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Research Article

Effectiveness of Single -Use Hot Pack on Labour Pain, Duration of Labour, and Satisfaction of Primigravidae: A Randomised Controlled Trial

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Abstract

Background: Labour pain is a highly individualized experience. Although heat influences labour pain, duration and maternal satisfaction, evidence on the effectiveness of single-use instant hot packs is scarce.

Objectives: To examine the effect of hot pack applied on the lower back of primigravid women in the active phase of labour on pain intensity and labour duration and to determine satisfaction with the labour and delivery experience.

Methods: A randomised controlled trial was conducted in Armed Forces Hospital with primigravidae in the active phase of labour. Participants were randomly selected and assigned to the intervention group (n = 45) and the control group (n = 46). The intervention group received an application of hot pack on the lower back for 30 min, followed by rest for 10 min; the cycle was continued until birth of the baby. The control group received routine care, that also included intermittent Entonox inhalation.

Finding: Of the 91 women, those who received hot packs had significantly lower labour pain intensity score at all assessment points (30, 60, 90, 120, 150, and 210 min) than women in the control group ($p<0.05$). The duration of labour did not differ significantly between the two groups ($p>0.05$). The intervention group had significantly higher satisfaction scores with the labour and delivery experience than the control group ($p<0.05$).

Conclusions: The application of hot pack is an effective nonpharmacologic method for reducing pain intensity during labour and provides women an overall satisfactory labour and delivery experience although ineffective in shortening the duration of labour.

Key words: heat therapy; hot packs; labour pain; duration of labour; satisfaction

1. Introduction

Labour pain is a highly individualized experience, and its role has been established [1]. Described as the most significant source of discomfort for women in labour, the perception of pain is highly variable [2] and often exceeds endurance levels. Pain, one of the key elements of childbirth fear[3], is a common concern of first-time mothers [4]. To ensure a satisfying childbirth experience, effective pain control is critical [5]. If inappropriately managed, pain can adversely affect both the woman and her fetus [6] and influence the labour and delivery experience. Pain relief gives women control and enables them to participate in the childbirth experience [7]. Most women prefer to use pain relief measures during labour. More than half (60%) of the women surveyed in a Saudi Arabian study, expressed their preference for pain relief measures [8]. Both, pharmacological and non-pharmacological measures to relieve labour pain are available. Nitrous oxide (N_2O) is among the widely used pharmacological measures, although evidence regarding it's analgesic effect is limited [9]. Most studies comparing it with other agents shows heterogeneous results regarding its effect on labour pain relief [10,11,12]. Although pharmacologic measures are known to have maternal and fetal side effects [13], it is used in most

settings. Some women routinely ask for intermittent Entonox inhalation and discontinue its use abruptly on experiencing side effects.

Increasing number of women seek non-pharmacological interventions of pain relief because of the minimal side effects compared to medications and other therapies [14]. Evidence shows that heat reduces labour pain intensity. Heat works on the principle of the gate control theory of pain. Melzac and Katz (1994), as cited [15], It increases blood flow, tissue metabolism, and connective tissue elasticity, leading to inhibition of the pain receptors' transmission to the brain. It stimulates heat receptors in the skin and deep tissue, causing the impulses to balance themselves at the spinal cord, thereby closing the gate of pain impulses from reaching the brain [16]. When calcium channels in the spinal cord are activated, pain receptor activity is inhibited [17]. Evidence shows that warm compresses [18,19], hot water bottles [20], warm bags [21], and warm showers [7,22,23] applied to different body sites were effective in reducing labour pain. However, a systematic review concluded that the evidence on pain relief was of very low uncertainty, stating that only three of the trials were of good quality [24].

Although heat increases uterine contractility and may shorten the duration of labour, there is lack of evidence about it's effectiveness [25] with most studies reporting inconsistent findings. In a comparison with routine care, author reported significantly shorter duration of the first and third stages of labour on applying heat to the lower back for 80 min and to the perineum for 5 min, with no difference in the second stage of labour [26]. Researchers found no difference in the duration of labour although it was effective in pain relief [21]. Although some studies had robust methodology such as clinical trials [17,19,22,26], others lacked randomization [19], resulting in inconsistent findings. For women to experience a meaningful childbirth experience, it is essential to manage labour pain. Women who experience less labour pain have higher satisfaction with the labour experience [3,27]. Further, a shorter duration of pain and suffering, has an influence on the satisfaction with childbirth experience [19].

Although a variety of pain relief methods are used, pain management during labour remains a serious topic for obstetricians and midwives alike [16]. There is limited use of non-pharmacological pain relief measures in Saudi Arabia because of the specific regulations and policies of the hospitals, lack of knowledge among health care providers, and women's unwillingness to use nonpharmacological treatments [28].

