Evidence on: Premature Rupture of Membranes

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What is PROM?

Prelabor or "premature" rupture of membranes (PROM), happens when your water breaks before the start of labor. *Term PROM* is when your water breaks before labor at ≥37 weeks of pregnancy. *Preterm PROM*, or PPROM, happens when your water breaks before 37 weeks.

In this article, we are going to focus on Term PROM.

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How many people experience term PROM?

Estimates vary, but researchers say that about 8-10%, or 1 in 10 people, will have their water break before the onset of labor (Gunn et al., 1970).

Where did the "24 hour clock?" come from?

Some people are under the impression that once a person's water breaks, the birthing person only has 24 hours to give birth or they will automatically need a Cesarean. In other parts of the world, some people have told me that birthing persons only have 24 hours to go into labor before they must be induced. Where did these opinions come from? Are they evidence-based?

Many doctors at this time said that women should give birth within 24 hours after their water broke, even if that required an automatic Cesarean.

In 1966, Shubeck et al wrote,

*"With rupture of membranes, the clock of infection starts to tick; from this point on isolation and protection of the fetus from external microorganisms virtually ceases…Fetal mortality, largely due to infection, increases with the time from rupture of membranes to the onset of labor" (**Shubeck et al., 1966**).*

When we looked at these historical articles, we too were struck by the large increase in the risk of stillbirth and newborn death the longer a mother's water was broken after PROM. One study found that as many as 50% of babies were stillborn or died after birth if their mothers developed a fever or had other signs of infection with PROM (Lanier et al., 1965).

No wonder doctors were so afraid of long periods between the water breaking and birth! In some studies, taking more than 24 hours for the baby to be born led to death rates that were 2 or 3 times higher than babies who were born within 24 hours after PROM!

However, it is important to understand the differences between how women were cared for in the 1950s and 1960s and how they are cared for today—many decades later.

First of all, nearly all of the studies back then had overall death rates that would be considered completely unacceptable today. Whether or not a mother experienced PROM, the overall stillbirth and newborn death rates in these studies were as high as 4% for hospital births.

The researchers did not usually report the number of breech births, Cesareans, and use of forceps during birth. Babies sometimes died from botched forceps deliveries. Because Cesareans were so uncommon back then, women who needed Cesareans to save their babies often did not have them.

One study mentioned that more than half of the mothers were African American. At that time, black women experienced severe racism from the health care system and were not provided with prenatal care. They were not given receive any medical help until many hours after their water had broken. Tragically, their chance of infection was five times greater than white patients who were provided with health care (Lanier et al., 1965).

In many of these papers, the authors mentioned that antibiotic treatment was not popular during this time. This means that many women who were at risk for infections or had early symptoms of infection were not treated until their infections were quite severe. These mothers could pass on those infections to their babies in utero. If doctors did use antibiotics, they were usually limited to only penicillin, which is not effective against some types of bacteria.

Also, Group B strep—an important risk factor for newborn infections—was not understood or treated at that time.

Another reason reported death rates were high back then was because some researchers did not separate term PROM from preterm PROM. In other words, they put all babies who were born after PROM in the same group—whether or not they were born prematurely. However, when they did separate the normal birth weight babies from the low birth weight babies, they still found that normal birth weight babies had higher death rates after 24 hours of PROM than normal babies who were born within 24 hours of PROM.

Finally, most of the studies from the 1950s-1960s were based on retrospective (looking back in time) chart reviews. This type of study can have problems with accuracy. Also, none of the researchers looked at how many vaginal exams these women had—one of the most important risk factors for infection with PROM.

Today, we have access to better quality research about what happens when women wait for labor to start on its own or induce labor after term PROM.

This research shows that with proper care, waiting for up to 48-72 hours after the water breaks does not increase the risk of infection or death to babies who are born to mothers who meet certain criteria.* However, waiting means that birthing person may have a higher chance of experiencing infection themselves (Hannah et al., 1996; Pintucci et al., 2014).

So the "24-hour clock" rule is no longer valid today.

**These criteria are important and we will talk more about them at the end of the article.*

If you have PROM, how long does it take for labor to start on its own?

If people with PROM are not induced, around 45% will go into labor within 12 hours (Shalev et al., 1995; Zlatnik, 1992).

Between 77% and 95% will go into labor within 24 hours of their water breaking (Conway et al., 1984; Pintucci et al., 2014; Zlatnik, 1992).

In a recent large study, 76.5% of people with term PROM went into labor within 24 hours, and 90% were in labor within 48 hours (Pintucci et al., 2014). Although some of these people (16%) were induced, most (84%) went into labor on their own.

In another large study, researchers assigned some women to wait for up to 72 hours for labor to begin after their water broke. Out of these women, 83% went into labor on their own and had a normal vaginal birth (Shalev et al., 1995).

Some researchers have found that it may take longer for people giving birth for the first time to go into labor after their water breaks.One study found that 20% of people giving birth for the first time waited longer than 48 hours for contractions to begin after PROM, while only 7% of those who had given birth before took longer than 48 hours after PROM (Morales & Lazar, 1986).

What could cause your water to break before labor?

