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ORIGINAL ARTICLE

Reproducibility of ultrasonic measurements of pelvic floor structures in women suffering from urinary incontinence

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Abstract The aim of this study was to examine the reproducibility of ultrasound (US) findings relating to pelvic floor muscle in women with urinary incontinence (UI). Eighteen women with UI were examined twice by the same examiners over an interval of 1 month. The US findings comprised of (1) distance between bladder neck and symphysis pubis (BN/SP) at rest, during contraction, and while performing the Valsalva maneuver and (2) distance between anorectal angle and symphysis pubis (AR-SP) during the same conditions. Statistical analysis included test–retest correlations ($ICC_{3,K}$), and the assessment of measurement error and smallest real difference (SRD) for change. BN-SP and AR-SP exhibited high ICCs. The lowest SRD values related to the AR-SP variables (10–19%). US-based measures of the bladder neck and the anorectal angle, distance, and displacement seem to offer reasonable clinical reproducibility.

Keywords Reproducibility · Ultrasound · Pelvic floor muscle · Urinary incontinence

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Introduction

Pelvic floor muscles (PFM) play an essential role in the support and functioning of the pelvic organs. When the integrity of the PFM is compromised, pelvic organ dysfunction may result [1]. For example, it has been shown by a recent magnetic resonance imaging study that more than half of the women with prolapse had major levator ani defects [2]. Other major problem of pelvic organ dysfunction, which mainly afflicts women, is urinary incontinence (UI). A rate of 9–72% has been reported for the age range 17–79 years [3]. UI is often a debilitating and demoralizing condition which causes major social and health problems for the individual and a huge economic burden worldwide. Therefore, medical research has focused on the efficiency of different treatment methods for UI.

There are several means for assessing PFM. Traditionally, muscle strength has been determined by digital palpation and by pressure perineometer [3–5]. More recently, ultrasound (US) scanning has been used to perform this task [6–13]. The main arguments in favor of using US are that it is noninvasive, relatively cheap, and easily performed examination [14]. Perineal US allows the assessment of bladder neck and urethral mobility during PFM contraction, Valsalva maneuver, and at rest. More recently, it has been shown that three- and four-dimensional perineal US can also diagnose and quantify major levator ani trauma after delivery such as the avulsion of the inferomedial aspects of the pubovisceral muscle off the pelvic sidewall [15, 16]. However, in order for US measurements to be of clinical value, the findings must be reproducible.

In a report issued by the Standardization Sub-committee of the International Continence Society (ICS) published in 2002 [17], it was suggested that pelvic floor contraction could be assessed by visual inspection, palpation, electromyography, or perineometry. Factors to be assessed included strength, duration, displacement, and repeatability. In the updated report of the ICS group from 2005 [4], it was stated that quantification of the function of the PFM was not easy due to the lack of simple and reliable measurement techniques and absence of smallest real difference for pathological conditions. Furthermore, the reproducibility of testing was questionable. The objective of this study is therefore to assess the reproducibility of US findings during PFM contraction and Valsalva maneuver, using a significant interval time of 1 month.

Materials and methods

Subjects

Twenty-one women aged 30 to 70 complaining of UI were recruited for this study. Out of this group, only 18 were able to complete the full protocol of two testing sessions whereas three dropped out during the intermission between visits for reasons of illness, pelvic pain, or discomfort from the procedure. All patients gave informed consent to this study, which was previously approved by the respective Institutional Review Boards of Tel Aviv University and the Sheba Medical Center. All patients underwent a general gynecological and neurological examination as well as a full urodynamic evaluation. The exclusion criteria included age (>70 years), inability to perform PFM contraction assessed by vaginal palpation, body mass index (BMI) >35, pelvic organ prolapse beyond vaginal vestibule while straining in the supine position, and cognitive and psychiatric impairment.

Measurement

Each woman was tested twice over a period of 4–6 weeks (4.4±0.6 weeks). Prior to the first testing session, patients were interviewed for medical history which was followed by physical examination that focused on the ability to perform PFM contraction. The same measurement protocol was conducted in each visit by the same examiners. The protocol included data recorded from the US.

