JCN Journal of Clinical Nursing

Journal of
Clinical Nursing

PAIN MANAGEMENT

Comparison of application times for ice packs used to relieve perineal pain after normal birth: a randomised clinical trial

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Aims and objectives. To compare the effect of an ice pack applied for 10, 15 and 20 minutes to relieve perineal pain after birth.
Background. Perineal pain after vaginal birth, with or without vaginal trauma, is one of the most common morbidities reported for postnatal women. Cryotherapy has been used in postpartum period to relieve perineal pain and investigated in several studies. However, cryotherapy treatment protocols in perineal care vary widely regarding temperature, frequency and duration of the application.
Design. A controlled trial, randomised for two groups and with a third group as a historical control.
Method. The intervention was carried out in a maternity hospital in São Paulo, Brazil. The study population consisted of three groups of 38 women who used an ice pack on the perineum, in a single application: group A-10 minutes; group B-15 minutes; group C-20 minutes (historical control from another clinical trial). Participants' perineal pain magnitude was evaluated through a numerical scale (0–10), at four different points: before the cryotherapy; immediately after and at 20 and 40 minutes after cryotherapy.
Results. After application of the ice pack, there was no statistical difference when comparing the perineal pain among groups in the second, third and fourth evaluations. Most of the postnatal women reported pain relief, with 72·8% reporting a decrease in pain >50%; 21·9% reported a decrease between 30–50%. All postnatal women subjected to cryotherapy were favourable to the procedure.
Conclusion. There is no difference in pain scores following ice pack application in three different times (10, 15 and 20 minutes) in women who report moderate or intense perineal pain after normal delivery.
Relevance for clinical practice. Ice treatment is safe, and application times of 10 or 15 minutes are as beneficial as an application time of 20 minutes to relieve perineal pain.

Key words: clinical trial, cryotherapy, obstetric nursing, pain, perineum, postnatal period

Accepted for publication: 26 February 2012

Introduction

Perineal pain is one of the most frequent reasons for complaints among women who vaginally give birth. High prevalence of perineal pain after birth has been found in several studies. Survey study carried out in the US with 1537 women two months following birth revealed that perineal pain was cited by 73% of primiparous women who had had a spontaneous birth, of whom 31% had had an episiotomy (Declercq *et al.* 2008). An Australian cohort study conducted

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on postnatal women who had vaginal births found 22% of the perineal pain in the eighth week, 6% in the tenth week and 3% in the twenty-fourth week (Thompson *et al.* 2002). Italian study found perineal pain incidence of 6·7 and 2·3%, three months after the delivery, in women who sustained and not sustained an episiotomy, respectively (Sartore *et al.* 2004). In a Brazilian cross-sectional study conducted on 303 women who had vaginal birth, 18·5% of them reported perineal pain up to 48 hours after the birth (Amorim Francisco *et al.* 2010). Perineal pain limits postnatal women' functional activities, such as: sitting, lying down, walking, eliminating (urinating and defecating), eating, sleeping and maintaining intimate hygiene, in addition to breastfeeding and newborn care (Macarthur & Macarthur 2004), (Steen & Marchant 2007), (Andrews *et al.* 2008). Therefore, these morbidity effects have negative impact in the maternity experience and deserve attention of postpartum care researchers.

Background

The approach for treating perineal pain postpartum encompasses several pharmacological and non-pharmacological treatments. Pharmacological treatments include oral and rectal analgesics and topical application of preparations in sitz baths or sprays. Non-pharmacological treatments include superficial applications of heat and cold, complementary therapies [transcutaneous electrical nerve stimulation, massages, acupressure techniques ('do-in')] and therapeutic ultrasounds (Demott *et al.* 2006). Topical treatments, such as applying cold to the perineal region, have been preferred because they do not produce side effects, do not interfere with breastfeeding and are more easily accessible.

The therapeutic use of cold applications predates Jesus. Greeks and Romans used snow and ice to treat various medical maladies (Knight 1995). In Obstetrics, the first references to using cold date to 1930 and refer to the application of cold pack in the rectal region to relieve haemorrhoid pains. The use of an ice pack increased gradually from the 1960s, primarily after the 1970s and 1980s, on account of the rapid expansion of knowledge concerning the treatment of damage to the pelvic floor (Rhode & Barger 1990) and the increase in episiotomy rates (Steen *et al.* 2006). The cryotherapy techniques cited are: application of ice or cold compress, ice massage, cold water bath, cold gel compress, immersion in ice and others (Knight 1995).

The psychological effects of applying cold to decrease pain, muscle spasm, metabolism and inflammation seem to be universally accepted despite their action mechanisms have not being completely clarified. The analgesic action from applying cold is related to vascular spasm and the decrease of local blood flow and, thus, to oedema. A decrease in pain occurs as a consequence of the decrease of excitability of the nerve endings and the transmission of receptors, an increase in the pain threshold and the release of endorphins, all caused by the cold (Knight 1995).

Various studies have investigated the use of ice to treat perineal pain. Treatment protocols for cryotherapy to treat perineal pain are very diverse in terms of use, frequency and duration of application. Studies were found that tested application durations from 15–30 minutes. Steen and Marchant (2007) conducted a clinical trial on the effects of the use of an ice pack and cooled gel pack to treat perineal pain after birth compared to no treatment in 316 women who had vaginal births with episiotomy or a second-degree rupture. Women from the gel-pack group reported less pain than women from the ice-pack group. Nevertheless, the authors did not report the duration of the intervention.

The study made by Rhode and Barger (1990) indicates that the duration of the therapy varied between 10 minutes and one hour. In a systematic review, the studies included applied a cold treatment for durations of 10 and 20 minutes. In clinical practice, this reflects the time necessary for the body's temperature to decrease (East *et al.* 2007).

Another systematic review shows evidence of a decrease in temperature in the first 10 and 20 minutes. The conclusion is that ice is effective but that it must be applied for 10 minutes intermittently to avoid secondary effects and lesions, with the goal being to reduce the temperature between 10–15 °C (Mac Auley 2001).

According to Palastanga (1994), when ice is applied to the skin, immediate cooling occurs, with a decrease of 15 °C within two to five minutes. Nevertheless, thicker muscle tissues, like those in the thigh, require more time to cool than do bonier regions (Knight 1995).

A systematic review which analysed seven clinical trials with 859 postnatal women as regards the application of cold to relieve perineal pain resulting from traumas after birth concluded that there was little evidence to support cryotherapy treatments. The reviewers state that none of the studies included evaluated the temperature of the skin or verified the decrease of the temperature of the perineum to 10–15 °C, the amount recommended for the analgesic effect. They suggested that variable studies should be included, such as: parity, type of birth, degree of perineal traumatism, duration of the cryotherapy sessions, viability of the use and inclusion of a non-treatment group for comparison, as well as the potential negative effects of prolonged treatment (East *et al.* 2007).

Therefore, it is justified the need for controlled and randomised clinical trials to evaluate the effectiveness of applying an ice pack to relieve perineal pain after birth for 10, 15 and 20 minutes, which correspond to the application periods recommended by most of the studies.

Methods

This study is the second part of a two-stage study, with the first stage completed in 2008. It consisted of a controlled, parallel, randomised clinical trial, with the evaluator blind to the outcome regarding the use of an ice pack to relieve perineal pain after normal birth. During this first stage, the population was divided into three groups: experimental, which consisted of postnatal women who were administered an ice pack on the perineum for 20 minutes; placebo, in which a water pack at room temperature was used and control, which did not use the pack. The study concluded that use of the ice pack for 20 minutes was effective to relieve perineal pain after normal birth (Leventhal *et al.* 2011). The second stage composes this present study, which is a controlled clinical trial, which was randomised for two groups and used a third group as historical control (the experimental group of the aforementioned study), registered in the Australian New Zealand Clinical Trials Registry (ACTRN 12608000551392).

The study was conducted in the Rooming-in unit (RU) at a maternity hospital in the city of São Paulo, Brazil. This service is a reference hospital for low-risk pregnancies and uses active management of labour. Normal birthing assistance is provided by the nurse midwife or midwife. Episiotomy is selectively indicated and interrupted suture is performed using Catgut thread. Women are usually discharged within 48 hours after childbirth.

While the patient is admitted at the RU, routine medical prescriptions for normal postpartum care include an oral analgesic (500 mg dipyrone every eight hours) and an oral anti-inflammatory (50 mg diclofenac every eight hours) administered when complaints of pain persist. This service does not commonly use non-pharmacological treatment to relieve pain in the perineum region.

The study population consisted of postnatal women with normal birth admitted to the RU. The population was divided into three groups of women who used the ice pack on the perineum -group A, for 10 minutes; group B, for 15 minutes and group C (historical control) for 20 minutes. The icepacks were applied in a single instance, in the RU and when women were not breastfeeding. During the intervention, women were asked to undress the underpants, to remove the hygienic pads and to remain in the dorsal recumbent position.

The inclusion criteria were the same as those from the first stage of the study: full-term nulliparous women ≥18 years of age, with a live, cephalic presenting singleton foetus, with perineal pain ≥3 on a numerical scale at the time of inclusion in the study, within 2–56 hours after childbirth, not having received an analgesic in the last six hours, not having received anaesthesia or analgesia, not presenting any clinical or obstetric problems (including haematomas, haemorrhoids or perineal oedema); no communication or understanding comprehension difficulties and newborn in healthy condition.

To calculate sample size (n), we used the formula proposed by Rosner (2006). For a 60% decrease in the prevalence of pain, supposing a prevalence of perineal pain of 50% and a significance level of 5% and power of 80%, 38 postnatal women were assigned to each group.

The women were randomly assigned by a person outside the study, the same as the previous stage, using a randomised computer-generated table with 76 numbers, 38 per group. The numbers that assigned the group to each woman were placed inside an envelope that was numbered and sealed. The envelope was opened by the research assistant at the time the postpartum woman was included in the study. Group C was randomised during the first stage of the study, and the group consisted of postnatal women with application of an ice pack on the perineum for 20 minutes (Leventhal *et al.* 2011). Thus, the total number in the sample was 114 postnatal women, randomised at once.

The intervention consisted of cryotherapy sessions encompassing the application of an ice pack on the perineum or postnatal women with a normal birth for 10 minutes (group A), 15 minutes (group B) or 20 minutes (group C).

The main outcome was a 30% reduction of perineal pain, evaluated according to a numerical scale used by each postpartum woman, before and immediately after cryotherapy. The postnatal women were shown a drawing of the numerical scale ranging from zero (no pain) to ten (the worst imaginable pain) and asked to indicate the pain they felt. For Farrar *et al.* (2001), a two-point reduction on the numerical scale represented a significant clinical change in assessment of the intervention to alleviate pain, and corresponded to a 30% decrease in pain. The secondary outcome was considered a reduction in perineal temperature, which should have come to between 10–15 °C after 10–15 minutes of application of the ice pack.

Data collection for the second stage, which took place from July–September 2008, was aided by two assistants from the previous stage and by another nurse who was also trained, in addition to the author of the current study. The equipment, instruments and procedures used in the second stage were the same as those used in the first stage.

The temperature of the room or ward was measured using an ambient thermometer (model TA 60.02; Incoterm, Porto Alegre, Brazil). Perineal temperature and pack temperatures were verified every 20 minutes using a 2-channel digital thermometer (model MT 405; Minipa Company, São Paulo, Brazil), a surface probe (model MTK01; Minipa Company, São Paulo, Brazil) and a immersion-type probe (model MTk13; Minipa Company, São Paulo, Brazil), which remained inside the ice pack throughout the cryotherapy session to measure the temperature. A digital clock (model HR 102; Oregon Scientific, São Paulo, Brazil) was used to control application time of the ice pack.

The thermometer was calibrated prior to collecting the data. The device can measure temperatures between −50 and 200 °C, with a precision rate of 0·75% of the reading, or ±2·2 °C. The end of the surface probe was protected with plastic film, placed close to the base of the woman's right hip, affixed with Micropore™ close to 3 cm from the fourchette, horizontally perpendicular to the vagina. The probe remained in place between the ice pack and the perineum throughout the entire application.

The pack consisted of a plastic sack 7·5 cm wide by 22 cm long, filled with 250 ml of water, subsequently placed in the freezer for over three hours and removed at 10 °C negative. The pack was then wrapped in fine, cotton cloth, like a cloth diaper, measuring 20 × 20 cm, to avoid direct contact with the perineum. Each ice pack and diaper covering were used once and were discarded after use.

After consent and signing the consent form, the envelope with the randomised group was opened to identify the application time to which the postpartum woman would be submitted. Perineum and pack temperatures were taken every five minutes for all women. Data were collected in the following sequence: interview; initial assessment of the perineal pain; randomisation; reading of ambient temperature and body temperature; and reading of the length of the perineal trauma using the Peri-rule™; application of the ice pack, reading of perineum and ice pack temperatures; removal of ice pack and application of the numerical scale immediately following, 20 minutes thereafter and 40 minutes thereafter. No follow-up was carried out after the women's discharge.

Adherence of the quantitative variables to normal distribution was assessed using the Kolmogorov–Smirnov test. Non-parametric tests were used for variables that did not express normal distribution. The socio-demographic and clinical characteristics of the groups were compared in the beginning of the study using the Kruskal–Wallis test and the Chi-square test of association. In the comparison of the groups before and after the intervention, a two-factor analysis of variance was used, with one factor being the group (independent measure) and the other factor being the moment (before and after the intervention). The multiple comparisons were made using the Tukey HSD (honestly significant difference) test. All statistical analyses adopted the significance level of $p \leq 0{\cdot}05$.

The research project was approved by the Research and Ethics Committee of the School of Nursing of the University of São Paulo (FR128862). All women in the study participated voluntarily in the study and were included in the research only after signing the consent form.

Results

There were 1719 births during the study; of these, 1385 (80·6%) were normal deliveries, 330 (19·2%) caesarean sections and 4 (0·2%) forceps. The eligibility criteria yielded 103 of 862 women (12%) with registered perineal pain ≥3 between 2–56 hours following spontaneous birth; there was one case with no follow-up, in the Group B. This woman was discharged before the researcher could assess her perineal pain; therefore she was lost to follow-up. Twenty-six women refused to participate in the research. Thus, 76 women participated in the study, or 38 in each group. The data from group C (application of the ice pack for 20 minutes) refer to the first stage of the study and were used as historical controls for comparative purposes against groups A and B.

There was no migration of women among the groups. No women gave up on participating in the study during the intervention or pain measurements. The flow of participants is presented in Fig. 1. The data show the similarity of the groups in terms of sociodemographic variables and perineal condition. On the other hand, ambient temperature and perineal temperature differ among groups in the first assessment (Table 1 and Table 3 respectively).

In the three groups, most women had remunerated occupation (between 50·0–57·9% ($p = 0{\cdot}781$). The data also do not show any statistical difference between the mean of the following quantitative variables: mean number of hours from the birth to the entry into the study (20·1–24 hours, $p = 0{\cdot}526$); weight of live birth (3146–3268 g, $p = 0{\cdot}293$) and axillary temperature (36·5–36·6 °C, $p = 0{\cdot}918$).

The mean temperature of the ice pack in the three groups showed a decrease from the initial moment until approximately 10 minutes, holding practically steady after that time (Table 2).

Within-group comparisons of mean pain for the four assessments were made between the first and second, second and third, and third and fourth assessments using the Tukey test (Table 3) for all groups. Significant differences appeared

