Original Research

Double-Balloon Device for 6 Compared With 12 Hours for Cervical Ripening

A Randomized Controlled Trial

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OBJECTIVE: To evaluate whether removal of a double-balloon device for cervical ripening for 6 compared with 12 hours in women with an unfavorable cervix will result in a shorter time to delivery, similar cervical ripening, and without affecting cesarean delivery rate.

METHODS: In a prospective randomized trial, cervical ripening was performed using a double-balloon device. Women were randomized to removal of the device after 6 compared with 12 hours. Primary outcome was time to delivery. Secondary outcomes included mode of delivery, Bishop score, and maternal and neonatal adverse outcomes. A sample size of 100 nulliparous and 100 parous women was required assuming a 95% CI, power of 80%, and mean decrease of 6 hours to delivery between the groups.

RESULTS: From March 2017 through February 2019, 688 women were screened, 243 were found eligible, and 197 were randomized as follows: nulliparous cohort (n=101): removal after 6 hours (n=48) compared with removal after 12 hours (n=53); parous cohort (n=96): removal after 6 hours (n=49) compared with removal after 12 hours (n=47). Insertion-to-delivery interval was significantly shorter in the 6-hour group for both nulliparous (25.6±12.8 hours vs 31.4±15.2 hours, $P<.04$; mean difference 5.8, 95% CI 0.2–11.3), and parous cohorts (18.0±6.8 hours vs 22.6±8.2 hours, $P=.003$; mean difference 4.7, 95% CI 1.6–7.7). Bishop score change and cesarean delivery rate were similar between groups regardless of parity. The 12-hour group in the combined cohort was associated with higher rates of maternal intrapartum fever (2% vs 10%, $P=.02$; odds ratio 5.3, 95% CI 1.1–24.8).

CONCLUSION: Insertion-to-delivery interval is shorter after 6 compared with 12 hours for both nulliparous and parous women. Cervical ripening with a double-balloon device may be achieved in 6 hours. The longer time was associated with a higher rate of intrapartum fever. Six hours should be considered as standard placement time for double-balloon catheters.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov, NCT03045939.

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In developed countries, around 25% of all deliveries at term involve induction of labor.[1] Before labor induction, cervical status is assessed. If cervical status is unfavorable, a ripening process is generally employed before induction, to shorten the duration of induction and improve the likelihood of a vaginal delivery. The two major techniques for cervical ripening are mechanical intervention and the use of pharmacologic agents.[2,3] A single balloon device (Foley catheter) or double-balloon device, has been used for decades[4] and yet there are variations among devices and protocols.[5–7] The benefits and harms of one method or duration of use over others are not proven. Prior nonrandomized studies have suggested that spontaneous expulsion of either a single or double catheter can occur earlier than 12 hours, regardless of the intended time.[7–10] Mitch et al (Mitch J, Mattingly P, Templin M, Ramsey K, Bliss S. 401: cervical ripening with a double balloon catheter for

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first vaginal delivery: 6 versus 12 hours: a randomized control trial [abstract]. Am J Obstet Gynecol 2018;218:S245–6.) report in an abstract that there was a similar time to delivery when assessing 6 compared with 12 hours intended time for a double-balloon catheter. A literature search conducted on December 29, 2019, in PubMed (using English-language and search terms "double balloon device" [title] AND "cervical ripening" [title] AND "induction of labor" [title] AND "hours" [title]) identified no randomized controlled trials of cervical ripening in less than 12 hours using either a single or double-balloon catheter, separately in nulliparous and parous women.

The double-balloon device is the customary technique in our department. We hypothesized that removal of this device after 6 hours compared with 12 hours, separately in nulliparous and parous women, will result in shorter time to delivery, without increasing cesarean delivery rate.

METHODS

This was a prospective randomized trial at our university-affiliated medical center. The study was approved by the local institutional review board (BNZ-0115-16) and is registered on ClinicalTrials.gov (ID–NCT03045939, available at: https://clinicaltrials.gov/ct2/show/NCT03045939, a full trial protocol can be accessed there). We recruited women who were having labor induction either electively or for medical or obstetric indications. All our physicians were defined as secondary investigators and could recruit these women. At admission, all women (regardless of whether they participated in the study or not) underwent a thorough assessment; including medical history, physical examination, and obstetric assessment (transabdominal ultrasound scan for fetal presentation, amniotic fluid volume, cervical length measurement by transvaginal ultrasound scan, and fetal wellbeing assessment using a nonstress test). Women were examined vaginally to define the Bishop score.

