


Term prelabor rupture of membranes: guidelines for clinical practice from the French College of Gynaecologists and Obstetricians (CNGOF)

Marie-Victoire Sénat^{a,b,c}, Thomas Schmitz^{d,e,f}, Hanane Bouchghoul^{a,b,c}, Caroline Diguisto^{f,g,h} , Aude Girault^{f,i,j}, Sabine Paysant^k, Jeanne Sibiude^{j,l}, Linda Lassel^m and Loïc Sentilhesⁿ



^aService de Gynécologie Obstétrique, Hôpital Bicêtre, AP-HP, Le Kremlin-Bicêtre, France; ^bUniversité Paris-Sud, Université de Médecine Paris-Saclay, Le Kremlin-Bicêtre, France; ^cCentre de recherche en épidémiologie et en santé en population, Université Paris-Saclay, Université Paris-Sud, Université de Versailles Saint-Quentin-en-Yvelines, INSERM, Paris, France; ^dService de Gynécologie Obstétrique, Hôpital Robert Debré, AP-HP, Paris, France; ^eUniversité de Paris, Paris, France; ^fEpidemiology and Statistics Research Center/CRESS, Université de Paris, INSERM, INRA, Paris, France; ^gService de Gynécologie Obstétrique, Centre Hospitalier Universitaire de Tours, Maternité Olympe de Gouges, Tours, France; ^hUniversité François Rabelais, Tours, France; ⁱService de Gynécologie Obstétrique, Maternité Port Royal, AP-HP, Paris, France; ^jDHU Risques et Grossesse, Université de Paris, Paris, France; ^kCollege National des Sages-Femmes de France, Paris, France; ^lService de Gynécologie Obstétrique, Maternité Louis Mourier, AP-HP, Paris, France; ^mDépartement de Gynécologie-Obstétrique et Reproduction humaine, CHU de Rennes, Rennes, France; ⁿService de Gynécologie-Obstétrique, Centre Hospitalier Universitaire de Bordeaux, Hôpital Pellegrin, Bordeaux, France

ABSTRACT

Objective: To determine the management of patients with term prelabor rupture of membranes.

Methods: Synthesis of the literature from the PubMed and Cochrane databases and the recommendations of French and foreign societies and colleges.

Results: Term prelabor rupture of membranes is considered a physiological process until 12 h have passed since rupture (professional consensus). In cases of expectant management and with a low rate of antibiotic prophylaxis, home care may be associated with an increase in neonatal infections (LE3), compared with hospitalization, especially for women with group B streptococcus (GBS) colonization (LE3). Home care is therefore not recommended (grade C). In the absence of spontaneous labor within 12 h of rupture, antibiotic prophylaxis may reduce the risk of maternal intrauterine infection but not of neonatal infection (LE3). Its use after 12 h of rupture in term prelabor rupture of the membranes is therefore recommended (grade C). When antibiotic prophylaxis is indicated, intravenous beta-lactams are recommended (grade C). Induction of labor with oxytocin (LE1), prostaglandin E2 (LE1), or misoprostol (LE1) is associated with shorter rupture-to-delivery intervals than expectant management; immediate induction is not, however, associated with lower rates of neonatal infection (LE1), even among women with a positive GBS vaginal swab (LE2). Thus, expectant management can be offered without increasing the risk of neonatal infection (grade B). Induction of labor is not associated with either an increase or decrease in the cesarean rate (LE2), regardless of parity (LE2) or Bishop score at admission (LE3). Induction can thus be proposed without increasing the risk of cesarean delivery (grade B). No induction method (oxytocin, dinoprostone, misoprostol, or Foley catheter) has demonstrated superiority over any another method for reducing rates of intrauterine or neonatal infection or of cesarean delivery or for shortening the rupture-to-delivery intervals, regardless of parity or the Bishop score.

