Comparison Between The Efficacy and Safety of The Single- (Love Baby) and Double-Balloon Catheters for Cervical Ripening and Labor Induction

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Abstract

Background: Induced labor is a progressively common obstetric procedure, Whether the specifically designed double-balloon catheter is better than the single-balloon device in terms of efficacy, efficiency and safety yet remains controversial.

Methods: In our study We have performed a Retrospective study in which 220 patients with immature cervix were admitted for induction of labor either through single cervix balloon catheter (love-baby) (SBC) or double cervix balloon catheter (DBC). The comparison showed that the cervical bishop score was slightly higher for the SBC after removal or expulsion of the balloon.

Results:This was a proof that SBC demonstrates slightly better efficacy for cervical ripening with a shorter time from balloon placement to spontaneous vaginal delivery than DBC. No significant differences in the comparison between SBC and DBC following other parameters like spontaneous vaginal delivery, the initiate uterine contractions rate, the number of patients that needed oxytocin, the balloon spontaneous expulsion rate and others have been detected. Interestingly, SCB showed a higher incidence in adverse reactions leading to taking out the balloon halfway. The multi-factor analysis showed that the spontaneous labor was a risk factor for the cesarean section in SBC patients.

Conclusion: These results prove that the new Chinese single balloon, also called love baby, can effectively induce labor as it may be highly recommendable for cervical ripening than DBC, though it could be with a higher incidence of adverse reactions causing the balloon to be pulled out halfway.

1. Background

The induced labor is defined as the use of drugs and/or machinery to induce uterine contractions before spontaneous delivery and start of labor and to achieve vaginal delivery. Many conditions lead to an induced labor. Among them are the delayed and prolonged pregnancy (more than 41 weeks), some maternal severe complications like gestational hypertension, gestational diabetes mellitus, kidney disease, etc. All require preterm termination of pregnancy in an assisted manner. Often, fetal factors exert pregnancy termination and they include fetal growth restriction (FGR), stillbirth, severe fetal malformation, fetal appurtenances factors such as oligohydramnios, premature rupture of membranes, and poor placental function, which also requires induced labor. It has reported that about 15% to 30% of all pregnancies require induced labor (1,2). Over the past decades, the incidence of childbirth induction has been increasing.

Cervical maturity is the decisive factor for the success of the induced labor. At present, there are many methods to promote cervical ripening, one of which is the disposable cervix balloon catheter which is made of silica gel. It provides stable and mild mechanical stimulation to the cervix, inducing it to soften, ripe and make uterine contractions in order to accelerate the progress of childbirth(2). For the purpose, the cervix balloon is currently widely used in clinical practice. Many studies refer to the use of the simple cervical balloon, which is made from Foley catheter and is filled with about 30-60 ml of water(3). The

modification of the simple balloon that we report here (also called love-baby) differs from the common simple balloon. The SBC modification, called love-baby, was independently developed and produced in China, with the modification in which the intrauterine balloon was filled with 150 ml of water. There have been few reports of this Chinese new type of single balloon catheter (SBC love-baby). In this study, we first reported the detailed comparison by efficacy and safety between this new single-balloon catheter and the COOK – the double-balloon catheter (DBC) in the process of ripening the cervix and inducing labor. We have also provided a relatively reliable guidance for clinical practice .

2. Methods

2.1. Patients' information and clinical data

The study is a retrospective study spanning between January, 2017 and November, 2019 in the First Affiliated Hospital of Xi'an Jiaotong University, Shannxi, China. In the study We split 220 pregnant women with term pregnancy who induced labor into two groups based on the use of single- or double balloon catheter.Both groups (SBC and DBC) encompassed 110 cases each. In SBC device the uterine balloon is one. The type called "love baby" SBC was produced by Jiangsu Aiyuan Medical Technology Co., Ltd (model: AY-K-1). The DBC had two balloons: one uterine balloon and one vaginal balloon. The brand of DBC was produced by COOK Medical Technology Co., Ltd and here, we designate it as COOK DBC. Both balloons were made of silica gel. Pictures of the two types of cervical balloons are shown in Figure 1.

2.2. Applied research method

All 220 pregnant women had indication for assisted induction of labor. The inclusion criteria included: (1) singleton pregnancy; (2) cephalic presentation; (3) full - term pregnancy (≥37 weeks); (4) intact fetal membrane; (5) cervical Bishop score ≤6; (6) no other contra-indications for vaginal delivery.

The exclusion criteria included: (1) a previous cesarean section or hysteromyomectomy; (2) placenta or prevascularization; (3) cephalopelvic disproportion and abnormal birth canal; (4) severe pregnancy complications which could not tolerate vaginal delivery; (5) infectious diseases of the reproductive tract; (6) obvious fetal distress; (7) allergy to silica gel. Patients underwent vaginal micro ecological, pelvic ultrasound, fetal heart monitoring and vaginal examinations.

2.3. Indicator factors used for comparison between SBC and DBC

The indicators used for comparison between the SBC and DBC induced childbirth included changes in cervical bishop score before and after the use of the balloon, vaginal delivery rate, caesarian section birth rate, vaginal delivery rate within 24 hours, time from balloon placement to spontaneous delivery, balloon shedding rate, incidence of premature rupture of membranes, amniotic fluid contamination rate, neonatal Apgar score, etc. In the two groups we have observed the incidence of adverse events, including vaginal bleeding, uterine contraction, discomfort, postpartum hemorrhage, fever, etc.

2.4. Statistical methods

All data were statistically analyzed in SPSS 22.0. The measurement data were expressed by mean values ± standard deviation (median and rang). The comparison between the two groups was tested by independent t test or the Mann-Whitney U test (in the case of abnormally distributed variables). The counting data were expressed by n (%) and compared by application of the Continuity Correction or Fisher's Exact Test when warranted. Furthermore, the univadate x2test and multivariate logistic regression model were used in the analysis of cesarean section related factors At P values ≤0.05, the data were accepted as statistically significant.

3. Results

3.1. Demographic data and factors leading to induced labor

The SBC group of patients included 110 pregnant women with an average age of 28.736±3.639 years old. The mean number of pregnancy weeks was 39.838±1.053 weeks. Among all patients, 89 (accounting for 80.9%) were primipara while 21 (19.1%) of the patients were multipara. There were 110 pregnant women in DBC group, the mean age of the patients was 29.35±3.598 years old, the median pregnancy week was 40.066±1.061 weeks. 8 of the patients (77.27%) were primipara while 26 (22.73%) patients were multipara. There was no significant difference in age, gestational week, parity (P=0.257;Mann-Whitney), (p=0.373;X2=0.794), (p=0.068; Mann-Whitney), respectively. All these data are summarized in Table 1.

The clinical diagnoses and medical data leading to the decision of induced labor in both groups are presented in Figure 2. In the SBC group diagnoses like oligohydramnios accounted for 43.6%, delayed pregnancy for 18.18%, while suspected fetal distress accounted for 8.18% only. In DBC group, these parameters were oligohydramnios (40%), delayed pregnancy (35.45%) and gestational diabetes mellitus (16.36%).

3.*2 Delivery outcome and related obstetric parameters*

Next, we have analyzed several other parameters in the two groups like the delivery outcome and other related obstetric parameters. These data are summarized in Table 2. Studying the difference in the vaginal delivery rate between the two groups showed no statistical significance. The vaginal delivery rate was 60.9% for SBC versus 58.18% for DBC while the cesarean section rate was 39.1% for SBC and 41.82% for DBC. In SBC group, the cervical bishop score was 3.664±1.416 before the balloon was placed and 6.418±1.511 after its removal off the cervix or its natural falling off. In the DBC group, the cervical bishop score was 3.355±1.324 before the balloon was placed, and 5.473±1.618 after its natural or assisted removal. The statistical analysis showed that there is a significant difference on this parameter between the two groups. The difference in the Bishop score after removal of the cervix balloon or its spontaneous falling off between SBC and DBC groups was statistically significant with P<0.0001, assessed by the Mann-Whitney test. The detected increase in the Bishop score between the two groups, i.e. 2.755±1.746 for SBC versus 2.109±1.350 for DBC was statistically significant with P value, calculated at Mann-Whitney test, equal to 0.008. This finding proves that SBC showed a better efficacy for cervical

ripening than DBC (see Table 2). The calculated spontaneous vaginal delivery rate that happed earlier than the 24th hour was 15.45% for SBC assisted labor and 8.18% for DBC assisted one with P values assessed after the statistical analysis 0.755;$\chi 2$ =0.098. The estimated spontaneous vaginal delivery time was 20.519±8.674 hours for SBC versus 27.069±12.817 hours for DBC with P and t values as follows: 0.013; 2.562. As seen in Table 2 the SBC assisted childbirth demonstrated a shorter time from the balloon placement to the spontaneous delivery than the DBC one. Interestingly, almost the same number of patients from the two groups, respectively 46.36% for the SBC and 50.00% for the DBC could not initiate uterine contractions with the balloons. The calculated statistical parameters were as follows: P=0.589 and$\chi 2$ =0.291. 73.64% versus 77.27% of the patients needed oxytocin for induction of labor after taking out of the balloon, proving that there were no significant differences between the two groups on this parameter (see Table 2). The spontaneous expulsion accounted for 17.27% and 13.64% within 24 hours in the single- and double-balloon groups, respectively with statistical parameters P=0.275 and$\chi 2$=1.513. The spontaneous expulsion time was 11.474±6.415 and 11.385±6.212 hours in the two groups, showing no significant difference between them. In terms of the cesarean section indications (Figure 3 and 4), our data showed that these indications were cephalopelvic disproportion calculated in 53.48% in SBC assisted childbirth and 47.82% in DBC one. The fetal distress was similar in both groups, i.e. 21.43% for SBC versus 23.91% for DBC. The failure to induced labor rate was 14.29% in SBC and 21.73% in the other group. There was no significant difference between the two groups (SBC vs DBC) (P >0.05).

3.*3 Detected adverse reactions and complications*

We have observed that in the SBC group, due to adverse reactions in 12 of the cases the balloon was taken out halfway. This led to premature rupture of membranes in 8 cases, to massive vaginal bleeding in 2 of the cases, to intolerant discomfort in 1 case and to a single case with uterine tetanic contraction. The detected situation in the DBC group was as follows: in 4 cases the balloon was taken out and led to premature rupture of membranes. Data are shown in Table 3. There were statistically significant differences in the frequency of detected adverse reactions between the two groups with P =0.041 and $\chi 2$ =4.157. These results show that SBC demonstrated a higher incidence of adverse reactions than DBC. The incidence of the premature rupture of membranes was 7.27% in SBC group and 3.64% in the DBC one. Other detected complications included 1 case of cervical laceration and 1 case of umbilical cord prolapse that occurred in SBC group and 1 case of precipitate labor in DBC group. No postpartum hemorrhage, nor fever, nor uroschesis were detected in both groups.

3.4 Amniotic fluid status and neonatal outcomes

In the SBC group, Meconium-stained amniotic fluid (MSAF) accounted for 17.27% of the cases. In DBC group,Meconium-stained amniotic fluid（MSAF）accounted for 11.82%.There was no significant difference in the amniotic fluid between the two groups (P=0.38; Mann-Whitney test).The results are given in Table 4.

The incidence of neonatal Apgar score□7□1 minute after birth) was 97.27% versus 99.09%. The incidence of neonatal Apgar score ≤7 was 2.73% versus 0.91% and included 1 case with 6 points, 2 cases with 7 points in the single balloon group, and 1 case with 6 points in the double balloon group. There was no significant difference in the neonatal scores between the two groups (P =0.627; χ2 =0.236588)**.** Results are shown in Table 4. The fetal macrosomia (≥4000g) was detected in 2 and 5 cases for SBC and DBC methods, respectively. These data show no significant difference in MSAF, in the neonatal Apgar score (1 minute) and in fetal macrosomia between the two groups.

3.5 Statistical analysis of the parameter "primipara women" between the SBC and DBC groups

Table 5 summarizes the statistical analysis of the parameter "first birth", i.e. the primipara women. The statistical analysis of this parameter between the two groups showed no significant difference in the delivery mode (P =0.969; χ2 =0.002). The cervical bishop score was 2.551±1.61 in SBC against 2.107±1.290 in DBC group, with a tendency of increased Bishop score (p□0.01; Mann-Whitney test), demonstrating better efficacy of SBC assisted childbirth in these women. The spontaneous vaginal delivery rates within less than 24 hours in the two groups of primipara women were similar. The statistical values were P=0.522 and χ2 =0.411, while the spontaneous vaginal delivery time was 20.1888. SBC demonstrated shorter time between the time from balloon placement to spontaneous delivery than DBC in the cohort of theprimipara women. We could not detect significant differences between the two groups of patients on parameters like lack of uterine contractions, oxytocin need in the period of time after 24 hours from balloon placement and balloon spontaneous expulsion. The values of all assessed statistical parameters were as follows P=0.402 and χ2=0.704, P=0.768 and χ2=0.087, and P=0.442 and χ2 = 0.59, respectively. There were also no significant differences between the two groups in the studied cesarean section indications in the primipara women cohort with values of the statistical parameters as follows: P=0.474 and χ2 =1.491). No statistically significant differences in the detected adverse reactions which caused the balloon to be removed halfway were calculated for this cohort of women between the two groups. The assessed statistical values were as follows P =0.144 and χ2 =2.13. There was no significant difference in the incidence of the Meconium-stained amniotic fluid□MSAF), nor in the incidence of the neonatal Apgar score (≤7) and in the fetal macrosomia(≥4000g) between the two groups. The values of the statistical parameters confirmed this (see Table 5).

3.6 Statistical analysis of the parameter "multipara women" between the SBC and DBC groups

In the cohort of the multipara women, there was no statistically significant difference in the delivery mode between the two groups (P =0.324;χ2 =0.961). Data are presented in Table 6. The mean cervical bishop score was calculated 6.810±1.816 in the SBC group and 5.654±1.958 in the DBC one. The mean increased Bishop score of the time after the removal of the balloon off the cervix or its natural falling off, was calculated as 3.619±2.061 against 2.115±1.558, p=0.03; p=0.011; Mann-Whitney test it shows that SBC showed a better efficacy than DBC for cervical ripening in multipara women. The spontaneous vaginal delivery < 24 hours and the spontaneous vaginal delivery time in the two groups were similar with estimated statistical values: P =0.435 andχ2 =0.611; p=0.616 and t=0.510, respectively. There were no

significant difference between the two groups in patients that could not initiate uterine contractions with the balloons, nor in those who needed oxytocin after 24 hours from the balloon placement and its spontaneous expulsion. The respective statistical values were calculated as follows P=0.76 and$\chi 2$ =0.093; P=0.721 and$\chi 2$ =0.127; P=0.459 and$\chi 2$ =0.547, and are shown in Table 6. respectively. There were no statistically significant differences between the two groups in regard to the cesarean section indications in the cohort of the multipara women (P =0.636). Moreover, no statistically significant differences were observed in the incidence of adverse reactions in this cohort and among the two groups. There was no significant difference in the incidence of the Meconium-stained amniotic fluid (MSAF) between the two groups (P=0.485 and$\chi 2$ =0.488). 1 case with neonatal Apgar score ≤7 in the double balloon group was detected among the multipara women. Interestingly, no further complications were found among the patients from this cohort.

3.7 Multivariate analysis of the cesarean section operation in the two groups of patients

We have performed a multivariate analysis of the caesarian section rate between the two groups and results are shown in Table 7. In the SBC group, the single factor analysis showed that the spontaneous labor, the parity, and the cervical Bishop score after the removal or the expulsion of the balloon increased the Bishop score and among the groups the differences in its values were statistically significant, furthermore were associated with the decrease of the cesarean section rate with P values < 0.05. The multivariate analysis model showed that the spontaneous labor (HR:5.393，95%CI:1.389-20.945) could be used as an independent predict factor of the cesarean section. In the SBC group (Table 8), the single factor analysis showed that the Bishop score was associated with the cesarean section (p=0.024).

4. Discussion

Cervical maturity is a decisive factor in the success of induced labor, as poor cervical conditions reduce the rate of vaginal delivery. Here, we have applied the cervical Bishop score to assess cervical maturity. The score with values ≥7 indicated that the cervix is mature and the success rate of the trial birth is more than 80%. Values of the Bishop score ≤6 were accepted as indicators of immature cervix that frequently led to assisted labor through promotion of cervical maturation. No surprise that an important question for all obstetricians has been the problem with the quick ripening of the cervix in a safe and effective for the induced labor way. A major requirement to the perfect method for cervix ripening is to be safe for both the mother and the fetus, to be cost effective, to lead to slightest discomfort and to not require extensive monitoring (3). At present, there are many methods to ripen the cervix and to induce labor, including drug and mechanical materials, both proven effective (4)(5). The most commonly used drugs include oxytocin, dinoprostone suppositories, misoprostol and others. The oxytocin is the most classic drug of inducing labor as it dilates the cervix by stimulating the contraction of the smooth muscles of the uterus. Its effect is not only related to the concentration of the oxytocin, but also to the uterine state and the number of oxytocin receptors. Dinoprostone suppositories and misoprostol have good effect on softening of the cervix and inducing contractions. The dose of misoprostol is not easy to master as the effective dose varies greatly in different patients. Although PGE2 significantly reduces the rate of cesarean section, it

has many disadvantages. At first, strong uterine contractions may cause uterine tonic contractions, fetal distress, placental abruption, acute labor, uterine rupture, postpartum hemorrhage, amniotic fluid embolism and other serious complications. Secondly, irregular uterine contractions also lead to poor tolerance of the patient. Next, theoretically PGE2 may lead to fever, vomiting, high blood pressure, diarrhea and asthma and other symptoms. Finally, the medical cares for such patients is a must, which increases the workload of medical staff (6).

Among the mechanical methods of inducing labor are the Foley catheter, the cervix balloon catheter, the seaweed rod and others. They are simple and safe, cost effective, mild and can be well controlled. The single balloon catheter (Foley) is the most commonly used mechanical method for inducing labor dating back to the 1960s and has been identified as a safe and effective method for mechanical induction of labor (7)(8). The original cervix double balloon was invented in 1991 by the American obstetrician-gynecologist Atad (9). The cervical dilatation balloon is recommended in promoting cervical maturation and induced labor since 2009 by the American Society of Obstetricians and Gynecologists (ACOG) and is outlined in labor induction guidelines. It was officially recommended by the WHO guidelines for induced labor in 2011. In 2013, the U.S. Food and Drug Administration (FDA) officially approved the Cook cervical balloon and has declared that the COOK double cervical balloon has the same mechanism and efficacy with the Atad double balloon (10).

The mechanisms of action of the cervical balloon can be described as follows: (1) mechanical compression of the cervical canal; (2) the cervical decidual separation induces the synthesis and release of local endogenous prostaglandin in the cervix; (3) the so-called Ferguso effect, i.e. the balloon of water causes uterine cavity expansion, and the hypophysin and oxytocin release increase, causing uterine contractions and further cervical effacement and dilatation (11). The advantages of the cervix balloon catheter can be summarized as follows: (1) it is slow, mild and continuous for cervical maturation; (2) has less adverse reactions, allows free movement for patients; (3) the efficacy for inducing labor is good. It is especially recommended for patients and fetuses who cannot tolerate prolonged uterine contractions, such as women with uterine scarring, placental dysfunction, fetal growth restrictions and oligohydramnios. It is a good method to promote cervical maturation and induce labor, and is much safer than the use of drugs (12).

At present, two kinds of cervical balloon are commonly used in China and they are the single cervical balloon (love-baby), made by Jiangsu Aiyuan Technology Co and the COOK balloon, which is a double balloon made by COOK Technology Co. Both are made of silica gel. Although the mechanism of the two balloons is similar, they have differences in their design and features. The single balloon (love-baby) is a Chinese self-produced intrauterine balloon, and can inject 150 ml of water and to expand to about 5-6 cm in diameter. It can also make the cervix to dilate up to 3 – 4 cm. It is different from the single catheters in other countries, which generally are 16F Foley catheters of 30-60 ml of water in the balloon. The COOK double balloon was imported and proved to be a very safe method for promoting cervix maturation abroad. It uses the 18F catheter, with an intrauterine balloon and a vaginal balloon, both injected with 80 ml water. The mechanism of the COOK double balloon catheter includes a mechanical pressure on the

cervix through the two balloons located in the inner and external part of the cervix. The mode of ripening of the cervix comes by the role of balloon compression. Due to the assistance of the vaginal balloon, the COOK double balloon is not easy to slip from the cervix, and the strength to the cervix is mild and continuous. In contrast, the single balloon (love-baby) with 150 ml water in the balloon applies greater gravity on the cervix than the double balloon and dilate the cervix mainly by the role of gravity force.

Some authors believe that the increase in the volume of the balloon heavily increases the separation between the amniotic membrane and the uterine decidua, resulting in increased local secretion of prostaglandin and enhanced ability to promote cervical maturation. It is shown that 60 ml or 80 mL of Foley single balloon catheters are more effective for inducing labor compared to 30 mL (13). Lin MG et al (14) found that the time from the induction of contractions to the child delivery assisted by the simple Foley balloon with water sac was shorter than that of the Foley balloon without a water sac, but there was no difference in the rate of cesarean section. Levy R (15) have found that ripening of the cervix with the larger balloon volume was associated with a significantly higher rate of dilatation of 3 cm or more. In primiparous women, the larger balloon volume can lead to a significantly higher rate of birth deliveries within 24 hours, and a significantly less requirements for use of oxytocin. Though other authors (16) have found that the Foley balloon with and without water sac has no difference in the induction of delivery interval, in the 24-hour vaginal delivery rate, and in the cesarean section rate.

Atad J (17) believes that the double balloon catheter has two balloons, thus giving greater compression to the cervix. However, Delaney S (18) showed that the COOK double balloon induced labor is not better than the 30 ml of Foley single balloon catheter. Currently, most studies have found that the single and the double balloon catheters have similar efficiency, safety and patient satisfaction, but the single-balloon method is considered to be more cost-effective and is more easily accepted by patients (12,19,15,20). Other authors (21) found that the mean intervention to the birth time, the vaginal delivery and the cesarean section rates, and maternal satisfaction were similar for both kind of balloons. Fang Yang (22) concluded that there was no significant difference in the estimated values for the cesarean section and vaginal delivery rate in 24 hours, nor in the average delivery time and improvement of Bishop score between the two groups. Raed Salim (23) found that the Length of time from balloon insertion to delivery, the incidence of the cesarean delivery had no statistically significant differences between the COOK double balloon and the single one without a difference among primiparous women. Furthermore, we have found that there was no significant difference in the vaginal delivery rate and the cesarean section rate between the two groups. The spontaneous vaginal delivery rate < 24 hours from balloon placement were similar in the two groups. In addition to the rate of patients who needed oxytocin after removal of balloon was similar again with no statistical difference in two groups.

However, some scholars have confirmed that there are differences in the efficacy of the double balloon and the single balloon induced labor. Other authors (21) showed that there was a significant difference in the change of the Bishop score in the single balloon group compared with the double group, suggesting that the single balloon has a more significantly significant increase in the cervical Bishop score while Hoppe et al. (24) reported that among the cohort of primipara women, a greater proportion of the double

balloon group achieved a Bishop score ≥6 at the time of catheter removal and vaginally delivered labor compared to the single-balloon catheter assisted labor. No difference in the catheter type for achieving a Bishop score ≥6 or vaginal delivery among multiparous women was detected, suggesting that the 80 mL double-balloon catheter is more effective than the 30 mL single-balloon catheter for pre-induction of cervical ripening and achieving a vaginal delivery in primipara. Mei-Dan E (25) found that although the success rates of cervical maturation between single and double balloon group is similar, the time from balloon insertion to expulsion and from insertion to delivery was significantly shorter in the simple balloon group compared with the double balloon group. Raed Salim (21) argues that the incidence of surgical delivery (forceps delivery or cesarean section) in the double balloon group was significantly higher than that in the simple group while Sayed Ahmed WA (26) found that balloon spontaneous expulsion rate in single balloon group happened more frequently than within the double balloon with a difference in the rate of up to 89.2%. The time from balloon insertion to expulsion and from insertion to delivery was significantly shorter among the single balloon group. However, the median Bishop score was significantly higher when using the double balloon compared with the simple double balloon catheter after balloon removal. Pennell CE (20) also found that in the simple balloon group the time to delivery was shorter than the double balloon.

In our study, we have detected statistically significant difference in the cervical bishop score after removal or expulsion of the balloon and improved Bishop score between the two groups. The single cervix balloon group showed a better efficacy for cervical ripening, while the single cervix balloon showed shorter time from the balloon placement to spontaneous delivery than the double cervix balloon. We could not detect significant differences in the other parameters, such as the rate of patients that could not initiate uterine contractions, the oxytocin used mode of delivery, etc. We have also found that both in primipara and multipara cohorts of women the single balloon showed a better efficacy for cervical ripening. The single cervix balloon group showed shorter time between the balloon placement to the spontaneous delivery than in the double cervix balloon group in the primipara women, but not in multipara.

