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ORIGINAL ARTICLE

Labor induction utilizing the foley balloon: a randomized trial comparing standard placement versus immediate removal

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OBJECTIVE: To compare time to delivery between two induction procedures. The Foley balloon is a mechanical method for cervical ripening. However, the device may also result in endogenous prostaglandin release following separation of the chorionic membrane and decidua. Prolonged Foley placement may therefore be unnecessary for successful labor induction.
METHOD: Randomized controlled trial of labor induction at LAC+USC Medical Center between 2010 and 2013. Subjects were assigned to either (a) standard placement of the Foley balloon or (b) Foley balloon insufflation and immediate removal. Oxytocin was administered to all subjects not in active labor after 12 h. Delivery information and neonatal outcomes were documented and all patients were followed for 6 weeks for adverse events.
RESULT: A total of 79 women were included in the analysis (37 standard and 42 immediate). Induction time was 8.6 h longer in the immediate removal group (23.5 vs 32.1, $P=0.002$), but the difference in delivery within 24 h did not meet the statistical significance (46.0 vs 28.6%, $P=0.11$). Similar rates of cesarean delivery, epidural use and abnormal APGAR scores were observed. After controlling for number of vaginal exams and duration of rupture, a decreased risk of infection was observed in the immediate removal group (odds ratio = 0.08, 95% confidence interval = 0.007 to 0.93, $P=0.04$). Further, when the analysis was stratified by parity, differences in induction time only persisted in nulliparous women.
CONCLUSION: Immediate removal of the Foley balloon may lead to longer overall induction time, but a lower risk of infection. Parous women may be particularly good candidates for this type of induction.

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INTRODUCTION

Labor induction is initiated when the risks of continuing a pregnancy are thought to outweigh the risks associated with the continuation of pregnancy. Rates of labor induction are increasing, up from 9.5% in 1990 to 23.2% in 2011.[1] Cesarean delivery rates also increased during that time. Foley balloon induction is considered safe and effective, and results in lower rates of uterine tachysystole compared with the other available methods.[2]

The transcervical Foley balloon is categorized as a mechanical method for cervical ripening, in contrast to Cervidil (dinoprostone) and misoprostol, which are exogenous synthetic prostaglandin analogs. In addition to the mechanical dilation, which is thought to occur following Foley balloon placement, there are data to suggest that the resulting separation of the decidua from the chorioamniotic membrane leads to the release of endogenous prostaglandins. This was demonstrated in a prospective trial whereby amniotic prostaglandin levels were noted to significantly increase following Foley insufflation.[3]

We hypothesize that cervical ripening with the Foley balloon is initiated with the insertion and insufflation of the Foley balloon. If this is the case, we believe immediate removal compared with prolonged placement of the Foley balloon will result in similar vaginal birth rates without increasing total induction time. Our study aims to compare the efficacy and safety of the Foley balloon when removed immediately to the Foley placed in a standard prolonged fashion.

METHODS

This was a randomized controlled prospective trial comparing standard placement of the transcervical Foley balloon to immediate removal. Approval was granted by the University of Southern California Health Sciences Institutional Review Board, and informed consent was obtained on all subjects. The informed consent discussion was conducted by an approved physician member of the research team. Pregnancies with a viable, singleton, cephalic fetus $\geqslant 34$ weeks of gestation and cervical dilation of $\leqslant 2$ cm requiring labor induction were eligible for inclusion. Exclusion criteria included prior attempt at labor induction in the current pregnancy, contraindication to vaginal delivery, latex allergy, prior uterine incision, suspected acute fatty liver of pregnancy or HELLP syndrome, known fetal anomaly, estimated fetal weight $\geqslant 4000$ g, chorioamnionitis, placenta previa, ruptured membranes or active HIV or hepatitis infection. Patients diagnosed with labor (either preterm or term) were also excluded.

Participants were randomized via computerized random number generator in a 1:1 allocation ratio and group assignments were placed inside sequentially numbered, sealed and opaque envelopes. Due to the nature of the treatments under investigation, traditional blinding was not possible for the patient or their obstetric care team. However, the data analyst was blind to the treatment group during monitoring and analysis.

