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Cervical Ripening in Pregnancy

Committee on Clinical Practice Guidelines–Obstetrics. This Clinical Practice Guideline was developed by the ACOG Committee on Clinical Practice Guidelines–Obstetrics in collaboration with Anjali J. Kaimal, MD, MAS, Uma M. Reddy, MD, MPH, and Veronica Gillispie-Bell, MD, MAS.

PURPOSE: The purpose of this document is to review current methods for cervical ripening and to summarize the effectiveness of these approaches based on appropriately conducted outcomes-based research. This document focuses on cervical ripening in individuals with term, singleton, vertex pregnancies with membranes intact, because this is the population in whom most studies were conducted. For more information on recommended timing of delivery based on maternal, fetal, and obstetric conditions and on labor management, refer to: American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No. 831, *Medically Indicated Late-Preterm and Early-Term Deliveries* (1); Practice Bulletin No. 217, *Prelabor Rupture of Membranes* (2); Obstetric Care Consensus No. 10, *Management of Stillbirth* (3); Practice Bulletin No. 205, *Vaginal Birth After Cesarean Delivery* (4); and Clinical Practice Guideline No. 8, *First and Second Stage Labor Management* (5).

TARGET POPULATION: Individuals with term, singleton, vertex pregnancies with membranes intact.

METHODS: This guideline was developed using an a priori protocol in conjunction with a writing team consisting of two maternal–fetal medicine subspecialists and one specialist in obstetrics and gynecology appointed by the ACOG Committee on Clinical Practice Guidelines–Obstetrics. ACOG medical librarians completed a comprehensive literature search for primary literature within the Cochrane Library, Cochrane Database of Systematic Reviews, ClinicalTrials.gov, Ovid MEDLINE, and PubMed and searched for guidelines from ACOG and other organizations. Studies that moved forward to the full-text screening stage were assessed by the writing team based on standardized inclusion and exclusion criteria. Included studies underwent quality assessment, and a modified GRADE (Grading of Recommendations Assessment, Development and Evaluation) evidence-to-decision framework was applied to interpret and translate the evidence into recommendation statements.

RECOMMENDATIONS: This Clinical Practice Guideline includes an overview of cervical ripening indications, contraindications, and methods and provides recommendations for pharmacologic, mechanical, and combination method cervical ripening in individuals with term, singleton, vertex pregnancies with membranes intact. Recommendations are classified by strength and evidence quality.

INTRODUCTION

Since its inclusion on U.S. birth certificates in 1989, the rate of labor induction has increased steadily each year. In 2022, 31.9% of births involved induction of labor (6). This increase is due in part to the increase in medical conditions requiring early-term delivery (1). Another possible contributor to the increase in the rate of inductions is the findings from the randomized controlled ARRIVE trial (Labor Induction versus Expectant Management in Low-Risk Nulliparous Women). Researchers found that, in low-risk nulliparous women at full term, induction of labor at 39 0/7–39 4/7 weeks of gestation resulted in decreased rates of cesarean delivery and hypertensive disorders of pregnancy as compared with expectant management (cesarean delivery: 18.6% vs 22.2%, relative risk [RR] 0.84, 95% CI, 0.76–0.93, $P<.001$; gestational hypertension and preeclampsia: 9.1% vs 14.1%, RR 0.64, 95% CI, 0.56–0.74, $P<.001$), with no significant difference in neonatal outcomes (7). Based on a large observational study (8), the rate of elective inductions increased by 42% (RR 1.42, 95% CI, 1.18–1.71) immediately after the publication of the ARRIVE trial. With the expansion of indications for labor induction and the knowledge, confirmed in the ARRIVE trial, that, on average, induction of labor is associated with longer length of stay on the labor and delivery unit, the demand for effective and efficient cervical ripening methods has grown accordingly.

Approximately 84% of individuals undergoing induction of labor require cervical ripening (9). Cervical ripening is the process of softening and effacing the cervix in preparation for labor. During cervical ripening, the cellular matrix changes as collagen bundles weaken and lose strength. At the same time, interaction of cytokines, hyaluronic acid, and elastase cause cervical effacement (10). Although this process occurs naturally as part of the progression to spontaneous labor, for individuals whose labor is being induced, cervical ripening can be stimulated by pharmacologic methods, mechanical methods, or a combination of both. The purpose of this Clinical Practice Guideline is to provide evidence-based recommendations for cervical ripening in individuals with term, singleton, vertex pregnancies with membranes intact.

