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Full length article

Vocalization during the second stage of labor to prevent perineal trauma: A randomized controlled trial

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ABSTRACT

Background and purpose: Most women suffer some degree of perineal trauma during vaginal delivery. Second stage management strategies, including vocalization, to protect the perineum have been investigated. Objective: To compare the frequency and degree of perineal trauma at vaginal delivery, with and without use of the vocalization maneuver during the second stage of labor.

Materials and methods: This is an open-label, randomized controlled trial. We conducted the study at the Center for Normal Deliveries of IMIP. We included low-risk women without prior cesarean deliveries. Women who met the inclusion criteria and signed the informed consent form were randomized to one of two groups: Group A (experimental) and Group B (control). A physical therapist encouraged women in Group A to maintain an open glottis during pushing and to emit sounds when exhaling (vocalization). Women in Group B underwent routine humanized vaginal deliveries. The outcomes of the study were perineal integrity and degree of perineal laceration. These were measured by the study team immediately after completion of the third stage of labor. Results: Women in Group A tended to have less severe perineal tear (less second and third degree lacerations) and smaller lacerations than women in group B. The vocalization maneuver reduced the risk of a perineal tear greater than 2 cm by 68% (NNT 2.2). There was no difference in other outcomes.

Conclusion: Encouraging women to follow a vocalization protocol coached by a physical therapist during the second stage of labor can be a helpful labor assistance technique, since this study showed that vocalization is associated with less extensive perineal tears.

Clinical Trial Registration: This study was registered on ClinicalTrials.gov (www.clinicaltrial.gov) registration number: NCT03605615.

Introduction

In the mid-twentieth Century, more and more and births occurred in hospitals, resulting in the institutionalization of normal labor and delivery [1]. In this context, perceptions of the birthing process shifted: it was no longer a natural process requiring a minimum of intervention, but rather a pathological one requiring maneuvers and interventions to prevent maternal and fetal injury [2].

One of the major interventions enacted by health professionals during hospital deliveries relates to the type of pushes encouraged during the second stage of labor. By contracting the abdominal muscles during a forced exhalation of air against a closed glottis, the woman creates a deliberate push that aims to shorten the second stage. Throughout the history of obstetrics, women have been encouraged to push in synchrony with uterine contractions in order to deliver the infant [3,4]. Such directed pushing is the breathing pattern most commonly recommended by obstetrical teams both in high and low-income countries [5–7].

Unlike during directed pushing, women who spontaneously push, emit vocalizations, such as cries, roars, whimpers and gasps. Spontaneous pushing most commonly occurs with a partially open glottis [8]. Opening the glottis results in recruitment of the abdominal muscles, especially the transversus abdominis, which is circumferential in nature and when contracted leads to a compression of the abdominal contents. This leads to an increase in intra-abdominal pressure and a consequent lengthening of the diaphragm [9,10].

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A randomized clinical trial compared the effects of directed pushing (closed glottis) and spontaneous pushing (open glottis) on pelvic floor structure and function. Directed pushing was associated with a negative impact on pelvic floor muscles up to two year postpartum. It is thought that a closed glottis causes an increase in intra-abdominal pressure which can result in muscle fiber destruction [11].

Perineal trauma has a negative impact on quality of life [12,13] Given its association with the second stage of labor, respiratory maneuvers during labor have been proposed as a means to help maintain pelvic floor integrity [14].

There is some evidence that pushing with an open glottis helps maintain perineal integrity [15]. Maneuvers to maintain an open glottis can therefore be useful during delivery. One of these maneuvers is vocalization, a technique in which voice is given to air exhalation, creating the sound of a vowel sung in a deep tone [16]. That said, a Cochrane review on this matter concluded that there is not enough evidence to determine the best type of push for the second stage of labor [17].

The objective of this study is to evaluate the effectiveness of the vocalization technique during the second stage of labor in terms of protecting the perineum during vaginal delivery.

