

ORIGINAL ARTICLE

Induction of labor by Foley catheter compared with spontaneous onset of labor after previous cesarean section: a cohort study

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OBJECTIVE: To evaluate the safety of induction of labor (IOL) with Foley catheter (FC) in women with a history of previous cesarean section (CS) and to assess risk factors for repeat CS and adverse maternal outcomes.

STUDY DESIGN: Cohort study of 1559 women with a history of previous CS in Helsinki University Hospital, Finland between 2013 and 2014.

RESULTS: Three hundred and sixty-one women (23.2%) underwent IOL by FC and 1198 (76.8%) had spontaneous onset of labor. The rate of repeat CS was higher in women undergoing IOL (38% vs 20.2%; $P < 0.001$). The overall rate of uterine rupture was 0.3% in induced labor and 0.8% in spontaneous onset of labor ($P = 0.47$). Adverse maternal outcomes were not significantly different. The intrapartum and postpartum infection rates were higher in women undergoing IOL compared with spontaneous onset of labor (6.1% vs 1.8%; $P > 0.001$ and 5.3% vs 1.3%; $P < 0.001$, respectively).

CONCLUSION: FC appears safe and effective method for IOL in women with a history of previous CS.

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INTRODUCTION

The rates of cesarean section (CS) are rising, currently varying between 15% in northern Europe, 32% in the United States and 48% in Brazil.^{1–4} CS is associated with an increased risk for maternal complications in subsequent pregnancy, including morbidly adherent placenta, placenta previa, postpartum hemorrhage, myometrial dehiscence and uterine rupture.^{5,6} Uterine rupture, leading to serious maternal and neonatal morbidity and mortality, complicates approximately 1% of attempted vaginal deliveries in women with a history of previous CS.⁷

Induction of labor (IOL) is a common obstetric procedure with an increasing incidence of 20% to 30% in the developed countries.¹ An increasing number of women undergoing IOL have a history of previous CS. IOL after previous CS is considered a risk factor for uterine dehiscence, uterine rupture and repeat CS compared with women with spontaneous onset of labor.⁸ However, conflicting evidence has been presented.^{9–12} Moreover, the risk of uterine rupture may depend on the method of IOL. Use of prostaglandins in a scarred uterus has previously been shown to increase the risk for adverse maternal and neonatal outcomes.^{13,14} Mechanical methods, including the Foley catheter (FC), are associated with lower risk of hyperstimulation and uterine rupture.^{10,15–17} However, as also highlighted by the recently published review on balloon catheter induction,¹⁸ the data on use of FC for IOL in women with unfavorable cervix and a history of previous CS is limited.^{10,15–17}

The aim of this cohort study was to evaluate the safety of IOL by FC compared with spontaneous onset of labor in women with a history of single prior CS and no vaginal delivery following the previous CS. The secondary objective was to assess factors

predictive for repeat CS and adverse maternal outcomes during the trial of labor (TOL).

METHODS

This retrospective cohort study of women with previous CS undergoing TOL was carried out in the Department of Obstetrics and Gynecology, Helsinki University Hospital, Helsinki, Finland. All pregnant women with previous lower segment transverse CS between 1 January 2013 and 1 January 2015 were identified in the hospital database. Women with scheduled repeat CS, preterm delivery, fetal demise, twin gestation, breech presentation or vaginal delivery following the previous CS were excluded from the study (Figure 1). We included term women with vital singleton pregnancy, cephalic presentation and an unfavorable cervix (Bishop score < 6) who underwent IOL by FC or had a spontaneous onset of labor (Figure 1). Three of the authors then independently collected all data from the patient records. Duration of pregnancy was defined by the fetal crown-rump length measurement performed at the time of the first trimester ultrasound screening. The study protocol was approved by the local Ethic Committee (No. 268/13/03/03/2012) and the management of Hospital district of Helsinki and Uusimaa. An informed consent was not required as this was a retrospective cohort study approved by the hospital management.

