754

Baya G[1], Janin P[2]
1. *Hospital Fundacio Althaia Manresa,* ***2.*** *Clicnique Pole Sante Leonard Da Vinci, Dours, France*

SURGICAL TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN WITH A SINGLE INCISION TOT TECHNIQUE. THREE YEARS FOLLOW UP.

Hypothesis / aims of study

The aim of the present study is to evaluate safety and efficacy of a new 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 three 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 multicenter study was carried out in 345 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): 7.45 (4-21) and Sandvick Test: 6.8 (2-12)), 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 367 subjects who enrolled in the study we present safety and efficacy data on 157patients (Mean age of the patients was 63,2 years (42- 81); parity: 2.8 (2-7) who have reached a minimum follow-up of 3 year.

After a mean follow-up period of 36 months, 132 patients (84,07%) achieved cure of stress incontinence (objective and subjective), 12 of them (7.64%) improved. A total of 13 patients (8.28%) were not objectively cured. Mean operating time was 7 min (range 4 - 20). ICI-Q (QoL) 1.9 (0-14) and Sandvick Test 0.6 (0-6). No bladder lesions or intraoperative complications occurred. No urinary retentions during inmediate post operative happened One patient had a mild hematoma.Mean hospital staying was 1.1 days (range 0.5-3). There were no cases of groin pain. As late complications there were 5 partial mesh erosion (2,95%), 4 of them solved with local estrogens, and in 1 case a secction of the eroded mesh was performed. Two patients had de novo urge incontinence. 34 patients(20.11%) have also UUI in treatment with anticolinergics.

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.

Three year follow up results are the same that other tension free procedures(TVT/ TOT), and no change in success rates regarding two year follow up cases are observed (2, 3). Further studies with longer follow up are needed.

References

1. 1- Needleless: A New technique for correction of urinary incontinence. Randomized Controlled Trial Compared with TVTO. Preliminary Results.IUGA 2007, Cancun, Mexico.
2. Minimal invasive surgical technique without Needles: (Contasure Needleless) for the surgical treatment of stress urinary incontinence: A multicentric trial. European Urology. EAU 2008 , Milan ,Italy.
3. - A new minimal invasive surgical technique without Needles for the surgical treatment of Stress Urinary Incontinence: Preliminary Results Needleless sling. Neurourology and Urodynamics.ICS 2007, Rotterdam, The Netherlands.

Specify source of funding or grant	**none**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Comitè d´Etica de la Xarxa Hospitalaria Fundació Manresa**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**