The effect of perineal massage during the second stage of birth on nulliparous women perineal: A randomization clinical trial

Roonak Shahoei1,2, Farzaneh Zaheri3, Lila Hashemi Nasab4, Fariba Ranaei4

1 Ph.D. of Midwifery, Associate Professor, Clinical Care Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran
2 Department of Midwifery, Faculty of Nursing & Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran
3 Ph.D. Student, Lecturer, Department of Midwifery, Faculty of Nursing & Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran
4 M.Sc. of Midwifery, Faculty Member, Department of Midwifery, Faculty of Nursing & Midwifery, Kurdistan University of Medical Sciences, Sanandaj, Iran

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Abstract
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1. Introduction
Childbirth and puerperium are of the most important periods in women’s lives and can affect different aspects of their lives (1). Although childbirth is a physiological process, there is a risk of perineal trauma when the neonate’s

Corresponding author:
Associate Professor Dr. Roonak Shahoei, Clinical Care Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran. Tel: +98.9183712759, Email: rshaho@yaho.com
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head is exiting, and thus, an episiotomy may be needed (2). Perineal trauma refers to any damage to the genital tract during childbirth spontaneously or because of episiotomy (3). Perineal injury occurs in 85% of vaginal childbirths of which over two thirds should be repaired (2), and pain occurs in more than 60% of the cases. Perineal injuries are followed by complications such as bleeding, hematoma, infection, vesico-vaginal and recto-vaginal fistulas, dyspareunia, and urinary and fecal incontinence (4), which influence thousands of women and cause physical, mental, and social health problems for them (2, 3). Perineal tissues should be pulled aside to allow the neonate exit from the vagina (4). Studies regarding the perineal pulling and massaging in the second stage of labor for relaxing the perineum and possibly preventing perineal laceration and episiotomy, have concluded that the perineal pulling and massaging increase possibility of childbirth with an intact perineum (1, 2, 5-7). Perineal massage increases elasticity and blood supply to the perineum and leads to easier pulling and less pain during childbirth. It also reduces the possibility of perineal laceration, the need to episiotomy, and postpartum perineal pain (4). Albers et al. (2005) believe that perineal massage increases the blood supply and softness of the perineum and helps mothers to be familiar with sensations, such as burning and tingling and thus feel less pressure and tension following the neonate's head exiting from the vagina (5). A study performed in Australia showed that perineal massage in the second stage of labor was not accompanied with higher possibility of intact perineum and did not reduce postpartum perineal pain, dyspareunia, urinary and fecal problems (8). Pirie et al. conducted a clinical trial to examine the effect of perineal massage in the second stage of labor and concluded that perineal massage increased the possibility of intact perineum and reduced perineal pain (9). The most frequent postpartum complication is perineal pain, which is highly prevalent in nulliparous women, and causes complications, including insomnia, anxiety, delay in or prevention of the development of mother-neonate bonding, and failure to have a favorable position for breastfeeding (10, 11). Perineal pain enervates mothers in caring for their neonate, and if it persists, it generates the mother’s fear of sexual intercourse (12). The prevalence of perineal pain has been reported as 92% one day after childbirth (13). Perineal pain continues even up to 18 months after childbirth in almost 10% of women (14). Some studies have shown less postpartum perineal pain following application of perineal massage during pregnancy or the second stage of labor (6, 9). However, results of two clinical trials showed the ineffectiveness of perineal massage during pregnancy or the second stage of labor in reducing perineal pain, the pain occurring when caring for the neonate, and urinary and fecal problems (9, 16). Some studies in Iran showed that perineal massage can prevent perineal damage during childbirth (17, 18). Regarding the disagreements on the effectiveness of perineal massage during the second stage of labor in prevention of perineal pain and other complications, and the researcher's experience of facing women complaining about postpartum problems caused by perineal lacerations or episiotomy, this study was conducted to determine the effect of perineal massage in the second stage of labor on perineal lacerations, episiotomy, and perineal pain in nulliparous women going to the childbirth unit of Be’sat Hospital in Sanandaj, Iran.