A single balloon catheter (Rüsch 2-way Foley, Couvelaire tip, catheter size 22 Ch, Teleflex Medical, Athlone, Ireland) with 50 ml of saline was used for cervical ripening. Light traction was applied so that the balloon rested on the internal os, and the catheter was taped to the inner thigh. Transvaginal ultrasound was performed to assure balloon placement. After spontaneous expulsion of the balloon, amniotomy was performed if the Bishop score was ≥ 6 . Oxytocin augmentation was started 2 to 24 h after amniotomy at the discretion of the obstetrician in charge. If the Bishop Score was < 6 after balloon expulsion, cervical ripening was continued with misoprostol 50 μg orally every 4 h or 25 μg vaginally every 4 to 6 h

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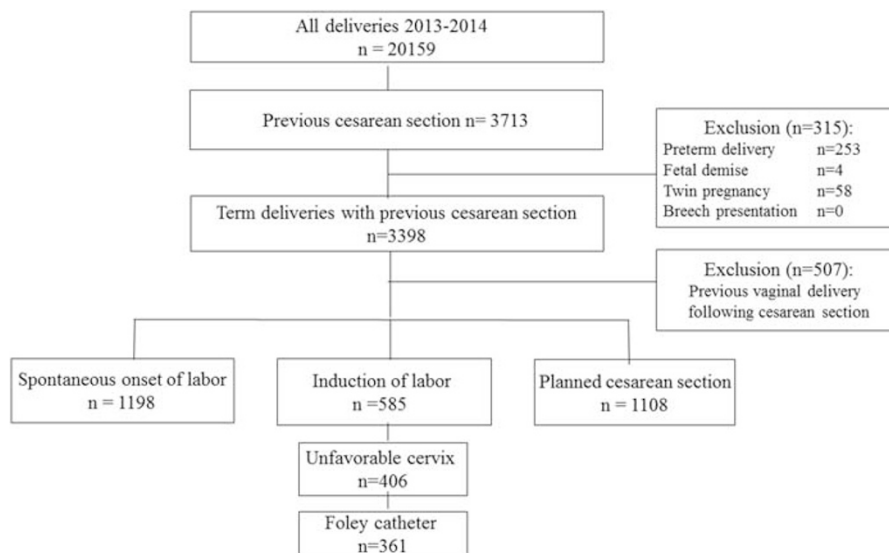


Figure 1. Flow chart of the study population

	Foley catheter, n = 361	Spontaneous onset of labor, n = 1198	P
Maternal age, years	32.2 (4.7)	31.9 (4.8)	0.30
BMI	26.6 (5.8)	24.0 (4.6)	< 0.001
BMI ≥ 30	95 (26.3)	134 (11.2)	< 0.001
Height	164.8 (6.2)	164.1 (6.3)	0.05
IVF	11 (3.0)	40 (3.3)	0.79
Smoking	27 (7.5)	80 (6.7)	0.60
Pregestational/gestational diabetes	121 (33.5)	246 (20.5)	< 0.001
Gestational age	40.5 (1.4)	40.2 (1.1)	< 0.001
Prolonged pregnancy (≥41)	148 (41.0)	345 (28.8)	< 0.001
Postterm pregnancy (≥42)	89 (24.7)	25 (2.1)	< 0.001
Prior vaginal delivery preceding CS	36 (10.0)	121 (10.1)	0.94
IOL in previous pregnancy with CS	155 (42.9)	299 ^a (25.0)	< 0.001
<i>Indication for previous CS</i>			
Planned	95 (26.3)	256 (21.4)	0.05
Unplanned	266 (73.7)	942 (78.6)	
<i>Indication for labor induction</i>			
Prolonged/postterm pregnancy	117 (32.4)		
PROM	60 (16.6)		
Pregestational/gestational diabetes	59 (16.3)		
Psychosocial reason	40 (11.1)		
Hypertensive disorder	30 (8.3)		
Obstetric cholestasis	15 (4.2)		
IUGR	13 (3.6)		
Other ^b	27 (7.5)		

Abbreviations: BMI, body mass index; CS, cesarean section; IOL, induction of labor; IUGR, intrauterine growth restriction; IVF, *in vitro* fertilization; PROM, premature rupture of membranes. Data are presented as n (%) or mean (s.d.). ^aMissing 15 values. ^bUnstable fetal presentation n = 1, previous fetal demise n = 2, previous obstetric complication n = 2, fetal disease n = 8, non-diabetic macrosomia n = 9, maternal disease n = 5.

according to the local practice. Continuous fetal cardiotocography was routinely used during labor.

