

# Foley Catheter vs Prostaglandin as Ripening Agent in Pregnant Women With Premature Rupture of Membranes

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**Context:** Although studies support the efficacy of the Foley catheter (FC) as a cervical ripening agent in pregnant women at term with intact membranes, its efficacy has not been well studied in women with premature rupture of membranes (PROM).

**Objective:** To compare the interval to delivery in women with PROM who underwent induction of labor and cervical ripening with mechanical (FC) vs nonmechanical (prostaglandin [PG]) cervical ripening agents.

**Design:** Retrospective medical record review at 2 hospitals of pregnant women who delivered between January 2009 and April 2011.

**Setting:** Thomas Jefferson University Hospital in Philadelphia, Pennsylvania, and Christiana Care Health System in Newark, Delaware.

**Patients:** Pregnant women with singleton gestations 36 weeks or greater who presented with PROM.

**Interventions:** Cervical ripening with FC or PG.

**Main Outcome Measures:** The primary outcome was time from induction until delivery. Secondary outcomes included epidural use, maximum temperature during labor, number of vaginal examinations, occurrence of tachysystole, oxytocin dose, delivery mode, chorioamnionitis, and neonatal Apgar score.

**Results:** Of 155 medical records of patients who met the inclusion criteria, 33 women underwent cervical ripening with PG (ie, misoprostol) and 122 with FC. The interval to delivery was almost halved in women who underwent cervical ripening with FC compared with misoprostol (736 vs 1354 minutes;  $P < .01$ ). Compared with the women in the misoprostol group, those in the FC group received a statistically significant higher dose of oxytocin ( $P < .01$ ). There were no statistically significant differences between the groups with respect to the remaining secondary outcomes. Of note, all of the women who received FC were from Christiana Care Health System, and all women who received misoprostol were from Thomas Jefferson University Hospital.

**Conclusion:** Foley catheters may help shorten the interval to delivery in women who are candidates for cervical ripening after PROM at or near term. There does not appear to be an increased risk for cesarean delivery or chorioamnionitis in those treated with FC.

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The percentage of labor inductions has steadily increased over the past 20 years.<sup>1</sup> In 2006, more than 22% of pregnant women underwent labor induction.<sup>2</sup> Ripening agents administered before oxytocin for the induction of labor in term patients with unfavorable cervixes and intact membranes are associated with decreased rates of cesarean delivery compared with oxytocin administration alone.<sup>3-5</sup> There are multiple approaches for preinduction cervical ripening, including mechanical (eg, Foley catheter [FC]) and nonmechanical (eg, prostaglandin [PG]) methods. Mechanical methods of cervical ripening have several advantages over pharmacologic agents, including low cost, ease of reversibility, and lower risk of tachysystole and fetal heart rate abnormalities.<sup>3</sup>

First described in 1967, the FC has been established as both a safe and effective ripening method for women with intact membranes.<sup>6,7</sup> The FC has been compared with PG for cervical ripening in women at term with intact membranes. A randomized clinical trial by Oliveira et al<sup>8</sup> compared the use of FC with vaginal misoprostol for cervical ripening and labor induction and concluded that FC was as effective as the PG misoprostol. Another randomized controlled study that compared FC with PG E2 gel for cervical ripening in women with unfavorable cervixes at term found that cesarean delivery rates were similar between the groups, and FC was associated with fewer fetal and maternal adverse effects.<sup>9</sup>

These studies support the efficacy of FC use as a ripening method in women at term with intact membranes; however, its efficacy has not been well studied in women with premature rupture of membranes (PROM); the optimal management of PROM remains unclear. Between 3% and 19% of all pregnancies are associated with PROM, including 8% to 10% of pregnancies at term.<sup>10</sup> Of women with PROM at term, approximately 40% will take longer than 24 hours after PROM to enter labor spontaneously.<sup>11</sup> Prolongation of latency for greater than 24 hours has been shown to be associated with an increased incidence of chorioamnionitis and

neonatal sepsis.<sup>10,12</sup> In a large randomized trial in women with PROM at term, outcomes associated with expectant management vs labor induction were evaluated.<sup>11</sup> Results demonstrated that expectant management was associated with a significantly increased incidence of clinical chorioamnionitis, postpartum fever, longer maternal hospital stay, and more infant days spent in the neonatal intensive care unit.<sup>11</sup> With these potential risks, expedient delivery seems to be the optimal management for women with PROM at term.

The objective of the present study was to evaluate mechanical vs nonmechanical methods of cervical ripening in women with PROM. Because the FC has already been shown to be as effective as other ripening agents in women with intact membranes but with the potential for less associated complications, we hypothesized that the FC would be as effective, if not more effective, than misoprostol in women with PROM.

## Methods

The institutional review board approved this retrospective study of women who underwent induction of labor after PROM at Thomas Jefferson University Hospital (TJUH) and Christiana Care Health System (CCHS). At both institutions, patient information is routinely entered into a computer database at the time of delivery. We used these databases to identify women with PROM who were induced between January 2009 and April 2011. After potential patients were identified, we reviewed their medical records to identify those who underwent cervical ripening with either FC or misoprostol, and necessary data were abstracted from their medical records.

Women were included if they had singleton gestations greater than or equal to 36 weeks in cephalic presentation, if they had PROM, and if they required cervical ripening with FC or PG (ie, misoprostol). Those with multiple gestations, contraindications to vaginal delivery (eg, noncephalic presentation), those who received oxytocin without preinduction cervical ripening,

and those who were in labor were excluded from analyses. Demographic variables included age at delivery, race, marital status, insurance source, gestational age at delivery, multiparity, body mass index, and group B *Streptococcus* (GBS) status. The primary outcome was time from start of induction until delivery (minutes). Secondary outcomes included epidural anesthesia delivery, maximum temperature during labor (degrees Fahrenheit), number of vaginal examinations, occurrence of tachysystole, maximum dose of oxytocin used (mU), mode of delivery, incidence of cesarean delivery performed for failure to progress, incidence of suspected chorioamnionitis, and the newborn's 5-minute Apgar score. Interval to delivery was calculated as the difference in minutes between delivery time and administration of the first dose of PG or placement of FC. Tachysystole was defined as more than 5 contractions in 10 minutes, averaged over a 30-minute window.<sup>1</sup> Intrapartum antibiotics were given to women who met criteria for GBS prophylaxis (positive GBS culture, PROM with unknown status, PROM >18 hours) or in the presence of clinical signs of chorioamnionitis. To include all potential cases of chorioamnionitis, we used a broad definition: chorioamnionitis was presumed present if placental pathology indicated as such or if the woman had an intrapartum temperature of 100.4°F and was treated with antibiotics.<sup>11</sup>

All of the women at TJUH received misoprostol for ripening. The route of administration was per physician preference, although typically it is given intravaginally at a dose of 25 µg every 4 hours or 50 µg every 6 hours. Oxytocin was started after a maximum of 4 doses of misoprostol or once the physician felt the cervix had been adequately ripened, whichever came first. At TJUH, oxytocin was started at 2 mU/min and increased by 2 mU every 45 minutes, typically to a maximum dose of 16 mU/min.

All of the study women at CCHS had received an FC for ripening. A 16F FC was inserted into the endocervical canal with or without direct visualization. Once past the

internal os of the uterus, 30 mL of sterile water was injected into the intrauterine balloon of the FC. Traction was then applied by taping the end of the catheter to the medial aspect of the woman's knee or thigh. The catheter was checked for expulsion from the cervix every 6 hours. If no spontaneous expulsion had occurred, the catheter was adjusted to continue traction. There was no set time limit on how long the FC could be kept in place. At CCHS, oxytocin was generally started after the FC was either removed or spontaneously expelled from the cervix; however, per physician preference, the oxytocin could be started earlier. At CCHS, oxytocin was started at 2 mU/min and increased by 2 mU every 15 minutes, typically to a maximum dose of 30 mU/min.

Statistical analysis was performed using SAS software (version 9.2, SAS Institute). To test for statistical differences between groups for categorical variables, a  $\chi^2$  and Fisher exact test were used, and the *t* test and Mann-Whitney test were used for continuous variables. A *P* value less than .05 was considered statistically significant.

## Results

We identified 155 patients and reviewed their medical records; of the 155 women who met the inclusion criteria, 122 underwent cervical ripening with FC and 33 underwent cervical ripening with misoprostol. Demographics are shown in *Table 1*. Both groups were similar in terms of maternal age, insurance source, gestational age at delivery, parity, body mass index, and GBS-positive status. However, the majority of women who received preinduction cervical ripening with an FC were married and white. All patients were treated with oxytocin, except 2 who were in the misoprostol group.

