

The Effect of Perineal Massage during the Second Stage of Labor on the Episiotomy Rate in Term Nulliparous Pregnant Women: A Randomized Controlled Trial

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Objective: To determine whether perineal massage during the second stage of labor would decrease the episiotomy rate in term nulliparous pregnant women.

Materials and Methods: Term singleton nulliparous pregnant women with a cephalic presentation in the second stage of labor between September 2022 and March 2023 were randomly allocated into two groups, the intervention group and the control group. The intervention group had perineal massage with normal saline solution (NSS) lubricant, while the control group had standard care without perineal massage. The episiotomy rate was evaluated.

Results: Fifty-eight term nulliparous pregnant women were equally and randomly assigned to the intervention and the control group with 29 participants each. The episiotomy rate in the intervention group was significantly lower than the control group at 44.8% versus 89.6% (RR 0.50, 95% CI 0.32 to 0.76, $p=0.001$). The rate of severe perineal tearing was not significantly different between the groups at 3.5% (one out of 29) versus 6.9% (two out of 29) ($p=0.55$). The rate of additional tears of the perineal massage group was greater than the control group without being statistically significant at 24.1% (seven out of 29) versus 6.9% (two out of 29) ($p=0.37$). There was no adverse effect related to perineal massage.

Conclusion: Perineal massage during the second stage of labor in term nulliparous pregnant women significantly decreases the episiotomy rate.

Keywords: Perineal massage; Episiotomy; Perineal tear; Nulliparous

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Perineal trauma includes any injury to the genital area from lacerations during vaginal birth. It is categorized as a first-, second-, third-, and fourth-degree tear⁽¹⁾. The rate of any perineal trauma associated with labor is around 85%⁽²⁾. Episiotomy is when an incision is made through the perineum to increase the vaginal diameter⁽³⁾. The episiotomy rates differ by countries, for example, 5% in Denmark, 11.6% in the U.S.A., 15.2% in the U.K., and more than 90% in Asian countries⁽⁴⁾. Episiotomy in Asian countries is high due to the risk of extensive tears explained by the shortness of the vaginal canal and

the greater strength of the perineum⁽⁵⁾.

Various short- and long-term complications have been reported in women who underwent episiotomy, such as suturing, bleeding, prolonged postpartum rehabilitation, delayed touching of mother and child, and perineal pain⁽⁶⁾. Episiotomy is one of the risk factors of severe perineal trauma of third- and fourth-degree perineal tears that causes pelvic floor muscle weakness, resulting in urinary and fecal incontinence, sexual dysfunction, and dyspareunia^(1,7,8). Prevention of perineal trauma could benefit many women and lead to cost savings due to less suturing and less medication and analgesic use⁽⁹⁾.

Various methods prevent perineal trauma, including the Ritgen maneuver, hands-on, warm compresses, and perineal massage^(10,11). A 2017 Cochrane Systematic Review assessed the techniques used to prevent perineal tears. It showed that most previous trials were inconclusive due to inadequate allocation concealment and incomplete outcome data. Efficacy remained uncertain due to substantial heterogeneity among studies, insufficient evidence, and a lack of data on women's experiences with

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perineal massage⁽¹²⁾. The previous studies conducted on the perineal massage technique have demonstrated that the perineum was massaged using the lubricated index and middle fingers inside the lower vagina, and the fingers were then moved from side to side for approximately one second in each direction, while the massage continued for the duration of pushing coordinated with contractions until crowning, which no major harm of perineal wound breakdown was reported^(3,6,10,13). However, there remained limited data on restrictive episiotomy in pregnant women in Southeast Asia⁽¹⁴⁾. It was hypothesized that perineal massage with lubricant could augment the elasticity of perineal muscles and decrease muscular resistance, allowing stretching of the perineum at delivery with no need for an episiotomy⁽¹⁵⁾. Therefore, the current randomized controlled trial was undertaken to determine the effect of perineal massage during the second stage of labor, thereby mainly decreasing the episiotomy rate and benefit of prevention severe perineal trauma as third- and fourth-degree perineal tears, among term nulliparous pregnant women.

