Published in final edited form as:

Am J Obstet Gynecol. 2013 September ; 209(3): 237.e1–237.e7. doi:10.1016/j.ajog.2013.05.005.

Progress of Labor in Women Induced with Misoprostol versus the Foley Catheter

Methodius G. TUULI, MD, MPH, Mary B. KEEGAN, MD, Anthony O. ODIBO, MD, MSCE, Kimberly ROEHL, MPH, George A. MACONES, MD, MSCE, and Alison G. CAHILL, MD, MSCI
Department of Obstetrics and Gynecology, Washington University School of Medicine, St. Louis, MO 63110

Abstract

Objective—To estimate and compare the duration and progress of labor in women induced with misoprostol versus Foley catheter plus oxytocin.

Study Design—We performed a retrospective cohort study of labor progress among 617 consecutive term pregnancies induced with misoprostol (n=503) or Foley catheter plus oxytocin (n=114) who completed the first stage of labor. Labor duration and progress in the entire cohort, and stratified by parity, were compared in multivariable interval-censored regression models adjusting for maternal obesity and birth weight. Repeated-measures analysis with 9th degree polynomial modeling was used to construct average labor curves.

Results—Total duration of labor was not significantly different in women induced with misoprostol compared to the Foley catheter median (median duration from 1 to 10 cm: 12 versus 14.2 hours, p=0.19). Progress from 1 to 4 cm was more rapid with the Foley catheter (median: 3.4 versus 5.6 hours, p<0.01), while progress from 4 to 10 cm was slower (median: 6.3 versus 3.6 hours, p<0.01). Labor curves demonstrated transition from latent to active labor at about 4 cm cervical dilatation with misoprostol and at 6cm for the Foley catheter. Similar general patterns were noted for nulliparous and multiparous women, except for a shorter duration of labor with the Foley catheter among multiparous women.

Conclusion—Induction of labor with the Foley catheter is associated with more rapid initial cervical dilation, but transition to active labor occurs later compared to misoprostol. These differences should be considered in the management of induced labor.

Keywords

Foley catheter; misoprostol; labor induction; labor progress

© 2013 Mosby, Inc. All rights reserved.

Corresponding Author: Methodius G. Tuuli, MD, MPH, Department of Obstetrics and Gynecology, Washington University School of Medicine, Campus Box 8064, 4566 Scott Avenue, St. Louis, MO 63110 Phone number: 314-362-8895, Fax number: 314-747-1720; tuulim@wudosis.wustl.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Disclosure statement: The authors report no conflict of interest.

INTRODUCTION

Induction of labor is frequently employed in contemporary obstetrics and rates continue to increase.¹ It is associated with increased risk of cesarean delivery, especially among women with an unfavorable cervix.²⁻⁴ This increased risk appears to be strongly influenced by the duration of the induction attempt.⁵ Yet there are no clear expectations of normal duration and course of induced labor. Using interval-censored regression analysis, we recently demonstrated that induced labor progresses slower than labor of spontaneous onset.⁶ However, the effect of different methods of labor induction on progress of labor has not been well characterized.

The Foley catheter and misoprostol are two common methods of labor induction in the United States when the cervix is unfavorable. The Foley catheter acts by mechanically dilating the cervix and releasing endogenous prostaglandins. Misoprostol, a synthetic prostaglandin E1, promotes biochemical remodeling of the cervix and triggers uterine contractions. Prior studies suggest both methods are effective for labor induction.⁷ However, data on their relative effects on the course of labor are limited. Prior studies assessing the course of labor in women induced with misoprostol or Foley catheter compared induction-to-delivery intervals.⁸⁻¹⁰ Such data are of limited value for the clinical management of labor where cervical dilatation is assessed intermittently and prospectively. Assessment of only induction-to-delivery intervals may obscure potentially important differences at different points in the labor course. For example, anecdotal evidence suggests women induced with the Foley catheter may not be in active labor even when the cervix is 3 - 4 cm or more dilated following expulsion of the Foley catheter. Establishing standards for onset of active labor in pregnancies induced with misoprostol or Foley catheter would potentially reduce the number of cesareans performed for failed induction of labor.

