Interobserver repeatability of three- and four-dimensional transperineal ultrasound assessment of pelvic floor muscle anatomy and function

M. MAJIDA*, I. H. BRÆKKEN†, W. UMEK‡, K. B؆, J. ŠALTYTĖ BENTH§ and M. ELLSTRØM ENGH*¶

*Akershus University Hospital, Department of Obstetrics and Gynaecology, Lørenskog and †Norwegian School of Sport Sciences, Department of Sports Medicine and §Helse Sør-Øst Health Services Research Centre and Faculty of Medicine and ¶Faculty Division Akershus University Hospital, University of Oslo, Oslo, Norway and ‡Medical University Vienna, Department of Obstetrics and Gynaecology, Vienna, Austria

KEYWORDS: interobserver repeatability; levator hiatus dimensions; pelvic floor muscle anatomy; transperineal ultrasound

ABSTRACT

Objective To evaluate the interobserver repeatability of measurement of the pubovisceral muscle and levator hiatus, and the position of related organs, during rest, muscle contraction and Valsalva maneuver using three- and fourdimensional (3D and 4D) transperineal ultrasound.

Methods Seventeen women were included in the study. The position and dimensions of the pubovisceral muscle and levator hiatus in patients at rest and during contraction and Valsalva were determined from stored 3D and 4D ultrasound volumes. Analyses were conducted offline by two observers blinded to the clinical data and to each others' measurements.

Results Measurements of levator hiatal dimensions at rest demonstrated intraclass correlation coefficient (ICC) values of 0.92 to 0.96. The ICC values for pubovisceral muscle thickness at rest varied between good and very good (ICC, 0.61–0.93), regardless of plane. During contraction, the ICC values for all measured parameters were very good, varying between 0.61 and 0.92. Measurement of the transverse diameter of the levator hiatus during the Valsalva maneuver showed good reliability (ICC, 0.86), but assessment of the anterior and posterior borders of the levator hiatus was only possible in 29% of cases.

Conclusions 3D and 4D transperineal ultrasound measurement of the pubovisceral muscle and levator hiatus is reliable in women with no or minor symptoms of prolapse at rest and during contraction. The technique for recording during the Valsalva maneuver requires improvement if it is to be useful in the diagnosis of pelvic organ prolapse. Copyright © 2009 ISUOG. Published by John Wiley & Sons, Ltd.

INTRODUCTION

It has been estimated that half of women who have given birth lose pelvic floor support, resulting in some degree of pelvic organ prolapse (POP), and that 10-20% of these women will seek medical attention for this condition 1,2 . Approximately 10% of all women will undergo surgery for a prolapse condition at some point in their lives³. The surgical treatment performed has been criticized for not being effective, with up to 30% recurrence rates of POP in the anterior compartment⁴. One of the reasons for the unsatisfactory results is that existing diagnostic tools fail to reveal the exact fascial or muscular defects of the pubovisceral muscle. While indirect information on the pubovisceral muscle can be obtained easily and cheaply using two-dimensional (2D) ultrasound systems, direct demonstration of the pelvic floor muscle is improved by using axial plane imaging⁵⁻⁸, which has previously only been possible with magnetic resonance imaging $(MRI)^{9,10}$. With the technical improvement of three- and four-dimensional (3D and 4D) transperineal ultrasonography, a new diagnostic tool has become available¹¹. The patient can be examined with minimal discomfort at little expense, and recordings in real time can easily be made. This makes the assessment of pelvic floor structures during movement and in the standing position possible. Improved ability to describe prolapse by visualizing the

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Correspondence to: Dr M. Majida, Department of Obstetrics and Gynecology, Akershus University Hospital, 1478 Lørenskog, Norway (e-mail: memona.majida@medisin.uio.no)

functional pelvic floor anatomy should make it possible to avoid unnecessary surgery and futile conservative treatment. Indirect imaging with 2D ultrasound has mainly been used to date to assess surgical outcomes, but seldom as a diagnostic tool in everyday practice. The question is whether or not access to the axial plane using 3D and 4D ultrasound can help us to be more precise in our diagnoses, thereby enabling us to offer our patients individualized treatment.

