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Research Paper





The Reliability of the Rehabilitative Ultrasound Imaging Method for Assessing Pelvic Floor Muscles Function in **Pregnant Women**

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ABSTRACT

Background: To our knowledge, there is scant research on the use of rehabilitative ultrasound imaging (RUSI) method for evaluating bladder base displacement in pregnant women. The RUSI is a non-invasive and simple method that assesses the function of pelvic floor muscles (PFM) based on the movement of the bladder base.

Objectives: This study aims to assess the reliability of the RUSI for the assessment of PFM function in pregnant women during voluntary muscle contractions.

Materials & Methods: In this cross-sectional study, 18 pregnant women with different gestational ages participated. The amount of bladder base displacement during PFM contraction was assessed in all women and considered an indicator of PFM function. The test re-test reliability was evaluated using the intraclass correlation coefficient (ICC) and Bland-Altman plot. The percentages of standard error of measurement (SEM%) and minimal detectable change (MDC%) were also calculated.

Results: The mean amount of bladder base displacement during PFM contraction at time points 1 and 2 was 4.89±1.43 and 4.81±1.41, respectively. The ICC was 0.989 (95% CI, 0.969%, 0.996%), which indicates excellent reliability. The Bland-Altman plot showed that all the points were within the 95% limits of agreement with no considerable trend or bias. The SEM% and MDC% were 3.09% and 8.41%, respectively.

Conclusion: The intra-rater reliability of the RUSI to assess PFM function in pregnant women is high, and can be useful for further studies on the PFMs in pregnant women.

Keywords: Pelvic floor muscle, Muscle function, Ultrasound imaging, Pregnant women, Reliability, Physiotherapy

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Highlights

- The rehabilitative ultrasound imaging (RUSI) is a non-invasive and simple method that assesses the function of PFMs.
- The RUSI is a highly reliable method to assess pelvic floor muscles (PFM) function in pregnant women.
- The RUSI can be used in further studies on the PFMs in pregnant women.

Introduction

he pelvic floor muscles (PFMs) build the pelvic diaphragm, urogenital diaphragm, and urethral and anal sphincters [1-3]. The role of PFMs is to support abdominopelvic organs, bladder continence, respiration, and trunk stabilization [4-6]. Contraction of the PFMs and their associated fascia supports the bladder, leading to displacement of the bladder base [7]. Poor contraction of these muscles can result in urinary and/ or fecal incontinence. Conversely, hyperactivity may lead to issues such as urinary retention, constipation, and painful bladder syndrome [8, 9]. Furthermore, the dysfunction of PFMs is associated with low back pain [10, 11]. Women may experience urinary incontinence for the first time during and after pregnancy [12]. Research indicates a notable decline in PFM strength among pregnant women with urinary incontinence compared to healthy peers [13].

The common techniques to evaluate PFM function include pelvic floor manometry, digital examination, and electromyography [14-18]. PFM function can also be determined by measuring bladder base displacement using the rehabilitative ultrasound imaging (RUSI) method. It is a widely used technique that is simple and safe to employ in a therapeutic setting. This method does not necessitate revealing intimate body parts and is applicable to individuals at any age and with any gender. Recent studies have demonstrated the validity of this method in determining bladder base displacement [15, 19-22]. However, there is scant research on the reliability of RUSI for assessing bladder base displacement in pregnant women.

Due to the prominent role of PFMs in urinary function and their possible dysfunction and weakness in pregnant women suffering from urinary incontinence, RUSI may be crucial for the assessment. In this study, we evaluate the reliability of the RUSI of PFM contraction in pregnant women for the first time. Thus, this study aims to evaluate the reliability of the RUSI for measuring bladder base displacement in pregnant women during voluntary PFM contractions.

Materials and Methods

Participants and sample size

This cross-sectional study was conducted on Iranian pregnant women aged 18-42 years and different gestational ages determined by a gynecologist. Inclusion criteria were pregnancy, the ability to correctly contract the PFMs, and willingness to participate in the research. Exclusion criteria were a diagnosed neurological disease, and inability to understand the instructions in Persian language. Prior to the study, all participants declared their consent by signing an informed consent form. The sample size was determined utilizing the equation proposed by Bonnet [23]. Using this equation and by considering an intraclass correlation coefficient (ICC) of 0.90, 95% confidence interval (CI), and width of 0.20, the minimum sample size was obtained at 15. Given a 15% sample dropout, the sample size increased to 18.

Procedure

For the RUSI, a diagnostic ultrasound imaging device with B-mode technology and a 3.5-5 MHz convex array transducer (Resona 6, Mindray Co., China) was employed. Recent studies have described the detailed procedure to measure bladder base displacement [24-26]. To ensure optimal imaging conditions, a consistent protocol for filling the bladder was implemented prior to imaging, confirming that women had an adequate amount of fluid in their bladders. Participants were instructed to drink 600-750 mL of water for 30 minutes, about one hour before to the measurement. They were then asked to abstain from urination until after the ultrasound imaging [15, 27, 28].

Before conducting the test, a trained pelvic health physiotherapist taught the participants how to activate





Figure 1. Ultrasound transducer placement for measurement

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PFMs correctly by digital examination. During testing, participants were at a supine position with a slight bend in the knees and hips, using one pillow beneath the head. The lumbar spine was maintained in a neutral position. The ultrasound transducer was positioned in the suprapubic area on the transverse plane tilted posterior caudally to get a clear view of the lower posterior section of the bladder in the ultrasound image (Figure 1). The angle of the ultrasound transducer varied, ranging from 15 to 30 degrees, depending on factors such as bladder fullness and abdominal size. Initially, a marker was po-

sitioned on the bladder base while the participant was at a resting position. Subsequently, participants were asked to execute a voluntary contraction of the PFMs by "squeezing and lifting the muscles upon the request". Once the contraction became visible on the ultrasound device screen, a snapshot of the image was taken, and then the participants were asked to release their PFMs [7, 29].

The indicator was placed on the bladder base at the location where the maximum displacement occurred



Figure 2. Ultrasonography image of the bladder base displacement during maximum contraction of PFMs

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Table 1. Demographic characteristics of the pregnant women (n=18)

Variables	Mean±SD
Age (y)	29.39±6.84
Height (cm)	159.11±7.03
Weight (kg)	67.4±13.65
BMI (kg/m²)	26.84±6.10

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while the muscles were contracting. The displacement of the bladder base from its initial resting position to the end of each contraction was measured and recorded in millimeters (Figure 2). Participants maintained the contraction for up to 3 seconds. The ultrasound transducer remained fixed throughout the testing process at a consistent position from the resting phase to the maximal contraction. Three PFM contractions were performed with a rest interval of 10 seconds, and the average of three measurements were used as a final outcome in the statistical analysis [15, 24].

Statistical analysis

In this study, continuous variables were presented as Mean±SD, median, and inter quartile range (IQR). Test re-test reliability of the RUSI was assessed using the ICC and Bland-Altman plots with lines of equality. The ICC was computed using a two-way mixed-effects model and single measurement (ICC_{3,1}). Regarding the line of equality, close agreement between measurements was obtained when scatter plots fall on the 45-degree line that passes through the origin. Regarding the interpretation of ICC values, a values < 0.5 indicates poor reliability, a value of 0.5-0.75 indicate moderate reliability, a value of 0.75-0.9 shows good reliability, and a value >0.9 represent excellent reliability [30]. Additionally, the standard error of measurement (SEM) and minimal detectable change (MDC) were determined using the Equations 1 and 2:

1. SEM=SD
$$\times \sqrt{(1-ICC)}$$

2.
$$MDC_{95}=1.96\times SEM\times\sqrt{2}$$

The SEM and MDC percentages were obtained as Equations 3 and 4:

- 3. SEM%= $(SEM/M) \times 100$
- 4. MDC%=(MDC/M)×100,

where M represents the mean of both observations from the two assessments conducted during the study. An SEM% <10% represents acceptable reliability, and an MDC% <30% was considered as acceptable and <10% as excellent. The statistical analysis was performed in SPSS software, version 26 (IBM Corp., Armonk, NY, USA) and plots were represented by GraphPad Prism software, version 8.0.1 (GraphPad Prism Software Inc., San Diego, CA, USA).

The intra-rater reliability of the RUSI was evaluated with the participation of 18 subjects. The rater conducted measurements first. After a 30-minute interval, the measurements were repeated in a blinded and randomized manner using the same procedure. The subjects and the sequence of measurements were randomly selected, different from the initial examination sequence, aiming to minimize the impact of memory effects. All test trials were carried out in a hospital affiliated to Shahid Sadoughi University in Yazd, Iran.

Results

Characteristics of participants

The demographic characteristics of participants are presented in Table 1. There were no statistically significant differences among subjects in terms of height, age, and weight. Their mean age was 29.39±6.84 years, ranging from 18 to 42 years and their mean body mass index (BMI) was 26.84±6.10 kg/m², ranging from 16.96 to 36.59 kg/m².

Table 2 presents the descriptive statistics of the transabdominal ultrasound measurement of the PFMs in the first and second measurements. The mean value in the first time point was 4.89 ± 1.43 , ranging from 2.8 to 9.0. The ICC (1.1) value for the reliability of RUSI were 0.99. This suggests a high level of intra-rater reliability for the RUSI.



