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Induction of labor at the 39th week and cesarean delivery: a retrospective study in a Shanghai-based maternity hospital

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Abstract. – OBJECTIVE: This study aimed at exploring the association between labor induction at the 39th week and CD in the setting where the baseline cesarean delivery rate is high.

PATIENTS AND METHODS: A retrospective cohort study was conducted during a 50-month period at a Shanghai-based secondary maternity hospital. A comparison was made of the maternal and neonatal outcomes, including the CD rate, between the women who underwent labor induction at the 39th week and those who were managed expectantly.

RESULTS: A total of 4,975 deliveries were included, which had been made by the low-risk nulliparous women beyond 39 weeks. The CD rate was 41.6% and 42.2% in the induction group (n = 202) and the expectant management group (n = 4,773), respectively (relative risk, 0.99; 95% CI, 0.83 to 1.17). Induction of labor at the 39th week increased the risk of postpartum hemorrhage ≥ 500 ml in 24 hours (adjusted relative risk, 2.32; 95% CI, 1.12 to 4.78) and intrapartum fever ≥ 37.5°C (adjusted relative risk, 4.73; 95% CI, 2.13 to 10.49). Differences in other maternal and neonatal outcomes were of no clinical significance. When stratified by the indications for labor induction, CDs performed because of non-reassuring fetal heart rate were more prevalent among the women who were induced for the same reason than those who were not.

CONCLUSIONS: As compared with that in the expectant management, labor induction at the 39th week does not seem to have an impact on CD within the setting of a high CD rate.

Key Words:
Cesarean section, Labor, Induced, Pregnancy, Retrospective studies, Watchful waiting.

Introduction

Induction of labor (IOL) is defined as the iatrogenic stimulation of uterine contractions prior to the onset of spontaneous labor. When considering the timing of IOL, the desire to prevent risks including stillbirth and other maternal and neonatal morbidities must be weighed against the risk of prematurity. It is well recognized that a pregnancy beyond 42 weeks poses a greater risk of harm to both the mother and her fetus, often ending up with a cesarean delivery (CD); therefore, an IOL is indicated when pregnancy reaches the 41st/42nd week, or when a medical condition develops, as recommended by the major guidelines in the world[1-3]. For decades, studies[4-7] have shown that IOLs are associated with a higher risk of CD when compared with spontaneous labors. But such a comparison has a major methodological flaw, as pointed out by Caughey[8], i.e., a spontaneous labor cannot be planned. Actually, an ongoing pregnancy can be either induced or not induced. The more logical comparison group to the IOL group should involve those who are not induced at a certain gestational age, also known as the expectant management (EM) group. Until recently, quite a few epidemiological studies and randomized controlled trials[9-12] (RCTs) have shown that IOL at the 39th week is associated with decreased risk of CD and hypertension, without increasing short-term maternal and neonatal morbidity. As for long-term morbidities, in an Australian study[13] where 31,120 deliveries and children were paired up, no difference was found in the testing outcomes of eight-year-old children's standardized literacy and numeracy between the mothers with elective IOL at the 39th week and the EM. These findings were similar to those of another study in Rhode Island[14].

China was among the countries with the highest rate of CD, which accounted for 46.2% in 2008[15].The most common reason behind this phenomenon has been the maternal request[16-18]. Since 2016, China has shifted from the one-child to the two-child policy; thus, the national growing CD rate came into a short plateau period during 2014-2016, followed by one more rise in

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2018[19]. In 2018, the ARRIVE study[12] reported that IOL at the 39th week experienced a reduction in CD rate from 22.2% to 18.6% among the low-risk nulliparous women. Afterwards, consistent results came to be reached, as indicated by a meta-analysis of the observational studies[20]. If the findings are applicable, hundreds of thousands of CDs can be avoided by IOL at the 39th week, given the annual number of over 14 million newborns. With a view to all the benefits of IOL, advocators argue that 39-week IOL in nulliparous women can be redefined as prophylactic or risk-reducing[21,22]. As promising as the findings of the ARRIVE trial seems, the actual effect of 39-week IOL in China is bound by other factors such as medical-legal environment, shifting staff working hours, and women's beliefs on the timing of birth.