An 18 French Foley catheter was placed transcervically under direct visualization after the participant's cervix was prepped with Betadine. The balloon was subsequently insufflated with 30 ml of sterile saline. For the experimental group (hereafter referred to as the immediate removal group), the Foley balloon was deflated after 1 min and removed. No further intervention was enacted on this experimental group until they reached active labor or 12 h passed, whichever occurred first. For the control group (hereafter referred to as the standard placement group), the Foley balloon

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was left within the cervix. According to standard institutional practice, the Foley balloon was removed after spontaneous expulsion, when failed induction of labor was diagnosed or spontaneous membrane rupture occurred. Also according to institutional practice, the Foley balloon was usually placed to traction if the patient was allocated to standard placement. If the Foley ballon could not be placed, then the patient continued to be on the study in their previously designated study group utilizing an intention to treat model.

Following initial Foley placement, all patients remained on labor and delivery with continuous fetal monitoring. In no other way did labor management differ systematically between groups. Oxytocin was only started in patients who had not yet reached active labor after 12 h. Active labor was defined as 4 cm dilation with regular uterine contractions. Frequency of cervical exams, amniotomy with placement of intrauterine pressure/fetal scalp electrode and initiation of oxytocin (after 12 h) were performed according to the standard local practice for labor induction. Also in accordance with institutional practice at the time, multiparas and primiparas were given 20 h of maximum oxytocin ($22\,mU\,min^{-1}$) to achieve active labor before a failed induction was diagnosed. Intravenous or regional anesthesia was made available during the labor and delivery process at patient request.

Participant data including patient demographics, indication for induction and initial cervical exam/Bishop score were recorded by the enrolling physician. The remainder of data, including labor course and adverse maternal and neonatal outcomes, was collected retrospectively using detailed chart review by the principal investigators. The primary outcome was defined as percentage of patients delivering within 24 h of transcervical Foley placement. Secondary outcomes included cesarean delivery rate, as well as both obstetrical and neonatal outcomes.

Despite our hypothesis that both induction methods would yield comparable induction times, we wanted to make sure that we would be able to detect any clinically relevant between-group differences in our primary outcome. Given the dearth of prior research, we made several assumptions in order to calculate our sample size. First, previous studies have examined the primary outcome and have demonstrated rates of delivery within 24 h at 55 to 60%.[4,5] There are no reliable data comparing delivery rates within 24 h between Foley induction and oxytocin induction.[6] However, there are data to show that the rate of delivery within 24 h does not differ between intracervical prostaglandins versus Foley induction.[7] Therefore, intracervical prostaglandin induction was used as a proxy for Foley induction to calculate the sample size. When comparing oxytocin to intracervical prostaglandins labor induction, there is a 1.49 relative risk for unsuccessful delivery within 24 h.[8] In order to detect a similar effect size, specifically a 20% decrease in delivery with 24 h, both groups required 76 participants at a *P*-value of 0.05 with 80% power to detect this difference. Due to the short time course and inpatient status of our participants, loss to follow-up was not expected to significantly impact the study. Recruitment goals were therefore set at 80 participants per group with a total of 160 patients to be enrolled. Early stopping criteria were established in an open session involving investigators, statistician and an independent Data Safety Monitoring Committee. Criteria included demonstration that the intervention is either clearly harmful, clearly beneficial or no additional information is likely to be gained by continuing the trial. These determinations were made based on the monitoring of time to delivery as well as occurrence of adverse events. After the single planned interim analysis, using O'Brien-Fleming group sequential methods and an effect size of ± 2.38 ($P < 0.017$), it was determined that criterion for early stopping was met. We therefore conducted our complete analysis using the standard significance threshold of $P < 0.05$.