2. Material and Methods
2.1. Trial design and participants
This study was a randomized clinical trial that was conducted from 2013 to 2014. This clinical trial was conducted in an Iranian governmental educational hospital (Be’sat). Be’sat Hospital in Sanandaj, Iran is the referral center in Kurdistan province and it is affiliated with Kurdistan University of Medical Sciences. The research population was comprised of nulliparous women who were admitted to the childbirth ward of the hospital. The sample size was 190 nulliparous women, 95 women in the intervention group and 95 women in control group.

2.2. Selection criteria
The inclusion criteria for participation in this study were: gestational age of 38-42 weeks; singleton pregnancy; cephalic presentation; lack of premature rupture of membranes, placental abruption, narrow pelvis, fetal distress, and vaginal infections and genital herpes; not doing Kegel exercises and exercising professionally. Exclusion criteria of the study were nulliparous women with failure to progress in labor, fetal distress, administration of narcotics (pethidine), administration of oxytocin, assisted birth (forceps or vacuum), erythematous rashes and edema of the perineum, mothers’ withdrawal from continuing the massage, the need for caesarian section, occiput posterior fetal position, and birth weight more than 4000 g and less than 2500 g.

2.3. Interventions and measurement
In this clinical trial, 190 nulliparous women were selected. The study was explained to the women and they were included in the study if they were willing to participate. After informed consent was obtained the participants were randomly assigned to two groups: intervention (95 nulliparous women) and control (95 nulliparous women). Firstly, the researcher selected three expert midwives working in the childbirth unit of Be’sat Hospital as research assistants, and they were taught how to select participants, complete an inventory, and massage. They were then requested to
massage with the presence of the researcher. In the second stage of labor (from the completion of cervical dilation to delivery), the research assistants massaged the perineum with a gentle up-down pressure toward rectum in a way that each part lasted one minute between 3 o’clock and 9 o’clock positions (U-shaped reciprocating motion) after wearing sterile gloves and lubricating their index and middle fingers with sterile lubricant (a colorless, odorless, and water-soluble substance called K – Y Jelly). The massage lasted 30 minutes, and the degree of downward pressure was determined according to mothers’ response, and if mothers expressed feelings of pain or burning, the pressure was reduced. If mothers withdrew from the study or had the exclusion criteria, massage was stopped, and they were excluded from the study. The control group received routine care. The research assistants were not involved in childbirth, and the childbirth was led by the midwife of the shift. The decision for performing episiotomy during childbirth in both groups was made regarding the diagnosed childbirth factor and indications of episiotomy. The perineum and vagina of the studied women were examined in terms of lacerations or episiotomy by the research assistants after childbirth, and the relevant papers were completed. All participants received postpartum routine care. All of them were taught about postpartum perineal pain and its severity, and the researcher followed them up 3 days, 10 days, and 3 months after childbirth by telephone. The data were collected using a questionnaire and through interviewing, examining women's medical records, and observing. The first part of the questionnaire included demographic specifications, including age, educational level, occupation, history of abortion, and gestational age. The second part of the questionnaire involved information about the second stage of labor, episiotomy, degrees of perineal laceration, neonate’s birth weight and circumference of head and chest, Apgar score, and sex of neonate. The third part of the questionnaire was about postpartum complications and pain 3 days, 10 days, and 3 months after childbirth. First-degree perineal laceration refers to damages to the skin and mucous membrane of perineum; second-degree perineal laceration involves those parts in the first-degree laceration along with muscles; third-degree perineal laceration involves those parts in the second-degree laceration along with anal sphincter; fourth-degree perineal laceration involves those parts in the third-degree laceration along with rectal mucous membranes. The validity of the questionnaire was determined through examining content validity in a way that the questioner was confirmed by five faculty members of the Midwifery Department of the School of Nursing and Midwifery, Kurdistan University of Medical Sciences. Reliability of the questionnaire was determined through observers’ agreement method. To examine the postpartum pain, the participants were taught how to use a pain ruler and report it properly, and their phone number was recorded for arranging necessary follow-ups. The researcher called the participants 3 days, 10 days, and 3 months after childbirth and completed a checklist related to the record of severity of perineal pain, if any.

2.4. Outcomes
The primary outcomes of our analyses were the comparison of the rate of episiotomy and perineal laceration during childbirth in the two groups. Also, the secondary outcomes from the analyses were the comparison of perineal pain and its severity among two groups after 3 days, 10 days, and 3 months after childbirth.

