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MATERNAL-FETAL MEDICINE

Is homecare management associated with longer latency in preterm premature rupture of membranes?

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Abstract

Purpose According to national guidelines, conventional management of preterm premature rupture of membranes (PPROM) is hospitalization until induction. Outpatient management could be another option. Our objective was to compare latency period between patients managed in hospital versus outpatients.

Methods A retrospective before/after monocentric study that occured from 2002 to 2015. Were included all patients with PPROM prior to 35 weeks with homecare inclusion criteria. The primary outcome measure was to study length of latency period (delay between PPROM and delivery). Second outcome measures were maternal and perinatal morbidities and mortalities.

Results Among the 395 women included after PPROM, 191 were managed as outpatients and 204 in hospital. In the outpatient group, the length of latency period was longer than in the inpatient group [39 (IQR 20 to 66) versus 21 (IQR 13 to 42) days; $p<0.001$]. Clinical chorioamnionitis was observed in 30 (15.7%) in outpatient group versus 49 (24.0%) in inpatient group ($p=0.039$). Concerning neonatal outcome, there were less neonatal transfer (49.2% versus 77.2%, $p<0.001$), less respiratory distress syndrome (29.4% versus 47.5%; $p<0.001$), less neonatal sepsis (13.9% versus 22.1%; $p=0.037$), less bronchodysplasia (2.7% versus 9.8%; $p=0.004$), and less pulmonary arterial hypertension (4.8% versus 10.3%; $p=0.040$) in the outpatient group than in the inpatient group.

Conclusion Home management seems to be a safe option to hospitalization in selected patients with PPROM. However, a randomized study would be required to approve those results.

Keywords Preterm premature rupture of membrane · Home care · Latency · Perinatal outcomes

Abbreviations

PPROM	Preterm premature rupture of membranes
IQR	Interquartile range
IUFD	Intrauterine Fetal Death

Introduction

Three percent of pregnancies are complicated by preterm premature rupture of membranes (PPROM). It coincides also for approximately one-third of all preterm births [1, 2]. Preterm delivery is the major reason of perinatal morbidity and mortality associated with PPROM [3]. Without severity criteria, hospital monitoring in an adapted maternity ward was performed until labor induction at 36 weeks of gestation. This management is based on the current guidelines [4–6].

Outpatient care is likely to be a suitable alternative to conventional hospitalization for the management of pathological pregnancies. In the context of PPROM, it may provide an adapted medical and social solution justified by maternal well-being [7, 8]. A Cochrane review, including only two randomized-controlled trials with 116 women in all, compared outpatient versus hospital care following PPROM [9]. The authors drew the conclusion that outpatient care was related with less days spent in the hospital and lower cost.

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Concerning maternal and neonatal outcomes, they could not reach significant conclusions. The French recommendations raised the possibility of home care management for selected women with PPROM [6], and recent studies have shown that outpatient care is as suitable as conventional hospitalization for the management of PPROM [10–14]. Nevertheless, the American College [15] statements specified the lack of data for new guidelines about inpatient or outpatient care. In our center, outpatient care management of PPROM overtook conventional hospitalization since 2009.

Concerning the latency; when a PPROM occurs, an expectant management (without obstetric complications) is valuable for the fetus by increasing gestational age at birth [3, 6, 16]. A couple of studies investigated latency duration as an independent risk factor for negative outcomes in preterm babies [17–19]. *EPIPAGE 2* is a nationwide population-based prospective cohort. This study showed that in cases of preterm birth after PPROM at 24–32 weeks, the prolonged latency period did not worsen neonatal prognosis. Survival and survival without severe morbidity were improved with increased gestational age at birth [20].

In summary, the purpose of this study was to compare the latency between patients managed in hospital versus outpatients in the context of PPROM. The secondary objective was to evaluate obstetric and neonatal outcomes.

Materials and methods

It was a before/after study in one center (Lille, France) from 2002 to 2015. This study was approved by the French National Commission on Informatics and Liberty (reference DEC16-210).

Women were included in case of eligibility of outpatient care: singleton pregnancy, gestational age between 24 and 35 weeks, absence of chorioamnionitis, clinical stability on day 5 after PPROM, cervical dilatation less than 3 cm (vaginal examination was not routine performed on admission but only in case of uterine contractions), and patient's home location (less than 30 min from our center and within 50 km). A protocol was made following the criteria as described before, and all the physicians used it to determine if patient was suitable for home care. Exclusion criteria were women with multiple pregnancy and PPROM beyond 35 weeks, because of the shortened delay between rupture and labor induction, and all the patients not suitable for home care following the protocol.