Women were eligible to participate in the study if they met the following inclusion criteria: age 18 years or older, Bishop score of 5 or less, singleton pregnancy with the fetus in a cephalic presentation, intact membranes, absence of painful and regular uterine contractions, and gestational age of 37 completed weeks or more. Women were excluded if they had a history of cesarean delivery, ruptured membranes, documented labor, fetal distress necessitating immediate intervention, known fetal malformations or genetic disorders, or any other contraindications for vaginal delivery.

A simple randomization sequence was generated by a computerized program (randomization.com) with a 1:1 allocation. Assignments were kept in sequentially numbered, opaque, sealed envelopes. Random allocation sequence remained concealed from those enrolling patients into the study. Allocation sequence was done separately for nulliparous and parous women. The envelopes were kept in a locked desk for investigators' access only. Randomization occurred after the patient signed informed consent for the study and catheter placement had to occur within 24 hours of randomization.

Women who were enrolled to the study and labored or had rupture of membranes before catheter placement were not included in the analysis. Allocation assignment was not fully blinded to the patient or the staff caring for the patient.

After signing an informed consent, women were randomized into two groups: double-balloon device removal after 6 hours (study group) compared with double-balloon device removal after 12 hours (control group) after its insertion.

The double-balloon device insertion procedure was carried out according to the manufacturer's instructions.[11] The device insertion was performed by the physician on call. The patient was placed in a lithotomy position, and a sterile speculum was inserted into her vagina until the cervix was visible. The exocervix and the vagina were irrigated with iodine solution. The double-balloon device was introduced into the cervical canal, and the internal balloon initially inflated to 40 mL of normal saline, followed by gentle traction downward to ensure proper placement of the device. Thereafter, the speculum was removed, the external balloon inflated to 40 mL, followed by further inflation of both balloons to a total of 80 mL in each.

In our institution, the double-balloon device is usually inserted during the evening, regardless of admission time.

After catheter insertion, the patient was monitored for 30 minutes in a maternity service separate from labor and delivery and allowed to rest. Oral analgesia was given on request. Patients were transferred to labor and delivery if oral analgesia provided insufficient pain relief, after the allocated time (6 or 12 hours) or if the catheter was spontaneously expelled. The catheter was removed if membrane rupture occurred.

After double-balloon device removal (or if spontaneously expelled before removal), a second Bishop score was recorded, artificial rupture of membranes performed, and oxytocin infusion was initiated according to our local protocol (10 international

units of oxytocin in 1,000 mL standard 3.3% solution, infusion of 10 mL/h, with 10 mL incrementation every 30 min until 3–5 regular painful contractions appear, maximal dose 120 mL/h). If artificial rupture of membranes was not possible (ie, floating fetal head), oxytocin alone was initiated. If the cervix was unfavorable after double-balloon device removal (Bishop score 5 or less), prostaglandins were administered.

Our primary outcome was time to delivery after double-balloon device insertion. Secondary outcomes included: cesarean delivery rate; indication for cesarean delivery; Bishop score after double-balloon device removal; delta Bishop score (difference between first and second Bishop scores); time to delivery after double-balloon device removal; duration of oxytocin infusion; maternal adverse outcomes (fever, postpartum hemorrhage; third and fourth degree perineal lacerations; hospitalization longer than 6 days) adverse neonatal outcomes (arterial cord pH less than 7, neonatal intensive care unit admission, 5-minute Apgar score less than 7); and maternal satisfaction based on a designed questionnaire. After the delivery and before discharge, women were given questions to evaluate their satisfaction (Appendix 1, available online at http://links.lww.com/AOG/B810). They were asked to rank from 1 to 5 their general satisfaction with the induction and delivery process, pain during insertion, and pain with the device in the cervical canal (1 being the lowest pain and 5 being the highest pain); and two "yes or no" questions: 1) would she do it again if necessary, and 2) would she recommend this process to her friend.

