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Agreement and reliability of pelvic floor measurements during rest and on maximum Valsalva maneuver using three-dimensional translabial ultrasound and virtual reality imaging

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KEYWORDS: 3D translabial ultrasound; agreement; levator hiatus; pelvic floor muscles; pelvic organ prolapse; reliability; virtual reality imaging

ABSTRACT

Objectives *Imaging of the levator ani hiatus provides valuable information for the diagnosis and follow-up of patients with pelvic organ prolapse (POP). This study compared measurements of levator ani hiatal volume during rest and on maximum Valsalva, obtained using conventional three-dimensional (3D) translabial ultrasound and virtual reality imaging. Our objectives were to establish their agreement and reliability, and their relationship with prolapse symptoms and POP quantification (POP-Q) stage.*

Methods *One hundred women with an intact levator ani were selected from our tertiary clinic database. Information on clinical symptoms were obtained using standardized questionnaires. Ultrasound datasets were analyzed using a rendered volume with a slice thickness of 1.5 cm, at the level of minimal hiatal dimensions, during rest and on maximum Valsalva. The levator area (in cm^2) was measured and multiplied by 1.5 to obtain the levator ani hiatal volume (in cm^3) on conventional 3D ultrasound. Levator ani hiatal volume (in cm^3) was measured semi-automatically by virtual reality imaging using a segmentation algorithm. Twenty patients were chosen randomly to analyze intra- and interobserver agreement.*

Results *The mean difference between levator hiatal volume measurements on 3D ultrasound and by virtual reality was 1.52 cm^3 (95% CI, 1.00–2.04 cm^3) at rest and 1.16 cm^3 (95% CI, 0.56–1.76 cm^3) during maximum Valsalva ($P < 0.001$). Both intra- and interobserver intraclass correlation coefficients were ≥ 0.96 for conventional 3D ultrasound and > 0.99 for virtual reality. Patients with prolapse symptoms or POP-Q Stage ≥ 2 had significantly larger hiatal measurements than those without symptoms or POP-Q Stage < 2.*

Conclusions *Levator ani hiatal volume at rest and on maximum Valsalva is significantly smaller when using virtual reality compared with conventional 3D ultrasound; however, this difference does not seem clinically important. Copyright © 2015 ISUOG. Published by John Wiley & Sons Ltd.*

INTRODUCTION

It has been shown that enlargement of the levator ani hiatus, so-called 'ballooning', is associated with an increased risk of pelvic organ prolapse for all three pelvic compartments[1–3]. Furthermore, it is associated with prolapse recurrence after previous prolapse surgery[4]. Therefore, imaging of the levator ani hiatus, especially on maximum Valsalva, can be of great value in the diagnosis and follow-up of patients with symptoms of pelvic organ prolapse.

The levator ani hiatus can be visualized using magnetic resonance imaging (MRI) or three-dimensional (3D) translabial or endovaginal ultrasonography[5–7]. However, there may be some limitations. It has been postulated that, in real multiplanar MRI construction, the levator hiatus is visualized as a non-Euclidean hyperbolic structure[8,9]. 3D translabial ultrasound measurements are currently performed on two-dimensional (2D) rendered images, obtained from data volume analysis of 3D/four-dimensional (4D) cineloops. The non-Euclidean

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nature, i.e. the concave and convex shape of the levator hiatus, is therefore not taken into consideration in volume measurements obtained by 3D translabial ultrasound. This may overestimate or underestimate the 'real' levator hiatal area.

The I-Space is a virtual reality system which enables 3D ultrasound datasets to be visualized as a 'hologram'[10]. The concave and convex features of the levator ani can therefore be visualized, allowing the investigator to measure the actual 3D volume. The I-Space has been used successfully for studies on prenatal ultrasonography[10,11] and this technique has recently been applied in a study on 3D translabial pelvic floor ultrasound[12]. This study showed that measurements of levator ani volume during contraction using virtual reality were reliable and comparable to conventional 3D ultrasound measurements[12].