Microbes (bacteria and yeast)

In looking for causes of Term PROM some studies have looked at vaginal microbe. The question is—are there types of microbes in your vagina that could put you at higher risk for PROM?

In one study (Veleminsky & Tosner, 2008), researchers found that more people who experienced term PROM had a yeast infection than people who did not have term PROM.

Also, people who did not have term PROM were more likely to have lactobacillus (the good bacteria of the vagina). So it's possible that having "good bacteria" in the vagina may help protect someone from PROM.

Vaginal exams

As you get closer to your due date, many providers will check your cervix vaginally (called a "vaginal exam," "cervical exam," or "cervical check") starting at around 35-37 wks. Some providers will continue these checks weekly until birth.

In 1984, a study by Lenihan clearly showed a relationship between weekly vaginal exams and PROM. In this study, 349 women were randomly assigned to weekly vaginal exams starting at 37 weeks, or no vaginal exams until after 40-41 weeks.

The group with weekly vaginal exams starting at 37 weeks had a three times higher chance of having PROM (18%) compared to those who had no weekly exams until 40 or 41 weeks (6%) (Lenihan, 1984).

In another study that took place in in 1992, 587 women were randomly assigned to weekly vaginal exams or no exams. They found no differences in the rates of PROM between the two groups. While they concluded there was no relationship between prenatal vaginal exams and term PROM, they also found no benefit to the weekly exams (McDuffie et al., 1992).

Sweeping of the membranes

There is some evidence that sweeping the membranes, also called membrane stripping, is related to an increased risk of term PROM.

In one study, 300 women were randomly assigned to have either a cervical exam (control group) or membrane sweeping weekly starting at 38 weeks (Hill et al., 2008). If a finger could not be put through the cervix (because the cervix was not dilated enough), women in the membrane sweeping group were given cervical massage instead, to encourage dilation. So women in the membrane sweeping group did not always receive membrane sweeping.

For both groups as a whole, there were no statistically significant differences in the rates of PROM (7% in the no-sweep group vs. 12% in the sweeping group). When we say that something is not "statistically significant," this means that the differences could have been due to chance.

A few women went into labor or had PROM after they were randomized but *before* they

received their assigned intervention at 38 weeks. When these women were kept out of the analysis, the rates of PROM were 10.3% in the sweep group and 5% in the non-sweep group. This was still not statistically significant.

However, for women who were more than 1 centimeter dilated at the time of the intervention, women in the membrane sweeping group were significantly more likely to develop PROM (9.1% vs. 0%).

This is important because these are the people who actually received membrane sweeping, instead of cervical massage.

Rates of maternal infection (chorioamnionitis) were similar between the two groups, for both GBS-negative and GBS-positive women.

Unfortunately, there have been no studies that have compared membrane sweeping to having no vaginal exams at all. Since there is some evidence that vaginal exams—by themselves—can increase the risk of PROM, it would be interesting to know the risk of membrane sweeping compared to no interventions at all.

Vitamin C

There is a theory that Vitamin C can strengthen the membranes and prevent them from breaking early. One study has found that low-dose Vitamin C may prevent PROM, while two studies have found that high-dose Vitamin C may actually increase the risk of PROM.

In a small but high-quality trial that took place in Mexico, 109 pregnant women were randomly assigned to receive a small dose of Vitamin C once per day (100 mg) or an identical-looking placebo pill, starting at 20 weeks. People could not be in the study if they were taking any other prenatal vitamins.

One in four people in the placebo group (25%) experienced PROM, compared to only 8% of the Vitamin C group (Casanueva et al., 2005).

It's important to note that the Vitamin C dose in this study (100 mg) was small—much lower than the highest recommended amount of 2,000 mg per day. The researchers warned that taking high doses of Vitamin C could possibly increase the risk of PROM.

In fact, in two other studies, researchers found a link between high doses of Vitamin C (when given with Vitamin E) and PROM (Spinnato et al., 2008; Xu et al., 2010).

The first of these studies randomly assigned 697 pregnant women at high risk for preeclampsia to take Vitamin C (1,000 mg) and Vitamin E (100 IU) once per day, or to take a placebo daily. Women assigned to the Vitamin C/E group had a two times higher risk of PROM (10.6% vs. 5.5%) compared to women who took a placebo (Spinnato et al., 2008).

In 2010, another group of researchers randomly assigned 2,647 low-risk and high-risk women to Vitamin C (1,000 mg) and Vitamin E (400 IU) twice per day, or to take a placebo. The trial was stopped early because they found that women who took Vitamin C and E were at increased risk of stillbirth or newborn death (1.69% vs. 0.78%), PROM (10.2% vs. 6.2%) and preterm PROM (6% vs. 3%) compared to women who took a placebo (Xu et al., 2010).

Researchers aren't sure why one study found a beneficial effect of Vitamin C, and two studies on Vitamin C found harmful effects, but itcould be that higher doses increase the risk of PROM, or maybe taking Vitamin C and E together increased the risk of harm.

FYI, a common prenatal vitamin may contain about 60 mg of Vitamin C and 30 IU of Vitamin E, much smaller doses than the Vitamins tested in these 2 studies that found evidence of harm.

Fatty acid supplements

Omega-3 fatty acids, which are commonly found in fish oils, may be able to lower inflammation. This decrease in inflammation could delay the inevitable increase in prostaglandins that leads to weakening of the membranes.

In 2014, researchers randomly assigned 129 women to receive 200 mg of DHA (Omega 3 fatty acids) daily and 126 to receive a placebo with olive oil from the 8th week of pregnancy until birth (Pietrantoni et al., 2014).

They found a link between DHA supplementation and a decrease in biochemical markers for inflammation—as well as fewer cases of PROM.

Women who received the DHA supplements were less likely to experience term or preterm PROM. Preterm PROM was experienced by 1 woman in the DHA group and 4 women in the placebo group. Term PROM was experienced by 5 women in the DHA group and 12 women in the placebo group.

Other risk factors for term PROM

Most of the evidence on preventing PROM focuses entirely on the prevention of *preterm* PROM (before 37 weeks).

We did not find any other studies on dietary methods of preventing term PROM, such as eating eggs or high levels of protein. This is an area where more research is needed.

Is term PROM sometimes a normal, physiological event?

In some cases, it is possible that prelabor rupture of membranes at term is normal. Fetal membranes are "programmed" to weaken toward the end of labor.

A combination of factors leads to the creation of a weak spot in the amniotic sac near the cervix. Certain inflammatory reactions of the immune system can make this process go faster, which is why a prenatal infection can lead to prelabor rupture of the membranes.

Most commonly, the pressure of contractions causes the membranes to finally give way at the weak spot, but occasionally this can happen before contractions begin (Moore et al., 2006).

Induction versus Waiting for Labor

When someone's water breaks before labor at term, one of the most important questions they will face is whether to induce labor or wait for labor to start on its own.

Waiting for labor to start on its own is called "expectant management."

Starting labor artificially with induction is called "active management."

Many researchers have tried to compare the risks and benefits of induction versus expectant management.

In almost all of the studies on this issue, researchers only looked at people with PROM who had a single baby in head-first position. And they usually did not allow people with other pregnancy complications, such as infection, high blood pressure, or gestational diabetes, in their studies.

So the results that we will talk about in this article apply mainly to low-risk people giving birth.

When researchers compare induction versus expectant management, they usually look at these health results:

- How long it took for the baby to be born after PROM
- How often mothers experienced chorioamnionitis (infection of the membranes, or amniotic sac)
- How many women had Cesareans
- How many newborns had infections (either actual infections or suspected infections)

Group B Strep and PROM

The evidence on induction versus waiting for labor with term PROM is hard to interpret. This is because each research study set its own standards for how labor was induced, how long people waited for labor to begin before being induced, and what conditions required a Cesarean. These differences can lead to very different findings among studies that are supposed to be answering the same question.

One of the most important problems with the evidence on term PROM is related to Group B Strep. Most of the studies that we will talk about, including the famous "TermPROM" study (Hannah et al., 1996), were carried out before people in the U.S. were screened and treated for Group B Strep.

It is very common for pregnant people to carry Group B Strep bacteria in their digestive systems. The CDC reports that 25% of women will carry the Group B Strep bacteria in their vaginas or rectums. Carrying this type of bacteria puts birthing people at higher risk for chorioamnionitis (infection of the membranes) and puts newborns at higher risk for Group B Strep infection.

Currently, most pregnant people in the U.S. and some other countries are screened for GBS in the third trimester, and if they are positive for GBS, most receive IV antibiotics when labor begins.

Screening and treatment for GBS did not happen in most all of the studies that looked at induction versus waiting for labor with term PROM. So the results from these studies probably *overestimate* the risk of infection that a birthing person or newborn might experience if they had term PROM today.

You can read more about GBS here: https://evidencebasedbirth.com/groupbstrep/

Ultimately, the question "With term PROM: Is induction or waiting for labor the better choice?" will remain controversialuntil another large-scale study is conducted using modern methods of screening and treating for Group B Strep bacteria.

Cochrane Review

Researchers have combined all of the results from randomized trials on this topic into one large study, called a meta-analysis.

In 2017, an updated Cochrane meta-analysis replaced the prior version that was published in 2009. The new review contained 23 randomized trials with a total of 8,615 people giving birth. Ten studies compared expectant management to induction with IV oxytocin, and 12 studies compared expectant management to induction with misoprostol or vaginal prostaglandin E2 (Middleton et al., 2017).

One problem that we noted with this review is that only 2 of the studies (contributing 320 participants out of the 8,615 total) screened and treated for Group B Strep. Five studies gave antibiotics to everyone, regardless of whether or not participants had Group B Strep.

Based on their assessment of each study's design, the reviewers stated that the overall quality of the evidence was low, meaning that their confidence in the results is limited. If the reviewers specified the exact level of evidence for each finding, we have noted that in

parentheses below.

The researchers found that overall, there may be more pros than cons to induction with term PROM. Women who were immediately induced after term PROM had shorter durations from PROM until birth, were less likely to experience maternal infections (low-quality evidence), and appeared to have no increase in the risk of Cesarean (low-quality evidence). Their babies were less likely to need antibiotics after birth and less likely to be admitted to the NICU, and both mothers and babies had shorter hospital stays.