According to Salim et al[12], time to delivery when using a balloon device before labor induction was 19.1±6.8 hours. In their study, they included nulliparous and parous women in the same cohort, and more than 50% of their cohort was based on nulliparous women. Other studies used a time-to-delivery interval of roughly 24 hours.[13,14] To be more conservative, we used a mean time to delivery of 24 hours with an SD of 10 hours. We suggested a 6-hour decrease in the mean time to delivery from the device insertion. The 6-hour difference was assumed owing to the study design, which included a reduction of 6 hours between the protocol of the intervention. Sample size was calculated using a 95% CI, power of 80%, and mean decrease of 6 hours to delivery. Based on these calculations, we needed to recruit 100 nulliparous and 100 parous women, with half of each assigned to each study arm. After accounting for a possible 20% of lost to follow-up, we expected to recruit a total of 240 women.

Statistical analysis was performed with the SPSS 25.0 package. Continuous variables were compared using Student's T-test and Mann-Whitney *U* test. The χ^2 and Fisher exact tests were used for comparing categorical variables, as appropriate. Differences were considered significant with $P<.05$. For continuous outcomes, the effect size was the mean difference–presented with 95% Cis. For binary outcomes, odds ratios (ORs) were presented with 95% Cis. Time to delivery from double-balloon device insertion was compared between women who had a double-balloon device for 6 hours compared with 12 hours. Analysis was performed separately for nulliparous women and parous women. We did not do an intention-to-treat analysis because we excluded randomized women who did not get the catheter placed. The primary endpoint effect size was compared between nulliparous and parous women by using a two-way ANOVA with interaction term.

RESULTS

From March 2017 through February 2019, 688 women were screened and 243 women were eligible to participate in the study. Women who had spontaneous labor before double-balloon device insertion, withdrew their informed consent, or refused to adhere to the study protocol, were excluded from statistical analysis (n=46, Fig. 1). We analyzed the results of 101 nulliparous women (48 in the study group and 53 in the control group), and 96 parous women (49 in the study group and 47 in the control group). The analysis was done by original assigned groups.

Baseline characteristics are presented in Table 1. Table 2 represents the primary outcome. Time to delivery from double-balloon device insertion was shorter in the 6-hour group than in the 12-hour group for the nulliparous cohort (25.6±12.8 hours vs 31.4±15.2 hours, $P=.04$; mean difference 5.8 hours, 95% CI 0.2–11.3) and for the parous cohort (18.0±6.8 hours vs 22.6±8.2 hours, $P=.003$; mean difference 4.7 hours, 95% CI 1.6–7.7) (Table 2). There was no significant difference between nulliparous and parous effect size (interaction $P=.735$).

Secondary outcomes are presented in Table 3. We found that Bishop score change was similar between the 6-hour and the 12-hour groups in nulliparous and parous cohorts. Admission-to-delivery interval and removal-to-delivery interval were also similar between the groups (Table 3).

A total of 4 women had an unfavorable cervix after double-balloon device removal; all of them nulliparous, three from the 12-hour group and one