Material and Methods

The present study was a randomized controlled study undertaken between September 2022 and March 2023 at the Department of Obstetrics and Gynecology, Khon Kaen Hospital. Before starting, the study was authorized by the Khon Kaen Hospital Institute Review Board in Human Research. The present study was registered at the Thai Clinical Trials Registry, ID: TCTR20220820001

The eligibility criteria were nulliparous, singleton pregnant women with gestational age of 37 weeks or more with a cephalic presentation in the second stage of labor and planned vaginal delivery. The exclusion criteria were pregnant women who (a) had a pelvic or genital tract infection such as intraamniotic infection, condyloma acuminata, and/or genital herpes simplex viral infection, (b) had a respiratory infection such as COVID-19 or tuberculosis (TB), (c) had a diagnosis of preeclampsia with severe features, (d) had a history of antenatal perineal massage, (e) had a history of perineal trauma, (f) had hypersensitivity of the perineum, (g) had an estimated fetal weight 3,500 grams or more, (h) were suspected of fetal non occiput anterior, (i) had a non-reassuring fetal status such as inability to remove suspicion in health of fetus by a specific pattern⁽¹⁾, and/or (j) had a fetus with gross anomalies.

All eligible pregnant women were informed about the study by research assistants during their

admission to the labor room. Written informed consent was obtained from each participant before the enrollment. Baseline characteristics were recorded and included age, pre-pregnancy body mass index (BMI), current BMI, gestational age, operator, oxytocin used, and underlying diseases. Standard care was given to all participants during the first stage of labor.

Before commencement of the present study, all experienced obstetric and gynecologic physicians and experienced labor room nurses were given standardized training on the criteria for restrictive episiotomy with aid of using written explanations. A 'restrictive episiotomy' was defined as an episiotomy allowed only when it meets one of three indications⁽¹⁴⁾. First, there were fetal indications including shoulder dystocia and/or fetal non-reassuring status⁽¹⁾. Second, when the operators decided to use operative vaginal delivery that included vacuum extraction or forceps extraction. Third, to prevent extensive tears of the birth canal as assessed by the operators. The risk factors for predicting extensive tears of the birth canal included pre-pregnancy obesity with a BMI of 30 kg/m² or more, excessive weight gain, gestational diabetes mellitus, pregestational diabetes mellitus, prolonged second stage of labor that last more than 30 minutes, and circumstances that the operators considered episiotomy might help prevent third- or fourth- degree perineal tears. The operators were provided with standardized training and instructed to apply their own judgment in making decision regarding episiotomy in order to prevent third- or fourth- degree perineal tears, due to the nature of intervention and episiotomy procedure, immediately switching the operators who could not perform. All the operators were required to adhere strictly to the criteria for restrictive episiotomy throughout the study.

The randomization was performed by computer-generated using a block of four and sequentially numbered opaque envelopes to ensure concealment. When women at 10 cm cervical dilatation with fetal head descent to station 2+, they were randomly assigned to the perineal massage group or the control group in a 1:1 ratio by research assistants. The women were then transferred from a waiting room to a labor room and received standard care during pushing in both groups composed of maternal heart rate and blood pressure measured every 15 minutes and fetal heart rate measured every 5 to 15 minutes.

In the perineal massage group, the perineum was massaged with lubricated gloves with normal

saline solution (NSS) using index and middle fingers into the women's lower vagina, 3 to 4 cm above the mucocutaneous junction, visualized vaginal canal like a clock with noon being at the pubic bone and 6 o'clock at the rectum. The index and middle fingers of both hands start at 6 o'clock. The index and middle fingers of the right hand moved from 6 o'clock to 3 o'clock, while the left hand moved from 6 o'clock to 9 o'clock simultaneously. They were then sweeping back from 3 o'clock and 9 o'clock to the endpoint at 6 o'clock. The total duration of one round, go and return, was about one second. After that, the perineum was pressed with gentle downward pressure. Appropriate pressure should be maintained so as to depress the vaginal wall 0.5 to 1 cm. To minimize the procedure-related pain or uncomfortableness, the perineal massage was performed only during contraction-coordinated pushing and continued until crowning. The total duration of perineal massage varied among women due to differences in the time period from the initiation of perineal massage until head crowning and the duration of uterine contractions. The perineal massage would be stopped if the woman had severe perineal pain or perineal abrasion. In the control group, women were given standard care while pushing without perineal massage.

