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AOGS SYSTEMATIC REVIEW

Increased single-balloon Foley catheter volume for induction of labor and time to delivery: a systematic review and meta-analysis

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Key words
Cervical ripening, Foley balloon, Foley catheter, labor induction, volume

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Conflict of interest
The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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Abstract

Introduction. Induction of labor is a common intervention. The objective was to investigate whether larger Foley catheter volumes for labor induction decrease the total time from induction to delivery. *Material and methods.* Randomized controlled trials comparing larger single-balloon volumes (60–80 mL) during Foley catheter cervical ripening with usual volume (30 mL) in women undergoing labor induction were identified by searching electronic databases (MEDLINE, Scopus, ClinicalTrials.gov, PROSPERO, EMBASE, Scielo and the Cochrane Central Register of Controlled Trials) from inception through 2017. The primary outcome was mean time from induction to delivery in hours. Secondary outcomes included time from induction to vaginal delivery, delivery within 24 h, time to Foley expulsion, cesarean section, chorioamnionitis, epidural use, hemorrhage, meconium staining, and neonatal intensive care unit admission. Meta-analysis was performed using the random effects model of DerSimonian and Laird (PROSPERO CRD42017058885). *Results.* Seven randomized controlled trials including 1432 singleton gestations were included in the systematic review. Women randomized to larger volumes of balloon had a significantly shorter time from induction to delivery (mean difference 1.97 h, 95% CI −3.88 to −0.06). There was no difference in cesarean section between groups (16 vs. 18%, relative risk 0.84, 95% CI 0.6–1.17). A larger balloon volume was associated with a nonsignificant decrease in time from induction to delivery in multiparous (mean difference 2.67 h, 95% CI −6.1 to 0.76) and nulliparous women (mean difference 1.82 h, 95% CI −4.16 to 0.53). *Conclusion.* Balloon volumes larger than 30 mL during Foley catheter induction reduce total time to delivery by approximately 2 h.

Abbreviations: CI, confidence interval; MD, mean difference; RCT, randomized controlled trials.

Introduction

Labor induction occurs in one in five pregnant women in the USA, and rates have increased over the past several decades (1). The Foley catheter is a useful means for cervical ripening due to its safety profile; however, there are several variations in how this method can be employed (2,3). A commonly used technique is to overinflate Foley catheter balloons or to use balloons that will accommodate larger volumes to decrease time to delivery and cause a faster change in Bishop score (4). Although this is used in many trials assessing obstetric outcomes for Foley catheter labor induction, data regarding the utility of this practice are mixed. The aim of this systematic review and meta-analysis of randomized controlled trials (RCTs) was to investigate whether the use of larger balloon volumes during single-balloon Foley catheter cervical ripening decreases total time from induction to delivery.

Material and methods

Sources

The review protocol was established by two investigators (C.S., V.B.) prior to commencement and was registered with the PROSPERO International Prospective Register of Systematic Reviews (registration No. CRD42017058885) before data extraction. Registration occurred prior to electronic literature search or data extraction.

Three authors (C.S., G.S., V.B.) identified trials by independently searching the electronic databases (MEDLINE, Scopus, ClinicalTrials.gov, the PROSPERO International Prospective Register of Systematic Reviews, EMBASE, SciELO and the Cochrane Central Register of Controlled Trials) with the use of a combination of text words: "Foley catheter," "Foley balloon", "induction of labor", "labor induction", "cervical ripening", "volume", "size", and "mL" from inception of each databases until April 2017. No language restrictions were used. Further hand-searching of bibliographies in published trials was performed to identify any missed studies. The full search strategy can be found in Supporting Information Appendix S1. Authors were contacted for any trials identified in abstract form or clinical trial registry to assess appropriateness for inclusion in the meta-analysis. Four trial authors responded (5–8), and three provided additional unpublished data and collaboration in the meta-analysis (5,7,8).

Study selection

RCTs comparing larger volumes of single-balloon Foley catheters during cervical ripening (i.e. intervention group) with standard volumes (30 mL) (i.e. comparison group) in women undergoing induction of labor at >24 weeks were included, with the intention to stratify results should many trials include preterm gestations. All catheter material types (i.e. latex, silicone), French sizes and catheter balloon sizes were included. Balloons that were inflated over the manufacturer's recommended limit were also included in the analysis. Double-balloon catheters were not included due to the potential for a different or supplemental mechanism of action with the addition of a vaginal balloon.

Data extraction

Two authors (C.S., G.S.) independently assessed inclusion criteria, risk of bias and data extraction. Disagreements were resolved by discussion with a third reviewer (V.B.). Data from each eligible study were extracted without modification of original data onto custom-made data collection forms. Differences were reviewed and resolved by common review of the entire process. Data not presented in the original publications were requested from the principal investigators. Data presented as median and interquartile range in original articles was recalculated to mean and standard deviation using original trial data by the respective trial authors.

