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# A RANDOMIZED CONTROLLED TRIAL STUDY, TO COMPARE COLPORRHAPHY VERSUS NAZCA TC™ ,MACROPOROUS POLYPROPYLENE MESH, IN SURGICAL TREATMENT TO GREATER ANTERIOR VAGINAL PROLAPSE .

Hypothesis / aims of study

To compare outcomes in largest cystocele, Ba Point ICS 96, grade III and IV, with or without stress incontinence in 9 mouths follow up. The primary outcome measure is recurrent anterior vaginal prolapse. secondary outcomes were effects on quality of life and sexual symptom scores, operative time, length of hospitalization, and adverse events.

Study design, materials and methods

Women 50 years and older with greater anterior vaginal prolapse, with stress incontinence or not, requiring surgical correction . Seventy eight patients with greater anterior vaginal prolapse, with stress incontinence or not, were randomly assigned to either colporrhaphy or polypropylene mesh repair( NAZCA TC™ POP REPAIR SYSTEM) . The primary outcome was recurrent anterior vaginal prolapse, Secondary outcomes are, first, operative time (from first incision to closure of last incision), blood loss (preoperative minus postoperative day one hemoglobin), length of hospitalization, adverse events, PQol , FSFI and Dyspareunia .. **This study is enrolling participants by invitation only.** α 0.05 power 80% (IC 95%)

Device: **NAZCA TC**™ POP REPAIR SYSTEM ,promedon® , argentina.
NCT00676325

Results

We have 92% anatomic success in mesh group , and 66% anatomic success in colporrhaphy (CP)group, median FU 9 mouths. Complication 2% in mesh group (erosion), Bladder outlet obstruction 8%, digital bladder perforation 2%. Didn`t have any complication in CP group, 34% fail in this arm with 9 mouths follow-up(median).
NNT : 4

Interpretation of results

The pre pubic and transobturator mesh kit (nazca tc™), can be effective and minimal invasive for the largest cystocele in 9 mouths follow up. 76% improvement your stress incontinence and 97% were satisfied.

Concluding message

We wish this RCT help in the understanding of the surgical treatment in greater cystocele. In this study when we used polypropylene mesh it was better than colporrhaphy.

References

1. Nguyen JN, Burchette RJ. Outcome after anterior vaginal repair:a randomized controll trial .Obstet Gynecol.2008 ;111: 891-898
2. Maher C, Baessler K Surgical management of anterior vaginal wall prolapse:an evidence based literature review IntUrogynecol J Pelvic Floor Dysfunct 2006;17:195–201
3. Hiltunen R, Nieminen K, Takala T, Heiskanen E, Merikari MNiemi K, et al. Low-weight polypropylene mesh for anteriorvaginal wall prolapse: a randomized controlled trial. Obstet Gynecol 2007;110:455–62.

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| ***Specify source of funding or grant*** | **the authors dont have conflicts of interest** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **Yes** |
| ***Specify Name of Public Registry, Registration Number*** | **NCT00676325** |
| ***Is this a Randomised Controlled Trial (RCT)?*** | **Yes** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |
| ***Specify Name of Ethics Committee*** | **federal university of sao paulo- brazil ethics commite number 1790/06 (unifespcep)** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |