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REVIEW ARTICLE

Use of lubricant gel to shorten the second stage of labor during vaginal delivery

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ABSTRACT

Background: Vaginal application of lubricant during labor has been studied to shorten the length of the second stage of labor.

Objective: To evaluate whether vaginal application of lubricant shortens the second stage of labor.

Data sources: Electronic databases were searched from their inception until February 2018. No restrictions for language or geographic location were applied.

Study eligibility criteria: Randomized controlled trials (RCTs) comparing the use of lubricant of the vaginal canal (i.e. intervention group) with a control group (i.e. no lubricant) in pregnant women with singleton gestation and cephalic presentation undergoing spontaneous vaginal delivery at term. Trials on other interventions that might impact second stage of labor (pushing methods, perineal massage, Ritgen's maneuver, etc.) were not included.

Study appraisal and synthesis methods: All analyses were done using an intention-to-treat approach. The primary outcome was the length of the second stage of labor. Pooled analysis was performed using the random-effects model of DerSimonian and Laird to produce summary treatment effects in terms of mean difference (MD) with 95% confidence interval (CI).

Tabulation, integration, and results: Three RCTs including 512 women evaluating the effect of lubricant application during labor were included in the meta-analysis. All trials included pregnant women with singleton gestations in cephalic presentation at term undergoing spontaneous vaginal delivery. One trial included only nulliparous women, while the other two included both nulliparous and multiparous women. Lubricant application started in the first stage before the active phase of labor, and was done intermittently by the midwife or the physician. A sterile gel was applied into the vaginal canal manually or with an applicator. All trials used water-soluble gel. The quantity of gel used was about 2–5 ml for each vaginal examination. There were no statistically significant differences, comparing women who received lubricant gel during labor with those who did not, in the lengths of second stage of labor (MD −7.11 min, 95% CI −15.60 to 1.38), of the first stage of labor, or of the active phase of the first stage of labor. No between-group differences were noticed in the risk of perineal lacerations, mode of delivery, and in the neonatal outcomes.

Conclusion: Vaginal application of lubricant during labor does not reduce the length of the second stage of labor in pregnant women with singleton gestations undergoing an attempt at spontaneous vaginal delivery at term.

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Cesarean; episiotomy; meta-analysis; perineal laceration; review

Introduction

The second stage of labor begins when the cervix becomes fully dilated and ends with delivery of the neonate [1]. A longer duration of the second stage of labor is associated with adverse outcomes, including puerperal infection, perineal lacerations, and postpartum hemorrhage [1]. Several procedures have been studied to decrease the length of labor and specifically the length of the second stage of labor [1–7].

Vaginal application of lubricant gel during labor has been studied to shorten the length of labor [8–11]. The use of the lubricant gel could act against the friction forces that affect vaginal childbirth and reduce the length of the second stage of labor.

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However, the efficacy of this procedure is still the subject of debate.

The aim of this systematic review and meta-analysis of randomized controlled trials (RCTs) was to evaluate whether or not the use of lubricant during vaginal delivery decreases the length of the second stage of labor.

Materials and methods

Search strategy and selection criteria

This review was performed according to a protocol designed *a priori* and recommended for systematic review [1]. 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: "lubricant," "gel," "vaginal," "perineal," "support," "trauma," "randomized," "clinical trial," "randomized," and "clinical trial." No restrictions for language or geographic location were 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 (C.I.A., V.B.). Differences were discussed, and consensus reached.

We included all RCTs comparing the vaginal application of lubricant during labor (i.e. intervention group) with a control group (i.e. no lubricant) in women with singleton gestation and cephalic presentation at term undergoing an attempt at spontaneous vaginal delivery. RCTs including multiple gestations and quasi-randomized trials (i.e. trials in which allocation was done on the basis of a pseudorandom sequence, e.g. odd/even hospital number or date of birth, alternation) were excluded. Trials on other interventions that might impact second stage of labor (pushing methods, perineal massage, Ritgen's maneuver, etc.) were not included.

Data extraction and risk of bias assessment

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 [12].

