

A Comparative Study on the Effects of B Massage and Entonox Gas on Pain Severity and Some Outcomes During Childbirth in Nulliparous Women: A Randomized Clinical Trial

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Abstract

BACKGROUND/AIMS: Reducing the intensity of labor pain is a way of encouraging women to select vaginal birth. The present study aimed to compare the effects of B massage and Entonox gas on pain severity during childbirth.

MATERIALS AND METHODS: This randomized clinical trial was conducted on 90 nulliparous women randomly selected from among those who were admitted for childbirth in Shahrivar Hospital of Saveh, Iran, from 6th August, 2015 to 13th April, 2016. Women with a gestational age of 37-42 weeks, a dilatation of 4-5 cm, and singleton pregnancy were selected. They were randomly divided into three groups as B massage, Entonox and control. The severity of pain was measured before the intervention and every 45 minutes after the first intervention using a visual analog scale. The data were analyzed by using chi-square, Tukey, Scheffe, Cramer and Spearman's correlation tests in SPSS software.

RESULTS: There was no significant difference between the three groups concerning their gestational age and their other demographic characteristics. ANOVA test showed lower pain intensity at 45, 90, 135, 180 and 225 minutes after the first intervention in the B massage group ($p < 0.001$). Pain intensity was significantly lower in the massage group in the second stage of labor compared to the other two groups ($F_3 = 15.61$, $df = 2$, $p < 0.001$). Chi-square test showed that cesarean section was more common in the Entonox group ($F_3 = 13.123$, $p < 0.001$), post-partum bleeding was more in the B massage group ($F_3 = 8.535$, $p = 0.014$) and newborn resuscitation was more frequently applied in the Entonox group ($F_3 = 11.118$, $p = 0.025$).

CONCLUSION: This study showed that B massage can reduce the intensity of labor pain but it increases post-partum bleeding and further studies on this type of massage are needed.

Keywords: Pain relief, massage, Entonox

INTRODUCTION

Reducing the intensity of labor pain is a way of encouraging women to select vaginal birth.^{1,2} Pain relief during childbirth can reduce fear and anxiety leading to benefits in the childbirth outcomes. Childbirth pain is reduced by different methods which are divided into two main

groups, namely pharmaceutical and non-pharmaceutical methods.^{3,4} One of the pharmaceutical methods used to relieve labor pain is Entonox (nitrous oxide gas). This gas was first used by Wales in 1844 for analgesia.^{5,6} Entonox is the equal mixture of 50% nitrous oxide and 50% oxygen. Administration of Entonox for analgesia is performed during the first and second stages of labor and its maximum effect appears

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within two minutes after use.⁷ Entonox helps relieve short-term pain and also reduces anxiety and pain in a wide range of painful actions, such as drainage, lumbar puncture or dressing.⁸ The advantages of using Entonox are that it is fast and effective, it leaves the body quickly and it is cost-effective. The disadvantages or complications of using Entonox are dry mouth, vertigo, lethargy, vomiting and uncomfortable feelings.⁹ As self-administrated Entonox inhalation was used, the depth of breathing and the amount of gas used could not be evaluated. The patient's sense of being able to control pain may not only be related to the usage of Entonox, but also to their self-control of the drug. The use of Entonox during labor pain could be a step towards natural vaginal deliveries in Iran where many women tend to undergo caesarian section. Factors that limit Entonox's acceptability include confusion, sleepiness, an unwillingness to use a mask and feelings of pain after stopping gas inhalation.^{9,10}

