OBSTETRICS

Early vs expectant artificial rupture of membranes following Foley catheter ripening: a randomized controlled trial

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BACKGROUND: Early amniotomy shortens the duration of spontaneous labor, yet there is no clear evidence on the optimal timing of amniotomy following cervical ripening. There are limited high-quality studies on the use of early amniotomy intervention following labor induction.

OBJECTIVE: This study aimed to evaluate whether amniotomy within 1 hour of Foley catheter expulsion reduces the duration of labor among individuals undergoing combined misoprostol and Foley catheter labor induction at term.

STUDY DESIGN: This was a randomized clinical trial conducted from November 2020 to May 2021 comparing amniotomy within 1 hour of Foley catheter expulsion (early artificial rupture of membranes) with expectant management. Randomization was stratified by parity. Labor management was standardized among participants. Individuals undergoing induction at ≥37 weeks with a singleton gestation and needing cervical ripening were eligible. Our primary outcome was time to delivery. Wilcoxon rank sum, Pearson chi-square, and Cox survival analyses with intent-to-treat principles were performed adjusting for age, body mass index, parity, mode of delivery, Bishop score, and the interaction between randomization group and parity. A sample size of 160 was planned to detect a 4-hour reduction in delivery time.

RESULTS: A total of 160 patients (79 early artificial rupture of membranes, 81 expectant management) were randomized. Early artificial rupture of membranes achieved a faster median time to delivery than expectant management (early artificial rupture of membranes: 11.1 hours; interquartile range, 6.25–17.1 vs expectant management: 19.8 hours; interquartile range, 13.2–26.2; $P<.001$). A greater percentage of individuals in the early artificial rupture of membranes group delivered within 24 hours (86% vs 70%; $P=.03$). There was no difference in the cesarean delivery rate between the 2 groups (22% vs 31%; $P=.25$). Individuals delivered 2.3 times faster following early artificial rupture of membranes (hazard ratio, 2.3; 95% confidence interval, 1.5–3.4; $P<.001$). There were no significant differences in maternal and neonatal outcomes.

CONCLUSION: Amniotomy within 1 hour of Foley catheter expulsion resulted in 2.3 times faster delivery than expectant management. Therefore, early artificial rupture of membranes should be considered in individuals undergoing mechanical cervical ripening at term.

Key words: amniotomy, cervical Foley, labor induction, vaginal

Introduction

Nearly 30% of pregnant individuals undergo labor induction in the United States, and the rates continue to grow.[1] Although various studies have offered strategies to optimize labor management,[2–6] failed labor induction remains a significant risk factor for cesarean delivery.[7] Amniotomy is a widely used labor intervention that is safe, inexpensive, and effective. Early labor interventions reduce cesarean delivery rates in protracted spontaneous labor,[8–10] but the timing of amniotomy for labor induction warrants further investigation. Although some retrospective studies have shown an increased risk of cesarean delivery associated with early amniotomy,[11,12] several prospective trials have demonstrated that early rupture is a safe and efficient method for speeding up delivery times without increasing cesarean rates during labor.[13–15]

Furthermore, theoretical concerns of umbilical cord prolapse, intraamniotic infection, and neonatal morbidity have limited the use of amniotomy despite lacking evidence.

Thus, the objective of this study was to evaluate whether amniotomy within 1 hour of Foley catheter expulsion reduces the time to delivery among individuals undergoing labor induction at term.

Materials and Methods

This trial was a randomized study conducted from November 2020 to May 2021 at a single tertiary care teaching hospital in Newark, Delaware. Before initiation of the study, approval was obtained from a convened institutional review board (CC# 40089) at our institution and registered with ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT04496908). The first participant was enrolled on November 11, 2020 and the final participant on May 22, 2021. This study was a randomized controlled trial of inpatient individuals on labor and delivery undergoing cervical ripening with misoprostol in combination with a Foley catheter at term. No external funding was used for this study.

A data safety monitoring board was established to independently evaluate the safety of the study. An interim safety assessment was performed for predefined adverse outcomes with recommendations to continue the study without changes.

Cite this article as: Gomez Slagle HB, Fonge YN, Caplan R, et al. Early vs expectant artificial rupture of membranes following Foley catheter ripening: a randomized controlled trial. Am J Obstet Gynecol 2022;226:724.e1-9.

0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2021.11.1368

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AJOG at a Glance

Why was this study conducted?

Amniotomy is commonly used for labor induction but the optimal timing of amniotomy for term induction warrants further investigation.

Key findings

Individuals undergoing amniotomy within 1 hour of Foley catheter expulsion had faster time to delivery by any mode and shorter time to vaginal delivery and active labor compared with expectant amniotomy.

What does this add to what is known?

Early amniotomy following Foley catheter induction leads to shorter labor duration following labor induction at term.

Participants

Individuals who presented to labor and delivery requiring cervical ripening were eligible for the trial. Individuals aged ≥18 undergoing term induction of labor at ≥37 0/7 weeks' gestation with a cephalic singleton pregnancy and undergoing combination Foley catheter and misoprostol induction were eligible for inclusion. Patients were enrolled and randomized if amniotomy was considered safe at the time of Foley catheter expulsion.

Individuals were excluded if they had a known previous uterine scar, fetal demise, known major fetal congenital anomaly, HIV infection, or hepatitis C before the start of labor induction. Additional exclusion criteria were: category 3 fetal heart rate tracing; hemolysis, elevated liver enzymes, and low platelets syndrome or eclampsia; growth restriction <10th percentile (based on Hadlock growth curves) with reversal of flow in umbilical artery Doppler studies; or growth restriction <5th percentile with elevated, absent, or reverse flow in umbilical artery Doppler studies. Participants were included in the study only once and none had received an induction agent before the study in their current pregnancy. Gestational age was determined using routine obstetrical guidance.[16]

Study procedures

All individuals in this trial underwent combination Foley catheter and misoprostol induction of labor. A Foley catheter was placed above the level of the internal os and inflated with 30 cc of sterile water.[17] Catheters were taped to the inner thigh with gentle traction and deflated and removed after 12 hours if still in place. In addition, 1 misoprostol tablet of 25-μg was placed high into the posterior vaginal fornix at the time of Foley catheter placement. Subsequent doses, if used, were repeated every 3 hours up to 5 additional doses or a maximum of 24 hours.[2] Oxytocin was initiated if there was a contraindication to another misoprostol dose or following Foley catheter expulsion. Our hospital protocol begins with 2 milliunits (mU) per minute of oxytocin increasing by 2 mU every 30 minutes until regular uterine contractions occur. The maximum dosage is considered to be 30 mU of oxytocin, with no limit on the length of time a participant can remain at 30 mU.[18]

Within an hour of Foley catheter expulsion, a cervical examination was performed. If amniotomy was deemed safe, informed consent was obtained and individuals were randomized to either immediate or expectant amniotomy. All individuals provided written informed consent. If patients were randomized to early amniotomy, a cervical exam was immediately repeated and membrane rupture was performed. If patients were randomized to expectant management, the cervical exam was repeated. In the expectant group, a team that included residents, midwives, and attendants made decisions about the exact timing of amniotomy. No prescriptive instructions were given for patients randomized to the expectant-management group. At our institution, cervical exams are performed every 4 hours in latent labor. Therefore, the earliest that a participant in the expectant-management group was ruptured was 4 hours from Foley catheter expulsion.

Labor interventions including amnioinfusion, fetal scalp electrodes, tocolysis, and management of the second stage (including operative delivery) were at the discretion of the managing providers. All patients had continuous fetal monitoring throughout induction, labor, and delivery. Cervical examinations were performed approximately every 4 hours in latent labor and every 2 hours in active labor. Cesarean delivery was at the discretion of the provider.

Randomization

Providers were notified within 1 hour of Foley catheter expulsion and a cervical exam was performed. If the obstetrical provider determined that amniotomy could be performed safely, participants were consented and randomized to 1 of 2 treatment groups at bedside. Computer-generated, stratified randomization with blocks of size 6 was used with 1:1 assignment to treatment group.[19] Study personnel were unaware of the randomization block sizes. Randomization was stratified by parity of 0 or parity ≥1. Neither the patients nor the providers were blinded to the assigned treatment group because this would not have been practical.

Outcome assessment

The primary efficacy outcome measure was time to delivery (hours) defined as the time from Foley catheter expulsion to delivery, regardless of mode of delivery. Secondary outcome measures included: cesarean delivery rate, time to vaginal delivery (hours), time to active labor (defined as dilatation ≥6 cm), delivery within 12 and 24 hours, maternal length of stay (defined as length of time from admission for induction to discharge postpartum in days), and indication for cesarean delivery. The analyzed maternal secondary outcomes included third/fourth degree perineal

laceration, blood transfusion, endometritis, wound separation—infection (defined by the need for additional wound closure or antibiotics), venous thromboembolism, hysterectomy, intensive care unit admission, or death. The analyzed labor secondary outcomes were intraamniotic infection (defined by the presence of maternal fever ≥100.4°F with maternal or fetal tachycardia or fundal tenderness), cord prolapse, use of terbutaline, placement of intrauterine pressure catheter, amnioinfusion, or epidural use.

