Lubricant for Reducing Perineal Trauma: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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Abstract

Background Different techniques have been reported to prevent perineal lacerations, but the effects of the use of lubricant have been unclear and is still subject of debate. Objective To assess the effect of lubricants on reducing perineal trauma during vaginal delivery. Search strategy PubMed, Embase, the Cochrane Library, CINAHL, China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBM), WanFang databases, ClinicalTrials.gov in 25 June 2021. Selection criteria Randomized controlled trials published in English or Chinese that compared the vaginal application of lubricant with standard care in women with cephalic presentation at vaginal delivery were included . Data collection and analysis Two independent reviewers selected eligible trials and extracted data on perineal trauma, duration of the second-stage labor, postpartum hemorrhage and Apgar score for meta-analysis. Main results Nineteen trials enrolling 5445 pregnant women were included. Compared with standard care, women using lubricants had a lower incidence of perineal trauma (RR 0.84, 95%CI 0.76 to 0.93), second-degree perineal laceration (RR 0.72, 95%CI 0.64 to 0.82) and episiotomy (RR 0.77, 95%CI 0.62 to 0.96), had a shorter duration of the second-stage labor (MD -13.72 minutes, 95%CI -22.68 to -4.77). Subgroup analysis indicated that women with obstetric gel had a shorter duration of the second-stage (MD -16.9 minutes, 95%CI -27.03 to -6.78 vs MD -8.38 minutes, 95%CI -11.11 to -5.65; P interaction=0.02) when compared with liquid wax. Conclusions Compared with standard care, lubricants could reduce the incidence of perineal trauma, especially second-degree perineal laceration, and shorten the duration of the second-stage labor.

Introduction

Perineal trauma is an extremely common and expected complication of vaginal birth. More than 85% of women having a vaginal birth suffer some degree of perineal trauma.[1] Perineal tears occur with varying degrees. In first-degree tear, superficial injury to the vaginal mucosa that may involve the perineal skin, whereas in second-degree tear lacerations extend to the vaginal mucosa and perineal body. In severe perineal tears (third- and fourth-degree), the anal sphincter and rectal mucosa are torn, respectively.[2-3]Among different degrees of perineal tears, severe perineal tears are linked to the greatest morbidity, including pain, dyspareunia, faecal incontinence, urinary problems.[1,4-5] For women who experience severe perineal trauma during childbirth, their physical and psychological outcomes can be complex, with some women experiencing social isolation and marginalization due to their ongoing symptomatology.[6] Therefore, prevention of perineal trauma, and third- and fourth-degree lacerations in particular is essential.

Different techniques have been reported to prevent perineal lacerations, including warm compresses,[7-8] perineal massage,[7,9] hands-on technique,[7,10]Ritgen's maneuver,[7,11] and lubricant gel.[12] Among these techniques, warm compresses and perineal massage showed a positive effect in reducing third-degree and fourth-degree perineal tears.[7-9] Hands-on technique and Ritgen's maneuver did not show any effect on severe perineal tears.[7,10-11] The effects of the use of lubricant have been unclear and is still subject of debate.[12]Lubricants can effectively reduce the friction of the vaginal wall, may facilitate the delivery of the fetus and reduce perineal trauma. The aim of this systematic review and meta-analysis of randomized controlled trials (RCTs) was to evaluate whether or not the use of lubricants during vaginal delivery decreases perineal trauma, to inform the recommendations of Chinese guideline on clinical practice guides for prevention and management of perineal laceration in vaginal delivery.

Methods

The systematic literature search was conducted according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.[13]

Eligibility criteria

RCTs published in English or Chinese that compared the vaginal application of lubricant (intervention group) with standard care (control group) in women with cephalic presentation at term undergoing an attempt at vaginal delivery where the outcome was perineal trauma, were included.

Exclusion criteria

Trials included pregnant women who received lubricant contemporaneous with other intervention (ie. 1% lidocaine hydrochloride, warm compresses) were excluded. Enrolled women who had premature rupture of membranes, suspected chorioamnionitis, infection or known foetal malformations and still births were also excluded.

Outcomes

The primary outcome was perineal trauma, including episiotomy, first- and second-degree perineal laceration, severe perineal laceration, and rates of intact perineum. Secondary outcomes included duration of the second-stage labor, postpartum hemorrhage, and Apgar score at 1 minute and 5 minutes.

