Implementing AHRQ Effective Health Care Reviews

Helping Clinicians Make Better Treatment Choices

Cervical Ripening in the Outpatient Setting

Practice Pointers by Tyler S. Rogers, MD, MBA, FAAFP, and Ben Lampe, MD,
Martin Army Community Hospital, Fort Benning, Georgia
Stephanie Skelly, MD, Womack Army Medical Center, Fort Bragg, North Carolina

Key Clinical Issue

What is the effectiveness and what are the harms of cervical ripening methods in the outpatient vs. inpatient setting?

Evidence-Based Answer

There is no significant difference in cesarean delivery rate or fetal harms (e.g., infection) with the use of prostaglandins in the outpatient setting compared with the inpatient setting. (Strength of Recommendation [SOR]: B, inconsistent or limited-quality patient-oriented evidence.) Mechanical methods of cervical ripening in the outpatient setting do not significantly differ from those in the inpatient setting in rates of cesarean delivery, maternal harms (e.g., uterine infection, postpartum hemorrhage), or fetal harms (e.g., birth trauma, shoulder dystocia). (SOR: B, inconsistent or limited-quality patient-oriented evidence.) In the outpatient setting, prostaglandin vs. expectant management, prostaglandin vs. placebo, and dinoprostone vs. membrane sweeping do not differ significantly in cesarean delivery rates, fetal harms, or maternal harms. (SOR: B, inconsistent or limited-quality patient-oriented outcomes.) Mechanical and pharmacologic ripening methods in the outpatient setting have similar cesarean delivery rates.[1] (SOR: B, inconsistent or limited-quality patient-oriented outcomes.)

Practice Pointers

Cervical ripening is a clinical intervention used to induce labor and increase the likelihood of a vaginal delivery. The likelihood of a successful induction, or cervical favorability, is calculated using the Bishop Score for Vaginal Delivery and Induction of Labor (https://www.mdcalc.com/bishop-score-vaginal-delivery-induction-labor). A score of less than 6 is considered unfavorable and suggests that a ripening agent is needed.[2]

Cervical ripening can be performed mechanically with a single- or double-balloon catheter, or pharmacologically with oral, intravaginal (insert or gel), or intracervical prostaglandin administration. The choice of method is based on clinician and patient preference.[3] Prostaglandins include dinoprostone and misoprostol. Pharmacologic ripening is generally more comfortable for patients than mechanical dilation.

Additional tables at https://www.aafp.org/afp/2022/0201/p193.html.

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to produce evidence to improve health care and to make sure the evidence is understood and used. A key clinical question based on the AHRQ Effective Health Care Program systematic review of the literature is presented, followed by an evidence-based answer based on the review. AHRQ's summary is accompanied by an interpretation by an *AFP* author that will help guide clinicians in making treatment decisions. For the full review, go to https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-238-cervical-ripening-final-report.pdf.

This series is coordinated by Kenny Lin, MD, MPH, deputy editor.

A collection of Implementing AHRQ Effective Health Care Reviews published in *AFP* is available at https://www.aafp.org/afp/ahrq.

CME This clinical content conforms to AAFP criteria for CME. See CME Quiz on page 124.

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CLINICAL BOTTOM LINE

Cesarean Delivery Primary Birth Outcomes

Key question	Intervention	Findings	Studies	Incidence	Relative risk (95% CI) I^2 for pooled analyses*
Prostaglandin: outpatient vs. inpatient	Dinoprostone	Low-strength evidence of little or no difference	2 RCTs (n = 1,120)	23% vs. 23%	0.97 (0.75 to 1.25)
	Dinoprostone	Low-strength evidence of little or no difference	4 cohort studies (n = 2,511)	33% vs. 33%	0.79 (0.67 to 0.98)
Mechanical method: outpatient vs. inpatient	Single-balloon catheter	Low-strength evidence of a small, but nonsignificant difference	3 RCTs (n = 370)	12% vs. 20%	0.59 (0.21 to 1.03)
	Single-balloon catheter	Low-strength evidence of a small, but nonsignificant, difference	2 cohort studies (n = 1,057)	33% vs. 30%	0.95 (0.72 to 1.22)
	Outpatient catheter vs. inpatient dinoprostone	Low-strength evidence of a small, but nonsignificant difference	2 RCTs (n = 549)	33% vs. 26%	1.24 (0.88 to 1.70)
Outpatient comparison of methods	Dinoprostone gel, 2.5 mg vs. 5.0 mg	Low-strength evidence of little or no difference	1 RCT (n = 116)	20% vs. 19%	1.07 (0.51 to 2.22)
	Prostaglandin vs. placebo	Low-strength evidence of a small, but nonsignificant difference	12 RCTs (n = 924)	16% vs. 21%	0.80 (0.58 to 1.09), I^2 = 4.3%
	Prostaglandin vs. expectant management	Low-strength evidence of little or no difference	4 RCTs (n = 615)	27% vs. 26%	0.95 (0.68 to 1.33)
	Dinoprostone vs. membrane sweeping	Low-strength evidence of a small, but nonsignificant difference	3 RCTs (n = 339)	22% vs. 15%	1.44 (0.85 to 2.36)
	Silicone vs. latex single-balloon catheters	Low-strength evidence of little or no difference	1 RCT (n = 534)	39% vs. 40%	0.98 (0.80 to 1.22)

RCT = randomized controlled trial.

*—I^2 = 0% unless otherwise indicated.

