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Hot Patch Applied to the Lower Back for Pain Relief during the Active Phase of the First-stage Labor: A randomized controlled trial

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ABSTRACT

Objectives: To determine the efficacy of hot patch for pain relief during the active phase of the first stage labor.

Materials and Methods: Fifty-eight singleton pregnant women undergoing normal delivery at Khon Kaen Hospital between February 5 and May 30, 2020, were randomly assigned into two groups: hot patch and standard care. The hot patch was applied to the lower back (dermatome T10 to L1) when cervix dilatation reached 4-6 cm until fully dilated. Pain scores were recorded before hot patch application and every hour until the end of the first stage labor.

Results: Baseline characteristics were not significantly different between groups ($p > 0.2$). The mean pain score of the hot patch group was significantly less than the control group at 1, 2, 3, 4, and 5 hours after intervention (4.4 ± 1.9 vs. 6.4 ± 1.8, 5.6 ± 2.2 vs. 7.4 ± 1.3, 5.4 ± 1.8 vs. 8.1 ± 0.8, 5.7 ± 2.2 vs. 8.4 ± 0.7, 8.0 ± 0.0 vs. 8.7 ± 0.5, $p < 0.001$, respectively). The mean duration of the active phase of the first stage labor in the hot patch group was significantly < 0.001). There was no adverse event found.

Conclusion: A hot patch applied to the lower back significantly reduced labor pain during the first stage labor.

Keywords: hot patch, non-pharmacologic, labor pain.

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การใช้แผ่นแปะร้อนบริเวณหลังส่วนล่างเพื่อบรรเทาอาการปวดในช่วงระยะแรกของการเจ็บครรภ์คลอดจริง: การทดลองแบบสุ่ม

ชนากานต์ สุทธิสุนทรวงศ์, ทุมวดี ตั้งศิริวัฒนา

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาประสิทธิผลของการใช้แผ่นแปะร้อนเพื่อลดอาการปวดในช่วงเวลาปากมดลูกเปิดเร็วของการคลอดระยะที่หนึ่ง*

วัสดุและวิธีการ: *หญิงตั้งครรภ์เดี่ยวจำนวนห้าสิบแปดคน ที่จะคลอดบุตรโดยวิธีธรรมชาติในโรงพยาบาลขอนแก่นระหว่างวันที่ 5 กุมภาพันธ์ ถึง 30 พฤษภาคม 2563 ได้รับการสุ่มออกเป็นสองกลุ่ม: กลุ่มแปะแผ่นร้อน และกลุ่มดูแลตามมาตรฐาน แผ่นแปะร้อนใช้บริเวณหลังส่วนล่าง (เดอร์มาโทม T10 ถึง L1) เริ่มที่ปากมดลูก 4-6 เซนติเมตร จนปากมดลูกเปิดขยายหมด คะแนนความเจ็บปวดถูกบันทึกก่อนการใช้แผ่นแปะร้อน และทุกๆ ชั่วโมง จนสิ้นสุดระยะแรกของการเจ็บครรภ์คลอด*

ผลการศึกษา: *ลักษณะพื้นฐานประชากรไม่แตกต่างกันอย่างมีนัยสำคัญระหว่างสองกลุ่ม ($p > 0.2$) คะแนนความเจ็บปวดเฉลี่ยของกลุ่มแผ่นแปะร้อนน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญที่ 1, 2, 3, 4 และ 5 ชั่วโมง ตามลำดับ (4.4 ± 1.9 และ 6.4 ± 1.8, 5.6 ± 2.2 และ 7.4 ± 1.3, 5.4 ± 1.8 และ 8.1 ± 0.8, 5.7 ± 2.2 และ 8.4 ± 0.7, 8.0 ± 0.0 และ 8.7 ± 0.5, $p < 0.001$ ตามลำดับ) ระยะเวลาเฉลี่ยของช่วงปากมดลูกเปิดเร็วของการคลอดระยะที่หนึ่งในกลุ่มแปะแผ่นร้อนน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ (138.5 ± 63.1 และ 222.7 ± 82.3, $p < 0.001$) และไม่พบเหตุการณ์ไม่พึงประสงค์*

