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VALIDATION OF THREE DIMENSIONAL PERINEAL ULTRASOUND AND MAGNETIC RESONANCE IMAGING MEASUREMENTS OF THE PUBOVISCERAL MUSCLE AT REST.

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Abstract

Objective: The aim of is study was to compare the biometric measurements of the pubovisceral muscle at rest measured using transperineal 3D ultrasound and MRI.

Methods: Eighteen female volunteers participated in this prospective study. 3D perineal ultrasound examinations were performed using a **GE Voluson E8 system**. The MR images were obtained using a Siemens Magnetom Harmony 1.0T scanner. All subjects were examined at rest in the supine position. Measurements analyzed were: area, anterioposterior and transverse diameter of the Levator hiatus (LH) (LHarea, LHap, and LHrl). The thickness of the pubovisceral muscle was measured lateral to the vagina and rectum on the right and left sides. (Thickness Rv, Thickness Lv, Thickness Rr, Thickness Lr). Levator urethral gap (LUG) was measured from the center of urethra to the insertion of pubovisceral muscle to the pubic rami. Interclass correlation coefficients (ICC) between the measurements obtained with 3D ultrasound and MRI were calculated. To quantify the inter-measurement agreement, the bias and SDs were calculated, and limits of agreement constructed. One investigator performed all the analyses.

Results: There was no significant difference between the mean values of the parameters examined. The ICC values showed very good agreement (0.80 - 0.97). A significant positive bias was observed for the levator urethral gap on the left side and muscle thickness on the right side of the vagina.

Conclusions: The results of the present study suggest that 3D ultrasound could be used instead of MRI when evaluating static pelvic floor anatomy in women without pelvic organ prolapse at rest.

Introduction

Pelvic floor dysfunction may cause a health problem which is increasing in magnitude[1-3]. The levator ani muscle is the major muscle in the pelvic floor and its integrity plays a key role in pelvic organ support and function maintenance. The levator ani muscle has two major components, the pubovisceral (PV) (entailing the pubococcygeus and puborectalis muscle) and the iliococcygeal muscle. The levator hiatus (LH) is the opening in the pubovisceral muscle defined as the area bordered by the pubovisceral muscle, the symphysis pubis (SP) and the inferior pubic ramus in the axial plane of minimal hiatal dimensions (Figure 1). Abnormalities in the PV muscle can give rise to dysfunction in the related organs such as genital prolapse, faecal and urinary incontinence[4].

The PV muscle lies hidden in the pelvis and until recently magnetic resonance imaging (MRI) has been the only imaging method capable of assessing the levator ani in the axial plane[5-7]. Using two dimensional ultrasound it was previously only possible to assess the PV muscle indirectly in the sagittal plane using the bladder neck as a marker for the position of the muscle in the pelvis. With the technological advances in three and four dimensional (3D / 4D) perineal ultrasound, a new diagnostic tool has become available. The upgraded technique with multiplanar imaging makes it possible to visualize the axial plane[8,9]. Although MRI still has a superior discriminatory capacity, three dimensional ultrasound imaging has the advantage of being more accessible and less expensive. With real time uptake it can also be used in monitoring the functional anatomy in different positions, and it can safely be performed during pregnancy. 3D ultrasound might be a suitable tool to be used, provided that results are reproducible[10,11]**.** Our research group has previously reported on test-retest and inter-observer reliability of the measurements of the pubovisceral muscle and the position of related pelvic organs at rest, during contraction and valsalva using three and four dimensional transperineal ultrasound[12,13] .

The aim of this prospective study was to validate the new three dimensional ultrasound technique by comparing the biometric parameters of the levator hiatus and pubovisceral muscle measured using three dimensional perineal ultrasound and magnetic resonance imaging at rest.

Materials and Methods

A convenient sample of 18 female volunteers was recruited. The exclusion criteria were inability to understand the instructions given in the Norwegian language and claustrophobic tendencies preventing them from undergoing MRI. No volunteers were excluded. The enrolment period was between January and June 2007. Written informed consent was obtained and all participants filled in a questionnaire covering personal data, obstetric history, and subjective symptoms of pelvic floor dysfunction. The time interval between the MRI and perineal ultrasound examinations was 1-3 weeks. The study was approved by the Regional Medical Ethics Committee, and the Data Inspectorate of Norway.

Ultrasound apparatus and procedure

A **GE Voluson E8 system** (GE Medical Systems, Zipf Austria) with 4-8 MHz curved array 3D/4D ultrasound transducer (RAB4-8l/obstetric) was used. The probe was covered with a condom and placed on the perineum. **The ultrasound probe was placed in the midsagittal plane.** Examinations were performed with an acquisition angle of 85º in the coronal plane. The field of view was set to its maximum of 70º in the sagittal plane and depth at 6.5 cm with focus at 3 cm.

