On the Safety of COOK Double Balloons to Promote Cervical Ripening in Pregnant Women With Group B Streptococcus Colonization

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Research Article

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Abstract

Background: For pregnant women who develop complications during the third trimester of pregnancy, or who have not given birth naturally after more than 41 weeks of pregnancy, artificial induction of labor is needed in order to obtain a healthy outcome for both the mother and the child. The 2014 edition of the *Guidelines for Promoting Cervical Maturation and Delivery in Late Pregnancy* point out that the use of COOK cervical ripening balloons to mechanically dilate the cervix can be used in the third trimester to promote cervical ripening and labor induction [1]. The disadvantage is the risk of infection, premature rupture of membranes, and umbilical cord prolapse [2]. The safety of balloon induction for pregnant women colonized by group B streptococcus (GBS) is currently lacking in multi-center clinical research data. This article will study the safety of COOK double balloon induction in pregnant women colonized by GBS.

Methods: A total of 1,681 pregnant women who used COOK double balloons for cervical ripening in Changsha Maternity and Child Health Hospital from September 2018 to September 2020 were selected as the research subjects, from which 125 cases with colonization of group B streptococcus in the reproductive tract were selected as the observation group. Pregnant women without group B streptococcus colonization (N = 1556) served as the control group. This study compares the two groups' delivery methods, postpartum complications, and neonatal conditions.

Results: The rate of transition to cesarean section in the observation group was slightly higher, and the difference was statistically significant (p = 0.049). The rate of postpartum hemorrhage was higher than that of the control group (p < 0.05). Although chorioamnionitis increased compared to the control group, the difference was not significant (p > 0.05). The comparison of newborn birth indicators between the two groups showed no statistically significant difference (p > 0.05).

Conclusion: When pregnant women with colonization of group B streptococcus of the genital tract use the COOK double balloon to promote cervical ripening, the success rate of labor induction is high. Use of the balloon does not increase the cesarean section rate and the incidence of chorioamnionitis, nor does it increase the risk of neonatal infection. However, the risk of postpartum hemorrhage increases, and it is necessary to take active measures to reduce this risk.

Materials And Methods

Research groups. More than 28,000 pregnant women gave birth at the Changsha Maternity and Child Health Hospital from September 2018 to September 2020. The total cesarean section rate is about 29–31%, which is the lowest rate of cesarean section in Changsha. In this period of time, 1681 pregnant women who underwent COOK double-balloon induction of labor were the research subjects. Pregnant women with GBS colonization were the observation group (N= 125), and 1556 pregnant women without GBS colonization were the control group.

Inclusion criteria. (1) Gestational age ≥ 37 weeks, with indications for labor induction, but no serious maternal comorbidities and complications such as severe preeclampsia, diabetes with poor blood sugar control, and severe organ dysfunction; (2) Single live birth, head position, no contraindications for vaginal delivery such as placenta previa and vascular previa; (3) Cervical score: five points; (4) No recent acute infection of respiratory tract, urinary tract, digestive teact ; (5) No chlamydia, herpes simplex virus, or other infections. Exhaust standard: Those who are allergic to penicillin.

Method. Both groups used the COOK cervical ripening balloon method. In this method, the patient takes the lithotomy position, the drape is routinely sterilized, the cervix is fully exposed, the double balloon is inserted into the cervical canal, and 80 ml of normal saline is injected into the piston marked with a red *U* and a green *V*. After ensuring that the water bladder is near the cervical canal, the end is fixed onto the patient's inner thigh with tape, without restricting the patient's activities [3]. The balloon was placed at 20:00 and then removed at 08:00 the next morning, and the membrane was artificially ruptured. If there were no regular contractions one hour after rupture, a small dose of intravenous oxytocin was used for cervical ripening. Penicillin was used intravenously to prevent infection 30 minutes before artificial rupture. The first dose was 4.8 g, and then a 2.4g dose was given every 4 hours until delivery.

Observation indicators. Delivery methods, postpartum complications during delivery, and birth conditions of newborns served as observation indicators in this study.

Statistical processing. This study uses SPSS 26.0 statistical software: ($\bar{x} \pm sd$) for measurement data, independent sample *t*-test for comparison of means, $\chi 2$ test for comparison of rates. *p*-values < 0.05 are deemed statistically significant.

Results

Comparison of general conditions of pregnant women. The general information of the two groups of pregnant women includes age, gestation times, parity times, and gestational weeks of delivery. The difference was not statistically significant ($p > 0.05$). See Table 1 for details.

Table 1
Comparison of general conditions of mothers

	Observation group	**Control group**	***t***	***p***
N	125	1556		
Age	29.45 ± 3.65	30.36 ± 4.70	-1.518	0.131
Number of pregnancies	2.04 ± 1.12	2.15 ± 1.28	-0.649	0.517
Number of deliveries	0.37 ± 0.51	0.45 ± 0.62	-1.245	0.062
Gestational week of delivery	39.63 ± 1.34	39.48 ± 0.97	0.908	0.365
Duration of labor(h)	7.48 ± 3.08	7.23 ± 3.32	0.518	0.605

Complications. The main comorbidities of the two groups of women undergoing COOK balloon induction of labor were hypertension during pregnancy, GDM, oligohydramnios, delayed pregnancy, and the composition ratio of ICP. The differences were not statistically significant between groups ($p > 0.05$). See Table 2 for details.

