OBSTETRICS

Induction of labor at full term in uncomplicated singleton gestations: a systematic review and metaanalysis of randomized controlled trials

Gabriele Saccone, MD; Vincenzo Berghella, MD

The aim of this study was to evaluate the risk of cesarean and any maternal and perinatal effects of a policy induction of labor in uncomplicated full-term singleton gestations. Searches were performed in an electronic database with the use of a combination of text words related to "induction" and "cesarean section" from inception of each database through December 2014. We included all randomized controlled trials of uncomplicated singleton gestations at full term (ie, between 39 weeks 0/7 days and 40 weeks 6/7 days) with intact membranes randomized to induction of labor or control (ie, expectant management). The primary outcome was the incidence of cesarean delivery. The summary measures were reported as risk ratio (RR) with 95% confidence interval (CI). Five randomized controlled trials, including 844 women, were analyzed. Full-term vertex singleton gestations receiving induction of labor had similar incidence of cesarean delivery compared to controls (9.7% vs 7.5%; RR, 1.25; 95% CI, 0.75−2.08). Rates of spontaneous (75.9% vs 80.2%; RR, 0.95; 95% CI, 0.87−1.02) and operative (13.1% vs 10.6%; RR, 1.22; 95% CI, 0.83−1.81) vaginal delivery were also similar. Induction was associated with similar rates of chorioamnionitis (9.6% vs 8.0%; RR, 1.17; 95% CI, 0.38−3.39), but statistically significantly less blood loss (mean difference −57.59 mL; 95% CI, −83.96 to −31.21) compared to controls. Regarding neonatal outcomes, induction was associated with a significantly lower rate of meconium-stained amniotic fluid (4.0% vs 13.5%; RR, 0.32; 95% CI, 0.18−0.57) and significantly lower mean birthweight (mean difference −135.51 g; 95% CI, −205.24 to −65.77) compared to control group. Induction of labor at full term in uncomplicated singleton gestations is not associated with increased risk of cesarean delivery and has overall similar outcomes compared to expectant management.

Key words: cesarean delivery, induction, labor

Data have shown that the lowest incidence of perinatal morbidity and mortality occurs around 39-40 weeks.[1] As perinatal morbidity and mortality rates are higher during the early-term period (37^0-38^6 weeks) compared with those delivered at ≥39 weeks, the American Congress of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine have recommended against nonmedically indicated deliveries <39 weeks.[2] Instead, perinatal mortality starts to increase again with late term (41^0-41^6 weeks) and postterm (≥42 weeks) pregnancies.[3]

Therefore, some have advocated induction of even uncomplicated singleton gestations once they reach full term (39^0-40^6 weeks).[4-8] Opponents of such a policy have remarked that induction has often been associated in observational studies with an increased risk of cesarean delivery.[9-12] Recently though, several randomized controlled trials (RCTs) of term or near-term pregnancies with indications for induction have shown that induction is not associated with an increased risk of cesarean, and is instead associated with some maternal and perinatal benefits.[13-15]

The aim of this study was to evaluate the risk of cesarean and any maternal and perinatal effects of a policy induction of labor in full-term asymptomatic and uncomplicated singleton gestations.

Materials and methods

Eligibility criteria

The research protocol was designed a priori. We performed electronic research in OVID (ie, LWW Health Library and Maternity and Infant Care), Scopus, ClinicalTrials.gov, MEDLINE, the PROSPERO International Prospective Register of Systematic Reviews, EMBASE, and the Cochrane Central Register of Controlled Trials with the use of a combination of text words related to "induction," "cesarean section," "cesarean," "expectant management," and "pregnancy" from inception of each database through December 2014. All results were then limited to "clinical trial." No restrictions for language or geographic location were applied.