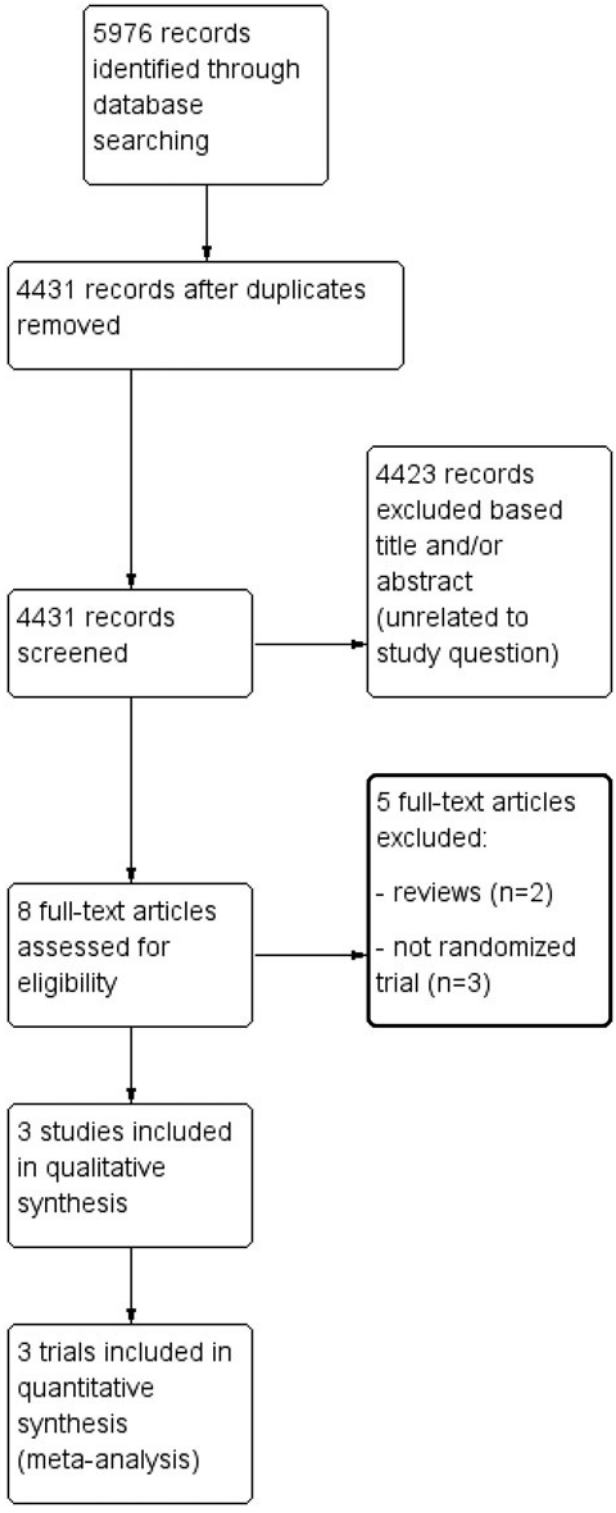

Figure 1. Flow diagram of studies identified in the systematic review. (Prisma template [preferred reporting item for systematic reviews and meta-analyses]).

Two authors (C.I.A., V.B.) 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.

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. Primary and secondary outcomes were defined before data extraction.

The primary outcome was the duration of the second stage of labor. The secondary outcomes were length of labor, perineal lacerations, mode of delivery, and neonatal outcomes.

Statistical analysis

The data analysis was completed independently by two authors (C.I.A., V.B.) 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