STRENGTH OF RECOMMENDATION

STRONG

ACOG recommends:

Benefits clearly outweigh harms and burdens. Most patients should receive the intervention.

ACOG recommends against:

Harms and burdens clearly outweigh the benefits. Most patients should not receive the intervention.

CONDITIONAL

ACOG suggests:

The balance of benefits and risks will vary depending on patient characteristics and their values and preferences. Individualized, shared decision making is recommended to help patients decide on the best course of action for them.

QUALITY OF EVIDENCE

HIGH

Randomized controlled trials, systematic reviews, and meta-analyses without serious methodologic flaws or limitations (eg, inconsistency, imprecision, confounding variables)

Very strong evidence from observational studies without serious methodologic flaws or limitations There is high confidence in the accuracy of the findings and further research is unlikely to change this.

MODERATE

Randomized controlled trials with some limitations Strong evidence from observational studies without serious methodologic flaws or limitation

LOW

Randomized controlled trials with serious flaws Some evidence from observational studies

VERY LOW

Unsystematic clinical observations
Very indirect evidence from observational studies

GOOD PRACTICE POINTS

Ungraded Good Practice Points are incorporated when clinical guidance is deemed necessary in the case of extremely limited or nonexistent evidence. They are based on expert opinion as well as review of the available evidence.

SUMMARY OF RECOMMENDATIONS

General Cervical Ripening

ACOG recommends use of pharmacologic, mechanical, or combination methods for cervical ripening. **(STRONG RECOMMENDATION, HIGH-QUALITY EVIDENCE)**

ACOG suggests the use of pharmacologic methods in combination with mechanical methods of cervical ripening to shorten the time from admission to delivery in appropriate candidates. **(CONDITIONAL RECOMMENDATION, HIGH-QUALITY EVIDENCE)**

Pharmacologic Methods of Cervical Ripening

ACOG recommends use of either oral or vaginal misoprostol for cervical ripening. (STRONG RECOMMENDATION, HIGH-QUALITY EVIDENCE)

ACOG recommends that vaginal dinoprostone may be used for cervical ripening. (STRONG RECOMMENDATION, MODERATE-QUALITY EVIDENCE)

Mechanical Methods of Cervical Ripening

ACOG recommends the use of mechanical methods of cervical ripening. (STRONG RECOMMENDATION, HIGH-QUALITY EVIDENCE)

Outpatient Cervical Ripening

ACOG suggests that outpatient cervical ripening is a safe and effective way to reduce the time from admission to delivery in low-risk patients. (CONDITIONAL RECOMMENDATION, HIGH-QUALITY EVIDENCE)

METHODS

American College of Obstetricians and Gynecologists (ACOG) Clinical Practice Guidelines provide clinical management recommendations for a condition or procedure by assessing the benefits and harms of care options through a systematic review of the evidence. This guideline was developed using an a priori protocol in conjunction with a writing team consisting of two maternal–fetal medicine subspecialists and one specialist in obstetrics and gynecology appointed by the ACOG Committee on Clinical Practice Guidelines–Obstetrics. A full description of the Clinical Practice Guideline methodology is published separately (11). The following description is specific to this Clinical Practice Guideline.

Literature Search

ACOG medical librarians completed a comprehensive literature search for primary literature within the Cochrane Library, Cochrane Database of Systematic Reviews, ClinicalTrials.gov, Ovid MEDLINE, and PubMed and searched for guidelines from ACOG and other organizations. Parameters for the search included human-only studies published in English. The search was restricted to studies from 2000 to 2023. The MeSH terms and keywords used to guide the literature search can be found in Appendix A (available online at http://links.lww.com/AOG/E138). Updated literature searches were completed in October 2023 and February 2024 and were reviewed by the writing team using the same systematic process as the original literature search. A final supplemental literature search was performed in January 2025 to ensure that any newly published, high-level sources were addressed in the final manuscript.

Study Selection

A title and abstract screen of all studies was completed by ACOG research staff. Studies that moved forward to the full-text screening stage were assessed by two authors from the writing team (A.J.K. and U.M.R.) based on standardized inclusion and exclusion criteria. To be considered for inclusion, studies had to be conducted in countries ranked very high on the United Nations Human Development Index (12), published in English, and include participants identified as pregnant women. Although systematic reviews, randomized controlled trials, and observational studies were prioritized, case reports, case series, and narrative reviews were considered for topics with limited evidence. A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram of the included and excluded studies can be found in Appendix B (available online at http://links.lww.com/AOG/E139). All studies that underwent quality assessment had key details extracted (study design, sample size, details of interventions, outcomes) and descriptions included in the summary evidence tables (Appendix C, available online at http://links.lww.com/AOG/E140).

Recommendation and Manuscript Development

A modified GRADE (Grading of Recommendations Assessment, Development and Evaluation) evidence-to-decision framework was applied to interpret and translate the evidence into draft recommendation statements, which were classified by strength and evidence quality (13, 14). The recommendations and supporting evidence tables then were reviewed, revised as appropriate, and affirmed by the Committee on Clinical Practice Guidelines–Obstetrics at a meeting. The guideline manuscript then was written and subsequently reviewed and approved by the Committee on Clinical Practice Guidelines–Obstetrics and other internal review bodies before continuing to publication.

CLINICAL OVERVIEW

Indications and Contraindications for Cervical Ripening

Although there is no universally accepted definition of an unfavorable cervix, the Bishop Score, originally developed in 1964 by Dr. Edward Bishop, is the most frequently used method to evaluate the "readiness" of the cervix for labor and to predict the likelihood of vaginal delivery within 24 hours based on cervical dilation,

position of the cervix, effacement, station, and cervical consistency (15) (Table 1). Bishop score thresholds ranging from 3 to 8 have been used to define populations of people in whom cervical ripening before starting oxytocin will increase the likelihood of vaginal delivery within 24 hours (7, 16, 17). Clinical factors such as parity and gestational duration also affect the course and outcomes of induction of labor and may be integrated into the decision for cervical ripening.

Once the clinical criteria for induction of labor are met and cervical ripening is deemed necessary, pregnant individuals should be counseled on the methods available for cervical ripening, as well as the benefits and risks of each method. Research evaluation of cervical ripening methods has assessed benefits, including likelihood of vaginal delivery and likelihood of delivery within 24 hours, and risks, including tachysystole (ie, more than five contractions in 10 minutes, averaged over a 30-minute interval) with and without fetal heart rate (FHR) decelerations and maternal and neonatal infection. Given the differences in administration methods and indicated maternal and fetal monitoring, additional patient preference and clinical context-specific considerations also may affect decision making. Patients undergoing induction of labor with cervical ripening should be educated on anticipated time course. In the ARRIVE trial, the median duration of stay on labor and delivery units was 20 hours for individuals in the induction group compared with 14 hours for those in the expectant-management group (7).

Not every candidate for induction of labor is eligible for all cervical ripening methods. Due to the risk of uterine rupture, misoprostol (and, by extrapolation, other prostaglandin preparations) is contraindicated in patients with a history of uterine surgery, including cesarean delivery (18). However, those patients may be candidates for mechanical methods, as well as oxytocin (4). Other contraindications to cervical ripening include allergy or sensitivity to the cervical ripening agent.

Overview of Cervical Ripening Methods

Methods for cervical ripening can be divided into three broad categories: pharmacologic, mechanical, and dual use of pharmacologic and mechanical. Commonly used pharmacologic methods for cervical ripening include the prostaglandins misoprostol (prostaglandin E_1 [PGE1]) and dinoprostone (prostaglandin E_2 [PGE2]). Mifepristone, an antiprogesterone agent known to cause softening and dilation of the cervix and increased uterine activity, has also been investigated for cervical ripening. As a single agent, it appears to be less effective than the alternatives, but it may be a useful adjunct to other methods (19–21). The most commonly used mechanical method for cervical ripening is a balloon catheter. Osmotic or hygroscopic dilators made from seaweed or synthetic materials have been studied but currently are less commonly used in clinical practice (22).

Misoprostol can be used for cervical ripening as well as induction of labor and can be administered orally, vaginally, or sublingually. It is currently available in a 100-microgram tablet that can be divided into 25-microgram or 50-microgram doses. Two dinoprostone preparations are available in the United States: a gel in a 2.5-mL syringe containing 0.5 mg of dinoprostone and a vaginal insert containing 10 mg of dinoprostone. The gel is placed in the cervical canal just below the internal os through a catheter that is provided with the insertion kit. After the initial dose, it can be repeated in 6 and 12 hours if cervical change is inadequate. The manufacturer recommends that the maximum cumulative dose of cervical gel not exceed 1.5 mg (three doses) within a 24-hour period. The vaginal insert is placed in the fornix of the vagina and can remain in place for up to 12 hours.