Nowadays, non-pharmacological methods of pain relief as a safe method have been widely used around the world and it is primarily based on empowering mothers. One of these methods is massage therapy, which in addition to relieving labor pain, leads to more communication with the mother, strengthens the effects of relaxation and reduces emotional stress.¹¹ Several theories have been proposed to explain the mechanisms by which massage can alleviate pain, including lowering cortisol and norepinephrine levels,^{12,13} and augmenting serotonin levels.¹⁴ Many researchers believe that mechanical massage pressure can accelerate blood flow, thereby increasing metabolism and oxygen supply.¹⁵ A five-minute massage on the waist can increase skin blood flow, blood volume muscle and lymph circulation. As a result, excretion of toxins and residual materials improves and nutrient flow to tissues increases and so reduces swelling and pain.^{16,17} In addition, Melzak and Wall¹⁸ proposed a mechanism whereby creating a stimulus which interferes with the transmission of pain to the brain, effectively "closes the gate" to the reception of pain.

Various massage techniques such as massage all over the back (Swedish massage), massage of the buttocks (Linda Kimber's massage) and the massage of the lower back and buttocks (B massage) are used during labor.^{19,20} There are many studies which have shown that Entonox gas and massage affect the severity of labor pain, however, little information is available about B massage and its comparison with Entonox. Therefore, the researcher decided to compare the effects of B massage and Entonox gas on pain severity and some outcomes type of delivery, the rate of augmentation of postpartum bleeding, newborn resuscitation during childbirth.

MATERIALS AND METHODS

This randomized clinical trial (IRCT 20180128038535N2) was performed on 90 nulliparous women in the delivery ward of 17 Shahrivar Hospital of Saveh, Iran from 6th August, 2015 to 13th April, 2016. The inclusion criteria were having their first pregnancy, a gestational age between 37-42 weeks, a singleton pregnancy, fetal head presentation, dilatation of 4-5 cm or more (active phase of the first stage of labor) and an anesthesiologist prescription for the Entonox group. High risk pregnant women (pre-eclampsia, eclampsia, diabetic women, those with chronic disease, those with cardiovascular disease etc.), pre-rupture of the membrane, pre-term labor, induction of labor, drug abuse or those who had skin or lumbar problems in the lower back in the massage group were not enrolled into this study. The exclusion criteria were dissatisfaction with continuing the study, any problems requiring

medical intervention, birth occurring within 225 minutes after starting the study, and using any pharmacological or non-pharmacological analgesics except for B massage or Entonox gas during the study. The cases were divided into three groups, namely B massage, Entonox gas and control. After explaining the study, 30 women were randomly selected in each group based on the confidence interval of 95% and power of 80% (Figure 1). To allocate the women randomly, numbered cards (1-3) were used. The cards were placed inside envelopes and the participants had to choose one of them. If they chose numbers 1, 2, 3, they were placed in the B massage, Entonox or the control groups respectively.

In this study, the researcher used observation, examination and questionnaire to collect the essential data. The questionnaire consisted of three parts: the first part related to the demographic characteristics, (occupation, education, location, residence status), the second part was delivery information (type of delivery, need of augmentation, postpartum hemorrhage, newborn resuscitation), and the third section was information corresponding to the pain intensity just before the intervention and at 45, 90, 135, 180 and 225 minutes after starting the study or the first intervention. Also, pain intensity was measured at the second stage of labor. Pain severity was measured using McGill's visual analog scale (VAS). Numbered cards (1-3) were used to randomly allocate the three groups. In the B massage²⁰ group, at dilatation of 4-5 cm, the participant was placed on their side or standing when the abdominal stiffening was declared by the mother so that she leaned forwards with her hands on the bed. The researcher was positioned behind and to the left or right of the mother. As soon as the abdomen tightened, with the palm of the hand, the massage was started from the lower back of the waist, moving from one side to the other, and moving the hand down the buttocks, and from the gap between the two buttocks moving up and then down. The massage is actually in the form of the letter B, the straight line is along the lower back and the two rings are on the two buttocks. The massage started from dilatation 4-5 cm and continued until the end of the first stage of labor. The massage began at the beginning of each uterine contraction and continued until the end of the contraction. Continued use of B massage in the second stage of labor depended on the mother's desire (Figure 2).