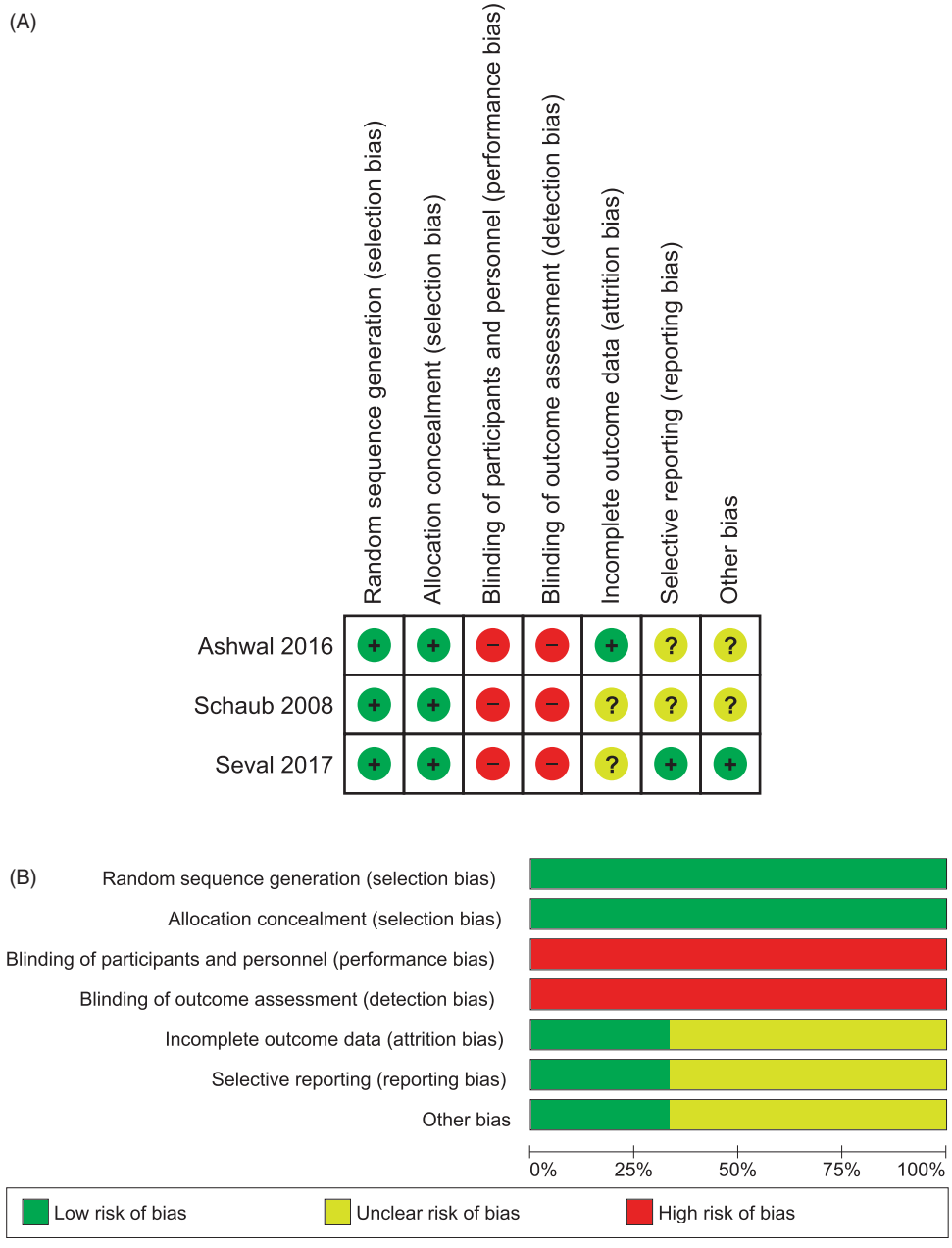

Figure 2. Assessment of risk bias. (A) Summary of risk of bias for each trial; Plus sign: low risk of bias; minus sign: high risk of bias. (B) Risk of bias graph about each risk of bias item presented as percentages across all included studies.

was assessed using the Higgins I^2 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 values $<.05$ were considered statistically significant.

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

Results

Three RCTs including 512 women evaluating the effect of lubricant application during labor were included in the meta-analysis (Figure 1) [9–11]. Publication bias, assessed using Begg's and Egger's test, was not significant ($p = .47$, and $p = .53$, respectively). The statistical heterogeneity between the trials was low with $I^2 = 38\%$ for the primary outcome.

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 (Figure 2).

All trials included pregnant women with singleton gestations in cephalic presentation at term undergoing spontaneous vaginal delivery. One trial included only nulliparous women, while the other two included both nulliparous and multiparous women (Table 1). For the calculation of main outcomes, on a total of 183 women (94 vs 89) in Schaub et al.'s study we considered only those who underwent spontaneous vaginal birth, that is 169 (86 vs 83) [9]. The same eligible criterion was applied to Ashwal et al.'s work: on a total of 200 parturients (100 vs 100), our evaluation was on 163 women (83 vs 80) [10], Table 4. None of the included trials reported on perineal techniques (e.g. perineal massage, warm compresses, hands-on, Ritgen maneuver, perineal devices) used during labor to decrease the risk of perineal tears.