Methods

Study design

We conducted an open-label randomized controlled trial comparing women who delivered using the vocalization technique during the second stage of labor with a control group undergoing usual care. The study site was the Normal Delivery Center (NDC), an area of the low-risk maternity ward of the Instituto de Medicina Integral Prof. Fernando Figueira (IMIP), located in the city of Recife in the State of Pernambuco, Brazil. We collected data from August 2018 to February 2019.

We did not find any studies comparing vocalization with usual humanized care at delivery on which to base a sample size calculation. We conducted this as an exploratory pilot study including 40 women and randomized 20 to each group.

The research project was approved by the Ethical Review Board of the hospital, protocol number CAAE 86696818.2.0000.5201. The protocol was registered at ClinicalTrials.gov (www.clinicaltrials.gov), trial number NCT03605615. There were no conflicts of interests.

Study population

Low-risk pregnant women in active labor admitted to the NDC were included in the study. Women were between 37 and 42 weeks pregnant and up to eight centimeters in cervical dilation at the time of enrollment. Their fetuses were in cephalic presentation. We excluded from the study women who had an indication for cesarean delivery at the time they were approached, women who did not have the capacity to understand or execute the vocalization maneuver, women with dysphonia, women with hearing deficiency, or those who had received oxytocin prior to randomization.

Randomization and interventions

We randomized women to vocalization or usual care using a list of random numbers generated by a collaborator who was not involved in data collection. Based on this list, we prepared sealed, opaque envelopes numbered one through 40. Each number corresponded to a group allocation (experimental or control) which was determined according to the random number sequence. The envelopes were prepared by another collaborator who was also not involved in data collection.

Women admitted to the NDC of IMIP who met eligibility criteria were invited to participate in the study. Those who agreed to participate signed an informed consent form. A sealed and numbered envelope containing the group allocation was then added to their medical chart. The envelope was opened once women were eight centimeters dilated. This was done in order to minimize the risk of losing patients after randomization. This was also a way to keep the group allocation concealed. After the group allocation was revealed, the researcher taught the vocalization technique to the women assigned to the experimental group, so that they could use it during the second stage of labor.

The researcher, a physical therapist specialized in labor coaching, taught the vocalization technique in a practical format in accordance with the protocol created for this research project (Fig. 1). First, she demonstrated the technique so that the women could see, hear, and understand it. Shortly after, she asked the women to repeat the technique. She taught vocalization in the form of exhaled and sung voice in deep tones, using the vowels A, O and U.

At the beginning of the second stage of labor, the researcher reviewed the vocalization technique with each woman in the experimental group. During the second stage, women were asked to use the vocalization technique every time they felt the urge to push. This was done in a natural fashion and with each contraction until delivery of the baby. Women were free to emit any sound, from expiration sounds to screams in deep tones – any sound to confirm that the glottis was at least minimally open. All women received usual labor and delivery care in addition to the study intervention.

Women randomized to the control group only received usual labor and delivery care, in which no specific respiration technique was recommended during the second stage. Women were left free to breathe and push as they desired. The control group was cared for by the hospital labor & delivery team, who is trained to maintain respect and guarantee basic rights as per the Brazilian's Ministry of Health's guidelines for assistance of normal delivery [18], and as per the World Health Organization's (WHO) guidelines [19].

Outcomes and follow-up

Our primary outcome was the presence or absence of perineal tears. Tears were defined as: first-degree, involving the skin and/or vaginal mucosa; second-degree, involving the perineal musculature; third-degree, involving the anal sphincter; and fourth-degree, involving the rectal mucosa. The researcher and healthcare provider (nurse or physician) examined the participants after delivery and determined which type of perineal tear, if any, had occurred. For the analysis, the perineal tears were collapsed into two groups: group 1, which included women without tears or with a first-degree tear; and group 2, including women with second-, third-, and fourth-degree tears. Shortly after delivery of the placenta, the researcher measured the size of the perineal tears in centimeters. The vaginal introitus was carefully opened to expose any lacerations and using an adapted ruler that was protected with a male condom prior to each use, measurement of the lacerations if present.

To evaluate the level of perineal pain, we used a pain measurement scale which combines a visual, categorical, numerical and faces scale. The scale varies in discrete numbers from zero to ten, zero being no pain and ten being the worst possible pain [20]. For the analysis, we coded perineal pain as absent or mild, corresponding to scores from zero to four, and moderate to severe, corresponding to scores from five to ten.

We considered all variables related to vaginal delivery to be perineal variables – including the presence of tears, characteristics of tears, intensity of pain and presence of edema. We only collected these variables for women who had a vaginal delivery.

The presence of perineal edema was assessed immediately after delivery of the placenta, this evaluation was made by the professional who assisted the delivery (nurse or physician).

Women satisfaction with childbirth was evaluated by the researcher in the rooming-in prior to hospital discharge. Women were asked how satisfied they were with their delivery experience: very satisfied, satisfied, somewhat satisfied or not satisfied. For the final analysis, the

First stage of labor
1. The researcher (a physical therapist) approached any woman admitted in labor
2. The researcher explained the vocalization technique and its possible benefits
3. The researcher demonstrated the technique in form of exhaled /sung voice in deep tones using A, O and U vowels, one vowel at a time, for at least 30 seconds, so that the woman could see and hear
4. The researcher and the woman repeated the technique, one vowel at a time, for at least 30 seconds, together with the women at the same time, (3 to 5 times), with each vowel, in the absence of uterine contractions
5. The researcher and the woman repeated the technique at the same time during uterine contractions
Second stage of labor
1. At the beginning of the second stage the researcher reviewed the vocalization technique with the woman
2. The researcher encouraged the woman to use the vocalization technique each time that she felt the urge to push, during each contraction of the second stage up to delivery of the baby
3. The researcher observed when the woman reported the urge to push or made efforts to push
4. The researcher waited for the end of the contraction and reviewed the vocalization technique as needed
5. The researcher encouraged the woman to use vocalization during pushes and the woman did so if willing
6. The researcher and the woman used the vocalization technique at the same time when the woman felt contractions or the urge to push.

** The technique was executed with all women who met eligibility criteria, signed informed consent forms, and were randomized to the experimental group.*
*** Women pushed according to their own urges and desires. The researcher reminded women to use the vocalization technique in between contractions, never during contractions.*

Fig. 1. Implementation protocol for the vocalization technique.

categories "very satisfied" and "satisfied" were analyzed together. All women, even those who had a cesarean delivery responded to this question.

Secondary outcomes were maternal and perinatal outcomes, perineal edema, perineal pain, and Apgar scores.

Statistical analysis

We conducted all statistical analyses using Epi-Info 3.5.4. Initially frequency and distribution tables were created for the categorical variables and measures of central tendency and dispersion were calculated for continuous variables. Mann-Whitney test for discrete, ordinal and not normally distributed variables was used.

We analyzed perineal variables only for women who had a vaginal delivery and excluded those who had cesarean deliveries because none of them made it to the second stage of labor. The satisfaction analysis was conducted as an intention-to-treat analysis.

To evaluate the associations between the independent variable (vocalization) and the dependent variables we used Pearson's Chi Square test or Fisher's Exact test. We calculated the relative risk (RR) and its 95% confidence interval (CI). For all analyses, the significance level was set at 5%. All p values were two-tailed. To calculate the number needed to treat (NNT), we used a public domain calculator available at ClinCalc.com [21].

Results

A total of 211 deliveries occurred in the low-risk maternity ward of IMIP during the study period. Of these, 42 women were approached, and all were eligible to participate in the study. Among the eligible women, two declined to participate. We therefore included 40 women in the study. Three women had a cesarean delivery due to failure to progress in labor and one did for non-reassuring fetal heart rate tracing. All participants completed the study. Three out of four of the women who had a cesarean delivery were in the control group, and one was in the experimental group. Perineal outcomes were not analyzed in the women who underwent cesarean delivery, but satisfaction was measured by intention-to-treat principles (Fig. 2).

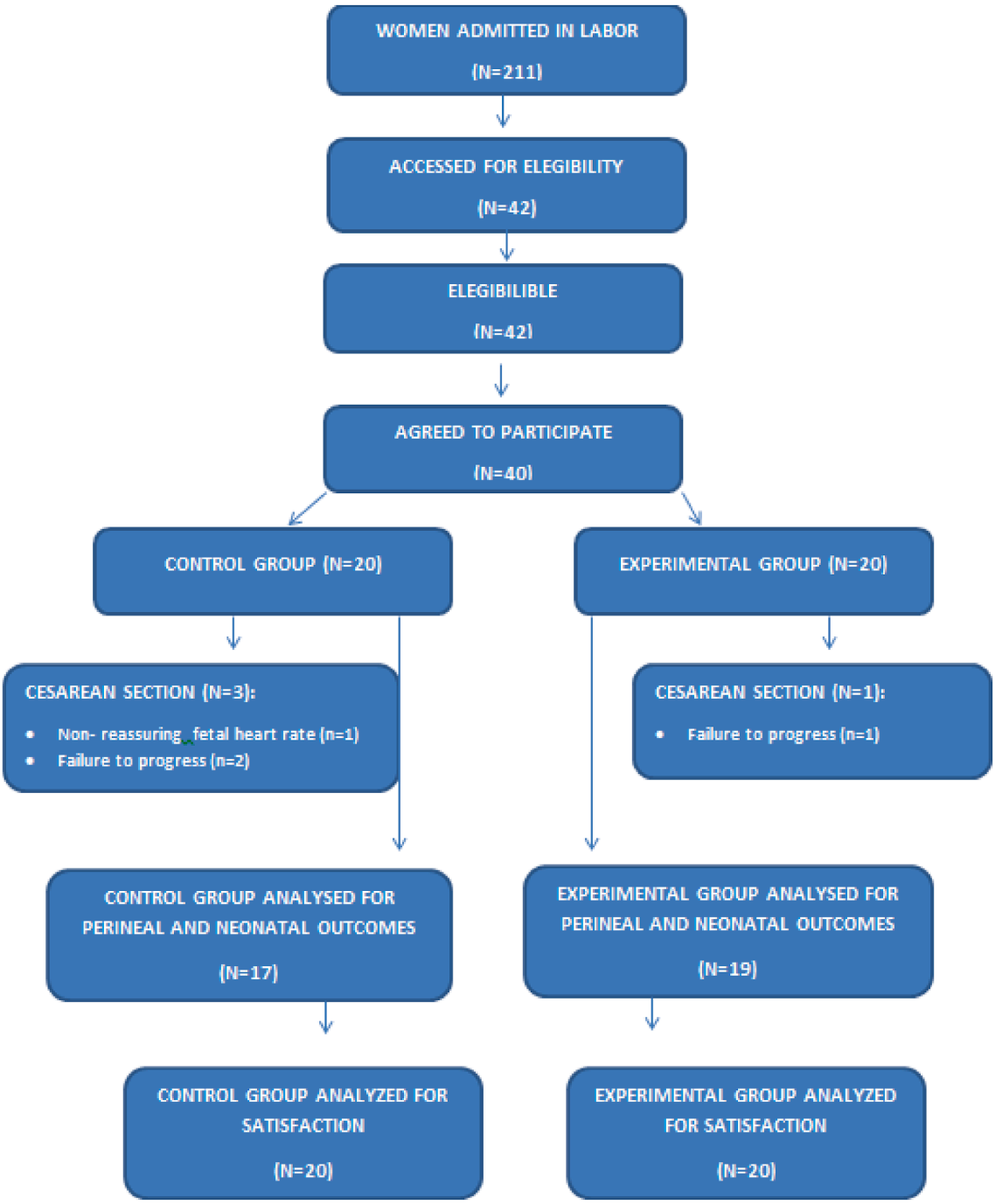

Fig. 2. Enrollment and follow-up flow chart.

