Childbirth simulation to assess cephalopelvic dystocia and chances for failed labor

Olivier Ami (olivier.ami@birthimaging.com)
Ramsay Generale de Sante, Clinique de La Muette, Paris

Jean Christophe Maran
University of Clermont Auvergne

Albert Cohen
Réseau d'Imagerie Paris Nord, Paris

Dr Israel Hendler
Sheba Hospital in Tel Aviv

Eric Zabukovec
Clinique de l'Estrée, Stains

Louis Boyer
Centre Hospitalier Universitaire de Clermont-Ferrand

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Abstract

Objectives: Reducing the rate of failed labor and emergency caesarean section is of vital significance. A childbirth simulation software tool based on 5 minutes' magnetic resonance imaging (MRI) performed at 37 weeks' gestation, used to enhance the consulting obstetrician's ability to predict the optimal delivery mode. Here, we aimed to analyze the predictive ability of this childbirth simulation software tool for choosing the optimal delivery mode compared with not using it. Methods: A retrospective cohort study was performed on 401 patients referred by their obstetrician for MRI pelvimetry at approximately 37 weeks of gestation between December 15, 2015 and December 15, 2016. We employed a childbirth simulation software to predict the optimal delivery mode. Those results were compared with results from the actual delivery mode. Results: The rate of emergency caesarean sections, inappropriately scheduled caesarean sections, and instrumental vaginal deliveries would have been reduced by 30·1%, 20·7%, and 20%, respectively, had the predictions from the childbirth simulation software been considered. The use of the childbirth simulation software did not significantly affect the overall caesarean section rate, but it improved the allocation between scheduled and emergency caesarean sections. Conclusions: The routine use of the childbirth simulation software as a clinical support tool for choosing the optimal delivery mode of singleton pregnancies with a cephalic presentation could reduce the number of emergency caesarean sections, insufficiently justified Caesarean sections, and instrumental deliveries.

Introduction

One of the major challenges in modern obstetrics is the accurate assessment of cephalopelvic disproportion (CPD)-related emergency deliveries in terms of clinical decision-making[1,2] with regard to the optimal delivery mode. These include the use of emergency cesarean section (ECS) and instrumental vaginal delivery (IVD).[3] A low-risk pregnancy follow-up does not guarantee a normal delivery (ND), and the delivery outcomes can be uncertain.[4] Many of these uncertain outcomes are related to CPD, which can lead to excessive fetal skull molding in order to allow the head to move into the birth canal.[5]

The value of 3D MRI assessment using 3D finite elements mesh reconstruction during the second stage of labor was demonstrated to reveal how the fetal brain is impacted by the molding of the cranial bones in a previous work[6]. The observations made on the modeling capabilities of the fetal head and brain during the second stage helped to develop a virtual trial of labor that can detect and prevent biomechanical risks linked to childbirth[6].

The time required for the head-molding process depends on the biomechanical compliance of the fetal head and can generate pressure on the fetal brain. The less malleable the skull, the slower the labor and delivery can become,[7,8] leading to a situation in which uterine cervix dilation ceases, and an IVD or ECS is required. Conversely, the more pliable the skull, the stronger the pressure exerted directly on the fetal brain,[9,10] even when the delivery is rapid. Sparse data exist in regard to the effect on the newborn's brain

of these cerebral pressure phenomena occurring at delivery, especially if intense and/or prolonged, both in terms of bleeding[11,12] and ischemia.[13]

To our current knowledge, no specific tools have been employed, to date, to effectively predict or negate the need for CPD-related ECS or IVD[14] prior to the start of labor. Only imprecise assessment methods are available, such as those based on pelvimetry with imaging,[15] clinical examination, simple CPD indices,[16,17] and transperineal ultrasound imaging during labor.[18] Radiopelvimetry,[19] pelvic computed tomography,[20] and MRI pelvimetry[21] have been routinely performed worldwide for decades without identified biological risks for fetuses under usual clinical practice conditions.

Recent evidence has shown that measuring the pelvis alone does not effectively predict the occurrence of CPD.[22–24] Some pelvises that appear small allow spontaneous deliveries, whereas others considered normal or large can undergo severe CPD.[15,24] Using the criterion of pelvis size alone is also generally recognized as insufficient for choosing the optimal delivery mode in women whose fetus has a cephalic presentation and an unfavorable Magnin index of 22 or less.[25,26] In addition, given that fetal ultrasound biometry has a margin of error of 10% to 40%, depending on the clinical situation, fetal biometrics are not sufficiently accurate to justify relying on their use alone.[27]

Despite the absence of clinical practice guidelines provided by professional societies due to insufficient evidence regarding the effectiveness of pelvimetry, approximately 10% of pregnant women in France undergo the procedure.[28] Criteria for the reliable assessment of CPD-related traumatic delivery risks do not exist, and many ECSs and IVDs currently cannot be predicted.[29]

Without a reliable tool for the prediction of the optimal delivery mode, obstetricians are frequently left with their experience and gut feeling as the only tools to support their choice for the most appropriate delivery mode, with wide margins of error. Thus, many women who fail to deliver normally experience traumatic deliveries; on the other hand, many unnecessary scheduled cesarean sections (SCSs) are being performed.

