# Do dynamometric variables of the pelvic floor muscles differ between women with and without stress urinary incontinence? A blind, cross-sectional study.


## ABSTRACT

**Objective:** The aim of the present study was to compare PFM contraction variables between women with and without SUI. **Material and Methods:** This cross-sectional study evaluated the PFMs of 17 healthy women and 17 women with SUI during a single test session using a vaginal dynamometer. Outcomes: peak time (time at which peak force occurred after the onset of contraction), passive force (baseline), maximum contraction force, impulse of contraction, average force and endurance time. Dada were recording during a single test session using a vaginal dynamometer. **Results:**The following PFM contraction variables were evaluated: Analysis of covariance (ANCOVA) with the Bonferroni post hoc test was used to compare the dynamometric data between groups (control and SUI), considering age and number of childbirths as co-variables. Significant difference was observed between groups with regard to endurance (F = 4.87, *P*< .03; ANCOVA test), whereas no significant differences were found for the other variables analyzed. **Conclusion:** The endurance time of PFM contraction is shorter in women with SUI, whereas variables related to the intensity of pelvic floor muscle contraction force and time from the onset to peak contraction of these muscles are similar between women with and without stress urinary incontinence.


**Keywords:** Physiotherapy, dynamometer, stress urinary incontinence, pelvic floor muscle

**Comment [1]:** Spelling and gramatical error.

## 1. INTRODUCTION

Urinary incontinence is described as any involuntary loss of urine. This condition has a tendency to aggravate over time and the prevalence figures increase with increasing age, and in women aged $\geq 70$ years more than 40% of the female population is affected [1].

Stress urinary incontinence (SUI) is the most common form of the disorder in women and is characterized by urinary leakage associated with some form of exertion, such as coughing, sneezing, squatting, physical exertion, and the practice of sports involving jumping, fast running, and rotational movements [2,3]. The cause of this phenomenon has not been fully clarified, but the loss of the integrity of the muscles that constitute the pelvic floor is one of the factors associated with this disorder [3].

In clinical practice, visual inspection and intra-vaginal palpation are the most common pelvic floor muscle (PFM) assessment methods, the latter of which is scored with different rating scales, the most often employed of which is the Oxford grading system [4,5]. These methods are minimally invasive, inexpensive and easy to perform, but are considered subjective, as the assessment of the PFM with vaginal palpation depends on the experience of the evaluator and the patient's voluntary participation as well as the positions of the patient and the examiner [6].

Moreover, divergent opinions are found in the literature regarding the reliability of these methods [5,7,8]. Thus, measurements obtained using electromyography, perineometry, dynamometry and different imaging methods (ultrasound, magnetic resonance and urodynamic analysis) have been used to determine and quantify the function of these muscles in a more precise manner [9].

Dynamometry, in particular, enables the objective evaluation of PFM force with the use of a vaginal probe. The PFM variables considered for such an evaluation include maximum strength, mean value of the strength curve, endurance, contraction velocity and passive force [10, 11]. However, a study has proposed further evaluation variables based on data obtained from a vaginal dynamometer, such as impulse of contraction, average force and the peak time (time that peak force occurs after the onset of PFM contraction) [12].

The reproducibility and reliability of these new indices are high, but no comparisons have been made between women with and without SUI. Such comparisons are important, as these indices may reveal clinical characteristics (impulse of contraction, average force and the peak time) of women with SUI that have not been described in previous studies. Such information is relevant to clinical practice, as it could help guide the use of variables obtained through vaginal dynamometry as part of the diagnosis of SUI. Therefore, the hypothesis tested in this study was that the variables passive force (baseline), maximum force, average force, impulse of contraction, time from the onset to peak contraction and endurance time have different values between women with and without SUI. Thus, the aim of the present study was to compare vaginal dynamometric variables between women with and without stress urinary incontinence during contraction of the pelvic floor muscles.

