

## COMBINED OBTURATOR - PRE PUBIC ANTERIOR VAGINAL WALL PROLAPSE REPAIR: REPORT OF A MULTICENTRIC CLINICAL TRIAL

### Hypothesis / aims of study

To present the early results of a new technique for the treatment of anterior vaginal prolapse, based on a new mesh, that combines pre-pubic and transobturator approach. The rationale for this procedure is to reinforce the pubourethral ligaments and the vesicovaginal fascia addressing the anterior and middle compartments as well. Cystocele, or anterior vaginal defect, may be lateral due to the tearing of the fascia to the tendinous arc, due to the tearing of the central fascia or a combination of both.

### Study design, materials and methods

A prospective multicentric study was conducted in seven centers in three countries. A total of 75 female patients with anterior vaginal prolapse (AVP) with or without urinary stress incontinence were submitted to the procedure. Objective quantification of the prolapse was based on POP-Q system. Simultaneous stress urinary incontinence (SUI) were assessed with International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF), one-hour pad weight test, and urodynamics pre and post-operatively. Subject self-reports, subject satisfaction with the device, and physician assessment were evaluated at office follow-up visits in the post-operative period at 1, 3, 6 and 12 months.

**Surgical Technique:** a midline vertical incision is made in the vaginal wall from the mid urethra to the hysterectomy scar. Sharp and blunt dissection should be done laterally to the medial edge of the ischio-pubic ramus and inferiorly up to the vaginal scar. Supra pubic points are marked 5 cm apart at just above of the pubic bone. The inferior marks are made using the following landmarks: genitofemoral folds at the level of the clitoris, than 3 cm below and 3 cm lateral. The index finger is used to protect the urethra and guide the needle in the pre pubic path all the way to the supra pubic mark. A small skin incision facilitates the exit of the needle. The handle is removed exposing the crochet tip. The same maneuvers are repeated on the other side. The arms of the graft are connected to the tip of the needles. The mesh is pulled the length till the Armpits take the superior part of the body of the mesh to the mid urethra with no tension. Next the inferior incisions are made. The needles are inserted parallel to the ascending ramus of the pubic bone, introducing till the tip is felt by the index finger and then just turning the wrist till it exits through the vaginal incision. After connectors fixation the inferior tapes are pulled through till the lateral edge of the cystocele. The mesh should be underneath the cystocele in a tension-free manner. The inferior part of the central body of the mesh is then placed underneath the bladder base and sutured with two stitches placed at the vaginal wall. Vaginal incision is closed using overlap technique, reinforcing the suburethral hammock and avoiding contact of the suture line with the mesh. Tridimensional CT reconstructions in the post operative period disclosed the mesh properly placed, supporting the bladder and the pre pubic armpits reinforcing the pubourethral ligaments.

### Results

Seventy-five patients were operated from 2004 to 2006. Mean age was 61,3 years (41 to 81) and vaginal deliveries ranged from 1 to 9. Previous surgeries included mostly hysterectomy (16%) and anterior repair (30%). All the patients had mean POP-Q stage (anterior vaginal wall) equal or greater than 2. Fifteen patients had at least POP-Q stage 2 for posterior vaginal wall and apical prolapse was diagnosed in 7 patients (stage 2 or lower). Simultaneous SUI was present in 22 patients (30%), with mean ICIQ-SF score of 10,2 (10 to 18). The median follow-up was 6 months (1 to 12 months). Anterior prolapse recurrence was verified in 1 patient (1,3%). Two patients developed apical prolapse/enterocele (2,8%). Extrusion/erosion were found in 3 patients (4%). Two patientes (2,7%) developed symptoms of bladder outlet obstruction (one of them required vaginal urethrolisis 3 months post-operative with complete relief of the symptoms). Transient disuria and vaginal pain was verified in 1,4 % of the patients. Two patients developed dyspareunia (2,7%). Persistent post-operative SUI was diagnosed in 6,7% (5 patients), but with mean ICIQ-SF of 2,91 (0 to 13). No patient developed symptoms suggesting overactive bladder syndrome.

### Interpretation of results

Besides de objective cure or improve of the prolapse and the acceptable rate of complications, this mesh proved to be usefull for simultaneous SUI treatment when it is desirable.

### Concluding message

These results allow us to assume that the combined prepubic–transobturator approach can be an effective minimally invasive technique for the treatment of the anterior vaginal prolapse. The low risk of sexual and urinary tract dysfunction, and the possibility of simultaneous correction of SUI adds unique advantages to this new device.

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**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study was approved by the Ethics Committee of the University of Campinas School of Medicine and followed the Declaration of Helsinki Informed consent was obtained from the patients.