Here, we present a retrospective study on the use of PREDIBIRTH™ childbirth simulation software (Babyprogress®) using MRI pelvimetry performed at 37 weeks of gestational age (WGA) to determine the software's ability to detect CPD and to prevent or reduce biomechanical risks during labor. The PREDIBIRTH™ software was accessible on SAAS mode through a platform called SIM37™.

The objective of this paper is therefore to determine whether the PREDIBIRTH™ tool has any value in assisting with the decision-making process for a tailored mode of birth for the newborn and the mother.

Materials And Methods

We conducted a retrospective observational study by analyzing MRI results of 401 patients from the Northern Paris Imaging Network (RIPN, *Réseau d'Imagerie Paris Nord*). These patients had been referred

by their obstetrician for MRI pelvimetry at approximately the 37th WGA. MRI examinations have replaced pelvic CT scans because they prevent pregnant women from being exposed to radiations, in compliance with the recommendations of the Council Directive 97/43/EURATOM, Ordinance 2001-270 of March 28, 2001.

Patient data files were the subject of an MR 003 procedure with the National Commission for Informatics and Freedoms (CNIL, *Commission Nationale de l'Informatique et des Libertés*) and database declared to CNIL under number 2099722v0. The patients were informed of the anonymous use of their data. According to current French regulations, written consent to participate in an anonymous retrospective study is not required.

Key inclusion criteria were that the patient had undergone an MRI between 36 and 38 weeks of gestation, with no obstetric complication, a cephalic fetal presentation, and a singleton pregnancy. The exclusion criteria were nonvertex presentation, a multiple pregnancy, being under the age of 18, having a protected adult status and a lack of verbal consent.

The MRI procedures were performed between December 15, 2015 and December 15, 2016. The images acquired enabled the visualization of the fetus and the maternal pelvis. No patients were injected with a contrast agent for this examination. Furthermore, none of the study patients experienced MRI-related adverse events. The Philips Ingenia 1.5T MRI system (Philips, Netherlands) was employed to perform a 3D T1 single-shot Balanced Fast Field Echo sequence (E-Thrive, Philips) without fat saturation and with the following parameters: echo time, 1·85 ms; repetition time, 3·70 ms; slice thickness, 2·5 mm; number of signal averages 1; matrix, 140x167 pixels; angle, 50°; turbo field echo factor, 82; 172 contiguous slices; size of the acquisition voxel, 2·5x2·5x2·5 mm^3; and the size of the reconstructed voxel, 1·37x1·37x2·5 mm^3. The sequences lasted a mean of 72 seconds, and the examinations lasted a maximum of 5 minutes.

A pelvimetry was performed by the radiologist team. The Magnin index was calculated by adding the obstetric conjugate diameter to the median transverse diameter.

A childbirth simulation was performed using PREDIBIRTH™, software making it possible to produce a Simulated Trial Of Labor (STOL) score, which assists in the decision-making process. The maximum (greatest risk) score is 8 points, with each criterion's interpretation and proposed decision in line with the guidelines of current obstetric practice.

The data were analyzed in two ways. We first grouped the STOL scores into three classes of different clinical situations; from 1 to 3, patients were classified as "favorable", representative of high probability for a successful normal vaginal delivery; from 4 to 6, patients were classified as "neutral", representative of a medium probability for successful spontaneous delivery and a higher need for instrumental delivery; and patients with scores of 7 and 8 were the "unfavorable" class, representative of CPD and better addressed by SCS. Marginal means were then calculated for this model and compared by using Tukey's honest significant difference (HSD) test. We also analyzed clinical outcomes versus STOL scores as a

continuous variable. We tested pairwise differences of slopes (the effect of STOL) on the probabilities of decisions by the nonparametric bootstrap of differences. In both cases, models were constructed by multinomial logistic regression with the R nnet library.[30]

Statistical analyses were performed using R software packages (R Core Team, 2017, Vienna, Austria; https://www.R-project.org/).[31] The figures showing our results were created using Microsoft Excel, R package ggplot2,[32] and VCD[33] (R package version 1.4-4).[34]

Results

The study population's baseline characteristics are shown in Table 1. The mean patient age was 30·6 years (±4·3 SD), with no Apgar score less than 7; the mean latency from MRI to childbirth was 16 days (±7·0 SD).