PPROM was diagnosed on a viewing of amniotic fluid loss and/or was assessed by the use of a PROM test (Actim-Prom, Medix Biochemica, Finland) [21]. We did not differentiate "classic" or "high" PPROM as recently proposed by Tchirikov et al. [5]. Gestational age was determined from the first-trimester ultrasound. The latency was defined as the difference between date of PPROM occurrence and the date of delivery. Oligoanamnios was defined with amniotic fluid index less than 20 mm. Chorioamnionitis was defined by the existence of at least one of the following criteria: maternal fever, elevated CRP, fetal tachycardia, and uterine contractions, with no other infection symptom.

All women were originally managed by the same protocol. At the beginning, all of them were hospitalized. Then, initial management included antenatal corticosteroids [22] and prophylactic antibiotics [23]. Tocolysis was used only in the existence of uterine contractions and no sign of chorioamnionitis (maximum during 2 days). Digital examination was not recommended and was only performed in case of painful contractions.

From 2002 to 2009, patients stayed in hospital until being delivered, as recommend by the guideline at this period. During this period, we included in the analysis all patients who were eligible for outpatient care. From 2009 to 2015, after 5 days in hospital, home care was proposed if the eligibility criteria were met: singleton pregnancy, gestational age between 24 and 35 weeks, absence of chorioamnionitis, clinical stability on day 5 after PPROM, cervical dilatation less than 3 cm (vaginal examination was not routine performed on admission but only in case of uterine contractions), and patient's home location (less than 30 min from our center and within 50 km). Therefore, all patients included in this group were patient who were suitable for home care.

In both groups, the historical control started after 5 days of hospitalization.

Inpatient care would consist of daily review including symptoms, abdominal palpation, and vital observations. Fetal heart rate (FHR) was performed once a day, non stress test (NST) once every week, and an antibiotic prophylaxis was given during 1 week. Biological evaluation would include maternal blood count and CRP twice a week, urine and vaginal sample (including group B streptococcus) were performed once a week. We also used ultrasound scans for assessment of amniotic fluid and fetal vitality which were generally performed every week.

Outpatient care was previously described [24]. Briefly, it consisted of an evaluation three times a week by a midwife, biological examination twice a week [bi-weekly full blood count and C-reactive protein (CRP)] and bacteriological assessment weekly (urine and vaginal samples). Every 15 days, a consultation in our center was organized for obstetric ultrasound follow-up (fetal growth and amniotic fluid quantity) and a summary of the management. In case of PPROM before 24 weeks, midwife or nurse supervision was established before integration into the homecare service, once the gestational age of 24 weeks was reached [18].

In both groups, labor was routinely induced at 36 weeks of gestation.

Rare severe obstetrical complications included intra-uterine fetal death, placenta abruption, and cord prolapse.

Neonatal complications included: respiratory distress syndrome, neonatal infection (defined as sepsis in a neonate with a positive blood, urine, or cerebrospinal culture in the first 48 h of life), necrotizing enterocolitis, intraventricular hemorrhage (two major types of cerebral lesions were assessed: subependymal IVH was classified as grade I, intraventricular IVH as grade II, and IVH associated with ventricular dilatation as grade III) and periventricular leukomalacia, characterized by the necrosis of white matter near the lateral ventricles), bronchodysplasia (O2 dependency at 36 weeks), and pulmonary arterial hypertension.

Statistical analysis

Data were collected from patient records. The categorical variables were expressed in frequencies (percentages), and the quantitative variables in mean ± standard deviation (SD) or median [interquartile range (IQR)]. Normality of distribution was checked graphically and by using the Shapiro–Wilk test. Comparisons between the two periods on obstetric and neonatal outcomes were made using the Chi-square test (or Fisher's exact test when expected cell frequency was < 5) for categorical variables and Student's *t* test or Mann–Whitney *U* test for quantitative variables. Statistical testing was done at the two-tailed α level of 0.05. Data were analyzed using the SAS software package, release 9.4 (SAS Institute, Cary, NC, USA).

Ethical approval

This study was approved by the French National Commission on Informatics and Liberty (reference DEC16-210) on the date of the 14/07/2017.

Results

Among the 395 women included, 204 were managed as inpatient and 191 as outpatient. Maternal and obstetrical characteristics are summarized in Table 1. There was no difference between the two groups. Regarding characteristics of PPROM (Table 2), gestational age at PROM was similar in both group [27.9 (IQR 24.0–31.0) vs 27.7 (IQR 24.3–31.3), $p = 0.60$]. Concerning vaginal examination, women in the outpatient group had more vaginal examination changed. The rate of leucocytes > 12.000/mm^3 was higher in inpatient group as well as the CRP. Fetal presentation and oligoanamnios were similar for both groups.

