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Double-balloon catheter for induction of labor in 362 women with and without prior cesarean section

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ABSTRACT

Objective: Balloon catheter is the preferred method for induction of labor in women with prior cesarean section. We sought to evaluate the rate of vaginal delivery, induction-delivery time and outcome predictors after induction with double-balloon catheter.

Study design: We conducted a retrospective cohort study including women with prior cesarean section undergoing induction of labor with a double-balloon catheter during the period January 2007–June 2014 at a large, tertiary Danish university hospital. For comparison, we included women with no prior cesarean section undergoing induction with double-balloon catheter after failed medical induction. Inclusion criteria were singleton pregnancy, an unfavorable cervix, intact membranes, cephalic presentation and either previous cesarean section or failed medical induction of labor. Exclusion criteria included contraindications for vaginal delivery, severe fetal malformation and stillbirth. Study subjects were identified in a local computerized system and data extracted from the medical records.

Results: Women with prior cesarean section ($n = 304$) induced with double-balloon catheter had a vaginal delivery rate of 50.3% (95% CI 44.7–55.9) compared to 51.7% (95% CI 39.2–64.1) in women with no prior cesarean section but preceding failed medical induction of labor ($n = 58$) ($p = 0.85$). BMI≥30 was associated with increased frequency of cesarean section. Median time from induction to vaginal delivery was 27.1(20.4–31.1) hours and 28.4(25.5–36.1) hours, respectively ($p = 0.05$). The rate of complete uterine rupture was 1.0%.

Conclusions: Similar success rates of approximately 50% for vaginal delivery were observed after induction of labor with a double-balloon catheter in women with and without prior caesarean section. A BMI ≥ 30 was associated with an increased frequency of caesarean section.

Introduction

Induction of labor (IOL) with a balloon catheter is the preferred method for IOL in women with prior cesarean section (CS) [1,2]. Balloon catheter inductions may, however, also be a method of choice in women without a previous CS. It may be used as a first line method, but also as the second line method when medical induction has failed. At present the literature has mainly focused on inductions in previous CSs.

In a systematic review, Kehl et al reported a vaginal delivery rate of 56.4% in 1447 women undergoing induction of labor with balloon catheter after prior CS [3]. A recent study even reported a slightly lower success rate of 51.4% after double-balloon catheter IOL [4]. However, previous studies have mainly focused on the use of Foley catheter whereas studies evaluating the efficacy of the double-balloon catheter for IOL in women with previous CS are sparse and limited by size. The number of CS's and the number of women who attempt trial of labor after cesarean (TOLAC) has increased over the last decades. Accordingly, the proportion of women with a previous CS undergoing IOL is expected to rise parallel. Many of these inductions will candidate for mechanical cervical ripening with double-balloon catheter. Knowledge on the efficacy and safety of the balloon catheter in this group of women is valuable. We therefore aimed to investigate the outcome of mechanical cervical ripening with a double-balloon catheter in women with a previous CS as evaluated by the rate of vaginal delivery, induction-delivery time and complication rate. Second, we sought to identify possible outcome predictors. Due to the frequent alternative use of balloon catheter as second choice method for IOL, we included women with no prior CS who

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underwent induction with double-balloon catheter due to failed medical induction. Despite differences, these two groups share some common properties, first and foremost the unripe cervix. From a clinician's point of view, these two groups represent the women scheduled for balloon catheter placement. Hence, our main outcomes were the time course and the success rates of balloon catheter induction in women with unfavorable cervix.

Material and methods

The study was conducted at department of Obstetrics and Gynecology, Aarhus University Hospital, Denmark, and was based on prospectively recorded data within the period January 2007–June 2014. Every year approximately 4600 births take place at Aarhus University Hospital, serving as both a district hospital with an admission area of 315 000 inhabitants and a tertiary referral hospital in the Central Denmark Region comprising 1 270 000 inhabitants.

In Denmark, all patients are assigned diagnosis and procedure codes at hospital admission. We used a local computerized system to identify all women registered with a procedure code of IOL with a double-balloon catheter ("KMCA96A") within the period. The procedure code was validated by review of medical records. Singleton pregnant women were eligible for inclusion if they had an unfavorable cervix, intact membranes, cephalic presentation and either previous CS or failed medical IOL. Exclusion criteria included contraindications for vaginal delivery, severe fetal malformation and stillbirth.

According to local guidelines, the double-balloon catheter was used for IOL in women with a previous CS and also in women with no previous CS who attempted a trial of labor after failed induction with the prostaglandin E_1-analogue misoprostol. Medical induction was performed with Misoprostol given vaginally or orally (either 50 μg. every 4 h or 25 μg. every 2 h, maximum dose 200 μg. per 24 h; pause at night) for 48 h. If amniotomy was still not possible, the woman was offered a balloon catheter as a second line IOL procedure. The double-balloon catheter was inserted with a cervico-vaginal balloon placed at the external cervical os and a uterine balloon at the internal cervical os and both balloons were infused with up to 80 mL sterile saline. The catheter was usually placed in the afternoon between 1 and 3 p.m. Unless spontaneously disengaged, the balloon catheter was removed after

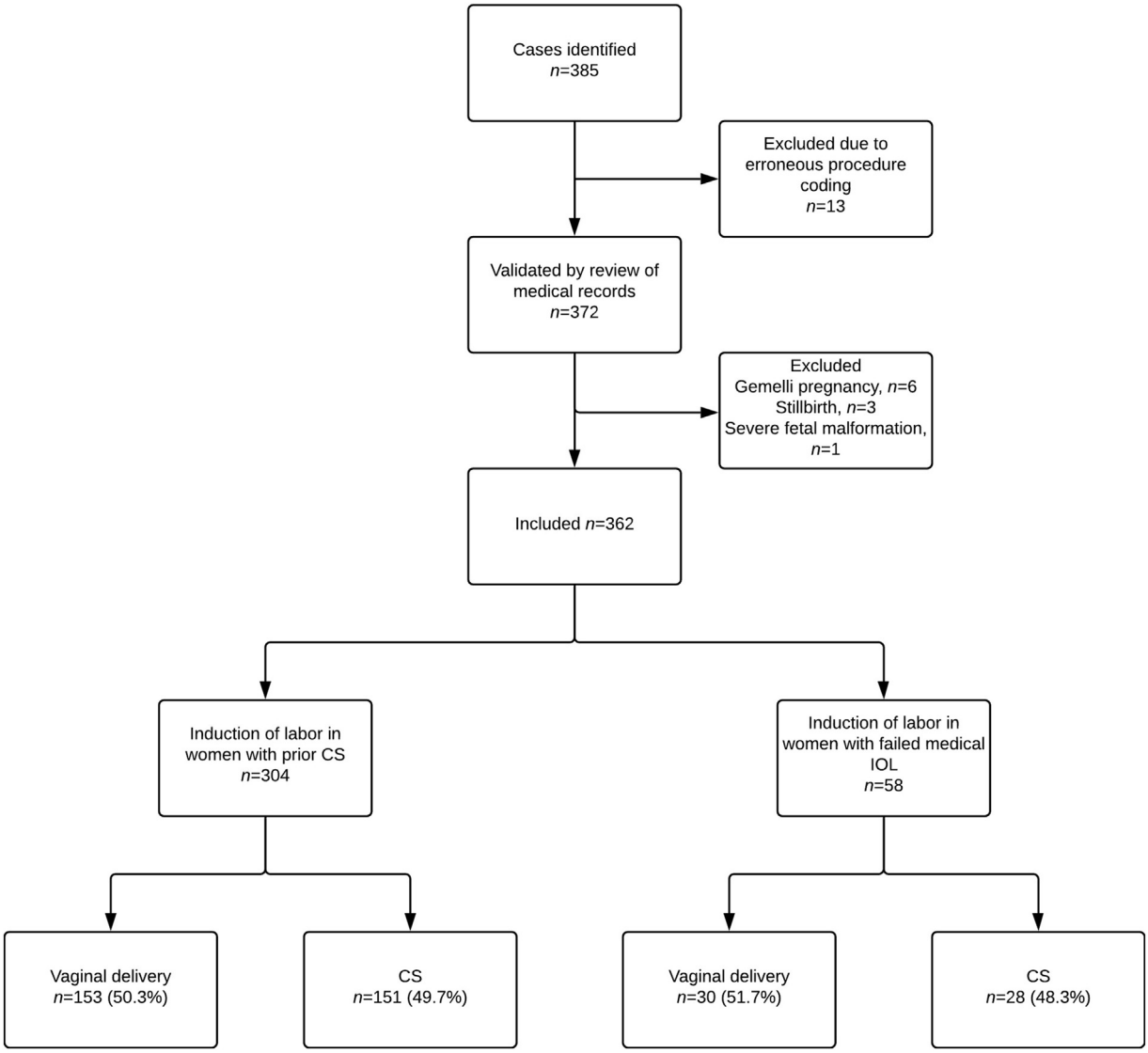

Fig. 1. Flowchart of inclusion process. Women eligible for inclusion and mode of delivery after induction with double-balloon catheter. CS, cesarean section; IOL, induction of labor.