## 2. MATERIALS AND METHODS

### 2.1 Design

This was a blind, cross-sectional study conducted after being approved by the Ethics Committee of the Nove de Julho University (process nº: 1.042.129). All individuals were properly informed regarding the objectives and procedures and signed a statement of informed consent prior to testing.

### 2.2 Sample size

The sample size was based on the study by Chamochumbi et al [13], considering the mean and standard deviation (±) of the maximum strength of PFM recorded with dynamometer (anteroposterior position) of women with and without SUI being the values respectively: 0.1±0.1 N and 0.3±0.2 N. For the calculation of the sample it was considered $\alpha = 0.05$ (5% chance of a type I error) and $1\text{-}\beta = 0.90$ (power of the sample). A minimum of 15 individuals was determined. This calculation was performed using the G*Power 3.1.9.2 software, as recommended by Faul et al [14].

### 2.3 Participants

Seventeen healthy women and 17 women with SUI aged 20 to 60 years were recruited from the academic community as well as urogynecology and physical therapy services to participate in the study.

The inclusion criteria for the SUI group were a report of urinary leakage in the previous three months and a positive answer to Question 3 of the Three Incontinence Questions used to distinguish between SUI and urgent urinary incontinence in adult women [15]. Women without a complaint of urinary leakage and without any of the exclusion criteria were selected for the control group.

The following were the exclusion criteria: responses of “moderately” or “a lot” on the symptoms scale of the King’s Health Questionnaire (KHQ) related to urgency and overactive bladder, urinary tract or vaginal canal infection, abnormal vaginal mucosa (candidiasis), current pregnancy,important organ prolapse (PopQ > Phase II) [16], use an analgesic or muscle relaxant [10; 18] and a history of urogynecology surgery.

**Comment [2]:** Kindly give explanation for the accuracy of the questionnare used to exclude patients with urgency or overactive bladder as sometimes patients present with mixed symptoms including both urgency and SUI.

**Comment [3]:** Kindly clarify the term used- Important ogran prolapse or pelvic organ prolapse.

### 2.4 Blinding

Independent evaluators performed the following procedures: Evaluator 1: triage and evaluation of clinical characteristics; Evaluator 2: vaginal dynamometer data collection; Evaluator 3: vaginal dynamometer signal processing and statistical analysis. Evaluators 2 and 3 were blinded in relation to the groups.

### 2.5 Evaluation procedures

The tests were performed in a single session. The clinical characteristics of women with SUI were assessed by a physiotherapeutic with at least 5 years of experience through the following instruments: i) the impact of urinary continence was evaluated using the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF; 0 to 21 points; $\geq$ 3 points indicates incontinence, with higher scores denoting greater severity) [19]; ii) severity of urinary leakage was evaluated using the Protection, Amount, Frequency, Adjustment and Body Image (PRAFAB) Questionnaire (≥ 14 points severe urinary incontinence) [20]; and iii) quality of life was evaluated using the KHQ (0 to 100 points, with higher scores denoting poorer quality of life) [21].

The PFM contraction data were collected using a vaginal dynamometer (Model: Power Gyneco, EMG System do Brasil®) composed of a shaft measuring 70 mm in length and 22 mm in diameter and weighing 258 g. Force was measured in Newtons (N). The dynamometer signal was acquired using a conditioner module (EMG System do Brasil®) and digitized by a 12-bit analog/digital converter with a sampling frequency of 1000 Hz connected to a computer. Both devices remained disconnected from the electrical grid during the readings to avoid interference.

The tests were performed beginning from the first day after the end of the menstrual period by a physiotherapist with experience in evaluating the PFMs of women with urinary incontinence. Prior to the test, the volunteer was asked to empty her bladder and was then placed in the dorsal lithotomy position.

