Intracervical Foley Balloon Use in Pre-labor Rupture of Membranes: Rates of Maternal and Neonatal Infections

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Objective

- Investigate the safety of intracervical foley balloons for cervical ripening in patients with pre-labor rupture of membranes (PROM) in relation to maternal and neonatal infections.

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Background

- Previous studies in PROM patients with foley balloon have demonstrated mixed results with some reporting significantly higher rates of chorioamnionitis and endometritis, while others have shown no significant differences.
- Inserting a catheter into the vagina through the cervix provides a potential pathway to the uterine cavity for bacteria and ascending infections.
- Risk of intrauterine infection increases with prolonged rupture of membranes.
- Multiple studies have shown that decreasing the time from rupture of membranes to delivery decreases rates of both maternal and neonatal infections.
- ACOG recommends delivery at 34 0/7 weeks or greater.

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Background

- Other risk factors known to increase maternal and neonatal infections during labor:
  - nulliparity
  - preterm gestational age
  - prolonged rupture of membranes
  - intrauterine pressure catheter (IUPC) use

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Hypothesis

- If the risk for maternal and neonatal infections is increased by creating a pathway for ascending bacteria from the vagina to the uterus, then intracervical foley balloon use for cervical ripening in patients with pre-labor rupture of membranes will increase rates of maternal and neonatal infections.

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Methods

- Retrospective cohort study
- Data collected via chart review from November 2019-April 2021 at Memorial Health University Medical Center
- Inclusion Criteria: All pregnant women with pre-labor rupture of membranes undergoing induction of labor with intracervical foley balloon vs other methods such as misoprostol and/or oxytocin
- Primary outcomes: rates of maternal and neonatal infections
- Secondary outcomes: parity, time from rupture of membranes to delivery, postpartum hemorrhage, APGAR scores, and neonatal intensive care (NICU) admission rate

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Methods

- Statistical analysis performed by Dr. Eric Shaw using the statistical software SPSS.
- Primary outcomes analyzed with Pearson Chi-Square and Fisher's Exact tests.
- Secondary outcomes analyzed with *t*-test, Mann-Whitney U test, or cross-tabulations and chi-square test as appropriate.
- Logistic regression performed to further explore the relationship between the independent binary variable and the secondary outcome variables.
- All inferential statistical tests were 2-tailed and used a tolerance for nominal type 1 error (alpha) of 0.05.

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Results: Primary Outcomes

- 379 total women ages 19-46 with pre-labor rupture of membranes
- 182 term GA
- 196 preterm GA
- 57 patients induced with foley balloon, 322 induced via other method such as misoprostol or oxytocin

	Foley Balloon	No Foley Balloon	P-value
Chorioamnionitis	12/57	31/322	0.012
Endometritis	9/57	21/322	0.029
Neonatal sepsis	0/57	2/322	1.000

