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ORIGINAL ARTICLE

Effects of perineal preparation techniques on tissue extensibility and muscle strength: a pilot study

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Abstract

Introduction and hypothesis Perineal preparation techniques for childbirth have been used with the aim of reducing perineal tears during the expulsive phase of labor. However, no studies were found to investigate the effects of instrument-assisted stretching versus perineal massage on pelvic floor muscle (PFM) variables. Therefore, the aim of this study was to evaluate the effect of instrument-assisted stretching versus perineal massage on the extensibility and strength of the PFMs.

Methods Primiparous women were randomized to the instrument-assisted stretching (IStr) group ($n = 13$) and perineal massage (PnM) group ($n = 14$). The groups participated in eight sessions, twice weekly, beginning at the 34th gestational week. The IStr group underwent the intervention for 15 min using EPI-NO®. The PnM group underwent a perineal massage protocol for 10 min. Each woman was evaluated by a blinded physiotherapist before, after four and after eight sessions for primary (PFM extensibility using the EPI-NO® circumference) and secondary (PFM strength using a manometer) outcomes. Covariate analysis (ANCOVA) was used to compare the groups using the baseline values as a covariate.

Results Both groups showed an increase in PFM extensibility compared with the evaluations before and after four and eight sessions (PnM group from 17.6 ± 1.8 to 20.2 ± 1.9 cm; IStr group from 19.9 ± 1.6 to 22.9 ± 1.6 cm; $p < 0.001$). There was no difference between groups. Regarding muscle strength, no statistical differences were observed between evaluations or between groups.

Conclusions Instrument-assisted stretching and perineal massage increase extensibility and do not alter the strength of PFMs in pregnant women.

Keywords Physical therapy specialty · Pelvic floor · Perineum · Muscle-stretching exercises · Natural childbirth

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Introduction

Natural birth has been proven to be very beneficial for women and their newborn babies. However, over the past decades, there has been a significant increase in the use of interventions during labor and birth. The medicalization of birth tends to decrease women's self-confidence in their ability to give birth and negatively influences the birth experience [1]. Therefore, the number of women seeking physical and psychological preparation and support during pregnancy to experience a humanized, respectful and non-interventional birth has increased as well. Consequently, perineal preparation techniques for birth have been used to stretch the tisssue and avoid perineal tears.

Skeletal muscle stretching can be defined as the application of an external pressure to muscle and connective tissue in the

opposite direction to the shortening, aiming to increase muscle extensibility. Regarding pelvic floor muscles (PFMs), the stretching is performed via widening of the hiatus in the axial plane [2], similarly to what happens during perineal massage and instrument-assisted stretching.

Perineal massage is a simple and easy-to-perform technique that was developed to relax and lengthen the pelvic floor musculature [3]. In a systematic review, Beckman and Stock verified that performing massage is associated with a decrease in the incidence of perineal tears requiring suture and also the probability of an episiotomy. In addition, women who had already had other vaginal deliveries reported a reduction in postpartum pain [3]. Instrument-assisted stretching is carried out using an inflatable silicon balloon coupled to a pressure display hand pump to gradually stretch the vagina and perineum in late pregnancy [4]. It was developed to improve the extensibility of the perineal muscles and, consequently, reduce the incidence of tears. Some studies have demonstrated benefits to using this equipment when outcome variables, such as the incidence of perineal tears, episiotomy and analgesia, are analyzed [5–8]. However, Brito et al. [9], in a systematic review, reported the lack of sufficient evidence regarding the benefits of instrument-assisted stretching in promoting perineal integrity.

Zanetti et al. demonstrated that a circumference > 20.8 cm achieved by a balloon introduced into the vaginal introitus was a predictive factor for perineal integrity in parturients [10]. Therefore, the PFM extensibility seems to be important for preventing perineal tears. Moreover, some studies reported a decrease in the strength of the PFM during pregnancy and associated this reduction with the development of pelvic floor dysfunctions [11–13]. As a result, practitioners are concerned about the likelihood that muscle stretching may cause a decrease in muscle strength.

