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Title:

Trial of labor after cesarean and contribution of pelvimetry in the prognosis of neonatal morbidity

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Abstract

Introduction : To estimate the association between an abnormal pelvic dimension at pelvimetry and the occurrence of severe neonatal morbidity after trial of labor after cesarean (TOLAC).

Materials and Methods: Retrospective observational cases-controls study conducted at a level 3 maternity units between 2006 and 2016. Included women were patient with trial of labor after one previous cesarean section, alive singleton fetus in cephalic presentation ≥ 37 WG. Two groups were compared according to pelvic mesures at pelvimetry: pelvic dimension considered as abnormal, defined by Conjugate Diameter <10.5 cm and/or Transverse Diameter <12 cm and pelvic dimension considered as normal for other women. The primary outcome was a composite criterion of neonatal morbidity and mortality. A logistic multivariate regression model was use to estimate the association between an abnormal pelvic dimension at pelvimetry and the occurrence of severe neonatal morbidity

Results: 2474 women were included. 863 (34.8%) have a normal pelvic dimension and 1611 (65.2%) an abnormal. Characteristics of labor were similar in two groups. Success of TOLAC was 84.7% in normal pelvic group and 64.6% in abnormal dimension of pelvic group. Neonatal morbidity was similar between two groups (1.7% in normal pelvic dimension group versus 2.3% in abnormal pelvic dimension group, p = 0.26; crude OR: 1.39 (0.77-2.49) ; adjusted OR : 0.93 (0.51-1.68)).

Discussion: There were no association between pelvic dimension at pelvimetry and neonatal morbidity. In case of abnormal pelvic dimension, a combination of more prudence, and stringent user practices, achieve a high rate of vaginal delivery and a neonatal morbidity comparable to the normal pelvic dimension group.

Key-words : Neonatal morbidity, Pelvimetry, Previous cesarean, Trial of labor after cesarean section (TOLAC)

Introduction :

We observe an increase rate of women with previous cesarean delivery over the world [1,2,3]. In France the rate of pregnant women with a history of cesarean delivery was 15.6% in 2010, and 16.2% in 2016 [2]. For the labor management of women with previous cesarean delivery, practionner can propose a planned iterative cesarean delivery or a planned vaginal delivery [4]. The main feared complication of trial of labor after cesarean (TOLAC) is the occurrence of uterine rupture because it is associated with an increased risk of maternal and neonatal morbi-mortality [5,6]. Guidelines of developed countries encouraged TOLAC, because cesarean delivery is associated with more neonatal and maternal complications at short and long term, that increase with the number of cesareans, and because the risk of uterine rupture is very sparse [7–10]. In case of previous cesarean, pelvimetry was studied for choosing the mode of delivery, predicting the success of TOLAC and the occurrence of uterine rupture [11]. Due to the absence of contribution of pelvimetry for decrease the failure of TOLAC and for predict uterine rupture, the National College of French Gynecologists and Obstetricians (CNGOF) conclude that the pelvimetry is not necessary for choosing the mode of delivery in case of previous cesarean [4]. Despite these guidelines, actually in France, some practitioners realize pelvimetry in case of previous cesarean, but the estimation of this practice was difficult to determine. One study limited to the Northeast region estimated this practice at 44% of maternity units [11]. For practitioners maintaining the pelvimetry, it is not for performing a planned cesarean delivery in case of abnormal dimension but for managing the TOLAC according to the pelvic dimension associated with others clinical data (indication of previous cesarean, estimated fetal weight, cervical dilatation…). Use of pelvimetry has been poorly studied in case of TOLAC to evaluate its contribution in the management of labor and in the neonatal prognosis.

The objective of this study was to estimate the association between an abnormal pelvic dimension at pelvimetry and the occurrence of severe neonatal morbidity after TOLAC.

Materials and Methods:

It was a retrospective observational case-control study conducted at a level 3 maternity unit between 2006 to 2016. The entire medical file was computerized and was completed prospectively at each visit, at delivery, and during the post partum period. All data were verified at the obstetrics staff meeting the day after the delivery. Inclusion criteria were history of one previous cesarean delivery, with a planned vaginal delivery, with alive singleton in cephalic presentation at or before 37 gestational age. Women were excluded if they had two or more previous cesareans, an in utero fetal death before labor, a termination of pregnancy, a fetal malformation, presentations other than cephalic, multiple pregnancies, planned cesarean delivery. Women with missing data for the pelvimetry or the neonatal outcomes were excluded.

We defined two study groups according to the pelvimetry : " pelvic dimension at pelvimetry considered as abnormal" defined by a transverse diameter (TD) < 12 cm, and/or conjugate diameter (CD) < 10.5 cm ; and "normal pelvic dimension at pelvimetry" for the other women. These cut offs were chosen because they are the usual cut off utilized [12-14].

All women with a previous cesarean whom delivered at this maternity, having a pelvimetry. The planned mode of delivery was discussed during the third trimester in meeting staff with the obstetrical team about obstetrical history, pelvimetry and estimated fetal weight. None cesarean delivery decision before labour was given on the pelvic components except for the pelvis, which was considered very abnormal (transverse diameter < 10.5 cm, and/or conjugate

diameter < 9.5 cm) [12-14]. Labor could be spontaneous, or induced in case of medical indication. There were no indication for cesarean delivery due to the absence of pelvimetry. The use of oxytocine during labor was possible for medical indication. An arrest of labour at two hours was autorized in case of uterine hypotonic dysfunction, beyond cesarean delivery was recommanded. Internal tocometry was not used in this maternity unit, but to appreciate uterin dynamic the use of an uterine palpation and vaginal examination was realized. In this department, a routine manual uterine examination after delivery was performed to ensure the integrity of the uterine scar. A uterine rupture was defined by complete rupture of the myometrium and serosa. In case of uterine rupture, surgical revision by laparotomy was considered only in cases of postpartum hemorrhage.

We collected the following data: the mothers' characteristics, any disease or disorders occurring during pregnancy, characteristics of labor and delivery, any complications of delivery, and neonatal characteristics.

The principal endpoint was a composite neonatal criterion, including at least one of following items: per partum or neonatal death defined as death within 28 days after birth, hypoxic ischemic encephalopathy defined as cerebral anomalies due to neonatal asphyxia (umbilical pH < 7.0), Apgar score less than 4 at 5 min, endotracheal tube for more than 24h within 72h after birth, or a proven neonatal sepsis defined as a positive hemoculture in the absence of any other recognized etiology.
The secondary endpoint was the occurrence of uterine rupture.

Neonatal medical records were reviewed individually and completely for newborn’s death, admitted to the NICU or neonatology unit.

We compared the characteristics of two groups based on Pearson's x2 test or Fisher exact test for categorical variables, and Student t-test or Wilcoxon-Mann-Whitney test for quantitative variables, as appropriate. Statistical significance was set at a two-tailed value of P.05. The association between pelvic dimension at pelvimetry and severe neonatal morbidity was analyzed with multivariable logistic regression. Causal assumptions between pelvic dimension at pelvimetry, severe neonatal morbidity, and covariates were represented with a directed acyclic graph to depict the exposure-outcome relations with confounding and intermediate factors (data not shown) for helping to select variables that are confounders (ie, variables associated with both the exposure and the outcome) and those that do not qualify as confounders (especially intermediate factors) [15]. The main regression model included only the strict confounder: intra uterine growth restriction (IUGR).

The analyses were performed with Stata software version 13.0.

This database was approved by the National Data Protection Authority (Commission Nationale de l'Informatique et des Libertes, CNIL no. 293683). Under French regulations, this study was exempt from Institutional Review Board approval because it was an observational study using anonymized data from medical records. Women were informed that their records could be used for the evaluation of medical practices and were allowed to opt out of these studies.

Results :

This study included 3083 women with a previous cesarean and with alive singleton in cephalic presentation at or after 37 gestational age (GA). We excluded 54 (1.7%) women with a fetus with a congenital malformation and 208 (6.7%) with planned cesarean delivery. Data

for pelvimetry were missing for 270 (8.7%) women, and neonatal data were missing for 77 (2.5%) newborn (Figure 2). Thus, 2474 women were included in this analysis.

Among included women, 1611 (65%) having a normal pelvic dimension at pelvimetry and 863 (35%) an abnormal dimension. Transverse diameter was less than 12 cm for 771 (31,2%) women, whose 418 (16,9%) with a transverse diameter less than 11,5 cm. Conjugate diameter was less than 10,5cm for 252 (10,2%) women, whose 70 (2,8%) with a conjugate diameter less than 10 cm. Among women with abnormal dimension, 160/863 (18.5%) women had both a transverse diameter < 12 and a conjugate diameter <10.5.

Compared with women with normal pelvic dimension at pelvimetry, women with abnormal pelvic dimension were more statistically younger (32.9 years vs 33.5 years; p = 0.01) and have less weight gain during pregnancy (10.3 kg vs 11.2 kg; p < 0.01), without these differences were clinically pertinent. There was no difference between the two groups for body mass index and parity.

Compared with women with normal pelvic dimension at pelvimetry, women with abnormal pelvic dimension have less previous vaginal birth after cesarean delivery (23.4% vs 28.6%; p < 0.01), more gestational hypertensive pathology (5% vs 3%; p = 0.01) and more suspected IUGR (1.6% vs 0.7% p=0.02) (Table 1).

No significant difference was found between the two groups regarding delivery term, onset of labor, methods of labor induction, analgesia, duration of labor and use of oxytocin during labor (Table 2).

Compared with women with normal pelvic dimension at pelvimetry, women with abnormal pelvic dimension have more cesarean delivery during labor (35.3% vs 15.2%; p < 0.01).

The rate of abnormal fetal heart rate (FHR), requiring cesarean delivery or instrumental delivery, was higher in abnormal pelvic dimension group.

No significant difference was found between the two groups regarding uterine dehiscence, uterine rupture, and postpartum hemorrhage. There was no maternal death.

In abnormal pelvic dimension at pelvimetry group, 8 uterine ruptures occurs (0.8%). In normal pelvic dimension at pelvimetry group, 10 uterine ruptures occurs (0.6%). Among the 18 uterine ruptures, 16 had an emergency cesarean for suspected uterine rupture and two had instrumental vaginal delivery for abnormal FHR and the diagnostic of uterine rupture was realized during the manual uterine examination and was required a surgery for post partum hemorrhage.

Neonatal morbidity was similar between the two groups (2.3% versus 1.7%, p = 0.26; crude OR : 1.39 (0.77-2.49) ; adjusted OR: 0.93 (0.51-1.68)) (Table 4).

In abnormal pelvic dimension at pelvimetry group, one neonatal death occurs due to hypoxic ischemic encephalopathy within 2 days after birth. It was an emergency cesarean delivery due to uterine rupture. In normal pelvic dimension at pelvimetry group, one neonatal death occurs due to hypoxic ischemic encephalopathy after cardiac failure (dilated cardiomyopathy). It was not detected on antenatal sonography. In the same group, the second cases with hypoxic ischemic encephalopathy was due to respiratory distress (endotracheal tube for more than 24h within 72h after birth) after an emergency cesarean for uterine rupture.

Discussion :

Based on this population of women with trial of labor after one previous cesarean delivery, we showed that abnormal pelvic dimension at pelvimetry was not associated with an increased neonatal morbidity.

Our study has some strenghts. Data were valid and exhaustive because they were collected prospectively through computer software used by all medical staff and verified every morning during collegial meeting, and for severe events such as uterine rupture, and neonatal morbidity, all medical record were analyzed. We used a severe composite neonatal criteria approved in many studies [16,17]. This primary outcome is pragmatic and logical, and it has good external validity. Due to the unicentric characteristic of this study, obstetrical practices were uniform in the management of patients during labor, for prenatal care and for the decision of cesarean.

Extrapolation of our results is limited since the study was conducted in a single center, realizing more than three thousands of delivery by year with a cesarean delivery rate lower than nationally rate. A limitation of this study was the pelvimetry cut-off value to define "abnormal pelvic". These cut-offs, although in common use, may have some limitations. Their determinations are old, and little documented. With stricter limit value, we would have decrease number of cases, and decrease study strength. Nevertheless it was pelvimetry cut-off value frequently used in French maternity [18].

The approach of this study was descriptive for having pragmatic results, and not explicative. Some hypothesis could have suggested a negative impact on neonatal outcomes of abnormal pelvic dimension. Duration of labor more longer, abnormal FHR more frequent and

instrumental vaginal delivery more complex are feared in case of trial of labor and abnormal pelvic dimension, with in case of obstetrical complications, a possible neonatal resounding. This was not found in our study not showing any difference in neonatal outcome according to pelvic dimension. It was an original result because it is the first study analyzing the association between dimension of pelvis and neonatal morbidity. Previously, some studies analyzed maternal outcomes (like uterine rupture) and obstetrical outcomes (like the rate of cesarean delivery) in case of TOLAC. An impact of pelvic dimension on neonatal morbidity would have been interesting to adapt pediatric management at the birth and prevent some critical situations.

Although the neonatal morbidity was similar in two groups of pelvic dimension, we found more abnormal FHR in abnormal pelvic dimension group. This could be explained by a different fetal head compression during its confrontation with the maternal pelvis during uterine contractions and expulsive efforts. Despite this abnormal FHR, neonatal morbidity was similar. It is possible that this is due to increased vigilance of the team who intervene quickly during labor for abnormal FHR or arrest of cervical dilatation, because of the knowledge of the pelvic dimension.

In accordance with literature, we showed that cesarean delivery rate was higher in case of abnormal pelvic dimension [13,19]. Due to the observational design of this study, an indication bias could not be excluded and explained this increased rate of cesarean delivery in the group of women with abnormal pelvic dimension. Indeed, all practitioners know the pelvic dimension, which may have influenced their decisions to realize a cesarean delivery for less strict indications in abnormal pelvic dimension group. However, global cesarean delivery rate in our study (22%) was lower than many studies (from 20 to 40%) [7,9]. It is fair to

confirm, in accordance with French guidelines, that pelvimetry should not have to use in planning mode of delivery. Thus the practice of pelvimetry does not necessarily cause an increased rate of cesarean delivery. The practice of such a complementary examination must be considered and the results adapted. The fear of increasing the rate of cesarean delivery because of the only realization of the pelvimetry does not seem to justify and is questioned.

The rate of uterine rupture was low (0.7%), similar with results of literature [20,21]. In this study, uterine rupture was not associated with pelvic dimension, but it was not the main endpoint and the power of this study is smaller to highlight a difference concerning the occurrence of such a rare event.

In conclusion, there was no association between pelvic dimension at pelvimetry and neonatal morbidity. This result does not question the recommendation on the pelvimetry for women with previous cesarean delivery, and obstetrical team realizing pelvimetry for this indication will probably continue its practice. For women with abnormal pelvic dimension, a combination of more prudence, and stringent user practices, can allow to achieve a high rate of vaginal delivery and a neonatal morbidity comparable to the normal pelvic dimension group. A further study, on the specific contribution of pelvimetry in the management of labor in case of TOLAC, cannot be conducted by a retrospective design, should be conducted prospectively.

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Authors contribution: NR contributions were the acquisition of data, analysis and interpretation of data, drafting the article and final approval of the version to be submitted.

DK contributions were the conception and design of the study, analysis and interpretation of data, drafting the article and final approval of the version to be submitted. CM contributions were the analysis and interpretation of data, revising the article critically for important intellectual content, and final approval of the version to be submitted. OS contributions were the conception and design of the study, analysis and interpretation of data, revising the article critically for important intellectual content, and final approval of the version to be submitted.

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338 **Figure 1 : Flow Chart**

