Introduction
Postpartum hemorrhage (PPH) refers to the blood loss of more than 500 cc after completing the third stage of labor (1,2). Nonetheless, this estimation is generally only half of the actual blood loss based on the evidence (3). In addition, PPH is known as one of the major reasons for maternal mortality (4). In other words, 28% and 10% of maternal deaths in developing and developed countries are related to PPH, respectively (2,5,6). Further, PPH is characterized by a 10% drop in hematocrit levels and the need for postpartum blood transfusions (7). It could lead to hypovolemic shock, disseminated intravascular coagulation, and acute renal failure (8, 9).

Treatments should address the causes of PPH. The possible causes of uterine postpartum bleeding are trauma, retained placenta, and uterine atony (10-12). Uterotonic drugs such as oxytocin, ergo derivatives, and misoprostol are used as the first line of treatments for PPH in Iran (7). Except for uterine massage, the other treatments of PPH have disadvantages on the mother (e.g., headache, vomiting, the elevation of blood pressure, and the like) or breastfeeding (1,13). Consequently, preventing PPH is highly important. Reducing hemorrhage is usually implemented by the routine active management of placenta delivery by drug using to contract the uterus such as oxytocin (11). Today, ice therapy is used as one of the new methods for the treatment of many diseases, even cancer by lessening pain, inflammation, and vasoconstriction (14). It can be one of the useful methods for preventing uterine atony and PPH (15). Based on the evidence, placing an icebag on the lower abdomen for cooling the uterus is one of the standard non-pharmacological prophylactic strategies to prevent PPH in low-risk women in Japan (15), and its argument is that cold compresses would contract the myometrium and decreases the amount of blood flow (16).

This study was designed to reduce maternal deaths as an important factor for children’s growth, specifically in poor countries (18) by using available methods such as oxytocin and icepack.
As the icebag. Meanwhile, in Iran, prophylactic oxytocin (10-20 units) is administrated during the third stage of labor (19), and icebag along with other uterotonic agents is used in the treatment of PPH while there is no evidence for separately detecting the effectiveness of this method. Moreover, the conflicting results in some studies on the effect of the routine use of synthetic drugs (1) and non-invasive therapeutic methods such as cooling lower abdominal need further assessment.

Materials and Methods
The study as a parallel, double-blind clinical trial determined the effect of the ice bag on the amount of blood loss and prevention of PPH in the first two hours after delivery. The design of the project strictly complied with the Guidelines for Reporting Parallel Group Randomized Trials (20).

This study was conducted in the labor wards of 3 hospitals in Qazvin, Iran, from February 20, 2019 to November 26, 2019. The subjects were women with normal vaginal delivery, with immediate placenta removal up to 2 hours. The study criteria were maternal aged 18-35 years, term pregnancy, alive and singleton pregnancy, fetal weight in the range of 2500-4000 g, gestational age between 37 and 42 weeks, vertex presentation, and normal second and third stage length. On the other hand, the exclusion criteria included pre-eclampsia, polyhydramnios, body mass index (BMI) more than 40, the disorder of blood coagulation, use of any anticoagulants, hepatic dysfunction, placental abruption, cesarean section birth, history of prenatal hemorrhage, rapid delivery less than 3 hours, deep and large laceration (grade 3 or 4), use of oxytocin at any stage of labor, previous cesarean section, or uterine surgery.

Randomization and Blinding
The sample size was 58. The intervention (cooling of the lower abdomen) and control (oxytocin) groups were randomly assigned during placenta delivery using block 4th allocation. Then, 13 blocks were made, letters A and B were written for the intervention and control groups (e.g., AABB, ABAB, and the like), respectively, and then were put into a bag. They were picked up one by one by a ward clerk, and finally, the sequences of the blocks were written and assigned to the intervention and control groups, respectively.

The participants were masked by a light sandbag the same as an ice bag. Therefore, the participant and data analyzers did not know what type of intervention they received although caregivers could not be masked due to the nature of this intervention.

Procedure
Before the study, midwives received training about who, when, and where to place the ice bag to cool the abdomen, then after placental removal, uterine massage, and clot removal, the control group received 20 units of oxytocin in 1 L of Ringer serum according to the health ministry protocol (19), and a light sandbag weighing 385 g (9.16lb) was placed on the uterus above pubis symphysis. In the intervention group, the icebag was placed on the lower abdomen. Each icepack was frozen under -18°C temperature for more than 8 hours. In addition, women in both groups were similarly managed by midwives and obstetricians. If the participants had abnormal bleeding, the midwives and obstetricians treated them based on determined protocols provided by the individual physician in both groups.

Outcome
The first and second outcomes were the rate of PPH and the amount of blood loss, respectively. PPH was determined as need transfusion or other management according to obstetrician diagnosis (19).

Data Collection
A checklist was used to record the data including delivery type, duration of the second and third stages, complications such as excessive PPH, hemoglobin, neonatal weight, neonatal gender, blood pressure, temperature, and pulse. The respiration rate and uterine contraction were monitored every 15 minutes at the first 2 hours (after placental removal). The duration of lactation and the duration of sucking by the infant were also recorded in this form.

The validity of the checklist was done by the content validity method with 10 midwives and obstetricians' teachers. Interrater methods were used and the coefficient of agreement (0.7) was calculated to obtain the reliability. The Japanese digital scale and weighting scale and the sensitivity of 1 g were daily checked for half a kilo weight to determine its scientific reliability.

To measure the amount of bleeding, after ensuring complete placental removal and the absence of PPH (as mentioned above), a new mat (Mark Bella, 85 g ± 7 g absorbent powder and 60×160 weighted dimensions) was placed under the mother, and then they were given a pad (with a large Mark My Lady weighting 10 g of 30 × 7 dimensions) for both groups. At the end of the first and second hour after delivery, all pads and mats were weighted by a person unaware of the study in both groups. It should be noted that all gauzes were weighted and recorded in the case of vaginal tampon in perineal...
laceration or episiotomy. Hemoglobin and hematocrit were routinely checked at admission and three hours after birth.

Data Analysis
Data were analyzed by the SPSS software (version 24, IBM, Armonk New York, USA). The t test was used for the comparison of continuous variables such as the amount of blood loss among the groups. Finally, the Chi-square test was applied to compare dichotomous variables such as the rate of PPH.

Results
In this study, 58 postpartum women were included and were randomly assigned to oxytocin (n = 29) and icebag (n = 29) groups in the third stage of delivery. Two groups were compared in parity, abortion, education, and job. Most of them were literate and housewives and 70% of women were multipara (Table 1).

The type of delivery and the percentage of episiotomy (41.1% in icepack versus 51.7% in the oxytocin group) were similar in both groups. There was no side effect in the oxytocin group except for the pain in 2 women although 52% of cases of the icebag group had a bad sensation of cold (Table 1). There were no significant differences between the two groups in terms of pre-pregnancy BMI, weight gain during pregnancy, neonatal weight, hemoglobin levels before and after delivery, lactation, and the second and third stage duration. Although the second stage showed significant differences between the primipara and multipara (it is longer in primipara than multipara), they were similar among the groups (Table 2).

The PPH rate was 12.1% (17.2% and 6.9% in the intervention and control groups, respectively), and no significant differences were observed between the two groups. Vaginal blood loss was 254 ± 68.11 and 245 ± 53.23 in the intervention and control groups, respectively, representing no significant differences between the two groups (Table 3).

Discussion
This study was done on 58 low-risk pregnant women. All samples were matched for the duration of lactation, neonatal weight, and socioeconomic factors affecting PPH, and the findings revealed no significant difference. Based on the results, the administration of 20 units of oxytocin or the use of an icebag on the lower abdomen (uterine) did not significantly change the rate of uterine bleeding after delivery. Normal blood loss in low-risk women is estimated to be a maximum of 500 mL (1). The data from this study estimated the mean total blood loss for multiparous women 275 (140-432) and primipara 270 (170-590) mL while the mean total blood loss demonstrated no reduction in the intervention group in comparison with the control group (254 vs. 245).

In the Masuzawa et al study in Japan, bleeding was estimated to be 473 in the untreated control and 513 mL in the intervention group (15), which is much higher than that of the current study. Due to collecting the lost blood method in the third stage after placental removal and uterine massage in the current study (because of ensuring abnormal bleeding), the new mat was placed for collecting blood loss, thus the amount of intrauterine bleeding associated with primary clotting was not measured after cleaning the placenta.