Study selection

We included all RCTs of asymptomatic and uncomplicated singleton gestations at full term (ie, between 39^0 and 40^6

From the Department of Neuroscience, Reproductive Sciences and Dentistry, School of Medicine, University of Naples Federico II, Naples, Italy (Dr Saccone); and Department of Obstetrics and Gynecology, Division of Maternal-Fetal Medicine, Sidney Kimmel Medical College of Thomas Jefferson University, Philadelphia, PA (Dr Berghella).

Received Jan. 11, 2015; revised March 17, 2015; accepted April 6, 2015.

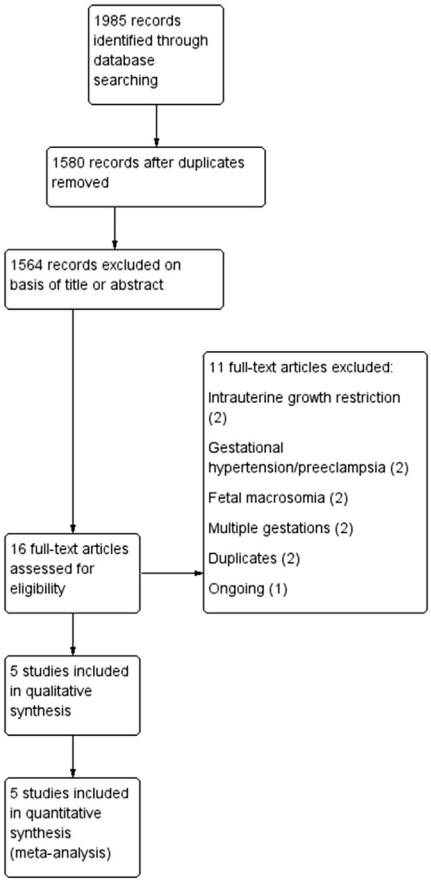
The authors report no conflict of interest.

Corresponding author: Vincenzo Berghella, MD. vincenzo.berghella@jefferson.edu

0002-9378/$36.00

http://dx.doi.org/10.1016/j.ajog.2015.04.004

FIGURE 1
Flow diagram of studies identified in systematic review



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weeks) with intact membranes randomized to induction of labor or control (ie, expectant management).

Only trials on asymptomatic singleton gestations without premature rupture of membranes or any other indications for induction evaluating the efficacy of induction of labor in full-term singleton gestations were included. Exclusion criteria included quasirandomized trials, and trials in women with premature rupture of membranes, with indication for induction (ie, intrauterine growth restriction, diabetes, gestational hypertension/preeclampsia, oligohydramnios, fetal macrosomia), and with multiple gestations.

The metaanalysis was reported following the Preferred Reporting Item for Systematic Reviews and Metaanalyses (PRISMA) statement.[16] Before data extraction, the review was registered with the PROSPERO International Prospective Register of Systematic Reviews (registration no. CRD42014014261).

Data abstraction

Data abstraction was completed by 2 independent investigators (G.S., V.B.). Each investigator independently abstracted data from each study and analyzed data separately. 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. The primary outcome was the incidence of cesarean delivery. Secondary outcome included spontaneous vaginal delivery, operative vaginal delivery (forceps or vacuum), chorioamnionitis, postpartum blood loss, and neonatal outcomes including meconium-stained amniotic fluid (MSAF), Apgar score <7 at 5 minutes, birthweight, admission to neonatal intensive care unit (NICU), and perinatal death. For studies that did not stratify data, composite data were extracted. All authors were contacted for missing data. We planned subgroup analyses in women with favorable cervix, in nulliparous women only, in women who received induction between 39^0 and 39^6, and in women with a previous cesarean delivery.

The risk of bias in each included study was assessed by using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions.[17]

Data analysis

The data analysis was completed independently by the authors using Review Manager 5.3 (2014; The Nordic Cochrane Centre, Cochrane Collaboration, Copenhagen, Denmark). The completed analyses were then compared, and any difference was resolved with review of the entire data. Statistical heterogeneity between studies was assessed using the Cochrane Q statistics and Higgins I^2 statistics.[17] In case of statistically significant heterogeneity, the random effects model of DerSimonian and Laird was used to obtain the pooled risk ratio (RR) estimate, otherwise a fixed effect model was planned.[17] The summary measures were reported as RR with 95% confidence interval (CI).[17] P value $< .05$ was considered statistically significant. This study had no funding source.