However, no studies evaluating the effects of both interventions on the extensibility and strength of PFM have been found so far. Therefore, the aim of this study was to evaluate the effects of perineal massage (PnM) versus instrument-assisted stretching (IStr) on PFM extensibility and strength.

Materials and methods

Study design

A pilot study was conducted with parallel randomization (1:1), concealed allocation and assessor blinding. The study was approved by the Ethics and Research Committee of the Federal University of Uberlândia (no. 1.824.321) and registered in the Brazilian Registry of Clinical Trials (no. RBR9XQ52). All study participants were informed about the procedures and signed the informed consent form.

Inclusion and exclusion criteria

The inclusion criteria were: women aged 18–40 years, primigravidae or previous pregnancies ended before the 21st week, gestational age of 33 weeks and who knew how to contract the PFM. Only women with a grade > 1 on the modified Oxford grading scale assessed by vaginal palpation were included [14]. The volunteers who missed two consecutive interventions, who had urinary tract infections during the study and whose the pregnancy ended before the last evaluation were excluded.

The pregnant women who met the established criteria were allocated into two groups: the PnM group ($n = 14$) and IStr group ($n = 13$). The randomization procedure was conducted using computer-generated random numbers. A researcher not involved in data collection or analysis developed a randomization schedule and produced consecutively numbered, sealed, opaque envelopes containing each participant's allocation. Immediately after collecting baseline data, the examiner opened the allocation envelope, which contained a paper on which the name of the group was written. Therefore, all participants were allocated to one of the two groups.

Assessments

The pregnant women were evaluated at three time points: before the intervention, after four sessions and after eight sessions. A blind examiner with experience in urogynecology performed all evaluations. During the three assessment sessions, the primary (PFM extensibility) and secondary outcomes (PFM strength) were evaluated. The examinations were conducted with the pregnant woman in the dorsal decubitus position, with the inferior limbs semiflexed and lower limbs and feet supported on the examination table. After delivery, contact was made with the women to collect information about the method of delivery and presence of laceration.

The primary examiner performed an initial assessment of test-retest reproducibility. Ten nulliparous women were tested on two different occasions, separated by a week, to determine the intraclass correlation coefficient (ICC) of all variables.

In the initial evaluation, all participants underwent a standard interview with questions about their urogynecological and obstetric history and their life habits. Next, the examiner performed vaginal palpation and requested the patient to contract the PFM to determine if the volunteer could perform a satisfactory activation of the musculature (ICC = 0.96).

Pelvic floor muscle strength was assessed by a vaginal manometer by Peritron™ (Cardio Design Pty. Ltd., Oakleigh, Victoria, Australia). The vaginal probe was protected with a non-lubricated condom, lubricated with a water-based gel, and was placed with its center 3.5 cm in the vaginal introitus. After accommodation, the device was calibrated (inflated to

100 cmH_2O). Three maximal contractions of the PFM were requested, with duration of 5 s each, with a minute interval in between. The contraction was considered valid when the examiner observed a contraction of the PFM without the use of accessory musculature. The mean values of the three contractions were used for the analysis (ICC = 0.98).

The PFM extensibility was evaluated using EPI-NO® Delphine (Starnerg Medical, Tecsana, Munich, Germany). The equipment was protected with a non-lubricated condom, lubricated with a water-based gel, and was inserted into the woman's vaginal introitus so that 2 cm of the balloon base was visible to the examiner. Before the EPI-NO® was inflated, the examiner explained to the expectant mother that she should keep the PFMs as relaxed as possible throughout the procedure and inform the examiner when stretching became uncomfortable. Thus, the examiner gradually inflated the equipment up until the maximum that could be tolerated by the participant. Once the volunteer reported discomfort, a 1-min interval was provided, and the same process was repeated two more times. After the third pause, the participant was instructed to expel the EPI-NO® during exhalation. With the equipment still inflated, the condom was removed, and, using a tape measure metric, the examiner measured the balloon at its largest circumference (ICC = 0.96).

