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ORIGINAL RESEARCH

Double Balloon Combined with Oxytocin in Labor Induction: Analysis of Multivariate Factors Affecting the Efficacy of Cervical Ripening

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Objective: Labor induction during the late trimester of pregnancy is a common option of terminating pregnancy by inducing uterine contractions through medication or cervical mechanical dilation. However, there are few researches on the factors influencing the effectiveness of cervical ripening balloon combined with oxytocin in inducing labor. To explore factors affecting the efficacy of cervical ripening double balloon combined with oxytocin in labor induction.

Methods: Using a convenient sampling method, this study retrospectively collected the clinical data of 230 pregnant women who underwent cervical ripening double balloon combined with oxytocin for labor induction in our hospital from September 2021 to August 2022. The included subjects were divided into a vaginal delivery group (n = 180) and a cesarean section group (n = 50) based on the delivery mode for comparing relevant indicators between the two groups.

Results: The presence of acute chorioamnionitis (*OR* = 1.456, *95% CI*: 1.257–2.112), fetal distress (*OR* = 1.371, *95% CI*: 1.331–2.633), and the placement of cervical ripening balloon catheter for >12h (*OR* = 1.563, *95% CI*: 1.231–3.263) were risk factors for successful application of cervical ripening double balloon combined with oxytocin for labor induction in pregnant women; while multi-gravidity (*OR* = 0.736, *95% CI*: 0.455–0.875) was a protective factor. In addition, evaluation of the predictive value revealed that acute chorioamnionitis, fetal distress, the placement of cervical ripening balloon catheter for >12h, and gravidity all had certain predictive value for the failure of cervical ripening double balloon combined with oxytocin for labor induction, with the highest predictive value found through joint predictive (AUC: 0.931, 95% CI: 0.714–0.811).

Conclusion: Cervical ripening double balloon combined with oxytocin for labor induction may have a high success rate in multigravida. Acute chorioamnionitis, fetal distress, and prolonged placement of the balloon may have a negative impact on the success rate of cervical ripening double balloon combined with oxytocin for labor induction.

Keywords: cervical ripening balloon, cervical ripening double balloon, labor induction, oxytocin

Introduction

In order to effectively reduce the rate of cesarean section, promote natural delivery, shorten the labor process and alleviate the pain of pregnant women, medical midwifery and instrument midwifery have played a great role. However, cesarean section is becoming increasingly common in China. Notably, some surgical complications may appear only many years after cesarean section, producing negative impacts on the health of both the mother and offspring, and even subsequent pregnancy.[1]

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Under the "universal two-child" policy, it is crucial to reduce the cesarean section rate during first delivery. As evidenced by accumulated data, parity is one of the important factors affecting the outcome of balloon dilator for labor induction; the use of cervical ripening balloon for labor induction in multiparae is higher than that in primiparas, with slight difference in the factors affecting the outcome in primiparas and multiparae.[2,3] With the change of China's fertility policy, there is an increase in the proportion of cesarean section indicated by scarred uterus, acting as the main reason for the increase in cesarean section rate currently, which may be explained by the too broad indications of cesarean section for the first delivery previously.[4] About 90% of patients with scarred uterus choose to terminate their pregnancy through cesarean section after giving birth again, leading to an increase in repeated cesarean sections. Significantly, vaginal delivery in primiparas lays the foundation for further vaginal delivery during subsequent pregnancy (pregnancies). Moreover, oxytocin can be secreted during delivery to stimulate lactation, promote postpartum uterine contractions, facilitate uterine involution, and prevent postpartum bleeding. Besides, newborns who undergo compression through the birth canal have stronger resistance compared to those who undergo cesarean section, considering that such compression can significantly benefit the establishment of pulmonary circulation and promote brain development in newborns.[5] Eventually, it highlights the significance of improving the success rate of labor induction in primiparas for reducing the total cesarean section rate as well as ensuring maternal and infant safety.

