*Systematic Review*

# Outpatient Cervical Ripening with Balloon Catheters

## *A Systematic Review and Meta-analysis*

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**OBJECTIVE:** To evaluate whether outpatient cervical ripening with a balloon catheter results in a shorter amount of time in the labor and delivery unit when compared with use in the inpatient setting.

**DATA SOURCES:** PubMed, Scopus, Cochrane Library, and ClinicalTrials.gov were searched from their inception until December 2020. No restrictions for language or geographic location were applied.

**METHODS OF STUDY SELECTION:** Using a predefined protocol and search strategy, 1,152 titles were identified and screened. Randomized controlled trials that compared outpatient and inpatient cervical ripening with balloon catheters were included.

**TABULATION, INTEGRATION, AND RESULTS:** Data extraction and risk of bias assessments were performed by two reviewers. Meta-analysis was performed to produce mean difference for continuous data and risk ratio (RR) for dichotomous data, both with a 95% CI. The primary outcome was the amount of time from admission to the labor ward until delivery. Additional secondary maternal and neonatal outcomes were evaluated. Eight trials (740 patients) were included; six studies (571 patients) reported on our primary outcome. Compared with the inpatient group, outpatient balloon cervical ripening was associated with significantly less time in the labor and delivery unit (outpatient 16.3±9.7 hours vs inpatient 23.8±14.0 hours; mean difference −7.24 hours, 95% CI −11.03 to −3.34). There were no differences in total induction time or total hospital admission. The outpatient group was significantly less likely than the inpatient group to undergo cesarean delivery (21% vs 27%), RR 0.76 (95% CI 0.59–0.98). There were no differences in other maternal or neonatal outcomes. There were no deliveries outside of the hospital and no stillbirths.

**CONCLUSION:** Outpatient balloon cervical ripening in low-risk patients is associated with a decreased amount of time from admission to labor and delivery until delivery by more than 7 hours and a significant 24% decreased risk of cesarean delivery. Outpatient balloon cervical ripening is a safe alternative for low-risk patients and has the potential for significant benefits to patients, and labor and delivery units.

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Induction of labor is one of the most performed obstetric procedures. In 2017, it was estimated that

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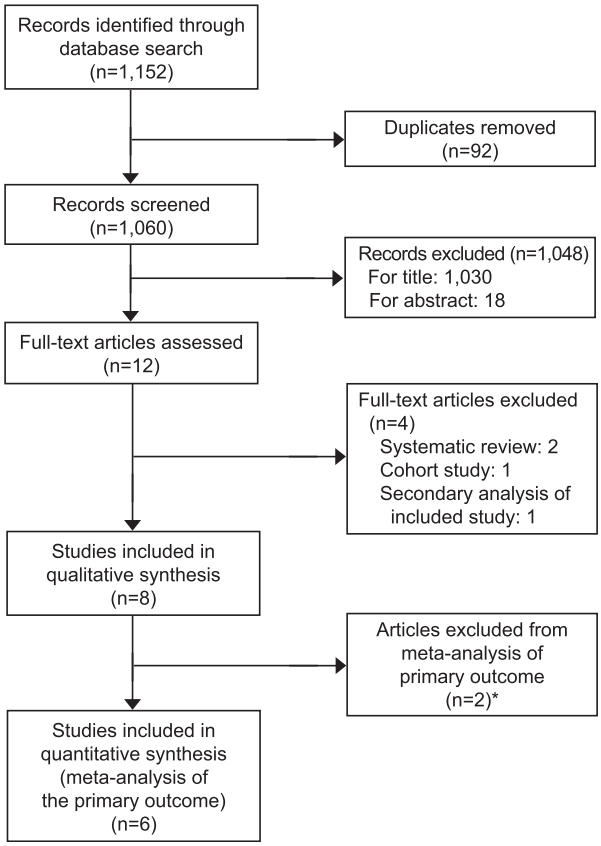


**Fig. 1.** Flow diagram of studies identified in the systematic review. *Studies excluded from meta-analysis of primary outcome due to nonreporting on this outcome.[14,15] These studies were included in meta-analysis of secondary outcomes.

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nearly 26% of all births in the United States follow an induction of labor.[1] Historically, inductions were largely performed for pregnancies that were either prolonged (extending past 40 weeks of gestation) or were in the setting of a maternal or fetal medical condition making delivery necessary; however, more recently there has been an increase in induction of labor as early as 39 weeks of gestation supported by the 2018 publication of the ARRIVE trial (A Randomized Trial of Induction Versus Expectant Management).[2] In 2019 the induction rate increased to 29.4%.[3]

Many patients present for induction with an "unfavorable" cervix and require cervical ripening with balloons, medications, or both, before labor. The process of cervical ripening can be achieved by mechanical dilation, and stimulation of local prostaglandin release, through the use of balloon catheters alone or in combination with pharmacologic agents such as misoprostol or oxytocin.[4] Studies have shown a decreased time to delivery with the use of dual agents, such as a balloon catheter with misoprostol or oxytocin[5]; however, misoprostol has been associated with increased rates of uterine hyperstimulation, or tachysystole, when compared with other agents including balloon catheters.[6,7] Due to these safety concerns and insufficient data on use in the outpatient setting, it cannot currently be recommended for this purpose. Multiple studies have shown unique advantages surrounding the use of balloon catheters. Notably, balloon catheters have proved to be safe and effective, as well as inexpensive.

Until recently, there were limited data in support of outpatient cervical ripening, and the American College of Obstetricians and Gynecologists reports that safety information is limited[8]; however, there are now numerous randomized controlled trials (RCTs) that depict equal efficacy, potential for decreased cost, and no differences in maternal or fetal outcomes. This is especially true for outpatient ripening with a balloon catheter (Chen V, Sheehan P. Outpatient versus inpatient catheter balloon cervical ripening-a randomised trial. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[9–15] Therefore, our aim was to determine whether patients who were undergoing outpatient balloon cervical ripening spend less time in the labor and delivery unit in comparison with those undergoing balloon ripening in the inpatient setting, by a meta-analysis of randomized trials. We additionally aimed to evaluate other maternal and neonatal outcomes to assess safety and efficacy.

## SOURCES

Before initiating the review and data extraction, a protocol was designed and the review was registered with the PROSPERO International Prospective Register of Systematic Reviews (registration No.: CRD42019140503, September 18, 2019). Electronic databases (PubMed, Scopus, Cochrane Library, and ClinicalTrials.gov) were searched from their inception until December 2020. Search terms used included the following: "Foley"; "Foley's"; "Foleys"; "catheter"; "outpatient"; "outpatients"; "out-patient"; "out-patients"; "ambulatory care"; "patient discharge"; "cervical ripening"; "cervical priming"; "cervix priming"; "preinduction"; "pre-induction"; "labor induced"; "labor"; "labour"; "oxytocics"; "oxytocin"; "misoprostol"; "prostaglandin"; "prostaglandins"; "bishop score"; "bishops score"; and "bishop's score". There were no restrictions for geographic location or language. Additionally, there was no restriction for publication period. The reference lists of all identified articles were examined to identify studies not found in the electronic searches. Two authors (R.P.-W., H.L.) independently assessed the search and the eligibility

**Table 1. Characteristics of the Included Studies**

| Study | No. of Patients* | Intervention | Control | Primary Outcome(s) |
|---|---|---|---|---|
| Sciscione 2001,[9] United States | 111 (50 vs 61) | 16F Foley catheter with 30-mL balloon placed and inflated to 30 mL; after 2 h of reactive and reassuring NST, randomized and discharged; advised to return at 6:00 am the next day<br>On admission, oxytocin administered; no other induction agents allowed | 16F Foley catheter with 30 mL balloon placed and inflated to 30 mL; randomized and admitted; catheter checked every 2–4 h, traction maintained; once catheter extruded, oxytocin administered | Change in Bishop score |
| Wilkinson 2015,[10] Australia | 48 (33 vs 15) | Cook catheter placed and each balloon inflated to 70–80 mL, then randomized; discharged after satisfactory CTG (minimum 20 min; advised to return to at 8:00 the next morning<br>On admission, amniotomy performed, then oxytocin if labor did not begin within 4 h | Cook catheter placed and each balloon inflated to 70–80 mL, then randomized; CTG monitoring for minimum 20 min; admitted and on the following morning amniotomy performed, then oxytocin if labor did not begin within 4 h | N/A† |
| Policiano 2016,[11] Portugal | 130 (65 vs 65) | Randomized, 16F Foley catheter placed and inflated to 40 mL; discharged after reassuring CTG with instructions to apply manual traction every 6 h; advised to return with catheter expulsion, rupture of membranes, pain or severe discomfort, decreased fetal movement, painful contractility, fever, or, if catheter still in place after 24 h<br>On admission, catheter removed if in place for 24 h; administered prostaglandins if Bishop score less than 6 (except with uterine scar) or oxytocin if Bishop score higher than 6 | Randomized, 16F Foley catheter placed and inflated to 40 mL (traction adjusted every 6 h); catheter removed after 24 h if no spontaneous expulsion; administered prostaglandins if Bishop score less than 6 (except with uterine scar) or oxytocin if Bishop score higher than 6 | Change in Bishop score |
| Kuper 2018,[12] United States | 129 (65 vs 64) | Randomized, 16F Foley catheter placed and inflated to 30; discharged after 30-min reassuring CTG without more than 3 painful contractions in 10 min; advised to return the next day<br>On admission, if catheter in place, oxytocin administered; catheter removed if not expelled in 24 h | Randomized, 16F Foley catheter placed and inflated to 30 mL (traction adjusted every 1–2 h); concurrent oxytocin administered; catheter removed if not expelled in 24 h | Duration of time from hospital admission to delivery |

(*continued*)

**Table 1. Characteristics of the Included Studies (*continued*)**

| Study | No. of Patients* | Intervention | Control | Primary Outcome(s) |
|---|---|---|---|---|
| Chen 2019, Australia‡ | 28 (13 vs 16) | Cook catheter placed and each balloon inflated to 40 mL; randomized and discharged after reassuring CTG; advised to return at 7:00 the next morning<br>On admission, oxytocin administered | Cook catheter placed and each balloon inflated to 40 mL; randomized and admitted; after balloon expulsion, oxytocin administered if needed | Length of hospital stay |
| Ausbeck 2020,[13] United States | 126 (63 vs 63) | Randomized, 16F Foley catheter placed and inflated to 30 mL; discharged after 20-min reassuring CTG; advised to return the next day<br>On admission, if catheter in place, oxytocin administered; catheter removed if not expelled in 24 h | Randomized, 16F Foley catheter placed and inflated to 30 mL (traction adjusted periodically); concurrent oxytocin administered; catheter removed if not expelled in 24 h | Total duration of time from hospital admission to delivery |
| Haavisto 2020,[14] Finland | 107 (53 vs 54) | After normal CTG, Cook catheter placed and each balloon inflated 80 mL (if constant pain, lower balloon emptied);§ randomized and discharged overnight; advised to return to hospital if pain was intolerable<br>All patients were surveyed on general, concurrent induction and postpartum experience | After normal CTG, Cook catheter placed and each balloon inflated 80 mL (if constant pain, lower balloon emptied);§ randomized and admitted, CTG performed based on guidelines<br>All patients were surveyed on general, concurrent induction and postpartum experience | Patient experiences |
| Rahman 2020,[15] Malaysia | 60 (25 vs 35) | Randomized, 20-min CTG performed, then 16 or 18F Foley catheter placed and inflated to 60 mL; discharged and advised to return next morning (12–24 h postinsertion)<br>On admission, after spontaneous balloon expulsion, if Bishop score 6 or higher, amniotomy performed; oxytocin administered for suboptimal contractions; if Bishop score less than 6, 3 mg intravaginal prostaglandin E2 administered | Randomized, 20-min CTG performed, then 16 or 18F Foley catheter placed and inflated to 60 mL; after spontaneous balloon expulsion, if Bishop score 6 or higher, amniotomy performed; oxytocin administered for suboptimal contractions; if Bishop score less than 6, 3 mg intravaginal prostaglandin E2 was administered | |

NST, nonstress test; CTG, cardiotocogram; N/A, not applicable.
* Total number (number in the intervention group vs number in the control group).
† Pilot study.
‡ Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067
§ Six patients (two outpatient, four inpatient) received single-balloon catheters inflated to 60–80 mL.

