False Labor at Term in Singleton Pregnancies

Discharge After a Standardized Assessment and Perinatal Outcomes

David B. Nelson, MD, Donald D. McIntire, PhD, and Kenneth J. Leveno, MD

OBJECTIVE: To evaluate perinatal outcomes in women sent home with a diagnosis of false labor at term and assess the time interval to return for delivery.

METHODS: This was a prospective observational cohort study of women at 37 0/7 to 41 6/7 weeks of gestation without pre-existing medical complications who presented to our hospital-based triage unit with symptoms of labor and underwent a standardized evaluation. Women diagnosed as having false labor with a live singleton fetus in cephalic presentation without a prior cesarean delivery and sent home were compared with a group of similar women diagnosed to be in spontaneous labor. Women with hypertension, diabetes, and known fetal malformations were excluded. Using a perinatal composite outcome of respiratory insufficiency, intraventricular hemorrhage, culture-proven sepsis, Apgar score 3 or less at 5 minutes, phototherapy, and perinatal death, we tested the noninferiority of being sent home compared with being admitted for labor. The relationship of cervical dilatation to the time interval from discharge home to delivery was also analyzed.

RESULTS: Between October 2012 and March 2016, a total of 3,949 women met inclusion criteria and were diagnosed with false labor, discharged, and returned to deliver, whereas 2,592 similar women were admitted in early labor. The mean interval from discharge to return

From the Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas, Texas.

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Each author has indicated that he or she has met the journal's requirements for authorship.

Corresponding author: David B. Nelson, MD, Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, 5323 Harry Hines Boulevard, Dallas, TX 75390-9032; email: DavidB.Nelson@utsouthwestern.edu.

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was 4.9 days. Cesarean delivery rates were not different between the study groups—11% for both (P=.69), and the perinatal composite outcome rates were not significantly different between those sent home and those admitted—3.2% compared with 3.1% (P=.79). Women with more advanced cervical dilatation at discharge returned and delivered significantly earlier than those with less dilatation regardless of parity.

CONCLUSION: Discharge with false labor at term after a standardized assessment in a triage unit was not associated with increased rates of adverse perinatal composite outcomes or cesarean delivery. The time interval to return for delivery was significantly associated with the cervical dilatation at discharge.

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he study of labor has come under scrutiny as a result of a rising cesarean delivery rate. Indeed, in a recent joint publication of the Obstetric Care Consensus Committee entitled, "Safe Prevention of the Primary Cesarean Delivery," the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine have suggested revised standards for adequate labor. 1 By strict definition, labor begins with uterine contractions that bring about effacement and dilatation of the cervix.² During early gestation and before the onset of labor, uterine activity is considered relatively quiescent with increasing activity typical of the last weeks of pregnancy. However, the transition from prelabor to active labor can be difficult to discern because this transition is often gradual.

We have previously described contraction frequency as an index of spontaneous labor.³ Specifically, 12 contractions or more per hour (one contraction every 5 minutes) was defined as a meaningful signal that true labor has either started or is imminent.³ We subsequently expanded our study of labor onset to include the diagnosis and natural

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history of false preterm labor. 4 Little data exist regarding the natural history of false labor at term. The purpose of this study was to further define the transition from prelabor to labor. Specifically, the aim of this study was to evaluate the natural history of labor symptoms in women who were sent home with a diagnosis of false labor at 37 0/7 to 41 6/7 weeks of gestation. As a corollary, the interval between presentation for labor symptoms and subsequent perinatal outcomes was analyzed according to the diagnosis of false labor at term-defined as the women discharged undelivered-compared with women admitted in labor after observation in a triage unit. We hypothesized that women with singleton pregnancies at term without pre-existing medical complications who were discharged home after a standardized evaluation in a hospital-based triage unit and subsequently returned for delivery would have perinatal outcomes similar to women admitted in labor. The objective of this study was to test this hypothesis as well as analyze the time interval from discharge to return for delivery according to cervical dilatation at discharge.

MATERIALS AND METHODS

This was a prospective, observational study of consecutive women presenting to the Parkland Obstetric Triage Unit between October 20, 2012, and March 15, 2016, with symptoms of labor at 37 0/7 to 41 6/7 weeks of gestation. Parkland is a county-supported institution serving the medically indigent women of Dallas County. Women who present for labor symptoms at 24 0/7 weeks of gestation or greater are routinely evaluated within the labor and delivery triage unit, which is contiguous to the labor and delivery unit. All women in the triage unit are evaluated by nurse practitioners and certified nursemidwives using written protocols. Women with intact membranes and cervical dilatation less than 4 cm receive continuous external fetal monitoring for 2 hours in the triage area and are then reevaluated. Women diagnosed to be in labor with cervical change or persistent uterine contractions after observation were transferred to the labor and delivery unit. Women without cervical change and with cessation of contractions were sent home with the diagnosis of false labor after review by a physician.