Conclusion: Term prelabor rupture of membranes is a frequent event. A 12-hour interval without onset of spontaneous labor was chosen to differentiate a physiological condition from a potentially unsafe situation that justifies antibiotic prophylaxis. Expectant management or induction of labor can each be proposed, even in case of positive screening for group streptococcus. The decision should depend on the woman's wishes and maternity unit organization (professional consensus).

ARTICLE HISTORY

Received 2 June 2020
Accepted 10 July 2020

KEYWORDS

Term prelabor rupture of membranes; initial management of term rupture of membranes; antibiotic prophylaxis; induction of labor; intrauterine and neonatal infection

1. Introduction and methods

The sponsor (the French College of Gynecologists and Obstetricians – CNGOF) appointed a steering committee (Appendix A) to define the exact questions to be

put to the experts, to choose them, follow their work, and draft the resulting synthesis of recommendations [1]. The experts analyzed the scientific literature on the subject to answer the questions raised. A literature

CONTACT Marie-Victoire Sénat  marie-victoire.senat@aphp.fr  Service de Gynécologie-Obstétrique, Hôpital Bicêtre, 78 avenue du Général Leclerc, Le Kremlin-Bicêtre, France

© 2020 Informa UK Limited, trading as Taylor & Francis Group

review identified the relevant articles through mid-2014 by searching the MEDLINE database and the Cochrane Library. The search was restricted to articles published in English and French [2,3]. Priority was given to articles reporting results of original research, although review articles and commentaries were also consulted. Guidelines published by organizations or institutions such as the American College of Obstetricians and Gynecologists (ACOG) [4], the National Institute for Health and Care Excellence (NICE) [5], the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) [6], the Society of Obstetricians and Gynaecologists of Canada (SOGC) [7] were reviewed, as well as previous guidelines published by the CNGOF. Additional studies were located by reviewing bibliographies of identified articles. For each question, each overview of validated scientific data was assigned a level of evidence based on the quality of its data, in accordance with the framework defined by the HAS (French Authority for Health) [3], summarized below.

1.1. Quality of evidence assessment

LE1: very powerful randomized comparative trials, meta-analysis of randomized comparative trials;
 LE2: not very powerful randomized trial, well-run non-randomized comparative studies, cohort studies;
 LE3: case-control studies;
 LE4: non-randomized comparative studies with large biases, retrospective studies, cross-sectional studies, and case series.

A synthesis of recommendations was drafted by the organizing committee based on the replies given by the expert authors. Each recommendation for practice was allocated a grade, defined by the HAS as follows.

1.2. Classification of recommendations

Grade A: recommendations are based on good and consistent scientific evidence;
 Grade B: recommendations are based on limited or inconsistent scientific evidence;
 Grade C: recommendations are based primarily on consensus and expert opinion.

1.2.1. Professional consensus

In the absence of any conclusive scientific evidence, some practices have nevertheless been recommended

on the basis of agreement between the members of the working group (professional consensus).

All texts were reviewed by persons not involved in the work, i.e. practitioners in the various specialties (Appendix A) concerned and working in different situations (public, private, university, or non-university establishments). Once the review was completed, changes were made, if appropriate, considering the assessment of the quality of the evidence.

2. Epidemiology: definition, frequency, risk factors, and complications of term prelabor rupture of membranes

The issue in ruptures of membranes at term is to distinguish the women in labor from the women for whom these ruptures persist without labor – defined as term prelabor rupture of membranes [8]. That is, among these ruptures of membranes at term, some women will go into labor spontaneously within a variable period of time. Others will not present any clinically evident uterine contractions associated with cervical modifications. These two situations present potentially different prognoses concerning maternal–fetal infection.