In the Entonox group (following the order of an anesthesiologist), at a dilatation of 4 to 5 cm, the unit of study was given an explanation and training on how to use Entonox gas and the time it was to be used. The patient was told by the researcher to put her hand on her abdomen, and as soon as the abdominal stiffness began, she administered Entonox through a facemask which was attached to a one-way valve which enabled the patient to breathe gas with each inhalation. Inhalation of the gas was carried out in the form of a deep and calm breaths, and this inhalation continued until the end of the pain. When using Entonox gas, the researcher was positioned next to the individual and helped her during the intervention. In the Entonox group, gas inhalation was begun by the mother at the beginning of each uterine contraction and continued until the end of each contraction. Continued use of Entonox gas in the second stage of labor depended on the mother's desire.

The control group received standard care according to the protocols of the Ministry of Health. The information about the type of delivery, Apgar scores for the first and the fifth minutes, the need for resuscitation of the newborn, the amount of excessive hemorrhage (estimated more than 500 cc) according to the need for checking hemoglobin in the first

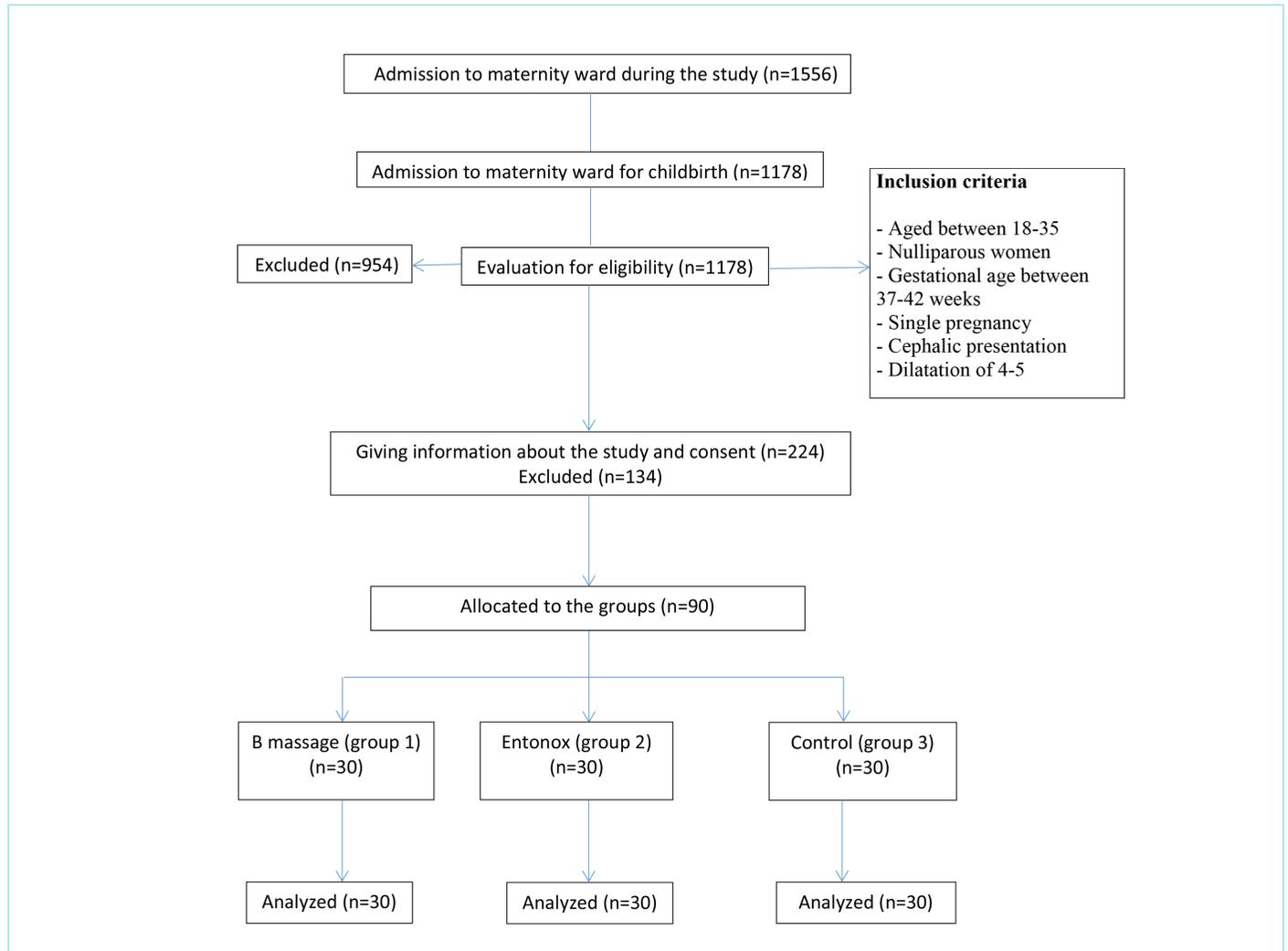


Figure 1. Consort flow diagram.

6 hours postpartum, blood transfusion, as well as the need for using misoprostol were collected and recorded via a questionnaire.

Statistical Analysis

