

Duration of Oxytocin and Rupture of the Membranes Before Diagnosing a Failed Induction of Labor

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OBJECTIVE: To compare maternal and neonatal outcomes based on length of the latent phase during induction with rupture of membranes before 6 cm dilation.

METHODS: This is a retrospective cohort study using data from the Consortium of Safe Labor study, including 9,763 nulliparous and 8,379 multiparous women with singleton, term pregnancies undergoing induction at 2 cm dilation or less with rupture of membranes before 6 cm dilation after which the latent phase ended. Outcomes were evaluated according to duration of oxytocin and rupture of membranes.

RESULTS: At time points from 6 to 18 hours of oxytocin and rupture of membranes, the rates of nulliparous

women remaining in the latent phase declined (35.9–1.4%) and the rates of vaginal delivery for those remaining in the latent phase at these time periods decreased (54.1–29.9%) Nulliparous women remaining in the latent phase for 12 hours compared with women who had exited the latent phase had significantly increased rates of chorioamnionitis (12.1% compared with 4.1%) and endometritis (3.6% compared with 1.3%) and increased rates of neonatal intensive care unit admission (8.7% compared with 6.3%). Similar patterns were present for multiparous women at 15 hours.

CONCLUSION: Based on when neonatal morbidity increased, in an otherwise uncomplicated induction of labor with rupture of membranes, a latent phase after initiation of oxytocin of at least 12 hours for nulliparous women and 15 hours in multiparous women is a reasonable criterion for diagnosing a failed induction.

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Institutions involved in the Consortium on Safe Labor are named in Appendix 1, available online at <http://links.lww.com/AOG/A828>.

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More than 22% of pregnant women underwent induction of labor in 2013, making it one of the most commonly performed procedures in the United States.¹ Although the goal of induction is to achieve a vaginal delivery, the criteria of failed induction of labor are not clear.²

The American College of Obstetricians and Gynecologists' statement that "cesarean deliveries for failed induction of labor in the latent phase can be avoided by... requiring that oxytocin be administered for at least 12–18 hours after membrane rupture before deeming the induction a failure"³ is based on limited data from small studies.^{2,4,5} Previous studies demonstrated that 13–60% of women in the latent phase after 12 hours of oxytocin and rupture of membranes eventually had vaginal deliveries.^{2,4,5} However, these studies were limited by a small number of women, precluding



evaluation of infrequent maternal and neonatal complications. Furthermore, data regarding maternal and neonatal complications in women remaining in the latent phase after more than 12 hours of oxytocin and rupture of membranes compared with women who exited the latent phase are limited. Determining whether an induction of labor is failed requires the balance between benefit of vaginal delivery and maternal–neonatal complications. Our study group was women undergoing induction of labor with an unfavorable cervix and rupture of membranes before the active phase of labor. We sought to compare maternal and neonatal outcomes between women in the latent phase and women who exited the latent phase according to the duration of oxytocin.

MATERIALS AND METHODS

The Consortium on Safe Labor was a retrospective cohort study of all women delivering at 23 weeks of gestation or greater between 2002 and 2008 in 12 clinical centers with 19 hospitals across nine American College of Obstetricians and Gynecologists districts.⁶ All participating institutions obtained institutional review board approval. Institutional review board approval was obtained for this analysis.

The Consortium on Safe Labor included a total of 228,562 deliveries with 233,736 newborns delivered at 23 weeks of gestation or greater after excluding 106 deliveries as a result of errors in identification. Data from the electronic medical record were abstracted and mapped to predefined categories at the data coordinating center. The accuracy of data was validated for four diagnoses including cesarean delivery for a nonreassuring fetal heart rate tracing, asphyxia, neonatal intensive care unit (NICU) admission as a result of a respiratory diagnosis, and shoulder dystocia. The variables were highly concordant with the medical records (greater than 95% for 16 of 20 variables and greater than or equal to 91.9% for all).⁶ We limited the current analysis to singleton gestations with cephalic presentation at 37 weeks of gestation or greater with known rupture of membranes time (premature, spontaneous, or artificial rupture of membranes) and oxytocin initiation time in women who underwent induction of labor (Appendix 2, available online at <http://links.lww.com/AOG/A828>). One study site did not report the time of rupture of membranes ($n=4,220$), and two sites did not report the time of oxytocin initiation ($n=8,543$). Therefore, these three sites were excluded. Women who had spontaneous labor and labor augmentation as recorded in the medical record were excluded in this study. We limited analysis to women with an unfavorable cervix defined as an initial cervical examination of 2 cm dil-

tion or less and rupture of membranes before cervical dilation 6 cm, which we defined as the point at which the active phase started. In our study, we did not take cervical ripening into account because the definition for failed induction³ does not take a prior cervical ripening agent into account. We also excluded women with a prior uterine scar, human immune virus infection, herpes simplex virus infection, induction of labor for chorioamnionitis, antepartum stillbirth, and major congenital abnormalities as well as maternal pre-existing comorbidities such as pre-existing diabetes, heart disease, and renal disease. To avoid intrapersonal correlation, we selected the first delivery from each participant in the study. The final analysis was limited to 18,470 deliveries.

We established three categories of precursors for induction: indicated, elective, and no recorded indication as previously described.⁷ We used the indication for induction to identify the precursors for delivery and classified using the following hierarchy. First, women with premature rupture of membranes were always classified as such. Second, we identified indicated precursors of induction including hypertensive disease (chronic hypertension, gestational hypertension, preeclampsia, and hemolysis, elevated liver enzymes, and low platelet count syndrome), postdates, fetal condition (including fetal growth restriction and abnormal antenatal testing), gestational diabetes, and abruption. More than one precursor for induction could be applicable for a given participant. Third, if a site indicated that the induction was elective without any indicated precursors of induction (including hypertensive disease, postdates, fetal condition, gestational diabetes, or abruption), the precursor for induction was designated as elective. Finally, the “no recorded indication” category encompassed all inductions without indications provided by site and with no other obstetric, fetal, or maternal conditions affecting the pregnancy.

Previous studies^{2,4,5} used the same definition (duration of oxytocin and rupture of membranes) to report outcomes of induction of labor. Therefore, we defined time zero as starting with the occurrence of both oxytocin and rupture of membranes. For example, if a woman was given oxytocin and then rupture of membranes occurred, the interval started with the time of rupture of membranes. If a woman had rupture of membranes and then oxytocin was started, the interval started with the oxytocin initiation time. According to the duration of oxytocin and rupture of membranes (6, 9, 12, 15, and 18 hours), women were assessed regarding their labor status (latent phase, active phase, delivered vaginally, delivered by cesarean delivery in the latent phase, delivered by cesarean



delivery in the active phase). All participants reaching vaginal or cesarean delivery outcomes from each former time point accumulated to the next time point. We defined the active phase of labor to begin at 6 cm dilatation or greater based on the findings from a previous study from the Consortium on Safe Labor data set, which found that the active phase of labor starts after 6 cm cervical dilation in both nulliparous and multiparous women.⁸ Thus, the latent phase ended when 6 cm dilation was achieved.

We evaluated eventual vaginal delivery rates of women in latent labor. We also evaluated maternal morbidity including chorioamnionitis, endometritis, and postpartum hemorrhage and neonatal morbidity including NICU admission, need for mechanical ventilation, and neonatal sepsis in women who were in the latent phase compared with women who exited the latent phase (active phase or delivered) at 6, 9, 12, 15, and 18 hours of oxytocin and rupture of membranes. Precursors for induction (hypertensive disease, postdates, fetal condition, premature rupture of membranes, gestational diabetes, and abruption), NICU admission, and mechanical ventilation were solely derived from medical records. Chorioamnionitis, endometritis, and neonatal sepsis were derived from medical records and supplemented with International Classification of Diseases, 9th Revision, Clinical Modification codes. Postpartum hemorrhage was defined as recorded in the medical record and estimated blood loss greater than 500 mL for vaginal delivery and greater than 1,000 mL for cesarean delivery and supplemented with International Classification of Diseases, 9th Revision, Clinical Modification codes.

Descriptive statistics were calculated for all study variables. Chi square test, Fisher exact test, or Wilcoxon rank-sum test was performed to determine associations between outcomes and the latent phase. Cochran-Armitage trend test was used to calculate the trend of eventual vaginal delivery rates in women who remained in the latent phase according to the duration of oxytocin and rupture of membranes. Multivariable logistic regression was used to calculate adjusted *P* values to compare maternal and neonatal outcomes between women who remained in the latent phase and women who exited the latent phase, controlling for gestational age at delivery, race-ethnicity, body mass index (calculated as weight [kg]/[height (m)]²) on admission, and hospital type. A *P* value <.05 was considered significant. All statistical analyses were performed using SAS 9.3.

RESULTS

Maternal, obstetric, and neonatal characteristics are presented in Table 1. In nulliparous women, 69.5% of the inductions were indicated, 18.0% were elective, and 12.6% had no recorded indication. Hypertensive disease was the most common precursor for induction in nulliparous women (21.8%) followed by postdates (16.0%). In multiparous women, 41.3% of inductions were indicated, 45.3% were elective, and 13.4% had no recorded indication. Hypertensive disease again was the most common precursor for induction in multiparous women (10.7%).

Labor status of women by duration of oxytocin and rupture of membranes is presented in Figure 1. For example, by 6 hours duration of oxytocin and rupture of membranes in nulliparous women, 25.4% had delivered vaginally, 5.1% had undergone cesarean delivery in the active phase, 10.1% had undergone cesarean delivery in the latent phase, 23.6% were in the active phase, and 35.9% were in the latent phase of labor. These numbers are cumulative. For example, in nulliparous women, the rate of vaginal delivery (43.7%) at 9 hours included the vaginal delivery rate (25.4%) at 6 hours. The majority of nulliparous women (97.2%) achieved the active phase or delivered after 15 hours of oxytocin and rupture of membranes. The majority of multiparous women (98.5%) achieved the active phase or delivered after 12 hours of oxytocin and rupture of membranes.

Eventual vaginal delivery rates of nulliparous and multiparous women remaining in the latent phase are presented in Figure 2. Women remaining in the latent phase with longer duration of oxytocin and rupture of membranes had a decreasing rate of vaginal delivery (*P*<.001 in both nulliparous and multiparous women). For example, at 12 hours of oxytocin and rupture of membranes, 6.5% of nulliparous women remained in the latent phase of labor, of whom 36.6% eventually had a vaginal delivery, and 1.5% of multiparous women remained in the latent phase, of whom 61.0% eventually had a vaginal delivery. At 18 hours of oxytocin and rupture of membranes, 1.4% of nulliparous women remained in the latent phase of labor, of whom 29.9% eventually had a vaginal delivery, and 0.3% of multiparous women remained in the latent phase, of whom 42.9% eventually had a vaginal delivery.

Maternal outcomes of nulliparous and multiparous women are presented in Figure 3. Nulliparous women who remained in the latent phase compared with women who exited the latent phase had increased rates of chorioamnionitis at all time points (*P*<.001 for 6, 9,



Table 1. Maternal, Obstetric, and Neonatal Characteristics for Women With Known Rupture of Membranes and Oxytocin Duration

