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OBSTETRICS

The Effectiveness of Cryotherapy in Reducing Postoperative Pain in Cesarean Delivery, Pfannenstiel Skin Incision: A randomized controlled trial

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ABSTRACT

Objectives: To evaluate the effectiveness of cold pack gel in reducing postoperative pain after cesarean delivery, Pfannenstiel skin incision.

Materials and Methods: This study was a randomized controlled trial. There were 48 post-cesarean patients who were divided into two groups; group 1 (n = 24) received cold pack gel and group 2 (n = 24) received no treatment. The standard postoperative analgesic medicine and care were used in both groups. The primary outcome was to compare the postoperative pain score using the numerical rating scale (NRS) at 6, 12 and 24 hours after operation. The secondary outcomes were to compare the amount of opioid used, length of hospital stay and side effects in both groups.

Results: The cold pack gel significantly decreased the amount of postoperative opioid consumption (mean opioid used 8.33 ± 19.03 mg vs 25.00 ± 32.97 mg, mean difference was 16.67 mg (95% confidence interval 8.56-24.76). However, the cold pack gel insignificantly decreased pain after cesarean delivery which mean NRS of intervention and control group at 6 hours, 12 hours, 24 hours postoperation were 3.96 ± 1.71 vs 4.92 ± 2.06, 2.62 ± 1.47 vs 3.29 ± 1.46 and 2.17 ± 1.24 vs 2.67 ± 1.66, respectively. There was no significant side effect from cold pack gel use.

Conclusion: The cold pack gel could reduce postoperative opioid use without any serious side effects. However, the postoperative pain scores were not decreased. It can be used as an additional multimodality care in post-cesarean delivery care.

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

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ประสิทธิผลของการบำบัดด้วยความเย็นเพื่อลดความปวดหลังการผ่าตัดคลอดทางหน้าท้องชนิดแผลผ่าตัดแบบ Pfannenstiel: การทดลองแบบสุ่ม

ภูริณัฐ ใจธรรม, โชคชัย โชติบูรณ์, เมธา ทรงธรรมวัฒน์, เอื้อมพร สุ่มมาตย์, เมธา ทรงธรรมวัฒน์

บทคัดย่อ

วัตถุประสงค์*: เพื่อประเมินประสิทธิผลของเจลเย็น (cold pack gel) ในการลดความเจ็บปวดหลังผ่าตัดคลอดแบบแผลผ่าตัด Pfannenstiel*

วัสดุและวิธีการ*: การศึกษานี้เป็นการศึกษาทดลองแบบสุ่ม ในผู้ป่วยหลังผ่าตัดคลอด 48 คน แบ่งเป็นสองกลุ่ม โดยกลุ่มที่ 1 (n = 24) ได้รับเจลเย็น และกลุ่มที่ 2 ไม่ได้รับเจลเย็น โดยได้รับการดูแลรักษาหลังผ่าตัดและยาแก้ปวดตามมาตรฐานเหมือนกันทั้งสองกลุ่ม วัตถุประสงค์หลักของการศึกษาเพื่อเปรียบเทียบค่าคะแนนความเจ็บปวด (Numerical rating scale) หลังผ่าตัดที่ 6, 12 และ 24 ชั่วโมงหลังผ่าตัด และวัตถุประสงค์รองเพื่อเปรียบเทียบ จำนวนการใช้ยาแก้ปวดชนิด Opioid ที่ใช้หลังผ่าตัด ระยะเวลาการนอนโรงพยาบาล และ ผลข้างเคียงของการใช้เจลเย็นระหว่างกลุ่ม*

ผลการศึกษา*: การใช้เจลเย็นหลังผ่าตัดคลอดสามารถลดการใช้ยา Opioid อย่างมีนัยสำคัญทางสถิติ (ค่าเฉลี่ยการใช้ยา 8.33 ± 19.03 มก. vs 25.00 ± 32.97 มก., ผลต่างค่าเฉลี่ย 16.67 มก. (95% confidence interval 8.56-24.76) โดยการใช้เจลเย็นมีผลลดความเจ็บปวดหลังผ่าตัดคลอดแต่ไม่มีนัยสำคัญทางสถิติ ที่ 6, 12, 24 ชั่วโมง 3.96 ± 1.71 ต่อ 4.92 ± 2.06, 2.62 ± 1.47 ต่อ 3.29 ± 1.46 และ 2.17 ± 1.24 ต่อ 2.67 ± 1.66 ตามลำดับ ไม่พบผลข้างเคียงร้ายแรงที่เกิดจากการใช้เจลเย็นประคบ*

สรุป*: การใช้เจลเย็นประคบมีประสิทธิผลในการลดการใช้ยา opioid หลังผ่าตัดคลอดและไม่มีผลข้างเคียงที่ร้ายแรง อย่างไรก็ตามไม่พบการลดลงของค่าคะแนนความปวดหลังผ่าตัด เจลเย็นสามารถเป็นการรักษาอีกทางเลือกเพิ่มเติมในการลดความเจ็บปวดแบบหลากหลายวิธีหลังการผ่าตัดคลอด*

คำสำคัญ*: ความเจ็บปวดหลังผ่าตัด, การบำบัดด้วยความเย็น, เจลเย็น, ผ่าตัดคลอด*

Introduction

Cesarean delivery is a one of the most common operations around the world and postoperative pain is an area of great concern to the patients[1]. A previous study in our center reported that 57.0% of the post-cesarean patients had moderate to severe pain with the pain score > 4 within 24 hours after the operation despite the use of intravenous opioid drugs[2]. Multimodal postoperative care was recommended to decrease pain after the procedure to facilitate the patient's wellbeing as well as to promote the important movement such as early breast feeding[3].

There are various pharmacological and non-pharmacological methods employed to decrease postoperative pain. Cryotherapy by cold pack gel is one of the effective methods used in gynecologic surgery and obstetrics procedure from the previous reports[4-6]. The mechanism of action is anti-inflammation by decreasing proinflammatory cytokine (Interleukin (IL) -1, tumor necrosis factor-α, IL-6, IL-12 and IL-17), reduced nerve conduction velocity and decreased oxidative stress[7, 8]. However, it has not been studied in the Pfannenstiel incision cesarean delivery which is a common operation in daily clinical practice. Therefore, this study aimed to study the effectiveness of the additional cryotherapy (cold pack gel) as one of the multimodalities

Materials and Methods

The present study was a randomized controlled trial which was conducted in the Department of Obstetrics and Gynecology, UdonThani Hospital, Udonthani, Thailand, from April to September 2024. The study protocol was approved by the Udonthani Hospital Ethical Committee in Human subject Research: No.74/2567 and was registered in thaiclinicaltrials.org (clinical trial number: TCTR20240812001).

There were 48 pregnant women included in this study, the inclusion criteria were term singleton pregnant women aged 18 years old or older who underwent cesarean section with Pfannenstiel skin incision. The exclusion criteria were those patients who had serious underlying diseases such as severe renal disease, valvular heart disease, having allergy to cold or cold pack gel or those who needed intensive care unit admission or ventilator use after surgery.

The study details were explained to all participants during their labor room admission and their written informed consents were received before participation. The randomization was performed using computer-generated numbers, prepared in sealed, opaque envelopes by the research assistants. The eligible patients were assigned into one of two groups, the first group was the cold pack gel group (n = 24), the second group was the no treatment group (n = 24). The cesarean delivery was done by both obstetricians and residents. The intraoperative anesthesia was conducted by anesthesiologist using both spinal and general anesthesia. The standard postoperative analgesics care, using intravenous opioid and paracetamol as the patient's requested every six hours, were used in both groups, In the cold pack gel group, the cold pack gel was a 3M company cold pack gel size 10x25 cm, and was frozen at zero degree Celsius in the freezer for two hours, covered by a 3M bag (in the box set), then placed on top of the Pfannenstiel incision cesarean wound dressing for two hours, after two hours postoperation[4].

Numerical rating scale (NRS)[9] with a score of 0-10 was used to evaluate postoperative pain after the cesarean section at 6, 12 and 24 hours. 0 reflected no pain and 10 reflected maximum pain. The postpartum ward nurses explained the meaning of the score to the patients, then asked them to verbally reflect their pain using that numerical scale. The pain score of less than 4 was classified as mild intensity pain, NRS score of 4 or more was moderate to severe pain[10]. The side effects of cold pack gel were evaluated by nurses at 24 hours after operation. The amount of opioid consumption and length of hospital stay were also recorded.

Sample size was calculated using the N4studies

application. Using the formula for comparing continuous outcomes in randomized controlled trial. The mean pain score postoperative pain at 6 hours of the treatment and control groups for calculation were 3.2 ± 2.4 and 5.3 ± 2.2[11], respectively. Power 80% with alpha error 0.05 were used, dropout rate was estimated to be 10%. The calculated sample size was 24 for each group[12-14].

Statistical analysis

STATA statistical program version 13 was used for analysis. Continuous data were reported as mean and standard deviation. Categorical data were shown as the number and percentage. Unpaired t-test was used for the comparison of continuous data, mean difference and 95% confidence interval (CI) and binary regression with relative risk and 95%CI, Pearson chi square and Fisher's exact test were used for categorical data. P value < 0.05 was considered statistically significant.

Results

Forty-eight pregnant women were assessed for eligibility, and all were accepted to participate with this study without anyone excluded. The randomization was done and all participants continued their participation without any dropout. The consort diagram is shown in Fig. 1.

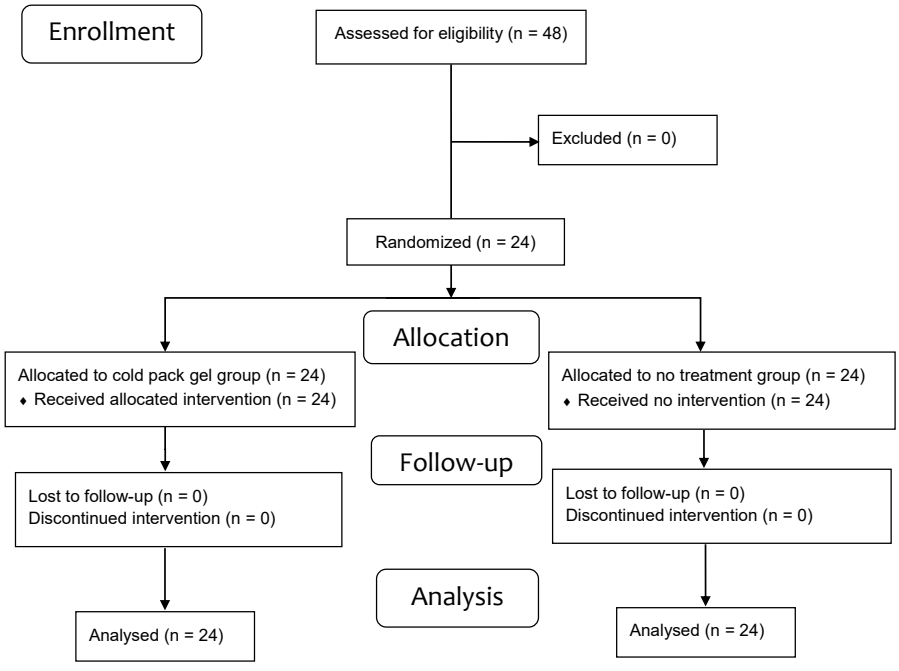

Fig. 1. The consort flow diagram.

The demographic characteristics between both groups including age, body mass index, gestational age, operative time, nulliparity, indication for cesarean section, tubal resection, types of anesthesia, estimated blood loss, baby sex and birthweight were not statistically different

in either group, the details are shown in Table1.

The postoperative pain scores at 6, 12 and 24 hours were insignificantly decreased in the cold pack gel group with the mean pain scores at 6 hours were 3.96 ± 1.71 in the cold pack gel group and 4.92 ± 2.06 in the placebo group, the mean difference was 0.95 (95%CI -0.14, 2.06), at 12 hours were 2.62 ± 1.47 in the cold pack gel group and 3.29 ± 1.46 in the placebo group, the mean difference was 0.67(95%CI -0.18, 1.52) and 24 hour were 2.17 ± 1.24 in the cold pack gel group and 2.67±1.66 in the placebo group, the mean difference was 0.5(95%CI -0.35, 1.35)

The opioid consumptions were decreased significantly in the cold pack gel group with the mean difference was 16.67 (95% CI 1.03, 32.31). The length of hospital stay was not significantly different between the groups. The details of primary and secondary outcomes are shown in Table 2.

Table 1. Baseline clinical characteristic.

Characteristics	Cold pack gel group (n = 24)	No treatment group (n = 24)	p value
Age (years), mean ± SD	27.83 ± 7.29	30.04 ± 7.81	0.317*
Body mass index (kg/m^2), mean ± SD	24.71 ± 4.20	25.59 ± 4.60	0.491*
Gestational age (weeks), mean ± SD	38.45 ± 1.10	38.33 ± 1.09	0.695*
Operative time (min), mean ± SD	43.96 ± 10.41	42.00 ± 9.92	0.508*
Nulliparity, n (%)	10 (41.67)	11 (45.83)	0.771**
Indication for cesarean delivery			
prior cesarean delivery, n (%)	8 (33.33)	11 (45.83)	0.376**
CPD, n (%)	7 (29.17)	5 (20.83)	0.505***
Other, n (%)	9 (37.50)	8 (33.33)	0.763**
Tubal resection, n (%)	10 (41.67)	9 (37.50)	0.768**
Types of anesthesia			
General anesthesia	4 (16.67)	5 (20.83)	0.712***
Spinal anesthesia	20 (83.33)	19 (79.17)	
Estimated blood loss (ml), mean ± SD	245.83 ± 58.82	258.33 ± 77.55	0.532*
Baby sex			
male, n (%)	14 (58.33)	13 (54.17)	0.771**
female, n (%)	10 (41.67)	11 (45.83)	
Birth weight (grams), mean ± SD	2,991.88 ± 297.02	3,083.13 ± 384.01	0.362*

SD: standard deviation, CPD: cephalopelvic disproportion.

*calculated by unpaired t-test, **calculated by Pearson chi square, ***calculated by Fisher's exact test

Table 2. Study outcomes.

Outcomes	Cold pack gel group (n = 24)	No treatment group (n = 24)	mean difference (95%CI) p value
Postoperative pain at 6 hour			
NRS, mean ± SD	3.96 ± 1.71	4.92 ± 2.06	0.95 (-0.14, 2.06) 0.086*
Moderate to severe pain, n (%)	15 (62.50)	19 (79.17)	RR 0.79 (95%CI 0.54-1.15) 0.213**
Postoperative pain at 12 hour			
NRS, mean ± SD	2.62 ± 1.47	3.29 ± 1.46	0.67 (-0.18, 1.52) 0.122*
Moderate to severe pain, n (%)	7 (29.17)	11 (45.83)	RR 0.63 (95%CI 0.30-1.36) 0.244**
Postoperative pain at 24 hour			
NRS, mean ± SD	2.17 ± 1.24	2.67 ± 1.66	0.5 (-0.35, 1.35) 0.243*
Moderate to severe pain, n (%)	3 (12.50)	7 (29.17)	RR 0.43 (95%CI 0.13-1.46) 0.176**
Opioid consumption (mg), mean ± SD	8.33 ± 19.03	25.00 ± 32.97	16.67 (1.03, 32.31) 0.037*
Length of hospital stay (days), mean ± SD	3.33 ± 0.48	3.42 ± 0.50	0.08 (-0.20, 0.36) 0.561*

NRS: numerical rating scale, SD: standard deviation, RR: relative risk, CI: confidence interval
*calculated by unpaired t-test, ** calculated by binary regression analysis

Discussion

The present study demonstrated that the cold pack gel could decrease the opioid consumption in the post-cesarean delivery patients without side effects. However, the mean pain score at 6, 12 and 24 hours after cesarean section were insignificantly decreased in the cold pack gel group. The proportion of moderate to severe pain and length of hospital stay were also insignificantly decreased.

The decremental of opioid consumption from cold pack gel were also reported in Nuangpho et al[5] and Suwannalert et al's studies[11] which reported postoperative opioid use decrement from cold pack gel use. However, the cold pack gel was reported to decrease postoperative pain in Chumkam et al[4], Nuangpho et al[5] and Srirussamee et al's[15] studies which studied in post gynecologic operation and Siripanthong et al's[16] study which studied in post-cesarean midline incision operation. The difference of result from this study might be due to the difference of the patient's setting, operation types and different cold pack technique.

The mean NRS of post-cesarean pain at 6 hours postoperation in the control group was 4.92 ± 2.06 with 79.17% having moderate to severe pain which was higher than the 57.0% reported in a previous study conducted in our center[2] that reflected the inadequate pain control even if the opioid was used. The adding of multimodality treatment is needed for proper pain management.

The clinical application of cold pack gel in post-cesarean delivery is recommended from the findings of this study. However, even though the cold pack gel was added, 62.50% still had moderate to severe pain postoperation. Therefore, other pain control methods should be added and the most appropriate method for pain control still needs further studies.

The strength of this study was the prospective randomized control trial study design together with an adequate sample size. However, the limitation of this study was the unblinding in the control group due to the nature of intervention.

Conclusion

Cold pack gel could reduce postoperative opioid use without any serious side effect in post-cesarean delivery, Pfannenstiel skin incision. However, the postoperative pain scores were not significantly decreased. It can be used as an additional multimodality treatment in post-cesarean delivery care.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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