Table 2
Comparison of the main complications of labor induction

	Observation group	Control group	χ^2	p
Hypertension in pregnancy	18/125 (14.4%)	223/1556 (14.33%)	0.000	0.983
GDM	41/125 (32%)	472/1556 (30.33%)	0.332	0.565
Oligohydramnios	23/125 (18.4%)	213/1556 (15.16%)	2.128	0.145
Postterm pregnancy	36/125 (28.8%)	498/1556 (32%)	0.548	0.459
ICP	5/125 (4%)	59/1556 (3.79%)	0.014	0.907

Comparison of delivery situation. There was no significant difference in the incidence of chorioamnionitis between the two groups. The rate of cesarean section in the observation group was slightly higher than in of the control group, and the postpartum hemorrhage rate of women with GBS colonization increased significantly ($p < 0.05$). See Table 3 for details.

Table 3
Comparison of delivery situation

	Observation group	Control group	χ^2 / t	p
Rate of cesarean section during delivery	30/125 (24%)	265/1556 (17%)	3.884	0.049
Vaginal delivery rate	95/125 (76%)	1291/1556 (83%)	3.884	0.049
Incidence of chorioamnionitis	11/125 (8.8%)	97/1556 (6.23%)	1.267	0.260
Postpartum hemorrhage rate	11/125 (8.8%)	63/1556 (4.05%)	5.963	0.015
Puerperal infection rate	0/125 (0%)	2/1556 (0.13%)	0.161	0.688

Comparison of newborns' birth conditions. There was no significant difference between the two groups of newborns ($p > 0.05$) in the 1-minute and 5-minute Apgar scores, the incidence of fetal distress, as well as the incidence of neonatal infection, asphyxia, pneumonia, and other complications. See Table 4 for details.

Table 4
Comparison of newborns' birth conditions

	Observation group	Control group	χ^2 / t	p
Apgar score(1-minute)	9.33 ± 0.49	9.35 ± 0.73	-0.337	0.736
Apgar score(5-minute)	9.72 ± 0.45	9.73 ± 0.66	-0.92	0.944
Fetal distress	10.4% (13/125)	9.85% (153/1556)	0.042	0.838
Newborn infection	6.40% (8/125)	5.53% (86/1556)	0.163	0.687
Neonatal asphyxia	0	9/1556 (0.57%)	0.727	0.394
Neonatal pneumonia	0.8%(1/125)	0.71% (12/1556)	0.001	0.972

Discussion

In postterm pregnancies, or in the event of comorbidities that risk termination of the pregnancy with no contraindications to vaginal delivery, in order to increase the vaginal delivery rate, different methods are

selected for induction of labor according to the pregnant woman's cervical ripening. The current methods for promoting cervical ripening mainly involve prostaglandin preparations and mechanical dilatation. Prostaglandin preparations include controlled-release dinoprostone suppositories and misoprostol. The disadvantage is that the rate of tonic contraction of the uterus is higher, and the incidence of fetal distress is increased [4]. Compared with dinoprostone suppositories, the cervical dilation balloon is a relatively mild means of inducing labor. The main mechanism of action is to simulate the fetal head continuously compressing the cervix, gradually softening and dilating the cervix through stable mechanical force while simultaneously stimulating the endogenous prostate. The synthesis and release of hormones induce uterine contractions. The operation is simple and safe, does not affect the daily activities of pregnant women, and can also reduce the risk of tonic contractions [5].

Infection is one of the main causes of adverse maternal and infant outcomes during the perinatal period. GBS is a β-hemolytic gram-positive bacteria that colonizes the gastrointestinal and urogenital tracts. Pregnant women, newborns, and the elderly are susceptible [6]. At present, GBS has become one of the main pathogenic bacteria that cause perinatal infections in mothers and children. There has been a lot of research into GBS infection in pregnant women in recent years. According to recent studies, the colonization rate of GBS in pregnant women abroad ranges from 3.3–26% [7–9].

According to research into different Chinese regions, the prevalence of GBS infection in pregnant women in China ranges from 3.7–32.4% [10–13]. In GBS-positive pregnant women, the rate of neonatal infection and asphyxia, as well as the incidence of chorioamnionitis, puerperal infection, premature membrane ruptures, fecal staining of the amniotic fluid, and cesarean sections were all higher compared to GBS-negative pregnant women. [14][15]. GBS infection leads to premature rupture of fetal membranes. After the rupture of the membranes, pathogens continue to invade the uterine cavity, causing infections of the fetal membranes and placenta, thereby increasing the incidence of intrauterine infection. GBS can cause amniotic fluid pollution. Aspiration of fetal amniotic fluid during childbirth can lead to neonatal infection and neonatal pneumonia, which usually appear within 6 to 12 hours after birth, manifesting as symptoms of respiratory distress, hypotension, and unstable body temperature.

