

CLINICAL ARTICLE

Obstetrics

Interval between balloon removal and oxytocin administration in cervical ripening with double-balloon in singleton pregnancies: An observational study

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Abstract

Objective: To analyze the influence of the resting interval after removal of a double-balloon for cervical ripening and oxytocin administration on the time to onset of active labor in singleton pregnancies.

Methods: A retrospective cohort study of women who required a cervical ripening with double-balloon was conducted between January 2019 and December 2022. We collected data for cervical ripening balloon insertion and removal, oxytocin administration, suspicious or pathological cardiotocographic trace, mode of delivery, maternal and neonatal complications, neonatal outcomes. Proportional hazards model comparing resting interval between double-balloon cervical ripening removal and oxytocin administration.

Results: A total of 403 singleton pregnancies were recruited and 213 pregnant women experienced a rest of 12h between cervical balloon removal and oxytocin administration (resting group). Oxytocin was administered immediately after balloon removal in 190 women (non-resting group). Median insertion-to-active labor interval and insertion-to-delivery interval were significantly shorter in the non-resting group: 18.5 versus 24.0h, HR 2.59 (CI 95%: 1.97–3.41) and 24.0 versus 29.0h, HR 2.38 (CI 95%: 1.85–3.05) respectively. Bishop score change and mode of delivery between were similar in both groups. No differences in maternal nor neonatal complications between both groups were found.

Conclusions: Oxytocin administration immediately after removal of a double-balloon for cervical ripening compared with 12h delayed interval resulted in a shortened time from insertion to active labor onset and to delivery interval without increasing maternal or neonatal adverse outcomes.

KEYWORDS

cervical balloon ripening, cervical ripening, delivery, resting time

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1 | INTRODUCTION

Around 25% of all deliveries at term involve induction of labor in the USA and Europe.^{1,2} Prior to labor induction, an evaluation of the cervical status is conducted. Should the cervical status be deemed unfavorable, a ripening process is typically employed before induction to reduce the duration of induction and enhance the probability of a vaginal delivery.

Methods of cervical ripening can be categorized into mechanical and pharmacological methods.³ Mechanical methods apply pressure from inside the cervical canal to promote dilation. The localized pressure stimulates the release of prostaglandins, which facilitate cervical remodeling. Recent clinical trials have been conducted to compare the effectiveness and safety of the double-balloon catheter with alternative methods, such as the Foley catheter,⁴ dinoprostone,⁵ and misoprostol,⁶ in order to ascertain its superiority. Although the outcomes have not yielded a definitive consensus, mechanical methods appear to reduce the risk of uterine hyperstimulation.⁷

Some groups have analyzed the time required to achieve effective cervical ripening with the use of the balloon,⁸⁻¹⁰ the subsequent administration of misoprostol^{7,11} and the possibility of outpatient¹² utilization when employing the balloon for cervical ripening. No studies analyzing the interval between balloon removal and oxytocin administration have so far been identified.

The double-balloon device is the standard technique used in our department for cervical ripening in pregnant women at high risk of uterine hyperstimulation (e.g., previous cesarean section, polyhydramnios, etc.). Traditionally in our center, patients are admitted for cervical ripening in the early morning. The device is removed in the late evening with the aim of improving maternal rest during the night and thus achieving a more physiological active labor onset. We hypothesize that removing the 12-h resting period after balloon withdrawal has no effect on the onset of active labor or the mode of delivery and reduces the length of hospital stay.

2 | MATERIALS AND METHODS

A retrospective analysis of all singleton pregnant women who required cervical ripening with a double-balloon in our center between January 2019 and December 2022 was conducted. The study was approved by the local institutional review board (CEID 4716/2023) of University of Murcia. Written informed consent for cervical ripening was obtained for all the participants. We enrolled women undergoing labor induction, either electively or for medical or obstetric reasons. Upon admission, a comprehensive evaluation was conducted, including medical history, physical examination, and obstetric assessment (transabdominal ultrasound scan to determine fetal presentation, amniotic fluid volume, and fetal well-being assessed using a cardiotocograph register). Vaginal examinations were performed to determine the Bishop score.

Women were considered eligible for the study if they met the following inclusion criteria: age 18 years or older, Bishop score of

5 or less, singleton pregnancy, cephalic presentation, intact membranes, absence of regular uterine contractions, and gestational age of 37 weeks or more. Women were excluded if they had ruptured membranes, documented labor, fetal distress necessitating immediate intervention, known fetal malformations or genetic disorders, or any other contraindications for vaginal delivery.