The interval to delivery was almost halved in women who underwent cervical ripening with an FC compared with those who underwent ripening with misoprostol (736.0 vs 1354.0 min;  $P < .01$ ) (*Table 2*). There was a greater rate of suspected chorioamnionitis in the miso-

**Table 1.**  
**Demographic Characteristics of Women With Premature Rupture of Membranes Requiring Labor Induction (N=155)**

Characteristics <sup>a</sup>	Foley Catheter (n=122)	Misoprostol (n=33)	P Value
Age, y <sup>b</sup>	27.0 (22.0-31.0)	28.0 (23.0-35.0)	.30
Race			
Black	41 (33.6)	15 (45.4)	
White	64 (52.5)	9 (27.3)	.03
Other	17 (13.9)	9 (27.3)	
Married	63 (51.6)	7 (21.2)	<.01
Public Insurance	46 (37.7)	16 (48.5)	.26
Gestational Age at Delivery, wk <sup>b</sup>	39.2 (37.8-40.2)	39.2 (38.6-40.3)	.21
Multiparity	18 (14.8)	4 (12.1)	.99
Body Mass Index <sup>b</sup>	25.7 (22.4-29.5)	24.5 (22.1- 27.6)	.44
GBS Positive	31 (25.4)	9 (27.3)	.70

<sup>a</sup> Data presented as No. (%) unless otherwise indicated.

<sup>b</sup> Data presented as median (interquartile range).

**Abbreviation:** GBS, group B *Streptococcus*.

prostaglandin group compared with the FC group (27.3% vs 11.5%;  $P=.05$ ). There were no statistically significant differences between the groups with respect to placement of epidural anesthesia, the maximum temperature during labor, the number of vaginal examinations, tachysystole, mode of delivery, failure to progress as the indication for cesarean delivery, and neonatal 5-minute Apgar score. However, those in the FC group received a higher dose of oxytocin than those in the misoprostol group (median [interquartile range], 12.0 [9.0-17.5] vs 8.0 [4.0-10.0], respectively;  $P<.01$ ).

## Discussion

Ideal characteristics of ripening agents include efficacy in decreasing time to delivery, a positive safety profile, and efficacy in increasing the likelihood of vaginal delivery.

Our study showed that FC may be superior to misoprostol in the setting of PROM with respect to interval to delivery, without increasing the rate of failed induction, cesarean delivery, chorioamnionitis, or low Apgar score. In addition, chorioamnionitis was suspected in fewer patients in the FC group. These 2 outcomes may be interrelated, because the sooner the patient delivers, the less time there is to develop chorioamnionitis.

We performed a Medline search through PubMed using the search terms *induction, cervical ripening, Foley catheter, Foley bulb, misoprostol, Cervidil, prostaglandin, term, near term, and oxytocin* with limits for English language to identify any studies that have been performed in women with term and near-term PROM in which FC was used as a ripening agent before induction. The intrauterine FC has been compared with oxytocin as well as misoprostol in women with intact membranes at

**Table 2.**  
**Maternal Outcomes of Women With Premature Rupture of Membranes**  
**After Labor Induction by Cervical Ripening Method (N=155)**

Maternal Outcome Variable <sup>a</sup>	Foley Catheter (n=122)	Misoprostol (n=33)	P Value
<b>Primary Outcome</b>			
Induction to delivery, min <sup>b</sup>	736.0 (585.0-955.0)	1354.0 (957.0-1872.0)	<.01
<b>Secondary Outcome</b>			
Epidural	117 (95.9)	30 (90.9)	.23
Maximum temperature during labor, °F <sup>b</sup>	99.0 (98.6-99.7)	99.4 (98.6-100.7)	.20
No. of vaginal examinations <sup>b</sup>	6.0 (5.0-7.0)	7.0 (5.0-9.0)	.06
Tachysystole	10 (8.2)	2 (6.1)	.99
Maximum oxytocin dose, mU <sup>b</sup>	12.0 (9.0-17.5)	8.0 (4.0-10.0)	<.01
<b>Mode of delivery</b>			
Vaginal	79 (64.8)	20 (60.6)	.66
Cesarean	43 (35.3)	13 (39.4)	
Cesarean delivery because of failure to progress <sup>c</sup>	30 (69.8)	8 (61.5)	.74
Suspected chorioamnionitis	14 (11.5)	9 (27.3)	.05
5-minute Apgar score <sup>b</sup>	9.0 (9.0-9.0)	9.0 (9.0-9.0)	.60

<sup>a</sup> Data presented as No. (%) unless otherwise indicated.

