Randomized Controlled Trial: Cervical Ripening Balloon With and Without Oxytocin for Cervical Ripening in Multiparas

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Project Proposal

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Background:

In the United States, more than 1 in 5 pregnant women undergo induction of labor. (1) The likelihood of vaginal delivery after induction of labor is increased if the cervix is favorable (Bishop score > 8). (3) However, in women with an unfavorable cervix (Bishop score < 6), cervical ripening is beneficial. (1, 3) Cervical ripening balloon placement is a safe and effective method of cervical ripening in which a Foley catheter is passed through the internal cervical os into the extra-amniotic space and inflated with saline. The balloon then rests against the internal os, physically causing gradual cervical dilation as well as causing the release of prostaglandins from the adjacent membranes and cervix. (3) Compared with prostaglandins, Foley catheter placement has the advantages of being low cost, with reduced risk of uterine tachysystole or fetal heart rate changes. (1)

Several studies have assessed variations in transcervical Foley catheter use. For example, studies have been conducted to assess the potential benefit of increased volume of inflation of the balloon (2), traction on the Foley balloon (4), extra-amniotic saline infusion (3), and the addition of adjunctive agents such as prostaglandins (3) or Oxytocin (4). The use of adjunctive agents is attractive to decrease the interval from induction to delivery, which has the potential to decrease healthcare related costs and improve patient satisfaction.

In a randomized study, Pettker et al found no significant difference in the proportion of deliveries achieved within 24 hours, the induction to delivery interval, or duration of cervical ripening when comparing transcervical Foley catheter alone and transcervical Foley catheter with Pitocin. However, a subgroup analysis of multiparous patients demonstrated an increase in deliveries within 24 hours (91 vs 68%, RR 1.33, 95% CI 1.06-1.67) and an average induction to delivery interval that was 4.6 hours shorter ($p = 0.046$). (4) Though a benefit was suggested in this subgroup analysis, there has been no primary outcome data on multiparous patients undergoing an induction of labor with transcervical Foley catheter and simultaneous oxytocin and the optimal ripening regimen remains unclear.
Objective: The purpose of this study is to determine the optimal method for induction of labor in multiparous women with an unfavorable cervix.
Hypothesis: Our hypothesis is that using Oxytocin while the cervical ripening balloon is in place will result in more rapid labor courses, without increase morbidity or increasing the need for operative delivery.

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Inclusion Criteria:

- Age > 18 years
- Gestational age > 34 weeks
- Prior spontaneous vaginal delivery
- Clinical or ultrasound estimated fetal weight < 4500 grams
- Singleton gestation
- Cervical dilation < 2 cm on admission

Exclusion Criteria:

- Placental abruption, chorioamnionitis, or systemic infection prior to induction
- Rupture of membranes prior to induction
- More than 1 prior cesarean delivery
- Placenta within 2 cm of cervical os
- Any contraindication to vaginal delivery
- Any contraindication to cervical ripening balloon placement or oxytocin administration

Study Protocol:

- Identify patients who are multiparous, who will be undergoing induction of labor, and obtain informed consent either during prenatal care or on admission to labor and delivery.
- Randomize patients to receive cervical ripening balloon (CRB) alone followed by oxytocin or CRB and simultaneous oxytocin for induction via random number generator in sequential opaque envelopes.
- CRB is placed digitally or with a speculum and balloon is inflated with 35 mL of normal saline. Care of the CRB per current MacDonald guidelines. Oxytocin is administered either when the balloon is removed (after 12 hours) or if spontaneously expelled sooner if in the control group, or is initiated when the balloon is placed in the experimental group.
- Fetal monitor and labor management is per current guidelines for all participants.

Statistical Analysis Plan:

Power Calculation: Using the data from Pettker, in the subgroup analysis of multiparous women, the rates of vaginal delivery within 24 hours were 75% and 55% respectively for women receiving transcervical Foley with oxytocin compared with transcervical Foley alone. Under assumption of 80% power and an alpha of 0.05, we estimated we would need 90 patients in each arm to demonstrate a 20% reduction (from 75% to 55%) in primary outcome in the treatment group.

Data Collection: Demographic variables (maternal age, race, parity, gestational age at delivery, indication for induction), time to expulsion of CRB, cervical dilation after expulsion, time to delivery, cesarean delivery rate, operative vaginal delivery rate, perinatal complications (including postpartum hemorrhage, chorioamnionitis, or cervical laceration), neonatal outcomes (including APGAR scores)

Analysis Plan: Intention to treat analysis, calculation of RR, 95% CI. Categorical and continuous variables will be assessed using parametric and non-parametric tests where appropriate.

References:

(1) Induction of labor. ACOG Practice Bulletin No. 107. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009; 114: 386-97.

(2) Delaney et al. Labor induction with a Foley balloon inflated to 30 mL compared with 60 mL. Obstet Gynecol 2010; 115(6): 1239-1245.

(3) Gabbe et al. Obstetrics: Normal and Problem Pregnancies, 6th Edition. 2012.

(4) Gibson KS, Mercer BM, Louis JM. Inner thigh taping vs traction for cervical ripening with a Foley catheter: a randomized controlled trial. American Journal of Obstetrics and Gynecology 2013; 209: 272.e1-7.

(5) Pettker CM, Pocock SB, Smok DP, Lee SM, Devine PC. Transcervical Foley catheter with and without oxytocin for cervical ripening. Obstet Gynecol 2008; 111(6): 1320-6.