For clinical use, it is important to obtain measurements of the levator ani hiatal volume at rest and especially during maximum Valsalva, because examination during maximum Valsalva determines the severity of prolapse[1,13].

This study was designed to compare levator ani hiatal volume at rest and on maximum Valsalva, measured using conventional 3D translabial ultrasound and virtual reality, and to establish the intra- and interobserver agreements of these measurements. Furthermore, we aimed to establish whether there is an association between levator ani hiatal volume at rest and on maximum Valsalva, measured using both conventional 3D translabial ultrasound and virtual reality, with prolapse symptoms and pelvic organ prolapse quantification (POP-Q) stage.

METHODS

Patients

The patient sample was the same as that in our previous publication[12] and comprised 100 female patients with an intact levator ani muscle (diagnosed by translabial pelvic floor ultrasound with the method of Dietz *et al.*[14]) who were selected randomly from the database of our tertiary pelvic floor clinic. All patients had undergone an interview using a standardized questionnaire, concerning medical history, urinary function, prolapse symptoms and bowel function. Prolapse symptoms were defined as complaints of pelvic discomfort and/or vaginal bulging. A clinical examination was performed, including POP-Q staging[15].

The current study was performed several years after our previous study[12] and some patient information was not well known in the first study. We therefore acquired additional patient characteristics or slightly different information.

Pelvic floor ultrasound imaging, with the patient in the supine position and after voiding, was performed at rest and during maximum Valsalva, using a Voluson 730 Expert system with a 4–8-MHz RAB abdominal probe (GE Healthcare, Chalfont St Giles, UK) as described by Dietz *et al.*[16]. The maximum Valsalva was defined as a forced expiration against a closed glottis[17], with a relaxed pelvic floor, for at least 6 s. Care was taken to avoid levator co-contraction. Offline analysis of the levator ani hiatus was performed blinded to the patient's history or clinical information.

Conventional three-dimensional ultrasound measurements

Conventional 3D ultrasound datasets were analyzed offline using a rendered volume, with a slice thickness of 1.5 cm at the level of minimal hiatal dimensions, at rest and on maximum Valsalva (Figure 1). The levator area (cm^2) at rest and on maximum Valsalva was measured using specialized 3D imaging software, 4D View version 9.0 (GE Healthcare), and the value was multiplied by 1.5 to obtain the conventional 3D ultrasound levator ani hiatus volume (cm^3). These conventional volume measurements were later compared with volume measurements obtained using virtual reality (cm^3).

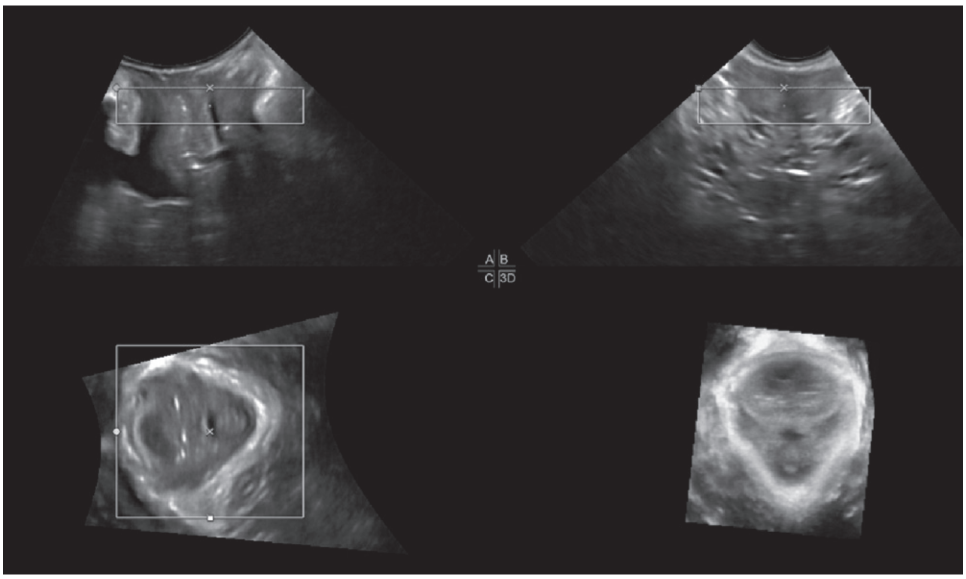

Figure 1 Rendered ultrasound volume (slice thickness of 1.5 cm) of a normal levator ani hiatus as seen and measured using 4D View.

