# **ARTICLE IN PRESS**

Women and Birth xxx (2017) xxx-xxx



Contents lists available at ScienceDirect

## Women and Birth



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

#### Original Research - Quantitative

### Ice pack induced perineal analgesia after spontaneous vaginal birth: Randomized controlled trial

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#### ARTICLE INFO

Article history: Received 26 January 2017 Received in revised form 15 December 2017 Accepted 22 December 2017 Available online xxx

Keywords: Perineal pain Postpartum period Cryotherapy Perineal trauma

#### ABSTRACT

*Background:* Ice-pack is widely used for alleviating postpartum perineal pain sustained after birth related perineal trauma. However, it lacks robust evidence on timing and frequency of applications, to ensure the effective and safe use of this therapy.

*Aims:* To evaluate if a 10 min ice-pack application relieved postpartum perineal pain and if the analgesic effect was maintained for up to 2 h.

*Methods:* A randomised controlled trial conducted from December 2012 to February 2013 with 69 primiparous women  $\geq$  18 years old, 6–24 h postpartum, with perineal pain  $\geq$  3, who had not received anti-inflammatory medication or analgesics after childbirth, who were randomised to a single ice-pack application on the perineum for 10 min or standard care. The primary and secondary outcomes were a reduction  $\geq$  30% in perineal pain intensity, immediately after the application and the maintenance of the analgesic effect for up to 2 h, respectively.

*Findings*: Immediately post-intervention, the proportion of women whose perineal pain decreased  $\geq$  30% was significantly higher in the experimental group. Within 2 h, there was no significant difference in the pain levels in both groups. Within 2 h, for 61.9% and 89.3% of women in the experimental and control group, respectively, the perineal pain levels remained unchanged. For the remaining participants, perineal pain was increasing after an average time of 1 h 45 min and 1 h 56 min for the experimental and control groups, respectively.

*Conclusion:* By applying an ice-pack for 10 min to the perineum, effective pain relief is achieved, that is maintained for between 1 h 45 min and 2 h.

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#### Statement of significance

#### Problem or issue

Ice-pack is an effective intervention for relieving postpartum perineal pain, but it lacks robust evidence on timing and frequency of applications.

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#### https://doi.org/10.1016/j.wombi.2017.12.011

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#### What is already known

Ice-pack is a non-pharmacological, non-invasive, low cost intervention widely used in midwifery. Ice-pack is frequently applied for 20 min, but knowledge is needed on the effect of applications shorter than 20 min for pain relief and duration of the analgesic effect.

#### What this paper adds

A single ice-pack application for 10 min to the perineum alleviates pain effectively from 1 h 45 min to 2 h and may reduce the need for oral analgesia to achieve adequate pain relief.

Please cite this article in press as: A.A. Francisco, et al., Ice pack induced perineal analgesia after spontaneous vaginal birth: Randomized controlled trial, Women Birth (2018), https://doi.org/10.1016/j.wombi.2017.12.011

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A.A. Francisco et al./Women and Birth xxx (2017) xxx-xxx

#### 1. Background

Birth-related perineal trauma, which is sustained by an episiotomy, spontaneous lacerations or both, is frequently associated with vaginal birth. Perineal trauma mainly affects primiparous women<sup>1,2</sup> and they are three times more likely to have an episiotomy compared to multiparous women.<sup>3</sup>

Perineal trauma can increase maternal morbidity in the postnatal period, which can impact negatively on physical and emotional women's health in the short and long term. Acute perineal pain is a major symptom after perineal trauma and its presence and intensity are directly related to perineal trauma severity.<sup>4–6</sup> However, even women with an intact perineum may also experience perineal pain due to the birth process.<sup>4</sup>

Perineal pain affects many women worldwide. In Brazil, between 18.5% and 92.3% of mothers reported perineal pain in the early postnatal period.<sup>7,6</sup> In Australia, approximately 90% of women reported perineal pain within 72 h after a vaginal birth.<sup>4</sup> In the UK, perineal pain was present in 96.7% of women immediately postpartum, 43.9% at six weeks and 17.8% at one year.<sup>8</sup> In the United States, a survey conducted with 2400 women found that among 1656 mothers who had vaginal birth, 40% of them reported perineal pain in the first two months after childbirth. Within six months, perineal pain was reported as a persistent problem, which made performing daily living activities difficult.<sup>5</sup>

