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The Effect of Uterine Cooling During Cesarean Delivery on Blood Loss in Patients Undergoing Cesarean Section: A Randomized Controlled Trial

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ABSTRACT

Background & Objective: Cooling the uterus during cesarean section has emerged as one of the non-pharmacological management for blood loss during cesarean section. The aim of this study was to evaluate the effect of uterine cooling during the cesarean section on decreasing postpartum hemorrhage.

Materials & Methods: In this single-blinded randomized clinical trial, a sample of 300 women with a singleton pregnancy, at 37 to 40 weeks gestation, who were scheduled for cesarean section, was divided into two groups of 150 participants. In the intervention group after placental delivery, the uterus was covered with cold saline-soaked surgical sponges at 0-4°C at the time of hysterotomy repair, and the control group received standard cesarean section. The volume of blood loss, the hemoglobin level before surgery and 24 h after surgery, the need for additional oxytocin therapy, and the incidence of adverse effects were recorded.

Results: The bleeding volume and hemoglobin concentration reduction were significantly lower in the intervention group than in the control group (260.86± 150.25 Vs 214.35± 83.51, P<0.0001 and 1.24±0.75 Vs 1.54±0.92, P = 0.007 respectively). There were no statistically significant differences between the two groups in the frequency of need for additional uterotonic drugs. (18% vs. 21.33%, P = 0.475.).

Conclusion: The use of uterine cooling during cesarean section reduced the volume of blood loss and the rate of decline in hemoglobin concentration.

Keywords: Cesarean Section, Post-partum Hemorrhage, Uterus, Delivery

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Introduction

Postpartum hemorrhage (PPH) is the most common cause of maternal death, which can occur suddenly without any underlying cause also post-partum hemorrhage is reported as 2%-4% after vaginal delivery and 6% after cesarean section with uterine atony being the cause in about 50% of cases **(1, 2)**. PPH without timely and appropriate treatment may cause disseminated intravascular coagulation, hemorrhagic shock, multiple organ failure, and even death. PPH is very common in both urgent and elective cesarean sections **(3).**

Nowadays, the incidence of fatal PPH has decreased because of active management of the third stage of labor which includes controlled cord traction, uterine fundal massage, use of uterotonic agents, and application of non-pharmacological methods **(4)**.

Despite the various methods to prevent blood loss during and after cesarean section, postpartum hemorrhage (PPH) is responsible for between one-third and one-fourth of obstetric deaths **(5)**.

Although the role of uterotonic agents (usually oxytocin) in the prevention of postpartum hemorrhage is well established, these drugs are sometimes accompanied by side effects such as hypotension (in case of rapid infusion of oxytocin), hypertension crisis (methyl Ergonovin), bronchospasm, headache, fever,

and diarrhea with use of prostaglandin analogs that limit their use **(6)**.

Furthermore, data about the preventive role of uterine massage and umbilical cord traction are inconclusive **(7)**. Cooling the uterus during cesarean section has emerged as one of the non-pharmacological management for blood loss during cesarean section **(3, 7-9)**. Cold therapy constricts blood vessels within the smooth muscles, leading to decrease blood flow **(10)**.

Calcium ions play a significant role in muscle contraction. In some smooth muscles, cold enhances contraction, perhaps by slow reuptake of calcium ions at the sarcoplasmic reticulum **(10-13).** Thereby, uterine cooling promotes uterine contraction leading to less blood loss **(3, 8, 9)**.

We hypothesized that the use of cooling during cesarean section may decrease blood loss after cesarean section with minimal side effects compared to the conventional method. To test our hypothesis; we designed this randomized controlled study to figure out if uterine cooling may decrease blood loss after cesarean section without causing serious side effects.

Methods

This was a prospective, randomized, single-blinded, clinical trial conducted in the obstetric unit of Kosar Hospital, an academic tertiary referral center, Qazvin, Iran, from June 2019 to September 2020. The study protocol was approved by the research ethics committee of Qazvin University of medical science and registered in the Iranian registry of a clinical trial. All Women with singleton pregnancies at 37–40 weeks of gestation, who underwent elective or urgent cesareans section under spinal anesthesia, were included in the study after obtaining written consent.

Excluded criteria were women with medical conditions such as bleeding diathesis, impaired hepatic and renal function and hypersensitivity to misoprostol and oxytocin and obstetrical complication such as polyhydramnios, hypertensive disorders of pregnancy, fetal macrosomia, prenatally suspected or intraoperative diagnosis of placenta previa and accreta, history of uterine incision other than lower segment incision, history of more than two previous uterine incisions, an extension of uterine incision to uterine arteries and who refused to sign consents. Randomization was performed using a computerized random number generator, which divided the cohort into 2 groups.

