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Noémie Bouchet*, Arnaud Joal, Angèle Gayet-Ageron, Marina Lumbreras Areta and Begoña Martinez de Tejada

Impact of the new guidelines on the management of premature rupture of membranes for the prevention of late preterm birth: an 11-year retrospective study

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Abstract

Objective: To evaluate the number of late preterm (LPT) births (between 34 0/7 and 36 6/7 weeks) that could have been prevented if expectant management of preterm premature rupture of membranes (PPROM) had been applied according to new recommendations.

Methods: A retrospective cohort study included all births at one Swiss center between January 1, 2002 and December 31, 2012. Births were categorized using an adapted evidence-based classification. Two scenarios were considered: best scenario (maximum averted cases) and a conservative scenario (minimum averted cases).

Results: Among 2017 LPT births (5.0% of all deliveries; $n=40,609$), 1122 (60.6%) women had PPRM. Spontaneous labor occurred in 473 (42.2%) cases and 649 (57.8%) had induction of labor or an elective cesarean section. In the latter group, 44 (6.8%) had evidence-based indications for LPT delivery and 605 (83.2%) had non-evidence-based indications. Depending on the scenario, the rate of avoided LPT cases would have varied between 4.2% (95% confidence interval [CI]: 3.4–5.2) if the conservative scenario was applied, and 30% (95% CI: 28.0–32.0) for the best scenario.

Conclusion: Adoption of new guidelines for the management of PPRM will prevent a considerable number of LPT births and help decrease the adverse effects and potential disability associated with late preterm infants.

Keywords: evidence-based; guidelines; late preterm birth; non-spontaneous; preterm premature rupture of membranes.

Introduction

Following an increased trend over the past two decades, the preterm birth rate appeared to stabilize in 2010 at a new high in Europe and the USA [1]. However, since 2015, the rate has increased again in the USA, mostly among infants born late preterm (LPT), i.e. birth between 34 0/7 and 36 6/7 weeks [2]. The past decades have seen advances in our general understanding of the characteristics of preterm delivery and efforts have been made to reduce medically-indicated deliveries [3, 4]. Nevertheless, weak indications for delivery persist, particularly in LPT births [5], which represent two-thirds of all preterm births [6]. LPT newborns have been wrongly considered as almost mature infants, whereas it is now known that they have higher rates of complications than those born at term [7]. In 2012, following a review of the literature, a set of evidence-based (EB) indications to justify a LPT delivery was proposed by Gyamfi-Bannerman et al. [8, 9]. The objective was to identify the optimal time of delivery and reduce perinatal morbidity and mortality related to these births. A recent report showed an LPT birth reduction of 17.2% by improving management policies for non-evidence-based LPT deliveries [10].

Preterm premature rupture of membranes (PPROM) after 34 weeks was considered previously either as a spontaneous LPT birth or as an EB-LPT birth as induction of labor was the standard of care for many years [11]. In 2016, Morris et al. published the results of a large randomized control study comparing expectant management vs. immediate delivery among women with PPRM between 34 and 37 weeks' gestation [12]. They showed that expectant management of PPRM during this period provided more benefits to the newborn without increasing the

*Corresponding author: Noémie Bouchet, MD, Obstetrics Service, Department of Obstetrics and Gynecology, Geneva University Hospitals and Faculty of Medicine, 30 Boulevard de la Cluse, Geneva 1205, Switzerland, Tel.: +41 79 5535 095, Fax: +41 22 3724 165, E-mail: Noemie.Bouchet@hcuge.ch

Arnaud Joal and Marina Lumbreras Areta: Obstetrics Service, Department of Obstetrics and Gynecology, Geneva University Hospitals, Geneva, Switzerland

Angèle Gayet-Ageron: Clinical Research Centre and Division of Clinical Epidemiology, Department of Community Health and Medicine, Geneva University Hospitals, Geneva, Switzerland; and Faculty of Medicine, University of Geneva, Geneva, Switzerland

Begoña Martinez de Tejada: Obstetrics Service, Department of Obstetrics and Gynecology, Geneva University Hospitals, Geneva, Switzerland; and Faculty of Medicine, University of Geneva, Geneva, Switzerland

rate of neonatal sepsis, thus confirming the results of a previous study [13]. Another randomized controlled study evaluating the benefits of lung maturation after 34 weeks was also published in 2016 [14, 15]. In this trial, newborns with lung maturation required less respiratory support and had less severe respiratory morbidity than those who did not receive antenatal corticosteroids.

