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Perineal massage and warm compresses – Randomised controlled trial for reduce perineal trauma during labor

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ABSTRACT

Objective: The aim of this study is to evaluate the effect of perineal massage and warm compresses technique on the perineum integrity during second stage of labor.
Design and setting: A single-center, prospective, randomized controlled trial was conducted between March 1st, 2019, and December 31st, 2020, at Hospital of Braga. Participants: Women with 18 years or older, between 37 weeks and 41 weeks pregnant, in whom a vaginal birth of a fetus in the cephalic presentation was planned were recruited. Eight hundred forty-eight women were randomly assigned (Perineal massage and warm compresses group, $n = 424$ and control group, $n = 424$), and 800 women, both perineal massage and warm compresses group ($n = 400$) and control group ($n = 400$) were included in the strict per protocol analysis. Intervention: In the perineal massage and warm compresses group, women received perineal massage and warm compresses and in the control group, women received hands-on technique.
Results: The incidence of intact perineum was significantly higher in the perineal massage and warm compresses group [perineal massage and warm compresses group: 47% vs control group: 26.3%; OR 2.53, 95% CI 1.86–3.45, $p<0.001$], whereas second-degree tears and episiotomy rate were significantly lower in this group [perineal massage and warm compresses group: 7.2% vs control group: 12.3%; OR 1.96, 95% CI 1.17–3.29, $p = 0.010$ and perineal massage and warm compresses group: 9.5% vs control group: 28.5%; OR 3.478, 95% CI 2.236–5.409, $p<0.001$, respectively]. Also, obstetric anal sphincter injury with and without episiotomy and second-degree tears with episiotomy were significantly lower in the perineal massage and warm compresses group [perineal massage and warm compresses group: 0.5% vs control group: 2.3%; OR 5.404, 95% CI 1.077–27.126, $p = 0.040$ and perineal massage and warm compresses group: 0.3% vs control group: 1.8%; OR 9.253, 95% CI 1.083–79.015, $p = 0.042$, respectively].
Conclusions: The perineal massage and warm compresses technique increased the incidence of intact perineum and reduced the incidence of second-degree tear, episiotomy and obstetric anal sphincter injury. Implications for practice: Perineal massage and warm compresses technique is feasible, inexpensive and reproductible. Therefore, this technique should be taught and trained to midwives students and midwives team. Thus, women should have this information and have the option to decide whether they want to receive the perineal massage and warm compresses technique in the second stage of labor.

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Problem: Perineal trauma are associated to short and long-morbidity. Women with episiotomy, second-degree tear and OASIS reported worse birth experience. Specifically women with OASIS presented a less positive attitude toward future pregnancies.
What is Already Known: The perineal massage and warm compresses technique decreased the need of perineal suturing and major perineal injury compared to hands-off. However, when compared to perineal massage alone, did not decrease the need of requiring suturing for perineal trauma, OASIS and episiotomy.
What this Paper Adds: The perineal massage and warm compresses technique increased the intact perineum and reduced the second-degree tear, episiotomy and OASIS.

Introduction

Approximately 85% of vaginal births are associated with some degree of perineal trauma, which can cause a significant morbidity in women (Begley et al., 2019). Perineal tears may cause short-term complications such as pain, infection and severe bleeding (Jiang et al., 2017) but when the anal sphincter is included, these injuries can be associated with long-morbidity including incontinence urinary, anal, pelvic pain and sexual dysfunction (Pierce-Williams et al., 2019). Generally, the degree of perineal pain is directly related to the degree of the perineal trauma. In the study developed by Manresa et al. (2020) the odds of pain at 10 days and dyspareunia at 6 months postpartum were four- and five-fold greater, respectively, in women with second-degree trauma or episiotomy, than if the perineum had remained intact or suffered a first-degree perineal trauma. Also, women with an episiotomy or obstetric anal sphincter injury (OASIS) mentioned a worse birth experience than those with first- and second-degree perineal tears (Molyneux et al., 2021). Specifically women with OASIS presented a less positive attitude toward future pregnancies (Rodaki et al., 2022). Nevertheless, the more recent evidence does not support routine episiotomy, since it is associated with an increased risk of OASIS and no clear difference in perineal infection rates, chronic pain, long-term dyspareunia (at least six months postpartum) and long-term urinary incontinence (at least six months postpartum) when compared with selective episiotomy (Jiang et al., 2017).Otherwise, the selective episiotomy increased the incidence of intact perineum without increased the incidence of anal sphincter tears (Franchi et al., 2020) Hence, the challenge is not only to reduce the incidence of OASIS, but also to reduce the incidence of minor lacerations (first- and second-degree tears) and routine episiotomies.

