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Comparison of the efficacy and safety of dinoprostone and double-balloon catheters in cervical ripening: a propensity score matching retrospective study

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ABSTRACT

Objectives: The methods of prompting cervical ripening (CR) include mechanical and pharmacological approaches. The former seems safer. However, this superiority may change with the application of a new labor curve. Therefore, we aimed to compare the efficacy and

safety of dinoprostone and double-balloon catheters (DBC) in promoting CR in induction of labor (IOL).

Material and methods: A total of 877 primipara women with Bishop score ≤ 6 were divided into the dinoprostone group (n = 502) and DBC group (n = 375) according to the IOL way. The women in the dinoprostone group received dinoprostone to perform IOL, while those in the DBC group received DBC to perform IOL. The natural birth rate, time to labor onset and birth, and maternal and neonatal complications were compared between the two groups. A propensity score match (PSM) was used to eliminate the selection bias.

Results: A total of 516 cases were left after PSM (1:1) to Bishop score. The dinoprostone was associated with an improved Bishop score. However, there were no significant differences in the vaginal delivery rate, the stage of labor, and the time from ripening to labor onset and delivery between the two groups ($p > 0.05$). The incidence rates of puerperal infection and blood loss were notably higher in the DBC group than in the dinoprostone group ($p < 0.05$). However, there was no statistical difference in the incidence of postpartum hemorrhage between the two groups ($p > 0.05$).

Conclusions: Dinoprostone is associated with a lower puerperal infection rate and improved Bishop score in IOL without an increased success rate of vaginal delivery.

Keywords: cervical ripening; double-balloon catheters; dinoprostone; induction of labor; Bishop score

INTRODUCTION

To achieve the purpose of delivery, induction of labor (IOL) is used to start the labor process before spontaneous onset for late-term pregnancy with obstetrical indications such as expired pregnancy, pregnancy complications, oligohydramnios, and suspicious placental dysfunction. The success of IOL largely depends on the maturity of the cervix. Usually, oxytocin is preferred when the cervix matures. However, the success rate remains low when the cervix is immature, and it may harm the health of the mother and her fetus, especially for

nulliparous women [1]. Methods to promote cervical ripening (CR) include drugs (such as prostaglandin) and mechanical methods (such as water sac), which increase the release of exogenous or endogenous prostaglandins, respectively [2]. Dinoprostone, a kind of locally applied prostaglandin E2 preparation, can be slowly and continuously released, and it has been proven to be safe and effective in clinic [3]. The double-balloon catheter (DBC, Cook) is a kind of mechanical method that has been widely applied to promote CR, while it is relatively more expensive [4]. The efficacy and safety of those two types of methods have been proved already, and both of them have been used in clinical practice for many years. Many studies about the effects of these two methods have mainly focused on vaginal delivery within 24 h, and the results are sometimes controversial [5]. Additionally, the application of the new labor curve provides women with more opportunities for vaginal delivery, and the endpoint may change. Taken together, in this retrospective study, we chose vaginal delivery rate within 24 h and labor rate as the primary outcomes, and the time to labor onset and delivery and the maternal and neonatal complications were used as the secondary outcomes. Therefore, the purpose of this study was to compare the efficacy and safety of dinoprostone and DBC in promoting CR in IOL.

MATERIAL AND METHODS

Subjects

This retrospective study was approved by the Clinical Research Ethics Committee of the Affiliated Changzhou Second People's Hospital of Nanjing Medical University (approval number: [2022]KY101-01). All subjects signed informed written consent before receiving any of the schemes above. A total of 877 primipara women with Bishop score ≤ 6 who were delivered in the Affiliated Changzhou Second People's Hospital of Nanjing Medical University from March 2016 to October 2019 were included. Inclusion criteria: (1) nullipara; (2) singleton pregnancies; (3) live fetuses; (4) vertex presentation; (5) intact membranes; and (6) immature cervix with cervical Bishop score ≤ 6. Exclusion criteria: (1) multipara; (2) multiple gestations; (3) stillbirth; (4) malpresentation; (5) premature rupture of membranes;

(6) active vaginitis or untreated vagina; (7) rectum group B hemolytic streptococcus (GBS) positive; (8) ripening cervix with Bishop score > 6; and (9) any contraindications for vaginal delivery, such as placenta previa or severe complications of maternal and fetuses. They were divided into the dinoprostone group (n = 502) and DBC group (n = 375) according to the IOL way. The women in the dinoprostone group received dinoprostone to perform IOL, while those in the DBC group received DBC to perform IOL. Both CR methods were conducted by experienced obstetricians who were uniformly trained.

Dinoprostone for cervical ripening

The pharmacological procedure of dinoprostone (dinoprostone suppositories, 10 mg) was as follows. The pregnant woman stayed in a bladder lithotomy position, the vulva was disinfected, and dinoprostone was inserted into the posterior vaginal vault. She was asked to lie flat on the bed for 30 min to perform electronic fetal heart monitoring and observation of drug adverse reactions. She received an electronic fetal heart monitoring and Bishop evaluation every 4 h. The suppositories were removed if any of the following events occurred, including nausea, vomiting, hypotension, tachycardia, fever, other drug reactions, pathologic contraction, fetal distress, strong or excessive uterus contractions, rupture of membranes, or no reaction at 24 h after the medication [6].

Double-balloon catheter for cervical ripening

The pregnant woman stayed in a bladder lithotomy position. The vagina and cervix were disinfected routinely. A speculum was inserted to explore the cervical access, and the cervix was sterilized carefully again. The catheter was introduced into the cervical canal to make sure both of the two balloons reached the extra-amniotic space. The uterine balloon was inflated with 40 mL of saline, and then the device was pulled back until it reached the internal cervical os. The vaginal balloon was visible outside the external cervical os, and then it was inflated with 40 mL of saline to make sure the two balloons were situated on the two sides of the cervix. Subsequently, both balloons were injected with saline to a maximum volume of 80 mL. Next, the woman was asked to lie flat on the bed for 30 min to perform electronic fetal heart monitoring [6, 7]. The catheter was removed if spontaneous expulsion did not occur to

make sure the device was left in place for less than 12 h. An amniotomy was provided. A low dose of oxytocin infusion was given 1 h later if she did not have a labor onset.

Data collection

The following data were collected from the inpatient medical records, including age, height, weight, body mass index (BMI), Bishop score before and after CR, indications of IOL, intervals of labor onset, intervals of delivery, mode of delivery, the indication of cesarean section, occurrence and type of fetal heart rate deceleration, blood loss within 24 h after delivery, neonatal Apgar score, stage of labor, cervix laceration, puerperal infection, neonatal asphyxia, and other poor clinical outcomes.

Statistical analysis

Data was analyzed using Statistical Package for the Social Sciences (SPSS) version 26.0. Quantitative data was expressed as means ± standard deviation (SD), while qualitative data were expressed as numbers and percentages. Categorical variables between the two groups were compared by χ^2 or Fisher's exact tests when necessary. Quantitative variables between the two groups were compared by student's t-test. Univariate analysis of the variables between the two groups was performed using nonparametric tests, including Fisher's exact test, Mann–Whitney U test, or Kruskal–Wallis test, as needed. $p < 0.05$ was considered statistically significant. Time-to-labor onset and delivery were subjected to survival analysis. Since this was a retrospective study, univariate analysis was given first to the baseline characteristics of all the subjects. Then a propensity score match (PSM) was used to decrease the bias caused by those statistically differentiated characteristics that might affect our results. Finally, the newly generated PSM dataset was analyzed by the scheme mentioned above.

RESULTS

Comparison of the baseline characteristics between the two groups

There were 877 cases included in our study, and 516 cases were left after PSM according to the baseline characteristics. After PSM, there were 258 cases in the dinoprostone

group, with an average age of 26.60 ± 2.73 years old. There were 258 cases in the DBC group, with an average age of 26.37 ± 2.80 years old. There were no statistical differences in the height, weight, BMI, gestational weeks, and Bishop scores between the two groups ($p > 0.05$, Tab. 1). Moreover, as shown in Table 2, there were 59 and 27 cases with oligohydramnios in the DBC and dinoprostone groups ($p < 0.01$). However, the other IOL indications had no statistical differences between the two groups ($p > 0.05$, Table 2).

Comparison of the maternal and infant pregnancy outcomes between the two groups after PSM

The maternal and infant outcomes in the two groups are shown in Table 3. The Bishop score after CR was significantly higher, and blood loss in 24 h and puerperal infection were significantly lower in the dinoprostone group in comparison with the DBC group ($p < 0.05$). There were no statistical differences in the vaginal delivery rate, fetal heart rate deceleration, postpartum hemorrhage (PPH), placenta abruption, chorioamnionitis, birth weight, Apgar scores within 1 or 5 min, severe meconium contamination, or bloody amniotic fluid between the two groups ($p > 0.05$). The incidences of fetal distress, asphyxia neonatorum, precipitate labor, and cervical laceration were slightly higher in the dinoprostone group compared with the DBC group without statistical significance ($p > 0.05$, Table 3).

Comparison of the indication of cesarean section between the two groups

There were 12(14.63%) cases and 3(3.80%) cases with failure of induction in the dinoprostone and DBC groups, respectively ($p = 0.018$). Moreover, there were 12 (14.63%) cases and 24 (30.38%) cases with abnormal labor courses in the dinoprostone and DBC groups, respectively ($p = 0.017$). However, there were no differences in fetal distress, chorioamnionitis, placenta abruption, social factors, or other obstetric indications between the two groups ($p > 0.05$, Table 4).

Comparison of the median survival time between the two groups

The median survival time from CR to labor onset was 14 h (95%CI: 11.723, 16.277) and 16 h (95%CI: 15.704, 16.296) in the dinoprostone and DBC groups, respectively ($p = 0.055$). Moreover, the median survival time from CR to delivery was 18.250 h (95%CI:

16.264, 20.236) and 22.583 h (95%CI: 21.823, 23.343) in the dinoprostone and DBC groups, respectively (p = 0.283). As shown in Figure 1 and Figure 2, there were no marked differences in the median survival time from CR to labor onset and median survival time from CR to delivery between the two groups (p > 0.05).

DISCUSSION

Induction of labor is very common (about 1 in 3–5 pregnancies) in the Obstetrics Department and is suitable for pregnant women who have indications for termination of pregnancy but cannot initiate naturally [8–10]. The most common method for IOL is the use of low-dose oxytocin infusion, and its success is greatly related to cervical maturity. For women with immature cervices, the routine application of oxytocin remains unsatisfactory [11–13]. Many studies have tried to seek the optimal approach to get a better cervical maturity to increase the success of IOL in various pregnancy states, mainly focusing on mechanical and pharmaceutical methods [1, 4–6,12,14–24]. However, the conclusions remain controversial. In this study, we compared the efficacy and safety of dinoprostone and DBC in promoting CR in IOL with a PSM to control confounding factors of baseline characteristics.

In our present study, there were respectively 258 cases in the dinoprostone and DBC groups after eliminating the confounding factors of baseline characteristics by PSM. The use of dinoprostone was highly associated with better Bishop scores after IOL than DBC, and this finding was consistent with previous studies [21, 25]. However, the vaginal delivery rates were similar in the two groups within 24 h or longer. This finding was not consistent with a previous report about the vaginal delivery rate in 24 h [15] but agreed with some other previous studies [19, 26]. Moreover, for the total vaginal delivery rate without a time limit, our results supported most of the previous studies [6, 15, 17, 18, 27]. Therefore, the degree of improvement in Bishop score might not contribute as much to the delivery mode as we thought.

In our study, DBC seemed to be associated with more blood loss within 24 h after IOL, and this was inconsistent with Brown’s research [20]. However, Brown et al. compared

the blood loss at delivery, and we compared the blood loss within 24 h. More importantly, we found that the incidence of PPH was similar between the two groups, which was likely caused by the use of a cervical balloon, making the lower segment of the uterus dilated for a longer time, thereby prolonging the time for its return to normal contraction. Moreover, this influence might not be serious enough to induce a PPH. In addition, our results suggested that the incidence of PPH had no statistical difference between the two groups, which was consistent with some previous studies [1, 6, 14, 15, 17, 27].

Our findings indicated that the poor outcomes between puerperia and infants were similar, except that the use of DBC was associated with a significantly higher incidence of puerperal infection. This finding was understandable because the device was placed over the cervix os, which might increase the risk of infection. Besides, this conclusion was similar to only a few reports [28]. Bleicher et al. [29] suggested that the use of the mechanical device for no more than 6 h could reduce the incidence of infection without decreasing the success of IOL. In addition, it was important to note that although there were no significant differences in other poor maternal and infant outcomes between the two groups, we still mentioned that the incidences of fetal distress, precipitate labor, cervical laceration, and asphyxia neonatorum in the dinoprostone group were slightly higher compared with the DBG group. Therefore, more careful observation and early intervention might be beneficial to prevent poor maternal and infant outcomes when using dinoprostone.