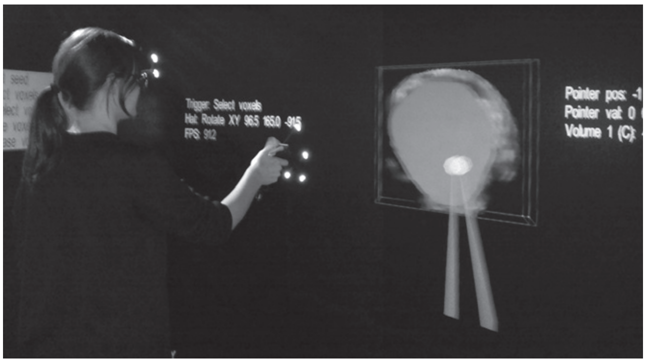

Figure 2 Operator in the I-Space virtual reality system examining the levator ani hiatus.

Virtual reality measurements

We measured the levator ani hiatal volume using virtual reality by storing the 3D datasets as Cartesian volumes using 4D View. These 3D datasets were then visualized in the I-Space, a so-called four-walled CAVE™ (Cave Automatic Virtual Environment)[18]-like virtual reality system, as described previously in our study on pelvic floor measurement during contraction[12].

In the I-Space, a researcher is surrounded by computer-generated stereo images, which are projected by eight high-quality digital light-processing projectors onto three walls and the floor of a small room. The I-Space allows medical professionals to view and interact with their volumetric data in all three dimensions. With the V-Scope[19] application (a volume-rendering application developed in-house), an interactive 'hologram' of the ultrasound image is created and can be manipulated and measured in all three dimensions by means of a virtual pointer, controlled by a wireless joystick. The interactive hologram is viewed with depth perception, using the same type of glasses with polarizing lenses that are used for 3D movies (Figure 2).

The levator ani volumes were enlarged, rotated and cropped. The outside of the puborectalis muscle was 'brushed' away with the eraser function to avoid segmentation of parts outside the levator ani. The hypoechoic inside of the levator ani was then selected by placing a seed point for the region growing segmentation algorithm, after setting an upper and lower gray-level threshold and an upper threshold for the standard deviation of the voxel's neighborhood. If the volume measurement is incomplete, the user can enlarge or shrink the segmented region manually with a spherical, free-hand 'paint brush', to add or delete voxels to or from the segmented structure as necessary. Figure 3 shows a complete virtual reality image (displayed in gray) of a volume measurement of the levator hiatal area during rest.

Agreement and reliability

Conventional 3D ultrasound and virtual reality volume measurements, at rest and on maximum Valsalva, in all 100 patients were performed by one operator (C.S.B.) and repeated three times, which is standard in the clinical application of ultrasound measurements. The mean of the three measurements obtained using 3D ultrasound and those obtained by virtual reality were used for comparison between the two imaging methods.

For calculating the interobserver reliability and agreement of both conventional 3D ultrasound and virtual reality, levator ani hiatal volume datasets from 20 randomly chosen patients were selected. Both investigators, C.S.B. and L.S., independently performed three volume measurements on each dataset by both imaging methods; the mean measurement was used for comparison.

To assess intraobserver reliability and agreement of both conventional 3D ultrasound and virtual reality, C.S.B. performed another three measurements in 20 randomly chosen datasets. The mean of these measurements was compared with the mean of the three previously obtained measurements by C.S.B. from the same 20 datasets. The second series of measurements by C.S.B. were performed at least 2 weeks later than the first to prevent recollection bias.

