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Perineal massage during labor: a systematic review and meta-analysis of randomized controlled trials

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Key message

Perineal massage during the labor is associated with less perineal trauma.

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JUST ACCEPTED

ABSTRACT

Background: Different techniques have been analyzed to reduce the risk of perineal trauma during labor.

Objective: To evaluate whether perineal massage techniques during vaginal delivery decreases the risk of perineal trauma.

Search strategy: Electronic databases (MEDLINE, PROSPERO, Scopus, ClinicalTrials.gov, EMBASE, Sciencedirect, the Cochrane Library, Scielo) were searched from their inception until February 2018. No restrictions for language or geographic location were applied.

Selection criteria: We included all randomized controlled trials (RCTs) comparing the use of perineal massage during labor (i.e. intervention group) with a control group (i.e. no perineal massage) in women with singleton gestation and cephalic presentation at ≥ 36 weeks. Perineal massage was defined as massage of the posterior perineum by the clinician's fingers (with or without lubricant). Trials on perineal massage during antenatal care, before the onset of labor, only in the early part of the first stage, were not included.

Data collection and analysis: All analyses were done using an intention-to-treat approach. The primary outcome was severe perineal trauma, defined as third and fourth degree perineal lacerations. Meta-analysis was performed using the random-effects model of DerSimonian and Laird to produce summary treatment effects in terms of either a relative risk (RR) with 95% confidence interval (CI).

Main results: Nine trials including 3,374 women were analyzed. All studies included women with singleton pregnancy in cephalic presentation at ≥ 36 weeks undergoing spontaneous vaginal delivery. Perineal massage was usually done by a midwife in the second stage, during or between and during pushing time, with the index and middle fingers, using a water-soluble lubricant. Women randomized to receive perineal massage

during labor had a significantly lower incidence of severe perineal trauma, compared to those who did not (RR 0.49, 95% CI 0.25 to 0.94). All the secondary outcomes were not significant, except for the incidence of episiotomy, which was significantly lower in the perineal massage group (RR 0.56, 95% CI 0.38 to 0.82).

Conclusion: Perineal massage during labor is associated with significant lower risk of severe perineal trauma, such as third and fourth degree lacerations. Perineal massage was usually done by a midwife in the second stage, during or between and during pushing time, with the index and middle fingers, using a water-soluble lubricant.

INTRODUCTION

Perineal trauma is any injury in the genital area that occurs from lacerations during labor; it can be associated with both short or long-term morbidities^{[1][2]}. Short-term complications are related to bleeding, prolonged recovery, slowed mother-newborn bond, and perineal pain^[1]. The most reported long-term morbidities concern urinary and fecal incontinence, dyspareunia, and perineal pain^[3]. The incidence of any perineal trauma with labor is up to 85%^[1]. Fear of pelvic trauma drives many patients to consider a planned cesarean delivery^[4].

Different techniques have been analyzed to reduce the risk of perineal trauma, including perineal massage, hands-on ^{[3][5]}, warm compresses^[3], and the Ritgen maneuver^[5]. There is conflicting evidence regarding the possible effect of perineal massage performed in labor, and different techniques have been reported^{[1][3][5][6][7][8][9][10][11]}.

A prior Cochrane^[12] has analyzed the effects of several perineal techniques during labor, including perineal massage. Perineal massage in late labor was associated with a significant reduction in third- and fourth-degree tears. The aim of our systematic review and meta-analysis of randomized controlled trials (RCTs) was to evaluate whether perineal massage during vaginal delivery decreases the risk of perineal trauma, with particular attention for demographic and labor patients' characteristics.

MATERIALS AND METHODS

Search strategy

This review was performed according to a protocol designed a priori and recommended for systematic review^[13]. Electronic databases (i.e. MEDLINE, PROSPERO, Scopus, ClinicalTrials.gov, EMBASE, Sciencedirect, the Cochrane Library, Scielo) were searched from their inception until February 2018. Search terms used were the following text words: “perineal massage”, “vaginal”, “perineal”, “support”, “trauma”, “review,” “randomized -controlled- trials”, “randomized,” “clinical trial,” “randomized,” and “clinical trial.” No restrictions for language or geographic

location where applied. In addition, the reference lists of all identified articles were examined to identify studies not captured by electronic searches. The electronic search and the eligibility of the studies were independently assessed by two authors (CIA, GS). Differences were discussed, and consensus reached.

Study selection

We included all RCTs comparing the use of perineal massage during labor (i.e. intervention group) with a control group (i.e. no perineal massage) in women with singleton gestation and cephalic presentation at or near term undergoing an attempt at spontaneous vaginal delivery. Perineal massage was defined as massage of the posterior perineum by the clinician's fingers (with or without lubricant). Trials on perineal massage during antenatal care, before the onset of labor, or only in the early part of the first stage (<5 cm), were not included. We also excluded trials where another intervention (e.g. warm compresses, hands-on, Ritgen maneuver, perineal devices) aimed at possibly decreasing perineal tears was studied together with perineal massage. RCTs including multiple gestations and quasi-randomized trials (i.e. trials in which allocation was done on the basis of a pseudo-random sequence, e.g. odd/even hospital number or date of birth, alternation) were excluded.

Risk of bias

The risk of bias in each included study was assessed by using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions. Seven domains related to risk of bias were assessed in each included trial since there is evidence that these issues are associated with biased estimates of treatment effect: 1) random sequence generation; 2) allocation concealment; 3) blinding of participants and personnel; 4)

blinding of outcome assessment; 5) incomplete outcome data; 6) selective reporting; and 7) other bias. Review authors' judgments were categorized as "low risk", "high risk" or "unclear risk" of bias^[13].

Two authors (CIA, VB) independently assessed inclusion criteria, risk of bias and data extraction. Disagreements were resolved by discussion. Data from each eligible study were extracted without modification of original data onto custom-made data collection forms. Differences were reviewed, and further resolved by common review of the entire process. Data not presented in the original publications were requested from the principal investigators, if possible.

All analyses were done using an intention-to-treat approach, evaluating women according to the treatment group to which they were randomly allocated in the original trials.

Outcomes

Primary and secondary outcomes were defined before data extraction.

The primary outcome was severe perineal trauma, defined as third and fourth degree perineal lacerations. Secondary outcomes were intact perineum, first-, second-, third-, and fourth-degree lacerations, incidence of episiotomy, and localization of other perineal lacerations. We planned subgroup analyses based on parity (nulliparous, versus multiparous women), and on perineal massage done exclusively during the second stage (as opposed to massage done both in the late first and in the second stage).

Statistical analysis

The data analysis was completed independently by two authors (CIA, GS) using Review Manager v. 5.3 (The Nordic Cochrane Centre, Cochrane Collaboration, 2014, Copenhagen, Denmark). The completed analyses were then compared, and any difference was resolved by discussion. Statistical heterogeneity across studies was assessed using the Higgins I² test. Meta-analysis was performed using the random-effects model of DerSimonian and Laird to produce summary treatment effects in terms of either a relative risk (RR) or a mean difference (MD) with 95% confidence interval (CI).

Potential publication biases were assessed statistically by using Begg's and Egger's tests. P value <0.05 was considered statistically significant.

The meta-analysis was reported following the Preferred Reporting Item for Systematic Reviews and Meta-analyses (PRISMA) statement.

RESULTS

Study selection and characteristics

From 4,836 records identified through database searching, 9 randomized controlled trials including 3,374 women evaluating perineal massage (n=1,725) versus no perineal massage (n=1,649) in the late first stage or in the second stage of labor were included in the review (Figure 1). Publication bias, assessed using Begg's and Egger's test, was not significant (P = 0.34, and =0.51, respectively).

Most of the included studies had low risk of bias in random sequence generation. Adequate methods for allocation of women were used in all the included trials, except three, in which details on methods used to conceal allocation were unclear. Blinding of participants, personnel and outcomes assessment was not possible in most cases (Figure 2).

All studies included women with singleton gestations in cephalic presentation at 36-42 weeks (Table 1). Usually, perineal massage was performed starting in the second stage (5/9, 55.6%)^{[3][5][6][9][10]}, or starting in the first (usually late) stage (4/9, 44.4%)^{[1][7][8][11]}, and was done by a midwife

(6/9, 66.7%)^{[1][3][5][6][9][11]}, during the pushing time in 3 studies^{[6][9][11]}, between and during pushing time in 3 studies^{[1][3][5]}, and between pushing time in one study^[7](Table 2). Perineal massage was usually performed introducing two fingers (i.e. middle and index fingers^{[1][5][8]}or thumbs^[7]) into the patient's vagina. The purpose of this technique is to gently stretch the perineum from side to side. The frequency of perineal massage was not reported in most studies (6/9, 66.7%). When it was reported, the total length of massage lasted for 5-15 minutes^{[1][5][7]}. When reported, the most used (5/6 83.3%) lubricant was a water-soluble lubricant^{[3][5][7][8][11]}. None of the included RCTs studied other perineal techniques (e.g. warm compresses, hands-on, Ritgen maneuver, perineal devices) aimed at possibly decreasing perineal tears in either the intervention group (perineal massage) or the control group (no perineal massage). Six trials included only nulliparous women (Table 1), and overall out of the 3,374 women included, 2,079 (61.6%) were nulliparous. Mean age (about 23 years old) and BMI (about 23 m²/kg) were similar in the two groups. Use of oxytocin was reported only in three trials^{[1][3][9]}, and was equal in both groups, as was the length of the second stage^{[1][3][5][6][7][9]}(Table 3). Fetal position (e.g. occiput anterior vs transverse vs posterior) was not reported in any RCTs. Two RCTs described in the text the different degrees of perineal lacerations, and both defined them as: First degree: involving skin of the perineum and vaginal mucosa; Second degree: involving deeper layer of perineal muscles; Third degree: involving the anus; Fourth degree: involving the anus and rectal mucosa^{[1][11]}.

Syntheses of results

Primary and secondary lacerations outcomes are reported in Table 4 and Table 5. Women randomized to receive perineal massage during labor had a significantly lower incidence of severe perineal trauma (third and fourth degree lacerations), compared to those who did not (RR 0.49, 95% CI 0.25 to 0.94; Figure 3). The incidence for intact perineum was significantly higher in the perineal massage group, compared to no perineal massage (RR 1.40, 95% 1.01 to 1.93). All other secondary outcomes were not significant, except for the incidence of episiotomy, which was significant lower in the perineal massage group (RR 0.56, 95% CI 0.38 to 0.82). Statistical heterogeneity between the trials ranged from low to high, with no inconsistency ($I^2=0\%$) in the primary outcome (Table 4). Maternal position at delivery, when described, was at the woman's preference

in two studies^{[3][5]} and lithotomy in another two^{[1][7]}. Perineal pain was similar when evaluated^{[1][5][11]}, while dyspareunia is considered in only two studies^{[1][11]} (Table 6). Patients' satisfaction was evaluated in one study by questionnaire: the majority answered that they would participate in such a trial again (62%).

The occurrence of labial, vaginal, clitorideal, periurethral, anterior, and posterior lacerations was not always reported in the RCTs and appears to be not significant when described (Table 5).

Almost all women delivered vaginally (Table 6). One RCT reported blood loss >500 ml, which was not significantly different between the groups (RR 0.91, 95% CI 0.61 to 1.36). Neonatal outcomes such as birth weight and Apgar scores were similar, too (Table 6). Low cord pH, neonatal intensive care admission, and need for intubation were not reported in any RCTs.

In nulliparous women, perineal massage was associated with significantly increased incidence of intact perineum, and with decreased incidence of episiotomy (Table 7). In multiparous women, no significant differences were seen in the perineal massage versus no perineal massage subgroups (Table 8). In the perineal massage only in the second stage group, perineal massage was associated with a significant increase in the incidence of intact perineum (Table 9).