The CDC guidelines in the United States recommend that GBS-positive pregnant women be given prophylactic antibiotics during childbirth, and penicillin is recommended [16] [17]. McNanley et al. [18] state that antibiotics given four hours before delivery can reduce the vaginal GBS count by a factor of 50. For GBS-positive pregnant women, administering adequate penicillin as soon as possible after delivery can reduce the amount of GBS carried in the vagina and rectum of the mother. When the interval between starting penicillin and childbirth, is less than one hour, the vertical infection rate of the GBS-positive mother and infant is more than 40%. When that interval is increased to four hours, the vertical infection rate is reduced to 1% [19]. The results of this study show that the prevalence of chorioamnionitis (8.8%) in pregnant women with GBS colonization using COOK balloons to promote cervical ripening was slightly higher than that of pregnant women without GBS infection (6.23%), but the difference was not significant. There was no significant difference in neonatal birth score, incidence of fetal distress, and

incidence of neonatal infection, asphyxia, pneumonia and other complications, which is considered to be a positive result of the active use of penicillin before delivery.

In this study, the cesarean section rate in the GBS group was 24%, slightly higher than 17% in the control group, and still lower than the total cesarean section rate of 29–31% in our hospital. In the GBS group, 10 primiparous women had no medical indications for cesarean section during vaginal delivery after the balloon was removed, but they refused to continue vaginal delivery and requested cesarean section. Parturients considering GBS colonization are concerned about the increased risk of fetal infections due to the prolonged labor process, and require cesarean section to end the delivery process as soon as possible. Therefore, the risks and countermeasures should be fully explained to GBS-positive women before introducing the COOK balloon, so as to enhance their confidence in vaginal delivery and reduce the incidence of caesarean section.

In this study, 11 cases of postpartum hemorrhage occurred in 125 pregnant women with GBS colonization, accounting for 8.8%, which was significantly higher than the control group's 4.05%. This finding is consistent with studies by Kwatra [20] and others. The causes of postpartum hemorrhage in the GBS group included seven cases of uterine asthenia, two cases of placental factors, and two cases of soft birth canal laceration. Among them, two cases were complicated with chorioamnionitis, accounting for 18.18% (2/11) of postpartum hemorrhage in the GBS group, which was much higher than the 9.52% (6/63) rate of postpartum hemorrhage and chorioamnionitis in the control group ($p = 0.015$). Considering that GBS colonized in the vagina, rectum, and urinary tract during pregnancy can spread ascending to infect the cervix, uterus and fetal membranes-soft birth canal due to inflammation and edema increased fragility, leading to soft birth canal laceration, thereby increasing the rate of postpartum hemorrhage; Intrauterine infection leads to uterine contractions. Fatigue also increases postpartum hemorrhage. Therefore, pregnant women with GBS colonization should receive active measures to prevent postpartum hemorrhage as soon as possible after delivery, including continuous uterine massage and medications to cause contractions, such as Carboprost tromethamineand ergonovine.

Conclusions

In summary, the application of COOK balloons to promote cervical ripening in pregnant women with GBS colonization of the genital tract can create conditions for vaginal delivery. Before the operation, it is necessary to fully evaluate the situation of the mother and child, and to inform the women and their families of the procedure's risks and countermeasures, thereby increasing their confidence in vaginal delivery. Treatment with antibiotics for more than four hours before delivery does not increase the risk of infection for pregnant women with GBS colonization or their children, but the rate of postpartum hemorrhage increases. Therefore, pregnant women who are colonized with GBS need to take more active and effective measures to prevent postpartum hemorrhage. In addition, whether combined GBS colonization can be an independent high-risk factor or a synergistic factor for postpartum hemorrhage needs to be further studied in future clinical work.

List Of Abbreviations

GBS Group B streptococcus

GDM Gestational diabetes mellitus

ICP Intrahepatic cholestasis of pregnancy

Declarations

-Ethics approval and consent to participate

The study was according to the ethical guidelines of the Helsinki Declaration and was approved by the Human Ethics Committee of Changsha Maternal and Child Health Hospital. Written informed consent was obtained from individual or guardian participants. The following is the review approval document.

-Consent for publication

Not applicable.

-Availability of data and material

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

-Competing interests

The authors declare that they have no competing interests

-Funding

Not applicable

-Authors' contributions

Ping Ni Weitao YangLihuiHuang contributed to the conception of the study;

Ping NiLe HuangJingPengHuaLi Check medical records, collect data;

Ping NiLanting YuLihuiHuang Wrote the main manuscript text;

Ping NiLanting Yu performed the data analyses and wrote the manuscript;

Ping Ni Lanting Yu Le Huang Weitao YangLihuiHuang HuaLi helped perform the analysis with constructive discussions.

All authors reviewed the manuscript.

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