Our study also compared the time from initiating the CR to labor onset or delivery, which demonstrated that the use of DBC was associated with a longer time in the two indexes above, while the difference was not statistically significant. Moreover, survival analysis also provided evidence that there was no statistical difference between the two groups from initiating the CR to labor onset or delivery. Furthermore, there was no significant difference in the labor stages. This finding was in agreement with a previous study [17] but was not consistent with another study [25]. We think that the differences might be caused by the procedure in our center with an active intervention after the removal of the medicine or DBC.

Our study also has several limitations. First, it is a retrospective study. Although we took PSM to reduce the bias, it was still not better than a random clinical trial. Second,

further studies are needed to explore why there are different degrees of improvement in cervical maturity after removing the device or dinoprostone with a similar vaginal delivery rate in 24 h.

CONCLUSIONS

In conclusion, dinoprostone could improve the Bishop score better with similar efficacy and safety compared with DBC. However, the use of DBC might increase the incidence of puerperal infection. Collectively, we would better pay more attention to observing the labor progress, uterine contraction, and fetal heart rate changes to reduce the incidence of fetal distress, precipitate delivery, cervical laceration, and asphyxia neonatorum when adopting dinoprostone.

Article information and declarations

Data availability statement

The simulation experiment data used to support the findings of this study are available from the corresponding author upon request.

Ethics statement

This study was approved by the Clinical Research Ethics Committee of The Affiliated Changzhou Second People's Hospital of Nanjing Medical University (approval number: [2022]KY101-01).

Author contributions

Chun Yang carried out study concepts & design, and manuscript editing; Liulan Qian and Qiucheng Jia contributed to clinical studies, data acquisition; Chun Yang, Liulan Qian and Qiucheng Jia helped to data & statistical analysis and manuscript preparation; Hao Mao were the guarantor of integrity of the entire study, helped to literature research and manuscript review.

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None.

Conflict of interest

The authors declared that they have no potential conflicts of interest.

Supplementary material

None.

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Table 1. Comparison of baseline characteristics between the two groups before and after PSM

Characteristics	Before PSM			After PSM		
	Dinoprostone (n = 502)	**DBC (n = 375)**	**p value**	**Dinoprostone (n = 258)**	**DBC (n = 258)**	**p value**
Age [years]	26.59 ± 2.75	26.42 ± 2.82	0.3945	26.60 ± 2.73	26.37 ± 2.80	0.3476
Height [cm]	162.12 ± 4.78	161.85 ± 5.11	0.4274	162.00 ± 4.91	161.59 ± 5.11	0.3475
Weight [kg]	73.45 ± 9.68	72.97 ± 10.79	0.4920	73.27 ± 10.16	73.12 ± 10.58	0.8699
BMI	27.91 ± 3.16	27.84 ± 3.76	0.7510	27.87 ± 3.25	27.98 ± 3.66	0.7064
Gestational weeks	40.22 ± 0.88	40.09 ± 0.81	0.0247	40.12 ± 0.93	40.10 ± 0.83	0.7512
Bishop scores	2.60 ± 1.06	3.59 ± 1.20	<0.001	3.11 ± 1.06	3.11 ± 1.06	1.0000

DBC — double balloon catheter; PSM — propensity score matching

Table 2. Indication of IOL before and after PSM

Characteristics	Before PSM			After PSM		
	Dinoprostone (n = 502)	**DBC (n = 375)**	**p value**	**Dinoprostone (n = 258)**	**DBC (n = 258)**	**p value**
Delayed pregnancy	262 (52.19%)	151 (40.27%)	0.0005	122 (47.29%)	105 (40.70%)	0.1316
Hypertension	62 (12.35%)	60 (16.00%)	0.1223	48 (18.60%)	41 (15.89%)	0.4147
PGDM/GDM	97 (19.32%)	82 (21.87%)	0.3551	52 (20.16%)	56 (21.71%)	0.6651
Oligohydramnion**	60 (11.95%)	84 (22.40%)	< 0.001	27 (10.47%)	59 (22.87%)	0.0002
ICP	4 (0.80%)	2 (0.53%)	0.9567	3 (1.16%)	1 (0.39%)	0.6157
ITP	7 (1.39%)	5 (1.33%)	0.9386	3 (1.16%)	3 (1.16%)	1.0000
Leep history	1 (0.20%)	3 (0.80%)	0.4238	1 (0.39%)	3 (1.16%)	0.6157
Placental dysfunction	3 (0.60%)	9 (2.40%)	0.0230	3 (1.16%)	5 (1.94%)	0.7216
Macrosomia	5 (1%)	6 (1.60%)	0.6252	3 (1.16%)	4 (1.55%)	1.0000
Other complication of pregnant	29 (5.78%)	18 (4.80%)	0.5251	12 (4.65%)	10 (3.88%)	0.6630

*p < 0.05; **p < 0.01; DBC — double balloon catheter; GDM — gestational diabetes mellitus; ICP — intrahepatic cholestasis of pregnancy; IOL — induction of labor; ITP — immune thrombocytopenia; PGDM — previous gestational diabetes mellitus; PSM — propensity score matching

Table 3. The maternal and infant pregnancy outcomes after PSM

Maternal and neonatal outcomes	Dinoprostone (n = 258)		DBC (n = 258)	p value
Remove time [h]	11.15 ± 6.69		11.33 ± 2.09	0.6775
Post-ripening Bishop score**	6.19 ± 1.75		5.27 ± 1.64	< 0.001
Late deceleration	0 (0.00%)		2 (0.78%)	0.4786
Variation deceleration	75 (29.07%)		76 (29.46%)	0.9229
Early deceleration	4 (1.55%)		6 (2.33%)	0.5230
Vaginal delivery within 24 h	117 (45.35%)		105 (40.70%)	0.286
Vaginal delivery without a time limit	176 (68.22%)		179 (69.38%)	0.7756
Spontaneous labor	174 (67.44%)		167 (64.73%)	0.5151
Cesarean delivery	82 (31.78%)		79 (30.62%)	0.7756
Assisted delivery**	2 (0.78%)		12 (4.65%)	0.0067
Blood-loss in24 hours(mL)*	296.74 ± 142.46		328.50 ± 190.75	0.0326
Postpartum hemorrhage	24 (9.30%)		26 (10.08%)	0.7660
Placenta abruption	2 (0.78%)		2 (0.78%)	1.0000
Chorioamnionitis	2 (0.78%)		4 (1.55%)	0.6813
Fetal distress	31 (12.02%)		18 (6.98%)	0.0509
precipitate labor	16 (6.20%)		9 (3.49%)	0.1512
Cervical laceration	17 (6.59%)		10 (3.88%)	0.1664
Puerperal infection*	1 (0.39%)		8 (3.10%)	0.0436
Severe meconium contamination or bloody amniotic fluid	75 (29.07%)		75 (29.07%)	1.0000
time to onset of labor [h]	15.38 ± 17.11	30 (8.74)	17.30 ± 8.74	0.1199
time to vaginal delivery [h]	22.05 ± 18.57	98 (7.52)	23.98 ± 7.52	0.1994
Total stage of labor [h]	7.32 ± 3.93		7.95 ± 4.03	0.1333
First stage of labor [h]	6.18 ± 3.60		6.71 ± 3.74	0.1734
Second stage of labor [h]	0.98 ± 0.74		1.08 ± 0.72	0.1704
Third stage of labor [h]	0.16 ± 0.12		0.16 ± 0.11	0.6523
Birth weight [g]	3435.66 ± 399.69		3451.55 ± 395.60	0.6501
Apgar in 1 min	8.90 ± 0.48		8.90 ± 0.41	0.4232
Apgar in 5 min	9.91 ± 0.36		9.92 ± 0.31	0.5084
Asphyxia neonatorum	8 (3.10%)		3 (1.16%)	0.1275

*p < 0.05; **p < 0.01; DBC — double balloon catheter

Table 4. Comparison of the indication of cesarean section between the two groups

Indication of cesarean	Dinoprostone (n = 82)	DBC (n = 79)	p value
Failure of induction*	12 (14.63%)	3 (3.80%)	0.018
Abnormal labor course*	12 (14.63%)	24 (30.38%)	0.017
Fetal distress	37 (45.12%)	31 (39.24%)	0.450
Chorioamnionitis	1 (1.22%)	5 (6.33%)	0.087
Placenta abruption	0 (0%)	2 (2.53%)	0.147
Social factor	9 (10.98%)	7 (8.86%)	0.654
Other obstetric indication	11 (13.41%)	7 (8.86%)	0.359

