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Clinical effects of Cook® cervical ripening balloon on promoting cervical dilation for early termination of pregnancy in high-risk parturients.

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Keywords: Cook® cervical ripening balloon; cervical dilation; high-risk parturient; termination of pregnancy.

Abstract. We aimed to evaluate the clinical effects of oxytocin, misoprostol, controlled-release dinoprostone suppository, and Cook® cervical ripening balloon on early termination of pregnancy in high-risk parturients. Four hundred high-risk full-term parturients not in labor who were unsuitable for awaiting delivery and treated from May 2018 to July 2020 were divided into groups I-IV with a random number table (n=100). They received labor induction by oxytocin, misoprostol, controlled-release dinoprostone suppository, and Cook® cervical ripening balloon, respectively. The general data, cervical ripening effect, delivery outcome, delivery time, adverse reactions, and neonatal conditions were compared. The time from the beginning of labor induction to labor and duration of the first, third, and total stages of labor were shorter in group II-IV than in group I ($p<0.05$). The incidence rates of excessive uterine contraction in groups II and III were higher than those of groups I and IV, and the incidence rates of fetal distress in groups I-III exceeded that of group IV ($p<0.05$). The neonatal Apgar scores of groups III and IV were higher than those of groups I and II ($p<0.05$). Cook® cervical ripening can promote cervical maturation and shorten the labor induction time and stage of labor.

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Efectos clínicos del balón de maduración cervical de Cook® sobre la dilatación cervical para la interrupción temprana del embarazo en las parturientas de riesgo alto.

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Palabras clave: balón de dilatación cervical COOK; maduracion cervical; parturientas de alto riesgo; interrupción del embarazo.

Resumen. Nuestro objetivo fue evaluar los efectos clínicos de la oxitocina, el misoprostol, el supositorio de dinoprostona de liberación controlada y el balón de maduración cervical de Cook® en la interrupción temprana del embarazo en parturientas de alto riesgo. Cuatrocientas parturientas a término de alto riesgo que no estaban en trabajo de parto y que no estaban aptas para esperar el parto y fueron tratadas desde mayo de 2018 hasta julio de 2020 se dividieron en grupos I-IV con una tabla de números aleatorios (n = 100). Recibieron inducción del trabajo de parto con oxitocina, misoprostol, supositorio de dinoprostona de liberación controlada y balón de maduración cervical de Cook®, respectivamente. Se compararon los datos generales, efecto de maduración cervical, resultado del parto, tiempo de parto, reacciones adversas y condiciones neonatales. El tiempo desde el inicio de la inducción del trabajo de parto hasta el parto y la duración de la primera etapa, tercera etapa y etapa total del trabajo de parto fueron más cortos en el grupo II-IV que en el grupo I ($p<0,05$). Las tasas de incidencia de contracción uterina excesiva en el grupo II y III fueron más altas que las del grupo I y IV, y las tasas de incidencia de sufrimiento fetal en el grupo I-III excedieron las del grupo IV ($p<0,05$). Las puntuaciones de Apgar neonatal del grupo III y IV fueron más altas que las del grupo I y II ($p<0,05$). El globo de maduración cervical de Cook® puede promover la maduración cervical, acortar el tiempo de inducción del parto y las etapas del parto.

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INTRODUCTION

Social development and lifestyle changes have made high-risk complications more commonly seen, such as gestational hypertension, diabetes, oligohydramnios, and prolonged pregnancy, which may endanger maternal and infant health. Induction of labor serves as a frequently used clinical method for managing high-risk pregnancies. It involves the adoption of manual interventions to stimulate uterine contractions and assist in early vaginal delivery before natural labor starts. Clinical experience has shown that the success of induced labor is closely correlated with the degree of cervical maturity and that induction of labor when the cervix is immature can lead to a prolonged labor process, fetal distress, and even failed induced labor, significantly increasing the risk of cesarean section in parturients [1]. According to the data, the failure rate of induced labor is

increased by six times, and the risk rate of cesarean section can be increased twice in parturients whose cervical Bishop score is below 3 points compared with those in parturients with a cervical Bishop score above 3 points, revealing that promoting cervical maturation is necessary for successful induced labor and natural delivery of parturients [2]. Currently, there are several clinical approaches to promote cervical maturation and induction of labor. Although there is extensive clinical experience in medication methods, individual differences make it challenging to fully guarantee efficacy and safety [3]. The Cook® cervical ripening balloon has been widely applied in clinical practice abroad, but it is still in the promotion stage in China. It certainly causes no adverse reactions and can stimulate the cervix mechanically and generate pressure, thereby promoting cervical maturation and inducing labor [4]. However, there has been no optimal plan yet. Therefore, 400 high-risk full-term parturients not in labor who were not suitable for awaiting delivery and treated in our hospital were selected in this study, and the clinical effects of oxytocin, misoprostol, controlled-release dinoprostone suppository, and Cook® cervical ripening balloon were explored, aiming to provide a solid basis to clinical application.