When women believe in the right time for pregnancy and labor, in many cases it is hard to convince them to end their pregnancy early. For those who do want to choose their own right time, however, a CD is always more predictable and controllable.

Currently, little data are available on IOL among the low-risk nulliparous women in China. It remains unknown whether the rule of 39-week IOL will survive in China. In the supercities of China, the CD rate reached 44% in 2018[19], almost 1.5-fold of that in the US[23]. Thus, the aim of our study was to explore the relationship of IOL at the 39th week with the CD rate in one of the "supercities" in China.

Patients and Methods

We conducted a retrospective cohort study on full-term, late-term, post-term, singleton and cephalic deliveries at Shanghai Pudong New Area Healthcare Hospital for Women and Children, a secondary maternal hospital where approximately 5,000 deliveries are annually performed. The study lasted 50 months from January 2017 to February 2021, with the relevant data derived from the electronic medical file records and the electronic doctor's prescription system (Hospital Information System 4.0, Shanghai Kingstar Winning Software Science and Technology).

We excluded the high-risk patients identified before the 39th week, who had gestational diabetes mellitus (GDM), hypertension, intrahepatic cholestasis of pregnancy (ICP), fetal growth restriction (FGR), placenta previa, stillbirth, and all the CDs for non-medical reasons. Because women who conceived through IVF (*in vitro* fertilization) have a higher risk of CD[24], we identified those who chose CD for IVF only and excluded them from both groups. Those who underwent IOL with intact membranes for any reason between 39 and 39^{+6} weeks were compared with those who were not induced in expectant management. Considering that premature rupture of membrane (PROM) occurs only if a pregnancy is managed expectantly, IOLs following PROM are assigned to the EM group.

Exact Bishop scores were not available from the medical records. A Bishop score of 4 or less is deemed an unfavorable cervix at our hospital, which needs cervical ripening, either with mechanical cervical dilators such as double balloon devices, or with prostaglandin E2 (PGE2) such as dinoprostone. An intravenous infusion of oxytocin is used as an alternative method of cervical ripening in pregnant women who have vaginitis or when the oxytocin challenge test is being performed for medical reasons.

A failed induction was declared only when at least 48 hours have elapsed after membrane rupture and the use of oxytocin, with the woman remaining in latent labor.

In our study, the primary outcome was CD rate, and the secondary outcomes included adverse maternal and neonatal results of the following: vaginal operative delivery, ICU admission, PPH > 1000 ml or blood transfusion needed, PPH> 500 ml, 3rd or 4th degree of laceration, intrapartum fever (≥37.5°C), and NICU admission. The diagnosis of chorioamnionitis, if any, was not recorded.

Statistical Analysis

All statistical analyses were performed using SAS version 9.4 (SAS Institute; Cary, NC, USA). The characteristics of the study population were compared *via* Chi-square test and student's *t*-test. The relative risks of CD and other maternal and neonatal outcomes were calculated by Univariable and Multivariable Poisson Regression (PROC GENMOD). All statistical tests were 2-sided, the level of significance was set at $p < 0.05$.

Results

Demographic Characteristics

Of 6,992 deliveries that met the inclusion criteria during the period of January 2017 to February 2021, 2,017 (28.8%) were excluded for the compli-

