

FIRST RESULTS – THE URGE 2 STUDY – RANDOMIZED TRIAL TO COMPARE SOLIFENACIN AND TRANSOBTURATOR TAPE PLACEMENT AFTER BILATERAL UTEROSACRAL LIGAMENT REPLACEMENT IN THE TREATMENT OF URGENCY URINARY INCONTINENCE

Hypothesis / aims of study

The etiology of urinary incontinence is unknown. Beside stress urinary incontinence (SUI), current treatment options are based on a neurological disorder or the detrusor. In the early 90s Ulmsten and DeLancey hypothesized an anatomical defect of the anterior vaginal wall: laxity of the 3 levels (the paraurethral tissue, the apical end and vesicourethral junction). Except SUI, and in regard to materials (length/width) and fixation/implantation sides no standardized surgical treatment for these levels were developed. In our URGE 1 study we introduced a standardized apical fixation: a bilateral mesh augmentation of the uterosacral ligaments: the cervicosacropexy (CESA) or vaginosacropexy (VASA) and compared the standard pharmacological treatment with the surgical approach of CESA or VASA in the treatment of urgency urinary incontinence (UUI) in women. The conclusion out of the URGE 1 study: CESA and VASA outperformed medication.

According to literature a cure rate over 20% for UUI after placement of suburethral tapes are reported.

In order to continue the evaluation of the different anatomical hypotheses we compared the therapeutic efficacy between solifenacin and transobturator tape placement in patients suffering from UUI or additional stress urinary incontinence (then MUI) after CESA or VASA surgical treatment.

Study design, materials and methods

Women with UUI and MUI symptoms and previous CESA or VASA surgery were eligible for this study. In all patients the uterosacral ligaments were previously replaced by CESA or VASA surgery. UUI and MUI symptoms were assessed according to validated questionnaires. Patients were randomized either in the solifenacin therapy arm (10mg) or in the surgical procedure arm (transobturator tape placement, TOT). After 4 months the efficacy of each treatment arm was assessed. Cure or continence was defined as voiding frequency <8 times/day and no involuntary leakage of urine, meaning no UUI or MUI symptoms.

Results

37 patients with UUI or MUI after CESA or VASA surgery were randomized and were evaluable for first analysis. In the solifenacin treatment arm none of the 17 patients treated with solifenacin were cured. In 15 out of 20 (75%) patients continence was restored after transobturator tape placement.

Interpretation of results

The replacement of the pubourethral ligaments with a transobturator tape (TOT) restored continence in 75% of patients with UUI or MUI. The standard pharmacological treatment (solifenacin) for UUI symptoms could not restore continence in these patients.

Concluding message

The bilateral replacement of the uterosacral ligaments by CESA and VASA surgical procedures (URGE 1 study) in addition with the replacement of the pubourethral ligaments by a transobturator tape (URGE 2 study) provided a therapy to restore continence in about 75% of patients with UUI and MUI. Surgery for UUI symptoms outperformed medication.

Disclosures

Funding: none **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov Identifier: NCT01737918 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Ethical committee of the Medical Faculty of the University of Cologne, Germany **Helsinki:** Yes **Informed Consent:** Yes