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Foley Balloon Catheter versus Oral Misoprostol for Induction of Labour after Prelabour Rupture of Membranes: A Retrospective Data Analysis

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Abstract

Objectives: The Foley balloon catheter (FC) is a viable method for cervical ripening, but concerns about infection risk restrict its use in cases of prolonged prelabour rupture of membranes (PROM). This study aims to evaluate the efficacy and safety of the FC compared to oral misoprostol for cervical ripening after PROM. **Study Design:** A retrospective data-analysis of 128 pregnant women was conducted. Of these, 49 underwent cervical ripening with an FC and 79 with oral misoprostol. We included all women with a vital singleton pregnancy at 37 - 42 weeks of gestation who underwent cervical ripening after ≥ 24 hours of PROM in specific time frames in two Dutch-secondary care and teaching hospitals. The primary outcome was the incidence of intrapartum infection, a composite of maternal and neonatal infection. In addition, we evaluated the mode of delivery, duration of priming and priming-to-delivery interval. Secondary endpoints included uterine hyperstimulation, umbilical cord prolapse, birth weight, Apgar scores, length of admission to the neonatal low dependency unit, admission to the (neonatal) Intensive Care Unit (ICU) and mortality. Statistical analyses included bivariate and multivariate techniques. **Results:** Cervical ripening with FC, compared with oral misoprostol, showed a higher incidence of intrapartum infection, respectively 32.7% (n = 16) vs. 12.7% (n = 10) (p = 0.006). However, after adjusting for epidural anaesthesia and pregestational BMI, the association was no longer significant. No difference was found in mode of delivery and total priming-to-delivery interval (median 21.3 hours vs. 22.0, p = 0.897). Furthermore, FC, compared with oral misoprostol, showed a longer duration

of cervical ripening and hence a shorter duration of active labour ($p < 0.001$). Apart from the 1-min Apgar score, secondary maternal and neonatal outcomes did not differ between the groups. **Conclusion:** In women who require cervical ripening after prolonged PROM at term, the FC and oral misoprostol are similar in terms of efficacy and safety. Advantages associated with the FC are its safe application in women with a history of caesarean section, although we did not study these women, and an implied shorter duration of active labour. Our study adds to the limited available data on the use of the FC after the rupture of membranes and a large randomized controlled trial is needed to strengthen our findings.

Keywords

Prelabour Rupture of Membranes (PROM), Balloon Catheter, Misoprostol, Cervical Ripening, Labour Induction, Chorioamnionitis

1. Introduction

Prelabour rupture of membranes (PROM) is associated with bacterial infection of the amniotic cavity. It is defined as rupture of the amniotic membranes prior to the onset of regular contractions [1]. PROM most frequently occurs after 37 weeks of gestation [1], affecting about 8% of all term pregnancies. The risk of developing chorioamnionitis increases with an increasing latent period between PROM and delivery [2] [3] [4].

In at least 90% of cases spontaneous onset of labour follows within 24 hours after PROM [5]. Nevertheless, in a significant minority of pregnancies medical interventions are needed to initiate delivery. In women with an unfavourable cervix, ripening of the cervix, also called priming, prior to administration of intravenous oxytocin is desirable. Pharmacologic priming is primarily done with prostaglandins, whereas the Foley balloon catheter (FC) is the principal mechanical priming method. FC is associated with the lowest rate of uterine hyperstimulation and therefore considered to be the safest option in women with a previous caesarean section. Although a large meta-analysis has validated the position of the FC in women with intact amniotic membranes [6], concerns have been raised over the possibility of ascending bacterial colonisation using mechanical dilation after the rupture of membranes. Apart from one study that showed FC may increase the risk of chorioamnionitis when used in addition to oxytocin [7], the limited data available on the safety of the FC do not support this theory [8] [9] [10] [11].

In the Netherlands, both oral misoprostol and FC are used as first choice for cervical ripening following PROM [12]. In women with a uterine scar, FC is preferable. The objective of this study was to evaluate whether priming with an FC is indeed a safe and effective alternative to oral misoprostol in women with term PROM and an unfavourable cervix.

2. Materials and Methods

This is a retrospective data-analysis of pregnant women who needed cervical ripening after prolonged PROM at term at the department of obstetrics in two teaching hospitals: OLVG, Amsterdam, between January 2017 and July 2020 and the Deventer Ziekenhuis, Deventer, between October 2015 and July 2020. Institution-specific timeframes for data inclusion were used based on the implementation of revised local protocols for the management of PROM.

Women with a vital singleton pregnancy at 37 weeks' gestation or more, ≥24 hours of PROM and an unfavourable cervix were included. Exclusion criteria were prenatal diagnosis of foetal congenital anomalies, twin pregnancy, contraindication for vaginal delivery, a history of caesarean section and clinical signs of a pre-existent intrapartum infection. The clinical criteria used to define chorioamnionitis vary among studies [13]. In our study, the development of maternal fever (≥38˚C) or foetal tachycardia (baseline ≥160 bpm) at any time before the start of priming, was considered pre-existent chorioamnionitis. PROM was diagnosed based on the history of a sudden loss or continuous leakage of vaginal fluid. When in doubt, an additional AmniSure® ROM test or microscopic visualisation of the amniotic fluid was performed.

Spontaneous labour was awaited for a period of 24 - 72 hours according to local protocols, whereafter induction was started. Pregnant women eligible for cervical ripening in hospital A received a hydrogel coated 20 Charriere FC as method of priming. The balloon was inserted into the endocervical canal and inflated using 50 mL normal saline. The catheter was then secured to the thigh without applying tension to the tube. These women were compared to women primed using oral misoprostol in hospital B. The starting dose was 50 µg misoprostol, followed by 25 µg every four hours for up to three doses daily.

According to Dutch guidelines, group B-streptococcus (GBS) screening was performed in all women included in the study after 24 hours of PROM using a recto-vaginal swab. Intravenous benzyl penicillin was administered prior to delivery to those women that tested positive, although in most cases results were not yet available at time of delivery. Mothers that exhibited intrapartum fever (≥38.0) were treated with intravenous amoxicillin/clavulanic acid in both hospitals, regardless of epidural anaesthesia and GBS status.

All data were obtained from electronic hospital databases. Baseline demographics that were collected included: maternal age at delivery, gestational age at PROM, gestational age at delivery, gravidity, parity, ethnicity, pregestational BMI, baseline cervical dilation, foetal presentation, administration of epidural anaesthesia, maternal culture-proven colonisation of GBS, the presence of meconium-stained amniotic fluid and the number of vaginal examinations. Duration of follow-up was 48 hours for both mother and the newborn.

The primary outcome was the incidence of presumed intrapartum infection, a composite of maternal and neonatal infection. Maternal infection was defined by the administration of anti-biotics in the presence of maternal fever (≥38˚C)

and/or foetal tachycardia (≥160 bpm). Clinical signs of maternal infection were recorded until delivery. Neonatal infection was assumed in case of blood culture positive sepsis and/or the administration of anti-biotics in the presence of any of the following clinical signs of infection: fever (≥38 degrees), hypothermia (<36˚C), elevated C-reactive protein (CRP) (≥10 mg/l) or respiratory distress. Respiratory distress was assumed in all newborns that had received any type of breathing support. Newborns were monitored during their first two days of life, for the reason that early-onset neonatal sepsis most often presents within 24 - 48 hours of birth [14]. We decided not to include late-onset neonatal sepsis as outcome variable, considering the inconclusive association with intrapartum infection.

In order to determine the efficacy of priming, mode of delivery, duration of priming and priming-to-delivery interval were analysed. Mode of delivery was categorised as spontaneous vaginal birth, instrumental vaginal birth or caesarean section. Duration of priming was described as the interval between the start of priming and the moment of assessing a favourable cervix. Secondary maternal outcomes included clinically significant uterine hyperstimulation requiring treatment with tocolytics and/or instrumental delivery and maternal admission to the Intensive Care Unit (ICU). With regard to the neonate, outcomes included birth weight, umbilical cord prolapse, the 1- and 5-minute Apgar scores, length of admission to the neonatal low dependency unit, admission to the neonatal intensive care unit (NICU) and mortality.