สรุป: *การใช้แผ่นแปะร้อนบริเวณหลังส่วนล่างช่วยบรรเทาอาการปวดในช่วงระยะแรกของการเจ็บครรภ์คลอดได้อย่างมีนัยสำคัญ*

คำสำคัญ: *แผ่นแปะร้อน, การบรรเทาอาการปวดที่ไม่ใช้ยา, ภาวะเจ็บครรภ์คลอด*

Introduction

Labor is unpredictable and is one of the most painful experiences for women. Approximately forty percent of women identify labor pain as the worst part of childbirth[1]. The longer the interval of uterine contractions, the deeper and more emotional stress experienced. Eighty-three percent of pregnant women used one or more pain medications during birthing whereas 17% do not require any[1].

There are two kinds of pain during labor, visceral and somatic. Visceral pain occurs during the early first stage and the second stage labor, while somatic pain occurs during the late first stage and second stage[2].

Pain from uterine contractions is referred to the dermatomes which are supplied by T10, T11, T12, and L1. As labor progresses, the pain becomes more severe and is referred to the abdomen, lower lumbar, and upper sacrum, areas supplied by T10 and L1[2]. A release of stress hormones such as cortisol and beta-endorphin can trigger pain, stress, and anxiety, which can adversely affect uterine activity and uteroplacental blood flow. Effective analgesia attenuates or eliminates these responses[3]. Several pain control methods have been studied and some of them have been used for decades, including pharmacological and non-pharmacological (e.g., opioids administration, epidural analgesia, nitrous oxide inhalation, massage, heat or cold therapy, transcutaneous electrical nerve stimulation (TENS), yoga, breathing exercise, reflexology, and music therapy).

According to a Cochrane review of pharmacological methods, epidural analgesia is an effective way of providing pain relief. The negative effects of epidural analgesia have, however, been reported, including a prolonged first and second stage of labor and increased oxygen use, malrotation, instrumental delivery, and cesarean section especially for dystocia[4]. As for non-pharmacological methods, massage, warm pack, and thermal manual methods were found to play a role in pain relief, reducing duration of labor and emotional experience improved with safety. Further high quality research is needed to address these outcomes and to determine the effectiveness of these methods for pain control[5].

One of the non-pharmacologic methods for labor pain reduction is heat therapy; it is simple, inexpensive, and readily available with few side effects[6]. The terminals of small A delta and C afferent nerve fibers act as receptors for nociception from superficial structures (skin and subcutaneous tissue), deep structures (muscle, fascia), and viscera[2]. When tissue injury occurs, a large amount of various chemical mediators are liberated. These include hydrogen ions, noradrenaline, bradykinine, histamine, and potassium ions[7]. Heat may stimulate heat receptors in dermal and deeper tissues. Based on the gate control theory[8], different impulses neutralize themselves at the level of spinal cord by leading to a closure of the gate and subsequently impeding neural impulses from reaching the brain. The other effect of heat therapy possibly shortens the duration of labor[9]. Khamis et al showed that heat induces a significant increase in uterine activity without causing any abnormal fetal heart change[10] and releases endorphins[11]. In addition, heat can stimulate touch and temperature receptors which promote a pleasure feeling and decrease the level of pain[12]. The optimum temperature range for superficial heat therapy is between 40 and 45°C[13].

To our knowledge, the intensity of labor pain increases when cervical progression especially when in active phase. Therefore, we started the intervention at 4-6 cm which is in the phase of maximum slope according to Friedman's curve which cervix is rapidly progress and cause severe labor pain. In the current study, we used a Japanese iron-filled hot patch. When exposed to the air, the iron oxidizes and heats up in about 10 min, and stays warm for about 10 hours. Air-activated hot patches generate heat up to 50°C. The natural therapeutic heat will last for 10 hours. Blood flow is increased by warming the affected area and inducing vasodilatation which increases the supply of oxygen and removal of metabolic waste, leading to better healing and reduced pain[14]).

According to a Cochrane review, evidence regarding the efficacy of heat therapy for pain relief with a warm pack and a warm towel in the first stage labor

remains insufficient[5]. We thus planned to study the efficacy of the Japanese iron-filled hot patch given its simplicity, affordability, and availability in drug and/or convenience stores.