Sample characteristics were computed for the total sample and described using number (%) for categorical variables, mean and s.d. for continuous variables, and median and range for ordinal variables and non-normally distributed continuous variables. For each participant, total induction time was calculated based on the interval between the date and time of induction initiation and the date and time of delivery. If this interval was $\leqslant 24$ h, the participant was counted as having delivered within 24 h. If this interval was $\leqslant 48$ h, the participant was counted as having delivered within 48 h. If a participant reported no previous live births, the participant was counted as being nulliparous. Duration of rupture was calculated based on the interval between the date and the time of spontaneous or artificial rupture and the date and time of delivery. If the interval exceeded 18 h, the participant was considered to have prolonged rupture of membranes. For the purposes of this protocol, infection was defined as maternal fever with one or more clinical criteria (maternal or fetal tachycardia, fundal tenderness, abnormal discharge or leukocytosis) and failed induction of labor was diagnoses after 20 h of maximum oxytocin ($22\,mU\,min^{-1}$) failed to result in cervical dilation exceeding 4 cm.

Categorical variables were compared between treatment groups using Pearson's χ^2 or Fisher's exact test when expected frequencies were very small. Numeric variables were compared using independent *t*-tests with or without equal variance and/or non-parametric Mann–Whitney's *U*-tests if normality assumptions were violated. Kaplan–Meier curves and log-rank tests for equality of survivor functions were used to test for between-group differences in time to delivery. Time to event analyses stratified by parity were planned *a priori*.

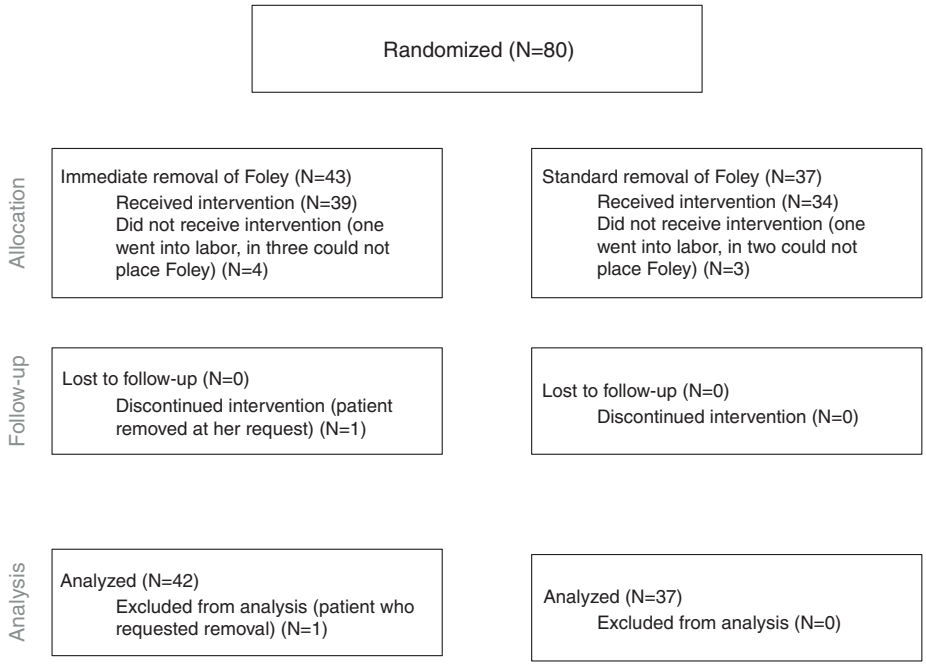

Figure 1. Flowchart of patients randomized to standard and immediate removal.

After looking at frequency distributions of infection rates, multivariate exploratory analyses were conducted including number of vaginal exams, duration of rupture, history of diabetes, amniotomy, body mass index and initial dilation as potential covariates. The model was first run with only treatment group as a predictor and then models adjusting for covariates were run to obtain the adjusted effects (odds ratio or Cohen's d effect size) on infection. Variables were included in the model if beta estimates changed by $>10\%$ after inclusion.

All analyses were performed using STATA (v.13. College Station, TX: StataCorp LP).

RESULTS

Between 1 June 2010 and 13 February 2013, 80 women were consented and randomized. One woman subsequently withdrew consent, so 79 women were included in the analysis. Forty-two were assigned to the immediate removal group and 37 were assigned to standard placement. Two women went into labor after randomization but prior to Foley placement (one in each group), therefore these women were analyzed with the intention to treat. In five women, practitioners were unable to place the transcervical Foley balloon (three in the immediate removal group and two in the standard placement group), and so these women were also analyzed with the intention to treat (Figure 1).