The objective of this study was to estimate and compare the duration and progress of labor in women induced with misoprostol or Foley catheter. Specifically, we sought to estimate onset of active labor in women induced with the two methods.

MATERIALS AND METHODS

We conducted a retrospective cohort study of consecutive term, vertex singleton deliveries from 2004 to 2008 at a single academic teaching hospital. The study was approved by the Washington University School of Medicine Human Research Protection Office. Women were eligible if they underwent labor induction and completed the first stage. We excluded women if they had cesarean delivery in the first stage of labor, were in spontaneous labor on admission or had a known fetal anomaly. Detailed demographic information was extracted from patients' records including medical and surgical history, obstetric and gynecologic history and prenatal history. We abstracted detailed labor and delivery information including medications, labor onset type, indications for induction, method of labor induction, cervical examination times, cervical dilatation (0 to 10 cm), fetal head station (-5 to +5) and mode of delivery. Inductions of labor without any obstetric or medical indication as classified as elective. Pregnancies were dated by a woman's last menstrual period and confirmed with first or second trimester ultrasonography using standard criteria. The comparison groups

were defined by induction with misoprostol or the Foley catheter. We excluded women induced with a combination of misoprostol and Foley catheter or with another type of prostaglandin.

Labor and delivery care was provided largely by resident physicians under the supervision of attending physicians. However, per institutional obstetric protocols women with prior cesareans were not induced with misoprostol. The decision to use the Foley catheter or misoprostol was determined by the admitting physician. Cervical examinations were performed at regular intervals, usually every two hours. Women undergoing induction with misoprostol received 25mcg vaginally every 4 hours until cervical ripening was achieved. Oxytocin was then started as needed, after at least 4 hours from when the last misoprostol was placed. Oxytocin was administered per standard institutional protocol starting at 2 milliunits per minute and increasing by 2 milliunits every 20 minutes until regular uterine contractions occurred. When the Foley catheter was used for induction, it was placed blindly or under direct visualization with the aid of a speculum. The balloon was inflated to 60cc and the catheter was taped under traction to the woman's thigh. Oxytocin was typically started at the same time and titrated until regular contractions occurred. The Foley catheter was examined periodically until it was expelled. Artificial rupture of membranes was performed once it was feasible.

We initially compared all women induced with misoprostol to those induced with the Foley catheter. All analyses were then further stratified into nulliparous and multiparous women. Univariable analysis was used to assess differences in baseline demographic and pregnancy characteristics. The chi-squared test or Fisher's exact test was used for categorical variables as appropriate. Continuous variables were examined for normality using the Kolmogorov-Smirnov test. The Student's t test was used for normally distributed continuous variables while the Mann Whitney test was used for non-normally distributed variables.

Median duration of labor and progress from one integer centimeter of cervical dilatation to the next (called traverse time) was estimated using interval-censored regression analysis with the assumption of log-normal distribution. This was necessary because cervical dilation is assessed intermittently and it is not possible to know exactly when cervical dilatation changed from one measure to another. Further, duration of labor is known to have a skewed distribution towards the left and generally fits a log-normal distribution.¹¹ Thus, interval-censored regression with the assumption of log-normal distribution enabled us to estimate median traverse times from one integer cervical dilation to another together with 5th and 95th percentiles. We controlled for confounders using multivariable interval censored regression models. Potential confounders were selected based on bivariate analysis. Statistically significant variables (maternal obesity and birth weight) were included in the final model.

We constructed average labor curves using repeated-measures analysis with 9th degree polynomial modeling. This involved taking the independent variable to sequential powers.¹² A 9th order polynomial was the best fit for our cervical dilatation data. Repeated-measures analysis was required to take into account the correlation of multiple cervical examinations in the same women. Because achievement of complete cervical dilatation was known with

certainty for all subjects in this cohort, we constructed labor curves starting at 10 cm cervical dilatation and worked backwards. The resulting curves were then reversed.

Tests with $p < 0.05$ were considered significant. We included all patients meeting inclusion criteria during the study period; formal sample size estimation was not performed. Statistical analyses were completed using STATA version 11.1 (College Station, Texas) and PROC LIFEREG of SAS 9.2 (Cary, NC).

