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Predictors for outcome of induction of labour with double balloon catheter as second-line method after dinoprostone

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Objectives: To determine the predictors for outcome of induction of labour (IOL) with double balloon catheter (DBC) as the second-line method after dinoprostone.
Methods: Medical records of patients who underwent IOL with DBC as the second-line method after dinoprostone between October 2016 and December 2019 at Pamela Youde Nethersole Eastern Hospital in Hong Kong were retrospectively reviewed. Inclusion criteria were singleton pregnancy, vertex presentation, gestational age of ≥36 weeks, unfavourable cervix (Bishop score <6) after initial priming by dinoprostone, intact membranes, and no contraindication for vaginal delivery. The primary outcomes were the success and failure rates of IOL, which were defined as the rates of vaginal delivery and caesarean delivery, respectively.
Results: 88 patients were included for analysis. The most common indications for IOL were gestational diabetes (23.86%) and past term pregnancy (19.32%). 79 (91.86%) patients had successful cervical ripening after DBC insertion, with a median improvement in Bishop score of 3. However, only 32 (36.36%) patients achieved vaginal birth, whereas 56 patients had caesarean birth. The most common indication for caesarean birth was failed IOL (40.91%). An occiput-anterior position of the fetal head at delivery was predictive of a vaginal birth/successful IOL (odds ratio=0.211, p=0.036), whereas a heavier birth weight was a risk factor for a caesarean birth/failed IOL (odds ratio=1.002, p=0.027).
Conclusion: The success rate of IOL with DBC as a second-line method was only 36.36%. The Bishop score before DBC insertion was not predictive of a successful IOL. Earlier consideration of caesarean section is suggested in patients with unsatisfactory response to dinoprostone as well as non-occiput-anterior position of the fetal head and heavier fetal weight.

Keywords: Dinoprostone; Labour, induced

Introduction

Induction of labour (IOL) is commonly used to shorten the duration of pregnancy. In developed countries, as high as 20% to 25% of term pregnancies are delivered following IOL[1]. IOL is performed when the risks of waiting for spontaneous onset of labour are deemed greater than those associated with IOL[2]. The Bishop score is used to assess the likelihood of a successful IOL[3]. A Bishop score of <6 is defined as an unfavourable cervix to achieve vaginal delivery. Dinoprostone is commonly used to ripen an unfavourable cervix. When pharmacological agents are contraindicated or ineffective, mechanical devices such as a double balloon catheter (DBC) is an alternative[4,5]. DBC is similarly efficacious and safer[6-8] and more cost-effective than dinoprostone[7,9]. However, the use of DBC remains unconventional in some obstetric units. This study aims to determine the predictors for outcome of IOL with DBC as the second-line method after dinoprostone.

Methods

This study was approved by the Hong Kong East Cluster Research Ethics Committee (Reference: HKECREC-2021-090). Medical records of patients who underwent IOL with DBC (Cook Cervical Ripening Balloon; Cook Medical, Bloomington [IN], US) as the second-line method after dinoprostone between October 2016 and December 2019 at Pamela Youde Nethersole Eastern Hospital in Hong Kong were retrospectively reviewed through the Clinical Management System. The hospital conducted 2300 to 2700 deliveries per year from 2016 to 2019.

Inclusion criteria were singleton pregnancy, vertex presentation, gestational age of ≥36 weeks, unfavourable cervix (Bishop score <6) after initial priming by dinoprostone, intact membranes, and no contraindication for vaginal delivery. Exclusion criteria were any contraindication for vaginal delivery and maternal request to terminate IOL.

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Patients indicated for IOL were admitted for in-patient care. IOL was offered at 41 weeks of gestation for post-term or at 40 weeks for gestational diabetes so as to achieve birth no later than 40 weeks plus 6 days as per recommendations of the National Institute of Health and Care Excellence[5,10]. The cervical status was assessed using the Bishop score, and a 30-minute cardiotocography was performed to rule out fetal distress. If the Bishop score was <6, the first-line method was to administer non-sustained released dinoprostone vaginal tablets once per day and up to two separate doses 24 hours apart. If dinoprostone tablets were deemed unsuitable (eg scarred uterus) or ineffective (the cervix remains unfavourable), the patient was counselled for DBC insertion. The DBC was inserted 36 hours after the last dose of dinoprostone to allow adequate weaning of its medical effect. The vaginal and uterine balloons were each inflated with a minimum of 40 mL of normal saline. Each balloon can hold a maximum of 80 mL of saline. Another 30-minute cardiotocography was performed to ensure fetal well-being. In patients with positive Group B Streptococcus screening, antibiotic prophylaxis was initiated immediately after insertion of the DBC. If a spontaneous pre-labour rupture of membrane occurred during cervical ripening, the DBC was removed and augmentation by syntocinon infusion was used to complete the IOL. The DBC was also removed in the event of an emergency such as severe vaginal bleeding, suspected fetal distress, or suspected scar rupture. Otherwise, the DBC was removed up to 12 hours after insertion. The cervical status was assessed again using the Bishop score. If the cervix was ripened (Bishop score ≥6), artificial rupture of membrane with syntocinon augmentation was performed. If the Bishop score remained <6, either Caesarean section or continuation with IOL was offered.

The primary outcomes were the success and failure rates of IOL, which were defined as the rates of vaginal delivery and caesarean delivery, respectively. The secondary outcomes were maternal and fetal complications, including pain intolerance, uterine hyperstimulation, uterine rupture, intrauterine infection, placental abruption, umbilical cord prolapse, low Apgar score, and admission to the neonatal intensive care unit.

Statistical analysis was performed using SPSS (Windows version 26; IBM Corp, Armonk [NY], US). A p value of <0.05 was considered statistically significant. Comparisons between successful IOL (vaginal delivery) and failed IOL (caesarean delivery) were made using the Chi-squared test for categorical variables and binary logistic regression for continuous variables. Significant variables in univariate analysis were included in logistic regression analysis to determine the predictors for outcome of IOL with DBC as the second-line method.

Results

Of 129 women who underwent IOL with DBC as the second-line method after dinoprostone, 41 were excluded according to the exclusion criteria and the remaining 88 were included for analysis (Table 1). The most common indications for IOL were gestational diabetes (23.86%) and past term pregnancy (19.32%). 79 (91.86%) patients had successful cervical ripening after DBC insertion, with a median improvement in Bishop score of 3. However, only 32 (36.36%) patients achieved vaginal birth, whereas 56 patients had caesarean birth. The most common indication for caesarean birth was failed IOL (40.91%).

There were eight maternal complications associated with the DBC. Five patients had intolerable vaginal pain, which was resolved by reducing the amount of fluid in the balloons. One patient had umbilical cord prolapse upon artificial rupture of membranes and underwent category 1 caesarean section. The patient was nulliparous and was induced at 41 weeks for post-term. She was transferred to the labour room for artificial rupture of membrane 20 minutes after removal of the DBC. The fetal head was stationed at -3, but there was no definite disengagement or palpable cord before artificial rupture of membrane. The fetal outcome was satisfactory. One patient had severe antepartum haemorrhage necessitating immediate removal of the DBC and emergency caesarean section. Nonetheless, maternal and fetal outcomes were good.

In logistic regression analysis, an occiput-anterior position of the fetal head at delivery was predictive of a vaginal birth/successful IOL (odds ratio=0.211, p=0.036), whereas a heavier birth weight was a risk factor for a caesarean birth/failed IOL (odds ratio=1.002, p=0.027) [Table 2]. The Bishop score before DBC insertion was not predictive of a successful IOL.

Discussion

The successful cervical ripening rate was 91.86% and the median improvement in Bishop score was 3, but the vaginal birth/successful IOL rate was only 36.36%. These findings are comparable with the 88% successful cervical ripening rate, the mean of 3.8 improvement in Bishop score[11], and the 55% to 68.6% vaginal delivery rate in 24 hours[6,7,11] reported in other studies. The lower vaginal delivery rate in our patients could be attributed

Table 1. Baseline characteristics, indications and outcomes of induction of labour (IOL) with double balloon catheter (DBC), and maternal and fetal complications of 88 patients

Parameter	Value*
Maternal age, y	32 (30-35)
Maternal body mass index, kg/m^2	23.89 (21.58-26.67)
Nulliparous	80 (90.91)
Multiparous	8 (9.09)
Indications of IOL	
Gestational diabetes	21 (23.86)
Past term	17 (19.32)
Hypertensive disorders (pregnancy-induced hypertension, pre-eclampsia)	13 (14.77)
Reduced fetal movement	9 (10.23)
Small for date fetus	8 (9.09)
Large for date fetus	5 (5.68)
Oligohydramnios	5 (5.68)
Prolonged latent phase	4 (4.55)
Maternal choice	2 (2.27)
Non-reassuring cardiotocography	2 (2.27)
Bad obstetric history	1 (1.14)
Polyhydramnios	1 (1.14)
Bishop score before insertion of DBC	
≤3	23 (26.14)
4-5	65 (73.86)
Bishop score after insertion of DBC (n=86)	
<6	7 (7.95)
6-7	71 (80.68)
>7	8 (9.09)
Improvement in Bishop score after DBC	3 (2-3)
Duration of DBC in place, min	660 (614.50-686.25)
Caesarean birth	56 (63.64)
Failed induction	36 (40.91)
Cephalo-pelvic disproportion	7 (7.95)
Abnormal cardiotocography	6 (6.82)
Obstructed labour due to persistent occiput-posterior position	4 (4.55)
Umbilical cord prolapse	1 (1.14)
Severe antepartum haemorrhage	1 (1.14)
Suspected intrauterine infection	1 (1.14)
Vaginal birth	32 (36.36)
Spontaneous vaginal birth	28 (31.82)
Forceps delivery	3 (3.41)
Vacuum extraction	1 (1.14)
Fetal head position at delivery	
Occiput-anterior	65 (73.86)
Non-occiput-anterior	23 (26.13)
Birth weight, g	3262.5 (2906.25-3502.5)
Material complication	
Intolerance secondary to vaginal pain	5 (5.68)
Umbilical cord prolapse	1 (1.14)
Severe antepartum haemorrhage	1 (1.14)
Intrauterine infection	1 (1.14)
Hyperstimulation	0
Neonatal complication	
1-min Apgar score <7	2 (2.27)
5-min Apgar score <7	0
Neonatal intensive care unit admission	1 (1.14)

* Data are presented as median (interquartile range) or No. (%) of participants

to patient selection, as only patients with failed IOL after dinoprostone were included.

An occiput-anterior position of the fetal head was predictive of a vaginal birth/successful IOL. An occiput-posterior position is well-recognised risk factor for caesarean delivery[12-15]. However, the fetal head position can only be ascertained at the time of delivery and thus it may be of limited predictive value. As the fetal head position changes dynamically as labour progresses, it is worthwhile to evaluate whether the head position at the initiation of IOL or before delivery predicts labour outcome.

A heavier birth weight was a risk factor for caesarean birth/failed IOL. Some studies reported comparable findings[16,17], but others reported no significant association[18-20]. Similar to fetal head position, birth weight can only be accurately measured after delivery and thus it may be of limited predictive value. Ultrasound scan to estimate fetal weight near labour is prone to measurement errors and can only achieve accurate estimates (±10% of the actual birth weight) in approximately 70% of patients[21-23].

Multi-parity has been reported as a predictor for successful IOL[16-18,24]. However, it was not predictive of IOL outcome in the present study. This may be explained by the

Table 2. Logistic regression analysis for predictors of outcome of induction of labour with double balloon catheter

Variable	Odds ratio (95% confidence interval)	p Value
Maternal age	1.114 (0.973-1.274)	0.117
Maternal body mass index	1.093 (0.956-1.250)	0.194
Multiparity	0.218 (0.036-1.336)	0.100
Gestational age at induction of labour	0.9099 (0.528-1.566)	0.732
Duration of double balloon catheter in place	1.001 (0.996-1.006)	0.789
Bishop score before insertion		
≤3	3.201 (0.683-14.996)	0.140
4-5	-	
Bishop score after insertion		
<7	2.624 (0.199-34.657)	0.464
≥7	-	
Improvement in Bishop score		
<3	1.092 (0.290-4.114)	0.896
≥3	-	-
Occiput-anterior position of the fetal head	0.211 (0.049-0.905)	0.036
Birth weight	1.002 (1.000-1.004)	0.027

limited number of multiparous patients (n=8); only half of them were able to achieve vaginal delivery, compared with 35% in the nulliparous patients.

Bishop score is a well-recognised predictor for IOL outcome[18-20,25-27]. However, it was not predictive of IOL outcome in the present study. The extent of improvement in the Bishop score was also not correlated to the IOL outcome, which is consistent with other studies[24,28]. Thus, the Bishop score should not be used solely to predict IOL outcome. Other parameters including maternal age, body mass index, gestational age at IOL, and duration of DBC in place were also not predictive of IOL outcome.

Maternal and neonatal complications of DBC insertion were uncommon. Although the rate of umbilical cord prolapse (1.14%) was higher than that in the general population (0.16%-0.18%)[29-31], the association lacks robust evidence[32,33]. Nevertheless, obstetricians should be aware of clinical signs such as an unengaged or highly stationed fetal head after removal of the DBC and should consider performing a controlled amniotomy or converting to caesarean delivery as indicated.

Because of the low success rate (36.36%) of IOL with DBC, it is reasonable to consider resolving to caesarean section earlier if the response to dinoprostone has not been satisfactory in patients with other unfavourable factors such as a heavier fetal weight or a need for prompt delivery (in case of severe pre-eclampsia).

There are limitations to the present study. The sample size was too small to produce analyses for indications of IOL and safety of the DBC. The sample was recruited in one centre; outcomes may be influenced by local obstetric practice and patient characteristics in this locality. Only patients who had IOL with DBC as the second-line method were included. A prospective study with a larger sample size from multiple centres that includes patients who use DBC as the first-line method may generate more useful findings.

Conclusion

The success rate of IOL with DBC as a second-line method was only 36.36%. The Bishop score before DBC insertion was not predictive of a successful IOL. Earlier consideration of caesarean section is suggested in patients with unsatisfactory response to dinoprostone as well as non-occiput-anterior position of the fetal head and heavier fetal weight.

Contributors

All authors designed the study, acquired the data, analysed the data, drafted the manuscript, and critically

revised the manuscript for important intellectual content. All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

All authors have disclosed no conflicts of interest.

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Data availability

All data generated or analysed during the present study are available from the corresponding author on reasonable request.

Ethics approval

The study was approved by the Hong Kong East Cluster Research Ethics Committee (Reference: HKECREC-2021-090). The patients were treated in accordance with the tenets of the Declaration of Helsinki. The patients provided written informed consent for all treatments and procedures and for publication.

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