2.5. Randomization and blinding
In this clinical trial, all participants were divided into two groups, i.e., those with massage of perineal during second stage of labor for 30 minutes and those without this intervention. The participants in each of the groups were assigned randomly to intervention and control groups on a 1:1 ratio. Randomization was done by one of researchers, who did not have a role in the intervention of the participants. The randomization was simple randomization method and the allocation concealment was done by the researcher who was responsible for the randomization. For this purpose, toss of a coin was used.

2.6. Statistical methods
Data analysis was conducted using SPSS Version 18 (SPSS, Inc., Chicago, IL., USA). We used descriptive statistics and analytical statistics, including t test, Chi-square test, and Fisher's test. The p<0.05 was considered as statistically significant.

2.7. Research ethics
This study’s research proposal was confirmed by the Research Council and the Ethics Committee of Kurdistan University of Medical Sciences, Iran. This study was also registered in the Iranian Registry of Clinical Trials (irct.ir) with the ID: IRCT2013090314556N1. Moreover, in this study, for ethical considerations, the participants were informed about the objective and nature of the study, and each participant provided her written consent in her formal language (Persian) prior to the study. Also, we were committed to keeping all the participants’ information confidential.
3. Results
In this clinical trial, 190 nulliparous women were selected. Then, the women were separately and randomly allocated to intervention or control groups. There were 17 losses of participants in the control group during the study. Figure 1 shows the CONSORT flow diagram of the trial. The results showed mean and standard deviation of the participants in the case group (receiving perineal massage) as 25.62±4.25 years and those in the control group as 25.31±3.86 years. The participants in both groups were mostly 21-25 years old. Regarding occupational status, 91.58% of women in the case group and 92.31% of women in the control group were housewives. Most participants in both groups had high school diploma (41.50% of women in the case group and 44.87% of women in the control group). Mean gestational age was 39±0.93 weeks in the case group and 39±0.97 weeks in the control group (p=0.47). Mean birth weight was 3000±893 g in the case group and 3100±852 g in the control group (p=0.088). Mean and standard deviation of head circumference was 34.51±1.21 cm in the case group and 34.67±1.18 cm in the control group (p=0.41). Mean and standard deviation of chest circumference was 32.88±1.25 cm in the case group and 33.08±1.22 cm in the control group. Mean one-minute Apgar score was 8.96±0.22 in the case group and 8.89±0.41 in the control group, and mean five-minute Apgar score was 9.99±0.1 in the case group and 9.97±0.15 in the control group (p=0.45). According to the results, there was no significant statistical difference between the two groups in terms of mean age, occupational status, educational level, gestational age, birth weight, circumference of head and chest, and one-minute and five-minute Apgar scores (Tables 1, 2). Frequency of episiotomy was 69.47% in the case group and 92.31% in the control group, and the difference was statistically significant (p<0.05). The results revealed 23.16% of first-degree perineal laceration and 2.11% of second-degree perineal laceration in the case group, and no vestibular laceration or third- and fourth-degree lacerations in the case group. However, there were 5.13% of vestibular laceration, 7.69% of first-degree laceration, 2.56% of second-degree laceration, and 1.05% of third-degree laceration (one woman) in the control group. Based on the results, the postpartum perineal pain was different in both groups. Comparison of degrees of pain in the two groups showed that the severity of pain 3 days and 3 months after childbirth was significant (p=0.01, p=0.008, respectively), but the severity of pain in the 10th day did not differ significantly (p=0.78) (Table 3). The results on frequency of complications did not show any significant difference between groups (p=0.413).
Table 1. Demographic characteristics of participants