Characteristic	Nulliparous Women (n=9,763)	Multiparous Women (n=8,379)
Maternal age (y)	25.2±5.8	29.4±5.2
BMI at delivery (kg/m ²)	31.4±6.4	31.2±6.1
Race or ethnicity		
Non-Hispanic white	4,980 (51.0)	5,526 (66.0)
Non-Hispanic black	2,030 (20.8)	1,110 (13.3)
Hispanic	1,645 (16.9)	1,112 (13.3)
Asian or Pacific Islander	380 (3.9)	164 (2.0)
Other or unknown	728 (7.5)	467 (5.6)
Insurance		
Private	5,952 (61.0)	5,838 (69.7)
Public or self-pay	3,152 (32.3)	2,152 (25.7)
Other	659 (6.8)	389 (4.6)
Hospital type		
University-affiliated hospital	4,181 (42.8)	2,206 (26.3)
Teaching community hospital	4,629 (47.4)	4,083 (48.7)
Nonteaching community hospital	953 (9.8)	2,090 (24.9)
Pregnancy complications		
Gestational diabetes	430 (4.4)	403 (4.8)
Chronic hypertension	383 (3.9)	271 (3.2)
Dilation on admission (cm)		
0	1,407 (14.4)	367 (4.4)
0.5	573 (5.9)	191 (2.3)
1	4,168 (42.7)	2,647 (31.6)
1.5	744 (7.6)	534 (6.4)
2	2,871 (29.4)	4,640 (55.4)
Effacement on admission	60 (20 to 80)	60 (30 to 80)
Station on admission	-2 (-4 to -1)	-2 (-3 to -1)
Group B streptococci infection	2,269 (23.2)	1,957 (23.4)
Precursors for induction*		
Hypertensive disease [†]	2,128 (21.8)	896 (10.7)
Postdates	1,559 (16.0)	521 (6.2)
Fetal condition [‡]	955 (9.8)	583 (7.0)
Premature rupture of membranes	824 (8.4)	309 (3.7)
Gestational diabetes	430 (4.4)	403 (4.8)
Abruptio	52 (0.5)	63 (0.8)
Other	660 (6.8)	618 (7.4)
Precursors for induction		
Indicated induction	6,780 (69.5)	3,457 (41.3)
Elective induction	1,758 (18.0)	3,797 (45.3)
No recorded indication	1,225 (12.6)	1,125 (13.4)
Gestational age at delivery (wk)	39.5±1.2	39.2±1.0
Neonatal birth weight (g)	3,351.2±453.2	3,388.8±432.1

BMI, body mass index.

Data shown as mean±standard deviation, n (%), or median (10th–90th percentile).

* Women could have more than one indication.

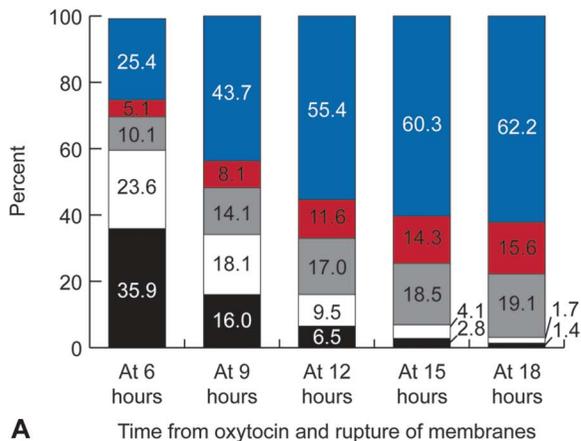
[†] Hypertensive disease included chronic hypertension, gestational hypertension, preeclampsia, and hemolysis, elevated liver enzyme, and low platelet count syndrome.

[‡] Fetal condition included conditions such as intrauterine growth restriction and abnormal antenatal testing.

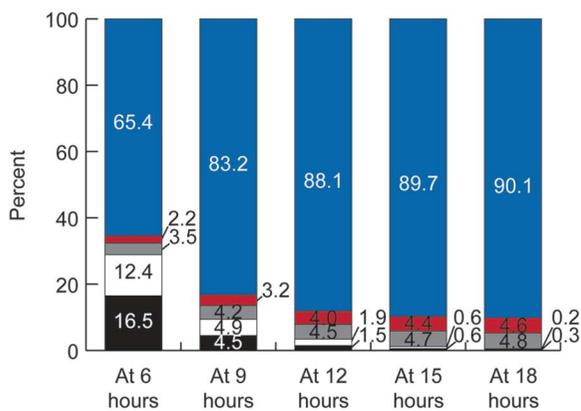
12, 15 hours and $P<.01$ for 18 hours) with the highest difference occurring at 15 hours of 13.0% compared with 4.3% ($P<.001$); endometritis at 6, 9, 12, and 15 hours ($P<.001$ for 6, 9, and 12 hours and $P<.01$ for 15 hours) with the highest difference occurring at 15 hours of 4.3% compared with 1.3% ($P<.01$); and postpartum

hemorrhage at 6, 9, and 15 hours ($P<.001$ for 6 and 9 hours and $P<.05$ for 15 hours) with the highest difference occurring at 15 hours of 6.5% compared with 4.0% ($P<.05$). Multiparous women who remained in the latent phase compared with women who exited the latent phase had increased rates of chorioamnionitis