Chi-square, Scheffe, Tukey, Cramar and Spearman correlation tests were used for data analysis in SPSS software (version 15; SPSS software, Chicago, IL, USA). All p-values less than 0.05 were considered significant.

Ethical Considerations

Ethical approval was obtained from the Human Research and Ethics Committee of Saveh University of Medical Sciences, (approval number: IR.SAVEHUMS.REC.139401). Prior to this study, all the mothers provided written informed consent and the study method was described in detail for all participants. A separate room was used for the comfort and privacy of the mothers and emotional communication was established for the three groups at all the stages of this study.

RESULTS

Among the 90 pregnant cases studied, their mean age was 28.31 (7.17) years in the B massage group, 29.43 (5.77) years in group of Entonox and 28.12 (4.81) years in the control group. Mean gestational age

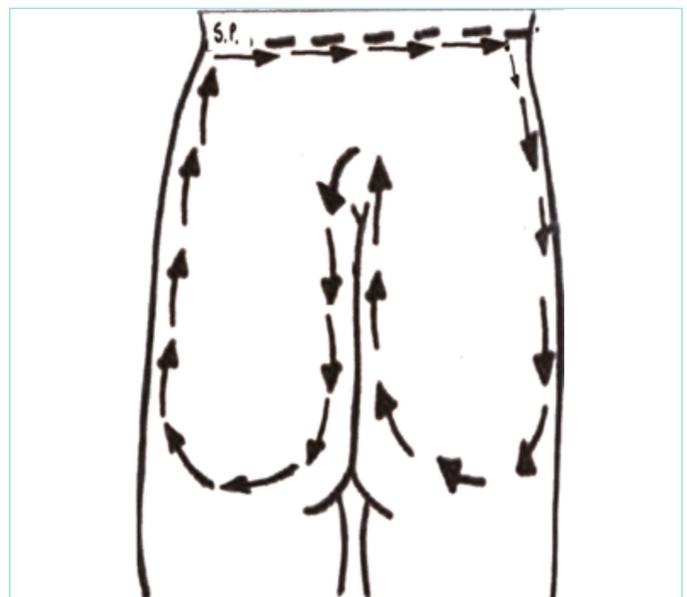


Figure 2. B massage protocol.¹⁹

based on the first day of menstruation and sonography of the first trimester were 39.08 (0.92) and 39.04 (0.93) weeks in the B massage group, 39.77 (1.02) and 39.70 (0.87) in the Entonox group and 39.16 (1.36) and 39.06 (1.34) weeks in the control group, respectively. There was no significant difference in the maternal age between the three groups ($F=0.371$, $DF=65$, $p=0.692$), gestational age (based on the first day of menstruation, ($F=0.205$, $DF=60$, $p=0.138$) and sonography of the first trimester ($F=2.318$, $DF=61$, $p=0.107$). The economic status, level of education and other demographic characteristics are shown in Table 1.