There were no differences between induction and expectant management groups in the risk of serious maternal infection (very-low quality evidence), definite newborn infection (very-low quality evidence), or *perinatal mortality*, a combined measure of stillbirth or newborn death (moderate-quality evidence).

Two possible side effects of medical induction are uterine *hyperstimulation* and uterine *tachysystole*. In 2010, the American College of Obstetricians and Gynecologists recommended abandoning the term hyperstimulation because it is vague and not defined. Instead, the term uterine tachysystole should be used.

Uterine tachysystole is defined as the uterus contracting too frequently (more than 5 contractions in 10 minutes, averaged over a 30-minute window), and can lead to a possible decrease in oxygen to the baby as well as fetal heart rate changes during labor. Four studies in the Cochrane review reported higher rates of hyperstimulation or tachysystole in the induction groups. The largest study that reported this side effect was carried out by Krupa et al. in 2005. In this study, there were 150 participants, and half of them were induced with misoprostol [Cytotec]. The researchers found that 10.7% of the induction with misoprostol group experienced tachysystole compared to 2.7% in the expectant management group. On the other hand, they found more fetal heart rate decelerations in the expectant management group (13.3% vs. 5.3%).

The Famous Term PROM Study

The most important study that has ever been done on term PROM is the “Term PROM” study. This high-quality study was published in the New England Journal of Medicine (Hannah et al., 1996).

Because it was such a large study, the Term PROM study results drive most of the findings in any meta-analysis, including the Cochrane review on this topic (Dare et al., 2006).

Therefore, we will focus on the findings of the Term PROM study in this article, while occasionally mentioning results from other studies.

Between the years of 1992-1995, a group of researchers from 72 hospitals enrolled 5,041 low-risk women from six different countries (Canada, United Kingdom, Australia, Israel, Sweden, and Denmark) into the Term PROM study.

Women were invited to be in the study if they came to the hospital with PROM. Everyone had a non-stress test before entering the study, and they were not included in the study if they had meconium staining of the amniotic fluid or any signs of infection when they arrived at the hospital.

Everyone was swabbed to check for Group B strep when they entered the study, but in most cases nobody knew the results of the GBS test until after the baby was born.

People with term PROM were randomly assigned to one of four groups:

1. Immediate induction of labor with oxytocin
2. Immediate induction of labor with prostaglandin gel (PGE2)
3. Waiting for labor to start for up to four days, followed by induction with oxytocin if needed
4. Waiting for labor to start for up to four days, followed by induction with prostaglandin gel if needed

Those people who were assigned to the waiting groups could wait for labor to begin either at home or in the hospital. They were told to check their temperatures twice per day and were told to report any fever, change in the color or smell of the amniotic fluid, or other problems.

People in the waiting (also called “expectant management”) groups were induced if they developed complications (such as signs of infection), if the mother requested an induction (which ended up being the most common reason for induction in the expectant management groups), or if labor did not start after four days.

Decisions about antibiotics were made by each person’s own healthcare provider.

What did researchers find in the Term PROM study and in other studies?

Cesarean Rates

In the Term PROM study, there were no differences in Cesarean rates between the induction groups and the waiting for labor groups. Cesarean rates were low in all four groups (13.7%-15.2%).

When the researchers separated out those people who had given birth before, versus those who were giving birth for the first time, they still found no differences between groups.

Among people giving birth for the first time, Cesarean rates were:

- 14.1% in the induction with oxytocin group
- 13.7% in the expectant management oxytocin group
- 13.7% in the induction with prostaglandin group
- 15.2% in the expectant management with prostaglandin group

Among people who had given birth before, Cesarean rates were:

- 4.3% in the induction with oxytocin group
- 3.9% in the expectant management oxytocin group
- 3.5% in the induction with prostaglandin group
- 4.6% in the expectant management with prostaglandin group

About 1 in 4 of people giving birth for the first time had forceps or vacuums used during their births. Among people who had given birth before, only 3.4 – 4.6% had forceps or vacuums used. There were no differences between induction and expectant management groups in rates of forceps or vacuum deliveries.

Most other studies that compare the rates of Cesarean section in induction vs. expectant management found no difference in Cesarean rates.

Infection in the Birthing Person

The *chorioamnion* (or membrane) is a physical barrier to bacterial invasion during pregnancy, so when the water or membranes break, this means the mother is at higher risk for infection.

Chorioamnionitis means inflammation of the membranes due to infection.

For the rest of this article, we will refer to this condition as *chorio*.

In the Term PROM study, the researchers defined chorio as:

- Mother's temperature >37.5° Celsius (99.5° Farenheit) on at least two time points more than one hour apart OR
- Any single temperature >38° Celsius (100.4° F) OR
- A white blood cell count of >20,000 per mm^3 (normal = 4,500-10,000) OR
- Foul smelling amniotic fluid

Researchers today frequently criticize the Term PROM definition of chorio for being "too loose." This means that the Term PROM researchers probably over-diagnosed chorio.