Lubricant application started in the first stage before the active phase of labor was reached, and was done intermittently by the midwife or the physician. A sterile gel was applied into the vaginal canal manually or with an applicator. All trials used water-soluble gel. Two trials used Dianatal Gel® [13].

Dianatal gel® is an obstetric gel based on cross-linked polyacrylic acid, hydroxyethylcellulose and propylene glycol, free of preservatives. Both Dianatal gels

Table 1. Characteristics of the included studies.

	Location	*N* of subjects[a]	Parity	Age (year)	BMI	Gestational age at randomization (weeks)	Exclusion criteria
Schaub 2008 [9]	Switzerland	169 (86 vs 83)	Nulliparous	18–40	28.5 vs 29.1	37–42	Contraindications for vaginal delivery; amniotic infection; fetal distress; prolonged rupture of the membranes (>24 h); suspected fetal malformations; severe maternal disease; water births
Ashwal 2016 [10]	Israel	163 (83 vs 80)	Nulliparous and multiparous	18–40	Not reported	37–41	Known fetal chromosomal or structural anomalies, hypertensive or diabetes disorders, fetal growth restriction, macrosomia, chorioamnionitis, prolonged rupture of the membranes (>24 h)
Seval 2017 [11]	Turkey	180 (98 vs 82)	Nulliparous and multiparous	18–40	27.6 vs 27.8	37–41	Contraindications for vaginal delivery, known fetal chromosomal or structural abnormalities, fetal growth restriction, chorioamnionitis, rupture of membranes >24 h, macrosomia, high-risk pregnancies

[a]Data are presented as total number (number in the intervention vs number in the control group).

Table 2. Details of the intervention.

	Type of lubricant	When lubricant was applied (start and end)	Technique	Application	Quantity of lubricant	Frequency	Where applied
Schaub 2008 [9]	Dianatal Gel Stage 1 ®	Started in the first stage of labor (<4cm) and ended with the delivery of the newborn	Application of gel with fingers in the vagina	Manually, done by a midwife	3–5 mL of gel	Intermittent application into the birth canal during vaginal examination, maximum duration: 30 seconds	Vaginal canal
Ashwal 2016 [10]	Dianatal Gel Stage 1 ® and Stage 2 ®	Started in the first stage of labor (<4cm) and ended with the delivery of the newborn's head	Application of gel with fingers or with syringes in the vagina: Dianatal Stage 1® was applied first. At full cervical dilation, Dianatal Stage 2® was distributed	With or without syringes, done by a midwife or a physician	2–4 ml of gel	Intermittent application into the birth canal during hourly vaginal examination	Vaginal canal
Seval 2017 [11]	Obstetric gel	Started in the first stage of labor (<5cm) and ended with the delivery of the baby	Application of gel with two syringes in the first stage and of one syringe in the second stage	With syringes, done by an resident or an Attending	3–5 ml a	Intermittent application into the birth canal during vaginal examination every 2 h	Vaginal canal

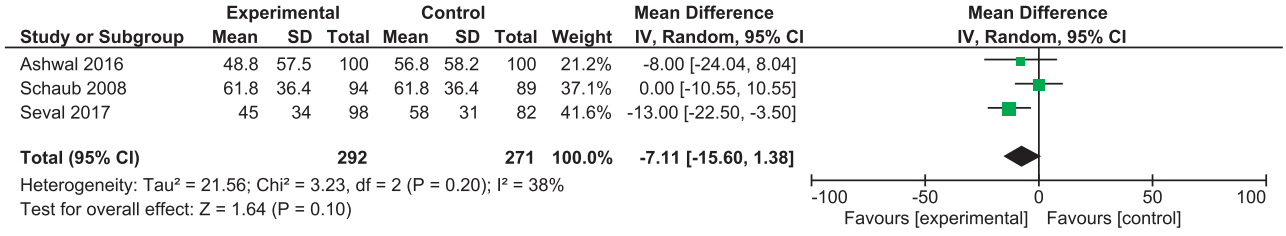

Figure 3. Forest plot for the risk of severe perineal trauma.

Table 3. Length of labor.