Assessment of risk of bias

The risk of bias in each included study was assessed using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (9). 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: (i) random sequence generation; (ii) allocation concealment; (iii) blinding of participants and personnel; (iv) blinding of outcome assessment; (v) incomplete outcome data; (vi) selective reporting; and (vii) other bias. Review authors' judgments were categorized as "low risk", "high risk" or "unclear risk" of bias (9).

Data synthesis

Primary and secondary outcomes were defined before data extraction. The primary outcome was the mean time

Key Message

Larger volumes of Foley catheters for cervical ripening decrease the total time from induction to delivery. This may be preferable for women undergoing labor induction and could impact complications associated with prolonged labor induction.

from induction to delivery, defined as time from balloon insertion to delivery in hours. Secondary outcomes included time from induction to vaginal delivery, delivery within 24 h, time from Foley insertion to expulsion, cesarean section, chorioamnionitis, endometritis, maternal discomfort, epidural use, postpartum hemorrhage (defined as blood loss >500 mL within 24 h of delivery), meconium staining and neonatal intensive care unit admission. We planned to assess the primary outcome (i.e. time to delivery) in planned subgroup analyses classifying whole trials by interaction tests as described by the *Cochrane Handbook for Systematic Review of Interventions* (9). The subgroup analyses planned to assess the primary outcome by volume used and by parity.

The data analysis was completed independently by two authors (G.S., C.S.) using Review Manager 5.3 2014 (The Nordic Cochrane Center, Cochrane Collaboration, Copenhagen, Denmark) (9). The completed analyses were then compared and any differences resolved by review of the entire data and independent analysis.

Meta-analysis was performed using the random effects model of DerSimonian and Laird, to produce summary treatment effects in terms of mean difference (MD) or relative risk with 95% confidence interval (95% CI). Heterogeneity was measured Higgins I^2.

Potential publication biases were assessed statistically using Begg's and Egger's tests.

The meta-analysis was reported following the Preferred Reporting Item for Systematic Reviews and Meta-analyses (PRISMA) statement (10).

Results

Study selection

The study identification flow diagram is shown in Figure 1. Seven RCTs (n = 1432) were identified as relevant and included in the systematic review (5–8,11–13). Publication bias, assessed statistically by using Begg's and Egger's tests, showed no significant bias (p = 0.37 and p = 0.32, respectively). Three authors provided additional unpublished data from their trials (7,8,12). One author kindly provided the entire database from the original trial (5).

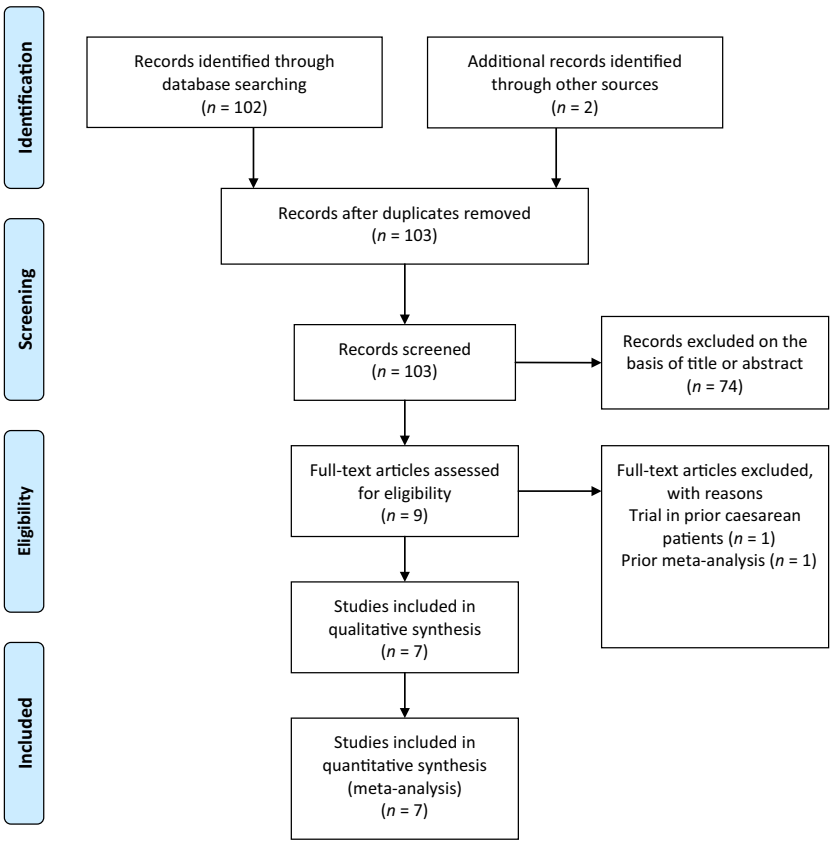

Figure 1. Flow diagram of studies identified in the systematic review [PRISMA template (Preferred Reporting Item for Systematic Reviews and Meta-analyses)]. [Color figure can be viewed at wileyonlinelibrary.com].

Study characteristics

The study by Kashanian et al. (11) was a three-arm RCT. One arm, including oxytocin alone without any balloon, was not considered in this meta-analysis (11). In Gu et al. women were randomly allocated in 1:1:1:1 ratio to receive one of the four treatments: (1) 30-mL balloon for a maximum of 12 h; (2) 30-mL balloon for a maximum of 24 h; (3) 80-mL balloon for a maximum of 12 h; (4) 80-mL balloon for a maximum of 24 h (8). For this meta-analysis Gu et al. was considered as two trials: the 24-h arms (i.e. study A) and the 12-h arms (i.e. study B) (Table 1).

All studies included only singleton gestations at term with cephalic presentation and with intact membranes at the time of admission for the induction of labor (Table 1). Regarding the intervention group, three RCTs used balloons inflated to 80 mL (6,8,11) and four used balloons inflated to 60 mL (5,7,12,13). All trials used the balloon inflated to 30 mL as the comparison group. Balloons were removed after 12 or 24 h or until spontaneous expulsion (Table 2). The balloons were overinflated in the intervention arm in four trials (5–7,12), with only one trial reporting Foley balloon rupture in 12 cases (14% rupture rate) (7). There were no maternal or neonatal adverse events reported as a result of the ruptured balloons. The balloon size was not specified in two additional trials, but no specific ruptures were reported, and the authors could not be reached for confirmation (11,13). The authors of the remaining trials confirmed that the overinflation did not result in Foley balloon rupture (0 of 238 large-volume balloons) (5,6,8,12). Sandberg et al. routinely performed amniotomy after expulsion of the balloon if the Bishop score was considered favorable (>6), otherwise a second Foley catheter was placed (Table 2) (7). Oxytocin infusion was started as needed for augmentation in all of the studies except Delaney et al. (5), where oxytocin was routinely started after the insertion of the Foley balloon (Table 1). As only one study started oxytocin infusion with Foley initiation, a sensitivity analysis to account for oxytocin timing was not performed.

Risk of bias of included studies

The overall risk of bias was low. All studies had low risk of bias in "random sequence generation" and used opaque randomized envelopes. In four trials (5,7,8,11), the randomization sequence was computer-generated by a statistician. Adequate methods for allocation of women were used in all the trials. No women were lost to follow up in any trial (Figure 2).

Synthesis of results

Table 3 and Supporting Information Table S1 show primary and secondary outcomes. Women randomized to larger (either 60 or 80 mL) inflation volumes of balloons had a shorter time from induction to delivery compared with the 30-mL inflation volume (MD −1.97 h, 95% CI −3.88 to 0.06; Figure 3). There was a moderate level of heterogeneity in the studies regarding the primary outcomes (I^2 = 75%). No significant differences were seen in the secondary outcomes, including time to vaginal delivery (MD −1.62 h, 95% CI −3.54 to 0.31), cesarean section (16 vs. 18%, relative risk 0.84, 95% CI 0.60–1.17) (Figure 4), time to Foley expulsion (MD 0.23 h, 95% CI −0.53 to 0.98), or epidural analgesia use (47% vs. 51%, relative risk 0.94, 95% CI 0.87–1.01). There were no differences in maternal and fetal complications reported but not all studies consistently reported the prespecified secondary outcomes. Endometritis and maternal discomfort could not be assessed. Maternal pain was reported in only one trial but was only reported for the intervention group, so it was not assessed (13).

Supporting Information Table S2 shows subgroup analyses for the primary outcome. Compared with the 30-mL balloon, the 60-mL volume decreased the total time to delivery by almost 4 h (MD −3.9 h, 95% CI −5.63 to −2.17). However, compared with 30 mL, there was no significant decrease in time to delivery for the 80-mL inflation volume balloon (MD −0.44 h, 95% CI −1.93 to 1.05). A larger (either 60 or 80 mL) inflation volume of the balloon was associated with a nonsignificant decrease in time from induction to delivery in multiparous women (MD −2.67 h, 95% CI −6.1 to 0.76); Figure 5a) and nulliparous women (MD −1.82 h, 95% CI −4.16 to 0.53); Figure 5b).

