OBSTETRICS

Efficacy of Cold Gel Pack in Reducing Postoperative Pain in Cesarean Delivery at Sanpasitthiprasong Hospital: Randomized controlled trial

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ABSTRACT

Objectives: To evaluate efficacy and safety of cold gel pack in adjunctive to standard pain control in reducing postoperative pain after Cesarean delivery

Materials and Methods: Between December 2019 and March 2020, 34 women who underwent Cesarean delivery under regional anesthesia with neuraxial opioid at Sanpasitthiprasong Hospital were recruited. They were randomized into two groups: 1) receiving adjunctive cold gel pack covering surgical wound at 2-hour postdelivery for 20 minutes (intervention group, n = 17) or 2) receiving standard pain control (control group, n = 17). Pain scores were assessed using visual analogue scale (VAS) at 2 hours (before intervention), 6 hours (4 hours after intervention) and 24 hours postdelivery. Data on additional analgesic drugs, possible complications, participant's satisfaction were recorded. Pain scores were compared between treatment groups using student t-test and occurrence of complications compared using chi-square test.

Results: With comparable initial pain score, intervention group had significantly lower postoperative pain at 6 hours after Cesarean delivery than control group (mean pain score ± standard deviation 3.53 ± 2.12 and 5.44 ± 1.56 respectively, p = 0.005), but there was no difference at 24 hours postdelivery. Patients in both groups required similar amount of additional analgesia. There were no significant differences between groups in postpartum hemorrhage, length of hospital stays and surgical wound infection. There were moderate and high patient satisfaction similarly observed for the two groups. No adverse effect from intervention happened in the intervention group.

Conclusion: Adjunctive cold gel pack was efficacious in reducing postoperative pain at 6 hours after Cesarean delivery without safety concerns.

Keywords: cold gel pack, postoperative pain, cesarean delivery.

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การศึกษาประสิทธิภาพของการใช้ถุงเจลให้ความเย็นในการลดระดับความปวดหลังผ่าตัดคลอดบุตรที่โรงพยาบาลสรรพสิทธิประสงค์: การศึกษาทดลองแบบสุ่มมีกลุ่มเปรียบเทียบ

พัชรีญา ศิริพานทอง, ปิยวดี วุฒิกรสัมมากิจ, ปริญญา ชำนาญ

บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาประสิทธิภาพของการใช้ถุงเจลให้ความเย็นในการลดระดับความปวดหลังผ่าตัดคลอดบุตร

วัสดุและวิธีการ: หญิงตั้งครรภ์หลังผ่าตัดคลอดบุตรที่โรงพยาบาลสรรพสิทธิประสงค์ อุบลราชธานี จำนวน 34 ราย ระหว่างวันที่ 18 ธันวาคม 2562 ถึง 18 มีนาคม 2563 โดยผู้เข้าร่วมการวิจัยทุกรายได้รับการระงับความรู้สึกโดยการฉีดยาชาและยาแก้ปวดในกลุ่มอนุพันธ์ของฝิ่นเข้าช่องน้ำไขสันหลัง ผู้เข้าร่วมการวิจัยได้ถูกแบ่งออกเป็น 2 กลุ่มๆ ละ 17 คนโดยสุ่ม คือ 1) กลุ่มที่ได้รับถุงเจลให้ความเย็นประคบบริเวณแผลผ่าตัดเป็นเวลา 20 นาที อีกกลุ่มคือกลุ่มควบคุมไม่ได้รับถุงเจลให้ความเย็น บันทึกระดับความเจ็บปวดหลังผ่าตัดโดยใช้ภาพอนาล็อกมาตราส่วน (visual analog scale; VAS)โดยตัวผู้เข้าร่วมการวิจัยเองที่ 2 ชั่วโมงหลังคลอด (ก่อนได้รับถุงเจลให้ความเย็น), 6 ชั่วโมงหลังคลอด (4 ชั่วโมงหลังได้รับถุงเจลให้ความเย็น) และ 24 ชั่วโมงหลังคลอด รวมถึงบันทึกปริมาณยาแก้ปวดที่ต้องการเพิ่มเติม, การตกเลือดหลังคลอด, การติดเชื้อของแผลผ่าตัด, ความพึงพอใจ, ระยะเวลาในการนอนโรงพยาบาล และผลข้างเคียงจากการใช้ถุงเจลให้ความเย็น