Labor induction during the late trimester of pregnancy is a common option of terminating pregnancy by inducing uterine contractions through medication or cervical mechanical dilation.[6] The maturity of the cervix exhibits an intimate association with the success of labor induction.[7] It is important to choose a safe and feasible method for labor induction, as the complications of natural delivery can arise when the cervical ripeness of pregnant women is not satisfactory for natural delivery. Cervical ripening can be roughly realized through drug and mechanical stimulation.[8] Intravenous infusion of oxytocin is the most common medicated choice for labor induction. However, intravenous infusion of oxytocin alone for labor induction often has the disadvantages of prolonged birth process and difficulty for the puerpera to persist. Moreover, poor cervical ripeness has a negative impact on the puerpera.[9] Mechanical methods were first used for cervical ripening or induction of labor.[8] Cervical ripening balloon is a mechanical device for inducing labor, and its roles for promoting cervical ripening and inducing labor may be related to the following aspects. Firstly, the balloon may compress the cervix directly to promote cervical canal softening, regression, and progressive dilation mechanically. Secondly, cervical ripening balloon can induce cervical epithelial cells to release various inflammatory factors and proteases and stimulate the synthesis and release of endogenous prostaglandins, thus initiating the delivery. Thirdly, balloon acting on the cervix can reflexively cause the release of pituitrin to induce uterine contractions, and further promote cervical regression and dilation to realize cervical ripening.[6,10] It is also characterized by safety and effectiveness, minimal side effects, and simple operation.[11] In view of the above, the application of cervical ripening balloon combined with intravenous infusion of oxytocin can greatly improve the delivery status of parturients and increase the success rate of labor induction.

However, current studies are performed by separately exploring the factors influencing the success of oxytocin and cervical ripening balloon for labor induction, with few research on the factors influencing the effectiveness of cervical ripening balloon combined with oxytocin in inducing labor. Therefore, the present study was performed for the first time to investigate the influencing factors of cervical ripening balloon combined with oxytocin for labor induction in primiparas.

Subjects and Methods

Subjects of Study

Using a purposive sampling method, this study retrospectively collected the clinical data of 230 pregnant women who underwent cervical ripening double balloon combined with oxytocin for labor induction in a Class 3A hospital in Changsha, Hunan, from September 2021 to August 2022. The included subjects were divided into a vaginal delivery group (n = 180) and a cesarean section group (n = 50) based on the delivery mode. Inclusion criteria: (1) pregnant women with fetus in cephalic position; (2) first-pregnant women with age of ≥18 years old; (3) pregnant women with intact fetal membranes; (4) pregnant women with single fetus; (5) pregnant women without cervical ripening (3 points ≤ cervical Bishop Score ≤ 5 points); and (6) pregnant women without medical history of cervical or uterine surgery in the past.

Exclusion criteria: (1) pregnant women with contraindications for vaginal delivery; (2) pregnant women with multiple fetuses in breech position; (3) pregnant women with abnormal cardiopulmonary function; (4) pregnant women who were unable to deliver vaginally due to fetal head abnormality and pelvic abnormality in the pregnant women; (5) pregnant women with contraindications for using cervical ripening balloons; (6) pregnant women with severe placental dysfunction; and (7) pregnant women who cannot tolerate vaginal delivery. This study was approved by the Ethics Committee of this hospital (No. 2021013), and all subjects of the study had signed informed consent forms.

Methods of Study

The main purpose of induction is to protect the mother and child, and the reasons include expired pregnancy, hypertensive diseases during pregnancy, early termination of pregnancy due to serious maternal illness, premature rupture of membranes, and fetal and appendage factors. Firstly, pregnant women are introduced to the details of the procedure for placing the balloon in order to reduce their fear and psychological stress. In addition, patients are given detailed information about double balloon combined with oxytocin, and the risks and benefits of the trial are fully explained. After obtaining informed consent, labor induction was performed by double balloon combined with oxytocin. After assisting pregnant women in keeping a lithotomy position, the next steps were disinfection of the external genitalia for 3 times, laying sterile towels, exposing the cervix with a vaginal speculum, and disinfection of the vagina and cervix with iodine-soaked cotton balls for 3 times. Following disinfection of the cervical canal with iodine-soaked cotton swab for 3 times, a disposable balloon dilator (Henan CLOT Industry Co Ltd., No. 20180029, model: type II 18F) was inserted into the cervical canal until both balloons entered the cervical canal and ensured that both balloons passed through the cervical opening. An amount of 80mL of physiological saline was slowly injected into the inner and outer cervical ripening balloons, respectively. The end of the balloon catheter was fixed with 3m tape on the inner thigh of pregnant women, without restricting their physical activity. The surgical process was smooth, without any discomfort found in pregnant woman. The fetal heart rate was monitored before and after the surgery, and the pregnant woman was guided to test fetal movement, with close observation of the delivery signs of the pregnant woman and fetal intrauterine conditions. Balloon was usually inserted between 16:00 and 18:00, the balloon was removed at 8am the next day, and the duration of the balloon application was generally 14–16 hours. Intravenous administration of oxytocin (Ringe 500mL+2.5U oxytocin) Starting from 4 drops/min for contractions and 8 drops/min for non contractions, observe every 20 minutes and adjust according to the frequency of contractions. If there is no contractions, increase the infusion rate by 4 drops/min each time, with a maximum dose not exceeding 40 drops, until regular contractions occur. Evaluate every half hour thereafter. In this study, vaginal delivery within 48 h of balloon placement was defined as successful induction of labor, while failure to deliver within 48 h and the use of other methods of induction or cesarean section were defined as failed induction of labor.[12]