The volunteer was asked to perform PFM contraction prior to the test and the responses were measured by the visual inspection performed by the examiner. Training was then performed for the volunteer to learn how to contract the PFMs without the contraction of other muscle groups, such as the abdominal and gluteus muscles. After these procedures, the dynamometer covered with a condom (OLLA®, Hypermarcas-S/A) was inserted into the vagina and the volunteer was instructed to relax the PFMs, at which time passive force (baseline) was recorded for ten seconds. A single command was then given for the volunteer to perform and sustain maximum contraction until exhaustion (endurance).

The data were recorded considering PFM contraction force on the sagittal (antero-posterior) plane. The insertion depth of the shaft of the dynamometer was not standardized, as the equipment was designed for the precise measurement of PFM contraction force independently of the location on the shaft at which the effort was performed [12]. The test was performed three times with a five-minute interval between trials. No volunteers reported any discomfort either during or after the test sessions.

**2.6 Outcome measures**

The signal from the vaginal dynamometer was used to calculate the contraction force variables described by Nagano et al [12]: passive force (PF), impulse of contraction (IC), average force (AF), peak time (PT) and maximum strength value (MSV). Endurance was calculated from the onset of contraction to the point of exhaustion (Figure 1). All signals were processed and analyzed using routines developed in Matlab® version 2022 (Mathworks inc., Natick, Massachusetts, USA).

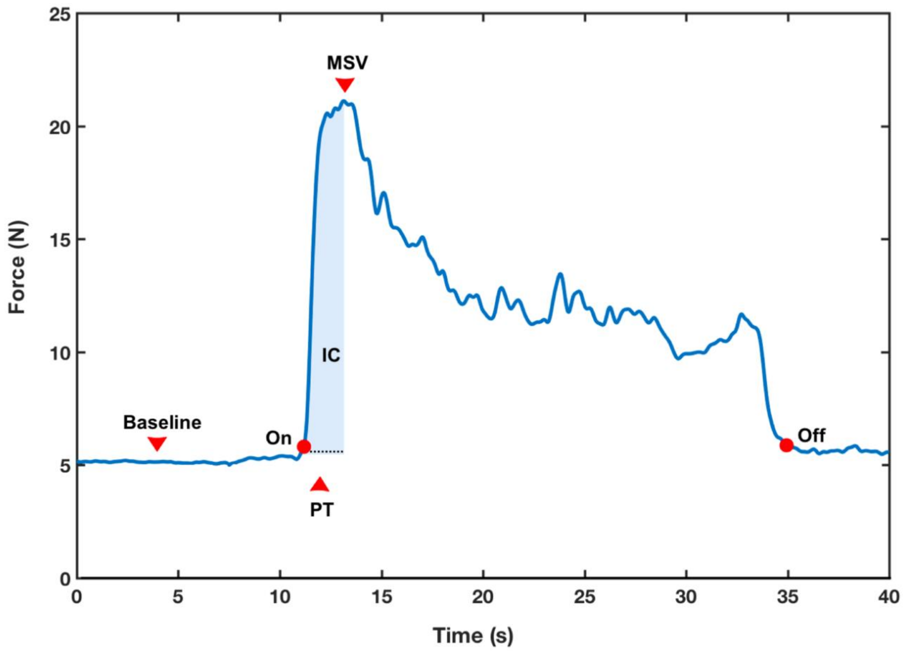


**Figure 1.** Strength test of the pelvic floor muscles. **Baseline:** passive force. **MSV:**maximum pelvic floor muscles strength value; **PT:** peak time. **IC:** impulse of contraction of the muscles strength. **On/Off:** endurance time.



### 2.7 Statistical analysis

The Shapiro-Wilk test was used to determine the normality of the data distribution. Demographic data from the two groups were compared using the independent *t*-test. Analysis of covariance (ANCOVA) with the Bonferroni post hoc test was used to compare the dynamometric data between groups (control and SUI), considering age and number of childbirths as co-variables. Age and number of childbirths were entered as a covariate in these analyses because these variables were significantly different between the groups ($P < .05$). A $P$-value $< .05$ was considered indicative of statistical significance. The partial eta squared value ($\eta p^2$) was used to calculate the effect of the interactions, the results of which were interpreted based on Cohen (1988): < 0.01 = small effect; 0.06 = moderate effect; and ≥ 0.14 = large effect. All statistical analyses were performed with the aid of SPSS version 20.0 (IBM Corporation, Armonk, NY, USA).