Table 1. Demographic Characteristics of the Participants

| Variable                        | Groups |       |       | P Value |
|---------------------------------|--------|-------|-------|---------|
|                                | Ice Packed | Oxytocin |       |         |
| Age (year), mean ± SD           | 28.17 ± 7.81 | 31.20 ± 4.63 | 0.08 |         |
| Maternal body mass at the beginning of pregnancy (kg), mean ± SD | 25.40 ± 4.20 | 24.75 ± 2.87 | 0.51 |         |
| Maternal weight gain in pregnancy (kg), mean ± SD | 10.45 ± 3.18 | 10.90 ± 4.26 | 0.67 |         |
| Parity                          |        |       |       |         |
| First                           | 8 (27.6) | 9 (31.0) |       | 0.67    |
| Second                          | 10 (34.5) | 12 (41.4) |       |         |
| Third                           | 5 (17.2) | 4 (13.8) |       |         |
| Fourth                          | 6 (20.7) | 4 (13.8) |       |         |
| Abortion history                |        |       |       |         |
| No                              | 21 (72.4) | 19 (65.5) |       | 0.12    |
| Yes                             | 8 (27.5) | 10 (34.5) |       |         |
| Education                       |        |       |       |         |
| Illiterate                      | 4 (13.8) | 1 (3.4) |       |         |
| Primary                         | 6 (20.7) | 1 (3.4) |       |         |
| Secondary                       | 9 (31.0) | 10 (34.5) |       | 0.07    |
| High school                     | 5 (17.2) | 10 (34.5) |       |         |
| Bachelor                        | 0 (0) | 2 (6.9) |       |         |
| MA                              |        |       |       |         |
| Job                             |        |       |       |         |
| Housewife                       | 24 (82.8) | 20 (69.0) |       | 0.19    |
| Employee                        | 4 (13.8) | 9 (31.0) |       |         |
| Hair stylist                    | 1 (3.4) | 0 (0.0) |       |         |

Note. SD: Standard deviation
As shown, the demographic data of the two groups were not significantly different.
placental removal. Overall, their results also showed no significant differences between the two groups, which is in line with the findings of the current study. However, in another study, cooling the lower abdomen was not useful for uterine activity during the two hours after placental delivery (17). In another study performed to evaluate the effect of uterine cooling on cesarean delivery, this method was found to be significantly effective in reducing post-caesarean bleeding (16), which is not in line with the findings of our study. However, cooling the uterus directly in the cesarean section causes shrinkage and reduces bleeding, and thus is more effective compared to indirect cooling beyond the abdominal skin.

Although there is no study in this area in Iran, the icebag is commonly used in combination with other drugs in PPH. A study by Mooshkbid Haghighi et al on postnatal hemorrhage showed that the administration of oxytocin could reduce the blood loss in the first hour after placenta removal compared with non-pharmacologic drugs such as massage (39.5 vs. 43.68) but this difference was not significant. They concluded that although blood loss decreased in the oxytocin group in the first hour after delivery, oxytocin administration was unnecessary 24 hours after birth (21). Dabbaghi Gale et al found that oxytocin administration is the same in reducing PPH in comparison with oral misoprostol (22). Likewise, Mojahed et al suggested the effectiveness of eating dates in preventing PPH (23). Another study pointed to the

| Variable                          | Ice Packed (No (%), n = 29) | Oxytocin (No (%), n = 29) | P Value |
|-----------------------------------|-----------------------------|---------------------------|---------|
| Baby weight (Mean ± SD)           | 3206 ± 437                  | 3284 ± 341                | 0.47    |
| Breastfeeding time in the first 2 hours (min), mean ± SD | 46.58 ± 22.30 | 52.85 ± 18.78 | 0.57    |
| Time of the second stage of labor (min), mean ± SD | 20.62 ± 20.28 | 19.74 ± 14.72 | 0.85    |
| Time of the second stage of labor in primipara (min), mean ± SD | 39.16 ± 26.53 | 34.37 ± 16.99 | 0.85    |
| Time of the second stage of labor multipara (min), mean ± SD | 14.44 ± 11.70 | 11.57 ± 8.09 | 0.85    |
| Time of the third stage of labor (min), mean ± SD | 7.54 ± 7.40 | 6.14 ± 3.31 | 0.38    |
| Hemoglobin at admission (g), mean ± SD | 12.73 ± 0.73 | 12.80 ± 0.64 | 0.73    |
| Hemoglobin 3 hours after delivery (g), mean ± SD | 12.71 ± 0.70 | 12.71 ± 0.60 | 0.74    |