In addition, several perineal management techniques used during labor have been studied and their effect on episiotomy, minor tears and OASIS have been published. A Cochrane systematic review published in 2017, concluded that the application of warm compresses, and the perineal massage during the second stage of labor, individually, may reduce the occurrence of OASIS but evidence on the benefits of these techniques on intact perineum are unclear (Aasheim et al., 2017). An overview of systematic reviews about this field developed by Zang et al. (2022) concluded that perineal massage and warm compresses, individually, in the second stage of labor could be the better choice for preventing perineal laceration. Two years ago, a study was published comparing the perineal massage and warm compresses technique to hands-off technique (Goh et al., 2021). Last year, another study was published comparing the perineal massage and warm compresses technique to perineal massage alone technique (Hong et al., 2022). Although, the traditional routine management of perineum during the second stage of labor has been hands-on technique (Trochez et al., 2011). Consequently, more research is needed to evaluate if perineal massage and warm compresses technique during the second stage of labor compared to hands-on technique could promote better perineal outcomes to women. The randomised controlled trial is considered the best design to evaluate interventions, as it distributes both measured and unmeasured confounding variables equally between study groups, assuming the sample is of adequate size (Abramson and Abramson, 2011). This randomised controlled trial entitled Perineal Massage and Warm Compresses (PeMWaC) was part of a bigger study and was conducted in a Tertiary Hospital maternity, in which high risk pregnancies and deliveries may be attended. This is the first study to compare the perineal massage and warm compresses during the second stage of labor with hands-on technique. These provide justification for this trial and assisted in the design of a randomised controlled trial for perineal protection intervention.

Aim

The aim of this study is to evaluate the effect of Perineal Massage and Warm Compresses intervention on the perineum integrity when applied in women on second stage of labor.

Methods

Design and trial size

The present study was a single-center, prospective, randomised controlled trial and parallel design. It was conducted between March 1st, 2019 and December 31st, 2020 at one Hospital, which is a tertiary hospital with an obstetric unit with more than 3000 births annually. The calculation of sample size was performed with https://clincalc.com/Stats/SampleSize.aspx. Briefly, the values of desired statistical power (80%), significance level (5%) and effect size (10% difference between groups, considering an intact perineum prevalence rate of 25% in the control group and 35% in the experimental group, according to previous works by Dahlen et al., 2007a and Rodrigues et al., 2019) were inserted in the software as input parameters, concerning a two-tailed Student's *t* test for independent samples. The automated calculation performed by software suggests a minimum sample size of 656 participants, equally distributed by the control (328 participants) and experimental (328 participants) groups. Assuming an estimated exclusion rate of 15%, as suggested by Lavesson et al., 2014, the minimum sample size was increased to 772 participants (= 656/0.85), considering the exclusion effect previously mentioned. The effective sample size of the study was 800 participants, 400 in the control group and 400 in the experimental group. The trial was approved by the Hospital Ethics Committee (reg. no. 2_2019 approved February 2019). It was registered in http://www.ClinicalTrials.gov:NCT05854888. CONSORT recommendations for reporting randomised, controlled, clinical trials involving nonpharmacologic treatment were followed (Boutron et al., 2017).

Inclusion criteria

Eligible participants were women with 18 years or older, between 37 and 41 weeks pregnant, in whom a vaginal birth of a fetus in the cephalic presentation was planned and had to be able to provide informed written consent. Exclusion criteria were multiple pregnancy, meconial amniotic fluid, fetal distress, suspicion of fetal growth restriction and gestational hypertensive disorders.

Recruitment of study participants

Recruitment started March 1st, 2019, and the trial was planned to proceed for 24 months but the necessary sample was reached on 31st December and then the recruitment period lasted less than 24 months. Study participants were women in labor, who anticipated a spontaneous vaginal birth in labor ward. On the labor ward, when the woman was in active labor, the midwife confirmed the eligibility and asked for informed consent to participate in the trial. All participants signed an informed consent form and received a copy wherein the study was described in detail. Women could withdraw from the study at any point without prejudice to their care or their relationship with their health practitioners.

Randomization and information

Block randomization was computer-generated, with blocks size of two, four and six, and used randomly mixed block sizes for the allocation to perineal massage and warm compresses technique or control group. The randomization was made by a third party not otherwise involved in the trial. Identical, opaque, sealed, sequentially numbered envelopes containing the randomization assignment were placed in the central office on the labor ward. The randomization envelope was opened by the midwife when the participant entered the second stage of labor and was destroyed thereafter. Participants were random allocated to one of the two groups, perineal massage and warm compresses on the second stage of labor or control group (hands-on). The allocation was only shown to the midwife and if necessary, the obstetrician.

Data collection and analysis

After the placenta delivery, a blinded midwife not otherwise involved in the birth but trained, assessed the perineum (graded the perineal tears) and registered the primary outcomes. Recorded third- and fourth-degree tears were validated through manual assessment of patient records and were incorporated into the final dataset. Midwives who assess the primary outcomes and the principal investigator were blinded to the randomization. The data about the variables included in the study (Clinical Characteristics and Labor Process) and the secondary outcomes (Apgar at five minutes and admission to neonatal intensive care unit) were registered by the midwife responsible for the birth. Twenty four hours after birth, a questionnaire was sent to the participants to assess their satisfaction with the intervention and whether they would recommend the intervention they were allocated to a friend. Data were recorded on clinical registration forms and inserted in a SPSS database (IBM ®SPSS® software SPSS Inc, Chicago, IL, USA) by the principal investigator.