The examination was performed by an US physician specialist using a Logiq 9, GE Ultrasound (KPI Ultrasound, Riverside, CA 92507, USA) with a 3.5-MHz curved array probe for *b* measures and 8-MHz curved array probe for the measures of a (see below). The measurements were performed while patient was in left side lying position. The following measures were recorded:

(a) The distance between bladder neck and symphysis pubis (BN-SP) at rest, during contraction, and while performing the Valsalva maneuver. The distance was established by the calculation of the oblique line between the *x*-axis going through the inferior border of the symphysis pubis and the *y*-axis going through the bladder neck, perpendicular to the *x*-axis, using Pythagoras theorem ($a^2+b^2=c^2$; Fig. 1). Bladder neck displacement from resting position to its position at contraction or at Valsalva was calculated using the same formula, while $a=(y^1-y^2)$ and $b=(x^1-x^2)$. This measure created six variables

(b) The distance between the anorectal angle and inferior border of the symphysis pubis (AR-SP), at the above conditions (Fig. 2). Anorectal angle displacement from resting position to its position at contraction or at Valsalva was also calculated, creating six variables

In all, 12 variables were recorded.

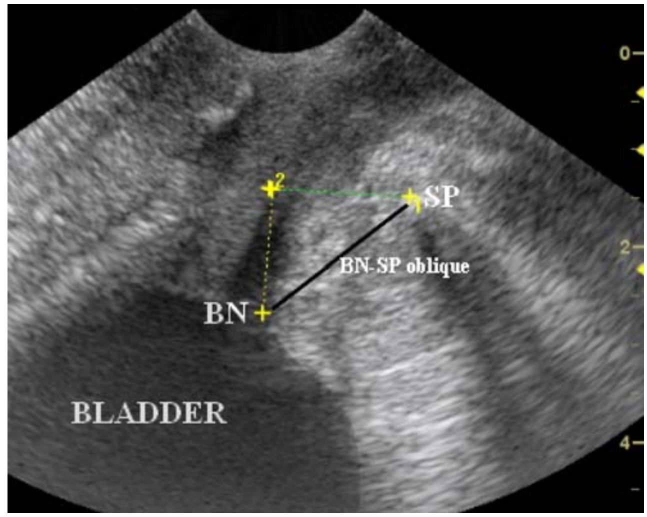

Fig. 1 Distance between bladder neck and symphysis pubis (*BN-SP*)

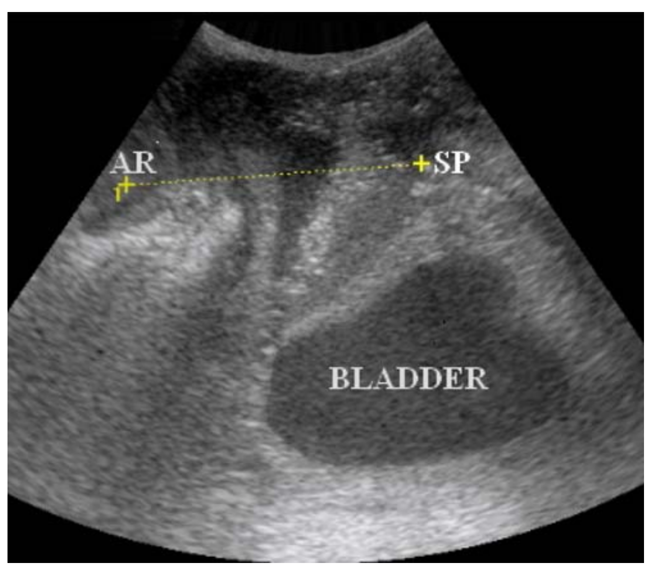

Fig. 2 Distance between the anorectal angle and symphysis pubis (*AR-SP*)

Table 1 Characteristics of the study group

Characteristics (N=18)	Mean (SD)	Range
Age (years)	50.6 (10.7)	29.6–68
BMI	25.04 (4.59)	19.29–33.66
Labors (number)	2.5 (1.15)	0–4[a]

[a] Only one woman was nulliparous

Data analysis

Data were processed using the SPSS 14.0 statistical software package. Descriptive analyses of the demographic and medical characteristics are presented in Table 1. Statistical analysis included paired T test, test–retest correlations using $ICC_{3,K}$, and calculation of the standard error of measurement (SEM), based on average measurements. Using the SEM, we calculated the individual-based smallest real difference (SRD) with the following formula: $SRD = 2.77\,(1 - ICC)^{0.5}$ [18, 19]. The reproducibility parameters are presented in Table 2.