MATERIAL AND METHODS

General data

Four hundred high-risk full-term parturients not in labor who were unsuitable for awaiting delivery and treated in our hospital from May 2018 to July 2020 were selected and divided into groups I-IV (n=100) using a random number table. Inclusion criteria were as follows: 1) primiparae aged 20-35 years old, 2) those with singleton pregnancy in cephalic presentation and gestational age of 37-42 weeks, 3) those without contraindications to induced labor and vaginal trial labor, 4) those with a cervical Bishop score <6 points, 5) those with indications for induced labor in the third trimester, including gestational diabetes mellitus, gestational hypertension and intrahepatic cholestasis of pregnancy, and those with oligohydramnios, delayed pregnancy and fetal growth restriction that could be tolerated, 6) those with complete clinical examination data, and 7) those whom or whose families signed the informed consent. Exclusion criteria were as follows: 1) parturients complicated with severe dysfunction of the heart, liver, or kidney, 2) those unable to cooperate in the study due to mental disorders, or 3) those with bleeding in the third trimester or a history of uterine surgery. This study was reviewed and approved by our hospital's Medical Ethics Committee.

METHODS

All parturients underwent detailed prenatal examinations, the vital signs of parturients and fetuses were monitored in real-time, and prenatal guidance and psychological comfort were given.

Oxytocin (NMPN: H31020850, Shanghai Harvest Pharmaceutical Co., Ltd.) was given to group I. 2.5 U of oxytocin added into 500 mL of normal saline was intravenously infused at 8 drops/min at first. The infusion speed was adjusted if no uterine contraction occurred, 40 drops/min at most. Intravenous infusion lasted 8-12 h a day until effective uterine contraction occurred, *i.e.,* uterine contraction three times within 10 min, more than 30 s per time. Cervical Bishop score was given to the parturients still not in labor after infusion with 2.5 U of oxytocin or regular uterine contraction for more than 6-8 h. Those with a cervical Bishop score <6 points continued to receive labor induction by oxytocin in the same way the next day. Those with a cervical Bishop score ≥6 points continued to receive labor induction by oxytocin if there was no effective uterine contraction with normal amniotic fluid one hour after the artificial rupture of the fetal membrane. If the parturients still failed to

enter the stage of labor at 3 d, the induced labor was deemed a failure, and they were converted to cesarean delivery.

Misoprostol (NMPN: H20000668, Beijing Zizhu Pharmaceutical Co., Ltd.) was applied to group II. After routine vaginal and vulvar sterilization, 25 μg of misoprostol was placed at the posterior fornix of the vagina, and the parturients were instructed to rest in bed. After 30 min, the uterine contraction was observed, and the fetal heart rate was monitored. If there was still no uterine contraction after six hours, misoprostol was applied once again, and the total dose was 50 μg at most within 24 h. Once persistent uterine contractions occurred, misoprostol was immediately taken out. The fetal membrane was artificially ruptured for the parturients with a cervical Bishop score >6 points. Oxytocin was also used if there was no effective uterine contraction with normal amniotic fluid after one hour. If the parturients still failed to give birth at 3 d, induced labor was considered a failure, and they were converted to cesarean delivery.

A controlled-release dinoprostone suppository (trade name: Propess, model MA09P01B, CTS, UK) was used in group III. After routine vaginal and vulvar sterilization, one 0.8 mm controlled-release dinoprostone suppository was placed at the posterior fornix of the vagina and rotated 90°, and the termination tape was rolled up and packed into the vaginal orifice. Then, the participants were instructed to rest in bed for 30 minutes, during which the fetal heart rate was monitored. If indications for labor were found, and uterine tetanic contraction or hyperstimulation, fetal distress, rupture of membranes, tachycardia, hypotension, nausea, and vomiting, or other severe adverse reactions occurred, the controlled-release dinoprostone suppository was taken out, and its placement time was 12 hours at most. The fetal membrane was artificially ruptured for the parturients with a cervical Bishop score >6 points. Oxytocin was also used if there was no effective uterine contraction with normal amniotic fluid after one hour. If the parturients still failed to give birth at 3 d, induced labor was considered a failure, and they were converted to cesarean delivery.