It is now considered that PPROM alone is not an EB-indication for LPT birth. Indeed, these fetuses benefit from expectant management with the advantage that lung maturation can be offered. However, there is still controversy about the optimal time to deliver in the case of LPT-PPROM and maternal carriage of group B *Streptococcus* (GBS). A study by a Dutch consortium showed that immediate delivery in women with PPROM and GBS carriage allowed reducing neonatal sepsis with a relative risk reduction of 86% [16]. By contrast, the PPROMT trial showed that immediate delivery appeared to be of no benefit in women with GBS carriage, but without overt signs of infection [12]. The aim of our study was to evaluate the additional number of LPT births that could have been prevented over an 11-year period if the new recommendations for PPROM management had been followed using an adapted classification for EB-LPT deliveries.

Materials and methods

The maternity unit of Geneva University Hospitals is the largest in Switzerland with approximately 4000 births per year. We conducted a retrospective cohort study including all LPT births between January 1, 2002 and December 31, 2012. This study is a secondary analysis of a former study published by our group, which showed that a total of 287 LPT births could have been potentially avoided in this same cohort if an evidence-based protocol for delivery indications had been used [17]. In the initial study, all LPT pregnancies with PPROM were induced. The novelty of the current analysis is to consider expectant management in LPT pregnancies with PPROM.

All women with a singleton pregnancy delivered between 34+0 and 36+6 weeks' gestation were included. Stillbirths and multiple gestations were excluded. All data were coded using a unique study number. The local Institutional Ethics Committee approved the research protocol. (Geneva Cantonal Ethics Committee [Commission Cantonale d'Ethique de la Recherche].)

The main outcome was the number of additional LPT births prevented by applying the new guidelines for PPROM management at 34–37 weeks' gestation, which recommend expectant management.

In the initial study, data were described on an annual basis. In the current study, the following variables were extracted: gestational age at delivery (based on the first trimester ultrasound); chorioamnionitis; PPROM; preeclampsia; cholestasis; intrauterine growth retardation (IUGR); abnormal fetal Doppler (umbilical and/or cerebral); abnormal fetal tracing; oligohydramnios; pre-labor uterine rupture; gestational hypertension; delivery onset: spontaneous or non-spontaneous (labor induction or elective cesarean); and indication

for delivery. We did not have access to the individual results for GBS carriage.

LPT births with PPROM were classified as either spontaneous or non-spontaneous. Spontaneous LPT-PPROM deliveries were those with birth occurring after the onset of spontaneous uterine contractions and cervical modifications. Non-spontaneous LPT-PPROM cases included deliveries that were either induced or an elective cesarean section. Following the classification by Gyamfi-Bannerman et al. [9] non-spontaneous LPT were further categorized as either EB or non-EB. EB indications included severe preeclampsia or eclampsia, IUGR retardation with abnormal testing (abnormal fetal Doppler or fetal heart tracing, oligohydramnios) or poor interval growth, acute abruption, non-reassuring fetal heart rate tracing, cholestasis (bile acids >40 $\mu\text{mol/L}$) and uterine rupture. In agreement with other recommendations, we also considered chorioamnionitis as an EB indication for LPT birth in the context of PPROM [18]. Cases with genital hemorrhage (not related to placental abruption) were also considered as EB in this adapted classification [19], whereas they were considered non-EB in the former study published by our group [17]. Non-spontaneous LPT-PPROM cases were considered as non-EB if the indication for delivery was the presence of the rupture of membranes alone or together with another non-EB indication.

We calculated the number of additional LPT births prevented by applying the following two possible scenarios. (1) Best scenario (maximum number prevented): all non-spontaneous LPT-PPROM cases without EB indications should have been treated conservatively and resulted in the avoidance of LPT birth. (2) Conservative scenario (minimum number prevented): we considered that some non-spontaneous LPT-PPROM cases would not reach 37 weeks for several reasons, i.e. hemorrhage [19], induction due to GBS carriage (prevalence rate of 19% in our center [20]), and chorioamnionitis during expectant management (estimated at 6% in the literature) [18]. Using data from previous studies, we estimated that 60% of women would go into labor spontaneously during the expectant management period and would not reach 37 weeks [12]. By subtracting the number of cases of non-expectant management allowed from the maximum number of prevented cases, we obtained an estimation of the minimum number of cases prevented with the conservative scenario according to the most recent literature.