In the outpatient group, the length of latency period was longer than in the inpatient group [39 (IQR 20–66) versus 21 (IQR 13–42) days; $p < 0.001$] (Table 3). Clinical chorioamnionitis was observed in 30 (15.7%) in outpatient group versus 49 (24.0%) in inpatient group ($p = 0.039$). The occurrence of other obstetrical complication (intra-uterine fetal death, placenta abruption, and cord prolapse) was similar.

Table 1 Characteristics of the population

	Outpatient group $n = 191$	Inpatient group $n = 204$	*p* value
Maternal age (years)	28.6 ± 5.9	28.8 ± 6.1	*0.65*
Smoking (%)	36 [4, 19]	48 [5, 23]	*0.32*
Nullipara (%)	84 (44,2)	83 (40,7)	*0.48*
Associated obstetrical condition (%)			
Premature labor	15 [7, 9]	20 [8, 9]	0.50
Cervical cerclage	3 [1, 6]	3 [1, 5]	NA
Gestational diabetes	20 [5, 10]	20 [8, 9]	0.83
Fetal pathology (%)			
IUGR	24 [6, 12]	25 [3, 12]	*0.93*
Fetal abnormalities	6 [1, 3]	5 [2, 5]	0.68
Hydramnios	1 (0,5)	2 (1,0)	NA
Invasive procedure (amniocentesis/CVS)	10 [2, 5]	21 [3, 10]	*0.062*

IUGR intra-uterine growth restriction: usually corresponds with SGA (small for gestation age) associated with evidence indicating abnormal growth (with or without abnormal uterine and/or umbilical Doppler): arrest of growth or a shift in its rate measured longitudinally (at least two measurements, 3 weeks apart), *CVS* chorionic villus sampling, *NA* not applicable

Concerning neonatal outcome (Table 4), there were less neonatal transfer in reanimation and in intensive care unit (49.2% versus 77.2%, $p < 0.001$), less respiratory distress syndrome (29.4% versus 47.5%; $p < 0.001$), less neonatal sepsis (13.9% versus 22.1%; $p = 0.037$), less chronic neonatal lung disease (20.2% versus 36.3%; $p < 0.001$), less bronchodysplasia (2.7% versus 9.8%; $p = 0.004$), and less pulmonary arterial hypertension (4.8% versus 10.3%; $p = 0.040$) in the outpatient group than in the inpatient group. The length of stay in neonatology is shorter in the outpatient group [9 (IQR 6.0—17.0) versus 21 (IQR 1.0–39.0) days; $p < 0.001$].

Discussion

In this before/after study, we have shown that the length of latency period was longer with a gain of 17.5 days in the outpatient group. It was correlated with less morbidity in the neonatal outcomes. Rare severe complications were not more often observed in case of outpatient care, which reassure on this management.

Our results confirm previous smaller studies. Beckman et al. showed that outpatients had a longer latency period [32.6 (14.3–43.2) vs 12 [2–14] days] and delivered at a later

Table 2 Characteristics of PPROM

	Outpatient group $n=191$	Inpatient group $n=204$	p value
GA at PPROM (wk) (%)	27.9 (24.0 to 31.0)	27.7 (24.3 to 31.3)	*0.60*
< 24	*47 (24.6)*	*51 (25.0)*	
24–28	*52 (27.2)*	*57 (27.9)*	
28–32	*56 (29.3)*	*56 (27.5)*	
> 32	*36 (18.8)*	*40 (19.6)*	
Cervical examination (%)			
Vaginal examination changed	44/78 (56.4)	33/96 (34.4)	*0.004*
Cervical length > 25 mm (sono)	61/83 (73.5)	27/43 (62.8)	*0.30*
Inflammatory biologic syndrome at admission (%)			
WBC count > 12.000/mm^3	43/175 (24.6)	69/204(33.8)	*0.049*
CRP > 5 mg/L	53/183 (29.0)	90/202 (44.6)	*0.002*
Infectious samples at admission (%)			
Positive vaginal sample[a]	26/179 (14.5)	35/201 (17.4)	*0.44*
Positive CBEU	21/179 (11.7)	17/202 (8.4)	*0.28*
Fetal presentation (%)			*0.44*
Cephalic	126 (66.0)	140 (68.6)	
Breech	52 (27.2)	56 (27.5)	
Transverse	13 (6.8)	8 (3.9)	
Oligoanamnios[b] (%)	56 (29.3)	61 (29.9)	*0.90*
Low-lying placenta (%)	20 (10.5)	20 (9.8)	*0.83*