approximately 18 h and the induction procedure continued by amniotomy if possible. The induction regime was supplemented by intravenous oxytocin when necessary.

Data on the following obstetric variables were obtained from the medical records: maternal age, maternal pre-pregnancy body mass index (BMI), parity, previous CS including underlying indication, indication for induction in the present delivery (index delivery), time for application of double-balloon catheter, amniotomy, oxytocin augmentation, time of delivery, mode of delivery, indication for CS at index delivery and fetal birthweight. The Bishop score is not routinely ascribed in inductions at our hospital and was accordingly not available from patients' records. Instead, journal records held information on descriptions of the cervix, e.g. as firm, long, orifice closed, posterior localization, and so forth. For clinical purposes, balloon inductions were performed in unfavorable cervices, usually corresponding to a Bishop score of 5 or less. Maternal complication data included development of uterine rupture. Finally, we obtained data on neonatal morbidity evaluated by Apgar score at one and five minutes. The main outcomes measurements were the vaginal delivery rate, time interval from application of the double-balloon catheter to delivery (induction time) and rate of uterine rupture. Secondary outcomes included the rate of acute CS and neonatal morbidity evaluated by Apgar score.

Normally distributed continuous data are presented as mean, standard deviation (SD) whereas non-normally distributed data are presented as median, interquartile range (IQR). For proportions 95% exact Mid-P confidence intervals are calculated. To test for differences between groups we used Student's *t*-test for normally distributed continuous data and Wilcoxon rank-sum test for non-parametric data whereas Pearson's $\chi 2$-test was used for binary data. We conducted multiple logistic regression analyses to identify associations between frequency of CS and obstetrics variables as well as potential confounders. *p*-values <0.05 were regarded as significant. Data was processed using STATA 13 and IBM SPSS Statistics 22.

The study was approved by the Danish Data Protection Agency (j.no 1-16-02-486-13) and the Danish National Board of Health (j. no. 3-3013-441/1).

Results

In total, 362 women were eligible for inclusion (Fig. 1). In 304 women double-balloon catheter was used due to prior CS, whereas in 58 women with no prior CS the method was used according to local guidelines after failure of a preceding medical IOL with prostaglandins. Data on maternal characteristics are presented in Table 1. The use of additional methods for cervical ripening and labor augmentation were comparable between the two groups as regards to amniotomy (88.6% vs. 86.5%, $p = 0.67$) whereas oxytocin was more frequently used in the group with frustrate medical IOL (71.8% vs. 87.0%, $p = 0.02$). The vaginal delivery rate was 50.3% (95% CI 44.7–55.9) among women with prior CS and 51.7% (95% CI 39.2–64.1) among women with failed medical IOL (NS, $p = 0.85$) (Table 1). Median time from application of the balloon catheter to delivery regardless of delivery mode was similar between the two groups with 28.0 (21.5–32.5) hours in women with prior CS and 27.9 (24.6–36.0) hours in women with failed medical IOL (NS), see Fig. 2. The corresponding induction time when only vaginal delivery was evaluated was 27.1 (20.4–31.1) and 28.4 (25.5–36.1) hours, respectively ($p = 0.05$). In the group with prior CS, 48 (15.8%) women achieved vaginal delivery within 24 h of balloon catheter application compared to 5 (8.6%) in the group with failed medical IOL (NS, $p = 0.16$). In 24 cases (6.6%) CS was performed after IOL with balloon catheter due to suspected uterine rupture. A total of three complete uterine ruptures were reported (1.0%) in addition to three partial ruptures/dehiscence (1.0%). All women with uterine rupture had a prior CS. Neonatal outcome is presented in Table 1. Multiple logistic regression analyses including all women showed that maternal BMI ≥ 30 was associated with increased frequency of CS (Table 2). Further, increasing parity was associated with decreased frequency of CS (Table 2). For indications for IOL and indications for prior CS see Tables 3 and 4 .

Table 1
Obstetric characteristics after induction with double-balloon catheter.

Characteristic	Prior CS (n = 304)	Failed medical IOL (n = 58)	*p*
Maternal age, years[a]	32.9 ± 4.5	32.3 ± 5.9	0.45
Pregestational BMI, kg/m^2[b]	24.5 [22.1-29.2]	25.8 [23.4-32.5]	**0.03**
BMI ≥ 30, *n*, (%)	73 (24)	19 (32.8)	0.16
Parity[a]	1.3 ± 0.8	0.4 ± 1.0	**<0.001**
Prior vaginal delivery, yes, (%)	66 (21.7)	11 (19.0)	0.64
Gestational age, days[a]	279.2 ± 11.0	279.0 ± 12.3	0.91
Birthweight, g[a]	3572 ± 541	3465 ± 722	0.36
Apgar ≤7 (1 min), (%)	13 (4.3)	2 (3.5)	0.90
Apgar ≤7 (5 min), (%)	7 (2.3)	0	0.28
Perinatal deaths	0	0	0
Mode of delivery, overall			
Vaginal, (%)	153 (50.3)	30 (51.7)	0.85
Instrumental, (%)	26 (8.6)	4 (6.9)	0.68
Cesarean section, (%)	151 (49.7)	28 (48.3)	0.85
Acute, within 15 minutes, (%)	16 (5.3)	1 (1.7)	0.24
Acute, within 30 minutes, (%)	58 (19.1)	8 (13.8)	0.34
Prior vaginal delivery	n = 66	n = 11	
Vaginal delivery, (%)	42 (63.6)	9 (81.8)	0.24
Cesarean section, (%)	24 (36.4)	2 (18.2)	
No prior vaginal delivery	n = 238	n = 47	
Vaginal delivery, (%)	111 (46.6)	21 (44.7)	0.81
Cesarean section, (%)	127 (53.4)	26 (55.3)	

CS, cesarean section; *IOL*, induction of labor.
[a] Mean ± Standard deviation, (SD).
[b] Median [Interquartile range, IQR].

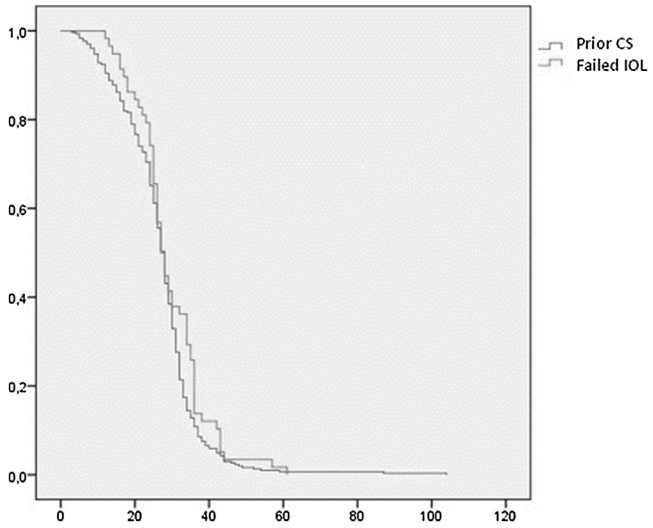

Fig. 2. Time to delivery. Kaplan-Meier curve of time to delivery after induction of labor using a double-balloon catheter given in hours. CS, cesarean section; IOL, induction of labor.

Comment

Our main findings include a vaginal delivery rate of 50.3% in women with prior CS after IOL with a double-balloon catheter. A similar rate was observed in women with no prior CS who underwent IOL with a double-balloon catheter after an unsuccessful attempt of induction with misoprostol.

Table 2
Multiple logistic regression analyses reporting odds ratio of cesarean section.