A double-balloon (Cook Medical) is used for cervical ripening in our center. The double-balloon device insertion procedure was carried out according to the manufacturer's instructions.¹³

The insertion of the device was performed by the attending obstetrician. The patient was positioned in lithotomy, and a sterile speculum was gently introduced into the vagina until the cervix became visible. Both the exocervix and the vagina were irrigated with an aqueous chlorhexidine solution. The double-balloon device was carefully placed into the uterine isthmus, and the internal balloon was initially inflated with 40 mL of sterile water, ensuring proper positioning by applying gentle downward traction. The speculum was subsequently removed, and the external balloon was inflated, followed by further inflation of both balloons to a total of 80 mL of sterile water in each balloon.

From January 2019 to June 2021, the double-balloon device was inserted in the morning (resting group). From July 2021 to December 2022, the double-balloon device was inserted in the evening (non-resting group). For both groups, the double-balloon was inserted for 12 h. From January 2019 to June 2021 (resting group), oxytocin administration began 12 h after balloon removal. From July 2021 to December 2022 (non-resting group), oxytocin was administered immediately after the balloon removal.

With the exception of the interval between balloon removal and oxytocin administration, the standard care protocol was the same for both groups. Following balloon insertion, patients were monitored for 30 min and allowed to rest. Analgesia was provided upon request. Subsequently, patients were transferred to the delivery room at 8.00 a.m. in the morning, either after the allocated time (resting or non-resting group) or if active labor initiated. The device was removed if membrane rupture occurred.

Following removal of the double-balloon device, a second Bishop score was recorded. Upon transfer to the delivery room, artificial rupture of membranes was performed, and oxytocin infusion was initiated according to our local protocol (10 international units of oxytocin in 500 mL saline solution, infused at a rate of 3 mL/h, with increments of 3 mL every 30 min until 3-5 regular painful contractions were achieved, with a maximum dose of 30 mL/h). If artificial rupture of membranes was not feasible (e.g., floating fetal head), just oxytocin was initiated.

Our primary outcome was time to active labor after double-balloon device insertion. Active labor is defined as cervical dilatation ≥ 6 cm and regular uterine contractions following the Consortium on Safe Labor statement.¹⁴ Failed induction was considered when active labor did not begin after 12 h of induction with regular uterine contractions and rupture of membranes. Arrest of labor was diagnosed if no progression of labor (cervical dilation or descent arrest) occurred within 4 h in a patient who began active labor. Secondary

outcomes included: operative delivery rate; cesarean delivery rate; indication for cesarean delivery; cardiotocographic (CTG) traces were compared following pathophysiological criteria;¹⁵ Bishop score before oxytocin administration; maximum oxytocin dose; maternal adverse outcomes (fever, mild postpartum hemorrhage solved with drugs, severe postpartum hemorrhage, perineal lacerations, hospitalization longer than 4 days) and adverse neonatal outcomes (arterial cord pH less than 7, neonatal intensive care unit admission, 5-min Apgar score less than 7).

Although the interval between device removal and oxytocin administration had not been previously analyzed, we considered a time-to-active labor onset interval of approximately 24 h based on reports from other research groups.^{8-10,12} The 12-h difference was assumed due to the study design, which involved a reduction of 12 h between the intervention protocols. The sample size was calculated using a 95% confidence interval (CI), 80% statistical power, and an expected mean decrease of 12 h in time to delivery. Based on these calculations, we needed to recruit 190 pregnant women in each group.¹⁶

Statistical analysis was performed with Stata/BE 17.0 (StataCorp., College Station, Texas USA). Normality and homoscedasticity were assessed for all continuous variables with the Shapiro–Wilk and Levene tests, respectively. Continuous variables were compared using student's *t*-test and Mann–Whitney U test. Proportions were compared using Pearson chi-squared test and Fisher correction when applied. Differences were considered statistically significant with *P* values less than 0.05. For continuous outcomes, the effect size was the mean presented with standard deviation (SD). For binary outcomes, odds ratios (ORs) are presented with 95% CIs. A survival analysis of neonatal brachial palsy recovery was performed and it was also adjusted by Cox regression. A survival analysis of time-to-active labor onset based on log-rank test was performed. Statistical adjustment was assured with a proportional hazards model including those variables with a *P* value below 0.2 in the bivariate analysis.