Women in the experimental and control group had similar demographic and clinical characteristics (Table 1). There was no significant difference in terms of age, gestational age, years of education, or number of pregnancies. Labor-related variables such as directed pushing and delivery position (on a stool versus in lithotomy) were also similar. In terms of infant characteristics which could be associated with perineal tears, infant weight was similar among groups, whereas head circumference was on average one centimeter less in the intervention group compared to the control group ($p = 0.01$) (Table 2). There were no episiotomies and no operative deliveries in any of the groups.

In terms of the presence and type of perineal tears (Table 3), in general, there was no significant difference among groups. Of 19 women who delivered using the vocalization technique, 14 had some degree of perineal tear: nine (64.3%) were first-degree tears and five (35.7%) were second-degree tears. Of the 17 women in the control group, 15 had a tear: four (26.7%) were first-degree tears, eight (53.5%) were second-degree tears, and three (20%) were third-degree tears. There were no fourth-degree tears in this study.

Considering the presence of second-degree and/or third-degree tears as one category, we observed that there was a tendency towards these tears being more frequent in group B (55%, as opposed to 25% in group A), $p = 0.052$, although this difference was not statistically significant. There were no serious injuries in the women in the experimental group with the vocalization technique and only three women in the control group had a third-degree severe perineal laceration.

In terms of perineal tear size (Table 3), we also found a tendency to a

Table 1
Participants' clinical and sociodemographic characteristics.

Maternal variable	Group A (n = 20)	Group B (n = 20)	*p*
Age, years (mean, SD)	22.4 (5.64)	25.0 (5.90)	0.17
Number of pregnancies (median, IQR)	1 (1–3)	1 (1–2.5)	0.86*
Parity (median, IQR)	0 (0–2)	0 (0–1)	1.00*
Gestational age, weeks (mean, SD)	39.1 (0.98)	39.0 (1.07)	0.64
Years of education completed (median, IQR)	8.5 (8–11)	8.5 (6.5–11)	0.43

Group A – experimental group.
Group B – control group.
SD – Standard deviation.
IQR – Interquartile range.
*Mann-Whitney.

Table 2
Postpartum and neonatal characteristics.

Maternal variable	Group A (n = 20) %	Group B (n = 20) %	RR	95 %CI	*p*
Directed pushing (n%)	2 (10.5)	3 (17.6)	0.72	0.23–2.23	0.53
Delivery on a stool (n%)	3 (15)	5 (25)	0.70	0.27–1.22	0.34*
Delivery in lithotomy (n/%)	4 (20)	2 (10)	1.41	0.72–2.76	0.33*
Newborn weight (mean, SD) (G)	3288 (456)	3364 (395)	–	–	0.59
Head circumference (mean, SD) (Cm)	33.5 (0.99)	34.5 (1.07)	–	–	0.01

Group A – experimental group.
Group B – control group.
SD – standard deviation.
IQR – interquartile range.
RR – relative risk.
CI – confidence interval.
*Fisher's exact test.
cm = centimeters.
g = grams.

shorter average tear in the experimental group (2.1 cm versus 3.2 cm in the control group; p = 0.058). The frequency of tears greater than 2 cm in length was significantly less in the vocalization group (21.4%, versus 66.7% in the control group; RR = 0.32, 95 %CI 0.11–0.93, p = 0.018), with a NNT of 2.2.

There were no significant differences between groups in terms of other outcome variables such as need for repair and number of sutures used.

There also was no significant difference in terms of duration of second stage (Table 3). However, women in the experimental group had tendency towards a higher average duration of second stage compared to those in the control group (51 min versus 41 min, p = 0.54).

