

EARLY ANATOMICAL CHANGES OF PELVIC SUPPORT 1-YEAR AFTER LEVATOR TRAUMA: A PROSPECTIVE CASE-CONTROL STUDY

Hypothesis / aims of study:

the association between enlarged hiatus and genital prolapse has been widely demonstrated in the literature. Women with levator ani muscle (LAM) defect may be about twice as likely to develop pelvic organ prolapse (POP) of stage II or higher later in life (1). So far, only few prospective studies evaluating clinical symptoms and anatomical modifications of pelvic support in the first period after LAM trauma, are available. This prospective case-control study was carried out to assess possible anatomical signs and symptoms of POP 1-year after vaginal delivery in patients with LAM defect.

Study design, materials and methods:

Between January and June 2009 primiparous women with 3D ultrasound diagnosis of LAM trauma on 2nd or 3rd day after vaginal delivery and confirmed after 12 months were included in the case group of our prospective study (group A). Women with same criteria of inclusion, but with intact LAM, served as controls (group B). LAM trauma was defined as a defect present in at least 3 consecutive tomographic slices at or above the plane of minimal hiatal dimension obtained with 3D perineal ultrasound. Prolapse symptoms were investigated with the Australian Pelvic Floor Questionnaire validated in German language (2). POP was assessed during maximum Valsalva manoeuvre according to the pelvic organ prolapse quantification (POP-Q) system (3). Pelvic floor muscle strength was assessed using the Oxford Grading Scale ranging from 0 to 5.

Results:

forty patients were included in this trial, comprising 20 patients with (group A) and 20 patients without (group B) levator trauma. Age and BMI were comparable between the two groups (Tab.1). In contrast to POP stage II and III, the occurrence of POP stage I was significantly higher in group A in comparison with group B ($p=0.003$). A strong positive association between POP stage I and LAM trauma was found [RR= 7.2 (IC 95%: 1.0-47.6)]. A normal support of the vagina (stage 0) was significantly more frequent in group B than in group A ($p<0.001$). The involvement of multiple compartment (anterior and posterior compartment, $p=0.003$, $p=0.01$ respectively) was significantly higher in group A patients (Tab.2). Only one woman of group A reported prolapse symptoms, absent in group B women ($p=1$). Digital evaluation of pelvic floor muscle strength showed no differences between the two groups (2.5 ± 1.1 in the group A, 2.7 ± 1.0 in the group B; $p=0.56$).

Interpretation of results:

This is the first prospective case-control study looking at morphological changes and symptoms of POP in patients with and without LAM trauma 1 year after vaginal delivery. At this follow-up period LAM trauma was asymptomatic in nearly all patients. However, our data demonstrated that early anatomical modifications of the pelvic support were found more frequently in patients with LAM trauma compared to women with an intact LAM 12 months postpartum. Our study suggests that a woman with a LAM defect is seven times more likely to reveal a prolapse Stage I involving multiple compartments one year after delivery compared to a woman with an intact levator. An intact LAM seems to have a protective effect against an initial process of genital descent.

Concluding message:

Although clinically still asymptomatic, LAM trauma is associated with increased incidence of early stage POP one year after vaginal delivery.

Tab 1. Patients' characteristics

	Group A (n=20)	Group B (n=20)	Pv
Age (y)	30 (± 5.0)	31.5 (± 4.8)	0.75
BMI	22 (18-32)	25.5 (16-44)	0.14

Data expressed as median (range), mean \pm standard deviation.

Tab 2. POP-Q evaluation

	Group A (n=20)	Group B (n=20)	Pv
POP stage 0	0	10 (50%)	<0.001
POP stage I	19 (95%)	10 (50%)	0.003
POP stage II	1 (5%)	0	1
POP stage III-IV	0	0	1
Anterior	19 (95%)	10 (50%)	0.003

compartment involvement			
Central compartment involvement	4 (20%)	0	0.1
Posterior compartment involvement	8 (40%)	0	0.01
Involvement of a single compartment	10 (50%)	9 (45%)	1
Involvement of multiple compartment	10 (50%)	1 (5%)	0.003

Data expressed as number (%).

References

1. Dietz HP, Simpson JM. Levator trauma is associated with pelvic organ prolapsed. BJOG 2008; 115: 979-984.
2. Baessler K, O'Neill S.M., Maher C, Battistutta D. Australian pelvic floor questionnaire: a validated interviewer-administered pelvic floor questionnaire for routine clinic and research. Int Urogynecol J 2009; 20: 149-158.
3. Haylen BT, de Ridder D, Freeman RM et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J 2010; 21:5–26.

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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	EUDRA CT NUMBER 2010-019816-19
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	LANDESÄRTZEKAMMER RHEINLAND-PFALZ
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes