Induction of labour in mid-trimester pregnancy using double-balloon catheter placement within 12 hours versus within 12-24 hours

Jing Peng
Maternal and Child Health Hospital of Hubei Province

Ruobing Li
Wuhan University of Science and Technology

Shuguo Du
Maternal and Child Health Hospital of Hubei Province

Heng Yin
Maternal and Child Health Hospital of Hubei Province

Min Li
Maternal and Child Health Hospital of Hubei Province

Xuan Zheng
Wuhan University of Science and Technology

Shiyao Wu
Wuhan University of Science and Technology

Yun Zhao (zhao020060@163.com)
Maternal and child health hospital of hubei province, affiliated hospital of tongji medical college, huazhong university of science and technology

Research article

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Abstract

Background

This study aims to evaluate the efficacy and safety of the induction of labour in mid-trimester pregnancy using double-balloon catheter (DBC) within 12 hours versus within 12–24 hours.

Methods

In this retrospective study, a total of 58 pregnant women with gestation age of 14 + 0 weeks to 27 + 6 weeks were enrolled as research objects, and they underwent intended termination of pregnancy at our birth center from January 1, 2017, to June 31, 2019. Based on the duration time of DBC, the cases were divided into two groups (DBC group within 12 hours and DBC group within 12–24 hours).

Results

All of the 58 cases were successful vaginal delivery and no one chose cesarean section. The success rate of induction (successful abortion of fetus and placenta without the implementation of dilatation and evacuation) was higher in the DBC group within 12–24 hours (96.3%, 29/31) than that in DBC group within 12 hours (71.0%, 18/27) (p < 0.05). At the same time, the time from DBC removal to delivery in 12–24 hours DBC group was significantly shorter than that in DBC group within 12 hours (3.0 h versus 17.8 h) (p < 0.05), the degree of cervical dilation after DBC removal in DBC group within 12–24 hours was larger than that in DBC group within 12 hours (p < 0.05).

Conclusion

In the clinic, the placement time of DBC is generally lasting for about 12 hours. However, considering the cervical condition is immature in the mid-trimester, properly extending the placement time of DBC to 24 hours will benefit for cervical ripening and lead to reduce chance of dilatation and evacuation.

Background

In prenatal screening, we often use ultrasound to measure the thickness of the fetal nuchal translucency with 11 + 0 to 13 + 6 weeks of gestation and carry out maternal serum screening to screen for fetal aneuploidy chromosome abnormalities in early pregnancy. Besides, ultrasound examination is normally performed at the 20 + 0 to 24 + 6 weeks of gestation to screen for structural abnormalities [1]. After learning about severe fetal abnormalities and their poor prognosis, most families will choose to terminate pregnancy in mid-trimester [2]. Induction of labor is a common obstetric intervention that occurs in a high proportion of pregnancies [3]. Both medical and surgical methods are available for mid-trimester pregnancy. Dilation and evacuation procedures (D&E) are more common methods in the United States.
contrast, medical methods such as mifepristone plus with misoprostol, are more common in the United Kingdom, Europe and developing countries [2, 4]. In our country, the common approach for induction of labor in mid-trimester pregnancy is to use pharmacological and mechanical devices. Pharmacological devices include mifepristone combined with ethacridine lactate, or mifepristone combined with misoprostol [5]. The mechanical devices include transcervical Foley balloon catheters, cervical double balloon catheters (DBC). Single balloon or DBC have been used increasingly in recent years at term with an immature cervix [6–7] or for pregnant women with history of previous cesarean section [3]. The mechanical methods are the earliest approaches to develop a mature cervix, and its effectiveness level is equivalent to that of prostaglandins [8–9]. The balloon treatment is well accepted by pregnant women [10–11], and will be not cause excessive stimulation or poor fetal heart monitoring (CTG) changes [12].

In our medical center, the common method for termination of mid-trimester pregnancy is to apply mifepristone combined with ethacridine lactate or misoprostol. We have also applied mifepristone combined with DBC for cases with liver and renal dysfunction, oligohydramnios and failure of the cervical ripening after using ethacridine lactate or misoprostol.