Maternal characteristics at enrollment were similar between groups (Table 1). Our participants averaged 28 years of age with pregnancies at 39 weeks of gestational age. The majority of our participants were Hispanic (71.4%) and obese (average body mass index was 31.7). The overall rate of nulliparity was 56%. Neonatal outcomes also did not differ between groups (Table 1). Indications for induction are described in Table 2.

Intrapartum characteristics were also similar between groups (Table 3). Rates of regional anesthesia use, amniotomy and oxytocin use did not differ between the two groups. In total, 83% of women received regional anesthesia during labor, 65.8% underwent amniotomy and 98% received oxytocin augmentation. Rates of infection did not differ between groups in univariate analysis, but after controlling for total number of vaginal exams and duration of rupture, a decreased risk of infection was observed in the immediate removal group (odds ratio = 0.08, 95% confidence interval = 0.007 to 0.93, $P = 0.04$). The risk of infection in the immediate removal group was 92% less than the risk in the standard placement group.

The average total time from induction until delivery was significantly increased in the immediate removal group when compared with the standard placement group (32.1 vs 23.5 h, $P = 0.002$). No statistical difference in rates of delivery within 24 h was observed (28.6% vs 46.0%, $P = 0.11$), but women who underwent standard placement were more likely to deliver within 48 h of initial placement than those in the immediate removal group (97.3% standard vs 83.3% immediate, $P = 0.04$; Table 4). However, when stratified by parity, between-group differences in all delivery time measures only persisted in nulliparous women (Table 5). This information is depicted graphically in Figures 2–4.

Type of delivery remained unrelated to treatment in both stratified and unstratified estimates. There was no difference in cesarean delivery rate between the groups (26.2% vs 27.0%, $P = 1.00$; Table 4). Operative vaginal delivery rates were also similar (4.76% vs 5.41%, $P = 1.00$). Indications for cesarean delivery were similar between groups (Table 6).

DISCUSSION

Our data show that immediate removal of the transcervical Foley balloon following insufflation results in prolonged time from

Table 2. Indication for induction

	N *(%)*
Oligohydramnios	25 (31.65%)
Post dates	12 (15.19%)
Decelerations	11 (14.10%)
Intrahepatic cholestasis of pregnancy	10 (12.66%)
Diabetes	9 (11.39%)
Breast cancer	1 (1.27%)
Myocardial infarction	1 (1.27%)

Table 1. Summary of maternal characteristics and neonatal outcomes by induction group

	Overall (n = *79*)	*Immediate removal* (n = *42*)	*Standard induction* (n = *37*)	P-*value*
Maternal characteristics				
Age	27.69 (7.01)	26.64 (7.17)	28.86 (6.82)	0.16
Gravidity	2 (1–9)	2 (1–9)	2 (1–9)	0.58
Parity	0 (0–6)	0 (0–6)	1 (0–5)	0.18
Nulliparous	44 (55.70)	27 (64.29)	17 (45.95)	0.10
BMI	31.68 (7.37)	32.36 (7.52)	30.89 (7.21)	0.44
Race[a]				
American Indian	2 (2.60)	0 (0.00)	2 (5.41)	0.74
Black	5 (6.49)	2 (5.00)	3 (8.11)	
Hispanic	55 (71.43)	30 (75.00)	25 (67.57)	
Non-Hispanic White	9 (11.69)	5 (12.50)	4 (10.81)	
Other	6 (7.79)	3 (7.50)	3 (8.11)	
Diabetes	11 (13.92)	7 (16.67)	4 (10.81)	0.45
Diabetics on insulin	4 (36.36)	2 (28.57)	2 (50.00)	0.58
Neonatal outcomes				
Birth weight	3152.09 (494.74)	3157.37 (450.17)	3146.24 (546.16)	0.92
Apgar 1 min	8 (3–9)	8 (3–9)	8 (4–9)	0.79
Apgar 5 min	9 (6–9)	9 (6–9)	9 (6–9)	0.94
Apgar 5 min <7	2 (2.53)	1 (2.38)	1 (2.70)	NA[b]
NICU admission	14 (17.95)	8 (19.51)	6 (16.22)	0.71
Meconium	8 (10.13)	3 (7.14)	5 (13.51)	0.46

Abbreviations: BMI, body mass index; NA, not applicable; NICU, neonatal intensive care unit. [a]Race not reported for 2 participants. [b]Occurred too infrequently for valid statistical comparison. Data are reported as mean (s.d.), median (interquartile range), or *n* (%).

