

8 YEARS AFTER. LONG TERM FOLLOW UP FOR THE SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN WITH A SINGLE INCISION TOT TECHNIQUE

Hypothesis / aims of study

The aim of the present study is to evaluate long term follow up safety and efficacy of a tension-free procedure (CONTASURE NEEDLELESS) for the surgical treatment of stress urinary incontinence (SUI) in female, and to review our data in patients with a minimum follow up of eight years. Our goal is to simplify the TOT technique since only a single incision is needed to perform this procedure. With this technique we avoid the major complications during surgery (TVT/TOT), when passing the needle via the transobturator route but keeping the Tension Free concept.

Study design, materials and methods

A prospective study was carried out in 254 patients with SUI. Subjects were evaluated under a clinical study protocol consisting in a urogynecology clinical history, quality of life questionnaire, (preoperative ICI-Q (QoL): 12,79(4-21) and Sandvick Test: 9 (4-11)), the clinical classification under Ingelman-Sundberg, urethral mobilization study with Q-tip test and urodynamic study. Subjects with ISD and recurrent urinary incontinence were excluded.

Surgical technique consist of placing under the midurethra a macroporus monofilament polypropylene sling of 11,4cm. length and 1,4cm. wide, with a Pocket Positioning System that allows to anchor the sling. Local or spinal anesthesia was used. After applying anesthesia, a longitudinal 1,5 cm incision is made in the anterior vaginal wall. Dissection of the paraurethral spaces is performed up to the ischiopubic ramus. Kelly clamp is introduced in the Pocket System at the edge of the mesh. Then the sling is introduced through the dissected spaces and penetrate at 45o from the horizontal plane perforating the fascia of the Internal Obturator muscle

Results

Of 254 subjects who enrolled in the study we present safety and efficacy data on 51 patients (Mean age of the patients was 61,52 years (35- 85);BMI: 28,7 (18,57-43,43); parity: 2.56 (0-8) who have reached a minimum follow-up of 8 years. Only 36,5% of patients have had previous conservative treatment. A 29,1% of patients also had a diagnosis of urge incontinence. After a mean follow-up period of 8 years 41 patients (80,39%, with an 95% Confidence Interval) achieved cure of stress incontinence (objective and subjective), 5 of them (9.8%) improved. A total of 5 patients (9.8%) were not objectively cured. Mean operating time was 7 min (range 4 - 20). A total of 30.9% of the surgeries were done unther local anesthesia plus sedation, 65,2% unther regional anesthesia and 3,9% unther general anesthesia. ICI-Q (QoL) 2,14 (0-14) and Sandvick Test 0.6 (0-6). No bladder lesions or intraoperative complications occurred. No urinary retentions during immediate post operative happened One patient had a mild hematoma. One patient had a urinary infection. Mean hospital staying was 0,8 days (range 0.5-3). There were no cases of groin pain. As late complications there were 1 partial mesh erosion (1,9%) solved with local estrogens. 2 patients had de novo urge incontinence (3,92%)

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

The present data suggest that the technique of midurethral synthetic sling placement of Needleless is reproducible, easy to master, and minimally invasive with respect to other tension free procedures. Patient surgical morbidity decreases with this technique with less peri operative and post operative complications. Eight years follow up results are the same that other tension free procedures(TVT/ TOT), and no change in success rates regarding three year follow up cases are observed (2, 3). Further studies with larger number patients are needed.

References

1. Needleless: A New technique for correction of urinary incontinence. Randomized Controlled Trial Compared with TVTO.
2. Minimal invasive surgical technique without Needle: (Contasure Needleless) for the surgical treatment of stress urinary
3. Contasure- Needleless single incision sling compared with transobturator TVT- O for the treatment of stress urinary incontinence: long-term results.

Disclosures

Funding: none **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Comité d'ètica Hospital Fundació Althaia, Manresa **Helsinki:** Yes **Informed Consent:** Yes