In this retrospective study, we evaluated the efficacy of DBC within 12–24 hours versus DBC within 12 hours on the termination of mid-trimester pregnancy from January 1, 2017, to June 31, 2019 in our birth center.

**Methods**

**Ethical approval and patient consent**

The study protocol was approved by the Ethics Committee of Maternal and Child Health Hospital of Hubei Province [2019] IEC(XM008). All included women signed written informed consent for therapeutic procedures and also for the publication of those reports.

**Selection of patients and study design**

The flowchart of the experimental program design is demonstrated in Figure 1. In this retrospectively study, we included pregnant women with gestation age between 14+0 weeks and 27+6 weeks. All included women underwent intended termination of pregnancy at our birth center from January 1, 2017, to June 31, 2019. Our center is a big birth center in China, with annual deliveries of nearly 30,000 in the last 3 years. Regarding inclusion criteria, the pregnant women with Chinese nationality and age of 18 to 50 years, who underwent DBC to induce labor for fetal death, fetal anomaly and maternal serious complication that prevented continue pregnancy were included in this study. For exclusion criteria, those with age less than 18 years or older than 50 years, those with non-Chinese nationality, and those who did not undergo DBC to induce labor (such as mifepristone combined with ethacridine lactate, mifepristone plus misoprostol or cesarean section) were excluded from this study. A total of 263 patients were selected in this study, excluding 160 cases undergoing induction of labor by using mifepristone combined with ethacridine lactate, 20 cases undergoing induction of labor via mifepristone plus misoprostol, 20
cases undergoing induction of labor by mifepristone only, 4 cases of spontaneous labor and 1 case of cesarean section, so finally the remaining 58 cases were included in our study. Based on the indwelling time of DBC, the 58 cases were divided into two group, namely DBC group within 12 hours (DBC time ≤ 12h) containing 31 cases, and DBC group within 12-24 hours (12 < DBC time ≤ 24h) containing 18 cases.

DBC

DBC is usually used as per the manufacturer’s instructions (Cervical Ripening Balloon; Cook OB/GYN, Spencer, IN, USA). It involves 2 balloons (uterine and vaginal balloons) and each balloon can fill with a maximum of 80mL of normal saline. First, the uterine balloon (red piston, marked with "U") was sent into the lower part of uterine cavity and 40mL of normal saline solution was injected into it. Then, the vaginal balloon (green piston, marked with "V") was placed outside the cervical orifice and 40mL of normal saline solution was injected into it. After vaginal examination for checking if DBC was placed normally, the fluid amount in the both balloons was alternatively increased by 20mL each time until each of the both balloons totally reached to 80mL. After making sure the balloons were positioned correctly, the proximal end of the catheter was fixed to the inside of the patient's thigh. If the patient felt unbearable with symptoms of sweating or flusterling, then withdraw 10-20mL of normal saline from both balloon till the patient can tolerate the DBC.

Based on the judgment of the attending physician on the cervical condition of the pregnant women in mid-trimester pregnancy, the longest placement time of DBC was set to 12 hours or 24 hours, but the device was removed immediately upon the occurrence of any of the following events, including spontaneous labor, expulsion, spontaneous ruptured of membranes, or unexplained vaginal bleeding [13]. If those events did not happen, the device of DBC was removed after holding for maximum of 12 hours in DBC group within 12 hours, and for 24 hours in DBC group within 12-24 hours.