Results

Study selection and study characteristics

We initially identified 16 RCTs evaluating the efficacy of induction in full-term gestations.[4-8,13-15,18-25] Eleven studies were excluded.[13-15,18-25] Five RCTs that met inclusion criteria for this metaanalysis were analyzed.[4-8] Figure 1 shows the flow diagram (PRISMA template) of information through the different phases of the review. Two authors provided unpublished data from their trials.[7,8]

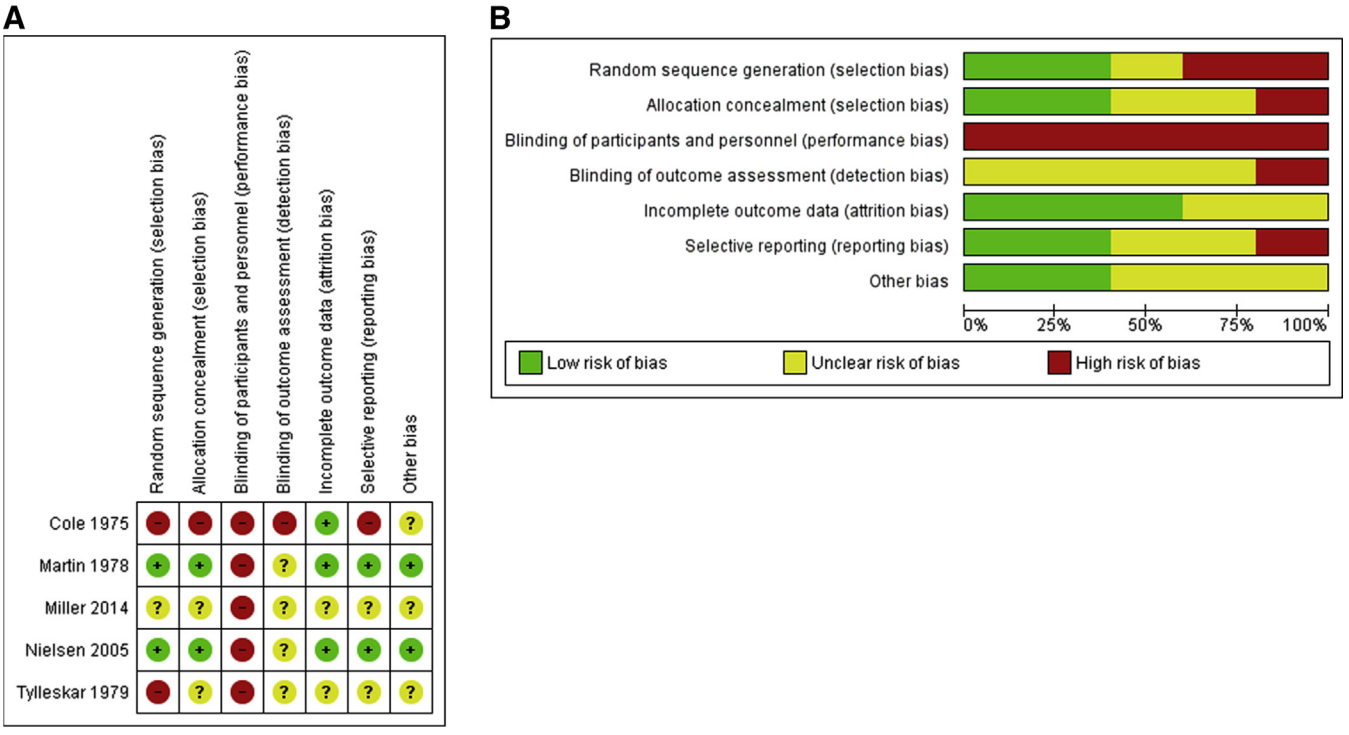
Most studies had a low risk of bias in selective reporting and incomplete outcome data according with the Cochrane Collaboration tool.[16] No study was double-blind because this was deemed difficult methodologically given the intervention (Figure 2).