Statistical analyses were performed using SPSS Statistics for Windows, version 26.0 [15]. Categorical variables were compared by the Chi-square test or Fisher exact test when appropriate. Data with continuous variables were analysed using a student t-test when data followed normal distribution or a Mann-Whitney U test when data did not follow normal distribution. Both linear as well as logistic regression analyses were performed to adjust for potential confounding factors. A p value of <0.05 was considered statistically significant. Because of the retrospective nature of this study, no power calculation was performed.

3. Results

In total, 128 pregnant women were included in the analysis. Of these, 49 (38.3%) underwent cervical ripening with an FC and 79 (61.7%) received oral misoprostol for cervical ripening. The study flowchart is shown in **Figure 1**.

Baseline and demographic data of both groups are presented in **Table 1**. Women treated with FC, compared with those treated with oral misoprostol, were on average younger, had a higher BMI and were less often nulliparous. In addition, in the FC group, the median interval between PROM and start of priming was shorter (41.7 vs. 52.8 hours; p = 0.023).

Primary outcome data are shown in **Table 2**. Whereas maternal infections were more common in the FC group (p = 0.002), no difference was seen in neonatal infections (p = 0.675). In univariable analysis, the FC group, compared

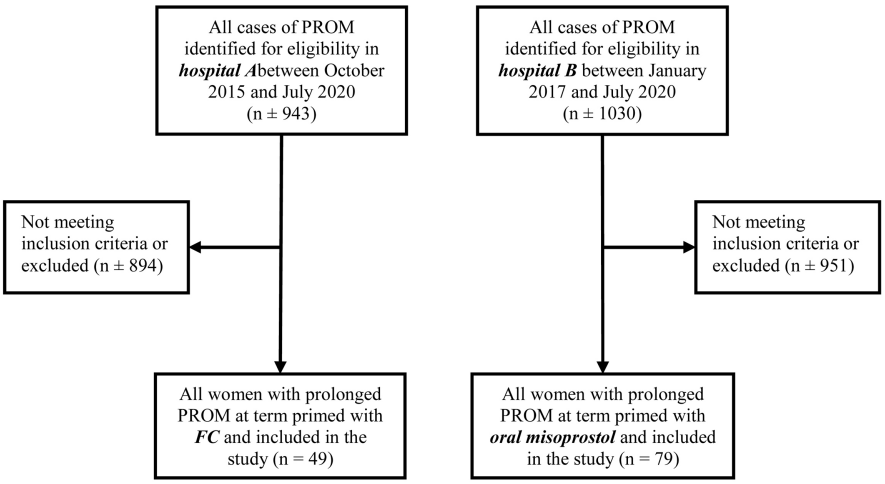

Figure 1. Study flow chart. Abbreviations: PROM: prelabour rupture of membranes; CS: caesarean section; GA: gestational age; FC: foley balloon catheter.

Table 1. Baseline and demographic characteristics.

	Foley (n = 49)	Misoprostol (n = 79)	p Value
Maternal age, mean (±SD), y	30.0 (5.6)	32.4 (4.8)	0.012
Nulliparous, n (%)	40 (81.6)	77 (97.5)	0.003
Ethnic origin			
Western European, n (%)	38 (77.6)	56 (70.9)	0.273
Other, n (%)	9 (18.4)	23 (29.1)	
Unknown, n (%)	2 (4.1)	0 (0.0)	
Pregestational BMI, median (IQR)	25.8 (23.0, 29.6)	22.8 (20.8, 25.8)	<0.001
Gestational age at PROM, median (IQR), d	277 (271, 285)	274 (266, 282)	0.285
Gestational age at birth, median (IQR), d	280 (274, 288)	278 (270, 285)	0.344
Foetal presentation			
Cephalic, n (%)	48 (98.0)	79 (100.0)	0.383
Breech, n (%)	1 (2.0)	0 (0.0)	
Baseline cervical dilation, median (IQR), cm	1.0 (0.0, 1.0)	1.0 (0.0, 1.0)	0.709
Culture-proven GBS colonisation, n (%)	8 (16.3)	12 (15.2)	0.987