As seen in Table 2, the mean of pain severity on the VAS before the intervention was not significantly different between the three groups. However, 45 minutes after starting the study (or after the first intervention), pain severity was significantly less in the B massage and Entonox groups compared to the control group ($p=0.001$). Post-hoc test (Tukey test) showed no significant difference between the B massage and Entonox groups ($p=0.177$). Post-hoc test (Tukey test) showed no significant difference between the Entonox and control groups 90 minutes after the first intervention ($p=0.077$). Post-hoc test showed pain severity was significant less in the Entonox group compared to the control group at 135, 180 and 225 minutes after the first intervention ($p=0.001$). Pain intensity in the second stage of labor was significantly

lower in the B massage and Entonox groups. Post-hoc test showed no significant difference between these two groups ($p=0.834$). The difference between the mean scores of pain intensity in the first stage of labor was significantly different between the three groups (confidence interval 95%) ($df =2$, $F=13.409$, $p=0.001$) and the mean pain intensity in the control group was more than the two other groups. The difference between the mean scores of pain intensity in the second stage of labor was significantly different between the three groups and the mean pain intensity in the control group was more than the other two groups (confidence interval 95%) ($df =2$, $F=19.106$, $p=0.001$).

Mann-Whitney test showed that the severity of pain in the first stage of labor was not significantly different between the three groups according to the need for newborn resuscitation ($p=0.12$). The Mann-Whitney test showed that the severity of pain in the first stage of labor was not significantly different between the three groups in terms of postpartum hemorrhage ($p=0.17$). The Mann-Whitney test showed that the severity of pain in the first stage of labor was not significantly different between the three groups in terms of the first and fifth minute Apgar scores ($p=0.19$). There was no significant difference between the three groups in terms of the rate of augmentation ($p>0.05$). There were significant differences between the three groups in terms of the type of delivery,

Table 1. Frequency distribution of demographic characteristics

| Demographic characteristics | | B massage, n (%) | Entonox, n (%) | Control, n (%) | Chi- square | df | p-value |
|-----------------------------|---------------|------------------|----------------|----------------|-------------|----|---------|
| Mother's education | Illiterate | 2 (6.7) | 4 (13.30) | 17 (56.70) | 2.81 | 2 | 0.246 |
| | Under diploma | 14 (46.70) | 4 (13.30) | 9 (30) | - | - | |
| | Diploma | 14 (46.70) | 18 (60) | 4 (13.30) | - | - | |
| | Academic | - | 4 (13.30) | - | - | - | |
| Husband's education | Illiterate | 5 (16.7) | - | 1 (3.3) | 1.30 | 2 | 0.522 |
| | Under diploma | 9 (30) | 8 (26.70) | 17 (56.7) | - | - | |
| | Diploma | 16 (53.3) | 18 (60) | 11 (36.7) | - | - | |
| | Academic | - | 4 (13.3) | 1 (3.3) | - | - | |
| Mother's occupation | Housewife | 30 (100) | 30 (100) | 28 (93.30) | 1.02 | 2 | 0.602 |
| | Employed | - | - | 2 (6.70) | - | - | |
| Husband's occupation | Employee | 4 (13.30) | 20 (64.30) | 6 (20) | 0.85 | 2 | 0.653 |
| | Self-employed | 26 (86.70) | 10 (35.70) | 24 (80) | - | - | |
| Location | Urban | 23 (76.70) | 22 (73.30) | 27 (90) | 1.52 | 2 | 0.467 |
| | Rural | 7 (23.30) | 8 (26.70) | 3 (10) | - | - | |
| Residence status | Owner | 16 (53.30) | 17 (56.70) | 10 (33.30) | 0.77 | 2 | 0.680 |
| | Tenant | 14 (46.70) | 13 (43.13) | 20 (66.70) | - | - | |