Discussion

This systematic review and meta-analysis from seven RCTs, including 1432 singleton gestations with cephalic presentation at term, showed that larger balloon volumes of 60 or 80 mL during Foley catheter induction significantly reduced total time to delivery compared with volumes of 30 mL. There was no increased risk of cesarean or chorioamnionitis associated with the use of a larger volume balloon. Subgroup analysis according to balloon size also showed a significantly decrease in time to delivery for the 60-mL balloon; however, this was not maintained for the 80-mL volume. And, although nonsignificant, there remained a trend towards shorter time to delivery for both multiparous and nulliparous women.

Table 1. Characteristics of the included trials.

	Study location	Number of patients at randomization[a]	Bishop score at random-ization	GA at randomization	Other ripening allowed prior to Foley	Timing of oxytocin	Oxytocin dose	Primary outcome
Levy 2004 (11)	Israel	203 (100 vs. 103)	<4	≥37 weeks	No	As necessary after amniotomy or immediately following Foley expulsion if amniotomy was not able to be performed	2.5 mU/min and increased by 2.5 mU/min every 20 min to maximum 40 mU/min for goal of 3 contractions in 10 min	Failure of cervical ripening
Kashanian 2009 (6)	Iran	180 (90 vs. 90)	≤5	37–42 weeks	No	Immediately following Foley expulsion	2.5 mU/min and increased every 15 min to maximum 40 mU/min for goal of 3 contractions in 10 min	Not reported
Delaney 2010 (5)	USA	192 (98 vs. 94)	<5	≥37 weeks	Yes (misoprostol)[b]	Within 30 min of Foley placement	2 mU/min and increased by 1–2 mU/min every 20 min to maximum 40 mU/min for goal of 3 contractions in 10 min	Delivery within 24 h
Wijepala 2013 (13)	Sri Lanka	88 (44 vs. 44)	≤5	≥$40^{2/7}$ weeks	Not reported	Infusion started when Bishop score ≥8	Not reported	Change in Bishop score 24 h after Foley insertion
Gu 2015 (8)[c]	China	249 (125 vs. 124)	<6	≥37 weeks	No	If at 30 min after amniotomy there were fewer than three contractions in 10 min	1 mU/min and increased by 2 mU/min every 20 min to maximum 25 mU/min for goal of 200–250 Montevideo units	Vaginal delivery within 24 h
Gu 2015 (8)[d]	China	246 (125 vs. 121)	<6	≥37 weeks	No	If at 30 min after amniotomy there were fewer than three contractions in 10 min	1 mU/min and increased by 2 mU/min every 20 min to maximum 25 mU/min for goal of 200–250 Montevideo units	Vaginal delivery within 24 h
Indira 2016 (12)	India	100 (50 vs. 50)	<6	≥37 weeks	No	Infusion started when Bishop score >6	2 mU/min and increased by 1 mU/min every 30 min to maximum 32 mU/min for goal of three contractions in 10 min	Time from induction to delivery and cesarean section rate
Sandberg 2017 (7)	Netherlands	174 (87 vs. 87)	<6	≥37 weeks	No	One hour after amniotomy	3.3 mU/min and increased by 1.6–3.3 mU/min every 20 min to maximum 23.3 mU/min for goal of three contractions in 10 min	Vaginal delivery within 8 h after amniotomy

GA, gestational age; min, minute; mU, milliunit.

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

[b]Additional unpublished data kindly provided by the author.

[c]24-h arms.

[d]12-h arms.

Table 2. Intervention and control group of the included trials.

	Intervention	Control	Foley French size (F)	Foley Balloon size (mL)	Duration of Foley use
Levy 2004 (11)	Balloon inflated to 80 mL	Balloon inflated to 30 mL	Not reported	Not reported	12 h or until spontaneous expulsion
Kashanian 2009 (6)	Balloon inflated to 80 mL	Balloon inflated to 30 mL	24F	30	6 h or until spontaneous expulsion
Delaney 2010 (5)	Balloon inflated to 60 mL	Balloon inflated to 30 mL	18F	30	Spontaneous expulsion
Wijepala 2013 (13)	Balloon inflated to 60 mL	Balloon inflated to 30 mL	22F (60 mL), 18 F (30 mL)	Not reported	24 h or until spontaneous expulsion
Gu 2015a (8)[a]	Balloon inflated to 80 mL	Balloon inflated to 30 mL	16F	30 (control) 80 (intervention)[b]	24 h or until spontaneous expulsion or SROM
Gu 2015b (8)[c]	Balloon inflated to 80 mL	Balloon inflated to 30 mL	16F	30 (control) 80 (intervention)[b]	12 h or until spontaneous expulsion or SROM
Indira 2016 (12)	Balloon inflated to 60 mL	Balloon inflated to 30 mL	18F	50[b]	12 h or until spontaneous expulsion
Sandberg 2017 (7)	Balloon inflated to 60 mL	Balloon inflated to 30 mL	14F[b]	30[b]	24 h or until spontaneous expulsion

SROM, spontaneous rupture of membranes.
[a]24-h arms.
[b]Additional unpublished data kindly provided by the author.
[c]12-h arms.