Participants in intervention groups underwent conventional cesarean section with lower segment incision. In the interventional group, during hysterotomy repair, the uterine fundus was wrapped with sterile saline-soaked surgical sponges which were refrigerated between 4-0°C. In the control group, the uterine fundus was wrapped with a dry surgical sponge. To all participants in both groups, after completion of placental delivery, 20 units of oxytocin diluted in a 1-liter ringer were infused in 1 hour. In both groups, the suction bottle was replaced after placenta delivery, and all gauzes and surgical drapes were weight before and after the C/S process. All Cesarean sections performed by staff and senior residents under supervision, and pre-operative and post-operative care, were the same in both groups. Hemoglobin concentration was checked at admission and 24 hours after surgery in all participants.

The Primary outcomes were the volume of intraoperative blood loss and decline in hemoglobin in the first 24 hours after surgery and secondary outcomes were the incidence of occurrence of uterine atony, need for an additional uterotonic agent, blood transfusion rate, admission to the intensive care unit, and need for surgical procedures for bleeding control (uterine artery or hypogastric artery ligation) and hysterectomy. Sample size estimation was based on the previous study, which reported that the mean amount of blood loss in the uterine cooling group was 29% less than the control group **(8)**.

Thus, considering 90 % power and 5 % error, the sample size was determined to be 100 cases in each group. We included 150 patients in each group to achieve statistical validity. Continues variables described with means and standard deviation and analyzed using student t-test and Mann-Whitney U test. Categorical variables were described with frequency and analyzed using the chi-square test.

The 95% confidence interval (CI) was calculated. A p-value < 0.05 was required to confirm statistical significance. Statistical analysis of data was performed using SPSS version 24 software (SPSS Inc., Chicago, IL, USA).

Results

A total of 300 patients were initially enrolled in this study, (Figure 1). There were no differences between both groups regarding baseline characteristics (maternal age, gestational age at delivery, and BMI (Table 1).

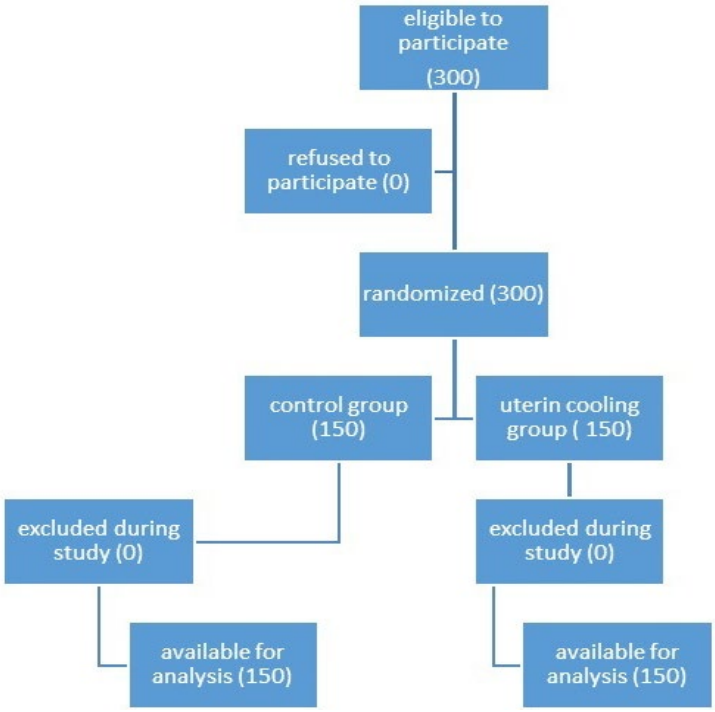


Figure 1. **Consort flow diagram**

Table 1. **Baseline characteristics of participants**

	Control group (mean± SD)	Uterine cooling group (mean± SD)	P.value
Maternal age	27.92±6.18	28.22±6.12	0.680
Gestational age	38.54±1.10	38.41±0.99	0.439
BMI	30.10±4.81	29.55±5.13	0.575
Pre-operative hemoglobin concentration	13.77±1.24	12.63±0.98	<0.0001

Table 2 shows the volume of intraoperative blood loss was significantly higher in the control group than in the uterine cooling group (260.86± 150.25 Vs 214.35± 83.51, P<0.0001). As shown in Table 2, hemoglobin decreased slightly after birth in two groups, but the mean decline of hemoglobin concentration was lower in the intervention (1.24±0.75) group compared with the control (1.54±0.92) group (P = 0.007).