Search strategy

Two researchers (YQY and XC) systematically searched PubMed, Embase, the Cochrane Library, CINAHL, and three additional Chinese literature databases, namely, CNKI, CBM and WanFang databases from inception to 25 June 2021 using a comprehensive search strategy (Appendix S1). We also searched ClinicalTrials.gov to identify ongoing or unpublished eligible trials. Additionally, reference lists of included articles and relevant systematic reviews were also screened.

Study selection

Two researchers (YQY and XC) independently screened the titles and abstracts and selected articles for full text review. We then independently reviewed full text articles for eligibility. Any discrepancies were resolved with discussion. A further independent reviewer (LG) determined eligibility if consensus was not met.

Data collection

Two independent researchers (YQY and XC) used a standard data extraction form to extract data from eligible trials. From each included trial, we extracted the following data: author, publication year, age, gestational age, number of participants, intervention details, outcomes.

Risk of bias in individual studies

Study quality was assessed independently by two reviewers based on the seven domains defined by the Cochrane Collaboration's tool for assessing risk of bias.[14] The tool includes the following domains: random

sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. We rated each domain as low risk, unclear risk, or high risk of bias. We assigned individual trials as high risk of bias if one or more domain(s) was deemed high risk of bias; otherwise, we assigned individual trials as low risk of bias.

Assessment of GRADE

We examined the certainty (quality) of evidence for outcomes using GRADE approach.[15] The certainty of evidence was classified as four levels: high, moderate, low, and very low. Two reviewers considered comprehensively five factors (risk of bias, inconsistency, indirectness, imprecision, and publication bias) to assess the certainty of evidence for the following outcomes: perineal trauma, episiotomy, first- and second-degree perineal laceration, severe perineal laceration, duration of second-stage labor. The evidence could be downgraded from 'high' by one level for serious (or by two levels for very serious) limitations.

Data synthesis

We performed statistical analyses using Review Manager 5 Software (version 5.3) and Stata (version 15.1). For dichotomous data, we calculated risk ratio (RR) with 95% confidence interval (CI) by using the Mantel-Haenszel approach. For continuous outcomes, we calculated mean differences (MD) with 95% confidence intervals using an Inverse Variance method. A P value of < 0.05 was considered statistically significant. Summary effects estimates were calculated using DerSimonian and Laird random-effects models.[16]We performed subgroup analysis on the basis of lubricants type, parity, overall risk of bias, birthweight and ethnicities when sufficient data for each subgroup. An interaction analysis (P for interaction) was performed to evaluate the difference between subgroups. Statistical heterogeneity was evaluated using the I^2 statistic and Cochran Chi-square test. Publication bias was assessed visually by funnel plots and quantitatively with Begg's test for asymmetry.[17] Sensitivity analysis was also undertaken to examine the effect of a single study on the overall effect size and the robustness of results with omitting one study at a time.

Results

Study selection

A total of 1450 unique articles were identified from the literature searches, of which 7 records were screened from reference lists of included articles and relevant systematic reviews. After screening of the title, abstract, and 103 full-text papers were screened again. Finally, 19 trials[17-35] enrolling 5445 women were eligible for inclusion (Figure S1).

Study characteristics

The year of publication of the included trials ranged between 1998 and 2020, spanning 22 years. Twelve trials included only nulliparous women, 2 trials included only multiparous women, 4 trial included both nulliparous and multiparous women, one trials didn't report the parity. Participants were full-term pregnant women (gestational age[?]37 weeks). Four Lubricants classes were evaluated, including obstetric gel (n=8), liquid wax (n=9), liquid petroleum jelly (n=1), and peanut oil (n=1). The number of participants ranged from 62 to 800 (Table S1).

Risk of bias assessment and certainty of evidence assessment

Figure S2 presents the risk of bias assessment for individual trials. Thirteen trials were deemed low risk of bias and 6 trials were deemed high risk of bias. Two trials were at high risk of random sequence generation, and 10 trials were at unclear risk of random sequence generation. All trials were unclear in describing the methods used to conceal allocation and therefore were at unclear risk of selection bias. Three trials were at high risk of performance bias owing to inadequate blinding of participants, and 16 were at unclear risk of performance bias. Four trials were at high risk of detection bias owing to inadequately blinding outcome assessment, and another 15 trials were at unclear risk of detection bias. All studies were at low risk of attrition bias and reporting bias. The overall certainty of evidence by GRADE was summarized in Table 1. Overall, moderate certainty of evidence was found for second-degree perineal laceration, while the evidence

for perineal trauma and severe perineal laceration was rated as low certainty. Very low certainty of evidence was found for episiotomy, first-perineal laceration, intact perineum, duration of the second-stage labor.