Abbreviations: SD: standard deviation; IQR: interquartile range; BMI: body mass index; PROM: prelabour rupture of membranes; GBS: group B streptococcus.

with oral misoprostol, showed a significantly higherincidence of intrapartum infection (32.7% vs. 12.7%; p = 0.006). Intrapartum infection is here defined as a composite of maternal and neonatal infection. However, after adjustment for BMI and epidural anaesthesia (shown in Table 3), the association between method of priming and the odds of intrapartum infection lost significance (p = 0.177). In the multivariate model, only epidural anaesthesia appeared to be a

Table 2. Primary outcome data.

	Foley (n = 49)	Misoprostol (n = 79)	p Value
Intrapartum infection, n (%)	16 (32.7)	10 (12.7)	0.006 0.177[a]
Maternal infection, n (%)	15 (30.6)	7 (8.9)	0.002
Administration of anti-biotics, n (%)	16 (32.7)	9 (11.4)	0.003
Fever, n (%)	15 (30.6)	14 (17.7)	0.018
Foetal tachycardia, n (%)	17 (34.7)	13 (16.5)	0.090
Neonatal infection, n (%)	5 (10.2)	10 (12.7)	0.675
Blood culture positive sepsis, n (%)	1 (2.0)	0 (0.0)	0.383
Administration of anti-biotics, n (%)	4 (8.2)	11 (13.9)	0.325
Fever or hypothermia, n (%)	6 (12.2)	5 (6.3)	0.332
Elevated CRP, n (%)	5 (10.2)	7 (8.9)	1.000
Respiratory support or intubation, n (%)	10 (20.4)	14 (17.7)	0.705

[a]Adjusted for epidural anaesthesia and pregestational BMI. Abbreviations: *CRP*: C-reactive protein.

Table 3. Secondary outcome data.

	Foley (n = 49)	Misoprostol (n = 79)	p Value
Mode of delivery			
Spontaneous vaginal, n (%)	31 (63.3)	59 (74.7)	
Vaginal instrumental, n (%)	7 (14.3)	8 (10.1)	0.388
Caesarean section, n (%)	11 (22.4)	12 (15.2)	
Total duration of ruptured membranes, h	67.9 (56.5, 83.0)	74.8 (56.3, 95.5)	0.221
PROM-to-priming interval, median (IQR), h	41.7 (35.1, 54.6)	52.8 (39.3, 63.4)	0.023
Priming-to-delivery interval, median (IQR), h	21.4 (17.1, 31.0)	21.9 (16.0, 30.1)	0.897
Duration of priming, median (IQR), h	16.6 (10.5, 25.0)	11.5 (7.5, 20.8)	0.042
Duration of active labour, median (IQR), h	6.1 (4.3, 8.4)	9.0 (6.3, 12.5)	<0.001
Meconium-stained amniotic fluid n (%)	12 (24.5)	10 (12.7)	0.085
Epidural anaesthesia, n (%)	23 (46.9)	35 (44.3)	0.771
Administration of oxytocin, n (%)	42 (85.7)	69 (87.3)	0.792
Number of vaginal examinations, median (IQR)	6.0 (4.0, 7.0)	6.0 (5.0, 8.5)	0.222
Uterine hyperstimulation, n (%)	1 (2.0)	1 (1.3)	1.000
Maternal ICU admission, n (%)	0 (0.0)	1 (1.3)	1.000
Neonatal birth weight, mean (±SD), g	3428.5 (508.1)	3313.7 (372.3)	0.174
Neonatal Apgar scores			
1 min score < 7, n (%)	11 (22.4)	7 (8.9)	0.032
5 min score < 7, n (%)	5 (10.2)	3 (3.8)	0.258
NICU admission, n (%)	1 (2.0)	2 (2.5)	1.000
Neonatal mortality, n (%)	0 (0.0)	0 (0.0)	-

Abbreviations: IQR: interquartile range; CRP: C-reactiveprotein; ICU: intensive care unit; SD: standard deviation; NICU: neonatal intensive care unit.

significant predictor (p = 0.047) of the composite variable intrapartum infection. Epidural anaesthesia were used in 61.5% (n = 16/26) of cases classified as intrapartum infection, as compared to 45.3% (n = 58/128) in the total study population (p = 0.063).