The characteristics of the 5 included trials are summarized in Table 1. Of the 884 women, 444 (50%) were randomized to induction group and 440 (50%) to control. All studies enrolled only uncomplicated full-term vertex singleton gestations.[4-8] Two studies enrolled only women with favorable cervix defined as a Bishop score of ≥5 in nulliparous or ≥4 in multiparous patients.[6,7] Only 1 study reported separate data in nulliparous and multiparous women.[6] No studies reported data about prior cesarean delivery.

Synthesis of results

Uncomplicated full-term singleton gestations receiving induction of labor had similar incidence of cesarean delivery compared to controls (9.7% vs 7.5%; RR, 1.25; 95% CI, 0.75−2.08) (Figure 3 and Table 2). Rates of spontaneous (75.9% vs 80.2%; RR, 0.95; 95% CI, 0.87−1.02) and operative (13.1% vs 10.6%; RR, 1.22; 95% CI, 0.83−1.81) vaginal delivery were also similar.

FIGURE 2
Assessment of risk of bias



A, Summary of risk of bias for each trial. **B**, Risk of bias graph about each risk of bias item presented as percentages across all included studies.

Cole[4]; Martin[5]; Tylleskar[6]; Nielsen[7]; Miller.[8]

+, low risk of bias; −, high risk of bias; ?, unclear risk of bias.

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Induction was associated with similar rates of chorioamnionitis (9.6% vs 8.0%; RR, 1.17; 95% CI, 0.38−3.39), but significantly less blood loss (mean difference −57.59 mL; 95% CI, −83.96 to −31.21) (Figure 4) compared to controls. Regarding neonatal outcomes, induction was associated with a significantly lower rate of MSAF (4.0% vs 13.5%; RR, 0.32; 95% CI, 0.18−0.57) (Figure 5 and Table 2), and significantly lower mean birthweight (mean difference −135.51 g; 95% CI, −205.24 to −65.77) compared to control group. There were no differences in other adverse neonatal outcomes, including Apgar <7 at 5 minutes, NICU admission, and perinatal death, between the 2 groups (Table 2).

Table 3 shows the results for primary outcome in the subgroup analyses. We found no differences in the rate of cesarean delivery in women with favorable cervix, in nulliparous women, and in women who received induction between 39^0 and 39^6 weeks (Table 3). No study stratified data by previous cesarean delivery. Since no studies stratified data for multiparous women with favorable cervices, this subgroup analysis was not feasible.

Comment

Main findings

This metaanalysis of the 5 RCTs evaluating full-term (39^0-40^6 weeks) uncomplicated vertex singleton gestations shows that induction of labor is not associated with an increased risk of cesarean delivery compared to controls expectantly managed at least until ≥41 weeks. Furthermore, induction of labor was associated with a significantly lower blood loss, albeit of only 58 mL, and significantly lower rate of MSAF. Although induction was associated with lower birthweight, a mean difference of about 136 g at full term is probably not clinically significant, and we found no differences in adverse neonatal outcomes, including Apgar <7 at 5 minutes, NICU, and perinatal death, between intervention and control groups.