Women enrolled in this study were those presenting to our triage unit with a live singleton fetus in cephalic presentation at 37 0/7 to 41 6/7 weeks of gestation without a prior cesarean delivery. Women with hypertension, pregestational or gestational diabetes, oligohydramnios, 42 weeks of gestation or greater, or known fetal malformations were excluded

as were women with obstetric conditions precluding vaginal birth such as placenta previa. Women diagnosed to have false labor and sent home were identified by a research nurse with prospective data collection of their triage encounter as well as during subsequent return visits. The outcomes of these women were analyzed using a comparison group of similar women diagnosed to be in spontaneous labor after observation at their first encounter in the triage unit. Put another way, the comparison group included women with presenting complaints of labor, intact membranes, and cervical dilatation less than 4 cm and no other complications. Women presenting with ruptured membranes, not in labor, or having cervical dilatation 4 cm or greater at first encounter in triage were excluded. Data collected for women diagnosed to have false labor as well as the comparison group were computerized and linked to a pre-existing obstetric database for all mother-neonate pairs delivered at our hospital. The projected sample size was calculated using the following rationale. We have previously reported that approximately 60% of women with uncomplicated pregnancies presenting to Parkland at term with contractions were diagnosed with false labor and sent home, whereas 40% were admitted for labor.³ Therefore, we anticipated a 60:40 (three to two) ratio of women presenting with complaints of labor at term and being sent home relative to those being admitted. Using previously reported rates of adverse neonatal outcomes at term at our hospital,⁵ we chose a composite adverse perinatal outcome to include respiratory insufficiency (mechanical ventilation in the first 24 hours), grades III and IV intraventricular hemorrhage grades, culture-proven sepsis, Apgar score 3 or less at 5 minutes, phototherapy, and perinatal death. We believe this composite would be a reasonable surrogate for adverse perinatal outcome at term and expected the rate to be 4.3% from our prior experience.⁵ This rate was used to test noninferiority of being sent home compared with being admitted in labor. We chose a noninferiority margin of 3% and calculated that at least 3,702 women sent home and 2,468 women admitted (three-to-two ratio) would have at least 80% power with a 95% confidence interval (CI), a onesided type I error of 0.025, to reject the hypothesis that the primary composite outcome in those sent home would be higher than those admitted using a one third rate increase–4.3% to 5.7%.

Statistical analysis was performed using SAS 9.3. Univariable analyses were performed using the χ^2 , Fisher exact, independent-group Student t tests and Wilcoxon rank-sum test. Adjusted analyses using

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logistic regression were performed for maternal characteristics. In adjusting for maternal characteristics, logistic regression was used for categorical outcomes and analysis of covariance for continuous outcomes. The relationship of cervical dilatation to the interval from discharge home to delivery for women diagnosed to have false labor was analyzed using the Kruskal-Wallis test for both nulliparous and parous women. This analysis included only women with perinatal outcomes available from delivery data at our hospital. Follow-up data from women discharged and delivered elsewhere were obtained through patient report and postpartum electronic medical record review. A separate analysis was performed for evaluation of fetal death after discharge for false labor by comparing rates of fetal death of women sent home with low-risk women presenting to triage during the study period. Results were considered significant if P < .05. This study was approved by the University of Texas Southwestern Medical Center institutional review board.

RESULTS

A total of 17,190 women with singleton, cephalic fetuses at 37 0/7 to 41 6/7 weeks of gestation met inclusion criteria and were encountered at least once in our triage unit during the study period, and 7,046 were considered not obviously in labor at first presentation and found to have intact membranes and cervical dilatation less than 4 cm (Fig. 1). Of these 7,046 women, 4,454 women were diagnosed to have

false labor and were sent home after at least a 2-hour observation period, and 2,592 women were admitted to the labor and delivery unit for labor after 2 hours or more in the triage unit (Fig. 1). Of the 4,454 women sent home, 3,949 women returned to Parkland Hospital for delivery with 505 of the women discharged delivered elsewhere. These 3,949 women discharged to home with false labor and returning for delivery at our hospital were compared with the 2,592 similar women with uncomplicated pregnancies with intact membranes and cervical dilatation less than 4 cm admitted in labor. The 4,454 women represented 26% of the 17,190 total number of women encountered in our triage unit during the study period. Demographic characteristics of those sent home with false labor and returned for delivery (n=3,949) were compared with those diagnosed to be in labor (n=2,592) (Table 1).

Women sent home after the diagnosis of false labor were in the triage unit an average of 2.7 hours. Cervical dilatation at discharge was 0 cm (19%), 1 cm (39%), and 2–3 cm (39%). The average interval from discharge to return and subsequent delivery was 4.9 days. Women with more advanced cervical dilatation at discharge returned and delivered significantly earlier than those with less cervical dilatation (Fig. 2). This relationship persisted when analyzed for both nulliparous and parous women, both P < .001.

Women with false labor were more likely to have delivered at or beyond 39 weeks of gestation and spent less time in the labor unit compared with

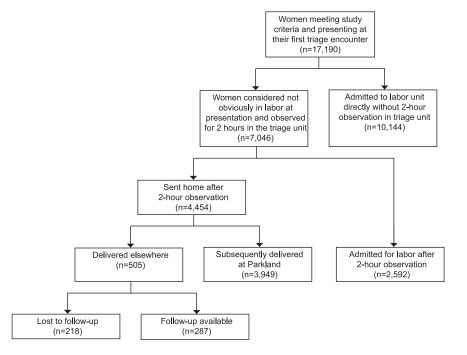


Fig. 1. Women meeting study criteria and presenting at their first triage encounter with a singleton fetus in cephalic presentation without prior cesarean delivery at 37 0/7 to 41 6/7 weeks of gestation between October 20, 2012, and March 15, 2016.

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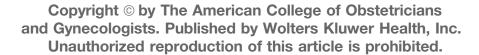


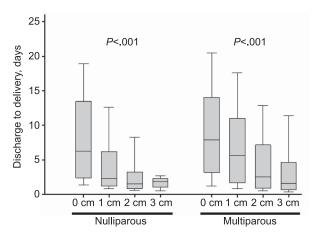


Table 1. Maternal Demographics of Women Sent Home With the Diagnosis of False Labor at 37 0/7 to 41 6/7 Weeks of Gestation (n=3,949) Compared With 2,592 Similar Women Admitted to the Labor and Delivery Unit for Spontaneous Labor

Demographic	Sent Home (n=3,949)	Admitted to Labor and Delivery (n=2,592)	P
Age (y)	26.2±6.2	26.3±6.1	.31
Younger than 18	221 (6)	136 (5)	.54
Older than 35	324 (8)	213 (8)	.99
Race-ethnicity			.02
Black	413 (10)	330 (13)	
White	96 (2)	56 (2)	
Hispanic	3,286 (83)	2,120 (82)	
Other	154 (4)	86 (3)	
Nulliparity	1,494 (38)	883 (34)	<.01
BMI (kg/m²)	31.7±5.6	30.9 ± 5.4	<.01
30 or greater	2,206 (58)	1,298 (54)	<.01

BMI, body mass index (available for 3,810 sent home and 2,413 admitted). Data are mean±standard deviation or n (%) unless otherwise specified.

those admitted without a history of false labor (Table 2). Rates of labor augmentation and chorioamnionitis were not significantly different between the women sent home with the diagnosis of false labor compared with those admitted in spontaneous labor after logistic regression adjusted for age, race, parity, and body mass index (Table 2). Cesarean delivery rates also were not different between the study groups—11% for both. The perinatal composite outcome rates (95% CI) were also



Parity and cervical dilatation at discharge for false labor

Fig. 2. Women sent home after the diagnosis of false labor (n=3,949) displayed according to the interval from discharge to subsequent return and delivery according to cervical dilatation at discharge for both nulliparous and parous women, both P<.001 using Kruskal-Wallis test. This P value examines the hypothesis of equality of distribution of the length of days from discharge to delivery across categories of cervical length. *Whiskers* in the figure extend from the 10th percentile to the 90th percentile.

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not statistically not different between the study groups—3.1% (2.6–3.7%) in women sent home with false labor compared with 3.0% (2.3–3.6%) in women admitted after observation—with a difference (95% CI) of 0.2% (-0.7 to 1.0%; P=.79) (Table 3).

We then examined the 505 women diagnosed with false labor but delivered elsewhere. Of these 505 women delivered elsewhere, selected delivery information was available for 287 women in the Parkland electronic medical record system. All 287 women reported delivering a healthy neonate, and the rate of cesarean delivery was not different from the remaining study cohort–12.5% for the 287 women delivered elsewhere compared with 11% in the 3,949 delivered at Parkland (P=.47). Conversely, a total of 218 (4.9%) of the original 4,454 cohort was seen in triage, discharged, and delivered elsewhere without delivery or neonate information available.

A separate analysis was performed for evaluation of fetal death after discharge for false labor (Fig. 3). There was a total of four stillbirths after women were sent home with false labor for a rate of 1 per 1,000 (95% CI 0.3/1,000-2.6/1,000). This rate was compared with the rate for 12,736 women with low-risk pregnancies eligible for this study but directly admitted to the labor unit during the same time period. The fetal death rate before arrival to the hospital was 1.9 per 1,000 in this comparison group (P=.24). As is routine at our hospital, a multidisciplinary review examines each stillbirth and assigns a cause when possible. In all four stillbirths in women sent home with false labor, the stillbirths were categorized as unexplained.



Table 2. Delivery Characteristics of Women Sent Home With the Diagnosis of False Labor at 37 0/7 to 41 6/7 Weeks of Gestation (n=3,949) Compared With 2,592 Similar Women Admitted to the Labor and Delivery Unit for Spontaneous Labor

Characteristic	Sent Home (n=3,949)	Admitted to Labor and Delivery (n=2,592)	P	Adjusted P*
Week of gestation at delivery	39.5±1.0	39.3±1.1	<.001	<.001
39 or greater	3,323 (84)	1,942 (75)	<.001	<.001
Oxytocin augmentation	1,556 (39)	956 (37)	.04	.52
Chorioamnionitis	446 (11)	233 (9)	.003	.07
Epidural analgesia	2,586 (65)	1,694 (65)	.91	.35
Time spent in labor unit (h)	7.6 (4.2, 12.0)	8.2 (5.3, 12.0)	<.001	<.001
Mode of delivery				
Spontaneous vaginal	3,380 (86)	2,203 (85)	.69	.08
Forceps	129 (3)	92 (4)	.46	.39
Cesarean	440 (11)	297 (11)	.69	.16

Data are mean±standard deviation, n (%), or median (quartile 1, quartile 3) unless otherwise specified.

DISCUSSION

There were four findings from this study of more than 17,000 women presenting for possible labor at term. First, the diagnosis of false labor is common. Approximately 25% of women presenting at 37 0/7 to 41 6/7 weeks of gestation were diagnosed to have false labor. Second, the interval from discharge to subsequent return for labor and delivery was approximately 5 days. This time interval was inversely related to cervical dilatation at discharge for false labor. A

shorter interval to delivery was associated with more advanced dilatation of the cervix when false labor was diagnosed in both nulliparous and parous women. Third, there were no significant differences in delivery outcomes in women sent home for false labor compared with those admitted for spontaneous labor. This included an 89% rate of vaginal delivery in both study groups. Lastly, there was not a significant increase in the rate of adverse neonatal outcomes nor fetal deaths among women sent home for false

Table 3. Perinatal Outcomes of Women Sent Home With the Diagnosis of False Labor at 37 0/7 to 41 6/7 Weeks of Gestation (n=3,949) Compared With 2,592 Similar Women Admitted to the Labor and Delivery Unit for Spontaneous Labor

Outcome	Sent Home (n=3,949)	Admitted to Labor and Delivery (n=2,592)	P	Adjusted P*
Birth weight (g)	3,456±432	3,384±434	<.001	<.001
Greater than 4,000	417 (11)	198 (8)	<.001	<.001
Apgar score 3 or less at 5 min	11 (0.3)	6 (0.2)	.72	.56
Intensive care admission	58 (1.5)	34 (1.3)	.90	.98
Respiratory distress				
Ventilation in first 24 h	10 (0.3)	7 (0.3)	.90	.098
Transient tachypnea	0	0	N/A	N/A
Grade III or IV interventricular hemorrhage	0	0	N/A	N/A
Sepsis				
Evaluation	652 (17)	367 (14)	.010	.19
Culture-proven	2 (0.1)	4 (0.2)	.175	.19
Phototherapy	94 (2.4)	50 (1.9)	.22	.31
Necrotizing enterocolitis requiring surgery	0	0	N/A	N/A
Neonatal death [†]	1 (0.3/1,000)	1 (0.4/1,000)	.76	.68
Composite	124 (3.1)	77 (3.0)	.70	.80

N/A, not applicable.

