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A NEW MINIMAL INVASIVE SURGICAL TECHNIQUE WIHTOUT NEEDLES FOR THE SURGICAL TREATMENT OS STRESS URINARY INCONTINENCE: PRELIMINARY RESULTS NEEDLELESS SLING.

Hypothesis / aims of study

The aim of the present study was to evaluate the safety and efficacy of a new tension-free procedure NEEDLELESS for the surgical treatment of SUI.With this procedure we try to avoid the mayor complications of the pass of the Needles. but keeping the Tension Free concept.The pass of the needles is always a complicate moment during the surgery (TVT/TOT)to avoid cases of bladder injury or injury to obturator nerves or vessels during needle passage via the transobturator route.

Study design, materials and methods

Before and after the treatment, the patients were evaluated under a clinical study protocol consisting in a urogynacology clinical history, quality of life questionnaire, (King's Health Questionnaire), the clinical classification under Ingelman-Sundberg, urethral mobilization study with Q-tip test, cough test and urodynamic study.
We only included patients with genuine stress urinary incontinence with urethral hyper mobility. Excluding all ISD or other urinary incontinence type

The intervention consist of placing under the midurethra a macroporus monofilament polypropylene sling of 14 cm length and 1,4 cm wide,with Pocket Positioning System in the lateral sides of the mesh that allow us to anchore the sling . In this group of patients local/regional anaesthesia was used.
After applying anaesthesia, a longitudinal 2 cm incision is made in the anterior vaginal wall. Through this incision the paraurethral spaces are dissected, A Surgical Forceps (Koher) is introduce in the Pocket system at the edge of the mesh.Then the sling is introduced through the dissected spaces and penetrate at 45º and the Internal obturator fascia is perforate with the surgical forceps. 25 female patients underwent a Needleless sling (Neomedic International,Spain). We present safety and efficacy data on 25 patients who have reached a minimum follow-up of 6 months.

Results

After a mean follow up period of 6 month 22 patients (88.%) achieved cure of stress incontinence (defined as negative cough and pad testing), 1 of them (4%) was improve. Two patients (8%) are not objectively cured. Mean operating time was 9 min (range7 -14).. No bladder lesions or intraoperative complications occurred. Mean hospital staying was 1.1 days (range 1-2). No infections or erosions have been observed.

Interpretation of results

Although complications with all anti-incontinence procedures exist, understanding the anatomical considerations and methodology of this unique procedure should minimize patient morbidity.

Concluding message

Preliminary reports and the experience at our institution suggest that the technique of midurethral synthetic sling placement of Needleless are reproducible, easy to master, and minimally invasive with respect to other tension free procedures

References

FUNDING: NONE
CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the University Hospital Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.