Intervention for pregnancy termination

In our hospital, we use DBC for termination of mid-trimester pregnancy in the following situations. First, oral mifepristone combined with extra-amniotic administration of ethacridine lactate (Rivanol) was applied, 150mg of mifepristone were administrated to patient in 3 days (each pill contains 25 mg of mifepristone, 2 pills a day), and an injection of 100mg of ethacridine lactate was performed at approximately 9:00 AM on the 4th day. Then, patients mostly delivered in the following 24-48 hours. If the patients still exhibited no response and their cervixes were immaturity in the following 72 hours, then the DBC was used. Second, we also used mifepristone plus DBC for cases with liver and renal dysfunction, or oligohydramnios. 150mg of mifepristone were administrated to patient in 3 days and the DBC was used at approximately 9:00 AM on the 4th day. After taking out DBC, the oxytocin was infused for both groups to assist labor at a dose of 2.5-5.0 units in 500 mL Ringer solution, with an infusion rate of 8-40 mL/h. At the same time, surgical method of dilatation and evacuation was used by experienced obstetrician when the body temperature of cases was up to 38.5°C or antenatal massive hemorrhage occurred.
**Observation indicators**

The gestational age estimated to be 11+0 and 13+6 weeks via ultrasonography. The Bishop scoring system is based on a digital cervical exam of a patient with zero point as minimum and 13 point as maximum. The scoring system can be used to evaluate cervical dilation, position, effacement, consistency of the cervix, and fetal station. Cervical dilation, effacement, and fetal station are allocated with 0 to 3 points, while cervical position and consistency are given 0 to 2 points [1]. To compare the efficacy of DBC in the two groups, the primary outcome was the success rate of labor induction, which means successful abortion of fetus and placenta without implementation of dilatation and evacuation. The secondary outcomes include the time from induction of DBC to labor and the time from taking out DBC to delivery, as well as the outcome parameters of the maternal and fetal, such as the rate of antepartum hemorrhage, uterine artery embolism (UAE) before delivery, postpartum hemorrhage (PPH), and puerperal infection.

**Statistical methods**

All analyses were conducted using the Statistical Package of Social Sciences software (SPSS Version 13.0 Inc., Chicago, IL, USA). The values and variables were reported in the form of mean±standard deviation. Student’s test was performed to compare the variables in Gaussian distribution. Chi-square test was used to evaluate the categorical variables. Wilcoxon test was used to evaluate the difference in non-Gaussian distribution between in the two groups. The difference was considered statistically significant at p<0.05.

**Results**

**Demographic data of the 12 hours group and the 24 hours group**

The baseline data and pregnancy characteristics of the two groups are listed (Table 1). There were no significant differences in maternal age, Gestation, parity, Nulliparous, Maternity insurance, gestational age at termination, the rate of placenta previa, history of previous cesarean section, body mass index between in the two groups (p>0.05). There was no significant difference in reasons for pregnancy termination between the two groups (p>0.05).

**The cervical ripen before and after DBC in within 12 hours group and within 12-24 hours group**

There was no significant difference in cervical ripen between the two groups according to Bishop scores (p>0.05), but after ripen by DBC for within 12 hours or within 12-24 hours, the cervix was more ripen in the 24h DBC group than in the 12 hours group (p<0.05) (Table 2, 3).

**The time from induction and DBC removal to delivery**

The time from induction to delivery in within12-24 hours group was shorter than that in within12 hours group (median time, 27.0 h versus 29.8 h), but the difference was not statistically significant (p>0.05).
However, the time from DBC removal to delivery in the within 12 hours group (median time, 17.8h) was longer than that in within 12-24 hours group (median time, 3.0h), indicating a significant difference (p<0.05) (Table 4).

**The maternal and fetal outcome parameters between in the two groups**

In the within 12-24 hours, there were 2 cases (3.7%, 2/27) undergoing hysterectomy using dilatation and evacuation after taking DBC out, while there was 9 cases in DBC group within 12 hours (29.0%, 9/31) (p<0.05) (Table 5). None of both groups underwent cesarean section to induce labor, and all of them had successful vaginal delivery.

There was no significant difference in the weight of fetus, blood loss at delivery, rate of antepartum hemorrhage, rate of puerperal infection, UAE before delivery, rate of PPH, and rate of ICU care (p>0.05) (Table 5).

**The WBC cell count and hemoglobin in the two groups**

There was no significant difference in the WBC cell count and hemoglobin at admission and discharge between in the two groups (p>0.05) (Table 6).