C.S.B. was performing these measurements in both 4D View and the I-Space for the first time and L.S. had only performed these measurements previously in a prior study on levator ani hiatus measurements during

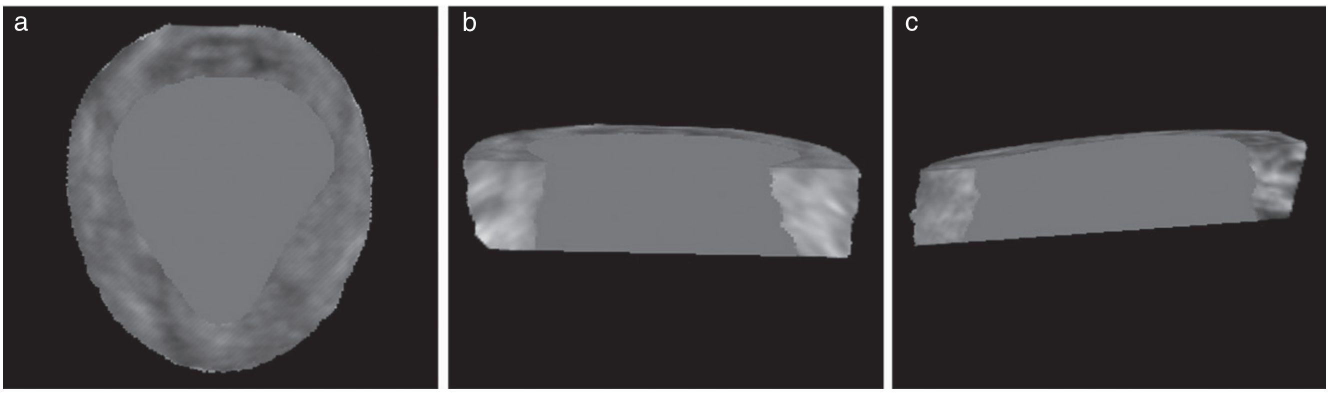

Figure 3 Two-dimensional virtual reality image of a volume measurement of the levator hiatal area, displayed in gray, showing axial (a), coronal (b) and midsagittal (c) planes. The concave and convex shape of the hiatus can be observed.

contraction. Both were trained in 4D View by A.B.S., who is experienced in pelvic floor measurements in 4D View but not with virtual reality.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 20.0 (IBM, Armonk, NY, USA). A two-sided *P*-value < 0.05 was considered to indicate statistical significance.

To compare measurements obtained using virtual reality with those on conventional 3D ultrasound, and determine the inter- and intraobserver variability, we calculated the mean difference, 95% CI of the mean difference, limits of agreement (mean difference $\pm$ 1.96 SD) and the intraclass correlation coefficient (ICC). Bland–Altman plots were used to determine whether the difference was influenced by the magnitude of the measurements[20,21]. An ICC value of 0.81–1.00 was considered to reflect excellent reliability[22,23].

The associations between prolapse symptoms, pelvic organ prolapse on POP-Q, conventional 3D ultrasound and virtual reality measurements were analyzed using the mean difference and 95% CI. For this analysis, we included only patients without a history of prolapse surgery.

RESULTS

Baseline clinical characteristics of the patients are presented in Table 1. Mean levator hiatal volume measurements at rest obtained with conventional 3D ultrasound and with virtual reality were 27.96 $\pm$ 5.91 and 26.44 $\pm$ 6.00 cm^3, respectively (Table 2). The mean difference between measurements was 1.52 cm^3 (95% CI, 1.00–2.04 cm^3) ($P < 0.001$; Figure 4a). Mean levator hiatal volume measurements on maximum Valsalva obtained with conventional 3D ultrasound and with virtual reality were 36.90 $\pm$ 10.50 and 35.74 $\pm$ 9.63 cm^3, respectively (Table 2). The mean difference was 1.16 cm^3 (95% CI, 0.56–1.76 cm^3) ($P < 0.001$; Figure 4b).