#### 2. Literature review

Cryotherapy (ice pack application) is a non-pharmacological, non-invasive, low cost therapy, which reduces local tissue temperature.<sup>9,10</sup> This localised method results in an anti-inflammatory effect that consequently leads to less local oedema and pain.<sup>11</sup> Although the physiopathology of cryotherapy is not clear, the local cooling results in central and peripheral responses that include: vasoconstriction reduction of cellular metabolism, oedema prevention, a brief increase followed by reduction of pain intensity and a decrease of muscle spasm.<sup>9</sup>

Ice pack is a widely used therapeutic procedure in Brazilian maternity care, especially when perineal trauma, oedema and haematoma occur after vaginal birth. In the United Kingdom and Australia, two studies on methods for pain relief have also identified the ice pack as being the second most widely used method of health professionals for perineal pain management, after oral analgesia.<sup>4,12</sup> Ice pack is usually easy and safe to apply, however excessive and prolonged exposure to cold can lead to adverse effects such as cold burns and ulcerations.<sup>9</sup> Therefore, the duration and the interval of ice pack applications are important parameters to consider when including this therapy in the care plan.

Although, a Cochrane systematic review concluded that ice pack application for 10–20 min is an effective method for postpartum perineal pain relief from 24 to up to 72 h after vaginal birth<sup>13</sup>, further investigation is required to assess the duration of adequate pain relief for the various levels of perineal trauma, maternal satisfaction and healing.

In sports injury management, cryotherapy sessions last from 20 to 30 min, but applications for 30 min or 40 min for large muscle masses, every 2 h or every hour if the patient is active between applications, have been recommended as the optimal length and interval of cooling.<sup>9</sup> On the other hand, there is some evidence that cooling for 10 min every 2 h is the optimal protocol for reaching the therapeutic levels of cryotherapy without adverse effects.<sup>14</sup> Therefore, the aim of this study was to evaluate if a ten minute ice pack application relieved postpartum perineal pain and if the analgesic effect was maintained for up to 2 h.

#### 3. Methods

#### 3.1. Design

This is a parallel, single blinded, randomised controlled trial (RCT).

#### 3.2. Study setting

This trial was conducted in the rooming-in unit (RU) of a midwife-led alongside, non-profit birth centre, Sao Paulo City, Brazil. In this birth centre, assistance during labour, childbirth and the postpartum period is provided by nurse-midwives. Perineal management during childbirth varies according to the midwife that provides the care. If perineal repair is required, it is preceded by a local anaesthetic administration and performed using conventional transcutaneous sutures (vaginal mucosa with continuous locking stitches, muscle and skin edges with interrupted stitches). First and second-degree tears are repaired using size 2–0 and 0 simple catgut thread, respectively.

Two hours after giving birth, postnatal care is provided at the rooming-in unit and usually within 48 h of childbirth, healthy women and their newborn baby are discharged home. Medicines to treat pain are routinely provided for all women: Metamizole (Dypirone<sup>TM</sup>, 500 mg administered orally every 6 h) – an analgesic widely used in South America and Diclofenac (Voltoral<sup>TM</sup> administrated orally every 8 h).

However, during the undertaking of this study these drugs were not routinely administered in order to control for any localized or systemic inflammatory effect.

#### 3.3. Participants

We included in this RCT women with a full-term pregnancy (37–42 weeks),  $\geq$ 18 years of age, with no previous vaginal birth, within 6–24 h following a spontaneous vaginal birth of a singleton live foetus in cephalic presentation, with perineal pain  $\geq$  3 points on the numeric rating scale (NRS), with intact perineum or perineal trauma, with no 3rd or 4th degree laceration, oedema or haematoma in the perineal region. Additional inclusion criteria were the women not receiving anti-inflammatory drugs or cryotherapy after giving birth and analgesic medication up to three hours prior to recruitment to the study. Women who had received analgesic medication up to two hours after being included in this study were excluded.

#### 3.4. Data collection

Recruitment and data collection were performed in the RU on a daily basis, by the first author, who recruited the participants, implemented the random allocation and applied the intervention, and by a research assistant (MHK), who assessed the outcomes (perineal pain levels immediately after and 2 h after the intervention), according to the following steps: a structured interview, an initial assessment of perineal pain presence and intensity, measurement of ward environment temperature, body and perineal temperature, intervention and then further assessments of pain. Perineal pain occurrence was investigated by the question: "Do you feel pain in the perineum region right now?". If the answer was "yes", the participants rated their pain intensity by pointing to the NRS from 0 to 10 (0 = no pain and 10 = worst pain imaginable).

We considered as pain when a woman has reported the following sensations: pain, sore, aching, burning, pinching and discomfort in the perineum.<sup>15</sup> Women who reported perineal pain intensity  $\geq$ 3 were included in this study and randomly assigned to the control or experimental group.

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