According to the American College of Obstetricians and Gynecologists, chorio can be diagnosed if a mother has a temperature > 38 degrees Celsius (100.4 F) AND usually at

least one other indicator: fast fetal heart rate, fast maternal heart rate, abdominal pain, high white blood cell count, or foul smelling fluid.

The American Academy of Pediatrics has even stricter standards for diagnosing chorio: a mother's temperature of >38 degrees Celsius (100.4 F) AND at least TWO other indicators: fast fetal heart rate, fast maternal heart rate, abdominal pain, high white blood cell count, or foul smelling fluid.

Using their looser definition of chorio, the Term PROM researchers found that chorio was less common in the immediate induction with oxytocin group (4%) compared to the group that waited for up to four days until induction with oxytocin (8.6%).

There were no differences in rates of chorio between people in the immediate induction with prostaglandins group compared to people in the waiting for labor for up to four days until induction with prostaglandins group.

The overall rate of chorioamnionitis in the Term PROM study was 6.7% (Seaward et al., 1997). This is a pretty high rate, and could be partially explained by the fact that very few people in the study had antibiotics for Group B Strep—a known risk factor for chorio.

In 2014, researchers published a large study that people with term PROM, and they found that with screening and treatment for GBS, the overall rate of chorio was 1.2% in a sample that included many women who waited for labor to begin on its own (Pintucci et al., 2014).

When we look at the Term PROM study, there are several potential reasons—other than the induction itself—that could help explain why those in the immediate induction with oxytocin group had lower rates of chorio. These reasons include the fact that people in the immediate induction group had fewer vaginal exams, shorter labors, and spent less time in the hospital compared to women in the waiting group.

Similarly, the 2017 Cochrane review found that induction is associated with a lower risk of infection in the mother.

However it is very important to note that most of the studies in the Cochrane review did not take into account the number of vaginal exams, nor they do not follow current GBS infection protocols.

Vaginal Exams

The number of vaginal exams that someone with PROM has after their water breaks is a very important (possibly the most important) predictor of whether someone with term PROM will develop chorio.

In the Term PROM study, a higher percentage of people in the waiting for labor groups (56%) had four or more vaginal exams compared to people in the immediate induction groups (49%).

Seaward and colleagues found that in the Term PROM study, a person's risk of chorio increased as the number of vaginal exams that they received increased (Seaward et al., 1997).

Compared to those who had *fewer than three vaginal exams*:

- 3-4 vaginal exams lead to 2 times the odds of having chorio
- 5-6 vaginal exams lead to 2.6 times the odds of having chorio
- 7-8 vaginal exams lead to 3.8 times the odds of having chorio
- >8 vaginal exams lead to 5 times the odds of having chorio

The strong link between the number of vaginal exams and the risk of chorio has been confirmed in many other studies. For example, in 2004, Ezra et al. found that seven or more vaginal exams were an important risk factor for infection in women whose water had broken (Ezra et al., 2004).

The reason vaginal exams can lead to infection is because even though care providers use sterile gloves, their fingers are pushing bacteria from the outside of the vagina up to the cervix as they conduct the exam. In fact, vaginal exams have been shown to nearly double the number of types of bacteria at the cervix (Imseis et al., 1999).

There is some evidence that a "sterile speculum exam" does not introduce extra bacteria to the cervix. In one small research study, five women had two sterile speculum exams, and their cervixes were swabbed to check for bacteria after each exam. There was no increase in bacteria on the cervix after the second speculum exam (Imseis et al., 1999).

In the Term PROM study, about two in five people (40%) received a vaginal exam (with sterile gloved hands) when they entered into the study. This is important because those people who were in the waiting groups took longer to give birth than those people who were induced with oxytocin. In other words, those in the waiting groups likely had an increased risk of infection due to the initial vaginal exam (Seaward et al., 1997).

Time to Give Birth

Not surprisingly, the Term PROM study found that people who are induced give birth more quickly than people who wait for labor to start on its own.

Women in the immediate induction with oxytocin group gave birth an average of 17 hours after their water broke, and women in the immediate induction with prostaglandins group gave birth an average of 23 hours after their water broke—compared to an average of 33

hours among those in the waiting groups.

Cord prolapse

There was no evidence that term PROM increases the risk of cord prolapse.

Cord prolapse only occurred two times out of more than 5,000 people with PROM who were enrolled in the study—once in the induction group and once in the waiting group.

To read more about cord prolapse and whether or not bed rest is required with term PROM, read this article from Evidence Based Birth®.

Newborn Infection

In the Term PROM study, blood samples were taken from most of the babies. There were no differences in newborn infection rates between any of the groups. Infection rates ranged from 2%-3%.

The Term PROM researchers carefully defined what an infection would be and even had separate doctors evaluate for newborn infection. Definite infection was defined as the presence of signs and symptoms of infection, plus one or more of the following: positive culture of blood, cerebrospinal fluid, urine, tracheal aspirate, or lung tissue; a positive Gram's stain of cerebrospinal fluid; a positive antigen-detection test with blood, cerebrospinal fluid, or urine; a chest x-ray consistent with pneumonia, or a tissue sample diagnosis of pneumonia. Blood samples were taken for culture in 80% of the babies in all four groups.

