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Original Article

Effects of Yixin Da cervical double-lumen balloon dilatation combined with low-dose oxytocin on cervical maturation in term labor induction

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Abstract: Objective: To evaluate the efficacy of the Yixin Da cervical double-lumen balloon dilatation combined with low-dose oxytocin in promoting cervical ripening during term labor induction. Methods: This retrospective study analyzed 100 full-term labor induction cases at Beijing Luhe Hospital Affiliated to Capital Medical University between January 2022 and December 2023. Participants were divided into a control group (n=50), receiving low-dose oxytocin, and a study group (n=50), receiving the Yixin Da cervical double-lumen balloon catheter combined with low-dose oxytocin. The outcomes assessed included cervical ripening efficacy, induction duration, Bishop score changes, labor progression, Endothelin-1 (ET-1) and Prostaglandin E2 (PGE2) levels, and the incidence of adverse events. Results: The study group exhibited higher cervical ripening efficacy (98.00% vs. 84.00%, P<0.05), a shorter induction-to-labor time, and reduced labor stages (P<0.05). VAS pain scores were lower (P<0.05), and Bishop scores showed greater improvement in the study group (P<0.05). Postpartum hemorrhage rates were lower in the study group (P<0.05). ET-1 and PGE2 levels post-treatment were significantly higher in the study group compared to the control group, despite no pretreatment differences (P<0.05). The incidence of adverse events was lower in the study group (2.00% vs. 16.00%, P<0.05), and patient satisfaction was higher (P<0.05). Conclusion: The combination of the Yixin Da balloon with low-dose oxytocin enhances cervical ripening, shortens labor duration, and reduces complications, demonstrating superior efficacy.

Keywords: Term pregnancy, induction of labor, Yixin Da cervical double-lumen balloon dilatation, oxytocin, cervical maturation

Introduction

The induction of labor in full term pregnancies is a critical intervention in modern obstetrics, typically performed when the risks of continuing pregnancy outweigh the benefits for maternal or fetal health [1]. In many developed countries, over 20% of pregnancies undergo induction, highlighting the importance of developing safe and effective cervical ripening methods [2]. The cervix's condition is a key factor in determining the success of induction. Specifically, an unripe cervix is strongly associated with induction failure and an increased likelihood of cesarean delivery [3]. Despite advancements in obstetric care, identifying optimal strategies for cervical ripening remains challenging. Research shows that inadequate cervical preparation contributes to 20% to 30% of failed inductions, which can result in prolonged hospitalization, higher healthcare costs, and increased risks for both mother and infant [4, 5]. This underscores the need for reliable, safe, and efficient cervical ripening protocols.

Traditional methods, such as oxytocin alone, have limitations [6]. While oxytocin effectively stimulates uterine contractions, its impact on cervical maturation is inconsistent, especially in nulliparous women with an unfavorable cervix [7]. Additionally, oxytocin infusion requires continuous monitoring and carries risks of uterine hyperstimulation and fetal distress [8]. These limitations have led to the exploration of alternative and complementary methods for cervical preparation.

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Mechanical methods, including cervical ripening balloons, have emerged as practical alternatives [9]. The Yixin Da double-lumen balloon offers unique advantages due to its dual-chamber design. It applies controlled pressure simultaneously to the internal and external cervical os, stimulating endogenous prostaglandin release while avoiding the systemic effects associated with pharmacological agents [10]. However, research on its combined use with low-dose oxytocin, particularly in Asian women, remains limited [11].

There is a sound rationale for combining both methods. Oxytocin primarily activates uterine receptors to produce contractions, while the balloon physically promotes cervical collagen remodeling [12]. The combination of both approaches could overcome the limitations of each method individually, potentially leading to better outcomes [13].

This study was designed to provide robust, clinically relevant data. Through a retrospective analysis of 100 cases, we compared various outcomes, including improvements in the Bishop score, labor duration parameters, pain scores, and adverse event rates. This multidimensional evaluation aims to offer clinicians practical evidence to guide their labor induction protocols.

Materials and methods

Study population

A retrospective study was conducted on 100 full-term pregnant women who underwent labor induction at Beijing Luhe Hospital, Affiliated with Capital Medical University, between January 2022 and December 2023. The study was approved by the Institutional Review Board and Research Ethics Committee of Beijing Luhe Hospital. Patient data were collected through the hospital's electronic medical record system. Since no patient harm or intervention was involved, informed consent was waived.

Inclusion Criteria: Patients were selected based on the Guidelines for Cervical Ripening in Late Pregnancy and Labor Induction [14]. Eligible patients had a gestational age between 37 and less than 42 weeks and were primiparous women aged 20-35 years with good cognitive function and compliance. Indications for induction included post-term pregnancy (≥41 weeks), maternal conditions (e.g., severe diabetes, hypertension), premature rupture of membranes without labor onset, suspected fetal distress, or fetal factors such as placental insufficiency.

Exclusion Criteria: Excluded participants were women with a history of cesarean section, gynecological diseases (e.g., pelvic inflammatory disease), contraindications to vaginal delivery, concomitant malignancies, severe organ dysfunction (heart, liver, kidneys), fetal demise, severe allergies, infections, antepartum hemorrhage, or psychiatric conditions.

Participants were divided into two groups: a control group (n=50) receiving low-dose oxytocin and a study group (n=50) receiving the Yixinda cervical double-balloon catheter combined with low-dose oxytocin.

Methods

Fetal heart and vital signs were monitored throughout labor induction, and regular cervical Bishop scores were assessed to observe uterine contractions and labor progress.

Control group: The control group received 2.5 U oxytocin (1 mL:10 U, Jiangsu Hengxin Pharmaceutical Co., Ltd., H32024969, complying with standard YBH01032023) diluted in 500 mL 0.9% sodium chloride solution (500 mL:4.5 g, Hunan Kelun Pharmaceutical Co., Ltd., H43020455, complying with the Chinese Pharmacopoeia 2015 edition) administered via intravenous infusion. The initial infusion rate was set at 8 drops/min, gradually adjusted to 15-30 drops/min, with a maximum rate of 40 drops/min, until uterine contractions occurred. Infusion was maintained for up to 10 hours per day, for a maximum of 3 days. If no significant uterine contractions occurred, labor induction was considered unsuccessful.

Study group: The study group received the same low-dose oxytocin regimen as the control group, in addition to the Yixinda cervical double-balloon catheter (Shenzhen Yixinda Medical Technology Co., Ltd., model CVB-18F-II). The procedure was as follows: After positioning the patient in lithotomy, the perineum was disinfected, and a speculum was inserted to expose the cervix. Using cervical forceps, the Yixinda catheter was inserted into the cervical canal.

Eighty mL of 0.9% sodium chloride solution was injected into the proximal balloon, and the balloon was retracted to the internal cervical os. Another 80 mL was injected into the vaginal balloon. The catheter was secured to the inner thigh using adhesive tape. The balloon fell out spontaneously after cervical dilation or was removed after membrane rupture. If cervical dilation was inadequate after 12 hours, artificial rupture of membranes was performed if uterine contractions were mature.

Assessment parameters

Cervical ripening effect: Cervical ripening was evaluated. Significant improvement was defined as a >3 point increase in the Bishop score within 24 hours, with labor induction completed within 24 hours; effective improvement was defined as a 2-3 point increase within 24 hours, with labor induction occurring between 24-48 hours; ineffectiveness was defined as a ≤2 point increase, with failure to induce labor after ≥48 hours. The overall effective rate was calculated by combining significant and effective improvements.

Labor induction time: The time from induction procedures (oxytocin infusion and balloon dilation) to regular contractions and cervical changes was recorded and compared. The first stage was from regular contractions to complete cervical dilation; the second stage was from dilation to delivery; the third stage was from fetal delivery to placental expulsion; total labor time was the sum of all stages.

Visual Analog Scale (VAS): Pain intensity was measured using a 10 cm VAS before intervention and during the first, second, and third stages of labor. The scale ranged from 0 (no pain) to 10 (maximum pain intensity).

Cervical bishop score: The Bishop score was assessed before intervention, at 12 hours post-intervention, and at 24 hours post-intervention. The score includes five parameters: cervical dilation, consistency, position, effacement, and fetal presentation, with a total score ranging from 0 to 13.

Labor induction status: Postpartum bleeding (2 hours), Apgar score (1 minute post-delivery), and the number of successful inductions and cesarean sections within 72 hours were recorded. The Apgar score evaluates skin color, heart rate, muscle tone, respiration, and response to stimuli, with higher scores indicating better neonatal health.

Endothelin-1 (ET-1) and Prostaglandin E2 (PGE2): Fasting venous blood samples (5 mL) were collected before and after treatment, centrifuged at 3,000 rpm for 10 minutes, and the serum was stored at -20°C for subsequent analysis. ET-1 and PGE2 levels were measured using a chemiluminescence immunoassay analyzer (CL-2000i, Mindray, China).

Adverse events: The incidence of neonatal asphyxia, abnormal fetal heart rate, meconium-stained amniotic fluid, and postpartum hemorrhage was compared.

Satisfaction level: Patient satisfaction was assessed across four domains: pain control, procedural comfort, satisfaction with outcomes, and patient-provider communication, using a 25-point scale. Total scores (0-100) were classified as: Dissatisfied (0-50), Moderately satisfied (51-70), Satisfied (71-85), and Highly satisfied (86-100).

Statistical methods

Statistical analyses were performed using SPSS version 25.0. Continuous variables were first tested for normal distribution through the Shapiro-Wilk normality test. For normally distributed continuous variables, intergroup comparisons were made employing independent samples t-tests. In all statistical tests, results were used for intergroup comparisons. Counts were reported as n (%) and group comparisons were conducted using the χ^2 test. A two-tailed *p*-value <0.05 was considered statistically significant when the two-tailed *p*-value was less than 0.05.

Results

Comparison of general information

Both groups demonstrated good balance in terms of demographic and clinical characteristics (all P>0.05), as shown in **Table 1**.

Comparison of cervical ripening effects

As shown in **Table 2**, the study group demonstrated superior cervical ripening efficacy com-

Table 1. Comparison of general information

	Study group (n=50)	Control group (n=50)	t/χ^2	p
Age (years)	26.96±2.65	27.34±2.39	0.745	0.458
Gestational age ($\bar{x}$±s, week)	39.62±0.34	39.71±0.51	1.038	0.302
BMI ($\bar{x}$±s, kg/m^2)	24.76±2.71	25.02±3.13	0.444	0.658
Cervical Bishop score [n (%)]			0.679	0.410
≤3	33 (66.00)	29 (58.00)		
4	17 (34.00)	21 (42.00)		
Indications for induction of labor [n (%)]			2.314	0.510
Oligohydramnios or polyhydramnios	7 (14.00)	3 (6.00)		
Gestational diabetes	13 (26.00)	11 (22.00)		
Gestational hypertension	16 (32.00)	19 (38.00)		
Post-term pregnancy	14 (28.00)	17 (34.00)		

BMI: Body Mass Index.

Table 2. Comparison of cervical ripening effects [n (%)]

Group	n	Significant	Moderate	None	Effective rate
Study	50	21 (42.00)	28 (56.00)	1 (2.00)	49 (98.00)
Control	50	11 (22.00)	31 (62.00)	8 (16.00)	42 (84.00)
x^2	-	-	-	-	4.396
p	-	-	-	-	0.036

pared to the control group. The total effective rate (combining significant and moderate improvements) was 98% in the study group, significantly higher than 84% in the control group. These results indicate that the combined intervention significantly enhances cervical ripening efficacy compared to oxytocin alone (χ^2=4.396, *P*=0.036).

Comparison of labor induction times

The study group demonstrated significantly shorter labor durations compared to the control group (all P<0.05, **Table 3**). Specifically, the induction-to-delivery time, first stage, and total labor time were all markedly reduced in the study group. While the second stage was also shorter, no significant difference was observed in the third stage duration (P=0.558).

Comparison of VAS scores

The study group exhibited significantly lower VAS pain scores across all labor stages compared to the control group (all P<0.05, **Figure 1**). During the first stage, the study group reported lower pain scores (*P*=0.007), which persisted in the second (*P*=0.017) and third stages (*P*=0.002). These findings demonstrate that the combined intervention effectively reduces labor pain intensity compared to oxytocin alone.

Comparison of cervical bishop scores

Both groups showed significant improvement in cervical Bishop scores after intervention (*P*<0.05, **Figure 2**). At 12 hours post-intervention, the study group had higher scores compared to the control group (*P*<0.001). This difference remained significant at 24 hours (*P*<0.001). Notably, while baseline scores were comparable (*P*=0.081), the study group achieved greater cervical maturation at both follow-up time points, indicating the superior efficacy of the combined intervention in promoting cervical ripening.

Comparison of labor induction conditions

Postpartum bleeding was significantly lower in the study group compared to the control group (*P*=0.044, **Table 4**). No significant differences were observed in the 1-minute Apgar score after birth (*P*=0.354) or the rate of successful inductions within 72 hours and cesarean section rate (*P*=0.162).

Comparison of ET-1 and PGE2 levels

Table 5 shows significant differences in ET-1 and PGE2 levels before and after treatment. For ET-1, no significant difference was found before treatment (*P*=0.580). However, post-treatment, the study group exhibited significantly higher ET-1 levels compared to the control group (P=0.009). Similarly, for PGE2, no

Table 3. Comparison of labor induction times ($\bar{x}$±s, h)

Group	n	Induction to delivery	First stage	Second stage	Third stage	Total labor time
Study	50	18.61±3.95	5.66±1.58	1.15±0.23	0.17±0.08	6.98±1.48
Control	50	34.16±10.06	9.15±3.01	1.27±0.33	0.18±0.09	10.60±1.97
t	-	10.174	7.259	2.110	0.587	10.389
p	-	0.001	0.001	0.038	0.558	0.001

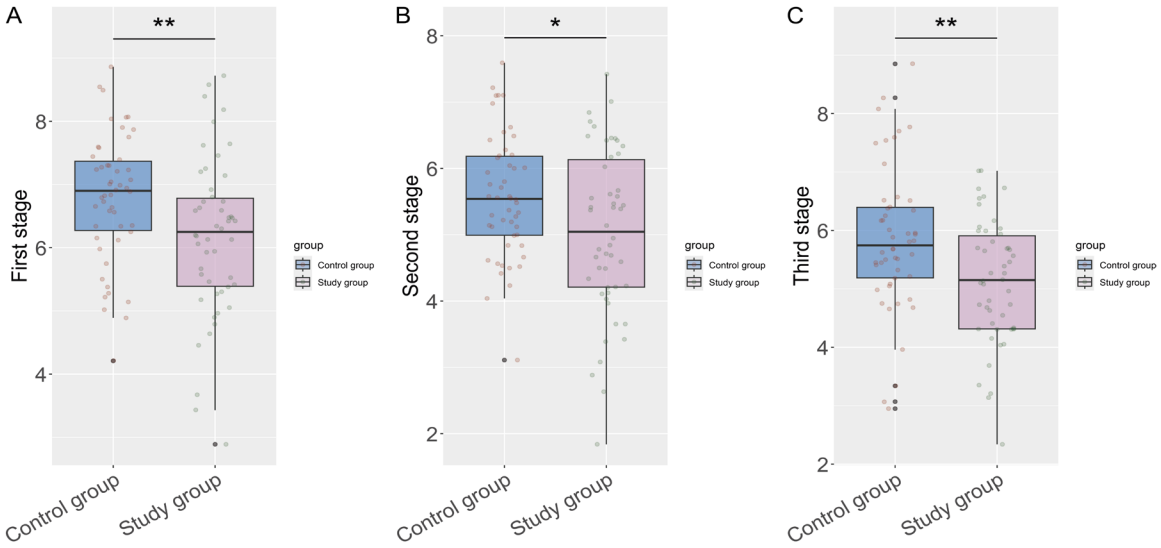

Figure 1. Comparison of VAS scores for various stages of labor and pain during delivery. A. VAS score during the first stage of labor; B. VAS score during the second stage of labor; C. VAS score during the third stage of labor. VAS: Visual Analog Scale; *: P<0.05; **: P<0.01.

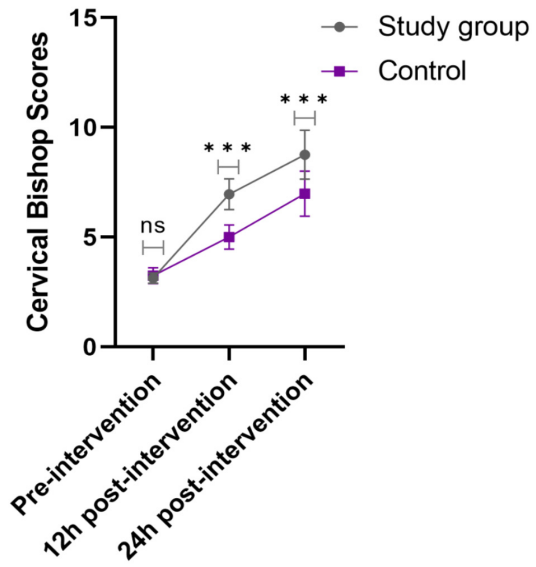

Figure 2. Comparison of cervical Bishop scores between the two groups. ns: no significant difference; ***: P<0.001.

significant difference was observed before treatment (P=0.647). After treatment, the study group exhibited significantly higher PGE2 levels compared to the control group (P=0.004).

Comparison of occurrence of adverse events

The study group exhibited a significantly lower overall incidence of adverse events compared to the control group (P=0.036, **Table 6**). Specifically, the control group reported neonatal asphyxia, abnormal fetal heart rate, meconium-stained amniotic fluid, and postpartum hemorrhage, while the study group had only one case of abnormal fetal heart rate. These findings suggest that the combined intervention with the Yixin Da cervical double-lumen balloon dilatation and low-dose oxytocin significantly reduces the risk of adverse perinatal outcomes compared to oxytocin alone.

Comparison of labor induction satisfaction

Table 7 shows that the study group had a significantly higher overall satisfaction rate compared to the control group, with a statistically significant difference in satisfaction distribu-

Table 4. Comparison of labor induction conditions

Group	n	Postpartum bleeding (mL)	1-minute Apgar score after birth (score)	Successful inductions within 72 hours [n (%)]	Cesarean section [n (%)]
Study	50	153.16±18.47	8.74±0.28	48 (96.00)	2 (4.00)
Control	50	161.65±22.87	8.68±0.39	43 (86.00)	7 (14.00)
t/x^2	-	2.042	0.931	1.954	
p	-	0.044	0.354	0.162	

Table 5. Comparison of ET-1 and PGE2 levels

Group	n	ET-1		PGE2	
		Before treatment	After treatment	Before treatment	After treatment
Study	50	2.15±0.42	6.74	5.34	10.52
Control	50	2.08±0.37	5.86	5.41	9.15
t	-	0.555	2.673	0.459	2.956
p	-	0.580	0.009	0.647	0.004

ET-1: Endothelin-1; PGE2: Prostaglandin E2.

Table 6. Comparison of adverse events [n (%)]

Group	n	Neonatal asphyxia	Abnormal fetal heart rate	Meconium-stained amniotic fluid	Postpartum hemorrhage	Occurrence rate
Study	50	0 (0)	1 (2.00)	0 (0)	0 (0)	1 (2.00)
Control	50	2 (4.00)	3 (6.00)	1 (2.00)	2 (4.00)	8 (16.00)
x^2	-	0.510	0.260	0.001	0.510	4.396
p	-	0.475	0.610	1.000	0.475	0.036

Table 7. Comparison of satisfaction level [n (%)]

Group	n	Highly satisfied	Satisfied	Moderately satisfied	Dissatisfied
Study	50	28 (56%)	16 (32%)	5 (10%)	1 (2%)
Control	50	16 (32%)	16 (32%)	13 15 (30%)	3 (6%)
x^2	9.273				
p	0.026				

tion between the two groups (χ^2=9.273, P= 0.026).

Discussion

The primary goal of labor induction in full-term pregnancies is to actively terminate the pregnancy when natural delivery does not occur as scheduled or when maternal or fetal complications arise. This intervention reduces potential risks to both mother and fetus, ensuring the safety of both and improving maternal and infant outcomes. Previous studies have indicated that factors such as parity, cervical score, and cervical ripening effectiveness can influence the success of labor induction [15]. Among these, cervical ripeness is the most crucial factor affecting labor induction and delivery. Higher cervical ripeness facilitates softening, shortening, dilation, and effacement of the cervix, promoting delivery and increasing the success rate of labor induction [16]. Thus, improving methods to promote cervical ripening and reduce the time required for this process remains an important area of research [17].

Oxytocin, a uterotonic peptide hormone, binds to oxytocin receptors in the uterine muscle, stimulating contractions and aiding cervical dilation and ripening [18]. The YiXinDa cervical double-balloon dilation device is a mechanical method designed to promote cervical ripening by using balloon compression to expand the

uterine cavity [19]. In this study, the combination of the YiXinDa cervical double-balloon and low-dose oxytocin was used for labor induction in full-term pregnancies. The results showed that the study group had a total effective cervical ripening rate of 98%, compared to 84% in the control group, indicating that this combined intervention significantly enhances cervical ripening efficacy. Oxytocin, synthesized and released from the hypothalamus, promotes uterine contractions and facilitates vaginal delivery under normal pregnancy conditions. Intravenous oxytocin infusion can simulate uterine contractions, playing a key role in fetal delivery. However, the need for 10-hour daily infusions limits women's daily activities [20], and small oxytocin doses prolong induction, which delays cervical ripening [21].

The YiXinDa cervical double-balloon dilation consists of two connected balloons - one placed inside the cervix and the other outside - exerting pressure in both directions to aid cervical dilation. Balloon compression mimics the stimulation of cervical tissues during fetal delivery, promoting endogenous prostaglandin and oxytocin release, collagen degradation, cervical softening, shortening, and dilation [22, 23]. Thus, the combined use of the YiXinDa cervical balloon with low-dose oxytocin enhances cervical ripeness more effectively than oxytocin alone [24].

Labor, the process from uterine contractions to fetal delivery, requires careful management for successful induction [25]. In this study, the induction-to-delivery time, first stage, second stage, and total labor duration were all significantly shorter in the study group. This indicates that the combination of YiXinDa cervical balloon and low-dose oxytocin can shorten labor duration. This effect may be due to the direct mechanical action of the YiXinDa balloon on the cervix, promoting cervical dilation and ripening. Additionally, the ability to ambulate after balloon placement improves patient compliance, which enhances cervical readiness and shortens both the latent and active phases of labor [26].

The Bishop score, a widely used tool for assessing cervical maturity, correlates with higher vaginal delivery success rates. In this study, the Bishop scores at 12 and 24 hours post-intervention were higher in the study group, indicating that the combined intervention improves cervical readiness. The YiXinDa double-balloon system applies simultaneous pressure to both sides of the cervix, facilitating more symmetrical dilation, improving Bishop scores, and contributing to higher induction success rates and lower cesarean rates compared to conventional single-balloon devices [27].

While existing studies show the efficacy of cervical balloons combined with oxytocin for labor induction, our study introduces several novel aspects. It uniquely investigates the YiXinDa cervical double-lumen balloon dilation, which provides bidirectional pressure for uniform cervical dilation. This study demonstrates the efficacy of combining the YiXinDa balloon with low-dose oxytocin, particularly focusing on Asian women - a group underrepresented in this area of research. Additionally, we measured ET-1 and PGE2 levels, which showed significant increases in the study group, indicating improved cervical ripening and labor progression. This research emphasizes real-world clinical outcomes and underscores the practical benefits of this combined approach in routine obstetric practice.

In conclusion, the combination of the YiXinDa cervical double-balloon and low-dose oxytocin is effective for term labor induction. It shortens labor, improves Bishop scores, reduces postpartum bleeding, and minimizes adverse events. However, this study has limitations, such as a small sample size and potential confounding factors influencing induction success. Larger studies are needed to validate the broader application of this combined approach.

Disclosure of conflict of interest

None.

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