European Journal of Obstetrics & Gynecology and Reproductive Biology: X 3 (2019) 100022

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology: X

journal homepage: www.elsevier.com/locate/eurox

Effect of intravaginal vibratory versus electric stimulation on the pelvic floor muscles: A randomized clinical trial

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ARTICLE INFO

Article history:
Received 15 November 2018
Received in revised form 19 March 2019
Accepted 16 April 2019
Available online 12 May 2019

Keywords:
Vibration
Electric stimulation
Physical therapy
Pelvic floor

ABSTRACT

Introduction: According to the International Urogynecological Association and International Continence Society people with normal pelvic floor muscle function should have the ability to voluntarily and involuntarily contract and relax these muscles. However, many women are unaware of their pelvic floor, and it is estimated that about 30–50% do not know how to actively contract these muscles. Within this context, therapeutic strategies to improve pelvic floor muscle strength and function are particularly relevant.
Aims: To compare the use of an intravaginal vibratory stimulus (IVVS) versus intravaginal electrical stimulation (IVES) on pelvic floor muscle functionality in women with pelvic floor dysfunctions who cannot voluntarily contract these muscles.
Materials and methods: Randomized clinical trial performed at a tertiary care hospital from June 2016 to September 2017. The sample comprised adult women with pelvic floor dysfunction who were unable to contract their pelvic floor muscles voluntarily. Women with latex allergy or other allergies in the pelvic region, vaginal or urinary tract infection, gynecological cancer, significant pain on palpation, or pelvic floor training over the preceding 6 months were excluded. After baseline assessment, women that met the inclusion criteria were randomized to receive once-weekly 20-minute sessions of IVVS or IVES for 6 weeks.
Results: Twenty-one women were randomly assigned to each group; 18 completed the IVVS and 17 completed the IVES protocols. The IVVS group presented a significant increase in PFM strength in relation to the IVES group ($p = 0.026$). There was a significant interaction between time and type of intervention for the same variable ($p = 0.008$) in the IVVS group.
Conclusion: Both techniques were beneficial, but IVVS was significantly superior to IVES in improving pevic floor muscle strength. Additional studies are warranted to consolidate the utility of IVVS as a treatment modality for pelvic floor dysfunction.

Contents

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http://dx.doi.org/10.1016/j.eurox.2019.100022
2590-1613/

Introduction

According to the International Urogynecological Association (IUGA) and International Continence Society (ICS), people with normal pelvic floor muscle (PFM) function should have the ability to voluntarily and involuntarily contract and relax these muscles. During a contraction, the PFMs must compress and execute an inward (ventrocephalad) movement of the pelvic openings [1].

The superficial and deep PFMs work together to serve four main purposes: supporting the pelvic organs, supporting a healthy sex life, and maintaining urinary and fecal continence. Furthermore, the PFMs must be able to voluntarily relax during micturition and defecation and to lengthen during childbirth [2,3]. Accordingly, PFM training is considered the first line of conservative physical therapy for conditions that involve PFM dysfunction, such as urinary incontinence and pelvic organ prolapse (POP) [4,5].

Many women are unaware of their pelvic floor, and it is estimated that about 30–50% does not know how to actively contract their PFMs. Instead, many women activate other muscles such as the glutei, adductors, and abdomen, present apnea, inhale too deeply, or cause a downward movement of the PFM [6–8].

For PFM training to be efficient, the ability to perform a correct contraction of these muscles is essential. Sometimes, a verbal command by the therapist explaining how to do the contraction is enough; at other times, some form of stimulation is necessary. According to the literature, intravaginal electric stimulation (IVES) helps women identify and strengthen these muscles [9,10]. Although it does not have significant side effects, some women report discomfort and do not like electrical stimulation [11–13]. Few studies have addressed the use of intravaginal vibratory stimulation (IVVS), although it is already an established therapeutic option used in clinical practice for PFM rehabilitation [14]. It is believed that IVVS produces afferent impulses that, via the pudendal nerve, reach the sacral spinal cord and generate PFM contraction as a response [15].

Within this context, the present study aimed to compare the effects of IVVS and IVES on PFM function in women with pelvic floor dysfunction who are unable to contract their PFMs effectively (degree of contraction equal to 0 or 1 on the Modified Oxford Scale).