Mechanical dilators promote cervical ripening by creating direct pressure on the cervix and causing an increase in inflammation and prostaglandin release. Single balloon catheters that are most commonly used for cervical ripening are silicone or latex Foley catheters. The single balloon is placed in the cervix above the internal os. In contrast, when using a double-balloon

Table 1. Bishop Scoring System

	Factor				
Score	Dilation (cm)	Position of Cervix	Effacement (%)	Station*	Cervical Consistency
0	Closed	Posterior	0–30	–3	Firm
1	1–2	Midposition	40–50	–2	Medium
2	3–4	Anterior	60–70	–1, 0	Soft
3	5–6	—	80	+1, +2	—

*Station reflects a −3 to +3 scale.

Adapted with permission from Wolters Kluwer Health, Inc.: Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol 1964;24:267.

catheter, one ballon is placed in the cervix above the internal os and the other is inflated in the vagina just outside of the external os. Placement of either type of balloon catheter can be accomplished with or without a speculum. The double balloon catheter is available with a stylet to facilitate insertion. Osmotic dilators are placed in the cervix to absorb water and expand to cause circumferential pressure on the cervix and prostaglandin release.

CLINICAL RECOMMENDATIONS AND EVIDENCE SUMMARY

General Cervical Ripening

ACOG recommends use of pharmacologic, mechanical, or combination methods for cervical ripening. **(STRONG RECOMMENDATION, HIGH-QUALITY EVIDENCE)**

Although the evidence base for pharmacologic, mechanical, and combination (pharmacologic with mechanical) methods of cervical ripening has developed over time, systematic reviews and meta-analyses have investigated the safety, efficacy, and effectiveness of each of these approaches, comparing them in various combinations (23–29). Outcomes assessed most commonly have included mode of delivery and time to delivery as measures of efficacy and effectiveness and FHR changes and tachysystole in terms of safety. Although the optimal approach for each patient will depend on their clinical characteristics, their personal preferences and history, and the setting in which they are receiving care, in general, the pharmacologic, mechanical, or combination methods described in detail in this document (summarized in Box 1) are all reasonable to consider in the absence of specific contraindications.

A single study showed no racial or ethnic differences in use of cervical ripening agents (30). In addition to evaluating racial disparities, studies are needed to evaluate the selection of cervical ripening agents based on hospital resources and staffing models.

ACOG suggests the use of pharmacologic methods in combination with mechanical methods of cervical ripening to shorten the time from admission to delivery in appropriate candidates. **(CONDITIONAL RECOMMENDATION, HIGH-QUALITY EVIDENCE)**

A network meta-analysis (ie, a technique for comparing three or more interventions simultaneously by combining both direct and indirect evidence across a network of studies [31]) including 11 systematic reviews summarizing 207 randomized controlled trials including more than 40,000 participants to determine the optimal method of cervical ripening found that Foley balloon inflated to 30 mL along with vaginal misoprostol at a dose of 25 micrograms was the most effective and safest strategy, because it was associated with lower odds of neonatal intensive care unit admission, tachysystole, operative vaginal delivery, and low Apgar scores, as well as the lowest odds of cesarean delivery and the highest odds of vaginal delivery within 24 hours (29). Limitations of this analysis include an inability to assess increased risk of infection (chorioamnionitis), which has been a concern in some investigations of this approach (32, 33); inability to assess the quality of some of the included studies; and inability to examine effect modifiers including but not limited to parity, gestational duration, indication for induction, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), cervical status, and labor management. Notably, other meta-analyses and randomized controlled trials have concluded that misoprostol-based regimens (23, 34) or regimens that combine a mechanical method with any of the pharmacologic options (misoprostol, oxytocin, or dinoprostone) are advantageous in comparison with any single method, particularly in terms of shorter time to vaginal delivery (25, 28, 35–46). Depending on the clinical

Box 1. Common Cervical Ripening Methods*

Pharmacologic methods:

- Misoprostol†
  - Oral: 50–100 micrograms every 4 h or 20–25 micrograms every 2 h
  - Vaginal: 25 micrograms every 3–6 h
- Dinoprostone†
  - Vaginal gel: 0.5 mg every 6 h, maximum of 3 doses
  - Vaginal insert: 10 mg for up to 12 h

Mechanical methods:

- Single or double balloon catheter
- Osmotic dilators

Combination methods (pharmacologic and mechanical):

- Balloon catheter plus misoprostol†
- Balloon catheter plus oxytocin

*This summary focuses on cervical ripening in individuals with term, singleton, vertex pregnancies with membranes intact. These are common cervical ripening methods and doses, but other options and doses may be appropriate in certain clinical scenarios.

†Contraindicated in patients with uterine scars.

characteristics and goals of the patient and the specific resources of the practice setting, specific single or combination methods may be preferred.