Parous women had significantly larger levator ani hiatal volume measurements on 3D ultrasound at rest and on maximum Valsalva than did nulliparous women, with mean differences of 5.13 cm^3 (95% CI, 0.62–9.63 cm^3) ($P = 0.03$) and 8.99 cm^3 (95% CI, 0.98–17.00 cm^3) ($P = 0.03$), respectively (Table 2). Volume measurements in virtual reality were only significantly larger in parous than in nulliparous women when measured during maximum Valsalva, with a mean difference of 8.63 cm^3 (95% CI, 1.30–15.95 cm^3) ($P = 0.02$). At rest, the difference in volume measurements did not reach statistical significance ($P = 0.07$).

Patients with prolapse symptoms had significantly larger levator ani hiatal volume measurements during maximum Valsalva on both conventional 3D ultrasound and on virtual reality when compared with those without symptoms, with a mean difference of 6.43 cm^3 (95% CI, 1.25–11.60 cm^3) ($P = 0.02$) and 6.21 cm^3 (95% CI, 1.62–10.80 cm^3) ($P = 0.01$), respectively. At rest, the difference in volume measurements in patients with *vs* those without prolapse symptoms did not reach statistical significance ($P = 0.34$ and $P = 0.59$, respectively).

Patients with POP-Q Stage ≥ 2 had significantly larger levator ani hiatal volume measurements during maximum Valsalva on conventional 3D ultrasound and on virtual reality, compared with patients with POP-Q Stage < 2; the mean differences were 11.26 cm^3 (95% CI, 7.03–15.49 cm^3) ($P < 0.01$) and 9.40 cm^3 (95% CI, 5.54–13.27 cm^3) ($P < 0.01$), respectively (Table 2).

Table 1 Baseline characteristics of 100 symptomatic women with normal levator ani hiatus attending a tertiary pelvic floor clinic

Characteristic	*Value*
Age (years)	57 (22–79)
Nulliparous	7
Previous prolapse surgery	19
Urinary incontinence (all types)	21
Prolapse symptoms	15
Fecal incontinence	20
Prior obstetric anal sphincter injury	5
Fistula	2
Obstructed defecation	2
Pain	7
No urogenital complaints (fibroids)	1
Combination of urinary incontinence and/or prolapse symptoms and/or obstructed defecation and/or fecal incontinence	27

Data are given as median (range) or *n*.

Table 2 Measurements of levator ani hiatal volume at rest and on maximum Valsalva, by conventional three-dimensional (3D) ultrasound and by virtual reality imaging in 100 symptomatic women attending a tertiary pelvic floor clinic

	3D ultrasound		*Virtual reality*	
Variable	*At rest (cm^3)*	*On maximum Valsalva (cm^3)*	*At rest (cm^3)*	*On maximum Valsalva (cm^3)*
All patients ($n = 100$)	27.96 $\pm$ 5.91	36.90 $\pm$ 10.50	26.44 $\pm$ 6.00	35.74 $\pm$ 9.63
Nulliparae ($n = 7$)	23.19 $\pm$ 4.01	28.54 $\pm$ 11.40	22.49 $\pm$ 4.43	27.72 $\pm$ 9.28
Parae ($n = 93$)	28.32 $\pm$ 5.88	37.53 $\pm$ 10.22	26.74 $\pm$ 6.01	36.35 $\pm$ 9.28
Prolapse symptoms* ($n = 23$)	28.87 $\pm$ 4.76	41.39 $\pm$ 9.58	26.92 $\pm$ 4.50	39.97 $\pm$ 9.42
No prolapse symptoms* ($n = 58$)	27.47 $\pm$ 6.31	34.96 $\pm$ 10.96	26.11 $\pm$ 6.62	33.76 $\pm$ 9.34
POP-Q Stage ≥ 2* ($n = 33$)	29.16 $\pm$ 6.15	43.46 $\pm$ 11.02	27.60 $\pm$ 7.13	41.09 $\pm$ 9.51
POP-Q Stage < 2* ($n = 48$)	26.98 $\pm$ 5.64	32.20 $\pm$ 8.11	25.46 $\pm$ 5.14	31.69 $\pm$ 7.91

Data are given as mean $\pm$ SD. *Only patients without history of prolapse surgery. POP-Q, pelvic organ prolapse quantification.

