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SURGICAL PROCEDURE WITH LOCAL ANESTHESIA FOR THE TREATMENT OF STRESS URINARY INCONTINENCE: A SINGLE INCISION TOT.

Synopsis of Video

In this video we show the Contasure Needleless (Neomedic, Spain) surgical technique performed under local anesthesia and systemic sedation, to treat stress urinary incontinence (SUI) in female.

Hypothesis / aims of study

To evaluate safety and efficacy of a new tension-free procedure performed with only a single vaginal incision for the surgical treatment of SUI. Contasure Needleless is a macropurus monofilament polypropylene sling, 11,4cm. length and 15.44cm² surface area, very similar to a standard TOT sling (18cm²), therefore tissue ingrowths and urethral support will be similar. With this technique, maintaining the Tension Free concept, we avoid the major complications, bladder perforation or groin pain that occurs with other tension free procedures (TVT/TOT).

Study design, materials and methods

A prospective multi-center study was carried out in 78 patients with SUI. Subjects with ISD and recurrent urinary incontinence were excluded. All patients were evaluated under a urogynecology clinical history, quality of life questionnaire, (preoperative ICI-Q (QoL): 7.85 (5-29) and Sandvick Test: 7 (3-11), the clinical classification under Ingelman-Sundberg, urethral mobilization study with Q-tip test and urodynamic study.

Surgical technique consist of placing a sling under the midurethra, with Pocket Positioning System in the lateral sides of the mesh, which allows to anchore it. With patient in a dorsal lithotomic position, a longitudinal 1,5 cm. midline incision is made in the anterior vaginal wall. This incision is the same as the incision made for a TOT procedure. Blunt dissection of the paraurethral spaces is performed up to the ischiopubic ramus. A Surgical Forceps (16mm Kelly) is introduced in the Pocket System at the edge of the sling. The Kelly is introduced through the dissected spaces and penetrate at 30° from the horizontal plane, the same way that a standard TOT sling, as far as it perforates the fascia of the Internal obturator muscle. Surgical Forceps, are opened widely up to extend de sling T pocket once in place. The process is repeated on the contra lateral side. Blue suture is removed and vaginal skin closed. If it's necessary sling can be repositioned.

Results

After a mean follow-up period of 12 months, 69 patients (88,4%) achieved cure of stress incontinence (objective and subjective), 4 of them (5.1%) improved. A total of 6 patients (7,69%) were not objectively cured. Mean operating time was 7 min (range 4 -20). ICI-Q (QoL) 1.7(0-13) and Sandvick Test 0.6 (0-6). No bladder lesions or intraoperative complications occurred. No urinary retentions during immediate post operative happened. We had a mild hematoma.Mean hospital staying was 8hours (range 4-24). There were no cases of inguinal pain. As late complications there were four partial mesh erosion (5,1%), solved with local estrogens. Two patients had de novo urge incontinence. Three patients had UUI in treatment with anticolinergics.

Concluding message

This video shows how this is a reproducible tecnique, easy to master, and minimally invasive with respect to other tension free procedures. Patient surgical morbidity, due to anesthesia and to the surgical procedure, decreases with this technique with less peri operative and post operative complications.

One year follow up results, are the same that other tension free procedures (TVT/ TOT).

<u>References</u>

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require eithics committee approval because	Tuis study did not need ethical approval because Material used is safely approved internationally for humans application, as well as, its usage in treatament of stress urinary incontinence but followed the Declaration of Helsinki Informed consent was obtaines from the patients
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes