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Cold Pack Compression to the Lower Abdomen after Childbirth to Reduce Blood Loss in Women Undergoing Vaginal Delivery: A randomized controlled trial

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ABSTRACT

Objectives: To determine the efficacy of cold pack compression to the lower abdomen after childbirth until 2 hours postpartum to reduce blood loss.

Materials and Methods: Sixty singleton pregnant women who underwent normal delivery at Khon Kaen Hospital between February and June 2020 were randomly allocated to two groups, one receiving cold pack compression to the lower abdomen after childbirth until 2 hours postpartum (n = 30) versus standard vaginal delivery (n = 30). The respective amount of blood loss in both groups was measured from after childbirth until 2 hours postpartum by calculating the total weight of blood from the blood collecting bag and diapers. Additional blood transfusion, adverse events from the cold pack, and the after-pain score were recorded.

Results: Baseline characteristics between groups were comparable. Mean blood loss in the cold pack compression group was significantly lower than the standard vaginal delivery group (183.87 ± 76.52 vs. 271.36 ± 103.80 ml, mean difference was -87.50, 95% confidence interval -134.62 to -40.37, $p < 0.001$). None of the participants in either group experienced postpartum hemorrhage or required blood transfusion. None of the participants in the cold pack compression group experienced any adverse events. There was no statistical difference in the after-pain score between groups.

Conclusion: Cold pack compression to the lower abdomen after childbirth until 2 hours postpartum could significantly reduce blood loss compared with standard vaginal delivery without serious adverse events.

Keywords: cold pack compression, vaginal delivery, blood loss.

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การวางประคบเย็นบริเวณหน้าท้องส่วนล่างหลังคลอดทารกเพื่อลดการสูญเสียเลือดในมารดาที่คลอดบุตรทางช่องคลอด: การศึกษาแบบสุ่มมีกลุ่มเปรียบเทียบ

ฐปนพ ธนสมทบชนมน, สาธิดา จันทนวิลัย, ภัทรพร ตั้งกีรติชัย

บทคัดย่อ

วัตถุประสงค์: *ศึกษาผลของการวางประคบเย็นบริเวณหน้าท้องส่วนล่างหลังคลอดทารกจนถึง 2 ชั่วโมงหลังคลอด เพื่อลดการสูญเสียเลือด*

วัสดุและวิธีการ: *สตรีตั้งครรภ์เดี่ยวครบกำหนดคลอดทางช่องคลอดที่โรงพยาบาลขอนแก่น ระหว่างเดือนกุมภาพันธ์ ถึงมิถุนายน 2563 กลุ่มตัวอย่างทั้งหมด จำนวน 60 ราย ถูกแบ่งเป็นกลุ่มทดลอง และกลุ่มควบคุม โดยวิธีการสุ่มกลุ่มละ 30 ราย กลุ่มทดลองได้รับการประคบเย็นที่บริเวณหน้าท้องส่วนล่างหลังคลอดทารกจนถึง 2 ชั่วโมงหลังคลอด การวัดปริมาณเลือดทำได้โดยการคำนวณน้ำหนักจากถุงตวงเลือด และผ้าอนามัยที่ใช้ใส่ซับเลือดก่อนและหลังการใช้ รวมถึงสังเกตการได้รับเลือดภายหลังคลอด ผลข้างเคียงของการประคบเย็นและอาการปวดท้องหลังคลอด*

ผลการศึกษา: *ลักษณะพื้นฐานของกลุ่มตัวอย่างมีลักษณะไม่แตกต่างกัน ปริมาณการสูญเสียเลือดในกลุ่มทดลองน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (กลุ่มทดลองค่าเฉลี่ยเท่ากับ 183.87 มิลลิลิตร, กลุ่มควบคุมค่าเฉลี่ยเท่ากับ 271.36 มิลลิลิตร, ผลต่างค่าเฉลี่ยเท่ากับ 87.50 มิลลิลิตร, ระดับความเชื่อมั่นร้อยละ 95 คือ - 134.62 ถึง - 40.37, $p < 0.001$) ไม่พบอุบัติการณ์ของการตกเลือดหลังคลอด การได้รับเลือดหลังคลอดหรืออาการข้างเคียงจากการประคบเย็นในกลุ่มตัวอย่างและไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของระดับความปวดบริเวณช่องท้องหลังคลอด*

สรุป: *การวางประคบเย็นบริเวณหน้าท้องส่วนล่างหลังคลอดทารกจนถึง 2 ชั่วโมงหลังคลอด สามารถลดปริมาณการสูญเสียเลือดได้อย่างมีประสิทธิผลเปรียบเทียบกับการคลอดทารกทางช่องคลอดปกติ และไม่พบภาวะแทรกซ้อนที่อันตราย*

คำสำคัญ: *การวางประคบเย็น, การคลอดทารกทางช่องคลอด, การสูญเสียเลือด*

Introduction

Maternal mortality remains unacceptably high. About 295,000 women died worldwide during and following pregnancy and childbirth in 2017, and the vast majority were preventable[1]. Nearly 75% of all maternal deaths are due to severe bleeding, infections, high blood pressure during pregnancy, complications from delivery, and unsafe abortion[2]. In the current study, we focused on severe bleeding after childbirth, which can kill a healthy woman within hours if she is unattended.

Postpartum hemorrhage (PPH) is a primary cause of maternal mortality. PPH accounts for about 20% of all cases of maternal death[3]. PPH is defined as blood loss of 500 ml or more within 24 hours after vaginal birth, mostly due to uterine atony[4]. Active management of the third stage of labor can reduce the incidence of PPH. Administration of uterotonic agents, placental delivery by control cord traction, and uterine massage are recommended for the prevention of PPH[5]. Even if all these methods are used, postpartum hemorrhage continue to be reported.

Mitchell et al[6] studied the effect of ice pack compression directly to the uterus during cesarean section to reduce intra-operative blood loss and found that the amount of blood loss in the intervention group was significantly lower than the control group. Another study on directly cooling the uterus during cesarean section from Nawasirodom et al[7], reveled a statistically significant reduction in intra-operative blood loss in the uterine cooling group compared with the routine cesarean section group. In contrast, in the only recent study about the effect of cold compression to reduce blood loss during vaginal delivery, Masuzawa et al[8], showed that cooling the lower abdomen with an icepack after placental delivery did not decrease blood loss among women who had a vaginal delivery with no prophylactic uterotonic in the third stage of labor. They also found that cooling the lower abdomen seemed to increase the amount of blood loss; however, data collection was after placental delivery which may not properly represent intrapartum blood loss. According to the normal physiology of vaginal delivery, blood loss mostly occurs from the detachment of placental spiral arteries during placental delivery. In our study, we aimed to collect blood loss data before placental delivery. Excessive maternal weight should, moreover, be excluded from the study because the thickness of the maternal subcutaneous fat layer can interfere with the result. In Japan, cold compression of the lower abdomen was used for post-vaginal delivery to decrease blood loss and prevent PPH[9]; however, the efficacy of the method was not well-established. The efficacy of cold compression to reduce blood loss in vaginal delivery thus remains unclear due to insufficient data. The current study's primary objective was to evaluate the efficacy of cold pack compression to the lower abdomen after childbirth until 2 hours postpartum to reduce blood loss in women who undergo vaginal delivery compared with standard vaginal delivery. The secondary objectives were to evaluate the additional blood transfusion, adverse events from cold pack compression, and after-pain score.

Materials and Methods

This randomized controlled trial was performed at the Department of Obstetrics and Gynecology, Khon Kaen Hospital, Thailand, between February and June 2020. Ethical approval was granted by the Khon Kaen Hospital Institute Review Board for Human Research. The eligible women were informed about the study, and written consent was obtained after admission to the labor room. The inclusion criteria were term pregnancy women, singleton pregnancy, cephalic presentation, spontaneous vaginal delivery, and maternal body mass index (BMI) at delivery < 30 kg/m^2. The exclusion criteria were maternal medical conditions, placental abnormalities, delivery by operative vaginal delivery, obstetric complications, or obstetric trauma.

The participants were randomized by a computer-generated block of four prepared in numbered sealed envelopes. The allocation was

performed by opening the envelope after childbirth and assigning the participant to the cold pack compression group or the standard vaginal delivery group. The study was blinded only to the researchers until the data were analyzed. For the study group, a 24 x 11 cm cold pack (3M Nexcare® reusable cold/hot pack) was compressed to the lower abdomen at the uterus after delivery of the fetus. The pubic symphysis was used as the landmark. Each cold pack was cooled in a freezer for more than 4 hours to provide a contact temperature of 6.4°C (± 0.2°C). The cold pack was covered with a single layer of toweling before it was placed on the lower abdomen, and it was changed every 30 minutes until 2 hours postpartum. If women in the study group felt discomfort from the cold pack or any adverse events from the cold pack (i.e., frostbite, blister of skin, or numbness), it was removed. All women received active management of the third stage of labor (oxytocin 10 units intramuscular injection after delivery of the fetus's anterior shoulder, cutting and clamping cord shortly after fetal birth, and placental delivery by control cord traction).

So as to minimize any contamination, before blood collection the amniotic fluid and meconium were wiped away from the perineum and vagina using an antiseptic agent. The blood collection bag was placed under the buttocks to collect blood from placental delivery until any episiotomy wound was repaired or perineal wound was checked. The participants were then transferred to the labor room's observational zone; then, blood loss was collected by diaper until 2 hours postpartum. After 2 hours postpartum, the after-pain score was assessed by each patient using the visual analogue scale before they were transferred to the postpartum ward. Blood loss was measured by the weight of the blood collecting bag, gauze, and diapers after being used subtracted by the weight of unused materials. The calculated value was weight in grams to milliliters (1.05 g to 1 ml)[10].

The quantity of blood (ml) = (weight of used materials - weight of unused materials)/1.05.

Baseline characteristics of all participants were recorded, including maternal age, gestational age, parity, BMI, duration of the second stage of labor, duration of the third stage of labor, oxytocin for augmentation, degree of perineal tear, and neonatal birth weight.

The primary outcome was the amount of blood loss from the third stage of labor until 2 hours postpartum. Additional blood transfusion, adverse events from a cold pack, and after-pain score were recorded.

The sample size was calculated based on a pilot study done in the labor room of Khon Kaen Hospital with 15 participants per group. Mean blood loss in the cold pack compression group was 198.5 ml compared with 294.1 ml in the control group (standard deviation 118.14 ml). We used a formula to test the difference between two independent means with a one-sided alpha error of 0.05, a power of 80%, and a 10% drop-out rate. The resulting sample size was 30 participants per group. Data were analyzed using STATA Version 13.0 statistical software. Differences in continuous variables were analyzed using the student t-test and were presented as means with standard deviation. Categorical variables were analyzed using the chi-square and Fisher's exact tests and presented as percentages.

Results

Sixty-seven eligible women who vaginally delivered at Khon Kaen Hospital's labor room between February and June 2020 were initially enrolled in the study. Seven participants were excluded due to third- and fourth-degree perineal tears and delivered by operative vaginal delivery. Sixty women were equally randomized into two groups: the cold pack compression group and the standard vaginal delivery group. The study flow diagram is shown in Fig 1. The demographic and clinical characteristics between groups were not different vis-à-vis maternal age, gestational age, parity, BMI, duration of the second stage of labor, duration of the third stage of labor, oxytocin for augmentation, degree of perineal tearing, or neonatal birth weight (Table 1).

