

PREVALENCES OF MAJOR LEVATOR ANI MUSCLE DEFECTS 6 WEEKS AND 1 YEAR POSTPARTUM AND FACTORS ASSOCIATED WITH PERSISTING MAJOR LEVATOR ANI MUSCLE DEFECTS 1 YEAR POSTPARTUM.

Hypothesis / aims of study

Tearing of muscle fibres of the levator ani muscle (LAM) from the pubic bone occurring during delivery, so called major levator ani muscle (LAM) defects are associated with pelvic organ prolapse. The prevalences of major LAM defects diagnosed by ultrasonography range between 13 and 39.5 % in primiparous women within the first year postpartum with the highest prevalences reported shortly after delivery (1). Several studies have described maternal and obstetric risk factors for these LAM defects, however the time of defect diagnosis in those studies range between a few days and up to 6 months after delivery (1). Thereby the time from delivery to diagnosis might influence the postulated associations. Our aim was to assess the prevalence of persisting major LAM defects and maternal and obstetric factors associated with persisting muscle defects at 1 year postpartum in primiparous women.

Study design, materials and methods

In this analysis 243 primiparous women with vaginal delivery were included. The overall design of the study was a combined observational cohort study and a randomized controlled trial (RCT) exploring the effect of organized pelvic floor muscle training between 6 weeks and 6 months postpartum. The study was conducted from December 2009 to December 2012 at a large university hospital.

At 6 weeks and 1 year postpartum all women underwent a 3D/4D transperineal ultrasound examination using the GE Voluson E8 (GE Medical Systems) with 4-8MHz curved array 3D/4D ultrasound transducer. The ultrasound images were stored offline by anonymous code numbers and analyzed using 4D View (v. 7.0 and 10.0; GE Healthcare). Major LAM defects were defined by using tomographic ultrasound imaging when an abnormal muscle insertion was present in three central slices; at the plane of minimal dimensions and 2.5 mm and 5 mm cranially to it using a methodology as suggested by Dietz et al. (2). The evaluation of muscle defects were performed by two of the investigators. Good to excellent inter- and intra-rater agreement for detecting LAM defects found ($\kappa \geq 0.79$). We defined two groups according to sonographic findings: "no LAM defect group" with no LAM defect at both times or major LAM defect at 6 weeks, but no persistent LAM defect at 1 year postpartum. The second group, "persistent LAM defect group", included women with major LAM defects at both examinations. Demographic and obstetric data was retrieved from the hospital's electronic birth records. The assessors were blinded to previous ultrasound assessment, the women's demographic data and obstetric histories. Statistical analysis was performed using SPSS Statistics 23.0. Independent sample t-test and Chi-square test were used to assess differences between groups. Logistic regression analysis was performed. Power calculation was performed and the minimum number required in the study to detect a prevalence of 15% of pelvic floor muscle injuries with a 95% degree of confidence with a true population estimate between 10% and 20% was 49.

Results

Mean maternal age of the 243 study participants was 29.7 years (SD 4.1), and the mean pre-pregnancy body mass index (BMI) was 23.7 kg/m² (SD 3.9). Mean gestational age at delivery was 281 days (SD 10.0). Mean follow up postpartum was 6.1 weeks (SD 1.0) and 51.6 weeks (SD 3.0). 191 women (78.6%) had a normal vaginal delivery, 47 women (19.3%) a vacuum delivery and 5 women (2.1 %) had a forceps delivery. At 6 weeks postpartum the prevalence of major LAM defects was 21.0% (n=51). The prevalence of persisting major LAM defects was 10.3% (n=25) 1 year postpartum. 10.7% (n=26) women had a LAM defect diagnosed at 6 weeks postpartum, but not 1 year postpartum. None of the women (n=192) without major LAM defect at 6 weeks had a major LAM defect 1 year postpartum. Women with persistent LAM defects had significantly longer second stage of labour (mean difference of 23.4 minutes, 95% CI = 3.4; 43.4) and a higher fetal birthweight (mean difference of 224.4 grams, 95% CI = 31.4;417.4). Further, persistent defects were associated with vacuum delivery (n=9, 36% versus n=38, 17.4%; crude odds ratio 3.0, 95% CI = 1.2;7.4) The same was true for obstetric anal sphincter injuries (OASIS) (n=4, 16% versus n=4, 1.8 %; crude odds ratio = 10.2, 95% CI = 2.4;43.7). 2 women (8%) in the persistent defect group and 3 women (1.4%) in the no defect group had a forceps delivery. In relation to maternal age, pre-pregnancy BMI, fetal head circumference, total gestational length, episiotomy, induction, oxytocin augmentation, epidural analgesia, vaginal tears and having participated in the training group in the RCT, there was no observed statistical difference between persistent defect and no defect group.

Interpretation of results

In our study 50% of the major LAM defects diagnosed at 6 weeks postpartum were not detectable 1 year postpartum. Both overdiagnosing at 6 weeks and/or natural recovery are plausible explanations for this finding. No major LAM defects were diagnosed only at 1 year postpartum, suggesting that a negative diagnosis might safely be diagnosed early postpartum. Previously described obstetric risk factors for major LAM defects diagnosed within 6 months postpartum such as longer second stage of labour, high fetal birthweight and OASIS could be confirmed as factors associated with persisting major LAM defects. This may implicate that the time of major LAM defect diagnosis is less likely to have an impact when conducting and comparing studies on risk factors for major LAM defects.

Several studies have described forceps but not vacuum as an independent risk factor for major LAM defects. In our study population, the majority of women exposed to instrumental vaginal delivery underwent a vacuum-assisted delivery and we found that vacuum-assisted delivery significantly increased the risk of having a persistent muscle defects. This could indicate that it is

not only the instrument used to facilitate the delivery that causes trauma to the pelvic floor but the fact that an urgent vaginal delivery by itself is a risk factor. Further, differences in obstetric management between hospitals could be an explanation.

Concluding message

The prevalence of major LAM defects decreases with time after delivery.

Negative diagnosis of major LAM might safely be diagnosed early postpartum. Persisting LAM defects 1 year postpartum was found to be associated with known obstetric factors indicating difficult vaginal births. In contrary to other studies vacuum-assisted delivery was found to increase the risk of having persisting LAM defects 1 year postpartum.

References

1. Schwertner-Tiepelmann N, Thakar R, Sultan AH, Tunn R. Obstetric levator ani muscle injuries: current status. *Ultrasound Obstet Gynecol.* 2012;39(4):372-83.
2. Dietz HP, Bernardo MJ, Kirby A, Shek KL. Minimal criteria for the diagnosis of avulsion of the puborectalis muscle by tomographic ultrasound. *International urogynecology journal.* 2011;22(6):699-704.

Disclosures

Funding: South-Eastern Norway Regional Health Authority **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** The Regional Ethics Committee (Cohort: REK South-East D 2009/170 and RCT: REK South-East D 2009/289a) and the Norwegian Social Science Data Service (Cohort: 2799026 and RCT: 2799004) approved the study **Helsinki:** Yes **Informed Consent:** Yes