Original paper

Med Ultrason 2016, Vol. 18, no. 3, 345-350
DOI: 10.11152/mu.2013.2066.183.zsu

Reproducibility in pelvic floor biometric parameters of nulliparous women assessed by translabial three-dimensional ultrasound using Omniview reformatting technique.

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Abstract

Aim: To assess the reproducibility of pelvic floor biometric parameters by translabial three-dimensional ultrasound compared with the OmniView® reformatting technique. **Material and methods:** We performed a prospective cross-sectional study involving 47 nulliparous women without symptoms of pelvic floor dysfunction. The hiatal area and right pubovisceral muscle width measurements were performed in the axial plane using both 3D ultrasound in the rendering mode and OmniView® techniques. To determine the occurrence of standardized error between examiners and the two sonographic methods, the paired t-test was used. The intra- and inter-observer reliability and agreement were estimated by concordance correlation coefficient (CCC) and limits of agreement, respectively. **Results:** We did not observe significant statistical differences among both measurements performed by the first examiner, both examiners and both methods in the assessment of the hiatal area; however, the measurements of the right pubovisceral muscle were significantly lower using OmniView®. The intra-observer reliability was good in the evaluation of all pelvic floor parameters; however, the inter-observer reliability was good only to the 3D rendering mode (CCC=0.87). The intra-observer agreement was good in the assessment of all pelvic floor parameters; however, the inter-observer agreement was found to be good only when 3DUS in the rendering mode was used (<±15%). **Conclusion:** Both 3D ultrasound in the rendering mode and OmniView® reformatting techniques were concordant in the assessment of pelvic floor parameters; however, the 3D ultrasound rendering in the mode demonstrated better inter-observer reliability and agreement.

Keywords: Pelvic floor, nulliparous, rendering mode, three-dimensional ultrasound, omniView®

Introduction

Currently, the three-dimensional ultrasound (3DUS) is a common method used to assess the anatomy and function of the pelvic floor structures, and it is used mainly in urogenital dysfunctions, such as genital prolapse and urinary incontinence. It was first described by Khullar et al [1] using an endovaginal probe and the focus was on the observation of urethra and paraurethral structures.

After 10 years, Dietz et al published the first paper using the translabial 3D convex probe to assess the pelvic floor in women [2]. The advantage of this modern equipment makes it possible to observe and analyze the dimensions of the pubic symphysis, urethra, bladder, bladder neck, vagina, anorectal angle, and pubovisceral muscles.

The inter-observer reproducibility of the pelvic floor biometric parameters at rest, during pelvic floor muscle contraction, and during the Valsalva maneuver using the

Received 11.11.2015 Accepted 30.01.2016
Med Ultrason
2016, Vol. 18, No 3, 345-350
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translabial 3DUS has been proved both in acquisition and off-line analysis [3,4]. In addition, the translabial 3DUS is a technique that can be learnt in a short time period [4].

OmniView® (GE Medical System, Zipf, Austria) is a software application for 3DUS that allows interrogation of volume datasets and simultaneous display of up to three independent (non-orthogonal) planes by manually drawing line, curve, polyline, or trace from any direction or angle [5]. The first line (yellow), the second line (fuchsia), and the third line (turquoise) should be applied to the region of interest, achieving non-orthogonal planes simultaneously displayed on 3D volume multiplanar rendering [6]. This technology has been applied in obstetrics to assess the fetal hard and soft palates [6], central nervous system [5], heart [7], and spine [8]. In gynecology, the OmniView® has been used to assess the location of intrauterine devices [9].

Recently, Youssef et al [10] proved good reproducibility of the pelvic hiatal area measurement using OmniView® software in nulliparous asymptomatic and in women with symptoms of pelvic floor dysfunction. A high agreement was shown between OmniView® and 3DUS in the rendering mode.

The objective of this study was to assess the reproducibility of OmniView® and 3DUS in the rendering mode in the assessment of hiatal area and right pubovisceral muscle width measurements of the pelvic floor of nulliparous women.

