Original Article

Cold Therapy for Pain Relief in Postoperative Cesarean Section: Randomized Controlled Trial

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Background: Cold therapy decreases tissue blood flow by causing vasoconstriction, reduces tissue metabolism, oxygen demands, inflammation and muscle spasm. It also causes alteration of nerve conduction velocity and inhibitation of nociceptors.

Objective: To study the effectiveness of cold therapy for reducing postoperative pain in pregnant women who underwent cesarean section.

Materials and Methods: Pregnant women who had indication for cesarean section were selected via inclusion criteria. The participants were randomized into study and control group with simple random sampling methods. Cold pack gel was applied at 2 hours after operation for 6 hours of duration. The visual analog scale (VAS) score was recorded at 2, 6, 12 and 24 hours postoperatively.

Results: Primary outcome measure was the visual analog scale (VAS) at 2, 6, 12 and 24 hours after surgery. Mean of VAS scores at 6 hours and 12 hours after surgery in the study group had statistically lower than the control group. Firstly, there was no difference at 24 hours after surgery. After the second analysis was done by repeated ANCOVA, mean of VAS scores at 6 hours, 12 hours and 24 hours after surgery in the study group were lower than the control group with statistical difference. For the secondary outcomes, meperidine consumption within 24 hours postoperative in study group had statistically decreased. No difference of time for the first dose of meperidine requirement and length of hospital stay.

Conclusion: Cold pack gel could be another therapeutic option for postoperative pain management. In the present study, intervention group had reduced their pain scores at 6 and 12 hours after surgery and had reduced the narcotic drugs consumption.

Keywords: Cold therapy, Pain, Cesarean section

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Cesarean delivery is currently the most common operation in the modern of obstetrics practice. It causes mostly postoperative pain within 24 hours after surgery. Soft tissue injury is the principal cause of local inflammation, nociceptors stimulation and sensitization. As a result, most of parturient experience ongoing pain at rest with increase hypersensitivity of primary hyperalgesia. Prostaglandins, interleukins, cytokines and neurotrophins accompany mediators that are locally and systemically released during and after the surgery contribute to nociceptor sensitization[(1)]. Cold therapy is available as an option for pain reducing. It has lesser side effects and cost than analgesic drugs using. The physiological processes is decreasing tissue blood flow by causing vasoconstriction. It reduces tissue me-tabolism, oxygen demands, inflammation and muscle spasm. Hypothermic effects at the local site can signal the spinal cord via neurologic and vascular mechanisms, decreasing the activation thresh-old of tissue nociceptors and the conduction velocity of nerve signals[(2)]. As a result, cold therapy is used as an additional postoperative pain treatment in orthopedic, general surgery and gynecologic surgery[(3-10)].

The aims of postoperative pain management in Cesarean patients are pain and discomfort reduction. Manageable pain allows early ambulation of new mothers, of which can promote healing process and lactation. Moreover, the early ambulation can prevent postoperative complications such as lung atelectasis, pulmonary infection and bowel ileus. Most parturient who underwent cesarean delivery received meperidine (opioid family) for pain relief. Nausea and vomiting are observed as its common side effects. An additional agent with negligible side effect which could reduce pain and resulted in meperidine dosage reduction will be quite welcome. Many recent literatures reported the effectiveness of cold therapy in postoperative pain reduction.

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According to Koc et al[3] cold therapy was an effective methods for providing pain relief after inguinal hernia repair. Cold therapy also reduced postoperative pain of orthopedic surgery as reported by Jon[4], Waterman[5] and Ana[6] from year 2010 to 2014. Wanlayanee[9] and Chumkam[10] reported that cryotherapy significantly reduced postoperative pain in patients who underwent gynecologic surgery. It is necessary to gain new comprehension into the management of postoperative pain.

The aim of the present study was to compare the effectiveness of cold therapy with routine postoperative pain management in cesarean section.

Materials and Methods

This randomized controlled trial was conducted at Obstetrics and Gynecology ward, Department of Obstetrics and Gynecology, Thammasat University Hospital, Pathumthani, Thailand. The approval from the Ethics Committee on Clinical Research of Faculty of Medicine, Thammasat University, was obtained prior to the study (MTU-EC-OB-2-192/61) and registered with the Thai Clinical Trials Registry (TCTR20190605007).

One hundred pregnant women who underwent cesarean section under spinal anesthesia at Thammasat hospital between June 15th, 2019 and July 31st, 2019 were enrolled in the study. Inclusion criteria included pregnant women who underwent cesarean section under spinal block with 0.5% hyperbaric bupivacaine and 0.2 mg morphine (the total of 2 to 2.2 ml), with Pfannenstiel incision and aged greater than 18 years old. Participants who had underlying diseases as cold urticaria and Raynuad phenomenon, infection or active skin lesion at surgical site were excluded. Participants were randomized into two groups by simple random sampling method. The demographic data included age, weight, height, occupation, education, income, and underlying disease. Obstetric history included gravida, number of vaginal delivery, number of prior cesarean section, number of abortion, age of last child, indication for cesarean section, incision length, time of operation and operative procedure. Group number was concealed in sealed envelopes that were opened after the completion of the surgery. Surgeons and patients were blinded to the assigned treatment group before the operation started. The envelope was randomly picked up by a nurse. Patients from both groups received same standard postoperative care which consisted of vital sign, intravenous fluid input/output, an analgesic drugs, an antibiotic drugs recording, Foley's catheter retention and surgical wound dressing with a waterproof transparent patch (Tegaderm® with pad or Op-site®). Participants in the intervention group received cold pack gel (Siriraj Jelly Cold-Hot Pack, Thailand) with its own thin fabric bag. The cold pack gel was kept at -4°Celsius. Then, the cold pack gel was placed on top of the surgical wound dressing firstly at 2 hours post-surgery. It was changed every 2 hours when the cold pack gel got warmer for 6 hours duration. Control group received standard routine postoperative care.

Postoperative pain scores were measured by visual analog scale (VAS) at 2 (before placing cold pack gel), 6, 12 and 24 hours after surgery. Participants were interviewed and requested to choose a number between 0 (no pain) to 10 (the worst pain) for describing their pain. Post cesarean pain was evaluated by the author. Twenty five milligram of meperidine was given to participants if requested every 4 hours. The total amount of meperidine consumption and its side effects, namely nausea, vomiting, dizziness, pruritus, urticaria, allergic reaction and respiratory depression were recorded within the first 24 hours after surgery by nurses at postpartum ward.

The sample size in the present study was calculated from Wanlayanee's study[9]. The formula for the test of difference in two independence proportions was used. The alpha and beta were set at 0.01 and 0.05, respectively. The least of 44 cases obtained from the calculation was the minimal sample size. The sample size was chosen at 50 participants per group after the additional of 10 percent for data loss prevention.

Primary outcome was measured by the visual analog scale (VAS) at 2, 6, 12 and 24 hours postoperatively. Participants were instructed to rate the pain intensity with scores between 0 to 10. The score of zero and ten represented no pain and the worst pain, respectively.

Secondary outcomes included total dose of meperidine consumption, time for the first dose of meperidine request, length of hospital stay and surgical site infection rate. Data collection was finished within 24 hours post operation. Parturients were also asked to complete a structural questionnaire for assessing their tolerance. Data were analyzed using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) for Windows, version 24. Continuous data were represented by mean, standard deviation and using analysis of covariant in repeated measure. The VAS score was analyzed by repeated analysis of covariance (ANCOVA). Categorized data were evaluated by Chi-square tests or Fisher exact test whichever appropriated. A *p*-value of 0.05 was used as the level of significance.

Results

One hundred pregnant women who underwent cesarean section deliveries were equally enrolled in the present study and control groups. Each group was composed of

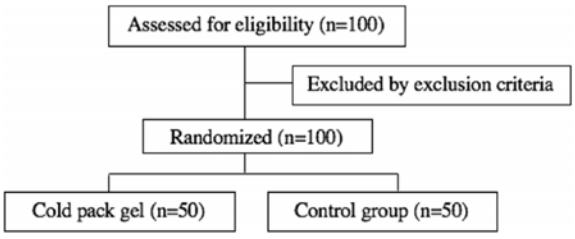

Figure 1. Flow chart of participants' progress through the study.

50 participants (Figure 1). Mean age of participants in the present study was 32 years old. Eighty percent of the participants had education level of bachelor degree or greater and most of them were employees of government offices and businesses. Around ninety percent of participants had monthly income of more than 30,000 baht (900 US dollars) and had no underlying disease. There was no statistically significant difference in the demographics data of both groups including age, weight, height, underlying disease, education, occupation and income (Table 1). Half of cases previously had cesarean delivery. Concurrent tubal sterilization was at 38 percent. Most operations were finished within one hour. The incisional length of the study group was slightly longer than the control group with statistical difference (9.36 versus 8.96 centimeters). Obstetrics data including gravida, number of vaginal delivery, number of prior cesarean section, number of abortion, last child age, indication for cesarean section, procedure and time of operation, were all presented no statistical difference in both groups (Table 2).

For the primary outcome, at 2 hours after surgery (before cold pack gel was placed), both groups had no difference in VAS scores. After cold pack gel was applied, mean of VAS scores at 6 hours and 12 hours after surgery in the study group was lower than that of the control group with statistical difference. There was no difference at 24 hours after surgery (Table 3). For the secondary outcomes, meperidine consumption within 24 hours after operation in the study group was statistical less than the control group (13.5 and 26.5 milligrams, respectively). Time interval from the finish of the operation to the first dose of meperidine request in the study group was slightly longer than the control group (7.42 versus 7.18 hours, respectively) without

Table 1. Demographic character of participants (50 cases per group)

	Control	Study	*p*-value
Age (years)*	32.84±4.89	32.60±4.49	0.799
Weight (kg)*	71.3±13.86	72.24±12.67	0.724
Height (cm)*	159.62±5.68	158.80±5.34	0.459
Education level**			0.562
Primary school	0 (0)	1 (2)	
High school	10 (20)	7 (14)	
Bachelor Degree	40 (80)	39 (78)	
Master's Degree	0 (0)	3 (6)	
Occupation**			0.770
Vacancy	0 (0)	3 (6)	
Self-employed	3 (6)	2 (4)	
Employee	45 (90)	39 (78)	
Government service	2 (4)	4 (8)	
Others[1]	0 (0)	2 (4)	
Income (baht)**			0.656
<10,000	1 (2)	0 (0)	
10,000-30,000	5 (10)	5 (10)	
30,000-50,000	41 (82)	42 (84)	
>50,000	3 (6)	3 (6)	
Underlying disease**			0.267
None	44 (88)	46 (92)	
Diabetes mellitus	3 (6)	3 (6)	
Heart disease	1 (2)	0 (0)	
Hypertension	0 (0)	1 (2)	
Thyroid disease	2 (4)	0 (0)	

* mean ± standard deviation (SD), ** n (%)
Others[1] = student, researcher

Table 2. Obstetrics history of participants (50 cases per group)

	Control	Study	*p*-value
Parity**			
Nulliparous	20 (40)	17 (34)	
Multiparous	30 (60)	33 (66)	
Vaginal delivery*	0.16±0.548	0.14±0.452	0.843
Prior C/S*	0.48±0.544	0.52±0.544	0.714
Abortion*	0.24±0.716	0.28±0.701	0.778
Last child age (years)*	2.33±2.995	2.38±2.898	0.933
Indication**			0.769
Elective C/S	16 (32)	17 (34)	
Prior C/S	24 (48)	25 (50)	
Others	10 (20)	8 (16)	
TR	19 (38)	19 (38)	1.000
Length (cm)*	8.96±1.16	9.36±0.631	0.035
Time (min)*	39.30±10.876	38.94±9.761	0.862

* mean ± standard deviation (SD), ** n (%)
Others = Cephalopelvic disproportion, placenta previa, non-ressuring fetal status, malpresentation, unprogress of labour, severe intrauterine growth restriction; C/S = Cesarean section, TR = Tubal resection; Length = Incision length; Time = Operative time

Table 3. Comparison of primary outcome and secondary outcome (50 cases per group)

	Control	Study	*p*-value
Primary outcome (VAS)			
2	3.38±1.227	3.88±1.932	0.124
6	5.48±1.359	3.5±1.199	0.018
12	5.06±1.150	4.04±1.577	0.002
24	4.10±1.129	3.34±1.206	0.090
Secondary outcome*			
Meperidine (mg)	26.5±19.827	13.50±19.698	0.001
Time for 1st dose (hr)	7.18±3.419	7.42±4.766	0.835
LOS (day)	3.32±0.513	3.22±0.418	0.288

* mean ± standard deviation (SD)
VAS = visual analog scale score; 2 = at 2 hours after surgery; 6 = at 6 hours after surgery; 12 = at 12 hours after surgery; 24 = at 24 hours after surgery; Meperidine = Meperidine consumption; Time for 1st dose = Duration time between postoperation and first dose of pethidine; LOS = Length of hospital stay

statistical difference (Table 3). There was no difference in the length of hospital stay in both groups. There was no immediate complication in the present study. The surgical wound infection was evaluated at one week after surgery and no complication was reported.

At the beginning of analysis, incision length and meperidine consumption were found to be statistically different in both groups. Therefore, the present study classified incision length and meperidine consumption as covariate factor. The dependent variable (VAS at 6, 12 and 24 hours after surgery) and means of VAS scores were adjusted due to the effects that the covariate had on it (Table4). The second analysis was done by repeated ANCOVA. Mean of VAS scores at 6 hours, 12 hours and 24 hours after surgery in the study group were lower than the control group with statistical difference as presented in Figure 2.

Discussion

Cold therapy for pain reduction was an optional methods for soft tissue injury, post orthopedic procedures, general surgery, gynecologic surgery and otorhinolaryngology surgery[3-14]. It diminished the inflammatory process reaction to trauma, tissue edema, hematoma formation and pain[2]. In the present study, cold therapy reduced post cesarean pain at 6 and 12 hours with statistical difference. Even though the cold pack application was placed on the patients for only 6 hours, its pain reduction effect still extended to 12 hours after surgery.

There were many previous clinical studies that examined the effectiveness of cold therapy as presented in Table 5. The study of Soheil[11] was the first literature in post cesarean pain relieving by cryotherapy. The temperature in their study was set as 6°Celsius by a special unit that operated by the running water for 48 hours postoperatively. They reported that cryotherapy could not reduce postoperative pain. In this current investigation, the temperature was set at -4°Celsius and applied for 6 hours. Koc et al[3] reported that cold compression could reduce postoperative pain of hernia

Table 4. Effect of mean score of pain change between groups after controlling the covariate effect from incision length and meperidine consumption (50 cases per group)

	Control	Study	*p*-value
Primary outcome (VAS)*			
6	5.278±10.15	3.702±0.15	<0.001
12	4.898±0.19	4.202±0.19	<0.014
24	4.093±0.169	3.347±0.169	<0.003

* mean ± standard deviation (SD)
VAS = visual analog scale score; 6 = at 6 hours after surgery; 12 = at 12 hours after surgery; 24 = at 24 hours after surgery

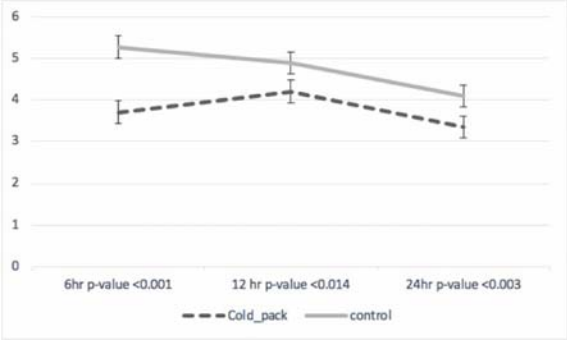

Figure 2. Effect of mean score of pain change between groups after controlling the covariate effect from incision length and pethidine consumption (50 cases per group).

Table 5. Comparison of cold therapy efficacies

Research	Soheil	Koc	Watkins	Wanlayanee	Chumkam	Present
Years	1992	2006	2013	2018	2018	2019
Country	USA	Turkey	USA	Thailand	Thailand	Thailand
Operation	C/S	Hernia	Gen Sx	Benign Gyn	Gyn	C/S
Type	N/A	Lichtenstein	Mid	Mid+LT	LT	Pfannenstiel
Number	62	40	55	28	100	100
Duration	48 hr	1/3 hr	24 hr	1/3 hr	6 hr	6 hr
Effect	N/A	24 hr	72 hr	6 hr	12 hr	12 hr
Result	DE	IE	IE	IE	IE	IE
LOS	ND			ND	ND	ND
Analgesic	ND	D	D	ND	ND	D

hr = hours; min = minutes; Gen Sx = general surgery; tonsil = tonsillectomy; gyn = gynecologic surgery; N/A = not available; Lichtenstein = Lichtenstein type repair; mid = midline incision; duration = duration of treatment (hr); effect = duration of effect (hr); number = number of sample size; LT = low transverse incision; LOS = length of hospital stay; analgesic = analgesic consumption; IE = increases efficacy; DE = decreases efficacy; ND = no difference; D = decreased consumption

repair for 24 hours. The time of cold pack application in their study was only 20 minutes which they didn't mentioned about temperature. They supported the present study that cold compression could reduce postoperative pain. Normally, length of herniorrhaphy incision was shorter than the cesarean section. Watkins et al[7] reported that cold therapy reduced the postoperative pain in the patient who underwent general surgery via low midline incision. Time of cold application in their study was 24 hours. Pain reducing efficacy was extended to 3 days after surgery. The present study shows similar result that cryotherapy could reduce postoperative pain. It seem that the longer duration of cold application allowed longer effect of pain reduction. Wanlayanee[9] and Chumkam[10] reported that cryotherapy could reduce post gynecologic surgery pain for only 6 hours and 12 hours, respectively. Time of application in Wanlayanee's study was shorter than the current study (20 minutes versus 6 hours). The application of cold pack in Chumkam's and current study were 6 consecutive hours. Both Wanlayanee and Chumkam supported the concept of cryotherapy for pain reducing after surgery.

Parturients who recently gave birth via cesarean section had more postoperative pain than vaginal delivery. The authors should encourage the parturients and obstetricians to choose vaginal birth as the first priority. In the situation that vaginal delivery was impossible, the cesarean delivery should be the final decision. Therefore, parturients who underwent cesarean delivery should receive appropriate and adequate postoperative pain management with minimal side effect of analgesic drugs. As a result, they could be early recovery and mobility stimulated as soon as possible.

The strength of the present study was a randomized controlled trial and all of obstetric parameters were controlled.

Conclusion

Cold pack gel can be alternative option for management of postoperative pain. In this study patients who underwent cesarean section had improved their pain scores at 6 and 12 hours after surgery and had reduced the narcotic drugs consumption. Due to lesser side effects, reusable and lesser expenses, in the author's aspect, cold pack gel should be used in postoperative pain control.

What is already known on this topic?

Cesarean delivery is the most common operation in the obstetrical procedure. It mostly causes postoperative pain within 24 hours postoperatively. Cold therapy is available as an optional for reduce this pain. The physiological processes include decreases tissue blood flow by causing vasoconstriction, reduces tissue metabolism, oxygen demands, inflammation and muscle spasm. It influenced effects both locally and at the level of the spinal cord via neurologic and vascular mechanisms, decreasing the activation threshold of tissue nociceptors and the conduction velocity of nerve signals. This local anesthetic effect called cold-induced neuropraxia.

What this study adds?

Cold therapy could reduce post cesarean pain at least 12 hours after surgery. There was no side effect from cold therapy.

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Potential conflicts of interest

The authors declare no conflicts of interest

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การรักษาด้วยความเย็นเพื่อบรรเทาความเจ็บปวดหลังจากทำการผ่าตัดคลอดทางหน้าท้อง

เมธาวีส์ เชาวลิต, เด่นศักดิ์ พงศ์โรจน์เผ่า, อธิตา จันทเสนานนท์, จรรยา ภัทรอาชาชัย, กรณ์กาญจน์ ภมรประวัติธนะ, คมสันติ์ สุวรรณฤกษ์

ภูมิหลัง: ความเย็นสามารถลดการไหลเวียนโลหิตในเนื้อเยื่อจากการที่มีภาวะหดตัวของเส้นเลือด ลดเมตาบอลิซึมในเนื้อเยื่อ ลดการใช้ออกซิเจน ลดการอักเสบ และลดภาวะกล้ามเนื้อหดเกร็ง

วัตถุประสงค์: เพื่อศึกษาประสิทธิภาพของเจลประคบเย็นในการลดปวดแผลผ่าตัดคลอดทางหน้าท้อง

วัสดุและวิธีการ: หญิงตั้งครรภ์ที่มีข้อบ่งชี้ในการผ่าตัดคลอดทางหน้าท้องจะถูกคัดเลือกตามเกณฑ์คัดเข้า ผู้เข้าร่วมวิจัยจะถูกสุ่มเพื่อแบ่งเป็น 2 กลุ่ม คือกลุ่มควบคุม และกลุ่มที่วางเจลประคบเย็นหลังผ่าตัดคลอด เจลประคบเย็นจะเริ่มวางที่ 2 ชั่วโมงหลังผ่าตัด และวางนานเป็นเวลา 6 ชั่วโมง คะแนนความเจ็บปวดจะถูกบันทึกที่เวลา 2, 6, 12 และ 24 ชั่วโมงหลังผ่าตัด

ผลการศึกษา: ผลลัพธ์หลักจะเป็นการประเมินคะแนนความเจ็บปวดที่ 2, 6, 12 และ 24 ชั่วโมงหลังผ่าตัด พบว่าระดับความเจ็บปวดที่เวลา 6 และ 12 ชั่วโมงหลังผ่าตัดในกลุ่มที่วางเจลประคบเย็น ต่ำกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ในขณะที่เวลา 24 ชั่วโมง พบว่าไม่แตกต่างกัน ผลลัพธ์รองพบว่าปริมาณการใช้ยา Meperidine ภายใน 24 ชั่วโมงหลังผ่าตัดในกลุ่มที่วางเจลประคบเย็นน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ และพบว่าไม่มีความแตกต่างในระยะเวลาของการขอยาครั้งแรก และระยะเวลาในการนอนโรงพยาบาลในทั้งสองกลุ่ม

สรุป: เจลประคบเย็นสามารถเป็นอีกทางเลือกการรักษาภาวะเจ็บปวดหลังผ่าผ่าตัดได้ ในการศึกษานี้พบว่าในกลุ่มที่วางเจลประคบเย็นมีระดับความเจ็บปวดลดลงที่เวลา 6 และ 12 ชั่วโมงหลังผ่าตัด และพบว่ามีปริมาณการใช้ยาแก้ปวดที่น้อยกว่ากลุ่มควบคุม