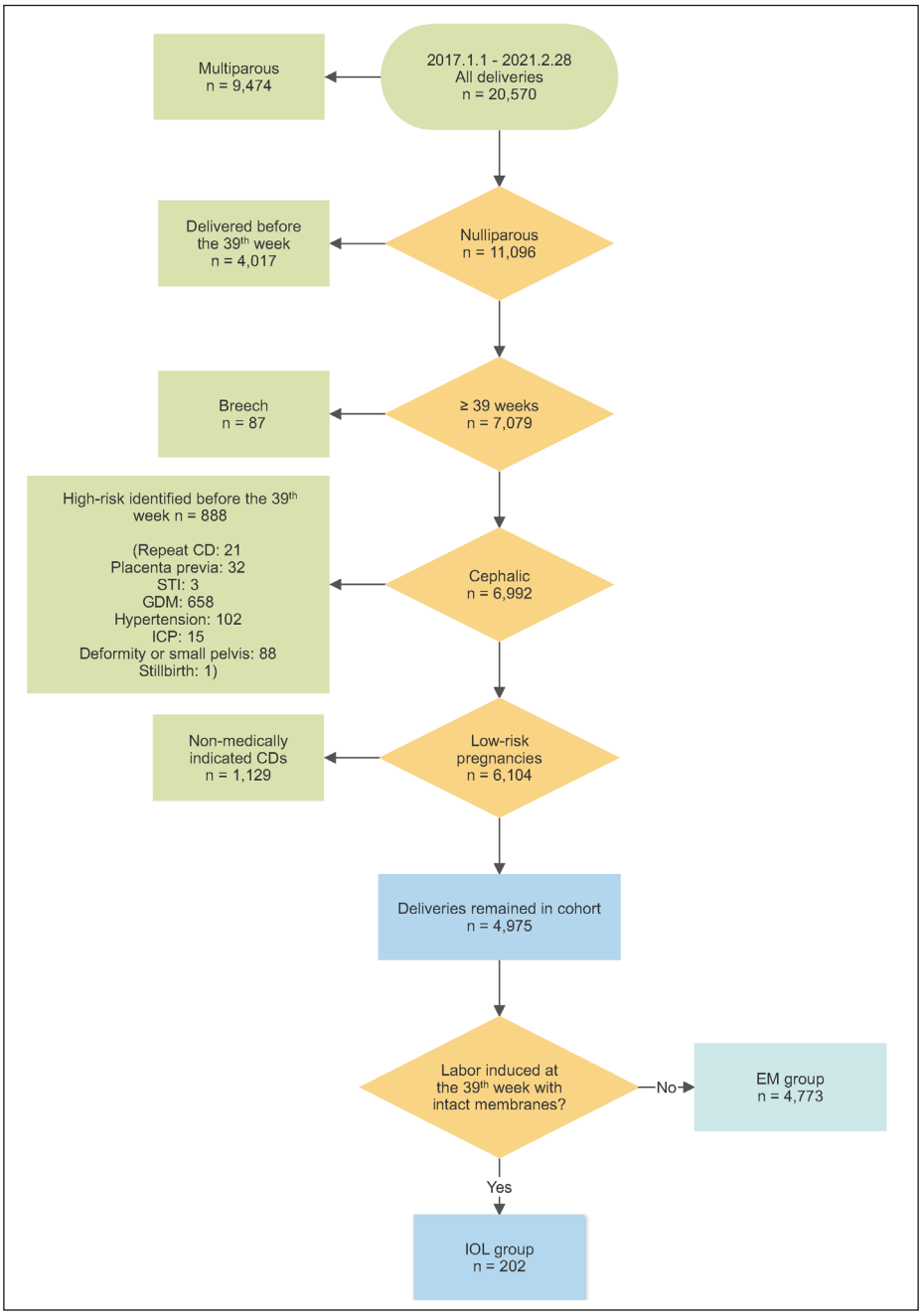

Figure 1. Study flow chart. CD, cesarean delivery; STI, sexually transmitted infection; GDM, gestational diabetes mellitus; ICP, intrahepatic cholestasis of pregnancy; EM, expectant management; IOL, induction of labor.

cations developed before the 39th week and for the planned CDs (Figure 1). The proportion of IOL at 39th week (39 weeks to 39+6 weeks) was 202/4,975 (4.1%). The average gestational age at delivery was 39.5 weeks in the IOL group and 40.1 weeks in the EM group, respectively. The women in the IOL group were more likely to be younger, have a lower gestational weight gain and bear a newborn with lower birth weight than those in the EM group (Table I).