Material and methods

This was a prospective cross-sectional study that involved 47 nulliparous asymptomatic healthy women between July 2013 and July 2014. This study was approved by the Ethical Committee of the Federal University of São Paulo. The consent form was signed by all volunteer patients included in this study. The inclusion criteria were as follows: 1) age between 18 and 35 years, 2) body mass index (BMI) between 20 and 25 Kg/m^2, 3) absence of symptoms of pelvic floor dysfunction.

3DUS assessment of the pelvic floor was performed with the patient in the lithotomy position with hips flexed and abducted, after voiding, using a Voluson 730 Expert (General Electric Medical System, Zipf, Austria) equipment with a convex volumetric probe (RAB 4–8L). All 3D volume scans were acquired at rest with an acquisition angle of 85 degrees. Only one 3D pelvic floor volume dataset was acquired for each patient, and transferred to a personal computer. The ultrasound exams were performed by only one examiner (ZIKJB) with four years experience in 3DUS of the pelvic floor.

The pelvic floor volume datasets were assessed offline using a 4D View version 10.0 (General Electric Medical System, Zipf, Austria). The hiatal area was measured on the plane of minimum hiatal dimension, which was referenced as mid-sagittal, comprising the area between the posterior region of the pubic symphysis and the anterior and posterior borders of the muscles of the levator ani, including the anorectal muscle (pubovisceral muscle). This transverse section in the axial plane enabled measurements of the hiatal dimension, such as area and transverse and anteroposterior diameters, as described by Dietz et al [11]. The thickness of the pubovisceral muscle was standardized in the axial plane and we chose the right pubovisceral width to define it. The measurement of pubovisceral muscle was performed in the place of the maximum width of the muscle. After this, the same measurements with the OmniView® were performed**.**The line from the OmniView® was drawn along the plane of least pelvic hiatal dimensions between the posterior margin of the symphysis pubis and the anterior margin of the puborectalis muscle, where it defines the anorectal angle, including a thickness of 3 to 10 mm. The plane of hiatal dimensions was automatically displayed on the right hand side. The trace method was then used to measure the hiatal area and right thickens pubovisceral muscle (fig 1).

The measurements, hiatal area in cm^2 and width of the right pubovisceral muscle in cm were performed by two blinded experienced examiners (ZIKJB and CAR). The first examiner repeated a new measurement 7 days later, either with the 3DUS in the rendering mode or by the OmniView® technique to assess the intra-observer reproducibility.

Statistical analysis

The statistical analysis was performed by one of the authors (WPM) using a Graph Pad Prism version 6.0 (GraphPad Software Inc., La Jolla, CA, USA) and Stata

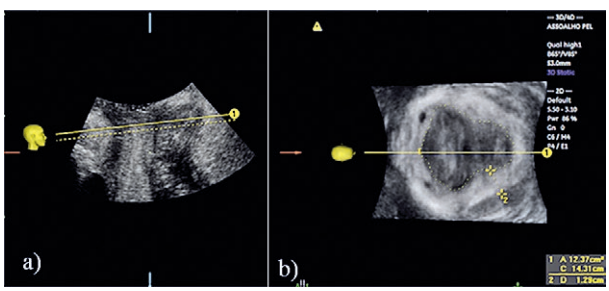

Fig 1. Ominiview® reformatting technique: a) The line of Ominiview® is drawn between the posterior margin of the symphysis pubis and the anterior margin of pubovisceral muscle with a thickness between 3 to 10 mm; b) The rendering mode image in the axial plane showing the hiatal area and right pubovisceral muscle measurements.

version 11.0 (StataCorp LP, College Station, TX, USA). Initially, the normality distribution using the D'Agostino-Pearson omnibus test was assessed. The mean ± standard deviation of participant characteristics, such as age, height, weight, BMI, hiatal area, and right pubovisceral muscle width measurements were performed. To determine the occurrence of standardized error (consistently higher or lower measurements) between examiners and the 3DUS in the rendering mode and OmniView® techniques, the related values for the same measurements were compared between the measurements and methods using the paired t-test.