Midwives play a crucial role in providing comfort to women in labour. Assessing the physical and emotional state of women and helping them cope with pain are important aspects of caring [29]. Effective pain management encourages women to seek normal vaginal delivery and to have a positive and satisfying childbirth experience. Single-use hot packs tends to be simple and easy for women to use and the can still maintain control during labour. It does not require intense training for nurses to use it for pain management. Although heat may reduce pain and may have an effect on the duration of labour, the effectiveness of single use hot packs is not known. Heat from the hot pack is generated by squeezing it between the palms of the hand to activate the prefilled magnesium sulphate and water. Therefore, we examined the efficacy of instant single-use hot packs during active phase of first stage of labour in reducing labour pain intensity and labour duration in comparison with routine care. We also examined the satisfaction of the women with the labour and delivery experience.

2. Methods

2.1 Study Design

We conducted this randomised controlled trial between August 2018 and July 2019. Participants were randomised to one of two arms: an intervention group (single-use instant hot packs; Dynarex) and a control group (routine care, including the use of intermittent Entonox inhalation).

2.2 Participants and setting

Participants were recruited by the first author from the labour and delivery unit of Armed Forces hospital, Southern Region. Women were included in the study if they met the criteria: primigravid, had normal onset of labour after a normal term pregnancy (>37-42 weeks of gestation), in the active phase of the first stage of labour with 6-8 cm cervical dilatation. Women were excluded if they had fever, skin infection, eczema, injury or inflammation of the back, bleeding, deep vein thrombosis, edema, other high risk complications, medical conditions, decreased fetal movement, intrauterine growth restriction, intrauterine fetal death, and history of infertility.

Using G power software (version 3.0.10), we calculated the sample size using two-tailed tests. A total of 90 participants, with 45 participants per arm, was required to achieve a power of 80% with an error probability of 5% and an effect size of 0.3. We assessed eligibility of 138 participants: assuming approximately 10% attrition rate, we recruited 100 participants. Initially, 50 participants were randomly allocated to intervention group and an equal number in the control group. Five participants were excluded from the intervention group because of emergency caeseran section (CS), (n = 3), Entonox administration on request (n = 1), or received an injection of pethidine (n = 1). In the control group four participants were excluded because of emergency CS (n = 2) or induction of labour (n = 2). The final sample consisted of 91 participants, with 46 in the intervention group and 45 in the control group. The consort flow diagram in Figure 1 presents the participants' passage through each group.