Secondary obstetric, maternal and neonatal outcome data are summarized in Table 3. No significant differences were seen in mode of delivery (p = 0.388). Although the total duration of rupture of membranes and the priming-to-delivery interval were comparable in both groups, priming with FC resulted in a shorter duration of active labour and delivery (p < 0.001). An independent association between method and duration of priming was not seen.

No differences were seen in oxytocin augmentation (p = 0.792) or epidural anesthesia (p = 0.771). The number of cases with meconium-stained amniotic fluid was also comparable in both groups (p = 0.085). There were no cases umbilical cord prolapse. Two cases of uterine hyperstimulation demanding treatment with tocolytics or instrumental delivery occurred, one in each group. One mother was admitted to the ICU, because of delayed emergence from anaesthesia and pseudo-seizures following manual placenta removal. She was primed with misoprostol.

Neonatal outcomes did not significantly differ between the groups, with the exception of the 1 minute Apgar score < 7 that was reported more often with FC (p = 0.032). In total, three newborns were admitted to the NICU, two in the misoprostol group and one in the FC group. Neonatal mortality did not occur.

4. Discussion

4.1. Main Findings

The FC group, compared with oral misoprostol, showed a significantly higherincidence of intrapartum infectionin univariable analysis. After adjustment for epidural anaesthesia and pregestational BMI, the association lost significance. The total priming-to-delivery interval was similar in both groups, however, priming with FC resulted in a shorter duration of active labour and foetal delivery. No difference was found in mode of delivery. Regarding the secondary maternal and neonatal outcomes, only the 1 minute Apgar score < 7 was found to be different, which we considered to be of little clinical relevance considering the comparable 5 minute Apgar score. Hence, our data suggest that in women with prolonged PROM at term, cervical ripening with FC is comparable to oral misoprostol.

4.2. Interpretation

In our study, pregestational BMI and epidural anaesthesia were found to be the most important predictors of intrapartum infection. This was not surprisingly, as obesity is a known risk factor for chorioamnionitis [16]. Epidural analgesia, on the other hand, is associated with an increase in body temperature during labour [17]. The distinction between hyperthermia as a sign of infection or a side

effect of anaesthesia cannot be made. Therefore, antibiotic treatment is indicated in all cases of maternal fever during labour. Because administration of antibiotics was included in our definition of intrapartum infection, it is likely that we have overestimated the total number of infections that occurred.

To our knowledge, there has only been one randomized controlled trial, by Kruit *et al.* [11], comparing cervical ripening with FC to oral misoprostol in patients with prolonged PROM (>18 hours) at term. Similar to our study, the rates of maternal and neonatal infection were comparable in both groups. The total incidence of infection in this study was relatively low compared to our data. This could be explained by the fact that the authors used a different definition of intrapartum infection. The definition was limited to maternal fever during labour, whilst foetal tachycardia has also been depicted as a reliable indicator of perinatal infectious morbidity [18]. Additionally, all women enrolled in the study by Kruit *et al.* [11], received prophylactic anti-biotics. Current literature does not recommend routine antimicrobial treatment in women with PROM at term or near term, as the advantages do not seem to outweigh the potential side effects and complications [19]. In our study, only five women received prophylactic antibiotic treatment in the absence of any clinical signs of infection: one in the FC group and four in the misoprostol group. These women had tested positive for rectovaginal GBS colonisation, a major additional risk factor for early-onset neonatal infectious disease [14]. Consistent with our study and the one by Kruit *et al.* [11], a retrospective study by Mackeen *et al.* [20] on women with PROM showed no increase in infection with FC, compared with misoprostol. Three studies comparing cervical ripening with FC to oxytocin in women with late preterm and term PROM demonstrated inconsistent findings on the risk of infection [7] [9] [10]. One of these, a retrospective study by Cabrera *et al.* [9], found that the mildly increased incidence of chorioamnionitis that was seen in the FC group could be explained by nulliparity and intrauterine pressure catheter use, rather than the method of priming. Nulliparity has indeed been delineated in literature as a risk factor for chorioamnionitis [21], probably due to prolonged labour. An independent correlation between nulliparity and intrapartum infection could not be confirmed in the present study. An obvious explanation is the fact that the majority (91.4%) of women included in our study were nulliparous, hence minimising the visible influence of parity on the development of infection.