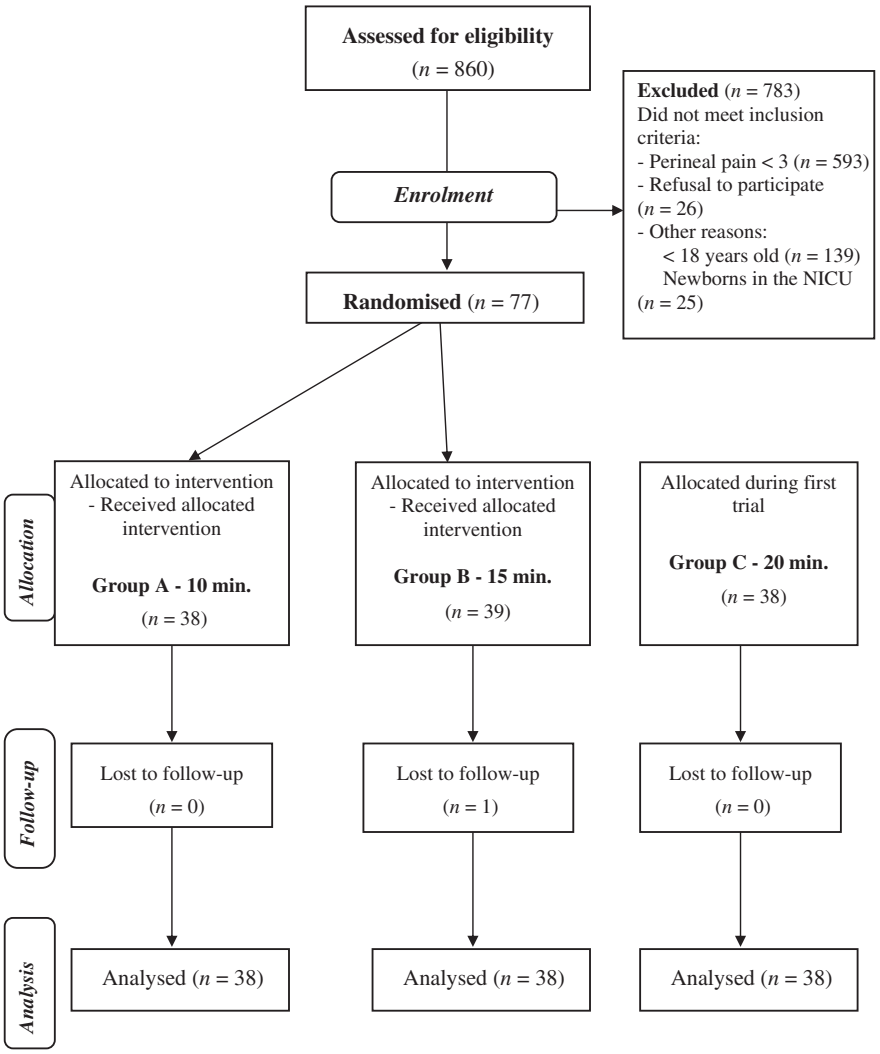

Figure 1 Consort diagram showing the recruitment of postpartum women and progression throughout the trial.

only in the first within-group comparison for all three groups. The other within-group comparisons revealed no statistical difference.

The three comparisons among the groups of mean pain following application of an ice pack also did not reveal any statistical difference (Table 3).

Only women in groups A and B (76 women) were asked about their satisfaction regarding treatment used. All postnatal women had a favourable opinion of cooling therapy, with 52·6% reporting such to be 'good' and 47·4% to be 'very good'.

The clinical criterion adopted in this study to establish an improvement in pain was a 30% decrease in the scores obtained with the numerical scale. Thus, pursuant to the numerical scale, the majority of the postnatal women reported pain relief (94·7%); of these, 83 (72·8%) reported a decrease in perineal pain greater than 50%, 25 (21·9%) between 30–50% and a mere six (5·3%) below 30% (Table 4). According to the Chi-square test of association, there was no significant difference among the groups, showing that application of the ice pack for 10, 15 and 20 minutes were equivalent to relieve the perineal pain.

Discussion

This study analysed the effects of an ice pack applied for 10, 15 and 20 minutes to relieve perineal pain after birth.

Until recently, studies focused merely on the pain experienced during childbirth. Postpartum pain was rather overlooked, as care during this stage focuses mostly on the newborn. Nevertheless, in recent years, a number of studies have been conducted to analyse morbidities resulting from perineal lesions after vaginal birth and to assess pharmacological and non-pharmacological treatments to relieve perineal pain. A systematic review carried out by Levitt *et al.* (2004) confirms these findings, identifying 671 studies concerning postpartum care.

Table 1 Sociodemographic characteristics, length of trauma and perineal temperature at trial entry

	Group (n = 114)						
	A (n = 38)		B (n = 38)		C (n = 38)		
Variable	n	%	n	%	n	%	p-value
Mean age (SD)	22·8 (4·9)		23·2 (4·8)		21·8 (4·0)		0·526*
Race							
Other	25	65·8	24	63·2	29	76·3	0·426†
Caucasian	13	34·2	14	36·8	9	23·7	
Education							
Illiterate and primary school	9	23·7	8	21·1	6	15·8	0·683†
Middle and high school	29	76·3	30	78·9	32	84·2	
Marital status							
Living together	28	73·7	32	84·2	29	76·3	0·510†
Living separately	6	15·8	5	13·2	4	10·5	
No companion	4	10·5	1	2·6	5	13·2	
Type of perineal trauma							
Intact and 1st tear	15	39·5	12	31·6	12	31·6	0·902†
2nd and 3rd tear	4	10·5	3	7·9	4	10·5	
Episiotomy‡	19	50·0	23	60·5	22	57·9	
Mean length of trauma (SD), cm	3·0 (1·5)		3·1 (1·5)		3·1 (1·4)		0·929*
Mean perineal temperature (SD), °C	31·1 (2·1)		31·6 (1·7)		32·7 (1·3)		**0·003***
Mean ambient temperature (SD), °C	19·8 (2·8)		20·0 (3·3)		27·1 (2·5)		**0·000***

*Kruskal-Wallis test.
†Chi-square test.
‡Includes right mediolateral episiotomy and medline.
Bold values: $p < 0.005$.

Table 2 Mean temperature (°C) of the perineum and ice pack at trial entry (T0) and at 5, 10, 15 and 20 minutes following the start of cryotherapy (T5, T10, T15 and T20)

		Perineum	Ice pack
Interval time (minutes)	n	Mean (SD)	Mean (SD)
T0			
Group A	38	31·1 (2·1)	1·9 (1·0)
Group B	38	31·6 (1·7)	2·1 (1·1)
Group C	38	32·7 (1·3)	3·8 (2·8)
T5			
Group A	38	17·6 (6·4)	1·1 (0·9)
Group B	38	15·9 (6·0)	1·2 (0·9)
Group C	38	18·7 (4·6)	2·6 (1·7)
T10			
Group A	38	13·3 (4·9)	0·6 (0·7)
Group B	38	13·7 (5·2)	0·6 (0·8)
Group C	38	15·3 (4·8)	2·3 (1·8)
T15			
Group A	38	–	–
Group B	38	11·3 (4·5)	0·6 (0·9)
Group C	38	13·7 (5·0)	1·9 (1·3)
T20*			
Group C	38	12·6 (4·8)	1·9 (1·5)

*Temperature measured only during the first stage of the study.

Table 3 Mean pain scores* and standard deviation (SD) at four evaluation interval times

Pain evaluation	Group A mean (SD)	Group B mean (SD)	Group C mean (SD)
1st (Before intervention)	5·2 (1·7)	5·4 (1·9)	4·6 (1·6)
p-value†	< 0·001	< 0·001	< 0·001
2nd Evaluation	1·6 (2·0)	0·9 (1·4)	1·6 (1·9)
p-value†	0·984	0·935	0·997
3rd Evaluation	1·5 (1·7)	1·1 (1·6)	1·5 (2·0)
p-value†	1·000	1·000	1·000
4th Evaluation	1·5 (1·8)	1·5 (2·0)	1·5 (1·9)

*Pain rated on a scale of 1–10, with 10 indicating the 'worst imaginable pain'.
†Tukey HSD test.
P-values refer to the results of the comparison between the 1st and 2nd evaluations, between the 2nd and 3rd evaluations and between the 3rd and 4th evaluations, in each separated group.

An initial comparison among the groups reveals the following variables to present statistical difference: ambient temperature, initial temperature of the perineum and perineal pain. The ambient temperature of group C was the highest, averaging 27·1 vs. 19·8 and 20 °C for groups A and B, respectively. This fact is owed to the collection of data during

Table 4 Percentage reduction of perineal pain immediately after intervention

	Group A (n = 38)	Group B (n = 38)	Group C (n = 38)	
Pain evaluation*	n (%)	n (%)	n (%)	Total
Improved > 50%	29 (76·3)	32 (84·2)	22 (57·9)	83 (72·8)
Improved 30–50%	6 (15·8)	6 (15·8)	13 (34·2)	25 (21·9)
Improved < 30%	3 (7·9)	–	3 (7·9)	6 (5·3)

*p = 0·066 (Chi-square test).

the first stage to have occurred in the summer (January and February), while data collection for the second stage took place in the winter (between July–September), with the lowest temperature recorded as 16 °C.

This study shows that the mean initial perineum temperature for group A and group B was statistically lower than that of group C. This difference owes itself to exposure to the cold ambient temperature. According to Knight (2000), some studies confirm that the reduced ambient temperature resulted in a decrease in the surface temperature of the body's extremities.

Studies that use cryotherapy to relieve perineal pain do not mention skin temperature prior to application of cold; hence, comparison data are missing to evaluate our results.

A reduction in the perineum temperature was observed in the three groups after 10 minutes of applying ice. This datum is compatible with the physiological responses described by Palastanga (1994), which confirms the occurrence of intense and immediate cooling of the surface tissue, with a drop of 15 °C within two to five minutes, when this therapy is used. On the other hand, this same author stresses that the deepest tissues show a small decrease in temperature by about 5 °C, which can take up to 20 minutes, with the temperature decreasing even slower if there is a thick layer of subcutaneous fat. Therefore, many of the results of cooling are a consequence of the effects to the skin and other surface tissues.