Statistical analysis

Categorical variables were described by their frequencies, relative overall proportion, LPT group and distribution per week of gestational age. We divided categorical variables between the two groups of non-spontaneous LPT (non-EB non-spontaneous LPT and EB non-spontaneous LPT) and used the χ^2 or Fisher's exact test for comparison of birth indications by gestational age. Statistical analysis was performed using Stata IC 15 (STATA Corp., College Station, TX, USA). Statistical significance was defined as a two-sided P-value of <0.05.

Results

Among a total of 40,609 singleton deliveries during the 11-year study period, 4223 were preterm (10.5%) and 2017 LPT (5.0%). Among the latter, 1122 (60.6%) had a

PPROM and 473 (42.2%) went into labor spontaneously. LPT-PPROM cases represented 2.8% of the total singleton deliveries (95% confidence interval CI: 2.6–2.9). In the 553 (85.2%) cases not going into spontaneous labor, the indication for delivery was PPRM alone. Among the 96 (14.8%) cases with an indication for delivery, 44 (46%) cases were considered as EB and 52 (54%) as non-EB (Figure 1). EB indications were 31 (4.8%) cases of severe preeclampsia, seven (1.1%) cases of non-reassuring fetal heart rate tracing, two (0.3%) cases of placenta abruptio, two (0.3%) cases of IUGR with abnormal testing, and two (0.3%) cases of chorioamnionitis. Indications for birth were no different between the three gestational age groups (Table 1). Non-EB indications for delivery were as follows: gestational hypertension or non-severe preeclampsia, 45 (6.9%); hemorrhage (not related to placental abruptio), six (0.9%); and IUGR with normal testing, one (0.2%) case. Again, there were no differences in indications for birth between the three gestational age groups (Table 2).

Following the best scenario (maximum number prevented), all non-spontaneous LPT-PPROM cases

without EB indications should have been treated conservatively and reached 37 weeks. This would have resulted in avoiding a maximum of 605 LPT [53.9% of all LPT-PPROM, corresponding to 1.5% of all singleton deliveries (95% CI: 1.4–1.6) and to 30.0% of all singleton LPT (95% CI: 28.0–32.0)], including 553 cases with PPRM alone and 52 cases with non-EB indications.

When following the conservative scenario (minimum number prevented) among the 605 non-spontaneous LPT-PPROM cases, we applied the estimated proportions for GBS carriage and chorioamnionitis from previous studies. We expected the following estimates: 115 GBS carriers (19.0%); 36 cases developing chorioamnionitis: (6.0%); and 363 cases of spontaneous labor during expectant management (60%). We also had six cases (1.0%) of genital hemorrhage associated with PPRM. Following the conservative scenario, a total of 520 cases should or would have delivered before 37 weeks. The remaining 85 cases (14.0%) were LPT-PPROM without additional indications for delivering before term. The conservative scenario would have allowed to avoid 85 cases [7.6% of all LPT-PPROM, corresponding to 0.2% of all singleton deliveries