Table 3. Summary of intrapartum characteristics by induction group

	Overall (n = *79*)	*Immediate removal* (n = *42*)	*Standard induction* (n = *37*)	P-*value*
EGA	38.71 (1.85)	38.84 (1.62)	38.55 (2.10)	0.50
EGA > 37 weeks	65 (82.28)	37 (88.10)	28 (75.68)	0.15
EGA > 39 weeks	38 (48.10)	21 (50.00)	17 (45.95)	0.72
Initial dilation	1.19 (0.63)	1.23 (0.66)	1.15 (0.60)	0.59
Bishop Score	4 (0–8)	5 (1–8)	4 (0–7)	0.23
Pitocin	78 (98.73)	42 (100.00)	36 (97.30)	0.47
Epidural	65 (83.33)	34 (82.93)	31 (83.78)	0.92
Amniotomy	52 (65.82)	25 (59.52)	27 (72.97)	0.21
Total number of exams	4 (1–10)	4 (1–10)	4 (1–8)	0.85
Duration of rupture (h)	7.38 (7.89)	9.00 (9.12)	5.69 (5.79)	0.07
Prolonged rupture (>18)	10 (13.33)	8 (20.51)	2 (5.56)	0.06
Prolonged decelerations	13 (16.46)	8 (19.05)	5 (13.51)	0.51
Tachysystole	1 (1.27)	0 (0.00)	1 (2.70)	NA[a]
Infection	8 (10.26)	2 (4.88)	6 (16.22)	0.14

Abbreviations: EGA, estimated gestational age; NA, not applicable. [a]Occurred too infrequently for valid statistical comparison.

Table 4. Summary of delivery outcomes by induction group

	Overall (n = *79*)	*Immediate removal* (n = *42*)	*Standard induction* (n = *37*)	P-*value*
Delivery in 24 h	29 (36.71)	12 (28.57)	17 (45.95)	0.11
Delivery in 48 h	71 (89.87)	35 (83.33)	36 (97.30)	0.04
Time to delivery	28.08 (12.77)	32.09 (14.07)	23.53 (9.38)	0.002
Type of delivery				
NSVD	54 (68.35)	29 (69.05)	25 (67.57)	1.00
VAVD	4 (5.06)	2 (4.76)	2 (5.41)	
Cesarean delivery	21 (26.58)	11 (26.19)	10 (27.03)	

Abbreviations: NSVD, normal spontaneous vaginal delivery; VAVD, vacuum assisted vaginal delivery.

Table 5. Summary of delivery outcomes based on parity

	Overall (n = *44*)	*Immediate removal* (n = *27*)	*Standard induction* (n = *17*)	P-*value*
Nullipara				
Delivery in 24 h	11 (25.00)	5 (18.52)	6 (35.29)	0.21
Delivery in 48 h	36 (81.82)	20 (74.07)	16 (94.12)	0.09
Time to delivery	33.82 (12.94)	38.11 (12.70)	27.01 (10.39)	0.004
Type of delivery				
NSVD	24 (54.55)	15 (55.56)	9 (52.94)	1.00
VAVD	3 (6.82)	2 (7.41)	1 (5.88)	
Cesarean delivery	17 (38.64)	10 (37.04)	7 (41.18)	
	Overall (n = *35*)	*Immediate removal* (n = *15*)	*Standard induction* (n = *20*)	P-*value*
Multipara				
Delivery in 24 h	18 (51.43)	7 (46.67)	11 (55.55)	0.63
Delivery in 48 h	35 (100)	15 (100)	20 (100)	NA
Time to delivery	20.86 (8.14)	21.25 (9.20)	20.58 (7.48)	0.66
Type of delivery				
NSVD	30 (85.71)	14 (93.33)	16 (80.00)	1.00
VAVD	1 (2.86)	0 (0.00)	1 (5.00)	
Cesarean delivery	4 (11.43)	1 (6.67)	3 (15.00)	

Abbreviation: NA, not applicable; NSVD; normal spontaneous vaginal delivery; VAVD; vacuum assisted vaginal delivery.

induction to delivery in nulliparous women. No statistically significant differences were observed among parous women and similar cesarean delivery rates and neonatal outcomes were observed among all groups. An increased infection risk was observed in the standard placement group.