## 3. RESULTS

Table 1 displays the demographic and clinical data of the volunteers. Age and number of childbirths differed significantly between the two groups. The table also displays the scores of the KHQ (quality of life), ICIQ-SF (impact of urinary incontinence) and PRAFAB (severity of urinary leakage) questionnaires in the group with SUI.

**Comment [4]:** It would be better to highlight some of the important findings in Result section apart from mentioning in the tables.

**Table 1**. Mean and standard deviation of demographic and clinical variables of women with (SUI) and healthy controls

Comment [5]: Kindly give explanation for the term used as 'healthy controls' mentioned in table 1 and table 2. If patients have other conditions such as urgency or overactive bladder, can they be labelled as healthy controls?

| | SUI | Controls | ***P-value*** |
|---|---|---|---|
| **Age (years)** | 45.35±10.61 | 31.24±10.23 | <0.001* |
| **Body mass index (Kg/m$^2$)** | 28.75±5.79 | 26.91±5.23 | 0.33 |
| **Parity** | 2.47±1.62 | 0.94±1.08 | 0.002* |
| **PRAFAB** | 10.29±2.77 | | |
| **ICIQ-SF** | 11.82±5.21 | | |
| **KHQ scores** | | | |
| General health perception | 33.82±23.29 | | |
| Impact of incontinence | 50.95±26.67 | | |
| Role limitation | 39.21±28.83 | | |
| Physical limitations | 46.08±35.12 | | |
| Social limitation | 17.65±24.86 | | |
| Personal relationship | 16.67±22.05 | | |
| Emotions | 30.72±31.80 | | |
| Sleep/energy | 30.39±30.75 | | |
| Severity measures | 46.35±22.05 | | |

**KHQ:**King's Health Questionnaire. **ICIQ-SF:** International Consultationon Incontience Questionnaire Short Form. **PRAFAB:** Protection, Amount, Frequency, Adjustment and Body Image Questionnaire.

***** Significant difference between groups (Independent *t*-test$P< .05$)

Table 2 displays the dynamometric findings. ANCOVA revealed a statistically significant difference between groups with regard to endurance ($F = 4.87$, $P < .03$; ηp2= 0.14), whereas no significant differences were found for the other variables analyzed.

**Table 2.** Mean and standard deviation values for dynamometric variables in women with stress urinary incontinence (SUI) and healthy controls

| | **SUI** | **Control** | **F** | ***P*-value** | $\eta_p^2$ |
|---|---|---|---|---|---|
| **Baseline (N)** | 6.06±1.62 | 6.21±1.26 | 0.15 | .69 | <0.01 |
| **MSV (N)** | 12.72±3.45 | 13.80±4.99 | 0.11 | .91 | <0.01 |
| **IC (N/s)** | 10.97±8.67 | 11.29±8.25 | 0.18 | .66 | <0.01 |
| **AF (N)** | 8.71±2.14 | 9.12±3.19 | 0.01 | .92 | <0.01 |
| **PT (s)** | 2.18±1.43 | 2.34±0.97 | 0.17 | .67 | 0.01 |
| **Endurance (s)** | 19.14±8.15* | 29.32±12.66 | 4.87 | .03 | 0.14** |

* Significant difference between groups (Ancova test).

** Large effect size

Baseline: passive force of the pelvic muscle floor. **MSV:** maximum pelvic muscle floor strength value. **IC:** impulse of contraction of the pelvic muscle floor. **AF:** Average contraction force of the pelvic muscle floor. **PT:** the time interval between the beginning and the peak of contraction of the pelvic floor muscles. **Endurance:** onset of contraction to the point of exhaustion.

