative there was one case of vaginal dehiscence. Four mesh exposures were registered, one treated with topical estrogen and 3 cases required mesh excision to resolve the exposure without registering POP recurrence for those women. Two cases (2.9%) of Urinary tract infection (UTI) needed antibiotic therapy and one woman (1.5%) complained of dyspareunia. Five cases of overactive bladder symptoms were identified in 5 subjects (7.4%) all successfully treated with anticholinergics. Sterile catheterization had to be performed for 7 days in 3 women due to urinary retention.

Table 2. Follow-up information

	Pre	3 months	6 months	12 months	24 months
N	68	48	31	19	6
Aa POP-Q point (Mean±SD)	2.1±1.0	-2.1±0.9	-2.0±1.1	-2.1±1.1	-2.7±0.5
Ba POP-Q point (Mean±SD)	3.4±1.6	-2.4±0.9	-2.3±1.0	-2.2±1.0	-2.7±0.5
C POP-Q point (Mean±SD)	-0.2±3.1	-7.0±1.6	-7.1±0.9	-6.8±1.5	-7.0±2.1
D POP-Q point (Mean±SD)	-2.4±4.8	-7.1±3.8	-7.7±1.2	-7.7±1.3	-8.0±2.4
ICIQ-SF*	13.3±5.1	1.1±3.5	2.6±5.7	3.1±5.8	NA**

*ICIQ-SF results from the patients with previously diagnosed SUI.

**None of these patients had a preoperative diagnosis of SUI.

CONCLUSIONS

Complications after 6 months and 1 year follow-up was reduced show values at or below those described in the literature. Severe complications did not occur.

Reversible urinary retention in 3 patients shows the importance of the evaluation of bladder function after surgery.

The lasting results demonstrate that the new anchoring system to sacrospinous ligaments allows for a D'Lancey level one correction as showed by the optimal POP-Q point C results in the follow-up.

The results in ICIQ-SF shows the multipoint fixation arms provided primary and stable suburethral support, keeping the mesh in the proper place and allowing for an effective treatment of SUI, if present.