| Variable                          | Ice Pack | Oxytocin | P Value |
|-----------------------------------|----------|----------|---------|
| Type of delivery                  | Normal   | 12 (41.4) | 0.75    |
|                                  | Episiotomy | 12 (41.4) |         |
|                                  | Laceration | 5 (17.2)  |         |
| Placental separation              | Schultz  | 25 (86.2) | 0.67    |
|                                  | Duncan   | 1 (13.8)  |         |
| Baby gender                       | Boy      | 18 (62.1) | 0.29    |
|                                  | Girl     | 11 (37.9) |         |
| Side effects                      | No       | 19 (65.5) | 0.01    |
|                                  | Yes      | 10 (34.5) |         |
| Lactation and skin contact        | Immediately after birth | 18 (62.1) | 0.18    |
|                                  | Up to 30 min | 4 (13.8)  |         |
|                                  | After 30 min | 7 (24.1)  |         |

Note: SD: Standard deviation

Based on the data, there is no significant difference regarding lactation, weight gain during pregnancy, and the duration of labor. The type of delivery and the rate of skin contact did not differ significantly between the two groups although the side effect was more considerable in the icebag group (cold feeling).

| Variable                          | Groups | P Value |
|-----------------------------------|--------|---------|
| Third stage blood loss (mg), mean ± SD | Ice pack | 254.50 ± 68.11 | 0.60    |
|                                  | Oxytocin | 245.74 ± 53.23 |         |
| PPH frequency                     | No      | 24 (82.8) | 0.22    |
|                                  | Yes     | 5 (17.2)  |         |
| Primipara, n = 17                 | No      | 239± 48.55 | 0.41    |
|                                  | Yes     | 275.56 ± 83.40 |         |

Note: SD: Standard deviation; PPH: As shown, no significant difference was observed in the blood loss amount between the two groups although the maximum and minimum bleeding rates were significantly higher in the primipar compared to multiparous women.
efficacy of consuming dill (24) and oxygen inhalation (3). The results of these studies corroborate with those of the present study, emphasizing that oxytocin is not the only safe drug for preventing PPH. Nonetheless, Hofmeyr et al reviewed two randomized controlled trials and agreed on uterine massage effectiveness after birth before or after the delivery of the placenta or both for reducing postpartum blood loss. However, the results of this review were inconclusive. The disadvantages of uterine massage were time-consuming for staff time and women discomfort. They emphasized no change in the recommended practice (11), which conforms with the results of the current study because of using a different intervention. It should be noted that the only complication of the icebag on the lower abdomen was the feeling of coldness which was mentioned in the Japanese study (15), this is the only barrier to the use of the icebag.

Conclusions
Based on the results, in low-risk deliveries, icebags as a non-pharmacological alternative can be as effective as oxytocin in preventing PPH, thus it is recommended for low-risk women who do not wish to use any medication. Finally, midwives could use the icebag without or/along with oxytocin after every vaginal delivery in order to prevent PPH.

Limitations
To prevent unpredictable PPH, the icebag method was performed cautiously, thus the investigation took a long time. The minimum sample size was estimated as this is a student project.

Suggestion for Future Studies
We will suggest doing this study on a large sample size and on multiparous women who are more likely to have uterine atony.

Authors’ Contribution
ZZ designed the study; ZZ and RM participated in data collecting; PH contributed to the data analysis; AN participated in data analysis, article preparation, article submission and study design.

Conflict of Interests
Authors declare that they have no conflict of interests.

Ethical Issues
The study protocol was approved by the Research Committee of the School of Nursing and Midwifery with Code of Ethics IR.QUMS.REC.1397.108. Further, this study was registered in the Iranian Clinical Trial System on July 24, 2019 (identifier: IRT20190430043433N2). The eligible women were informed about the goal of this study both verbally and nonverbally, and all participants provided written informed consent.

Financial Support
Vice-chancellor for research of Qazvin University of Medical Sciences supported the study.

Acknowledgments
This study is the result of a student research project approved by the Student Research Committee of the School of Nursing and Midwifery. We appreciate the Research Assistants and the members of the Student Research Committee, as well as all participants in this research.

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