**Hospitalization days and expenditure**

In the within 12-24 hours, the average hospitalization day was 9.8d, which was shorter than that in the within 12 hours (12.3d) (p<0.05). At the same time, the hospitalization expenditure in the 24 hours group was lower than that in the 12 hours group (p<0.05) (Table 7).

**Discussion**

In recent few years, family policy issued by central government in China has been changed. The former one-child policy was gradually replaced by universal two-child policy (2015). With the increasing rate of multiparous women in China, birth defects are a challenging issue. Women at very advanced maternal age (≥ 43 years) have a higher risk of preeclampsia, intrauterine growth retardation, stillbirth, and placental abruption than the younger counterparts [14]. Zhang X et al [15] analyzed 1,260,684 births from the surveillance system in Zhejiang province, China, and found that the rate of birth defects during 2013, 2015, and 2017 was 245.95, 264.86, and 304.36 per 10,000 births, respectively, and there was age-related anomalies after the release of China's new two-child policy. There were many clinical problems during induced labor need to be solved, especially complete placenta previa [16], and immature cervical condition [2]. More and more women in developing countries choose to postpone pregnancy [17], and studies have found an association between elder pregnant women and a high risk of chromosomal abnormalities, miscarriages and preterm birth with gestation of less than 34 weeks. In addition, stillbirths are more commonly in women aged 35–39 [17]. Therefore, the methods, safety, effectiveness and postoperative complications of labor induction in mid-trimester pregnancy are worth pondering and exploring. Our study observed the pregnant women who underwent intended termination of pregnancy for
fetal death, fetal anomaly and maternal serious complication in mid-trimester pregnancy. Of those selected 58 cases, there were 22 cases using DBC for lasting immature cervical condition after applying mifepristone combined with rivanol, or mifepristone plus with misoprostol, and the other 36 cases were subjected to mifepristone plus DBC directly for liver and kidney dysfunction or oligohydramnios.

The mechanism of DBC-based labor induction is basically the compression effect of DBC balloon on cervix, which leads to the release of endogenous prostaglandins [9]. In addition to the local effect, mechanisms that involve neuroendocrine reflexes (such as the Ferguson reflex) may promote the onset of contractions [8]. Researchers have evaluated the effectiveness of these devices by comparing them with prostaglandins, and have reported that they are equally effective, and the incidence of tachycardia is lower than that of prostaglandins [9]. Placing a transcervical DBC can be the primary method, or one of the alternative medical methods if the patient and/or obstetrician prefers not to conduct surgical operation [2]. DBC are commonly used for cervical ripening to induce labor with and without prior cesarean section in term [18, 19]. Korb D et al. [18] compared the effectiveness of cervical ripening by DBC(n = 117) and prostaglandins(n = 127) in women with history of previous cesarean delivery and an unfavorable cervix(Bishop score ≤6), and found there was no significant difference between the them in terms of cesarean rate and the median interval between the start of ripening and delivery (42.5% and 28.7 h in the prostaglandin group vs 42.7% and 25.6 h in the DBC group). There are very few studies on induced labor in mid-trimester pregnancy by using DBC.

In the clinic, the placement time of DBC generally lasts for 12 hours. In our experiment, the placement time of DBC was extended to 24 hours for the first time if there was no occurrence of spontaneous labor, expulsion, or spontaneous ruptured of membranes. We compared the effects of DBC within 12 hours and in that within 12–24 hours for induction of labor in mid-trimester pregnancy. We founded that the success rate of induction of labor was higher in DBC group within 12–24 hours (96.3%, 29/31) than that in DBC group within 12 hours (71.0%, 18/27). It can be known that properly extending the time of DBC can reduce the chance of surgical induction of labor, thereby reducing maternal damage, and also help to obtain complete fetal tissues. Although there was no significant difference in the time from induce to delivery between two group, the time from DBC removal to delivery in the within 12–24 hours group was significantly shorter than that in the within 12 hours group (3.0 h versus 17.8 h). This may help reduce risk of fever and the labor pain by using pharmacological methods to assist labor. In addition, the hospitalization days and expenditure in the within 12–24 hours group were lower than that in the within 12 hours. There was no significant difference in the rate of antepartum hemorrhage, rate of UAE before delivery, rate of PPH, rate of ICU care as well as in the WBC cell count and hemoglobin at admission and discharge between the two groups, but the hospitalization days was longer and expenditure was higher in the within 12 hours group.