Apart from its safety profile, the quality of an induction method is measured by its effectiveness in achieving vaginal delivery. We found no difference in mode of delivery between the study groups, which implies cervical ripening with FC following prolonged PROM does not seem to increase the risk of caesarean section. These results are in concordance with the majority of previous studies [7] [10] [11] [20] on the use of FC in the setting of PROM. Only Cabrera *et al.* [9] reported an increased incidence of caesarean section in women managed with FC as compared to oxytocin alone. Parity was however significantly different in both study groups and not adjusted for.

Multiple studies have shown that a reduction in the duration of rupture of membranes is associated with lower rates of bacterial infection [2] [3] [4], hence the ideal method for cervical ripening following PROM should be quick. We found a median interval of 21.3 hours between application of the FC and delivery, which is comparable to 21.9 hours reported by Kruit *et al.* [11]. This priming-to-delivery interval was similar in our two groups. Our findings therefore suggest that in women with term PROM, induction with FC is at least as fast as oral misoprostol in achieving birth. In fact, it seems to relatively shorten the active stage of labour, which is characterised by the most intense and painful contractions. Kruit *et al.* [11] similarly did not find a difference in the interval to delivery following priming with FC versus oral misoprostol. Mackeen *et al.* [20] have even reported a halving in the priming-to-delivery interval in women who underwent cervical ripening with FC when compared to misoprostol.

4.3. Strengths and Limitations

The availability of near-complete electronic hospital databases strengthens our study. In fact, the percentage of missing data per individual variable was less than 2%, with the exception of duration of priming (8.6%) and pregestational BMI (11.7%). As all women with prolonged PROM who delivered in the given time periods were identified for eligibility, selection bias was limited as well. Finally, we did not experience any losses to follow-up.

The most important limitation of our study is its design. Retrospective analyses are prone to numerous bias, including information and recall bias. In addition, we acknowledge the study might be subject to unmeasured confounding, as the two methods of priming were performed in two different hospitals. However, both hospitals are secondary care and teaching hospitals, presuming no difference in general abilities. The relatively small sample size of 128 patients represents another drawback of our study. Finally, although BMI was corrected for, substantial differences in baseline patient characteristics should be borne in mind. This goes especially for parity, as the number of nulliparous women was significantly larger in the misoprostol group.

5. Conclusion

This study suggests that in women who require cervical ripening after prolonged PROM at term FC is comparable to oral misoprostol in terms of efficacy and safety. This finding should be confirmed in an adequately powered randomized controlled trial. For now, the use of an FC in women with prolonged PROM is warranted given the available evidence. Although we did not study women with a history of caesarean section, the FC is especially considered to be a valuable alternative in women with a uterine scar where misoprostol is contra-indicated for induction of labour.

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We would like to thank Joyce Faber for her commitment to the study.

Statement of Ethics

The study was approved by the local ethics committees of both hospitals (Deventer Hospital, approval number ME-48; OLVG Hospital, approval number WO 20.156). Due to the retrospective nature of the study, written informed consent was waived according to national legislation (Medical Research Act, WMO) [22].

Data Availability Statement

The data that support our findings are available on request from the corresponding author, Anna Bouwknegt. To protect the privacy of research participants the data are not publicly available.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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