

APICAL LIGAMENT SPECIFIC REPAIR WITH NAZCA-R.

Hypothesis / aims of study

Aim of this study is to confirm the efficacy and safety of Nazca-R for the treatment of vaginal vault prolapse.

Study design, materials and methods

In a prospective observational long term follow study, we used posterior Nazca-R procedure (minimally invasive) to treat 20 patients affected by vaginal vault prolapse (3°/4° degree) associated with cystocele in 6 patients (30%) and rectocele in 3 patients (15%) of whom 11 after abdominal hysterectomy and 9 after vaginal hysterectomy, between March 2006 and July 2008. We performed Nazca-TC procedure in patients affected by cystocele. The study protocol include preoperative: clinical history, physical and pelvic examination, urodynamic investigation, perineal ultrasound (PUS) for imaging pelvic floor (during straining were measured movements of the bladder base, proximal vagina and anterior wall of the rectum), quality of life (QoL) was assessed. The aim of Operative procedures was to achieve minimal invasiveness: by excising minimal vaginal epithelium, avoiding surgery to the distal 1 cm of the vaginal epithelium and avoiding surgically induced vaginal tension, used the Nazca-R (Promedon) in spinal anaesthesia. Patients were followed up at 4 weeks, 3 months and 1 year after surgery.

Results

The mean patients age was 61 (range 48 - 72 years), operation time for Nazca-R placement was mean 45 minutes (range 37- 56), blood loss was 68 ml (55 – 90 ml), generally from the longitudinal vaginal incision, no patients required transfusion, no hematomas or post operative pyrexia were noted. All patients for only Nazca-R procedure were discharged within 48 hours of surgery. There was no intraoperative rectal perforation. Cure of prolapse was assessed as follow the patient was examined in litotomy position with straining and assessed position of vaginal vault. All were cured after 1-3 month after surgery. At follow-up controls we observed 1 case of recurrent cystocele in patients who underwent to associated Nazca-TC procedure (cure rate 83,3%). In patients who underwent to Nazca-R for associated rectocele, no case of recurrence was detected (cure rate 100%). PUS showed reduction in movement of the bladder base, vagina and anterior rectal wall, after Nazca-R procedure. Polypropilene tape rejection was no find. We observed no case of rectal tape erosion. Symptoms cure were based on QoL and defined as >80% reduction in the pelvic pain and genital prolapse.

Interpretation of results

Our initial results with Nazca-R procedure has similar efficacy to other more established surgical techniques for the cure vault prolapse, but with less surgical morbidity and patients discomfort.

Concluding message

The surgical procedure is a promising mininvasive option in the treatment of vaginal vault prolapse. Therefore it can be applied in associated posterior vaginal wall prolapse. The association with cystocele repair (Nazca-TC procedure) did not alterate the cure rate of vaginal vault prolapse. The procedures is efficacy and safe by: shorter operation time, use spinal anesthesia, small peri-operative and postoperative complications, faster convalescence by hospital stay and resumption of usual activities.

References

1. Prospective evaluation of the safety and efficacy of the Apogee system for treatment of vault prolapse
2. Morbidity associated with posterior intravaginal slingplasty for uterovaginal and vault prolapse

Specify source of funding or grant	We hane no interest conflict with the society that produce the mesh used to repair the prolapse.
Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require eithics committee approval because	the tecnique is already codified.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes