Comparison of the effectiveness and pregnancy outcomes of labor induction with dinoprostone or single-balloon catheter in term nulliparous women with borderline oligohydramnios

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Abstract

Backgrounds: At present, there is no consensus on the induction methods in term pregnancy with borderline oligohydramnios. This study aimed to compare the effectiveness and pregnancy outcomes of labor induction with dinoprostone or single-balloon catheter (SBC) in term nulliparous women with borderline oligohydramnios.

Methods: We conducted a retrospective cohort study from January 2016 to November 2018. During the study period, a total of 244 cases were enrolled. Of these, 103 cases were selected for induction using dinoprostone and 141 cases were selected for induction with SBC. The pregnancy outcomes between the two groups were compared. Primary outcomes were successful vaginal delivery rates. Secondary outcomes were maternal and neonatal adverse events. Multivariate logistic regression was used to assess the risk factors for vaginal delivery failure in the two groups.

Results: The successful vaginal delivery rates were similar between the dinoprostone group and the SBC group (64.1% [66/103] *vs.* 59.6%, [84/141] $P = 0.475$), even after adjustment for potential confounding factors (adjusted odds ratio [aOR]: 1.07, 95% confidence interval [CI]: 0.57–2.00, $P = 0.835$). The incidence of intra-amniotic infection was lower in the dinoprostone group than in the SBC group (1.9% [2/103] *vs.* 7.8% [11/141], $P < 0.001$), but the presence of non-reassuring fetal heart rate was higher in the dinoprostone group than in the SBC group (12.6% [13/103] *vs.* 0.7%, [1/141] $P < 0.001$). Multivariate logistic regression showed that nuchal cord was a risk factor for vaginal delivery failure after induction with dinoprostone (aOR: 6.71, 95% CI: 1.96–22.95). There were three factors related to vaginal delivery failure after induction with SBC, namely gestational age (aOR: 1.51, 95% CI: 1.07–2.14), body mass index (BMI) >30 kg/m^2 (aOR: 2.98, 95% CI: 1.10–8.02), and fetal weight >3500 g (aOR: 2.49, 95% CI: 1.12–5.50).

Conclusions: Term nulliparous women with borderline oligohydramnios have similar successful vaginal delivery rates after induction with dinoprostone or SBC, with their advantages and disadvantages. In women with nuchal cord, the risk of vaginal delivery failure is increased if dinoprostone is used in the induction of labor. BMI >30 kg/m^2, large gestational age, and estimated fetal weight >3500 g are risk factors for vaginal delivery failure after induction with SBC.

Keywords: Borderline oligohydramnios; Induction of labor; Single-balloon catheter; Dinoprostone; Nuchal cord

Introduction

Amniotic fluid is one of the determining factors of fetal well-being during pregnancy, and it is essential for normal fetal growth and development.[1,2] Changes in amniotic fluid volume are considered an important indicator of placental function.[3] The amniotic fluid index (AFI) is the most commonly used quantitative method for assessing amniotic fluid volume and is obtained by ultrasonic measurement.[4] Oligohydramnios is defined as an AFI of ≤5.0 cm, whereas borderline oligohydramnios (or borderline AFI) is defined as an AFI of 5.1 to 8 cm measured using the four-quadrant technique.[5]

Previous studies have revealed that oligohydramnios (AFI ≤ 5.0 cm) is closely related to adverse perinatal outcomes, complications during pregnancy, and cesarean delivery.[6,7] However, the accuracy of borderline oligohydramnios for predicting adverse perinatal outcomes is uncertain and controversial. Some studies suggest that borderline oligohydramnios is associated with an increase in adverse perinatal outcomes, including an increase in preterm births, cesarean delivery because of non-reassuring fetal heart rate (NRFHR), and fetal growth restriction.[8-11] However, other studies have found no significant difference in pregnancy outcomes between pregnant women with borderline oligohydramnios and those with

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normal AFI in terms of cesarean delivery for fetal distress, meconium-stained amniotic fluid (MSAF), and neonatal complications.[12,13]

It is currently believed that women with borderline oligohydramnios have no serious complications, so it is generally managed expectantly in conjunction with enhanced fetal surveillance. Once the amniotic fluid decreases progressively or other complications occur, the induction of labor should be considered promptly.

At present, there is no consensus on the induction methods in term pregnancy with borderline oligohydramnios. Chemical methods (such as prostaglandins) and mechanical methods (such as trans-cervical balloon and Foley catheter) are most widely used for cervical ripening. Prostaglandins are effective for cervical ripening and induction of uterine contractions. However, they cause overstimulation of the uterus, sometimes causing changes in the fetal heart rate.[14,15] Atrans-cervical balloon provides an alternative to prostaglandins for labor induction. Cases of oligohydramnios, fetal growth restriction, pregnancy complicated with asthma, hypertension, and uterine scarring favor a balloon catheter for cervical ripening because of the high risk of using prostaglandins.[16,17] However, studies have found that induction of labor with a balloon catheter has a higher probability of intra-amniotic infection than induction with dinoprostone.[16] Moreover, studies have shown that an AFI <8 cm and nulliparity are risk factors for intra-amniotic infection after induction with a single-balloon catheter (SBC).[18] A recent retrospective cohort study has shown that, in women with term isolated oligohydramnios, the use of prostaglandins for labor induction is superior to induction with an extra-amniotic balloon, not only in cervical ripening success but also in successful vaginal delivery rates.[19] Until now, none of the current studies suggest which type of pregnant women with borderline oligohydramnios is more suitable for induction with dinoprostone or a balloon catheter, so we cannot provide guidance for these women to choose individualized labor induction methods and achieve a higher success rate of vaginal delivery.

We conducted a retrospective cohort study in our hospital between January 2016 and December 2018. During the study period, all term nulliparous women with borderline oligohydramnios were delivered in our hospital and underwent induction with dinoprostone or SBC. The effectiveness of induction and maternal-fetal outcomes were compared and the risk factors for vaginal delivery failure in the two groups were separately analyzed to provide guidance for individualized induction methods in these patients.

Methods

Ethical approval

This study was conducted in accordance with the *Declaration of Helsinki* and was approved by the Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University (No: IRB-20200002-R). As this was a retrospective study, written informed consents were not obtained, but all patients' records/information were anonymized before analysis.

Patients

Data of 244 term nulliparous women with unfavorable cervices and borderline oligohydramnios who underwent induction with dinoprostone (dinoprostone 10 mg controlled-release vaginal insert (Controlled Therapeutics [Scotland] Limited, East Kilbride, Scotland) or SBC (Aiyuan Technology Corp., Ltd., Taizhou, Jiangsu, China) in our hospital between January 2016 and December 2018 were recruited for our retrospective cohort study. Among them, 103 cases were women who underwent induction with dinoprostone vaginal insert (dinoprostone group) and 141 cases were women who underwent induction with SBC (SBC group).

Selection criteria

Pregnant women with a gestation between 37^{+0} weeks and 41^{+6} weeks, singleton, vertex presentation, borderline oligohydramnios (AFI 5.1–8.0 cm), medical indication for induction of labor, and unripe cervix with Bishop score ≤ 6 as well as nulliparous women with intact membranes were eligible for inclusion. We excluded women with in utero fetal deaths, malpresentation (breech presentation or transverse lie presentation), twin pregnancy, Bishop score >6, natural labor not requiring induction of labor, and refusing to try vaginal delivery and requiring cesarean section; women who had any other cesarean section or uterine surgery history, any other contraindication for vaginal delivery and labor induction (macrosomia, placenta previa, fetal distress, oxytocin challenge test positive, suspicious placental abruption, or cephalopelvic disproportion), any other fetal or maternal diseases (fetal malformation, gestational hypertension, or preeclampsia), and cases of further reduction in amniotic fluid during vaginal delivery and refusal to continue a trial of vaginal delivery were also excluded. Those undergoing application of an SBC followed by intravaginal dinoprostone or cases undergoing dinoprostone induction followed by SBC induction were also excluded. To reduce the potential confounding factors caused by parity, only nulliparous women were selected for this study.

Ultrasound examinations were performed on pregnant women to evaluate gestational age and amniotic fluid volume. The gestational age was calculated from the ultrasound measurement before 12 weeks gestation. The AFI was determined using the four-quadrant technique and borderline oligohydramnios was defined as an AFI of 5.1 to 8.0 cm.

Clinical management

Women were given information about this mechanical or chemical method of induction, and risks and benefits about trial of labor were discussed. Informed consent was obtained on the last prenatal visit and it was confirmed on admission for induction of labor. At present, there is no consensus on the induction methods in term pregnancy with borderline oligohydramnios. Therefore, in this study, pregnant women and doctors had no preference for the selection of induction methods.

If women chose the chemical method of induction, a single dose of 10 mg slow-release dinoprostone vaginal insert was used for induction of labor in women with an unfavorable cervix, whereas oxytocin augmentation was used if the progress of labor was considered insufficient. The vaginal dinoprostone was removed in the presence of uterine hyperstimulation (>5 contractions in 10 min), NRFHR, successful ripening (Bishop score >7), or 24 h after insertion regardless of the Bishop score.

If women chose the mechanical method of induction, an SBC was used for cervical ripening by filling the balloon with up to 150 mL of saline. Once the SBC was correctly placed, it was strapped to the inner aspect of one leg without traction. The catheter was removed within 24 h. If the catheter caused discomfort for the woman, the amniotic membranes ruptured, there was onset of active labor, or there was a NRFHR pattern, the balloon was removed. If the cervical score was higher, oxytocin induction was indicated.

Discontinuous fetal heart rate monitoring was performed during the induction process. Labor was managed by the obstetricians and mid wives according to the existing protocols in the hospital. Continuous fetal heart rate monitoring was used during oxytocin induction and active labor.

Statistical analyses

Study data were collected from delivery information that was recorded by the research team. Baseline maternal data and perinatal outcomes were recorded for descriptive and multivariate analyses. Outcome data are presented as percentages (*n* [%]), median (interquartile range), and mean ± standard deviation. Comparison between groups was analyzed using Student *t* test, Wilcoxon rank sum test, and chi-square test. ORs and 95% confidence intervals [CIs] were calculated to determine which factors increased the possibility of failure of vaginal delivery related to induction with dinoprostone or SBC when a difference was found. IBM SPSS Statistics 21.0 (IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY, USA) was used for statistical analyses and calculations. A P value < 0.050 was considered statistically significant.

Results

Recruitment and baseline data

Over the study period, 2370 women were diagnosed with pregnancy with borderline AFI. However, 2126 women were excluded for not meeting the selection criteria. Finally, 103 patients in the dinoprostone group and 141 women in the SBC group were included in the study. There were no losses to the follow-up and complete information required were available in all cases [Figure 1].

Comparison of the baseline characteristics between the dinoprostone group and SBC group

Compared with the SBC group, the dinoprostone group had a higher Bishop score after cervical ripening (8 [6–9] *vs.* 7 [6–8], $P = 0.002$). Duration of cervical ripening was shorter in the dinoprostone group as compared with the SBC group (13.0 h ± 6.5 h *vs.* 15.8 h ± 4.8 h, $P < 0.001$). They all had significant differences, whereas the maternal age, gravidity, parity, gestational age, body mass index (BMI), AFI, and initial Bishop score showed no significant differences (all $P > 0.050$) [Table 1].

Comparison of maternal-fetal outcomes between the two groups

The rate of successful ripening was higher in the dinoprostone group as compared with the SBC group (58.3% [60/103] *vs.* 36.9%, [52/141] $P < 0.001$). The incidence of intra-amniotic infection was lower in the dinoprostone group as compared with the SBC group (1.9% [2/103] *vs.* 7.8%, [11/141] $P < 0.001$), but the occurrence of a NRFHR was higher in the dinoprostone group than in the SBC group (12.6% [13/103] *vs.* 0.7% [1/141], $P < 0.001$). There were more interventions with oxytocin in the SBC group as compared with the dinoprostone group (85.8% [121/141] *vs.* 33.0% [34/103], $P < 0.001$). They all had significant differences, where as the fetal weight, the rate of successful vaginal delivery, operative vaginal delivery, placental abruption, cesarean section, MSAF, postpartum hemorrhage, nuchal cord, 1 min or 5 min Apgar score <7, and neonatal intensive care unit (NICU) admission showed no significant differences (all $P > 0.050$) [Table 2].

Post hoc analysis following adjustment to potential confounders: ripening methods (dinoprostone *vs.* SBC), oxytocin use, maternal age, gravidity, gestational age, BMI, AFI, and initial Bishop score was elaborated in Table 3. There was still no difference regarding successful vaginal delivery rate between the two induction methods (aOR: 1.07, 95% CI: 0.57–2.00, $P = 0.835$).

Univariate and multivariate analyses of risk factors for failure of vaginal delivery in the dinoprostone group

In the dinoprostone group ($n = 103$), 66 cases (64.1%) had successful vaginal delivery and 37 cases (35.9%) had failed vaginal delivery (successful group, $n = 66$; failed group, $n = 37$). Univariate analysis showed that the Bishop score after removal of dinoprostone in the successful group was higher than that of the failed group (8 [7–8] vs. 6 [5–8], $P < 0.001$); the diameter of cervical dilatation in the successful group was larger than that in the failed group (1.5 [0.5–2.0] cm *vs.* 0 [0–1] cm, $P < 0.001$); the incidence of nuchal cord in the successful group was lower than that in the failed group (22.7% [15/66] *vs.* 43.2% [16/37], $P = 0.029$). They all had significant differences, where as the maternal age, gravidity, parity, gestational age, BMI, AFI, initial Bishop score, duration of cervical ripening, fetal weight, MSAF rate, and incidence of 1 or 5 min Apgar score < 7 between the two groups showed no significant differences (all $P > 0.050$) [Table 4].

After univariate analysis [Table 4], the Bishop score after removal of dinoprostone, the diameter of cervical dilatation after removal of dinoprostone and nuchal cord were related to the failure of vaginal delivery after induction with dinoprostone. After multivariate logistic regression, only nuchal cord was the risk factor for vaginal delivery failure

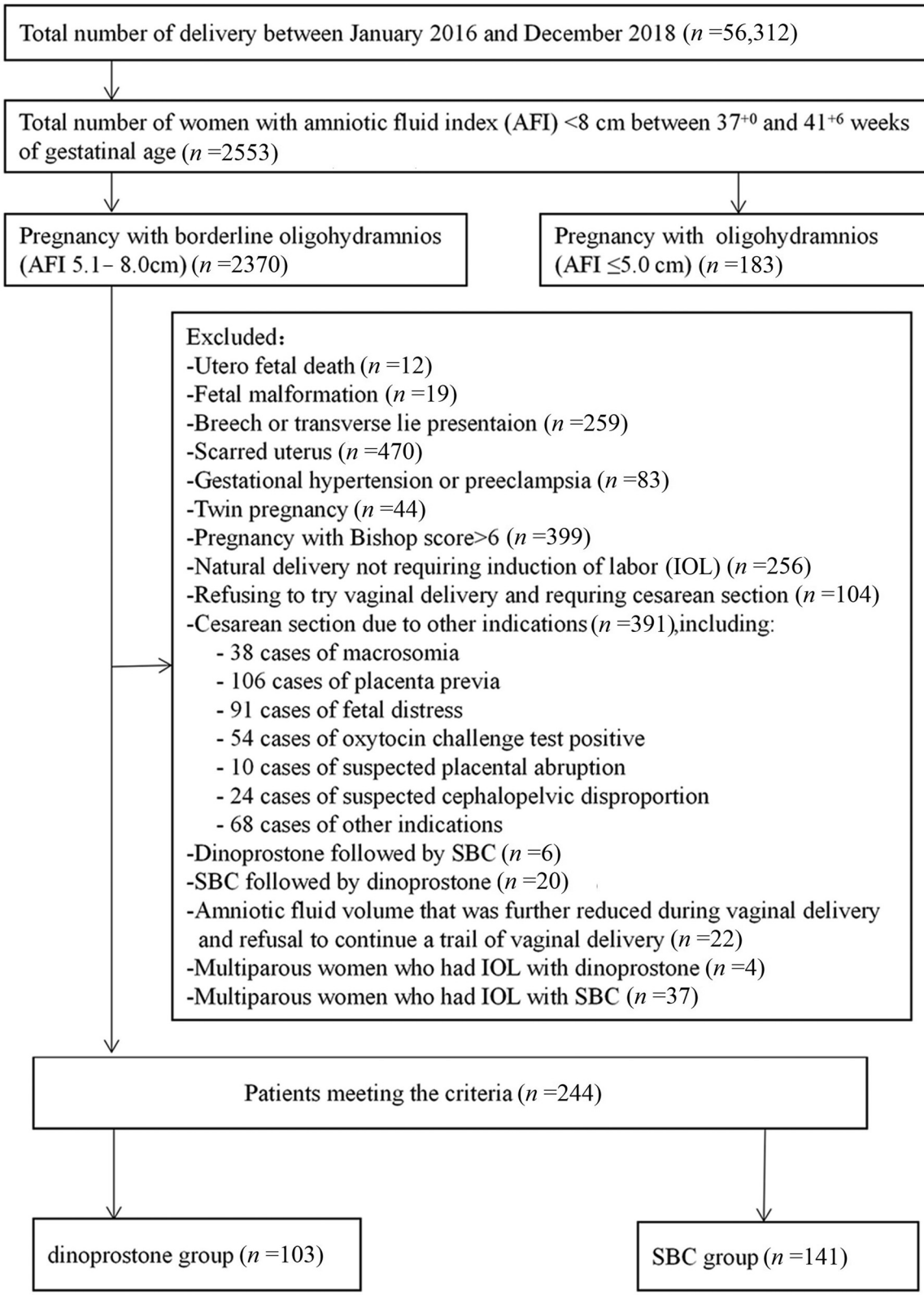

Figure 1: Enrollment flow diagram. SBC: Single-balloon catheter.

after induction with dinoprostone (aOR: 6.71, 95% CI: 1.96–22.95, $P = 0.002$). On univariate analysis, the Bishop score after removal of dinoprostone and diameter of cervical dilatation after removal of dinoprostone were significantly associated with vaginal delivery failure after induction with dinoprostone; however, these relationships became insignificant after adjustment for potentially confounding factors (all $P > 0.050$) [Table 5].

Table 1: Baseline characteristics of the dinoprostone group and SBC group.

Factors	Dinoprostone group ($n = 103$)	SBC group ($n = 141$)	Statistics	*P* value
Maternal age (years)	28.9 ± 3.5	29.0 ± 3.0	–0.326*	0.745
Gravidity	1 (1–2)	1 (1–2)	0.868†	0.386
Parity	0 (0–0)	0 (0–0)	0.000†	1.000
GA (weeks)	40 (39–41)	40 (39–40)	–1.529†	0.126
37 weeks 0 day–37 weeks 6 days	4 (3.9)	4 (2.8)		
38 weeks 0 day–38 weeks 6 days	12 (11.6)	16 (11.3)		
39 weeks 0 day–39 weeks 6 days	13 (12.6)	34 (24.1)		
40 weeks 0 day–40 weeks 6 days	42 (40.8)	55 (39.0)		
≥41 weeks	32 (31.1)	32 (22.7)		
BMI (kg/m^2)	26.7 ± 3.0	26.7 ± 3.2	–0.017*	0.987
AFI (cm)	6.5 ± 0.9	6.4 ± 0.8	0.868*	0.386
Bishop score 1	4 (3–4)	4 (3–5)	–1.651†	0.100
Bishop score 2	8 (6–9)	7 (6–8)	–3.167†	0.002
Δ Bishop score	4 (2–5)	3 (2–4)	–3.817†	<0.001
Duration of cervical ripening (h)	13.0 ± 6.5	15.8 ± 4.8	–3.930*	<0.001

Values were shown as mean ± SD, *n* (%), or median (IQR). * *t* value. † *Z* value. Bishop score 1: Initial Bishop score before cervical ripening; Bishop score 2: Bishop score after cervical ripening; Δ Bishop score: Bishop score 2 – Bishop score 1. AFI: Amniotic fluid index; BMI: Body mass index; d: Day(s); GA: Gestational age; IQR: Interquartile range; SBC: Single-balloon catheter; wk: Weeks.

Table 2: Comparison of maternal and neonatal outcomes between the two groups.

Factors	Dinoprostone group ($n = 103$)	SBC group ($n = 141$)	Statistics	*P* value
Successful ripening	60 (58.3)	52 (36.9)	10.949*	0.001
Vaginal delivery	66 (64.1)	84 (59.6)	0.510*	0.475
Normal vaginal delivery	57 (86.4)	79 (94.0)	1.732*	0.188
Operative vaginal delivery	9 (13.6)	5 (6.0)	1.732*	0.188
Intra-amniotic infection	2 (1.9)	11 (7.8)	4.052*	0.044
Placental abruption	2 (1.9)	8 (5.7)	2.109*	0.146
Cesarean delivery	37 (35.9)	57 (40.4)	0.510*	0.475
Intra-amniotic infection	1 (2.7)	8 (14.0)		
Placental abruption	0 (0.0)	4 (7.0)		
Prolonged latent phase	0 (0.0)	5 (8.8)		
Relative cephalopelvic disproportion	1 (2.7)	4 (7.0)		
Fetal distress	21 (56.8)	23 (40.4)		
Persistent occipitoposterior position	1 (2.7)	1 (1.8)		
Macrosomia	2 (5.4)	0 (0.0)		
Failed induction of labor	11 (29.7)	12 (21.0)		
NRFHR	13 (12.6)	1 (0.7)	15.616*	<0.001
MSAF	28 (27.2)	31 (23.1)†	0.511*	0.475
Oxytocin use	34 (33.0)	121 (85.8)	71.629*	<0.001
Intrapartum hemorrhage (mL)	257.5 ± 116.0	252.5 ± 104.8	0.351‡	0.726
Postpartum hemorrhage	2 (1.9)	3 (2.1)	0.010*	0.919
Birth weight (g)	3281.2 ± 423.6	3294.3 ± 381.3	–0.253‡	0.800
Nuchal cord	31 (30.1)	37 (26.2)	0.440*	0.507
1 min Apgar score <7	6 (5.8)	2 (1.4)	2.101*	0.147
5 min Apgar score <7	0 (0)	0 (0)	NA	–
NICU admission	14 (13.6)§	13 (9.2)‖	1.156*	0.282

Values were shown as mean ± SD, *n* (%), or median (IQR). * χ^2 value. † Seven cases were suspected of having placental abruption with bloody amniotic fluid and were excluded. ‡ *t* value. § In the dinoprostone group, a total of 14 neonates were admitted to the NICU, including six cases of mild neonatal asphyxia, five cases of respiratory distress, two cases of intra-amniotic infection, and one case of postpartum fever. ‖ In the SBC group, a total of 13 neonates were admitted to the NICU, including 11 cases of intra-amniotic infection and two cases of mild neonatal asphyxia. IQR: Interquartile range; MSAF: Meconium-stained amniotic fluid; NA: Not applicable; NRFHR: Non-reassuring fetal heart rate; NICU: Neonatal intensive care unit.

Table 3: Multivariable logistic regression analysis for successful vaginal delivery.

Factors	Crude OR (95% CI)	Unadjusted *P* value	Adjusted OR (95% CI)	Adjusted *P* value
Ripening methods				
Dinoprostone	Referent	–	Referent	–
SBC	0.83 (0.39–1.40)	0.476	1.07 (0.57–2.00)*	0.835
Oxytocin use				
No	Referent	–	Referent	–
Yes	0.39 (0.21–0.71)	0.002	0.37 (0.19–0.73)	0.004
Maternal age	0.94 (0.87–1.02)	0.147	0.94 (0.87–1.03)	0.180
Gravidity	0.76 (0.54–1.07)	0.117	0.82 (0.56–1.20)	0.307
GA	0.70 (0.54–0.91)	0.007	0.70 (0.53–0.93)	0.012
BMI	0.92 (0.84–0.99)	0.045	0.93 (0.85–1.02)	0.108
AFI	0.91 (0.67–1.23)	0.528	0.93 (0.67–1.30)	0.683
Bishop score 1	1.09 (0.86–1.37)	0.483	1.11 (0.86–1.42)	0.420

* Adjusted for ripening methods (dinoprostone *vs*. SBC), oxytocin use (Yes or No), maternal age, gravidity, GA, BMI, AFI, and Bishop score 1. Bishop score 1: Initial Bishop score before cervical ripening. AFI: Amniotic fluid index; BMI: Body mass index; GA: Gestational age; OR: Odds ratio; SBC: Single-balloon catheter.

Table 4: Univariate analysis of risk factors for failure of vaginal delivery in the dinoprostone group.

Factors	Dinoprostone success group ($n=66$)	Dinoprostone failure group ($n=37$)	Statistics	*P* value
Maternal age (years)	28.6 ± 3.5	29.5 ± 3.5	–1.311*	0.194
Gravidity	1 (1–2)	1 (1–2)	–1.144†	0.253
Parity	0 (0–0)	0 (0–0)	0.000†	1.000
GA (weeks)	40 (39–41)	40 (39.5–41)	–0.148†	0.295
BMI (kg/m^2)	26.6 ± 2.8	26.9 ± 3.4	–0.414*	0.680
>30	7 (10.6)	5 (13.5)	0.195‡	0.659
AFI (cm)	6.4 ± 0.9	6.6 ± 0.9	–1.479*	0.143
Bishop score 1	4 (3–4)	4 (3–5)	–0.096†	0.923
Bishop score 2	8 (7–10)	6 (5–8)	–4.233†	<0.001
>7	45 (68.2)	15 (40.5)	7.449‡	0.006
Duration of cervical ripening (h)	12.1 ± 6.0	14.6 ± 7.0	–1.940*	0.052
Diameter of cervical dilatation after removal of dinoprostone (cm)	1.5 (0.5–2.0)	0 (0–1)	–4.146†	<0.001
Fetal weight (g)	3228.6 ± 371.2	3377.0 ± 494.9	–1.733*	0.086
>3500	20 (30.3)	15 (40.5)	1.108‡	0.293
1 min Apgar score <7	4 (6.1)	2 (5.4)	0.019‡	0.892
5 min Apgar score <7	0 (0)	0 (0)	NA	–
Nuchal cord	15 (22.7)	16 (43.2)	4.742‡	0.029
1 turn	15	12		
≥ 2 turns	0	4		
MSAF	15 (22.7)	13 (35.1)	1.844‡	0.174

Values were shown as mean ± SD, *n* (%), or median (IQR). Bishop score 1: Initial Bishop score before cervical ripening; Bishop score 2: Bishop score after removal of dinoprostone. * *t* value. † *Z* value. ‡ χ^2 value. AFI: Amniotic fluid index; BMI: Body mass index; GA: Gestational age; IQR: Interquartile range; MSAF: Meconium-stained amniotic fluid; NA: Not applicable; SD: Standard deviation.

Univariate and multivariate analyses of risk factors for failure of vaginal delivery in the SBC group

In the SBC group ($n=141$), 84 cases (59.6%) had successful vaginal delivery and 57 cases (40.4%) had failed vaginal delivery (successful group, $n=84$; failed group, $n=57$). Univariate analysis showed that the gestational age, rate of BMI > 30 kg/m^2, and fetal weight > 3500 g were higher in the failed group than in the successful group. They all had significant differences, whereas the maternal age, gravidity, parity, AFI, initial Bishop score, duration of cervical ripening, amniotomy rate, diameter of cervical dilation after removal of SBC, nuchal cord rate, and incidence of 1 or 5 min Apgar score <7 between the two groups showed no significant differences (all $P > 0.050$) [Table 6].

After univariate analysis [Table 6], the gestational age, BMI > 30 kg/m^2, fetal weight > 3500 g, and Bishop score after removal of SBC were related to the failure of vaginal delivery after induction with SBC. After multivariate logistic regression, the three factors associated with

Table 5: Multivariate analysis of risk factors for failure of vaginal delivery in the dinoprostone group ($n = 37$).

Factors	Crude OR (95% CI)	Unadjusted *P* value	Adjusted OR (95% CI)	Adjusted *P* value
Diameter of cervical dilatation after removal of dinoprostone	0.43 (0.19–0.94)	0.034	0.52 (0.22–1.25)	0.141
Bishop score after removal of dinoprostone	1.40 (0.95–2.06)	0.087	1.32 (0.86–2.02)	0.209
Nuchal cord	5.77 (1.79–18.59)	0.003	6.71 (1.96–22.95)	0.002

Adjusted for maternal age, BMI, initial Bishop score, duration of cervical ripening, and fetal weight. BMI: Body mass index; OR: Odds ratio.

Table 6: Univariate analysis of risk factors for failure of vaginal delivery in the SBC group.

Factors	SBC success group ($n = 84$)	SBC failure group ($n = 57$)	Statistics	*P* value
Maternal age (years)	28.9 ± 3.4	29.3 ± 2.4	–0.741*	0.460
Gravidity	1 (1–1.75)	1 (1–2)	–1.343†	0.179
Parity	0 (0–0)	0 (0–0)	0.000†	1.000
GA (weeks)	40 (39–40)	40 (40–41)	–2.914†	0.004
BMI (kg/m^2)	26.2 ± 2.9	27.4 ± 3.5	–2.274*	0.024
>30	8 (9.5)	17 (29.8)	9.594 ‡	0.021
AFI (cm)	6.4 ± 0.8	6.3 ± 0.9	0.438*	0.662
Bishop score 1	4 (3–5)	4 (3–5)	–1.210†	0.226
Bishop score 2	6 (6–7)	6 (5–7)	–2.682†	0.007
>7	19 (22.6)	6 (10.5)	3.404‡	0.065
Duration of SBC cervical ripening (h)	15.3 ± 4.9	16.4 ± 4.7	–1.371*	0.173
Amniotomy	40 (47.6)	19 (45.2)§	0.064‡	0.801
Diameter of cervical dilation after removal of SBC (cm)	1.0 (0.5–2.0)	1.0 (0–2.0)	1.045†	0.296
Fetal weight (g)	3218.8 ± 354.8	3405.6 ± 394.7	–2.931*	0.004
>3500	20 (23.8)	24 (42.1)	5.295‡	0.021
1 min Apgar score <7	1 (1.2)	1 (1.8)	0.077‡	0.781
5 min Apgar score <7	0 (0)	0 (0)	NA	–
Nuchal cord	24 (28.6)	13 (22.8)	0.583‡	0.445
1 turn	23	12		
≥2 turns	1	1		

Values were shown as mean ± SD, *n*(%), or median (IQR). Bishop score 1: Initial Bishop score before cervical ripening. Bishop score 2: Bishop score after removal of SBC. *t value. †Z value. ‡χ^2 value. §Fifteen cases were excluded without a ruptured membrane. AFI: Amniotic fluid index; BMI: Body mass index; GA: Gestational age; IQR: Interquartile range; MSAF: Meconium-stained amniotic fluid; NA: Not applicable; SBC: Single-balloon catheter; SD: Standard deviation.

vaginal delivery failure for those who underwent SBC induction were gestational age (aOR: 1.51, 95% CI: 1.07–2.14, $P = 0.020$), BMI > 30 kg/m^2 (aOR: 2.98, 95% CI: 1.10–8.02, $P = 0.031$), and fetal weight > 3500 g (aOR: 2.49, 95% CI: 1.12–5.50, $P = 0.025$). The relationship between the Bishop score after removal of the SBC and the vaginal delivery failure became insignificant after adjustment for potentially confounding factors ($P > 0.050$) [Table 7].

Clinical characteristics of cases of emergency cesarean sections because of NRFHR in the dinoprostone group

There were 13 cases of NRFHR in the dinoprostone group, in which emergency cesarean section was performed. Of these 13 cases, nine cases had severe variable decelerations and four cases had late decelerations. There were seven cases with nuchal cord (four of which had nuchal cord for one turn and three cases with nuchal cord for two turns) [Supplementary Table 1,http://links.lww.com/CM9/A837].

Clinical characteristics of cases of intra-amniotic infection in the SBC group

In the SBC group, a total of 11 cases (11 of 141, 7.8%) developed intra-amniotic infections; of which, five cases (5 of 11) had a BMI > 30 kg/m^2, except for one case, no rupture of membranes led to cesarean section, and the other eight cases (8 of 10) had a cervical dilation of <3 cm when the membranes ruptured. Finally, nine cases underwent cesarean section, one underwent operative vaginal delivery, and one was a normal vaginal delivery; all newborns were admitted to the NICU [Supplementary Table 2, http://links.lww.com/CM9/A837].

Discussion

For term pregnancy with borderline oligohydramnios, if there is a progressive decrease in amniotic fluid or other complications, the induction of labor should be considered promptly. A wide range of chemical methods (such as prostaglandins) and mechanical methods (such as trans-

Table 7: Multivariate analysis of risk factors for failure of vaginal delivery in the SBC group ($n = 57$).

Factors	Crude OR (95% CI)	Unadjusted *P* value	Adjusted OR (95% CI)	Adjusted *P* value
Gestational age	1.49 (1.06–2.10)	0.023	1.51 (1.07–2.14)	0.020
BMI > 30 kg/m^2	3.11 (1.16–8.33)	0.024	2.98 (1.10–8.02)	0.031
Fetal weight >3500 g	2.39 (1.09–5.21)	0.029	2.49 (1.12–5.50)	0.025
Bishop score after removal of SBC	0.79 (0.59–1.05)	0.106	0.84 (0.62–1.14)	0.254

Adjusted for maternal age, initial Bishop score, and duration of SBC cervical ripening. BMI: Body mass index; OR: Odds ratio; SBC: Single-balloon catheter.

cervical balloon and Foley catheter) have been described, with no consensus on preferred management. How to choose the most suitable induction method for these patients to improve the success rate of vaginal delivery has always been a challenge in obstetrics.

Our research shows that, in nulliparous women with borderline oligohydramnios, the use of dinoprostone and SBC for labor induction have similar successful vaginal delivery rates. Wang *et al*[20] also found that induction of labor with double-balloon catheter has a similar vaginal delivery rate to that of dinoprostone in term nulliparous women with oligohydramnios (83.5% [56/67] *vs*. 77.9% [46/59]).

Our study also found that the incidence of intra-amniotic infection was lower in the dinoprostone group than in the SBC group (1.9% [2/103] *vs*. 7.8% [11/141], $P < 0.001$). Although the safety of balloon catheter induction is often mentioned, little has been written about the total spectrum of maternal–fetal severe complications associated with induction of labor using a balloon catheter. Intra-amniotic infection was one of the most severe complications during induction with a balloon catheter. The incidence of intra-amniotic infection related to trans-cervical balloon induction was reported to be 7.2% to 11.3%.[21,22] In a prospective study, He *et al*[16] found that the incidence of clinical diagnosis of intra-amniotic infection in the balloon catheter group was higher than in the dinoprostone group (11% [7/66] *vs*. 6% [4/62], $P < 0.050$). In a retrospective case-control study, Zhang *et al*[18] found that AFI < 8 cm and nulliparity were both risk factors for intra-amniotic infection related to induction with an SBC. For the women defined in our present study, induction with an SBC had a higher probability of intra-amniotic infection than induction with dinoprostone because of the presence of these two risk factors.

Our study found that the occurrence of NRFHR was higher in the dinoprostone group than in the SBC group (12.6% *vs*. 0.7%, $P < 0.001$). This result is consistent with other reports in the literature.[21,23] A systematic review showed that all known prostaglandins, including low-dose prostaglandin E2 agents, can cause uterine overstimulation and even changes in the fetal heart rate. However, induction of labor with a balloon catheter significantly reduces the risk of uterine hyperstimulation. This mechanical method is particularly beneficial for patients who should avoid uterine hyperstimulation, such as those with intrauterine growth restriction, preeclampsia, oligohydramnios, and scarred uterus.[16,23]

Our study also suggests for the first time that nuchal cord was a risk factor for vaginal delivery failure after labor induction with dinoprostone, which has not been reported in previous studies. In our present study, in the failure group after induction with dinoprostone ($n = 37$), 16 cases (16/37, 43.2%) had nuchal cord (including 12 cases with nuchal cord for one turn and four cases with nuchal cord for two turns); of which, seven patients underwent emergency cesarean section because of NRFHR (including five patients with severe variable decelerations and two patients with late decelerations). Oligohydramnios in the presence of nuchal cord entanglement might represent an increased risk of ominous intrapartum fetal heart rate patterns.[22] In a large retrospective cohort study, Ogueh *et al*[24] showed that the proportion of abnormal fetal heart rate patterns was higher in the presence of nuchal cord (aOR: 1.61, 95% CI: 1.55–1.68). The possible reasons are as follows: the application of dinoprostone for labor induction can lead to uterine overstimulation, but the reduction of amniotic fluid leads to a decrease in the buffering capacity of the amniotic fluid to the uterine contraction pressure, which significantly increases the compression of the umbilical cord or the fetus, causing severe fetal heart decelerations. Therefore, we believe that, for term women with borderline oligohydramnios, it is important to conduct an ultrasound examination to determine whether there is nuchal cord before induction of labor, which is very important for the selection of labor induction methods. If there is a nuchal cord, in view of the high risk of uterine overstimulation and even the risk of changes in the fetal heart rate caused by the application of dinoprostone, the induction of labor with a balloon catheter can significantly reduce the risk of uterine hyperstimulation. Therefore, for such cases, we first recommend the use of a balloon catheter for labor induction. However, given the small sample size of women with nuchal cord in this study, this conclusion needs to be confirmed by further studies with large sample sizes.

Our study also showed that, in the SBC group, increased gestational age and fetal weight > 3500 g were risk factors for failure of induction of labor. As the gestational age increases, the fetal weight will gradually increase. Fetal weight was identified to be an important parameter in the prediction of cesarean delivery, which also increased risk of maternal complications.[25]

We also found that BMI > 30 kg/m^2 was also a risk factor for vaginal delivery failure after induction with SBC, which is consistent with the results of Boisen *et al*.[26] One of the leading theories behind the reason for failure of

induction is the decreased sensitivity of the myometrium to prostaglandins and oxytocin in obese women, resulting in reduced contractile ability; however, studies regarding this topic are lacking. Another study showed that BMI > 30 kg/m^2 was a risk factor for intra-amniotic infection after induction with SBC, which also leads to an increase in the cesarean section rate.[18] There are only a few studies comparing the efficacy of different cervical ripening agents in obese women, and there is no recommendation as to which method can lead to the greatest chance of successful vaginal delivery.[26,27] Suidan *et al*[28] found that, in obese women undergoing the induction of labor, misoprostol led to a higher successful cervical ripening rate and a lower cesarean delivery rate than dinoprostone, with a similar rate of peripartum complications and neonatal outcomes. They further compared women who received oral *vs.* vaginal misopros-tol, and there was no difference in the rates of successful cervical ripening or cesarean delivery. At present, there have been no reports on the comparison of the effects between the use of dinoprostone and balloon catheter for induction of labor in obese women.

Because the induction of labor with a balloon catheter can significantly reduce the risk of uterine hyperstimulation, obese women have decreased sensitivity to oxytocin or prostaglandin, making it difficult to cause uterine contractions. Based on the results of this study, BMI > 30 kg/m^2 is a risk factor for vaginal delivery failure when using an SBC for labor induction (aOR: 2.98, 95% CI: 1.10–8.02), and for the specific high-risk cases of intra-amniotic infection in this study (i.e., AFI < 8 cm and nulliparity), we do not recommend using a balloon catheter for labor induction in nulliparous obese women with borderline oligohydramnios. However, given the small sample size of women with a BMI > 30 kg/m^2 in this study (a total of 37 cases, including 12 cases in the dinoprostone group and 25 cases in the SBC group), it is not enough to prove which of the two induction methods is more suitable for obese women. Are the advantages of choosing dinoprostone for labor induction better than that of the balloon catheter? This question needs to be further verified by large sample studies.

This is a large retrospective cohort study of dinoprostone or SBC labor induction in term nulliparous women with borderline oligohydramnios, and we compared the effectiveness and pregnancy outcomes of the two induction methods. We have proposed for the first time that, for term nulliparous women with borderline oligohydramnios, it is important to conduct an ultrasound examination to determine whether there is nuchal cord before induction of labor. If there is a nuchal cord, induction with dinoprostone may cause uterine hyperstimulation and even severe fetal heart decelerations, resulting in increased rates of cesarean delivery. For women with BMI > 30 kg/ m^2, larger gestational age, and an estimated fetal weight > 3500 g, if SBC is used for labor induction, the risk of vaginal delivery failure increases.

Study limitation

However, there are still many limitations in our study. First, this is a retrospective study and we cannot exclude the possibility of collection bias. We were able to present only data that were accurately entered into patient charts during hospital encounters. There may be other factors that affect the success rate of vaginal delivery, but they were not analyzed in this study. Second, because of the sample size, this study only proposed the risk factors for vaginal delivery failure but failed to further prove whether induction of labor using dinoprostone or SBC was more effective in women with nuchal cord. Third, in this study, we only pointed out that the possibility of vaginal delivery failure increases in obese women if an SBC was used for labor induction, but the question of which is the safer method for labor induction in obese women still needs to be further confirmed by case–control studies with larger sample sizes or prospective randomized controlled studies.

Conclusions

Term nulliparous women with borderline oligohydramnios have similar successful vaginal delivery rates after induction with dinoprostone or SBC, with their advantages and disadvantages. In women with nuchal cord, the risk of vaginal delivery failure increases if dinoprostone is used for induction of labor. BMI > 30 kg/m^2, large gestational age, and estimated fetal weight >3500 g are risk factors for vaginal delivery failure after induction with SBC.

Conflicts of interest

None.

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