Data on the study population characteristics, including maternal age, body mass index (BMI) in early pregnancy, height, use of *in vitro* fertilization (IVF), parity, smoking, pregestational or gestational diabetes, indication for previous CS, Bishop Score at the start of IOL and indication for IOL, were obtained from the hospital records. Obesity was defined as BMI ≥ 30 kg m⁻². Gestational diabetes was diagnosed by an oral glucose tolerance test. Medication-dependent gestational diabetes included both insulin and metformin treatments. Prolonged pregnancy was defined as 41st gestational weeks and postterm pregnancy was defined as ≥ 42nd weeks of gestation. In cases with term premature rupture of membranes, labor was induced after 24 h of expectant management according to local guidelines.

The primary outcomes were the rates of repeat CS and adverse maternal outcome (including uterine rupture, uterine dehiscence, hysterectomy, urinary tract lesion, postpartum hemorrhage ≥ 1500 ml, blood culture positive septicemia and laparotomy). The secondary outcomes included maternal intrapartum and postpartum infections, umbilical artery blood gas values, Apgar score, induction-to-delivery interval and duration of labor.

Uterine rupture was defined as complete tear extending across myometrium and peritoneum. Uterine dehiscence was defined as incomplete rupture or detachment with intact peritoneum. Maternal intrapartum infection was defined as fever > 38.0 °C, fetal tachycardia and total white cell count > 20 × 10⁹ l⁻¹ combined with the start of antibiotics. Postpartum infections included endometritis (with the criteria described above), wound infection and urinary tract infection within 1 week from delivery. Active phase of labor was defined as regular contractions in every 3 to 5 min and/or cervical dilation ≥ 6 cm. Labor arrest in the first stage of labor was defined as failure to progress after ≥ 6 cm of cervical dilation despite of ruptured membranes and a minimum of 4 h of adequate uterine contractions.¹⁹ Failed induction was diagnosed after ruptured membranes, 12 h of oxytocin administration and cervical dilation of < 6 cm.¹⁹ The induction-to-delivery interval was defined as the time from insertion of FC to delivery. Duration of labor was calculated from the start of active phase of labor to delivery.

The data was de-identified before the analysis. All calculations were carried out using the Microsoft Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) for Windows v22.0. Categorical variables were compared by the chi-squared and Fisher's exact tests when appropriate. Data with continuous variables were analyzed by the *t*-test when the data followed normal distribution and by a Mann-Whitney *U*-test if this was not the case. Comparison of rates of cesarean delivery and adverse maternal outcome between women with and without prior vaginal delivery preceding previous CS was performed by the chi-squared test. Univariate and multivariate logistic regression analyses were performed to assess relative risks for cesarean delivery, adverse maternal outcome and maternal

Table 2. Delivery outcomes (*n* = 1559)