Comparison with existing literature

Two other metaanalyses have addressed induction of labor and cesarean delivery.[26,27] Both included women with indications for induction, such as intrauterine growth restriction, hypertensive complications, or ≥41 weeks.[26,27] Both showed not only no increase in cesarean delivery, but in fact a significant decrease in the incidence of cesarean. However, there were concerns about the translation of these findings into actual practice due to a type II error and due to a high heterogeneity between the studies, thus both reviews called for future research.[26,27] Another recent review showed that the risk of cesarean delivery was lower among women whose

TABLE 1
Characteristics of included studies

Characteristic	Cole et al,[4] 1975	Martin et al,[5] 1978	Tylleskar et al,[6] 1979	Nielsen et al,[7] 2005	Miller et al,[8] 2014
Location	United Kingdom	United Kingdom	Sweden	United States	United States
Sample size, n (induction/control)	228 (111/117)	184 (92/92)	84 (43/41)	226 (116/110)	162 (82/80)
Inclusion criteria	Singleton, uncomplicated	Singleton, uncomplicated	Singleton, uncomplicated, favorable cervix	Singleton, uncomplicated, favorable cervix	Singleton, uncomplicated, nulliparous, unfavorable cervix
Range GA at randomization, wk	39^0–40^6	38^0–38^6	40^0–40^6	38^0–38^6	38^0–38^6
Range GA at induction, wk	39^0–40^6	39^0–39^6	40^0–40^6	39^0–39^6	39^0–39^6
Induction method	AROM, oxytocin	AROM, oxytocin	AROM, oxytocin	AROM, oxytocin	Misoprostol followed by Foley bulb and oxytocin, or Foley bulb and oxytocin
Control group	Expectant management and possible induction at 41 wk	Expectant management and possible induction at 42 wk	Expectant management	Expectant management and possible induction at 42 wk	Expectant management
Study primary outcomes	Meconium staining	Serum bilirubin levels, meconium staining	N/R	Cesarean delivery	Cesarean delivery

AROM, artificial rupture of membranes; *GA*, gestational age; *N/R*, not reported.

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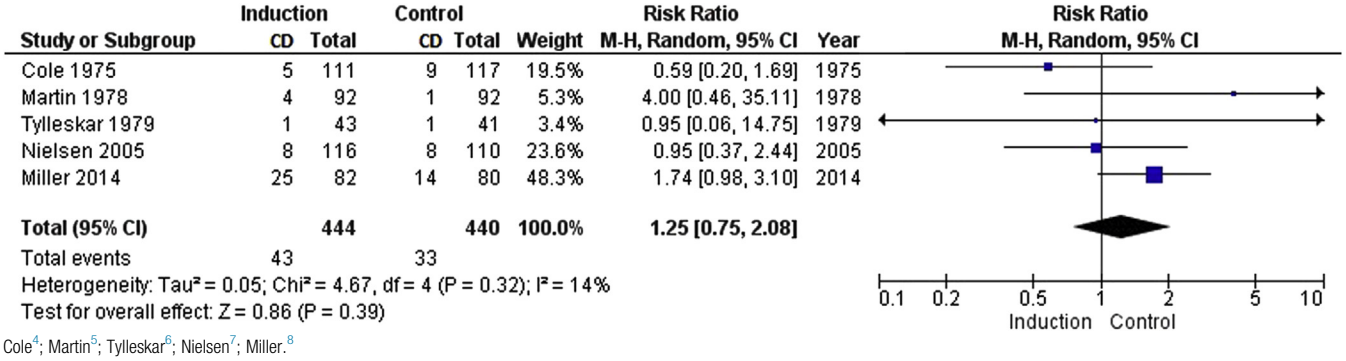
labor was induced than among those managed expectantly in term and postterm gestations.[28] That study included all RCTs in women at near term, early term, full term, and postterm with and without medical indication for induction.[28] Instead, we included only women at full term with no medical indication for induction. No other prior meta-analysis included only full-term singleton uncomplicated pregnancies without indications for induction.

Some have referred to inductions without an indication at term as "elective," but we prefer avoiding the use of this term, as it lacks as the necessary scientific specificity.[29] We instead prefer to always document the specific indication (whether medical or nonmedical) for the intervention or procedure. In this case, "induction for full-term gestation" could be used. If no indication is present, the term "elective" should still be avoided, and instead "nonmedically indicated induction" could be used.