Incidence of perineal

trauma

Nineteen trials involving 5445 women reported on this outcome, 5353 women contributed data. The result of meta-analysis indicated that women in lubricant group had a lower incidence of perineal trauma when compared with those in standard care group (RR 0.84, 95%CI 0.76 to 0.93; I^2=99%; low certainty due to serious risk of bias and serious inconsistency) (Table 1, Figure S3).

Subgroup analyses showed that there was significant subgroup effect between parity groups ($P_{\text{interaction}}$=0.01) (Figure S4), but not between lubricants type groups ($P_{\text{interaction}}$=0.15) (Figure S5) and between overall risk of bias groups ($P_{\text{interaction}}$=0.40) (Figure S6). The heterogeneity of multiparous women groups and obstetric gel groups was significantly reduced after subgroup analysis (I^2=0% and I^2=62%, respectively), while significant heterogeneity remained within nulliparous women groups and liquid wax groups (I^2=99% and I^2=99%, respectively). Hence, this heterogeneity might partially result from studies of nulliparous women and liquid wax.

The result analyzed based on parity showed that both nulliparous women (RR 0.85, 95%CI 0.77 to 0.95; I^2=99%) (Figure S4) and multiparous women (RR 0.72, 95%CI 0.66 to 0.78; I^2=0%) (Figure S4) in lubricant group had statistically difference in the incidence of perineal trauma when compared with those in standard care group.

Incidence ofepisiotomy

Twelve trials involving 3285 women were included in this outcome, 3193 women contributed data. The result of meta-analysis indicated that women in lubricant group had no statistically difference in the incidence of episiotomy when compared with those in standard care group (RR 0.77, 95%CI 0.62 to 0.96; I^2=84%; very low certainty due to serious risk of bias, serious inconsistency and serious imprecision) (Table 1, Figure S7).

Subgroup analyses based on lubricants type and overall risk of bias were not significant subgroup effect between subgroups ($P_{\text{interaction}}$=0.95 and $P_{\text{interaction}}$=0.33, respectively) (Figure S8, Figure S9). The heterogeneity of obstetric gel groups and high risk of bias groups was reduced after subgroup analysis (I^2=58% and I^2=54%, respectively), while significant heterogeneity remained within liquid wax groups and low high risk of bias groups (I^2=94% and I^2=88%, respectively). This heterogeneity might partially result from studies of liquid wax and low high risk of bias (Figure S8, Figure S9).

When analyzed based on parity, there was not significant in the incidence of episiotomy in lubricant group versus standard care group for nulliparous women (RR 0.80, 95%CI 0.63 to 1.01; I^2=85%) (Figure S10). There was insufficient data to perform subgroup analysis for this outcome for multiparous women.

Incidence of first-degree perineal laceration

Eleven trials involving 3618 women were included in this outcome, 3581 women contributed data. The result of meta-analysis indicated that women in lubricant group had no statistically difference in the incidence of first-degree perineal laceration when compared with those in standard care group (RR 1.18, 95%CI 0.92 to 1.52; I^2=87%; very low certainty due to serious risk of bias, serious inconsistency and serious imprecision) (Table 1, Figure S11).

Subgroup analyses showed that there was significant subgroup effect between parity groups ($P_{\text{interaction}}$<0.001) (Figure 12), but not between lubricants type groups and between overall risk of bias ($P_{\text{interaction}}$=0.66 and $P_{\text{interaction}}$=0.58, respectively) (Figure S13, Figure S14). The heterogeneity of multiparous women groups, obstetric gel groups and high risk of bias groups was significantly reduced after subgroup analysis (I^2=0%, I^2=48% and I^2=20%, respectively), while significant heterogeneity remained within nulliparous women groups, liquid wax groups and low high risk of bias groups (I^2=82%, I^2=92% and

I^2=90%, respectively). This heterogeneity might partially result from studies of nulliparous women, liquid wax and low risk of bias (Figure S13, Figure S14).