	Foley catheter, <i>n</i> = 361	Spontaneous onset of labor, <i>n</i> = 1198	P
Epidural/spinal analgesia	296 (82.0)	1030 (86.0)	0.06
Oxytocin induction or augmentation	308 (85.3)	1151 (96.1)	< 0.001
<i>Cesarean section</i>	137 (38.0)	242 (20.2)	< 0.001
Fetal distress	43 (11.9)	107 (8.9)	0.01
Failed induction	50 (13.9)		
Labor arrest	77 (7.5)	117 (9.8)	0.14
Intrapartum infection	12 (3.3)	2 (0.2)	
Other	5 ^a (1.4)	16 ^b (1.4)	
CS in II stage of labor	19 (5.3)	68 (5.7)	0.002
Operative vaginal delivery	55 (15.2)	148 (12.4)	0.001
Placental retention	11 (3.0)	46 (3.8)	0.48
Postpartum hemorrhage ≥ 1500 ml	24 (6.6)	72 (6.0)	0.66
Intrapartum infection	22 (6.1)	21 (1.8)	< 0.001
Postpartum infection	19 (5.3)	15 (1.3)	< 0.001
Blood culture-positive septicemia ^c	3 (0.8)	3 (0.3)	0.14
Uterine rupture	1 (0.3)	10 (0.8)	0.47
Uterine dehiscence	8 (2.2)	12 (1.0)	0.10
Laparotomy or relaparotomy	5 (1.4)	0	
Induction-to-delivery interval (h)	29.7 (17.9–39.1)		
Vaginal delivery in 24 h from IOL	95 (26.3)		
Vaginal delivery in 48 h from IOL	201 (55.7)		
Duration of active labor (h)	8.5 (1.5–37.5)	9.6 (0.30–51.1)	< 0.001
Birth weight (g)	3651 (513)	3577 (467)	0.01
Apgar 1 min < 7	34 (9.4)	107 (8.9)	0.78
Apgar 5 min < 7	19 (5.3)	39 (3.3)	0.08
Umbilical artery pH < 7.05	13 (3.6)	39 (3.3)	0.75

Abbreviation: IOL, induction of labor. Data are presented as *n* (%), mean (s.d.) or median (range). ^aMaternal request *n* = 2, preeclampsia *n* = 1, umbilical cord prolapse *n* = 1, suspicion of uterine rupture *n* = 1. ^bBreech *n* = 4, maternal request *n* = 8, preeclampsia *n* = 3, placenta previa *n* = 1. ^cAlso included in intrapartum or postpartum infection rates.

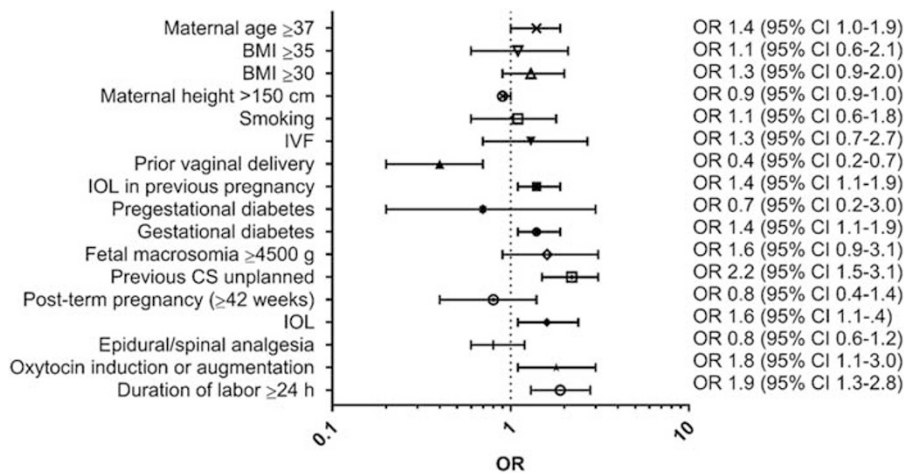


Figure 2. Forest plot of odds ratios (ORs) for repeat cesarean section (CS), adjusted for prior vaginal delivery, induction of labor (IOL) in previous pregnancy, planned/emergency CS in previous pregnancy, maternal age, height, body mass index (BMI), smoking, *in vitro* fertilization (IVF), IOL, postterm pregnancy, pregestational diabetes, gestational diabetes, fetal macrosomia, oxytocin induction or augmentation, epidural or spinal analgesia and duration of labor ≥ 24 h. CI, confidence interval.

infectious morbidity. Adjusted odd ratios (ORs) with 95% confidence intervals (CIs) were calculated by modeling the data to control for possible confounding variables, such as prior vaginal delivery; IOL in previous pregnancy; planned/emergency CS in previous pregnancy; maternal characteristics such as age, height and BMI; smoking; IVF; labor induction; postterm pregnancy; pregestational diabetes; gestational diabetes; fetal macrosomia; duration of labor ≥ 24 h; oxytocin use and epidural or spinal analgesia. A *P*-value < 0.05 was considered statistically significant.