The Cook® cervical ripening balloon (model J-CRB-184000, Cook, USA) was used in group IV. After it was confirmed that related examination results were normal and the oxytocin challenge test result was negative, the bladder was emptied, the parturients lay in a lithotomy position, the vulva, vagina, and cervix were sterilized, and a speculum was placed to expose the cervix fully. Then, the Cook® cervical ripening balloon was placed into the uterine cavity, with both balloons entering the cervical canal. 40 mL of normal saline was injected from the red tube marked by U to fill the uterine balloon. The uterine balloon was pulled backward to make it cling closely to the cervix. Besides, 20 mL of normal saline was injected from the green tube marked by V to fill the vaginal balloon in the outer cervix. After that, the speculum was withdrawn, the balloons were placed on both sides of the cervix, and normal saline (80 mL at most) was injected into each balloon. The tail end of the balloon was fixed on the inner thigh, followed by timing. The uterine contraction and fetal heart rate were monitored. When there was vaginal discharge or persistent uterine contraction, the balloon was withdrawn, or it was removed after 12 h. The fetal membrane was artificially ruptured for the parturients with a cervical Bishop score >6 points, and the uterine contraction and character of amniotic fluid were closely monitored. If there was no effective uterine contraction with normal amniotic fluid after one hour, oxytocin was used until the uterine orifice opened 3 cm. The parturients with a cervical Bishop score <6 points continued to receive labor induction by oxytocin. If they still failed to enter the stage of labor at 3 d, the induced labor was deemed a failure, and they were converted to cesarean delivery.

Observation indices

The basic data of parturients, cervical ripening effect, delivery outcome, delivery time, adverse reactions, neonatal Apgar score, and body weight in each group were recorded.

Before and at 12 h after intervention in induced labor, the cervical ripening effect was assessed according to the cervical Bishop score, including five indices (position of uterine orifice, the openness of uterine orifice, cervical stiffness, cervical canal regression, and presentation position). The total score is 13 points, in which 10-13 points, 7-9 points, 4-6 points, and 0-3 points indicate a success rate of spontaneous labor of nearly 100%, 80%, about 50%, and failure of artificial rupture of fetal membrane, respectively. The effectiveness evaluation criteria were markedly effective: in labor or an increase in the cervical Bishop score by 3 points or more. Effective: an increase in the cervical Bishop score by 2 points. Ineffective: an increase in the cervical Bishop score by less than 2 points. Total effective rate = (markedly effective cases + effective cases)/total cases × 100%.

Neonatal Apgar score was given at 5 min after birth. Regarding skin color, redness of systemic skin and mucosa, redness of body and blue-violet color of four limbs, and blue-violet or pale color of the whole body were scored 2 points, 1 point, and 0 point, respectively. Regarding heart rate, >100 beats/min, <100 beats/min, and no heartbeat after birth were scored 2 points, 1 point, and 0 point, respectively. Regarding response, 2 points, 1 point, and 0 points were given to normal response after birth, slight movement, and no response, respectively. As for muscular tension, 2 points, 1 point, and 0 points were given to free movement of four limbs, slight flexion of four limbs, and low muscular tension, respectively. As for breathing, regular breathing after birth, slow and irregular breathing, and no breathing were scored 2 points, 1 point, and 0 points, respectively. The total scores of 8-10 points, 4-7 points, and 1-3 points indicated normal condition, mild asphyxia, and severe asphyxia, respectively.

Statistical analysis

IBM® SPSS 16.0 software was used for statistical analysis. Numerical data were expressed as n (%) and compared among groups by the chi-square (χ^2) test. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$) and compared among groups by one-way variance analysis and between two groups by independent *t*-test in the case of statistical significance. $p<0.05$ suggested that the difference was statistically significant.

RESULTS

Baseline clinical data of parturients

There were no significant differences in the parturients' age, gestational age, BMI, cervical Bishop score before the intervention, and indications for induced labor among groups ($p>0.05$) (Table 1).

Cervical ripening effects

No significant differences were found in the cervical Bishop score and total effective rate of cervical ripening between group I and group II and between groups III and IV ($p>0.05$). The cervical Bishop score and total effective rate of cervical ripening in group III and group IV were higher than those in groups I and II ($p<0.05$) (Table 2).