Results

Out of the 18 women who completed the full test–retest protocol, five complained of stress urinary incontinence, seven complained of urge urinary incontinence, and six complained of mixed urinary incontinence. No significant statistical differences were found between the three groups, regarding the US. The baseline characteristics of the patients are displayed in Table 1.

The results relating to the reproducibility of the US findings are presented in Table 2. Eleven out of 12 variables had an ICC >0.75 (p highly significant) which is considered acceptable clinically.

The range of SRD for all 12 variables ranged 10–220%. The lowest SRD values (10.2–18.7%) related to the three AR-SP-associated variables whereas the highest referred to the AR displacement and BN-SP oblique at Valsalva, 220 and 124%, respectively. Notably, positive and significant correlations (r 0.58–0.86, $p<0.012$) were found between BN-SP oblique at rest to BN-SP oblique at contraction and similarly for the AR-SP distance.

Discussion

This study assessed the reproducibility of US findings relating to PFM in women with UI. The US findings indicate that the reproducibility of the "distance between anatomic structures" variables is acceptable in the sense that relatively small changes may indicate a sound clinimetric change, probably the most stringent indicator for change. In the present study, we used the anorectal angle distance and displacement measures which seem to be almost identical to the anteroposterior diameter of the levator hiatus as reported by others [20, 21]. Unlike previous reports [12, 22, 23], the AS-SP measures exhibited higher reproducibility than those of the bladder neck and therefore should be given a higher specific weight. This finding may be explained by the fact that AR-SP is a numerically larger parameter than BN-SP which means that the "signal to noise ratio" is better. Moreover, AR-SP distance involves only one parameter vs. two measures in the case of BN-SP. Another assumption is that since BN is anatomically closer to the vagina, air might disturb the US image, affecting its accuracy.

Previous studies [12, 22–24] that tested the reproducibility of bladder neck distance and displacement reported similar outcomes (ICC 0.75–0.98) but only one [24] related to the measurement error. Although ICC is often used, its serious drawbacks for assessing of reproducibility are well known, and therefore, recent years have seen the growing application of absolute parameters such as the SEM and

Table 2 Reproducibility of US measures

Variable	Visit 1 (SD)	Visit 2 (SD)	$ICC_{3,K}$	Lower	Upper	p value
BN-SP oblique at rest	(0.39) 2.79	(0.43) 2.89	0.751	0.336	0.907	0.0032
BN-SP oblique at contraction	(0.52) 2.9	(0.6) 2.8	0.899	0.731	0.962	0.000
BN-SP oblique at Valsalva	(1.57) 0.69	(1.47) 0.76	0.949	0.864	0.981	0.000
BN displacement at contraction	(0.26) 0.44	(0.4) 0.57	0.787	0.431	0.920	0.0013
BN displacement at Valsalva	(1.22) 2.41	(1.36) 2.15	0.827	0.538	0.935	0.000
BN displacement at contraction/Valsalva	(1.14) 2.68	(1.29) 2.51	0.774	0.398	0.915	0.0018
AR-SP distance at rest	(0.75) 5.95	(0.59) 5.92	0.886	0.697	0.957	0.000
AR-SP distance during contraction	(0.65) 4.72	(0.83) 4.67	0.812	0.497	0.929	0.000
AR-SP distance while performing Valsalva maneuver	(1.28) 6.34	(1.52) 6.47	0.951	0.860	0.982	0.000
AR displacement at contraction	(0.53) 1.28	(0.57) 1.19	0.716	0.242	0.894	0.006
AR displacement at Valsalva	(1.12) −0.39	(1.55) −0.59	0.904	0.725	0.966	0.000
AR displacement at contraction/Valsalva	(1.53) 2.26	(1.45) 2.3	0.934	0.844	0.981	0.000

SRD [18, 19]. Following this knowledge, SRD which was calculated from the error of measurement was presented at this study. Furthermore, the intermission between the two measurement visits was uniquely of 4.4 weeks average, taking into account a reasonable time frame for clinical change. On the other hand, this study was limited by some exclusion criteria, thus compromising its generalizability. For instance, patients with major prolapse and obesity were excluded in order to avoid difficulties performing the US measures. Consequently, the SRDs presented in this study may be applied only for women presenting with similar characteristics.

Conclusions

US measurements of distance between anatomic structures seem to offer reasonable clinical reproducibility. The study also points out to the superiority of the anorectal angle distance and displacement in terms of test–retest stability.

Conflicts of interest None.

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