According to unpublished data from the 2016 French National Perinatal Survey, term rupture of membranes occurs before admission to the labor room in 26.5% of women with singleton pregnancies, although it is not always possible to determine precisely if this rupture of membranes is actually prelabor (LE3). The literature reports a frequency of term prelabor rupture of membranes around 6–22% of singleton pregnancies (LE3). In the 2016 National Survey, term prelabor rupture of membranes was not followed by labor within 12 h for 35.6% of the women with term rupture of membranes and for 8.9% of all singleton pregnancies (LE3). Term prelabor rupture of membranes may be associated with the risk of fever before (LE3), during (LE3), and after labor (LE3), as well as of intrauterine and neonatal infection (LE3). The frequency of these complications in settings that use routine antibiotic prophylaxis is unknown. The expert advisory group chose an interval of 12 h without entry into spontaneous labor to differentiate a physiological situation from a potentially at-risk situation that could justify medical intervention (professional consensus). The risk factors for term prelabor rupture of the membranes are a history of term prelabor membrane rupture (LE3), nulliparity (LE3), uterine contractions requiring treatment (LE3), and first-trimester vaginal bleeding (LE3).

3. Initial management

When expectant management has been decided with women with term prelabor rupture of membranes, management at home in settings with a low rate of antibiotic prophylaxis may be associated with a higher risk of infection than hospitalization (LE3), especially if group B streptococcus (GBS) colonization exists (LE3) [9]. Management at home is therefore not recommended (grade C). In woman with term prelabor rupture of membranes, it is recommended to look for clinical signs of intrauterine infection (professional consensus) and to limit the number of digital cervical examinations before and during labor (grade C). White blood cell counts and plasma C-reactive protein (CRP) concentrations perform poorly in predicting neonatal infection (LE3). Insufficient data exist to justify recommending either of these tests for the diagnosis of term prelabor rupture of membranes (professional consensus). Nonetheless, should these markers be used, CRP must be preferred because of its excellent negative predictive values (grade C).

The French authority for health recommends routine screening for GBS carriage by a vaginal sample around the end of pregnancy – between 34 and 38 weeks of gestation [10]. If it has been performed, and regardless of its result, it is recommended that it not be at the time of the rupture (professional consensus). If a vaginal sample was not tested between 34 and 38 weeks of gestation, this testing is recommended at admission (grade C). An ultrasound at admission to assess the quantity of amniotic fluid is not recommended (professional consensus). An analysis of fetal heart rate is recommended at admission for term prelabor rupture of membranes (professional consensus). The benefit of antibiotic prophylaxis for women with term prelabor rupture of membranes for reducing the risk of neonatal infection has not been demonstrated (LE2). Its value has not been shown in cases of immediate induction but it may reduce the rate of intrauterine infection when expectant management exceeds 12 h (LE3). In cases of term prelabor rupture of membranes that do exceed 12 h, it is recommended that a beta-lactam be administered as first-line treatment (grade C), either intravenously or intramuscularly (grade C) because these are the only routes of administration that have been assessed in randomized trials (LE3).

4. Induction of labor: when and how?

Two options are available in cases of term prelabor rupture of the membranes: an interventionist attitude

with immediate induction of labor or an expectant attitude until entry into spontaneous labor [11,12]. The objective of induction of labor would be to reduce the risk of intrauterine infection and of the maternal and neonatal morbidity that may be associated with it. Expectant management would aim to reduce the risk of cesarean delivery and to limit the iatrogenic infection potentially associated with unnecessary medical intervention.

Induction makes it possible to shorten the interval between rupture of membranes and delivery, compared with expectant monitoring, when it is performed by oxytocin (LE2), E2 prostaglandin (LE2), or misoprostol (LE2). The existing studies concerning the Cook balloon® (LE2), the Foley catheter® (LE2), osmotic dilators (LE2), and acupuncture (LE2) are limited and do not show a reduction in the rupture-to-delivery interval.

The only study to use a robust method to compare the benefit and risks of a policy of induction versus expectant management was the TERM PROM study [13]. Nonetheless, this trial, performed more than 20 years ago, has as its principal defects that the women's GBS status was unknown at the moment of delivery and that the antibiotic prophylaxis rate was low (12%). TERM PROM did not find that immediate induction of labor, compared with expectant management, was associated with a reduction in neonatal infection (LE1), regardless of the women's GBS status (LE2). Induction was not associated with higher or lower cesarean rates than expectant management (LE2), regardless of parity (LE2), or the Bishop score (LE3). Induction by oxytocin (LE2), rather than by prostaglandins (LE2), was associated with lower risks of intrauterine infection and postpartum fever than expectant management.