Data Collection

The patient data and procedures were taken from a file or computerized recorded. Data collection involved age, body height, pre- and post-pregnancy body mass index (BMI), gravidity, gestational weeks of induced labor, cervical Bishop score before balloon dilatation, perinatal anxiety, neonatal weight, amniotic fluid index, pregnancy-induced hypertension, gestational diabetes, acute chorioamnionitis, fetal distress, and reasons for balloon removal.

Pregnant women were assessed for prenatal anxiety after admission. Anxiety status was evaluated using the Perinatal Anxiety Screening Scale (PASS). This scale included factor 1 (acute anxiety and adjustment) had eight items that addressed symptoms of panic disorder, dissociative disorder and adjustment difficulties; factor 2 (general worry and specific fears) included 10 items covering symptoms of generalised anxiety disorder and phobia; factor 3 (perfectionism, control and trauma) had eight items covering symptoms of obsessive-compulsive disorder and post-traumatic stress disorder; and factor 4 (social anxiety) had five items that addressed social anxiety.[13] The Cronbach's α coefficient of the Chinese version of the scale was 0.954, with a split-half reliability of 0.886 and a test–retest reliability of 0.967.[14] The total score of the scale was 93 points, and subjects with higher score might have more severe anxiety level (0–20 point(s), no anxiety; 21–41 points, mild-to-moderate anxiety; and 42–93 points, severe anxiety).

Diagnostic criteria for fetal distress: when there were no contraction and no fetal movement, fetal distress is diagnosed when the fetal heart rate was >160 beats/min or <110 beats/min. Late cardiac deceleration, variational deceleration, or lack of baseline variation in fetal heart contractions (CTG) indicate fetal distress.

Diagnostic criteria for acute chorioamnionitis: Its diagnosis can be determined based on a maternal fever of ≥38°C, accompanied by any of the following symptoms: tachycardia, heart rate ≥100 beats/min, white blood cell count ≥15×109/L, neutrophils ≥90%, fetal tachycardia, fetal heart rate ≥160 beats/min, vaginal discharge odor, and uterine tenderness. Moreover, pathological examination of the placenta or fetal membranes might show inflammatory cell infiltration after delivery.

Statistical Analysis

Statistical analysis in this study used SPSS 26.0 statistical software. With K-S method employed for normality test, measurement data that satisfied normality were represented by (x ± s), and *t*-test was used for inter-group comparison. Counting data were expressed as frequency (n) or rate (%) and assessed using χ^2 test or Fisher's exact test according to different sample sizes as proper. Variables with a $P < 0.05$ in univariable analyses were included in the further multivariable logistic regression analyses to determine the influencing factors of the effect of cervical ripening balloon combined with oxytocin on labor induction. Additionally, the predictive value of various indicators on the failure of cervical ripening balloon combined with oxytocin for labor induction was explored using receiver operating characteristic (ROC) curve. *P* value <0.05 was considered statistically significant.

Results

Univariate Analysis of Relevant Factors in the Vaginal Delivery Group and Cesarean Section Group of Patients

There were 180 cases in the vaginal delivery group, and 50 cases in the cesarean section group, with an average age of (29.91 ± 4.51) and (29.60 ± 3.66) years old, respectively. As shown in Table 1, the results of univariate analysis showed that there were statistically significant differences in the comparison of gravidity (2.17 ± 1.35 VS 1.62 ± 0.95 times, t=3.302, P<0.001), prenatal anxiety proportion (24/180 VS 23/50, χ^2 = 25.682, P<0.001), acute chorioamnionitis proportion (5/180 VS 27/50, χ^2 = 85.718, P<0.001), fetal distress proportion (13/180 VS 32/50, χ^2 = 80.157, P<0.001), and the placement of cervical ripening balloon catheter for >12h (74/180 VS 34/50, χ^2=11.359, P<0.001), while no significant difference was found between the two groups in age, body height, pre- and post-pregnancy BMI, gestational weeks for labor induction, cervical score before balloon dilatation, neonatal weight, amniotic fluid index, pregnancy-induced hypertension, gestational diabetes, etc. (P>0.05).

