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Jäger W[1], Dr.Ludwig S[2], Martin S[3], Peter M[2]
1. *Dept Urogyne Cologne,* ***2.*** *Dept OB/GYN Cologne,* ***3.*** *Dept OB/GYNE Cologne*

MEDICAL AND SURGICAL TREATMENTS FOR URGE URINARY INCONTINENCE: URGE 1 - A RANDOMIZED, COMPARATIVE CLINICAL TRIAL

Hypothesis / aims of study
Urge urinary incontinence (UUI) in women is considered a neurophysiological disorder of the bladder muscle. Patients with UUI are treated with several forms of medication.
However, UUI is only symptomatic in the upright body position, and it only affects humans. Several researchers have assumed that the main cause of UUI is a decreased function of the anatomical bladder holding apparatus. This apparatus mainly comprises the pubocervical fascia (PCF), which is a part of the endopelvic fascia between the bladder and anterior vaginal wall. Its suspensions are the uterosacral ligaments (USLs), the pubourethral ligaments (PULs), and lateral the arcus tendinous fascia pelvis.
Since decades, several surgical procedures have been used for treating UI. All procedures ranging from anterior colporrhaphy to suburethral Kelly stitches and colposuspension can result in continence. These treatments focus on the suspension of the bladder basis, several of the most effective ones by elevating the PCF.
In previous studies, we observed that the bilateral suspension of the USL and replacement of the PUL restored continence in 71%–82% of patients with UUI.
In this randomized clinical trial (RCT), we compared the clinical effects of the replacement of the USL with a standard medical treatment with solifenacin (URGE 1).

Study design, materials and methods
The enrolled patients were diagnosed as having untreated UUI or mixed UI (MUI). They were randomized to receive either 10 mg of solifencin daily (control) or a surgical replacement of the USL as cervicosacropexy (CESA) or vaginosacropexy (VASA) (www.cesa-vasa.com). The USL repair procedure was identical in all patients. They received an 8.8-cm long Dynamesh CESA tape or a 9.3-cm long Dynamesh VASA tape. The primary aim was to determine the effects of CESA or VASA alone on UUI. The secondary aim was to examine the effects of CESA and VASA on MUI. Incontinence was determined by a doctor or study nurse by conducting preoperative interviews using standardized questionnaires.

Results
The RCT included 96 patients; 41 patients were in the control arm and 55 patients in the treatment arm of the study, respectively. 23 patients (42%) were free of any incontinence symptoms after CESA or VASA. In 15 patients (27%), the symptoms of MUI disappeared. In the control group, a patient (2%) became continent and 4 patients (10%) reported an improvement in their UUI symptoms. This difference was considered highly significant; therefore, the study was terminated by the ethical committee.

Interpretation of results
This study confirms previous observations that UUI can be effectively treated with surgery. The USL exerted tension on the apical end of the pubocervical fascia. In our approach, the bilateral replacement of the USL by identical tapes with identical lengths of the USL in all patients resulted in continence rates of 42% [confidence interval (CI): 29%–55%]. In contrast to the surgical treatment in the control arm, symptom improvement was detected only in 4 patients (CI: 1%–19%). Therefore, the preliminary study was terminated.

Concluding message
CESA and VASA aimed to tighten the anterior vaginal wall. The apical fixation at the posterior vaginal wall through sacrocolpopexy did not lead to continence in previous studies. Furthermore, it was noted that the replacement of the USL must be bilateral; otherwise, the patients did not become continent again.
Future studies will evaluate the role of other surgical procedures in combination with CESA or VASA in order to treat UUI.

Disclosures
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