The result analyzed based on parity indicated that both multiparous and nulliparous women in lubricant group had statistically difference in the incidence of first-degree perineal trauma when compared with those in standard care group. Multiparous women had a lower incidence of first-degree perineal trauma (RR 0.69, 95%CI 0.59 to 0.80; I^2=0%) (Figure S12), while nulliparous women had a higher incidence of first-degree perineal trauma (RR 1.38, 95%CI 1.03 to 1.86; I^2=82%) (Figure S12), which might be associated with decreasing for incidence of second-degree perineal laceration and the incidence of first-degree perineal trauma was increasing relatively. Therefore, it was uncertain whether lubricant increased or reduced the incidence of first-degree perineal trauma for nulliparous women.

Incidence of second-degree perineal laceration

Ten trials involving 3447 women were included in this outcome, 3410 women contributed data. The result of meta-analysis indicated that women in lubricant group had a lower incidence of second-degree perineal laceration when compared with those in standard care group (RR 0.72, 95%CI 0.64 to 0.82; I^2=9%; moderate due to serious risk of bias) (Table 1, Figure S15).

Subgroup analyses based on lubricants type, overall risk of bias and parity were not significant subgroup effect between subgroups ($P_{\text{interaction}}$=0.16, $P_{\text{interaction}}$=0.50 and $P_{\text{interaction}}$=0.97, respectively) (Figure S16, Figure S17 and Figure S18).

The result analyzed based on parity indicated that both in nulliparous women (RR 0.75, 95%CI 0.60 to 0.93; I^2=25%) (Figure S18) and multiparous women (RR 0.75, 95%CI 0.60 to 0.93; I^2=0%) (Figure S18) in lubricant group had statistically difference in the incidence of second-degree perineal laceration when compared with those in standard care group.

Incidence of severe perineal laceration

Six trials involving 2180 women were included in this outcome, 2143 women contributed data. The result of meta-analysis indicated that women in lubricant group had no statistically difference in the incidence of severe perineal laceration when compared with those in standard care group (RR 0.3, 95%CI 0.05 to 1.88; I^2=0%; low due to serious risk of bias and serious imprecision) (Table 1, Figure S19). Subgroup analysis showed that there was not significant subgroup effect between lubricants type subgroups ($P_{\text{interaction}}$=0.93) (Figure S20).

When analyzed based on parity, there was not significant in the incidence of severe perineal laceration in lubricant group versus standard care group for nulliparous women (RR 0.28, 95%CI 0.23 to 2.69; I^2=0%) (Figure S21). There was insufficient data to perform subgroup analysis for this outcome for multiparous women.

Rates of intact perineum

Seven trials involving 2143 women were included in this outcome, 2129 women contributed data. The result of meta-analysis indicated that women in lubricant group had no statistically difference in the incidence of intact perineum when compared with those in standard care group (RR 1.22, 95%CI 0.99 to 1.50; I^2=75%; very low certainty due to serious risk of bias, serious inconsistency and serious imprecision) (Table 1, Figure S22).

Subgroup analyses based on lubricants type and overall risk of bias were not significant subgroup effect ($P_{\text{interaction}}$=0.40 and $P_{\text{interaction}}$=0.22, respectively) (Figure S23, Figure S24). The heterogeneity of obstetric gel groups and high risk of bias groups was significantly reduced after subgroup analysis (I^2=40% and I^2=0%, respectively), while significant heterogeneity remained within liquid wax groups and low high risk of bias groups (I^2=69% and I^2=86%, respectively). This heterogeneity might partially result from studies of liquid wax and low high risk of bias (Figure S23, Figure S24).

The result analyzed based on parity indicated that there was significant in the rate of intact perineum in lubricant group versus standard care group for nulliparous women (RR 1.18, 95%CI 1.04 to 1.33; I^2=0%) (Figure S25). There was insufficient data to perform subgroup analysis for this outcome for multiparous women.

Duration of the second-stage labor

Eight trials involving 1809 women were included in this outcome, 1723 women contributed data. The result of meta-analysis indicated that women in lubricant group had a shorter duration of the second-stage labor when compared with those in standard care group (MD -13.72 minutes, 95%CI -22.68, -4.77; I^2=98%; very low certainty due to serious risk of bias, serious inconsistency and serious imprecision) (Table 1, Figure S26).