To ensure that perineal massage and warm compresses technique did not cause markedly more perineal trauma, interim analyses were performed by a data monitor not otherwise involved in the trial after the first year and consecutively thereafter 6 months.

Outcome measurements

Primary outcomes were intact perineum (absence of tissue separation at any site), first-degree tear (involves skin of the perineum and vaginal mucosa); second-degree tear (involves deeper layers of perineal muscle); third-degree tear (involves the anus); fourth-degree tear (involves the anus and rectal mucosa); OASIS (third and fourth-degree tears) and the incidence of episiotomy. The Sultan Classification of Perineal trauma was used, which is internationally validated, allowing data reproducibility (Sultan and Kettle, 2007). Of the thirteen guidelines published between 2013 and 2019, twelve guidelines included the Sultan classification (Roper et al., 2020). Secondary outcomes were newborn Apgar score at five minutes, newborn admission to neonatal intensive care unit, maternal satisfaction with intervention (satisfied or not satisfied) and recommend an intervention allocated to a friend (yes or no).

Statistical analyses

Continuous variables were assessed for normal distribution with the Kolmogorov–Smirnov test. When normally distributed, they were analysed with an independent *t*-test, and when not, with a Mann–Whitney U test. Categorical variables including the primary outcome were analysed with the Pearson chi-squared test or Fisher's exact test as appropriate, and Adjusted Odds Ratio (OR's)s of the perineal subtypes were calculated using logistic regression controlling for baseline characteristics with significant differences between the two groups (presented as a1 OR) and known predisposing factors (presented as a2 OR) including maternal age, parity, BMI, type of previous birth, analgesia, duration of oxytocin augmentation in second stage of labor, length of the active second stage of labor, birth position, height perineum, newborn birthweight, occiput posterior presentation and fundal pressure. The odds ratios were presented with 95% confidence intervals (Cis). A two-sided P value <0.05 was considered as significant. Data analyses was performed using IBM SPSS Statistics 27 version (SPSS Inc).

Pilot study

The principal investigator trained five keypersons to be coordinators and secure uniform use of the perineal massage and warm compresses technique. All midwives were trained for the perineal massage and warm compresses technique by the principal investigator and the coordinators to secure uniform use of the technique. Training sessions included an introductory video of the combined technique and practical training in the deliver ward during the pilot study. The midwives attended the three educational sessions (including theoretical training in anatomy, assessment, and classification of perineal tears and suturing techniques) developed in the Hospital to ensure uniform training. All midwives involved in the trial were trained in the technique and had regular updates sessions in the pilot study stage. The perineal massage and warm compresses had not been used by most of the midwives participating in the trial previously, so education and training occurred in the pilot study stage (during one month before the start of the trial). Perineal massage and warm compresses technique was standardized in a pilot study with 30 women in labor. Clear protocols on the application of perineal massage and warm compresses were available in the delivery ward. There were coordinators to supervise the procedure according to the protocol of the study. Regular checking of the procedure by the principal investigator ensured protocol compliance.

Procedure

A soft perineal massage/warm compresses in the second stage of labor program: In the second stage of labor, the midwife performed a soft perineal massage between 3 o'clock and 9 o'clock positions (U-shaped reciprocating motion) wearing sterile gloves and lubricated their hand with sterile lubricant. The massage lasted 10 min and the degree of downward pressure by the thumb was determined according to mothers' response (Mei-dan et al., 2008). Perineal massage was established on the II Hodge Plan, between maternal contractions and regardless of maternal position (Demirel et al., 2015). After the perineal massage, the women could change and adopted the birth position that she preferred. The application of warm compresses was performed by the midwife be-

Table 1
Clinical characteristics, Portugal, 2019–2020.

		PeMWaC group $n = 400$	Control group $n = 400$	p
Clinical characteristics				
Maternal age (years), mean (SD)		31.8 (5.1)	31.4 (4.8)	0.276
Body mass index (kg/m2), mean (SD)		28.7 (4.2)	28.9 (4.6)	0.460
Parity, n (%)	Nullipara (without vaginal birth)	206 (51.5)	224 (56)	0.114
	Multipara	194 (48.5)	176 (44)	
Prenatal childbirth preparation course, n (%)	Yes	154 (38.5)	181 (45.3)	0.025
	No	246 (61.5)	216 (54)	
Gestational age (weeks), mean (SD)		39.3 (1.1)	39.3 (1.1)	0.717
Type Previous Birth, n (%)	Vaginal birth	182 (45.5)	167 (41.8)	0.536
	Cesarean section	24 (6)	33 (8.3)	
	Vaginal birth + Cesarean section	10 (2.5)	11 (2.8)	
Newborn birthweight (g), mean (SD)		3345 (385)	3328 (400)	0.545