<sup>b</sup> Data presented as median (interquartile range).

<sup>c</sup> Denominator is the number of patients who underwent cesarean delivery.

term without significant differences in efficacy.<sup>8,14,15</sup> Prager et al<sup>7</sup> compared the safety and efficacy of induction of labor using vaginal dinoprostone, vaginal misoprostol, or transcervical catheter and concluded that labor induction with a transcervical catheter is safe and effective and can be recommended as a first-choice method. Sciscione et al<sup>16</sup> compared the efficacy of vaginal misoprostol with FC in women presenting for induction with intact membranes and unfavorable cervixes and found that the 2 are equivalent for cervical ripening. We identified one small pilot study that assessed the efficacy of FC in the setting of PROM; however, the study sample

was small.<sup>17</sup> Our study adds to the limited data on the use of FC, specifically in the setting of PROM.

Although our data show a difference in maximum dose of oxytocin between the groups, this finding is likely related to the dosing protocol of the 2 institutions. At CCHS, oxytocin is increased after 15 minutes to a maximum of 30 mU/min, and at TJUH, the oxytocin is increased after 45 minutes to a maximum of 16 mU/min. Regardless, the mean dose was low in both groups at 12 mU/min and 7 mU/min, respectively.

Although most patients received oxytocin augmentation after the FC was expelled, the decision to start oxy-

tocin while the catheter was still in place was at the discretion of the physician. As a result, 38 of the 122 patients in the FC group received oxytocin before the FC was out. However, in a randomized controlled trial by Pettker et al,<sup>15</sup> the addition of oxytocin to FC did not shorten the time to delivery and had no effect on the vaginal delivery rate.

Women at TJUH received misoprostol via various routes of administration, mostly intravaginally. A number of studies have evaluated routes of delivery, but the findings are mixed. Zahran et al<sup>18</sup> found no difference in the induction-to-delivery interval between oral and vaginal delivery of misoprostol, whereas Cheng et al<sup>19</sup> found that oral administration was associated with shorter intervals to delivery, and Shetty et al<sup>20</sup> identified shorter intervals to delivery time with vaginally administered misoprostol. Given the small number of women in our study who received misoprostol as a ripening agent (n=33), we did not believe it would be statistically appropriate to further divide this group on the basis of route of administration.

There were some limitations to the present study. Because of the study's retrospective design, we were unable to define chorioamnionitis on the basis of clinical findings of uterine tenderness, foul odor of the amniotic fluid, maternal leukocytosis, and fetal tachycardia. However, as chorioamnionitis is an important consideration when choosing a ripening agent, to include all potential cases of chorioamnionitis, we used a broad definition.<sup>13</sup>

Another limitation of the present study was that all women who received FC ripening were at one institution and all women who received misoprostol were at the other institution. When the study first started, we planned to include all women who received mechanical ripening or PG ripening at both institutions. After data were collected, we noted that the 2 institutions preferentially used either FC or misoprostol. Given that institutions tend to have protocols for the management of certain conditions (eg, PROM in patients who are not in labor), we would likely not have been able to perform this study retrospec-

tively at a single institution. The differences observed between groups in terms of marital status and race are likely secondary to demographic differences that exist between patient populations at TJUH and CCHS.

## Conclusion

The present study adds to the limited data on the use of the FC, specifically in the setting of PROM. We found that the interval to delivery was decreased with the use of the FC without increasing the incidence of cesarean delivery. We believe the present study can provide useful pilot data on which to base a prospective randomized clinical trial to further assess the use of the FC for cervical ripening in the setting of PROM.

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## Author Contributions

Drs Mackeen, Walker, and Ruhstaller provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; Drs Mackeen, Schuster, and Sciscione drafted the article or revised it critically for important intellectual content; and all authors gave final approval of the version of the article to be published.

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