The intra- and inter-observer reliability was estimated by the concordance correlation coefficient (CCC), being the estimative accuracy assessed by their respective 95% confidence intervals (CI). The intra- and inter-observer agreement was estimated by the limits of agreement (LoA) of the relative differences and also by Bland-Altman plots. The interpretation of the results of reliability and agreement was performed according to a recent publication on this subject [12].

Results

A random selection of 47 nulliparous women who fulfilled the inclusion criteria were included in the final statistical analysis. The mean age was 27.6 5.4 years old, the mean height was 162.9 7.7 cm, the mean weight was 60.9 10.2 kg, and the mean BMI was 22.9±2.8 kg/m².

There was no difference between the two measurements performed by the first examiner, the measurements performed between both examiners, and also between both methods (3DUS in the rendering mode and OmniView®) regarding the systematic error of the hiatal area measurement. Although a systematic error between the examiners was not observed, a slight significant difference between OmniView® and 3DUS in the rendering mode techniques regarding the right pubovisceral muscle width which was smaller in the OmniView® method was identified (Table I).

In the evaluation of intra- and inter-observer reliability, despite the intra-observer reliability was reasonable (CCC 0.88–0.94), the inter-observer reliability was very poor (CCC 0.36–0.58), except for the measurement of the hiatal area using the 3DUS in the rendering mode, with CCC = 0.87 (Table II). The results for the agreement analysis were consistent with data from the reliability analysis (Table III, figures 2–5). The intra-observer differences were usually lower than ± 15%; however, the values were higher for inter-observer differences, reaching approximately ± 40% variation only by repeat testing. The exception was the hiatal area measurement by 3DUS in the rendering mode, where the difference of measurements between the examiners was usually less than ± 15%.

Table I. Evaluation of the systematic errors between the examiners measurements and between the methods (3DUS in the rendering mode and Omniview®).

	Examiner 1A		**Examiner 1B**		**Examiner 2**		**p (1A vs. 1B)**	**p (1A vs. 2)**
Hiatal Area (cm²)	Mean	SD	Mean	SD	Mean	SD		
3DUS in the rendering mode	11.63	1.88	11.81	1.77	11.36	1.91	0.09	0.06
Omniview	11.45	1.48	11.45	1.47	11.06	1.75	0.09	0.11
Comparison 3DUS vs. Omniview	0.34		0.05		0.10			
Right Pubovisceral Muscle Width (cm)								
3DUS in the rendering mode	1.05	0.20	1.07	0.21	1.01	0.17	0.92	0.08
Omniview	0.98	0.17	0.99	0.18	0.93	0.15	0.50	0.10
Comparison 3DUS vs. Omniview	0.002		<0.001		<0.001			

p – values determined by paired t-tests. SD: standard deviation.Examiner 1A – first measurement performed by first examiner. Examiner 1B – second measurement performed by first examiner. Examiner 2 – measurement performed by second examiner.

Table II. Assessment of intra- and inter-observer reliability by concordance correlation coefficient (CCC) and their respective 95% confidence intervals (CI).

	Intra-observer		**Inter-observer**	
Hiatal Area	CCC	95% CI	CCC	95% CI
3DUS in the rendering mode	0.92	0.86-0.95	0.87	0.78-0.93
Omniview	0.94	0.89-0.97	0.58	0.36-0.75
Right Pubovisceral Muscle Width				
3DUS in the rendering mode	0.92	0.86-0.95	0.44	0.19-0.64
Omniview	0.88	0.80-0.93	0.36	0.10-0.57

Table III. Assessment of intra and inter-observer agreement by the estimation of mean difference and the limits of agreement (LoA).