**Conclusion**

Clinically, the placement time of DBC generally last for about 12 hours and the cervical condition is still immature after removal of DBC in mid-trimester pregnancy. Properly extending the placement time of
DBC to 24 hours can benefit cervical ripening and lead to reduced chance of dilatation and evacuation in mid-trimester pregnancy.

**Limitation**

First, this study was a retrospective study, in which the data were only collected from patients’ medical record and the Bishop score was the only index for cervix evaluation. Second, the most seriously complication for induced labor in mid-trimester pregnancy by DBC lasting for 12 hours to 24 hours was infection, so some sensitive index of infection should be added in addition to body temperature, WBC count.

**Abbreviations**

DBC: double-balloon catheter; D&E:Dilation and evacuation procedures; UAE:uterine artery embolism; PPH:postpartum hemorrhage; ICU:Intensive Care Unit

**Declarations**

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**Author's contributions**

Conceptualization: Shuguo Du, Yun Zhao.

Investigation: Heng Yin, Min Li, Xuan Zheng, Shiyao Wu.

Visualization: Yun Zhao.

Writing-original draft: Jing Peng, Ruobing Li.

Writing -review and editing: Yun Zhao.

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**Availability of data and materials**
All data generated or analysed during the current study are available from the corresponding author on reasonable request.

**Ethics approval and consent to participate**

The study protocol was approved by the Ethics Committee of Maternal and Child Health Hospital of Hubei Province [2019] IEC(XM008). All included women signed written informed consent for therapeutic procedures and also for the publication of those reports.

**Consent for publication**

All included women signed written informed consent for therapeutic procedures and also for the publication of those reports.

**Competing interests**

The author has no conflict of interest regarding the publication of this paper.

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Tables

Tab 1: Baseline demographics and pregnancy characteristics

| Groups                             | 12h-CRB (n=31) | 24h-CRB (n=27) | t/Z/Χ² | P     |
|-----------------------------------|----------------|----------------|--------|-------|
| Age (yr ± s)                      | 28.6 ±5.5      | 31.2 ±4.5      | -1.969 | 0.054 |
| Gestation (min-mix)               | 1-6            | 1-6            | -1.890 | 0.059 |
| Parity (min-mix)                  | 0-2            | 0-3            | -0.679 | 0.497 |
| Nulliparous (n%)                  | 4, 12.9        | 3, 11.1        | 1.000  | 0.579 |
| Maternity insurance (n%)          | 12, 38.7       | 7, 25.9        | 1.071  | 0.301 |
| Gestational age (wk ± s)          | 23.0 ±6.1      | 22.2 ±6.2      | 0.528  | 0.600 |
| History of previous cesarean delivery (n%) | 8, 25.8 | 11, 40.7 | 1.461 | 0.227 |
| Body mass index (kg/m² ± s)       | 22.7±3.4       | 23.7±4.6       | -0.924 | 0.359 |
| Placenta previa (n%)              | 6, 19.4        | 9, 33.3        | 1.471  | 0.225 |
| Indications for pregnancy termination |                  |                |        |       |
| Fetal death                       | 7              | 8              |        |       |
| Fetal anomaly                     | 23             | 18             | -0.530 | 0.596 |
| Severe complications              | 1              | 1              |        |       |
| Methods of induce (n,%)           |                |                |        |       |
| Failure of ethacridine            | 15(48.4)       | 7(25.9)        | 3.092  | 0.079 |
| Mifepristone + DBC               | 16(51.6)       | 20(74.1)       |        |       |