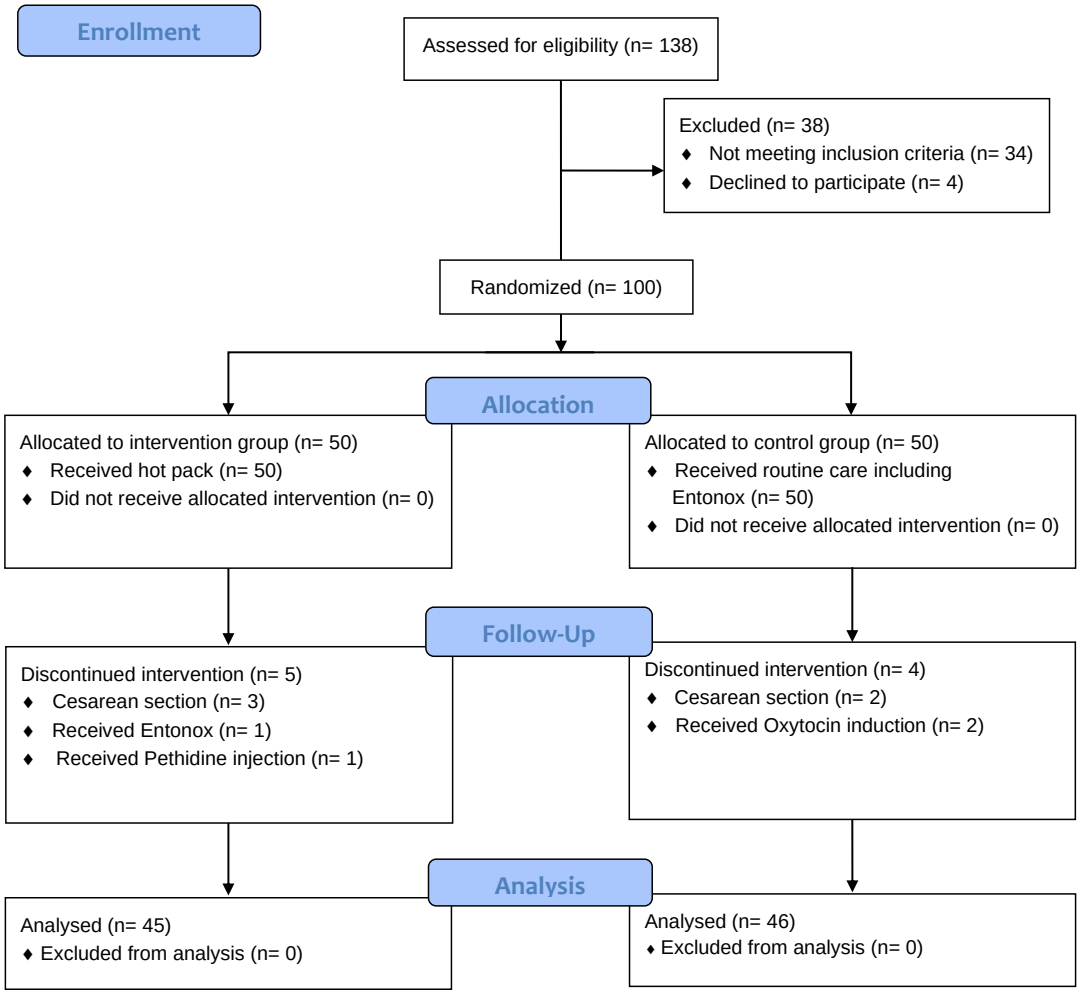

Figure 1: CONSORT flow diagram. Participants' passage through each group.

2.3 Randomisation

The hospital records were assessed to determine the eligibility of the women to participate; they were randomly allocated to the intervention group (single-use instant hot pack) or control group (routine care including use of intermittent Entonox) using a computer-generated block randomisation sequence that involved a block size of two. Blinding was not possible due to the nature of the intervention.

2.3.1 Intervention

The intervention consisted of application of single-use hot packs on the women's lower back for 30 minutes followed by 10 minutes period of rest, and the cycle was continued until delivery. The hot pack (Dynarex, first voice, disposable instant hot pack measuring 5x9 inches, that contained magnesium sulfate and water had approval from the US Food and Drug Administration). It was activated by squeezing it from the outer edges toward the center and applying friction with the palms of the hands. To ensure intervention fidelity, the temperature of the physical environment was maintained between 22°C and 24°C.

2.3.2 Control

The control group received routine care that included monitoring of general well-being, uterine contractions, vaginal examination, cardiotocography monitoring, intravenous fluid administration, oxygen administration if needed, enema, catheterization, and appropriate nursing care. As per the protocol of the labour and delivery unit, women received optional intermittent Entonox inhalation for labour pain management. Entonox consisted of premixed 50% oxygen and 50% nitrous oxide in a cylinder and was inhaled via a facemask. The women took a deep breath via Entonox mask during contractions to breathed normally without Entonox between the contractions. [11] Women in the control group were observed by the researcher until birth.

2.4 Ethical considerations

The Research ethical committee of Armed Forces Hospital, Southern Region approved the study on April 2018 (H-06-KM-001). Administrative approval was provided by the Head of the Labour and Delivery Unit. Written informed consent was taken from participants, who also had the right to withdraw

without consequences. Confidentiality and privacy were maintained throughout the study.

2.5 Data collection

Eligible women who were randomly allocated to the intervention group received verbal information about the hot pack application, the voluntary nature of the study and the right to withdraw without any consequences and they signed the consent form. At baseline, demographic data that included maternal age, education, employment status, family type, family income, and physical characteristics (height and weight) were collected through interview. Obstetrical data that included gestational age, characteristics of uterine contractions, and cervical assessment were gathered from the participant's hospital records and entered in a record analysis sheet [11,20,28].