Strengths and limitations

One of the strengths of our study is the inclusion of RCT data on induction of pregnancy in a specific population, ie,

FIGURE 3
Forest plot for cesarean delivery



Cole[4]; Martin[5]; Tylleskar[6]; Nielsen[7]; Miller.[8]

CD, cesarean delivery; *CI*, confidence interval; *M-H*, Mantel-Haenszel.

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TABLE 2
Primary and secondary outcomes of included studies

Variable	Cole et al,[4] 1975	Martin et al,[5] 1978	Tylleskar et al,[6] 1979	Nielsen et al,[7] 2005	Miller et al,[8] 2014	Total	RR (95% CI)
Cesarean delivery	5/111 (4.5%) vs 9/117 (7.7%)	4/92 (4.3%) vs 1/92 (1.1%)	1/43 (2.3%) vs 1/41 (2.4%)	8/116 (6.7%) vs 8/110 (7.8%)	25/82 (30.5%) vs 14/80 (17.5%)	43/444 (9.7%) vs 33/440 (7.5%)	1.25 (0.75–2.08)
SVD	72/111 (64.7%) vs 82/117 (70.1%)	N/R	41/43 (95%) vs 38/41 (92.7%)	100/116 (86.2%) vs 93/110 (84.5%)	54/82 (65.9%) vs 66/80 (82.5%)	267/352 (75.9%) vs 279/348 (80.2%)	0.95 (0.87–1.02)
Operative vaginal delivery[a]	34/111 (30.6%) vs 26/117 (22.2%)	N/R	1/43 (2.3%) vs 2/41 (4.9%)	8/116 (6.9%) vs 9/110 (8.2%)	3/82 (3.7%) vs 0/80	46/352 (13.1%) vs 37/348 (10.6%)	1.22 (0.83–1.81)
Chorioamnionitis	N/R	N/R	N/R	7/116 (6.0%) vs 6/110 (5.5%)	12/82 (14.6%) vs 9/80 (11.3%)	19/198 (9.6%) vs 15/190 (8.0%)	1.17 (0.38–3.39)
Mean blood loss, mL	185 vs 233	N/R	N/R	303 vs 312	754 vs 900	—	Mean difference −57.59 mL (−83.96 to −31.21)[b]
Meconium-stained amniotic fluid	1/111 (0.9%) vs 13/117 (11.1%)	3/92 (3.3%) vs 13/92 (14.1%)	N/R	6/116 (5.2%) vs 11/110 (10%)	6/82 (7.3%) vs 17/80 (21.3%)	16/401 (4.0%) vs 54/399 (13.5%)	0.32 (0.18–0.57)[b]
Apgar <7 at 5 min	N/R	N/R	N/R	0/116 vs 0/110	0/82 vs 1/80	0/198 (0%) vs 1/190 (0.5%)	0.33 (0.01–7.87)
Mean birthweight, g	3250 vs 3390	N/A	3638 vs 3720	3459 vs 3604	3401 vs 3513	—	Mean difference −135.51 (−205.24 to −65.77)[b]
NICU admission	N/R	N/R	N/R	0/116 vs 0/110	5/82 (6.1%) vs 5/80 (6.3%)	5/198 (3.0%) vs 5/190 (2.6%)	0.98 (0.47–2.04)
Perinatal death	0/111 vs 1/117 (0.9%)	0/92 vs 1/92 (1.1%)	N/R	0/116 vs 0/110	0/82 vs 0/80	0/401 (0%) vs 2/399 (0.5%)	0.35 (0.04–3.37)

Data are presented as n induction vs n control (percentage).

CI, confidence interval; *NICU*, neonatal intensive care unit; *N/R*, not reported; *RR*, risk ratio; *SVD*, spontaneous vaginal delivery.

[a] Forces or vacuum; [b] Statistically significant.