Several other studies have looked at risk factors for newborn infection. These risk factors included:

- A higher number of vaginal exams (Pintucci et al., 2014; Seaward et al., 1998)
- Mother carries Group B Strep (Pintucci et al., 2014; Hannah et al., 1997), (although the Hannah study did not use modern GBS screening and treatment)
- Having a mother who developed chorio during labor (Pintucci et al., 2014; Seaward et al., 1998).
- People whose labors took longer than 48 hours to start (Seaward et al., 1998).

In some studies, mothers whose labor took longer to start after their water broke were more likely to have newborns who were admitted to the NICU, or having a longer stay in the NICU (Akyol et al., 1999; Hallak & Bottoms, 1999; Hannah et al., 1996). It was not clear if this was because care providers were being more cautious with these infants.

Newborn Death

In the Term PROM study, there were no statistical differences in stillbirths or newborn deaths between the groups.

Despite the fact that the study included more than 5,000 mothers, it was still not a large enough study to tell a statistical difference in deaths.

Because stillbirths and newborn deaths are such a rare event, you would need more than 28,000 people in a randomized trial to tell a difference in mortality rates between groups

However, there were four deaths not related to birth defects in the Term PROM study. There were two deaths in the expectant management oxytocin group, two deaths in the expectant management prostaglandins group, and zero deaths in the induction groups.

The fact that all four of these deaths occurred in the two waiting groups could have been due to chance, or it could have been related to the waiting for labor to begin. Because the study was not big enough to tell differences in death rates, we will never know the answer to that question.

- A 41-week baby was stillborn after 14 hours of waiting for labor in the hospital. Labor was induced after fetal heart tones disappeared. Death was caused by asphyxia (lack of oxygen to the baby).
- A 39-week baby was stillborn after 19 hours of waiting for labor in the hospital. The fetal heart tones disappeared shortly before labor began on its own. Death was due to Group B Strep infection.
- A 37-week baby died after birth following three days of waiting for labor at home. Labor was induced electively, and after showing signs of fetal distress, the baby was born by a difficult Cesarean that included the use of forceps. The baby died from birth trauma.
- A 40-week baby died after birth following 28 hours of waiting for labor at home. Labor began spontaneously, but the baby was born by Cesaeran five hours later due to fetal distress. The cause of death was asphyxia.

Other newborn outcomes

In the Term PROM study, there were no differences between groups in the following newborn health issues:

- Apgar scores
- Need for resuscitation
- Seizures due to low oxygen levels
- Decreased level of consciousness
- Abnormal feeding at 48 hours

Fewer babies in the oxytocin induction group (7.5%) had to take antibiotics compared to

the waiting for labor group (13.7%), even though there was no difference in infections. This may be because mothers in the waiting group were more likely to have chorio, and it is quite common for babies to receive antibiotics if their mother experienced chorio.

Babies in the oxytocin induction group were also less likely to have a >24 hour stay in the NICU (6.6%) compared to the expectant management oxytocin group (11.6%).

The researchers suggested that these longer NICU stays might have happened because care providers are more worried about infants born to mothers with prolonged rupture of membranes and want to provide more monitoring for them.

Satisfaction

In the Term PROM study, mothers in the oxytocin induction group were less likely to say that there was nothing they liked about their treatment (5.9% vs. 13.7%) compared to women in the expectant management oxytocin group.

Likewise, fewer women in the induction with prostaglandin group said there was "nothing they liked about their treatment" (5.1% compared to 11.7%) compared to women in the expectant management prostaglandin group.

In other words, rates of satisfaction were high in both groups, but higher in the induction groups.

If someone chooses to wait for labor to start on its own, is there any evidence that it is safe to wait at home?

The only evidence that we have on waiting at home comes from the Term PROM study. People who were randomly assigned to the expectant management groups were given the choice of waiting in the hospital, or returning home to wait for labor to begin there.

Out of the entire study, 653 women decided to go home, and 1,017 decided to stay in the hospital. It's important to remember that before they went home, they were evaluated, had a non-stress test, and roughly a third had vaginal exams, which could increase their risk of infection.

The researchers found that there was an increase in some risks among people who waited for labor to start at home.

Compared to those who stayed in the hospital, people who waited at home were:

- More likely to have chorio (10.1% vs. 6.4%)
- More likely to receive antibiotics (28.2% vs. 17.5%)
- More likely to give birth by Cesarean (13.0% vs. 8.9%)

More babies born to mothers who waited at home received antibiotics (15.3% vs. 11.5%) and had a NICU stay greater than 24 hours (13.0% vs. 9.1%).

Certain factors increased some of these risks. Mothers giving birth for the first time who waited at home were even more likely to need antibiotics before delivery. Mothers who tested negative for GBS were more likely to need a Cesarean if they waited at home. Despite these increased risks, more people reported being satisfied with their care when they waited for labor at home (Hannah et al., 2000).

Because the evidence we have is limited, the benefits and risks of waiting at home are not clear. In the next section, we will talk about a recent, large study in which women waited for up to 48 hours for labor to begin. However, these people waited in the hospital, and they received antibiotics immediately if they were GBS positive, or at 24 hours for everybody else (See below).