Neonatal morbidity outcomes included severe respiratory distress syndrome (defined as intubation and mechanical ventilation for a minimum of 12 hours), culture proven—presumed neonatal sepsis, neonatal blood transfusion, hypoxic ischemic encephalopathy, intraventricular hemorrhage grade 3 or 4, necrotizing enterocolitis, or receipt of head cooling. Other analyzed neonatal outcomes were neonatal intensive care unit (NICU) admission, NICU admission >48 hours, and neonatal length of stay (days).

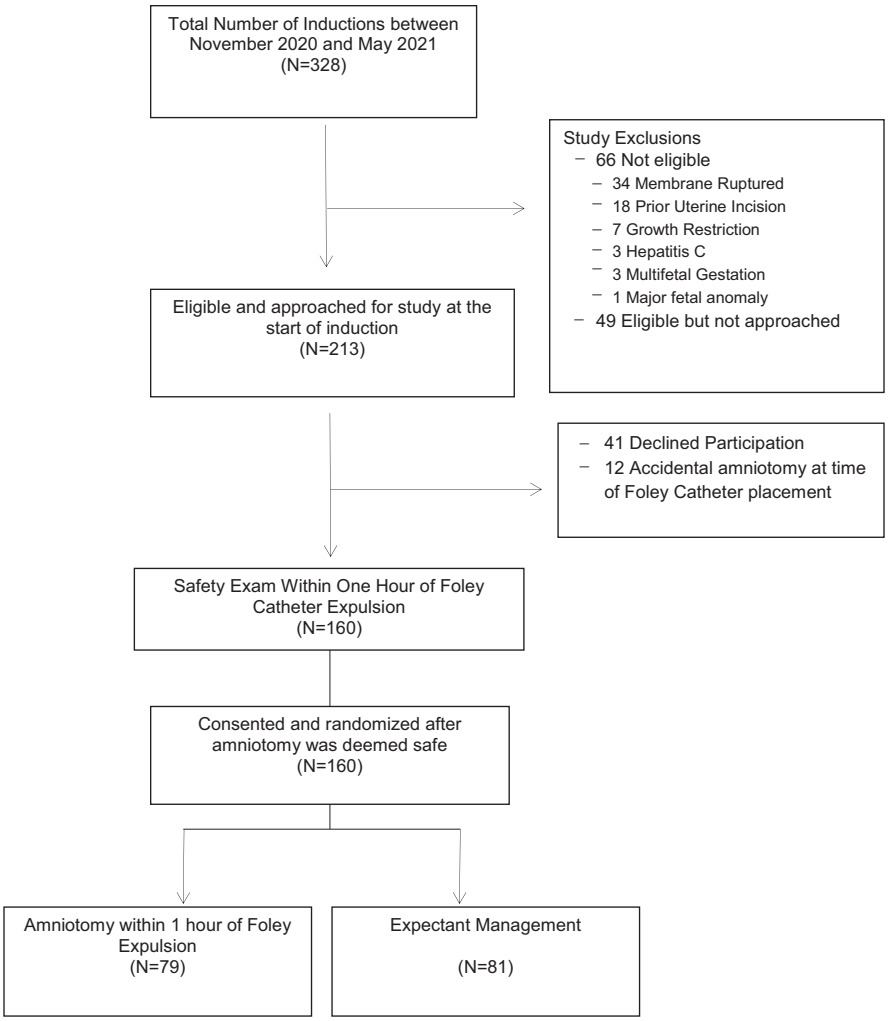
Trained research staff, uninvolved with the clinical care, collected all induction, labor, and delivery information, maternal demographics, and maternal and neonatal outcomes.

Statistical analysis and sample size calculations

A 4-hour reduction in time to delivery was considered clinically meaningful.[2] The mean time to delivery for patients undergoing combination pharmacologic and mechanical induction of labor is 18 hours±8.5.[2,17] Assuming 80% power, equal group sizes, and a 2-sided *P* value, we assumed 71 patients in each group for a total sample size of 142. We used a type-I alpha error rate of 0.05. A final sample size of 160 was estimated assuming a crossover—dropout rate of 10%.

Descriptive statistics are reported by randomization group. Statistical analyses were performed using an intention-to-treat principle. Univariate analyses were carried out using the Wilcoxon rank sum test for continuous variables, and the Pearson chi-square or Fisher exact test for categorical variables, as appropriate. Delivery results are presented by parity. Time-to-event regression analysis for labor length was modeled with a Cox proportional hazards model, adjusting for maternal age, body mass index (BMI), parity, mode of delivery, Bishop score, and the interaction between randomization group and parity. Hazard ratios (HR) with a 95% confidence interval (CI) are reported. Tests for interaction between assigned randomization group and parity were done using Cox regression for time-to-event outcomes and logistic regression for binary outcomes. Aalen-Johanssen estimators of the probabilities of delivery by group are graphed for vaginal and cesarean deliveries. Statistical significance for the primary outcome was set at $P<.05$ without adjustment for multiple comparisons. All analyses were based on assigned group and completed with R statistical software (version 4.02; R Foundation for Statistical Computing, Vienna, Austria).

FIGURE 1
CONSORT diagram



The total number of individuals identified, excluded, and included in the final study population is presented. *Downward pointing arrows* indicate next filter, and *arrows pointing to the right* indicate those who were excluded.

CONSORT, Consolidated Standards of Reporting Trials.

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TABLE 1
Maternal and labor characteristics by randomized treatment group

Characteristics	Early amniotomy (n=79)	Expectant amniotomy (n=81)
Maternal age (y), median, IQR	29.0 (25.0–31.0)	30.0 (26.0–32.0)
Nulliparous, n (%)	49 (62.0)	51 (63.0)
Race, n (%)		
White	31 (39.2)	32 (39.5)
Hispanic	10 (12.7)	9 (11.1)
Black	33 (41.8)	33 (40.7)
Asian	5 (6.33)	7 (8.64)
Public insurance, n (%)	39 (49.4)	40 (49.4)
Maternal BMI (kg/m^2), median (IQR)	32.8 (29.3–37.2)	32.9 (30.4–36.4)
Gestational age at induction (wk), median (IQR)	39.1 (38.2–40.0)	39.0 (38.0–39.4)
Indication for induction, n (%)		
Late term or post term[a]	14 (17.7)	12 (14.8)
Maternal[b]	35 (44.3)	37 (45.7)
Fetal[c]	5 (6.33)	3 (3.70)
39 wk induction	25 (31.6)	28 (34.6)
Other[d]	0 (0.00)	1 (1.23)
Bishop score at randomization, median (IQR)	2.00 (2.00–2.00)	2.00 (2.00–2.00)
Dilation at randomization, median (IQR)	1.50 (1.00–2.00)	1.50 (1.00–2.00)
Dilation at amniotomy, median (IQR)[e]	3.00 (3.00–4.00)	5.00 (4.00–6.50)
Maternal comorbidity, n (%)		
Gestational diabetes	10 (12.7)	12 (14.8)
Pregestational	1 (1.27)	2 (2.47)
Chronic hypertension	5 (6.33)	6 (7.41)
GHTN	14 (17.7)	12 (14.8)
Preeclampsia without severe features	3 (3.80)	4 (4.94)
Preeclampsia with severe features	2 (2.53)	2 (2.47)
History of other medical morbidity	2 (2.53)	3 (3.70)
Tobacco use in pregnancy, n (%)	13 (16.5)	14 (17.3)

BMI, body mass index; *GHTN*, gestational hypertension; *IQR*, interquartile range.

[a] Defined as ≥41 weeks; [b] Examples include: chronic hypertension, gestational hypertension, preeclampsia, diabetes, renal disease, history of venous thromboembolism, cardiac disease, or other chronic medical condition where induction was recommended; [c] Examples include: Oligohydramnios, intrauterine growth restriction, abnormality on fetal testing; [d] Examples of "other" include: history of an intrauterine fetal demise, vaginal bleeding at term, or cholestasis; [e] $P<.001$.

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Results

Participant characteristics

There were 328 inductions of labor during the study period from November 2020 to May 2021, 66 of which were not eligible for recruitment and 49 were not approached. Of the 213 women who met eligibility criteria and were approached for participation, 41 declined involvement, whereas 12 patients had accidental amniotomy at the time of Foley catheter placement. A safety exam was performed within 1 hour of Foley catheter expulsion for all eligible participants, and 160 patients were consented and randomized into the 2 treatment groups (Figure 1).

Maternal demographic characteristics by treatment group are provided in Table 1. Overall, randomization achieved balanced groups. There were no demographic differences between the groups. A total of 63% of the participants were nulliparous. Individuals who identified as Black comprised 41% of the cohort. Forty-nine percent of participants had public insurance. The median gestational age of both groups was just over 39 weeks of gestation. The most common

TABLE 2
Time to delivery outcomes among treatment groups

Delivery outcomes	Early amniotomy (n=79)	Expectant amniotomy (n=81)	Group comparison *P* value	Interaction *P* value
Time to delivery (h)	11.1 (6.25–17.1)	19.8 (13.2–26.2)	<.001	.005
Nulliparous	13.2 (10.2–21.8)	20.8 (16.9–27.4)	<.001	
Multiparous	6.35 (4.45–10.9)	15.5 (9.88–20.4)	<.001	
Time to vaginal delivery (h)	10.1 (5.14–13.1)	17.2 (11.3–20.6)	<.001	.006
Nulliparous	11.3 (8.05–16.9)	19.1 (13.9–20.7)	<.001	
Multiparous	6.35 (4.47–10.5)	14.1 (9.82–18.6)	<.001	
Time to active labor (h)	6.71 (4.06–9.15)	14.2 (10.2–17.7)	<.001	<.001
Nulliparous	8.03 (5.21–12.0)	14.8 (12.1–17.5)	<.001	
Multiparous	5.02 (2.43–7.23)	13.0 (9.18–17.6)	<.001	
Delivery within 24 h, n (%)	68 (86.1)	57 (70.4)	.03	.99
Nulliparous	38 (77.6)	33 (64.7)	.2	
Multiparous	30 (100)	24 (80.0)	.02	
Delivery within 12 h, n (%)	47 (59.5)	18 (22.2)	<.001	.51
Nulliparous	21 (42.9)	6 (11.8)	.001	
Multiparous	26 (86.7)	12 (40.0)	<.001	
Cesarean delivery, n (%)	17 (21.5)	25 (30.9)	.25	.76
Nulliparous	15 (30.6)	21 (41.2)	.4	
Multiparous	2 (6.67)	4 (13.3)	.7	

Data are presented as median hours (interquartile range), unless otherwise indicated. Categorical variables were compared with chi-square or Fisher exact tests and continuous variables were compared with Wilcoxon rank sum tests.

Interaction *P* values are reported from Cox regression including interaction between group and parity for time to event outcomes and from logistic regression for binary outcomes.

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indications for induction were maternal (45%) and 39-week (33%) inductions. Bishop score and dilation at randomization were similar between the 2 groups. The median time from Foley expulsion to amniotomy in the expectant-management group was 10 hours (10.0 hours; interquartile range [IQR], 6.9–13.7). Amniotomy was performed within 1 hour of Foley expulsion in the early-amniotomy group per study protocol (0.37 hours; IQR, 0.0–0.0).

Primary outcomes

A total of 173 individuals (73.8%) had a successful induction and delivered vaginally (Table 2). The primary outcome of time to delivery by any mode from expulsion of Foley catheter was significantly shorter for individuals undergoing amniotomy within 1 hour of Foley catheter expulsion than for those in the expectant-management group (median [IQR], early: 11.1 hours [6.25–17.1] vs expectant: 19.8 hours [13.2–26.2]; $P<.001$) (Table 2, Figure 2). Time to vaginal delivery was significantly shorter in the early amniotomy than in the expectant-management group (median [IQR], early: 10.1 hours [5.14–13.1] vs expectant: 17.2 hours [11.3–20.6]; $P<.001$). This trend was observed both in nulliparous and multiparous individuals. We graphed the probability of delivery by mode and randomization group. Early amniotomy was associated with faster time to delivery among patients who had a vaginal delivery (Figure 2).

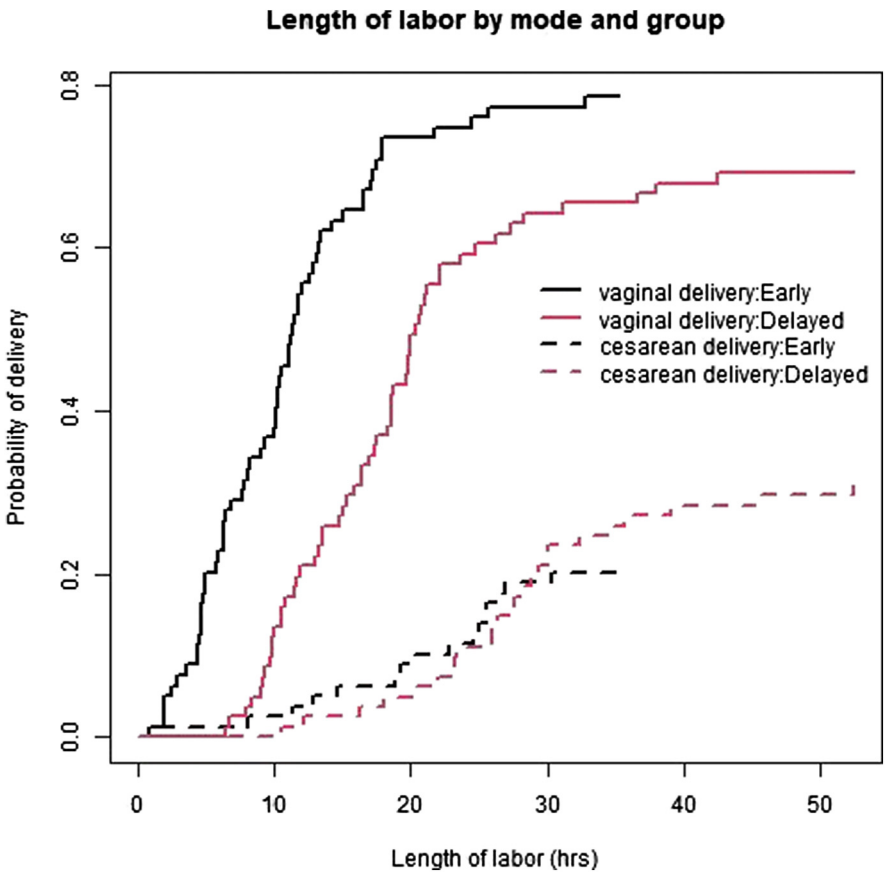
Cox proportional hazards model was used to compare time to delivery between early and expectant amniotomy. Individuals undergoing amniotomy within 1 hour of Foley catheter expulsion had a shorter time to delivery using unadjusted Cox proportional hazards model (HR, 2.3; 95% CI, 1.7–3.2; $P<.001$). Early amniotomy was associated with shorter time to delivery after adjusting for maternal age, BMI, parity, mode of delivery, Bishop score, and the interaction between randomization group and parity (HR, 2.3; 95% CI, 1.5–3.4; $P<.001$).

Secondary outcomes

There was no statistical difference in the rate of intraamniotic infection between the 2 groups (n [%], early: 5 [6.33%] vs expectant: 5 [6.17%]; $P=1.0$). There was 1 case of cord prolapse in each group (n [%], early: 1 [1.27%] vs expectant: 1 [1.23%]; $P=1.0$).

Time to active labor was significantly shorter for patients undergoing

FIGURE 2
Probability of vaginal and cesarean delivery by timing of amniotomy



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amniotomy within 1 hour of Foley catheter expulsion (median [IQR], early: 6.71 [4.06−9.15] vs expectant: 14.2 [10.2−17.7]; $P<.001$). The rate of delivery within 24 hours from start of induction was significantly higher in the early-amniotomy group (n [%]; 68 [86.1%] vs expectant: 57 [70.4%]; $P=.03$). Similarly, the rate of delivery within 12 hours was significantly higher in the early-amniotomy group (47 [59.5.8%] vs 18 [22.2%]; $P<.001$).

There was no statistical difference in the cesarean delivery rate between the 2 groups, (17 [21.5%] vs 25 [30.9%]; $P=.25$). The cesarean delivery rates were not statistically different for both nulliparous and multiparous individuals in the study. There were no significant differences in indications for cesarean delivery, endometritis, use of terbutaline, placement of intrauterine pressure catheter, amnioinfusion, or epidural use (Table 3).

There were no differences in neonatal outcomes including severe respiratory distress syndrome, Apgar scores, or NICU admission. There were no cases of neonatal blood transfusion, hypoxic ischemic encephalopathy, intraventricular hemorrhage grade 3 or 4, necrotizing enterocolitis, or head cooling in either group (Table 3).

Comment

Principal findings

In this trial, individuals who underwent early amniotomy within 1 hour of Foley catheter expulsion were likely to deliver more rapidly, deliver vaginally within 12 hours, and achieve active labor faster than individuals in the expectant-management group. There were no differences in cesarean delivery rate or other adverse safety events.

Results in context

Although several studies have cautioned against the use of early amniotomy and reported an increased risk of cesarean delivery,[11,12] multiple randomized controlled trials have shown lower rates of labor dystocia and cesarean delivery associated with early rupture.[13−15] Additional investigation is warranted given that current published literature shows conflicting results. Levy et al[20] randomized patients who underwent mechanical ripening at ≥37 weeks of gestation and either immediate amniotomy at the time of Foley catheter expulsion or delayed amniotomy when regular contractions or cervical change was achieved. This trial found that patients undergoing immediate amniotomy had higher rates of cesarean delivery and concluded that amniotomy should be postponed in patients undergoing cervical ripening. However, this trial reported an institutional cesarean delivery rate of 8% to 9%,[20] which is significantly lower than that found in our own practice. Furthermore, Levy et al[20] excluded patients after randomization if amniotomy was deemed unsafe, which may have contributed to selection bias favoring delayed amniotomy. This is in contrast to the trial by Macones et al,[21] which found that early amniotomy shortens the time to delivery by over 2 hours without increasing maternal or neonatal morbidity. This trial used a cervical dilation cutoff of ≤4 cm to differentiate early amniotomy from standard management, which can be highly dependent on the individual examiner. Furthermore, Macones et al[21] included a diverse range of both single and combination pharmacologic and mechanical induction methods with varying effectiveness.[2] This study used a uniform combination of pharmacologic cervical ripening with Foley catheter placement for all enrolled patients.

Clinical implications

We have found that amniotomy within 1 hour of Foley catheter expulsion reduces the time to delivery by nearly 9 hours

TABLE 3
Secondary outcomes by treatment groups

Outcomes	Early amniotomy (n=79)	Expectant amniotomy (n=81)	*P* value
Maternal outcomes			
Indication for cesarean delivery			.8
Failed IOL	8 (47.1)	11 (44.0)	
NRFHT	2 (11.8)	3 (12.0)	
Dilation arrest	4 (23.5)	4 (16.0)	
Descent arrest	1 (5.88)	4 (16.0)	
Elective or other	1 (5.88)	0 (0.00)	
Intrauterine pressure catheter	6 (7.59)	4 (4.94)	.5
Oxytocin used in active labor	74 (93.7)	80 (98.8)	.1
Amnioinfusion	5 (6.33)	4 (4.94)	.7
Epidural use	75 (94.9)	79 (97.5)	.4
Umbilical cord prolapse	1 (1.27)	1 (1.23)	1.0
IV narcotics	1 (1.27)	3 (3.70)	.6
Terbutaline used	0 (0.00)	1 (1.23)	1.0
Chorioamnionitis	5 (6.33)	5 (6.17)	1.0
Endometritis	1 (1.27)	5 (6.17)	.2
Third or fourth degree laceration	2 (2.53)	6 (7.41)	.3
Blood transfusion	1 (1.27)	4 (4.94)	.4
Operative delivery	2 (2.53)	3 (3.70)	1.0
Postpartum hemorrhage	6 (7.59)	9 (11.1)	.6
Wound separation or infection	0 (0.0)	0 (0.0)	1.0
Total length of stay	3.00 (2.00–3.00)	3.00 (3.00–4.00)	<.001
Venous thromboembolism	0 (0.0)	0 (0.0)	1.0
Hysterectomy	0 (0.00)	1 (1.23)	1.0
Maternal death	0 (0.0)	0 (0.0)	1.0
Neonatal outcomes			
Birthweight (kg) median (IQR)	3.21 (2.95–3.54)	3.37 (3.13–3.59)	.05
Apgar at 5 min, median (IQR)	9.00 (9.00–9.00)	9.00 (9.00–9.00)	.8
NICU admission	7 (8.86)	11 (13.6)	.5
>48 h	6 (7.59)	8 (9.88)	.8
Severe respiratory distress syndrome[a]	5 (6.33)	9 (11.1)	.4
Culture proven–presumed neonatal sepsis	3 (3.80)	5 (6.17)	.7
Neonatal blood transfusion	0 (0.00)	0 (0.00)	—
Hypoxic ischemic encephalopathy	0 (0.00)	0 (0.00)	—
Intraventricular hemorrhage grade 3 or 4	0 (0.00)	0 (0.00)	—
Necrotizing enterocolitis	0 (0.00)	0 (0.00)	—
Receipt of head cooling	0 (0.00)	0 (0.00)	—

Data are presented as number (percentage) unless otherwise indicated. Categorical variables are compared with chi-square and Fisher exact tests and continuous variables are compared with Wilcoxon rank sum tests unless otherwise indicated.