Although the balloon placement duration stated in the instructions was 12 hours, we found that it is too short to get a good efficacy for cervical ripening. Studies have concluded that it is safe to extend the placement time to 24 hours for pregnant women (27). Therefore in this study we have placed the cervical balloon for 24 hours. It is important the balloon to pass through the cervical canal and to be placed into the uterine cavity. In theory, there will be some complications such as uterine infection, premature rupture of membranes, cervical injury, umbilical cord prolapse and other conditions. In addition, the pressure and gravity action may cause discomfort to the patient. A recent systematic review suggests that mechanical methods reduced uterine hyperstimulation compared with PGE2 and misoprostol, but increased maternal and neonatal infectious morbidity compared with other methods(28). Limited data, though, from the Sciscione AC (29) Zieminska A (30) showed that there is no evidence that the cervical balloon catheter increases the risk of infection rates. Henry A (31) prove that the cervical balloon group had shorter hospital stay prior to birth and led to less pain and more sleep compared with vaginal PGE2. It is obvious that the outpatient balloon catheter ripening should be further investigated as an option for women (32).

Jozwiak M (33) proved that the single balloon catheter had the lowest pain score with no increase in the risk for chorioamnionitis or endometritis.

Maslovitz S (34) retrospectively analyzed 1083 cases of women who had a placed balloon to promote cervical maturation and induced labor, which accounted for 7.8% of the women with complications, acute transient fever (3%), pain (1.7%), vaginal bleeding(1.8%). The position of the fetus changed from head position to breech in 1.3% of the cases. Some authors state (30) that statistically the complications includes: 7.34% cases of premature rupture of the membranes (PROM), 10.09% cases were with a balloon which was taken out halfway due to pain and discomfort and 1.84% cases of bleeding. Salim R (23) concluded that there was no significant difference between the single and double balloon groups in the following aspects: maternal infection, postpartum hemorrhage, low Apgar score and NICU admission, placental abruption, uterine overstimulation, umbilical cord prolapse, infertility, Hoppe KK (24) found that there was no statistical difference in the incidence of post-delivery fever between the two groups, while Pennell CE (20) et al showed no significant difference in the incidence of postpartum hemorrhage in the two kinds of induced labor. However, other researchers have shown that the side effects in the two types of balloon were different. Cromi A (35) thinks the patient's discomfort in the single balloon is more obvious because gravity action, while Raed Salim (23) observed in the simple balloon group, adverse reactions which were significantly lower compared with double balloon group. Including fever and umbilical cord prolapse. In our study, we could not detect statistically significant differences in the detected adverse reactions. The single cervix balloon group had a higher incidence of such reactions than the double balloon group, including premature rupture of membranes, massive vaginal bleeding, intolerant discomfort and uterine tetanic contractions. Only 1 case of cervical laceration and 1 case of umbilical cord prolapse occurred in the single balloon group, while only 1 case of precipitated labor was detected in the double balloon group. There were no cases of postpartum hemorrhage, fever and uroschesis in the two groups.

5. Conclusion

Our results show that we are the first that report the efficacy and safety between this new single-balloon (lobe baby) and the COOK double-balloon in ripening the cervix and inducing labor. We have found that both the SBC and the DBC have equivalent efficacy in inducing labor, the new Chinese single balloon, also called love baby, can effectively induce labor as it may be highly recommendable for cervical ripening than DBC, though it could be with a higher incidence of adverse reactions causing the balloon to be pulled out halfway.

6. Abbreviations

SBC single cervix balloon catheter

DBC double cervix balloon catheter

FGR fetal growth restriction

MSAF Meconium-stained amniotic fluid

PGE2 prostaglandin E2

ACOG American Society of Obstetricians and Gynecologists

FDA Food and Drug Administration

7. Declarations

7.1 Ethics approval and consent to participate

This study is a retrospective clinical study, which has no impact on patients' life safety and treatment plan, and will not lead to adverse consequences.Therefore, All patients gave informed consent,and oral consent was obtained from the Ethics Committee of the First Affiliated Hospital of Xi 'an Jiaotong University.

7.2 Consent for publication

All Authors Consent to publish this article.

7.3 Availability of data and material

All data in our article can be obtained from the medical record system of the First Affiliated Hospital of Xi 'an Jiaotong University.

7.4 Competing interests

There are no conflicts of interest.

7.5 Funding

There is no funding for this research.

7.6 Authors' contributions

all authors read and approved the final version of the manuscript

HM;(acquisition of data, or and drafting the article;

WWH(analysis and interpretation of data)

LD (revising article)

LXL(conception and design,fnal approval of the version to be published)

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Tables

Table 1 Demographic data in the two groups

	single cervix balloon group (n=110)	double cervix balloon group (n=110)	P
age (years old)	28.736±3.639 (28, 20-41)	29.355±3.598 (29, 21-42)	0.257
parity			0.373
primipara	89 (80.9%)	84 (77.27%)	
multipara	21 (19.1%)	26 (22.73%)	
gestational weeks	39.838±1.053(40.071, 37.429-41.714)	40.066±1.061 (40.214, 37-42)	P=0.068

Table 2 delivery outcome and related obstetric parameters in the two groups

	single cervix balloon group (n=110)	double cervix balloon group (n=110)	P
Delivery way			0.68
Vaginal delivery	67(60.9%) (1 forceps)	64(58.18%) (1 forceps)	
Cesarean section	43(39.1%)	46(41.82%)	
Improvement of cervical score			
before	3.664±1.416 (4, 1-6)	3.355±1.324 (3, 0-6)	0.089
after	6.418±1.511 (6, 3-13)	5.473±1.618 (5, 2-10)	<0.0001
increased	2.755±1.746 (3, 0-8)	2.109±1.350 (2, 0-6)	0.008
Spontaneous delivery within 24 hours from balloon placement	17 (15.45%)	13 (8.18%)	0.755
Spontaneous delivery time from balloon placement(hours)	20.519±8.674 (22, 7-34)	27.069±12.817 (27, 3-57)	0.013
Can not initiate uterine contractions with balloons	51 (46.36%)	55 (50%)	0.589
need use oxytocin after 24 hours from balloon placement	81 (73.64%)	85 (77.27%)	0.396
Balloon spontaneous expulsion within 24 hours from balloon placement	19 (17.27%)	13 (13.64%)	0.275
Balloon Spontaneous expulsion time (hours)	11.474±6.415 (13, 1-22)	11.385±6.212 (11, 2-20)	0.969

Table 3 Adverse reactions and complications.

	single cervix balloon group (n=110)	double cervix balloon group (n=110)	P
Adverse reactions (take out balloon halfway)	12	4	0.041
premature rupture of membranes	8 (7.27%)	4 (3.64%)	0.248
massive vaginal bleeding	2	0	
Can't tolerate	1 (Abdominal distension and pain)	0	
Uterine Tetanic contraction	1	0	
complications	2	1	
precipitate labour (<3h vaginal delivery)	0	1	
Cervical laceration	1	0	
Umbilical cord prolapse	1		
Postpartum hemorrhage	0	0	
Fever	0	0	
uroschesis	0	0	

Table 4 amniotic fluid status and Neonatal outcomes in two groups

	single cervix balloon group (n=110)	double cervix balloon group (n=110)	P
Clear amniotic fluid	97 (88.18%)	90 (81.82%)	0.186
Meconium-stained amniotic fluid (MSAF)	13 (11.82%)	19 (17.27%)	0.38
III°	7 (6.36%)	16 (14.55%)	
II°	5 (4.55%)	2 (1.82%)	
I°	1 (0.91%)	1 (0.91%)	
Neonatal Apgar score (1 minute after birth)			0.627
≤7	3 (2.73%)	1 (0.91%)	
>7	107 (97.27%)	109 (99.09%)	
fetal macrosomia (≥4000g)	2	5	0.442

table 5 Demographic data of primipara in two groups.