Pharmacologic Methods of Cervical Ripening

ACOG recommends use of either oral or vaginal misoprostol for cervical ripening. (STRONG RECOMMENDATION, HIGH-QUALITY EVIDENCE)

Oral misoprostol dosing of 25 micrograms every 2 hours (47) to 50–100 micrograms every 4 hours (48, 49) and vaginal misoprostol 25 micrograms every 3–6 hours are effective regimens for cervical ripening. A Cochrane database systematic review in 2021 of 33 trials (6,110 participants) compared oral misoprostol (50 micrograms or less) with vaginal misoprostol and found that vaginal use was more effective, because oral use resulted in fewer vaginal births within 24 hours (49.3% vs 60.8%, RR 0.81, 95% CI, 0.68–0.95) and longer time from induction to vaginal birth (mean hour difference 1.90, 95% CI, 0.54–3.25). However, oral administration was associated with less tachysystole with FHR changes (3.9% vs 5.7%, RR 0.69, 95% CI, 0.53–0.92). There was no difference in overall cesarean delivery rates but the cesarean delivery rate for fetal distress was lower with oral misoprostol (47).

In a recent single-center cluster randomized trial (49), 2,546 participants at term were randomized to oral (100 micrograms every 4 hours for up to two doses) or vaginal (25 micrograms every 3 hours up to five doses) misoprostol regimens. The rate of vaginal delivery in patients induced with vaginal misoprostol compared with oral misoprostol protocols was not significantly different (78.1% vs 77.2%, adjusted RR 1.01, 95% CI, 0.97–1.05), and mean time to delivery was 19.7 hours in both groups. Tachysystole with FHR changes was less frequent with vaginal misoprostol compared with oral (3.5% vs 5.9%, adjusted RR 0.59, 95% CI, 0.40–0.87). The higher rate of tachysystole is likely due to the higher dose of oral misoprostol used compared with the 50 micrograms or less dosing used in the studies included in the prior Cochrane review (48). Vaginal compared with oral misoprostol reduced the need for oxytocin use before delivery (68.8% vs 78.4%, adjusted RR 0.88, 95% CI, 0.84–0.92) (49). This may be of benefit when nursing staff availability is limited to manage oxytocin in early or latent phase of labor. The risks of clinical chorioamnionitis and estimated blood loss and transfusion within 12 hours of delivery were not different between the groups (49). Neonatal outcomes overall do not differ between oral and vaginal administration, including 5-minute Apgar score lower than 4 (49), umbilical cord blood pH less than 7.0 (49, 50), meconium aspiration syndrome (47), birth asphyxia (47), neonatal encephalopathy or seizures (47), sepsis (49), and perinatal death (47). Neonatal intensive care unit admission was not different in the Cochrane review (47), although it was more frequent in the vaginal misoprostol group, with low rates (2.0% vs 1.0%, adjusted RR 2.08, 95% CI, 1.06–4.09) in the recent U.S. trial (49) compared with the oral misoprostol group.

When discussing cervical ripening options, a trauma-informed approach should be used in considering the option of oral misoprostol as compared with vaginal pharmacologic or mechanical methods. Considering potential trauma history as well as prioritizing patient autonomy, comfort, and feelings of safety can help to reduce distress or fear associated with multiple vaginal examinations and promote a supportive health care experience (51).

Sublingual or buccal administration of misoprostol leads to rapid absorption and higher peak serum levels compared with other routes, potentially making it more effective in a shorter time. A meta-analysis and systematic review of five clinical trials found no difference between the sublingual and vaginal misoprostol groups in the rate of vaginal delivery within 24 hours or cesarean delivery but found an increased risk of uterine tachysystole in the sublingual misoprostol group. Therefore, the sublingual route is not recommended for routine use in cervical ripening (52). A randomized controlled trial of 300 participants found that vaginal misoprostol compared with buccal misoprostol was associated with shorter time to vaginal delivery by 8 hours, higher rate of vaginal delivery within 24 hours, and fewer cesarean deliveries performed for FHR abnormalities (53).

Dosing, Route, and Frequency

Vaginal Misoprostol. In a 2010 Cochrane database systematic review of 21 trials (2,913 participants), vaginal misoprostol regimens (ranging from 12.5 micrograms to 50 micrograms) were compared with higher-dose regimens (ranging from 25 micrograms to 100 micrograms). There were no significant differences in failing to achieve vaginal delivery in 24 hours. However, significantly more oxytocin was used in the lower-dose groups, defined as 12.5–35 micrograms (RR 1.30, 95% CI, 1.14–1.49). There was less tachysystole with FHR changes in the lower-dose groups (RR 0.51, 95% CI, 0.37–0.69). No significant differences were noted in cesarean delivery rates (54).

