

Efficacy and Influencing Factors of Induction of Labour by Foley Catheter Balloon at Term in Primiparas: A Retrospective Study

Abstract

Problem: Although IOL is one of the most common and effective interventions for pregnant women, it is not always successful and can have poor outcomes.

Background: The induction of labor (IOL) has been used more and more frequently in recent years.

Aim: In the present study, we would assess the efficacy and influencing factors of induction of labor by Foley catheter balloons at term in primiparas.

Methods: 688 primiparas who received cervical ripening with a Foley catheter balloon were recruited. We faithfully recorded the detailed medical data.

Findings: In all the cases, the number of vaginal deliveries was 508 (73.8%). Maternal residence (AOR=0.648, 95% CI: (0.460, 0.912), BMI<28 (AOR = 1.740, 95% CI: 1.193, 2.539), Bishop Score before induction started (AOR = 0.631, 95% CI: 0.440, 0.906), time from the start of induction to delivery (AOR = 1.764, 95% CI: 1.234, 2.522), change in the color of amniotic fluid (AOR = 0.487, 95% CI: 0.284, 0.835), intrauterine infection (AOR = 0.21, 95% CI: 0.275, 0.881) and fetal distress (AOR = 0.137, 95% CI: 0.275, 0.239) were significantly associated with the success of the induction of labor.

Discussion: The factors identified to be significantly associated with the success of IOL in this study were: maternal residence, BMI<28, Bishop Score before induction started, time from the start of induction to delivery, change in the color of amniotic fluid, intrauterine infection, fetal weight and fetal distress.

Conclusion: Cervical ripening with a Foley catheter balloon was very effective in achieving vaginal delivery, but there were many high-risk factors affecting the success of induction of labor, so we need to pay more attention to and take corresponding measures to improve this situation.

Research Article

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Keywords

Foley catheter balloon • Induction of labor • Intrauterine infection • Bishop score • Cervical ripening

Statement of significance

Problem or issue: For the IOL to succeed, it is essential to identify and ameliorate the gaps. However, there haven't been sufficient studies conducted in the study area.

What is already known: Although IOL is one of the most common and effective interventions for pregnant women, it is not always successful and can have poor outcomes.

What this paper adds: We assessed the efficacy and influencing factors of induction of labor by Foley catheter balloons at term in primiparas.

Introduction

The induction of labor (IOL) has been used more and more frequently in recent years, approximately one in five deliveries in the United Kingdom were induced [1]. In the United States, the rate of induction of labor more than doubled from 1990 through 2010, from 9.6% to 23.8% [2]. Therefore, induction is one of the most common interventions for pregnant women. A poor Bishop score is associated with an unacceptably high induction failure rate [3]. Medical interventions are necessary to induce cervical ripening before initiation of labor if the Bishop score is ≤ 6 [4–6].

Labor can be induced by mechanical and pharmacologic methods [7-9]. Mechanical methods have been recommended by many institutions, such as the ACOG [10], WHO [11] and Canada IOL guide lines [12]. Recent studies have found that the mechanical methods were as effective as pharmacological methods in achieving vaginal delivery [7,13,14]. Although IOL is one of the most common and effective interventions for pregnant women, it is not always successful and can have poor outcomes. A review of the literature suggested that vaginal delivery was achieved in only 84% of mothers in Saudi Arabia [15], 80.6% in India [16], 75.9% in Nigeria [17] and 59.7% in Ethiopia [18] with IOL implantation.

For the IOL to succeed, it is essential to identify and ameliorate the gaps. However, there haven't been sufficient studies conducted in the study area. Foley catheter balloon labor induction is a very common method of IOL. Therefore, in the present study, we will assess the efficacy and influencing factors of induction of labor by Foley catheter balloons at term in primiparas. Conceptual framework.

Material and methods

Design

A retrospective study was undertaken between January,2018 and December, 2022. All patients signed informed consents and the study was reviewed by the Institutional Review Board on June 1, 2017 (2017003) and was unanimously approved. All procedures were performed in compliance with the Declaration of Helsinki.

Sample

From January 2018 to December 2022, 688 primiparas who intended to receive cervical ripening with a Foley catheter balloon with a clinical need were recruited. Eligibility criteria included: term (37–42 weeks), singleton, primipara, intact membranes, Bishop score of <7, cephalic presentation and appropriately grown; cervical ripening being done for such reasons: at or beyond 41 weeks, gestational hypertension, gestational diabetes, oligoamnios and other maternal factors, excluding postdates and social inductions. Women were excluded if they had placenta praevia or any other contraindication to vaginal delivery.

Before the starting of the ripening and induction process, the Bishop scores were assessed by doctors. A standardized Bishop score was used for this purpose [19]. The catheters were inserted by specially trained doctors. The Foley catheter balloons were inserted in the evening in accordance with the manufacturer's instructions. If the Foley catheter balloon did not fall out spontaneously, it was removed after 12 hours. After removal of the balloon catheter, the Bishop scores were assessed again. If labor did not start after mechanical ripening, an amniotomy was performed followed by an oxytocin infusion.

Data collection

We faithfully recorded the detailed medical data, including the sociodemographic factors (maternal age, place of residence, body mass index), indications of IOL (at or beyond 41 weeks of gestation, gestational diabetes, gestational hypertension, Oligohydramnios and other Factors), methods of delivery (spontaneous vaginal instrumental, cesarean section), obstetric delivery, characteristics (gestational age, bishop score, time from start of induction to delivery, change in the color of amniotic fluid, intrauterine infection) and fetal condition (fetal weight and fetal distress). All the placentas were pathologically inspected and intrauterine infection was diagnosed as maternal fever (≥38°C), accompanied by maternal tachycardia (>100 bpm), or uterine fundal tenderness, or fetal tachycardia (>160 bpm), or purulent amniotic fluid, or chorioamnionitis found by placental pathologic examination.

Data analysis

All statistical analyses were performed using SPSS 23.0, Quantitative data were expressed as Mean±SD, the enumeration data were expressed as a rate (%). After we checked the data for its completeness and consistency, data were cleaned, coded and entered into Epi data version 4.6 and exported to the SPSS 23.0 software package for data analysis. We used bivariable analysis to assess the association of potential factors with the outcome variable. A p-value of ≤0.05 were taken as statistically significant determinants of the success of IOL. In addition, we used Hosmer Lemeshow goodness-of-fit test to check model fitness with a p-value > 0.05.

Study variables

The dependent variable was the success of IOL whereas the independent variables were the sociodemographic factors (maternal age, place of residence, body mass index), obstetric characteristics (gestational age, bishop score, time from start of induction to delivery, change in the color of amniotic fluid, intrauterine infection), indications of IOL (at or beyond 41 weeks of gestation, gestational diabetes, gestational hypertension, Oligohydramnios and other Factors) and fetal condition (fetal weight and fetal distress).

Definition of terms

Induction of labor in terms is the artificial initiation of labor to deliver the fetus vaginally (after the 37 weeks of gestation) and before the onset of spontaneous labor.

Successful induction of labor: when a woman had achieved vaginal birth after labor was induced.

Body mass index (BMI): BMI is defined as the weight in kilograms divided by the square of the height in meters(kg/m)², The pregnant women were classified by pre-pregnancy BMI according to the "WS/T428-2013 Adult Weight Determination" standard issued by the National Health and Family Planning Commission of the People's Republic of China in 2013 [20], Pregnant women were grouped according to the pre-pregnancy BMI classification criteria: a BMI<18.50 kg/m2 was considered low weight before pregnancy, a BMI of 18.50-23.90 kg/m2 was considered normal weight before pregnancy, a BMI of

24.00-27.90 kg/m2 was considered overweight and a BMI ≥28.00 kg/m2 was considered obese. In this study, the number of women with pre-pregnancy BMI<18.50 kg/m2 was small and we focused on the effect of maternal obesity on labor induction, so the underweight, normal weight and overweight groups were combined into one group for analysis.

Fetal distress: Normal fetal heart rate pattern was defined as a baseline heart rate of 110–160 beats per minute with variability of 5–25 beats per minute and no repetitive decelerations. All findings that deviated from this normal fetal heart rate pattern definition were considered fetal distress [21].

Bishop score: A score of \leq 3 indicates a severe cervical immaturity, whereas a score of > 3 but < 7 indicates a cervical immaturity.

Results

The trial was carried out from January 2018 to December 2022. During this study period, 51,985 women were delivered in our hospital and labor was induced in 9825 (18.9%). A total of 767 primiparas intended to receive cervical ripening with a Foley catheter balloon, were hospitalized in the ward of Changzhou Women and Children Health Hospital, but 79 cases gave up using Foley catheter balloon because of vaginal inflammation or severe cervical erosion and finally, 688 cases successfully received cervical ripening with a Foley catheter balloon, no woman was excluded from the study due to catheterassociated issues: clinician unable to insert catheter, spontaneous rupture of membranes on balloon inflation and fetal heart rate deceleration noted at insertion. After catheter placement, 25 Foley catheter balloons fell out spontaneously (3.6%), 107 pregnant women spontaneously started labor (15.6%) and 556 pregnant women needed amniotomy followed by oxytocin infusion after mechanical ripening (80.8%). Most of the inductions in this study were carried out because the pregnancies were at or beyond 41 weeks of gestation (49.7%).

The cervical Bishop scores after catheter placement were significantly higher than before $(5.92\pm1.13 \text{ VS } 3.98\pm0.91, P<0.05)$. In all the cases, the number of vaginal deliveries was 508 (73.8%) and the number of cesarean sections was

180 (26.2%). The total incidence of intrauterine infection was 13.4%, the total incidence of postpartum hemorrhage was 11.2%, and the total incidence of fetal distress was 5.7%. Only one case of placental abruption was observed and only one case of perineum hematoma was observed. An incomplete rupture of the uterus was found in a woman, who induced labor because of previous cesarean sections. No case of hyperstimulation was observed. The odds of successful IOL in non-obese women (BMI<28) were 1.740 times (AOR = 1.740, 95% CI: 1.193, 2.539) more than that in obese women (BMI \geq 28). Similarly, the odds of IOL were higher among women who gave birth within 24 h of the start of labor induction compared with their counterparts (AOR = 1.764, 95% CI: 1.234, 2.522).

Maternal residence in rural areas is 0.352 times less likely to success of IOL than maternal residence in urban areas, with an odds ratio of (AOR=0.648, 95% CI: (0.460, 0.912). The success of IOL was 36.9% times lower among women with severe cervical immaturity (Bishop score≤3) (AOR = 0.631, 95% CI: 0.440, 0.906). The success of IOL was 50.8% times lower among women with fetal macrosomia (AOR = 0.492, 95% CI: 0.275, 0.881). The success of IOL was 86.3% times lower among women with fetal distress (AOR = 0.137, 95% CI: 0.079, 0.239). The success of IOL was 79% times lower among women with intrauterine infection (AOR = 0.21, 95% CI: 0.133, 0.332). Furthermore, the success of IOL was 51.3% times less likely among women with a change in the color of amniotic fluid (AOR = 0.487, 95% CI: 0.284, 0.835).

Discussion

The induction of labor (IOL) is one of the most common interventions among pregnant women. Most recently in the United States, the rate of induction was approximately 23.3% [22]. In our hospital, the rate of induction was 18.9%. 49.7% of the inductions were carried out because the pregnancies were at or beyond 41 weeks of gestation, gestational diabetes (19.8%) and hydramnios (11.6%) were also important indications of labor induction, which was consistent with what S Kehl et al. reported [23]. In Germany, the failure of catheter placement occurred in 4 out of 168 women [23]. But in our study, all the Foley catheter balloons were placed successfully, it may be related to the fact that all our doctors who were responsible The efficacy of Foley catheter balloon for induction of labor at term has been widely recognized. In our study, the cervical Bishop scores after catheter placement increased evidently, which was consistent with S Kehl et al.'s study [24]. In the present study, the rate of normal vaginal delivery was 72.2%, the rate of surgical vaginal delivery was 1.6% and the rate of cesarean section was 26.2%. In the S Kehl et al.'s study [25], the rate of normal vaginal delivery was 67.9%, the rate of surgical vaginal delivery was 10.5% and the rate of caesarean section was 21.6%. But the data could vary greatly from study to study, the rate of normal vaginal delivery was between 50.4% and 75% [24,25], the rate of caesarean section ranged from 17.3% to 39.1% [26,27,28].

It is still a matter of debate that whether the placement of a balloon catheter into the uterus increases the risk of infection or not. Wilkinson et al. [28] reported that there was no case of infections attributed to the ripening catheter. But in the present study, the total incidence of intrauterine infection was 13.4%, we analyzed the possible reason for this: in our study, all the placentas were pathologically inspected, which increased the detection rate of infection. In addition, our study found that the total incidence of postpartum hemorrhage was 11.2%, which was lower than the report of Wilkinson et al [28].

In addition, this study provides important information on the success of induction of labor by Foley catheter balloon and related factors, such as maternal sociodemographic factors, obstetric factors and fetal factors. In terms of sociodemographic factors, our study did not find a relationship between maternal age and the success of labor induction, but in the study non-obese women (BMI<28) were found to be 1.74 times more successful in inducing labor than obese women. However, some studies [29,30] reported that advanced age was associated with induction failure and in a study in Somaliand [31] reported that no significant relationship was found between BMI and the success of labor induction. The reason for this difference may be related to racial and regional differences. In addition, our study found that the success of induction in women living in rural areas was 0.352 times less likely to that in women living in urban areas, this finding is in line with a study conducted in Southeast Ethiopia [32].

In terms of obstetric factors, our study did not find a relationship between gestational age and the success of labor induction. However, the success of IOL was 36.9% times lower among women with severe cervical immaturity (Bishop score≤3). The current finding is in line with the study done in Hawassa public facilities [33] and Jimma University Specialized Hospital [34]. At the same time, this study showed that the success of IOL was 51.3% times less likely among women with a change in the color of amniotic fluid. Similarly, another study in India indicated a significant association between amniotic fluid-stained meconium and failed induction [35]. And this might be due to that amniotic fluid-stained meconium may easily lead to a non-reassuring fetal heartbeat pattern when uterotonic agents are administered.

In terms of fetal factors, this study showed that the success of IOL was 50.8% times lower among women with fetal macrosomia. This finding is supported by studies conducted by Bertinelli [36] and Rashida [37]. At the same time, we found that the success of IOL was 86.3% times lower among women with fetal distress. This finding is in line with some previous studies [33]. This could be because the presence of fetal heart rate abnormality could guide to fetal death and failure of induction.

Conclusion

Cervical ripening with a Foley catheter balloon was very effective in achieving vaginal delivery, but there were many high-risk factors affecting the success of induction of labor, so we need to pay more attention to and take corresponding measures to improve this situation.

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Availability of data and materials

Not applicable

Author's contributions

The manuscript has been read and approved by all authors and all authors contributed to the manuscript. CSF and CFS conceived and designed the study. HHJ undertook the collection, cleaning, analysis and interpretation of the data and wrote the earlier manuscript drafts. CFS revised subsequent manuscript drafts, reviewed records and prepared tables and figures. CSF supervised all aspects of the study.

Ethics approval and consent to participate

All patients signed informed consents and the study was reviewed by the Institutional Review Board of Changzhou Women and Children's Health Hospital Affiliated to Nanjing Medical University on June 1, 2017 (2017003) and was unanimously approved. Ethical Approval Statement: The Institutional Review Board (Ethics Committee of Changzhou Maternal and Child Health Hospital) has reviewed this study project and unanimously approved the conduct of this study (details as per supplementary file).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no financial or nonfinancial conflicts of interest related to the subject matter or materials discussed in the manuscript.

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