	Primipara		
	single cervix balloon group (n=89)	double cervix balloon group (n=84)	P
Delivery way			0.969
Vaginal delivery	49 (55.0%)	46 (54.8%)	
Cesarean section	40 (45.0%)	38 (45.2%)	
cervical score			
before	3.775±1.371 (4, 1-6)	3.598±1.404 (3, 0-6)	0.076
after	6.326±1.428 (6, 3-10)	5.417±1.507 (5, 2-10)	0.091
increased	2.551±1.61 (2, 0-7)	2.107±1.290 (2, 0-6)	<0.001
Spontaneous delivery within 24 hours from balloon placement	10 (11.23%)	7 (8.33%)	0.522
Spontaneous delivery time from balloon placement(hours)	20.188±7.943 (22, 8-32)	32.870±15.104 (30, 3-72)	0.005
Can not initiate uterine contractions with balloons	42 (47.19%)	45 (53.57%)	0.402
need use oxytocin after 24 hours from balloon placement	65 (73.03%)	63 (75%%)	0.768
Balloon Spontaneous expulsion within 24 hours from balloon placement	13 (14.6%)	9 (10.7%)	0.442
Balloon spontaneous expulsion time (hours)	12.154±5.550 (14, 1-20)	12.111±5.231 (11, 3-20)	0.986
Indications of cesarean section			0.474
cephalopelvic disproportion	22(55.0%)	18(47.37%)	
fetal distress	7(17.5)	9(23.68%)	
Failure to induced labor	6(15%)	9(23.68%)	
Adverse reactions (take out balloon halfway)	8	3	0.144
premature rupture of membranes	5	3	0.781
massive vaginal bleeding	1	0	
Can't tolerate	1	0	
Uterine Tetanic contraction	1	0	
complications	2	1	
precipitate labour(<3h vaginal delivery)	0	1	
Cervical laceration	1	0	
Umbilical cord prolapse	1	0	
Fever	0	0	
Meconium-stained amniotic fluid (MSAF)	12 (13.5%)	15 (17.9%)	0.408
Neonatal Apgar score (1 minute after birth) ≤7	3	0	0.261
fetal macrosomia(≥4000g)	2	5	0.395

table 6 Demographic data of multipara in two groups.

	Multipara		
	single cervix balloon group (n=21)	double cervix balloon group (n=26)	P
Delivery way			0.324
Vaginal delivery	18 (85.7%)	18 (69.2%)	
Cesarean section	3 (14.3%)	8 (30.8%)	
cervical score			
before	3.190±1.537 (3, 1-6)	3.538±1.029 (4, 1-5)	0.387
after	6.810±1.816 (7, 4-13)	5.654±1.958 (5.5, 2-10)	0.03
increase	3.619±2.061 (3, 1-8)	2.115±1.558 (2, 0-6)	0.011
Spontaneous delivery within 24 hours from balloon placement	7 (33.33%)	6 (23.08%)	0.435
Spontaneous delivery time from balloon placement(hours)	21±9.990 (22, 7-34)	18.778±9.324 (23, 3-29)	0.616
Can not initiate uterine contractions with balloons	9 (42.86%)	10 (38.46%)	0.76
need use oxytocin after 24 hours from balloon placement	16 (76.19%)	22 (84.62%)	0.721
Balloons spontaneous expulsion within 24 hours from balloon placement	6 (28.6%)	4 (15.4%)	0.459
Balloons spontaneous expulsion time (hours)	10±8.390 (8, 2-22)	9.75±8.732 (8.5, 2-20)	0.965
Indications of cesarean section			0.636
cephalopelvic disproportion	1	4	
fetal distress	2	2	
Failure to induced labor	0	1	
Adverse reactions	4	1	0.228
premature rupture of membranes	3	1	0.454
massive vaginal bleeding	1	0	
Can't tolerate	0	0	
Uterine Tetanic contraction	0	0	
complications	0	0	
precipitate labour(<3h vaginal delivery)	0	0	
Cervical laceration	0	0	
Umbilical cord prolapse	0	0	
Fever	0	0	
Meconium-stained amniotic fluid (MSAF)	1 (13.5%)	4 (17.9%)	0.485
Neonatal Apgar score (1 minute after birth) ≤7	0	1	
fetal macrosomia(≥4000g)	0	0	

Table 7 Multivariate analysis of cesarean section operation in SBC group

	single factor analysis				multiple-factor analysis		
	Cesarean section	Vaginal delivery	P	x 2	P	OR	0.95 of OR
Spontaneous labour							
Yes	4	26	<0.001	13.668	0.015	5.393	1.389-20.945
no	40	42					
Parity							
primipara	41	50	0.01	6.707	0.051	0.256	0.065-1.006
multipara	3	18					
Balloon Spontaneous expulsion					-	-	-
Yes	5	14	0.21	1.574			
no	39	54					
age (years)	28.209±3.709(28, 20-38)	29.075±3.077 (28, 21-41)	0.28	-	-	-	-
gestational weeks	40.020 ± 1.092(40.286 , 37.429-41.714)	39.721 ± 1.019(39.714 , 37.571—41.429)	0.109	-	-	-	-
Bitshop score before (points)	3.953 ± 1.308(4, 1-6)	3.478±1.460(3,1-6)	0.0782	-	-	-	-
Bitshop score after (points)	6.00±1.215 (6, 3-8)	6.687 ± 1.626 (7, 4-13)	0.032	-	0.977	-	-
Developed Bitshop score	2.047±1.379 (2, 0-5)	3.209±1.813(3,0-8)	0.001	-	0.086	-	-