3 | RESULTS

From January 2019 through December 2022, 403 pregnant women were recruited. The double-balloon was removed 12 h before oxytocin administration in 213 (52.9%) women and the device was removed immediately before oxytocin administration in 190 (47.1%) pregnant women (Figure 1).

Baseline characteristics are presented in Table 1. Both groups are comparable except for previous cesarean section rate (71.8% vs 39.5%, *P* < 0.001). Other causes of cervical ripening included: large for gestational age, cholestasis, suspicious CTG trace, single umbilical artery at term and active maternal disease (Addison disease, Crohn disease, symptomatic pulmonary or mitral valvulopathy, paroxysmal supraventricular tachycardia, maternal thrombocytopenia).

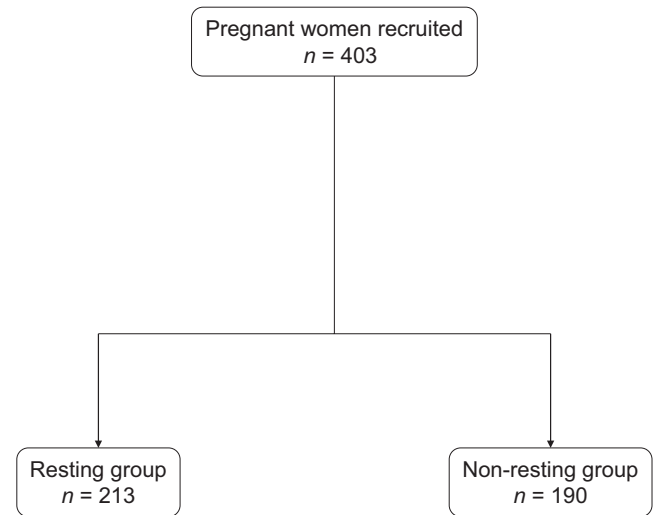


FIGURE 1 Flow chart.

Table 2 represents the primary outcome. Active labor was established on 159 (74.6%) pregnant women in the resting group and 142 (74.7%) in the non-resting group (*P* = 0.984). Time to active labor onset from balloon insertion was shorter in the non-resting group than in the resting group (18.5 vs 24 h, *P* < 0.001). When time-to-active labor onset was compared between both groups adjusting by gestational age, previous cesarean section, nulliparity and fetal growth restriction (Figure 2), this difference is also reported (adjusted hazard ratio 2.65, CI 95%: 1.97–3.56, *P* < 0.001).

Time to delivery from device insertion was shorter in the non-resting group than in the resting group (24.0 vs 29.0 h, *P* < 0.001). No differences were found when time-to-delivery was compared between both groups adjusted by gestational age, previous cesarean section, nulliparity and fetal growth restriction (Figure 3): adjusted hazard ratio 2.38, CI: 95%: 1.82–3.11, *P* < 0.001.

Secondary outcomes are reported in Table 3. However, we found that Bishop score change was higher in the resting group than in the non-resting group (7.0 vs 6.3, *P* = 0.036). Mode of delivery is presented in Table 3. No differences in the mode of delivery were observed, nor in indications for cesarean delivery between groups. No differences in suspicious or pathological CTG were reported (Table 4). Other indication for cesarean section included: seven cases of cephalopelvic disproportion, five transverse lies, four of cord prolapse, a case of uterine rupture, one abruptio placentae and one case of face presentation.

Neonatal admission rate is presented in Table 3. No neonate was admitted to the neonatal intensive care unit (NICU). Maternal adverse outcomes are presented in Table 5. No maternal fever during labor was reported. Although four cases (two in each group) of pathologic CTG trace compatible with fetal inflammatory response (an increase in baseline and absence of cycling) were reported, no chorioamnionitis, maternal or neonatal fever was observed. Maternal complications and cause of neonatal admission were similar in both groups.

TABLE 1 Baseline characteristics.