During the final evaluation, the volunteers were asked to provide the date of delivery by text message, and they were informed that they would be contacted by telephone after 2 weeks. In addition, the volunteer was asked to question the doctor who attended the delivery about laceration and take notes. Thus, the information regarding lacerations and mode of birth was collected by telephone contact with the volunteers 2 weeks after delivery. During the telephone contact, the women were asked about the mode of birth and whether or not there was perineal laceration; in case of a positive answer, they were asked whether suturing was performed or not.

Intervention

A trained physiotherapist with experience in gynecology who was blind to the evaluations performed both interventions. Each group performed two sessions per week for 4 weeks, completing eight sessions. In both groups, the interventions were performed with the participants in the dorsal decubitus position, with the inferior limbs semi-flexed and the lower limbs and feet supported on the examination table.

The PnM group was submitted to perineal massage using coconut oil. The physiotherapist initially performed circular movements in the external area of the participant's vulva, around the vagina and in the central tendon of the perineum, respecting the clockwise direction of the skin and connective tissue. Subsequently, with the index and middle fingers inserted approximately 4 cm in the vaginal introit, internal massage was performed on the lateral walls of the vagina. Movements were performed following a semicircular pattern, so that it started in the lateral wall of the vagina and ended toward the anus. The physiotherapist performed these movements four times on each side, using pressure that was tolerable to the pregnant woman, for approximately 30 s. Still with her fingers on the vaginal introitus of the participant, the physiotherapist maintained pressure on each lateral wall of the vagina for 2 min and then downwards to the center of the tendon. At the end, the lower portion of the vagina was massaged, simulating the letter "U." The entire procedure lasted approximately 10 min [3].

The IStr group performed the intervention using the Delphine® EPI-NO for 15 min. Time was defined based on the protocols used in previously published articles [5–8]. The EPI-NO® was protected with a non-lubricated condom, lubricated with a water-based gel, and was inserted into the participant's vaginal introitus so that 2 cm of the balloon was visible. Therefore, the physiotherapist inflated the equipment slowly and gradually according to how the pregnant woman tolerated the stretching. At the end, the participant was instructed to keep the pelvic floor musculature relaxed and to expel EPI-NO® during exhalation.

Data analyses

An a priori power analysis was performed using G*Power 3.0 software to estimate the number of participants needed to obtain a statistical power of 0.80 at an alpha level of 0.05. Based on a pilot sample, we sought to power the study to identify an anticipated difference between the groups of 5 cm for the primary outcome. The anticipated SD from the pilot data was 2.7 cm. Using a Student's bilateral t-test, the minimum sample size required was nine participants per group.

Statistical analyses were performed using the SISVAR software. The normality of the data was tested by the Shapiro-Wilk test. To compare the quantitative demographic data of the volunteers of the PnM and IStr groups, the t-test was used. The chi-square test was used to compare the mode of birth and laceration data using a Monte Carlo simulation with 2000 re-samplings. In the laceration variable, the number of volunteers who performed vaginal delivery in each group was considered the denominator.

To compare the groups with respect to the extensibility and strength variables in the three different evaluations, analysis of variance (ANCOVA) was carried out using "split-plot" overtime, in which the interaction between groups and times was also tested (Tukey test: 5%). Covariance correction was performed considering the pre-intervention measure as covariate. Adjustment was made by a linear model, assuming that the variation of the contraction pressure and extensibility of the treatments can be quantified by the same coefficient: Zij = Yij - b. (Xij - ..X), where Yij = the value of the variable at moments 2 or 3, Xij = the

value of the variable at time zero (baseline), b = the residual regression coefficient of Yij, as a function of Xij, estimated according to Steel and Torrie's protocol (1980) [15]. Also, ..X = the mean baseline variable in both groups.

Results

Thirty-seven volunteers were assessed, who were primigravidae or had previous pregnancies ended before the 21st week, aged between 23 and 37 years and gestational age of 33 weeks. Ten pregnant women were excluded, five because they were unavailable for the visits, four because they were not able to contract the PFM and one because of a medical contraindication.