IOL Indication Changes

During the 50-month period, the proportion of IOL at the 39th week increased from 2.1% in 2017 to 8.5% in 2020. The most common indication of IOL remained a non-reassuring fetal heart rate

Table I. Demographic characteristics of the study population.

	IOL		EM		*p*-value
	n = 202		n = 4773		
Gestational age at delivery (w)	39.5±0.3		40.1±0.7		**<0.001*** **
Maternal age (y)	26.1±3.4		26.6±3.5		**0.021***
Method of conception					0.946
ART	2	(1.0%)	45	(1.0%)	
Natural conception	200	(99.0%)	4,728	(99.0%)	
Local residents					0.126
Yes	88	(43.6%)	1,824	(38.2%)	
No	114	(56.4%)	2,949	(61.8%)	
Maternal height (cm)	162.5±5.0		162.4±5.8		0.836
Pre-gestation BMI (kg/m^2)	21.4±3.1		21.4±2.9		0.974
Pre-labor BMI (kg/m^2)	26.9±3.5		27.2±3.3		0.152
Gestational weight gain (kg)	14.6±4.5		15.4±4.9		**0.038***
Previous no. of abortions					0.720
0	148	(73.3%)	3,449	(72.3%)	
1	43	(21.3%)	994	(20.8%)	
>1	11	(5.5%)	330	(6.9%)	
Covered by medical insurance					0.945
Yes	129	(63.9%)	3,054	(64.0%)	
No	73	(36.1%)	1,719	(36.0%)	
Neonatal sex					0.117
Boy	90	(44.6%)	2,396	(50.2%)	
Girl	112	(55.5%)	2,377	(49.8%)	
Neonatal birth weight (g)	3,346±329		3,443±376		**<0.001*** **
Macrosomia (≥4.000 g)	7	(3.5%)	376	(7.9%)	**0.021***

*p<0.05; ***p<0.001. ART, assisted reproductive techniques; BMI, body mass index; IOL, induction of labor; EM, expectant management.

(NRFHR) or reduced fetal movement (RFM) throughout the study period, while the elective was the rarest indication (Table II and Figure 2).

Maternal and Neonatal Outcomes

There was no statistical difference on the CD rate between the two groups (41.6% vs. 42.2%; relative risk, 0.99; 95% CI, 0.83 to 1.17). Those who underwent IOL at the 39th week were more likely to develop postpartum hemorrhage (PPH ≥ 500 ml; 4.0% *vs.* 1.7%; relative risk, 2.36; 95% CI, 1.16 to 4.82; $p = 0.018$) and chorioamnionitis (4.0% *vs.* 0.9%; relative risk, 4.61; 95% CI, 2.19 to 9.71; $p < 0.001$). When adjusted for the resident status, the insurance status, maternal age, height,

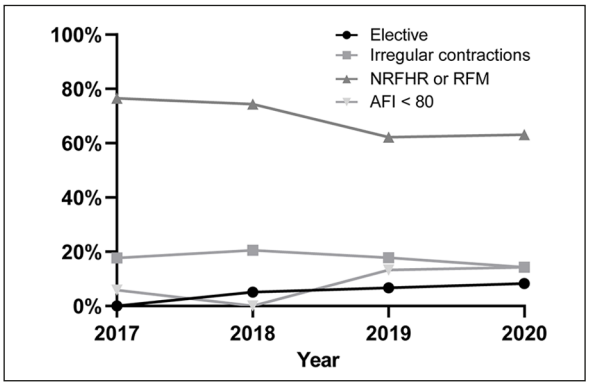

Figure 2. Indications of IOL classified by year. NRFHR, non-reassuring fetal heart rate; RFM, reduced fetal movement; AFI, amniotic fluid index.

Table II. Indications of IOL classified by year.

	2017		2018		2019		2020†		*p*-value
	n = 34		n = 39		n = 45		n = 84		
All IOL	34	2.1%	39	3.3%	45	3.8%	84	8.5%	<0.001***
Elective	0		2	5.1%	3	6.7%	7	8.3%	
Irregular contractions	6	17.7%	8	20.5%	8	17.8%	12	14.3%	0.179
NRFHR or RFM	26	76.5%	29	74.4%	28	62.2%	53	63.1%	
AFI< 80 mm	2	5.9%	0		6	13.3%	12	14.3%	

***p<0.001. †: Lasting from January 2020 to February 2021. NRFHR, non-reassuring fetal heart rate; RFM, reduced fetal movement; AFI, amniotic fluid index.