**Table 2. Inclusion and Exclusion Criteria of the Included Trials**

| Study | Inclusion | Exclusion |
|---|---|---|
| Sciscione 2001,[9] United States | Singleton, vertex presentation, at least 37 wk of gestation, Bishop score 5 or lower | Previa or lying placenta, undiagnosed vaginal bleeding, preeclampsia, anomalies, FGR, Rh isoimmunization, IUFD, ruptured membranes, maternal heart disease, latex allergy, active genital HSV, previous transfundal uterine surgery, poor access to telephone, excessive distance (more than 30 min) from hospital, unreliable transportation, nonreactive or nonreassuring NST, AFI less than the 5th percentile, patients transferred from outlying hospitals |
| Wilkinson 2015,[10] Australia | Singleton, vertex presentation, term (37–42 wk), healthy pregnancy, intact membranes, Bishop score less than 7, appropriately grown fetus | Previous cesarean, maternal or fetal compromise |
| Policiano 2016,[11] Portugal | Singleton, vertex presentation, at least 41 wk of gestation or medical indication for induction of labor (high-risk pregnancy group), Bishop score less than 6 | Indication for elective cesarean, spontaneous labor, polyhydramnios, nonreassuring NST, ruptured membranes, active vaginal bleeding, GBS infection, HIV infection, cervical injury, previous cesarean delivery with recurrent indication |
| Kuper 2018,[12] United States | Singleton, vertex presentation, 39 0/7–42 0/7 wk of gestation, parous, 18 y or older, reliable transportation, access to a telephone and resides less than 30 min from the hospital, cervix 3 cm or less or, if 2–3 cm dilated, less than 80% effaced, reassuring fetal heart rate monitoring | FGR, oligohydramnios, polyhydramnios, prior cesarean or uterine surgery of the myometrium, chronic hypertension requiring more than 1 antihypertensive medication, diabetes mellitus (other than diet-controlled gestational diabetes), gestational hypertension, preeclampsia, hepatitis B or C or HIV, fetal anomalies or IUFD, nonreassuring antenatal testing, labor, latex allergy, non–English-speaking, contraindications to vaginal delivery, require immediate hospitalization |
| Chen 2019,* Australia | Singleton, vertex presentation, 37–42 wk of gestation, uncomplicated pregnancy, Bishop score less than 7, intact membranes | Inadequate transport, cesarean scar, any contraindication to vaginal delivery or induction |
| Ausbeck 2020,[13] United States | Singleton, vertex presentation, 39 0/7–41 6/7 wk of gestation, nulliparous, 18 y or older, reliable transportation, telephone access, lives within 30 min of the hospital, modified Bishop score less than 5, cervical dilation 2 cm or less immediately before randomization | IUFD, major anomalies, FGR, suspected macrosomia, oligohydramnios, polyhydramnios, nonreassuring fetal status (BPP result 6/10 or less), prior uterine surgery involving the myometrium, gestational hypertension or preeclampsia, uncontrolled pregestational diabetes mellitus, hepatitis B or C or HIV, latex allergy |
| Haavisto 2020,[14] Finland | Singleton, vertex presentation, 37 0/7–41 5/7 wk of gestation, uncomplicated pregnancy, intact membranes, Bishop score less than 6, normal CTG, lives within 30 min from hospital, sufficient knowledge of the Finnish language | Medical conditions or pregnancy complications (ie, medically treated gestational diabetes, hypertension, preeclampsia, FGR, fetal distress) |
| Rahman 2020,[15] Malaysia | Singleton, vertex presentation, more than 37 wk of gestation, older than 18 y, intact membranes, Bishop score less than 6, lives less than 10 km or less than 30 min from hospital with transportation | IUFD, FGR, EFW more than 4,000 g, anomalies, abnormal NST, unstable lie, multiple pregnancy, sepsis, hypertension, latex allergy, uterine scar, history of antepartum hemorrhage, parity more than 6, suspected cephalopelvic disproportion, placenta previa |

FGR, fetal growth restriction; IUFD, intrauterine fetal death; HSV, herpes simplex virus; NST, nonstress test; AFI, amniotic fluid index; GBS, group B streptococcus; HIV, human immunodeficiency virus; BPP, biophysical profile, CTG, cardiotocogram; EFW, estimated fetal weight.

* Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067.

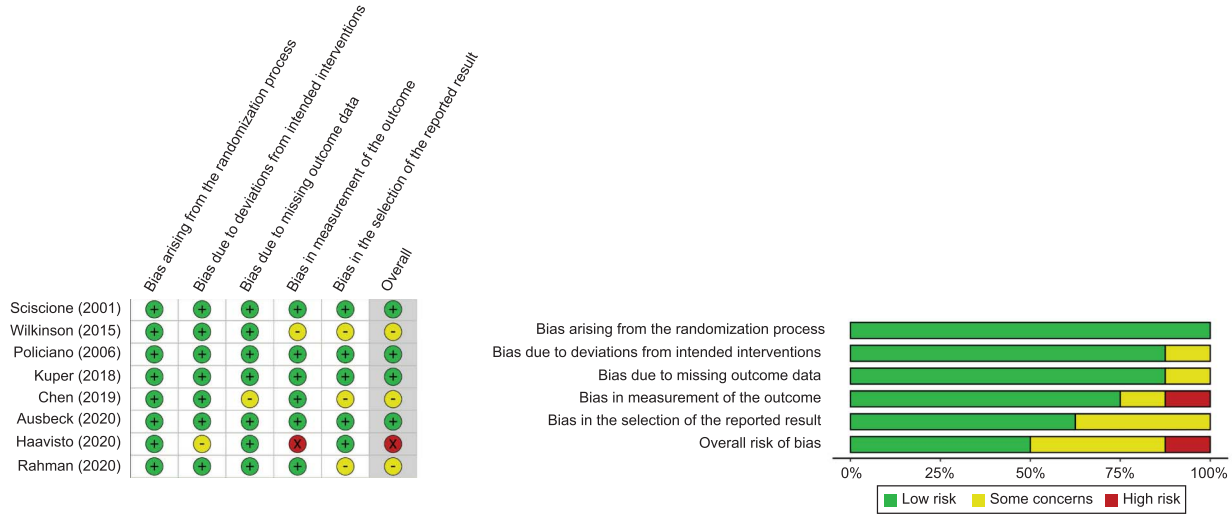


**Fig. 2.** Assessment of risk of bias. Summary of risk of bias **(A)** and risk of bias graph **(B)** demonstrating the proportion of risk of bias in each domain.

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of the studies. If any differences were identified, they were discussed and a consensus reached. The electronic search strategy is included in Appendix 1, available online at http://links.lww.com/AOG/C544.

## STUDY SELECTION

Randomized controlled trials that compared cervical ripening with balloon catheter use in the outpatient setting compared with the inpatient setting were eligible for inclusion. Balloon catheters used for cervical ripening could include Foley or Cook catheters. Studies were excluded if both arms did not include use of the balloon catheter. We included all published and unpublished RCTs that examined the outpatient (ie, intervention group) compared with inpatient (ie, control group) use of a balloon catheter for cervical ripening.

Risk of bias was assessed according to the revised Cochrane risk-of-bias tool for randomized trials.[16] We assessed the risk of bias based on our primary outcome, time in the labor and delivery unit (from admission to delivery). In those studies where our primary outcome was not reported, the risk of bias was assessed based on a primary outcome of the individual study. The five domains

**Table 3. Maternal Baseline Characteristics**

| Characteristic | Sciscione 2001[9] (61 vs 50) | Wilkinson 2015[10] (33 vs 15) | Policiano 2016[11] (65 vs 65) | Kuper 2018[12] (65 vs 64) | Chen 2019* (13 vs 16) |
|---|---|---|---|---|---|
| Age (y) | 29.8±5.8 vs 28.4±6.5 | 28.9±4.2 vs 29.1±6.8 | 30.5±6.3 vs 31.7±5.5 | 26.6±4.3 vs 25.8±4.2 | 33.3±3.6 vs 34.4±4.1 |
| Gestational age (wk)† | 40.1±1.3 vs 39.8±1.2 | Reported median with IQR | 40.3±1.3 vs 39.9±1.4 | 39.2±0.6 vs 39.2±0.3 | 40.6±1.2 vs 40.3±1.4 |
| BMI (kg/m²) | NR | NR | 24.4±6.2 vs 25.6±6.4 | 33.9±6.9 vs 33.2±6.4 | 24.8±3.6 vs 24.6±5.0 |
| Parity | NR | | | | |
| Nulliparous | | 25 (76) vs 11 (73) | 50 (77) vs 47 (72) | 0 (0) vs 0 (0) | 13 (100) vs 15 (94) |
| Multiparous | | 8 (24) vs 4 (27) | 15 (23) vs 18 (28) | 65 (100) vs 64 (100) | 0 (0) vs 1 (6) |
| Prior cesarean delivery | 3 (5) vs 4 (8) | NA | 6 (9) vs 10 (15) | NA | NA |

MD, mean difference; NR, not reported; BMI, body mass index; NA, not applicable.
Data are mean±SD or n (%) unless otherwise specified.
* Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067.
† Gestational age at induction or randomization.

assessed are the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Two authors (R.P.-W., H.L.) independently assessed the risk of bias and resolved any disagreements through discussion.

We followed an intention-to-treat approach, and patients were evaluated in the group to which they were randomly assigned. The primary outcome was time in the labor and delivery unit, defined as the time from admission to the unit until time of delivery. The secondary outcomes included total time of labor induction (from start of cervical ripening until delivery), use of oxytocin, duration and maximum dose of oxytocin, prostaglandin use, duration of cervical ripening (duration of time during which balloon catheters or medications, such as prostaglandins, were used to ripen the cervix), route of delivery (spontaneous vaginal, operative vaginal, cesarean), Bishop score, rupture of membranes (spontaneous vs artificial), neuraxial anesthesia use, chorioamnionitis, endometritis, and postpartum hemorrhage. Maternal baseline characteristics collected included age, race, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), gestational age at delivery, parity, and prior cesarean deliveries. Neonatal outcomes included birth weight, Apgar scores, neonatal intensive care unit admission, and umbilical cord arterial pH.

Data were extracted from each eligible study article, without modification, into custom-made forms, by two authors (R.P.-W., H.L.). Additional unpublished study data were provided by the investigators of three studies (Appendix 2, available online at http://links.lww.com/AOG/C544) (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[12,13] Meta-analysis was performed to produce mean difference for continuous data using inverse variance and a random effects model, and risk ratio (RR) for dichotomous data using the Mantel-Haenszel method and a random effects model, both with a 95% CI. Heterogeneity was assessed using I-squared. Means and SDs were compared between groups using combined means and SDs. Categorical variables in baseline characteristics were compared using the $\chi^2$ test. Two authors (R.P.W., G.S.) independently completed the meta-analysis using Review Manager 5.3. After analysis, results were compared for any differences that were resolved through review and discussion. The PRISMA (Preferred Reporting Item for Systematic Reviews and Meta-analyses) statement was followed.[17]

## RESULTS

Figure 1 shows the flow diagram of study identification. Eight RCTs, including 740 patients, were eligible for inclusion (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067)[9–15]; six studies (571 patients) reported on our primary outcome (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[9–13] Tables 1 and 2 outline characteristics of the included studies and inclusion and exclusion criteria, respectively. All studies included singleton gestations of at least 37 weeks of gestation. Pregnancies were primarily low-risk, because many excluded complications such as fetal

| Ausbeck 2020[13] (63 vs 63) | Haavisto 2020[14] (53 vs 54) | Rahman 2020[15] (25 vs 35) | Total | MD (95% CI) | $I^2$ (%) | *P* |
|---|---|---|---|---|---|---|
| 22.9±4.5 vs 22.2±3.7 | 30.1±4.1 vs 30.5±4.4 | 30.0±3.8 vs 31.1±3.1 | 740 (378 vs 362) | 0.01 (−0.65 to 0.68) | 1 | — |
| 39.3±0.4 vs 39.3±0.5 | 41.1±1.0 vs 41.0±1.0 | NR | 632 (320 vs 312) | 0.05 (−0.06 to 0.15) | 0 | — |
| 31.0±5.4 vs 34.0±7.5 | 25.6±4.8 vs 25.9±3.9 | 25.8±1.0 vs 27.4±1.0 | 581 (284 vs 297) | −1.09 (−2.00 to 0.18) | 41 | — |
| | | | 629 (317 vs 312) | NA | NA | .42 |
| 63 (100) vs 63 (100) | 32 (60) vs 33 (61) | 11 (44) vs 12 (34) | 194 (61) vs 181 (58) | | | |
| 0 (0) vs 0 (0) | 21 (40) vs 21 (39) | 14 (56) vs 23 (66) | 123 (39) vs 131 (42) | | | |
| NA | 1 (5) vs 2 (10) | NA | 26 (10 vs 16) | NA | NA | .19 |

**Table 4. Delivery Outcomes**

| Outcome | Sciscione 2001[9] | | Wilkinson 2015[10] | | Policiano 2016[11] | | Kuper 2018[12] | |
|---|---|---|---|---|---|---|---|---|
| No. of patients | Out 61 | In 50 | Out 33 | In 15 | Out 65 | In 65 | Out 65 | In 64 |
| Total time in labor and delivery unit (h) | 12.4±2.4 | 24.5±16.3 | 14.3±7.3 | 21.5±5.3 | 23.4±13.8 | 35.5±15.0 | 12.4±7.4 | 13.5±7.0 |
| Total time in hospital (h) | NR | NR | NR | NR | NR | NR | 63.3±12.5 | 65.7±13.3 |
| Cesarean delivery | 18 (30) | 22 (44) | 6 (18) | 5 (33) | 18 (28) | 25 (39) | 2 (3) | 3 (5) |
| Oxytocin use | NR | NR | 23 (70) | 14 (93) | NR | NR | 63 (97) | 63 (98) |
| Prostaglandin use | 0 (0) | 0 (0) | 4 (12) | 2 (13) | 42 (65) | 39 (60) | 0 (0) | 0 (0) |
| Duration between balloon expulsion and delivery (h) | NR | NR | NR | NR | NR | NR | 17.5±10.2 | 9.6±5.7 |
| Postpartum hemorrhage | NR | NR | 6 (18) | 2 (13) | NR | NR | 0 (0) | 1 (2) |
| Chorioamnionitis | 0 (0) | 0 (0) | NR | NR | 3 (5) | 3 (5) | 3 (5) | 3 (5) |
| Endometritis | 0 (0) | 0 (0) | NR | NR | NR | NR | 1 (2) | 1 (2) |