Our research group has previously reported on test-retest and intraobserver reliability of measurements of the pubovisceral muscle and the position of related pelvic organs at rest and during movement, conducted in the supine and standing positions using 2D, 3D and 4D transperineal ultrasound¹². The variables reported were used as outcome parameters in a randomized controlled trial exploring the effects of pelvic floor exercise on POP. In this interobserver study we focused on measurements obtained using 3D and 4D ultrasound, with the aim of evaluating the interobserver repeatability of measurement of the dimensions of the pubovisceral muscle and levator hiatus, and position of related organs, during rest, muscle contraction and Valsalva maneuver.

METHODS

A convenience sample of 17 healthy female volunteers was recruited for the study. The inclusion criterion was the ability to contract the pelvic floor muscles. Correct contraction was defined as inward lift of the pubovisceral muscle as assessed using ultrasonography. The exclusion criterion was the inability to understand instructions given in the Norwegian language. No volunteers were excluded. The demographic data of the volunteers have previously been reported in the intraobserver study¹². Mean age was 47.9 (range, 29-71) years, body mass index was in the normal range (20.7-24.9 kg/m²), mean number of births was 1.8 (range, 0-4), two (13%) of which were instrumental deliveries. Two women reported moderate prolapse symptoms. The Regional Medical Ethics Committee approved the study, and all subjects gave their written informed consent to participate.

A Voluson 730 Expert ultrasound system (GE Medical Systems, Zipf, Austria) with a 4–8-MHz curved array 3D/4D ultrasound transducer (RAB 4–8 l/obstetric) was used. The probe was covered with a condom and placed on the perineum in the sagittal plane. The field of view angle was set to its maximum of 70° in the sagittal plane, and the volume angle to 85° in the coronal plane.

One gynecologist (M. M.) performed all ultrasound examinations. A physiotherapist (I. H. B.) gave instructions to the participants and supervised the test procedure. Participants were instructed to void their bladder before the examination, which took 45 min. Three 3D static volumes were recorded in the lithotomy position with the participants at rest. Automatic image acquisition took about 3 s each. Subsequently, the participants were asked to stand upright with their legs slightly abducted. In this position, the participants were asked to perform three maximum voluntary contractions of the pubovisceral muscle and three Valsalva maneuvers. A Valsalva maneuver was defined as a forced expiration against a closed glottis, and the participants were encouraged to push as during delivery. To minimize the variation in probe angle used during recordings, the operator supported her arm on her knee. Each pubovisceral muscle contraction and Valsalva maneuver took approximately 10 s to perform and was recorded with 4D real-time ultrasound.

Analyses of 2D, 3D and 4D ultrasound volumes and cine loops were conducted offline on a laptop using the 4D View v. 5.0 software (GE Medical Systems). The analyses were performed with the observers blinded to clinical data and to one anothers' measurements.

The interobserver reliability tests were performed independently by two investigators (M. M. and I. H. B.). The best of the three recordings was used and analyzed three times. The best pubovisceral muscle contraction was defined as the one with the most cranial displacement. The best Valsalva maneuver was defined as the one with the most caudal displacement, and where the entire posterior border of the levator hiatus was visible.

Levator hiatus dimensions

The area of the levator hiatus (LHarea) was defined and measured as the area bordered by the pubovisceral muscle, pubic symphysis and inferior pubic ramus in the axial plane of minimal hiatal dimensions (Figure 1). The plane of minimal hiatal dimensions was identified as the minimal distance between the hyperechogenic posterior aspect of the pubic symphysis and the hyperechogenic anterior border of the pubovisceral muscle at the anorectal angle, as described by Dietz et al.¹³. The anorectal angle is formed by the pubovisceral muscle and can be seen in the mid-sagittal view as the junction between the rectum and anal canal. In order to ensure that the absolute minimal hiatal dimensions were found, the axis of rotation was moved to the inferoposterior margin of the pubic symphysis, and the mid-sagittal plane was rotated while the axial plane was carefully observed to find the plane where the levator hiatus had the absolute minimal dimension in the anterior/posterior direction (LHap) (Figure 1). Analyses were conducted on 3D static images recorded in the lithotomy position. Measurements of the LHarea were also obtained from 4D real-time volumes in the standing position. The transverse diameter of levator hiatus from right to left (LHrl) was measured on the widest part, perpendicular to LHap (Figure 1).