In cases of term prelabor rupture of membranes, expectant management can be offered without increasing the risk of neonatal infection (grade B), even when GBS screening has been positive (professional consensus), and induction can be proposed without increasing the risk of a cesarean (grade B). The timing of induction will depend principally on the organization of care at the maternity unit and on the woman's preference after she has been informed of the risks and benefit of these two potential strategies (professional consensus). In the case of meconium or rupture of the membranes >4 days, induction of labor is recommended (professional consensus).

The randomized trials, mostly of small size, that specifically compared the different methods of induction (oxytocin, dinoprostone, misoprostol, and Foley

catheter) have not shown the superiority of one strategy compared with another for reducing any of the rates of intrauterine or neonatal infections or cesarean deliveries or for shortening the induction-to-delivery interval, regardless of the Bishop score or parity. All these methods can therefore be used (professional consensus). Nonetheless these data are insufficient to rule out an excess risk of infection associated with use of the Foley catheter.

5. Conclusion

In cases of term prelabor rupture of the membranes, home management is not recommended (grade C). At 12 h after the rupture, it is recommended that antibiotic prophylaxis (grade C) be prescribed with B-lactams as the first-line treatment (grade C). After term prelabor rupture of membranes, expectant management or induction of labor can be proposed, even if screening for GBS is positive. This choice depends on the woman's preference and the organization of care at the maternity unit (professional consensus).

Disclosure statement

LS was a board member of and carried out consultancy work and lectured for Ferring, and LL for MSD. No potential conflict of interest was reported by the author(s).

Funding

This work is supported by the CNGOF (Collège national des gynécologues et obstétriciens français).

ORCID

Caroline Diguisto  <http://orcid.org/0000-0002-1176-0991>

References

- [1] Lassel L, Schmitz T, Sentilhes L, et al. Term prelabor rupture of membranes: CNGOF guidelines for clinical practice – introduction. *Gynecol Obstet Fertil Senol.* 2020;48(1):12.
- [2] Senat MV, Schmitz T, Lassel L, et al. Term prelabor rupture of membranes: CNGOF guidelines for clinical practice—methods and organization. *Gynecol Obstet Fertil Senol.* 2020;48(1):13–14.
- [3] HAS. Les recommandations pour la pratique clinique. Base méthodologique pour la réalisation en France. Available from: http://www.has-sante.fr/portail/jcms/c_431294/les-recommandations-pour-la-pratique-clinique-base-methodologique-pour-leur-realisation-en-france
- [4] Committee on Practice Bulletins-Obstetrics. ACOG practice bulletin no. 188: prelabor rupture of membranes. *Obstet Gynecol.* 2018;13:e1–e14.
- [5] National Institute for Care and Health Excellence (NICE). Intrapartum care for healthy women and babies. Clinical guideline; 2014. Available from: <http://www.nice.org.uk>
- [6] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Term prelabour rupture of membranes (term PROM); 2010.
- [7] Leduc D, Biringer A, Lee L, et al. Induction of labour. *J Obstet Gynaecol Canada.* 2013;35(9): 840–857.
- [8] Diguisto C. Term prelabor rupture of membranes: CNGOF guidelines for clinical practice – definition, epidemiology, complications and risk factors. *Gynecol Obstet Fertil Senol.* 2020;48:19–23.
- [9] Bouchghoul H. Term prelabor rupture of membranes: CNGOF guidelines for clinical practice – initial management. *Gynecol Obstet Fertil Senol.* 2020;48(1): 24–34.
- [10] Haute Autorité de Santé. Accouchement normal: accompagnement de la physiologie et interventions médicales Méthode Recommandations pour la pratique clinique Recommandations de bonne pratique [Internet]; 2017 [cited 2019 Mar 10]. Available from: www.has-sante.fr.
- [11] Sibiude J. Term prelabor rupture of membranes: CNGOF guidelines for clinical practice—timing of labor induction. *Gynecol Obstet Fertil Senol.* 2020; 48(1):35–47.
- [12] Girault A. Term prelabor rupture of membranes: CNGOF guidelines for clinical practice – methods for inducing labor. *Gynecol Obstet Fertil Senol.* 2020;48: 48–58.
- [13] Hannah ME, Ohlsson A, Farine D, et al. Induction of labor compared with expectant management for prelabor rupture of the membranes at term. *N Engl J Med.* 1996;334(16):1005–1010.