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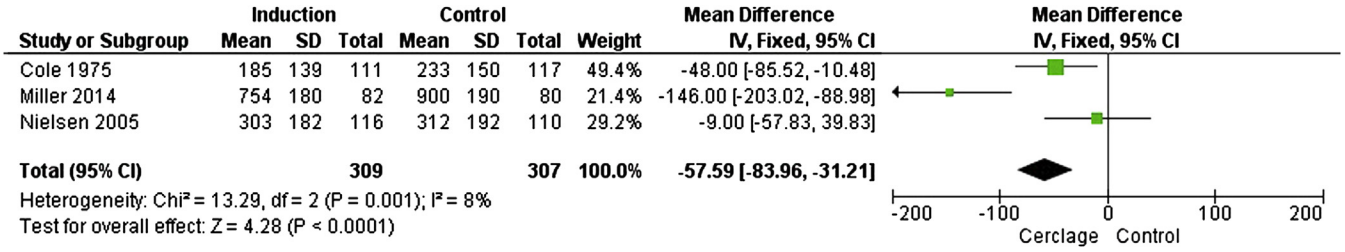
FIGURE 4
Forest plot for blood loss



Cole[4]; Nielsen[7]; Miller.[8]

CI, confidence interval.

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asymptomatic and uncomplicated singletons at full term. Furthermore, most of the included RCTs were at low risk of bias according to the Cochrane risk of bias tool, and the number of women analyzed was high. The risk of publication bias was assessed by visual inspection of funnel plot and the symmetric plot suggested no publication bias (Figure 6). Two authors provided additional data from their trials.[7,8] Our study included both nulliparous and multiparous women, and we performed in addition a subgroup analysis in only nulliparous women.

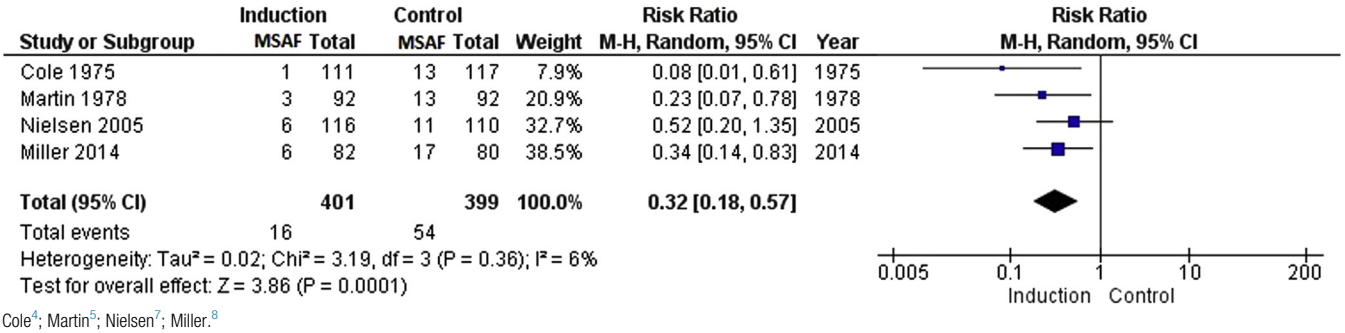
Limitations of our study are inherent to the limitations of the included RCTs. Only 2 of the included RCTs had cesarean delivery as primary outcome. No long-term outcomes were reported in any of the trials. The overall rate of cesarean is slightly less than expected, and this raises the question of external generalizability to the current US population. Even with a summary estimate from 5 well-designed RCTs, the ability to discern differences in important clinical outcomes was impaired by a type II error. The number of included women in subgroup analyses was low, and so these comparisons were underpowered. This may be particularly important to point out for the nulliparous population (n = 200), where there is the most controversy regarding induction without medical indication (Table 3).