A meta-analysis of 13 studies (1,945 participants) compared vaginal misoprostol regimens of 25 micrograms and 50 micrograms. The 25-microgram regimen was less efficacious than the 50-microgram regimen, with lower rates of delivery after one dose and vaginal delivery within 24 hours and a higher rate of oxytocin use, but it had an improved safety profile, with lower rates of tachysystole, cesarean delivery for nonreassuring FHR, neonatal intensive care unit admission, and meconium passage (55).

Vaginal misoprostol 25 micrograms every 3–6 hours is effective for cervical ripening. Although 50 micrograms of vaginal misoprostol has a higher rate of delivery within 24 hours, the higher rate of tachysystole favors the 25-microgram dose. However, in some situations, 50 micrograms every 6 hours has been used (54, 55). A recent randomized controlled trial of 180 participants with BMI 30 or higher found that those receiving 50 micrograms of vaginal misoprostol experienced a similar time to delivery and cesarean delivery rate compared with those who received 25 micrograms of misoprostol. However, multiparous patients had a significantly reduced time to delivery when 50 micrograms was used (15.2 hours vs 12.0 hours, 95% CI, 0.04–0.97). The rate of tachysystole with reassuring FHR was more frequent in the 50-microgram group (22% vs 10.2%, *P*=.043), but the rates of tachysystole associated with nonreassuring FHR changes were not significantly different (2.3% vs 2.2%) (56).

Oral Misoprostol. Oral administration of misoprostol was examined by two separate Cochrane database systematic reviews. The first review, in 2014, examined regimens ranging from 25 micrograms to 100 micrograms. Two trials (113 participants total) compared regimens of 20–25 micrograms and 50 micrograms and found no significant difference in outcomes but concluded that data are limited (48). This review noted that the plasma half-life of oral misoprostol is short (20–40 minutes); therefore, dose is more important than frequency. Similar tachysystole rates were noted when the dose of oral misoprostol was double that of the vaginal dose; the use of the same doses orally and vaginally resulted in generally lower tachysystole rates in the oral group. Furthermore, because in comparison with vaginal dinoprostone most trials using oral misoprostol doses of 20–25 micrograms found a lower cesarean delivery rate, the review concluded that the optimal dosage of oral misoprostol is 20–25 micrograms given every 2 hours (48).

The second Cochrane database systematic review, in 2021, included 33 trials (6,110 participants) and compared only low-dose misoprostol (50 micrograms or less). Subgroup analysis of oral misoprostol compared with vaginal misoprostol showed that 10–25 micrograms was associated with less tachysystole with FHR changes, whereas 50 micrograms was not. The authors concluded that a starting dose of 25 micrograms may offer a good balance of achieving vaginal delivery and lower tachysystole rates (47).

Static oral misoprostol should be used instead of titrated oral misoprostol, because static dosing has similar efficacy as an hourly titrated dose but fewer side effects and lower complication rates, including lower incidence of cesarean delivery and tachysystole (57, 58).

The data are limited regarding optimal dosing interval and the maximum dose of oral misoprostol for achieving vaginal delivery within 24 hours; more studies are needed.

ACOG recommends that vaginal dinoprostone may be used for cervical ripening. **(STRONG RECOMMENDATION, MODERATE-QUALITY EVIDENCE)**