RESULTS

Of 5,388 consecutive women with singleton term pregnancies and vertex presentation who completed the first stage of labor during the study period (2004 – 2008), 617 were induced with misoprostol ($n=503$) or Foley catheter ($n=114$). For the entire cohort, women induced with misoprostol or the Foley catheter were comparable with regard to several demographic and pregnancy characteristics (**Table 1**). Specifically, there were no significant differences in parity, race, indications for induction and use of regional anesthesia. However, women induced with the Foley catheter had higher median Bishop score on admission, were more likely to require oxytocin augmentation. All women with prior cesareans were in the Foley catheter group.

Total duration of labor in the entire cohort by induction method was not significantly different (duration from 1 to 10 cm: 12.0 versus 14.2 hours, $p=0.19$) (**Table 2**). However, women induced with the Foley catheter progressed more rapidly from 1 to 4 cm (3.4 versus 5.6 hours, $p < 0.01$), and slower from 4 to 10 cm (6.3 versus 3.6 hours, $p < 0.01$). Analyses of centimeter to centimeter progress confirmed that dilations from 2 to 3 and 3 to 4 cm were more rapid in the Foley catheter group, while progress in centimeter increments was more rapid in the misoprostol group thereafter. Notably, times for progress from each cervical dilation to the next after 4 cm were significantly shorter in the misoprostol group. Labor curves for the entire cohort demonstrated transition from latent to active labor at approximately 4 cm cervical dilation for misoprostol and at approximately 6 cm for the Foley catheter (**Figure 1**).

In all, 265 nulliparous women were induced with misoprostol while 49 were induced with the Foley catheter (**Table 3**). Nulliparous women induced with misoprostol and the Foley catheter were similar in several baseline characteristics. As observed for the entire cohort, the median Bishop score on admission was slightly higher in women induced with the Foley catheter. The indication for induction with misoprostol was more likely to be elective compared to the Foley catheter (70/265 [28.8%] versus 4/49 [12.1%]). A total of 238 multiparous women were induced with misoprostol and 65 with the Foley catheter. Again, multiparous women induced with misoprostol and the Foley catheter had similar baseline characteristics except for a higher median Bishop score among women induced with the Foley catheter.

Labor progress in nulliparous (**Table 4**) and multiparous women (**Table 5**) induced with the two methods demonstrated comparable general patterns to those observed for the entire cohort. In both nulliparous and multiparous women, transition to active labor occurred at

about 6 cm cervical dilation among women induced with the Foley catheter and 4 cm in labor induced with misoprostol (**Figure 2**). However, while total duration of labor was similar in nulliparous women induced with misoprostol or the Foley catheter (15.2 versus 13.1 hours, $p=0.48$), duration of labor was notably shorter among multiparous women induced with misoprostol (11.7 versus 17.1 hours, $p=0.03$).

COMMENT

We found that whereas total duration of labor in women induced with misoprostol or the Foley catheter were generally similar, there were significant differences in detailed labor progress. The Foley catheter was associated with more rapid initial cervical dilation, but transition to active labor occurred later compared to misoprostol. Active labor did not start until about 6 cm cervical dilation with the Foley catheter and at about 4 cm with misoprostol.

The finding of comparable total durations of labor is consistent with some prior studies that showed total duration from induction to delivery was not significantly different between women induced with the two methods.^{8,9} In contrast, other studies found misoprostol^{10,13} or the Foley catheter¹⁴ to be associated with shorter induction-to-delivery interval. The different findings in these studies may be attributable to different populations studied and the different labor management protocols used. One study examined progress of labor in nulliparous women undergoing induction, stratified by favorability of the cervix at the time of induction¹⁵. Similar to our results, they found that progress in one centimeter increments from 3 to 6 cm was slower with the Foley catheter compared to spontaneous labor, but labor patterns were similar thereafter. Another study found that multiparous women undergoing induction with the Foley catheter were slower to enter the active phase compared to spontaneous labor, but active labor was more rapid in women induced with the Foley catheter.¹⁶ Labor patterns associated with misoprostol induction were not assessed in either study.