The 27 included women were randomly divided between the PnM and IStr groups. However, four woman in the PnM group and three in the IStr group discontinued the interventions because of the lack of time or because the birth occurred before the last evaluation. Therefore, 20 pregnant women completed the interventions and were included in the analysis (Fig. 1). No statistical differences were observed between groups regarding age, body mass index, educational level, marital status, activity level, mode of birth and lacerations (Table 1).

An increase in PFM extensibility was observed in both groups. However, the analysis of time and group interaction did not show statistically significant differences between groups for this variable. In both groups, an increase in the PFM extensibility was observed at four and eight intervention sessions ($p < 0.001$). Regarding the strength variable, no statistically significant differences were observed over time or between groups (Table 2).

Considering the cutoff value proposed by Zanetti et al. [10] for perineal integrity of 20.8 cm, 4/10 (40%) of the women in the PnM group and 9/10 (90%) of the women in the IStr group reached values higher than the cutoff value after eight sessions. Among the volunteers who had vaginal deliveries, 40% of the women in the IStr group had intact perinea, while none of the women in the PnM group presented intact perinea after delivery. No women in either group presented third or fourth degree lacerations.

Discussion

The results of the present study demonstrate that both PnM and IStr are equally able to increase perineal extensibility without affecting the PFM strength. In clinical practice, the use of both interventions aims to increase the extensibility of the area to allow passage of the fetus through the vaginal canal minimizing perineal tears. Although some studies demonstrated a reduction of perineal tears following the use of PnM and IStr [5–8], no studies were found to verify the effects of these techniques on the extensibility and strength of the PFM.

The present study demonstrates that the effects of stretching techniques found in other skeletal muscles are also observed in PFM. It is known that the lengthening of skeletal muscles modifies the viscoelastic properties of the muscle-tendon unit. This process decreases the tension peak of the musculature and, consequently, the chances of injury [16].