Women in both groups received equal access to restrictive episiotomy criteria performed by standardized operators. All pregnant women received local anesthesia with lidocaine injection before the episiotomy. The operators could perform any type of episiotomy, such as median or mediolateral, according to their preference. The operator who performed delivery and perineal massage was the same person because of the inherent nature of the intervention, which involved experienced obstetric and gynecologic physicians and experienced labor room nurses. In order to ensure that the expertise of these operators would not affect the delivery process and outcomes, only the experienced obstetric and gynecologic physicians, which included first year of residency training of more than six months, second and third years of residency, as well as those with a Diploma of obstetrics and gynecology physicians and additionally, the experienced labor room nurses who worked for more than one year were given standardized training before commencement of the present study. As a result, all operators were supposed to have an equal level of experience.

Both groups received equal access to standard care during the third stage of labor. All experienced

obstetric and gynecologic physicians and experienced labor room nurses received standardized training, with the aid of written explanations and step-by-step diagrams, on perineal massage techniques using NSS as the lubricant, as well as perineal tear grading. A first-degree tear involves injury to the vaginal epithelium or perianal skin. A second-degree tear involves damage to the perineal muscles, including the bulbospongiosus and superficial transverse perineal muscles. A third-degree tear includes (3a) a tear of less than 50% of the external anal sphincter (EAS), (3b) a tear of more than 50% of the EAS, or (3c) tears to both the EAS and internal anal sphincter (IAS). The fourth-degree tear involves tears of the perineal body, anal sphincter complex, and anorectal mucosa⁽¹⁾. The investigators regularly assessed the perineal massage techniques, adherence to restrictive episiotomy criteria, and accuracy of perineal tear grading assessment. The outcome assessor was blinded.

The primary outcome of the present study was the episiotomy rate. The sample size calculation was based on a pilot study of 30 pregnant women with a power of 90%, an α level of 0.05, and a dropout rate of 10%. The result from a pilot study, the episiotomy rate in the control group and the perineal massage group were 86% ($p_1=0.86$) and 40% ($p_2=0.40$), respectively. Fifty-eight participants, with 29 in each group, were thus required. The secondary outcomes were (a) duration of second-stage of labor, (b) first- and second-degree perineal tears, (c) third- and fourth-degree perineal tears, which are severe perineal tears, (d) additional tears, (e) suturing time, (f) total lidocaine requirement during suturing, (g) perineal pain, (h) estimated blood loss, (i) immediate postpartum complications, (j) two hours adverse events after delivery, (k) neonatal birth weight, (l) birth asphyxia (APGAR score at five minutes of 7 or less, and (m) neonatal intensive care unit (NICU) or sick newborn admission. Data were analyzed using Stata, version 14 (StataCorp LP, College Station, TX, USA) based on an intention-to-treat analysis. The student's t-test and the Mann-Whitney U test were used to analyze continuous data. At the same time, the chi-squared test and Fisher's exact test were used to analyze categorical data. A p-value of less than 0.05 was considered statistically significant.

Results

Between September 2022 and March 2023, 58 eligible term singleton nulliparous pregnant women who planned vaginal delivery were enrolled in the

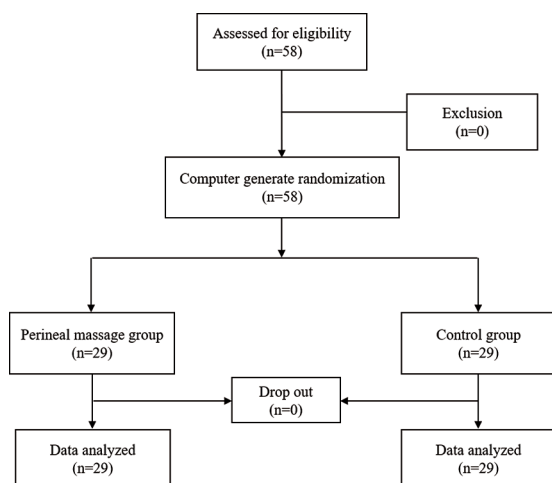
Table 1. Baseline characteristics of participants

	Perineal massage (n=29)	Control (n=29)	p-value
Age (years); mean±SD	24.6±4.4	24.0±4.0	0.73 ^c
Pre-pregnancy BMI (kg/m ²); mean±SD	21.7±4.7	22.6±4.4	0.35 ^c
Current BMI (kg/m ²); median (IQR)	25.5 (23.4 to 29.7)	27.7 (24.8 to 30.0)	0.32 ^d
Gestational age (days); mean±SD	271.4±7.1	272.3±4.8	0.51 ^c
Healthcare providers; n (%)			1.00 ^b
Obstetrics and gynecology physicians	25 (86.2)	26 (89.6)	
Labor room nurses	4 (13.8)	3 (10.4)	
Oxytocin used; n (%)	7 (24.1)	9 (31.0)	0.55 ^a
Underlying diseases, n (%)	6 (20.6)*	4 (13.7)	0.73 ^b
Gestational diabetic mellitus	2 (6.9)	1 (3.4)	
HIV infection	1 (3.4)	1 (3.4)	
Syphilis	2 (6.9)	1 (3.4)	
Hyperthyroidism	2 (6.9)	0 (0.0)	
Thalassemia	1 (3.4)	0 (0.0)	
Schizophrenia	0 (0.0)	1 (3.4)	