MD, mean difference; RR, risk ratio; NA, not applicable; NR, not reported.
Data are mean±SD or n (%) unless otherwise specified.
* Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067
† n=14; two patients excluded from original study's analysis (one had Cook in situ for 24 hours due to lack of beds, and one had 2- hour delay in continuation of labor induction after Cook removal due to lack of beds).
§ Time with balloon in situ.
‡ n=15; one patient excluded from original study's analysis (24-hour delay in continuation of labor induction after Cook removal due to lack of beds).

anomalies, growth restriction, abnormal placentation, poorly controlled maternal diabetes, and hypertension; however, three studies included a total of 26 patients with prior cesarean delivery, and rates of prior cesarean did not differ between groups.[9,11,14] In six RCTs, no additional agents were used for cervical ripening while the balloon was in place for either arm (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[9,11,14,15] Three RCTs allowed for use of prostaglandins after the balloon in either group, typically if amniotomy was unacceptable or for a Bishop score less than 6 (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[10,11] In two RCTs, those in the inpatient arm received oxytocin concurrently with the balloon.[12,13] Data on the primary outcome were available for six RCTs (n=571) (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[9–13]

The risk of bias for each study is shown in Figure 2. The risk of bias was assessed based on our primary outcome; however, our primary outcome was not reported in two studies, and therefore the risk of bias was based on the primary outcome of the individual studies.[14,15] In the study by Haavisto, the primary outcome of patient experience was assessed through questionnaires.[14] As some of the patients did not complete postpartum questionnaires and required follow-up, the potential for recall bias resulted in a high risk of bias. For Rahman et al,[15] risk of bias was assessed based on one of the primary outcomes reported, cesarean delivery rate.

Baseline maternal data are outlined in Table 3. The BMI was slightly lower in the outpatient group, mean difference −1.09 (95% CI −2.00 to −0.18). There were no differences in other characteristics between groups including maternal age, gestational age at randomization or induction, or parity.

Regarding the primary outcome, duration of time in the labor and delivery unit, there was a significant difference, with the outpatient group spending 16.3±9.7 hours in the labor and delivery unit compared with the inpatient group spending 23.8±14.0 hours (mean difference −7.24 hours, 95% CI −11.03 to −3.34). When excluding the two unpublished studies (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067),[15] the mean difference in time in the labor and delivery unit remained significantly different (−7.02 hours, 95% CI −11.19 to −2.85, n=544). The primary outcome of time in the labor and delivery unit also remained significantly different when only analyzing those studies of low risk of bias (mean difference −7.06 hours, 95% CI −12.30 to −1.30, n=496).[9,11–13] There were no differences in duration of cervical ripening, total induction time, or duration of oxytocin use (Table 4). The total duration of hospital admission did not differ significantly between

| Chen 2019* | | Ausbeck 2020[13] | | Haavisto 2020[14] | | Rahman 2020[15] | | Total | MD (95% CI) | RR (95% CI) | $I^2$ (%) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Out 13 | In 16 | Out 63 | In 63 | Out 53 | In 54 | Out 25 | In 35 | 740 (378 vs 362) | NA | NA | NA |
| 17.2±11.2 | 26.1±6.2† | 17.4±7.4 | 21.7±9.1 | NR | NR | NR | NR | 571 (300 vs 271) | −7.24 (−11.03 to −3.34) | NA | 83 |
| 65.5±25.5 | 72.9±23.9 | 78.8±22.7 | 83.1±20.8 | NR | NR | 40.8±14.4 | 60±16.8 | 344 (166 vs 178) | −8.12 (−16.60 to 0.36) | NA | 77 |
| 5 (39) | 5 (31) | 15 (24) | 20 (32) | 12 (23) | 8 (15) | 3 (12) | 10 (29) | 740 79/378 (21) vs 98/362 (27) | NA | 0.76 (0.59–0.98) | 0 |
| 12 (92) | 14 (88) | 62 (98) | 63 (100) | 26 (49) | 31 (57) | 18 (72) | 25 (71) | 499,204/252 (81) vs 210/247 (85) | NA | 0.97 (0.91–1.03) | 42 |
| 1 (8) | 1 (6) | 0 (0) | 0 (0) | 10 (19) | 18 (33) | 1 (4) | 3 (9) | 740 58/378 (15) vs 63/362 (17) | NA | 0.98 (0.77–1.25) | 0 |
| 16.8±11.1 | 15.2±7.1‡ | 18.9±16.7 | 15.5±13.2 | NR | NR | NR | NR | 283 (141 vs 142) | 5.19 (1.22–9.17) | NA | 51 |
| 2 (15) | 5 (31) | 4 (6) | 3 (5) | NR | NR | 1 (4) | 2 (6) | 392 13/199 (7) vs 13/193 (7) | NA | 0.87 (0.40–1.89) | 0 |
| NR | NR | 14 (22) | 8 (13) | NR | NR | NR | NR | 496 20/254 (8) vs 14/242 (6) | NA | 1.44 (0.76–2.75) | 0 |
| 0 (0) | 0 (0) | 1 (2) | 2 (3) | NR | NR | NR | NR | 395 2/202 (1) vs 3/193 (2) | NA | 0.67 (0.11–4.03) | 0 |

groups (mean difference −8.12 hours, 95% CI −16.60 to 0.36). Data on route of delivery were available for all eight RCTs (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[9–15] The outpatient group was significantly less likely than the inpatient group to undergo cesarean delivery (21% vs 27%), with a RR of 0.76 (95% CI 0.59–0.98). The RR of cesarean delivery remained significantly lower in the outpatient group when excluding unpublished studies (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067)[15] (RR 0.76, 95% CI 0.58–0.99, n=651) and when including only studies of low risk of bias (RR 0.71, 95% CI 0.53–0.95, n=496).[9,11–13] There was a shorter duration of time from balloon expulsion to delivery in the inpatient group, based on three studies that included 283 patients (mean difference 5.19 hours, 95% CI 1.22–9.17) (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067).[12,13]

Maternal adverse outcomes, which included intrapartum fever, chorioamnionitis (also called Triple I, for intrauterine infection, inflammation, or both), endometritis or postpartum hemorrhage, occurred infrequently in each group (Table 4). There were no reports of deliveries occurring outside of the hospital or reports of the need for urgent delivery due to nonreassuring fetal status on admission from the outpatient setting, and there were no stillbirths diagnosed (0/378, 95% CI 0.0000–0.0097).

Table 5 outlines the neonatal outcomes analyzed. The birth weight for the inpatient group was slightly higher, with a mean difference of 62.43 g (95% CI 3.35–121.50). Adverse neonatal outcomes were also infrequent in both groups and included 5-minute Apgar scores less than 7, neonatal intensive care unit admission, umbilical cord arterial pH less than 7.1, and birth injuries. There were no neonatal deaths reported in any studies.