DISCUSSION

Main findings

This meta-analysis of 9 RCTs, including 3,374 women with singleton gestations in cephalic presentation at or near term showed that perineal massage during the late first stage or usually in the second stage of labor was associated with less severe perineal trauma, defined as third or fourth degree lacerations, and less incidence of episiotomy. In most of the included trials, massage was done by a midwife, during the pushing time or

between and during pushing time, and usually performed introducing the middle and index fingers into the patient's vagina to gently stretch the perineum from side to side, using a water-soluble lubricant.

On a total of nine RCTs, five of them described the eventual occurrence of lacerations of third or fourth degree, and two RCTs registered these events. A previous Cochrane^[12] has analyzed the effects of several perineal techniques during labor, including perineal massage. They also showed that perineal massage in late labor was associated with a significant reduction in third- and fourth-degree tears. They included seven RCTs^{[3][5][6][8][9][10][11]}. While they excluded two RCTs (which we included) because perineal massage started in the first stage^{[1][7]}, they included two RCTs which also included perineal massage started in the first stage^{[8][11]}. Furthermore, our review considered not only severe perineal lacerations (Table 4), but also other statistical results about: localizations of lacerations (Table 5), birth weight, Apgar score, perineal pain and dyspareunia (Table 6), with particular attention for subgroups' outcomes as in nulliparous and multiparous patients and as in cases of massage performed by second stage (Tables S 1, 2, 3). The Cochrane Review did not report specific demographic and labor characteristics, as well as the details of how and when perineal massage was performed (tables 1-3)^[12].

Our study has several strengths. To our knowledge, no prior meta-analysis on this issue is as large, up-to-date or comprehensive. None of the included RCTs studied other perineal techniques (e.g. warm compresses, hands-on, Ritgen maneuver, perineal devices) aimed at possibly decreasing perineal tears in either the intervention group (perineal massage) or the control group (no perineal massage), so that our results involve only the effect of perineal massage. We also were able to describe in detail how to perform perineal massage as studied in most RCTs, so to make implementation easier for the practitioner. We were also able to look at subgroup analyses, showing that the best evidence for effectiveness for perineal massage is for nulliparous women, and for performing it in the second stage. The statistical heterogeneity within the studies in the primary outcome and in most of the secondary outcomes was low, particularly in relation of selection, attrition and reporting bias. Limitations of our study are inherent to the limitations of the included RCTs. Several RCTs did not report many of our outcomes of interest (Tables 4-6). The primary

outcome was reported by only 5 RCTs^{[3][6][9][10][11]}; third and fourth degree lacerations were also reported separately by only 5 RCTs^{[3][6][9][10][11]} (Table 4). Given the intervention, none of the included trials were double-blind. Despite the large number of RCTs and women included, there could still remain the possibility of type II errors, for example for some secondary outcomes such as third or fourth degree lacerations, which trended for benefit for perineal massage, but were not significant (Table 4). Episiotomies should seldom be performed^[14], so the incidence of 20-30% (Table 4) in the included RCTs is probably higher than current recommended practice. The associated decreased incidence of episiotomy in the perineal massage group is therefore of unclear clinical significance with current labor management.

Trauma to the perineum during childbirth can cause women other morbidities such as pain and long-term problems. Therefore, different techniques have been studied to reduce the risk of perineal trauma and to reduce the length of labor improving obstetric outcomes^[14-20]. Adverse obstetric outcomes may be associated with both maternal factors,²⁷⁻²⁶ and fetal factors, including macrosomia.²⁷⁻²⁹ Asian race, for example, has been showed to be an independent risk factor for severe perineal lacerations in the United States.³⁰ The risk of severe perineal lacerations increases with duration until the third hour of the second stage of labor, with instrumental delivery being the most significant risk factors.³¹

Reducing perineal lacerations has been deemed very important to improve women's health by the American College of Obstetricians and Gynecologists^[16]. Our meta-analysis confirms that perineal massage in labor prevents third and fourth degree lacerations, which are the ones associated with the most harm for women. In addition, we found that perineal massage was usually done by a midwife, during the pushing time or between and during pushing time, and usually performed introducing the middle and index fingers into the patient's vagina to gently stretch the perineum from side to side, using a water-soluble lubricant. Given the benefit, and lack of harm, we believe perineal massage in late labor, in particular in the second stage, and in nulliparous women, could become routine. More research is needed to see if the addition of other techniques, such as for example warm compresses^[12], would further decrease the 1% incidence of severe perineal lacerations if perineal massage is performed (Table 4).

Conclusions

In summary, perineal massage during late labor is associated with significantly lower risk of severe perineal trauma, such as third and fourth degree lacerations, and therefore a significantly higher incidence of intact perineum (no lacerations). Perineal massage was usually done by a midwife in the second stage, during or between and during pushing time, with the index and middle fingers, using a water-soluble lubricant.

JUST ACCEPTED

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TABLES

Table 1. Characteristics of the included studies

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	Study location	Number of participants*	Parity included	Maternal age (years)	Gestational age at enrollment (weeks)	Exclusion criteria
Stamp 2001 ^[11]	Australia	1,340 (708 vs 632)	Nulliparous and Multiparous	Not reported	≥36	Complicated labor, no-English speakers, indications for cesarean delivery
Albers 2005 ^[3]	USA	807 (403 vs 404)	Nulliparous and Multiparous	≥18	≥37	Preterm delivery, medical complications, <18 years, other languages (not English or Spanish)
Attarha 2009 ^[6]	Iran	170 (85 vs 85)	Nulliparous only	Not reported	38-42	Multiple gestations, medical complications, lack of labour progress, the occurrence of fetal distress, opioids prescription (pethidine), birth with forceps and vacuum, rash, erythema and perineal edema, withdrawal of mothers from massage
Galledar 2010 ^[8]	Iran	141 (71 vs 70)	Nulliparous only	18-35	Full term	Prolonged second stage of labor, rapid birth, cesarean birth, shoulder dystocia, posterior position of fetal head, fetal distress, failure to fit over the hips, birthweight > 4000g or <2500g and the change of address or telephone of participants
	Iran			18-35	37-41	

Fahami 2012 ^[5]		66 (33 vs 33)	Nulliparous only			Lack of progress in labour, fetal distress in the second stage of labour in each group, using vacuum or forceps in birth, perineal oedema or rash occurrence, the mothers' withdrawal from partnership in the study
Geranmayeh 2012 ^[9]	Iran	90 (45 vs 45)	Nulliparous only	18-30	38-42	Fetal distress during delivery, instrumented assisted delivery, indications for cesarean section
Karacam 2012 ^[1]	Turkey	396 (198 vs 198)	Nulliparous only	18-35	37-42	Multiple pregnancies, macrosomic fetuses, breech presentation, occipito-posterior position, polyhydramnios, fetal distress, intrauterine deaths, prematurity, post-maturity, and vacuum-assisted delivery
Sohrabi 2012 ^[10]	Iran	80 (40 vs 40)	Nulliparous only	18-35	37-42	Unwillingness of women to continue to co-operate, prolonged second stage of labour, fetal distress, meconium discharge, dystocia, detachment, attempting to use vacuum, induction and accelerate birth
Demirel 2015 ^[7]	Turkey	284 (142 vs 142)	Nulliparous and multiparous	Not reported	37-42	>2 gestations, pregnancy-related complications, systemic conditions, indications for cesarean delivery

Intervention group vs Control group

**Data are presented as total number (number in the intervention group vs number in the control group).*

Table 2.Details of perineal massage

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	When started	Executor	When done	Technique	Frequency	Type of lubricant	Control
Stamp 2001 ^[11]	First stage and Second Stage (≥ 5 cm if multiparous and ≥ 8 cm if nulliparous)	Midwife	During pushing time, stopping when uncomfortable	Two fingers inside the vagina with a sweeping motion, gently stretched the perineum	Not reported	Water-soluble jelly	Routine care
Albers 2005 ^[3]	Second stage	Midwife	During and between pushes, stopping when uncomfortable	Gentle and slow massage with two fingers from side to side inside patient's vagina, with a downward pressure toward the rectum.	For one second in each direction until crowning.	Water-soluble lubricant	No touching of the perineum until crowning
Attarha 2009 ^[6]	Second stage	Midwife	During pushing time	Two fingers inside the vagina using a sweeping motion gently to stretch the perineum.	Not reported	Not reported	Routine care
Galledar 2010 ^[8]	First ($\geq 6-7$ cm) and Second Stage	Researcher	Not reported	Finger and middle fingers were placed in the vagina and slidered to the size of fingers	Not reported	Key jell (water soluble)	Routine care

5-4 cm between
3 to 9 o' clock
alternatively.

Fahami 2012 ^[5]	Second stage	Midwife	During and between pushes	The middle finger and index finger were used for a slow massage of the vagina (in a reciprocating U- shaped motion) with gentle pressure toward the rectum from one wall to another.	1 minute for each side (for a total length of 5-10 minutes)	Water- soluble lubricant	No touching the perineum until crowning.
Geranmaye 2012 ^[9]	Second stage (after crowning)	Midwife	During uterine contractions and continued until baby's head was out.	Sweeping and rotating perineal massage	Not reported	Vaseline	Routine care
Karacam 2012 ^[1]	First stage (≥8cm) and Second Stage	Midwife	During and between pushes, discontinued if the women felt uncomfortable	The index and the middle finger in the vagina, with lateral movements in aspect of half circle pressing perineum downward	For about 1 second, for a maximum of 10-15 minutes.	No lubricant. In cases of dryness, water soluble lubricant	Routine care

				toward the rectum.				
Sohrabi 2012 ^[10]	Second stage	Researcher	Not reported	Not reported	Not reported	Not reported	Routine care	
Demirel 2015 ^[7]	First and Second stage	Researcher	Between contractions stopping when uncomfortable	Thumbs 2-3 cm into the vagina for the massage. The patient was also asked to contract and relax the muscles of the perineal area.	First stage: four times, pressurizing action continued for 2 minutes for each vaginal side. Second stage: massage continued for 10 minutes, with a rest of a minimum of 30 minutes before repeating the massage.	Glycerol (water soluble)	Routine care	

Table 3. Maternal and labor characteristics

	Age (year)	Nulliparous	BMI	Use of oxytocin	Length of the second stage (min)
Stamp 2001 ^[11]	Not reported	353/708 (49.9%) vs 332/632 (52.5%)	Not reported	Not reported	Not reported
Albers 2005 ^[3]	24.5±5.2 vs 24.5± 5.1	154/403 (38.2%) vs 155/404 (38.4%)	25.0±5.3 vs 25.5±5.8	129/403 (32.0%) vs 141/404 (34.9%)	33±38 vs 36 ±44
Attarha 2009 ^[6]	Not reported	85/85 (100%) vs 85/85 (100%)	Not reported	Not reported	40.1 ±20.7 vs 51.1 ± 21.2
Galledar 2010 ^[8]	Not reported	71/71 (100%) vs 70/70 (100%)	Not reported	Not reported	Not reported
Fahami 2012 ^[5]	22.5±3.7 vs 23.7±4.2	33/33 (100%) vs 33/33 (100%)	22.2±2.3 vs 22.0±3.0	Not reported	49.1±29.3 vs 38.5±20.3
Geranmayeh 2012 ^[9]	21.0±3.0 vs 22.0±3.0	45/45 (100%) vs 45/45 (100%)	Not reported	33/45 (73%) vs 30/45 (67%)	37±20 vs 46 ±20
Karacam 2012 ^[11]	22.9±3.7 vs 23.0 ± 3.6	198/198 (100%) vs 198/198 (100%)	21.6±3.4 vs 22.8±9.6	193/198 (97.5%) vs 188/198 (94.9%)	34.1 ±17.7 vs 33.8±18.9
Sohrabi 2012 ^[10]	Not reported	40/40 (100%) vs 40/40 (100%)	Not reported	Not reported	Not reported
Demirel 2015 ^[7]	24.3±4.1 vs 23.4±3.7	71/142 (50.0%) vs 71/142 (50.0%)	Not reported	Not reported	25.3±5.5 vs 28.2 ±6.6
Totals	23.0 vs 23.3	1050/1725 (60.9%) vs 1028/1649 (62.3%)	22.9 vs 23.4	355/646 (54.9%) vs 359/647(55.3%)	*36.4 vs 38.9

Data are presented as number in the intervention vs number in control group with percentage

** Standard Deviation not reported*

Table 4. Primary and Secondary Outcomes

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	Stamp 2001 ^[1]	Albers 2005 ^[3]	Attarh 2009 ^[6]	Galledar 2010 ^[8]	Fahan 2012 ^[5]	Geranma 2012 ^[9]	Keraca 2012 ^[1]	Sohrabi 2012 ^[10]	Demirell 2015 ^[7]	Total	RR (95% CI)	I ²
	12/ 708 (1.7%) vs 24/632 (3.8%)	5/ 403 (1.2%) vs 26/404 (1.5%)	0/85 (0%) vs 5/85 (5.9%)	Not reported	Not reported	0/45 (0%) vs 0/45 (0%)	Not reported	0/40 (0%) vs 0/40 (0%)	Not reported	17/128 (1.3%) vs 35/120 (2.9%)	1.49 (0.25 to 0.94)	10%
Intact perineum	198/ 708 (28.0%) vs 171/632 (27%)	94/403 (23.3%) vs 90/404 (22.3%)	37/85 (43.5%) vs 42/85 (49.4%)	21/71 (29.6%) vs 8/70 (11.4%)	7/33 (21.2%) vs 6/33 (18.2%)	12/45 (26.7%) vs 2/45 (4.4%)	7/198 (3.5%) vs 7/198 (3.5%)	20/40 (50.0%) vs 16/40 (40.0%)	129/142 (90.8%) vs 136/142 (95.8%)	525/1725 (30.4%) vs 438/1649 (26.6%)	1.54 (1.01 to 0.93)	87%
Intact perineum excluding episiotomy	Not reported	Not reported	Not reported	Not reported	7/33 (21.2%) vs 6/33 (18.2%)	Not reported	Not reported	20/40 (50.0%) vs 16/40 (40.0%)	Not reported	27/73 (37.0%) vs 22/73 (30.1%)	1.23 (0.80 to 1.91)	0%
First- degree lacerations	122/708 (17.2%) vs 106/632 (16.8%)	81/403 (20.1%) vs 89/404 (22.0%)	24/85 (28.2%) vs 44/85 (51.8%)	50/71 (70.4%) vs 32/70 (45.7%)	13/33 (39.4%) vs 19/33 (57.6%)	15/45 (33.3%) vs 4/45 (8.9%)	85/198 (42.9%) vs 71/198 (35.9%)	12/40 (30.0%) vs 18/40 (45.0%)	Not reported	412/1583 (26.0%) vs 343/1507 (22.8%)	3.21 (0.92 to 0.75)	75%
Second- degree lacerations	190/708 (26.8%) vs 164/632 (25.9%)	83/403 (20.6%) vs 74/404 (18.3%)	10/85 (11.8%) vs 46/85 (54.1%)	21/71 (29.6%) vs 38/70 (54.3%)	13/33 (39.4%) vs 8/33 (24.2%)	3/45 (6.7%) vs 1/45 (2.2%)	9/198 (4.5%) vs 7/198 (3.5%)	3/40 (7.5%) vs 4/40 (10.0%)	Not reported	322/1583 (20.3%) vs 302/1507 (20.0%)	3.99 (0.77 to 0.72)	43%

88%

First & Second-degree lacerations	312/708 (44.1%)	864/4034 (40.7%)	4/85 (0%)	71/71 (100%)	26/33 (78.8%)	18/45 (40.0%)	94/198 (47.5%)	15/40 (37.5%)	Not reported	734/1583 (46.4%)	312 (0.93)
	vs	vs	vs	vs 70/70	vs	vs 5/45	vs	vs 22/40		vs	to
	170/632 (42.7%)	263/404 (40.3%)	4/85 (11.8%)	(100%)	27/33 (81.8%)	(11.1%)	78/198 (39.4%)	(55.0%)		645/1507 (42.8%)	736
Third-degree lacerations	12/708 (1.7%)	84/403 (1.0%)	0/85 (0%)	Not reported	Not reported	0/45 (0%)	Not reported	0/40 (0%)	Not reported	16/128 (1.2%)	10.57 (0.16)
	vs	vs				vs 0/45 (0%)		vs 0/40 (0%)		vs	to
	23/632 (3.6%)	22/404 (0.5%)	5/85 (5.9%)							30/1206 (2.5%)	6.02
Fourth-degree lacerations	0/708 (0%)	1/403 (0.2%)	0/85 (0%)	Not reported	Not reported	0/45 (0%)	Not reported	0/40 (0%)	Not reported	1/128 (0.1%)	0.26 (0.04)
	vs	vs				vs 0/45 (0%)		vs 0/40 (0%)		vs	to
	1/632 (0.2%)	4/404 (1.0%)	0/85 (0%)							5/1206 (0.4%)	1.61
Major perineal trauma*	378/708 (53.4%)	85/403 (21.1%)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	472/1110 (42.5%)	1.97 (0.89)
	vs	vs								vs	to
	358/632 (56.6%)	82/404 (20.3%)								440/1036 (42.5%)	6.06
Episiotomy	76/708 (24.9%)	8/403 (1.7%)	14/85 (16.5%)	23/71 (32.4%)	0/33 (0%)	15/45 (33.3%)	103/198 (52.0%)	80/40 (0%)	44/142 (31.0%)	382/1725 (22.1%)	15.56 (0.38)
	vs	vs	vs	vs	vs	vs	vs	vs 0/40	vs	vs	to
	170/632 (26.9%)	2/404 (0.5%)	68/85 (80.0%)	47/70 (67.1%)	0/33 (0%)	38/45 (84.4%)	120/198 (60.6%)	(0%)	99/142 (69.7%)	544/1640 (33.0%)	8.2