The outcome measure labour pain intensity was assessed using the visual analogue scale (VAS) for pain intensity and the duration of labour was assessed with the partograph [31]. The extensively used valid and reliable VAS consists of a horizontal line with a marking 0 cm (*no pain*) to 10 cm (*worst or intolerable pain*). Participants assigned scores on the VAS based on their perception of labour pain intensity at baseline then every 30 minutes intervals until the delivery. The test–retest reliability (0.71–0.94) and a correlation coefficient (r=0.79–0.96) when compared with common pain measures [32] provided evidence of the scale reliability. The WHO-modified partograph has graphical information of fetal condition, progress of labour, and maternal condition: fetal heart rate, liquor, cervical dilatation, descent of the presenting part, and uterine contractions. The duration of labour was computed using the data from the partograph [33]. The satisfaction of the women with the labour and delivery experience was measured 2 hours after delivery using an author-developed, 13-item, five-point Likert-type Labour and Delivery Satisfaction Scale (LDSS). Responses were rated as 1 = *very dissatisfied*, 2 = *dissatisfied*, 3 = *neither satisfied nor dissatisfied*, 4 = *satisfied*, and 5 = *very satisfied.* The score ranged from 13–65, with a higher score indicating greater satisfaction. Items were developed based on literature and specifically consulting a previous study [34]. Five experts (four faculty with maternity nursing specialization and one clinical practitioner with an obstetrical and gynecology specialty) validated the English version of the scale. Items were retained if 80% of the experts agreed on the relevance. After modification, it was translated to the Arabic language and back-translated to English by a language expert to ascertain language validity. After pretesting the instrument, two items were modified to improve clarity. The scale was reliable (alpha = 0.846). Participants took 5 minutes, on an average, to complete the scale. One item, "Overall satisfaction," gave participants the opportunity to provide a global rating of their satisfaction. They did not respond to the open -ended item "any other comments."

The control group received routine care that also included optional Entonox inhalation. All measurements were done similar to that of the intervention group. Prior to data collection, a pilot study on a different sample of 10 women ensured feasibility of the study.

2.6 Statistical analyses

Data were analysed using IBM Statistical Package for Social Sciences (version 20.0). The frequency and percentage for categorical data and the mean and standard deviation for continuous variables were computed. Independent *t* tests were used to analyse normally distributed continuous variables. Mann–Whitney *U* and Fisher's exact test were applied to data that were not normally distributed. A two-tailed *P* value was set at an alpha level of 0.05 and confidence interval was computed.

3. Results

3.1 Baseline characteristics of participants

A total of 100 women were randomly allocated at first; 50 each in the intervention and the control groups. Five women from the intervention group and four women from the control group were excluded because of attrition (n=9, attrition rate =9.9%). Finally, 45 women from the intervention group and 46 from the control group were included in the study. No statistically significant difference was observed in the demographic and obstetrical data when the two groups were compared at baseline ($p > 0.05$) Table 1 presents the findings.

Variables	Total (n=91)	Intervention group (n=45)	Control group (n=46)	*P* value
Maternal age (y), mean (SD)	25.4 (4.64)	25.2 (4.27)	25.5 (5.01)	0.778[b]
Educational level, no. (%)				
≤ High school	44 (48.4)	25 (55.5)	19 (41.3)	0.104[a]
Graduate	47 (51.6)	20 (44.4)	27 (58.7)	
Employment, no. (%)				
Yes	3 (3.3)	2 (4.4)	1 (2.2)	0.617[a]
No	88 (96.7)	43 (95.6)	45 (97.8)	
Family income (SR);1 SR = 3.75 $US), no. (%)				
< 5000	7 (7.7)	6 (13.3)	1 (2.2)	0.122[a]
5000–10000	65 (71.4)	31 (68.9)	34 (73.9)	
>10000	19 (20.9)	8 (17.8)	11 (23.9)	
Height (cm), mean (SD)	153.7 (5.85)	153.9 (5.48)	153.6 (6.23)	0.779[b]
Weight (kg), mean (SD)	66.3 (10.9)	65.7 (10.6)	66.9 (11.3)	0.610[b]
Gestational age (w), mean (SD)	38.8 (1.03)	39.0 (.929)	38.7 (1.10)	0.191[b]
Uterine contraction				
Frequency, no. (%)				0.386[a]
≤ 3 in 10 min	73 (80.2)	34 (75.6)	39 (84.8)	
4–5 in 10 min	18 (19.8)	11 (24.4)	7 (15.2)	
Intensity, no. (%)				0.347[a]
Moderate	43 (47.3)	19 (42.2)	24 (52.2)	
Strong	48 (52.7)	26 (57.8)	22 (47.8)	
Duration (sec), mean (SD)	57.2 (7.06)	56.6 (6.30)	57.6 (7.76)	0.499[b]

Interval (min). mean (SD)	2.00 (.494)	1.98 (.543)	2.02 (.447)	0.674[b]
Cervical assessment				
Dilatation (cm), mean (SD)	6.62 (.928)	6.67 (.953)	6.61 (.930)	0.770[b]
Effacement (%), mean (SD)	77.4 (7.58)	76.4 (7.73)	78.2 (7.39)	0.255[b]
Presenting part station, no, (%)				0.138[a]
(- 3)	22 (24.1)	14 (31.1)	8 (17.4)	
(- 2)	48 (52.8)	23 (51.1)	25 (54.3)	
(- 1)	14 (15.4)	5 (11.1)	9 (19.6)	
(0)	7 (7.7)	3 (6.7)	4 (8.7)	
Membranes' status, no, (%)				0.414[a]
Intact	19 (20.9)	11 (24.4)	8 (17.4)	
Ruptured	72 (79.1)	34 (75.6)	38 (82.6)	

Abbreviation: (n) Sample size, (y) Years, (SD) Standard Deviation, (%) Percentage, (SR) Saudi Riyals, (cm) Centimeter, (kg) Kilograms, (w) Weeks, (sec) Seconds, (min) Minutes.