Adapted from McDonagh M, Skelly AC, Hermesch A, et al. Cervical ripening in the outpatient setting. Comparative effectiveness review no. 238. (Prepared by the Pacific Northwest Evidence-Based Practice Center under contract no. 290-2015-00009-I.) AHRQ publication no. 21-EHC011. Agency for Healthcare Research and Quality; March 2021. Accessed April 30, 2021. https://effectivehealthcare.ahrq.gov/sites/default/files/cer-238-cervical-ripening-evidence-summary.pdf

Cervical ripening has historically been performed in the inpatient setting, although more institutions are implementing policies for outpatient ripening, which is the focus of the Agency for Healthcare Research and Quality (AHRQ) review. A potential benefit of cervical ripening in the outpatient setting is decreased time from admission to delivery, which may be more cost-effective.[4,5]

The AHRQ review included 30 randomized controlled trials and 10 cohort studies of fair quality that included outcomes such as fetal infection, birth trauma, shoulder dystocia, meconium aspiration syndrome, uterine infection, and postpartum hemorrhage. The mean age of participants was 28.8 years, and most were nulliparous at term (mean gestational age = 40 weeks and six days). The most common reason for cervical ripening was postterm pregnancy. Because most studies excluded pregnant people undergoing trial of labor after cesarean delivery, the review is most applicable to uncomplicated singleton pregnancies.

Although cervical ripening in the outpatient setting did not reduce fetal or maternal harms or cesarean rates, the similarity in these outcomes compared with cervical ripening in the inpatient setting suggests that it may be safe to offer outpatient cervical ripening to low-risk patients. Because there were no significant differences in cesarean

rates and maternal or fetal harms between pharmacologic and mechanical methods, it is reasonable to choose either in most cases.

The AHRQ review supports current guidance from the American College of Obstetricians and Gynecologists, the Royal College of Obstetricians and Gynaecologists, and other organizations that there is no evidence that any method of cervical ripening is superior to others.[2,6] The review's limitations point to areas for future research. Prospective cohort studies with larger sample sizes could potentially identify which ripening method and setting is superior among subgroups, but they would need to control for confounding factors. Because serious maternal and fetal adverse events are relatively uncommon, larger studies may produce stronger recommendations.[7]

The views expressed in this article are those of the authors and do not reflect the policy or position of the U.S. Army Medical Department, Department of the Army, Department of Defense, or the U.S. government.

Editor's Note: *American Family Physician* SOR ratings are different from the AHRQ Strength of Evidence ratings.

Address correspondence to Ben Lampe, MD, at benjamin.s.lampe.mil@mail.mil. Reprints are not available from the authors.

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eTABLE A

Primary Fetal Harms Outcomes

Key question	Intervention	Outcome	Findings	Studies	Incidence	Relative risk (95% CI) I^2 for pooled analyses*
Prostaglandin: outpatient vs. inpatient	Dinoprostone	Infection	Low-strength evidence of little or no difference	2 RCTs (n = 1,120)	4% vs. 3%	1.39 (0.67 to 3.03)
Mechanical method: outpatient vs. inpatient	Single-balloon catheter	Birth trauma	Low-strength evidence of little or no difference	1 RCT (n = 129)	2% vs. 3%	0.49 (0.05 to 5.30)
	Single-balloon catheter	Shoulder dystocia	Low-strength evidence of a moderate, but non-significant difference	1 RCT (n = 129)	3% vs. 11%	0.28 (0.06 to 1.30)
Outpatient comparison of methods	Dinoprostone vs. placebo	Meconium aspiration syndrome	Low-strength evidence of a small, but nonsig-nificant difference	2 RCTs (n = 134)	2% vs. 4%	0.76 (0.03 to 22.33)
	Prostaglandins vs. placebo	Shoulder dystocia	Low-strength evidence of a small, but nonsig-nificant difference	3 RCTs (n = 270)	3% vs. 0.70%	Risk difference = 0.01 (−0.02 to 0.04)
				2 RCTs (n = 150)	6% vs. 1%	3.40 (0.55 to 20.95)

RCT = randomized controlled trial.

*—I^2 = 0% unless otherwise indicated.

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eTABLE B

Primary Maternal Harms Outcomes

Key question	Intervention	Outcome	Findings	Studies	Incidence	Relative risk (95% CI) I^2 for pooled analyses*
Mechanical method: outpatient vs. inpatient	Single-balloon catheter	Uterine infection	Low-strength evidence of little or no difference	2 RCTs (n = 259)	5% vs. 5%	0.99 (0.31 to 3.19)
	Outpatient catheter vs. inpatient dinoprostone	Postpartum hemorrhage	Low-strength evidence of a small, but nonsignificant difference	2 RCTs (n = 549)	28% vs. 25%	1.10 (0.62 to 1.56)
Outpatient comparison of methods	Prostaglandins vs. placebo	Uterine infection	Low-strength evidence of a small, but nonsignificant difference	7 RCTs (n = 771)	7% vs. 10%	0.75 (0.40 to 1.39)
	Prostaglandins vs. expected management	Uterine infection	Low-strength evidence of little or no difference	1 RCT (n = 294)	6% vs. 5%	1.21 (0.45 to 3.24)
	Prostaglandins vs. membrane sweeping	Uterine infection	Low-strength evidence of a small, but nonsignificant difference	2 RCTs (n = 269)	7% vs. 4%	1.22 (0.56 to 2.75)

RCT = randomized controlled trial.

*—I^2 = 0% unless otherwise indicated.

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