## 4. DISCUSSION

The hypothesis that different vaginal dynamometric variables related to PFM contraction would be different between women with and without SUI was only confirmed for endurance time, whereas no significant differences between groups were found with regard to variables related to the intensity of the PFM contraction force (PF, IC, AF and MSV) or PT.

There is a growing body of evidence that lends support to the reasoning that an improvement in the tone of the PFMs can assist in improving and/or controlling SUI [22,23]. Such observations suggest the occurrence of functional alterations in the PFMs of women with SUI in relation to healthy women and that components of muscle strength are associated with this disorder.

Therefore, the aim of PFM training for women with SUI is generally to improve the strength, endurance and co-ordination of these muscles [24, 25].

However, the possible alteration in the components of muscle strength in women with SUI was not confirmed by the results in the present study, as no significant differences were found for any of the variables related to the contraction force of the PFMs (PF, IC, AF and MSV) in the groups with and without SUI. Moreover, this relationship has not yet been clarified in other investigations involving dynamometry [26,27]. Previous studies have demonstrated that the development of active strength in the tissues of the pelvic floor may [13, 27] or may not [26] be significantly reduced in women with SUI.Conflicting results are also found in the analysis passive mechanical forces measured using dynamometry with the patient at rest[13, 26,27].

**Comment [6]:** Please clarify this statement further.

These different responses in the literature regarding PFM contraction force may stem from differences in the evaluation methods employed during the tests as well as differences in the equipment used to measure PFM strength. The dynamometer used in the present study was designed with a load cell positioned in the center of the shaft so that PFM contraction force could be measured precisely, independently of the location of the shaft at which the effort was performed [12]. Dynamometers used for the evaluation of the PFMs are generally constructed with stain gauges located at the base of the shaft and therefore distant from the point at which the device receives the PFM contraction force rest [13, 26,27]. This characteristic of the equipment increases the chance of a measurement error.

A previous study reports similar results regarding the association between endurance and SUI [26]. Therefore, this response indicates that the PFMs of women with SUI may be less resistant to fatigue than those of healthy women. However, this association was not found in a another investigation, in which no difference was found regarding the time at which the fatigue of these muscle occurs [27]. This divergence may be explained by differences in the protocols employed for the data collection process.

**Comment [7]:** Grammatical error.

**Comment [8]:** Please clarify the protocol differences in between two studies impacting the results.

The time between the onset and peak PFM contraction was calculated to determine whether the time required for the recruitment of fibers in these muscles to reach maximum force is altered in women with SUI. This possibility was not confirmed in the present study, as no difference was found between the two groups.

### 4.1 Implications for physiotherapy practice

The present findings seem to demonstrate the dynamometric variables related to PFM contraction force do not enable distinguishing between women with and without SUI and that endurance (sustained contraction) time may be the only variable that can be used for this purpose. However, this issue needs to be investigated further in future studies. Moreover, it is important to stress that such observations are only valid with regard to the use of these variables as a possible way of diagnosing SUI, whereas use in clinical practice to evaluate changes in the PFMs over time or following treatment is viable, as these variables have demonstrated good reproducibility [12].

### 4.2 Research limitations

The limitation of the present study was the fact that the volunteers were not matched for age and number of childbirths. However, the latter limitation was minimized by the inclusion of these two variables used a co-variable in the statistical analysis of the data.

**Comment [9]:** Grammatical error.

## 5. CONCLUSIONS

In the present study, women with stress urinary incontinence demonstrated a shorter endurance time of pelvic floor muscle contraction in comparison to healthy women, whereas no differences between groups were found for variables related to the intensity of the contraction force of the pelvic floor muscles (passive force, impulse of contraction, average force and maximum strength value) or time from the onset to peak contraction of these muscles.

**CONSENT**

As per international standard or university standard, patient(s) written consent has been collected and preserved by the authors.

**ETHICAL APPROVAL**

To carry out the study, the authorization of the Local Health Research Ethics Committee of the University was obtained (process nº: 1.042.129).



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