Thickness of the pubovisceral muscle

The thickness of the pubovisceral muscle was measured from 3D static volumes recorded in the lithotomy position. Six measurements were taken. In the axial plane of minimal hiatal dimensions the thickness was measured lateral to the vagina on the right and left side, perpendicular to the presumed pubovisceral muscle fiber direction (Figure 1a). The thickness was also measured



Figure 1 (a) Measurements in the axial plane of minimal levator hiatal dimensions. a, levator hiatus area; b, levator hiatus anteroposterior diameter; c, levator hiatus transverse diameter (right–left). d–g, thickness of pubovisceral muscle lateral to the vagina (d, e) and rectum (f, g), on right and left sides, respectively. (b) Sagittal image showing quantification of bladder neck (BN) position relative to a horizontal reference line at the level of the inferoposterior margin of the pubic symphysis (PS) (x-axis and y-axis, horizontal and vertical distances from the inferoposterior margin of the PS, respectively).

in the plane of maximal pubovisceral muscle thickness, posterolaterally to the vagina and to the rectum, on the right and left sides¹³.

Pubovisceral muscle contraction and Valsalva maneuver

Pubovisceral muscle contractions and Valsalva maneuvers were performed by patients in the standing position

and 4D real-time volumes were obtained. Narrowing and widening of the LHarea was measured in the axial plane of minimal hiatal dimensions as the difference between measurements at rest and during maximal contraction and Valsalva, respectively (Figure 2).

At rest, and during maximum contraction and Valsalva, the position of the internal urethral meatus (middle of the bladder neck) was identified in the mid-sagittal plane relative to a horizontal reference line, at the level of the inferoposterior margin of the pubic symphysis¹⁴ (Figure 1b). The reference line is horizontal relative to the ultrasound frame/screen's image, i.e. at a 90° angle to the transducer head. To ensure a true horizontal reference line when examining in the standing position, the transducer has to be precisely pointed in the cranial orientation. During contraction and Valsalva, the displacement of the bladder neck was measured as the hypotenuse of a right-angled triangle (Displacement = $\sqrt{(\Delta x^2 + \Delta y^2)}$). The levator plate angle was measured and defined as the angle between two lines, one from the inferoposterior margin of the pubic symphysis to the anorectal angle, the other being the horizontal reference line described above. Only a small part of the pubic symphysis was scanned in order be able to include the back sling of the pubovisceral muscle. Displacement of levator plate angle was calculated as the difference in this angle from maximum contraction and Valsalva to resting position^{13,14}.

Statistical analysis

A general linear univariate model was used to calculate different variance components needed for ICC estimation when evaluating interobserver agreement. The scale from Altman was used in classification of the reliability values¹⁵. 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 ICC¹⁶, we also used the Bland–Altman approach to assess the agreement between two observers¹⁷. To quantify the interobserver agreement, the differences between averaged measurement values (bias) and SD were calculated, as were the limits of agreement¹⁷. No a priori definition of the maximum width for limits of agreement was made before analyzing the results, since there were not enough data to suggest how large a difference would be clinically important. Statistical analyses were performed using Excel (Microsoft Corp., Redmond, WA, USA) and SPSS version 15.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Levator hiatus dimensions at rest

Interobserver agreement for all hiatal dimensions demonstrated very good reliability (Table 1). There was no difference in the ICC values of the hiatal area when analyzing the 4D volumes in the standing position or 3D volumes in the lithotomy position. The two examiners agreed that 13 volume acquisitions for women in the



Figure 2 Axial images of the levator hiatus at rest (a), during contraction (b) and during Valsalva maneuver (c). A, anal opening; U, urethra; V, vagina.