The finding that the Foley catheter is associated with more rapid initial cervical dilation, but delayed transition to active labor is biologically plausible. Acting mechanically, the Foley catheter rapidly dilates the cervix without significant effacement as soon as it is placed and inflated. Thus, women may not be in active labor even when the cervix is 3 - 4 cm or more dilated following expulsion of the Foley catheter. In contrast, misoprostol promotes more gradually cervical remodelling to facilitate cervical dilation. The practical implication of this observation is that diagnosis of failed induction or failed progress of labor should be made with caution prior to 6 cm cervical dilation in women induced with the Foley catheter.

We used a well-characterized cohort with detailed patient-level information. This enabled us adjust for potential confounders. We also used interval-censored and repeated-measures polynomial regression analyses which took into account the interval-censored and correlated nature of cervical dilation data. Importantly, we improved upon prior studies by providing detailed information on labor progress that may be used in clinical practice. Specifically, we provide estimates of cervical dilation after which active labor would be expected in women induced with each method.

Despite these strengths there are limitations that should be considered when interpreting our results. We included only women who completed the first stage of labor. While it allowed us to characterize normal labor in women induced with misoprostol or Foley catheter, exclusion of women delivered by cesarean in the first stage may lead to selection bias. Since women delivered by cesarean in the first stage are more likely to have protracted labor, their exclusion likely shortened the total duration and times needed to progress in one centimeter increments. This makes the relatively long 95th percentiles required for cervical change all the more remarkable. Our analyses only covered cervical dilation from 1 to 10 cm. While this was necessary because women had to be at least 1 cm dilated to be induced with the Foley catheter, we are unable to comment on the progress from 0 to 1 cm with the two methods.

We did not control for multiple comparisons in our analysis. This raises the possibility that some differences could have occurred by chance alone. We supplemented results of the interval-censored regression analysis with reconstructed labor curves. The consistency of findings from the two techniques is reassuring. Women induced with misoprostol and the Foley catheter differed in some baseline characteristics. While we controlled for confounding using appropriate statistical methods, there is the possibility of residual confounding. It is noteworthy that all women with prior cesareans were induced with the Foley catheter. This could bias our results if labor progress significantly differs in women with prior cesarean. However, published data suggest no significant differences in labor progress in women with prior cesareans when compared to those without such a history.¹⁷ Finally, we included all women meeting inclusion criteria during the study period without a formal sample size estimation. While we found statistically significant differences in progress during the early part of cervical dilation, the lack of statistical differences in total duration of labor could be attributed to lack of adequate statistical power. However, it is reassuring that our sample size is similar to prior studies.

In conclusion, we found that the Foley catheter is associated with more rapid initial cervical dilation, but transition to active labor occurs later compared to misoprostol. Active labor did not occur until about 6 cm cervical dilation with the Foley catheter and about 4 cm with misoprostol. These differences should be considered in the management of labor induced with the two methods. Based on these findings we recommend that diagnosis of failed induction of labor be made with caution prior to 6 cm cervical dilation, especially in women induced with the Foley catheter.

Acknowledgments

Financial support: Dr. Tuuli is supported by a Women's Reproductive Health Research Career Development grant from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NIH/NICHD – 1K12HD063086-01).

Dr. Cahill is a Robert Wood Johnson Foundation Physician Faculty Scholar, which partially supports this work. The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official view of the NIH or Robert Wood Johnson Foundation.