A Time from oxytocin and rupture of membranes



B Time from oxytocin and rupture of membranes

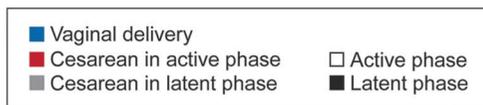
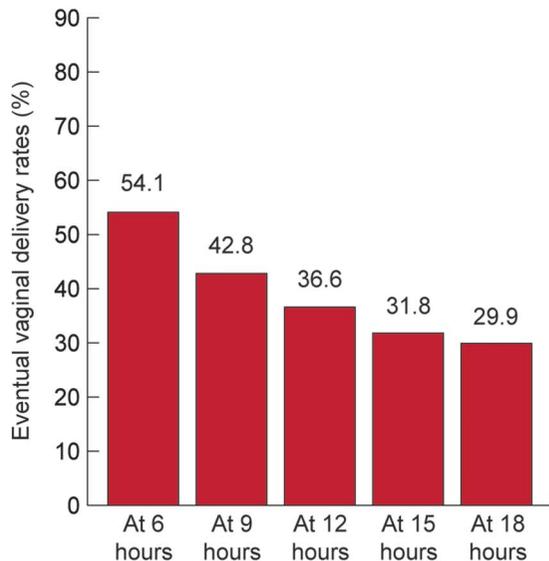


Fig. 1. Labor status by time from oxytocin and rupture of membranes. **A.** Nulliparous women ($n=9,763$). **B.** Multiparous women ($n=8,379$). Latent phase was defined as ending when cervical examination of 6 cm was achieved. Active phase was defined as starting when 6 cm dilation was achieved. For example, by 6 hours' duration of oxytocin and rupture of membranes in nulliparous women, 25.4% had delivered vaginally, 5.1% had undergone cesarean delivery in the active phase, 10.1% had undergone cesarean delivery in the latent phase, 23.6% were in the active phase, and 35.9% were in the latent phase. These numbers are cumulative. All participants reaching vaginal or cesarean delivery outcomes from each former time point accumulated to the next time point.

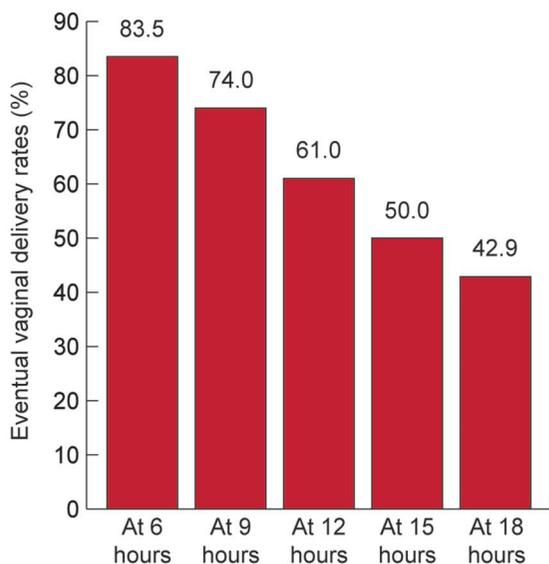
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at all time points ($P<.001$ for all) with the highest difference occurring at 18 hours of 14.3% compared with 0.8% ($P<.001$), and postpartum hemorrhage at 6, 12, and 15 hours ($P<.05$ for 6 hours and $P<.001$ for 12,



Latent phase	At 6 hours	At 9 hours	At 12 hours	At 15 hours	At 18 hours
n=	3,509	1,564	636	277	137
%	35.9	16.0	6.5	2.8	1.4

A Time from oxytocin and rupture of membranes



Latent phase	At 6 hours	At 9 hours	At 12 hours	At 15 hours	At 18 hours
n=	1,380	377	123	54	28
%	16.5	4.5	1.5	0.6	0.3

B Time from oxytocin and rupture of membranes

Fig. 2. Eventual vaginal delivery rates of women remaining in the latent phase. **A.** Nulliparous women ($n=9,763$). **B.** Multiparous women ($n=8,379$). The X-axis displays the duration of oxytocin and rupture of membranes. P for both nulliparous and multiparous women was $<.001$ (Cochran-Armitage trend test). %, number of women in the latent phase divided by all women. Kawakita. *Failed Induction of Labor. Obstet Gynecol* 2016.