Table 1 Interobserver differences in measurement of the dimensions of the levator hiatus (LH) at rest

		Mean (95% CI)	n	ICC	Bias	SD	Limits of agreement		
Parameter	Observer						Lower limit (95% CI)	Upper limit (95% CI)	
Lithotomy positio	n†								
LHap (cm)	. 1	6.0 (5.7 to 6.3)	17	0.96	-0.12*	0.20	-0.56 (-0.80 to -0.32)	0.32 (0.08 to 0.56)	
	2	6.1 (5.8 to 6.4)							
LHrl (cm)	1	4.4 (4.1 to 4.7)	17	0.96	-0.03	0.28	-0.65 (-0.99 to -0.31)	0.59 (0.25 to 0.93)	
	2	4.4 (4.2 to 4.7)							
LHarea (cm ²)	1	18.6 (17.3 to 19.9)	17	0.92	-0.46	1.64	-4.05 (-5.94 to -2.16)	3.13 (1.24 to 5.02)	
	2	19.1 (17.8 to 20.3)							
Standing position:	ŧ								
LHarea (cm ²)	1	21.7 (18.5 to 24.8)	13	0.93	0.82	3.60	-6.39 (-10.45 to -2.34)	8.04 (3.99 to 12.09)	
	2	20.4 (17.4 to 23.4)					. ,	. ,	

*Significant at the level of 5%. †Measured from stored three-dimensional ultrasound image. ‡Measured from stored four-dimensional real-time ultrasound scan. ap, anteroposterior diameter. rl, right–left transverse diameter.

standing position were measurable. There was a significant systematic interobserver bias shown for LHap.

Thickness of the pubovisceral muscle at rest

Table 2 shows interobserver values for all six measurements of pubovisceral muscle thickness. In each patient the ICC values of muscle thickness varied between good and very good independent of plane (minimal hiatal dimensions, maximal muscle thickness) or side (right, left).

Levator hiatus during pubovisceral muscle contraction

All measurements of the levator hiatus in the axial plane during contraction showed very good reliability (Table 3). The calculated change in hiatal opening showed good reliability. Both measurements of the elevation of the pelvic floor estimated in terms of the bladder neck displacement in the cranioventral direction and the change in the levator plate angle from rest to maximum contraction showed good reliability. There was a significant systematic interobserver bias in the measurement of LHap during contraction.

Levator hiatus during Valsalva maneuver

The measurements of LHrl showed good reliability (ICC, 0.86). The assessors disagreed on the number of recordings in which it was possible to estimate LHap during maximum Valsalva (9 vs. 5), with both observers agreeing that it could be assessed in five of the cases. In only 29% of the cases did both assessors agree on having seen borders of the levator hiatus, which during maximum Valsalva extended beyond the stored volume in the remaining cases. Very good reliability was shown for the remaining measurements (Table 3). Fair repeatability was found in the calculated proportional increase in the hiatal dimensions. It was only possible to estimate changes in levator plane angle from rest to maximum Valsalva in two patients, and we therefore excluded these data from further analysis.

DISCUSSION

In this interobserver study we found very good and good reliability of measurements of the levator hiatus and pubovisceral muscle thickness at rest, respectively. These

	Observer	Mean (95% CI)	n	ICC	Bias	SD	Limits of agreement	
Parameter							Lower limit (95% CI)	Upper limit (95% CI)
Plane of minimal hiat	al dimensions							
ThicknessL (cm)	1	0.8 (0.7 to 0.9)	15	0.75	-0.14	0.40	-0.92 (-1.29 to -0.55)	0.65 (0.28 to 1.02)
	2	0.9 (0.7 to 1.1)						
ThicknessR (cm)	1	0.8 (0.7 to 1.0)	14	0.82	-0.14	0.28	-0.70 (-0.97 to -0.42)	0.41 (0.13 to 0.68)
	2	0.9 (0.8 to 1.1)						
Plane of maximum m	uscle thickness	5						
ThicknessLv (cm)	1	0.9 (0.8 to 1.0)	17	0.87	0.03	0.22	-0.39 (-0.58 to -0.19)	0.45 (0.26 to 0.65)
	2	0.8 (0.7 to 0.9)						
ThicknessRv (cm)	1	0.9 (0.7 to 1.0)	16	0.93	-0.01	0.17	-0.35 (-0.60 to -0.10)	0.32 (0.07 to 0.57)
	2	0.9 (0.8 to 1.0)						
ThicknessLr (cm)	1	0.8 (0.7 to 0.9)	17	0.80	0.01	0.17	-0.32 (-0.49 to -0.14)	0.33 (0.16 to 0.50)
	2	0.8 (0.7 to 0.8)						
ThicknessRr (cm)	1	0.8 (0.7 to 0.9)	17	0.61	-0.07	0.20	-0.46 (-0.65 to -0.28)	0.32 (0.14 to 0.51)
	2	0.9 (0.8 to 0.9)						