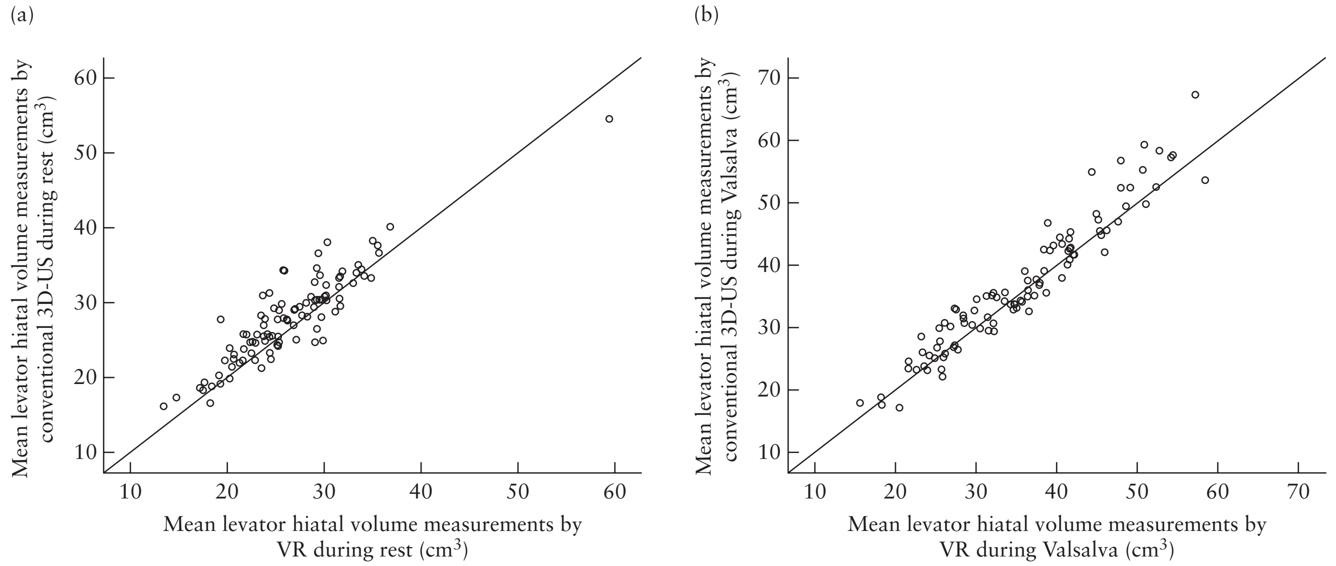

Figure 4 Scatterplots showing relationship between levator ani hiatal volume, at rest (a) and during maximum Valsalva maneuver (b), measured by conventional three-dimensional (3D) ultrasound (US) and by virtual reality imaging (VR) in 100 symptomatic women attending a tertiary pelvic floor clinic. The line of equality is shown.