Data are expressed as mean (SD) or count (%).

tween Hodge plans III and IV, [the height of the fetal presentation was assessed by the plans of Hodge (World Health Organization, 2018)] during pushes and regardless of maternal position. A metal jug filled with warm water (between 45° and 59 °C) was used to soak the compresses, which were squeezed out before being gently placed on the perineum during contractions. The compresses were rewarmed between pushes. Water was changed each fifteen minutes and the compresses were changed as needed to maintain warmth and cleanliness at the end of the second stage of labor. Women assigned to the standard care group did not have the combination of perineal massage and warm compresses applied to their perineum on the second stage of labor (Dahlen et al., 2007a).

Considering the technique hands-on, the midwife placed the index, middle ring and little fingers of the non-dominant hand close together on the infant's occiput, with the palm turned toward the anterior region of the perineum, when the infant's head was crowning. In this manner, expulsion was controlled, by maintaining the flexion of the head. Simultaneously, the dominant hand was flattened out and placed on the posterior perineum, with the index finger and the thumb, forming a "U" shape, exerting pressure on the posterior region of the perineum during the crowning process. During the birth of the shoulders and the remainder of the body, the dominant hand was kept in place, protecting the posterior region of the perineum, while the non-dominant hand supported the infant's head, allowing external rotation and the birth of the shoulders spontaneously. After both shoulders had been delivered, the midwife removed the dominant hand from the posterior perineum and supported the infant's neck with one hand, while supporting the remainder of the body with the other hand (De Costa et al., 2006).

Results

From March 2019 to December 2020, 848 women were randomised, 826 women received the protocol but were 800 women that received the strict protocol. The flow of participants is illustrated in Fig. 1. Clinical characteristics are shown in Table 1, Labor process variables are show in Table 2. Most characteristics were similar between groups. Table 3 shows the primary and secondary outcomes for 400 women randomised to PeMWaC and for 400 women in control group. The incidence of intact perineum was 188/400 (47%) [PeMWaC] vs 104/400 (26.3%) [control group]; second degree tear was 29/400 (7.2%) [PeMWaC] vs 49/400 (12.3%) [control group], and episiotomy was 38/400 (9.5%) [PeMWaC] vs 114/400 (28.5%) [control group], which significantly differed between groups. After adjustment for clinical characteristics, labor process variables with significant group differences and for predefined risk factors, the results of intact perineum (a2 OR 2.533, 95% CI 1.861–3.447, $p<0.001$); second degree tear (a2 OR 1.966, CI 1.174- 3.293, $p = 0.010$) and episiotomy (a2 OR 3.478, 95% CI 2.236–5.409, $p<0.001$) did not change.