	Length of first stage (min)	Length of active phase of first stage (min)	Length second stage (min)[a]
Schaub 2008 [9]	186.3 ± 137.9 vs 208.9 ± 125.5	NR	61.8 ± 36.4 vs 88.1 ± 60.5
Ashwal 2016 [10]	NR	203.1 ± 157.1 vs 215.1 ± 219.5	48.8 ± 57.5 vs 56.8 ± 58.2
Seval 2017 [11]	NR	153 ± 78 vs 170 ± 104	45 ± 34 vs 58 ± 31
MD (95% CI)	−22.60 min (−60.77 to 15.57)	−15.95 min (−40.21 to 8.31)	−7.11 min (−15.60 to 1.38)
I^2	NA	0%	38%

Data are presented as number in the intervention vs number in the control group as mean difference ± standard deviation.
NA: not applicable; NR: not reported; MD: mean difference; CI: confidence interval.
[a]Primary outcome.

Stage 1 and Stage 2® are distributed by Happy Child Birth AG, Basel, Switzerland. These gels have the same ingredients (distilled water, propylene glycol, and carbomers), but in different quantities: i.e. gel A is composed of 76% distilled water and is of high viscosity (dynamic viscosity of 15 Pascal-second), while gel B is composed of 81% distilled water and is of low viscosity (dynamic viscosity of 5 Pascal-second). The ingredients of both gels also include thickening agents, but no preservatives [9–11].

In one RCT, researchers analyzed the effects of a sterile obstetric gel without a specific brand, but with these properties: high mucoadhesive activity, high viscosity, electric conductivity, and non-allergenicity. This gel contains propylene glycol, carmomer, hydroxyethyl cellulose, and purified water. It resulted safe for women and their children [11].

The quantity of gel used was about 2–5 ml for each vaginal examination (Table 2).

Table 4. Perineal lacerations and mode of delivery.

	Schaub 2008 [9]	Ashwal 2016 [10]	Seval 2017 [11]	Total	RR (95% CI)	I^2
Spontaneous vaginal delivery	86/86 (100%) vs 83/83 (100%)	83/83 (100%) vs 80/80 (100%)	77/98 (78.6%) vs 72/82 (87.8%)	246/267 (92.1%) vs 235/245 (95.2%)	0.98 (0.93 to 1.05)	89%
Operative delivery (cesarean, forceps, etc)	0/86 (0%) vs 0/83 (0%)	0/83 (0%) vs 0/80 (0%)	21/98 (21.4%) vs 10/82 (12.2%)	21/267 (7.9%) vs 10/245 (4.1%)	1.76 (0.88 to 3.52)	NA
Intact perineum	32/86 (37.2%) vs 19/83 (22.9%)	49/ 83 (59.0%) vs 54/80 (67.5%)	94/98 (95.9%) vs 71/82 (86.6%)	175/267 (65.5%) vs 144/245 (58.8%)	1.09 (0.86 to 1.38)	67%
Any degree lacerations	54/86 (62.8%) vs 64/83 (77.1%)	51/83 (61.5%%) vs 47/80 (58.7%)	63/98 (64.3%) vs 61/82 (74.4%)	168/267 (62.9%) vs 172/245 (70.2%)	0.89 (0.77 to 1.02)	19%
First-degree laceration	NR	22/83 (26.5%) vs 12/80 (15.0%)	NR	22/83 (26.5%) vs 12/80 (15.0%)	1.77 (0.94 to 3.33)	NA
Second-degree laceration	NR	12/83 (14.4) vs 14/80 (17.5)	NR	12/83 (14.4%) vs 14/80 (17.5%)	0.83 (0.41 to 1.68)	NA
Third-degree laceration	2/86 (2.3%) vs 0/83 (0%)	0/83 (0%) vs 0/80 (0%)	NR	2/169 (1.2%) vs 0/163 (0%)	4.83 (0.24 to 99.07)	NA
Fourth-degree laceration	0/86 (0%) vs 0/83 (0%)	0/83 (0%) vs 0/80 (0%)	NR	0/169 (0%) vs 0/163 (0%)	NA	NA
Episiotomy	24/86 (27.9%) vs 20/83 (24.1%)	17/83 (20.4%) vs 21/80 (26.2%)	59/98 (60.2%) vs 50/82 (60.9%)	100/267 (37.4%) vs 91/245 (37.1%)	0.98 (0.80 to 1.20)	0%

Data are presented as number in the intervention vs number in the control group.
NA: not applicable; NR: not reported; RR: relative risk; CI: confidence interval.

Table 5. Neonatal characteristics and outcomes.