Variable	Resting group		Non-resting group		P value
	Mean/Count	SD/Frequency	Mean/Count	SD/Frequency	
Age, years	34.1	5.2	33.0	5.9	0.085
Gestational age, weeks	39.9	1.5	39.5	1.5	<0.001
Nulliparous	164	76.9%	122	64.2%	0.005
Previous cesarean section	153	71.8%	75	39.5%	<0.001
Post-term	91	42.7	59	31.1	0.719
FGR	39	18.3	65	34.2	0.016
Gestational diabetes mellitus	35	16.4	26	13.7	0.442
Bishop pre-balloon	2.1	1.4	2.0	1.2	0.537
Indication of labor					
Post-term	91	42.7%	59	31.1%	0.719
FGR	39	18.3%	65	34.2%	0.016
GDM	35	16.4%	26	13.7%	0.442
Oligoamnios	9	4.2%	14	7.4%	0.201
Gestational hypertension	8	3.8%	7	3.7%	>0.99
Pre-eclampsia	8	3.7%	2	1.1%	0.112
Other cause for induction	23	10.8%	17	8.9%	0.374

Abbreviations: FGR, fetal growth restriction; GDM, gestational diabetes mellitus; SD, standard deviation.

TABLE 2 Time to active labor onset and time to delivery.

Outcome	Resting group	Non-resting group	OR	CI 95%	P value	Adjusted OR ^a	CI 95%	P value
	Count (frequency)	Count (frequency)						
Active labor onset	158 (74.2%)	142 (74.7%)	1.03	0.66–1.61	0.898	0.81	0.50–1.32	0.404
Vaginal delivery	111 (52.1%)	108 (56.8%)	1.21	0.82–1.79	0.342	0.87	0.56–1.35	0.528
	Median (IQR)	Median (IQR)	HR	CI 95%	P value	Adjusted HR ^a	CI 95%	P value
Insertion-to-active labor onset time, hours	24 (16–27)	18.5 (15.5–21)	2.59	1.97–3.41	<0.001	2.65	1.97–3.56	<0.001
Insertion-to-delivery time, hours	29 (24–35)	24 (20–27.5)	2.38	1.85–3.05	<0.001	2.38	1.82–3.11	<0.001

Abbreviations: CI, confidence interval; IQR, interquartile range; OR, overall response.

^aAdjusted by gestational age, previous cesarean section, nulliparity and fetal growth restriction.

4 | DISCUSSION

4.1 | Main findings

This study analyzed the influence of the time interval between the removal of the double-balloon and the oxytocin administration. This is a novel topic since, as far as we are aware, no previous publication has reported this data. We found that sequential oxytocin administration immediately after device removal resulted in: (1) a shorter time-to-active labor onset, (2) shorter time-to-delivery interval, (3) similar delivery pattern and (4) similar perinatal outcomes.

When oxytocin is administered sequentially following the device removal, the time from insertion to the onset of the active phase of labor (18.5 vs 24h, adjusted hazard ratio 2.65, CI 95%: 1.97–3.56, $P < 0.001$) and time-to-delivery (24.0 vs 29.0h, adjusted hazard ratio 2.38, CI 95%: 1.82–3.11, $P < 0.001$) are significantly reduced. Neither the mode of delivery nor the obstetric or perinatal outcomes are altered.

To the best of our knowledge, no previous publications have analyzed the influence of the interval between device removal and oxytocin administration. Some authors have compared the duration during which the device is inserted.^{8,17} No differences have been

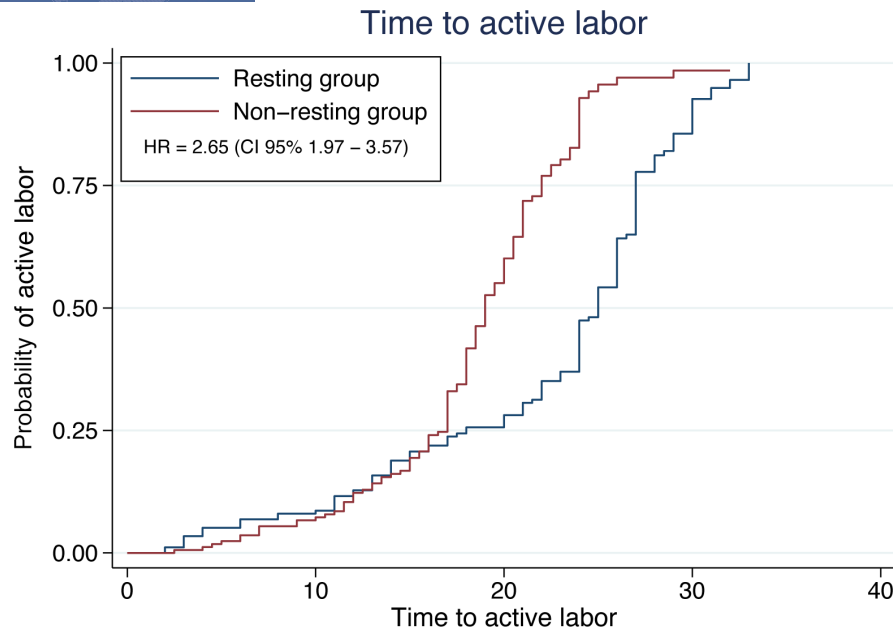


FIGURE 2 Kaplan–Meier chart showing proportional hazards model comparing time-to-active labor onset for immediately and delayed oxytocin administration adjusted by gestational age, previous cesarean section, nulliparity and fetal growth restriction.