Table III. Maternal and neonatal outcomes.

	IOL		EM		RR	95% CI	RR′	95% CI
	n = 202		n = 4,773					
Cesarean delivery	84	41.6%	2013	42.2%	0.99	0.83-1.17	1.06	0.90-1.25
Operative vaginal delivery	2	1.0%	104	2.2%	0.45	0.11-1.83	-	-
PPH≥500 ml	8	4.0%	80	1.7%	**2.36**	**1.16-4.82**	**2.32**	**1.12-4.78**
PPH≥1,000 ml or blood products needed	0		8	0.2%	-	-	-	-
3rd or 4th degree perineal laceration	1	0.5%	3	0.1%	7.88	0.82-75.39	-	-
Intrapartum fever	8	4.0%	41	0.9%	**4.61**	**2.19-9.71**	**4.73**	**2.13-10.49**
PP stay ≥7 d	2	1.0%	53	1.1%	0.89	0.22-3.63	1.04	0.25-4.26
Maternal death	0		0		-	-	-	-
Admission to ICU	0		0		-	-	-	-
Perinatal death	0		1	0.0%	-	-	-	-
Admission to NICU	3	1.5%	54	1.1%	1.31	0.41-4.16	0.93	0.23-3.74
Apgar<7 at 5 min	1	0.5%	5	0.1%	4.73	0.55-40.26	3.90	0.41-37.00
Shoulder dystocia	0		2	0.0%	-	-	-	-
Meconium-stained amniotic fluid	28	13.9%	932	19.5%	0.71	0.50-1.01	0.74	0.52-1.05

IOL, induction of labor; EM, expectant management; PPH, postpartum hemorrhage; PP, postpartum; ICU, intensive care unit; NICU, neonatal intensive care unit; RR, relative risk; RR', relative risk adjusted for maternal age, resident status, insurance status, maternal height, pre-labor BMI, gestational weight gain, neonatal birth weight and year of birth.

Table IV. All indications for cesarean delivery.

	IOL		EM		RR	95% CI	*p*-value
	n = 202		n = 4,773				
All indications	84	41.6%	2,014	42.2%	0.99	0.83-1.17	0.868
CPD or suspected macrosomia	22	10.9%	1,052	22.0%	0.49	0.33-0.74	**<0.001*****
NRFHR or MSAF	54	26.7%	809	17.0%	1.58	1.24-2.00	**<0.001*****
Prolonged labor	5	2.5%	140	2.9%	0.84	0.35-2.04	0.705
Persistent OP/OT	4	2.0%	69	1.5%	1.37	0.50-3.72	0.541
Intrapartum fever	7	3.5%	31	0.7%	5.34	2.38-11.97	**<0.001*****
PA or UCP	0		7	0.2%	-	-	1.000

***$p<0.001$. IOL, induction of labor; EM, expectant management; CPD, cephalopelvic disproportion; NRFHR, non-reassuring fetal heart rate; MSAF, meconium-stained amniotic fluid; persistent OP/OT, persistent occiput posterior/occiput transverse positions; PA, placental abruption; UCP, umbilical cord prolapse.

Table V. Indications for CD stratified by indications for IOL.

	IOL for NRFHR, RFM or AFI<80		IOL for other reasons		EM		*p*-value
	n = 156		n = 46		n = 4,773		
CD	67	43.0%	17	37.0%	2,014	42.2%	0.759
CD for NRFHR or MSAF	47	30.1%	9	19.6%	840	17.6%	**<0.001*****
CD for other reasons	20	12.8%	8	17.4%	1,174	24.6%	
Vaginal delivery	89	57.1%	29	63.0%	2,759	57.8%	

***$p<0.001$. IOL, induction of labor; EM, expectant management; CD, cesarean delivery; NRFHR, non-reassuring fetal heart rate; RFM, reduced fetal movement; AFI, amniotic fluid index; MSAF, meconium-stained amniotic fluid.

pre-labor BMI, neonatal birth weight, and year of birth, proportions of PPH and chorioamnionitis remained statistically higher in the IOL group than in the EM group. Other maternal and neonatal outcomes were found to be similar between the two groups (Table III).