	Birth weight (g)	Head circumference (cm)	Low cord pH*	Admission to NICU	Need for intubation
Schaub 2008 [9]	3433.7 ± 454.9 vs 3384.9 ± 388.1	34.9 ± 1.4 vs 35.1 ± 1.1	NR	0/86 (0%) vs 0/83 (0%)	0/86 (0%) vs 0/83 (0%)
Ashwal 2016 [10]	3341.3 ± 429.8 vs 3331.7 ± 444.5	NR	0/83 (0%) vs 0/80 (0%)	0/83 (0%) vs 0/80 (0%)	0/83 (0%) vs 0/80 (0%)
Seval 2017 [11]	3290 ± 380 vs 3388 ± 423	33.3 ± 4.3 vs 34.0 ± 1.5	NR	NR	NR
Total	–	–	0/83 (0%) vs 0/80 (0%)	0/169 (0%) vs 0/163 (0%)	0/169 (0%) vs 0/163 (0%)
RR or MD (95% CI)	−14.37 g (−100.87, 72.13)	−0.27 cm (−0.61, 0.07)	NA	NA	NA
I^2	35%	0%	NA	NA	NA

Data are presented as number in the intervention vs number in the control group.
NA: not applicable; NR: not reported; RR: relative risk; CI: confidence interval; MD: mean difference; NICU: neonatal intensive care unit.

There were no statistically significant differences comparing women who received lubricant gel during labor with those who did not in the length of second stage of labor (MD −7.11 min, 95% CI −15.60 to 1.38) (Figure 3), first stage of labor, and active phase of first stage of labor (Table 3). No between-group differences were noticed in the risk of perineal lacerations, mode of delivery, and in the neonatal outcomes (Tables 4 and 5).

Discussion

This meta-analysis of three RCTs, including 512 participants, showed that the use of lubricant gel during labor in pregnant women at term, did not reduce the length of the second stage of labor, and was not associated with reduced risk of perineal lacerations or improved neonatal outcomes.

Strengths and limitations

Our meta-analysis has several strengths. This study included all RCTs published so far on the topic. To our knowledge, no prior meta-analysis on this issue is as large, up-to-date, or comprehensive. The statistical heterogeneity within the studies in the primary outcome and in most of the secondary outcomes was low. The rigorous statistical approach is the major strength of the review.

Limitations of our study are inherent to the limitations of the included RCTs. The study is limited by the low number of the included trials and included women. Given the low number of included trials, performing subgroup analyses and sensitivity analyses were not feasible. All the trials had the length of the second stage of labor as primary outcome and therefore the meta-analysis was underpowered for the secondary outcomes, including perineal lacerations. Dianatal gel®, used in two of the three RCTs included, is not universally available.

Implications

The use of lubricant is an ancient practice, established today as a gold standard in veterinary medicine, but even promoted by the Greek Chiron to facilitate the delivery of a horse in the fourth century BC [14,15]. In a porcine model under mechanical conditions simulating human vaginal delivery, obstetric gel significantly reduced dynamic friction forces by 30–40% in comparison of distilled water, supporting the recommendation of using lubricant during childbirth [14,15].

Pelvic floor injury is a severe comorbidity of vaginal delivery and could be linked with several conditions as sexual dysfunction, pain, urinary, and fecal incontinence depending on the severity of the trauma [16–19]. Prolonged second stage is a very common risk factor for pelvic floor injury in both nulliparous and multiparous [18,19].

Several procedures have been studied to decrease the impact of perineal trauma at delivery, reduce the blood loss after delivery, and to shorten the length of labor with the aim of improving obstetric outcomes [2–4,20–24]. The effects of the use of lubricant have been unclear and is still subject of debate. The lubricant is a substance introduced to reduce friction, applied on the perineal area and/or in the vaginal canal with or without an applicator. Gel could work through a purely physical effect, reducing the opposite force to vaginal childbirth. Our meta-analysis provides evidence that the use of lubricant gel during labor does not reduce the length of labor or improve maternal or neonatal outcomes. Given trends for shorter labor (Table 3), more research is needed.

Conclusions

In summary, vaginal application of lubricant during labor does not reduce as studied up-to-date the length of the second stage of labor in pregnant women with singleton gestations undergoing an attempt at spontaneous vaginal delivery at term.

Disclosure statement

No potential conflict of interests was reported by the authors.

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