Of the 401 patients referred for pelvimetry examinations, 87 (21·7%) underwent SCS, and 314 (78·3%) had a trial of labor (TOL) based on physician consultation. Of the women who had a TOL, 183 (45·6% of the total study population and 58.3% of the TOL population, respectively) had a ND, 53 underwent an IVD (13·2% of the total study population and 16.9% of the TOL population, respectively), and 78 (19·5% of the total study population and 24.8% of the TOL population, respectively) underwent an ECS. The total cesarean section (CS) rate, including SCS and ECS, was 41·1% (n=165).

According to the theoretical predictions based on the STOL scores, 125 patients (31·2%) had an unfavorable score, 101 (25·2%) had a neutral score, and 175 (43·6%) had a favorable score.

A total of 45 patients (36%) in the unfavorable STOL group and 27 patients (52%) in the ECS group had a Magnin index greater than 23 (Table 2). In the SCS group, 38 patients (44%) had a Magnin index less than 23, and none had a favorable STOL score.

In the SCS group, 47% were scheduled for CS due to uterine scarring, 30% were scheduled due to a history of traumatic childbirth, and 23% were scheduled due to other causes. The proportion of patients with a Magnin index less than 22 was 19% in the ECS group, 1% in the ND group, and 5% in the IVD group.

Considering the entire study population, a total of 183 patients (45·6%) gave birth normally, 108 (59·0%) of whom had a STOL indicating a favorable.

Some 48 patients (55·2%) scheduled for CS had an unfavorable STOL score, which predicted CPD and reinforced the observed relevant indications for these cases, whereas 18 (20·7%) had a favorable STOL score, and 21 patients (24·3%) had a neutral STOL score.

We performed multinomial logistic regression followed by estimated marginal means to test potential relationships between STOL categories ("favorable", "neutral", "unfavorable") and delivery outcomes

(Figure 1A). The ANOVA of the model was significant ($X2(10) = 89·512$; $p < 0·001$). When testing the marginal means, making use of Tukey's HSD test adjusted for $p \leq 0·05$, we found that, for STOL class "favorable", the significantly most common outcome was ND, whereas all other outcomes did not significantly differ among themselves in terms of frequency. The "unfavorable" category was also statistically divided into two groups. One group with higher probabilities consisted of ND, SCS, and CPD-related ECS (rECS), with the remaining outcomes grouped together. Finally, the "neutral" category had a more complex relationship with the outcomes. The overall trends appeared to show an inverse association between STOL and ND and a direct association between STOL, SCS, and rECS. Thus, an increased STOL score leads to a decreased ND rate and to an increased rate of SCS and rECS.

To explicitly test these relationships, we also modelled the outcomes versus STOL score as a continuous variable (Figure 1B). The predicted probabilities at each score illustrated changes in the outcome probabilities, given the STOL score ranged from 1 (more low-risk delivery) to 8 (less low-risk delivery). This model allowed us to compare slopes of the outcome probabilities versus increasing STOL scores. Bootstrap testing of pairwise differences again revealed two groups. As the STOL increased, the probability of SCS and rECS increased significantly. The remaining group consisted of all other outcomes, all of which had reduced probability as STOL increased.

Following the PREDIBIRTH recommendations would have led to 276 TOLs, including 54 patients who would have undergone ECS (13·5% of the total study population and 19·5% of the TOL population, respectively). The number of ECSs and rECSs would therefore have been reduced by 30·8% and 46.1%, respectively. Furthermore, following the PREDIBIRTH recommendations would have seen 179 patients undergoing CS (44·6% of the total study population), of which 125 would have undergone SCS (31·2% of the total study population) with the other 54 having undergone ECS as already mentioned above. This proportion of 44·6% does not differ significantly from the value of 41·1% of CS deliveries that occurred (179 versus 165). However, 13·5% of the total number of deliveries would have been by ECS (30·2% of CSs) and 31·2% would have been by SCS (69·8% of CSs), compared with the actual ECS and SCS rates of 19·5% (47·2% of CSs) and 21·7% (52·7% of CSs), respectively.

In summary, had PREDIBIRTH been employed systematically, the overall CS rate would have been comparable; however, instead of an ECS rate of 47·2% and an SCS rate of 52·7% of all the CSs, the rates would have been 30·1% and 69·8%, respectively. In terms of proportions of total deliveries, this would have led to fewer ECSs (54 versus 78) but more SCSs (125 versus 87).

Discussion

Currently, the main application of childbirth simulation is to train medical professionals.[35,36] To the knowledge of the authors, we offer a novel 3D simulation software tool to detect CPD and support clinical decisions on the optimal route of delivery. The use of such tools will reduce the numbers of unnecessary scheduled CSs, ECSs, and traumatic childbirths.

The STOL score generated by PREDIBIRTH is simple to use and helps classify patients into three delivery categories: favorable for a low-risk delivery (score of 1, 2 or 3); neutral requiring a physician to be in attendance and increased risk for instrumental delivery (score of 4, 5 or 6); and unfavorable that might be complicated by CPD or likely brain compression (score of 7 or 8), hence mandating a SCS as a possible alternative to vaginal delivery.

Many of the patients in the ECS group had CPD, which the PREDIBIRTH test can detect, thereby confirming that the smaller the pelvis, the more likely CPD is to be present. However, the PREDIBIRTH tests demonstrated that pelvis size is not the only criterion and that only by simulating the movement of the fetal head into the maternal pelvis using 3D simulation software is it possible to assess more accurately the risk level of childbirth.

The vast majority of traumatic deliveries in obstetrics are related to CPD, which can result in increased postpartum bleeding,[37,38] urinary incontinence,[39] fecal incontinence,[40] pelvic prolapse,[41] obstetric fistulas,[42] risk to the infant's brain, [43] and risk to the mother's perineum.[44] CPD can result in a negative and traumatic experience for families, with difficulty in the bonding between mother and child during the first hours of the newborn's life. When an emergency occurs during labor that subsequently leads to an IVD or ECS, the delivery might be perceived as a failure, with significant trauma inflicted upon the mothers[45] and their families.

ECS deliveries lead to morbidity and mortality rates up to 7 times higher than that associated with a CS scheduled prior to labor,[46] demonstrating the critical need for the early classifying of patients prior to labor. The detection and prevention of CPD has the potential to optimize the organization of services and patient flow management.

Based on our analysis and considering the distribution of vaginal delivery failures in our population, the ECS rate would have been reduced by 30·8% (by 46·1% if we only consider rECS), the SCS rate would have increased by 43·7%, and the rate of inappropriately scheduled CSs would be reduced by 20·7%, had the STOL score recommendations been employed, without changing the total rate of CSs. Using STOL therefore enables obstetricians to better select the appropriate patients for SCS.

IVDs could not be definitively predicted, but the possibility of an IVD could be determined with the PREDIBIRTH test. IVDs in the upper inlet are no longer recommended in most countries.[47] However, IVDs performed when the infant's head is low enough can help to speed up the second phase of labor, thereby accelerating the birth to a greater degree than ECS. It is, therefore, not surprising that the IVD group had few unfavorable STOL scores.

For excessively long labors, in which the infant's brain is at significant risk, forceps can help to protect the brain while extracting the infant more quickly during the second phase of labor.[48] However, instrumental extractions are also associated with greater maternal perineal trauma.[49]

Future versions of the PREDIBIRTH software will include recent observations made on the maternal urogenital sinus changes during the second phase of labor with MRI[50], and it will evaluate the levator ani stretching when the fetal head molding has been intense.

Over the past two decades of use, evidence supports that performing an MRI at 37 weeks of pregnancy results in less radiation exposure compared with X-rays and is safe for the mother and the fetus.[51] Having no requirement for a contrast agent is also an asset when employing this technology, avoiding both the risk of maternal allergy and fetal teratogenicity.[52]

There are limitations to this study. It was a retrospective, population-based study of the radio pelvimetry indications requested by practitioners. Hence, this patient group had a bias towards a higher rate of significant CPD risk, which explains the high observed CS rate. It is therefore not representative of the general population of France, where the official national CS rate is approximately 21%, compared with the rate of 41·1% observed in the population studied in this work.

Inescapably, we do not know what the outcome would have been for the SCS group if SCS had not been performed. The STOL score provided useful information to determine whether women scheduled for CS, based solely on the criterion of pelvis size, might otherwise undergo a TOL to determine their actual need for such a procedure.

Prospective studies with a larger, more diverse populations, are therefore necessary to clarify the real impact of PREDIBIRTH as a decision support tool for the delivery management guidance after the 37th week of gestation.

Conclusions

A simple 5-minute MRI performed at 37 weeks of pregnancy analyzed by the PREDIBIRTH childbirth simulation software tool can enhance the choice of the optimal mode of delivery for pregnant mothers and can reduce the number of inappropriately scheduled CSs, ECSs, and traumatic deliveries.