Materials and Methods

We recruited pregnant women 18 or older who had their labor at Khon Kaen Hospital between February 5 and May 30, 2020. All eligible pregnant women gave informed consent before enrolling in the study. Inclusion criteria were: age 18 or older, being at the beginning of the active phase of labor (cervical dilation between 4 and 6 cm), gestational age between 37 and 41 weeks, singleton, low-risk pregnancy, and cephalic presentation. The exclusion criteria were: any abnormal patterns of external fetal heart rate monitoring, history of chronic pelvic pain, and/or cutaneous lesion(s) involving the lower back.

The study was reviewed and approved by the Khon Kaen Hospital Institute Review Board in Human Research. The randomization list was kept in a sealed opaque envelope. The sealed opaque envelopes were opened by residents or nurses at the labor room after the participants were enrolled in the study. The participants were randomly allocated into two groups by computer-generated randomization using block of four. Group 1: Japanese iron-filled hot patch was applied to the lower back; Group 2: no Japanese iron-filled hot patch. Both groups received the same intrapartum standard care. The intervention started from the beginning of the active phase (cervical dilatation 4-6 cm). For the Japanese iron-filled hot patch, a 9x12 cm, 40-45 °C Japanese iron-filled hot patch was placed on the patient's clothing over the lower back (dermatome T10 to L1). Skin temperature and appearance at hot patch placement was monitored every 1 hour by thermoscan (Xiaomi mijia iHealth thermometer, China). The Japanese iron-filled hot patch will be immediately removed if there is any abnormal skin reaction (clear water blisters, redness, or loss of sensation). In the control group, standard care with no Japanese iron-filled hot patch was provided. Pain scores were recorded by residents on service at the labor room, using a visual analogue scale (VAS). A horizontal line, 10-cm in length, with the descriptive words "no pain" and "worst pain" at each end. Participants were asked to put a mark on the line at the point that represented the most severe pain that they experienced before the intervention (cervix dilated 4-6 cm), and every 1 hour until full cervical dilatation. The two groups received routine nursing care including vital signs were recorded every 4 hours, uterine contractions and fetal heart were recored every 30 minutes. Vaginal examinations were performed every 2 hours by residents. Additional pain control with pethidine 50 mg intramuscularly injection every 4 hours was provided for all participants when needed. At the end of delivery, participants' satisfaction of the hot patch application was recorded by using the questionnaire.

The primary outcome was pain scores during the active phase of labor comparing between the Japanese iron-filled hot patch and no Japanese iron-filled hot patch. The secondary outcomes were (a) the duration of the active phase of the first-stage labor, (b) route of delivery, (c) adverse events, (d) participant satisfaction, and (e) skin temperature.

The sample size was based on the data from a pilot study with 90% power and a 5% dropout rate. The appropriate sample size was thus 58 participants 29 in each group. Data were analyzed using repeated measures by the generalized estimating equation (GEE). Continuous variables were analyzed using the student t-test and presented as means and standard deviation (SD). Categorical variables were analyzed using the chi-square and Fisher's exact test and presented as percentages. The mean difference of the pain score between groups was analyzed and presented with 95% confidence intervals. A p value < 0.05 was considered statistically significant.

Results

Sixty eligible pregnant women were enrolled, two were excluded due to abnormal fetal heart rate and pregnancy-induced hypertension. The 58 participants were randomized into 29 cases per group (Fig. 1). Three from each group withdrew from the study before recording the pain data because they were diagnosed as having cephalopelvic disproportion and fetal distress

so a cesarean section was performed. Ultimately, 26 subjects in each group were included for analysis.

The demographic and obstetric variables (mean age, gestational age, body mass index (BMI), parity, pain score (VAS) before intervention) were similar between groups (Table 1).