Methods

This randomized clinical trial followed the CONSORT recommendations [16]. From June 2016 to September 2017, using a non-probabilistic convenience sampling strategy, we enrolled women who were referred for pelvic physical therapy for conservative management of pelvic floor dysfunction by medical staff of outpatient obstetrics and gynecology clinic of Hospital de Clínicas de Porto Alegre (HCPA), a tertiary care center in Southern Brazil. The study was approved by the HCPA Ethics Committee (opinion no. 1.714.922) and registered at ClinicalTrials.gov (accession no. 03273309).

The inclusion criteria were age > 18 years and inability to voluntarily contract the PFMs efficiently (degree of contraction = 0 or 1 on the Modified Oxford Scale [17]) even after verbal instructions and a manual stimulus showing which muscle should be contracted during evaluation. The exclusion criteria were latex allergy, other allergies in the pelvic region, vaginal or urinary tract infection, gynecological cancer, significant pain on palpation, and having done PFM training during the preceding 6 months.

The sample size was estimated in WinPEPI (PEPI-for-Windows, version 11.65), considering the proportion of women with urinary incontinence and/or pelvic organ prolapse who were unable to contract their PFM at initial assessment as described by Kim, Wong and Moore [18]. Considering a 95% confidence interval (CI), a 1:1 ratio of sample sizes between groups, significance set at 5%, power of 0.80, the proportion of women unable to contract their PFM at initial assessment (0.24), and a 10% attrition rate, 38 participants (19 in each group) would be necessary for this study.

The first stage of assessment consisted of a thorough history to characterize the sample. The second stage was PFM evaluation through bidigital vaginal palpation and the first four items of the New PERFECT scale17: P (performance), E (endurance), R (repetitions), and F (fast contractions). Power measures PFM strength by the Modified Oxford Scale (graded from 0 to 5). Endurance measures the duration of a maximum voluntary contraction until its strength is reduced by 50% or more. Repetitions assesses the number of repetitions of the previous contraction, and fast assesses the number of fast contractions performed in 10 s.

Women who met the inclusion criteria were referred to the physiotherapist responsible for the study, were invited to participate, received the necessary instructions, signed the informed consent form and scheduled the physiotherapy sessions. Participants were then randomly distributed into an intravaginal vibratory stimulation group (IVVSG) and an intravaginal electric stimulation group (IVESG) through a sequence generated in WinPepi. For allocation concealment, coded, numerical, sequenced and opaque envelopes were used. Assessments were performed by an investigator blinded to group allocation.

Two people attended the practical part of the research: one for pre and post treatment evaluations and another for the application of the protocols. The person who performed the evaluations was a specialist physiotherapist in this area, with years of practical experience in attending patients with pelvic floor dysfunctions and PhD student of the postgraduate program where the research was conducted. The person who applied the protocols was a specialist physiotherapist in this area too and master student of the same postgraduate program.

Sessions were held at the HCPA Clinical Research Center. The protocol (adapted from Sonksen et al.15) consisted of six 20-minute sessions held once a week. After the last session, history and physical examination were repeated and the first four items of the New PERFECT scale were applied again.

For the IVVSG, a polyacetal intravaginal apparatus and probe (Fig. 1) developed by the HCPA biomedical engineering team was used to deliver the vibratory stimulus (frequency 95 Hz, amplitude 1.5 mm, 8 s on/16 s off). For the IVESG, electrical stimulation was delivered using an apparatus developed by the same team (Fig. 2). The stimulus consisted of an asymmetric biphasic current with fixed parameters, adapted from Correia et al19: frequency 50 Hz, pulse width 300 ms, and on-and-off time as in the vibratory stimulus group. The current intensity was adjusted according to patient tolerance, and a Quark Medical® intravaginal electrode was used. In both groups, women were verbally encouraged to try to perform a voluntary PFM contraction during the on cycles of the device.

Data were tabulated by the double-key entry method and analyzed in PASW Statistics, Version 18.0. Symmetric variables

Fig. 1. Intravaginal vibratory stimulus device.

Fig. 2. Intravaginal electrostimulation device.

were expressed as mean and standard error of the mean (SEM) or median and 95%CI as appropriate. Categorical variables were described as absolute and relative (%) frequencies. To compare means between groups, Student's *t*-test for independent samples was applied. In case of data asymmetry, the Mann–Whitney *U* test was used instead. The chi-square test with standardized residuals was used to determine associations between two nominal variables. To assess the effect of intervention type (IVES *vs.* IVVS) and PFM outcomes between and within groups simultaneously, the generalized estimating equations (GEE) model with Bonferroni adjustment was used. The significance level was set at 5% for all analyses.

