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CLINICAL EFFICACY OF A TROCAR GUIDED MESH KIT FOR THE REPAIR OF ANTERIOR LATERAL DEFECTS.

Hypothesis / aims of study

Aim:

To assess the effects of anterior trocar guided transvaginal mesh repair versus anterior colporrhaphy on lateral defects one year after surgery.

Study design, materials and methods

This is an ancillary analysis of a randomised controlled trial comparing anterior colporrhaphy with anterior trocar guided transvaginal mesh kit (GYNECARE PROLIFT® Anterior Pelvic Floor Repair System kit, Ethicon, Somerville, NJ) for anterior vaginal wall prolapse (1)(www.clinicaltrials.gov, identifier NCT00566917). The study was a 12-month, multicenter, parallel group, randomized controlled trial conducted at 53 hospitals throughout Sweden, Norway, Finland and Denmark. Both surgical procedures were standardized prior to initiation of the study and performed in an identical fashion across participating centers.

Patients were invited to participate if they were aged 18 years or older and presented with primary or recurrent symptomatic prolapse \geq stage 2 of the anterior vaginal wall according to the Pelvic Organ Prolapse Quantification System (POP-Q). Additional clinical assessment of lateral defects was performed at baseline and the 1 year follow-up in all patients according to a set of standardised criteria. Oral and written informed consent was obtained from all participants. Exclusion criteria included any previous pelvic organ cancer, systemic corticosteroid treatment, insulin treated diabetes, or if patients were physically or mentally unable to participate in follow-up or provide informed consent. Concomitant surgery was not permitted in the trial. The manufacturer of the trial device did not provide the mesh kits for this trial and had no influence over study design, data collection, analysis, writing the manuscript, or the decision to submit the results for publication.

The present substudy included all patients with pelvic organ prolapse of the anterior compartment classified as having lateral defect preoperatively. In all, 107 patients randomly assigned to either anterior colporrhaphy (n=45) or anterior trocar guided transvaginal mesh (n=61) were classified as having a lateral defect before surgery and were included.

Results

One year after surgery, a persistent lateral defect was significantly more common after colporrhaphy compared to transvaginal mesh (12/37 (32.4%) vs 1/44 (2.3%), $P < 0.001$) (Figure 1A). This corresponded to an increased risk ratio of 14.3 (95% CI 1.9-104.7) of having a lateral defect one year after surgery with colporrhaphy compared to transvaginal mesh. One year after surgery, having anatomic recurrence was significantly more common in the colporrhaphy group compared to the transvaginal mesh group (18/43 (41.7%) vs 4/60 (6.7%), $P < 0.001$) (Figure 1B).

Interpretation of results

Anterior vaginal wall prolapse surgery using a trocar guided transvaginal mesh kit resulted in significant improvements in the repair of lateral defects compare to anterior colporrhaphy. This is a novel finding, however not entirely surprising since the mesh covers and supports the central and lateral anterior vaginal wall in contrast to anterior colporrhaphy where the midline plication only corrects the central defect. In light of this it is interesting to note that although results were inferior to the mesh group, patients in the colporrhaphy group had successful correction of their lateral defects in 68% of the cases. Anterior colporrhaphy with midline plication of the pubocervical fascia corrects the central defects and it is possible that the lateral defect then will be masked.

Concluding message

In conclusion we found that the trocar guided transvaginal mesh kit is superior to traditional anterior colporrhaphy with regard to the correction of lateral defects and restoration of vaginal topography. However, the optimal use of trocar guided mesh kits in routine clinical practise requires further studying and long-term follow-up to determine durability of success.

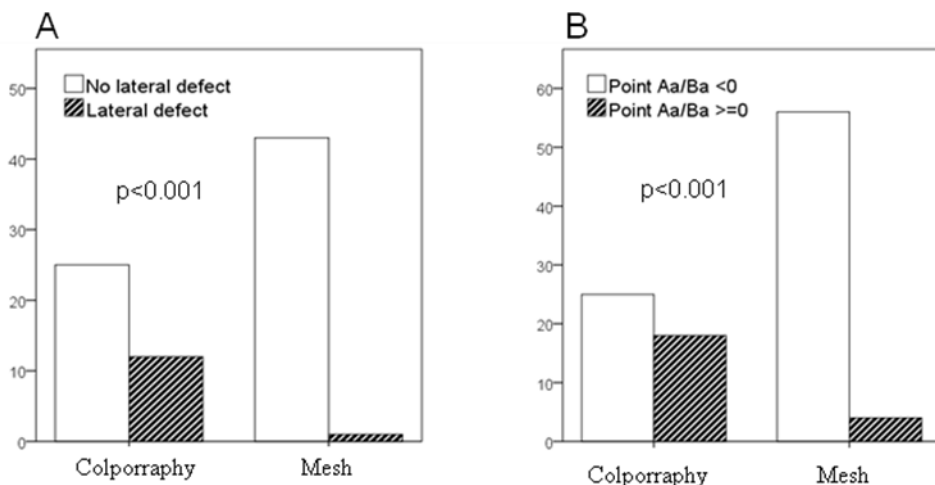


Figure 1A: Less lateral defects in the mesh group compared to the colporrhaphy group at the one year follow up.

Figure 1B: Better anatomical outcome in the mesh group compared to the colporrhaphy group at the one year follow up.

References

- Altman, Väyrynen, Ellström Eng, Axelsen, Falconer. Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic Organ Prolapse. In press N Eng J Med

Specify source of funding or grant

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Is this a clinical trial?

Yes

Is this study registered in a public clinical trials registry?

Yes

Specify Name of Public Registry, Registration Number

www.clinicaltrials.gov, identifier NCT00566917

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

Stockholm Regional Board of Ethics at Karolinska Institutet, Stockholm, Sweden, reg numberr 2007/783-31/3

Was the Declaration of Helsinki followed?

Yes

Was informed consent obtained from the patients?

Yes