Student's test, Chi-square test and Wilcoxon test were used

Tab 2: The Bishop scores of cervices before DBC insert between in the two groups

Wilcoxon test was used
Tab 3: The dilation of cervix after taking out DBC between in the two groups

|       | n  | 0(cm) | 1(cm) | 2(cm) | ≥3(cm) |
|-------|----|-------|-------|-------|--------|
| 12h DBC | 31 | 10    | 9     | 10    | 2      |
| 24h DBC  | 27 | 3     | 9     | 7     | 8      |
| Z       | -2.185 | |
| P       | 0.029 | |

Wilcoxon test was used

Tab 4: The time from induction and DBC removal to delivery

| Lasting time                  | 12h-DBC (n=31) | 12-24h DBC (n=27) | Z     | P     |
|-------------------------------|----------------|-------------------|-------|-------|
| Induction to delivery (h, Median,95%CI) | 29.8(19.0-35.7) | 27.0(24.7-30.2) | -0.405 | 0.685 |
| DBC removal to delivery (h, Median,95%CI) | 17.8(7.0-23.7) | 3.0(0.7-6.2) | -4.366 | 0.000 |

Wilcoxon W test was used

Tab 5: The maternal and fetal outcome parameters between in the two groups
| Groups                        | 12h-CRB (n=31) | 24h-CRB (n=27) | t/Z/X² | P    |
|-------------------------------|----------------|----------------|--------|------|
| ICU in %                     | 5, 16.1        | 4, 12.9        | 0.019  | 1.000|
| Puerperal infection in %      | 3, 9.7         | 5, 18.5        | 0.949  | 0.453|
| Antepartum hemorrhage in %    | 5, 16.1        | 2, 7.4         | 1.034  | 0.432|
| UAE before delivery in %      | 4, 12.9        | 2, 7.4         | 0.470  | 0.675|
| Dilatation and evacuation     | 9, 29.0        | 2, 3.7         | 4.391  | 0.047|
| Weight of fetus (g, Median, 95%CI) | 340, 20-1000   | 300, 45-1045   | -0.047 | 0.963|
| Blood loss at delivery        |                |                |        |      |
| Volume (mL, \( \bar{x} \pm s \)) | 271.4±131.6    | 306.2±89.6     | -1.161 | 0.251|
| PPH 500ml in %                | 5, 16.1        | 3, 11.1        | 0.306  | 0.712|

UAE: Uterine artery embolization

T test, Wilcoxon W test, Chi-square test and Fisher exact test are used

**Tab 6: The WBC cell count and hemoglobin in the two groups**

| Groups                        | 12h-CRB (n=31) | 24h-CRB (n=27) | t      | P    |
|-------------------------------|----------------|----------------|--------|------|
| WBC at admission (10⁹, \( \bar{x} \pm s \)) | 8.9 ±2.3       | 9.4 ±2.1       | -0.720 | 0.474|
| WBC at discharge (10⁹, \( \bar{x} \pm s \)) | 13.3±3.5       | 13.0±2.0       | 0.364  | 0.717|
| Hb at admission (g/L, \( \bar{x} \pm s \)) | 115.4±11.8     | 113.9±11.2     | 0.507  | 0.614|
| Hb at discharge (g/L, \( \bar{x} \pm s \)) | 108.3±11.3     | 103.8±12.0     | 1.467  | 0.148|

T test was used

**Tab 7: Hospitalization days and expenditure of inpatients**
| Groups                        | 12h-CRB (n=31) | 24h-CRB (n=27) | t/Z/X²  | P    |
|------------------------------|----------------|----------------|--------|------|
| Hospitalization days $\bar{d} \pm s$ | 12.3 ±4.4      | 9.8 ±3.8       | 2.258  | 0.028|
| Expenditure of Inpatients $\text{RMB, Median,95\%CI}$ | 13810.5         | 5217.9         | -2.019 | 0.044|
|                              | 3423.6-32659.9 | 3056.7-34215   |        |      |

T test, Wilcoxon W test, Chi-square test, Fisher exact test