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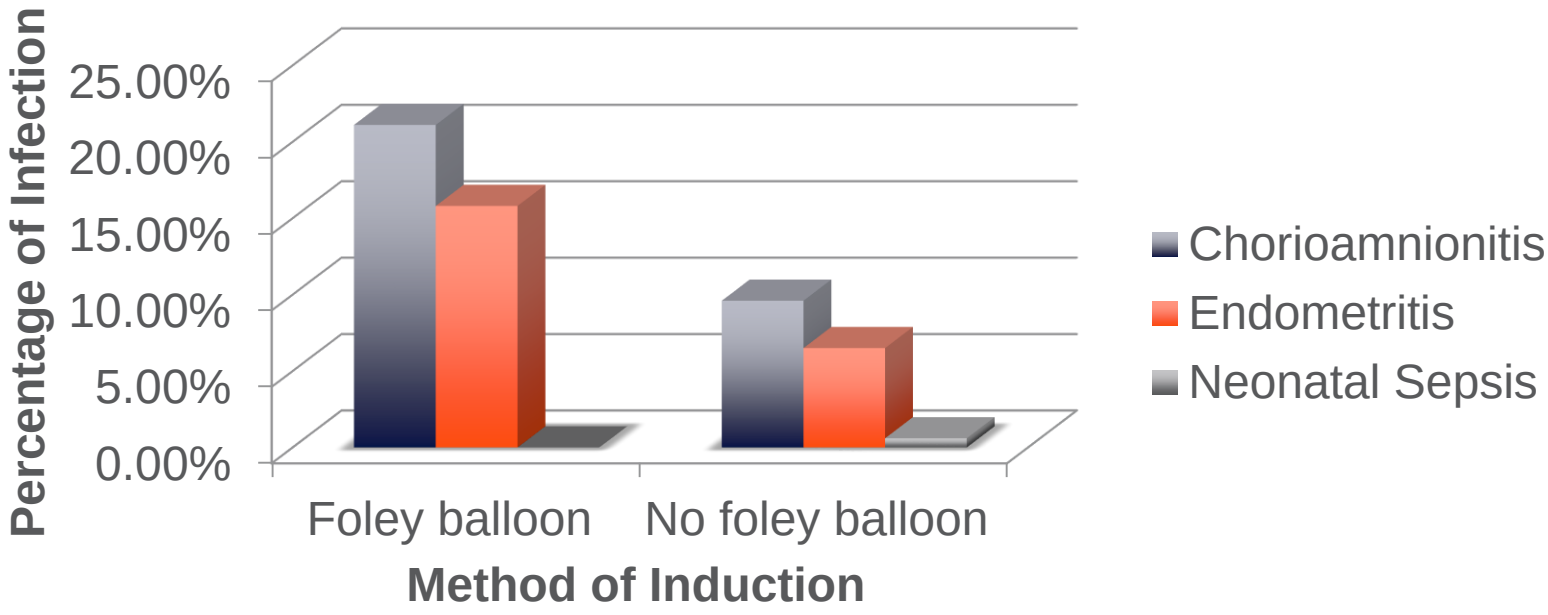
Results: Primary Outcomes

Intracervical Foley Balloon Use in Patients with Pre-labor Rupture of Membranes: Percentage of Maternal and Neonatal Infections



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Results: Secondary Outcomes

	Foley Balloon	No Foley Balloon	P-value
Postpartum Hemorrhage	12.3%	8.4%	0.343
Prolonged Rupture of Membranes	10.5%	12.7%	0.641
Parity	1.68	2.29	0.002
APGAR Scores at 1 and 5 Minutes	6.47, 8.35	6.16, 7.64	0.433, 0.043
NICU Admission Rates	29.8%	44.7%	0.036

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Results: Logistic Regression

P-values for primary outcomes in patients with PROM and foley balloon vs no foley balloon controlling for preterm gestational age, parity, and prolonged rupture of membranes

	Chorioamnionitis	Endometritis
Foley balloon use for cervical ripening vs no foley balloon	0.074	0.041

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Conclusion

- Hypothesis was partially correct.
- Statistically significant increase in both chorioamnionitis and endometritis in patients with PROM induced with a foley balloon.
- However, when controlling for other variables rates of chorioamnionitis became **NOT** statistically significant, while rates of endometritis remained significantly increased.
- No cases of neonatal sepsis in patients with a foley balloon and 2 in patients without a foley balloon. No statistical significance.
- No statistically significant increase in rates of postpartum hemorrhage, prolonged rupture of membranes, NICU admissions, or decrease in APGAR scores in PROM patients with a foley balloon.

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Discussion

- Reasons why rates of endometritis remained statistically significantly increased even after controlling for other variables
  - inadequate preoperative antibiotics prior to c-section
  - GBS positive status
- Limitations
  - Small sample size
  - Unable to obtain data regarding IUPC due to lack of standardized documentation/coding issues
- Future research regarding relationship to maternal or neonatal infection
  - Perioperative antibiotics in PROM patients with foley balloon delivered via c-section
  - GBS status

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