| Variable                  | Intervention group | Control group |
|---------------------------|--------------------|---------------|
|                           | n      | %     | n      | %     |
| Age (year)                |        |       |        |       |
| 15-20                     | 18     | 18.95 | 13     | 16.67 |
| 21-25                     | 32     | 38.69 | 34     | 43.59 |
| 26-30                     | 33     | 34.74 | 25     | 32.05 |
| ≥ 31                      | 12     | 12.63 | 6      | 7.69  |
| Occupation                |        |       |        |       |
| Housewife                 | 87     | 91.85 | 72     | 92.31 |
| Employee                  | 8      | 8.42  | 6      | 7.69  |
| Educational status        |        |       |        |       |
| Primary school            | 28     | 29.5  | 20     | 25.64 |
| Diploma                   | 39     | 41.00 | 35     | 44.87 |
| Post graduate             | 28     | 29.5  | 23     | 29.49 |
| History of abortion       |        |       |        |       |
| Yes                       | 4      | 4.21  | 7      | 8.97  |
| No                        | 91     | 95.79 | 72     | 91.03 |
| Gestational age (week)    |        |       |        |       |
| ≤ 37                      | 5      | 5.26  | 5      | 6.41  |
| ≥ 38                      | 90     | 94.74 | 73     | 93.59 |

Table 2. Distribution of neonatal of Participants

| Variable                  | Intervention group | Control group |
|---------------------------|--------------------|---------------|
|                           | n      | %     | n      | %     |
| Gender                    |        |       |        |       |
| Male                      | 48     | 50.53 | 45     | 57.69 |
| Female                    | 47     | 49.47 | 33     | 42.31 |
| Weight (gr.)              |        |       |        |       |
| 2500-3000                 | 32     | 33.68 | 23     | 29.49 |
| 3000-3500                 | 30     | 31.58 | 16     | 20.51 |
| 3500-4000                 | 33     | 34.74 | 39     | 50.00 |
| Head circumference (cm)   |        |       |        |       |
| 31-33                     | 16     | 16.84 | 15     | 19.23 |
| 34-36                     | 74     | 77.89 | 58     | 74.36 |
| ≥37                       | 5      | 5.26  | 5      | 6.41  |
| Chest circumference (cm)  |        |       |        |       |
| 30-32                     | 32     | 33.68 | 23     | 29.49 |
| 33-35                     | 30     | 31.58 | 16     | 20.51 |
| ≥36                       | 33     | 34.74 | 39     | 50.00 |

Table 3. Comparison of perineal pain and its severity in two groups

| Variable                  | Intervention group | Control group | p-value |
|---------------------------|--------------------|---------------|---------|
|                           | n      | %     | n      | %     |       |
| Perineal pain             |        |       |        |       |       |
| Third day                 | 76     | 80.00 | 74     | 94.87 | 0.004 |
| Tenth day                 | 46     | 48.42 | 63     | 80.77 | 0.000 |
| After 3 month             | 24     | 25.26 | 64     | 82.05 | 0.008 |
| Pain severity             |        |       |        |       |       |
| Third day                 |        |       |        |       |       |
| Mild                      | 32     | 33.68 | 9      | 11.54 | 0.000 |
| Moderate                  | 28     | 29.47 | 44     | 56.41 |
| Sever                     | 16     | 16.84 | 21     | 26.92 |
| Ten day                   |        |       |        |       |       |
| Mild                      | 30     | 31.58 | 40     | 51.28 | 0.78  |
| Moderate                  | 15     | 15.78 | 20     | 25.64 |
| Sever                     | 1      | 1.05  | 3      | 3.85  |
| After 3 month             |        |       |        |       |       |
| Mild                      | 12     | 12.63 | 20     | 25.64 | 0.28  |
| Moderate                  | 0      | 0.00  | 2      | 2.56  |
| Sever                     | 12     | 12.63 | 22     | 28.21 |