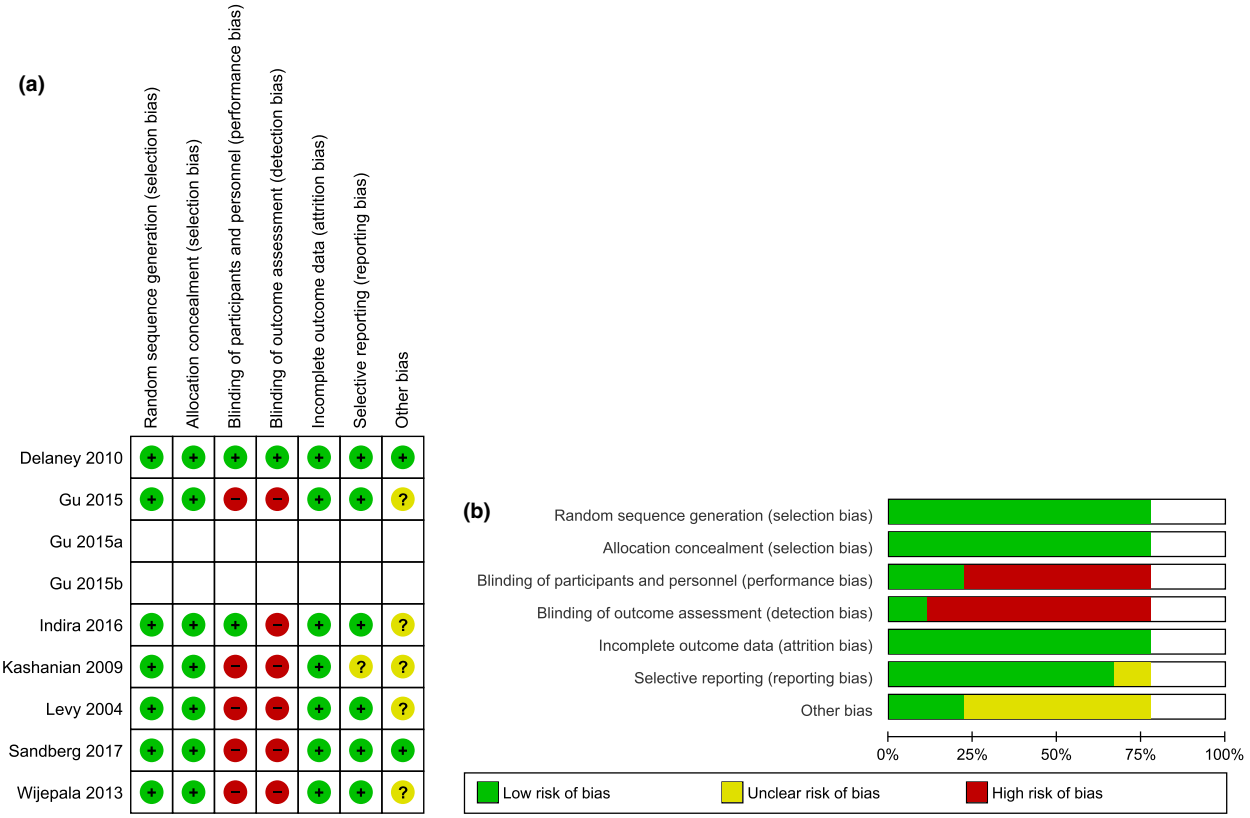

Figure 2. Assessment of risk of bias. (a) Summary of risk of bias for each trial; Plus sign: low risk of bias; minus sign: high risk of bias; question mark: unclear risk of bias. (b) Risk of bias graph about each risk of bias item presented as percentages across all included studies. [Color figure can be viewed at wileyonlinelibrary.com].

Table 3. Delivery outcomes.