Table 8 Multivariate analysis of cesarean section operation in DBC group

	single factor analysis				multiple-factor analysis		
	Cesarean section	Vaginal delivery	P	x 2	P	OR	0.95 of OR
Spontaneous labour					-	-	-
Yes	8 (17.4%)	18 (28.1%)	0.191	1.708			
no	38 (82.6%)	46 (71.9%)					
Parity					-	-	-
primipara	38 (82.6%)	46 (71.9%)	0.191	1.708			
multipara2	8 (17.4%)	18 (28.1%)					
Balloon Spontaneous expulsion			0.145	2.128	-	-	-
Yes	3 (6.5%)	10 (15.6%)					
no	43 (93.5%)	54 (84.4%)					
age (years)	29.422±3.258 (29, 21-36)	29.297±3.870 (29, 24-42)	0.425	-	-	-	-
gestational weeks	40.048 ± 1.166 (40.429, 37.142-42)	40.096 ± 0.990 (40.214, 37-41.571)	0.728	-	-	-	-
Bitshop score before (points)	3.178±1.302 (3, 0-6)	3.453±1.332(4, 1-6)	0.336	-	-	-	-
Bitshop score after (points)	5.133±1.517 (5, 2-10)	5.179 ± 1.667 (6, 2-10)	0.024	-	-	-	-
Developed Bitshop score (95%CI)	1.956±1.313 (2, 0-6)	2.25 ± 1.357 (2, 0-61.894-2.598)	0.226	-	-	-	-