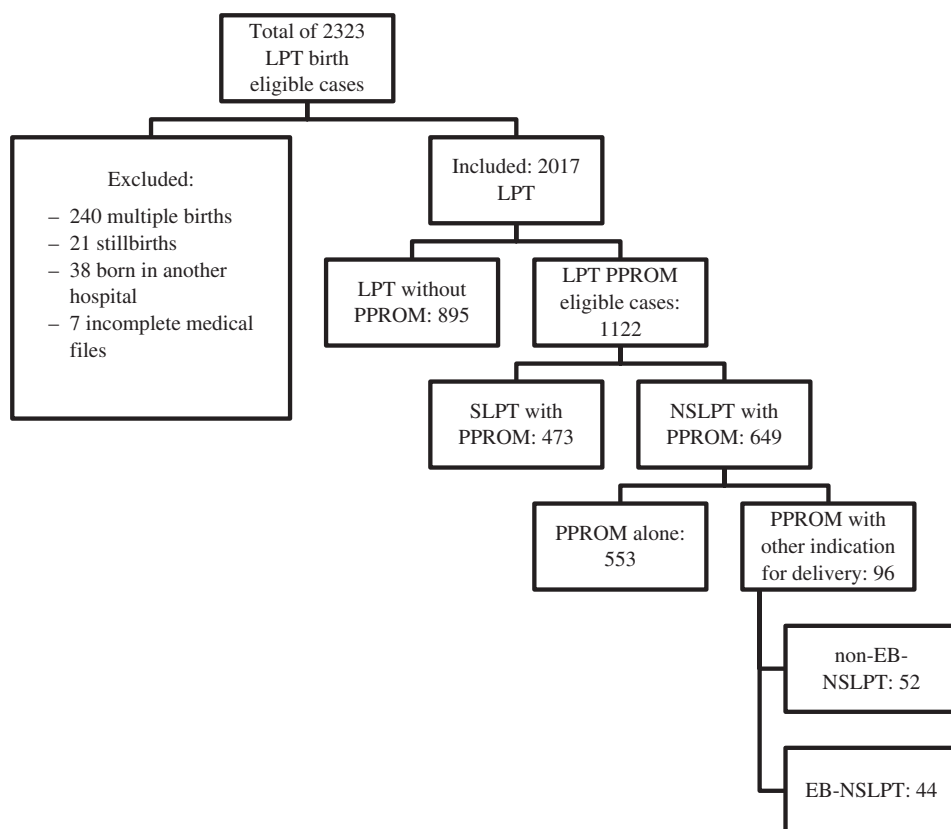


Figure 1: Flowchart of the study population.

LPT, late preterm; PPRM, preterm premature rupture of membranes; SLPT, spontaneous late preterm; NSLPT, non-spontaneous late preterm; EB, evidence-based.

Table 1: Evidence-based indications for birth among a population with PPRM, Geneva University Hospitals, 2002–2012.

Gestational age groups	n (%)			P-value
	34+0 to 34+6 (n=16)	35+0 to 35+6 (n=9)	36+0 to 36+6 (n=19)	
Indication for birth				0.637 ^a
Chorioamnionitis	2 (12.5)	0 (0)	0 (0)	0.165 ^b
Severe preeclampsia	9 (56.3)	7 (77.8)	15 (79.0)	0.295 ^c
IUGR with abnormal testing	1 (6.2)	0 (0)	1 (5.3)	0.999 ^d
Non-reassuring fetal heart tracing	3 (18.8)	1 (11.1)	3 (15.8)	0.999 ^e
Placenta abruptio	1 (6.2)	1 (11.1)	0 (0)	0.317 ^f

PPROM, preterm premature rupture of membranes; IUGR, intrauterine growth retardation. ^aP-value assessing the distribution of the indications between the three gestational age groups among EB-indications for birth. ^bP-value assessing the distribution of chorioamnionitis (vs. no chorioamnionitis) between the three gestational age groups. ^cP-value assessing the distribution of severe eclampsia (vs. no severe eclampsia) between the three gestational age groups. ^dP-value assessing the distribution of IUGR with abnormal testing (vs. no IUGR with abnormal testing) between the three gestational age groups. ^eP-value assessing the distribution of non-reassuring fetal heart tracing (vs. no non-reassuring fetal heart tracing) between the three gestational age groups. ^fP-value assessing the distribution of placenta abruptio (vs. no placenta abruptio) between the three gestational age groups.

(95% CI: 0.17–0.26) and to 4.2% of all singleton LPT (95% CI: 3.4–5.2)].

Thus, the implementation of the new guidelines for the management of PPRM would have allowed to prevent a minimum of 4.2% (85) and a maximum of 30.0% (605) LPT cases.

Discussion

In our study, non-spontaneous LPT-PPROM cases were treated by immediate delivery as recommended by former international guidelines [11]. However, these recommendations have recently changed, and an expectative attitude is recommended for LPT-PPROM in the absence of chorioamnionitis [12, 14], although some controversies exist for cases with GBS carriage [12, 16, 21, 22]. We calculated that between 4.2% (85) and 30.0% (605) LPT births of our maternity unit could have been avoided over a period of 11 years if the new PPRM guidelines had been applied.

The maximum theoretical number of prevented cases following the best scenario was 605 (30.0%), which included cases with PPRM alone as indication for delivery and non-EB-PPROM LPT cases. PPRM-LPT with EB indications according to the proposed categorization by Gyamfi-Bannerman et al. and last recommendations for chorioamnionitis management [18] required delivery and could not be avoided.