The women were examined with an empty bladder, in the supine position with legs slightly abducted and buttocks slightly elevated. 3D ultrasound volumes were acquired and stored on the hard disc of the ultrasound machine. Data were afterwards transferred to a PC for analysis. Each recording was completed in about three seconds. Three volume recordings were taken from each participant (Figure 2a, 2b).

Magnetic resonance imaging apparatus and procedure

The same posture was repeated during the MRI examination. MR images were recorded using a Siemens MAGNETOM Harmony 1.0 T. scanner (Siemens AG, Munich, Germany). T2-tse-sag protocol series and Pd/T2 -Tra were acquired and analyzed. Pd+T2 with TR /TE 3120 ms / 14 ms slice thickness 3 mm protocol for axial plane was used. T2-weighted, slice thickness 4mm slice gap 2 mm TR / TE 4500 ms / 99 ms Matrix 256 X 256 and field of view 280 mm.Scan time 5-8 min. A reference image in the sagittal plane was marked from the middle of the posterior inferior margin of the symphysis pubis (SP) to the anorectal angle with minimal antrioposterior diameter[14] (Figure 3a). Ten images in the sagittal plane and 22-29 images in the axial plane were obtained in order to be sure to capture the levator hiatus in minimal dimensions (Figure 3b).

Definitions of the biometric measurements done on the images obtained by both imaging techniques

Levator hiatus dimensions

Levator hiatus dimensions were assessed by measuring: area, anterior-posterior and transverse diameter of the levator hiatus (LHarea, LHap, and LHrl) at the plane of minimal hiatal dimensions. The plane of minimal hiatal dimensions is thought to represent the true levator hiatus and is measured in the axial plane[8,9] . This plane is identified as the minimal distance between the posterior- inferior aspect of the SP and the anterior border of the pubovisceral muscle at the anorectal angle[9,15]. The anorectal angle is formed by the pubovisceral muscle and can be seen in the mid-sagittal images as the junction between the rectum and the anal canal where the levator hiatus have the absolute minimal dimension in the anterior-posterior (LHap) direction. The inferior border of the SP and PV muscle appears hyperechogenic on ultrasound and hypoechogenic on MR imaging (Figure 2, Figure3). On MR images a similar selection was performed looking through the 22-29 images obtained in the axial plane. The levator hiatus (LHarea) was defined and measured as the area bordered by the pubovisceral muscle, the symphysis pubis (SP) and the inferior pubic ramus. **The transverse diameter of the levator hiatus from right to left (LHrl) was measured as the widest distance between the inner margins of the pubovisceral, perpendicular to LHap. All the measurements including the transverse diameter were performed on the image of the minimal hiatal dimensions in the axial plane (Figure 4a, 4b).** The levator urethral gap (LUG) was measured from the mid-urethra to the insertion of the pubovisceral muscle on the right and left sides (LUGR, LUGL) (Figure 5a, 5b).

The thickness of the pubovisceral muscle

The thickness of the pubovisceral muscle was measured lateral to the vagina and rectum on the right and left sides. (Thickness Rv, Thickness Lv, Thickness Rr, Thickness Lr) (Fig5a, 5b). The lateral aspect of the puborectalis muscle can be difficult to define on ultrasonography. This is due to less apparent distinction between puborectalis and pubococcygeus. In the analyses of the ultrasound volumes rotation of the image using 4Dview programme was sometimes useful. All measurements were performed on the axial image at the level of minimal hiatal dimensions.

Analyses of the ultrasound volumes

Analyses of the 3D volumes were conducted offline at a later date, on a laptop using the software “4DView version 6.2 (GE Healthcare, Zipft Austria) according to a protocol used in our previous studies[13,15,16]. **All volumes were previewed. The volume with the best imaging quality (visible symphysis pubis, inner and posterior margins of pubovisceral muscle) was selected from the three volumes recorded for each participant. The search for the plane with the minimal dimensions of (LH) was performed in this volume. In order to ensure that this plane was found a multiplanar image display of the levator hiatus was used (Figure 1). The multiplanar image contains three sections. Section A shows the**

sagittal plane, section B the coronal plane and section C the axial plane. The axis of rotation was moved to the posterior- inferior margin of the SP in the sagittal plane (section A), and the mid-sagittal plane was rotated in the cranial or caudal direction, while the axial plane (section C) was carefully observed to find the plane where levator hiatus had the absolute minimal dimension in the anterior posterior direction (LHap)[8]. The image with the minimal hiatus dimensions was searched and measured three times from the same volume recording. The mean of these three values was used in further statistical calculations. None of the volunteers were excluded.

Analyses of the MR images

MR images were recorded on a CD and analyses of the images were conducted with the software Syngo view and Syngo Leonardo systems (Siemens AG, Munich. Germany) using the method described by Kruger et al[17]. This method has shown substantial correlation and narrow limits of agreements for the measurements of the levator hiatus at rest. The MR images were analyzed in the axial plane at the level of minimal dimensions three times. The same investigator (MM) performing the ultrasound analyses performed the analyses of the MR images while blinded to ultrasound and clinical data.