The present investigation is, to our knowledge, the first to compare standard placement of the transcervical Foley balloon to immediate Foley removal. However, previous studies have examined the efficacy of various volumes for balloon insufflation.[9–11] These authors compared balloons insufflated with 30 ml

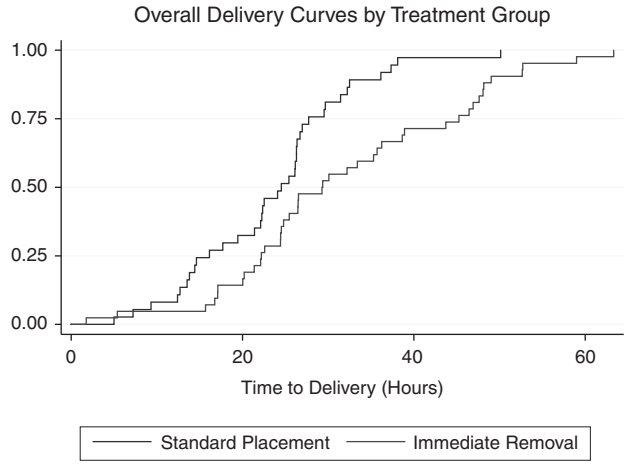

Figure 2. Overall delivery curves by treatment group. Log-rank test for equality of survivor functions indicate significant difference in time to event between groups ($\chi^2 = 10.22$, $P = 0.001$).

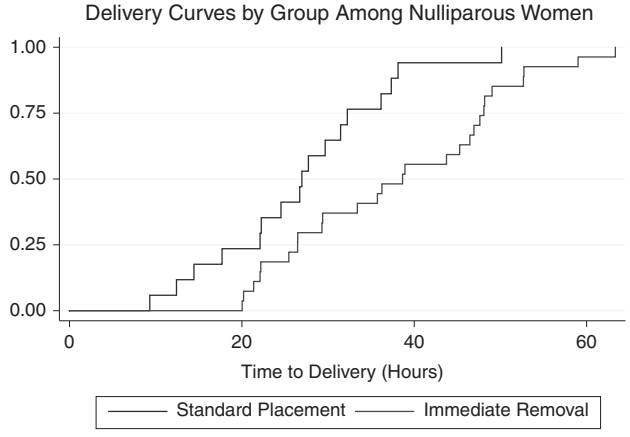

Figure 3. Delivery curves by treatment group among nulliparous women. Log-rank test for equality of survivor functions indicate significant difference in time to event between groups ($\chi^2 = 7.56$, $P = 0.006$).

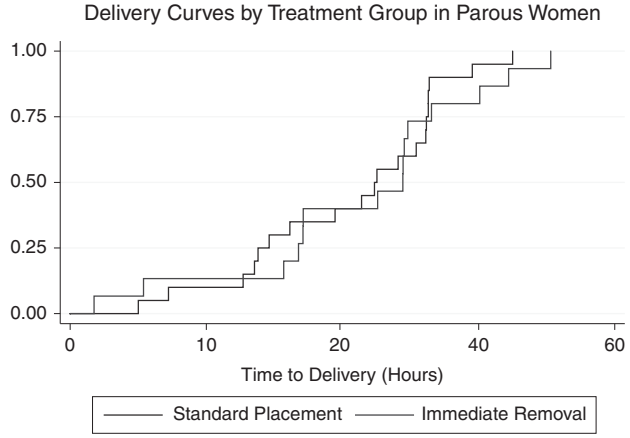

Figure 4. Delivery curves by treatment group among parous women. Log-rank test for equality of survivor functions indicate significant difference in time to event between groups ($\chi^2 = 0.52$, $P = 0.47$).