IOL, induction of labor; *IQR*, interquartile range; *IV*, intravenous; *NICU*, neonatal intensive care unit; *NRFHT*, nonreassuring fetal heart tracing.

[a] Defined as intubation and mechanical ventilation for a minimum of 12 hours.

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than in expectant management. A reduction in time to delivery was true for both multiparous and nulliparous individuals in our study. As labor induction rates continue to rise, labor and delivery units across the nation are strategizing ways to optimize the process. Exploring the optimal methods to achieve vaginal delivery is important because the length of labor is correlated directly with maternal chorioamnionitis and neonatal infection.[22,23] In addition, we propose that an average 9-hour difference in labor length has important ramifications for resource utilization and staffing.

Research implications

The effectiveness of early amniotomy has been described in spontaneous-labor and several retrospective studies,[10,13,24–26] but the use of early amniotomy following cervical ripening warrants further investigation. Furthermore, the optimal exam frequency and oxytocin protocol during labor induction has not been established.[5,27] Additional investigation is needed to comment on the association between cesarean delivery and early amniotomy for labor induction, given that our current study was not powered to detect a difference. Future research for guiding clinicians on best practices is warranted. In addition, further studies on patient preferences and satisfaction levels regarding their experience with induction of labor are needed.

Strengths and limitations

A major strength of our trial was that it randomized participants, which reduced bias in comparison with previous trials. We used 1 uniform induction method with combination misoprostol and Foley catheter and a clear definition of early amniotomy. Another major strength of our study was making amniotomy safety a necessary inclusion criterion for enrollment and randomization, which minimized treatment-crossover rate. To our knowledge, this is one of the few trials comparing early amniotomy to expectant management following misoprostol combined with Foley catheter induction at term. Our randomization was also stratified by parity, which is another strength of the study. Lastly, our pragmatic trial design of expectant amniotomy should enhance the generalizability of our study. A weakness of our study is that neither the patients nor the providers were blinded to the allocation group, which could potentially result in unbalanced distribution of interventions from obstetrical providers. Given that time to delivery is an objective measure, we do not believe that the lack of blinding differentially affected our primary outcome. Furthermore, we are reassured that the rate of interventions like amnioinfusion and epidural use were similar between the 2 groups. This was also a single-center study, and thus the results may not be generalizable to other centers with different labor management practices and/or labor outcomes.

Conclusion

We found that amniotomy within 1 hour of Foley catheter expulsion was superior to expectant management with regard to labor duration. Early amniotomy achieved shorter time to delivery by any mode and shorter time to vaginal delivery and active labor among nulliparous and multiparous individuals at term. Early amniotomy resulted in 2.3 times faster delivery than with expectant management, with no difference in cesarean delivery rates, labor characteristics, or maternal or neonatal morbidity. Therefore, amniotomy within 1 hour of Foley catheter expulsion may be considered among individuals undergoing a combined pharmacologic and mechanical induction at term. ■

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Received Oct. 18, 2021; revised Nov. 19, 2021; accepted Nov. 23, 2021.

The authors report no conflict of interest.

The authors report no funding source for this study.

Clinical Trial Registration:
1) Date of registration: August 4, 2020
2) Date of initial participant enrollment: November 11, 2020
3) Clinical trial identification number: NCT04496908
4) URL of the registration site: https://clinicaltrials.gov/ct2/show/NCT04496908

Data sharing information
1. Will individual participant data be available (including data dictionaries)? Yes
2. What data in particular will be shared? Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).
3. What other documents will be available (eg, study protocol, statistical analysis plan, etc.)? Study Protocol, Statistical Analysis Plan, Informed Consent Form
4. When will data be available (start and end dates)? Beginning 3 months and ending 5 years following article publication.
5. How will data be shared (including with whom, for what types of analyses, and by what mechanism)? Researchers who provide a methodologically sound proposal will be given access to the data to achieve aims in the proposal. Proposals should be directed to Helen.gomez@christianacre.org. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (link to be included).

This study will be presented as an oral presentation at the 42nd annual meeting of the Society for Maternal-Fetal Medicine, Kissimmee, FL, January 31—February 5, 2022.

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