Vaginal dinoprostone is effective for cervical ripening; however, vaginal misoprostol has higher efficacy and less need for oxytocin augmentation. The Cochrane database systematic review in 2010 that compared vaginal misoprostol with vaginal dinoprostone in 38 trials (7,022 participants) showed a lower rate of failure to achieve vaginal delivery in 24 hours (RR 0.77, 95% CI, 0.66–0.89) and reduced need for oxytocin augmentation with misoprostol (RR 0.68, 95% CI, 0.60–0.76). There were no differences in the rates of cesarean delivery or tachysystole with FHR changes (54). A second review in 2010, which included 11 randomized clinical trials (1,572 participants), compared the 10-mg sustained-release dinoprostone vaginal insert with vaginal misoprostol tablets for cervical ripening. Individuals who received dinoprostone had a lower incidence of vaginal delivery within 24 hours of prostaglandin application compared with misoprostol (54.9% vs 66.8%, RR 0.83, 95% CI, 0.74–0.94). There was no difference between the groups in cesarean delivery and tachysystole rates. There was an increased need for oxytocin augmentation in the dinoprostone group (67.2% vs 46.0%, RR 1.45, 95% CI, 1.20–1.74) (24). An individual participant data meta-analysis in 2024 of eight trials (4,180 participants) showed that low-dose vaginal misoprostol (50 micrograms or less every 4 hours or more) was equivalent to vaginal dinoprostone in achieving vaginal delivery (77.6% vs 77.4%, adjusted odds ratio 0.95, 95% CI, 0.80–1.13), with an 11.8% rate of a composite adverse perinatal outcome of stillbirth, neonatal death, 5-minute Apgar score lower than 7, arterial umbilical cord pH less than 7.1, suspected or proven neonatal infection, neonatal seizures, hypoxic ischemic encephalopathy, neonatal intensive care unit admission, need for mechanical ventilation, meconium aspiration syndrome, and severe neonatal respiratory compromise in both groups. However, vaginal misoprostol was associated with a lower incidence of a composite adverse maternal outcome of intensive care unit admission, maternal infection (suspected or confirmed), postpartum hemorrhage of 1,000 mL or more, uterine rupture, and maternal death compared with vaginal dinoprostone (10.1% vs 11.9%, adjusted odds ratio 0.80, 95% CI, 0.65–0.98) (59).

Vaginal dinoprostone was compared with oral misoprostol in a Cochrane database systematic review in 2021, which included 13 trials (9,676 participants). Oral misoprostol decreased the risk of cesarean delivery (21.2% vs 25.2%, RR 0.84, 95% CI, 0.78–0.90). When studies were divided by their initial dose of oral misoprostol,

10–25 micrograms was associated with a decreased risk of cesarean delivery compared with vaginal dinoprostone, whereas the higher 50-microgram misoprostol dose did not reduce the risk (47). Neonatal outcomes including birth asphyxia, neonatal encephalopathy, seizures, infection, and perinatal death were not different between groups. Of note, compared with misoprostol, dinoprostone is more expensive and requires refrigeration.

Vaginal dinoprostone is more effective than the intracervical route for cervical ripening (60, 61). The Cochrane database systematic review in 2008 that compared intracervical dinoprostone with vaginal dinoprostone included 29 trials (3,881 participants) and found the risk of not achieving vaginal delivery within 24 hours was increased with intracervical dinoprostone (RR 1.26, 95% CI, 1.12–1.41). There was no difference in cesarean delivery rates or tachysystole with FHR changes (60). A recent randomized controlled trial of 212 pregnant individuals found that vaginal dinoprostone had a shorter induction-to-delivery interval (vaginal 15 hours vs intracervical 28 hours; $P<.001$), a higher rate of vaginal delivery within 24 hours of labor induction (63.3% vs 40.6%; $P=.002$), and a higher rate of successful induction of labor (95.9% vs 86.5%; $P=.020$) compared with intracervical dinoprostone (61).

Mechanical Methods of Cervical Ripening

ACOG recommends the use of mechanical methods of cervical ripening. **(STRONG RECOMMENDATION, HIGH-QUALITY EVIDENCE)**

A systematic review including 113 trials and more than 20,000 participants concluded that mechanical cervical ripening with a balloon is similarly effective to vaginal dinoprostone and misoprostol regimens with regard to cesarean delivery and rate of vaginal delivery within 24 hours but has a more favorable safety profile, as assessed by uterine hyperstimulation with FHR changes (22). A smaller systematic review and meta-analysis of four trials contributing individual-level data for 2,815 participants reached similar conclusions, finding a trend toward decreased vaginal birth (RR 0.95, 95% CI, 0.91–0.99) but also a decrease in composite adverse perinatal outcomes (RR 0.71, 95% CI, 0.48–1.05) when comparing cervical ripening with a balloon to oral misoprostol (27). Several prior systematic reviews and meta-analyses concluded that mechanical dilation with a balloon as a single method had a more favorable safety profile than pharmacologic methods but also may have a longer time to delivery and, in some cases, a lower vaginal delivery rate in comparison with cervical ripening with misoprostol (62–64).

More recently, a systematic review and meta-analysis of 14 studies including 2,380 participants comparing osmotic dilators with dinoprostone showed comparable maternal and neonatal outcomes with a lower risk of hyperstimulation in the osmotic dilator group (65). Studies of synthetic osmotic dilators also have compared them to pharmacologic methods and mechanical methods with a single balloon and have found the effectiveness and safety profiles to be similar, with some studies showing higher patient satisfaction with osmotic dilators (66–72).