*p < 0.05; **p < 0.01; DBC — double balloon catheter

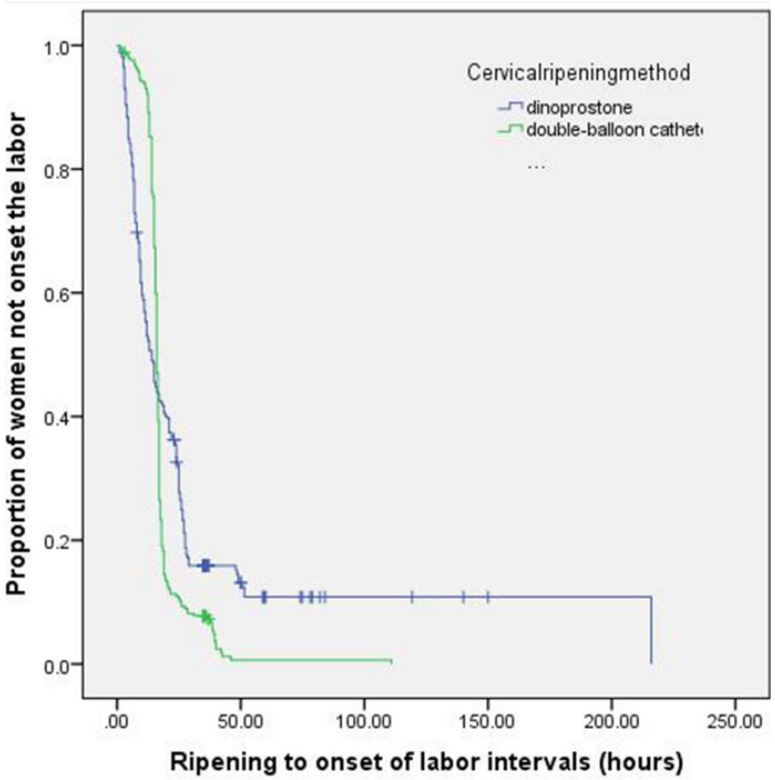

Figure 1. Survival curves analysis for intervals to the onset of labor; Kaplan–Meier survival curves illustrate a fraction of women who have labor onset at a given time after initiation of cervical ripening; the blue line refers to dinoprostone vaginal insert, and the green line refers to the double-balloon catheter

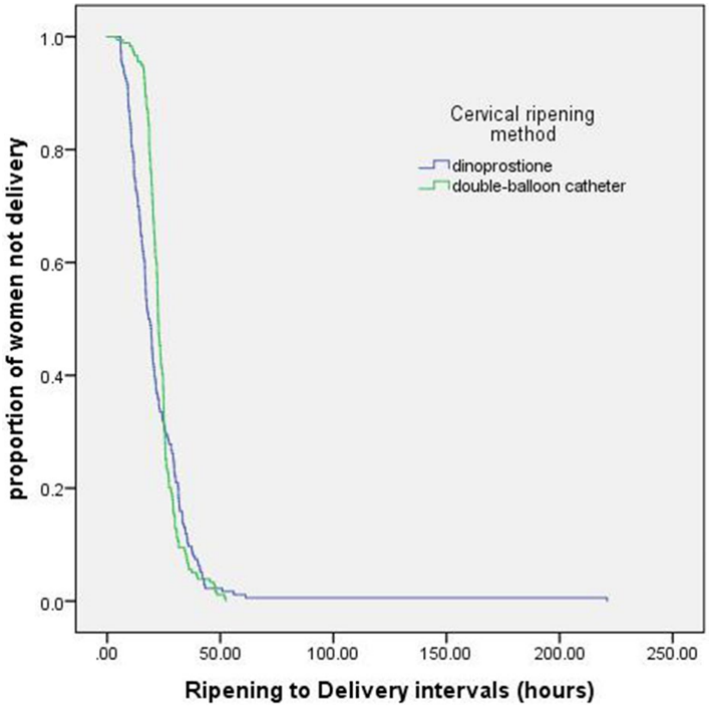

Figure 2. Survival curves analysis for intervals to delivery; Kaplan–Meier survival curves illustrate a fraction of women who gave vaginal delivery at a given time after initiation of cervical ripening; the blue line refers to dinoprostone vaginal insert, and the green line refers to the double-balloon catheter