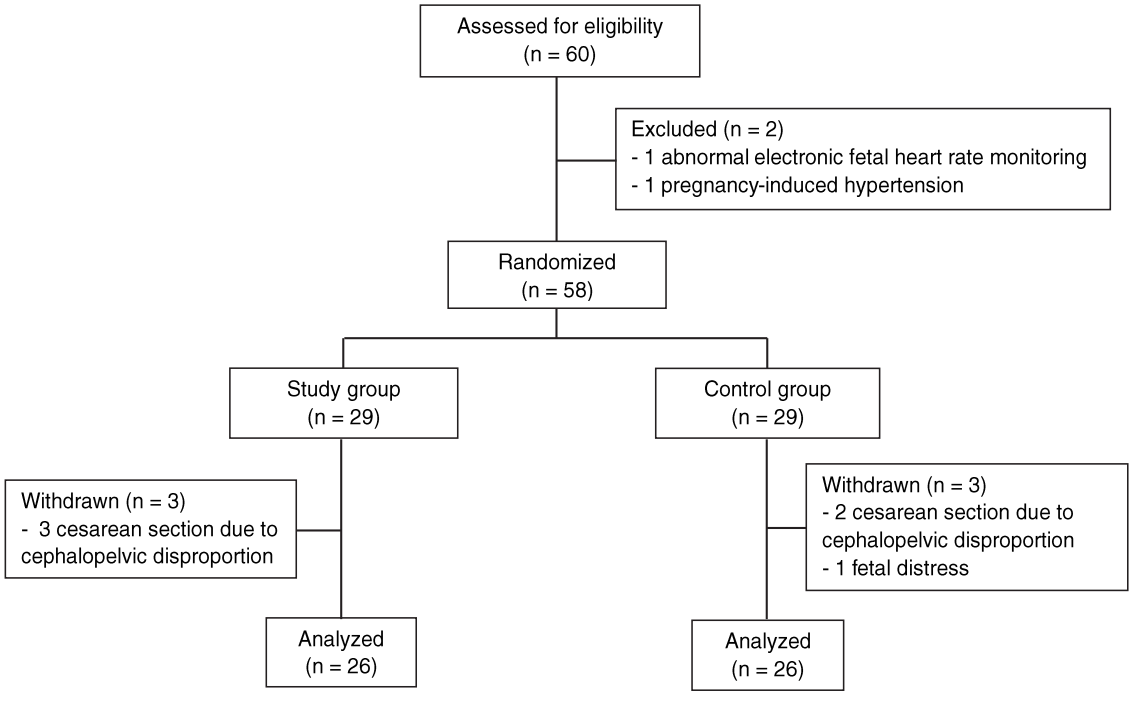

Fig. 1. Study flow diagram.

Table 1. Demographics and characteristics of the cases.

Characteristic	Hot patch group (n = 26) mean ± SD	Standard care group (n = 26) mean ± SD	p value
Age (years)	26.7 ± 4.9	25.1 ± 5.4	0.28[b]
Gestational age (weeks)	39^{+1} ± 0.9	39^{+2} ± 1.0	0.66[b]
Parity, n (%)			
- Nulliparous	12 (46.2)	12 (46.2)	1.00[a]
- Multiparous	14 (53.8)	14 (53.8)	
Maternal BMI (kg/m^2)	28.1 ± 3.3	26.9 ± 3.7	0.23[b]
Pain score (VAS) before intervention	4.7 ± 0.9	5.2 ± 2.3	0.26[b]

[a] chi-square test, [b] student t-test

BMI: body mass index, SD: standard deviation, VAS: visual analogue scale

The respective mean pain score in the control and Japanese iron-filled hot patch group are shown in Table 2. The primary outcome was pain scores during the active phase of the first stage labor, which was

recorded every hour after intervention. There was a significant difference in labor pain reduction between the Japanese iron-filled hot patch group and the control group ($p < 0.001$) (Table 2). Pain perception among the nulliparous women in the Japanese iron-filled hot patch group was lower than in the control group at 1, 2, 3, 4, and 5 hours after intervention ($p < 0.001$) (Table 3). The multiparous pain score was lower in the Japanese iron-filled hot patch at 1, 2, 3, and 4 hours ($p < 0.001$) (Table 4). Regularly uterine contractions before and during the intervention were observed in both groups. None of the participant requested for additional pain control.

Table 2. Pain score (VAS) in the active phase of the first stage labor.

	Hot patch group (n = 26) mean ± SD	Standard care group (n = 26) mean ± SD	mean difference	95%CI	p value
1 hour	4.4 ± 1.9 (n = 26)	6.4 ± 1.8 (n = 26)	-1.32	-2.11 to -0.52	0.001[c]
2 hours	5.6 ± 2.2 (n = 20)	7.4 ± 1.3 (n = 26)			
3 hours	5.4 ± 1.8 (n =12)	8.1 ± 0.8 (n = 21)			
4 hours	5.7 ± 2.2 (n = 5)	8.4 ± 0.7 (n = 16)			
5 hours	8.0 ± 0.0 (n = 1)	8.7 ± 0.5 (n = 3)			

[c] Generalized estimation equation (GEE), VAS: visual analogue scale, SD: standard deviation, CI: confidence interval

Table 3. Nulliparous pain score (VAS).

	Hot patch group (n = 12) mean ± SD	Standard care group (n = 12) mean ± SD	mean difference	95%CI	p value
1 hour	3.9 ± 1.0 (n = 12)	6.8 ± 1.9 (n = 12)	- 1.41	- 1.99 to - 0.84	< 0.001[c]
2 hours	5.6 ± 2.2 (n = 12)	7.7 ± 1.4 (n = 12)			
3 hours	5.8 ± 1.5 (n = 7)	8.0 ± 0.8 (n = 11)			
4 hours	7.1 ± 0.8 (n = 2)	8.3 ± 0.6 (n = 9)			
5 hours	8.0 ± 0.0 (n = 1)	8.7 ± 0.6 (n = 3)			

[c] Generalized estimation equation (GEE), VAS: visual analogue scale, SD: standard deviation, CI: confidence interval

Table 4. Multiparous pain score (VAS).

	Hot patch group (n = 14) mean ± SD	Standard care group (n = 14) mean ± SD	mean difference	95%CI	p value
1 hour	4.8 ± 2.3 (n = 14)	6.1 ± 1.7 (n = 14)	- 1.31	- 2.1 to - 0.51	0.001[c]
2 hours	5.7 ± 2.9 (n = 8)	7.3 ± 1.2 (n = 14)			
3 hours	5.0 ± 2.4 (n=5)	8.2 ± 0.9 (n = 10)			
4 hours	4.3 ± 2.5 (n=3)	8.5 ± 0.9 (n = 7)			

[c] Generalized estimation equation (GEE), VAS: visual analogue scale, SD: standard deviation, CI: confidence interval

Secondary outcomes showed that the mean duration of the active phase of the first stage labor in the Japanese iron-filled hot patch group was 138.5 ± 63.1 vs. 222.7 ± 82.3 min in the control group, with a mean difference of 84.3 min shorter in the Japanese iron-filled hot patch group. There was one woman in the control group who had arrest of descent after full cervical dilatation so a cesarean section was performed. In the Japanese iron-filled hot patch group, skin temperature was maintained at between 41 and 43°C during the intervention without any adverse event. All of the participants in the Japanese iron-filled hot patch group were satisfied with the intervention (Table 5). The duration of the first stage labor in the Japanese iron-filled hot patch was significantly reduced in both nulliparous and multiparous women (p = 0.004, p = 0.006) (Table 6).

Table 5. Secondary outcomes.

	Hot patch group (n = 26) mean ± SD	**Standard care group (n = 26) mean ± SD**	**mean difference (95%CI)**	**p value**
Duration of the active phase of the first-stage labor (minutes)	138.5 ± 63.1	222.7 ± 82.3	- 84.3 (- 125.1 to - 43.4)	< 0.001[b]
Adverse events, n (%)				
- Skin burn	0 (0.0)			
- Skin allergy	0 (0.0)			
Route of delivery, n (%)				0.32[d]
- Vagina	26 (100)	25 (96.2)		
- Cesarean section	0 (0)	1 (3.8)		
Skin temperature (°C)				
At 0 hour	41.6 ± 0.6			
At 1 hour	42.2 ± 0.6			
At 2 hours	42.6 ± 0.9			
At 3 hours	42.8 ± 0.7			
At 4 hours	43.1 ± 0.5			
Maternal satisfaction	100%			

[b] student t-test, [d] Fisher's exact test, SD: standard deviation, CI: confidence interval.

Table 6. Duration of the active phase of the first stage labor.

	Hot patch group (n = 26) mean ± SD	**Standard care group (n = 26) mean ± SD**	**mean difference**	**95%CI**	**p value**
Nulliparous	**(n = 12)**	**(n = 12)**			
	160.4 ± 51.3	255.4 ± 90.5	- 95.0	- 157.3 to - 32.7	0.004[b]
Multiparous	**(n = 14)**	**(n = 14)**			
	119.6 ± 67.9	194.6 ± 65.3	- 75.0	- 126.7 to - 23.3	0.006[b]

[b] student t-test, SD: standard deviation, CI: confidence interval.

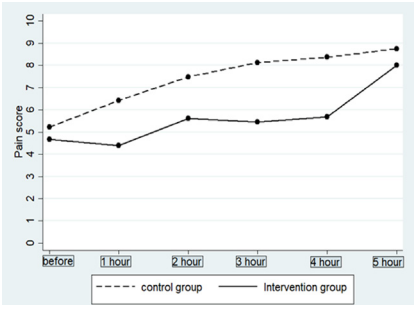

Fig. 2. Pain score visual analogue scale in the active phase of the first stage labor.

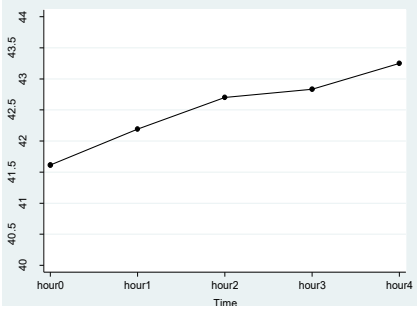

Fig. 3. Skin temperature (°C).

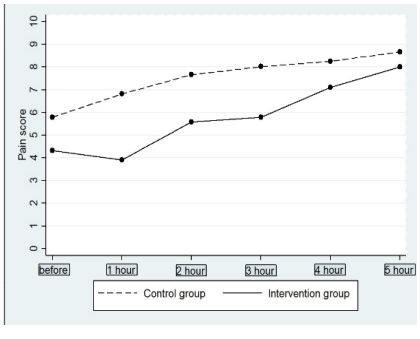

Fig. 4. Nulliparous pain score visual analogue scale in the active phase of the first stage labor.

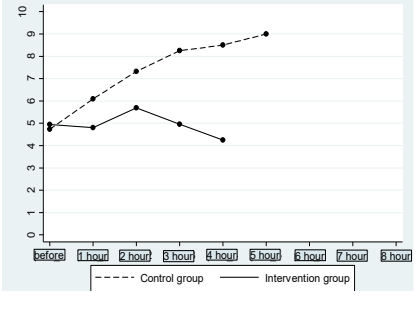

Fig. 5. Multiparous pain score visual analogue scale in the active phase of the first stage of labor.

Discussion

The present study showed that the Japanese iron-filled hot patch group had a lower labor pain score than the control group. The finding was consistent with those of Behmanesh et al who reported a significant difference in labor pain between the heat and control groups in the first and second stage[9]. Many studies have shown that various forms of heat therapy (warm bag, warm water, and immersion) significantly reduced labor pain in the first stage labor[9, 15-16]. Lenstrup et al, studied the effects of warm tub bathing during labor and found that pain relief and cervical dilatation trended greater with a warm bath albeit there was no statistically significant difference[17]. Recent studies have shown that the effect of heat in various forms in reducing labor pain and raising mother satisfaction[9, 18-19].

