DO LEVATOR ANI MUSCLE DEFECTS PREDICT RECURRENT POP AFTER ANTERIOR COLPORRHAPHY?

Hypothesis / aims of study
Hypothesis of the study was that levator ani muscle defects are associated with increased anatomic recurrent anterior vaginal wall prolapse after an anterior colporrhaphy.

Study design, materials and methods
A multicenter prospective cohort study was performed in the Netherlands. The primary aim of the study was to validate 3D translabial ultrasound for diagnosing levator defects compared to MR imaging (MRI). Women with POP-Q stage 2 or more anterior vaginal wall prolapse, who were planned for an anterior colporrhaphy where asked to participate. The exclusion criteria were inability to understand the instructions given in Dutch language, contra-indication for undergoing MRI or planned surgery with mesh material or incontinence surgery. Prior to surgery, POP-Q staging according to the Pelvic Organ Prolapse Quantification classification system, was performed and patients were asked to fill in validated questionnaires (Urinary Distress Inventory (UDI), Defecation Distress Inventory (DDI),and questions on subjective feelings of recurrence). All patients underwent prior to surgery 3D translabial ultrasound and MRI to assess levator defects. Grading of the levator defects was performed for translabial ultrasound and MRI using the classification systems described by Dietz and Delancey[1,2]. At 6 and 12 months after anterior colporrhaphy a physical examination was performed again including POP-Q staging. Subsequently, patients were asked to complete the same questionnaires.

Anatomical (objective) recurrence was defined as an anterior vaginal wall prolapse stage 2 or more (POP-Q classification). Subjective recurrence was defined as (1) feeling and/or (2) seeing a vaginal bulge, with at least a judgment of one of these two symptoms as moderately bothersome, or both of these two symptoms as somewhat bothersome, according to the scoring system of the validated UDI questionnaire. A secondary outcome was “compound recurrence” which was defined as a combination of subjective and anatomical recurrence. All clinical examiners were blinded for the clinical background of the patient.

The power calculation for the study was designed for the primary aim of the study, which resulted in an intended sample size of 140 patients. Statistical analysis was conducted using Data SPSS 19.0 (SPSS Inc., Chicago, IL). Student’s t-test was performed for continuous variables and Chi² analysis for categorical variables. Logistic regression models were employed to calculate odds ratios (OR) and 95% confidence intervals (CI). A p value of <0.05 was considered to be statistically significant.

Results
Between March 2010 and July 2012 a number of 140 patients were included in 9 hospitals. Twelve months after surgery, 76 women out of 139 (55%) had a recurrent anterior vaginal wall prolapse stage 2 or more. Only 12 women out of 135 women (9%) reported symptoms of subjective recurrence. Ten patients (7%) met the criteria of “compound recurrence”. There were 135 translabial ultrasound images and MR images available to diagnose the presence of levator defects. On ultrasound, 49 patients (36%) were diagnosed with major levator defects while on MRI 41 patients (30%) were diagnosed with major levator defects. There was no significant association between recurrent anatomic (objective) anterior vaginal wall prolapse after pelvic floor surgery and the presence of a major levator defect both diagnosed with translabial ultrasound (p = 0.44; OR 1.3, CI 0.65-2.69), or MRI (p = 0.34; OR 1.4, 95% CI 0.68 – 3.03 ). In addition, there was no statistically significant association between subjective recurrence or compound recurrence and the presence of a major levator defect diagnosed with translabial ultrasound and MRI (see Table 1).

Table 1. Association between major levator ani muscle defects and outcome recurrence

<table>
<thead>
<tr>
<th>Major levator defect</th>
<th>Outcome</th>
<th>OR</th>
<th>p</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Translabial ultrasound</td>
<td>Objective recurrence</td>
<td>1.32</td>
<td>0.44</td>
<td>0.65-2.69</td>
</tr>
<tr>
<td></td>
<td>Subjective recurrence</td>
<td>2.31</td>
<td>0.19</td>
<td>0.67-8.03</td>
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<tr>
<td></td>
<td>Compound recurrence</td>
<td>2.41</td>
<td>0.21</td>
<td>0.62-9.46</td>
</tr>
<tr>
<td>MR imaging</td>
<td>Objective recurrence</td>
<td>1.44</td>
<td>0.34</td>
<td>0.68-3.03</td>
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<tr>
<td></td>
<td>Subjective recurrence</td>
<td>2.20</td>
<td>0.22</td>
<td>0.63-7.69</td>
</tr>
<tr>
<td></td>
<td>Compound recurrence</td>
<td>2.01</td>
<td>0.32</td>
<td>0.51-7.93</td>
</tr>
</tbody>
</table>

OR: odds ratio, 95%CI: 95% confidence interval, P value: <0.05 significant

Interpretation of results
Our study shows that major levator defects are not associated with recurrent anterior wall prolapse after anterior colporrhaphy.
Other ultrasound studies which did find these association between levator defects and recurrent prolapse after surgery were retrospective studies, meaning that the ultrasound examination for diagnosing levator defects was performed after surgery usually at the same time POP-Q staging for diagnosing a recurrence took place [3].

Our study is the first prospective study which studied whether the preoperative finding of a levator defect is associated with recurrence 12 months after surgery. The most critical advantage of our study design is the availability of preoperative data, especially preoperative prolapse staging and pelvic floor status.

Possible explanations of the difference between the findings in the retrospective studies and our prospective study using translabial ultrasound could be, that the existence of a prolapse influences the echoscopic appearance of the pelvic floor mimicking a levator defect or, that the surgery itself influences the echoscopic appearance of the pelvic floor anatomy and levator defects are interpreted differently. Possibly these facts led to systematic bias in the retrospective studies.

Concluding message
Major levator defects on ultrasound or MRI did not predict objective or subjective recurrence following anterior colporraphy.

References

Disclosures
Funding: No disclosure Clinical Trial: Yes Registration Number: Trial Register Netherlands, 2220 RCT: No Subjects: HUMAN Ethics Committee: The study was approved by the institutional review board of the Maastricht University Medical Centre, in Maastricht. Ethical approval for this study and local approval was obtained on 22-02-2010, number 08-2-093. Helsinki: Yes Informed Consent: Yes