The benefits of the cooling may be reduced depending on the skin protection used upon application of the ice pack. A systematic review shows that, for analgesia to occur, the temperature of the skin must be between 10–15 degrees Celsius (Mac Auley 2001). LaVelle and Snyder (1985) analysed the effect of the protection barriers most used and found that, 30 minutes after application of the ice pack between 0–0·5 °C on the ankle, the mean temperature was 30·5 °C using a cushioned bandage, 20·5 °C using just a bandage, 17·8 °C using a try towel, 10·8 °C with no barrier and 9·9 °C with a moist towel. In a study of the different types of cryotherapy application, Kanlayanaphotporn and Janwantanakul (2005) found that, after 20 minutes of cooling, the temperature had decreased to 13·9 °C with a gel pack, 14·4 °C with crushed ice, 10 °C with a mixture of gel and alcohol and 10·2 °C with the application of an ice pack. All forms of cooling were wrapped in a 100% cotton towel that had been soaked in water at room temperature. The temperature of 10·2 °C found with application of the ice pack in this study was less than the temperatures of the perinea in our work, which ranged from 11·3–13·3 °C.

We found no studies reporting ulcerations from the cold as a result of applying ice for a short period, 30 minutes (Knight 1995). In this study, no negative effect was found as a result of application of the ice pack on the perineum.

To assess the temperatures of the ice pack, we used an immersion probe that remained inside the packs throughout application. The data reveal that temperatures decreased slowly for about 10 minutes, at which point they remained practically constant. In group A, the mean temperature at the beginning of application was 1·9 °C, decreasing to 0·6 °C after 10 minutes; in group B, the temperature decreased from 2·1–0·6 °C in the same 10-minute interval and in group C, the initial temperature recorded was 3·8 °C, decreasing to 2·3 °C after 10 minutes. This shows that the pack, despite heat transfer, remained cool, even in the summer, which was when the data for group C were collected.

Few studies cite the temperature of the cooling methods used. The study performed by Ramler and Roberts (1986) used a cold sitz bath at 15·6–18·3 °C for 20 minutes. LaFoy and Geden (1989) also used a sitz bath, although the water temperature was kept at 0 °C, and the duration of the application was 15 minutes, administered between 6–24 hours postpartum. Meanwhile, Hill (1989) used an ice pack at 33°F (0·5 °C) for 20 minutes in the first 24 hours postpartum.

The mean scores for perineal pain prior to intervention (first assessment) differed among the groups, with the highest mean reported in groups A and B (5·2 and 5·4, respectively) and the lowest mean in group C (4·6), although all within the statistical significance limit (p = 0·049). Despite the statistical difference, in clinical practice, these values can be considered equivalent and correspond to moderate pain. Those studies that involved cold therapy to treat perineal pain used different scales to measure complaints of pain. One of the few studies to report on the intensity of perineal pain prior to intervention was that of LaFoy and Geden (1989), which used the visual analogical scale (0, 25, 50, 75 and 100 points). This study revealed that, of the 20 women, 13 reported a pain score of 25 (light), five postnatal women reported a pain score of 50 (moderate) and only two reported a pain score of 75 (intense); none reported a pain score greater than 75.

Steen *et al.* (2006) conducted a review of the use of cold in perineal trauma, to identify types of cooling methods used, analysing the efficacy of these therapies in relation to reducing the level of perineal pain, interfering in the inflammatory response, in the healing process and in maternal satisfaction. The authors conclude that there still is not enough evidence as to which cooling method is most effective; nevertheless, cold treatments do decrease pain and the inflammatory response and that the woman's preference should be taken into consideration.

A between-group comparison for pain reporting from the first to second assessment (prior to and after intervention) revealed a significant difference for the three groups, that is to say the ice pack decreased perineal pain for all postnatal women. There was no statistical difference among the pain measurements for the three groups just after application of the ice pack, with equivalence among them in terms of promoting the relief of perineal pain.

Likewise, a between-group comparison for pain reporting from the second to third assessment and from the third to fourth assessment did not reveal significant differences in any of the groups, which confirms that the analgesic effect remained in place for 40 minutes after the intervention.

The groups A and C reported a slight decrease in pain measurements 20 minutes after completion of the cryotherapy, although this did not present a statistical difference. These findings partially confirm those claimed by Droegemuller (1980) that cryotherapy continues to provide a partial anaesthetic effect for 30 minutes following completion.