Logistic Regression Analysis of Suspicious Factors for the Success of Cervical Ripening Balloon Combined and Oxytocin for Labor Induction

Using whether cesarean section occurred as the dependent variable (occurrence = 1, nonoccurrence = 0), factors with statistically significant differences in univariate analysis were included as independent variables (variable coding in Table 2). With stepwise regression applied for including and excluding independent variables (α_{entry} = 0.05, $\alpha_{removal}$ = 0.1), a logistic regression model was established after the elimination of influencing factors with interactive effects. No variables were excluded during the inclusion and exclusion of variables, and all variables were included in the model finally. According to the results of multivariate analysis (Table 3), the presence of acute chorioamnionitis (*OR* = 1.456, *95% CI*: 1.257–2.112), fetal distress (*OR* = 1.371, *95% CI*: 1.331–2.633), and the placement of cervical ripening balloon catheter for >12h (*OR* = 1.563, *95% CI*: 1.231–3.263) were risk factors for successful application of cervical ripening double balloon combined with oxytocin for labor induction in pregnant women; while multi-gravidity (*OR* = 0.736, *95% CI*: 0.455–0.875) was a protective factor.

The Predictive Value of Various Indicators for the Failure of Cervical Ripening Balloon Combined with Oxytocin for Labor Induction

Evaluation of the predictive value revealed that acute chorioamnionitis, fetal distress, the placement of cervical ripening balloon catheter for >12h, and gravidity all had certain predictive value for the failure of cervical ripening double balloon combined with oxytocin for labor induction (Table 4). Among them, the area under the curve (AUC) of acute chorioamnionitis, fetal distress, the

Table 1 Univariate Analysis of Relevant Factors in the Vaginal Delivery Group and Cesarean Section Group of Patients

Items	Vaginal Delivery Group (n = 180)	Cesarean Section Group (n = 50)	t/χ^2 value	*P* value
Age (years, x±s)	29.91±4.51	29.60±3.66	0.448	0.654
Body height (cm, x±s)	159.01±5.6 2	159.71±7.71	1.423	0.159
Pre-pregnancy BMI (kg/m^2, x±s)	21.68±2.81	21.93±2.93	−0.545	0.586
Post-pregnancy BMI (kg/m^2, x±s)	27.51±2.85	28.23±3.18	−1.543	0.124
Gravidity (times, x±s)	2.17±1.35	1.62±0.95	3.302	<0.001
Gestational weeks for labor induction (weeks, x±s)	39.68±1.23	39.88±1.04	−1.083	0.280
Cervical score (points, x±s)	4.95±0.21	4.90±0.30	1.220	0.227
Prenatal anxiety (n)	24	23	25.682	<0.001
Neonatal weight (g, x±s)	3292.66±446.87	3398.60±412.78	−1.507	0.133
Amniotic fluid index (n)			1.982	0.159
≤50 mm	11	6		
50–250 mm	169	44		
Complication (n)				
Pregnancy-induced hypertension	20	3	1.136	0.287
Gestational diabetes	68	16	0.563	0.453
Acute chorioamnionitis	5	27	85.718	<0.001
Fetal distress	13	32	80.157	<0.001
Reason for balloon removal (n)				
Placement of cervical ripening balloon for >12h	74	34	11.359	<0.001
Spontaneous balloon shedding	64	11	3.272	0.070
Regular contractions for delivery	32	12	0.979	0.322
Premature rupture of membranes	9	1	0.847	0.357

Abbreviation: BMI, body mass index.