Data are presented as number in the intervention vs number in control group with percentage

*Third or fourth degree lacerations

**Second, third, fourth lacerations or episiotomy

RR, relative risk; CI, confidence interval

Boldface data, statistically significant

Table 5. Other obstetric lacerations

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	Stamp 2001	Albers 2005 ^[3]	Attarh 2009	Galled 2010	Baham 2012	Gerank 2012	Kayca 2012	Sohral 2012	Demird 2015 ^[7]	Total	RR	I ²
	[11]		[6]	[8]	[5]	[9]	[1]	[10]				
Labial lacerations	Not reported (49.1%) vs 191/404 (47.3%)	Not reported	Not reported	Not reported	Not reported	Not reported	31/198 (15.7%) vs 19/198 (9.6%)	Not reported	Not reported	229/601 (38.1%) vs 210/602 (34.9%)	1.21 (0.79 to 1.85)	62%
Vaginal lacerations	Not reported (40.9%) vs 160/404 (39.6%)	Not reported	Not reported	Not reported	Not reported	Not reported	15/198 (7.6%) vs 17/198 (8.6%)	Not reported	Not reported	180/601 (29.9%) vs 177/602 (29.4%)	1.02 (0.87 to 1.21)	0%
Clitoridea lacerations	Not reported (3.2%) vs 20/404 (4.9%)	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	13/403 (3.2%) vs 20/404 (4.9%)	0.65 (0.33 to 1.29)	Not applicable
Periurethral lacerations	Not reported (9.9%) vs 53/404 (13.1%)	Not reported	Not reported	Not reported	Not reported	Not reported	31/198 (15.7%) vs 19/198 (9.6%)	Not reported	Not reported	71/601 (11.8%) vs 72/602 (12.0%)	1.09 (0.51 to 2.30)	81%
Anterior lacerations	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	31/198 (15.7%) vs 19/198 (9.6%)	Not reported	Not reported	31/198 (15.7%) vs 19/198 (9.6%)	1.63 (0.95 to 2.79)	Not applicable
Posterior lacerations	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	33/198 (16.7%) vs	Not reported	Not reported	33/198 (16.7%) vs	1.14 (0.72 to 1.85)	Not applicable

29/198
(14.6%)

29/198 to
(14.6%)1.80)

*Data are presented as number in the intervention vs number in control group with percentage
RR, relative risk; CI, confidence interval*

Table 6.Mode of delivery and neonatal Outcomes

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	Vaginal delivery	Cesarean delivery	Birth weight	Apgar Score <7 at 5 min	Perineal pain	Dyspareunia
Stamp 2001 ^[11]	684/708 (96.6%) vs 609/632 (96.4%)	24/708 (3.4%) vs 23/632 (3.6%)	Not reported	9/708 (1.3%) vs 9/632 (1.4%)	416/708 (58.8%) vs 359/632 (56.8%)	78/708 (11.0%) vs 68/632 (10.8%)
Albers 2005 ^[3]	400/403 (99.3%) vs 398/404 (98.5%)	3/403 (0.7%) vs 6/404 (1.5%)	3349±462 vs 3345±440	1/403 (0.2%) vs 2/404 (0.5%)	Not reported	Not reported
Attarha 2009 ^[6]	85/85 (100%) vs 85/85 (100%)	0/85 (0%) vs 0/85 (0%)	Not reported	Not reported	Not reported	Not reported
Galledar 2010 ^[8]	71/71 (100%) vs 70/70 (100%)	0/71 (0%) vs 0/70 (0%)	Not reported	Not reported	Not reported	Not reported
Fahami 2012 ^[5]	33/33 (100%) vs 33/33 (100%)	0/33 (0%) vs 0/33 (0%)	3337.9±293.5 vs 3239.4±267.1	Not reported	14/33 (42.4%) vs 15/33 (45.5%)	Not reported
Geranmayeh 2012 ^[9]	45/45 (100%) vs 45/45 (100%)	0/45 (0%) vs 0/45 (0%)	3200±400 vs 3300±400	0/45 (0%) vs 0/45 (0%)	Not reported	Not reported
Karacam 2012 ^[1]	198/198 (100%) vs 198/198 (100%)	0/198 (0%) vs 0/198 (0%)	3188.7±390.6 vs 3164.5±389.3	1/198 (0.5%) vs 0/198 (0%)	138/198 (69.7%) vs 144/198 (72.7%)	45/135 (33.6%) vs 34/144 (24.5%)
Sohrabi 2012 ^[10]		0/40 (0%) vs 0/40 (0%)	Not reported	Not reported	Not reported	Not reported

	40/40 (100%) vs 40/40 (100%)					
Demirel 2015^[7]	142/142(100%) vs 142/142(100%)	0/142 (0%) vs 0/142 (0%)	Not reported	Not reported	Not reported	Not reported
Total	1698/1725 (98.4%) vs 1620/1649 (98.2%)	27/1725 (1.6%) vs 29/1649 (1.8%)	*3268.9 vs 3262.2	11/1725 (0.6%) vs 11/1649 (0.7%)	568/939 (60.5%) vs 518/863 (60.0%)	123/843 (14.6%) vs 102/776 (13.1%)
RR (95% CI)	1.00 (1.00, 1.00)	0.85 (0.51, 1.43)	13.56 (-36.04, 63.17)	0.89 (0.36, 2.23)	1.01 (0.93, 1.08)	1.15 (0.90, 1.45)
I²	0%	0%	14%	Not applicable	0%	41%

*Data are presented as number in the intervention vs number in control group with percentage
RR, relative risk; CI, confidence interval*