All women expressed satisfaction with perineal ice application, and the majority considered the treatment very good. Similar results were found in a randomised clinical trial conducted in northern England that compared two types of cooling (ice pack and gel pack) with a non-treatment group. The study included 316 postnatal women with spontaneous and assisted birth. Pain was assessed using a four-point scale. Significant differences were found between the groups in terms of pain reported after five and 10 days, with pain assessed as lower in the gel group. The participants' satisfaction rate was statistically greater in the gel group (93%) than in the other two groups (ice pack: 76% and no treatment: 84%) (Steen & Marchant 2007). In our study, 52·6% of the women considered application of ice on the perineum to be good, and 47·4% stated it was very good. On the other hand, research conducted by Steen *et al.* (2000) found that only 27% of postnatal women rated the procedure as good or very good.

While woman may assess this treatment positively, refusal to accept ice application on the perineum must be taken into consideration. In the Leventhal *et al.* (2011) study, three women refused to participate, and in this study, 26 did not want to participate; many alleged that the ambient temperature was very cold and that they would feel uncomfortable with the intervention. LaFoy and Geden (1989) showed that, of the 27 women who met the inclusion criteria, seven refused to participate in the study. The refusal to this study may be a result of the cooling techniques used, which was a sitz bath, in other words the women would have had to sit in an appropriate bath, cooling not only the perineum region, but also the vulva, buttocks and surrounding areas. The use of localised cooling devices seems to be the method most accepted by women (Steen *et al.* 2006).

This study found that there was no significant difference among the three groups, showing that applying the ice pack for a duration of 10, 15 and 20 minutes provided similar results in terms of relieving perineal pain. The group C reported lower percentages for pain relief, although the difference is not statistically significant. The justification for this difference could be that, at the beginning of this study, this group of women reported lower mean perineal pain.

The first stage of this study compared the effectiveness of an ice pack applied for 20 minutes (historical control) to a water bag at ambient temperature (placebo group) to a no-treatment group (control group) as an intervention to relieve perineal pain. It found a significant decrease from mean pain reported initially to that reported following intervention in all three groups ($p < 0{\cdot}001$). The women expressed an improvement in perineal pain in all groups, including the group that did not receive any treatment (Leventhal *et al.* 2011). This may be due to the fact that people demonstrate a tendency to change their behaviour when they receive special attention and know that they are an object of interest, regardless of the nature of the intervention they receive. This phenomenon is known as the Hawthorne effect (Fletcher & Fletcher 2005).

One limitation of this study was the fact that neither the study assistants nor the women studied were blinded on account of the type of treatment applied. Nevertheless, the participants were not informed of the randomised group to which they had been assigned, in other words, they did not know the length of the ice pack application. Moreover, the use of analgesics by the women was not assessed as an outcome of the intervention and there was no possibility for follow-up for women during the postpartum period.

Conclusion

This study assessed the time of a single application of an ice pack to relieve perineal pain during the first 56 hours following normal birth, taking into consideration application times of 10, 15 and 20 minutes. The results confirm the

hypothesis that there is no difference in the analgesic effectiveness of the ice pack applied for the three different application times on women who report moderate or intense pain. The results showed that all postnatal women submitted to cryotherapy responded favourably despite the high number of women who refused to participate in the study.

Relevance for clinical practice

This study investigated a clinical practice that could provide relief for perineal pain following birth without producing side effects or interfering in breastfeeding. The use of an ice pack for 10 minutes is sufficient to relief complaints of pain. Pragmatic elements of reality (routine use of analgesics in the postpartum period) strengthened the external validity of the results, increasing the possibility of applying these findings to clinical practice.

Implications for medical practice include the affirmation that ice treatment is safe and that the application of an ice pack for 10 or 15 minutes is as of benefit as application for 20 minutes to relieve perineal pain, although the individual needs of each women should be taken into account. Further studies are necessary to assess the duration of the analgesic effect to determine the frequency of application. Moreover, this procedure does not produce side effect and does not interfere in breastfeeding.

Acknowledgements

This research was funded by the Research Support Foundation of the Sao Paulo state (FAPESP), Brazil.

Contributions

Study design: SMJVO, MRCN; data collection and analysis: SMJVO, MRDOL and manuscript preparation: SMJVO, FMBS, MLGR.

Conflict of interests

The authors have no conflicts of interest to disclose.

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