There was no significant difference in terms of degree of perineal edema shortly after placental delivery (Table 4). In terms of postpartum perineal pain, 68.4% of women in the vocalization group reported pain, similar to 52.9% in the control group. Median pain intensity, measured using visual analogic scale (2 in the vocalization group and 1 in the control group, p = 0.6). Most women reported no pain or mild pain (EVA < 5), without statistically significant differences among groups (68.4% versus 70.6%, p = 0.88).

In terms of satisfaction with the delivery experience (Table 4), there were no significant differences, but there was a tendency towards higher satisfaction in the experimental group, since 19/20 women in the vocalization group were satisfied, whereas four women in the control group were not satisfied.

There was no difference among groups in terms of neonatal Apgar scores (Table 4) both at one at five minutes. There was no need for neonatal resuscitation or neonatal intensive-care unit admission in the 36 vaginal deliveries and four cesarean deliveries.

Table 3
Perineal results, duration of second stage and repair of lacerations.

Outcome variables	Group A (n = 19)	Group B (n = 17)	RR	95 %CI	*p*
Perineal tear (n/%)	14 (73.7)	15 (88.2)	0.8	0.60–1.14	0.27
Second- or third-degree perineal tear (n, %)	5 (25)	11 (55)	0.45	0.19–1.07	0.052
Posterior location (n/%)	9 (45)	8 (40)	1.12	0.54–2.31	0.74
Size of tear in cm using	2.1 (1.16)	3.2 (1.65)	–	–	0.058
Frequency of tears ≥ 2 cm#	3 (21.4)	10 (66.7)	0.32	0.11–0.93	0.0018**
Duration of second stage in minutes (mean, SD)	51 (38)	41 (22)	–	–	0.54*
Number of suture packets (mean, IQR)	1(1–1)	1(1–2)	–	–	0.2
Need for repair of perineal tear (n/%)***	10 (71.4)	13 (86.7)	0.82	0.56–1.21	0.29**

Group A – experimental group.
Group B – control group.
SD – standard deviation.
IQR – interquartile range.
RR – relative risk.
CI – confidence interval.
cm = centimeters.
*Mann-Whitney.
** Fisher's Exact test.
*** Total of 29 women with tears, 14 in group A and 15 in group B.
# Number needed to treat = 2.2 (number of women needed to avoid a laceration >2 cm).

Table 4
Maternal and perinatal secondary outcomes.

Variables	Group A (n = 20)	Group B (n = 20)	RR	95 %CI	*p*
Perineal edema shortly after placental delivery (n/%)	12 (63.2)	10 (58.8)	1.07	0.63–1.81	0.78
Presence of postpartum perineal pain (n/%)	13 (68.4)	9 (52.9)	1.29	0.75–2.22	0.34
Perineal pain VAS (median, IQR)	2 (0–5)	1(0–5)	–	–	0.6
No or mild perineal pain (VAS < 5) (n/%)	13 (68.4)	12 (70.6)	0.96	0.62–1.49	0.88*
Satisfied / very satisfied (n/%)	19 (95.0)	16 (80.0)	2.71	0.45–16.0	0.17*
1-minute Apgar score (median, IQR)	9 (9–10)	9 (7–10)	———	———	0.19*
5-minute Apgar score (median, IQR)	10 (10–10)	10 (7–10)	———	———	0.3*

Group A – experimental group.
Group B – control group.
SD – standard deviation.
IQR – interquartile range.
RR – relative risk.
CI – confidence interval.
VAS- visual analog scale.
*Fisher's Exact Test.

Discussion

In this study, we could not prove that the vocalization technique contributed to maintaining perineal integrity. However, we did find that it significantly reduced risk of perineal tears with more than 2 cm. Since it does bring risks and may have benefits, vocalization during the second stage of labor can be integrated within a low-intervention model for

labor and delivery care.

Our results confirm those of a systematic review published in 2016 about methods used during the second stage to maintain an open glottis in order to prevent perineal tears, which found inconclusive results. Its authors concluded that there is not enough evidence to recommend the various techniques to prevent perineal tears [22].