	Intra-observer		Inter-observer	
Hiatal Area	MD (%)	LoA (%)	MD (%)	LoA (%)
3DUS in the rendering mode	-1.7	-15.2 to 11.7	2.4	-13.5 to 18.3
Omniview	-0.1	-8.9 to 8.7	3.8	-21.1 to 28.7
Right Pubovisceral Muscle Width				
3DUS in the rendering mode	-1.7	-16.9 to 13.5	3.8	-32.8 to 40.5
Omniview	-0.8	-17.0 to 15.3	4.2	-30.8 to 39.1

MD = mean difference; LoA = limits of agreement

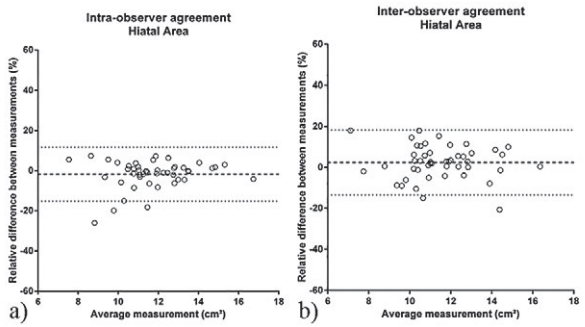

Fig 2. The Bland-Altman plot of (a) intra- and (b) inter-observer reproducibility of hiatal area measurement using the 3DUS in the rendering mode.

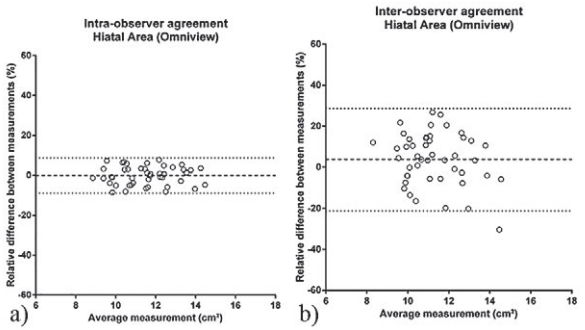

Fig 4. The Bland-Altman plot of (a) intra- and (b) inter-observer reproducibility of hiatal area measurement using the Omniview® reformatting technique.

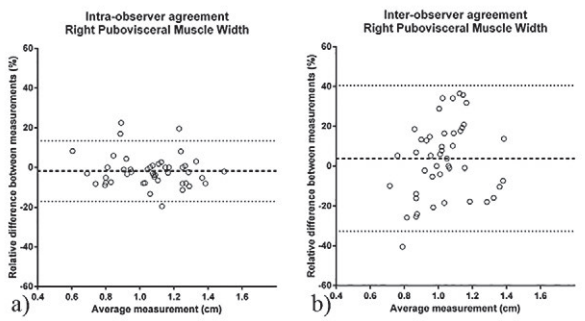

Fig 3. The Bland-Altman plot of (a) intra- and (b) inter-observer reproducibility of the right pubovisceral muscle width measurement using the 3DUS in the rendering mode.

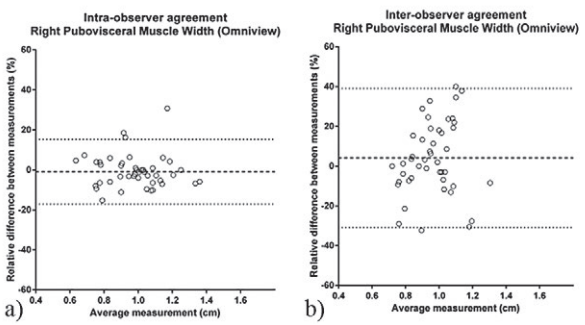

Fig 5. The Bland-Altman plot of (a) intra- and (b) inter-observer reproducibility of right pubovisceral muscle width measurement using the Omniview® reformatting technique.

Discussions

In this study, we assessed the reproducibility of 3DUS in the rendering mode and OmniView® techniques to assess pelvic floor parameters. We observed that both techniques are concordant; however, the 3DUS in the rendering mode demonstrated better inter-observer reliability and agreement.

In this study we preferred to use CCC to assess the reliability instead of intraclass correlation coefficient (ICC) which is usually applied to pelvic floor parameters [3,4,13]. We preferred the CCC because there are several models for ICC–choosing the most appropriate method could be complicated–and because ICC is only valid when analysis of variance assumptions are present, which is frequently not the case [14]. According to Martins and Nastri, a good/moderate reliability/agreement of ultrasound measurements is obtained with ICC/CCC of 0.90–0.99 and LoA of approximately 5%–10%. This method may be applied for the purpose of research,

but must be employed with caution in clinical practice [12].

