284

Dias A[1], Assis L[1], Barbosa A[1], Santini A C[1]
1. *Botucatu Medical School*

VALIDATION OF PERINEOMETRIC AND BIDIGITAL TEST FINDINGS TO PREDICT URINARY INCONTINENCE OCCURRENCE IN PRIMIGRAVIDAS

Hypothesis / aims of study

The pelvic floor (PF) plays a leading role in protecting and sustaining pelvic and abdominal organs,as well as in maintaining fecal and urinary continence (1). As pregnancy advances, pelvic floor muscle function (PFMF) decreases due to hormone and biomechanic changes that normally occur during gestation (2). These changes associated with increase in body mass índex, parity and duration of the expulsation phase can weaken pelvic floor muscles, and lead to urinary incontinence (UI) (1). Studies have shown that incontinent women have a significant PFMF deficit in comparison with continent women (1,2). Several techniques have been proposed for the assessment of PFMF, but the bigital test and perineometry are the most commonly used (1). According to the literature, despite being two distinct methods, bidigital test and perineometry correlate positively. However, there is no consensus method for PFMF assessment (3). Both perineometry and bidigital palpation are limited because vaginal pressure normality parameters in pregnant women and the cutoff points predictive of UI during pregnancy have not been so far determined. Thus, the purpose of this study was to validate perineometric and bidigital palpation measurements in primigravidas, and to determine the cutoff point predictive of UI occurrence for both these methods.

Study design, materials and methods

This study is an extension of a pragmatic randomized clinical trial that was approved and registered on *clinicaltrials.gov*. The 87 primigravida women (20-35 years) included in this study were interviewed for the collection of demographic data and information on their pre-gestational status. All participants underwent PF assessment by bidigital palpation and perineometry, using the classification system proposed by Amaro (2000), and a grading scale ranging from 0 to 12cmH_2O, respectively. All participants were assessed at 18, 22, 26, 30, 34, and 38 weeks of gestation and completed a urinary loss report form.

Simple linear regression was used to check whether the correlation between the bidigital test and perineometry was statistically significant before simultaneous comparison with the gold-standard (reported urine loss). The sensitivity and specificity of the methods in identifying urine loss between 18 and 38 weeks of gestation were determined. The minimum sample size was estimated as 42 measures per visit, assuming a 5% significance level and 80% power. Statistical analyses were performed using software SPSS/PASW Statistics, version 17.0.2.

Results

All 87 participants enrolled attended all visits and completed the urinary loss report form. A total of 522 PFMF measurements were obtained for each test. Of these, 87 were taken during the first visit at 18 weeks of gestation. In order to standardize UI identification, these measurements were excluded from analysis, resulting in 435 measurements, of which 237 were related to urine loss complaints (54.48%) whereas 198 were not.

Correlations between the bidigital test and perineometry were high at all six evaluation visits (r^2between 0.65 and 0.70), producing well adjusted linear models and statistically significant variance analyses. Therefore, a global model comprising all time points with the same results pattern was used to generate the following equation for the prediction of the perineometric measure (P) in function of the bidigital test result (BD): P = 0.991 + 3.60 BD. The model adjustment remained adequate, with good linear correlation (adjusted r^2 = 0.723), normal residual distribution and significant analysis of variance ($p<0.001$).

Following the identification of a positive linear correlation between tests, their sensitivity and specificity values were estimated. Perineometric values of up to 8,8cmH_2O generated optimal balance between sensitivity (82,8%) and specificity (81,8%), i.e., an approximation to the cutoff point predictive of UI demonstrating that higher values indicate that a continent pregnancy is highly probable. Given that the scale of the equipment used is categorical, it may be assumed that values above 9cmH_2O predict continence with high sensitivity and specificity. The predictive value of the bidigital test was quite inferior to that of perineometry. Indeed, it reached optimal balance with 33.8% sensitivity and 92.4% specificity.

Interpretation of results

The results obtained in this study suggest that perineometry provides more reliable and reproducible data on PFMF. There seems to be an association between the presence of urine loss and perioneometric PFMF in the sense that the higher the measure the lower the risk of UI. This relationship was not so explicit when the bidigital test was used.

Our findings also indicate that the bidigital test can predict with good certainty perineometric results. Nonetheless, perineometry was superior in predicting UI occurrence.

Concluding message

Given that a decline in PFMF is expected to occur between 20 weeks of gestation and 6 months after delivery, perineal function should be addressed during pregnancy through physiotherapy. Perineal training can help prevent urinary problems and maintain and/or improve PFMF.

The high prevalence of UI during pregnancy as a result of PFMF decrease is a good argument in favor of implementing preventive interventions such as an intensive program of PF muscles exercises to maintain urinary continence satisfactory and thus provide integral women's care and improve the quality of life of pregnant women.

References

1. Bø K, Sherburn M. Evaluation of Female Pelvic-Floor Muscle Function and Strength. Physical Therapy, 2005;85(3):269-82
2. Oliveira C, Lopes MAB, Pereira LCL, Zugaib M. Effects of pelvic floor muscle training during pregnancy. Clinics. 2007; 62(4):439-46.

3. Fitzgerald MP, Burgio KL, Borello-France DF, et al. Pelvic-floor strength in women with incontinence as assessed by the brink scale. Phys Ther 2007; 87:1316–24.

Specify source of funding or grant	**Fundação de Amparo à Pesquisa do Estado de São Paulo, number 2008/01149-0**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**registered on clinicaltrials.gov under the number NCT00740428 on 08/22/2008.**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**approved by the local Research Ethics Committee, of the Assis Regional Hospital - Brazil**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**