[a]Fisher exact test.

[b]Independent-samples *t* test, $p \leq 0.05$

Table 1. Comparison of baseline characteristics between intervention and control group

Among the 91 women who completed the study, the mean age was 25.4 (SD = 4.64) years, and 51.6% had a college education. Most of them (96.7%) were unemployed, and 71.1% had a monthly family income of 5000–10000 Saudi Riyals (approximately one Saudi Riyal = 3.75 $US). The mean gestational age of the women was 38.86 (SD = 1.03) weeks; most (80.2%) had ≤three uterine contractions in 10 min, and the mean duration of the contractions was 57.2 (SD = 7.06) seconds. The mean interval between uterine contractions was 2 min (SD = 0.494). It was determined that the mean cervical dilatation was 6.62 (SD = 0.928) cm, and mean effacement was 77.4% (SD =7.58); the fetal head in 52.8% was at -2 station and the membranes were ruptured in 79.1% of the women. These obstetrical data were not statistically different between the intervention and control group ($p > 0.05$).

3.2 Labour pain intensity

We hypothesized that the application of single-use instant hot packs on the lower back of primigravid women in the active phase of labour would significantly reduce the mean labour pain intensity scores as compared with that of the controls (H_1). At baseline, the mean pain intensity scores of the intervention group (8.02; SD = 0.84) and control group (8.07; SD = 0.95) were not statistically different (p = 0.820, 95%, CI= 0.331, −0.417). After the intervention, the mean pain intensity scores at all measurement points (30, 60, 90, 120, 150, 180, and 210 min) were significantly lower compared to the control group. After 30 min ($p \leq 0.05$, CI: −0.775,−1.913) and 60 min measurement points ($p \leq 0.05$, CI:−0.707,−1.760), the sample size decreased as the women transitioned from the active stage of labour to complete dilatation and delivery (at 90 min, n= 43, at 120 min, n= 34, at 150 min, n= 24, at 180 min, n= 21 and at 210 min, n=15) (Figure 2). However, there was a significant decrease in the measurement points at 90 min ($p \leq 0.05$, CI: −0.839 to −1.859), 120 min ($p \leq 0.05$, CI: −0.833 to −1.886), 150 min ($p \leq 0.05$, CI: −0.435 to −1.502). 180 min ($p \leq 0.05$, CI: −0.751 to −1.916) and 210 min ($p \leq 0.05$, CI: −0.933 to −2.314), showing the efficacy of the hot pack in decreasing the intensity of labour pain (Table 2).

Assessment periods	Intervention Group Mean, (SD)	Intervention Group n (%)	Control Group Mean, (SD)	Control Group n (%)	t-test	P value	95% Confidence Interval
At baseline	8.02, 0.84	45 (100)	8.07 ± 0.95	46 (100)	−0.228	0.820	0.331 to -.417
At 30 Min	6.18 ± 1.41	45 (100)	7.52 ± 1.31	46 (100)	−4.693	0.000*	−0.775 to −1.913
At 60 Min	6.27 ± 1.38	45 (100)	7.50 ± 1.13	46 (100)	−4.652	0.000*	−0.707 to −1.760
At 90 Min	6.49 ± 1.31	43 (96)	7.84 ± 1.04	43 (93)	−5.263	0.000*	−0.839 to −1.859
At 120 Min	6.41 ± 1.10	34 (76)	7.77 ± 1.08	35 (76)	−5.154	0.000*	−0.833 to −1.886
At 150 Min	6.79 ± 1.02	24 (53)	7.76 ± 0.831	25 (54)	−3.649	0.001*	−0.435 to −1.502
At 180 Min	6.67 ± 1.01	21 (47)	8.00 ± 0.873	22 (48)	−4.621	0.000*	−0.751 to −1.916
At 210 Min	6.73 ± 1.03	15 (33)	8.36 ± 0.745	14 (30)	−4.825	0.000*	−0.933 to −2.314

*Independent-samples *t* test, significance level at $p \leq 0.05$.