Table 7. Outcomes in subgroup analysis of nulliparous woman only

	Attarha 2009 ^[6]	Galledar 2010 ^[8]	Fahami 2012 ^[5]	Geranmayer 2012 ^[9]	Karacam 2012 ^[1]	Sohrabi 2012 ^[10]	Total	RR (95% CI)	I ²
	0/85 (0%) vs 5/85 (5.9%)	Not reported	Not reported	0/45 (0%) vs 0/45 (0%)	vs Not reported	0/40 (0%) vs 0/40 (0%)	0/170 (0%) vs 5/170 (2.9%)	0.09 (0.01 to 1.62)	Not applicable
Intact perineum	37/85 (43.5%) vs 2/85 (2.3%)	21/71 (29.6%) vs 8/70 (11.4%)	7/33 (21.2%) vs 6/33 (18.2%)	12/45 (26.7%) vs 2/45 (4.4%)	7/198 (3.5%) vs 7/198 (3.5%)	20/40 (50%) vs 16/40 (40.0%)	104/472 22.41 (22.0%) vs 41/471 (8.7%)	1.09 to 5.35)	78%
Intact perineum, excluding episiotomy	Not reported	Not reported	7/33 (21.2%) vs 6/33 (18.2%)	Not reported	Not reported	20/40 (50.0%) vs 16/40 (40.0%)	46/73 (63.0%) vs 43/73 (58.9%)	1.02 (0.80 to 1.30)	12%
First- degree laceration	24/85 (28.2%) vs 4/85 (4.7%)	50/71 (70.4%) vs 32/70 (45.7%)	13/33 (39.4%) vs 19/33 (57.6%)	15/45 (33.3%) vs 4/45 (8.9%)	85/198 (42.9%) vs 71/198 (35.9%)	12/40 (30.0%) vs 18/40 (45.0%)	199/472 (42.2%) vs 148/471 (31.4%)	1.39 (0.89 to 2.17)	81%
Second- degree laceration	10/85 (11.8%) vs 6/85 (7.1%)	21/71 (29.6%) vs 38/70 (54.3%)	13/33 (39.4%) vs 8/33 (24.2%)	3/45 (6.7%) vs 1/45 (2.20%)	9/198 (4.5%) vs 7/198 (3.5%)	3/40 (7.5%) vs 4/40 (10.0%)	59/472 (12.5%) vs 64/471 (31.4%)	1.09 (0.62 to 1.93)	56%
First & Second- degree laceration	34/85 (40.0%) vs 10/85 (11.8%)	71/71 (100%) vs 70/70 (100%)	26/33 (78.8%) vs 27/33 (81.8%)	18/45 (40%) vs 5/45 (11.1%)	94/198 (47.5%) vs 78/198 (39.4%)	15/40 (37.5%) vs 22/40 (55.0%)	258/472 (54.7%) vs 212/471 (45.0%)	1.39 (0.72 to 2.68)	98%

Third-degree laceration	0/85 (0%) vs 5/85 (5.9%)	Not reported	Not reported	0/45 (0%) vs 0/45 (0%)	Not reported	0/40 (0%) vs 0/40 (0%)	0/170 (0%) vs 5/170 (2.9%)	0.09 (0.01 to 1.62)	Not applicable
Fourth-degree laceration	0/85 (0%) vs 0/85 (0%)	Not reported	Not reported	0/45 (0%) vs 0/45 (0%)	Not reported	0/40 (0%) vs 0/40 (0%)	0/170 (0%) vs 0/170 (0%)	Not applicable	Not applicable
Major perineal trauma**	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	0/0 (0%) vs 0/0 (0%)	Not applicable	Not applicable
Episiotomy	14/85 (16.5%) vs 68/85 (80.0%)	23/71 (32.4%) vs 47/70 (67.1%)	0/33 (0%) vs 0/33 (0%)	15/45 (33.3%) vs 38/45 (84.4%)	103/198 (52.0%) vs 120/198 (60.6%)	0/40 (0%) vs 0/40 (0%)	155/472 (32.8%) vs 273/471 (58.1%)	0.44 (0.23 to 0.83)	93%

Data are presented as number in the intervention vs number in control group with percentage

*Third or fourth degree lacerations

**Second, third, fourth lacerations or episiotomy

RR, relative risk; CI, confidence interval

Boldface data, statistically significant

Table 8. Outcomes in subgroup analysis of multiparous woman only

JUST ACCEPTED

	Stamp 2001^[11]	Albers 2005^[3]	Demirel 2015^[7]	Total	RR (95% CI)	I²
	12/ 708 (1.7%) vs 24/632 (3.8%)	5/ 403 (1.2%) vs 6/404 (1.5%)	Not reported	17/1111 (1.5%) vs 30/2036 (1.5%)	1.06 (0.59 to 1.92)	0%
Intact perineum	198/ 708 (28.0%) vs 171/632 (27.0%)	94/403 (23.3%) vs 90/404 (22.3%)	129/142 (90.8%) vs 136/142 (95.8%)	421/1253 (33.6%) vs 397/1178 (33.7%)	0.99 (0.88 to 1.11)	47%
Intact perineum, excluding episiotomy	Not reported	Not reported	Not reported	0/0 (0%) vs 0/0 (0%)	Not applicable	Not applicable
First-degree laceration	122/708 (17.2%) vs 106/632 (16.8%)	91/403 (22.6%) vs 89/404 (22.0%)	Not reported	213/1111 (19.2%) vs 195/1036 (18.8%)	1.03 (0.86 to 1.22)	0%
Second-degree laceration	190/708 (26.8%) vs 164/ 632 (25.9%)	73/403 (18.1%) vs 74/404 (18.3%)	Not reported	263/1111 (23.7%) vs 238/1036 (23.0%)	1.02 (0.88 to 1.19)	0%
First & Second-degree laceration	312/708 (44.1%) vs 270/632 (42.7%)	164/403 (40.7%) vs 163/404 (40.3%)	Not reported	476/1111 (42.8%) vs 433/1036 (0.4%)	1.02 (0.93 to 1.13)	0%
Third-degree laceration	12/708 (1.7%) vs 23/632 (3.6%)	4/403 (1.0%) vs 2/404 (0.5%)	Not reported	16/1111 (1.4%) vs 25/1036 (2.4%)	0.78 (0.20 to 3.07)	59%