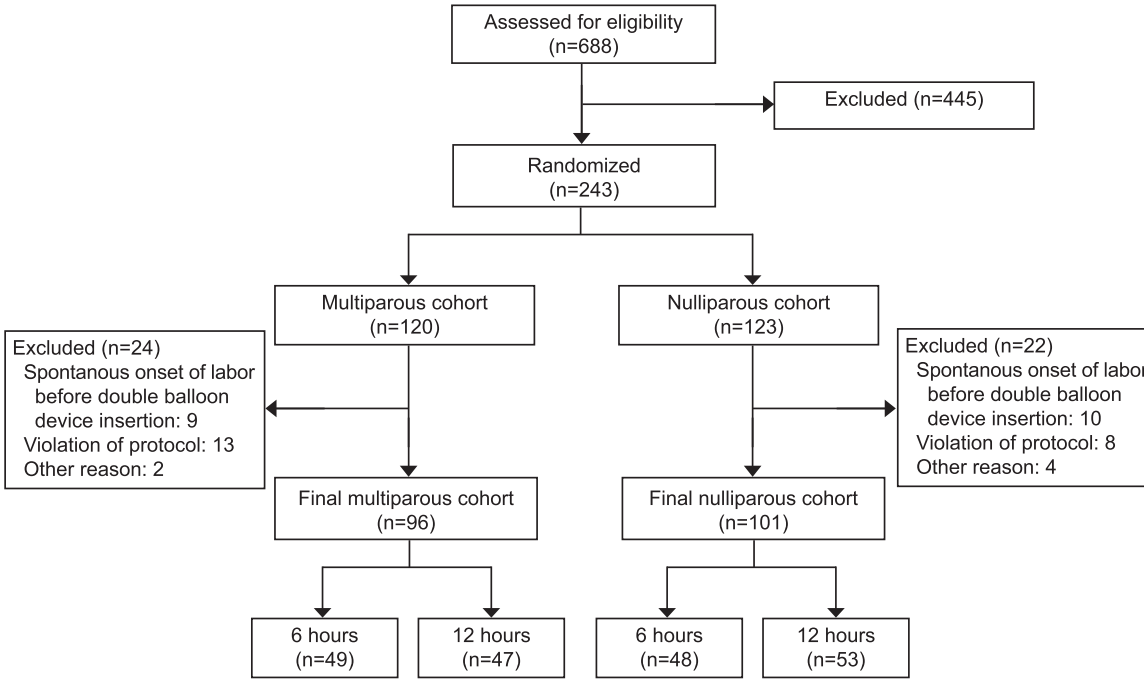

Fig. 1. Flowchart.

Bleicher. Double-Balloon Device for 6 or 12 Hours. Obstet Gynecol 2020.

Table 1. Baseline Characteristics: Nulliparous and Parous Women

	Nulliparous		Parous	
Patient Characteristics	**6 Hours (n=48)**	**12 Hours (n=53)**	**6 Hours (n=49)**	**12 Hours (n=47)**
Maternal age (y)	28.2±4.6	27.8±5.0	31.4±4.3	32.8±4.7
Gestational age at delivery (wk)	39.2±1.3	39.6±1.2	39.6±1.2	39.3±1.2
Cervical length at admission (mm)	29.0±5.9	28.0±7.7	31.7±7.4	34.0±7.6
Bishop 1*	2.5±1.6	2.2±1.5	2.5±1.1	2.7±1.3
Neonatal weight (g)	3,185±437	3,336±460	3,577±465	3,401±391
Prolonged pregnancy	13 (27)	21 (40)	22 (45)	17 (36)
Hypertensive disorders	3 (6)	2 (4)	5 (10)	3 (6)
Oligohydramnios	10 (20.8)	12 (22.6)	9 (18.4)	4 (8.5)
NRFHR	8 (17)	5 (9)	6 (12)	4 (9)
Fetal macrosomia	3 (6)	6 (11)	7 (14)	3 (6)
FGR	4 (8)	0 (0)	0 (0)	1 (2)
Cholestasis of pregnancy	2 (4)	2 (4)	0 (0)	3 (6)
Reduced fetal movements	8 (17)	4 (8)	6 (12)	14 (30)
Gestational diabetes	3 (6)	2 (4)	3 (6)	4 (9)
Other reasons	5 (10)	5 (9)	1 (2)	3 (6)
Analgesia with the DBD in situ†	29 (73)	24 (69)	19 (46)	20 (53)
Analgesia during labor	47 (98)	52 (98)	46 (94)	44 (94)
Epidural during labor‡	44 (94)	47 (90)	44 (96)	42 (96)
Difficulties at insertion	1 (2)	2 (4)	3 (6)	1 (2)

NRFHR, nonreassuring fetal heart rate; FGR, fetal growth restriction; DBD, double-balloon device.
Data are mean±SD or n (%).
* Bishop 1 is the Bishop score calculated on admission.
† Data were available for 75 of 101 women.
‡ Percentage of women who received analgesia during labor.

Table 2. Primary Outcome: Time to Delivery

Outcome	Nulliparous (n=101) 6 h (n=48)	12 h (n=53)	P	Effect Size (95% CI)	Parous (n=96) 6 h (n=49)	12 h (n=47)	P	Effect Size (95% CI)
Total balloon time (h)*	6.3±1.6	11.3±2.9	<.001	5.0 (4.1–5.9)	6.2±2.4	10.0±4.9	<.001	3.8 (2.2–5.3)
Insertion-to-delivery time (h)	25.6±12.8	31.4±15.2	.04	5.8 (0.2–11.3)	18.0±6.8	22.6±8.2	.004	4.7 (1.6–7.8)

Data are mean±SD unless otherwise specified. For continuous variables, the effect size is presented as the mean difference between the two study arms.