A Cochrane review compared the Valsalva maneuver with other pushing techniques. It included a total of 815 women, and found that there was no significant difference in terms of perineal tears [17]. On the other hand, in one randomized clinical trial of primiparous women, the authors found a significant reduction in the risk of perineal tear among women who maintained an open glottis during pushing compared to those who closed it and those who used Valsalva [23].

The development of perineal tears depends on various factors, and especially on how deliveries are assisted [24]. Delivery position, infant size, the use of maneuvers or of synthetic oxytocin are factors that can influence the risk of perineal tears independently of the vocalization technique and of whether the glottis is kept open [24–26]. It is possible that changing only the vocalization technique as the only intervention without changing the delivery position and the type of assistance at delivery could have biased these studies.

Another bias that could explain these conflicting results is that of the control group (as compared to other studies). In our study, all women received usual low-risk care provided by nurse midwives, following a minimal intervention model of care designed to allow for physiologic birthing. This means that neither group received any intervention that could increase the control group's chance of having larger and more serious tears. In the intervention group, the physiotherapist taught women how to use the vocalization technique in addition to usual care.

This fact likely decreased the effect of the vocalization maneuver when compared to traditional models of labor assistance. This is in part because a woman in a low-intervention care model is in charge of her own labor and vocalizes in a spontaneous fashion. It is possible that with a larger sample size and if the control group received a different kind of assistance, we would have found an effect on the frequency of perineal tears. For example, we could have compared the vocalization technique with the Valsalva maneuver or with directed pushing, instead of with usual care.

When we analyzed the results for the second- and third-degree tears, we noticed that among the women in the vocalization group only five had second-degree tears and none had third- or fourth-degree tears, for a total of only 25% of women in the experimental group. On the other hand, in the control group, 11 (55%) had second- and third-degree tears. Of these, three had third-degree tears and eight had second-degree tears. However, this difference did not reach statistical significance ($p = 0.052$). We believe that with a larger sample size we may be able to show a protective effect of the vocalization technique in terms of more serious perineal tears.

Severe lacerations occur when there are injuries involving the anal sphincter, which can compromise the functionality of the pelvic floor musculature [13–15]. The women in the experimental group who used the vocalization technique and were assisted by the physical therapist did not present severe second-third degree lacerations and only three patients of the control group presented severe third-degree laceration. Since the perianal tears were infrequent in our sample, we decided to analyze together second and third-degree injuries to be able to make the comparison between the groups and when we added them together we had a higher frequency, but we know that perineal injuries that do not reach the anal sphincter are not considered serious [19]. Anyhow, second-degree tears, although not serious, generally implicate in sutures. So if the technique reduces these lesions, this could be a advantage of its application.

We did not find any studies examining the vocalization technique and its effects on the degree of perineal tear. However, retrospective studies showed that directed pushing to facilitate delivery may increase the risk of moderate and serious perineal tear and are associated with more pelvic floor dysfunction.

In terms of size of perineal tear, in this study we found a tendency to smaller lacerations in the experimental group. Using 2 cm as a cutoff point, we found that the vocalization technique reduced by 68% the risk of a tear greater than 2 cm. The NNT was 2.2, that is, it would be enough to use the maneuver in two women to obtain a reduction in perineal tear size.

One randomized clinical trial compared women using a blowing technique with open glottis (similar to our vocalization technique) to women using the Valsalva maneuver, and found a reduction in degree and depth of perineal tears in the experimental group [26]. The authors concluded that the increase in intra-abdominal pressure caused by the Valsalva maneuver may cause more nerve and muscle damage in the pelvic floor. On the other hand, the blowing technique with open glottis allows the vaginal muscles to be slowly elongated which may reduce perineal trauma [26].

In our study, we found a longer length of second stage in the experimental group, but this difference was not statistically significant. Another study including 116 women randomized to spontaneous versus directed pushing did find a difference in second stage duration (63.2 ± 21.3 for spontaneous pushing versus 46.6 ± 23.4 min for Valsalva or directed pushing, $p = 0.001$). It is possible that we did not find a difference in second stage duration due to our small sample size.