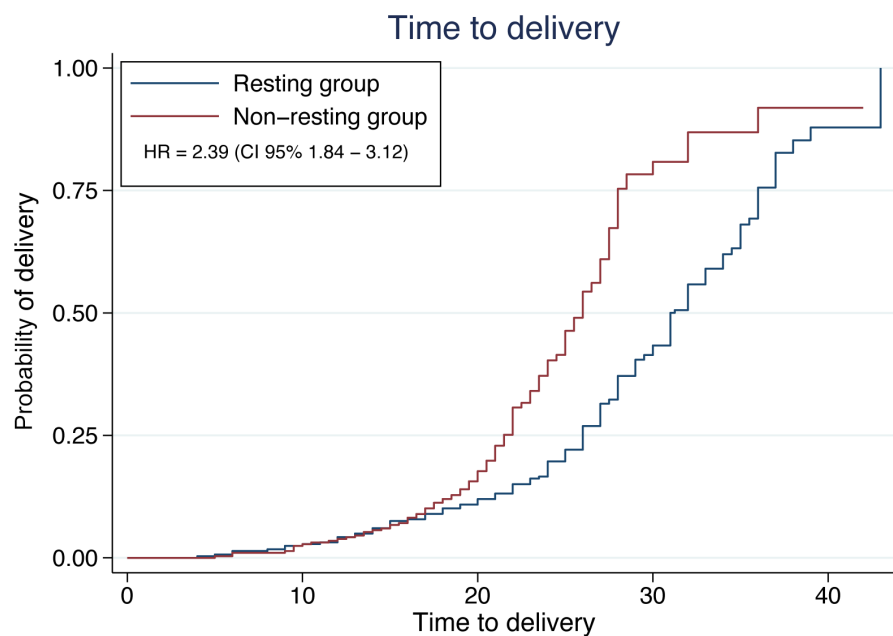


FIGURE 3 Kaplan–Meier chart showing proportional hazards model comparing time-to-delivery for immediately and delayed oxytocin administration adjusted by gestational age, previous cesarean section, nulliparity and fetal growth restriction.

reported when a double-balloon was inserted for 6 h compared with 12 h.⁸

Other authors compared the simultaneous or sequential oxytocin administration with double-balloon for cervical ripening.¹⁸ Bauer et al. proposed the simultaneous oxytocin administration with the double-balloon for cervical ripening in multiparous pregnant women.¹⁸ However, other randomized controlled trials found contradictory results and found no notable disparity in delivery occurring within 24 h or the duration between induction and delivery

among patients who received simultaneous oxytocin and cervical ripening balloon compared with sequential use.^{19–21}

4.2 | Strengths and limitations

This was a retrospective study with the inherent limitations of this type of research: limited external validity, temporal ambiguity, selection bias, and the potential influence of confounders. The baseline

TABLE 3 Secondary outcomes.

Outcome	Resting group		Non-resting group		OR	CI 95%	P value	Adjusted OR ^a	CI 95%	P value
	Mean/Count	SD/Frequency	Mean/Count	SD/Frequency						
Spontaneous delivery rate	80	37.6%	84	44.2%	1.32	0.88–1.96	0.175	0.94	0.59–1.49	0.784
Operative delivery rate	31	14.6%	24	12.6%	0.85	0.48–1.51	0.575	0.85	0.46–1.57	0.594
Cesarean delivery rate	102	47.9%	82	43.2%	0.83	0.55–1.22	0.341	1.15	0.74–1.80	0.528
Indication for CS										
Failed induction	42	41.1%	37	45.1%	1.16	0.64–2.08	0.631	1.20	0.63–2.28	0.586
Labor arrest	28	27.5%	22	26.8%	0.96	0.50–1.84	0.893	0.99	0.49–2.01	0.979
NRFHR Suspicious or pathological CTG	20	19.6%	12	14.6%	0.74	0.34–1.63	0.454	0.67	0.29–1.56	0.353
Other cause	12	11.7%	11	13.4%	1.15	0.48–2.76	0.756	1.22	0.43–3.42	0.711
Bishop preoxytocin	9.1	2.0	8.3	2.6			<0.001	0.32	0.19–0.52	<0.001
Bishop difference	7.0	2.2	6.3	2.7			0.036	0.39	0.22–0.67	0.001
Maximum oxytocin dose, mL/h	19.4	14.1	21.5	14.4			0.206	7.66	0.32–180.9	0.206
Arterial cord pH < 7	0	NA	1	0.5	NA					
1-min Apgar score < 7	5	2.3	2	1.1	0.333	0.08–2.3	0.333	0.38	0.07–2.25	0.289
5-min Apgar score < 7	0	NA	0	NA	NA					