	Time from induction to delivery (h)	Time from induction to vaginal delivery (h)[a]	Delivery in 24 h	Time from balloon insertion to expulsion (h)	Cesarean delivery	Epidural analgesia
Levy 2004 (11)	10.6 ± 6.5 vs. 13.0 ± 8.4	Not reported	75/100 (75%) vs. 60/103 (58%)	7.8 ± 3.9 vs. 7.4 ± 4.2	12/100 (12%) vs. 11/103 (11%)	70/100 (70%) vs. 74/103 (72%)
Kashanian 2009 (6)	9.9 ± 2.8 vs. 9.7 ± 2.9	Not reported	80/90 (95%) vs. 70/90 (91%)	Not reported	9/90 (10%) vs. 15/90 (17%)	Not available to patients [b]
Delaney 2010 (5)	17.3 ± 8.4 vs. 20.7 ± 9.6[b]	17.8 ± 9.4 vs. 21.6 ± 9.6[b]	65/98 (66%) vs. 60/94 (64%)	4.6 ± 4.1 vs. 4.6 ± 4.1[b]	23/98 (25%) vs. 20/94 (20%)	85/98 (90%) vs. 88/94 (90%)
Wijepala 2013 (13)	34.2 ± 17.6 vs. 45.6 ± 14.1	Not reported	Not reported	Not reported	3/44 (6.8%) vs. 12/44 (27.3%)	Not reported
Gu 2015a (8)[c]	31.6 ± 14.6 vs. 31.7 ± 16.1[b]	29.1 ± 12.9 vs. 27.8 ± 13.9[b]	31/125 (25%) vs. 43/124 (35%)[b]	Not reported	24/125 (19%) vs. 26/124 (21%)	23/125 (18%) vs. 26/124 (21%)
Gu 2015b (8)[d]	26.9 ± 17.2 vs. 26.0 ± 10.3[b]	23.9 ± 11.1 vs. 24.6 ± 9.1[b]	63/125 (50%) vs. 69/121 (57%)[b]	Not reported	24/125 (19%) vs. 14/121 (12%)	15/125 (12%) vs. 24/121 (20%)
Indira 2016 (12)	23.3 ± 20.3 vs. 22.7 ± 18.6[b]	19.2 ± 21.1 vs. 18.9 ± 15.8	25/50 (50%) vs. 24/50 (48%)[b]	7.2 ± 3.2 vs. 6.3 ± 2.3	7/50 (14%) vs. 10/50 (20%)	Not available to patients [b]
Sandberg 2017 (7)	28.4 ± 8.5 vs. 32.2 ± 9.4[b]	27.2 ± 7.5 vs. 30.3 ± 9.1[b]	16/87 (18%) vs. 13/87 (15%)[b]	14.0 ± 7.0 vs. 15.5 ± 7.1[b]	11/87 (13%) vs. 21/87 (24%)	56/87 (64%) vs. 56/87 (64%)
Total	22.4 vs. 24.1 h	24.1 vs. 25.3 h	355/675 (53%) vs. 339/669 (51%)	8.4 vs. 8.6 h	113/719 (16%) vs. 129/713 (18%)	249/535 (47%) vs. 268/529 (51%)
RR or MD (95% CI)	−1.97 h (−3.88 to −0.06)	−1.62 h (−3.54 to 0.31)	1.05 (0.92 to 1.2)	0.23 h (−0.53 to 0.98)	0.84 (0.60 to 1.17)	0.94 (0.87 to 1.01)
I^2	75%	47%	51%	30%	47%	0%

Data are presented as number in the intervention group vs. number in the control group. Data are shown as number (percentage) or as mean difference ± standard deviation.
CI, confidence interval; MD, mean difference; RR, relative risk.
[a]Excluding cesarean delivery.
[b]Additional unpublished data kindly provided by the author.
[c]24-h arms.
[d]12-h arms.

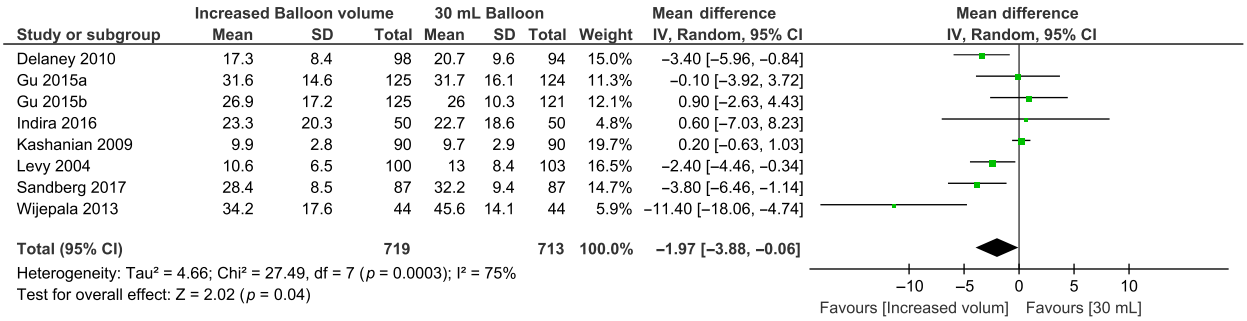

Figure 3. Forest plot for the mean of time from induction to delivery in hours in overall population. CI, confidence interval; IV, independent variable. [Color figure can be viewed at wileyonlinelibrary.com].