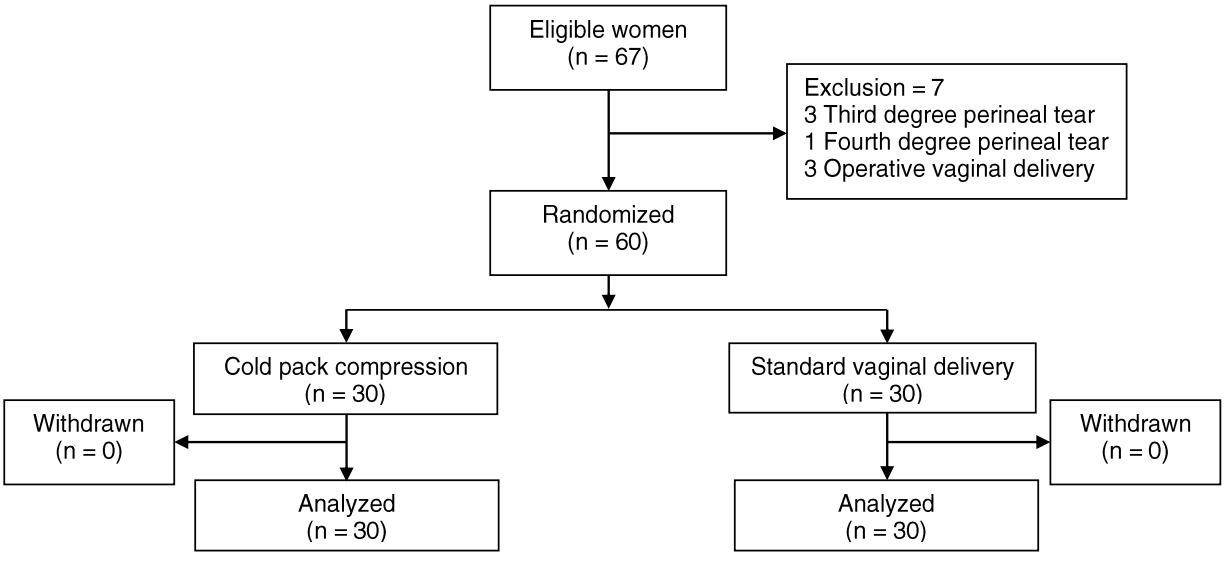

Fig. 1. Study flow diagram.

Table 1. Baseline characteristics of the study participants.

Characteristics	Cold pack compression (n = 30)	Standard vaginal delivery (n = 30)	p value
Maternal age (years), mean ± SD	26.8 ± 6.2	26.1 ± 5.5	0.64
Gestational age (weeks), mean ± SD	38.1 ± 0.9	39.1 ± 1.1	0.07
Parity (%)			0.43
Nulliparous	18 (60.0)	18 (60.0)	
Multiparous	12 (40.0)	12 (40.0)	
Maternal BMI (kg/m²) mean ± SD	26.0 ± 2.5	25.2 ± 2.8	0.24
Duration of the second stage of labor (mins), mean ± SD	13.9 ± 1.9	14.1 ± 1.3	0.92
Duration of the third stage of labor (mins), mean ± SD	2.63 ± 0.85	2.57 ± 0.73	0.74
Oxytocin for augmentation (%)			0.79
No	19 (63.3)	18 (60.0)	
Yes	11 (36.7)	12 (40.0)	
Perineal tear (%)			0.42
None	2 (6.7)	4 (13.3)	
First degree	0	1 (3.3)	
Second degree	28 (93.3)	25 (83.4)	
Birth weight (grams), mean ± SD	2989.3 ± 302.1	3067.6 ± 298.7	0.24

SD: standard deviation

Mean blood loss after childbirth until 2 hours postpartum was significantly lower in the cold pack compression group compared with the standard vaginal delivery group (183.87 ± 76.52 and 271.36 ± 103.80 ml, mean difference was -87.50 ml 95% confidence interval (CI) -134.62 to -40.37; p < 0.001). There were no participants in either group who had postpartum hemorrhage or requiring blood transfusion. No participants in the cold pack compression group had any adverse events from cold pack compression. The respective after-pain score between groups was not statistically different. The study outcomes was shown in Table 2.