REFERENCES

1. Martin JA, Hamilton BE, Sutton PD, Ventura SJ, Mathews TJ, Kirmeyer S, et al. Births: final data for 2007. *Natl Vital Stat Rep.* 2010; 58:1–85. [PubMed: 21254725]
2. Macer JA, Macer CL, Chan LS. Elective induction versus spontaneous labor: a retrospective study of complications and outcome. *Am J Obstet Gynecol.* 1992; 166:1690–6. discussion 1696–7. [PubMed: 1615976]
3. Maslow AS, Sweeny AL. Elective induction of labor as a risk factor for cesarean delivery among low-risk women at term. *Obstet Gynecol.* 2000; 95:917–22. [PubMed: 10831992]
4. Vahratian A, Zhang J, Troendle JF, Sciscione AC, Hoffman MK. Labor progression and risk of cesarean delivery in electively induced nulliparas. *Obstet Gynecol.* 2005; 105:698–704. [PubMed: 15802393]
5. Rouse DJ, Owen J, Hauth JC. Criteria for failed labor induction: prospective evaluation of a standardized protocol. *Obstet Gynecol.* 2000; 96:671–7. [PubMed: 11042299]
6. Harper LM, Caughey AB, Odibo AO, Roehl KA, Zhao Q, Cahill AG. Normal progress of induced labor. *Obstet Gynecol.* 2012; 119:1113–8. [PubMed: 22569121]
7. Jozwiak M, Bloemenkamp KWM, Kelly AJ, Mol BWJ, Irion O, Bouvain M. Mechanical methods for induction of labour. *Cochrane Database of Systematic Reviews.* 2012; (3) Art. No.: CD001233. DOI: 10.1002/14651858.CD001233.pub2.
8. Chung JH, Huang WH, Rumney PJ, Garite TJ, Nageotte MP. A prospective randomized controlled trial that compared misoprostol, Foley catheter, and combination misoprostol-Foley catheter for labor induction. *Am J Obstet Gynecol.* 2003; 189:1031–5. [PubMed: 14586350]
9. Sciscione AC, Nguyen L, Manley J, Pollock M, Maas B, Colmorgen G. A randomized comparison of transcervical Foley catheter to intravaginal misoprostol for preinduction cervical ripening. *Obstet Gynecol.* 2001; 97:603–7. [PubMed: 11275035]
10. Moraes Filho OB, Albuquerque RM, Cecatti JG. A randomized controlled trial comparing vaginal misoprostol versus Foley catheter plus oxytocin for labor induction. *Acta Obstet Gynecol Scand.* 2010; 89:1045–52. [PubMed: 20636243]
11. Vahratian A, Troendle JF, Siega-Riz AM, Zhang J. Methodological challenges in studying labour progression in contemporary practice. *Paediatr Perinat Epidemiol.* 2006; 20:72–8. [PubMed: 16420344]
12. Zhang J, Troendle J, Mikolajczyk R, Sundaram R, Beaver J, Fraser W. The natural history of the normal first stage of labor. *Obstet Gynecol.* 2010; 115:705–10. [PubMed: 20308828]
13. Owolabi AT, Kuti O, Ogunlola IO. Randomised trial of intravaginal misoprostol and intracervical Foley catheter for cervical ripening and induction of labour. *J Obstet Gynaecol.* 2005; 25:565–8. [PubMed: 16234141]
14. Culver J, Strauss RA, Brody S, Dorman K, Timlin S, McMahon MJ. A randomized trial comparing vaginal misoprostol versus Foley catheter with concurrent oxytocin for labor induction in nulliparous women. *Am J Perinatol.* 2004; 21:139–46. [PubMed: 15085496]
15. Vahratian A, Hoffman MK, Troendle JF, Zhang J. The impact of parity on course of labor in a contemporary population. *Birth.* 2006; 33:12–7. [PubMed: 16499527]
16. Hoffman MK, Vahratian A, Sciscione AC, Troendle JF, Zhang J. Comparison of labor progression between induced and noninduced multiparous women. *Obstet Gynecol.* 2006; 107:1029–34. [PubMed: 16648407]
17. Graseck AS, Odibo AO, Tuuli M, Roehl KA, Macones GA, Cahill AG. Normal first stage of labor in women undergoing trial of labor after cesarean delivery. *Obstetrics and gynecology.* 2012; 119(4):732–6. [PubMed: 22433336]

CONDENSATION

Induction of labor with misoprostol and the Foley catheter yield significantly different labor patterns which should be considered in the management of induced labor.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

CLINICAL IMPLICATIONS

- Induction with the Foley catheter was associated with more rapid initial cervical dilation, but transition to active labor occurred later than with misoprostol.
- Active labor did not start until about 6 cm of cervical dilation with the Foley catheter and about 4 cm with misoprostol.
- These differences should be considered in the management of labor induced with the studied methods.
- We recommend that diagnosis of failed induction of labor be made with caution prior to 6 cm of cervical dilation, especially in women induced with the Foley catheter.

Figure 1.

Average labor curves of all women induced with misoprostol or the Foley catheter Labor curves for the entire cohort demonstrated transition from latent to active labor at approximately 4 cm cervical dilation for misoprostol and at approximately 6 cm for the Foley catheter.

Figure 2.

Average labor curves of women induced with misoprostol or the Foley catheter, stratified parity.

In both nulliparous and multiparous women, transition to active labor occurred at about 6 cm cervical dilation among women induced with the Foley catheter and 4 cm in labor induced with misoprostol. While total duration of labor was similar in nulliparous women induced with misoprostol or the Foley catheter (15.2 versus 13.1 hours, $p=0.48$), duration of labor was notably shorter among multiparous women induced with misoprostol (11.7 versus 17.1 hours, $p=0.03$).

Table 1Baseline characteristics of all women induced with misoprostol or the Foley catheter

Characteristic	Misoprostol (n=503)	Foley catheter (n=114)	P value
Maternal age (years), mean (sd)	24.7 (6.2)	24.9 (6.40)	0.81
Maternal weight (Kg), mean (sd)	90.1 (21.1)	86.1 (18.3)	0.06
Maternal BMI, Kg/m ² , mean (sd)	33.3 (7.5)	32.6 (6.60)	0.34
Obese (BMI >30Kg/m ²), n (%)	319 (64.7)	65.0 (58.0)	0.19
Parity, n (%)			
Nulliparous	206 (41.0)	38 (33.3)	0.13
Multiparous	297 (59.1)	76 (66.7)	
Maternal race, n (%)			
Black	323 (64.2)	85 (74.6)	0.06
White	129 (25.7)	24 (21.1)	
Other	51 (10.1)	5 (4.4)	
Chronic Hypertension, n (%)	30 (6.0)	7 (6.1)	0.94
Diabetes, n (%)	14 (2.8)	6 (5.3)	0.18
Smoking, n (%)	80 (15.9)	27 (23.7)	0.05
Alcohol use, n (%)	4 (0.8)	2 (1.8)	0.35
Indication for induction, n (%)			
Elective	152 (33.1)	16 (24.2)	0.41
Oligohydramnios	62 (13.5)	11 (16.7)	
Maternal comorbidity	51 (11.1)	12 (18.2)	
Preeclampsia	57 (12.4)	6 (9.1)	
Non-reassuring fetal status	39 (8.5)	7 (10.6)	
Other	98 (21.4)	14 (21.2)	
Admission Bishop score, median (range)	1 (0 -7)	3 (0 – 8)	<0.01
Admission cervical dilation, median (range)	1 (0 – 2)	1 (0 -3)	<0.01
Gestational age (weeks), mean (sd)	39.1 (1.4)	39.3 (1.3)	0.41
Prior cesarean, n (%)	0 (0)	24 (21.1)	<0.01
Fetal sex, n (%)			
Male	235 (46.8)	61 (53.5)	0.20
Female	267 (53.2)	53 (46.5)	
Birth weight (grams), mean (sd)	3261.1 (560.6)	3256.4 (519.0)	0.94

Characteristic	Misoprostol (n=503)	Foley catheter (n=114)	P value
Macrosomia (birth weight >4000grams), n (%)	5 (4.4)	30 (6.0)	0.51
Oxytocin augmentation	385 (76.5)	99 (86.8)	0.02
Regional anesthesia	466 (92.6)	107 (93.9)	0.65

sd=standard deviation

Table 2Time in hours for cervical dilation in all women induced with misoprostol or the Foley catheter

