Does Cervical Ripening Via Intracervical Balloon Placement Increase the Risk of Chorioamnionitis in Patients with Premature Rupture of Membranes at Term?

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Does Cervical Ripening Via Intracervical Balloon Placement Increase the Risk of Chorioamnionitis in Patients with Premature Rupture of Membranes at Term?

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Abstract:

INTRODUCTION: To evaluate whether cervical ripening in patients with term premature rupture of membranes (PROM) via intracervical balloon placement (ICB) increases the risk of chorioamnionitis when compared to women with term PROM ripened with other methods.

METHODS: Retrospective cohort study of term singleton gestations undergoing ripening after PROM delivered between July 2009 and June 2012. Exposure of interest was ICB placement. Primary outcome of interest was chorioamnionitis. Demographic and labor characteristics were compared between groups. Statistical analysis included bivariate and multivariate techniques.

RESULTS: 129 term PROM patients were identified as eligible: 43 were ripened by an ICB (33.3%) and 86 were ripened with either intravenous oxytocin (n=82, 63.6%) or intravaginal misoprostol (n=4, 3.1%). A higher number of women who were ripened with an ICB were nulliparous (n=36, 83.7% ICB vs. n=48, 55.8% other methods, p=0.002). There was a trend towards a higher rate of chorioamnionitis in women ripened with an ICB vs. other methods (p=0.07). Table 2 shows a higher rate of cesarean delivery, intrauterine pressure catheter (IUPC) use, median length of membrane rupture and active labor in women ripened with an ICB. After adjustment, chorioamnionitis was not explained by ICB placement but by nulliparity [AOR 13.9 (1.53, 125.4), p=0.02] and IUPC use [AOR 5.68 (1.42, 22.8), p= 0.01].

CONCLUSIONS: The rate of chorioamnionitis, although slightly higher in women ripened with an ICB, was explained by nulliparity and IUPC use. Future prospective studies are needed to evaluate the potential contribution of ICB and IUPC use towards the development of chorioamnionitis in women undergoing cervical ripening after term PROM.

Material and Methods:

A retrospective cohort study was performed of singleton intrauterine gestations with term premature ruptures of membranes requiring cervical ripening who were induced and delivered at Lehigh Valley Health Network from July 2009 to June 2012.

Inclusion Criteria:

Exposed (Study) Group:

- Patients with a singleton gestation admitted with term premature ruptures of membranes at ≥37 weeks gestation
- Cervical ripening with intracervical balloon placement (ICB)
- Complete records of the pregnancy and delivery within our network

Non-exposed (Study) Group:

- Patients with a singleton gestation admitted with term premature ruptures of membranes at ≥37 weeks gestation
- Cervical ripening with non-mechanical methods (oxytocin, misoprostol)
- Complete records of the pregnancy and delivery within our network

Exclusion Criteria:

- Gestational age less than 37 weeks gestation
- Induction of labor for indications other than PROM
- Multi-fetal gestations in either exposed or control group
- Major fetal anomalies in either exposed or control group
- Aneuploidy in either exposed subjects or control group
- Incomplete pregnancy and delivery information
- Diagnosis of chorioamnionitis at the time of admission for PROM

Primary Outcome:

The rate of chorioamnionitis in women induced with term PROM by ripening method (mechanical vs. non mechanical).

Secondary Outcomes:

The rate of cesarean delivery, length of first and second stage of labor and neonatal outcomes by ripening method.

Comparisons were made with Student's t-test or Mann Whitney U test for continuous variables and chi-square analysis or Fisher's exact test for categorical variables. Logistic regression models, controlling for confounding, were developed and adjusted odds ratios (AOR) with 95 percent confidence intervals (C.I.) were derived from the models. For statistical analysis, we used Stata 9.0 SE software (Stata, College Station, Texas, USA).

Results:

- 129 patients met criteria for study analysis
  - 43 (33.3%) patients were ripened with an ICB
  - 86 (66.7%) patients were ripened with non-mechanical methods

Table 1. Patient Demographics Among Women With Term PROM by Ripening Method

Demographics	ICB (n=43)	Other Methods (n=86)	p-value
Maternal age (yrs)	27.0 ±6.1	28.9 ± 5.9	0.09
Caucasian vs. other (%)	31 (72.1)	61 (70.9)	0.89
Government insurance (%)	9 (20.9)	18 (20.9)	1.00
Obesity (%)	8 (18.6)	20 (23.3)	0.55
BMI (kg/m^2)	26.3 ± 4.4	26.7 ± 6.8	0.68
Marital Status			
• Married	24 (55.8)	55 (64.0)	
• Divorced/Widowed	1 (2.3)	2 (2.3)	
• Single	18 (41.9)	29 (33.7)	0.66
Residence Service (vs. private) (%)	12 (27.9)	13 (15.12)	0.0
Nulliparity (%)	36 (83.7)	48 (55.8)	0.002
Tobacco use (%)	4 (9.3)	4 (4.7)	0.30
Alcohol use (%)	0 (0)	2 (2.33)	0.31
Gestational age at first visit (wks)	11.2 ± 5.0	11.1 ± 4.6	0.91
Any pregnancy complication (%)	14 (32.6)	31 (36.1)	0.70
• Any Diabetes (%)	4 (9.3)	4 (4.7)	0.30
• Any Hypertension (%)	4 (9.3)	18 (20.9)	0.10