Figures

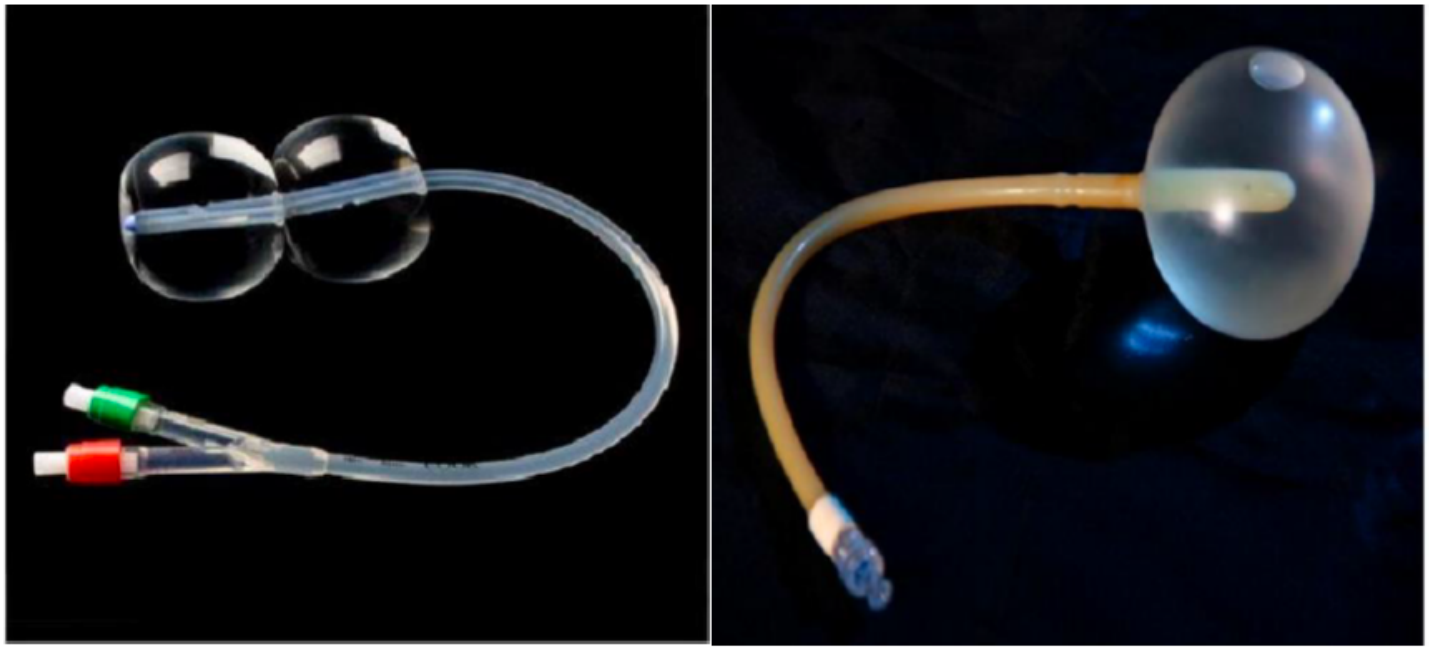

Figure 1

two types of cervical balloon

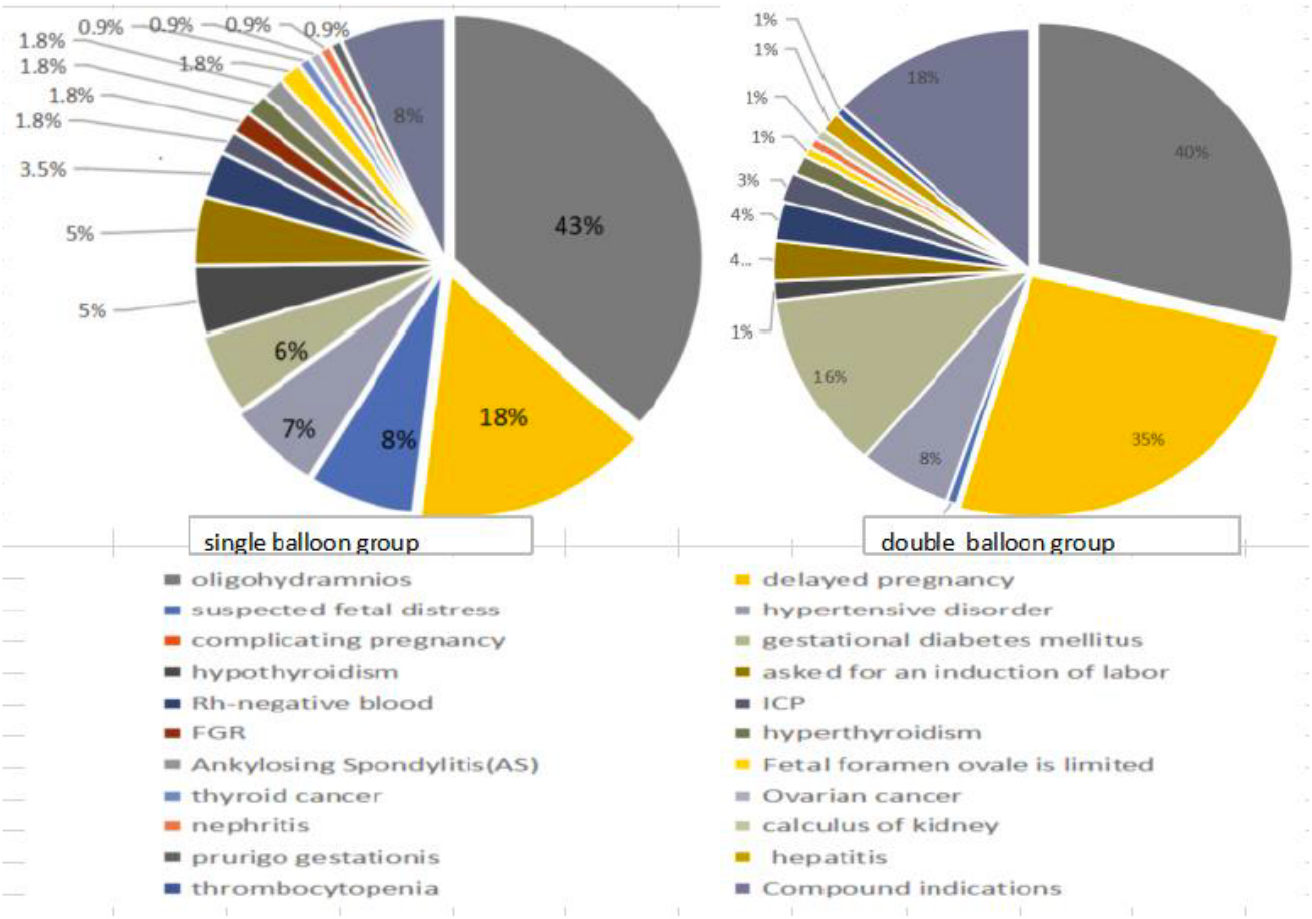

Figure 2

The indications of induced labor in the two groups

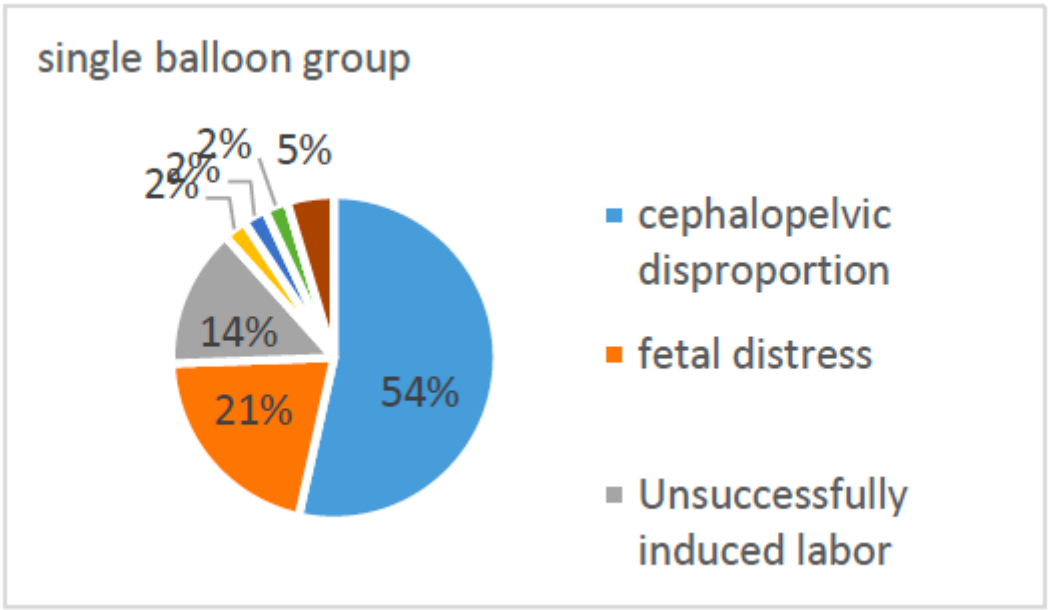

Figure 3

indications of cesarean section in SBC group

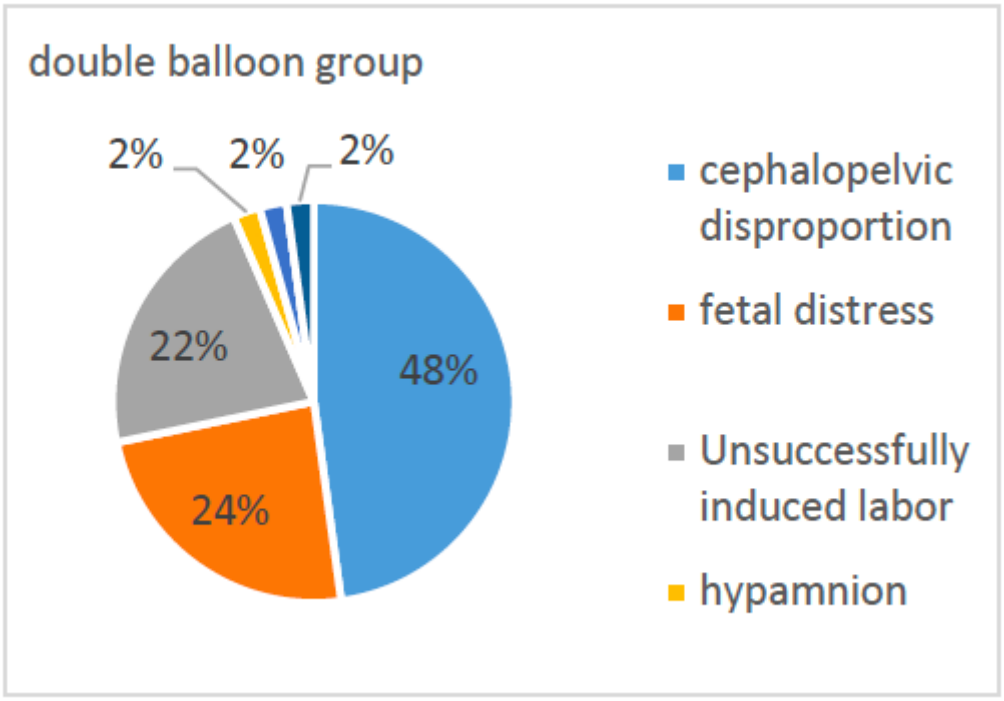

Figure 4

indications of cesarean section in DBC group