Forest plots with corresponding funnel plots of delivery, maternal, and neonatal outcomes are presented in Figures 3 and 4. Additional delivery outcomes are included in Appendix 3, available online at http://links.lww.com/AOG/C544.

## DISCUSSION

In this meta-analysis of mostly low-risk patients, outpatient cervical ripening with a balloon catheter is significantly associated with more than 7 fewer hours that patients spend in the labor and delivery unit, and with a 24% decreased risk of cesarean delivery, when compared with inpatient balloon induction. There was a shorter duration of time from balloon expulsion to delivery in the inpatient group, which could be attributed to more frequent adjustments and evaluation for balloon expulsion while inpatient (see Table 1). Additionally, there was no increased risk of adverse maternal or neonatal outcomes, and no stillbirths in the 378 patients who received outpatient balloon cervical ripening.

The safety outcomes are in line with the American College of Obstetricians and Gynecologists' statement that mechanical methods for cervical ripening may be particularly appropriate for induction in the outpatient setting[8]; however, we might have had limited power to find a significant difference between groups. Sciscione et al[18] found no adverse outcomes for 1,905 patients, when using a Foley catheter for inpatient preinduction cervical ripening

**Table 5. Neonatal Outcomes**

| Outcome | Sciscione 2001[9] | | Wilkinson 2015[10] | | Policiano 2016[11] | | Kuper 2018[12] | | Chen 2019* | |
|---|---|---|---|---|---|---|---|---|---|---|
| No. of patients | Out 61 | In 50 | Out 33 | In15 | Out 65 | In 65 | Out 65 | In 64 | Out 13 | In 16 |
| Birth weight (g) | 3,000† | 3,000† | 3,537±494 | 3,721±552 | 3,265.± 425.8 | 3,280.2±479.2 | 3,271.2±316.7 | 3,179.9±330.5 | 3,629±443 | 3,471±472 |
| 5-min Apgar score less than 7 | NR | NR | 2 (6) | 0 (0) | NR | NR | 0 (0) | 1 (2) | 1 (8) | 0 (0) |
| NICU admission | -‡ | -‡ | 1 (3) | 0 (0) | 1 (2) | 1 (2) | 5 (8) | 5 (8) | 0 (0) | 0 (0) |
| Umbilical cord arterial pH less than 7.1 | NR | NR | NR | NR | NR | NR | 1 (2) | 4 (6) | NR | NR |
| Birth injuries | NR | NR | NR | NR | NR | NR | 1 (2)§ | 2 (3)§ | NR | NR |

MD, mean difference; RR, risk ratio; NA, not applicable; NR, not reported; NICU, neonatal intensive care unit.
Data are mean±SD or n (%) unless otherwise specified.
* Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067.
† SD not reported, not included in analysis.
‡ Study data reported only as percentages, which do not calculate to whole numbers (excluded from meta-analysis).
§ Birth injuries were reported as: Kuper: one outpatient brachial plexus injury, one inpatient cephalohematoma, one inpatient laceration and cephalohematoma; Ausbeck: one outpatient brachial plexus injury.

in low-risk nulliparous patients. In a systematic review on the safety of outpatient balloon ripening, the prevalence of adverse events was 0.00–0.26%, with the most prevalent adverse event being pain or discomfort.[19] Among the studies included in our meta-analysis, Rahman reported no episodes of hyperstimulation, and Kuper reported that on admission to the hospital, all fetuses had category I fetal heart tracings.[12,15]

Although not included as an outcome in our meta-analysis, it is worth noting the effects on patient satisfaction with outpatient cervical ripening. Wilkinson evaluated discomfort after balloon placement with visual analogue scales, and surveyed postpartum patients regarding satisfaction.[10] Patients reported equal rates of satisfaction and feeling safe.[10] Sciscione et al[9] used visual analog scale to assess discomfort during cervical ripening and reported no differences between groups. Finally, Rahman et al reported that outpatients felt less lonely, got more sleep, and felt safe. Sixty percent of patients in the inpatient group reported that in future inductions they would prefer outpatient cervical ripening.[15] In a secondary analysis of the RCT by Kuper, among parous patients there was no difference in satisfaction between outpatient and inpatient groups.[20]

This is currently the most comprehensive meta-analysis of RCTs that compared outpatient balloon cervical ripening to inpatient balloon cervical ripening. Multiple authors contributed additional unpublished study data to strengthen our meta-analysis. Our preplanned, preregistered analysis of multiple maternal and neonatal outcomes allowed us to assess the efficacy and safety of outpatient balloon cervical ripening for both mother and newborn.

Several limitations should be noted. Given the nature of the intervention, there was no way to blind participants or research personnel. At the time of writing of this article, one study was published as an abstract only, though the authors provided additional data for our meta-analysis (Chen V, Sheehan P. Aust N Zeal J Obstet Gynaecol 2019;59:39–40. doi: 10.1111/ajo.13067). A second study has not yet been peer reviewed.[15] These studies were included to decrease nonreporting bias. With exclusion of these studies the primary outcome of difference in time in the labor and delivery unit remained significantly different, and the RR of cesarean delivery remained significantly lower. There was heterogeneity in the study designs, with some allowing simultaneous pharmacologic agents for the inpatient control group (ie, balloon and oxytocin), others allowing subsequent cervical ripening agents (ie, prostaglandins) in both groups (only once admitted), and others directly comparing only balloon use in each arm. The RCTs included in our meta-analysis included only balloon use outpatient, as the intervention group. Many institutions are now using concurrent balloon and misoprostol cervical ripening. None of the studies included in our analysis compared outpatient balloon

| Ausbeck 2020[13] | | Haavisto 2020[14] | | Rahman 2020[15] | | Total | MD (95% CI) | RR (95% CI) | $I^2$ (%) |
|---|---|---|---|---|---|---|---|---|---|
| Out 63 | In 63 | Out 53 | In 54 | Out 25 | In 35 | 740 (378 vs 362) | NA | NA | |
| 3,247.7±355.1 | 3,216.6±301.8 | 3,939.1±454.2 | 3,845.5±352.5 | 3,208±286.6 | 3,030±442.5 | 629 (317 vs 312) | 62.43 (3.35–121.50) | NA | 0 |
| 1 (2) | 2 (3) | 0 (0) | 0 (0) | NR | NR | 439 4/227 (2) vs 3/212 (1) | NA | 0.99 (0.24–4.13) | 0 |
| 6 (10) | 6 (10) | NR | NR | NR | NR | 462 13/239 (5) vs 12/223 (5) | NA | 1.01 (0.48–2.13) | 0 |
| 6 (10) | 4 (6) | 3 (6) | 2 (4) | NR | NR | 362 10/181 (6) vs 10/181 (6) | NA | 1.07 (0.40–2.85) | 12 |
| 1 (2)[§] | 0 (0)[§] | NR | NR | NR | NR | 255 2/128 (2) vs 2/127 (2) | NA | 0.94 (0.14–6.31) | 0 |

with concurrent misoprostol to inpatient balloon with concurrent misoprostol. In a 2020 network meta-analysis by Orr et al,[21] the time to vaginal delivery was not different when comparing Foley with prostaglandins to Foley with oxytocin (mean duration 1.3 hours; 95% CI −2.0 to 4.7). Based on this, we could expect findings that compared outpatient balloon to inpatient balloon plus misoprostol to be similar to our findings, but more research, in the form of RCTs, is needed. Study protocols also differed in their use of

