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PROSPECTIVE STUDY OF A SINGLE-INCISION MIDURETHRAL SLING (CONTASURE NEEDLELESS) FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE USING A RETROPUBIC APPROACH. EFFICACY, COMPLICATIONS AND QUALITY OF LIFE AT TWO YEARS OF FOLLOW UP

Hypothesis / aims of study

The aim of the study was to evaluate the efficacy, complications and improvement of quality of life in women treated of stress urinary incontinence employing the single incision sling Contasure Needleless® (Neomedic International, Inc) using a retropubic approach, after two years of follow up.

Study design, materials and methods

Longitudinal, prospective, unicentric, open study; we have included 73 patients who have not received previously surgical treatment for stress urinary incontinence (SUI) and/or genital prolapse. Other inclusion criteria were: diagnosis of pure SUI (grades I or II, according to Ingelman-Sundberg´s classification) (1) or mixed urinary incontinence (MUI) in which the predominant component were the stress symptoms; pelvic organ prolapse (if present) not over grade III (Baden-Walker classification), age not over 75 years and body mass index (BMI) inferior to 30. A total of 63 patients completed evaluations at two years of follow up, ten patients were lost to follow up. Basal characteristics of the women who completed the study are shown in Table 1. Preoperative and postoperative (at 1, 6, 12 and 24 months) assessments included cough stress test, completion of International Consultation of Incontinence Questionnnaire Short-Form (ICIQ-SF), King´s Health Questionnaire (KHQ) and Patient Global Impression of Improvement (PGI-I). Complications were grading according to IUGA/ICS classification (2). Statistical analysis was performed using SPSS (version 15.0)

Table 1. Baseline characteristics of the study population

Characteristics	Data	Characteristics,%	Data
Age, years, mean (SD) (range)	56.8 (11.7) (29-75)	Prolapse grade I	21 (33.3)
Parity, mean (SD) (range)	2.7 (1.0) (1-6)	Prolapse grade II	33 (52.3)
Menopausal status,%		Prolapse grade III	4 (6.3)
Premenopausal	16 (25.3)	Clinical diagnosis,%	
Posmenopausal	47 (74.6)	Mixed urinary incontinence	24 (38.1)
BMI, kg/m^2, %		Pure SUI	39 (61.9)
< 25	22 (34.9)	Preoperative SUI grade, %	
25–29.99	41 (65.1)	Grade I	20 (31.7)
Associated pelvic organ prolapse , %		Grade II	43 (68.3)
No prolapse	5 (7.9)		

Results

In five cases (5/63, 7.9%) sling insertion was the only procedure performed. In 58 cases (58/63, 92%), a surgical correction of the defects (anterior and/or posterior colporrhaphy, vaginal hysterectomy, Manchester procedure, colpocleisis) was carried out during the same surgical act but before the sling insertion. In no case a mesh was used, apart form the Contasure Needleless sling system. In all cases we performed an intraoperative diagnostic cystoscopy, using a 70º cystoscope, with the object to rule out any damage to the bladder and/or urethra during the sling insertion. Mean operation time was 77.7± 39.1 minutes (15-180) and mean duration of sling insertion was 10.7 ± 2.1 (7-15). Mean length of hospital stay was 3.4±1.5 days (1-9) mainly due to the surgical correction of pelvic floor defects. In the five cases of isolated sling insertion hospital stay lasted < 24 hours.

No peri-operative complication directly related with sling insertion was encountered. No injury to the urethra, bladder, vessels or nerves was noted, neither significant intra-operative bleeding. Postoperative complications: 5 erosions (7.9%) (2AT2S1, 2A2TS1, 2AT3S1, 3BbT2S1, 3AT3S1), the last two patients were reoperated (partial resection of the sling and vaginal resuture) and 2 cases of urinary retention (both 4BT2S1). There were no cases of postoperative pain, haematoma or absceses. One patient was reoperated of urinary incontinence (insertion of another suburethral sling) at 15 months from primary procedure. Although now she is asymptomatic, she has been classified as failure at 24 months.

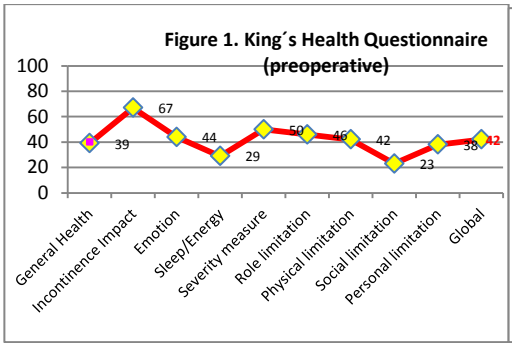
Table 2 shows subjective and objective outcomes of the procedure. We also have calculated outcomes taking into account lost to follow up (LTF) patients in two scenarios: intention-to-treat analysis (all LTF are failures) and best possible analysis (all LTF are cured). Among patients who have beed diagnosed of MUI, in 11 cases (11/24, 45.8%) symptoms of overactive bladder ceased after surgery, whereas in 13/24 (54.2%) OAB symptoms were present. Among patients diagnosed of pure SUI we have diagnosed 3 cases of de novo incontinence (3/39, 7.7%)

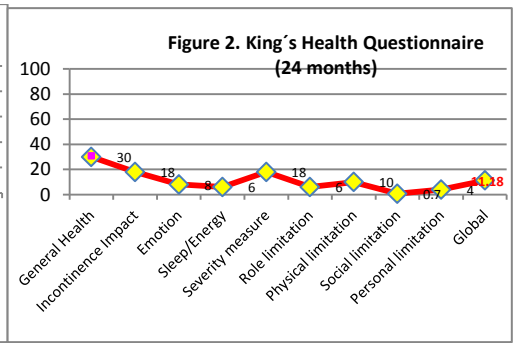
Figures 1 and 2 shows mean scores for each category of KHQ (preoperative and at 24 months), as well as an average total KHQ. We have observed a marked improvement of KHQ scores along all categories.

Table 2. Subjective and objective outcomes and LTF analysis

Subjective outcome	N (%) (CI95%)
Cured	51 (80.9) (69.5-88.7)
Improved	3
Unchanged	6

Worsened	3
Cured plus improved	54 (85.7) (75.0-92.3)
Objective outcome	
Cough stress test negative	53 (84.1) (73.1-91.1)
Patients lost to follow-up (10)	
Intention-to-treat analysis	53/73 (72.6) (61.4-81.5)
Best possible analysis	63/73 (86.3) (76.5-92.3)





Interpretation of results

Retropubic slings could be more effective than transobturators but are associated with more and more severe complications. Using a single incision sling in a retropubic approach we have observed a good efficacy rates in the long place with minimal complications, particularly we have not detected urinary (vesical or urethral lesions) which are tipically associated with the traditional retropubic slings. Not only efficacy and complication rates are important, but also quality of life of patients is improved as reflected by KHQ scores.

Concluding message

The results confirm the efficacy previously obtained by others (3) at a longer follow up and reaching a very low rate of minor complications using a new approach. Additionally, another point of value of our study could be that it has been performed following realistic surgical and clinical criteria, that are that most patients suffered from SUI and POP simultaneously, and both were corrected at the same time. Ideally, these results should be confirmed in a broad range of patients (e.g. elderly women or as a not primary incontinence procedure).

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Disclosures

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