Table 2: Comparison of labour pain intensity scores between the intervention and control group

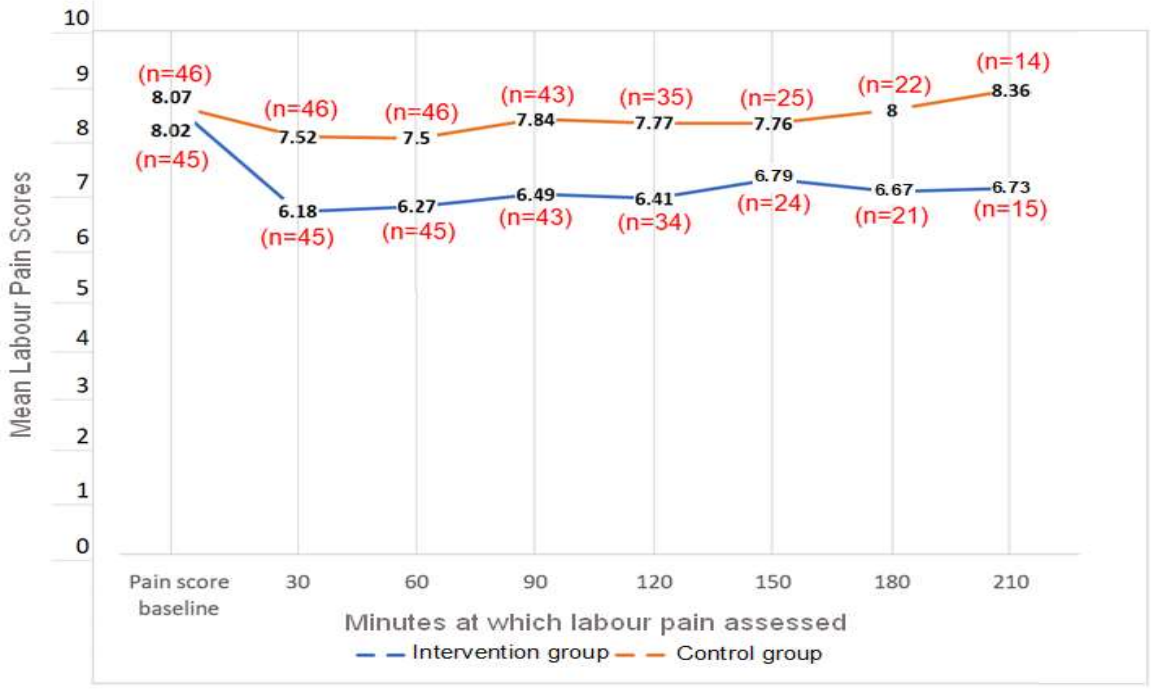

Figure 2: Mean labour pain scores with sample size in the intervention and control groups

3.3 Duration of labour

We hypothesized that the application of single -use hot packs on the lower back of women in the active phase of labour would significantly reduce the mean duration of labour as compared with the controls (H_2). The overall mean labour duration in the intervention group (7.5 hours /451.5 min; SD = 162.2 min) was shorter than that of the control group (7.8 hours/467.3 min; SD = 155.2 min). However, the difference was not statistically significant (p = 0.617). In addition, there was no statistical difference in the mean duration of the first, second and third stage of labour between the groups. ($p > 0.05$), indicating that the hot pack application was not effective in shortening the duration of labour (Table 3).

Duration of Labour Stages (in min)	Intervention group n = 45	Control group n = 46	Z Score	P value
	Mean± Standard Deviation	Mean± Standard Deviation		
First Stage	418.8 ± 152.7	436.6 ± 155.5	-.512	0.608
Second Stage	26.1 ± 24.1	29.3 ± 27.2	-.636	0.525
Third Stage	5.4 ± 1.2	5.6 ± 2.1	-.379	0.704
Total labour duration	451.5 ± 162.2	467.3 ± 155.2	-.500	0.617

*Mann–Whitney *U* test, significance level at $p \leq 0.05$.

Table 3: Comparison of the Duration of Labour in the Intervention and Control Groups

3.4 Satisfaction with labour and delivery experience

The women in the intervention group had significantly higher overall mean satisfaction score (p= .000) compared to the control group. Their mean score was significantly higher on all items, except the satisfaction regarding the 'happiness with the care received' and 'labour and delivery experience,' were not significantly different between the groups (p = 0.918 and 0.257, respectively) (Table 4)

Satisfaction Scale	Intervention group n = 45	Control group n = 46	Z Score	P value
	Mean± Standard Deviation	Mean± Standard Deviation		
I'm satisfied with the method of pain relief	4.56 ± .546	3.91 ± .985	−3.55	.000*
I'm satisfied with the level of pain relief	4.53 ± .694	3.65 ± 1.016	−4.80	.000*