Table 2 Interobserver differences in measurement of the thickness of the pubovisceral muscle at rest

L, left; R, right; r, assessed lateral to rectum; v, assessed lateral to vagina.

Table 3 Interobserver differences in measurement of the levator hiatus (LH) dimensions and displacement of the bladder neck and levator plate during contraction and Valsalva

	Observer	Mean (95% CI)	n	ICC	Bias	SD	Limits of agreement	
Parameter							Lower limit (95% CI)	Upper limit (95% CI)
LHap								
During contraction (cm)	1	5.0 (4.6 to 5.4)	16	0.82	0.43*	0.72	-0.98 (-1.66 to -0.31)	1.85 (1.18 to 2.52)
	2	4.6 (4.2 to 5.0)						
Reduction (%)	1	16.8 (9.9 to 23.6)	16	0.72	-7.96*	13.31	-34.05 (-48.17 to -19.93)	18.13 (4.01 to 32.25
	2	26.9 (19.9 to 33.9)						
During Valsalva (cm)	1	6.8 (6.13 to 7.5)	5	0.90	0.48	0.41	-0.32 (-1.24 to 0.60)	1.28 (0.36 to 2.21)
_	2	6.1 (5.3 to 7.0)						
Increase (%)	1	11.7 (9.9 to 13.4)	5	0.22	9.28	9.77	-9.87 (-44.42 to 24.69)	28.44 (-6.12 to 62.99)
	2	1.5 (-13.0 to 16.1)						
LHarea								
During contraction (cm ²)	1	15.8 (14.1 to 17.5)	15	0.92	0.73	2.85	-4.86 (-7.58 to -2.14)	6.31 (3.60 to 9.03)
-	2	15.2 (12.7 to 17.6)						
Narrowing (%)	1	25.8 (17.2 to 34.3)	12	0.84	-2.43	15.17	-32.16 (-48.92 to -15.40)	27.30 (10.54 to 44.86)
	2	28.6 (20.7 to 36.6)						
During Valsalva (cm ²)	1	24.1 (17.9 to 30.3)	4	0.98	1.26	3.65	-5.90 (-16.72 to 4.92)	8.42 (-2.40 to 19.24)
	2	25.8 (14.5 to 37.1)						
Enlargement (%)	1	24.1 (15.9 to 32.3)	4	0.70	3.34	18.65	-33.21 (-88.83 to 22.40)	39.89 (-15.72 to 95.51)
	2	24.7 (9.7 to 39.7)						
Displacement of bladder nec	k							
During contraction (cm)	1	1.0 (0.7 to 1.2)	17	0.61	0.01	0.63	-1.22 (-1.77 to -0.67)	1.23 (0.68 to 1.78)
	2	1.0 (0.8 to 1.2)						
During Valsalva (cm)	1	1.7 (1.4 to 1.9)	17	0.83	-0.38	0.43	-2.28 (-4.88 to 0.33)	1.51 (-1.09 to 4.12)
	2	2.1 (1.9 to 2.2)						
Displacement of levator plat	e angle							
During contraction (°)	1	12.3 (5.8 to 18.8)	13	0.64	-2.61	9.05	-20.35 (-30.38 to -10.33)	15.13 (5.11 to 25.16)
_	2	15.8 (10.4 to 21.3)						