RESULTS

The study population consisted of 1559 women, of which 361 (23.2%) underwent IOL by FC and 1198 women (76.8%) had spontaneous onset of labor. The characteristics of the study population are shown in Table 1. Women undergoing IOL were more obese, more often had prolonged or postterm pregnancy and more often were also induced in the previous pregnancy, compared with women with spontaneous onset of labor (Table 1).

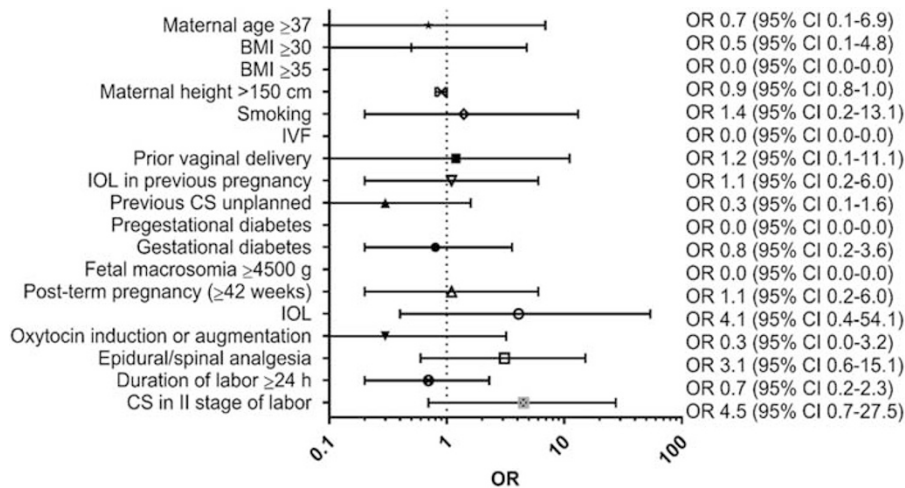


Figure 3. Forest plot of odds ratios (ORs) for adverse maternal outcome, adjusted for prior vaginal delivery, induction of labor (IOL) in previous pregnancy, planned/emergency cesarean section (CS) in previous pregnancy, maternal age, height, body mass index (BMI), smoking, *in vitro* fertilization (IVF), IOL, postterm pregnancy, pregestational diabetes, gestational diabetes, fetal macrosomia, oxytocin induction or augmentation, epidural or spinal analgesia, duration of labor ≥ 24 h and CS in the second stage of labor. CI, confidence interval.

The indications of previous CS did not differ between the groups (Table 1). Majority of women in both groups had no prior vaginal delivery (Table 1). The most common indications for IOL were prolonged/postterm pregnancy and premature rupture of membranes. All women had an unfavorable cervix at the start of IOL, with 204 (56.5%) women having a Bishop score ≤ 3 .

Table 2 shows the delivery outcomes. The CS rate was 38% in the women undergoing IOL by FC and 20.2% in the women with spontaneous onset of labor (OR 2.4 (95% CI 1.9 to 3.1); $P < 0.001$) (Table 2). After adjustment, the risk for repeat CS was lowest (OR 0.4 (95% CI 0.2 to 0.7)) in case of prior vaginal delivery (Figure 2). The risk for repeat CS was increased if previous pregnancy had been induced (adjusted OR 1.4 (95% CI 1.1 to 1.9)) or if the previous CS had been unplanned (adjusted OR 2.2 (95% CI 1.5 to 3.1)) (Figure 2). Other significant risk factors for repeat CS were IOL, gestational diabetes, oxytocin induction or augmentation and prolonged labor > 24 h (Figure 2). If comparing only women with no previous vaginal delivery ($n = 1402$, Table 1), the rate of repeat CS was 16.7% ($n = 6$) in the IOL group and 12.4% ($n = 15$) in women with spontaneous onset of labor ($P = 0.51$).