Data are expressed as median (interquartile range) for quantitative variables and frequency (percentage) for categorical variables, excepted for cervical examination, inflammatory biologic syndrome, and infectious samples where data are expressed as frequency/total of examination realized (percentage)

GA gestational age, *d* days, *wk* weeks, *WBC* white blood cell, *CBEU* cytobacteriological examination of the urine

[a]*Agalactiae*, *Escherichia Coli*, and others common germs

[b]Definition of oligoamnios was AFI of less than 20 mm

Table 3 Obstetrical outcomes following PPROM

	Outpatient group $n=191$	Inpatient group $n=204$	p value
Gestation age at delivery (GA)	35.6 (32.0 to 36.1)	32.4 (29.3 to 35.0)	*< 0.001*
Latency (d)	39 (20 to 66)	21 (13 to 42)	*< 0.001*
Rare severe complications			
IUFT (%)	2 (1.0)	0	*NA*
Placental abruption (%)	4 [2]	3 (1.5)	*NA*
Cord prolapse (%)	1 (0.5)	3 (1.5)	*NA*
Clinical chorioamnionitis (%)	30 (15.7)	49 (24.0)	*0.039*
Induction of labor (%)	84 (44.0)	44 (21.6)	*< 0.001*
C-section (N) (%)	49 (25.8)	66 (32.5)	*0.14*
Elective C-section	26 (53.1)	49 (74.2)	*0.018*
Emergency C-section	23 (46.9)	17 (25.8)	*0.018*

Data are expressed as median (interquartile range) or frequency (percentage)

PPROM preterm pre-labor rupture of membranes, *d* days, *GA* gestational age, *IUFD* intra-uterine fetal death, *NA* not applicable

gestation (32.7 versus 30.4 weeks). Neonates in case of PPROM managed as outpatient had also a higher birthweight [2121 g (776) versus 1602 g (688)] and spent fewer days in NCIU [20.2 days (21.2) versus 32.8 days (25.5)]. There was no more neonatal complication in the outpatient group [10]. In 2017, Palmer included 176 women in a retrospective

Table 4 Neonatal outcomes after PPROM

	Outpatient group $n=189$	Inpatient group $n=204$	p value
Weight at birth (g)	2310 (1690–2680)	1860 (1170–2265)	*< 0.001*
Apgar score < 7 after 5 min	15 (8.2)	30 (15.1)	*0.037*
Arterial pH < 7,1	10 (6.2)	5 (2, 7)	*0.12*
Neonatal death (%)	4 (1, 2)	8 (3, 9)	*0.30*
Neonatal transfer (%)	93 (49.2)	156 (77.2)	*<0.001*
Neonatal complications (%)			
Respiratory distress syndrome	55 (29.4)	97 (47.5)	*< 0.001*
Neonatal infection	26 (13.9)	45 (22.1)	*0.037*
Necrotising enterocolitis	5 (2.7)	2 (1.0)	*NA*
Intraventricular hemorrhage	3 (1.6)	10 (4.9)	*0.068*
Bronchodysplasia	5 (2.7)	20 (9.8)	*0.004*
Pulmonary arterial hypertension	9 (4.8)	21 (10.3)	*0.040*
Length of stay in neonatology (d)	9 (6–17)	21 (10–39)	*<0.001*

Data are expressed as median (interquartile range) or frequency (percentage)

PPROM preterm pre-labor rupture of membranes, *g* gram, *d* days, *GA* gestational age, *IUFD* intra-uterine fetal death, *NA* not applicable

study: 87 women were managed as outpatient and 89 as inpatient. Latency increased in the outpatient management with 17 days (4–120) versus 12 days (4–221) for inpatient management ($p < 0.001$). There was no difference in severe maternal morbidity (adjusted odds ratio [aOR] 0.64, 95% confidence interval [CI] 0.35–1.17) or neonatal morbidity/mortality (aOR 0.63, 95% CI 0.31–1.30). Also, length of stay decreased with outpatient care (7 days (3-82) versus 14 days (5-56)) ($p < 0.001$) [14]. In the series of Dussaux et al., women receiving outpatient care had a longer latency period with a gain of 18 days compared with conventional hospitalization. The patients delivered at a later gestational age (33.6 versus 32 weeks) and were more likely to have vaginal delivery. Again, no increase was observed in adverse maternal and perinatal outcomes for women receiving outpatient care following PPROM, compared with prolonged inpatient care [13].