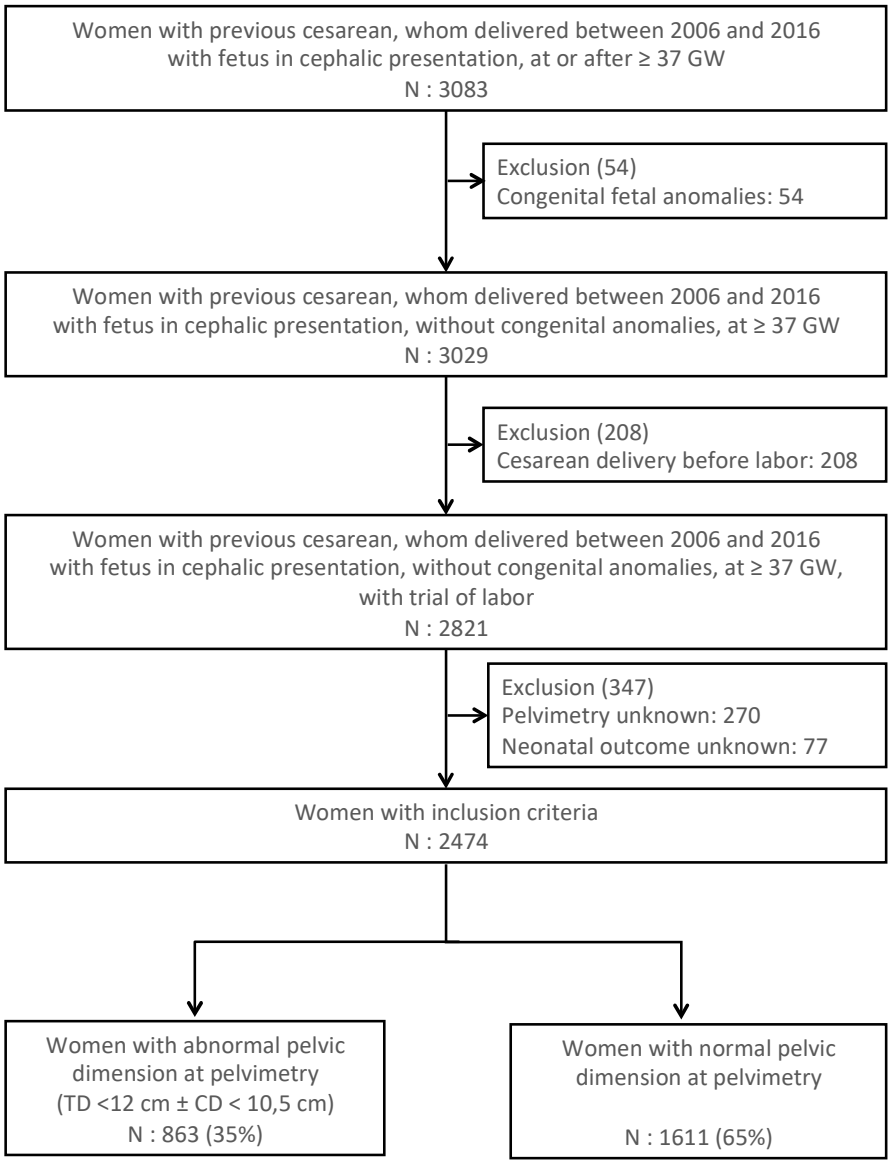


Table 1: Maternal and obstetrical characteristics

	Abnormal pelvic dimension at pelvimetry n=863 N (%)	Normal pelvic dimension at pelvimetry n=1611 N (%)	p
Maternal age (mean ± SD)	32.9 ± 5.1	33.5 ± 5	0.01
< 30	252 (29.2)	426 (26.4)	0.04
(30-39)	546 (63.3)	1019(63.3)	
≥ 40	65 (7.5)	166 (10.3)	
Body mass index	25.4±5.3	25.2±5.37	0.24
< 18.5	37 (4.3)	89 (5.5)	
(18.5-24)	363 (42.1)	696 (43.2)	
(25-29)	248 (28.6)	431 (26.8)	
≥ 30	151 (17.5)	295 (18.3)	
Weight gain (mean ± SD)	10.3±6.1	11.2±5.9	< 0.01
Previous medical conditions			
Hypertensive pathology	30 (3.5)	55 (3.4)	0.93
Preexisting diabetes at pregnancy	13 (1.5)	29 (1.8)	0.59
Parity			0.59
2	512 (60.0)	929 (58.0)	
≥ 3	351 (40.0)	682 (42.0)	
Previous pregnancy-related disease			
Gestational hypertensive pathology	64 (7.0)	141 (9.0)	0.25
Gestational diabetes	53 (6.1)	112 (7.0)	0.44
Shoulder dystocia	24 (2.8)	29 (1.8)	0.10
Vaginal delivery after cesarean delivery	202 (23.4)	460 (28.6)	0.006
Pregnancy-related disease			
Gestational hypertensive pathology	46 (5.0)	52 (3.0)	0.01
Gestational diabetes	70 (8.1)	120 (7.4)	0.55
Preterm labour	22 (2.5)	44 (2.7)	0.79
Premature ruptur of membranes	3 (0.3)	2 (0.1)	0.23
Suspected IUGR	14 (1.6)	11 (0.7)	0.02