* For the 6-hour group: in nulliparous women, 6 of 48 women had the device for less than 6 hours owing to expulsion (between 2 and 4 hours); 9 of 48 women had the device for more than 6 hours owing to lack of vacancy in labor and delivery unit (6 women for 7 hours, 1 woman for 9 hours, 10 hours, 12 hours). In parous women, 12 of 49 women had the device for less than 6 hours owing to expulsion (1 woman up to 1 hour, 5 women for 2–4 hours, 6 women for 4–6 hours); 21 of 49 women had the device for more than 6 hours owing to lack of vacancy in the labor and delivery unit (12 women up to 1 hour, 7 women for 1–2 hours, 1 woman for 12 hours, 1 woman for 18 hours). For the 12-hour group: in nulliparous women, 12 of 53 women had the device for less than 12 hours owing to expulsion (1 woman for up to 1 hour, 2 women for 4 hours, 7 women for 6–8 hours, 2 women for 10–11 hours); 24 of 53 women had the device for more than 12 hours owing to lack of vacancy in the labor and delivery unit (15 women for up to 1 hour, 7 women for 1–2 hours, 2 women for more than 2 hours). In parous women, 25 of 47 women had the device for less than 12 hours (1 woman for up to 1 hour, 6 women for up to 4 hours, 4 women for 4–6 hours, 4 women for 6–8 hours, 3 women for 8–10 hours, 7 women for 10–12 hours); 17 of 47 women had the device for more than 12 hours owing to lack of vacancy in the labor and delivery unit (11 women up to 1 hour, 6 women up to 1–3 hours).

from the 6-hour group. They received prostaglandins as a second line cervical ripening agent.

Mode of delivery is presented in Table 4. No difference in cesarean delivery rate was observed between 6 hours or 12 hours in nulliparous and parous groups (19% vs 30%, *P*=.183; OR 1.9, 95% CI 0.7–4.7, 2% vs 9%, *P*=.199; OR 4.5, 95% CI 0.5–41.5, respectively). There were no differences in indications for cesarean delivery between the groups (Table 4).

Maternal and neonatal adverse outcomes are presented in Table 5. Maternal intrapartum fever was similar in nulliparous cohort and parous cohort, but analysis of the combined cohort (6 hours nulliparous and parous vs 12 hours nulliparous and parous) showed lower rates of maternal intrapartum fever (2% vs 10%, *P*=.02; OR 5.3, 95% CI 1.1–24.8) in the 6-hour group compared with the 12-hour group.

We did not find any difference regarding satisfaction between groups. Women were asked regarding their general satisfaction with the entire induction process and specifically about their delivery. Ninety

Table 3. Secondary Outcomes

Outcome	Nulliparous (n=101) 6 h (n=48)	12 h (n=53)	P	Effect Size (95% CI)	Parous (n=96) 6 h (n=49)	12 h (n=47)	P	Effect Size (95% CI)
Bishop 2	5.7±1.5	5.3±1.6	.291	−0.4 (−1.0 to 1.8)	5.3±1.3	5.6±1.3	.215	0.2 (−0.3 to 0.8)
Delta Bishop*	3.3±1.8	3.1±2.0	.432	−0.3 (−1.0 to 0.5)	2.8±1.7	2.9±1.6	.823	0.04 (−0.6 to 0.7)
Spontaneous expulsion	4 (8)	12 (23)	.059	0.3 (0.09–1.0)	11 (22)	21 (45)	.021	0.4 (0.2–0.9)
Removal-to-delivery time (h)	19.4±12.9	20.1±14.9	.897	0.8 (−4.8 to 6.3)	11.8±6.2	13.2±7.6	.521	−1.4 (−1.4 to 4.2)
Admission-to-insertion time (h)	14.7±10.4	10.7±5.4	.009	−3.9 (−7.2–0.7)	10.8±6.2	11.7±5.1	.273	9.6 (−1.4 to 3.3)
Admission-to-delivery time (h)	40.1±16.6	42.1±16.6	.434	1.9 (−4.7 to 8.4)	36.3±12.4	35.5±11.4	.720	−0.9 (−5.7 to 4.0)
ROM-to-delivery time (h)	11.6±6.9	11.4±7.2	.833	−0.1 (−2.9 to 2.6)	5.8±4.6	7.5±6.1	.200	1.8 (−0.4 to 3.9)
Total Pitocin time† (h)	15.4±7.1	14.3±7.1	.416	−1.2 (−4.1 to 1.8)	8.7±5.0	9.6±7.0	.878	−0.9 (−1.8 to 3.6)