Appendix A

Sponsor

CNGOF (Collège national des gynécologues et obstétriciens français) 91 boulevard de Sébastopol – 75002 Paris

Organizing committee: Linda Lassel, President (gynecologist-obstetrician, Rennes), MV. Senat, coordinator (gynecologist-obstetrician, UHC Le Kremlin-Bicêtre, CNGOF), L. Sentilhes, coordinator (gynecologist-obstetrician, UHC Bordeaux, CNGOF), Thomas Schmitz gynecologist-obstetrician, UHC Robert Debré, CNGOF, Sabine Paysant (CNSF, National College of French Midwives).

Working group experts: Hanane Bouchghoul (gynecologist-obstetrician, UHC Le Kremlin-Bicêtre), Caroline Diguisto, gynecologist-obstetrician, UHC Tours, Aude Girault (gynecologist-obstetrician, Maternité Port Royal, Paris), Jeanne Sibiude (gynecologist-obstetrician, UHC Colombes).

Reviewers: C. Arthuis (gynecologist-obstetrician UHC, Nantes), R. Béanger (midwife, UHC, Rennes), D. Body-Bechou (gynecologist-obstetrician, PSPH, Nantes), JB. Brest (gynecologist-obstetrician, CH, Morlaix), J. Cirier

(gynecologist-obstetrician, UHC, Tours), P. Delorme (gynecologist-obstetrician, UHC, Paris), P. Dias (midwife, UHC, Colombes), C. Garabedian (gynecologist-obstetrician, UHC, Lille), B. Harvey (pediatrician, CH, Saint-Cloud), M. Le Lous (gynecologist-obstetrician, UHC, Rennes), A. Letourneau (gynecologist-obstetrician, UHC, Clamart), C. Le Ray (gynecologist-obstetrician, UHC, Paris), E. Lorthé (midwife, INSERM, Paris), H. Madar (gynecologist-obstetrician, UHC, Bordeaux), E. Maisonneuve (gynecologist-obstetrician, UHC, Paris), D. Menzella (gynecologist-obstetrician, PSPH, Paris), É. Misbert (gynecologist-obstetrician, UHC, Nantes), A. Nguyen (gynecologist-obstetrician, libéral, Paris), F. Pachy (gynecologist-obstetrician, CH, Saint-Maurice), V. Peyronnet (gynecologist-obstetrician, CHU, Colombes).

C. Plesse (midwife, UHC, Rennes), S. Pomès (sage-femme, UHC, Tours), T. Quibel (obstetrician-gynecologist, CHI, Poissy), A. de Quillacq (obstetrician-gynecologist, private practice, Paris), M. Rajguru (obstetrician-gynecologist, Community hospital center, Versailles), E. Rault (obstetrician-gynecologist, UHC, Lyon), É. Serre (obstetrician-gynecologist, Community hospital center, Nevers), C. Tardif (obstetrician-gynecologist, UHC, Rennes), C. Thuillier (obstetrician-gynecologist, CHI, Poissy), C. Vérot (midwife, UHC, Paris), S. Vigoureux (obstetrician-gynecologist, UHC, Le Kremlin Bicêtre), A. Vincent (obstetrician-gynecologist, PSPH, Paris), and M. C. Wimmer (obstetrician-gynecologist, Community hospital center, Saint-Malo).