Cervical Dilation	Misoprostol	Foley catheter	P value *
From 1 to 10 cm	12.0 (5.1,28.0)	14.2 (6.1,33.2)	0.19
From 4 to 10 cm	3.6 (0.9,14.6)	6.3 (1.6,25.5)	<0.01
From 1 to 2 cm	2.7 (0.6,12.1)	1.8 (0.4,8.4)	0.69
From 2 to 3 cm	1.4 (0.3,7.9)	0.8 (0.1,4.3)	0.03
From 3 to 4 cm	1.5 (0.2,11.3)	0.8 (0.1,5.8)	<0.01
From 4 to 5 cm	0.9 (0.1,7.2)	1.6 (0.2,12.7)	<0.01
From 5 to 6 cm	0.4 (0.04,3.4)	0.8 (0.1,7.2)	<0.01
From 6 to 7 cm	0.3 (0.03,2.0)	0.4 (0.1,3.4)	<0.01
From 7 to 8 cm	0.2 (0.03,1.0)	0.2 (0.03,1.2)	0.02
From 8 to 9 cm	0.2 (0.02,1.0)	0.3 (0.04,1.7)	<0.01
From 9 to 10 cm	0.2 (0.03,1.3)	0.2 (0.04,1.4)	<0.01

Data presented in hours as median (5th percentile, 95th percentile)* Adjusted for obesity (body mass index greater than 30Kg/m²) and birth weight greater than 4000g.

Table 3Baseline characteristics of nulliparous and multiparous women induced with misoprostol or the Foley catheter

	Nulliparous			Multiparous		
Characteristic	Misoprostol (n=265)	Foley catheter (n=49)	P value	Misoprostol (n=238)	Foley catheter (n=65)	P value
Maternal age (years), mean (sd)	22.4(6.0)	21.0 (5.0)	0.12	27.3 (5.5)	27.8 (5.8)	0.50
Maternal weight (Kg), mean (sd)	85.5 (18.7)	82.4(18.8)	0.29	95.1(22.5)	88.8(17.5)	0.04
Maternal BMI, Kg/m ² , mean (sd)	31.8 (6.6)	31.4(6.6)	0.71	35.0 (8.0)	33.5 (6.5)	0.18
Obese (BMI >30Kg/m ²), n (%)	147 (57.0)	25 (51.0)	0.59	172 (73.2)	40 (63.5)	0.13
Maternal race, n (%)						
Black	157 (60.4)	37 (77.1)	0.09	166 (70.3)	48 (73.9)	0.31
White	74 (28.5)	8 (16.7)		55 (23.3)	16 (24.6)	
Other	29 (11.2)	3 (6.3)		15 (6.4)	1 (1.5)	
Chronic Hypertension, n (%)	10 (3.8)	0 (0)	0.37	20 (8.4)	7 (10.8)	0.55
Diabetes, n (%)	4 (1.5)	2 (4.1)	0.24	10 (4.2)	4 (6.2)	0.51
Smoking, n (%)	31 (11.7)	9 (18.4)	0.20	49 (20.6)	18 (27.7)	0.22
Alcohol use, n (%)	2 (0.8)	0 (0)	1.00	2 (0.8)	2 (3.1)	0.20
Indication for induction, n (%)						
Elective	70 (28.8)	4 (12.1)	0.02	81 (36.5)	11 (29.0)	0.47
Oligohydramnios	32 (13.2)	5 (15.2)		29 (13.1)	6 (15.8)	
Maternal comorbidity	20 (8.2)	3 (9.1)		26 (11.7)	8 (21.1)	
Preeclampsia	38 (15.6)	4 (12.1)		22 (9.9)	2 (5.3)	
Non-reassuring fetal status	5 (2.1)	5 (15.2)		5 (2.3)	1 (2.6)	
PROM	25 (10.3)	3 (9.1)		13 (5.9)	4 (10.5)	
Other	53 (21.8)	9 (27.3)		46 (20.7)	6 (15.8)	
Admission Bishop score, median (range)	2 (0-7)	3 (1-8)	<0.01	1(0-7)	3 (0-8)	<0.01
Admission cervical dilation, median (range)	1 (0-2)	1 (0-3)	<0.01	1 (0-3)	1 (0-3)	<0.01
Gestational age (weeks), mean (sd)	39.2 (1.4)	39.1 (1.4)	0.68	39.3 (1.3)	39.4 (1.2)	0.34
Prior cesarean, n (%)	0	0	-	0	24 (36.9)	<0.01
Fetal sex, n (%)			0.09			0.85

