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# Combination Foley Catheter–Oxytocin versus Oxytocin Alone following Preterm Premature Rupture of Membranes

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## Abstract

**Objective** The benefit of mechanical ripening agents following preterm premature rupture of membranes (PPROM) has not been established. We sought to compare the time to delivery in women who received transcervical Foley catheter plus oxytocin infusion versus oxytocin infusion alone in patients with unfavorable cervices and PPROM.

**Study Design** This is a retrospective cohort study of patients presenting with PPROM of a live, singleton gestation between $24^{0/7}$ and $36^{6/7}$ weeks' gestation from January 2005 to October 2018 at a single, tertiary care institution. Patients with an unfavorable cervical examination (≤2-cm dilation), no contraindication to labor and undergoing labor induction were analyzed. Time to delivery was analyzed using multivariable linear regression adjusting for cervical dilation at induction and nulliparity. Bivariate and multivariate analyses were used where appropriate.

**Results** A total of 260 participants were included: 109 who received a Foley catheter and oxytocin (Foley/oxytocin) and 151 who had oxytocin alone. Demographic characteristics were similar between the two groups. Unadjusted time to delivery was significantly shorter in the oxytocin only group (Foley/oxytocin: 20.35 hours vs. oxytocin alone: 14.7 hours, $p < 0.001$). No differences in length of labor were detected after adjusting for cervical dilation at induction and nulliparity ($p = 0.5$). The unadjusted rate of cesarean delivery was higher in the combination Foley/oxytocin group (Foley/oxytocin: 16.5% vs. oxytocin alone: 7.3%, $p = 0.03$), but no differences were found in the adjusted analysis ($p = 0.06$). There were no differences in clinical chorioamnionitis rates between the two groups (Foley/oxytocin: 8.3% vs. oxytocin alone: 9.3%, $p = 0.83$). Furthermore, no significant differences were found in maternal and neonatal outcomes between the two groups.

**Conclusion** In patients with PROM, the use of a transcervical Foley catheter in addition to oxytocin is not associated with a shorter time to delivery compared with oxytocin alone.

**Keywords**
- labor induction
- cervical Foley
- cervical ripening
- rupture of membranes
- PPROM

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## Key Points

- Transcervical Foley catheter did not shorten length of labor in PPROM.
- Transcervical Foley catheter did not increase infection risk.
- Pitocin alone can be used in PPROM population.

Preterm premature rupture of membranes (PPROM) complicates 3% of pregnancies.[1] Intrauterine infection is a significant risk among patients with premature membrane rupture with an estimated incidence of 15 to 25%.[2] Moreover, preterm neonates have been well documented to have higher rates early-onset sepsis than term infants. Induction of labor is recommended between 34 and 36 $^{6/7}$ weeks' gestation following preterm membrane rupture, but the optimal induction method has not yet been established.[3,4] Combination cervical ripening with mechanical and pharmacological agents shortens time to delivery compared with single-agent induction methods in term pregnancies with intact membranes.[5–8] The Foley catheter, however, has a theoretical risk of introducing infection in ruptured membranes. While studies have examined balloon-related infectious morbidity in term membrane rupture,[9–12] infectious morbidity in preterm membrane rupture has not been established. Thus, the study objective was to evaluate effectiveness and safety of the balloon catheter for induction in preterm membrane rupture and determine whether balloon catheter for cervical ripening reduces time to delivery or cesarean section rate compared with oxytocin alone in this preterm population.

## Materials and Methods

### Screening and Recruitment

After approval from the institutional review board at Christiana Care Health Services (Newark, DE, CCC no.: 38169), we conducted a retrospective cohort study on all patients 18 years and older diagnosed with PPROM between 24$^{0/7}$ and 36$^{6/7}$ weeks' gestation from January 2005 to October 2018 at our academic tertiary care hospital. Women were included if they met the diagnosis of PPROM by clinical assessment and findings on exam including pooling of amniotic fluid, positive nitrazine test, visible ferns, and/or oligohydramnios on ultrasound, as described by the American College of Obstetricians and Gynecologists.[11] Gestational age was estimated using date of last menstruation, confirmed by sonogram per standard criteria.[12] For pregnancies conceived with artificial reproductive technology, the date of embryo transfer was used.

Patients with an unfavorable cervical examination ($\leq$2-cm dilation), no contraindication to labor and undergoing labor induction were analyzed. Individuals were excluded if they presented in active labor, had clinical or objective signs of intra-amniotic infection, had nonreassuring fetal heart rate tracing, or any other indication for immediate delivery. Pregnancies with fetal anomalies, multiple gestation, and unknown rupture time were excluded from the analysis.

### Statistical Analysis

Continuous variables were calculated as median (interquartile range). The data were then tested for normality using the Shapiro–Wilk test and Student's *t*-test or Mann–Whitney U test were then used as appropriate. Categorical variables were calculated as proportions and compared using the chi-square test. Time to delivery was analyzed using multivariable linear regression model with prespecified adjustment for cervical dilation at induction and nulliparity.

## Results

A total of 260 participants were included: 109 in the combination Foley catheter and oxytocin group (Foley/oxytocin) and 151 in the oxytocin alone group. Demographic characteristics were similar between the two groups (►Table 1). Unadjusted time to delivery was significantly longer in the combination Foley/oxytocin group (Foley/oxytocin: 20.35 hours vs. oxytocin alone: 14.7 hours, $p < 0.001$, ►Table 2). The unadjusted rate of cesarean delivery was higher in the combination Foley/oxytocin group (Foley/oxytocin: 16.5% vs. oxytocin alone: 7.3%, $p = 0.03$).

Statistical adjustments were made for a cervical dilation less than 1 cm at induction initiation and nulliparity; there was a trend toward higher rates of cesarean delivery in the combination Foley/oxytocin group (Foley/oxytocin: 16.5% vs. oxytocin alone: 7.3%, $p = 0.06$, ►Table 2).

No differences in length of labor were detected after adjusting for cervical dilation at induction and nulliparity ($p = 0.5$). There were no differences in clinical chorioamnionitis rates between the two groups (Foley/oxytocin: 8.3% vs. oxytocin alone: 9.3%, $p = 0.83$). Furthermore, no significant differences were found in maternal and neonatal outcomes between the two groups (►Table 3). There were no significant differences in survival or neonatal outcomes. Rates of intraventricular hemorrhage and necrotizing enterocolitis did not differ between the two groups. Rate of neonatal deaths, sepsis, and Apgar at 5 minutes were similar between the two groups.

## Discussion

### Principal Findings

This study did not identify a difference in time to delivery between patients with PPROM who received a combination of oxytocin and a Foley catheter versus oxytocin alone. There were no differences in the cesarean delivery rate, chorioamnionitis rate, or the rate of adverse neonatal outcomes.

**Table 1** Maternal and pregnancy characteristics by labor induction method

| | Combination Foley, Pitocin ($n = 109$) | Pitocin only ($n = 151$) | *p*-Value |
|---|---|---|---|
| Maternal age (y), median, IQR | 30.0 [25.0; 36.0] | 30.9 [27.0; 35.0] | 0.90 |
| Black race, *n* (%) | 26 (23.9) | 47 (31.1) | 0.21 |
| Hispanic ethnicity, *n* (%) | 20 (18.3) | 26 (17.2) | 0.87 |
| Nulliparous, *n* (%) | 68 (62.4) | 64 (42.4) | 0.002 |
| Indication for induction | | | |
| ≥34 weeks' gestation | 103 (94.5) | 141 (93.4) | 0.22 |
| Clinical chorioamnionitis | 5 (4.6) | 7 (4.6) | |
| NRFHT | 1 (0.92) | 3 (2.0) | |
| Cervical dilation ≤ 1 cm at Induction, *n* (%) | 79 (72.5) | 34 (22.5) | <0.001 |
| Group B *Streptococcus* positive status, *n* (%) | 13 (11.9) | 27 (17.9) | 0.22 |
| Magnesium sulfate for fetal neuroprotection, *n* (%) | 9 (8.3) | 12 (7.9) | 1.0 |
| Betamethasone administration, *n* (%) | 30 (27.5) | 34 (22.5) | 0.38 |
| Tocolysis administration, *n* (%) | 10 (9.2) | 14 (9.3) | 1.0 |
| Maternal comorbidities, *n* (%) | | | |
| History of preterm birth | 3 (2.8) | 11 (7.3) | 0.16 |
| History of LEEP | 1 (0.9) | 1 (0.7) | 1.0 |
| History of short cervix | 2 (1.8) | 5 (3.3) | 0.70 |
| Gestational diabetes | 11 (10.1) | 9 (6.0) | 0.24 |
| Gestational hypertension | 5 (4.6) | 9 (6.0) | 0.78 |
| Asthma | 11 (10.1) | 24 (15.9) | 0.20 |
| Maternal thyroid disease | 7 (6.4) | 7 (4.6) | 0.58 |
| IVF pregnancy, *n* (%) | 5 (4.6) | 2 (1.3) | 0.13 |
| Tobacco use in pregnancy, *n* (%) | 16 (14.7) | 22 (14.6) | 1.0 |

Abbreviations: IQR, interquartile range; IVF, in vitro fertilization; LEEP, loop electrosurgical excision procedure; NRFHT, nonreassuring fetal heart tracing.