ผลการศึกษา: ระดับความเจ็บปวดที่ 6 ชั่วโมงหลังคลอด ในกลุ่มที่ได้รับถุงเจลให้ความเย็นน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ ค่าเฉลี่ยระดับความเจ็บปวด (mean pain score ± SD) 3.53 ± 2.12 และ 5.44 ± 1.56 ในกลุ่มควบคุม (p = 0.005), ในขณะที่ระดับความเจ็บปวดตั้งต้นที่ 2 ชั่วโมงและ 24 ชั่วโมงหลังคลอด ไม่แตกต่างกัน ความต้องการยาแก้ปวดเพิ่มเติม การตกเลือดหลังการผ่าตัดคลอด ระยะเวลานอนโรงพยาบาล การติดเชื้อของแผลผ่าตัดคลอดไม่มีความแตกต่างอย่างเป็นนัยสำคัญทางด้านสถิติ ส่วนความพึงพอใจอยู่ในระดับปานกลางถึงมากทั้งสองกลุ่มแต่ไม่มีความแตกต่างอย่างเป็นนัยสำคัญทางด้านสถิติ นอกจากนี้ยังไม่พบอาสาสมัครใดมีผลข้างเคียงจากการได้รับถุงเจลให้ความเย็น

สรุป: การใช้ถุงเจลให้ความเย็นเพื่อช่วยลดความเจ็บปวดหลังการผ่าตัดคลอดสามารถช่วยลดความเจ็บปวดจากการผ่าตัดคลอดได้อย่างมีประสิทธิภาพ ที่ระยะเวลา 6 ชั่วโมงหลังคลอด

คำสำคัญ: ถุงเจลให้ความเย็น, ความเจ็บปวดหลังผ่าตัด, การผ่าตัดคลอดบุตรทางหน้าท้อง

Introduction

Effective postoperative pain control has been shown to relate to high patient satisfaction, rapid recovery, lower risk of deep vein thrombosis, heart and pulmonary complications and reduced costs of treatment[1].

In addition to conventional pharmacological postoperative pain management, a non-pharmacological approach has also been used in patients receiving operations. Among many modalities, cryotherapy has been increasingly used both as primary and adjunctive postoperative analgesia. It is believed that cryotherapy may reduce postoperative pain through decreasing the activation threshold of tissue nociceptors and the conduction velocity of pain nerve signals. Besides, this technique may help reduce pain through its effect on reduced cell metabolism and inflammation[2] and a decreased risk of surgical wound infection[3].

However, clinical benefits of cryotherapy on postoperative pain control remain uncertain. Although cryotherapy has reportedly been helpful as primary analgesia and adjunct analgesia in some surgical operations; for example, abdominal[4] and inguinal hernia surgeries[5] and emergency laparotomy[3]. The evidence of its benefits on pain control in obstetric and gynecologic operations is limited and available studies showed inconsistent results[6,7]. While the previous study showed that cryotherapy using cold gel pack could reduce postoperative pain in gynecologic surgeries under general anesthesia[6], other study suggested no benefits on pain control in Cesarean section[7]. In Cesarean delivery, neuraxial opioids were usually added during regional anesthesia (subarachnoid block) and adjunct analgesia may be needed for effective postoperative pain control. This study aimed to evaluate the efficacy of using cold gel pack as an adjunct analgesia in reducing postoperative pain in women undertaking Cesarean delivery under regional anesthesia (subarachnoid blockage) with neuraxial opioid at a referral tertiary hospital. We also examined the adverse effects and safety of cold gel pack as well as patient satisfaction.

Materials and Methods

Women aged 17-45 years old who underwent emergency or elective Cesarean delivery under regional anesthesia with neuraxial opioid from December 18th, 2019 to March 18th, 2020 at Sanpasitthiprasong hospital were invited to participate in this 2-arm parallel-group randomized control trial. The women who received parecoxib (Dynastat®), had a history of cold hypersensitivity, had any lesions at surgical wound, or developed severe complications during intra- and postpartum period, such as, cardiac arrest, eclampsia, and respiratory failure, were excluded from this study. This study was registered at http://www.thaiclinicaltrials.gov (TCTR20200205004) and was approved by the Sanpasitthiprasong Hospital Ethics Committee (Ref. no: 041/62C).

After giving written informed consent, baseline sociodemographic data, such as, age, occupation, education, income, types of health insurance, were recorded. Data on clinical and obstetric characteristics were obtained, and these included gravidity, parity, abortion, gestational age (GA), body mass index (BMI), mother's antenatal complications, obstetric complications, indication of operation, details of operation, type of skin incision, operative time, surgeons, and intraoperative blood loss.

After that, the participants were randomized into 2 groups: 1) receiving cold gel pack to cover surgical wound for 20 minutes at 2-hour after surgery in adjunct to standard pain control (intervention group), use only 1 cold gel pack. Nurses did not change cold gel pack during applying or 2) receiving standard pain control which was neuraxial opioids and additional analgesia such as paracetamol and pethidine (control group). Randomization numbers were generated using Microsoft Excel version 2010 and put in sealed opaque envelops.

At 2 hours postdelivery, the surgical wound of participants in the intervention group was covered by 5-plies-gauzed and waterproof-adhesive wrapped (Tegaderm® without pad) and cold gel pack which was wrapped by 2 mm-thick clothes. The cold gel

Siripanthong P, et al. *Efficacy of Cold Gel Pack in Reducing Postoperative Pain in Cesarean Delivery at Sanpasitthiprasong Hospital*

pack was frozen and stored at -10 C to 0 C for a minimum of 2 hours before using.

Primary outcomes were pain scores at 2 hours, 6 hours, and 24 hours post Cesarean delivery. Pain scores were assessed using visual analogue scale[8]. The participants put a mark on a 10 cm long straight line with the terms "no pain" at the left most and "the most unbearable pain" at the right most ends. Secondary outcomes included additional analgesia required, postpartum hemorrhage, surgical wound infection, length of hospital stays, patient's satisfaction, and adverse effects of cold gel pack.

Estimated total blood loss was computed based on recorded intraoperative blood loss and tampon used within 24 hours postpartum. Each tampon was weighed before and after using to estimate the volume of blood loss. Postpartum hemorrhage was defined as blood loss of at least 1,000 ml within 24 hours postdelivery. Surgical wound infection was defined as the presence of one or more symptoms/signs of infections: pain or tenderness around the incision site, localized swelling, redness, or warmness, with or without pus draining within 7-10 days after procedures[9]. In this study, the surgical wound was opened in the third day to evaluate surgical wound infection before discharge. Length of hospital stays counted in days from admission until discharge. Patient's satisfaction was evaluated as being highly satisfied, moderate satisfied and dissatisfied at 24 hours after delivery.

Statistical analyses

From previous studies, there had researches about cryoanalgesia in obstetrics such as inflammation and pain in postpartum mothers[10], efficacy of cryoanalgesia in decreasing pain during second trimester genetic amniocentesis: a randomized trial[11]. The first research was different from our study due to different position of wound. Second research had less pain from our study therefore these 2 studies were difficult to compare.