The increased latency period is clearly the main benefit of outpatient care management. Indeed, the EPIPAGE 2 study has shown that prolonged latency period did not worsen neonatal prognosis. For every latency duration range (from 12 h to 2 days (18%), 3 to 7 days (38%), 8 to 14 days (24%), and > 14 days (20%), there were no statistically significant incidence of severe bronchopulmonary dysplasia, grade 3 intraventricular hemorrhage, cystis periventricular leukomalacia, stage 2 necrotizing enterocolitis, and stage 3 or more retinopathy of prematurity for any latency period, especially after 14 day latency period duration. Survival and survival without severe morbidity were improved with increased gestational age at birth. They concluded that increasing gestational age at birth, benefit the fetus, because it reduces prematurity without risking neonatal complications [25, 26].

Concerning neonatal outcome, we observed severe complications in the 2 groups: 2 IUFD in the outpatient group against 0 in the inpatient group, 4 placental abruption versus 3, 1 cord collapse versus 3, and 4 neonatal death versus 8. Concerning the results for IUFD, the rate of stillbirth among the hospitalized women was significantly higher on others studies [10, 13]. The low rate of stillbirth in our study does not allow us to make a conclusion. Even if some authors [27] discourage homecare management in PPROM to prevent those complications, we believe that the events occurred at home would have taken place even in hospital with the same issue. Moreover, perinatal mortality (IUFT and neonatal death) had the same rate in the two groups. But clearly, due to the increased latency period, neonatal morbidity was lower in case of outpatient management with less neonatal transfer, less respiratory distress syndrome, less neonatal sepsis, less bronchodysplasia, and less pulmonary arterial hypertension.

In addition, outpatient care has an economic benefit. Our study was retrospective with variation of costs and we were not able to evaluate cost effectiveness of homecare, but Carlan et al. have shown that hospital care following PPROM was likely to be associated with higher cost to the healthcare system [8]. Depending on the studies, outpatient care management would allow saving between 3000 and 57,000 dollars per patient [28].

There are several hypotheses to explain this latency period difference. First, inpatient care may increase the likelihood of earlier delivery by increasing the risk of nosocomial infections. We notice that there are less chorioamnionitis in the outpatient group versus the inpatient group (30 (15.7%) vs 49 (24.0%)). This result supports our hypothesis,

even if previous studies comparing conventional hospitalization versus home care management did not find any significant difference [9]. Second, the stressors associated with prolonged antenatal hospitalization are described, as well [29]. Indeed, stress may have an important psychological impact and we can hypothesize that outpatient care reduces this stress. Patients get a better comfort and quality of life which increases indirectly the latency. Third, hospitalization may be iatrogenic for women managed long-term, and as more interventions occur (i.e., vaginal examination), then biological sampling leading to antibiotic therapy and probably more induced birth.

To our knowledge, this study involves the largest number of subjects and is based with practices consistent with current worldwide recommendations (i.e., antenatal corticosteroids and antibiotics for PPROM) [6, 15]. Another major strength is the clinically relevant population, which includes complicated cases of PPROM (with abruptio placentae, chorioamnionitis, or intra-uterine fetal death). Such cases which can be linked to adverse neonatal outcomes were often excluded from previous studies or trials [30], which led to underestimation of serious maternal and fetal consequences. Our study has some limitations as it was an observational retrospective study, and unmeasured confounders might have biased our findings. The study spans nearly 15 years (2002-2015). Practice changes over such a long span in general outcomes would also affect outcomes. There have been also many changes in the world of neonatology from 2002 to 2015, which likely also account for more than some of the improved neonatal outcomes. There is also an overt selection bias given the non-randomized. Presumably women deemed lower risk were sent home and those with higher risk for early delivery were kept inpatient. Even if several outcomes seem to be better in the outpatient group (later gestational age at delivery and lower rate of cesarean section), we cannot conclude that outpatient care was associated with better outcomes without considering potential selection bias and change in neonatal practice over study period.

Conclusion

Based on these results, outpatient care management may be a feasible alternative to hospitalization in selected patients with PPROM between 24 and 35 weeks. It is associated with a prolonged latency and a better neonatal outcome. It will be interesting to evaluate the cost effectiveness of this practice and the psychological impact for patients.

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Compliance with ethical standards

Conflict of interest The authors report no conflict of interest.

Ethical approval This article does not contain any studies with human participants performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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