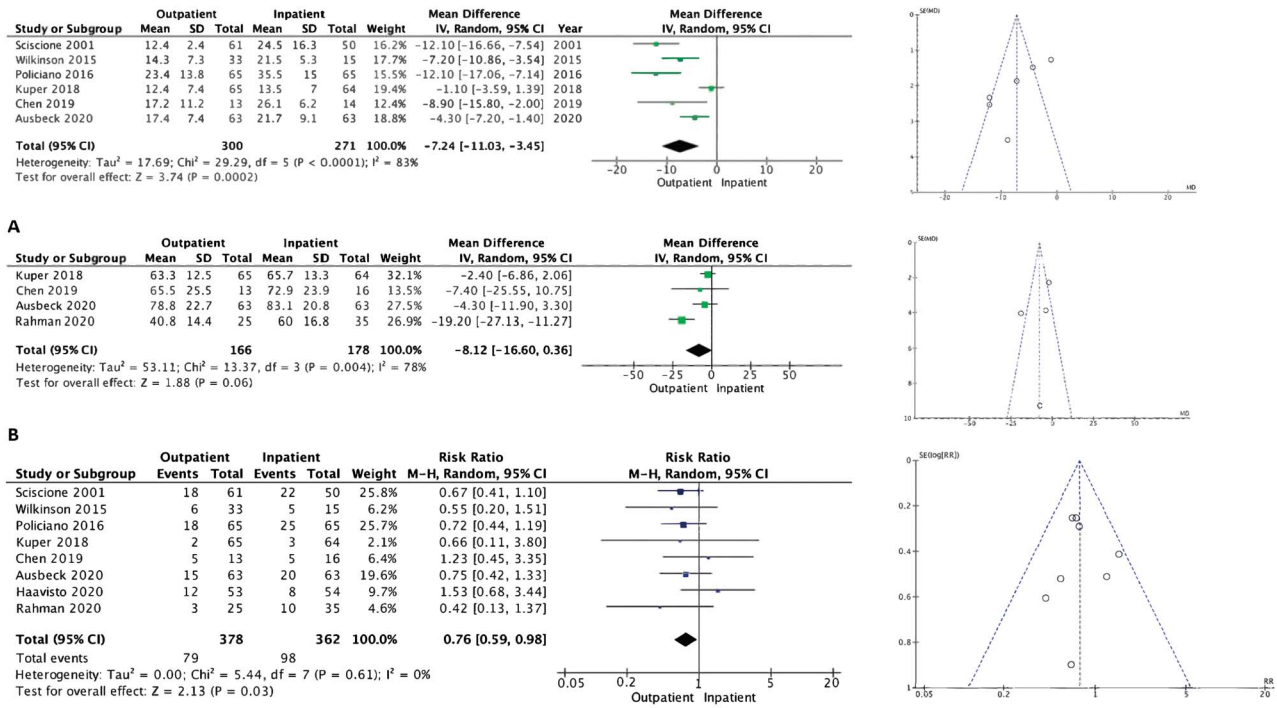


**Fig. 3.** Forest plots and corresponding funnel plots of labor and delivery outcomes. Primary outcome: time in the labor and delivery unit (hours) **(A)**; total inpatient time (hours) **(B)**; cesarean deliveries **(C)**. IV, independent variable; df, degrees of freedom; M-H, Mantel-Haenszel.

*Pierce-Williams. Outpatient Balloon Cervical Ripening. Obstet Gynecol 2022.*

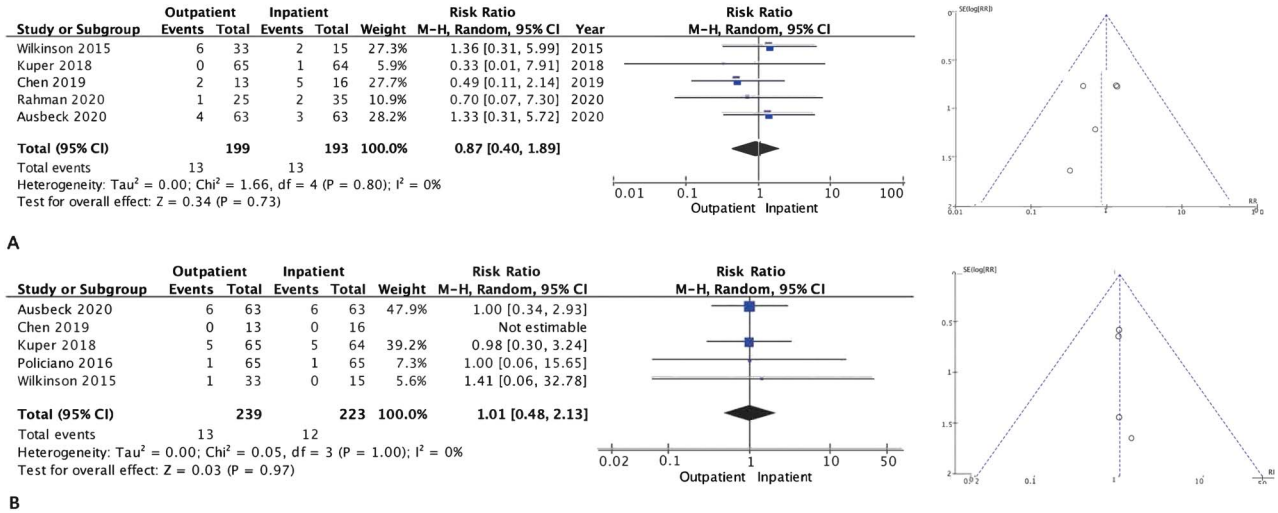


**Fig. 4.** Forest plots with corresponding funnel plots of select maternal and neonatal outcomes. Postpartum hemorrhage **(A)**, neonatal intensive care unit admission **(B)**. M-H, Mantel-Haenszel; df, degrees of freedom.