Table 2. Study outcomes compared between cold pack compression group and standard vaginal delivery group.

Outcomes	Cold pack compression (n = 30)	Standard vaginal delivery (n = 30)	Mean difference	p value	95%CI
Blood loss (ml), mean ± SD	183.8 ± 76.5	271.3 ± 103.8	87.5	< 0.001	-134.6 to - 40.37
After pain score, mean ± SD	3.1 ± 1.0	3.1 ± 1.1	-	0.81	-

SD: standard deviation, CI: confidence interval

Discussion

Mean blood loss after childbirth until 2 hours postpartum was significantly lower in the cold pack compression group compared to the standard vaginal delivery group (183.87 ± 76.52 and 271.36 ± 103.80 ml, mean difference was -87.50 ml 95%CI -134.62 to -40.37; p < 0.001). The result agreed with Mitchell et al who studied the efficacy of ice pack compression directly to the uterus during cesarean section to reduce intra-operative blood loss. Mitchell et al found that the amount of blood loss in the intervention group (ice pack group) was 29% less than the control group and the incidence of PPH was 57% less in the intervention group. In a study by Nawasirodom et al on directly cooling the uterus during cesarean section revealed that there was a significant reduction in intra-operative blood loss in the uterine cooling group when compared with the routine cesarean section group (252.8 ± 133.8 vs. 472.9 ± 201.8 ml, mean difference 220 ml 95%CI 166.6 to 273.5; p < 0.001). According to the literature review, the effect of cold from cold pack compression improves myometrium contraction. Based on the science of muscle contraction, the latter occurs during the release of calcium ions from the sarcoplasmic reticulum (SR), while muscle relaxation occurs during the re-uptake of calcium ions. Cold can improve muscle contraction by slowing the re-uptake of calcium ions in smooth muscle cells[11-13]. The cold also causes blood vessels within the smooth muscles to constrict, which subsequently decreases blood flow through sympathetic innervation. This system's neurotransmitters are norepinephrine and epinephrine, which are secreted into the blood vessels, resulting in vasoconstriction[14].

In contrast, from the only recent study about the effect of cold compression to reduce blood loss in women undergoing vaginal delivery in Japan, Masuzawa et al[8], showed that cooling the lower abdomen with an icepack after placental delivery did not decrease blood loss among women who had a vaginal delivery with no prophylactic uterotonic. Notwithstanding, Masuzawa et al[8], reported that cooling the lower abdomen seemed to increase blood loss (513.3 ± 333.2 vs. 478.1 ± 310.1 ml, mean difference 35.2 ml 95%CI -65.3 to 135.7; p = 0.49), albeit the results were not statistically significant and therefore mooted. A primary difference between the

study by Masuzawa et al[8], and our study was the timing of the collected blood loss. In our study, cold pack compression was performed then blood loss was collected before delivery of the placenta. In the normal physiology of vaginal delivery, blood loss mostly occurs from the placenta's spiral arteries, which detach from the myometrium. Consequently, cooling of the lower abdomen is performed to evaluate blood loss and blood collection, and these measures should be started before placental delivery to evaluate the amount of blood loss correctly.

There was no significant difference vis-à-vis requiring blood transfusion, adverse events from cold pack compression, or the after-pain score between groups.

The study's strength was the measurement of blood loss calculated by converting the weight of blood into a volume that provided a measured amount of blood loss instead of an estimate. Limitations of the study were (a) that it was not blinded to the health care providers or participants and (b) it only collected data 2 hours postpartum for analysis, which may not represent all the incidents of PPH that can occur up to 24 hours postpartum.

Conclusions

Cold pack compression to the lower abdomen after childbirth until 2 hours postpartum could significantly reduce blood loss compared with standard vaginal delivery without serious adverse events.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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