Delivery outcomes

There was no significant difference in the delivery mode between group I and group II and between groups III and IV ($p>0.05$), but the spontaneous labor rate in group III and group IV was higher than that in group I and group II ($p<0.05$). The postpartum blood loss was not significantly different among group I, group II, and group III ($p>0.05$), but it was more significant than that in group IV ($p<0.05$) (Table 3).

Table 1
Baseline clinical data of parturients.

ouGrop	n	Age (year, $\bar{x} \pm s$)	Gestational age (week, $\bar{x} \pm s$)	BMI (kg/m^2, $\bar{x} \pm s$)	Cervical Bishop score (point, $\bar{x} \pm s$)	Indication for induced labor [n (%)]			
						Prolonged pregnancy	Oligohy-dramnios	Gestational diabetes mellitus	Gestational hypertension
Group oup I	100	28.55±4.05	39.55±1.71	28.57±2.86	2.96±1.43	43 (43.00)	34 (34.00)	16 (16.00)	7 (7.00)
Group II	100	27.56±3.41	39.48±1.79	29.11±2.83	2.85±1.40	39 (39.00)	36 (36.00)	15 (15.00)	10 (10.00)
Group III	100	28.25±3.17	39.51±1.66	28.92±2.93	3.12±1.46	42 (42.00)	35 (35.00)	15 (15.00)	8 (8.00)
Group IV	100	28.21±3.49	39.51±1.76	28.42±3.02	2.76±1.33	40 (40.00)	38 (38.00)	16 (16.00)	6 (6.00)
F/χ2		0.819	0.263	1.294	1.586	1.682			
P		0.354	0.708	0.116	0.215	0.996			

The count data were expressed as n (%), and compared among multiple groups by the chi-square (χ^2) test. The measurement data were expressed as mean ± standard deviation ($\bar{x} \pm SD$) and compared among multiple groups by one-way analysis of variance (F value). p values indicated the differences among multiple groups.

Table 2
Cervical ripening effects.

Group	n	Cervical Bishop score (point, $\bar{x} \pm s$)	Cervical ripening effect [n (%)]			Total effective rate (%)
			Markedly effective	Effective	Ineffective	
Group I	100	5.36±1.67	29 (29.00)	36 (36.00)	35 (35.00)	65.00
Group II	100	5.54±1.71	32 (32.00)	35 (35.00)	33 (33.00)	67.00
Group III	100	6.79±1.49ab	53 (53.00)	34 (34.00)	13 (13.00)	87.00ab
Group IV	100	6.85±1.74ab	57 (57.00)	35 (35.00)	8 (8.00)	92.00ab
F/χ^2		5.672	39.862			32.761
p		<0.001	<0.001			<0.001

The count data were expressed as n (%), and compared among multiple groups by the chi-square (χ^2) test. The measurement data were expressed as mean ± standard deviation ($\bar{x} \pm SD$) and compared among multiple groups by one-way analysis of variance (F value). [a] $p<0.05$ *vs.* group I, [b] $p<0.05$ *vs.* group II.

Table 3
Delivery outcomes.

Group	n	Delivery mode [n (%)]		Postpartum blood loss (mL, $\bar{x} \pm s$)
		Spontaneous labor	Cesarean delivery	
Group I	100	63 (63.00)	37 (37.00)	236.85±24.71
Group II	100	66 (66.00)	34 (34.00)	232.49±23.59
Group III	100	85 (85.00)[ab]	15 (15.00)[ab]	238.74±24.62
Group IV	100	90 (90.00)[ab]	10 (10.00)[ab]	205.53±18.47[abc]
F/χ^2		29.934		8.317
p		<0.001		<0.001

The count data were expressed as n (%), and compared among multiple groups by the chi-square (χ^2) test. The measurement data were expressed as mean ± standard deviation ($\bar{x} \pm SD$) and compared among multiple groups by one-way analysis of variance (F value). [a] $p<0.05$ *vs.* group I, [b] $p<0.05$ *vs.* group II, [c] $p<0.05$ *vs.* group III.

Delivery time

There was no significant difference in the duration of the second stage of labor among groups ($p>0.05$). The time from the beginning of labor induction to labor and the duration of the first, third, and total stage of labor had no significant differences among group II, group III, and group IV ($p>0.05$), but they were all shorter than those in group I ($p<0.05$) (Table 4).