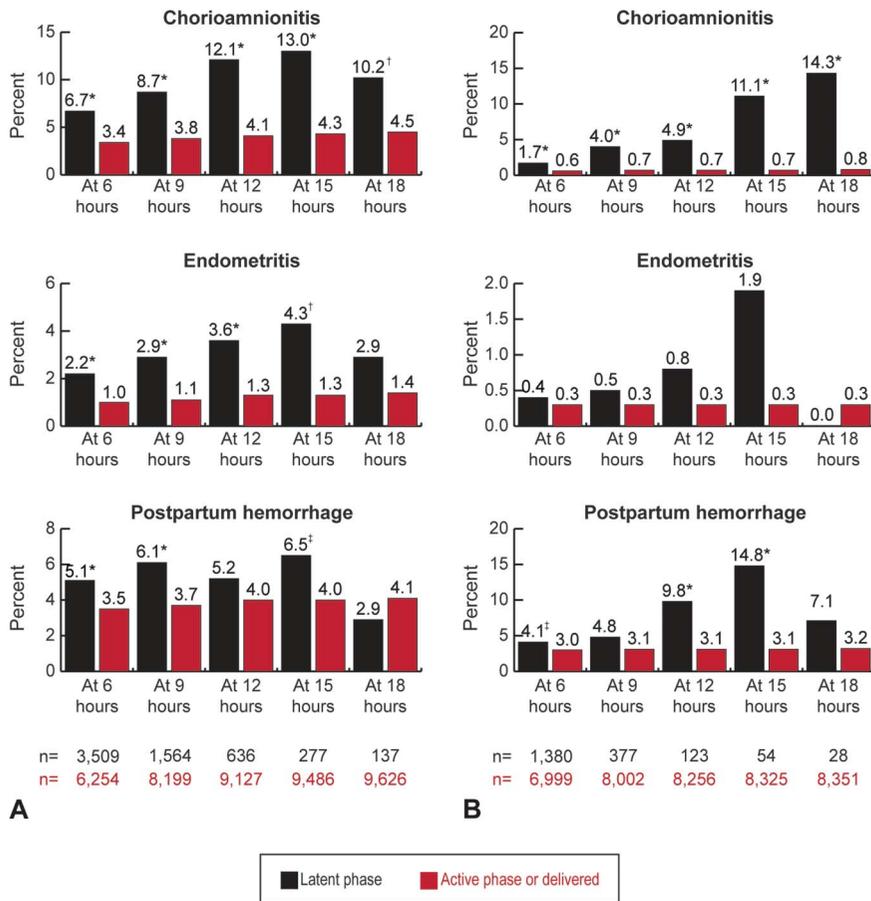


Fig. 3. Maternal outcomes of women remaining in the latent phase compared with those in the active phase or who had delivered. **A.** Nulliparous women (n=9,763). **B.** Multiparous women (n=8,379). The X-axis displays the duration of oxytocin and rupture of membranes. Adjusted *P* values were controlled for gestational age, race-ethnicity, body mass index (kg/m²) on admission, and hospital type. Latent phase was defined as ending when cervical examination of 6 cm was achieved. Active phase was defined as starting when 6 cm dilation was achieved. *Adjusted *P*<.001; [†]adjusted *P*<.01; *adjusted *P*<.05. Kawakita. *Failed Induction of Labor.* *Obstet Gynecol* 2016.

and 15 hours) with the highest difference occurring at 15 hours of 14.8% compared with 3.1% (*P*<.001).