Results

Fifty women met the eligibility criteria and 42 were randomized for the study (n = 21 per group). At the end of the trial, 18 women had completed the vibratory stimulation protocol and 17 had completed the electric stimulation protocol, for a total of 35 participants. Among the women who dropped out of treatment, only one (in the electrical stimulation group) did so due to discomfort; no other patient reported adverse events. A flow diagram of the trial is shown in Fig. 3.

Table 1 shows the characteristics of the sample. The mean ($\pm$SEM) age was 58 ± 1.77 years, and the mean body mass index (BMI) was 30.11 ± 0.88 kg/m2. The majority of participants were single (61.9%), had a low educational level (50.0%), were menopausal (76.2%), nonsmokers (69.0%), used some type of medication – mainly antidepressants and antihypertensives (54.8%) and considered their bowel function normal (61.9%), with no significant differences between groups. In relation to pelvic floor dysfunction, all participants had some type of urinary incontinence, but prolapse urinary incontinence (MUI) was the main complaint (71.5%); 52% had any type of POP. Medical staff diagnosed urinary incontinence and POP before women were referred for physical therapy.

Comparisons between the intervention groups before and after treatment are shown in Table 2. There was no significant difference in the variables of interest regarding PFM function (performance, endurance, repetitions, and fast contractions) between intervention groups ($p > 0.05$). At the end of treatment, PFM contraction strength in the IVVS group had improved significantly in relation to the IVES group (Mann-Whitney *U*, $p = 0.026$). The ICIQ-SF questionnaire showed post-treatment improvements in UI in each group, but did not show significant between-group differences.

A group effect was observed only for the degree of PFM contraction. IVVSG women exhibited a significant increase in contraction strength when compared to IVESG women ($p = 0.027$). A time effect was significant for the numerical variables of interest ($p \leq 0.001$ for all analyses), showing that PFM measurements improved significantly after 6 weeks of both forms of stimulation. However, a significant interaction of time and stimulation type was observed only for PFM contraction strength ($p = 0.008$); IVESG women stimulated for 6 weeks had lower contraction strength rates compared to IVVSG women (Table 3).

Discussion

Considering the importance of the pelvic floor muscles, the aim of this study was to compare the effects of vibratory versus electrical intravaginal stimulation in women with pelvic floor dysfunction and absent or minimal PFM strength (grade 0 or 1 on the Modified Oxford Scale). After 6 weeks of treatment, PFM contraction strength (element P in the New PERFECT scale) showed significant improvement in the IVVS group compared to the IVES group.

Electric stimulation (ES) is widely used in muscle rehabilitation because it generates an action potential that triggers nerve fiber activation and release of acetylcholine, one of the essential neurotransmitters involved in muscle contraction [19]. When applied intravaginally, ES stimulates the pudendal nerve and its branches, producing reflex responses from the striated pelvic floor musculature. ES is well documented in the literature as an initial