Aspects of Management of the Balloon Catheter for Cervical Ripening

Either single balloon or double balloon catheters may be used for cervical ripening. The double balloon catheter is significantly more costly and has not been shown to be more effective in terms of vaginal delivery rate or time to delivery in multiple studies (73–76). In a systematic review of four trials including 600 patients, digital placement of the mechanical balloon as compared with placement with a speculum was associated with improved patient satisfaction without negatively affecting any clinical outcomes (77). Randomized noninferiority trials of digital placement compared with placement with a speculum found a similar failure rate and length of time for placement but improved maternal satisfaction or preference for digital placement (78–81). Duration of balloon placement, including immediate removal, 6 hours, and 12 hours, has been studied (82–88). There does not seem to be a clear advantage to the balloon remaining in place longer than 6 hours in these studies, although it is notable that many studies of combination methods allowed the balloon to stay in place up to 12 hours. The optimal volume for inflation also has been investigated, ranging from 30 mL to 80 mL. Interval to delivery was shorter with volumes larger than 30 mL in a meta-analysis of seven randomized trials including 1,432 people (mean difference 1.97 hours, 95% CI, −3.88 to −0.06), but cesarean delivery rates were similar (16% vs 18%, RR 0.84, 95% CI, 0.6–1.17) (89–91). Reported patient discomfort is higher with higher-volume inflation (92, 93). Finally, whether the application of tension to the catheter is necessary also has been studied; this does not have any positive or negative effect on clinical outcomes, including time to delivery (94, 95).

Outpatient Cervical Ripening

ACOG suggests that outpatient cervical ripening is a safe and effective way to reduce the time from admission to delivery in low-risk patients. **(CONDITIONAL RECOMMENDATION, HIGH-QUALITY EVIDENCE)**

Outpatient cervical ripening has been investigated as a way to safely reduce the amount of inpatient time required during induction of labor for low-risk patients, with the goal of optimizing resource utilization and patient experience. A systematic review and meta-analysis of 30 randomized controlled trials and 10 cohort studies

including more than 9,000 patients found that there was the most evidence for the use of dinoprostone or single balloon catheters in the outpatient setting and that the evidence was most generalizable to pregnant people aged 25–30 years without major comorbidities based on the populations included in the analyzed studies, which were predominantly nulliparous (65%) and undergoing induction for late-term or postterm pregnancy (61%) (9). This analysis concluded that there was no evidence of an increase in cesarean delivery or other reported maternal or fetal harms (ie, infection, postpartum hemorrhage, meconium aspiration, birth trauma, shoulder dystocia) and that outcomes were generally similar in comparison with use of the same interventions in the inpatient setting, although the certainty of the evidence was low and more studies are needed. These findings are consistent with other meta-analyses, some of which included both pharmacologic and mechanical methods and others that focused on mechanical methods (96–100). Although the evidence for use of misoprostol was assessed as insufficient in the review by McDonagh et al (9), a network meta-analysis that focused specifically on pharmacologic methods of outpatient cervical ripening including 42 trials with more than 6,000 participants concluded that vaginal misoprostol at a dose of 25 micrograms was the most effective at reducing the time to vaginal delivery and was not associated with a change in the odds of cesarean delivery, need for additional ripening methods, or adverse perinatal outcomes (101). Synthetic osmotic dilators also have been investigated in the outpatient setting and have been found to decrease hospital length of stay without significant adverse outcomes (68).

Of note, by necessity, the absence of an indication for maternal or fetal monitoring during the cervical ripening period is an inclusion criterion for these studies, which affects the generalizability of these findings. Comparative evidence for the optimal mode of fetal assessment as part of an outpatient cervical ripening protocol was not identified, and the data were inadequate to determine the characteristics of pregnant individuals who will benefit the most or have the lowest risk of harm or to identify the optimal pharmacologic or mechanical method for the outpatient setting.

Use of Language

ACOG recognizes and supports the gender diversity of all patients who seek obstetric and gynecologic care. In original portions of this document, the authors seek to use gender-inclusive language or gender-neutral language. When describing research findings, this document uses gender terminology reported by the investigators. ACOG's policy on inclusive language can be reviewed at https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language.

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Appendices

Supplemental Digital Content

A. Literature search strategy: available online at http://links.lww.com/AOG/E138
B. PRISMA diagram: http://links.lww.com/AOG/E139
C. Evidence tables: http://links.lww.com/AOG/E140

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