



Does the addition of the Foley bulb to vaginal misoprostol for cervical ripening and labor induction reduce the time to delivery?

Yes. In this prospective, randomized trial of 123 pregnant women undergoing induction of labor with an unfavorable cervix (Bishop score ≤ 6), the mean induction-to-delivery time was 3.1 hours shorter for the combination of the Foley bulb and vaginal misoprostol than for vaginal misoprostol alone (95% CI, -5.9 to -0.3). The mean time from induction to complete cervical dilation was shorter by 3.5 hours for the combination of the Foley bulb and vaginal misoprostol (95% CI, -6.7 to -0.4). There were no differences in labor complications or adverse neonatal and maternal outcomes. The rate of cesarean delivery was comparable between groups.

FAST TRACK

In this trial, the combination of vaginal misoprostol and the Foley bulb reduced the time from induction to delivery to a greater extent than vaginal misoprostol alone

Carbone JF, Tuuli MG, Fogertey PJ, Roehl KA, Macones GA. Combination of Foley bulb and vaginal misoprostol compared with vaginal misoprostol alone for cervical ripening and labor induction. A randomized controlled trial. Obstet Gynecol. 2013;121(2):247-252.

► EXPERT COMMENTARY

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In this trial, women who had a singleton pregnancy at 35 weeks' gestation or later were randomly allocated to the Foley bulb plus vaginal misoprostol (n = 56) or to vaginal misoprostol alone (n = 61) for cervical ripening and labor induction. All women had a vertex presentation, intact membranes, and an unfavorable cervix.

Women assigned to the combination

group received vaginal misoprostol 25 μ g every 4 hours and a Foley bulb inserted into the internal cervical os and filled with 60 mL of normal saline. Women assigned to vaginal misoprostol alone were given 25 μ g every

WHAT THIS EVIDENCE MEANS FOR PRACTICE

Given the contradictory findings of Carbone and colleagues and an earlier trial of similar design,⁶ it is very unlikely that this trial is robust enough to change current clinical practice, which is highly variable. Among the methods for cervical ripening and labor induction in current use are oxytocin administration, oral or vaginal misoprostol, prostaglandin administration, the Foley bulb, vaginal dinoprostone, or a combination of methods.

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4 hours. Intravenous oxytocin was given in each group when indicated, according to the discretion of the managing physician, at a rate of 2 mU/min, increasing by 2 mU every 20 min until regular uterine contractions occurred.

The primary outcome of the trial was the time from induction to delivery. Secondary outcomes were mode of delivery, tachysystole, and postpartum hemorrhage.

The median Bishop score was 3 in each group (range, 3–6).

Strengths and limitations of the trial

The strength of this study is its randomized design.

Among the limitations are its small sample size, which was inadequate to evaluate serious maternal and neonatal morbidities, and its lack of blinding, which may introduce bias among the managing physicians.

The primary outcome of induction-to-delivery time is not clinically important, particularly when multiparous women and those with a Bishop score above 5 are included, as they were in this study. Moreover, only women with a gestational age of at least 35 weeks were included, so the results do not apply to those with lower gestational ages.

Goal of induction is to achieve vaginal delivery within 24 hours

In the United States, at least one in every four pregnant women undergo induction of labor for any of a variety of obstetric, medical, and social indications.¹ In nulliparous women who have an unfavorable cervix, induction of labor is associated with increased rates of prolonged labor, cesarean delivery, chorioamnionitis, and postpartum hemorrhage. The goal of induction of labor should be to achieve vaginal delivery within 24 hours and reduce the rate of cesarean delivery without increasing adverse maternal and neonatal outcomes.

Several methods are used for induction of labor with or without cervical ripening. They include the administration of oxytocin, oral or vaginal misoprostol in various doses, different preparations of prostaglandins, use of a Foley balloon filled with 30 to 100 mL of saline, or a combination of these methods. To date, none of these approaches has been shown to reduce the rate of cesarean delivery.

A similarly designed study produced very different findings. Data from multiple studies are mixed in regard to the induction-to-delivery time, rate of delivery within 24 and 48 hours, and side effects.^{1–6} These studies vary in inclusion criteria, method of induction or cervical ripening, dose of induction agent, Bishop score at randomization, primary outcomes, and sample size. A study from Brazil with a design similar to that of the study by Carbone and colleagues found a shorter mean time from induction to vaginal delivery in the vaginal misoprostol group, compared with the group allocated to the Foley bulb plus oxytocin. There were also more vaginal deliveries in the misoprostol group at 12 hours and 18 hours.⁶

References

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No single method (or combination of methods) of cervical ripening and labor induction has been proven superior