Table 2. Descriptive statistics of the transabdominal ultrasound measurement of PFMs in pregnant women in the first and second time points

Transabdominal Ultrasound Measurement	Range (mm)	Mean±SD	Median (IQR)
Time 1	2.80-9.00	4.89±1.43	4.65 (3.95-5.78)
Time 2	3.00-9.00	4.81±1.41	4.50 (4.00-5.72)

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Test re-test data were collected from 18 pregnant women at a 30-min interval. The ICC was 0.989 (95% CI, 0.969%, 0.996%). The visual examination of the consistency between test and re-test results of ultrasound measurement of PFMs using the Bland-Altman plot with lines of equality was also conducted. As can be seen in Figure 3, the scatter plots indicate that the data points fell on or were close to the line of equality.

The Bland-Altman plot (Figure 3) also revealed that all points fall on the lower and upper limits of agreement. Furthermore, no significant trend or bias was evident in the scattering of points. Both plots demonstrated high agreement between the test and re-test data.

As presented in Table 3, the SEM% was 3.09% which is considered acceptable, and MDC% was 8.41% which is considered excellent.

Discussion

The RSUI method is novel and valid approach for evaluating the patterns of muscle activation during contraction. Ultrasound imaging method is commonly used to assess both voluntary and involuntary muscle activity at the subconscious level. In this study, we focused on measuring voluntary contractions. This is the first study that evaluates the reliability of RSUI in pregnant women. The findings of our study indicated that the RSUI was a reliable method for evaluating PFM contractions in pregnant women (ICC=0.99). Similar findings have been reported in recent studies [15, 24, 31], although these studies examined reliability in healthy women or women with urinary disorders. According to Landis et al. [32], the ICC of 0.81-1.00 is considered "almost perfect" agreement, 0.61-0.80 as "substantial," 0.41-0.60 as "moderate," 0.21-0.40 as "fair," and 0-0.20 as "slight". Therefore, in our study, the reliability of the RSUI was excellent.

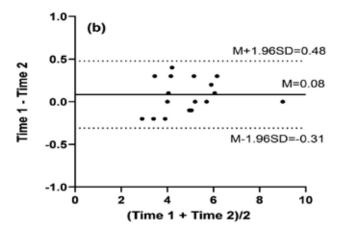


Figure 3. The Bland-Altman plot

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Table 3. Test re-test reliability results of transabdominal ultrasound assessment of PFM in pregnant women

Method	ICC (95% CI)	SEM	SEM%	MDC	MDC%
RSUI	0.989 (0.969-0.996)	0.150	3.09	0.408	8.41

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By the use of RSUI in this study, we were able to observe the extent to which the PFMs had activation to prevent urinary incontinence. This highlighted the simplicity and effectiveness of studying PFM activities. In summary, the application of a diagnostic ultrasonic imaging device enabled the reliable measurement of bladder base displacement in pregnant women.

Conclusion

The RSUI has high reliability for evaluating PFM contractions in pregnant women. It can be used in future studies on pregnant women. Further studies are recommended to assess the effectiveness of bladder base displacement in the management and prevention of urogynecological disorders during pregnancy.

Limitations

One limitation of this study was that the RSUI for assessing the bladder base displacement lacks a fixed reference point, unlike transperineal ultrasound imaging, which is considered the gold standard for evaluating bladder neck displacement. Due to the nature of bladder base displacement that is related to a potentially movable starting point, the maintenance of the fixed position of transducer is crucial for achieving accurate and repeatable measurements. Another limitation of this study was the inability to assess inter-rater reliability, as only one rater was involved. Hence, future studies should involve multiple raters to explore inter-rater reliability of the RSUI.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (Code: IR.SBMU.RETECH.REC.1400.611). All participants were informed about the study objectives and the voluntary nature of participation.

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Authors contributions

Conceptualization: Seyed Majid Hosseini, Farideh Dehghan Manshadi and Parisa Ghadiri Harati; Methodology: Farideh Dehghan Manshadi; Investigation: Atiyeh

Javaheri and Parisa Ghadiri Harati; Formal analysis: Alireza Akbarzadeh Baghban; Resources: Seyed Majid Hosseini and Parisa Ghadiri Harati; Writing the original draft: Parisa Ghadiri Harati; Review & editing: Farideh Dehghan Manshadi and Seyed Majid Hosseini; Supervision: Farifdeh Dehghan Manshadi and Atiyeh Javaheri.

Conflict of interest

The authors declared no conflicts of interest.

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