Table 2 Variable Grouping and Coding

Variables	Grouping	Coding
Prenatal anxiety	With	1
	Without	2
Acute chorioamnionitis	With	1
	Without	2
Fetal distress	With	1
	Without	2
Placement of cervical ripening balloon for >12h	With	1
	Without	2
Gravidity	Original value input	

Table 3 Logistic Regression Analysis of Suspicious Factors for the Success of Cervical Ripening Balloon Combined and Oxytocin for Labor Induction

Influencing Factors	S.E	Wald χ^2	*P* value	*OR*	*OR* (95% CI)
With prenatal anxiety	1.231	1.982	0.159	1.796	0.575–3.123
With Acute chorioamnionitis	1.412	7.208	0.001	1.456	1.257–2.112
With fetal distress	1.113	7.763	0.001	1.371	1.331–2.633
Placement of cervical ripening balloon for >12h	1.145	7.423	0.001	1.563	1.231–3.263
Multi-gravidity	0.142	9.089	0.001	0.736	0.455–0.875

Abbreviations: OR, odds ratio; CI, confidence interval.

Table 4 The Predictive Value of Various Indicators for the Failure of Cervical Ripening Balloon Combined with Oxytocin for Labor Induction

Items	AUC	95% CI	Sensitivity (%)	Specificity (%)
Acute chorioamnionitis	0.856	0.719–0.924	80.61	81.70
Fetal distress	0.789	0.702–0.814	81.44	83.48
Placement of cervical ripening balloon for >12h	0.861	0.725–0.938	82.01	73.82
Gravidity	0.712	0.679–0.811	83.49	84.57
Joint prediction	0.931	0.714–0.811	91.24	90.73

Abbreviations: AUC, area under the curve; CI, confidence interval.

placement of cervical ripening balloon catheter for >12h, and gravidity was 0.856 (95% CI: 0.719–0.924), 0.789 (95% CI: 0.702–0.814), 0.861 (95% CI: 0.725–0.938), and 0.712 (95% CI: 0.679–0.811) in predicting the failure of cervical ripening balloon combined with oxytocin for labor induction, respectively, with the highest predictive value found through joint predictive (AUC: 0.931, 95% CI: 0.714–0.811).

Discussion

In the presence of various comorbidities or complications threatening maternal and fetal health during the late trimester of pregnancy, artificial intervention is needed to initiate and terminate the birth process, ie, third-trimester induction of labor. The key to successful induction of labor lies in the ripening of the cervix. Under clear indications for induction of labor but with poor condition of the cervix, cervical ripening should be adopted to shorten, soften, thin, and expand the cervix. There may be higher success rate of labor induction when there is a better condition of the cervix. To improve the effectiveness of labor induction, cervical ripening balloon is usually used in combination with oxytocin in clinical practice.

Among all eligible pregnant women included in this study based on the inclusion criteria, there were 180 cases of vaginal delivery and 50 cases of cesarean section, with a vaginal delivery rate of 78.26%, indicating a good effect of cervical ripening balloon combined with oxytocin for labor induction, which was consistent with previous research.[15]

Parity is an important factor affecting the outcome of cervical ripening balloon for labor induction.[2,16] The success rate of cervical ripening balloon for labor induction in multiparae with unripe condition of the cervix is higher than that in primiparas. The use of cervical ripening double balloon catheter can promote cervical ripening in multiparae with unripe condition of the cervix, and the vast majority of which can give birth through vaginal delivery with fewer maternal and neonatal complications. Therefore, the use of cervical ripening double balloon catheter can be an effective option for multiparae to promote cervical ripening for planned delivery. It may be explained by the better compliance of the soft birth canal in multiparae, the easier dilation of the cervix, and the lower possibility of the bony birth canal, all of which are more conducive to fetal delivery. While for primiparas with unripe condition of the cervix, further research is needed on exploring better strategies for promoting cervical ripening and planned delivery, so as to reduce the cesarean section rate of the primiparas and reduce maternal and neonatal complications.[17] Parity has been commonly reported as a factor affecting the outcome of labor induction using cervical ripening balloon, and there is, however, few research regarding the impact of gravidity on the outcome of labor induction using cervical ripening balloon. Therefore, with the exclusion of the interference factors of parity on the outcome of labor induction, this study was performed to analyze the factors affecting the outcome of using cervical ripening double balloon combined with oxytocin for labor induction in primiparas, and predicted the success rate of the proposed strategy for labor induction in primiparas. Sciscione et al[18] observed in their research that the cervix of primiparas with multiple pregnancies was more likely to shorten in the second-third trimester of pregnancy compared to that of the first-time pregnant women; moreover, compared with primiparas without history of miscarriage, primiparas who have undergone ≥1 times of curettage had a 2-fold increased risk of cervical shortening in the second-third trimester of pregnancy. The present study revealed that multi-gravidity was a protective factor for the success of cervical ripening balloon combined with oxytocin for labor induction, which was consistent with the aforementioned studies.

In view of the mechanism of cervical ripening balloon, prolonged placement can improve cervical ripening, thereby increasing the success rate of labor induction. In this study, prolonged placement of the balloon was a risk factor for the failure of labor induction in pregnant women, yet without statistically significant correlation found between the cervical score before balloon placement and successful labor induction. It was not consistent with previous research findings. For instance, a prior research revealed that the cervical score after using balloon was correlated with gestational weeks at the time of balloon placement, cervical score, parity, indications for labor induction, and balloon placement duration.[19] The difference in the results may be related to the inclusion of primiparas with unripe condition of the cervix (cervical score <6 points) in the present study. The reason was that primipara has worse cervical compliance than that of multipara, and cervical ripening balloon may exert a role in inducing labor through mechanical compression to the cervix, which has a more significant effect on primiparas with relatively longer cervical canals.

Furthermore, acute chorioamnionitis is an inflammation caused by placental chorionic and amniotic membrane infections,[20] and its severity shows an intimate association with the expression of inflammatory factors. Acute chorioamnionitis during pregnancy and delivery has serious impacts on both maternal and fetal health. It has been reported that this disease was an independent risk factor for cesarean section.[21] It can be interpreted that when the puerpera suffers from acute chorioamnionitis, high levels of inflammatory factors and pathogens can increase endotoxin levels in the fetus to elevate the risk of fetal infection. Pathogens and inflammatory factors in amniotic fluid may further enter the respiratory tract after delivery, leading to a higher incidence of fetal aspiration pneumonia and hence an increased risk of fetal asphyxia.[22] Therefore, in order to reduce the risk of fetal hypoxia or infection, pregnancy should be terminated in a timely manner through cesarean section in the late trimester of pregnancy based on the clinical symptoms of patients. Similar to the aforementioned study, our research found that acute chorioamnionitis was a risk factor for successful labor induction through cervical ripening balloon combined with oxytocin.

Meanwhile, fetal distress in uterus may produce a direct impact on the blood oxygen supply relationship between mother and baby, resulting in potential fetal hypoxia, as well as increased risks of neonatal asphyxia,[23] neonatal hypoxic-ischemic encephalopathy, and permanent neural tube defect.[24,25] With aggravated persistent hypoxia, serious adverse perinatal outcomes, such as an increased risk of perinatal death, may have adverse effects on fetal growth and development. Besides negative impact on the newborn, fetal distress may cause higher risks of postpartum hemorrhage, puerperal infection and other adverse perinatal outcomes than those of normal puerpera.[26] In case of fetal distress, there may be obstructed vaginal delivery, the best solution is cesarean section, which requires timely termination of the pregnancy to ensure maternal and fetal health. This study indicated that fetal distress was a risk factor for successful labor induction through cervical ripening balloon combined with oxytocin, which was consistent with the above study.

However, there are still some limitations in this study. Firstly, this study is a retrospective and single-center study, the inclusion criteria of subjects, collection of clinical data, and processing of data may be subjective, and the results are not so objective as the multi-center prospective studies. Secondly, some objective indicators should be further considered to evaluate the influencing factors of cervical ripening balloon combined with oxytocin on the outcomes of full-term primiparas more comprehensively. Finally, the sample size of this study is relatively small. Further in-depth research is needed to expand the sample size for the effect of cervical double balloon combined with oxytocin in inducing labor, improve the data, and provide more accurate practical basis for more effective treatment.

Conclusion

To sum up, cervical ripening double balloon combined with oxytocin provides a new way and method for vaginal delivery, which is worthy of clinical application. The success rate of labor induction by cervical ripening double balloon combined with oxytocin is higher for multigravida, but acute chorioamnionitis, fetal distress, and prolonged placement of balloon may reduce the success rate of induction, thus affecting the health of mother and child. High-quality prospective and randomized trials are needed to provide a more accurate and practical basis for cervical ripening double balloon combined with oxytocin in labor induction.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Changsha Hospital for Maternal & Child Health Care Affiliated to Hunan Normal University (Approval No. 2021013). All participants signed an informed consent form for inclusion in the study.

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Disclosure

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