Neonatal outcomes of nulliparous and multiparous women are presented in Figure 4. Neonates of nulliparous women who remained in the latent phase compared with women who exited the latent phase had higher rates of NICU admission with increasing duration; however, only increased rates of NICU admission in women who remained in the latent phase of labor after 12 and 15 hours were statistically significant (*P*<.05 for 12 hours and *P*<.01 for 15 hours). There was no statistically significant difference in the rates of mechanical ventilation and neonatal sepsis. For nulliparous women remaining in the latent phase, the rates of neonatal sepsis at 12, 15, and 18 hours were 1.9–2.2%, which were higher than the 1.1% at 6 hours and 1.4% at 9 hours, and were also higher compared with the 1.1–1.3% rate at all time points for women who exited the latent phase. For neonates of multiparous women who remained in the latent phase, the rates of neonatal sepsis at 15 and 18 hours were 1.9–3.6%, which were higher than 0.6–0.8% at 6, 9, and 12 hours, and were also higher compared with

the 0.4–0.5% rates at all time points for women who exited the latent phase. There was no difference in NICU admission, mechanical ventilation, or neonatal sepsis. Detailed information on maternal and neonatal outcomes in nulliparous and multiparous women is provided in Appendices 3 and 4, available online at <http://links.lww.com/AOG/A828>.

DISCUSSION

In this large, multiinstitutional cohort of women undergoing induction of labor with an unfavorable cervix, we found that only 6.5% of nulliparous and 0.6% of multiparous women remained in the latent phase of labor at 12 and 15 hours, respectively. Even so, 36.6% and 50.0% of these women, respectively, delivered vaginally. We also found that nulliparous women who remained in the latent phase had increasing rates of chorioamnionitis, endometritis, and postpartum hemorrhage compared with women who exited the latent phase. The rate of NICU admission for nulliparous women remaining in the latent phase at 12 and 15 hours was increased compared with women who exited the latent phase. Multiparous women who