ROM, rupture of membranes.

Data are mean±SD or n (%) unless otherwise specified. For continues variables, the effect size is presented as the mean difference between the two study arms. For categorical variables, the effect size is presented as odds ratio.

* Delta Bishop was defined as the difference between first and second Bishop scores.

† Pitocin time was calculated from first infusion until delivery.

Table 4. Delivery Mode and Indications for Cesarean Delivery

Outcome	Nulliparous (n=101)				Parous (n=96)			
	6 h (n=48)	12 h (n=53)	*P*	Effect Size (95% CI)	6 h (n=49)	12 h (n=47)	*P*	Effect Size (95% CI)
Cesarean delivery	9 (19)	16 (30)	.183	1.9 (0.7–4.7)	1 (2)	4 (9)	.199	4.5 (0.5–41.5)
Indication for cesarean delivery								
NRFHR	6 (67)	8 (50)	.677	0.3 (0.06–1.5)	1 (100)	3 (75)	1.000	5.3 (0.5–59.3)
NPL	2 (22)	4 (25)	1.000	1.5 (0.2–10.1)	0 (0)	0 (0)	1.000	NS
Other	1 (11)	4 (25)	.621	2.7 (0.3–28.4)	0 (0)	1 (25)	1.000	NS

NS, not significant; NRFHR, nonreassuring fetal heart rate; NPL, nonprogressive labor.
Data are n (%) unless otherwise specified. For categorical variables, the effect size is presented as odds ratio.

percent of women were pleased with the delivery (89% in the 6-hour group vs 91% in the 12-hour group; OR 1.4, 95% CI 0.5–3.7). Seventy-five percent of women in both groups described a bearable pain while the double-balloon device was inserted (OR 1.0, 95% CI 0.5–1.9), and 70% of women described a bearable pain with the double-balloon device in place (OR 1.3, 95% CI 0.6–2.5), with no difference between the 6-hour and 12-hour groups.

DISCUSSION

We found that removal of the double-balloon device 6 hours after its insertion resulted in: 1) shorter time-to-delivery interval, 2) similar Bishop score change, 3) decreased odds for intrapartum fever, and 4) similar cesarean delivery rate.

Based on the results of an English-language literature search of PubMed conducted on December 29, 2019 (using search terms {"double balloon device" [title] AND "cervical ripening" [title]) AND ("induction of labor" [title] AND "hours" [title])}, this is the first study to show a shorter time-to-delivery interval when placing a double-balloon device for less than 12 hours. Moreover, we showed a similar Bishop score change after double-balloon device removal in the 6-hour group compared with the 12-hour group. The fact that cervical ripening was accomplished within 6 hours (ie, 6 hours sooner than usual) is the main explanation for shorter time to delivery because the removal-to-delivery interval remained unchanged between all groups. Mitch et al (Mitch J et al. Am J Obstet Gynecol 2018;218:S245–6.) attempted to answer the same question when comparing double-balloon device placement for 6 compared with 12 hours. The data from this study are limited because only an abstract was available. According to their abstract, they included nulliparous and parous women in the same cohort, along with women with a prior cesarean delivery and could not show shorter time to delivery. Sherman et al[7] presented their experience with a Foley catheter for cervical ripening and demonstrated that the average time to spontaneous expulsion of the catheter was 6 hours.[7]

Removing the double-balloon device 6 hours after its insertion resulted in fewer cases of intrapartum fever. This might be explained by the fact that