		95% C.I.	
Variable	Odds Ratio	Lower	Upper
Failed medical IOL	1		
Prior CS	0.25	0.04	1.48
Week of gestation			
<37	2.86	0.50	16.34
37	1.63	0.59	4.50
38	1.91	0.88	4.15
39	2.65	1.13	6.25
40	1		
41	1.92	0.86	4.31
42	2.32	0.95	5.65
Birthweight, g			
<3000	0.80	0.36	1.81
3000- <3500	0.72	0.38	1.34
3500-<4000	1		
4000-<4500	1.22	0.61	2.42
4500-5130	1.80	0.46	7.10
Parity			
0	1		
1	0.30	0.04	2.02
≥2	0.09	0.01	0.63
Maternal age, years			
19-25	2.04	0.64	6.51
25-30	1		
30-35	1.09	0.56	2.10
35-40	1.36	0.67	2.74
>40	1.37	0.45	4.18
BMI, kg/m^2			
<18.5	0.37	0.04	3.60
18.5- <25	1		
25- <30	1.62	0.88	2.99
30- <35	2.68	1.17	6.14
35- 54	3.08	1.28	7.43

95% C.I., 95% confidence interval; *IOL*, induction of labor; *CS*, cesarean section.

Our findings of a 50.3% vaginal delivery rate in women with prior CS are in excellent accordance with the largest study to date, reporting a 51.4% vaginal delivery rate in 418 women induced with double-balloon catheter [4]. Further, Kehl et al reported a vaginal delivery rate of 56.4% based on a meta-analysis including 16 studies comprising 1447 women who underwent induction of labor with single- ($n = 1290$) or double-balloon ($n = 157$) catheter after prior CS [3]. However, the studies included in this meta-analysis are each characterized by limited samples sizes and a high degree of heterogeneity as regards to type of balloon catheter, filling volume, exposure time and use of supplementary labor augmentations methods. This may explain the varying findings of a vaginal delivery rate from 23.1 to 75.0% [3]. It should also be taken into account that some prostaglandins, e.g. Dinoprostone, are sometimes used as an IOL strategy in previous CS patients and our results are not applicable to such approaches. Finally, women with a previous CS have given birth before, and we noted that increasing parity equal to previous CS and/or previous vaginal delivery was associated with decreased frequency of CS after balloon catheter IOL.

We report a similar vaginal delivery rate of 51.7% in women undergoing induction with double-balloon catheter after failed medical IOL with orally administered misoprostol. This is in accordance with Mizrachi et al who reported a vaginal delivery rate of 49.0% in 49 women who underwent induction with balloon catheter after failed medical induction with prostaglandin E2 [5]. In 2012, a Cochrane Review reported a CS rate of 27% (404/1505) in unselected women after induction with balloon catheter [1]. When interpreting our findings of a substantially higher CS rate after failed medical IOL it must be considered that these women have proven unresponsive to medical IOL and therefore constitute a selected group with unfavorable cervical conditions and potentially low response to induction techniques. For this reason, our results cannot be extrapolated to all women with no prior CS. Instead, our results reflect a real life clinical setting where balloon catheter often may be a second choice for IOL in women with no prior CS. Interestingly, our success rates in both women with and without previous CS correspond very closely to the findings by Torralba et al [4]. Taken together, it therefore appears that the success rate of IOL using a double balloon catheter is approximately 50%, independent of the presence of a previous uterine scar or not.

We found a positive association between increasing BMI and frequency of CS. In comparison no association between maternal weight gain during pregnancy and mode of delivery has been reported, though maternal BMI was not included in that study [4]. Our results are in accordance with previous findings of a positive association between BMI and risk of CS after IOL [6–11]. Suggestions have been made that this effect is due to reduced sensitivity to prostaglandins and oxytocin in obese women, however studies regarding this topic are lacking. Furthermore, many induction regimes do not discriminate between normal weight, overweight and obese women why similar doses of prostaglandins are used in women of highly different weight. In continuation of this it is noteworthy, that the group of women with no prior CS had a prevalence of BMI ≥ 30 of 32.8% which may have been contributing to the high rate of CS.

Our study is one of the largest studies on labor induction with balloon catheter after prior CS. The present study is strengthened by extensive data on co-variables, including BMI, and all data was

Table 3
Indications for induction of labor in 362 women scheduled for balloon catheter induction of labor.

Indication	Prior CS group n = 304 (%)	Failed medical IOL group n = 58 (%)
Prolonged pregnancy	72 (23.7)	14 (24.1)
Gestational Hypertension/preeclampsia	51 (16.8)	9 (15.5)
Diabetes mellitus	37 (12.2)	8 (13.8)
Macrosomia	31 (10.2)	4 (6.9)
Placental insufficiency	23 (7.6)	6 (10.3)
Maternal request	13 (4.3)	0
Obstetric cholestasis	12 (4.0)	3 (5.2)
Molimina	8 (2.6)	8 (13.7)
Previous pregnancy/birth complications	8 (2.6)	0
Pelvic dysfunction	6 (2.0)	0
Reduced fetal movements	5 (1.6)	0
Polyhydramnios	2 (0.7)	1 (1.7)
Other	23 (7.6)	3 (5.2)
Unknown	13 (4.3)	2 (3.5)

IOL, induction of labor; *CS*, cesarean section.