Sample size was calculated to address the research question "whether cold gel pack as an adjunct was efficacious in postoperative pain control in Cesarean delivery." Based on results from a study by Nuangpho W, et al[6] which showed that cold gel pack reduced postoperative pain at 6 hours after benign gynecologic surgery, with a percentage of having reduced or mild postoperative pain being 75% and 0% in cold gel pack and control groups. Using the formula below, at 99% confidence level ($\alpha = 0.01$), 90% power ($\beta = 0.1$) and 20% missing data and loss of follow-up assumed, 17 participants were required in each group.

Statistical analysis was performed using SPSS version 25.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics: number (percentage), mean (± standard deviation (SD)), median (interquartile range (IQR)) were used to describe participant's characteristics. Continuous data was tested for their distribution using Komolokov-Smirnov test. Comparisons of these characteristics between the intervention and control groups were performed using chi-square test, student t-test, Mann-Whitney-U test for categorical, normally and non-normally distributed continuous variables, respectively. An intention-to-treat analysis was used. Pain scores as primary outcome were compared between the two treatment groups using the student t-test. Adverse events and complications were compared between the two groups using chi-square test. A p value of < 0.05 was considered statistically significant.

Results

Fig. 1. shows flow of participant recruitment, randomization, application of intervention and outcome ascertainment in this 2-arm parallel-group randomized control trial. A total of 37 participants were presented at Sanpasittiprasong Hospital, Department of Obstetrics and Gynecology during the study period. Two cases who refused to participate in this study, and additional one case who did not received neuraxial opioids during her regional anesthesia were excluded from this study, leaving a final study sample of 34 women, 17 in each group. There was no lost to follow-up in both groups.
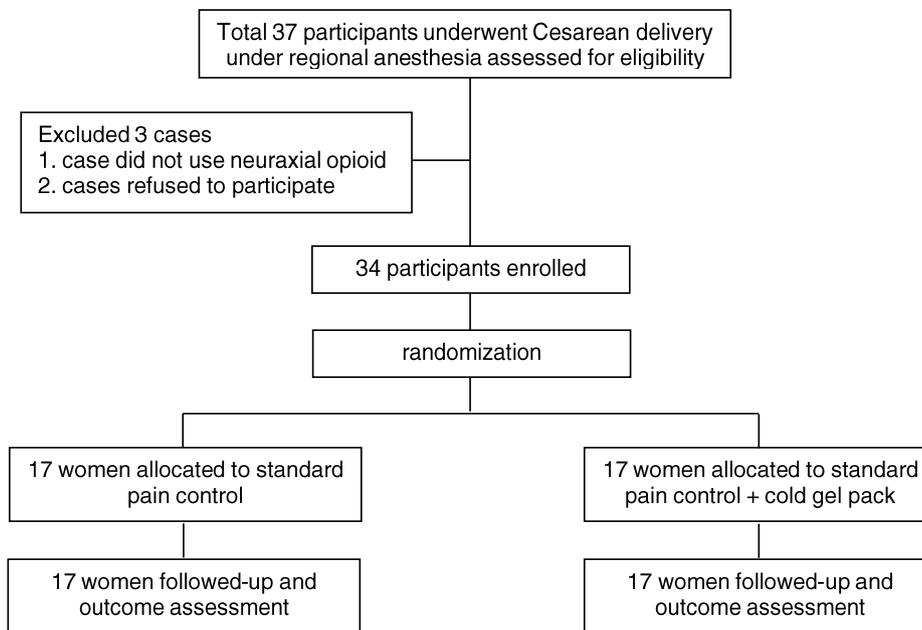
Fig. 1. Flow of recruitment, randomization, intervention and outcome ascertainment in this 2-arm parallel-group randomized control trial.

Table 1 shows sociodemographic, clinical and obstetric characteristics of study participants, total and by treatment groups. The median (IQR) age of study participants was 28.0 (26.0 - 32.0) years. Almost half of all participants were housewives. Two-thirds reported secondary school as the highest education and had universal coverage health insurance. Median gravidity and gestational age were 2.0 (IQR 1.0 - 3.0) and 39.0 (IQR 37.0 - 39.3) weeks, respectively. Approximately 56% and 41% of participants had cephalopelvic disproportion and previous cesarean section as an indication for Cesarean delivery. Most participants had low midline skin incision. Four-fifths of the Cesarean sections were performed by doctors in training and median operative time was 40.0 (IQR 35.8 - 49.0) minutes. Concerning intraoperative analgesia, median heavy marcaine of 1.95 ml and spinal morphine of 0.18 mg were used. Median intraoperative blood loss was 500 ml. Approximately 21% and 70% of participants had at least one of maternal complications and obstetric complications.

The only characteristic found different between the two groups was indication for Cesarean section, where the intervention group had a higher proportion of cephalopelvic disproportion than the control group. All of the remaining sociodemographic, clinical and obstetric characteristics were comparable between those in the intervention and control groups.

Pain scores assessed at 2, 6 and 24 hours postdelivery in the intervention and control groups are presented in Table 2. The initial pain scores at 2 hours postdelivery before applying cold gel pack were comparable between the two treatment groups. After applying cold gel pack, difference in pain scores between treatment groups was observed, with significantly lower pain scores at 6 hours after delivery in the intervention than control groups (p = 0.005). There was no statistically significant difference in pain score evaluated at 24 hours postdelivery. Reduce/mild pain was no statistically significant difference evaluated at 2, 6 and 24 hours postdelivery.

Table 1. Baseline characteristics of participants.

	Total (n=34)	Intervention (n=17)	Control (n=17)	p value
Age (years)	28.0 (26.0, 32.0)	28.0 (26.0, 32.0)	27.0 (25.0, 30.0)	0.322
Occupation				0.424
Business	2 (5.9%)	1 (5.9%)	1 (5.9%)	
Housewife	15 (44.1%)	8 (47.1%)	7 (41.2%)	
Teacher	2 (5.9%)	2 (11.8%)	0 (0%)	
Employee	10 (29.4%)	5 (29.4%)	5 (29.4%)	
Farmer	5 (14.7%)	1 (5.9%)	4 (23.5%)	
Education				0.791
Primary school	2 (5.9%)	1 (5.9%)	1 (5.9%)	
Secondary school	23 (67.6%)	11 (64.7%)	12 (70.6%)	
Vocational school	3 (8.8%)	1 (5.9%)	2 (11.8%)	
Bachelor's degree	6 (17.6%)	4 (23.50)	2 (11.8%)	
Income (baht)				0.486
Less than 10,000	23 (67.6%)	12 (70.6%)	11 (64.7%)	
10,000 – 20,000	10 (29.4%)	4 (23.5%)	6 (35.3%)	
More than 20,000	1 (2.9%)	1 (5.9%)	0 (0%)	
Insurance				0.375
Universal coverage	22 (64.7%)	11 (64.7%)	11 (64.7%)	
Cash	1 (2.9%)	0 (0%)	1 (5.9%)	
Government welfare	2 (5.9%)	2 (11.8%)	0 (0%)	
Social worker welfare	9 (26.5%)	4 (23.5%)	5 (29.4%)	
Body mass index (kg/m2)	28.9 (24.9, 33.4)	31.2 (25.9, 34.5)	27.2 (24.7, 31.0)	0.493
Gravidity	2 (1.0, 3.0)	2 (1.0, 2.0)	2 (1.5, 3.0)	0.143
Parity	1 (0, 1.0)	0 (0,1.00)	1 (0.50,1.00)	1.000
Abortion	0 (0, 1.0)	0 (0,0)	0 (0,1.00)	0.120
Gestational age (weeks)	39.0 (37.0, 39.3)	39.0 (38.0, 40.0)	38.0 (36.0, 39.0)	0.686
Indication				0.046
Cephalopelvic disproportion	19 (55.9%)	13 (76.5%)	6 (35.3%)	
Previous Cesarean section	14 (41.2%)	4 (23.5%)	10 (58.8%)	
Unfavorable cervix	1 (2.9%)	0 (0%)	1 (5.9%)	
Operation				0.078
Cesarean section	21 (61.8%)	13 (76.5%)	8 (47.1%)	
Cesarean section with tubal resection	13 (38.2%)	4 (23.5%)	9 (52.9%)	
Skin incision				0.473
Low midline	22 (64.7%)	10 (58.8%)	12 (70.6%)	
Pfannenstiel	12 (35.3%)	7 (41.2%)	5 (29.4%)	
Operative time (min.)	40.0 (35.8, 49.0)	40.0 (35.5, 48.5)	40.0 (36.0, 51.5)	0.919
Heavy Marcaine (ml.)	1.95 (1.80, 2.00)	1.95 (1.75, 2.00)	1.95 (1.80, 2.00)	0.731
Spinal morphine (mg.)	0.18 (0.10, 0.20)	0.20 (0.15, 0.20)	0.10 (0.10, 0.20)	0.170
Surgeon				0.072
Staff	6 (17.6%)	5 (29.4%)	1(5.9%)	
Resident	28 (82.4%)	12 (70.6%)	16(94.1%)	
Intraoperative blood loss (ml.)	500 (500.0, 500.0)	500 (500.0, 500.0)	500 (500.0, 500.0)	1.000
Composite maternal complicationsa	7 (20.6%)	4 (23.5%)	3 (17.6%)	0.671
Composite obstetric complicationsb	24 (70.6%)	11 (64.7%)	13 (76.5%)	0.452

Data are presented as number (percentage) or median (interquartile range).

[a] composite maternal complications defined as the presence of one or more of the following complications: urinary tract infection, asthma, cerebrovascular sequelae, upper respiratory tract infection, diarrhea, chronic renal failure, sepsis, anemia

[b] composite obstetric complications defined as the presence of one or more of the following obstetric complications: premature ruptured of membrane, preterm labor, fetal growth restriction, elderly gravidarum, gestational diabetes mellitus, twin, pregnancy induced hypertension, obesity, teenage pregnancy

Table 2. Comparison of pain score between intervention and control groups at 2 hours (before intervention), 6 hours (4 hours after intervention) and 24 hours postdelivery.

Time after cesarean delivery	Intervention (n=17)	Control (n=17)	p value
Pain score			0.424
2 hours (before use cold gel pack)	2.67±2.20	4.19 ± 2.50	0.083
6 hours (after delivery)	3.53 ± 2.12	5.44 ± 1.56	0.005
24 hours (after delivery)	4.82± 1.99	4.57 ± 2.11	0.200
Reduce/mild paina	1 (5.9%)	4 (23.5%)	
2 hours (before use cold gel pack)	7 (41.2%)	10 (58.8%)	0.303
6 hours (after delivery)	8 (47.1%)	4 (23.5%)	0.151
24 hours (after delivery)	3 (17.6%)	6 (35.3%)	0.244

Data are presented as mean ± standard deviation or number (percentage).

[a] reduce/mild pain defined as pain score VAS < 4

Concerning postoperative outcomes, both the intervention and control groups required a similar amount of additional analgesia (Table 3). There was no statistically significant difference between the two treatment groups in amount of blood loss in 24 hours, postpartum hemorrhage, blood transfusion, length of hospital stays and surgical wound infection. Patient satisfaction was not different between the two groups. No adverse event of the cold gel pack was reported.

Table 3. Comparison between treatment groups in postoperative outcomes.

	Total (n=34)	Intervention (n=17)	Control (n=17)	p value
Additional analgesia				
Paracetamol 1 dose	9 (26.5%)	4 (23.5%)	5 (29.4%)	0.687
Pethidine 1 dose	3 (8.8%)	0 (0%)	3 (17.6%)	0.070
Infected surgical wound at day 3	1 (2.9%)	0 (0%)	1 (5.9%)	0.310
Infected surgical wound at day 10	1 (2.9%)	0 (0%)	1 (5.9%)	0.310
24 hours blood loss (ml)	622.0 (586.5,660.0)	612.0 (577.0,652.0)	631.0 (599.5,678.5)	0.150
Postpartum hemorrhage	0 (0%)	0 (0%)	1 (5.9%)	0.310
Satisfaction				0.730
Dissatisfied	0 (0%)	0 (0%)	0(0%)	
Neutral	15 (44.1%)	7 (41.2%)	8 (47.1%)	
Satisfied	19 (55.9%)	10(58.8%)	9(52.9%)	
Length of hospital stay (days)	2.5 (2.0,3.0)	2(2.0,3.0)	3(2.0,3.0)	0.786

Data are presented as number (percentage) or median (interquartile range).

Table 4 shows neonatal outcomes in the intervention and control groups. The birthweight of neonates was significantly higher in the intervention than control groups (mean ± SD weight 3,456.18 ± 565.8 and 2,633.24 ± 842.57 grams, respectively, p = 0.002). There was no difference between the two groups in Apgar scores at 1, 5 and 10 minutes, intubation and other neonatal morbidities. Some neonatal complications were reported and these included neonatal jaundice, polycythemia, hypoglycemia, neonatal anemia, birth asphyxia, urinary tract infection and respiratory complications as well as serious complications, namely acute renal failure, respiratory distress syndrome, neonatal sepsis, and intraventricular hemorrhage. However, there was no difference in the occurrence of these neonatal complications between the two treatment groups.

Table 4. Comparison between treatment groups in neonatal outcomes.

	Total (n=34)	Intervention (n=17)	Control (n=17)	p value
Birthweight (gram)	3044.7 ± 820.9	3456.2 ± 565.8	2633.2 ± 842.6	0.002
Apgar at				
1 minute	9 (9.0, 9.0)	9 (9.0, 9.0)	9 (8.0, 9.0)	0.150
5 minutes	10 (10.0, 10.0)	10(10.0, 10.0)	10(9.8, 10.0)	0.245
10 minutes	10 (10.0, 10.0)	10(10.0, 10.0)	10(10.0,10.0)	0.786
Intubation	2(5.90%)	0(0%)	2(11.8%)	0.145
Composite neonatal complications[a]	13(38.2%)	6(35.3%)	7(41.2%)	0.724
Composite neonatal respiratory complications[b]	18(52.9%)	8(47.1%)	10(58.8%)	0.730
Composite neonatal serious complications[c]	3(8.8%)	0(0%)	3(17.6%)	0.070

Data are presented as number (percentage), mean ± standard deviation, or median (interquartile range).

[a] Composite neonatal complications defined as the presence of one or more of the following neonatal complications: neonatal jaundice, polycythemia, hypoglycemia, neonatal anemia, birth asphyxia, urinary tract in+fection

[b] Composite neonatal respiratory complications defined as the presence of one or more of the following complications: transient tachypnea of newborn, pneumonia, respiratory distress syndrome, nasal block, persistent pulmonary hypertension, atelectasis, delayed adaptation, bronchopulmonary dysplasia, meconium aspiration syndrome.

[c] Composite neonatal serious complications defined as the presence of one or more of the following neonatal complications: acute renal failure, respiratory distress syndrome, neonatal sepsis, intraventricular hemorrhage.

Discussion

In this 2-arm randomized control trial, cold gel pack significantly reduced postoperative pain at 6 hours after Cesarean delivery but such the benefit did not maintain up to 24 hours postdelivery. It should use cold gel pack for longer period; however, it must observe complication such as back pain, frostbite. There was no significant of additional analgesia required, postpartum hemorrhage, length of hospital stays, satisfaction, surgical wound infection and neonatal complications between the two groups.

Among many modalities of postoperative analgesia using for abdominal surgery, especially for Cesarean section, subarachnoid block with neuraxial opioid is preferred. Although this analgesia used, there were some patients suffered from postoperative pain and required additional analgesic drugs[12]. This study demonstrated the efficacy of cold gel pack as an adjunctive analgesia for post Cesarean delivery which significantly reduced pain score at 4 hours after applying. Cryotherapy induces effects both locally and at the level of the spinal cord via neurologic and vascular mechanisms. Topical cold treatment decreases the temperature of the skin and underlying tissues to a depth of 2 to 4 cm, decreasing the activation threshold of tissue nociceptors and the conduction velocity of pain nerve signals[2]. This effect might not last for long that was proved by losing its effect at 24 hours after delivery. This may be explained that the pain after Cesarean delivery also caused by the visceral pain from uterine contraction which could not be affected by this topical therapy. The efficacy of cold gel pack in our study was similar to recent studies in gynecologic surgery[6,13,14]. For further analgesia beyond 24 hours post-surgery, the additional applying might be needed[4].

Our study was different from Kılıc E, et al[3] which reported no difference in pain score between treatment group with therapeutic hypothermia for pain control in urgent abdominal surgery. This may be explained by timeframe evaluation of pain score and the general anesthesia in emergency laparotomy cases while our study evaluated pain score at specific point of time after surgery in Cesarean delivery participants under spinal anesthesia with neuraxial opioid.

Subarachnoid block with spinal morphine in total abdominal hysterectomy lasted for 90 minutes. Median pain score of 4-5 and 27-30% requirement of additional analgesia observed in previous study[15]. Whereas in setting of Cesarean section in our study, with similar pain score and proportion additional analgesic requirement, cold gel pack could exert more effects with less pain score of 3-4 and 23.5% additional paracetamol usage. This may because of less devastating tissue injury in Cesarean section than total abdominal

hysterectomy.

The decreased blood flow effect of cold gel pack[16] might affect the amount of blood loss postpartum. This study clearly showed that cold gel pack did not affect either postpartum hemorrhage or amount of blood loss in 24 hours post Cesarean delivery which correlate with previous study[17]. Regarding the effect of decreased inflammation[2], this study also showed that cold gel pack did not increased risk of surgical wound infection which consistent with previous study[3]. The length of hospital stays in our study was not significantly different between two groups because there was no serious postpartum complication which prolonged hospital stays in both groups.

Although the cold gel pack cooling efficiency was reported around 31 minutes[18], but in our study proved that its effect still remains at 4 hours after applying. This may be explained by many mechanisms such as decreased muscle spasm, decreased blood supply, and reduced inflammation[2]. According to safety data, application of cold gel pack for 20 minutes caused least cooling compared to other modalities[18] which may cause frost bite[19]. In this study, there was no complication from cold gel pack found. Since cold gel pack was applied after delivery, there was no adverse neonatal effect.

This study was the well-designed randomized controlled trial proved efficacy of cold pack gel as an adjunctive analgesia after Cesarean delivery with no adverse effect and insignificant maternal complications. Cold gel pack may be routine use in adjunctive reducing postoperative pain after Cesarean delivery. However, there was limitation of double blinding which was impossible due to nature of cold gel pack. There was more proportion of Cesarean delivery due to cephalopelvic proportion in intervention group which resulted in significant higher neonatal birthweight. This might be another factor affecting pain score evaluated postpartum.

Conclusion

Cold gel pack was efficacious in adjunctive reducing postoperative pain after Cesarean delivery under spinal anesthesia with neuraxial opioid at 6 hours without significant complications.

Potential conflicts of interest

The authors declare no conflicts of interest.

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Siripanthong P, et al. *Efficacy of Cold Gel Pack in Reducing Postoperative Pain in Cesarean Delivery at Sanpasitthiprasong Hospital*

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