Subgroup analyses showed that there was significant subgroup effect between lubricant type subgroups ($P_{\text{interaction}}$=0.02) (Figure S27), and not between overall risk of bias subgroups ($P_{\text{interaction}}$=0.37) (Figure S28). Subgroup analysis according to lubricant type indicated that obstetric gel (MD -16.9 minutes, 95%CI -27.03 to -6.78) had a shorter duration of the second-stage labor than liquid wax (MD -8.38 minutes, 95%CI -11.11 to -5.65). The heterogeneity of high risk of bias groups was reduced after subgroup analysis (I^2=65%), while significant heterogeneity remained within low high risk of bias groups (I^2=99%). This heterogeneity might partially result from studies of low high risk of bias (Figure S28).

The result analyzed based on parity indicated that nulliparous women in lubricant group had a shorter duration of the second-stage labor when compared with those in standard care group (MD -14.46 minutes, 95%CI -24.58, -4.34; I^2=98%) (Figure S29). There was insufficient data to perform subgroup analysis for this outcome for multiparous women.

Postpartum hemorrhage

Two trials that only included nulliparous women provided data on this outcome. The result of meta-analysis indicated that women in lubricant group had no statistically difference in postpartum hemorrhage when compared with those in standard care group (MD -41.06 ml, 95%CI -112.47 to 30.35; I^2=95%) (Figure S30). There was insufficient data for subgroup analysis.

Apgar score at 1 minute and 5 minutes

Three trials provided data on the Apgar score at 1 minute and 5 minutes. The result of meta-analysis indicated that women in lubricant group had no statistically difference in Apgar score at 1 minute (MD 0.29 points, 95%CI 0.00 to 0.58; I^2=0%) (Figure S31) and 5 minutes (MD -0.06 points, 95%CI -0.6 to 0.48; I^2=73%) (Figure S32) when compared with those in standard care group. There was insufficient data for subgroup analysis.

Sensitivity analysis and publication bias

A leave-one-out sensitivity analysis was conducted among studies examining the association between lubricants and perineal trauma, episiotomy, first- and second-degree perineal laceration. The sensitivity analysis shows that none of these studies was found to have substantially altered the overall results of the analysis (Appendix S2). Publication bias for four outcomes (perineal trauma, episiotomy, first- and second-degree perineal laceration) was calculated using the funnel plot (Appendix S3), and there was no evident asymmetry. Moreover, Begg's test showed that there was no obvious publication bias (P =0.32,P =0.09, P =1 and P =0.37 for perineal trauma, episiotomy, first- and second-degree perineal laceration, respectively).

DISCUSSION

Main findings

This systematic review aimed to evaluate the research evidence of how different lubricants could contribute in reducing the severity of perineal trauma. Nineteen trails enrolling 5445 women were eligible for inclusion. Our meta-analyses showed that with moderate certainty of evidence, lubricant use reduced the incidence of second-degree perineal laceration; and with very low to low certainty of evidence, lubricant reduced the

incidence of perineal trauma, episiotomy, and shortened the duration of second-stage labor, but did not affect rates of intact perineum, first-degree perineal laceration, severe perineal laceration, postpartum hemorrhage and Apgar score. Subgroup analysis indicated that women with obstetric gel had a shorter duration of the second-stage when compared with liquid wax. For nulliparous women, lubricant use reduced the incidence of perineal trauma, second-degree perineal laceration, shortened the duration of second-stage labor, and increased the rate of intact perineum. For multiparous women, lubricant use reduced the incidence of perineal trauma, first- and second-degree perineal laceration.

Strengths and limitations

Our meta-analysis had several strengths. This study included primarily high quality RCTs providing the highest protection against bias, used the GRADE approach to assess the overall certainty of evidence. The study also had several limitations. Firstly, we restricted the inclusion of studies in English and Chinese, which could have led to missing of some relevant trials. Secondly, we observed statistically significant heterogeneity across studies. Such heterogeneity might preclude pooling of some intervention effects, so caution should be exercised when interpreting the results. Thirdly, due to insufficient data, we were unable to conduct subgroup analysis for birthweight and ethnicities. Fourthly, because of insufficient RCT for peanut oil and liquid petroleum jelly, so the interpretation of results should be cautious.