Some authors believe that when pushing spontaneously women do not exert continuous pressure; they pause to breathe, which can increase the duration of the second stage. [32] It is important to stress that with the vocalization technique women maintained an open glottis but were allowed to pause and breathe whenever they found it necessary. Even so, we did not find any differences among groups in terms of second stage duration.

No other studies have evaluated pushing technique and the need for suture repair of perineal tears, of the number of suture packages used, of perineal edema and perineal pain. Some studies correlated perineal pain to the use or non-use of thermal compresses and perineal massage during delivery, and others evaluated perineal edema based on postpartum positioning [26–29]. In our study, we did not find any significant differences with respect to these outcomes.

We did not find any difference among groups in terms of Apgar scores, which confirms the findings from a randomized controlled trial which compared perinatal outcomes in women using the Valsalva maneuver versus spontaneous pushing [28].

One study using the vocalization technique was completed among pregnant women during prenatal care and found that women were more relaxed and emotionally free, had less anxiety, and coped better with pain. The authors concluded that using this technique of voice toning helped with personal relaxation [16].

Various authors suggest that there are different ways to push naturally and by promoting relaxation, hence why it is difficult to establish one technique as being superior to others in preventing perineal tears [28,29]. On the other hand, authors of a clinical trial conducted in 2006 found that women who pushed with an open glottis had fewer perineal tears [23].

Our study found that vocalization was associated with high levels of maternal satisfaction postpartum, perhaps because it is a way to help promote relaxation and positive sensations. It is worth noting that evaluating maternal satisfaction with birth experiences is difficult, because women may be confusing their satisfaction with the technique used with their satisfaction with the delivery in and of itself. In this study, we asked women about their satisfaction with their delivery and therefore could not determine whether this was directly related with the vocalization maneuver or with the model of care in general, which is different from that offered in many hospitals.

To this date, we did not find any studies (Medline/Pubmed, 1966–2019; Lilacs, 1982–2019; Cinhal, 1976–2019) comparing the vocalization technique with usual care for the prevention of perineal tears. In our study, the women were not directed as to when to open their

glottis and complete a Valsalva maneuver. Rather, they were able to decide when to start pushing. This differs from other studies which compare spontaneous pushing with an open glottis without any vocalization technique with directed pushing using the Valsalva maneuver [25–27]. Our study was pioneering, since it used a vocalization protocol designed specifically for it by a physical therapist specialized in labor and delivery assistance. The protocol also respected the usual principles of woman-centered birth.

A limitation of this study is that it was a pilot study with a small sample size. It was not possible to perform a sample calculation based on information from the literature, and the Cochrane systematic review about spontaneous pushing [17], included studies that compared breathing exercises or sounds other than vocalization, limiting the performance of a sample calculation. A larger sample size is necessary, especially to detect the heterogeneity of characteristics for the various outcomes, and thus obtain better results and conclusions. As this is an open study, we know that measurement bias may exist. Unfortunately, we were not able to control this bias for operational reasons. We are aware of the limitation of this bias, however, as the primary outcome was the presence of perineal laceration and this information was made available by the nurse or physician who were providing care during childbirth, we believe that this bias did not interfere with the result found.

Conclusions

In conclusion, this study found that in the context of woman-centered and minimally invasive care for vaginal deliveries provided by a multidisciplinary team including a physical therapist, the vocalization technique significantly impacts the size of perineal lacerations. Using this technique in a low-risk and low-intervention population may also impact the type of tear and has high maternal satisfaction rates. However, more studies are needed to apply this technique to a larger sample size.

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.

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Ethical approval

The research project was approved by the Ethical Review Board of the hospital, protocol number CAAE 86696818.2.0000.5201. The protocol was registered at ClinicalTrials.gov (www.clinicaltrials.gov), trial number NCT03605615. There were no conflicts of interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejogrb.2022.06.007.

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