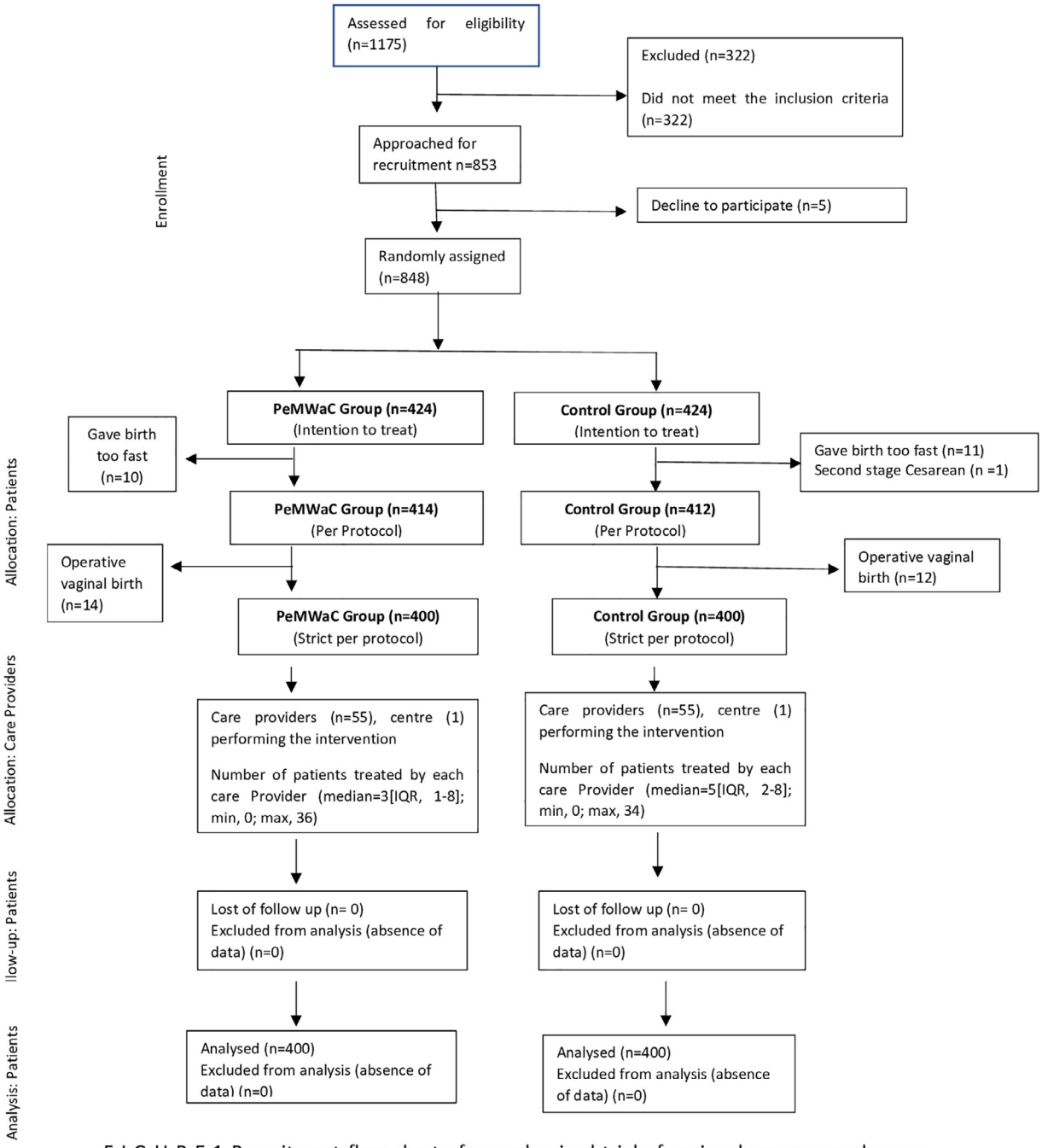
The incidence of OASIS total (with and without episiotomy) was 2/400 (0.5%) [PeMWaC] vs 9/400 2.3% [control group] and did not differ between the groups. After adjustment for clinical characteristics and labor process variables with significant differences between groups, the result did not change. However, after adjustment for predefined risk factors, significantly differences between groups were found (a2 OR 5.404, 95% CI 1.077–27.126, $p = 0.040$). The incidence for second-degree tears with episiotomy was (1/400 0.3% [PeMWaC] vs 7/400 (1.8%) [control group] and did not differ between the groups. After adjustment for clinical characteristics, labor process variables with significant differences between groups and for predefined risk factors (a2 OR 9.253, 95% CI 1.083–79.015, $p = 0.042$), significantly differences between groups were found.

In the secondary outcomes, the maternal satisfaction with intervention and recommend an intervention allocated to a friend was significantly higher for women in the PeMWaC group compared to control group. There was no difference in APGAR scores and newborn admission to neonatal intensive care unit between the groups.

Discussion

Primary outcomes

Several systematic reviews have shown the increased of intact perineum and reduction in episiotomy and OASIS rates after individually these techniques has been performed on second stage of labor (Magoga et al., 2019; Aquino et al., 2020; Li et al., 2023). Which is consistent with our results. Since 2016, first the warm compresses technique and then the perineal massage technique have been recommended (ACOG, 2016; WHO, 2018; Gimovsky et al., 2022). However, recent systematic review about perineal massage during the second stage of labor indicated a decreased in episiotomy rate but did not find a reduction in incidence and severity of perineal tears (Marcos-Rodríguez et al., 2023). On the other hand, another systematic review showed that perineal massage during labor decreased OASIS, but not episiotomy (Venugopal et al., 2022). Contrary, a systematic review concluded that intervention during labor was not effective for the prevention of perineal trauma when compared to no intervention. However, prenatal perineal massage was associated with a lower risk of perineal tear (da Silva et al., 2023). On the other hand, another study suggested that women who did not performed prenatal perineal massage can benefit from receiving perineal massage during labor (Kiremitli et al., 2022).



F I G U R E 1 Recruitment flow chart of a randomised trial of perineal massage and warm compresses technique compared with control group (hands-on technique) in the second stage of labor

Fig. 1. Recruitment flow chart of a randomised trial of perineal massage and warm compresses techinque compared with control group (hands of techinque) in the second stage of labor.

The results from the present study are in line with a randomised controlled trial which involved 180 nulliparas and demonstrated that combined perineal massage and warm compresses during active second stage pushing decreased the need of perineal suturing, episiotomy and major perineal injury (second-degree tears or worse) compared to control group "hands off" technique (Goh et al., 2021). Our study added that PeMWaC technique decreased the incidence of episiotomy plus second-degree tear compared to control group (hands-on). Another trial involved 282 term nulliparas reported that the combined perineal massage and warm compresses during second stage of labor did not decrease the likelihood of nulliparous women requiring suturing for perineal trauma, episiotomy and OASIS rates compared to perineal massage alone group (Hong et al., 2022). The evidence from recent studies, at first site seems to be controversial, but we know the control group was different between studies. In Hong et al. (2022) the control group was alone perineal massage and in Goh et al. (2021) the control group was hands-off technique, while in the present study was hands-on technique which is the current practice in the hospital. After a critical analysis, it allowed

Table 2
Labor Process Variables, Portugal, 2019–2020.