To calculate the minimum theoretical number following conservative management, we excluded cases that were estimated to progress to spontaneous labor during expectant management, those who would have developed

chorioamnionitis, and GBS carriers. We also excluded cases reported with genital hemorrhage (not related to placental abruptio). Based on the results of the PPROMT trial, 60% of LPT-PPROM cases will probably go into labor spontaneously during expectant management [12], which translates into 363 LPT cases. In the PPROMEXIL-2 trial, women in the expectant management group delivered approximately 3.5 days later (95% CI: 1.8–5.2) than women in the immediate delivery group [23]. However, even a short delay allows time for pulmonary maturation and thus contributes to improve neonatal outcomes [14]. We also took into account a 6% risk of developing chorioamnionitis during expectant management [12], which translated into 36 supplementary cases justifying active management.

For the most conservative scenario, we decided also to exclude GBS carrier cases from the prevented group as there is some controversy as to whether these patients might benefit from active management following PPRM after 34 weeks' gestation [16, 21, 22]. At our center, the rate of GBS colonization is 19%, [20] which represented another 115 cases removed. We also considered the association of PPRM with hemorrhage as an EB indication for delivery as these cases are at high risk of complications with a severe maternal/neonatal prognosis that is not justified to be taken at this gestational age (34–36 weeks) [19]. This is also in agreement with the new recommendations of the American College of Obstetricians and Gynecologists [24]. Thus, we estimated that the minimum number of cases prevented was 85 (4.2% of all LPT) following this scenario.

The strengths of our study are related to the use of an accepted categorization of LPT [10], thus ensuring

Table 2: Non-evidence-based indications for birth among a population with PPROM, Geneva University Hospitals, 2002–2012.

Gestational age groups	n (%)			P-value
	34+0 to 34+6 (n = 127)	35+0 to 35+6 (n = 155)	36+0 to 36+6 (n = 323)	
Indication for birth				0.219 ^a
PPROM alone	121 (95.3)	138 (89.0)	294 (91.0)	0.166 ^b
Gestational hypertension	1 (0.8)	1 (0.6)	5 (1.5)	0.881 ^c
Non-severe preeclampsia	4 (3.1)	12 (7.7)	22 (6.8)	0.243 ^d
IUGR with normal testing	0 (0)	0 (0)	1 (0.3)	0.999 ^e
Genital hemorrhage	1 (0.8)	4 (2.6)	1 (0.3)	0.045 ^f

PPROM, preterm premature rupture of membranes; IUGR, intrauterine growth retardation. ^aP-value assessing the distribution of the indications for birth between the three gestational age groups among non-EB indications. ^bP-value assessing the distribution of PPROM alone (vs. no) between the three gestational age groups. ^cP-value assessing the distribution of gestational hypertension (vs. no gestational hypertension) between the three gestational age groups. ^dP-value assessing the distribution of non-severe preeclampsia (vs. no non-severe preeclampsia) between the three gestational age groups. ^eP-value assessing the distribution of IUGR with normal testing (vs. no IUGR with normal testing) between the three gestational age groups. ^fP-value assessing the distribution of genital hemorrhage (vs. no genital hemorrhage) between the three gestational age groups.

reproducible results and allowing to compare practices within our institution and internationally, as well as the high number of cases assessed over a long period. Our study has some limitations. First, this is a retrospective study with data from one center and limits the generalizability of our findings. We did not have information on GBS carriage and used the rate reported in a previous study conducted at our institution [20]. We also hypothesized the number of cases of chorioamnionitis and women going into labor based on data from previous studies, but real numbers could have been different.

Recently, and for the first time, it has been possible to reduce the non-spontaneous LPT rate by the categorization and clarification of EB and non-EB indications to deliver during the LPT period [10]. Although the number of avoided cases in the two scenarios is very different, the implementation of the new management for PPROM at LPT will have a major impact when applied universally. In addition, new evidence shows that the beneficial effect of corticosteroid prophylaxis for neonatal lung maturation after 34 weeks might reinforce the importance of expectant management after PPROM without an EB-indication for immediate delivery [14, 15].

Conclusion

By applying the new guidelines for the conservative management of PPROM between 34 and 36 weeks' gestation and depending on the possible scenarios evaluated, the rate of avoided LPT cases could vary between 4.2% (95%

CI: 3.4–5.2) and 30% (95% CI: 28.0–32.0). The implementation of expectant management worldwide will have a huge impact on the global number of LPT infants. Even if a large number of LPT-PPROM cases treated with expectant management will not reach term, the implementation of this strategy could still allow for antenatal lung maturation and an improved neonatal outcome. Future prospective studies should be conducted to show if the results are similar in other centers, as well as the differences in numbers between the best and the conservative scenario.

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