Adverse maternal outcomes were not significantly different between the women undergoing IOL and the women with spontaneous onset of labor (Table 2). No cases of maternal death occurred. Uterine rupture occurred in 1 (0.3%) woman in the IOL group and in 10 (0.8%) women in the group of spontaneous onset of labor ($P = 0.47$; Table 2). Most cases of uterine rupture were diagnosed during CS, but two cases were observed after vaginal delivery. The rates of myometrial dehiscence were similar in the two groups (2.2% vs 1.0%; $P = 0.10$; Table 2). None of the uterine rupture occurred in the 66 women who underwent subsequent cervical ripening with misoprostol. If comparing only women with no previous vaginal delivery ($n = 1402$, Table 1), 2 (1.7%) women with spontaneous labor onset had uterine rupture, while no ruptures were observed following IOL. After multivariate logistic regression analysis, no independent risk factors for adverse maternal outcomes were found (Figure 3). The rates of postpartum hemorrhage ≥ 1500 ml were not significantly different between the two groups (Table 2). One woman who underwent IOL had an emergency hysterectomy due to atonic postpartum hemorrhage. Five women (1.4%) in the IOL group had laparotomy due to uterine rupture and/or postpartum hemorrhage. One case of urinary tract lesion occurred in both groups (0.3% vs 0.1%).

The overall maternal intrapartum infection rate was 2.8%, and the postpartum infection rate was 2.2%. The infection rates were higher in women undergoing IOL compared with women with spontaneous onset of labor (Table 2). In univariate analysis, obesity, prolonged induction-to-delivery interval ≥ 24 h and prolonged labor for over ≥ 24 h were associated with increased risk for intrapartum infection (OR 2.6 (95% CI 1.6 to 5.1); $P = 0.004$, OR 4.7 (95% CI 2.5 to 8.7); $P < 0.001$ and OR 5.3 (95% CI 2.2 to 12.5); $P < 0.001$, respectively). After adjustment, only the association with prolonged labor remained significant (OR 3.0 (95% CI 1.3 to 7.2); $P = 0.01$). Postpartum infection was associated with obesity, prolonged induction-to-delivery interval and cesarean delivery (OR 1.8 (95% CI 0.8 to 4.1); $P = 0.141$, OR 3.6 (95% CI 1.7 to 7.3); $P < 0.001$ and OR 4.1 (95% CI 2.1 to 8.2); $P < 0.001$, respectively). After adjustment, only the association with prolonged induction-to-delivery interval remained significant (OR 3.6 (95% CI 1.3 to 9.9); $P = 0.01$).

The neonatal outcomes were not significantly different between the groups of IOL and spontaneous onset of labor (Table 2).

The median induction-to-delivery interval was 29.7 (range 17.9 to 39.1) h (Table 2). Duration of active labor was the average 1.1 h shorter in the induction group than in the group of spontaneous onset of labor (Table 2).

DISCUSSION

The vaginal delivery rates of 62% in women undergoing IOL by FC and 79.8% in women with spontaneous onset of labor in our study were comparable to the previously reported rates.^{8,18} The risk for repeat CS was associated with IOL, unplanned previous CS, gestational diabetes, oxytocin use and prolonged labor. No differences in adverse maternal outcomes between the women with induced labor and the women with spontaneous onset of labor were found. The overall rate of uterine rupture was low. Women undergoing IOL had higher rates of maternal intrapartum and postpartum infection.