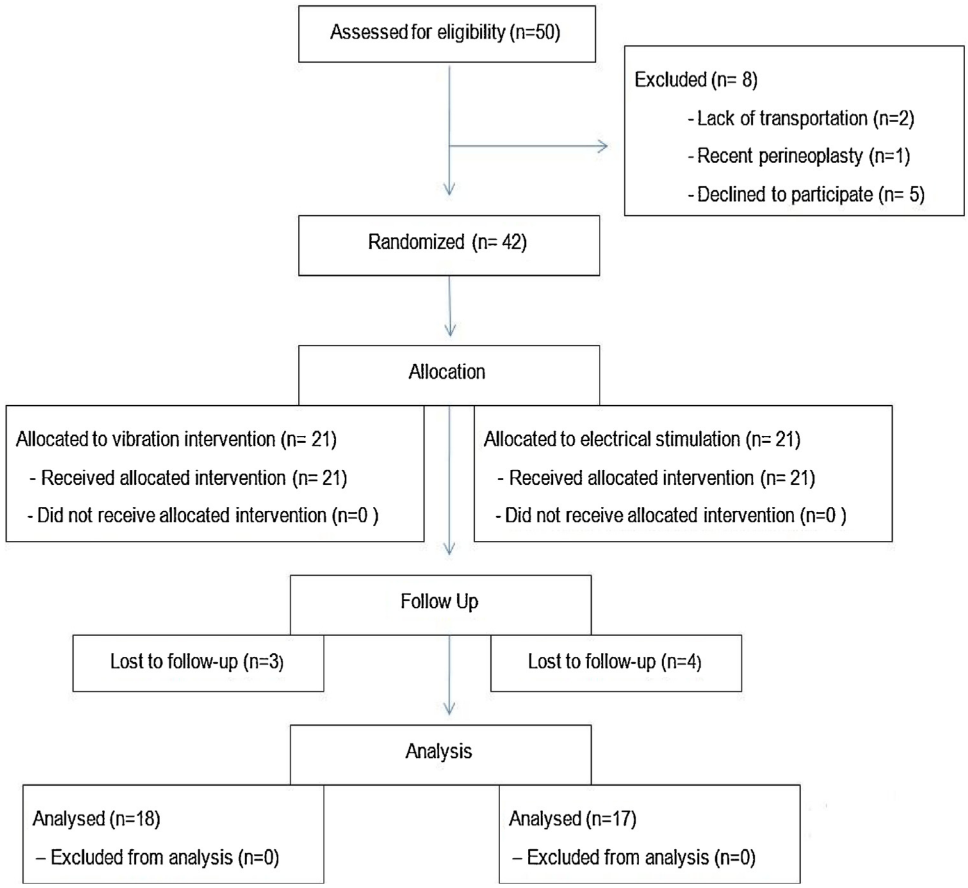

Fig. 3. Flow chart selection of subjects randomized in electrical (EE) and vibratory (EV) stimulation groups.

Table 1
Characteristics of the sample.

Variables	Total ($N = 42$)	Groups		p-value*
		IVVS ($n = 21$)	IVES ($n = 21$)	
Age (years) – mean ± MSE	58.00 ± 1.77	58.57 ± 2.87	57.43 ± 2.13	0.751
BMI (kg/cm^2) – mean ± MSE	30.11 ± 0.88	29.56 ± 0.91	30.66 ± 1.51	0.538
Parity (number) – md[CI95%]	3.00[2.35–3.65]	3.00[1.72–3.71]	3.00[2.40–4.17]	0.319
Births (number) – md[CI95%]	3.00[2.35–3.65]	3.00[1.72–3.71]	3.00[2.40–4.17]	0.949
Episiotomy (number) – md[CI95%]	1.00[0.85–1.87]	1.00[0.44–2.04]	1.00[0.78–2.18]	0.529
C-section (number) – md[CI95%]	0.00[0.46–1.20]	0.47[0.13–1.02]	1.00[0.49–1.70]	0.147
Urinary incontinence – *n*(*n*%) SUI UUI MUI	8(19.0) 4(9.5) 20(71.5)	3(14.3) 1(4.8) 17(81.0)	5(23.8) 3(14.3) 13(61.9)	0.384
Pelvic organ prolapse – *n*(*n*%)	22(52.4)	10(47.6)	12(57.1)	0.758
Gynecological Surgeries – *n*(*n*%) Yes No	22(52.4) 20(47.6)	11(52.4) 10(47.6)	11(52.4) 10(47.6)	1.000

Caption. IVVS: intravaginal vibratory stimulation; IVES: intravaginal electric stimulation; n: absolute frequency; n%: relative frequency; md: median; CI95%: confidence interval of 95%; MSE: mean standard error; BMI: body mass index; SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence; p: statistical significance. *Pre-intervention intergroup comparisons, measured by Student's t-tests for independent samples, Mann-Whitney or Chi-square, when applicable. Statistical significance was $p \leq 0.05$ for all analyses.

treatment for patients who cannot identify or contract their PFMs, strengthening these muscles and significantly assisting management of pelvic floor dysfunction [20,21].

Recently, some studies have focused on vibratory stimulation instead. Some research using whole-body vibration has reported improvement of PFM activation in individuals with weak muscles [22,23] and in healthy young women [24], as well as improvement in PFM strength and quality of life in women with stress urinary incontinence [25].

