

NAZCA: A MONOPROSTHESIS FOR THE SIMULTANEOUS MANAGEMENT OF CYSTOCELE AND STRESS URINARY INCONTINENCE: A PROSPECTIVE MULTICENTRIC STUDY

Hypothesis / aims of study

NAZCA is a device system that allows for correction of stress urinary incontinence (SUI) and anterior vaginal wall prolapse at the same time. The aim of this open prospective multicentric trial was to evaluate the safety and efficacy of this new mesh.

Study design, materials and methods

A total of 100 women with anterior vaginal wall prolapse associated or not with SUI underwent a combined approach, pre pubic and transobturator, monoprosthesis. The mean age was 61 years. Previous surgeries included 30% of anterior repair and 16% of hysterectomies. There were 50 (50%) patients with associated SUI. For anatomical results the POP-q system was used. Functional results were evaluated by the following questionnaires: ICIQ-SF. The ICIQ-SF questionnaire disclosed a mean value of 10.2 pre operatively. All patients presented grade III or higher cystoceles, 15 presented posterior wall prolapse and 7 apical defect. The mean follow-up was 1 year. A midline incision is made from the midurethra to the cervix. Next mark needle entry points on the suprapubic and vulvar skin. Suprapubic points are marked 2 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 superior needles are inserted transvaginally in a pre-pubic manner, towards the previously made marks on each side. The arms of the graft are connected to the tip of the needles and 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 helical transobturator needles are inserted parallel to the ascending ramus of the pubic bone, and turning the wrist and guided by the surgeon index finger, exit through the vaginal incision. After connectors fixation the inferior tapes are pulled through till the lateral edge of the cystocele. Vaginal incision is closed using overlap technique to avoid contact of the suture line with the mesh. Finally, the remaining flap is sutured over the interposed flap to cover it. A Foley catheter and vaginal packing is let in place overnight.

Results

Seventy tree patients were cured of the anterior prolapse. There was 1 recurrence. SUI persisted in 3 (4%) patients. The mean ICI-q value was 2,9. Complications included 3 meshes exposure (4%), dyspareunia in 2 (2.7%), 1 (1.4%) patient developed enterocele. The Anova test was used to compare the results.

Interpretation of results

There were significant improvement in ICIQ as well in the POP-Q results.

Concluding message

Preliminary results are very encouraging, demonstrating a safe and effective procedure. Mesh exposure incidence was low, comparing with others similar devices. SUI was cures in 78% of the cases and no de novo SUI or overactive bladder symptoms were observed in this series.

References

FUNDING: None

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 Comitê de Ética em Pesquisa - UNICAMP and followed the Declaration of Helsinki Informed consent was obtained from the patients.