IOL increases the risk for repeat CS compared with spontaneous onset of labor.^{8,12} This was also seen in our study, in which the risk for repetitive CS was 1.6-fold in women undergoing IOL. The greatest predictor for success of TOL is a prior vaginal delivery,^{12,20} as also noted in our study. We chose a cohort of women with no prior vaginal birth after cesarean, as specifically a prior vaginal birth after cesarean is known to increase the success of vaginal

birth and to decrease the risk for uterine rupture in subsequent pregnancies.²⁰ The rates of successful TOL were also higher in women who had nonrecurring indication, such as breech presentation for the previous CS, compared with women who had recurring indication such as labor dystocia.^{12,21} Also, in our study, women with unplanned previous CS had higher risk for repeat CS. Previous studies have concluded that advanced maternal age >35 years and obesity are associated with higher rates of repeat CS,^{22–26} but this was not seen in our study. Gestational diabetes was one of the risk factors for repeat CS in our study, as also noted previously.²⁷

The main advantages of cervical ripening with FC are low risk of hyperstimulation and uterine rupture.^{16,28–31} In a previous cohort study, the risk of uterine rupture was 0.8% if labor was induced without prostaglandins and 2.24% in IOL with prostaglandins.³² In our study, the overall rate of uterine rupture was 0.7%, similar to the rates reported by two recent systematic reviews.^{8,18} IOL has been shown to increase the risk of uterine rupture and dehiscence compared with spontaneous onset of labor,⁸ but this was not seen in our study. A Dutch multicenter study demonstrated a uterine rupture rate of 1.5% in women undergoing TOL, which is twofold higher than ours.³³ This may partly be explained by distinguishing uterine rupture and dehiscence in our study, while in the previous study some cases of uterine dehiscence were included in the rupture rate. However, uterine dehiscence is a critical outcome measurement, as asymptomatic uterine dehiscence in women who delivered vaginally may have been unnoticed. In our study, only one case of uterine dehiscence was diagnosed following vaginal delivery, while the rest were diagnosed during CS.

Postpartum hemorrhage has previously been shown to complicate IOL more often than spontaneous onset of labor after previous CS.³⁴ In our study, no difference in the rates of postpartum hemorrhage between the groups was found.

Infectious morbidity was higher in women undergoing IOL compared with women with spontaneous onset of labor. Similar intrapartum infection rates of 5% were reported by two previous studies.^{16,35} The highest rate of endometritis is shown to occur in women who attempt an unsuccessful TOL compared with women with successful vaginal birth after cesarean or planned repeat cesarean.^{36,37} A similar trend was seen also in our study. The use of FC in women with ruptured amniotic membranes has raised concerns of infectious morbidity. We have previously shown low rates of maternal and neonatal infections following the use of FC in women undergoing IOL for premature rupture of membranes.³⁸ Similar reassuring results have also been reported by a small pilot study and a retrospective cohort study.^{39,40}

The strengths of this study are the large sample size, an unselected population database, uniform pregnancy dating, active labor management in our institution and uniform definitions of uterine rupture and dehiscence. Instead of relying on The International Classification of Diseases, Tenth Revision codes, we explicitly collected and confirmed all data on adverse maternal outcomes and infections. Our study has some major limitations, though. First, this was a retrospective 2-year cohort study including two very different groups of women undergoing labor induction and spontaneous onset of labor. We acknowledge the selection bias of more high-risk population of women with obesity, gestational diabetes and prolonged/postterm pregnancy ending up in the induction group, but we wanted to evaluate the FC induction in terms of safety and repeat CS compared with spontaneous onset of labor, as the lowest rates of uterine rupture and repeat CS have been shown to occur following spontaneous onset of labor. We also regret not having the data on neonatal intensive care unit admissions. Interestingly, women with spontaneous onset of labor more often had oxytocin augmentation than the women with induced labor. This is a bias as CS was in most cases performed due to labor arrest in the IOL group. It may be speculated that perhaps oxytocin augmentation was less used for

the fear of increased risk for uterine rupture. Unfortunately, we did not differentiate between oxytocin augmentation during the first and the second stages of labor.

In conclusion, FC appears to be a safe and effective method for IOL in women with history of previous CS. The rates of maternal adverse outcomes, including uterine rupture, did not differ from the women with spontaneous onset of labor. In the absence of large randomized clinical trials, our study with a relatively large sample size adds to the limited data available on use of the FC in women with previous CS. As the rates of IOL and the number of women with a history of previous CS are increasing, further studies are needed to substantiate these findings.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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