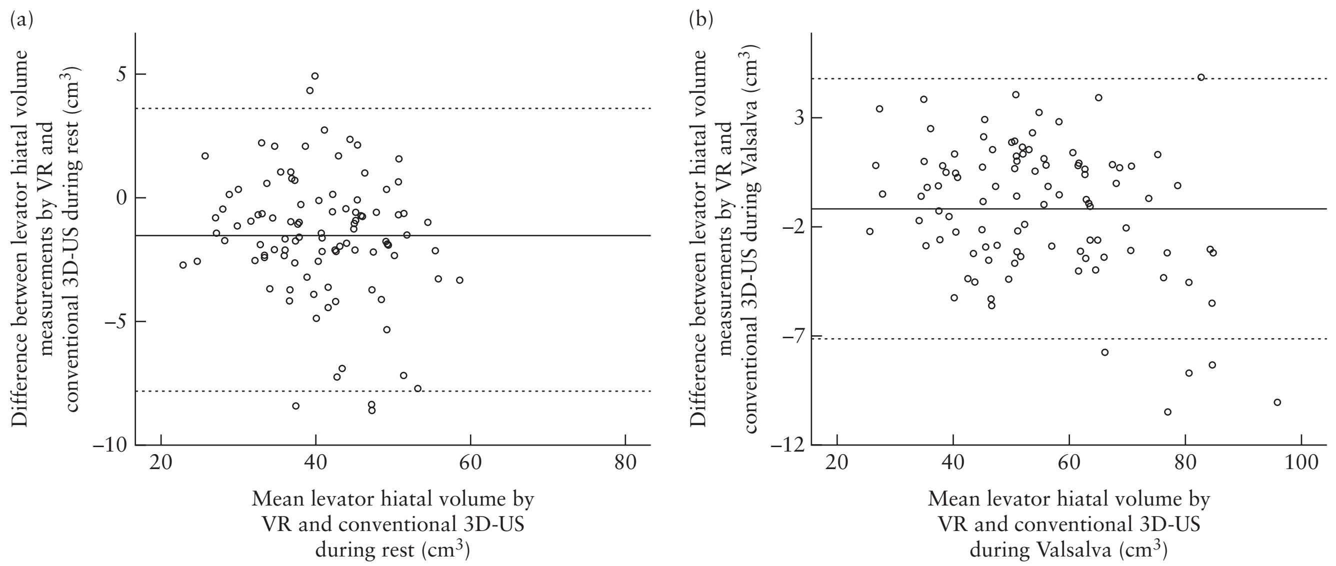

Figure 5 Bland–Altman plots showing agreement between levator ani hiatal volume, at rest (a) and during maximum Valsalva maneuver (b), measured by conventional three-dimensional (3D) ultrasound (US) and by virtual reality imaging (VR) in 100 symptomatic women attending a tertiary pelvic floor clinic. Mean (——) and 95% limits of agreement (·······) are shown.

For the analysis to determine an association between levator ani hiatal volume, measured at rest and on maximum Valsalva by conventional 3D translabial ultrasound and by virtual reality, with prolapse symptoms, we included all patients with symptoms of prolapse ($n = 23$) who had no history of previous prolapse surgery. Fifteen patients had only symptoms of prolapse (Table 1), whereas the other eight patients also had other complaints such as urinary incontinence, shown in Table 1 as combination of urinary incontinence and/or prolapse symptoms and/or obstructed defecation and/or fecal incontinence.

Intraobserver and interobserver intraclass correlations coefficients for levator ani hiatal volume measurements

Table 3 Intra- and interobserver agreement for measurements of levator ani hiatal volume at rest and on maximum Valsalva maneuver, obtained by three-dimensional ultrasound and by virtual reality imaging in 20 women selected randomly from study group

	ICC (95% CI)	
Method	*At rest*	*On maximum Valsalva*
Intraobserver		
Ultrasound	0.982 (0.957–0.993)	0.949 (0.914–0.968)
Virtual reality	0.995 (0.988–0.998)	0.991 (0.977–0.996)
Interobserver		
Ultrasound	0.960 (0.901–0.984)	0.998 (0.995–0.999)
Virtual reality	0.993 (0.982–0.997)	0.987 (0.969–0.995)

ICC, intraclass correlation coefficient.

were ≥ 0.96 for conventional 3D ultrasound and > 0.99 for virtual reality (Table 3). Bland–Altman plots showing the agreement between hiatal volume measurements obtained at rest and on maximum Valsalva are shown in Figure 5.

DISCUSSION

This study demonstrates that volume measurements obtained by conventional 3D translabial ultrasound can be compared with virtual reality imaging for research investigation of levator ani hiatal volume at rest and on maximum Valsalva. Furthermore, it demonstrates that levator hiatal measurements obtained using virtual reality are significantly smaller than those obtained using conventional 3D ultrasound, at rest and on maximum Valsalva. It shows excellent inter- and intraobserver agreement for both imaging techniques. Furthermore, a positive association was found between parity, prolapse symptoms and POP-Q Stage ≥ 2 and levator ani hiatal volume measurements, especially on maximum Valsalva.

Our hiatal area measurements in cm^2 in patients with no levator avulsion were comparable to measurements of previous published research[24].