4. Discussion

According to the results, frequency of episiotomy in the case group (receiving perineal massage) was significantly lower than that in the control group, and this result agrees with results of some previous studies (10 & 17). However, Stamp et al. did not find any significant difference between perineal massage group and control group in terms of the frequency of episiotomy and concluded that perineal massage during second stage of labor did not affect the degree of intact perineum, pain, urinary and fecal incontinence, and sexual intercourse. They had studied both
nulliparous and multiparous women, and the results were related to all participants (9). However, the present study was performed only on nulliparous women. Pirie et al. (2012) reported the frequency of episiotomy as 32.4% in the perineal massage group and 67.1% in the control group (10). Attarha conducted a clinical trial to compare the effect of perineal massage using lavender essential oil with that of perineal massage alone on frequency of episiotomy and perineal laceration. Participants were divided into three groups: perineal massage using lavender essential oil, massage alone, and with no intervention. Results of that study showed the frequency of episiotomy as 8% in the group receiving perineal massage using lavender essential oil, 16.5% in the group receiving massage alone, and 80% in the group with no intervention, and the difference was statistically significant. Attarha concluded that perineal massage, especially with lavender essential oil, in the second stage of labor was an appropriate method for increasing possibility of intact perineum (18). Perineal massage has been mentioned as a method helping perineal muscle relaxation and preventing episiotomy (9). The higher frequency of episiotomy in the case group in the present study against that in other similar studies might be due to hospitals being educational and fear of perineal laceration. In this study, the frequency of perineal laceration in the case group was higher than that in the control group, and there were no vestibular lacerations or third- and fourth-degree lacerations in the case group although there were vestibular lacerations and one case of third-degree laceration in the control group. The difference in this regard was significant. These results conformed to those in the study of Attarha et al. in which the frequency of perineal laceration in the group receiving massage was higher than that in the control group, but severity of laceration in the case group was less than that in the control group, and lacerations in the case group were mostly of the first-degree type and as severe as a scratch that did not need repair (17). However, Bonder – Alder et al. (2012) did not report a significant difference in terms of perineal laceration, vaginal laceration, or labial laceration, and although frequency of third-degree perineal laceration in the massage group was lower than that in the control group, the difference was not significant, unlike the result obtained in the present study (8). Albers et al. (2005) conducted a clinical trial to examine methods to reduce damages to the genital tract during childbirth, and divided the participants into three groups: warm compress on perineum, massaging with a lubricant, and no intervention until the head crowning. The perineal and vaginal injury was frequent in all the three groups to the same extent. They stated that nulliparity and fetal macrosomia were the most important predictors of perineal injury, and mothers’ sitting position during childbirth was effective in prevention of perineal injury (5). Zare et al. examined the effect of perineal massage in the second stage of labor on frequency of episiotomy and perineal laceration in 145 nulliparous women in a clinical trial. The case group received perineal massage using a sterile lubricant, and the control group did not receive any intervention. The results showed the frequency of intact perineum, episiotomy, and perineal laceration respectively as 22.2%, 44.4%, and 33.3% in the case group and 20.2%, 49.3%, and 28.3% in the control group. The difference in this regard was not significant, and the researchers concluded that the perineal massage with a lubricant was neither effective nor harmful in reduction of perineal injury (19).

The results of this study showed that the two groups were significantly different in terms of perineal pain 3 days, 10 days, and 3 months after childbirth, and the severity of pain 3 days and 3 months after childbirth was significant, but the severity of pain in the 10th day did not significantly differ. These results were similar to those in the study of Pirie et al. in which the incidence of perineal pain significantly differed from one group to the other, but severity of pain 3 days and 10 days after childbirth in the massage group did not significantly differ from that in the control group (10). These results did not conform to those in the study of Stamp et al. in which they did not find any significant difference between massage group and control group in terms of the frequency of perineal pain 3 days and 10 days after childbirth (9). In the study of Eogan et al., severity of perineal pain 3 days after childbirth was lower in the massage group than that in the control group, and they concluded that the perineal massage considerably reduced perineal pain (6).

5. Study limitation
Limitations of this study included the small sample size, thus, future similar studies are recommended to recruit a larger sample. Moreover, educational hospitals, presence of residents and midwifery students, cautions about the complete control of head, and possible severe perineal laceration do not allow making appropriate decisions about necessity of episiotomy. Therefore, it is recommended to conduct similar studies in non-educational hospitals active in physiological childbirth. Given that intervention and childbirth in the present study were performed in lithotomy position, and other studies have shown that lying on either side during childbirth and control of perineum are important interventions for reducing perineal injuries (20), it is recommended to perform future interventions and childbirth in non-lithotomy positions. Strengths of this study included its performance on only nulliparous women and follow up to 3 months after childbirth.
6. Conclusions
Regarding the results of this study and those of other studies, perineal massage during the second stage of labor can reduce the need for episiotomy, and avoid perineal injuries, and perineal pain.

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Trial registration:
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Conflict of Interest:
There is no conflict of interest to be declared.

Authors’ contributions:
All authors contributed to this project and article equally. All authors read and approved the final manuscript.

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