*Pierce-Williams. Outpatient Balloon Cervical Ripening. Obstet Gynecol 2022.*

Foley or Cook catheters, and the inflation volumes. All studies but one[14] followed intention-to-treat analysis. When analyzing only those studies with low risk of bias, the primary outcome of time in the labor and delivery unit, as well as the RR of cesarean delivery, remained significantly different between groups.[9,11–13] We are also limited by the small number of studies, and, therefore, lack power to adequately assess publication bias.[22,23] Although no stillbirths were reported, owing to the rarity of such an event, the sample size is probably not large enough to completely reassure about this most important of outcomes, even if the CIs now allow a clinician to counsel a patient that the risk of a stillbirth while undergoing outpatient balloon cervical ripening is less than 1%.

In comparison with existing literature, a recently published meta-analysis on outpatient cervical ripening with prostaglandins and mechanical methods assessed the effectiveness and potential harms of outpatient compared with inpatient cervical ripening.[24] This meta-analysis included four RCTs (n=418) [9–12] that compared mechanical cervical ripening (Foley or Cook catheters) in the inpatient and outpatient setting, highlighting the robustness of our meta-analysis including eight RCTs. The meta-analysis also showed no differences in harm. There was no difference in cesarean deliveries between groups.[24] A 2020 Cochrane Review on home compared with inpatient induction of labor that analyzed only three RCTs[9–11] found that home induction with a balloon catheter may decrease the length of hospital stay and time from induction to birth, while also reporting that at-home patients may have increased pain.[25] An earlier meta-analysis by Abdelhakim et al[26] found a reduction in the rate of cesarean deliveries, a reduced length of hospital stay with outpatient balloon induction, and no differences in adverse events[25]; however, this meta-analysis included a study by Subramaniam et al (Subramaniam A, Blanchard CT, Kuper SG, Jauk VC, Szychowski JM, Tita AT, et al. Outpatient versus inpatient cervical ripening in obese parous women: 660 [abstract]. Am J Obstet Gynecol 2019;220:S437. doi: 10.1016/j.ajog.2018.11.682), which was a secondary analysis of the 2018 study by Kuper, thereby duplicating the data for 108 patients included in the meta-analysis.

No cost analysis was performed in the individual RCTs, or our meta-analysis; however, it is likely that a 7-hour reduction in time in the labor and delivery unit would also translate into decreased hospital costs. A cost-effectiveness analysis based on a theoretical cohort of 760,000 low-risk nulliparous patients undergoing outpatient Foley cervical ripening found a cost difference of $2,159, favoring outpatient ripening (Christensen AA, Hersh AR, Caughey AB, Hermesch A, Sciscione AC. Outpatient Foley catheter for preinduction cervical ripening in low risk women [25P] [abstract]. Obstet Gynecol 2020;135:174S. doi: 10.1097/01.AOG.0000663876.96742.5c). The Foley balloon catheter itself is also a significantly more readily available option, because it is inexpensive and easy to store.

Regarding the implementation of outpatient balloon cervical ripening in routine practice,

**Box 1. Proposed Outpatient Balloon Cervical Ripening Protocol**

**Potential candidates***
- Induction for 39 weeks of gestation
- Late and postterm gestations
- Chronic hypertension, well controlled
- Diabetes (gestational and pregestational), well controlled
- Bishop score 6 or lower

**Before induction†**
- Counseling (a handout should be provided)
  - What to expect with the balloon (normal discomfort, light spotting or bloody mucus discharge or both)
  - Pain-management options (warm showers, acetaminophen as needed)
  - Phone number to call with questions or concerns
  - When to return: 12 h after placement (may remain at home up to that time if balloon is expelled) or with leakage of fluid, regular uterine contractions, vaginal bleeding, or decreased fetal movement
- Maternal evaluation
  - Vital signs
  - Cervical examination to assess need for cervical ripening
- Fetal evaluation
  - Confirm fetal cephalic presentation
  - Evaluate amniotic fluid (MVP greater than 2 cm)
  - NST without decelerations; if nonreactive, BPP 8/10 or higher

**Procedure‡**
- Place balloon (Foley or Cook) and inflate per institutional protocols
- Latex-free balloons recommended for those with latex allergy
- External fetal monitoring
- Location institution-specific: antepartum testing unit, office, labor and delivery unit
- Duration: minimum 30 min, up to 2 h
- Discharge home with instructions (above)

**Labor and delivery unit admission**
- Assess cervical examination: remove balloon if in place for 12 h (longer periods can be considered based on clinical examination findings or institution protocols
- Continue induction per institution protocols (consider amniotomy after balloon removal, oxytocin as needed)

Levine and Sciscione[27] have also proposed an algorithm for outpatient balloon cervical ripening, so we suggest readers review that reference as well when designing evidence-based protocols for their institutions.

MVP, maximum vertical pocket; NST, nonstress test; BPP, biophysical profile.
*Consider excluding prior cesarean delivery or myomectomy, poorly controlled diabetes or hypertension, gestational hypertension or preeclampsia, unexplained vaginal bleeding, low-lying placenta, maternal coagulopathy, multifetal gestation, oligohydramnios (MVP less than 2 cm), polyhydramnios, ruptured amniotic membranes, major fetal anomaly, fetal growth restriction, poor access to telephone or transportation, any maternal or fetal condition necessitating inpatient monitoring.
†If maternal or fetal status are not reassuring (ie, new-onset hypertension, electronic fetal monitoring with decelerations, or BPP less than 8/10), admit for inpatient induction.
‡Admit for inpatient induction for rupture of membranes, vaginal bleeding greater than expected with balloon placement, labor, or nonreassuring fetal tracing.

institutions should create and adhere to evidence-based guidelines. In 2019 Levine et al published a proposed algorithm for outpatient balloon cervical ripening.[27] We agree with their inclusion of low-risk candidates, including those with well-controlled chronic hypertension and diabetes, because this is similar to the inclusion and exclusion criteria for most of the studies included in our analysis. After confirmation of normal vital signs, cephalic presentation, amniotic fluid volume and a reassuring nonstress test, the balloon should be placed. Most studies included in our review reported discharging patients home after "reassuring" cardiotocogram for 20–30 minutes. In a study of 1,905 patients who were undergoing inpatient cervical ripening with a Foley catheter, during the 2-hour fetal monitoring period after balloon placement, two patients underwent cesarean delivery for nonreassuring fetal heart rate.[18] Interestingly, based on a protocol of 2 hours of fetal monitoring postballoon placement before discharge home, these patients would not have been eligible for discharge home because they experienced either spontaneous labor or rupture of membranes during that time.[18] Levine et al recommend 2 hours of reassuring, continuous monitoring before discharge.[27] See Box 1 for our proposed workflow.

In summary, compared with inpatient cervical ripening using balloon catheters, outpatient balloon induction is associated with significantly shorter time in the labor and delivery unit by more than 7 hours, and a significant 24% decreased risk of cesarean delivery. There were no stillbirths or neonatal deaths in the outpatient balloon group, and no reports of hyperstimulation or need for urgent delivery on admission from the outpatient setting. In low-risk patients outpatient balloon cervical ripening should be considered a safe, effective and beneficial option.

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