Table 2. The mean score of pain severity during childbirth (VAS)

| Group | B massage, mean (SD) | Entonox, mean (SD) | Control, mean (SD) | F | df | p-value |
|--------------------------------|----------------------|--------------------|--------------------|-------|----|---------|
| Before intervention | 5.69 (85) | 5.71 (0.73) | 5.18 (1.42) | 1.80 | 2 | 0.173 |
| 45 minutes after intervention | 4.38 (0.77) | 5.05 (0.86) | 5.47 (1.13) | 5.70 | 2 | 0.005 |
| 90 minutes after intervention | 3.69 (0.86) | 4.86 (0.79) | 5.56 (1.31) | 13.91 | 2 | 0.0001 |
| 135 minutes after intervention | 3.38 (0.51) | 4.23 (0.99) | 5.56 (1.26) | 21.14 | 2 | 0.0001 |
| 180 minutes after intervention | 3.08 (0.28) | 4.05 (0.80) | 5.41 (0.99) | 41.41 | 2 | 0.0001 |
| 225 minutes after intervention | 4.00 (0.00) | 4.81 (0.68) | 6.09 (1.11) | 31.31 | 2 | 0.0001 |
| Second stage of labor | 5.17 (1.47) | 5.50 (0.55) | 7.67 (0.71) | 15.61 | 2 | 0.0001 |

SD: standard deviation, VAS: visual analog scale.

| Table 3. Frequency distribution of delivery type, augmentation, postpartum hemorrhage and newborn resuscitation | | | | | | | |
|---|----------------------------|------------------|----------------|----------------|----------|----|---------|
| Group variable | | B massage, n (%) | Entonox, n (%) | Control, n (%) | χ^2 | df | p-value |
| Type of delivery | NVD ¹ | 30 (100) | 28 (93.3) | 30 (100) | 13.123 | 2 | 0.001 |
| | Cesarean section | 0 (0.0) | 2 (6.7) | 0 (0.0) | | | |
| The rate of augmentation | Yes | 17 (56.7) | 14 (46.7) | 10 (33.3) | 2.700 | 2 | 0.259 |
| | No | 13 (43.3) | 16 (53.3) | 20 (66.7) | | | |
| Post-partum hemorrhage | No intervention | 7 (23.3) | 18 (60) | 0 (0.0) | 8.535 | 2 | 0.014 |
| | Massage of uterus | 18 (60) | 12 (40) | 30 (100) | | | |
| | Checked Hb ² | 5 (16.7) | 0 (0.0) | 0 (0.0) | | | |
| Newborn resuscitation | No resuscitation | 20 (66.7) | 9 (30) | 30 (100) | 11.118 | 4 | 0.025 |
| | Stimulation of the newborn | 10 (33.3) | 17 (56.7) | 0 (0.0) | | | |
| | Mechanical ventilation | 0 (0.0) | 4 (13.3) | 0 (0.0) | | | |

NVD¹: normal vaginal delivery, Hb²: hemoglobin.

postpartum bleeding and new born resuscitation ($p < 0.05$) (Table 3). Out of 90 cases in the three groups, two cases in the Entonox group underwent cesarean section due to fetal distress.

The mean neonate Apgar score in the first minute after birth was 8.66 (1.26) in the B massage group, 7.80 (0.40) in group of Entonox and 9.00 (0.00) in the control group. The mean neonate Apgar score at 5 minutes after birth was 9.80 (0.76) in the B massage group, 9.40 (0.40) in group of Entonox and 10.00 (0.00) in the control group. The mean Apgar score at the first and fifth minutes after birth was not significantly different among the three groups ($p > 0.05$).

