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## **INTRA- AND INTER-RATER RELIABILITY STUDY OF DIAGNOSING MAJOR DEFECTS OF THE PUBOVISCERAL MUSCLE ON 3D/4D ULTRASOUND IN PRIMIPAROUS WOMEN SIX WEEKS AFTER VAGINAL DELIVERY.**

### Hypothesis / aims of study

There is emerging evidence that major pubovisceral muscle (PVM) defects are one of the links between vaginal delivery and pelvic organ prolapse [1]. Trauma to the PVM resulting in persistent major muscle defects have been detected using MRI and recently also 3D/4D transperineal ultrasound. Major PVM defects have been diagnosed in 21-36% of women who delivered vaginally [2]. Most studies, however, have been performed in women several years after delivery, while few studies examine the PVM in the postnatal period. The short time between delivery and day of diagnostic assessment makes it more difficult to define tissue structures and anatomical landmarks. To our knowledge there are no intra- and inter-rater studies assessing major defects shortly after delivery using 3D/4D transperineal ultrasound.

The aim of the present study was to evaluate the intra- and inter-rater reliability in diagnosing major defects of the pubovisceral muscle in primiparous women 6 weeks after vaginal delivery.

### Study design, materials and methods

This intra- and inter-rater reliability study was conducted at a university hospital July 2010 to January 2011. A convenient sample of 40 primiparous women participating in an ongoing cohort study investigating changes of the pelvic floor muscle during and after pregnancy were included. Inclusion criteria were primiparous women delivering vaginally not earlier than 36 weeks of pregnancy and who could understand and speak the native language.

At six weeks postpartum all women underwent a 3D/4D transperineal ultrasound examination at maximal pelvic floor muscle contraction using the GE Kretz Voluson E8 system (GE Medical Systems) with 4-8MHz curved array 3D/4D ultrasound transducer (RAB4-8I/obstetric). The ultrasound images were stored offline by anonymous code numbers and analyzed using 4D View (v. 7.0 and 10.0; GE Healthcare). The 3D/4D transperineal ultrasound was performed by one investigator, who did a first evaluation of the PVM regarding major defects directly after the clinical examination. To ensure at least 30% of PVM defects in the sample, a project nurse picked 40 datasets randomly out of a list, stratified 1:3. The images were re-analyzed by two investigators 2-4 months after the clinical examination. They were blinded to all previously collected data and each others' results. Major PVM defects were defined by using tomographic ultrasound imaging (TUI) when an abnormal PVM insertion was present in three slices; at the plane of minimal dimensions and 2.5mm and 5.0mm cranially to it [3]. Injuries were graded as unilateral (left /right) and bilateral. In doubtful cases the levator-urethral gap (LUG) was used, with values > 2.5 cm as abnormal.

Statistical analysis was performed using SPSS v 15. Mean values for demographic data were computed. Percentual agreement and Cohen's kappa coefficient were calculated to determine intra- and inter-rater agreement. Kappa values > 0.75 represent excellent agreement, 0.4-0.75 fair to good and < 0.4 moderate to poor agreement.

### Results

For the 40 women included, mean time from delivery was 44.6 days (CI 95%; 42.4-46.9), mean age 28.1 (CI 95%; 27.0-29.2), and mean body mass index 25.3 kg/m<sup>2</sup> (CI 95%; 24.0-26.0). All recorded volumes were possible to assess.

At the initial evaluation, 45% major PVM defects were found in the sample. The second assessment with two investigators rendered 45% and 42.5% major defects, respectively. The first assessor found 7.5% bilateral, 37.5% unilateral (22.5% left and 15% right) whereas the second investigator found 5% bilateral and 37.5% unilateral (left 20% and right 17.5%) defects.

The intra-rater agreement for detecting any major PVM defect was excellent yielding a Cohen's kappa of 0.79 (p< 0.001) with percentual agreement of 90%. The inter-rater agreement was good, with kappa of 0.74 (p< 0.001) and percentual agreement of 87.5%.

Bilateral and right-sided major defects had excellent inter-rater agreement (kappa 0.79; p<0.001 and kappa 0.91; p<0.001 respectively), whereas defects on the left side showed good agreement (kappa 0.63; p<0.001).

### Interpretation of results

In the present study we found good to excellent intra- and inter-rater agreement for detecting major pubovisceral muscle defects in women few weeks after their first delivery using tomographic ultrasound imaging. This could contribute to expanding clinical use of 3D/4D transperineal ultrasound, where women can obtain reliable information concerning the status of their pelvic floor muscle shortly after delivery. The information can be used to motivate early start of conservative, preventive treatment such as pelvic floor muscle training. This again might be preventive for the development of pelvic organ prolapse, although further high quality randomized controlled trials are needed to clarify this. In a research context the assessment by 3D/4D ultrasound seems to be reliable to use as outcome measure in the postnatal period. To ensure validity tomographic ultrasound imaging has to be compared to magnetic resonance imaging, the first method by which PVM defects were detected.

### Concluding message

Tomographic ultrasound imaging of the axial plane seems to be a reliable tool for detecting major pubovisceral muscle defects shortly after childbirth.

### References

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<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Regional Ethical Committee, Oslo, Norway: REK Sør-Øst D 2009/170</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
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