		PeMWaC group $n = 400$	Control group $n = 400$	p
Labor Process Variables				
Onset of labor, n (%)	Spontaneous	267 (66.8)	258 (64.5)	0.291
	Induction	131 (32.8)	139 (34.8)	
Rupture of membranes, n (%)	Before labor	93 (23.3)	111 (27.8)	0.078
	During labor	307 (76.8)	287 (71.8)	
Analgesia, n (%)	Epidural	386 (96.5)	371 (92.8)	0.135
	Raquianestesy	4 (1)	12 (3)	
	No analgesy	10 (2.5)	15 (3.8)	
First stage of labor, n (%)	No	102 (25.5)	115 (28.8)	0.824
	Birth ball	1 (0.25)	0	
	Hidroterapy	1 (0.25)	2 (0.5)	
	Walking	96 (24)	87 (21.8)	
	Birth ball +walking	45 (11.3)	47 (11.8)	
	Hidroterapy +walking	39 (9.8)	39 (9.8)	
Maternal birth position, n (%)	Lithotomy	204 (51)	224 (56)	0.083
	Semiseated	134 (33.5)	124 (31)	
	Lateral	58 (14.5)	50 (12.5)	
	All fours	4 (1)	2 (0.5)	
Length of the first stage of labor (h), mean (SD)		5.37 (3.6)	4.85 (2.9)	0.025
Length of the active second stage of labor (min), mean (SD)		40.80 (30.5)	37.53 (30.1)	0.128
Duration of oxytocin augmentation in second stage of labor (min), mean (SD)		16.5 (24.9)	15.3 (23.1)	0.467
Type of cephalic presentation, n (%)	Occiput anterior	366 (91.5)	363 (90.8)	0.402
	Occiput posterior	34 (8.5)	37 (8.2)	
Nuchal cord, n (%)	Yes	244 (61)	276 (69)	0.006
	No	156 (39)	120 (30)	
Height Perineum (cm), mean (SD)		3.30 (0.58)	3.35 (0.54)	0.268
Perineal edema, n (%)	Yes	37 (8.2)	34 (8.5)	0.402
	No	363 (90.8)	366 (91.5)	
Fundal Pressure, n (%)	Yes	66 (16.5)	69 (17.3)	0.425
	No	334 (83.5)	331 (82.7)	
Valsalva				
Maneuver, n (%)	Yes	60 (15)	53 (13.3)	0.267
	No	340 (85)	347 (86.7)	
Method of pushing, n (%)	Directed pushing coaching	28 (7)	28(7)	0.263
	Spontaneous pushing	239 (59.8)	237 (59.3)	
	Both	133 (33.2)	135 (33.7)	

Data are expressed as mean (SD) or count (%).

us to conclude that the groups that included perineal massage showed a reduction in perineal trauma and this finding is consistent with our findings. In Hong et al. (2022) study, in the massage alone group, the participants received perineal massage continuously during and between pushes whereas in the combined group massage was done only during contractions in the second stage. In Goh et al. (2021) study, the perineal massage was restricted for the duration of the pushing coordinated with contractions until near crowning. In the other hand, in this study was different to other studies because the perineal massage was only performed between contractions. In systematic review and meta-analysis developed by Aquino et al. (2020), from 9 randomised controlled trials (RCT'S), in one trial, the perineal massage was performed between contractions which is line to our study. In the other 8 trials, in three, the perineal massage was performed during and between pushing time, in four trials was only performed during the pushing time and in one was not reported. Despite, these differences between RCT'S, Aquino et al. (2020) in the systematic review and meta-analysis, concluded that perineal massage during labor was associated with significant higher intact perineum rate and lower risk of OASIS and episiotomy which converges with our results. Thus, the different timings of perineal massage between studies, allowed us to assume that regardless the timing to perform the perineal massage, this perineal protection technique showed a reduction in perineal trauma. However, in this study, the perineal massage was performed only between contractions and pushes, with the purpose to not cause more discomfort during contraction or when fetal presentation progressing in the birth canal.