*Significant at the level of 5%. ap, anteroposterior diameter.

values are comparable to the results in our intraobserver study and are in accordance with the findings of other researchers^{12,18}. The 4D measurements of the levator hiatus during contraction of the pubovisceral muscle showed very good reliability in the axial plane, with measurement of displacement of the bladder neck and the levator plate showing good reliability in the sagittal plane. It was more difficult to capture 4D datasets of the levator hiatus during Valsalva maneuver, as the borders of the posterior part of the muscle were found to disappear from the frame in most cases. This difficulty in assessing the levator hiatus during Valsalva has also been reported by others¹⁹.

One of the suggested advantages of the 3D and 4D ultrasound techniques as compared with MRI is the possibility of visualizing the functional pelvic floor anatomy in the axial plane with the patient standing up. In our study this could be done with good repeatability during rest and contraction. The size of the levator hiatus has been shown to correlate with the degree of pelvic organ descent²⁰. It has been suggested that the dimensions of the levator hiatus during Valsalva have a stronger correlation with the degree of prolapse than do the dimensions during rest and contraction²¹. This underlines the importance of improving the acquisition of measurements during this movement. We had difficulty in capturing the posterior border of the levator hiatus during Valsalva despite having access to a transducer with a wide acquisition angle (85°) . Having the patient in the standing position during the examination makes it more difficult for the examiner to get an overview and to hold the transducer at the required angle in relation to the perineum as compared with having the patient in the traditional lithotomy position. There are, however, data suggesting that the erect position might not be very important, and that comparable results can be achieved with the patient in the lithotomy position²².

Although only four women in our group of volunteers were nulliparous, only two of the participants reported minor symptoms of prolapse. Patients with pelvic organ prolapse might have tissue that is more difficult to capture. For obvious reasons, patients with stage three and four prolapse would be even more difficult to examine during Valsalva.

The optimal study design when testing the repeatability of a new technique is to have at least two examiners each performing independent ultrasound examinations of the patients and thereafter analyzing the results²³. However, the design of the present study was chosen for logistical reasons, since there was only one gynecologist at the department trained to perform the examination at the time of data collection.

We chose to use limits of agreement as recommended by Bland and Altman when evaluating interobserver repeatability²⁴. Using this approach it is possible to detect systematic bias, i.e. a situation where one of the examiners consistently gets higher values than the other. In this study there were very few measurements with bias reaching significant values, implying that they should be interpreted with caution. We did not find it meaningful to try to define the maximum width for limits of agreement since there are not enough data to explain which differences in estimates are clinically important.

Many authors have recommended indirectly assessing the position of the pelvic floor in the sagittal plane by measuring the position of the bladder neck using a coordinate system with a reference line through the axis of pubic symphysis²⁵. The accuracy of the method has been challenged, because one of the major sources of variance is the inability to assess the central axis accurately²⁶.

Instead of using the line through the axis of the pubic symphysis a line horizontal to the transducer has been suggested by Dietz¹¹. It may be challenging to get women to stand with the exact same pelvic inclination and for the examiner to point the transducer in the vertical orientation while performing the examination.

In this study we tested interobserver reliability for the measurement of the pelvic floor muscle using transperineal ultrasonography. There are at least three types of coefficient of reliability: stability (test-retest method), alternate forms (parallel-form method or equivalence method) and internal consistency. We have previously published a study on test-retest data showing good to very good intraobserver repeatability for measurements in the axial plane¹². To ensure validity the present ultrasound measurements would have to be compared with a gold standard. Previous work comparing MRI and 3D transperineal ultrasound has shown moderate to substantial agreement between the two modalities¹⁹, particularly for parameters measured at rest (findings we have also obtained (unpubl. data)) and during contraction.

In conclusion, our results from this interobserver study support our previous findings that 3D and 4D transperineal ultrasound could be a reliable method for obtaining additional information on the functional anatomy of the pubovisceral muscle during rest and contraction in women with few, if any, subjective symptoms of prolapse. However, more work remains to be done before we can recommend that the technique be used for recording during a Valsalva maneuver.

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