Table 6. Summary of indication for CS by induction group

	Overall (n = *21*)	*Immediate removal* (n = *11*)	*Standard induction* (n = *10*)	P-*value*
Arrest	10 (47.62)	4 (36.36)	6 (60.00)	0.39
Failed IOL	2 (9.52)	2 (18.18)	0 (0.00)	0.48
Decelerations	9 (42.86)	5 (45.45)	4 (40.00)	1.00

Abbreviation: IOL, induction of labor.

to those with 60 ml and with 80 ml. They demonstrated more rapid rates of cervical dilation for higher balloon volumes, especially in nulliparous patients, but failed to demonstrate a difference in cesarean delivery rates. Other studies have also investigated the necessity of concomitant oxytocin use. Pettkar *et al.*[5] determined that the addition of oxytocin to the Foley balloon for preinduction cervical ripening did not shorten the interval to delivery or increase the delivery rate within 24 h. It was for this reason we did not initiate oxytocin at the onset of Foley balloon induction but rather at 12 h. Those allocated to standard placement usually had their Foley balloon placed to traction, though no data exist to describe the utility of this practice.

Interestingly, a lower infection rate was observed in the immediate removal group compared with the prolonged placement group after controlling for number of vaginal exams and duration of membranes. Infection rates observed during Foley induction are quoted in the literature to range from 1 to 18.5%.[5,12–15] Our overall infection rates were significantly lower in those women randomized to immediate removal. In our study, all patients had the Foley placed under direct visualization and after the cervix had been prepped with Betadine.

Notably, our study utilized institutional labor induction protocols that predated the recent American College of Obstetricians and Gynecologists/Society for Maternal-Fetal Medicine consensus publication outlining recommendations for safe prevention of the first cesarean delivery.[16] Namely, this publication recommends defining active labor at 6 cm and advocates against cesarean delivery for prolonged latent phase. Our previous definition for failed induction included 20 h of maximum oxytocin for both primagravida and multigravida participants. However, upon reviewing indications for cesarean delivery in our sample, only one participant may have avoided cesarean delivery (in the immediate removal group, arrest was diagnosed at 4 cm).

The safety and efficacy demonstrated here provides the basis for designing an outpatient trial to investigate immediate removal of the Foley for preinduction cervical ripening. Although overall induction time with this method might be longer, total admission duration could possibly be truncated. Previously Sciscione *et al.* randomized women to inpatient versus outpatient prolonged Foley placement and found no difference in maternal or neonatal adverse outcomes.[17] Those randomized to the inpatient arm underwent intermittent monitoring until oxytocin was started after extrusion or spontaneous membrane rupture. Those randomized to outpatient ripening were instructed to return the following morning at which time oxytocin was started. They found that those randomized to outpatient management spent 9.6 h less in the hospital without prolonging total induction times. They reported similar cesarean delivery rates between groups and a chorioamnionitis rate of 7%. By immediately removing the Foley balloon in an outpatient induction protocol, we may be able to even further decrease the infection rate with immediate removal.

Our study is not without limitations. Though prospective and randomized, it was not blinded. Obstetric management not otherwise delineated by protocol was determined by the managing provider and could have affected multiple outcomes, particularly delivery times and cesarean delivery rates. Further,

because the difference in total induction time was so significant, this trial was stopped after its planned interim analysis. Although additional data collection would certainly have been unlikely to yield different conclusions about our primary outcome and early stopping was in line with ethical research practices, detection of certain real differences may be limited by low numbers. On the other hand, the low numbers make the detected relationships that much more remarkable. Even a conservative interpretation of these data provides support for multiple areas of future research, including replication, well-powered exploration of the relationship between induction methods and post-induction infection and the development of a convenient, cost-effective outpatient induction procedure.

In conclusion, we have demonstrated that immediate removal of the transcervical Foley results in longer induction times in nulliparous women without increasing cesarean delivery rate, maternal or neonatal adverse outcomes. Immediate removal may also result in lower infection rates and therefore is worth exploring as an additional induction option, particularly for parous women.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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