As electric stimulation, vibratory stimulation could be applied intravaginally as well, but few studies on this method have been published. According to a systematic review, studies suggest that vibration could have a positive impact on PFM strength, urinary incontinence, and sexual function. However, the small number of studies and the heterogeneity of protocols, durations of intervention, and ways of evaluating variables of interest preclude any definitive conclusion about the efficacy of this technique [14].

In general, one of the neuromuscular components stimulated by mechanical vibration is the tonic vibration reflex (TVR). The TVR is a result of rapid stretching of a musculotendinous unit that will alter the length of the neuromuscular spindle and activate the alpha motor neurons, causing a reflex response to the distension that is the muscular contraction [24]. Specifically regarding the pelvic floor, it has been hypothesized that direct vibration produces

Table 2
Comparison between groups pre- and post-treatment.

Variable	Total pre-intervention (N = 42)	Pre-intervention		*p value	Total post-intervention (N = 35)	Post-intervention		p-value*
		IVVS (n = 21)	IVES (n = 21)			IVVS (n = 18)	IVES (n = 17)	
Performance – md[CI95%]	0.00[0.16–0.46]	0.00[0.11–0.55]	0.00[0.08–0.50]	0.742	1.00[1.18–2.08]	2.00[1.43–2.79]	1.00[0.58–1.66]	0.026
Endurance – md[CI95%]	0.00[0.45–1.55]	0.00[0.21–1.88]	0.00[0.17–1.73]	0.854	3.00[2.11–3.89]	4.00[2.22–5.11]	3.00[1.25–3.33]	0.165
Repetitions – md[CI95%]	0.00[0.67–2.09]	0.00[0.44–2.42]	0.00[0.23–2.43]	0.782	3.00[2.27–4.24]	3.50[2.21–5.24]	3.00[1.40–4.13]	0.398
Rapid – md[CI95%]	0.00[0.97–2.89]	0.00[0.54–3.17]	0.00[0.48–3.52]	0.926	5.00[3.65–5.84]	5.50[3.49–6.73]	5.00[2.73–5.98]	0.423
Degree of UI (ICIQ-SF) – *n*(*n*%) No UI Light Mild Severe	0(0.0) 0(0.00) 17 (40.5) 25(59.5)	0(0.0) 0(0.00) 5 (23.8) 16(76.2)	0(0.0) 0(0.00) 12 (57.1) 9(42.9)	0.019	3(8.6) 4(11.4) 17 (48.6) 11(31.4)	1(5.6) 0(0.0) 11 (61.1) 6(33.3)	2(11.8) 4(23.5) 6 (35.3) 5(29.4)	0.118

Caption. IVVS: intravaginal vibratory stimulation; IVES: intravaginal electric stimulation; n: absolute frequency; n%: relative frequency; md: median; CI95%: confidence interval of 95%; *Pre-intervention intergroup comparisons, measured by Student's t-tests for independent samples and Mann-Whitney when applicable. ICIQ-SF: International Consultation on Incontinence Questionnaire – Short form. Statistical significance was $p \leq 0.05$ for all analyses.

Table 3
Group, time and interaction pairwise comparisons using Generalized estimating Equations.

Variable	Pre-intervention		Post-intervention		GEE *p*-value*		
	IVVS (n = 21)	IVES (n = 21)	IVVS (n = 18)	IVES (n = 17)	Group	Time	Interaction
Performance (PFM strength by Modified Oxford)	0.33 ± 0.10^{aA}	0.29 ± 0.10^{aA}	2.11 ± 0.3^{aB}	1.12 ± 0.25^{bC}	0.027	≤0.0001	0.008
Endurance (seconds)	1.05 ± 0.39^{aA}	0.95 ± 0.37^{aA}	3.63 ± 0.65^{aB}	2.27 ± 0.47^{aB}	0.191	≤0.0001	0.113
Repetitions	1.43 ± 0.47^{aA}	1.33 ± 0.51^{aA}	3.74 ± 0.69^{aB}	2.67 ± 0.60^{aB}	0.396	≤0.0001	0.253
Fast contractions	1.86 ± 0.62^{aA}	2.00 ± 0.71^{aA}	5.05 ± 0.73^{aB}	4.41 ± 0.74^{aB}	0.765	≤0.0001	0.456

Group, Time and Interactions (group x time) effects were observed by variables and measurements (moments) pairwise comparisons using Generalized Estimating Equations (GEE). Data expressed as mean ± standard error of mean. Legend: IVVS: intravaginal vibratory stimulation; IVES: intravaginal electric stimulation; n: absolute frequency. ^{Ab} Different lowercase letters indicate difference proportion among the studied groups. ^{AB} Different uppercase letters show the evolution of a certain group over time. Significance set as $p \leq 0.10$ for all analysis.

afferent nerve impulses that, via the pudendal nerve, generate a sacral somatic response (S2-S4) that causes contraction of the PFMs [15]. By combining these two conditions, directly stimulating the PFMs could yield better results than whole-body vibration, especially in women who are unable to efficiently contract these muscles.