SD=standard deviation; IQR=interquartile range; BMI=body mass index

(a) Chi-square test, (b) Fisher's exact test, (c) Student t-test, (d) Mann-Whitney U test

* One woman had syphilis and hyperthyroidism, and one woman had HIV and syphilis

**Figure 1.** Study flow diagram.

study. Fifty-eight eligible women were randomly assigned into two groups with 29 to the perineal massage group and 29 to the control group. There were no dropouts, and no patients discontinued the perineal massage due to severe pain or abrasion. Figure 1 presents the study flow diagram. Baseline characteristics were similar between groups and included age, pre-pregnancy BMI, current BMI, gestational age, operator, oxytocin used, and underlying diseases (Table 1).

The episiotomy rates were 44.8% and 89.6% in the perineal massage group and the control group, respectively. The risk ratio (RR) was 0.50 (95% CI

0.32 to 0.76, $p=0.001$).

Women allocated to the perineal massage group had a lower rate of severe perineal tears, or third- and fourth-degree perineal tears, than women in the control group, albeit the difference was not statistically significant at 3.5% versus 6.9% ($p=0.55$), and less perineal pain immediately after suturing without statistical significance, with a visual analog scale (VAS) mean of 4.0 ± 2.7 versus 4.2 ± 2.6 ($p=0.61$) (Table 2).

Women in the perineal massage group had an increased risk of additional tears albeit not statistically significant ($p=0.37$), including anterior vaginal wall tear at 10.3% versus 3.4%, lateral vaginal wall tear at 3.4% versus 0%, and combined tears at 6.9% versus 0% (Table 2). There were no adverse effects related to the use of perineal massage.

Women who were performed episiotomy both in the perineal massage and the control group had a lower rate of severe perineal tears or third- and fourth-degree perineal tears, than women without episiotomy, albeit the difference was not statistically significant at 2.6% versus 10% ($p=0.23$). Whereas women who were performed episiotomy both in perineal massage and control groups had a lower risk of additional tears when compared with women without episiotomy with statistically significant, including anterior vaginal wall tear at 0% versus 15% ($p=0.014$), and lateral vaginal wall tear at 2.6% versus 25% ($p=0.008$).

Table 2. Maternal and fetal outcomes

	Perineal massage (n=29)	Control (n=29)	p-value
Episiotomy rate; n (%)	13 (44.8)	26 (89.6)	0.001 ^{b*}
Duration of second stage of labor (minutes); median (IQR)	11 (8 to 20)	13 (9 to 23)	0.67 ^d
Perineal tears; n (%)	29 (100)	29 (100)	
First- and second-degree tears	28 (96.5)	27 (93.1)	0.50 ^b
Third- and fourth-degree tears	1 (3.5)	2 (6.9)	0.55 ^b
Additional tears; n (%)			0.37 ^b
Anterior vaginal wall tear	3 (10.3)	1 (3.4)	
Lateral vaginal wall tear	1 (3.4)	0 (0.0)	
Cervical tear	1 (3.4)	1 (3.4)	
Combine	2 (6.9)	0 (0.0)	
Suturing time (minutes); median (IQR)	15 (10 to 20)	15 (10 to 20)	0.91 ^d
Total lidocaine requirement during suturing (mL); median (IQR)	10 (8 to 10)	10 (10 to 10)	0.49 ^d
Perineal pain (VAS 1 to 10); mean±SD	4.0±2.7	4.2±2.6	0.61 ^c
Perineal pain (VAS 1 to 10); n (%)	29 (100)	29 (100)	0.65 ^b
Mild (<4)	9 (31.0)	11 (37.9)	
Moderate (4 to 7)	17 (58.6)	17 (58.6)	
Severe (>7)	3 (10.4)	1 (3.5)	
Estimated blood loss (mL); median (IQR)	100 (100 to 120)	100 (100 to 150)	0.26 ^d
Immediate postpartum complications#; n (%)	5 (17.2)	3 (10.3)	0.70 ^b
2 hours adverse events after delivery@; n (%)	0 (0.0)	0 (0.0)	
Neonatal birth weight (g); mean±SD	2,815.8±384.3	2,933.2±264.9	0.31 ^c
APGAR score at 5 minutes ≤ 7; n (%)	0 (0.0)	0 (0.0)	
NICU or sick newborn admission; n (%)	1 (3.4)	0 (0.0)	1.00 ^b