CD Indications

It was found that the CD rate was similarly high in both groups, even after planned CDs were excluded. But the CD indications showed statistical differences, as indicated by the prevalence of cephalopelvic disproportion (CPD) which was lower in the IOL group than in the EM group (10.9% *vs*. 22.0%; relative risk, 0.49; 95% CI, 0.33 to 0.74; $p < 0.001$), while the prevalence of NRFHR or meconium stained amniotic fluid (MSAF) (26.7% *vs*. 17.0%; relative risk, 1.58; 95% CI, 1.24 to 2.00; $p < 0.001$) and intrapartum fever (3.5% *vs*. 0.7%; relative risk, 5.34; 95% CI, 2.38 to 11.97; $p < 0.001$) was higher in the IOL group than in the EM group (Table IV).

When stratified by the IOL indications, CDs performed because of NRFHR or MSAF were more prevalent among the women induced with the same reason, than those who were induced with other reasons and those in the EM group ($p < 0.001$) (Table V).

Discussion

Our study showed that IOL at the 39th week did not increase the CD rate, and that it even helped prevent the occurrence of macrosomia to a certain degree, but not shoulder dystocia, when compared with the expectant management. As for maternal and neonatal adverse outcomes, IOL increased the possibility of PPH (≥ 500 ml in 24 hours) from 1.7% to 4.0%, but not of severe PPH (≥ 1,000 ml in 24 hours). Furthermore, IOL increased the proportion of intrapartum fever, but not of chorioamnionitis, from 0.9% to 4.0%, which was statistically significant, but it made no difference in clinical management because IOL did not prolong the postpartum hospital stay.

We also found that the CDs performed because of NRFHR or MSAF were significantly more common in the IOL group than in the EM group (26.7% *vs*. 17.0%; relative risk, 1.58; 95% CI, 1.24 to 2.00; $p < 0.001$). Further investigation into this phenomenon showed that most of those CDs were among women who were induced for the same reason in the IOL group. The fear of intrapartum stillbirth, though the risk was very small, may have been the driving force behind overused CD.

Because of the non-medically IOL ban before 41 weeks of gestation in the national guideline[25], in our study, almost every pregnant woman was induced because of a medical condition at the 39th week. Methodologically like our study, other cohort investigations on IOL with medical indications reached inconsistent conclusions. In 2006, the first published report by Caughey et al[8] stated that expectant management, instead of spontaneous labor, should be the group with which IOL is compared. In this retrospective study the women in the IOL group were compared at a given week with those who were not induced at the same week and still remained pregnant one week after (also known as the redefined expectant management group), showing a lower CD rate in the IOL group at the 39th week in the nulliparous women. Another study by Glantz[26], however, modified the expectant management from one week after to the same week when the IOL took place, which was methodologically similar to our study, from which it was found that IOL at the 39th week was associated with an increased CD rate. Both studies, which involved both low-risk and high-risk nulliparous women with preeclampsia or gestational diabetes, did not record the indication for IOL or CD. The indication for IOL per se might put women at a high risk for CD, as indicated in our study in which 30.1% of NRFHR or borderline oligohydramnios with IOL indications resulted in CD for the same reason, having a significantly higher proportion than 19.6% in the IOL group with other indications, or than 17.6% in the expectant management group. IOL at the 39th week might reach a lower CD rate, which suggested that there would be more elective IOLs, now that in the updated consensus the non-medically IOL ban moves up to the 39th week[27].