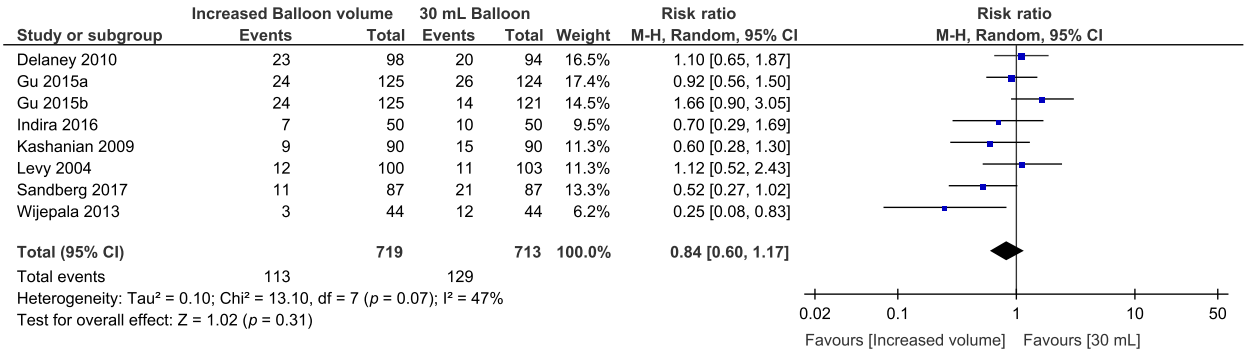

Figure 4. Forest plot for the risk of cesarean section in overall population. CI, confidence interval. [Color figure can be viewed at wileyonlinelibrary.com].

Berndl and colleagues previously published a meta-analysis on this topic which included 575 women. The primary outcome of interest was cesarean section, and they showed no difference in this intervention as a result of Foley balloon volume size (4). However, delivery within 24 h was more likely to be achieved with the larger balloons. We confirmed the findings of the prior meta-analysis, including that the total time of induction is decreased with larger volumes. This meta-analysis more than doubles the number of women included in the previous publication and was able to obtain unpublished data from several studies that were unavailable at the time (5,7,8).

Our study has several strengths. The quality of the included trials was high. Publication bias was not apparent by statistical analysis. There were no reports of adverse effects in relation to an increased Foley balloon volume. However, due to inconsistent reporting between trials, the meta-analysis is underpowered to detect these differences.

Limitations of our study are mostly inherent in the limitations of the included studies. Given the intervention, almost all trials were open label except Delaney et al., which was double-blinded. Indira et al. was single-blinded to the participant. Labor induction methods that occurred after ripening were not standard throughout all trials and may influence results. We used a random effect model in all analyses given the moderate statistical and clinical heterogeneity within the trials. Indeed, trials differed in terms of primary outcome, Foley type as well as duration of Foley use. Additionally, there are potential safety concerns due to the possibility of Foley balloon rupture (14). The rupture rate for overinflated balloons could be as high as 4% (12/325 confirmed overinflated balloon). It has to be noted that this rate is driven by the results of one trial and further attention should be paid to this factor (7). There are commercially available Foley catheters that are designed to hold higher volumes, as were used in the trial by Gu et al. (8) Until the safety concerns can be assessed, these catheters should be preferred over smaller balloons that are filled past capacity. Increased volume in the Foley catheter may increase discomfort, lead to more nursing intervention during the ripening period, and may steer providers away from more non-intervention settings (outpatient ripening) (15). Although these issues have not been studied, they remain