Statistical analyses

Statistical analysis was performed with SPSS version 15 (SPSS, Chicago, IL, USA).

To evaluate the agreement between the measurements, interclass correlation coefficient (ICC) was calculated using a general linear univariate model to identify different variance components. The scale developed by Altman was used in classification of the reliability values [18]. ICC values under 0.20 were considered poor, 0.21- 0.40 fair, 0.41-0.60 moderate, 0.61-0.80 good, and 0.81-1.00 very good. Because of some of the drawbacks of ICC[19], we also used the Bland-Altman approach to estimate the agreement between the two methods[20]. The *limits of agreement* are defined as an interval within which 95% of the differences will lie, and is given as the bias with 95 %CI. To quantify the inter-measurement agreement, the differences between averaged measurement values (bias) and SDs were calculated, and limits of agreement constructed[20]. No "a priori" definition of the maximum width for limits of agreement was made before analyzing the results, since there is not enough data to suggest how large a difference would be clinically important.

Results

The median age of participants was 47.5 (range 30 - 61), the median body mass index (BMI) was 23.5 (range 19.3 - 36.2), while the median parity was 2 (range 0 - 3). All participants met the inclusion criteria. Three (8.3 %) participants had instrumental deliveries**.** Only one woman had minor symptoms of genital prolapse. There was no significant difference between the absolute mean values of the levator hiatus and levator urethral gap measured by ultrasound and MRI (Table 1). The ICC values showed very good agreement (0.89- 0.97) in all parameters measured (Table 2). A significant positive bias was observed for the levator urethral gap on the left side (Table 2). There was no significant difference in the mean values for the PV muscle thickness on the left and the right sides (Table 1). The ICC values for measurements of PV muscle thickness were very good (0.80 - 0.91) (Table 2). A significant bias was noted for the measurement of the muscle thickness on the right side of the vagina (Thickness Rv) (Table 2).

Discussion.

This validation study of the measurements of the biometric parameters of the levator hiatus and pubovisceral muscle thickness obtained by three dimensional ultrasonography and magnetic resonance imaging at rest shows very good correlation. This is in concordance with the data presented by Kruger at al. who also made their measurements at the plane of minimal hiatal dimensions of the levator ani in both modalities and used patients without prolapse symptoms[17,21]. Our findings are contradicted by an earlier study that showed moderate to poor correlation between levator hiatus measurements[21]. The differences in outcomes might be explained by the fact that they chose a different plane for the MRI scans and included women with symptoms of pelvic organ prolapse.

We chose to use limits of agreement as recommended by Bland and Altman when evaluating and comparing the new method with the established one [22]. Using this approach it is possible to detect systematic bias, e.g. the situation where one of the modalities constantly gets higher values. In this study there was a significant systematic bias in the measurements of thickness of the PV muscle on the right side of the vagina (Thickness Rv) and the left urethral gap (LUGL) implying that the limit of agreement for these two parameters should be interpreted with caution. We did not find it meaningful to try to define the maximum width for limits of agreement since there is not enough data to indicate what differences in estimates would be clinically important. Generally the limits of agreement were narrow.

In the present study we enrolled participants with almost no subjective symptoms of prolapse Patients with pelvic organ prolapse, might have tissue that is more difficult to capture, and patients with stage three and four prolapse are more difficult to examine[21,23].

Due to the limitation of our MRI equipment only acquisitions of the biometric parameters at rest were obtained. However, the majority of research preformed using MRI as the diagnostic tool when scanning the pelvic floor has been performed as static imaging. Only recently has the scanning capacity of the MRI enabled real-time scanning [24]. Although to date MRI has a superior resolution capability, and should be used as the gold standard for monitoring patients in the resting position, it can be argued that there is not enough data to support the gold standard status of MRI when investigating functional anatomy. On the other hand, it might be suggested that the three and four dimensional ultrasound could compete for that position.

Except for a couple of test patients there was only one investigator analysing the data. Even if it would have added strength to the study having two observers analyzing the data, the reproducibility of the imaging using both MRI and 3 D ultrasound have been reported extensively and found to be good especially in static imaging[9,14,25-28]. We have previously published the test-retest data and inter-observer reliability for measurement of the pelvic floor using three and four dimensional ultrasound, showing good to very good intra- and inter-rater repeatability for measurements in the axial plane[12,13]. To ensure validity of the present ultrasound measurements we have now also tested the method comparing it to a gold standard, MRI. Our results in this validation study imply that three dimensional perineal ultrasound could be a reliable method, adding information about the anatomy of the pubovisceral muscle at rest in women with no or little subjective symptoms of prolapse. Although confirmation studies in patients with pelvic organ prolapse are needed, we feel confident about using the three dimensional ultrasonography as a tool for further research exploring the anatomy of the pelvic floor.

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