Adverse reactions

The incidence rates of amniotic fluid pollution, laceration of the birth canal, intrauterine infection, and postpartum hemorrhage had no significant differences among groups ($p>0.05$). Group II and Group III had a higher incidence rate of excessive uterine contraction than Group I and Group IV, and Group I, Group II, and Group III had a higher incidence rate of fetal distress than Group IV ($p<0.05$) (Table 5).

Neonatal conditions

There was no significant difference in the neonatal birth weight among groups ($p>0.05$). The neonatal Apgar score was higher in Group III and Group IV than that in Groups I and II ($p<0.05$) (Table 6).

DISCUSSION

The degree of cervical maturity is a critical factor in determining the success of induced labor. According to data, induced labor can be successful among parturients with a cervical Bishop score ≥9 points, while the success rate of induced labor is only 20% among those with a cervical Bishop score of <6 points, so measures of cervical ripening need to be taken[5]. Currently, the commonly used cervical ripening and labor induction methods include medication (oxytocin, misoprostol, and controlled-release dinoprostone suppository) and mechanical methods (Cook® cervical ripening balloon). Daykan *et al.* [6] found that the total effective rate of cervical ripening by Propess was significantly higher than that by misoprostol and oxytocin. The success rate of cervical ripening by the Cook® cervical ripening balloon is far higher than that produced by a low-dose intravenous infusion of oxytocin [7]. Herein, the cervical ripening effect was compared among four commonly used methods of labor induction, and the conclusions were consistent with the above reports. Oxytocin is a commonly used traditional drug for induced labor, and it mainly acts on the receptors in

Table 4
Delivery time.

Group	n	Time from beginning of labor induction to labor (h, $\bar{x} \pm s$)	First stage of labor (h, $\bar{x} \pm s$)	Second stage of labor (h, $\bar{x} \pm s$)	Third stage of labor (h, $\bar{x} \pm s$)	Total stage of labor (h, $\bar{x} \pm s$)
Group I	63	15.41±3.76	9.52±2.37	0.42±0.15	0.20±0.07	10.34±1.09
Group II	66	12.11±2.95[a]	5.30±1.44[a]	0.40±0.13	0.16±0.05[a]	5.92±0.96[a]
Group IIII	85	12.04±2.22[a]	5.17±1.54[a]	0.41±0.12	0.15±0.07[a]	5.90±1.05[a]
Group IV	90	11.41±2.90[a]	5.18±1.36[a]	0.39±0.15	0.15±0.06[a]	5.83±1.09[a]
F		7.326	14.238	1.324	4.753	23.542
P		<0.001	<0.001	0.169	<0.001	<0.001

The measurement data were expressed as mean ± standard deviation ($\bar{x}$ ± SD) and compared among multiple groups by one-way analysis of variance (F value). [a] P<0.05 *vs.* group I.

Table 5
Adverse reactions.

Group	n	Amniotic fluid pollution [n (%)]	Excessive uterine contraction [n (%)]	Laceration of birth canal [n (%)]	Intrauterine infection [n (%)]	Fetal distress [n (%)]	Postpartum hemorrhage [n (%)]
Group I	100	4 (40.00)	2 (2.00)	8 (8.00)	2 (2.00)	14 (3.00)	3 (3.00)
Group II	100	11 (11.00)	11 (11.00)[a]	7 (7.00)	3 (3.00)	18 (18.00)	3 (3.00)
Group III	100	10 (10.00)	12 (12.00)[a]	9 (9.00)	3 (3.00)	13 (5.00)	4 (4.00)
Group IV	100	6 (6.00)	1 (1.00)[bc]	5 (5.00)	4 (4.00)	2 (2.00)[abc]	2 (2.00)
χ^2		4.581	16.619	1.301	0.687	13.574	0.687
p		0.205	0.001	0.729	0.876	0.004	0.876

The count data were expressed as n (%), and compared among multiple groups by the chi-square (χ^2) test. [a] p<0.05 *vs.* group I, [b] p<0.05 *vs.* group II, [c] p<0.05 *vs.* group III.