VAS=visual analog scale; IQR=interquartile range; SD=standard deviation

(a) Chi-square test, (b) Fisher's exact test, (c) Student t-test, (d) Mann-Whitney U test, * Significant p<0.05

Immediate postpartum complications, e.g., uterine atony, retained placenta, hematoma

@ 2 hours adverse events after delivery, e.g., hematoma, perineal wound infection, perineal wound dehiscence

Other delivery outcomes were similar between groups, including duration of second-stage of labor, first- and second-degree perineal tears, suturing time, total lidocaine requirement during suturing, perineal pain, estimated blood loss, immediate postpartum complications, two hours adverse events after delivery, neonatal birth weight, birth asphyxia with APGAR score at five minutes of 7 or less, and NICU or sick newborn admission (Table 2).

The mean score ± standard deviation (SD) of the operator's satisfaction was 6.4±1.7 (range of 0 to 10). The mean score of the operator trend to use perineal massage in further vaginal delivery was 7.3±1.4 (range of 0 to 10). All the operators intended to use perineal massage on the next vaginal delivery.

Discussion

The present study showed that perineal massage during the second stage of labor in term nulliparous pregnant women significantly decreased the episiotomy rate to 44.8% versus 89.6%, RR 0.50, 95% CI 0.32 to 0.76, p=0.001).

Approximately one-half (55.2%) of the women in the perineal massage group did not need an episiotomy compared to 10.4% in the control group. These results were similar to the results of a systematic review and meta-analysis⁽⁶⁾ of nine clinical trials, which included 3,374 women. They found that in the perineal massage group, the episiotomy rate was significantly lower than in the control group (RR 0.56, 95% CI 0.38 to 0.82), especially for nulliparous pregnant women. Furthermore, Geranmayeh et al.⁽³⁾ also reported a lower episiotomy rate of 45% versus 88% (p<0.001) in the perineal massage group compared to the control group. Goh et al.⁽¹³⁾ studied the combined effect of massage and warm compress (MassComp) on the perineum in the second stage of labor among 156 nulliparous women at term. They found that the episiotomy rates were significantly lower in the MassComp group at 37% versus 53% (RR 0.72, 95% CI 0.52 to 0.98, p=0.043). Based on the information from a 2017 Cochrane Review⁽¹²⁾ on perineal techniques during the second stage of labor had reported that a warm compress

to the perineum significantly reduced third- and fourth-degree tears but did not positively impact on episiotomy rates, or intact perineum. Whereas perineal massage might reduce episiotomy rates and third- and fourth-degree tears rate and increase in intact perineum is to be evaluated. Therefore, Goh et al.⁽¹³⁾ studied a combination of perineal massage and warm compression that could synergistically and positively impact the intact perineum. It was assumed that perineal massage could be a significant part of the procedure to help decrease episiotomy rates. The current study agreed with these three previous studies, such as the systematic review and meta-analysis⁽⁶⁾, Geranmayeh et al.⁽³⁾, and Goh et al.⁽¹³⁾. These previous studies and the current study supported the hypothesis that perineal massage increases the elasticity of the perineal muscles, thereby lowering resistance and allowing gentle stretching of the perineum at delivery without the need for an episiotomy.

The perineal massage group experienced a lower rate of severe perineal tears or third- and fourth-degree perineal tears, without being statistically significant. This result was similar to Goh et al.⁽¹³⁾ studied in Asian pregnant women and found that third- or fourth-degree perineal tears were not significantly different across the MassComp and control group at 1% versus 2% ($p>0.999$). While a systematic review and meta-analysis⁽⁶⁾ showed a significantly lower risk of severe perineal tears or third- and fourth-degree tears (RR 0.49, 95% CI 0.25 to 0.94) in the perineal massage group during labor. A 2017 Cochrane Review⁽¹²⁾ revealed that the perineal massage group experienced fewer third- or fourth-degree perineal tears (RR 0.49, 95% CI 0.25 to 0.94). The current study showed that perineal massage tended to decrease risk of third- and fourth-degree perineal tears although there was no statistically significant difference between groups. The differences in the current results and Goh et al.⁽¹³⁾ from the other studies, including the systematic review and meta-analysis⁽⁶⁾, and 2017 Cochrane Review⁽¹²⁾, may be explained by shorter duration of second stage of labor and lower neonatal birth weight.