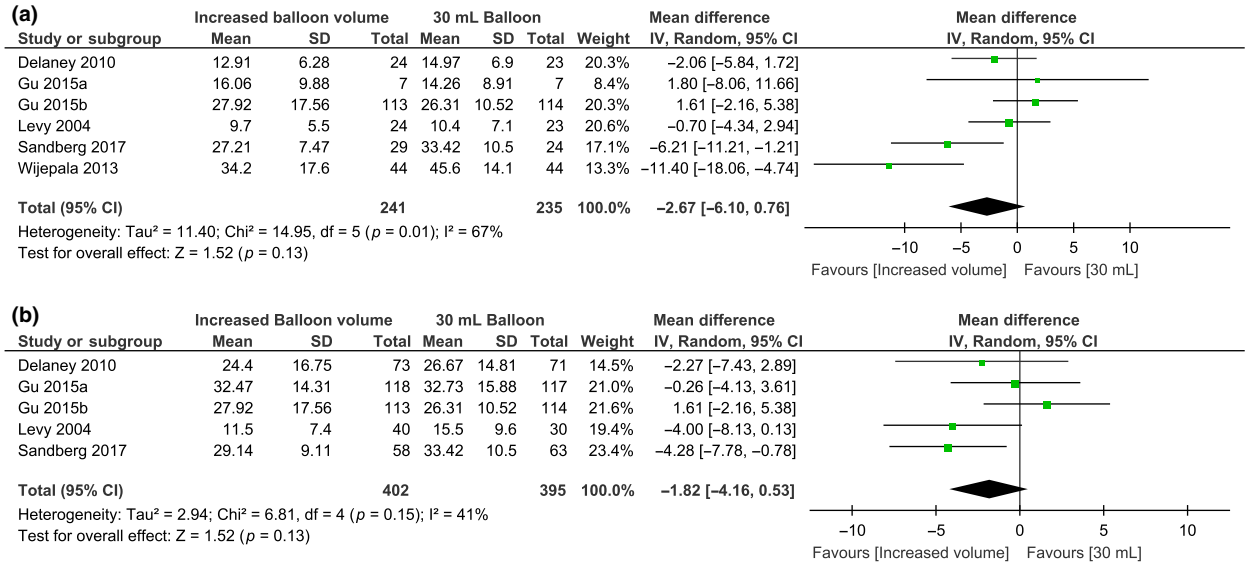

Figure 5. Forest plot for the mean of time from induction to delivery in hours in (a) multiparous and (b) nulliparous women. CI, confidence interval; IV, independent variable. [Color figure can be viewed at wileyonlinelibrary.com].

theoretical concerns. Other commercial large-volume catheters include the double-balloon catheter, which is the most expensive catheter available for labor induction (16). There have been two recent meta-analyses comparing the double-balloon to single-balloon catheter for cervical ripening (17,18). No additional benefit in terms of reduced time to delivery or cesarean risk was found when a double-balloon catheter was used, and women have a significantly higher satisfaction rate with the single-balloon catheters (17,18). Since no clinical benefit or benefits to women have been found, these catheters are not recommended for use until head-to-head trials confirming benefit have been performed.

Foley catheters function by both mechanical dilation and endogenous prostaglandin release. It is possible that the slightly larger dilation achieved after using larger volumes of balloon shortens the longest period in the labor curve, the latent phase prior to 6 cm. Reduced induction time was significant even with the variation in the study protocols and the wide range in mean induction times found in the trials. Induction times ranged from 9.9 to 34.2 h for 60- or 80-mL balloons and from 9.7 to 45.6 h for 30-mL balloons. This may be accounted for by the heterogeneity in the induction protocols, and that standardizing management would likely reduce the 75% I^2 obtained for time to induction outcome. There may even be a further increase with a larger balloon, but this cannot be determined based on this analysis. In trials with longer induction periods, timing of amniotomy and/or oxytocin was typically delayed until a certain Bishop score was achieved (7,13) or a second attempt at ripening was performed (7). Delay in initiating the induction portion of labor management (amniotomy and oxytocin) likely only increases the time to delivery without reducing cesarean rates, and should be avoided if possible (8). However, the inclusion of trials that differed in management after Foley catheter placement does increase the generalizability of the study, as the timing of amniotomy and oxytocin infusion frequently varies between institutions. Standard Foley catheters cost less than catheters that are graded for large volumes and are more widely available, and this study did not address the cost effectiveness of this intervention (16). However, a reduction of several hours on the labor floor will likely balance this cost and should be assessed in future studies. As labor induction is increasing across the world, timely management of labor beds becomes an important part of the logistics surrounding intrapartum care. Most importantly, the decision to use a larger balloon volume should be discussed with the woman in the context of her values. Individuals may view a reduction of 2 h very differently, and discomfort has not been adequately assessed in clinical trials. Additionally, since standard balloons can rupture when overinflated, it is recommended to follow manufacturer recommendations for balloon volumes (7).

Conclusion

In summary, larger (60–80 mL) balloon volumes during Foley catheter induction reduce total time to delivery compared with 30-mL balloon volumes. Maternal and neonatal complications do not appear to be increased

with use of the larger volumes. These latest findings should be interpreted with caution as they are underpowered. Further trials are still indicated, and optimally should be performed by parity status and account for maternal discomfort as well as rare outcomes such as Foley balloon rupture and malpresentation during labor.

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Supporting information

Additional Supporting Information may be found in the online version of this article:

Table S1. Maternal and fetal complications.

Table S2. Primary outcome (i.e. time from induction to delivery in hours) assessed in the subgroup analysis.

Appendix S1. Search strategy according to database searched.