Despite differences in protocol, the results of the present study corroborate those of Ong et al. (2015) [25] regarding the improvement of PFM contraction strength with IVVS. After 16 weeks of stimulation applied daily by the woman herself at home and with a monthly meeting with a physiotherapist, these authors observed that PFM contraction improved significantly in the group that used vibration in comparison to the group that did isolated PFM training. However, the degree of contraction before and after treatment was not reported.

Sønsken et al. (2007) [15] also used a six-session protocol performed once weekly, but only evaluated the effect of vibration on female stress urinary incontinence. They observed a significant reduction in number of urinary loss episodes and number of pads, but did not assess the effect of vibration on PFM function.

In the present study, after 6 weeks of application, IVVS was able to modify the degree of PFM contraction, which improved from grade 0 to grade 2 ($p = 0.026$). Extrapolating these data to clinical practice, these participants would already be able to make progress in physical therapy sessions and start active PFM training, considered to be the first line of intervention to treat pelvic floor dysfunctions such as urinary incontinence and POPs [9]. Thus, IVVS may play a fundamental role in identification and improvement of PFM contraction and may become an important tool for initial treatment of abnormalities in female pelvic floor function.

Although this study suggests that IVVS improved strength of PFM contraction as compared with IVES, certain limitations should be considered when evaluating these results. First, this is an initial study; its results should be considered preliminary and in need of replication. Some findings probably failed to reach statistical significance because the sample size was relative small for some comparisons (type II error). Additionally, the possibility exists that one or more significant findings may be a reflection of type I error. Second, the sample was rather homogeneous. Third, the study used reported data from PFM assessments after 6 weeks of the IVVS and IVES interventions; investigation of longer treatment periods or more repetitions are needed. Some results might also be attributable to the particular methods used herein (e.g., type of device, probes, electrodes). Bidigital vaginal palpation was used for evaluation, and this method is subject to variation according to the examiner's perception. Finally, it is importante to say that vibratory stimulation is a recent technique with few studies about it, so our settings are not and can not be considered standards.

Despite these limitations, vibration is an easy-to-administer PFM stimulation method and warrants further investigations for possible mitigation of the aforementioned limitations, optimizing intravaginal vibratory stimulation for outcomes of interest in PFM dysfunction. Vibration is an accessible, easier and cheaper material to access than other interventions such as electrostimulation for example, and can be a good alternative for public services or home exercises for pelvic floor muscles.

Given its effects on the neuromuscular system, IVVS is a promising new option for conservative physical therapy of female pelvic floor dysfunctions. However, few studies have assessed the effect of IVVS on the PFM, and data to explain the physiological effects of vibration on these muscles are lacking. Further randomized clinical trials with homogeneous protocols, longer intervention time, and larger samples are needed to assess the effect of IVVS on the pelvic floor muscles more consistently.

Conclusion

IVVS was effective and significantly superior to IVES in improving PFM strength. Considering that the participants were unable to voluntarily contract their PFMs at baseline, an improvement in muscle strength also entails an improvement in awareness of their bodies overall and of the pelvic area in particular, a fundamental condition for achieving better results in conservative treatment of pelvic floor dysfunction. IVVS seems to be easier to use, less expensive and less uncomfortable than IVES, but there are no qualitative data to assert this safely as well. As practical, IVVS may be done at home. So, more studies are needed to consolidate the use of IVVS in clinical practice for women with altered PFM functionality.

Conflicts of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Acknowledgments

This work was supported by grants from the Fundo de Incentivo à Pesquisa e Eventos (FIPE) — Hospital de Clínicas de Porto Alegre (HCPA, Porto Alegre/RS, Brasil), and the National Coordination for Improvement of Higher Education Personnel (CAPES, Brasil). We express our deepest gratitude to the participants for their time and patience throughout this study.

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