I'm satisfied because I have no side effects of the pain management methods	4.69 ± .596	4.04 ± .868	−4.03	.000*
I felt happy about the care I received	4.49 ± .549	4.41 ± .748	-.103	.918
I felt happy about labour and delivery experience	3.44 ± 1.078	3.26 ± 1.084	−1.13	.257
My wishes were always respected	4.42 ± .839	4.07 ± .879	−2.30	.021*
The staff gave me sufficient information about my progress	4.69 ± .701	4.35 ± .674	−3.07	.002*
The midwife was with me as much as I wanted	4.80 ± .405	4.39 ± .682	−3.15	.002*
The midwife gave me the care I needed	4.82 ± .387	4.48 ± .658	−2.90	.004*
The midwife paid attention to my comfort during labour	4.69 ± .557	4.50 ± .506	−2.04	.041*
The midwife communicated well with me	4.82 ± .387	4.37 ± .610	−3.87	.000*
I'm satisfied with the privacy provided to me	4.84 ± .367	4.48 ± .623	−3.31	.001*
Overall satisfaction	4.78 ± .471	4.24 ± .603	−4.60	.000*

*Mann–Whitney *U* test, significance level at $p \leq 0.05$.

Table 4: Comparison of Mean Satisfaction between the Intervention and Control Groups

4. Discussion

The mean pain scores of the intervention group were significantly lower than the control group at all measured points showing that application of single-use hot packs on the lower back in active phase of labour was effective in reducing labour pain intensity. The findings echo that of a study that reported significantly lower pain in women who received warm compresses compared to routine care [18]. Our findings are also consistent with reports that heat effectively decrease labour pain [19-22, 27, 35, 36].

Findings of a clinical trial shows that heat applied to lower back in the first stage and to the perineum in the second stage was effective in pain relief [35]. Another randomised control trial also reported a significant decrease in pain intensity among nulliparous women at 60, 90, and 120 min after the application of heat, to the sacrum–perineum in the active phase of labour [27]. It is note-worthy that the design and the site of application were not similar to our methodology. Further, cervical dilatation when pain was assessed also varied. Our participants were selected at 6–8 cm of cervical dilatation based on the hospital protocol as opposed to participants in other studies who were selected at 3–4 cm of cervical dilatation [36], 4–5 cm[18], 5–6 cm [20], 7 and 10 cm [19]. Our study participants had hot packs for a lesser duration compared to previous studies [18,19,20,36]. Furthermore, the two groups did not differ statistically in the duration of labour. Overall, women in the intervention group had significantly higher satisfaction with their labour and delivery experience compared to the control group who also received intermittent Entonox inhalation as part of the routine care. The Entonox inhalation could not be withheld for ethical reasons. Although, it is believed to increase the activity of inhibitory pain pathways in the brain, its role in pain relief remains unclear9. A Cochrane review of 26 randomised controlled trials in 2959 women showed that flurane derivatives were slightly more effective than nitrous oxide, although nitrous oxide helped to relieve pain when compared with no treatment [10]. In a comparison with oxygen, nitrous oxide was effective in labour pain relief [11]. We did not observe the amount, duration, and frequency of Entonox inhalation which may have influenced the findings. Despite the use of Entonox in the control group, heat application was found to be effective in relieving pain in the intervention group.

Contrary to our expectations, hot packs were not effective in reducing the duration of labour. Our results reinforce the findings of an experimental study that found heat was ineffective in reducing labour duration as compared with routine care [18]. However, conflicting results exist on its effect in different stages of labour. For instance, a randomised control trial found no difference in the duration of the first stage of labour between the warm pack group and the use of routine care and a birth ball [26]. Likewise, a randomised clinical trial reported no difference in the duration of the first stage labour [21]. Contrary to our findings, those authors reported a shorter third stage, which may be attributed to heat application on the perineum in the second stage. In a similar study, researchers used warm compresses in the first stage and heat to the perineum in the second stage and found no effect in the first stage but a significantly shorter second stage of labour [19]. Whereas researchers reported a significantly shorter first and third stage of labour with the application of warm bags to the lower back in the active phase and to the perineum in the second stage [35].