Conclusions and implications

Induction of labor in asymptomatic and uncomplicated singleton gestations at full term (39^0-40^6 weeks) is not associated with increased risk of cesarean delivery and has overall similar outcomes compared to expectant management, with some significant maternal (less blood loss) and perinatal (lower risk of MSAF) benefits. MSAF is associated with an increased risk of adverse fetal outcomes including meconium aspiration syndrome (MAS), cerebral palsy, seizure, and pulmonary disease.[30-32] MAS occurs in 5% of the cases of MSAF and >4% of infants with MAS die, accounting for 2% of perinatal deaths.[33,34] Furthermore, earlier delivery is associated with higher women's satisfaction.[35] However, given the limitations of power, a firm conclusion could not be drawn.

Larger properly powered trials are needed, particularly in nulliparous women. We observed that with an α of 0.05 and 80% power, a sample size of 2000 women is required to detect an

FIGURE 5
Forest plot for meconium-stained amniotic fluid



Cole[4]; Martin[5]; Nielsen[7]; Miller.[8]

CI, confidence interval; *M-H*, Mantel-Haenszel; *MSAF*, meconium-stained amniotic fluid.

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TABLE 3
Primary outcome (incidence of cesarean delivery) in subgroup analyses

Population	Outcome	Included studies	Total	RR (95% CI)
Favorable cervix	Cesarean delivery	Tyllerskar 1979[6] Nielsen 2005[7]	9/159 (5.7%) vs 9/151 (6.0%)	0.95 (0.39–2.32)
Nulliparous women	Cesarean delivery	Tylleskar 1979[6] Miller 2014[8]	26/102 (25.5%) vs 15/98 (15.3%)	1.67 (0.94–2.95)
Induction 39^0–39^6	Cesarean delivery	Martin 1978[5] Nielsen 2005[7] Miller 2014[8]	37/290 (12.8%) vs 23/282 (8.2%)	1.55 (0.96–2.51)

CI, confidence interval; *RR*, risk ratio.

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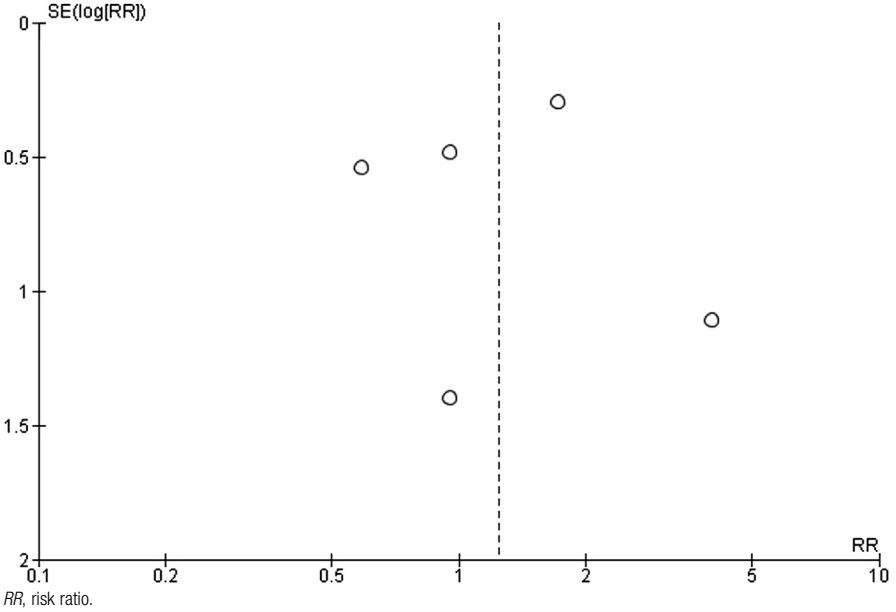
FIGURE 6
Funnel plot assessing publication bias



RR, risk ratio.

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increase in cesarean from 7.5-9.7%. We eagerly await results of the ongoing *Eunice Kennedy Shriver* National Institute of Child Health and Human Development trial.[36] ■

ACKNOWLEDGMENTS

We thank Dr Nielsen and Dr Miller for providing additional unpublished data from their trials.

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