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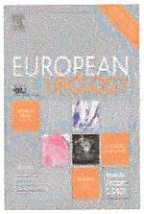

Minimal invasive surgical technique without needles (ContaSure Needleless) for the surgical treatment of stress urinary incontinence: A multicentric trial

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Introduction and Objective

The aim of this on going study is to confirm the efficacy and tolerability of Contasure Needleless (Neomedic International) in a large number of patients. A Macro porous, Monofilament, knitted polypropylene that is placed in a Minimal invasive single vaginal incision technique avoiding the pass of the Needles. The technique include the concept of pocket positioning and fixation, that avoids the needles passage, a complicate moment during the surgery (TVT/TOT) to avoid cases of bladder injury or inguinal pain due to the needle passage via the transobturator route.

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, (ICQ), the clinical classification under Ingelman-Sundberg, urethral mobilization study with Q-tip test, cough test and urodynamic study. Only patients with genuine stress urinary incontinence with urethral hyper mobility were included, prolaps was not an exclusion criteria. Exclusion criteria include all ISD or neurogenic urinary incontinence.

The intervention consist of placing under the midurethra a macroporus monofilament polypropylene sling of 114 mm length and 12 mm wide in its central part with a Pocket Positioning System in the lateral sides of the mesh of 22 mm wide that allows to anchor 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 introduced into the Pocket system at the edge of the mesh. Then the sling is

introduced through the dissected spaces and penetrate at 30° from the horizontal plane and the Internal obturator fascia is perforated with the surgical forceps. A total of 230 patients were included in the study.

Results

The mean age of the patients was 51 years (41-70). A total of 230 patients were included in the trial. After a mean follow up period of 12 month 198 patients (86 %) were objectively cured of stress incontinence. 14 (6%) were improved. 18 patients (8%) were clasified as failures. Mean operating time was 9 min (range 7 -14). During inmediate postoperative there was five acute urinary retentions that were solved by temporal catheterization. Two patients had slight hematoma. There were no cases of inguinal pain No bladder lesions or intraoperative complications occurred. Mean hospital staying was 1.1 days (range 1-3). As late complications there are two cases of partial sling extrusion treated with estrogens medication, one is cured and one improving.

Conclusions:

This Study shows encouraging results for the Contasure Needleless technique as a first line treatment for patients with pure SUI in terms of effectiveness, peri-operative and post operative complications. Anatomical considerations and methodology of this new procedure should minimize patient morbidity. Contasure seems an effective alternative for the treatment of urinary incontinence. Further studies with longer follow up will be published to confirm long term effectiveness of this technique.