The trial was underpowered to assess the OASIS, however, the difference in the rates was sufficient to warrant further investigation. In this study, OASIS incidence was 11/800 (1.4%), higher than reported in the literature (1%) from 2019 to 2020 data in spontaneous vaginal birth in Portugal (OECD, 2021). However, equal to the average for OECD countries between 2019 and 2020 in spontaneous vaginal birth (1.4%) (OECD, 2021). In Portugal, the OASIS rate increased from 0.4% between 2012 and 2017 (OECD, 2019) to 1% between 2019 and 2020 in spontaneous vaginal birth (OECD, 2021). On the other hand, Blondel et al. (2016) reported 66.8% episiotomy rate in spontaneous vaginal birth in Portugal from 2010 data and was among the European countries with the highest rate of episiotomies. However, the episiotomy rate in spontaneous vaginal birth has been gradually decreasing in Portugal, from 63% in 2013 to 54.0% in 2015 (Teixeira et al., 2022). In a recent study, the data from surveys answered by 21,027 women of 12 countries in Europe (1683 women in Portugal) demonstrated that Portugal presented 40.1% of episiotomy rate in spontaneous vaginal birth between 2020 and 2021 (Lazzerini et al., 2022). According to data from public hospitals in Portugal between 2000 and 2015, OASIS rate decreased in women with spontaneous vaginal birth without episiotomy but increased in women with episiotomy (Teixeira et al., 2022). Therefore, the rationale for conducting routine episiotomies to prevent OASIS was not justified by a recent literature (Jing et al., 2017; Franchi et al., 2020; Teixeira et al., 2022) and is consistent with our findings. After a critical analysis, we found significantly fewer OASIS (0.5%) in PeMWaC group compared to control group (2.3%) and fewer episiotomies (11.1%) in PeMWaC group compared

Table 3
Primary and secondary outcomes, Portugal, 2019–2020.

	PeMWaC group $n = 400$		Control group $n = 400$					
Primary Outcomes	n (%)	n (%)	OR (95% CI)	p	a1ORa (95% CI)	p	a2ORb (95% CI)	p
Intact Perineum	188 (47)	104 (26.3)	2.502 (1.858–3.369)	$p<0.001$	2.552 (1.877–3.470)	$p<0.001$	2.533 (1.861–3.447)	$p<0.001$
First degree tear	138 (34.5)	105 (26)	0.733 (0.536–1.003)	$p = 0.052$	0.710 (0.520–0.970)	$p = 0.031$	0.748 (0.546–1.024)	$p = 0.070$
Second degree tear	29 (7.2)	49 (12.3)	1.826 (1.091–3.054)	$p = 0.022$	1.914 (1.147–3.195)	$p = 0.013$	1.966 (1.174- 3.293)	$p = 0.010$
Episiotomy (without spontaneous tears)	38 (9.5)	114 (28.5)	3.692 (2.456–5.551)	$p<0.001$	3.690 (2.379–5.722)	$p<0.001$	3.478 (2.236–5.409)	$p<0.001$
Episiotomy Total	44 (11.1)	135 (33.8)	3.010 (2.125–4.251)	$p<0.001$	3.284 (2.456–4.465)	$p<0.001$	3.135 (2.275–4.358)	$p<0.001$
Episiotomy + first degree tear	4 (1)	12 (3)	2.867 (0.904–9.089)	$p = 0.074$	3.275 (1.017–10.548)	$p = 0.047$	3.206 (0.976–10.528)	$p = 0.055$
Episiotomy + second degree tear	1 (0.3)	7 (1.8)	7.920 (0.971–64.618)	$p = 0.053$	9.507 (1.147–78.824)	$p = 0.037$	9.253 (1.083–79.015)	$p = 0.042$
Episiotomy + OASIS (Episiotomy+ third or fourth-degree tear)	1 (0.3)	2 (0.5)	2.466 (0.218–27.897)	$p = 0.466$	3.253 (0.238–44.475)	$p = 0.377$	2.719 (0.177–41.836)	$p = 0.473$
OASIS (Third or fourth-degree tear)	1 (0.3)	7 (1.8)	7.107 (0.870–58.031)	$p = 0.067$	7.427 (0.900–61.280)	$p = 0.063$	7.060 (0.810–61.539)	$p = 0.077$
OASIS Total (with and without episiotomy)	2 (0.5)	9 (2.3)	4.581 (0.983–21.335)	$p = 0.053$	4.697 (0.999–22.073)	$p = 0.050$	5.404 (1.077–27.126)	$p = 0.040$
Secondary Outcomes								
Admission NICU	1 (0.3)	0		$p = 0.497$				
Apgar 5 min	10 (10–10)	10 (10–10)		$p = 0.347$				
Maternal satisfaction with intervention, n (%)	Satisfeid	386 (96.5)	371 (92.8)	$p = 0.019$				
Recommend an intervention allocated to a friend, n (%)	Not satisfeid	14 (3.5)	29 (7.2)	$p = 0.019$				
	Yes	386 (96.5)	371 (92.8)					
	No	14 (3.5)	29 (7.2)					