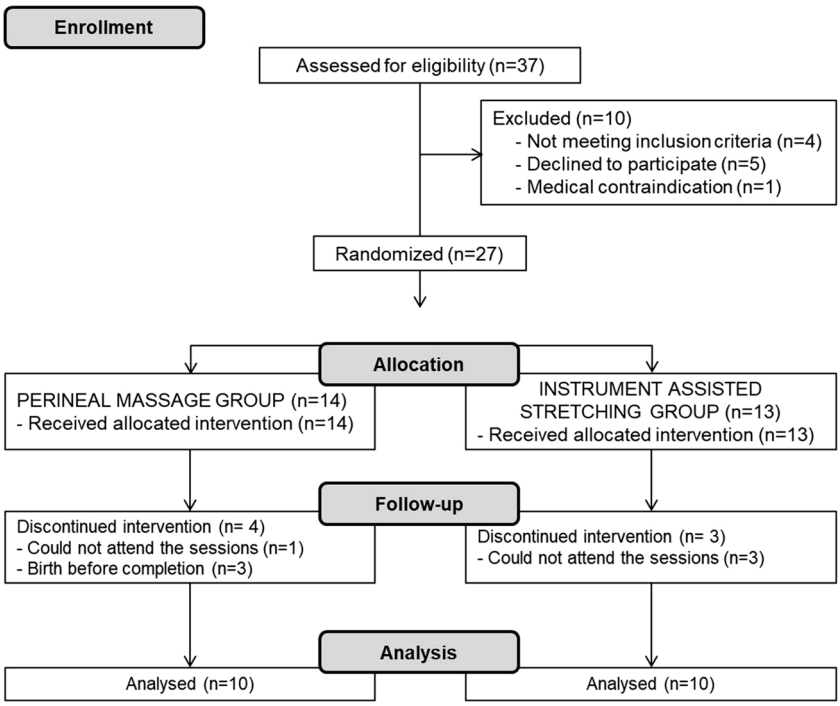

Fig. 1 Study flowchart

Table 1 Clinical and demographic characteristics of the study participants

Variables		PnM group ($n = 10$)	IStr group ($n = 10$)	P value
Age (years)		29.8 ± 4.0	29.2 ± 4.2	0.63
Body mass index (kg/m^2)		26.2 ± 3.5	26.5 ± 4.0	0.54
Education level, *n*(%)	High school degree	1 (10)	3 (30)	0.22
	Bachelor degree	3 (30)	4 (40)	
	Postgraduate degree	6 (60)	3 (30)	
Marital status, *n*(%)	Yes	10 (100)	10 (100)	1.0
Activity level (%)	Active	10 (100)	7 (70)	0.18
	Inactive	0	3 (30)	
Mode of birth, *n* (%)	Vaginal birth	7 (70)	5 (50)	0.63
	Cesarean	3 (30)	5 (50)	
Laceration, *n*/*N* (%)	No laceration	0	2/5(40)	0.23
	I	6/7(71.4)	2/5(40)	
	II	1/7(28.6)	1/5(20)	
	III	0	0	
	IV	0	0	

PnM perineal massage, *IStr* instrument-assisted stretching

McHugh and Cosgrave, after reviewing 38 articles, established a theory that can possibly justify the reduction of muscle injuries after stretching protocols [16]. According to their theory, lengthening makes the muscle-tendon unit more compliant, which allows greater production of strength by the muscles and generates greater resistance to stretching. It is possible that the greater resistance to muscle stretching achieved by PnM and IStr is the reason for the reduction of perineal tears during vaginal delivery, as demonstrated by previous studies [5–8].

The examination of the extensibility of the PFM has some limitations. Unlike the other muscle groups, which usually have their lengthening measured by the range of motion of a joint, the PFM does not involve the movement of specific joints, which makes its measurement extremely difficult [2]. Therefore, the authors of this study chose to assess extensibility using EPI-NO®, since good intra-examiner reliability was shown in an initial test with the assessor of the present study. In addition, other studies have also used the same equipment to measure the tissue extensibility of the perineum [10, 17, 18].

Zanetti et al. [10], Nakamura et al. [17] and Petricelli et al. [18] used EPI-NO® to assess the PFM extensibility of pregnant women. In the first two studies, the evaluation was performed with parturients and, in the latter, with women at between 35 and 40 gestational weeks. In all three studies, the equipment was protected with a non-lubricated condom, lubricated with a water-based gel, and was inserted and inflated to the participant's tolerance level and then slowly removed.

Differently from the above-mentioned studies, the authors of the present study opted to inflate the equipment to the maximum tolerance of the participant, providing three 1-min pauses. This procedure ensured that the extensibility of the tissue was not underestimated and achieved similar physiological effects of labour since the stretching of the vaginal canal usually occurs gradually during each contraction in the

Table 2 Values for the assessments at baseline, after 4 sessions and after 8 sessions regarding perineal extensibility and strength

	Baseline	After 4 sessions	After 8 sessions	Intragroup difference at the end of the intervention program (95%IC)	Intergroup difference at the end of the intervention program (95% IC)
Perineal extensibility (cm)					
PnM group	17.6 ± 1.8	18.9 ± 1.4	20.2 ± 1.9[a]	2.5 (2.0, 3.0)	0.4 (−1.6, 0.8)
IStr group	19.9 ± 1.6	21.0 ± 1.5	22.9 ± 1.6[a]	2.9 (1.6, 4.1)	
Strength (cmH_2O)					
Mean					
PnM group	33.1 ± 9.9	34.0 ± 7.8	37.5 ± 9.4	4.4 (−0.3, 9.1)	−2.8 (−2.8, 8.2)
IStr group	22.5 ± 8.9	25.5 ± 12.8	24.1 ± 8.4	1.6 (−2.3, 5.4)	

PnM perineal massage, *IStr* instrument-assisted stretching

[a] Statistically significant difference compared with the assessment after four sessions (ANCOVA test)

expulsive period [19]. Another adaptation in the evaluation performed in the present study was the method to remove the EPI-NO®. In other studies, the instrument was slowly removed from the vaginal canal at the end of the session. In the current study, the volunteers were guided through the performance of EPI-NO® expulsion, aiming at training for the expulsive phase and having a lower chance of laceration because this method respected the tolerance level of the pregnant woman. All participants were instructed to keep the PFM relaxed and to expel the equipment during expiration, slowly and gradually.

