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Efficacy of Heat Patch Applied on Lower Back for Reducing Postoperative Pain after Cesarean Delivery: A randomized controlled trial

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ABSTRACT

Objectives: To study the efficacy of using a heat patch to reduce postoperative pain after cesarean delivery.

Materials and Methods: Women who underwent cesarean delivery under a spinal block were randomly allocated into two groups, comprising one group who received a heat patch and one who received standard postoperative care. The heat patch group received a 40-degree Celsius heat patch applied to the lower back (dermatome T10 to L1) 6 hours postoperatively, while the control group received standard postoperative pain control. The primary outcome was assessed based on postoperative pain scores at 8 hours using a 10-cm visual analogue scale (VAS).

Results: Seventy-eight postoperative women, 39 in each group, were recruited between September 2023 and March 2024. The heat patch group expressed significantly less postoperative pain than the control group 8 hours after cesarean delivery (3.5 ± 0.3 vs 4.7 ± 0.4; mean difference 1.2; 95%CI: 0.4-2.1; p = 0.006). The time to first ambulation in the heat patch group was significantly shorter than the control group (1,073 ± 267.7 min vs 1,261.9 ± 205.3 min; mean difference 189 min; 95%CI: 81.4-296.6; p < 0.001). The heat patch group required fewer additional analgesic drugs compared to the control group (56.4% vs 82.1%; p = 0.014). No adverse events were reported.

Conclusion: A heat patch applied on the lower back resulted in significantly reduced pain 8 hours after cesarean delivery.

Keywords: heat patch, postoperative pain, cesarean delivery.

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การศึกษาประสิทธิภาพของแผ่นแปะร้อนบริเวณหลังส่วนล่างในการลดความเจ็บปวดหลังผ่าตัดคลอดบุตร: การทดลองแบบสุ่มที่มีกลุ่มควบคุม

วิลาณี สิทธิศักดิ์นวกุล, สาธิดา จันทนวิลัย

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพของแผ่นแปะร้อนในการลดความเจ็บปวดหลังผ่าตัดคลอดบุตร*

วัสดุและวิธีการ: *สตรีที่เข้ารับการผ่าตัดคลอดบุตรด้วยวิธีระงับความรู้สึกบริเวณกระดูกไขสันหลัง จะถูกสุ่มแบ่งออกเป็น 2 กลุ่ม ได้แก่ กลุ่มที่ได้รับการติดแผ่นแปะร้อน และกลุ่มที่ได้รับการดูแลหลังผ่าตัดตามมาตรฐาน โดยกลุ่มที่ได้รับการติดแผ่นแปะร้อน จะได้รับแผ่นความร้อน 40 องศาเซลเซียส ติดที่บริเวณหลังส่วนล่าง (เดอร์มาโทม T10 ถึง L1) ที่เวลา 6 ชั่วโมงหลังผ่าตัดคลอด ขณะที่กลุ่มควบคุมได้รับการดูแลความเจ็บปวดหลังผ่าตัดตามมาตรฐาน โดยจุดประสงค์หลักในงานวิจัยคือคะแนนความเจ็บปวดหลังผ่าตัดที่ระยะเวลา 8 ชั่วโมง โดยใช้ภาพอนาล็อกมาตราส่วน 0-10เซนติเมตร (visual analog scale; VAS)*

ผลการศึกษา: *สตรีหลังผ่าตัดจำนวน 78 คน กลุ่มละ 39 คน ระหว่างเดือนกันยายน 2566 ถึงเดือนมีนาคม 2567 กลุ่มที่ได้รับการติดแผ่นแปะร้อนที่เวลา 8 ชั่วโมงหลังผ่าตัดคลอด มีอาการปวดหลังผ่าตัดน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ (กลุ่มทดลอง 3.5 ± 0.3 vs กลุ่มควบคุม 4.7 ± 0.4; mean difference 1.2; 95%CI: 0.4-2.1; p = 0.006)) ระยะเวลาในการลุกเดินครั้งแรกในกลุ่มที่ได้รับการติดแผ่นแปะความร้อนน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ (1,073 ± 267.7 นาที vs 1,261.9 ± 205.3 นาที; mean difference 189นาที; 95%CI: 81.4-296.6; p < 0.001) กลุ่มที่ได้รับการติดแผ่นแปะร้อนมีปริมาณการใช้ยาแก้ปวดเพิ่มเติมน้อยกว่าเมื่อเปรียบเทียบกับกลุ่มควบคุม (56.4% vs 82.1%; p = 0.014) ไม่มีรายงานเหตุการณ์ไม่พึงประสงค์*

สรุป: *การใช้แผ่นแปะร้อนที่บริเวณหลังส่วนล่างช่วยลดอาการปวดอย่างมีนัยสำคัญที่ 8 ชั่วโมงหลังการผ่าตัดคลอด*

คำสำคัญ: *แผ่นแปะร้อน, ความเจ็บปวดหลังผ่าตัด, การผ่าตัดคลอดบุตรทางหน้าท้อง*

Introduction

Cesarean delivery is one of the most common surgical procedures in Obstetrics. A prevalent issue that many women face after undergoing a cesarean section is pain. Discomfort arises from various factors, including pain at the incision site, lower back pain, and pain due to uterine contractions, which adversely affect a woman's comfort during the postpartum phase. The pain from uterine contractions is referred to the dermatomes that are supplied by T10, T11, T12, and L1[1]. Nowadays, there are various methods of dealing with pain after cesarean section. Treatment of postoperative cesarean delivery pain is divided into pharmacologic and non-pharmacologic treatment.

Pharmacological treatments are often favored for managing pain after a cesarean section due to their capacity to alleviate discomfort in a relatively short time frame. Typically, non-steroidal anti-inflammatory drugs and paracetamol-based medications are used.

Non-pharmacological strategies should also be integrated into pain management to complement pharmacological treatments and reduce reliance on analgesics. A systematic review conducted by Cochrane on complementary and alternative therapies for post cesarean pain has identified various non-pharmacological methods. These include acupuncture or acupressure, aromatherapy, electromagnetic therapy, massage therapy, music therapy, reiki, relaxation, and transcutaneous electrical nerve stimulation (TENS)[2].

One of the non-pharmacologic methods for pain reduction is heat therapy; it is simple, cost-effective, requires no special skills, and is readily available with few side effects when applied appropriately[3,4].

The mechanism by which heat alleviates pain is explained by the gate theory of pain. Heat provides relief to the mother by activating heat receptors in the skin and deeper tissues, which interrupts the transmission of pain signals to the brain by effectively closing the pain control gate system within the spinal cord[4]. Furthermore, heat promotes vasodilation, leading to increased blood flow[5]. It also relaxes superficial muscles and reduces muscle spasms. In addition, heat can stimulate touch and temperature receptors, which promote a pleasurable feeling and decrease the level of pain[6]. The optimum temperature range for superficial heat therapy is between 40 and 45°C[7].

Current research indicates that heat can help reduce pain in various cases, such as those involving lower back pain, muscle strain, pain during labor, dysmenorrhea, and pain after surgical procedures like hernia surgery and cystoscopy[8-14]. However, there is still insufficient information regarding the study of heat application for pain relief after cesarean delivery. Additionally, a systematic review conducted by Cochrane in 2020[2] examined several strategies for alleviating pain following cesarean delivery, as previously noted. However, it revealed that, while numerous methods exist, the application of heat for pain management post-cesarean delivery was not included in this study. Based on all the research and information mentioned, it is clear that studies focusing on the use of heat for reducing pain after cesarean section remain limited.

Materials and Methods

This study was conducted as a randomized controlled trial involving postpartum women aged 18 years or older who had undergone operative procedure cesarean delivery at Khon Kaen Hospital from September 2023 to March 2024. The inclusion criteria specified that participants were at least 18 years old, had the ability to read, write, and understand Thai, had a low transverse uterine incision, and underwent cesarean delivery with a spinal block and morphine, and exhibited none of the exclusion criteria applied, such as 1) the woman experienced intraoperative complications including postpartum hemorrhage, intensive care unit admission, high block anesthesia, 2) pelvic infection:

chorioamnionitis, 3) maternal fever, 4) myoma uteri, 5) uterine anomaly, 6) history of uterotonic drugs used except syntocinon, 7) cutaneous lesions on the lower back, 8) vascular disease like vasculitis, 9) heat hypersensitivity, 10) sensory nerve loss, 11) postoperative cesarean section resulting in hematoma at the surgical wound, and 12) adhesions from previous cesarean sections intraoperatively. This study received approval from the Khon Kaen Hospital Institute Review Board for Human Research (reference number: KEF66019). Participants provided informed consent before enrolling in the study at the postpartum ward. Participants were randomly allocated by computer generation using a block of four into two groups. Group 1: The intervention group received a heat patch placed on the lower back (dermatome T10-L1) 6 hours post cesarean delivery. Group 2: The control group received standard postoperative care without a heat patch. Allocation concealment was achieved using sealed opaque envelopes.

The current study used a Japanese iron-filled heat patch that begins to warm up a few minutes after being opened, reaching its maximum temperature within 20 minutes to 1.5 hours and maintaining warmth for up to 10 hours[15]. Enhanced blood circulation is achieved by warming the specific area, which promotes vasodilation and, ultimately results in pain reduction.

This study selected the Japanese iron-filled heat patch due to its simplicity, safety, cost-effectiveness, and affordability[16]. Earlier studies have demonstrated various methods of heat application to alleviate pain, including hydrocollator packs, radiant heat systems, heat wraps, and heat patches[8-14]. In this research, a heat patch was selected because previous findings indicated that the Japanese iron-filled heat patch could help reduce pain during the active phase of the first stage of labor[8]. Consequently, the heat patch was chosen as the intervention for this investigation.

In the Anesthetics Department of Khon Kaen Hospital, the local anesthetic bupivacaine is used in combination with opioid morphine for women undergoing cesarean delivery. The effect of bupivacaine assists in blocking both motor and sensory functions, ensuring that the patient does not experience pain prior to the surgery, with an onset period of 2-4 hours[17]. The analgesic morphine has been proven to be effective in alleviating pain for as long as 24 hours post-administration[18]. Consequently, patients will start to experience pain again roughly 2-4 hours after the surgery, once the effects of the bupivacaine anesthetic have diminished. Therefore, the researchers decided to start data collection once the mothers began to regain motor and sensory function for safety during the study. Pain scores will be recorded 6 hours post-surgery to establish a baseline pain score. After that, a heat patch will be applied, and pain scores will be measured again 2 hours after the patch is applied, allowing the heat patch to gradually release heat and increase the temperature to 40-45°C, which takes about 20 minutes to 1.5 hours after application[15]. The researchers will then consider the primary outcome as the pain score measured 8 hours after surgery (2 hours after applying the heat patch).

Baseline characteristics were documented, including age, body mass index (BMI), underlying, prior abdominal surgery, parity, operative time and indications of cesarean section, as well as surgeon, intraoperative blood loss, and other obstetric problems.

The intervention was initiated 6 hours after post-cesarean delivery. For the heat patch, a 9.5x13 cm, 40-45°C patch was placed on the postpartum women's clothing over the lower back during the dermatome T10-L1 and was not applied directly to the skin area for 6 hours until 16 hours post-cesarean delivery. The total time to apply the heat patch was 10 hours.

The person tasked with applying the heat patch had to be a general physician or an obstetric resident. Those who applied the patches were given

instructions and clarifications in this study before applying them. After attaching the patch, the postpartum women wore a belly band over the area where the patch was attached to prevent slipping out of place. Before the experiment, investigators tested the pregnancy's consciousness and sensory perception. The nurse at the postpartum ward will assist in measuring the pain score for both the study group and the control group, starting at 6 hours after the cesarean section.

Skin temperature and appearance at heat patch placement were monitored every 2 hours by thermoscan. A Xiaomi mijiai Health thermometer (China) was used to control the temperature not to exceed 50°C. Postpartum women were evaluated for complications of the heat patch by verbal interviews and were asked about their pain scores at 6-, 8-, 12-, and 24-hours post cesarean delivery by using a visual analog scale (VAS). The heat patch was immediately removed if there was any abnormal skin reaction (clear water blisters, burned skin, or loss of sensation) or temperature over 50°C. In the control group, standard care with no heat patch was provided. Both groups received the same standard of post-operative management. Additional medications used for analgesia in this study included tramadol, ibuprofen, and acetaminophen. Both groups received additional analgesia postoperatively. On postoperative day 1, tramadol 50 mg was administered intravenously as needed, every 6 hours, for a VAS pain score greater than 4. After starting a step diet, acetaminophen 500 mg (1–2 tablets) was given orally as needed for pain every 4–6 hours, and ibuprofen 400 mg (1 tablet) was given orally three times a day if the VAS score remained greater than 4. The amount of additional analgesic use was measured within 24 hours after surgery. At the end of the study, the data were concluded by the principal investigator.

The primary outcome was the pain score at 8 hours post cesarean delivery. Secondary outcomes included pain score at 6, 12, and 24 hours post cesarean delivery, additional analgesic drugs required, time to first ambulation, time to first flatus, and adverse effect of heat patch.

Statistical analysis

$$n_{trt} = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \left[\sigma_{trt}^2 + \frac{\sigma_{con}^2}{r}\right]}{\Delta^2}$$

$$r = \frac{n_{con}}{n_{trt}}, \Delta = \mu_{trt} - \mu_{con}$$

The calculation of the sample size for this study was based on a pilot study with 15 women per group. The average pain score in the treatment group was 5.05 with a standard deviation (SD) of 2.28, whereas the control group exhibited a mean pain score of 3.55 with an SD of 1.51. With a power of 90% and an alpha error of 5%, accounting for a 10% dropout rate, the study required a total population of 78 participants, with 39 in each group. Continuous variables were assessed using the student t-test and were expressed as mean and SD. Categorical variables were analyzed with chi-square or Fisher's exact test, with results presented as percentages. The mean difference in the pain score between groups was analyzed and presented with 95% confidence intervals. A p value < 0.05 was considered statistically significant. STATA version 17 was used for all analyses.

Results

Seventy-eight women were enrolled in the study. All participants were randomly allocated to either the study group (heat patch) or the control group, with 39 individuals in each group. No participants withdrew from the study (Fig. 1). The demographic data of both groups were not significantly different (ages, body mass index, underlying disease, prior abdominal surgery, parity, gravidity, gestational age, operative time, indication of cesarean delivery, surgeon, and intraoperative blood loss (Table 1).

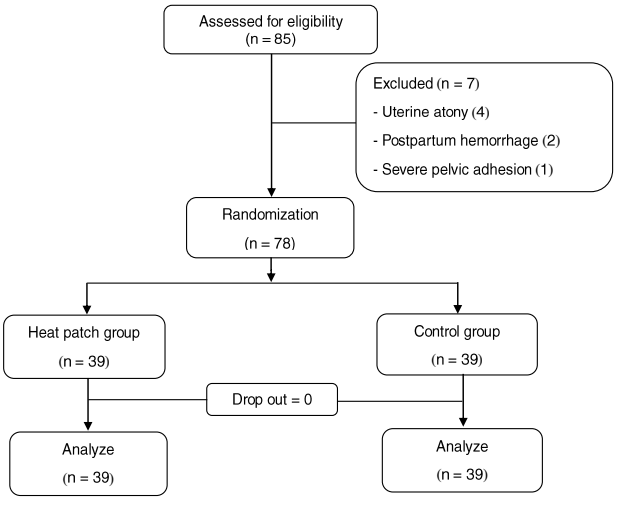

Fig. 1. Study flow diagram.

Table 1. Baseline characteristics of participants.

Baseline characteristics	Heat patch group (n = 39)	Control group (n = 39)	p value
Age (years), mean ± SD	26.9 ± 4.8	29.2 ± 5.2	0.050[a]
BMI (kg/m^2), mean ± SD	26.9 ± 3.8	28.8 ± 5.7	0.088[a]
Underlying diseases, n (%)	0 (0.0)	4 (10.3)	0.115[c]
Prior abdominal Surgery, n (%)			
Yes	14 (35.9)	22 (56.4)	0.069[b]
Gravidity, n (%)			
1	14 (35.9)	10 (25.6)	0.584[c]
2	18 (46.1)	19 (48.7)	
3	7 (18.0)	9 (23.1)	
4	0 (0.0)	1 (2.6)	
Parity, n (%)			
Nulliparous	16 (41.0)	13 (33.3)	0.482[b]
Multiparous	23 (59.0)	26 (66.7)	
GA (weeks), mean ± SD	38.4 ± 1.0	38.0 ± 1.4	0.321[a]
Operative time min, mean ± SD	42.9 ± 11.7	46.9 ± 13.9	0.164[a]
Indication of CD, n (%)			
Cephalopelvic disproportion	15 (38.4)	12 (30.7)	0.475[b]
Previous CD	11 (28.2)	18 (46.2)	0.101[b]
Breech	6 (15.4)	3 (7.6)	0.288[b]
Fetal macrosomia	2 (5.1)	1 (2.6)	0.556[c]
Failed induction	2 (5.1)	0 (0.0)	0.494[c]
Non reassuring FHS	1 (2.6)	4 (10.3)	0.358[c]
Vaginal condyloma	1 (2.6)	1 (2.6)	1.000[c]
Bad obstetric history	1 (2.6)	0 (0.0)	0.500[c]
Surgeon, n (%)			
Staff	23 (59.0)	18 (46.2)	0.257[b]
Residents	16 (41.0)	21 (53.8)	
Intraoperative blood loss ml, mean ± SD	348.7 ± 92.1	318 ± 87.7	0.135[a]
Another obstetric problem, n (%)	0 (0.0)	0 (0.0)	-

[a] Two-sample t-test, [b] chi-square test, [c] Fisher's exact test
BMI: Body mass index, SD: Standard deviation, CD: Cesarean delivery, GA: gestational age

The primary outcome was pain scores at 8 hours post cesarean delivery. There was a statistically significant difference in reducing postoperative pain between the heat patch group and the control group (3.5 ± 0.3 vs 4.7 ± 0.4, p = 0.006) (Table 2). In terms of the secondary outcome, postoperative pain score at 6 hours or before applying the heat patch tended to be higher in the study group but not significant (5.4 ± 0.3 vs 4.9 ± 0.4, p = 0.181), and pain score in the heat patch group was lower than in the control group at 12 and 24 hours post cesarean delivery (3.6 ± 0.3 vs 4.3 ± 0.4, p = 0.104) and (3.2 ± 0.3 vs 4.0 ± 0.3, p = 0.100), respectively, though not statistically significant (Table 2).

Table 2. Primary and secondary outcomes.

Pain score	Heat patch group (n = 39) mean ± SD	Control group (n = 39) mean ± SD	mean difference (95%CI)	p value
At 6 hours	5.4 ± 0.3	4.9 ± 0.4	0.7 (0.3-1.7)	0.181[a]
(Before using heat patch)				
At 8 hours	3.5 ± 0.3	4.7 ± 0.4	1.2 (0.4-2.1)	0.006[a]
(2 hours after intervention)				
At 12 hours	3.6 ± 0.3	4.3 ± 0.4	0.8 (0.2-1.7)	0.104[a]
(6 hours after intervention)				
At 24 hours	3.2 ± 0.3	4.0 ± 0.3	0.7 (0.1-1.6)	0.100[a]

[a] two-sample t-test
SD: standard deviation, CI: confidence interval

Time to first ambulation and first flatus in the heat patch group were significantly shorter in the heat patch group compared to the control group (1,073 ± 267.7 vs 1,261.9 ± 205.3, p < 0.001) and (1,194.4 ± 398.9 vs 1,636.8 ± 349.4, p < 0.001), respectively (Table 3). Additionally, the study group exhibited significantly lower consumption of additional opioids compared to the control group (22 (56.4) vs 32 (82.1), p = 0.014). Notably, there were no postoperative complications in either group (Table 4).

Table 3. Time to first ambulation and time to first flatus.

	Heat patch group (n = 39) mean ± SD	Control group (n = 39) mean ± SD	mean difference (95%CI)	p value
Time to first ambulation	1,073 ± 267.7	1,261.9 ± 205.3	189.0 (81.4-296.6)	< 0.001[a]
(min)				
Time to first flatus	1,194.4 ± 398.9	1,636.8 ± 349.4	442.4 (273.3-611.6)	< 0.001[a]
(min)				

[a] two-sample t-test
SD: standard deviation, CI: confidence interval

Table 4. Additional analgesic drugs and maternal adverse event.

	Heat patch group (n = 39)	Control group (n = 39)	p value
Additional analgesia, n (%)	22 (56.4)	32 (82.1)	0.014[b]
Maternal adverse events, n (%)			
Blister	0 (0.0)		
Burn skin	0 (0.0)		
Loss of sensation	0 (0.0)		

[b] chi-square test

Discussion

The management of postoperative pain involves multimodal strategies. Non-pharmacological methods are increasingly common due to their lower side effects and higher cost-effectiveness. One such non-pharmacological method for pain reduction is heat therapy. Heat aids in alleviating pain to a certain degree by activating heat receptors, which inhibit pain signal transmission to the brain through the pain control gate system in the spinal cord[4]. Numerous studies have shown that the application of heat is effective for various types of pain, including lower back pain, muscle strain, pain during labor, dysmenorrhea, and pain after surgical procedures[8-14].

Suthisuntornwong et al demonstrated that applying a hot patch to the lower back significantly reduced labor pain during the active phase of the first stage of labor ($p < 0.001$)[8]. Similarly, a study by Kaur et al revealed that warm compression (using a hydrocollator pack) decreased labor pain in the active phase of the first stage of labor ($p < 0.001$) and improved maternal satisfaction[9]. Additionally, Melling et al found that warming (via a radiant heat system) helped to reduce pain after hernia surgery two hours post application and during the first seven postoperative days ($p < 0.05$), potentially aiding in wound healing[10]. A systematic review and meta-analysis of complementary and alternative (CAM) therapies for post cesarean pain of 37 clinical trials (3,076 women) investigated eight distinct CAM therapies for alleviating post cesarean pain (acupuncture or acupressure, aromatherapy, electromagnetic therapy, massage therapy, music therapy, reiki, relaxation, TENS[2], concluding that these therapies might help reduce post cesarean pain for up to 24 hours. Siripanthong et al utilized a cold gel pack to alleviate postoperative pain in cesarean delivery, They found that the cold gel pack effectively reduced postoperative pain 6 hours after the procedure[19]. Further, Singhdaeng et al demonstrated that using an abdominal binder could reduce postoperative wound pain 6, 24, and 48 hours after using the binder, and reduced the used of analgesic drugs in postoperative cesarean delivery, though no significant differences were found in the time to first ambulation between the two groups[20]. However, no studies have investigated the use of heat to reduce pain after cesarean delivery. Therefore, this study aimed to assess the efficacy of using a heat patch to reduce pain after cesarean delivery. After conducting the research, it was found that the heat patch group reported significantly lower postoperative pain levels than the control group 8 hours after cesarean delivery (3.5 ± 0.3 vs 4.7 ± 0.4; mean difference: 1.2; $p = 0.006$). While the difference in pain scores between the groups was statistically significant, it amounted to 1.2 points on the VAS. However, this difference may not be clinically significant. For the secondary outcome, which measured pain scores at 6, 12, and 24 hours after cesarean delivery, it was found that the pain scores did not differ between the two groups. Since the pain score recorded 6 hours post surgery was before the application of the heat patch, it served as a baseline measurement. This may explain why the VAS score in the study group did not show a reduction compared to the control group. At 12 hours post surgery, or 6 hours after the heat patch was applied, the VAS score did not show statistically significant differences. This could be because, by this point, the temperature of the heat patch gradually decreased, falling below the effective temperature range for superficial heat therapy, resulting in insufficient pain relief. Additionally, the pain score measured 24 hours post surgery was taken after the heat patch had been removed. Therefore, this score may have been influenced by the administration of additional analgesics, and it was the pain score measured after the heat patch was removed.

One of the goals of this study was not only to reduce pain but also to promote early ambulation to reduce other postoperative complications. The heat patch maintains a temperature of about 40-45°C and is placed on the lower back (dermatome T10-L1), as the optimum temperature range for superficial heat therapy is between 40 and 45°C. Pain from uterine contractions is referred to the dermatomes that are supplied by T10 to L1, which was consistent with the

findings by Suthisuntornwong et al[8]. This randomized controlled trial validated the efficacy of the heat patch as an additional analgesic method post cesarean delivery without adverse events and maternal complications.

The strengths of this study included its randomized controlled design and the absence of participant dropout. A limitation of the present study was that we did not blind the intervention due to the nature of the heat patch, which might have influenced the outcomes.

Conclusion

A heat patch applied on the lower back resulted in significantly reduced pain 8 hours after cesarean delivery.

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Potential conflicts of interest

The author declares no conflicts of interest.

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