Data are expressed as mean (SD), median (interquartile range), or count (%).
OR odds ratios. NICU, neonatal intensive care unit.
aa1OR: OR adjusted for significant characteristic differences between the two groups (Tables 1 and 2), length of the first stage of labor, nuchal cord and prenatal childbirth preparation course.
ba2OR: OR adjusted for predefined risk factors: maternal age, parity, BMI, type of previous birth, analgesia, duration of oxytocin augmentation in second stage of labor, length of the active second stage of labor, birth position, height perineum, newborn birthweight, occiput posterior presentation and fundal pressure.

to control group (33.8%). This study found a positive relation between episiotomies and OASIS. Thus, the reason for the increase in the OASIS rate appears to be a better diagnosis of OASIS rather than the decreased in episiotomy rate. Thus, it is considered safe decreased the episiotomy rate in Portugal (Teixeira et al., 2022) and the accepted indications for episiotomy are to shorten the second stage of labor when there is suspected fetal hypoxia; to prevent obstetric anal sphincter injury in vaginal operative births, or when obstetric sphincter injury occurred in previous births (Laine et al., 2022)

Studies with aggregated data suggested that obstetric practices as maternal birth position and perineal protection techniques on the second stage of labor could contribute to differences in rates of OASIS and episiotomies (Blondel et al., 2016; Teixeira et al., 2022). In this study, perineal massage and warm compresses technique contributed to differences in episiotomy rate and OASIS between groups, with maternal birth positions being similar between groups. Nevertheless, the solution for OASIS problem include education, communication and teamwork (Persson et al., 2023).

Secondary outcomes

Women's preferences and experiences are an important part of the clinical decision-making process. In this study, participants expressed higher satisfaction with the intervention in PeMWaC group compared to hands-on group. A different satisfaction metric was also used, that of recommending an intervention allocated to a friend, and we found that more women allocated to PeMWaC group would recommend this intervention to their friends. The findings from this study were in line with Goh et al. (2021) that reported significantly higher maternal satisfaction score with combined massage and warm compresses compared to "hands off" technique. Contrary, in other trial, the maternal satisfaction was not significantly different between groups which combined perineal massage and warm compresses compared to massage only (Hong et al., 2022). It allowed us to conclude that the groups that included perineal massage showed more satisfaction with the technique. Also, according to Dahlen (2007b), 85.7% of women preferred to use warm compresses again for the next birth and would also recommend them to friends. Despite, the evidence on women's preferences being insufficient to make recommendations, our data demonstrated that PeMWaC technique was satisfactory for women.

Otherwise, according to the feedback from the coordinators, the entire team of midwives participated in the study. After completing participant recruitment, the team of midwives adopt the technique, as they continued to perform the perineal massage and warm compresses technique. This is a feasible, inexpensive and reproductible technique.

Strengths and limitations

This study has several strengths, the first strength was the inclusion of confounders variables as fundal pressure, Valsalva maneuver and perineal edema during the second stage of labor, that were not included in previous studies about this field. In this study these confounding variables were similar between groups. The second strength was the sample size, in this study the sample size is approximately three times larger than recent studies on the same topic (Goh et al., 2021; Hong et al., 2022). The third strength was the fact that was analysed the incidence of episiotomy plus another degree of tear, was not investigated in previous studies about this topic. This study found that perineal massage and warm compresses reduced spontaneous second-degree tears in women with episiotomy.

This study also has some limitations, like the validity of this trial that could be affected by the fact that several midwives performed the intervention, and the perineal tears were evaluated by several midwives, although numerous birth assistants is the reality at most centres, which increases the external validity and reproductible of the results. Other limitation is that it was a single-center trial, which might be interpreted as a limitation although it increases internal validity of the trial. The anal examination was only performed in women with second-degree tears and OASIS. We tried to overcome this limitation, by validating all cases of OASIS included in the trial through the access of the clinical files and sending two questionnaires, one about the pelvic floor function and other about sexual function at three and six months after birth to all the women included in the trial.

Conclusion

This study showed a protective effect of perineal massage and warm compresses technique during the second stage of labor compared with control group (hands-on), particularly with an increase in incidence of intact perineum and a decrease second-degree tear, OASIS, and episiotomy rates. The morbidity generated by perineal trauma during spontaneous vaginal birth justifies the need to find an intervention to minimize it, and this technique is feasible, inexpensive and reproductible. Therefore, this technique should be taught and trained to midwives students and midwives team. In addition, the midwives should provide perineal massage and warm compresses technique according to women's preferences. Thus, women should have this information and have the option to decide whether they want to receive the perineal massage and warm compresses technique in the second stage of labor.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Silvia Rodrigues: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing – original draft, Writing – review & editing. **Paulo Silva:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Software, Validation. **Fátima Rocha:** Visualization. **Ligia Monterroso:** Visualization. **João Neves Silva:** Methodology, Validation. **Natacha Quintal de Sousa:** Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Ramon Escuriet:** Methodology, Project administration, Software, Supervision, Validation, Writing – original draft, Writing – review & editing.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.midw.2023.103763.

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