In the present study, there was no change in muscle strength estimated by PFM contraction pressure after the intervention using PnM or IStr. It is known that during pregnancy, alterations such as hormonal changes, increased uterine volume and body weight may alter the PFM function [20]. Palmezoni et al. [13] found a reduction in the PFM strength in primigravidae in the third gestational trimester.

The authors of this study have not found studies that evaluated the effect of stretching on the strength of PFM. However, other studies have evaluated the effect of stretching on the strength of lower limb muscles. Rosário et al., for instance, evaluated the effect of global postural re-education and static stretching on the strength of the lower limbs [21]. The groups underwent two sessions per week, each lasting 30 min. Both groups had increased strength of the lower limbs after the intervention. Conversely, a study by Endilich et al. concluded that the use of a protocol of stretching before activities involving strength training negatively affects the strength capacity of the lower limbs [22]. In the current study, despite the increase in perineal extensibility, there was no change in muscle strength. Thus, it is possible that, unlike in the other muscles, the increase in PFM extensibility is not sufficient to modify the strength of these muscles.

In the present study, a high percentage of cesareans was observed, which is in agreement with the Brazilian obstetric reality. Currently, 40% of deliveries that take place in the public sector in Brazil end up being surgical procedures. Surprisingly, the rates rise to 84.6% in the private sector [23]. In this study, there were no differences between the groups regarding the mode of birth or perineal tears. This study has the limitation that it was not possible for the delivery of the volunteers to be monitored in the same hospital with the same medical team. Also, it is known that there are many factors that interfere with birth variables, such as maternal age, fetal weight, parity, and training and experience of the care team [24–28].

Despite the absence of differences in obstetrical perineal injuries, considering the cutoff value proposed by Zanetti et al., it was observed that a higher number of women in the IStr group reached the cutoff value than in the PnM group. In addition, only intact perinea were observed in the IStr group. Despite the lack of statistical significance, postpartum perineal outcomes appear to be more favorable with IStr. Based on these results, further studies should be performed using IStr in which the women's labors and deliveries are accompanied by a medical team blinded to the intervention. In addition, it is important for the medical team to follow the current scientific evidence during delivery and allow the woman to have freedom of position and access to non-pharmacological analgesia and not to perform an episiotomy in order to reach a definitive conclusion.

Unlike the other studies that evaluated the effects of IStr, the present study carried out fully supervised interventions. Studies that used IStr to prepare the perineum for childbirth only guided pregnant women in how to use the equipment in their own homes, without the supervision of a professional, which limited control over the positioning of the probe in the vaginal canal, time and frequency of use of the equipment [5–8]. Physiotherapist supervision is believed to be necessary to maintain the correct positioning of the ballon so that it lengthens the muscles properly based on specific anatomic knowledge. In addition, the clinician can observe if the volunteer has relaxed the muscles of the pelvic floor and can expel the equipment during expiration, without performing the Valsalva maneuver, which can be harmful during the expulsive phase of labor.

This study was the first to demonstrate that perineal preparation techniques can alter muscle extensibility. Therefore, these results show professionals working with perineal preparation techniques that these methods have effects on the tissues of pregnant women. According to studies, there is no doubt that the levator hiatus, in particular the puborectalis muscle, has to distend markedly to allow vaginal childbirth [29]. The degree of muscle distension at vaginal delivery may lead to PFM trauma, which can be macroscopic or microscopic secondary to direct disruption, or neurological and/or ischemic insult [30–32]. The results of this study do not allow us to conclude that the more extensible muscle can suffer fewer lesions and thus result in a fewer PFM dysfunctions in the future. The present study opens perspectives for new investigations on this subject.

Conclusion

Based on the results of this study, it can be concluded that both perineal massage and physiotherapeutic intervention using EPI-NO® increase extensibility without altering the strength of the PFM after eight interventional sessions.

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Compliance with ethical standards

Conflicts of interest None.

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