



Rachel Dubay, MD;
Nicola Rentschler, MD;
Dara Jolly, MD;
Jon O. Neher, MD
Valley Family Medicine,
Renton, WA

Sarah Safranek, MLIS
Librarian Emeritus,
University of Washington,
Seattle

DEPUTY EDITOR

Richard Guthmann,
MD, MPH
Advocate Illinois Masonic
Family Medicine Residency,
Chicago

doi: 10.12788/fjp.0353

Q/ Does adjunctive oxytocin infusion during balloon cervical ripening improve labor induction?

EVIDENCE-BASED ANSWER

A/ YES. Compared to the use of a transcervical balloon alone, combined cervical ripening with a balloon catheter and oxytocin shortens the time to overall delivery by 3 hours and the time to vaginal delivery by 4 hours, without altering the rate of cesarean section (strength of recommendation [SOR]: **A**, network meta-analysis). The effect is more pronounced in nullipa-

rous patients (SOR: **A**, meta-analysis).

When combined therapy is used, 6 hours of balloon time may result in faster delivery than 12 hours (SOR: **B**, single randomized controlled trial [RCT]). Fixed-dose oxytocin and titrated oxytocin appear to have similar effect when combined with a cervical ripening balloon (SOR: **C**, underpowered RCT).

Evidence summary

Time to delivery is shortened with combined therapy

Two recent high-quality meta-analyses investigated the effect of adding oxytocin to transcervical Foley balloon placement for cervical dilation. A network meta-analysis, including 30 RCTs (with 6465 pregnant patients), examined the efficacy of multiple combinations of cervical ripening methods.¹ A subset of 7 trials (n = 1313) compared oxytocin infusion with transcervical Foley (inflated to 30-60 mL) to Foley alone. Patients were at > 24 weeks' gestation with a live fetus and undergoing elective or medical induction of labor; exclusion criteria were standard contraindications to vaginal delivery.

Compared to Foley alone, Foley plus oxytocin reduced both the time to the primary outcome of vaginal delivery (mean duration [MD] = -4.2 h; 95% CI, -1.9 to -6.5) and the time to overall (vaginal and cesarean) delivery (MD = -3.1 h; 95% CI, -1.5 to -4.6). There were no differences in rates of cesarean section, chorioamnionitis, epidural use, or neonatal intensive care unit admission. This analysis did not stratify by parity.¹

In a standard meta-analysis, researchers identified 6 RCTs (N = 1133) comparing transcervical Foley balloon and oxytocin to Foley balloon alone for cervical ripening in pregnant patients at > 23 weeks' gestation (1 trial was limited to patients at > 37 weeks' gestation).² Foley balloons were inflated with 30 to 60 mL saline, and oxytocin infusions started at 1 to 2 mU/min and were titrated up to 10 to 40 mU/min. Balloon time was usually 12 hours, but not always stated.

The authors found no statistically significant difference in cesarean rates (the primary outcome) between Foley plus oxytocin vs Foley alone (relative risk [RR] = 0.91; 95% CI, 0.76-1.1). Overall delivery within 12 hours was more likely with combined therapy (RR of remaining pregnant = 0.46; 95% CI, 0.34-0.63), but delivery at 24 hours was not (RR = 0.94; 95% CI, 0.92-1.05). However, in a sub-analysis by parity, nulliparous women who received combined therapy had higher overall delivery rates in 24 hours than did multiparous women (RR = 0.77; 95% CI, 0.62-0.97).²

Adding oxytocin may allow shorter transcervical balloon times

One recent RCT (N = 177) compared labor induction with oxytocin and a single transcervical balloon (Cook catheter with only the intrauterine balloon inflated) removed at either 6 or 12 hours.³ Patients were pregnant women (mean age, 31 years) with a term singleton vertex pregnancy, a Bishop score ≤ 6 , and no contraindications to vaginal delivery. All patients received a balloon inflated to 60 mL with an oxytocin infusion (2-30 mU/min). The intervention group had the balloon removed at 6 hours, while the control group had it removed at 12 hours.

The mean Bishop score changed by 6 points in each group. Time to overall delivery (the primary outcome) was significantly shorter with 6 hours of balloon time than with 12 hours (19.2 vs 24.3 h; $P < .04$). Overall delivery within 24 hours was also significantly more likely in the 6-hour group (67.4% vs 47.4%; $P < .01$), although vaginal delivery in 24 hours did not change (74% vs 59%; $P = .07$). No differences were seen in cesarean delivery rates or maternal or neonatal morbidity rates.

A look at fixed-dose vs titrated oxytocin

Another RCT (N = 116) examined the effectiveness of cervical ripening using a Foley balloon plus either fixed-dose or titrated low-dose oxytocin.⁴ Patients (mean age, 26 years) had singleton pregnancies at ≥ 37 weeks' gestation with a Bishop score < 6 and presented for induction of labor. Foley balloons were inflated to 30 mL, and patients received either a fixed oxytocin infusion of 2 mU/min or a titrated infusion starting at 1 mU/min, increasing by 2 mU/min every 30 minutes to a maximum of 20 mU/min.

There was no statistically significant difference in median time from Foley placement to overall delivery (the primary outcome) between the fixed low-dose and incremen-

tal low-dose groups in either nulliparous women (24 vs 19 h; $P = .18$) or multiparous women (16 vs 12 h; $P = .68$). The authors acknowledged the study may have been underpowered to detect a true difference.

Recommendations from others

A 2009 Practice Bulletin from the American College of Obstetricians and Gynecologists (ACOG) recommended the Foley catheter as a reasonable and effective alternative to prostaglandins for cervical ripening and the induction of labor (based on good-quality evidence).⁵ The guideline stated that Foley catheter placement before oxytocin induction reduced both the duration of labor and risk of cesarean delivery, but that the use of oxytocin along with a Foley catheter did not appear to shorten the time to delivery.

Editor's takeaway

High-quality evidence shows us that the addition of oxytocin to balloon cervical ripening shortens the time to delivery. This newer evidence may prompt an update to the 2009 ACOG statement. **JFP**

> High-quality evidence shows that the addition of oxytocin to balloon cervical ripening shortens the time to delivery.

References

1. Orr L, Reisinger-Kindle K, Roy A, et al. Combination of Foley and prostaglandins versus Foley and oxytocin for cervical ripening: a network meta-analysis. *Am J Obstet Gynecol.* 2020;223:743.e1-743.e17. doi: 10.1016/j.ajog.2020.05.007
2. Gallagher LT, Gardner B, Rahman M, et al. Cervical ripening using Foley balloon with or without oxytocin: a systematic review and meta-analysis. *Am J Perinatol.* 2019;36:406-421. doi: 10.1055/s-0038-1668577
3. Lassey SC, Haber HR, Kanbergs A, et al. Six vs twelve hours of single balloon catheter placement with oxytocin administration for labor induction: a randomized controlled trial. *Am J Obstet Gynecol.* 2021:S0002-9378(21)00185-X. doi: 10.1016/j.ajog.2021.03.021
4. Fitzpatrick CB, Grotegut CA, Bishop TS, et al. Cervical ripening with Foley balloon plus fixed versus incremental low-dose oxytocin: a randomized controlled trial. *J Matern Fetal Neonatal Med.* 2012;25:1006-1010. doi: 10.3109/14767058.2011.607522
5. ACOG Practice Bulletin No. 107: Induction of labor. *Obstet Gynecol.* 2009;114(2 pt 1):386-397. doi: 10.1097/AOG.0b013e3181b48ef5