	Nulliparous			Multiparous		
Characteristic	Misoprostol (n=265)	Foley catheter (n=49)	P value	Misoprostol (n=238)	Foley catheter (n=65)	P value
Male	121 (45.8)	29 (59.2)		114 (47.9)	32 (49.2)	
Female	143 (54.2)	20 (40.8)		124 (52.1)	33 (50.8)	
Birth weight (grams), mean (sd)	3213 (551)	3143 (632)	0.42	3315 (567)	3342(399)	0.72
Macrosomia (birth weight >4000grams), n (%)	12 (4.5)	2 (4.1)	1.00	18 (7.6)	3 (4.6)	0.58
Oxytocin augmentation	213 (80.4)	44 (89.8)	0.12	172 (72.3)	55 (84.6)	0.04
Regional anesthesia, n (%)	256 (96.6)	47 (95.9)	0.81	210 (88.2)	60 (92.3)	0.35

sd=standard deviation

Table 4

Time in hours for cervical dilation in nulliparous women induced with misoprostol or the Foley catheter

Cervical Dilation	Misoprostol	Foley catheter	P value *
N	265	49	
From 1 to 10 cm	15.2 (7.2,32.3)	13.1 (6.2,27.9)	0.48
From 4 to 10 cm	5.1 (1.6,16.9)	7.7 (2.3,25.2)	<0.01
From 1 to 2 cm	3.3 (0.8,12.6)	3.7 (1.0,14.2)	0.92
From 2 to 3 cm	1.5 (0.3,7.9)	0.9 (0.2,4.5)	0.14
From 3 to 4 cm	1.6 (0.2,10.7)	0.7 (0.1,4.6)	0.02
From 4 to 5 cm	1.1 (0.2,5.3)	2.5 (0.5,11.6)	<0.01
From 5 to 6 cm	0.6 (0.1,4.0)	0.8 (0.1,6.1)	0.01
From 6 to 7 cm	0.4 (0.04,3.1)	0.5 (0.1,4.6)	0.23
From 7 to 8 cm	0.2 (0.03,1.4)	0.2 (0.04,1.4)	0.94
From 8 to 9 cm	0.2 (0.04,1.4)	0.2 (0.03,1.2)	0.85
From 9 to 10 cm	0.3 (0.1,2.1)	0.3 (0.05,1.6)	0.46

Data presented in hours as median (5th percentile, 95th percentile)

* Adjusted for obesity (body mass index greater than 30Kg/m²) and birth weight greater than 4000g.

Table 5

Time in hours for cervical dilation in multiparous women induced with misoprostol or the Foley catheter

Cervical Dilation	Misoprostol	Foley catheter	P value *
N	238	65	
From 1 to 10 cm	11.7 (4.5,30.0)	17.1 (6.7,43.9)	0.03
From 4 to 10 cm	3.4 (0.7,16.8)	7.1 (1.5,34.6)	<0.01
From 1 to 2 cm	1.8 (0.3,10.8)	1.4 (0.2,8.1)	0.70
From 2 to 3 cm	1.4 (0.2,8.3)	0.7 (0.1,4.3)	0.12
From 3 to 4 cm	1.4 (0.2,11.7)	0.9 (0.1,7.2)	0.18
From 4 to 5 cm	0.9 (0.1,9.5)	1.1 (0.1,11.8)	0.51
From 5 to 6 cm	0.3 (0.03,3.3)	0.7 (0.1,7.1)	0.03
From 6 to 7 cm	0.2 (0.03,1.2)	0.7 (0.1,4.7)	<0.01
From 7 to 8 cm	0.1 (0.02,0.6)	0.3 (0.05,1.5)	<0.01
From 8 to 9 cm	0.1 (0.02,0.7)	0.4 (0.1,2.2)	<0.01
From 9 to 10 cm	0.1 (0.02,0.6)	0.3 (0.1,1.9)	<0.01

Data presented in hours as median (5th percentile, 95th percentile)

* Adjusted for obesity (body mass index greater than 30Kg/m²) and birth weight greater than 4000g.