DISCUSSION

An exhaustive review of the relevant literature showed that there had not been any similar studies conducted previously which compared the efficacy of the implementation of B massage and Entonox on labor pain reduction and the outcomes of childbirth. Hence, the findings of the present study were compared with findings obtained in studies dealing with other similar massage techniques and the use of Entonox.

As previously specified, labor pain is a progressive process as it increases in severity with increasing dilation. In the present study, pain severity was less in the B massage group compared to the Entonox and control groups after the intervention. The reason may be due to the fact that massage stimulates large-diameter nerve fibers to wrinkle as the mechanism of cortex pain coverage which leads to pain relief.²¹⁻²⁶ In Janssen et al.²⁷ study titled "Massage therapy and labor results", 77 nulliparous women with spontaneous onset of labor were randomly divided into two groups, namely a Swedish massage group and a control group. The results showed that pain intensity in the intervention group was less than the control group, and in this regard, it is consistent with our study. In the study by Silva Gallo et al.¹⁷ titled "Massage reduced the severity of labor pain (clinical trial)", 44 cases received massage by a physiotherapist for 30 minutes. The severity of labor pain after the intervention was statistically lower than the control group. Aghdam et al.²⁸ studied the effect of massage on the duration and severity of labor pain in nulliparous women. Their result showed that massage significantly reduced the severity of labor pain, which is consistent with our study. Sananpanichkul et al.²⁹ in their study titled the "Possible role of Court-Type Thai traditional massage during parturition: a randomized controlled trial", 59 cases were enrolled into c-TTM massage and control groups. They reported that there was no statistical difference of pain

score during the intrapartum period between the two groups, which is not consistent with our study. Their research is a different procedure from the present study because c-TTM massage was applied only once in the active phase of labor.

Naddoni et al.³⁰, in their research, showed that the intensity of labor pain was significantly lower in the Entonox group compared to the oxygen group (60 and 120 minutes after starting the study) which is not similar to our study. Foji et al.³¹ compared the effect of Entonox inhalation and spinal anesthesia on reducing labor pain. Their findings showed that spinal anesthesia was more effective than Entonox gas. In our study, the effect of Entonox on pain intensity was less, and in this regard, their result is consistent with our study. Masoudi and Akbari³² compared the effect of Entonox and warm water for pain relief during childbirth. They found that the pain scores in the Entonox group was significantly lower than the warm water group. The similarity of our study with Masoudi and Akbari³² study is the use of a non-pharmacological method in comparison to Entonox gas but, in our study, the pain intensity was lower in the non-pharmacological method (massage), and in this regard, their result is not consistent with our study.

In relation to the type of childbirth, our results show no significant difference between the three study groups. Bolbol Haghighi et al.³³ in her study reported no significant difference between the massage and control groups in terms of the mode of delivery. In the study of "the effect of Saninjiao point massage on the active phase of labor in nulliparous women", Kashanian et al.³⁴ reported that the rate of cesarean section in the massage group was significantly lower than the control group. Sananpanichkul et al.²⁹ reported no significant differences between the c-TTM massage and control groups in terms of cesarean section. Janssen et al.²⁷ reported that there was no statistically significant differences in the mode of delivery between the Entonox and control groups. In Parsa et al.³⁵ study in the type of delivery, there was no significant difference between the two groups of Entonox and control, which did not conform to our research results.

The rate of cesarean section in our study was 2.5% (only two cases in the Entonox group had cesarean sections). This can be both a weakness and a strength point of our study. In support of this, the American College of Obstetricians and Gynecologists have also found that active management of childbirth cannot reduce cesarean rates in all cases.³⁶ The World Health Organization in 1985 stated that an increase in cesarean section rates to 10-15% is not related to increases in maternal and neonatal

health and outcomes. In this study, continuous emotional support and one-on-one care for the mother and caregiver or midwife may have reduced the rate of cesarean section to less than 5%. On the other hand, reducing cesarean sections may have long-term complications which have not been studied in our research.