According to the previous studies of non-pharmacologic methods, the aim of the studies was to avoid invasive pharmacological methods of pain management in labor. They did not provide any additional pain killer in both groups. Taavoni et al, revealed that warm packs to the sacrum and perineum during active phase of the first stage labor reduced pain and improved maternal satisfaction and they performed only reclining position without ambulation and any other intervention in control group[19]. Lee et al, studied in warm showers reported significantly lower VAS scores at 4-cm and 7-cm cervical dilations than the control group ($p < 0.01$) and no other pharmacologic drug added, except those for induction of labor[18]. Shirvani et al revealed that the degree of pain during acceleration phase was significantly lower in cold therapy group than in control group ($p < 0.02$) as well as during the maximum of slope, deceleration phase and the second stage of labor with $p = 0.0001$, no other pain-relieving method was applied in control group in order to eliminate the effect of supporter factor[20]. Ganji et al studied local warming with intermittent cold pack versus routine care on labor pain and founded that the difference in pain severity at the end of the acceleration phase was statistically significant lower in the intervention group ($p = 0.002$) and during the maximum of slope, the deceleration phase and the second stage with $p = 0.0001$[21]. This non-invasive, non-pharmacological modality provides a safe alternative for mother and fetus and also provides mothers with a choice if they would prefer to avoid invasive pharmacological methods of pain management in labor. This method may be particularly attractive to mothers who want to be more involved and in control of their own care. However, the current study provided additional pain control for the participants in both groups but none of them needed. In our institute, we give analgesic drug as needed, but most of them can tolerate labor pain and did not request for analgesia.

From these results, it seems that the form of heat can influence outcomes. Pain reduction might be related to heat mechanisms that cause endorphin hormone release as well as stimulating touch and temperature receptors which result in a feeling of pleasure and in pain relief. Some mechanisms include providing stimuli from peripheral sensory receptors to inhibit pain awareness, anti-nociceptive effects on the gate control system, decreasing muscle tension and distraction of attention from pain[22-24]. Heat therapy possibly increases the internal oxytocin, causing uterine contraction and decreased bleeding after delivery[9, 21]. In the current study average skin temperature was 41 to 43°C, which is within the optimum therapeutic range for heat treatment. Superficial heat, 1 cm from skin (i.e, 40 - 45°C) could relief pain by stimulate peripheral nerve and induce muscle relaxation without adverse effect to the fetus[13] (Fig. 3).

The present study included both nulliparous and multiparous while previous studies recruited only nulliparous[9, 19, 21]. The current study showed that both nulliparous and multiparous women who received the Japanese iron-filled hot patch had significantly lower labor pain than those who received standard care (Fig. 4, 5). Only moderate pain perception (pain score 4-6) was reported in either nulliparous or multiparous women in the Japanese iron-filled hot patch group whereas the control group experienced severe pain (Fig. 2). Pain scores in the multiparous women in the hot patch group at 4 hours after intervention was lower than in the nulliparous ones. This might be from multiparous women

had labor pain experience which cause different pain perception from nulliparous women who had not. In addition, when they received non-pharmacologic support such as hot patch, it could make they feel more comfortable from its effect of pain reduction and muscle relaxation. However, small sample size might cause bias these results.

The present study found that duration of the active phase of the first stage labor in the Japanese iron-filled hot patch group was significantly shorter than in the control group. This finding was comparable with a study by Khamis et al, who reported that heat increased uterine activity and so decreased the duration of labor without abnormal changes in the fetal heart rate[10]. Others studies have shown that warm water immersion decreased the duration of labor phases[25-26]. One study revealed that the duration of the first and third stages labor decreased significantly in the heat group compared to the control group[9].

Application of superficial heat therapy to manage labor pain is a convenient, effective and inexpensive method with few side effects. The method does not require high skill, provides relief and comfort, provides active participation of women in the birthing process, and promotes a more positive birth experience. Heat therapy should be used if desired[21]. All of the participants in the current study were satisfied with the hot patch and no serious adverse event were found.

The strengths of our study which make our results different from those of the previous studies were firstly, we monitored skin temperature to ensure that the temperature remained in the therapeutic range during intervention which plays an important role in regulating pain control. Secondly, we used repeated measure GEE to analyze pain score in the different time. Thirdly, both nulliparous and multiparous women were included into the study while the previous studies enrolled only the nulliparous ones. Lastly, we used hot patch which is the simply intervention with long duration that could maintain the longer heat effect than other forms of heat therapy. The limitation of present study was that we did not blind the intervention because the participants were in the same labor room.

Conclusion

A Japanese iron-filled hot patch applied to the lower back could significantly reduce labor pain in the active phase of the first stage labor.

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Potential conflicts of interest

The authors declare no conflict of interest.

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