Of note in our study, the overall CD rate of the low-risk nulliparous women was 42.2%, much higher than the CD rate of 25.6% reported in the 2019 US national vital statistic reports[28], and of 22.2% reported in the ARRIVE study[29]. Such differences could be ascribed to the wide gap between the demographics of the population, local culture, patient preferences, and medical-legal environment.

China implemented the one-child policy in 1980, the two-child policy in 2016, and the three-

child policy in 2021, respectively[30]. A cross-sectional study[31] conducted in Chongqing, one of the four municipal cities in China, found that the nulliparous women who intended to have a second child were less likely to request a CD, from which it could be decided the decreasing CD rate began with the implementation of the two-child policy. For each individual health practitioner, however, the benefits to the future delivery of the second child are not convincing enough to sway their belief toward the ongoing delivery, given that it is time-consuming and risky to care for those who experience NRFHR or prolonged labor. Additionally, an individual woman or her family members do not care about the CD rate, but the safety and painlessness of her and her baby.

In our study, we enrolled women who delivered between January 2017 and February 2021, all belonging to the two-child policy era in China, in which we found an incredibly low rate of NICU admission (1.1%) and operative vaginal delivery (2.1%), as well as a high rate of NRFHR and CPD indicated CDs, which indicated that the fear for injuries to the mother and her fetus may be the reason behind overusing CDs. Back in 1985, when the national CD rate was 20.5%, the repeated IOL after the first failed attempt was common in obstetrical practice[32,33]. In a small experimental study[34], it was found that 75% of the women with the failed IOL attempt achieved vaginal delivery using an alternate mechanical method. Unfortunately, such an approach is no longer routinely practiced, which explained why there were none encountered in our study. Also, having a persistent posterior occipital position can lead to failed induction of labor, which may require a cesarean section if not identified accurately. The use of ultrasound to assist in determining the position of the fetal head and rotating to the anterior occipital position before the head is exposed may reduce the need for unnecessary cesarean or forceps assisted deliveries[35]. In China, ultrasound practitioners are significantly short staffed, so obstetricians and midwives need to be trained in the skill if intrapartum ultrasound is to become a standard procedure. As a maternal health institution in an area with a high cesarean rate, we have implemented analgesic and doula deliveries to improve the maternal delivery experience, and given that waterbirth has been proven to be safe and effective[36], the next step may be to introduce waterbirth to further promote natural childbirth.

To our knowledge, we pioneered the study on the association between IOL at the 39th week and CD in the setting of a high CD rate in the mainland China. The indications for IOL and CD were analyzed for the first time, showing that the safety of the mother and her fetus was overstressed, among other possible factors, which contributed to the overused CD. Although the CD rate has not increased, IOL at the 39th week among Shanghai-based low-risk nulliparous women may not have the same promising benefit as that in the USA.

Limitations

Our study had several limitations. The IOL sample size was relatively small in the study. Although up to 5,000 deliveries were involved there, only 202 were induced at the 39th week, the majority of which were of medically induced labor. Selection bias from differences in cervical maturity, pelvis condition, and possibility of uteroplacental insufficiency between the IOL and EM group might have an impact on the results of CD risk. Next, although non-reassuring fetal heart rate was among the indications for CD, the information on fetal heart-rate monitoring during labor was not recorded in the medical records of the women who had undergone vaginal delivery. This could have been misleading in interpreting the actual prevalence of NRFHR. Additionally, causal relationships could not be inferred from the single-sited retrospective associations; therefore, our findings may not apply to other settings with different diagnostic and therapeutic practices.

Conclusions

In conclusion, IOL at 39th week may have a nuanced impact in high CD rate settings until other clinical care practices can be met.

Ethics Approval

The study was approved Shanghai by Pudong New Area Healthcare Hospital for Women and Children Ethics Committee [2019 (001)]. All methods were carried out in accordance with the rules of the Declaration of Helsinki.

Informed Consent

The informed consent of patients was waved because of the retrospective nature of the study.

Conflict of Interest
The author declares no conflicts of interest.

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Availability of Data and Materials
The data that support the findings of this study are not openly available due to human data and are available from the corresponding author upon reasonable request.

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