SD : standard deviation

369 **Table 2: Labor characteristics**

	Abnormal pelvic dimension at pelvimetry n = 863 N (%)	Normal pelvic dimension at pelvimetry n = 1611 N (%)	p
Gestational age at delivery			0.11
(37-38)	155 (18.0)	303 (18.8)	
(39-40)	525 (60.8)	911 (56.5)	
41	156 (18.1)	324 (20.1)	
≥ 42	27 (3.1)	73 (4.5)	
Spontaneous labour	656 (76.0)	1199 (74.4)	0.38
Induced labour	207 (24.0)	412 (25.6)	
Ocytocine	57 (27.0)	94 (23.0)	0.15
Intracervical prostaglandin	150 (73.0)	318 (77.0)	
Intracervical prostaglandin and misoprostol	9 (7.0)	48 (15.0)	0.08
Peridural analgesia	785 (91.0)	1434 (89)	0.12
Artificial rupture of membranes	432 (50.1)	797 (49.5)	0.37
Labour duration (min) (mean ± SD)	380 ± 216	369 ± 208	0.28
Median (Q1-Q3)	374 (223-516)	350 (287-507.5)	
Use of ocytocine	516 (59.8)	948 (58.8)	0.80
Max dose (median (Q1-Q3))	40 (20-60)	40 (20-50)	0.75
Duration (min) mean+/-SD	51 ±100	45 ±103	0.17
Arrest of labour	145 (16.8)	286(17.8)	0.55
Clinical estimated fetal weight (mean ± SD)	3374 ± 369	3393 ± 384	0.23

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Table 3: Delivery characteristics

	Abnormal pelvic dimension at pelvimetry n = 863 N (%)	Normal pelvic dimension at pelvimetry n = 1611 N (%)	p
Mode of delivery			<0.001
Cesarean	305 (35.3)	245 (15.2)	
Vaginal delivery	558 (64.7)	1366 (84.8)	
Cesarean			0.26
Indication			
Fetal*	118 (38.6)	107 (43.6)	
Maternal**	6 (0.6)	8 (3.4)	
Obstetrical***	181 (59.3)	130 (53.0)	
Vaginal delivery			
Spontaneous	366 (66.0)	905 (66.0)	0.97
Instrumental	192 (34.0)	461 (34.0)	
Indication			<0.001
FHR anormalies	142 (74.0)	260 (57.0)	
Default of progression	50 (26.0)	201 (43.0)	
Shoulder dystocia	10 (1.2)	8 (0.5)	0.06
Uterine scar			
Dehiscence scar	20 (2.3)	40 (2.5)	0.79
Uterine rupture	8 (0.9)	10 (0.6)	0.24
Postpartum hemorhage	48 (5.0)	90 (5.0)	0.37
Embolization	0	1 (0.1)	
Hysterectomy	0	0	
Ligature	0	1 (0.1)	
Transfusion	10 (1.2)	16 (1.0)	
Sulprostone	28 (3.2)	63 (4.0)	
Capitonnage	0	3 (0.2)	
Bakri balloon	0	2(0.1)	

*abnormal FHR

**preeclampsia, HELLP syndrom

***arrest of labor, failure of induced labor

Table 4: Neonatal outcomes

	Abnormal pelvic dimension at pelvimetry n=863 N (%)	Normal pelvic dimension at pelvimetry n=1611 N (%)	p	OR	aOR*
Composite criteria	**20 (2.3)**	**27 (1.7)**	**0.26**	1.39 (0.77-2.49)	0.93 (0.51-1.68)
Neonatal death	1 (0.1)	1 (0.1)	0.65		
Hypoxic ischemic Encéphalopathy	2 (0.2)	1 (0.1)	0.25		
5-min Apgar score < 4	6 (0.7)	4 (0.2)	0.09		
Materno-fetal infection	6 (0.7)	14 (0.9)	0.64		
Intubation > 24H	10 (1.2)	10 (0.7)	0.15		
umbilical pH < 7.10	40 (4.6)	29 (1.8)	< 0.001		
umbilical pH < 7.0	10 (1.2)	8 (0.5)	0.16		
Birth weight in grams (mean±SD)	3322±428	3460±498	< 0.001		
<2500 grams	26 (3.0)	43 (2.7)	0.62		
≥ 4500 grams	3 (0.3)	32 (2.0)	0.001		

*adjusted for IUGR