Furthermore, researchers experimented with hot water bottles on the lower back and abdomen in the first stage and perineum in the second stage and reported shorter first and second stages of labour [20]. The heterogeneity in results can be attributed to variations in the study design. Unlike our study that used single-use instant hot packs at 30-minute intervals, with a rest period of 10 min, from 6–8 cm of cervical dilatation until delivery, heat was applied to the perineum in the second stage by other researchers, leading to conflicting results. Future studies can apply single-use hot packs on the perineum in the second stage of labour and test the effect on labour duration. Heat causes connective tissue elasticity, and the temperature level and duration of application may influence the effect of heat therapy on blood flow, tissue metabolism, and tissue elasticity [36]. Further, the use of Entonox by the control group may be attributed to the negative results on duration of labour, in our study. It's role on uterine contractility is debatable. Entonox does not have an effect on uterine contractions or labour progression, however others claim its effectiveness in shortening the duration of labour [37]. For example, studies reported shorter first and second stages of labour and pain duration in women who received Entonox as compared to oxygen inhalation [10,11]. Researchers should consider this potential bias when designing future studies.

Women who received hot pack had significantly higher overall satisfaction with their labour and delivery experience as compared with those who received routine care. Our findings are comparable with findings of a randomised control trial that demonstrated the efficacy of heat in satisfying women in labour when compared to routine care [27]. Further, an experimental study reported moderate satisfaction with heat therapy [18]. Researchers recommended the routine provision of a warm shower for labouring women, reinforcing that it helped enhance their feeling of

acceptance, making childbirth experience more positive as compared with the standard care group [22]. Heat in combination with other modalities was also shown to be satisfying to women in labour. High satisfaction was reported by those who had intermittent heat- and cold-pack application for pain relief during labour, whereas most women who received routine care reported low satisfaction [16]. Studies measured overall satisfaction using rudimentary scales such as the VAS and rating scale that do not identify individual aspects of satisfaction [18,27]. In that context, the strength of our study is that we used a 13-item valid and reliable satisfaction scale that measures various aspects of satisfaction.

Two items, "because the midwife was with her most of the time" and "communicated and provided sufficient information and respected the women." were rated high on the satisfaction scale. It appears that the researcher's presence and interaction might have enhanced satisfaction via facilitating women-centered care, which is one of the core concepts of midwifery care [22]. Blinding was not possible due to the nature of the intervention; the researcher's presence may have positively influenced pain relief and satisfaction in the intervention group, causing a potential bias [27]. The researcher's interaction may have been perceived as supportive, and the relief of pain, comforting. Contentment is due not only to the pain relief but also the care provided [38]. According to Kolcaba (1990), specific interventions enhance comfort through a sense of relief, ease, and transcendence [39]. It may be noted that two items, 'I was happy about the care I received' and 'I was happy about the labour and delivery experience,' were not significantly different between the two groups. It is possible that the word *satisfaction* would have been more appropriate in place of *happy* in these two items. A factor analysis would provide information on the factor structure of the LDSS.

The control group, who received self-administered Entonox inhalation, had lower satisfaction levels than that of the intervention group. It is possible that, like most nonpharmacological pain management methods, hot pack, which is effective in reducing pain intensity, has no side effects and has the potential to promote control, thereby achieving a positive birth experience. We did not assess the self-control of the women during labour. However, future studies can incorporate self-control as a variable and its relationship with pain and satisfaction.

Although the strength of this study is that it is the first to determine the effect of single-use hot packs on pain and duration of labour with an adequate representative sample, some potential limitations should be considered when interpreting the results. First, due to the labour room protocol, our participants were selected with ≥6 cm cervical dilatation, thereby restricting the generalizability of the findings to only those with ≥6 cm of cervical dilatation. Second, the control group had the choice of intermittent self-administered Entonox as part of routine care. We did not observe the duration and amount of its use which might influence the validity of the findings. Third, the nature of the intervention rendered blinding impossible, thereby introducing an element of bias. Fourth, data on cervical dilatation was calculated from the patient records which may have affected the validity of the findings. Fifth, although the validity and reliability of the LDSS is established, a factor analysis would help establish the instrument's construct validity.

5. Conclusion

The study provides evidence that application of single-use hot pack in active phase of labour can effectively reduce labour pain intensity; however, is not effective in reducing duration of labour. This non-pharmacological method is a promising option for pain relief because of its ease of application and does not need training of the nurses/midwives. It, however, requires them and the women to ensure measures to avoid burns at the site of application. Continuing education for nurse/midwives should emphasize heat therapy as a non-pharmacological measure for pain relief in labour. Nurse administrators must encourage the use of hot packs in labour room settings, to provide a satisfying labour and delivery experience to the women in labour. It would be prudent to conduct future studies where Entonox inhalation is not a part of routine care.

Authors Contributions

HA: Conceptualization, methodology, data collection, data analysis, original draft

JLD: Conceptualization, methodology, supervision, revising the draft, review and editing.

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Data availability statement

Datasets related to this article can be found at http://dx.doi.org/10.17632/cvgdz93p5z.2, an open-source online data repository hosted at Mendeley Data (Alshahrani and LinnetteD'Sa, 2021).

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