Table 6
Neonatal conditions

Group	n	Neonatal Apgar score (point, $\bar{x} \pm s$)	Birth weight (g, $\bar{x} \pm s$)
Group I	100	8.99±0.19	3299.28±239.10
Group II	100	9.02±0.18	3315.37±242.96
Group III	100	9.35±0.20[ab]	3286.35±231.89
Group IV	100	9.40±0.23[ab]	3336.34±231.10
F		7.618	1.328
p		<0.001	0.125

The measurement data were expressed as mean ± standard deviation ($\bar{x}$ ± SD) and compared among multiple groups by one-way analysis of variance (F value). [a] p<0.05 *vs.* group I, [b] p<0.05 *vs.* group II.

decidual cells to promote the synthesis and release of prostaglandins, stimulating and exciting the uterine smooth muscle and inducing uterine contraction. However, its receptors are widely distributed in the uterus but less distributed in the cervix, leading to a limited effect. Misoprostol, as a prostaglandin E1 preparation, enhances the effective softening of uterine fibrous tissues and the degradation of collagen fibrin by promoting the release of a variety of proteases by cervical connective tissues, thereby inducing uterine smooth muscle contraction, cervical dilation, and uterine muscle excitement. However, it is difficult to control its dosage, and the inaccurate dosage can not only harm cervical ripening but also cause a series of adverse reactions. In this study, the spontaneous labor rate in the four groups was in accord with the view that the degree of cervical maturity determines the success of labor induction and also consistent with multiple early reports [8].

The labor time and duration of the stage of labor of parturients in the balloon group were significantly shortened compared with those of the oxytocin group [9]. In a retrospective controlled study, the time from drug or balloon placement to labor and the duration of the total stage of labor in the dinoprostone suppository group was evidently shorter than those in the balloon group [10]. In this study, the results did not fully agree with the above reports. The reason is that the delivery time was compared among participants receiving successful labor induction so the results may be incompletely consistent due to differences in sample size and research methods. However, it is recognized clinically that labor induction with oxytocin has a low success rate and a long stage of labor.

In addition to the cervical ripening effect and the success rate of labor induction, maternal-infant safety cannot be ignored. The ideal methods of cervical ripening and labor induction should cause no excessive uterine contraction and damage to maternal health and lead to no adverse reactions in infants, such as organ damage and respiratory depression. It has been reported early that the overall safety of full-term parturients using oxytocin is not high, and they often suffer from complications such as cervical edema, intrauterine fetal distress, and neonatal asphyxia [11]. The application of misoprostol in the vagina has a specific risk of causing excessive uterine contraction, meconium-stained amniotic fluid, abnormal fetal heart rate, emergency cesarean section, postpartum hemorrhage, and neonatal asphyxia[12]. Dinoprostone suppository can result in persistent and uterine solid contraction, so magnesium sulfate needs to be used to inhibit uterine contraction and fetal distress can be caused in severe cases, in which case parturients need to be converted to emergency cesarean section [13]. In this study, the misoprostol and controlled-release dinoprostone suppository used in groups II and III were prostaglandin E1 and E2 preparations, respectively. Multiple studies in China and foreign countries have revealed that the more severe adverse reaction caused by prostaglandins in labor induction is uterine hyperstimulation, and fetal distress may even occur. In group I, oxytocin was used for a long time, and uterine inertia also lasted for an extended period, thus increasing the incidence of fetal distress. In group IV, the Cook® cervical ripening balloon had small and mild stimulation, significantly reducing uterine hyperstimulation, and it can even be applied in the scarred uterus. As a result, Groups II and III had a higher incidence rate of excessive uterine contraction than Group I and Group IV, and Group I, Group II, and Group III had a higher incidence rate of fetal distress and a more considerable postpartum blood loss than Group IV. Moreover, the neonatal Apgar score was higher in Groups III and IV than in Groups I and II, and the possible reason is closely related to the short stage of labor in Groups III and IV.

Regardless, this study is limited. This is a single-center study with a small sample

size. Further multicenter studies with more cases are needed to confirm our findings.

In conclusion, Cook® cervical ripening balloons can exert an excellent effect, shorten the duration of induced labor and stage of labor, raise the spontaneous labor rate, and reduce adverse maternal-infant outcomes, worthy of clinical popularization and application. In clinical practice, however, it is still necessary to first check the specific position of the placenta by ultrasound and determine whether there is placenta previa or low-lying placenta in parturients. The balloon should be placed into the uterine cavity in the contralateral direction of the placenta to avoid placental abruption. The balloon should not be placed for more than 12 hours, and corresponding measures should be taken later according to the specific situation.

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Conflicts of interest

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Authors' contribution

XH, JC designed this study and significantly revised the manuscript; WD, YL performed this study and wrote the manuscript.

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