Interpretation

The finding of our meta-analysis seems to contradict the previous meta-analysis,[12] which was performed to deny the impact of lubricant gel on the duration of second-stage labor. The previous meta-analysis included three RCTs with 512 women for analysis, which also included in our study, and revealed that vaginal application of lubricant gel during labor did not significantly reduce the duration of the second-stage of labor in pregnant women (MD -7.11 minutes, 95% CI -15.60 to 1.38). Our analysis included seven RCTs with 1332 women for analysis, and suggested that pregnant women in obstetric gel group had a shorter duration of the second-stage labor (MD -16.9 minutes, 95%CI -27.03 to -6.78). Compared with previous meta-analysis, we included other four recent RCTs, with the added statistical power of having 892 women, the present meta-analysis suggested that obstetric gel shortened the duration of the second-stage labor. The previous meta-analysis focused only on the effect of gel on the duration of the second-stage labor. Besides this outcome, our meta-analysis also focused on other important outcomes such as perineal trauma, postpartum hemorrhage and Apgar score. Our analysis suggested that use of obstetric gel during vaginal delivery did not increase the risk of postpartum hemorrhage and neonatal asphyxia. In addition, finding from our meta-analysis showed that liquid wax had a positive effect on reducing perineal trauma, which was simple and practical and had no adverse to the women and their newborn.[26, 29]

Conclusions

Moderate certainty of evidence demonstrated that the use of lubricants could reduce the incidence of second-degree perineal laceration. Low certainty of evidence suggested that the use of lubricants might reduce the incidence of perineal trauma, episiotomy and shorten the duration of second-stage labor. For both nulliparous and multiparous women, lubricant use reduced the incidence of perineal trauma, second-degree perineal laceration. In addition, nulliparous women used with lubricant had a higher rate of intact perineum and shortened the duration of second-stage labor while multiparous women had a lower incidence of first-degree perineal laceration. Future researches should evaluate if lubricants are associated with reduced perineal trauma in different birthweight and ethnicities. To our knowledge, none of the studies included in this review have women's acceptability of the interventions as an outcome. This could be considered in further research.

Disclosure of interests

None declared.

Contribution to authorship

YQY and CX screened abstracts, selected eligible papers, extracted data and wrote the first draft of the paper. SSH and MYS screened abstracts and selected eligible papers. HHL, LYH and QW performed the statistical analysis. CLW, YW, LX and XFL helped in the final selection of papers in case of disagreement and reviewed the manuscript critically. JHT, LG and LS designed the study and revised the manuscript.

Details of ethics approval

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Table 1. GRADE assessment for the certainty of evidence

Outcomes	Number of women (Studies)	RR/MD (95%CI)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Certai of eviden
Perineal trauma	5353 (19)	0.84 (0.76, 0.93)	Downgraded *	Downgraded #	Not downgraded	Not downgraded	Not downgraded	Low
Episiotomy	3193 (12)	0.77 (0.62, 0.96)	Downgraded *	Downgraded #	Not downgraded	Downgraded §	Not downgraded	Very lo
First-degree perineal laceration	3581 (11)	1.18 (0.92, 1.52)	Downgraded *	Downgraded #	Not downgraded	Downgraded §	Not downgraded	Very lo
Second-degree perineal laceration	3410 (10)	0.72 (0.64, 0.82)	Downgraded *	Not downgraded	Not downgraded	Not downgraded	Not downgraded	Modera
Severe perineal laceration	2143 (6)	0.30 (0.05, 1.87)	Downgraded *	Not downgraded	Not downgraded	Downgraded §	Not downgraded	Low
Intact perineum	2129 (7)	1.22 (0.99, 1.50)	Downgraded *	Downgraded #	Not downgraded	Downgraded §	Not downgraded	Very lo
Duration of second-stage labor	1723 (9)	-13.72 (-22.68, -4.77)	Downgraded *	Downgraded #	Not downgraded	Downgraded §	Not downgraded	Very lo

RR = risk ratio; MD = mean difference; CI = confidence interval

* Downgraded by one level because one domain of risk of bias was high

Downgraded by one level because heterogeneity (I^2) >50%

§ Downgraded by one level because the limits of the 95% confidence interval were 20 points different to smallest worth

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