**Table 2** Labor outcome by labor induction method

| | Combination Foley, Pitocin ($n = 109$) | Pitocin only ($n = 151$) | Unadjusted *p*-value | Adjusted *p*-value |
|---|---|---|---|---|
| Cesarean delivery, *n* (%) | 18 (16.5) | 11 (7.3) | 0.03 | 0.06 |
| Operative delivery, *n* (%) | 4 (3.7) | 4 (2.6) | 0.72 | – |
| Unadjusted time to delivery, h, median, IQR | 20.35 [12.4; 26.3] | 14.7 [7.51; 21.34] | <0.001 | 0.23 |
| Clinical intra-amniotic infection and inflammation, *n* (%) | 9 (8.3) | 14 (9.3) | 0.83 | – |
| Suspected placental abruption, *n* (%) | 5 (4.6) | 7 (4.6) | 1.0 | – |
| Endometritis, *n* (%) | 2 (1.8) | 0 (0.0) | 0.18 | – |
| Wound infection, *n* (%) | 0 (0.0) | 0 (0.0) | – | – |

Abbreviation: IQR, interquartile range.



 

**Table 3** Neonatal outcomes by labor induction method

| | Combination Foley, Pitocin ($n = 109$) | Pitocin only ($n = 151$) | *p*-Value |
|---|---|---|---|
| Composite neonatal morbidity[a] | 75 (68.8) | 97 (64.2) | 0.51 |
| Birth weight (kg) median, IQR | 2.31 [2.17; 2.79] | 2.35 [2.25; 2.85] | 0.22 |
| Apgar score <7 at 5 min, *n* (%) | 6 (5.5) | 9 (6.0) | 1.0 |
| Female infant, *n* (%) | 46 (42.2) | 66 (43.7) | 0.90 |
| Infant death | 1 (0.9) | 0 (0.0) | 0.42 |
| NICU admission | 74 (67.9) | 96 (63.6) | 0.51 |
| NICU length of stay | 9.3 [9.0; 9.0] | 8.3 [9.0; 9.0] | 0.28 |
| Intraventricular hemorrhage | 2 (1.8) | 2 (1.3) | 1.0 |
| Necrotizing enterocolitis | – | – | |
| Culture proven–presumed neonatal sepsis | 5 (4.6) | 11 (7.3) | 0.44 |

Abbreviations: IQR, interquartile range; NICU, neonatal intensive care unit.
[a]Composite of neonatal death, NICU admission, Apgar < 7 at minute 5, necrotizing enterocolitis, intraventricular hemorrhage, sepsis.
Notes: Data are presented as *n* (%) unless otherwise indicated. Categorical variables are compared with chi-square and Fisher's exact tests and continuous variables are compared with Kruskal–Wallis tests, unless otherwise indicated.

### Results in Context

The trials aimed at determining the optimal delivery timing in PPROM do not study optimal methods of labor induction. The PPROMEXIL trial[12] did not compare prostaglandins and oxytocin, and subsequent follow-up trials[13,14] did not clearly specify the induction methods used. Among the various trials and meta-analyses comparing methods of cervical ripening, none have studied patients with preterm membrane rupture.

Amorosa et al compared oxytocin alone with a combination of a Foley catheter and oxytocin,[11] among patients ≥ 34 weeks with premature membrane rupture. Compared with oxytocin alone, the Foley catheter and oxytocin immediately after the membrane rupture diagnosis did not reduce the time from induction to birth; both groups also had similar caesarean rates. However, a total of 15 patients were $34^{0/7}$ to $36^{6/7}$; the majority of patients recruited had PROM at term.

Mackeen et al included over 40 patients with PROM at ≥ 34 weeks and found that the use of a transcervical Foley catheter in addition to oxytocin does not shorten the time to delivery compared with oxytocin alone; however, they did find an increased incidence of chorioamnionitis in the cohort who had a Foley catheter.[15] Currently, there are no data to support evidence-based recommendations regarding the method of choice for labor induction following preterm membrane rupture.

## Strengths and Limitations

A strength of our study is large number of diverse participants with an unfavorable cervix at the time of induction. A weakness of our study is that the retrospective analysis may introduce selection bias. However, demographic characteristics were similar between the two groups. This was also a single-center study, and thus, the results may not be generalizable to other centers with different labor management practices and/or labor outcomes.

## Conclusion

In patients with PROM, the use of a transcervical Foley catheter in addition to oxytocin is not associated with a shorter time to delivery compared with oxytocin alone. However, the use of a Foley catheter is not associated with an increased risk of chorioamnionitis. A randomized prospective study is needed to confirm these findings.

### Condensation

The use of a transcervical Foley catheter in addition to oxytocin is not associated with a shorter time to delivery compared with oxytocin alone in patients with preterm membrane rupture.

### Note

The Poster Presentation of this study was held at the Society for Maternal-Fetal Medicine's 43rd Annual Pregnancy Meeting, February 6 to 11, 2023.

### Funding

None.

### Conflict of Interest

None declared.

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