Abbreviations: CTG, cardiotocographic; NA, not applicable; NRFHR, non-reassuring fetal heart rate.

^aAdjusted by gestational age, previous cesarean section, nulliparity and fetal growth restriction.

TABLE 4 Secondary outcomes. Cesarean section indicated for suspicious or pathological cardiotocographic analysis.

Suspicious or pathological CTG	Resting group		Non-resting group	
	Count	Frequency	Count	Frequency
Acute hypoxia	7	35%	3	25%
Subacute hypoxia	4	20%	2	16.7%
Gradually evolving hypoxia	7	35%	5	41.7%
Chronic hypoxia	2	20%	2	16.7%

Abbreviation: CTG, cardiotocographic.

TABLE 5 Adverse events and cause of neonatal admission.

Maternal adverse events	Resting group		Non-resting group	
	Count	Frequency	Count	Frequency
Fetal malposition	5	2.3%	1	0.5%
Mild postpartum hemorrhage	2	0.9%	3	1.6%
Severe postpartum hemorrhage	2	0.9%	0	
Dural puncture	2	0.9%	2	1.1%
Manual placental removal	2	0.9%	0	
Cord prolapse	1	0.5%	3	1.6%
Uterine rupture	1	0.5%	0	
Shoulder dystocia	1	0.5%	0	
Tachysystolia	1	0.5%	0	
Superficial venous thrombosis	0		1	0.5%
Neonatal admission	Count	Frequency	Count	Frequency
Hypoglycemia	1	0.5%	2	1.1%
Neonatal distress	1	0.5%	2	1.1%
Low weight	2	0.9%	1	0.5%
Malformations	1	0.5%	2	1.1%

revealed a selection bias in the proportion of previous cesarean section in the rest group (71.8% vs 39.5%, $P < 0.001$), growth delay (18.3% vs 34.2%, $P = 0.016$), and nulliparity (76.9 vs 64.2 weeks, $P = 0.005$). Despite this potential bias, the comparability of both groups was achieved by comparing all outcomes using a regression model that adjusts for these variables.

However, it should be noted that, to the best of our knowledge, this is the only study to have compared the influence of the time between double-balloon removal and oxytocin administration. The large population recruited make the results more robust. This was a single-center study with the same protocol that ensures the care homogeneity. Despite these strengths, all these results should be confirmed in further research.

4.3 | Interpretation

No benefit is observed when the oxytocin administration is delayed 12h after double-balloon removal. The sequential oxytocin administration immediately after device removal resulted in shorter

time-to-active labor onset, shorter time-to-delivery interval, similar delivery pattern and similar perinatal outcomes.

5 | CONCLUSION

In summary, oxytocin administration immediately after removal of a double-balloon for cervical ripening compared with 12h delayed interval resulted in a shortened time from insertion to active labor onset and to delivery interval without increasing maternal or neonatal adverse outcomes. Sequential oxytocin administration immediately after device removal appears to be a reasonable option for reducing admission time.

AUTHOR CONTRIBUTIONS

Javier Sánchez-Romero, José Eliseo Blanco-Carnero, Aníbal Nieto-Díaz and Judit Pérez-Buendía designed the study. Inmaculada Ruiz-Boluda, Almudena Juan-Pérez, Judit Pérez-Buendía and Mónica Motos-Garrido acquired the data. Javier Sánchez-Romero performed the data analysis. All authors participated in drafting and redaction of the manuscript and approved the final version.

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CONFLICT OF INTEREST STATEMENT

Javier Sánchez-Romero, José Eliseo Blanco-Carnero, and Aníbal Nieto-Díaz are affiliated with the University of Murcia. This institution has covered the expenses for open access publication.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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