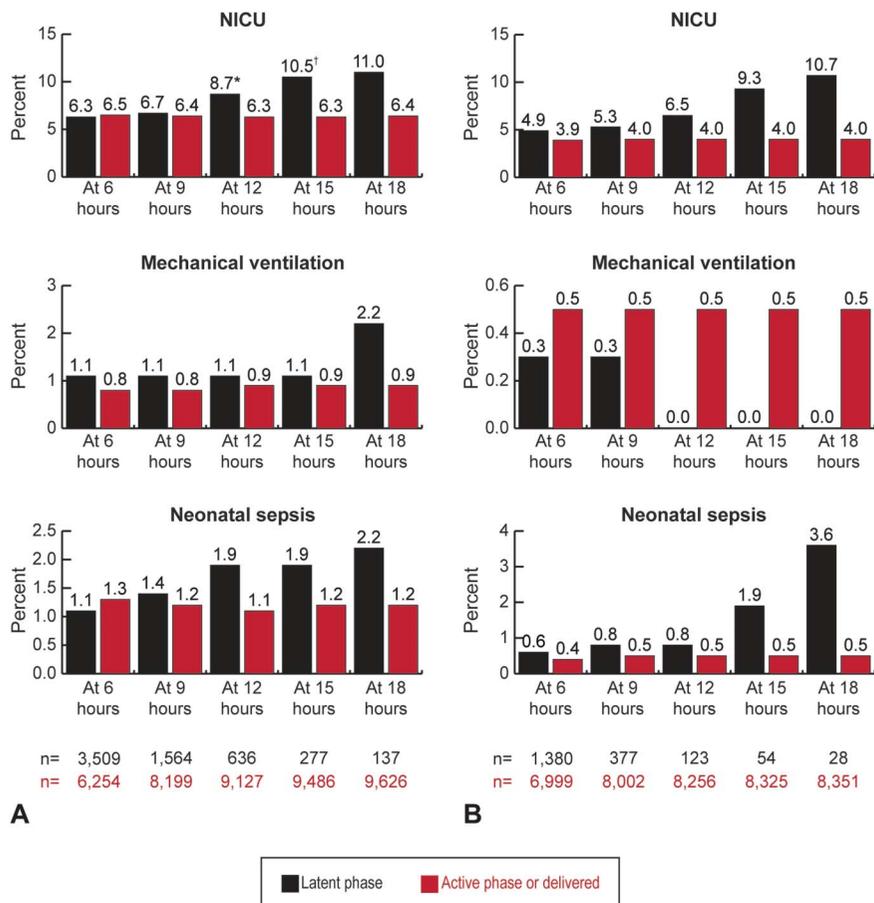


Fig. 4. Neonatal outcomes of women remaining in the latent phase compared with those in the active phase or who had delivered. **A.** Nulliparous women (n=9,763). **B.** Multiparous women (n=8,379). The X-axis displays the duration of oxytocin and rupture of membranes. Adjusted *P* values were controlled for gestational age, race-ethnicity, body mass index (kg/m²) on admission, and hospital type. Latent phase was defined as ending when cervical examination of 6 cm was achieved. Active phase was defined as starting when 6 cm dilation was achieved. *Adjusted *P*<.05; †adjusted *P*<.01. NICU, neonatal intensive care unit.

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remained in the latent phase had increasing rates of chorioamnionitis and postpartum hemorrhage compared with women who exited the latent phase. The rates of NICU admission and neonatal sepsis for multiparous women who remained in the latent phase rose at 15 hours compared with women who exited the latent phase, although these were not statistically significant.

Consistent with previous studies, we found that remaining in the latent phase was uncommon (less than 5%) after 15 hours of oxytocin and rupture of membranes in nulliparous women and 12 hours in multiparous women.^{2,4,5} Our findings of decreasing vaginal delivery rates with longer duration of oxytocin and rupture of membranes are consistent with previous studies.^{2,4,5} We found only one study that investigated the differences in maternal outcomes between women in the latent phase and women who exited the latent phase.⁴ In that study, the difference in endometritis was highest at 12 hours, although that study did not investigate after 12 hours. Our study demonstrated novel findings that rates of maternal morbidity continued to rise at 15 hours and 15–18 hours in nulliparous

and multiparous women, respectively. Unlike previous studies,^{2,4,5} our study with a larger sample size demonstrated increased NICU admission rates in nulliparous women who remained in the latent phase at 12 and 15 hours. Therefore, at least 12 hours of oxytocin and rupture of membranes are reasonable before considering an induction failed in nulliparous women. In multiparous women, the rates of NICU admission and neonatal sepsis rose at 15 hours for women who remained in the latent phase compared with women who exited the latent phase, although these were not statistically significant. Therefore, in multiparous women, at least 15 hours of oxytocin and rupture of membranes are reasonable before considering an induction failed.

The major strength of this study is the large cohort with clinical data from a contemporary U.S. population with the ability to study a wide variety of outcomes, particularly neonatal morbidity, associated with longer duration of oxytocin and rupture of membranes. Prior data on women with prolonged oxytocin and rupture of membranes have been available from single sites with small numbers limiting generalizability. In addition, our



study was able to describe the labor characteristics and morbidity of multiparous women with long duration of oxytocin and rupture of membranes lasting 12 hours or longer.

The main weakness of our study is that labor management was not standardized. We postulate that an unknown percentage of those cesarean deliveries performed in the latent phase less than 12 hours might have been avoided if a standard protocol was in place to compel clinicians to wait longer. The rate of complications and route of delivery also could have been different if there was standardized labor management. However, our findings reflect current obstetric practice given the age of the Consortium on Safe Labor data. Also, there was no protocol regarding cervical examination, which made it difficult to determine the exact time when women entered into the active phase of labor.

In summary, we found women remaining in the latent phase with longer duration of oxytocin and rupture of membranes had decreasing vaginal delivery rates. Women who remained in the latent phase had higher maternal morbidity compared with women who exited the latent phase. Neonates of nulliparous women who remained in the latent phase compared with those of women who exited the latent phase started to have increased risk of NICU admission at 12 hours. In multiparous women, the rates of NICU admission and neonatal sepsis rose at 15 hours for women who remained in the latent phase compared with women who exited the latent phase. Based

on retrospective data, we cannot make the definitive definition of failed induction of labor. However, in light of when neonatal morbidity increased, at least 12 hours of oxytocin and rupture of membranes in nulliparous women and 15 hours in multiparous women seem reasonable before considering an induction failed as long as maternal and fetal condition allows.

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