The results of this study are in line with those of our previous study[12], comparing levator ani hiatal measurements during contraction using conventional 3D ultrasound with virtual reality (mean difference of 0.10 cm^3 (95% CI, −0.15 to 0.35 cm^3; $P = 0.41$)). However, this difference was not significant, contrary to the differences found in the present study. This may be explained by the fact that differences in measurements can be greater when the volumes are larger, because volumes measured during contraction are smaller than those measured at rest or on maximum Valsalva. Although statistically significant, we believe that the small differences of 1.52 and 1.16 cm^3 that we found would be unlikely to have clinical consequences.

Virtual reality imaging is a unique way to visualize ultrasound data with perception of depth and offers the possibility for measuring non-planar structures. To our knowledge, this is the first study to compare conventional 3D translabial ultrasound visualization with virtual reality for levator ani hiatal volume measurements obtained at rest and on maximum Valsalva.

Unfortunately, CAVE™-like virtual reality systems such as the I-Space are currently only available in a limited number of research centers throughout the world and are costly. A smaller, low-cost desktop virtual reality system is currently available for use in an outpatient clinical setting[25].

Both operators found that measuring volumes in virtual reality was easier to learn than with 4D View. One of the advantages of virtual reality is that the levator ani volumes can be enlarged, rotated and cropped. Discrimination of the pubic bone and the inner margins of the levator ani hiatus are better visualized in virtual reality. In contrast to selecting subjectively the margins of the levator ani as for conventional 3D ultrasound, in virtual reality, a large portion of levator ani hiatus is selected automatically by the computer system after planting a seed point.

In this study, the intraobserver and interobserver ICC values for virtual reality measurements were slightly better than those for conventional 3D ultrasound measurements; however, both were excellent. The slightly better ICCs for virtual reality measurements might be explained by the abovementioned advantages of measuring in virtual reality. It is questionable whether these differences between ICC values are clinically relevant.

Using both methods, parous women had significantly larger levator ani hiatal volumes on maximum Valsalva compared with nulliparous women. We expect to find pelvic floor changes after a vaginal birth. Our levator ani hiatal volume measurements in nulliparous women are comparable to those of previously published research[26–28]. A recent study showed that vaginal parity was associated strongly with hiatal area measurements on conventional 3D ultrasound during maximum Valsalva[26].

Patients with prolapse complaints and patients with clinical signs of prolapse also had significantly larger volume measurements on maximum Valsalva utilizing both imaging methods. These findings are in concordance with those of previous studies, which showed that the size of the levator hiatus is strongly associated with both signs and symptoms of pelvic organ prolapse and recurrence[1–3]. We see this association in both 3D translabial ultrasound measurements and in virtual reality, which indicates that normal 3D translabial ultrasound can be used to obtain these measurements.

Some potential limitations of this study should be acknowledged. The studied group of patients was heterogeneous. We do not believe that this influenced the measurements obtained with conventional 3D ultrasound and virtual reality or the inter- and intraobserver ICCs. However, it might have influenced the association found between clinical complaints and prolapse severity with levator ani hiatal volume measurements. Furthermore, measurements obtained during maximum Valsalva may be biased by the fact that levator co-activation can occur during maximum Valsalva. This would provide a smaller levator ani hiatal volume measurement during maximum Valsalva than is the true volume when there is no co-activation.

In conclusion, virtual reality is a novel method for visualizing ultrasound data which has the benefit of depth perception. This offers the possibility for measuring non-planar structures, such as the pelvic floor. This study demonstrates that measurement of levator ani hiatal volume on virtual reality imaging at rest and on maximum Valsalva is reliable and correlates with clinical symptoms and signs of prolapse on POP-Q, in patients with a normal levator ani. Current measurements of the levator ani hiatus by conventional 3D ultrasound in patients with an intact levator ani muscle are reliable and only differ slightly from those measured with virtual reality. Further research is warranted to determine whether these small differences will either increase or decrease in patients with levator ani avulsion or defect and therefore become of clinical importance.

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