Table 2. Labor Characteristics Among Women With Term PROM by Ripening Method

Labor Characteristics	ICB (n=43)	Other Methods (n=86)	p-value
Gestational age at delivery (wks)	39.3 ± 1.16	39.1 ± 1.14	0.45
Bishop Score			
• Mean	2.6 + 1.2	3.0 + 1.1	0.03
• Median	3 (0, 4)	3 (0, 4)	0.03
GBS colonization (%)	8 (18.6)	28 (32.6)	0.10
Epidural placement (%)	42 (97.7)	78 (90.7)	0.14
Cesarean delivery (%)	19 (44.2)	21 (24.4)	0.02
IUPC placement (%)	22 (51.2)	24 (27.9)	0.009
Latent phase (hours)			
• Mean (±SD)	13.9 ± 6.7	16.7 ± 16.2	0.18
• Median (range)	13.1 (5.3, 35.7)	12.5 (3.0, 129.6)	0.73
Active phase (hours)			
• Mean (±SD)	6.7 + 3.0	4.3 + 3.3	0.001
• Median (range)	6.8 (1.8, 13.1)	3.5 (0.05, 20.9)	< 0.001
Second stage of labor (hrs)			
• Mean (±SD)	1.6 + 0.9	31 (36.1)	0.53
• Median (range)	1.5 (0.03, 3.0)	0.9 (0.1, 5.3)	0.11
Length of membrane rupture (hrs)	4 (9.3)	18 (20.9)	0.10
• Mean (+SD)	22.2 + 7.8	21.5 + 16.4	0.75
• Median (range)	21.1 (4.1, 43.0)	18.6 (2.5, 137.5)	0.03
Chorioamnionitis (%)	13 (30.2)	14 (16.3)	0.07

The primary outcome, chorioamnionitis, was slightly higher in women ripened with an ICB (30.2%) vs. other methods (16.3%), with a trend towards statistical significance. Overall intrapartum and postpartum complications were similar between both groups (data not shown).

Table 3. Neonatal Outcomes by Ripening Method

Neonatal Outcomes	ICB n=43 (33.3%)	Other n=86 (66.7%)	p-value
Male gender (%)	25 (48.8)	42 (58.1)	0.03
Neonatal birthweight (grams)			
• Median	3415 (2590, 4260)	3367.5 (2120, 4205)	0.40
• Mean	3394.1 ± 374.7	3314.3 ± 429.8	0.30
Arterial cord pH	7.26 (7.14, 7.5)	7.26 (7.06, 7.5)	0.74
Admission to transitional nursery (%)	10 (23.3)	8 (9.3)	0.05
Neonatal antibiotic use (%)	10 (23.3)	14 (16.3)	0.34
Neonatal length of stay (days)	3 (2,4)	3 (2,5)	0.21
Major neonatal malformation (%)	0 (0)	4 (4.7)	0.15
Infant resuscitation at birth (%)	1 (2.3)	9 (10.5)	0.10

Univariate analyses were performed to evaluate risk factors for chorioamnionitis besides ripening method (Table 4).

Table 4. Unadjusted Analyses of Potential Predictors of Chorioamnionitis

Potential Predictor	Chorioamnionitis
ICB use	RR 1.86 (0.96, 3.59), p=0.07
Bishop score	RR 1.01 (0.70, 1.46), p=0.95
GBS colonization	RR 0.45 (0.17, 1.21), p=0.09
Length of the latent phase	RR 1.00 (0.97, 1.03), p=0.84
Length of the active phase	RR 1.10 (0.96, 1.27), p=0.15
Length of the second stage	RR 1.19 (0.80, 1.78), p=0.39
Duration of membrane rupture	RR 1.02 (0.99, 1.04), p=0.27
Number of cervical exams	RR 1.19 (1.02, 1.39), p=0.02
Nulliparity	RR 4.29 (1.36, 13.5), p=0.004
BMI≥30	RR 0.63 (0.24, 1.66), p=0.33
IUPC use	RR 2.62 (1.33, 5.17), p=0.004
Any co-morbidity	RR 0.65 (0.30, 1.43), p=0.27
Residence service obstetrician (vs. private)	RR 1.39 (0.53, 3.64), p=0.50
Cesarean delivery	RR 1.30 (0.66, 2.60), p=0.45
Epidural use	RR 0.94 (0.26, 3.34), p=0.92

Data are expressed as relative risk (95% confidence interval).

Logistic regression models were constructed to evaluate the relationship between ICB ripening and chorioamnionitis controlling for confounders identified in univariate analysis (p< 0.20; Table 4). Using logistic regression, nulliparity and IUPC placement remained significantly associated with chorioamnionitis (AOR 13.9 (1.53, 125.4), p=0.02] and 5.68 [1.42, 22.8, p= 0.01], respectively) independent of ripening method.

Conclusion:

In our retrospective cohort study, the rate of chorioamnionitis was higher in women induced with an ICB. However, after adjusting for potential confounders, the risk of chorioamnionitis was explained by nulliparity and IUPC use, not by the use of a mechanical ripening method.

Our study is limited by its retrospective nature and its sample size. Therefore, larger prospective studies are needed to evaluate the potential contribution of ICB and IUPC use towards the development of chorioamnionitis in nulliparous women undergoing cervical ripening after term PROM.