

INCREASED LEVATOR HIATAL AREA IS A RISK FACTOR FOR CYSTOCELE RECURRENCE AFTER SURGERY IN A PROSPECTIVE COHORT STUDY

Hypothesis / aims of study

We hypothesized that an increased levator hiatal area, measured preoperatively with three-dimensional (3D) transperineal ultrasound, was associated with cystocele recurrence 12 months after anterior colporrhaphy.

Study design, materials and methods

A multicenter prospective cohort study was performed in the Netherlands, with the primary aim to assess the diagnostic accuracy of 3D transperineal ultrasound in the diagnosis of levator defects in women with pelvic organ prolapse. (1) Women who were planned for conventional anterior colporrhaphy because of cystocele, were included. These women completed a validated questionnaire, underwent physical examination with staging of pelvic organ prolapse according to the Pelvic Organ Prolapse Quantification (POP-Q) classification system, and received 3D transperineal ultrasound prior to surgery. At 12 months after surgery they completed the same questionnaire and underwent physical examination once again. Anatomical recurrence was defined as a cystocele POP-Q stage 2 or more. The power calculation for this study was designed for the primary aim of the study, which resulted in an intended sample size of 140 patients. (1) An intraclass correlation (ICC) was calculated to estimate the interobserver reliability of hiatal measurements. Using multivariate analysis, women with and without anatomical cystocele recurrence 12 months after surgery were compared to assess the association with age, body mass index (BMI), parity, preoperative POP-Q stage, concomitant surgery, major levator defects and levator hiatal area at rest and during Valsalva.

Results

Of the 140 women who were included in 9 hospitals, 1 patient withdrew from the study after surgery. For the remaining 139 patients, mean age was 57.4 years (range 31 to 78 years), mean BMI was 25.7 kg/m² (range 17.5 to 41.9 kg/m²) and mean parity was 2.3 (range 1 to 7). Seventy-seven women (55.4%) had POP-Q stage 2 preoperatively and 62 women (44.6%) had POP-Q stage 3 or 4 preoperatively. Concomitant surgery was performed in 96 women (69.1%), whereas 41 women (29.5%) received only anterior colporrhaphy and in 2 cases (1.4%) this information was missing. Major levator defects were diagnosed in 49 women (35.3%) prior to surgery, while 4 women (2.9%) had inadequately recorded volumes. The measurements of the levator hiatus area could be assessed in 134 datasets. The mean levator hiatal area was 23.8 cm² (range 13.7 to 54.1) at rest and 34.0 cm² (range 16.8 to 67.4) during Valsalva. Twelve months after surgery 76 women (54.7%) had cystocele recurrence POP-Q stage 2 or more. Univariate and multivariate analyses are depicted in table 1.

The interobserver reliability between the assessments of the ultrasound scans by two independent observers was good with an ICC of 0.78 (95% confidence interval (CI) 0.69 - 0.85) for levator hiatal area at rest and 0.75 (95% CI 0.65 - 0.83) for hiatal area during Valsalva.

Table 1 Risk factors for anatomical cystocele recurrence

Possible risk factors	N	Univariate analysis			Multivariate analysis		
		OR	95% CI	p-value	OR	95% CI	p-value
Age, years	139	1.0	1.0-1.0	0.99			
BMI, kg/m ²	116	1.0	0.9-1.1	0.46			
Parity, number	128	1.1	0.7-1.6	0.65			
Preoperative POP-Q stage 3 or 4	139	3.0	1.5-6.1	<0.01	3.5	1.7-7.3	<0.01
Concomitant surgery	137	0.8	0.4-1.7	0.56			
Major levator defect	135	1.3	0.7-2.7	0.44			
Levator hiatal area at rest, cm ²	134	1.0	1.0-1.1	0.44			
Levator hiatal area during Valsalva, cm ²	134	1.1	1.0-1.1	0.01	1.1	1.0-1.1	0.02

OR = Odds ratio, 95% CI = 95% Confidence Interval

Interpretation of results

Preoperative POP-Q stage 3 or 4 and increased levator hiatal area during Valsalva on 3D transperineal ultrasound were independent risk factors for anatomical cystocele recurrence after surgery.

In a retrospective cohort study with measurement of the levator hiatus after surgery, Rodrigo et al also found a significant correlation between levator hiatal area and recurrent pelvic organ prolapse after surgery with an odds ratio of 1.0 (95% CI 1.0 - 1.1). (2) Preoperative POP-Q stage 3 or 4 was found to be an independent risk factor for cystocele recurrence after surgery in previous studies as well. (3) These factors may be used in the counselling of women with cystocele prior to surgery. Age, BMI, parity, concomitant surgery, major levator defects and levator hiatal area at rest were not significantly associated with anatomical cystocele recurrence.

A limitation of our study was that cystocele recurrence was defined as anatomical recurrence, which is not clinically relevant. It is known that anatomical recurrence is more frequent than symptomatic recurrence. (3) The power calculation for this study was designed for the primary aim of the study, so that the sample size was too small to examine the association between levator hiatal area and symptomatic recurrence.

Concluding message

This multicenter prospective cohort study demonstrated that an increased levator hiatus area during Valsalva prior to surgery and a preoperative POP-Q stage 3 or 4 were independent risk factors for anatomical cystocele recurrence 12 months after anterior colporrhaphy. This information is in line with previous literature and should be taken into account in individually tailored counselling for the most effective treatment.

References

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Disclosures

Funding: None **Clinical Trial:** Yes **Registration Number:** Trial registration in "Nederlands trial register" Registration number: NTR2220. **RCT:** No **Subjects:** HUMAN **Ethics Committee:** The study has been approved by the institutional review board of the Maastricht University Medical Centre, in Maastricht. Ethical approval for this study was obtained on 22-02-2010, number 08-2-093. **Helsinki:** Yes **Informed Consent:** Yes