Table 2 shows, that the use of additional uterotonic agents was higher in the control group compared with the uterine cooling group, but this difference was not statistically significant (21.33% Vs 18% P = 0.475).

No patient in either group showed any early postpartum hemorrhage within 24 hours after surgery, need for surgical intervention and hysterectomy for bleeding control, blood transfusion, and need for ICU admission.

Table 2. **Main outcomes**

	Control group (mean± SD)	Uterine cooling group (mean±SD)	P.value
Blood loss	260.86±150.25	214.35±83.51	**<0.0001**
Hemoglobin decline	1.54±0.92	1.24±0.75	**0.007**
Need for additional uterotonic agents	32 (21.33%)	27 (18%)	**0.475**

Discussion

The results of this study revealed that uterine cooling reduced the amount of blood loss during and after cesarean section, and also the mean decline of hemoglobin in the cooling group significantly was smaller than control groups. There are few studies on the use of ice therapy in reducing postpartum hemorrhage during cesarean section or delivery.

Parallel to the results of two similar studies by Mitchell, et al. **(8)** and Nawasirodom, et al. **(9)** in this study uterine cooling could reduce the volume of blood loss during cesarean section compared to conventional cesarean section **(8, 9)**. The volume of blood loss in the uterine cooling group in our study was lower than reported by Nawasirodom, et al. **(9)**, perhaps, the different temperatures of swabs that were used for uterine cooling (4-0°C in our study Vs 2°C). Likewise, the volume of blood loss in the control group in our study was lower than the volume reported by Nawasirodom, et al. **(9)**. This difference can also be attributed to different rates of oxytocin infusion during surgery in the two studies. We administrated 20 units of oxytocin diluted in ringer at the rate of 1000 cc/h 1000 but in the Nawasirodom study, 20 units of oxytocin were administrated at the rate of 100-120 cc/h.

Consistent with the results reported by Mitchell, et al. **(8)**, we observed no significant differences between the two groups in need of additional uterotonic agents, which differed from the results of study Nawasirodom, et al. **(9)**, which could be attributed to the differences in the rate of oxytocin infusion.

However, these results are in line with other uterotonics agents that the WHO recommended such as oxytocin alone as the first choice or with uterine massage, tranexamic acid **(14)**. Studies done by Delorme, et al. **(15)** and Morfaw, et al. **(16)** for preventing PPH, suggested Carbetocin, and misoprostol, respectively. Also, these agents had side effects that limited their usage, for example, shivering and fever are common side effects of misoprostol **(17)**.

Conclusion

Nerveless, more multicenter randomized trials are needed to achieve definitive results. Anyway, the strength of the present study includes a larger sample size compared with previous studies and the use of quantitative measurement of blood loss were the strength of this study, the validity of the randomized controlled trial methodology, the integrity of data collection, and close monitoring of patients for adverse events. We investigated the effect of uterine cooling during a cesarean section on the volume of blood loss in low-risk women. A future study is needed to examine the effectiveness of this strategy in high-risk groups. Based on the results of our study, uterine cooling during cesarean section can reduce the volume of blood loss in low-risk women. Uterine cooling can be used as a safe auxiliary method for patients undergoing cesarean section to reduce postpartum hemorrhage.

Acknowledgments

This study had been approved by the ethics review board at Qazvin University of Medical Sciences (Approval ID: IR.QUMS.REC.1398.032). The authors thank the Clinical Research Development Unit of Kowsar Hospital and Clinical Research Development Unit of Advanced Medicine.

Authors' Contribution

H.P. and M.K Conceived and designed the study, conducted research, and provided research materials. K.E and M.K. wrote the initial and final draft of an article and provided logistic support. V.P. analyzed and interpreted data. N.A., V.P. Contributed to the collected and organized data. S.M. took the lead in writing the manuscript and H.P., K.E., V.P., and S.M read and approved the final manuscript. All authors provided critical feedback and helped shape the research, analysis, and manuscript.

Ethical Approval

This study was approved by the ethics committee of Qazvin University of Medical Sciences (IR.QUMS.REC.1398.032). (IRCTID: IRCT20120104008611N11).

Conflict of Interest

The authors declare no conflict of interest.

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