Data are mean±standard deviation, n (%), or n (/1,000) unless otherwise specified.

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^{*} Adjusted for age, race, parity, and body mass index.

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[†] Of the additional 287 women delivered elsewhere, all reported having a healthy neonate without any neonatal deaths. Adding these 287 women to the 3,949 women sent home provided neonatal follow-up for 95.1% of the women sent home undelivered.

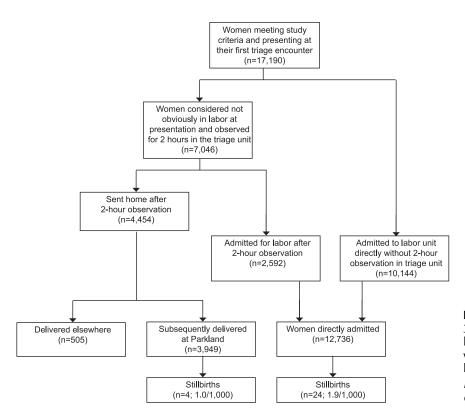


Fig. 3. Distribution of stillbirths of 3,949 women discharged with false labor compared with 12,736 women directly admitted to the labor unit.

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labor. Taken altogether, discharge with false labor at term after a standardized assessment in a triage unit was not associated with an increased rate of adverse perinatal outcomes.

Limited data are available regarding the natural history of false labor at term. The authors of two recent reports analyzed cervical dilatation and associated perinatal outcomes in women admitted at term in spontaneous labor.^{6,7} Wood et al⁶ in 2016 found that decreasing cervical dilatation at admission was a risk factor for cesarean delivery. Similarly, Kauffman and associates⁷ in a retrospective cohort study found that early admission-ie, less than 4 cm cervical dilatation-was a risk factor for increased medical intervention and cesarean delivery. Although the authors of both of these studies suggested that deferred delivery may be preferable, these studies were different from our study in which women with false labor were discharged undelivered.^{6,7} Put another way, we prospectively examined the maternal and neonatal consequences of deferring admission. We found that discharge from triage for false labor was without increased risk to the mother or her neonate when compared with other similar women admitted in spontaneous labor. Thus, health care providers and their patients can be reassured that being sent home after a brief

observation period—usually lasting less than 3 hours—is not associated with increased rates of adverse perinatal outcomes or cesarean delivery.

This study was powered to assess the effect of women presenting at term without pre-existing medical conditions and being sent home. Given the rarity of adverse perinatal outcomes in this cohort, a perinatal composite outcome was used. Our study was not powered for smaller but potentially meaningful differences in specific components of the composite or other perinatal outcomes. Our analysis centered on a comparison group of women admitted in spontaneous labor with cervical dilatation less than 4 cm at presentation but in whom labor was diagnosed after observation in the triage unit. We excluded women with mitigating factors such as advanced cervical dilatation and rupture of membranes in an effort to provide an equivalent comparison group.

Although this single-center report may not be generalizable to other populations, we believe that our findings support our health care system approach, which depends on use of written protocols by nurse practitioners and certified nurse-midwives in an inner-city hospital. Another caveat was that 505 women were seen in our triage unit and discharged with false labor but did not return to deliver at our hospital. For the current analysis, we examined only women delivered at our



hospital with complete maternal and neonatal data available for study; however, we were able to ascertain neonatal information in more than half of the 505 women through postpartum patient reporting and electronic medical record review. Importantly, we did not identify any increase in cesarean delivery or adverse perinatal outcomes in 287 women discharged and delivered elsewhere because they all had living, healthy neonates. That said, a limitation of our analysis was that 218 women-4.9% of the false labor cohort (and 1% of the total triage encounters)-were lost to follow-up. By incorporating a standardized process into our health care system, we demonstrated that diagnosing false labor at term and sending such women home were not associated with increased risk to the mother or her neonate.

The American College of Obstetricians and Gynecologists recently provided recommendations for hospital-based triage of obstetric patients.8 These recommendations highlighted the importance of established written guidelines and stressed coordination and communication between obstetric providers. The use of certified nurse-midwives and nurse practitioners to improve efficiency, reduce length of stay, and improve screening and evaluation was also emphasized.^{8,9} We believe our report illustrates the importance of these principles.

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