Fourth-degree laceration	0/708 vs 1/632 (0.2%)	1/403 (0.2%) vs 4/404 (1.0%)	Not reported	1/1111 (0.1%) vs 5/1036 (0.5%)	0.26 (0.04 to 1.61)	0%
Major perineal trauma**	378/708 (53.4%) vs 358/632 (56.6%)	85/403 (21.1%) vs 82/404 (20.3%)	Not reported	463/1111 (41.7%) vs 440/1036 (42.5%)	0.95 (0.87 to 1.04)	0%
Episiotomy	176/708 (24.9%) vs 170/632 (26.9%)	7/403 (1.7%) vs 2/404 (0.5%)	44/142 (31.0%) vs 99/142 (69.7%)	227/1253 (18.1%) vs 271/1178 (23.0%)	0.82 (0.40 to 1.65)	92%

Data are presented as number in the intervention vs number in control group with percentage *Third or fourth degree lacerations

**Second, third, fourth lacerations or episiotomy

RR, relative risk; CI, confidence interval

Boldface data, statistically significant

Table 9. Outcomes in subgroup analysis of women randomized in the second stage of labor

JUST ACCEPTED

	Albers 2005^[3]	Attarha 2009^[6]	Fahami 2012^[5]	Geranmayer 2012^[9]	Sohrabi 2012^[10]	Total	RR (95% CI)	I²
	5/403 (1.2%) vs 6/404 (1.5%)	0/85 (0%) vs 5/85 (5.9%)	Not reported	0/45 (0%) vs 0/45 (0%)	0/40 (0%) vs 0/40 (0%)	5/573 (0.9%) vs 11/574 (1.9%)	0.40 (0.05 to 3.40)	53%
Intact perineum	94/403 (23.3%) vs 90/404 (22.3%)	37/85 (43.5%) vs 2/85 (2.3%)	7/33 (21.2%) vs 6/33 (18.2%)	12/45 (26.7%) vs 2/45 (4.4%)	20/40 (50.0%) vs 16/40 (40.0%)	170/606 (28.1%) vs 116/607 (19.1%)	2.16 (1.01 to 4.60)	83%
Intact perineum, excluding episiotomy	Not reported	Not reported	7/33 (21.2%) vs 6/33 (18.2%)	Not reported	Not reported	7/33 (21.2%) vs 6/33 (18.2%)	0.86 (0.32 to 2.28)	Not applicable
First-degree laceration	91/403 (22.6%) vs 89/404 (22.0%)	24/85 (28.2%) vs 4/85 (4.7%)	13/33 (39.4%) vs 19/33 (57.6%)	15/45 (33.3%) vs 4/45 (8.9%)	12/40 (30.0%) vs 18/40 (45.0%)	155/606 (25.6%) vs 134/607 (22.1%)	1.37 (0.73 to 2.57)	83%
Second- degree laceration	73/403 (18.1%) vs 74/404 (18.3%)	10/85 (11.8%) vs 6/85 (7.1%)	13/33 (39.4%) vs 8/33 (24.2%)	3/45 (6.7%) vs 1/45 (2.2%)	3/40 (7.5%) vs 4/40 (10.0%)	102/606 (16.8%) vs 93/607 (15.3%)	1.10 (0.85 to 1.41)	0%
First & Second- degree laceration	164/403 (40.7%) vs 163/404 (40.3%)	34/85 (40.0%) vs 10/85 (11.8)	26/33 (78.8%) vs 27/33 (81.8%)	18/45 (40%) vs 5/45 (11.1%)	15/40 (37.5%) vs 22/40 (55.0%)	257/606 (42.4%) vs 227/607 (37.4%)	1.31 (0.87 to 1.99)	84%

Third-degree laceration	4/403 (1.0%) vs 2/404 (0.5%)	0/85 (0%) vs 5/85 (5.9%)	Not reported	0/45 (0%) vs 0/45 (0%)	0/40 (0%) vs 0/40 (0%)	4/573 (0.7%) vs 7/574 (1.2%)	0.53 (0.02 to 12.16)	72%
Fourth-degree laceration	1/403 (0.2%) vs 4/404 (1.0%)	0/85 (0%) vs 0/85 (0%)	Not reported	0/45 (0%) vs 0/45 (0%)	0/40 (0%) vs 0/40 (0%)	1/573 (0.2%) vs 4/574 (0.7%)	0.25 (0.03 to 2.23)	Not applicable
Major perineal trauma**	85/403 (21.1%) vs 82/404 (20.3%)	Not reported	Not reported	Not reported	Not reported	85/403 (21.1%) vs 82/404 (20.3%)	1.04 (0.79 to 1.36)	Not applicable
Episiotomy	7/403 (1.7%) vs 2/404 (0.5%)	14/85 (16.5%) vs 68/85 (80.0%)	0/33 (0%) vs 0/33 (0%)	15/45 (33.3%) vs 38/45 (84.4%)	0/40 (0%) vs 0/40 (0%)	36/606 (5.9%) vs 108/607 (17.8%)	0.47 (0.18 to 1.24)	85%

Data are presented as number in the intervention vs number in control group with percentage

*Third or fourth degree lacerations

**Second, third, fourth lacerations or episiotomy

RR, relative risk; CI, confidence interval

Boldface data, statistically significant

FIGURES

Figure 1. Flow diagram of studies identified in the systematic review. (*Prisma template [Preferred Reporting Item for Systematic Reviews and Meta-analyses]*)

Figure 2. Assessment of risk of bias. (A) *Summary of risk of bias for each trial; Plus sign: low risk of bias; minus sign: high risk of bias; question mark: unclear risk of bias.* (B) *Risk of bias graph about each risk of bias item presented as percentages across all included studies.*

Figure 3. Forest plot for the risk of severe perineal trauma.

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