Is there any other evidence that we should know about?

In 2014, Pintucci and colleagues published a prospective research study in which they followed 1,315 people with term PROM (Pintucci et al., 2014).

The people in this study waited for labor to begin for up to 48 hours unless there was a medical reason for induction.

People were not allowed to be in the study if they were already in active labor, had a baby in breech position, or a high-risk condition such as diabetes or high blood pressure. A vaginal exam was done on entry into the study to confirm that the water had broken, to make sure there wasn't a cord prolapse, and to check the cervix. Every six hours, the mother's temperature was taken, a non-stress test was done to check the baby, and amniotic fluid was examined. The fetal heart rate was monitored every two hours.

Antibiotics were started after 24 hours of ruptured membranes, immediately if the woman was GBS positive, or if she developed any signs and symptoms of chorio (fever, meconium staining, fast heart rate in the mother or baby). Labor was induced at 48 hours (using oxytocin, prostaglandin gel, or both depending on cervical score) if it had not begun on its own.

The people whose labors began on their own had a 2.5% Cesarean rate, and the people who were induced had a 15.5% Cesarean rate (overall rate 4.5%).

The authors conclude that people who were induced at any time point had 6.8 times the odds of having a Cesarean compared to people who had expectant management.

However, these results should be interpreted carefully—participants were only induced if they had medical reasons for an induction (such as infection), so this may explain why the

Cesarean rate was higher in that group. The length of time from rupture of membranes to birth was not related to Cesarean section in this study.

If you recall, the overall rate of chorio in the Term PROM study was 6.7% (Seaward et al., 1997). In the Pintucci et al. study that included screening and treatment for GBS, the overall rate of chorio was 1.2%– in a sample that included many people who waited for labor to begin on its own (Pintucci et al., 2014).

The newborn infection rate was 2.5%. Newborn infection was defined as having at least one of the following: a low blood leukocyte count, high or low neutrophil count, elevated C-reactive protein (a measure of inflammation), or two or more symptoms such as vomiting, low temperature, fever, blue color, not breathing, fast breathing, trouble breathing, or high blood sugar.

When they only looked at babies born more than 24 hours after PROM, the rate of infection increased slightly to 2.8%.

Mothers who developed chorio or had more than 8 vaginal exams during labor had an increased risk of having a newborn with an infection.

The results from the Pintucci study are important, because this is the first large study to look at those with term PROM who had modern testing and treatment for Group B Strep. Basically, the results showed this group of people was able to wait for labor to begin on its own, with very good outcomes for both mothers and babies.

Why are most people in the U.S. induced when their water breaks at term?

In 1998, the American College of Obstetricians and Gynecologists (ACOG) recommended that women with term PROM be offered the option of inducing labor or waiting 24-72 hours for labor to start on its own. ACOG stated that there was “Level A evidence” (highest level of evidence) for this recommendation.

But in 2007, ACOG reversed this opinion and recommended that women with PROM at term should be induced immediately. Again, they said there was Level A evidence, or the highest level of evidence, for this new recommendation.

But the same evidence (from the exact same research studies) was used to support both the 1998 and the 2007 statements.

The consequences of the new guideline were strong. Many people in the U.S. who experienced term PROM went from being offered the option of waiting for labor or inducing labor immediately, to now being told they “must” be induced. To learn more about what happened during this time point, you can read this article on Science and

Sensibility.

In 2013, ACOG replaced bulletin number 80 with bulletin number 139. In this newest practice guideline, ACOG continued to recommend induction of labor for term PROM– but this time the rating changed from Level A evidence, down to Level B evidence ("based on limited or inconsistent scientific evidence.")

And then in 2016, ACOG changed its recommendation again. Although they still recommended induction of labor at term for people who experience PROM (Level B evidence), they also state "However, a course of expectant management may be acceptable for a patient who declines induction… as long as clinical and fetal conditions are reassuring and she is adequately counseled regarding the risks of prolonged PROM."

Other Professional Guidelines

The American College of Nurse Midwives (ACNM 2012) states that women with term PROM should be informed about the risks and benefits of expectant management versus induction, and that if women meet certain criteria, they should be supported in choosing expectant management as a safe option. These criteria for safe expectant management include:

- Term, uncomplicated, singleton pregnancy
- Clear amniotic fluid
- No infections, including GBS
- No fever
- Normal fetal heart rate
- No vaginal exam at baseline; keep vaginal exams to a minimum

The NICE guidelines from the United Kingdom state that women should be offered a choice between induction or expectant management, and that induction is appropriate at 24 hours after PROM. To learn more, visit here or here.

The Society of Obstetricians and Gynaecologists of Canada states, "In the setting of ruptured membranes at term, oxytocin should be considered before expectant management."

The Association of Ontario Midwives states that women with term PROM should be offered induction or expectant management. In the absence of Group B Strep, complications, or signs of infection, expectant management for up to 96 hours is a reasonable option. The AOM also provide guidelines for monitoring should the birthing person choose expectant management.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) states, “Women with PROM at term should be informed of the risks and benefits of the options of active and expectant management.”