In relation to the need of augmentation (need of oxytocin), our results showed no significant difference between the three groups. In support of this finding, Bolbol Haghighi et al.³³ and Janssen et al.²⁷ also found no significant difference between the groups of massage and control for the need of oxytocin and augmentation.

In our study, the amount of postpartum bleeding was measured based on the need for uterine massage, checks for hemoglobin and no need for intervention. Many studies have shown that massage can improve and speed up blood circulation, thereby increasing muscle blood volume which may cause an increase in postpartum bleeding.^{37,38} Agah et al.³⁹ in their research titled "the effects of continuous use of Entonox in comparison with intermittent method on obstetric outcomes: A randomized trial" reported that in 4% of the intermittent group, postpartum hemorrhage happened due to uterine atony in contrast to the continuous group in which post-partum hemorrhage was 0%; there was no significant difference ($p=0.2$). Also, they reported that uterine atony decreased with the continuous method, however, neither method was associated with massive postpartum hemorrhage. The similarity of our study with this research is in the intermittent use of Entonox. Similarly, Arthurs and Rosen⁴⁰, Esfandiari et al.⁴¹, and Najefian et al.¹ stated that there was no severe postpartum hemorrhage due to uterine atony due to using Entonox. In the study of Sananpanichkul et al.²⁹, there was no significant difference between the massage and control groups for postpartum bleeding and also the rate of bleeding was in the usual range (200-300 mL).

33% of newborns in the group of B massage needed stimulation. Massage can increase vagal activity by lowering blood pressure, changing the heart rate and lowering cortisol levels, and so, excessive fetal activity is reduced.^{37,38} This may have been the reason for the need of stimulation in the massage group. In the Entonox group, neonatal stimulation and mechanical ventilation were more frequent and 4 newborns needed resuscitation while no cases in the B massage or control groups needed resuscitation. Also, in the control group, none of the newborns needed the process of resuscitation.

Entonox has transient effects due to excretion from the lungs and has no significant side effects on the fetal cardiovascular, respiratory or nervous systems⁴² so it is used as a healthy and safe method in home birth due to its lack of risk for the mother and fetus. However, it is possible that it actually causes fetal distress.⁴³ In our study, the Apgar score was lower and the rate of resuscitation was higher in Entonox group but these differences were not significant. Agah et al.³⁹ reported that the Apgar scores of neonates at the first and fifth minutes between the Entonox and control groups were acceptable and had no significant difference ($p=0.3$).

CONCLUSION

B massage has a greater pain relief effect compared to Entonox and it can be used as a method to reduce labor pain, but it increases postpartum bleeding. It is necessary to conduct more research on this type of massage and its disadvantages and advantages during childbirth.

MAIN POINTS

- One of the strengths of our study is its investigation of a type of massage that has been rarely studied.
- The second strength of this study was the comparison of three groups, which included both pharmacological and non-pharmacological methods.
- Another strength of this study is the estimation of postpartum hemorrhage. This variable has received little attention in other massage-related studies.
- An important conclusion to be understood from this study is that massage can affect the amount of postpartum hemorrhage. Although the amount of bleeding in our study was above the normal range, in future studies, special attention should be paid to the effects of massage on postpartum bleeding.
- One of the limitations of this study was that the research had to be designed based on the conditions of the delivery room and routine care.

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ETHICS

Ethics Committee Approval: Ethical approval was obtained from the Human Research and Ethics Committee of Saveh University of Medical Sciences, (approval number: IR.SAVEHUMS.REC.139401).

Informed Consent: Prior to this study, all the mothers provided written informed consent and the study method was described in detail for all participants.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: M.R., Design: Sh.D., Supervision: M.R., Fundings: Sh.D., Materials: M.R., Data Collection and/or Processing: M.R., Analysis and/or Interpretation: M.R., Literature Search: Sh.D., Writing: M.R., Critical Review: Sh.D.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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