The result about an intact perineum, Geranmayeh et al.⁽³⁾ reported that women who underwent perineal massage with Vaseline lubricant were far more likely to have an intact perineum at 27% versus 4% ($p=0.004$) compared to the non-perineal massage group. A systematic review and meta-analysis⁽⁶⁾ and 2017 Cochrane Review⁽¹²⁾, studied in both nulliparous and multiparous pregnant women most in Western and Asian populations reported that the rate of intact

perineum was significantly higher in the perineal massage group than the non-perineal massage group. The current research among Southeast Asian nulliparous pregnant women used NSS lubricant showed most women had second-degree perineal tears and no intact perineum. The differences in the present study results from the other studies may be explained by the number of parities, diverse types of lubricant, shortness of the vaginal canal, and strength of the perineum presented by most Asian women⁽⁵⁾.

The incidence of vaginal wall tears and combined tears in women assigned to the perineal massage group was higher than the control group albeit not statistically significant. Still, most were mild tears that did not require substantial suturing. These results were comparable to those of Sangkomkamhang et al.⁽¹⁴⁾, who showed that the restrictive episiotomy group had a higher risk for additional vaginal wall tears. Still, routine episiotomy was not recommended for vaginal wall tears prevention. Furthermore, they also evaluated women who planned vaginal delivery vis-à-vis the adverse maternal and neonatal outcomes associated with restrictive episiotomy use. They found that the women who underwent restrictive episiotomy had comparable rates of postpartum hemorrhage, wound complications, birth asphyxia, and NICU admission compared to the routine episiotomy group. The current study confirmed that perineal massage with NSS lubricant and restrictive episiotomy did not increase adverse maternal and neonatal outcomes.

Strength and limitation

The current study was a RCT comparing perineal massage in the second stage of labor with standard care without perineal massage in term nulliparous pregnant women who planned a vaginal delivery. Owing to limited information on the results of perineal massage, especially in women of Southeast Asia, the current study results provide up-to-date knowledge to fill a gap. In addition, the operator's satisfaction, and the trend to use perineal massage were assessed.

The present study had limitations. First, the authors did not blind the operators who performed perineal massage and made the decision of episiotomy because the nature of the intervention, perineal massage, was performed until crowning as other studies such as Geranmayeh et al.⁽³⁾, and Goh et al.⁽¹³⁾. However, the authors minimize confounding factors and bias by standardizing the operators on restrictive episiotomy criteria before the commencement of the

study and regularly assessed the adherence. Second, the duration of intervention perineal massage was not collected. Third, the satisfaction of pregnant women on perineal massage and long-term consequences such as sexual function, pelvic floor muscle relaxation, and quality of life, were not assessed.

Further study should focus on the duration of perineal massage, satisfaction of pregnant women, and long-term consequences.

Conclusion

Perineal massage during the second stage of labor in term nulliparous pregnant women significantly decreases the episiotomy rate.

What is already known about this topic?

According to previous studies, women who received perineal massage during the second stage of labor had a higher incidence of intact perineum and a lower rate of third- or fourth-degree tears, but there was no difference in the requirement for episiotomy. However, the previous evidence was low to moderate quality, and the results were inconclusive due to inadequate allocation concealment. The efficacy of perineal massage remains uncertain due to substantial heterogeneity between studies, insufficient evidence, and a lack of data on women's experiences with perineal massage.

What does this study add?

This study showed that perineal massage during the second stage of labor in term nulliparous pregnant women significantly decreased the episiotomy rate. The perineal massage group experienced a lower rate of severe perineal tears or third- and fourth-degree perineal tears, without being statistically significant. The current study among Southeast Asian nulliparous pregnant women also showed most women had second-degree perineal tears and no intact perineum. Furthermore, the incidence of vaginal wall tears and combined tears in women assigned to the perineal massage group was higher than the control group albeit not statistically significant. Still, most were mild tears that did not require substantial suturing.

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Conflicts of interest

The authors declare no conflict of interest.

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