In Summary

The current evidence that we have suggests that people who experience term PROM should be counseled about the potential benefits and harms of both induction and expectant management, so that they can make the choice that is best for their unique situation.

Inducing labor for term PROM is a valid, evidence-based option for most people. At the same time, waiting for labor to start is also a valid, evidence-based option for most people. The person’s values, preferences, goals, and unique medical situation should always be taken into account when discussing their treatment options.

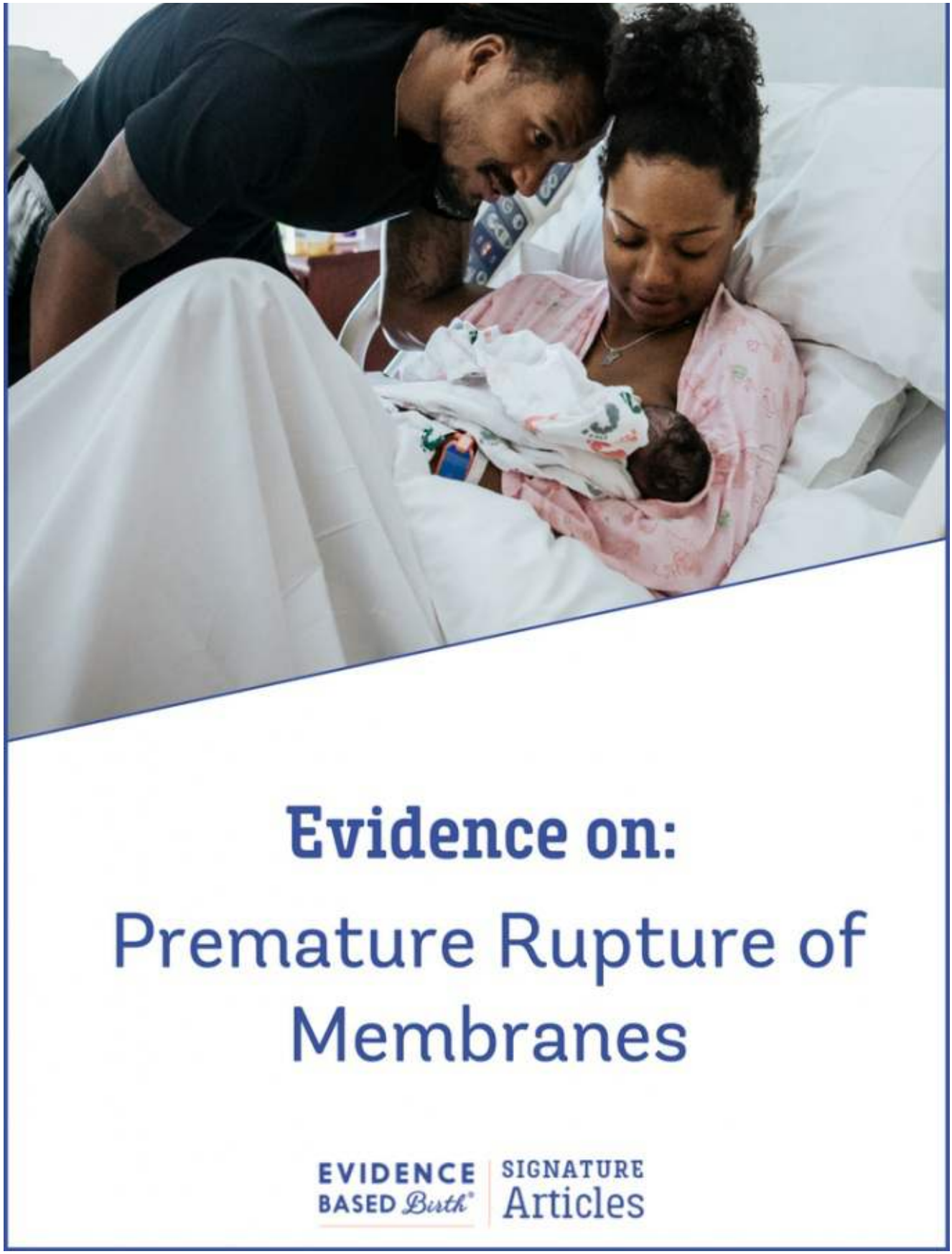
The Term PROM authors concluded, “Induction of labor with intravenous oxytocin, induction of labor with vaginal prostaglandin E2 gel, and expectant management are all reasonable options for women and their babies if membranes rupture before the start of labor at term, since they result in similar rates of neonatal infection and cesarean section.”

What’s the bottom line?

- Having labor induced with oxytocin for term PROM may lower a person’s chances of experiencing infection, but does not have an effect on the Cesarean rate or newborn infections.
- One of the most important ways to prevent infection after your water breaks is to avoid vaginal exams as much as possible during labor.
- As long as both mother and baby are doing well and meet certain criteria, waiting for up to 2-3 days for labor to begin on its own is an evidence-based option. At the same time, induction is also an evidence-based option.
- In today’s era with access to antibiotics if needed, the “24-hour clock” for giving birth is no longer based on evidence.

References:

Resources:



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