Majida et al [9] used a translabial 3DUS in the rendering mode to assess the reproducibility of hiatal area and thickness of pubovisceral muscle in 17 healthy women at rest, contraction, and during Valsalva maneuver. They observed a good inter-observer reliability (ICC = 0.92) and inter-observer agreement LoA approximately ±18% to the hiatal area at rest; however, the thickness of pubovisceral muscle at rest demonstrated poor inter-observer reliability (ICC 0.61–0.75). In our study, we obtained similar results with a good inter-observer reliability (CCC=0.87) and inter-observer agreement LoA (−13.5%18.3%) to the hiatal area at rest; however, poor reliability and agreement to the thickness of the right pubovisceral muscle, CCC=0.44 and LoA approximately ±35%, respectively, using the 3DUS in the rendering mode, was noted. We believe that this poor reproducibility of the thickness of pubovisceral muscle is a consequence of the difficulty to obtain clear and well-defined edges of the pubovisceral muscle in the translabial 3DUS in the rendering mode. Besides the pubovisceral muscle presents irregular edges, hindering the location of its maximum measurement. In a study using endovaginal 3DUS in the rendering mode, Yang et al [13] assessed the pelvic floor parameters of 59 nulliparous Chinese women. They observed better inter-observer reproducibility of the pubovisceral muscle area (ICC=0.78) than the hiatal area (ICC=0.63), probably because of the use of a higher frequency probe (RIC 5–9W), allowing better quality of pubovisceral muscle edges. In our study, we did not use the transvaginal approach, because it is a more invasive technique. Furthermore, the transabdominal approach allows a higher scanning window, enabling all edges of pubvisceral muscle to be included in the 3D volume dataset.

Siafarikas et al [4] performed a study to analyze the learning curve for acquiring translabial 3D volume datasets of the pelvic floor to improve the inter-observer reproducibility. This prospective study involved 22 women in whom the 3D volumes were acquired by two examiners (inexperienced and experienced). After the training, 20 volumes acquired by experienced examiners were analyzed offline by an inexperienced examiner to assess the levator hiatus dimensions. The inter-observer reliability study showed reasonable ICC values (ICC 0.81–0.97) for all levator hiatus measurements except the pubic arc (ICC=0.67). This study proved that the learning curve of the translabial 3DUS in the rendering mode is quick and effective. In our study, the acquisition of 3D volume datasets were performed by only one experienced sonographer and the offline analysis were performed by another experienced operator.

Recently, Youssef et al [10] assessed the reproducibility of OmniView® for pelvic hiatal area measurement at rest and agreement with the 3DUS in the rendering mode. They evaluated 124 nulliparous asymptomatic women and 118 women with symptoms of pelvic floor dysfunction. They observed that the OmniView® showed good intra- and inter-observer reliability (ICC=0.926 and 0.930, respectively) and agreement (LoA ±13.6 and ±12.6, respectively) in asymptomatic women. In addition, they observed a good intermethod agreement (ICC=0.917). In our study, we observed a good intra-observer and a poor inter-observer reliability and agreement using the OmniView® reformatting technique. We believe that the poor inter-observer reproducibility is a consequence of the absent learning curve for the second examiner that is proved for the 3DUS in the rendering mode [4]. As both examiners presented great experience in the 3DUS in the rendering mode, the inter-observer reliability, and agreement to the hiatal area measurement was good. Omniview reformatting technique, despite several applications in gynecology and obstetrics area, is a new technique in the assessment of pelvic floor and more experience is necessary before clinical practice application.

Conclusion

In summary, both 3DUS in the rendering mode and the OmniView® techniques were concordant in the assessment of pelvic floor parameters; however, the 3DUS in the rendering mode showed better inter-observer reliability and agreement.

Conflict of interest: none

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