Table 4
Indications for performing cesarean section in previous pregnancy in 304 women scheduled for balloon catheter induction of labor.

Indication	n = 304 (%)
Arrested labor	88 (29.0)
Non-reassuring fetal status	60 (19.7)
Breech or transverse presentation	56 (18.5)
Preeclampsia/HELLP	25 (8.2)
Other	23 (7.6)
Twin pregnancy	12 (4.0)
Placental abruption	9 (2.9)
Placental insufficiency	8 (2.6)
Other malpresentations	6 (2.0)
Placenta praevia	5 (1.6)
PROM/PPROM	5 (1.6)
Macrosomia	4 (1.3)
Maternal request	3 (1.0)
Umbilical cord prolapse	1 (0.3)

validated by review of medical records. However, certain limitations must be considered. First, the study is limited by the observational design as compared to a prospective design. Furthermore, the lack of a control group subjected to other IOL procedures makes us unable to draw any conclusions regarding the efficacy of double-balloon catheter as induction method compared to other methods. Conversely, as balloon inductions are the only available method for induction of labor in previous CS when the cervix is unfavorable, the most pertinent group for comparison might be balloon inductions in women with no prior CS. In this group, medical induction has proven unsuccessful and when amniotomy is precluded, a balloon induction takes places. As also noted here, some differences between the groups exist. The group with precious CS has given birth before, why the parity is higher in this group. The second group has proven unresponsive to medical induction. Nevertheless, the two groups are comparable in their unfavorable cervix and their method of induction. As such, these two groups represent groups of women who are met frequently in daily-day practice and who are treated very similarly during the course of induction. In our setting, Bishop's scores are not noticed for women scheduled for IOL; instead, clinical practice is to evaluate the cervix and the possibilities for performing amniotomy.

We report a rate of complete uterine rupture of 1.0% in women with prior CS. This is in accordance Torralba et al who reported a rupture rate of 1.2% in 418 women induced with double-balloon catheter after prior CS [4]. Also, Kehl et al reported an overall rupture rate of 1.2% (18/1447) in 16 studies on induction with single- or double-balloon catheter after CS [3]. The size of our study does not allow us to assess the risk of an infrequent incident as a rupture of the uterus accurately, however Kehl et al in their systematic review reported an uterine rupture rate of 0.7% (45/6364) in women with spontaneous onset of labor. However, nine of 18 ruptures were reported in one study with 138 balloon induced women, and when excluded from the meta-analysis, the risk for uterine rupture was no longer statistically significantly increased [3]. We report no perinatal deaths and a low rate of reduced Apgar scores in the neonates (Table 1). Our findings support the general view that balloon catheter, though associated with a slightly increased risk of uterine rupture compared to spontaneous onset of labor, is a safe method for IOL after cesarean delivery. No ruptures were seen among patients without previous CS, however, we report from only a modest number of pregnancies without previous CS.

Overall 8 women (2.2%) had CS after induction with balloon catheter due to breech, transverse or other fetal mal-presentation though cephalic presentation was confirmed by the treating physician previous to application of the double-balloon catheter. Fetal rotation has previously been suggested as a possible complication to cervical ripening with balloon catheter [12]. The ability of a fetus to change position during IOL probably indicates that women induced with balloon catheters have fetuses at high stations when IOL commences.

In conclusion, we describe a vaginal delivery rate of 50.3% in women with prior CS after IOL with double-balloon catheter. A similar vaginal delivery rate was found in women with no prior CS undergoing induction with balloon catheter after failed medical IOL. BMI $\geq$ 30 was associated with an increased OR of CS whereas increasing parity was associated with decreased OR of CS. The moderate vaginal delivery success rate reported reflects the use of balloon catheter in women with an unfavorable cervix and is in our opinion legitimized by the alternative being an elective CS. However, we advocate that these success rates for vaginal delivery should be discussed with the pregnant woman scheduled for IOL to plan the most optimal delivery strategy.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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