Table 5. Maternal and Neonatal Outcomes in Nulliparous and Parous Women

Outcome	Nulliparous (n=101)				Parous (n=96)			
	6 h (n=48)	12 h (n=53)	*P*	Effect Size (95% CI)	6 h (n=49)	12 h (n=47)	*P*	Effect Size (95% CI)
Intrapartum fever	2 (4)	8 (15)	.096	4.1 (0.8–20.3)	0 (0)	2 (4)	.237	NS
Intrapartum antibiotics	6 (13)	12 (23)	.184	2.0 (0.7–6.0)	5 (10)	4 (9)	1.000	0.8 (0.2–3.3)
PPH	0 (0)	2 (4)	.496	NS	2 (4)	0 (0)	.495	NS
Hospital stay longer than 6 d	3 (6)	6 (11)	.493	1.9 (0.4–8.1)	0 (0)	2 (4)	.237	NS
5-min Apgar score less than 7	1 (2)	6 (11)	.115	0.7 (0.02–1.4)	0 (0)	1 (2)	.490	NS
NICU	2 (4)	3 (6)	1.000	1.4 (0.2–8.6)	0 (0)	1 (2)	.490	NS

NS, not significant; PPH, postpartum hemorrhage; NICU, neonatal intensive care unit.
Data are n (%) unless otherwise specified. For categorical variables, the effect size is presented as odds ratio.

the 12-hour group had a longer time to delivery, which is known to be associated with an increased rate of chorioamnionitis.[1,15,16] Furthermore, the presence of the double-balloon device in the cervix might act as a foreign body, which may also increase the risk of infection.[17]

When cesarean delivery rate was assessed in several studies[16,18] comparing different methods of cervical ripening, no differences were documented, regardless of which method was used. Although the cesarean delivery rate was similar between the groups in our study, longer time to delivery and higher rate of infection (as was seen in the 12-hour group) are risk factors for cesarean delivery.[1,15,16] Larger sample size is needed to confirm this speculation that cesarean delivery rate might be reduced when time from insertion to delivery is shortened (as in the 6-hour group).

Bishop score improvement can be achieved earlier than 12 hours, and time to delivery can be shortened without increasing adverse maternal and neonatal outcomes. This has a clinical effect on the management of cervical ripening and induction of labor regarding initiation time of the process, duration of the process, and its effect on maternal discomfort and infection rate.

We did not find a clinically or statistically significant difference among women regarding their satisfaction from the delivery. Maternal satisfaction and pain perception may be affected by various factors including: parity, expectations, age, psychological aspects, and more.[18] This should be taken into consideration when consulting women regarding induction of labor methods, and merits further studies.

If a favorable cervix can be achieved in 6 hours, it may influence the time of insertion and might shorten not only time to delivery from double-balloon device insertion, but also time to delivery from admission. That might also have an effect on women's satisfaction and admission costs. In our study, we could not show this because the double-balloon device was inserted during the late evening hours in both groups, so admission to delivery time was similar between the groups.

This study has some strengths. This was a prospective randomized trial that included both nulliparous and parous women. We evaluated nulliparous and parous women after calculating a power analysis for each group separately and we excluded women with a prior cesarean delivery.

This study has some limitations. The results cannot be generalized to use of a single-balloon catheter. Participants and study personnel were not blinded to ripening time. Additionally, we could not show a significant difference in cesarean delivery rate and women's satisfaction because it was not powered to show that as secondary outcomes. Lastly, we could not demonstrate a shorter time to delivery from admission because as part of our departmental protocol, we inserted all the devices late in the evening, which in some cases even prolonged admission-to-delivery interval.

Cervical ripening with a double-balloon catheter removal at 6 hours, rather than 12 hours, results in a shortened time from insertion to delivery interval without increasing maternal or neonatal outcomes. This was shown for both nulliparous and parous women. Decreasing dwell time to 6 hours for the double-balloon catheter should be considered an appropriate protocol.

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Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Individual requests will be considered.*

What data in particular will be shared? *Individual requests will be considered and discussed.*

What other documents will be available? *Individual requests will be considered and discussed.*

When will data be available (start and end dates)? *Beginning 1 month after publication ending 1 year after publication.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Data will be shared with researchers who provide a methodologically sound proposal, to achieve the aim of approved proposal. Each request should be sent to the primary author at innableicher@gmail.com. Individual link will be provided for a specific set of data on request after the majority of the authors approve.*

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