Future prospective studies in this field are necessary to ensure future births occur under the best conditions of safety for the mother and child. Such studies would require a much larger and diverse population set to ascertain the potential extent of the usefulness of this tool in obstetrics decision making.

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Tables

Table 1. Study population characteristics.

	Patient age, years	Foetal weight at birth, g	Time from MRI to childbirth, days	Apgar score at 1 min	Apgar score at 5 min	MT*	PRP*	BS*	Magnin Score	BIP*	HC*
Mean	30·7	3371·5	16·0	9·7	9·9	12·3	11·7	10·7	24	9·7	34·1
Median	31·0	3350·0	15·0	10·0	10·0	12·3	11·7	10·7	24	9·7	34·1
5th percentile	22	2726·5	3	8	9	10·9	10	9·1	20·9	9	32·1
95th percentile	40	4173·5	30	10	10	13·7	13·4	12·3	27·1	10·4	36·6

*in centimetres

Abbreviations: MT, median transverse diameter; PRP, promontory-retropubic diameter; BS, bisciatic diameter; BIP, biparietal diameter; HC, head circumference.

Table 2. STOL score based on delivery route.

STOL score	Delivery Route						TOTAL
	SCS	ND	rIVD	uIVD	rECS	uECS	
1-3	4·5%	26·9%	3·7%	2·2%	1·5%	4·7%	43·6%
4-6	5·2%	10·7%	3·0%	1·2%	4·0%	1·0%	25·2%
7-8	12·0%	8·0%	2·5%	0·5%	7·5%	0·7%	31·2%
TOTAL	21·7%	45·6%	9·2%	4·0%	13·0%	6·5%	100·0%

Abbreviations: CPD, cephalopelvic disproportion; ECS, emergency caesarean section; IVD, instrumental vaginal delivery; SCS, scheduled caesarean section; rIVD, CPD-related IVD; uID, CPD-unrelated IVD; rECS = CPD-related ECS; uECS, CPD-unrelated ECS; STOL, simulated trial of labour; ND, normal delivery.

Declarations

Compliance with ethical standards:

Guarantor:

The scientific guarantor of this publication is Professor Louis Boyer.

Conflict of interest:

Dr Olivier Ami has received compensation as inventor of the PREDIBIRTH software and owns stock in the Babyprogress company and intellectual property part. Dr Eric Zabukovec and Dr Albert cohen own stock in the Babyprogress company. Dr Israel Hendler, Prof. Louis Boyer and Jean Christophe Maran declare no potential conflict of interest.

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Statistics and biometry:

One of the authors has significant statistical expertise.

Informed consent:

Written informed consent was not required for this study because it was a retrospective study.

Ethical approval:

Institutional Review Board approval was not required because it was a retrospective study.

Methodology:

- retrospective
- observational
- performed at one institution

Abbreviations And Acronyms

3D: three dimensional

BIP: biparietal diameter

BS: bisciatic diameter

CPD: cephalopelvic disproportion

CS: cesarean section

ECS: emergency cesarean section

HSD: honest significant difference

IVD: instrumental vaginal delivery

MT: median transverse diameter

ND: normal delivery

PRP: promontory-retropubic diameter

rECS: CDP-related ECS

rIVD: CDP-related IVD

SCS: scheduled cesarean section

STOL: simulated trial of labor

TOL: trial of labor

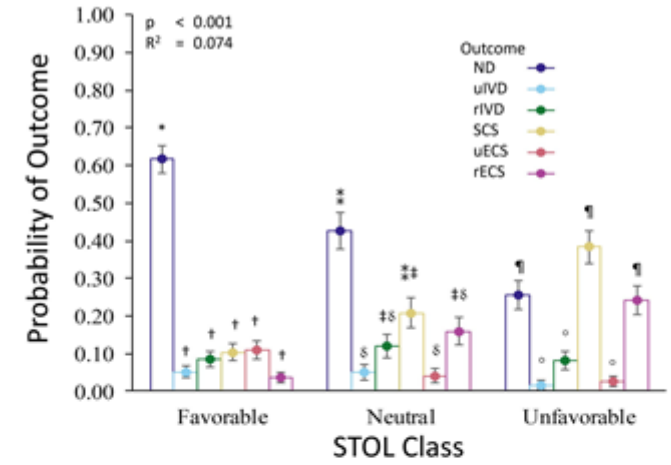
uECS: CPD-unrelated ECS

uIVD: CPD-unrelated IVD

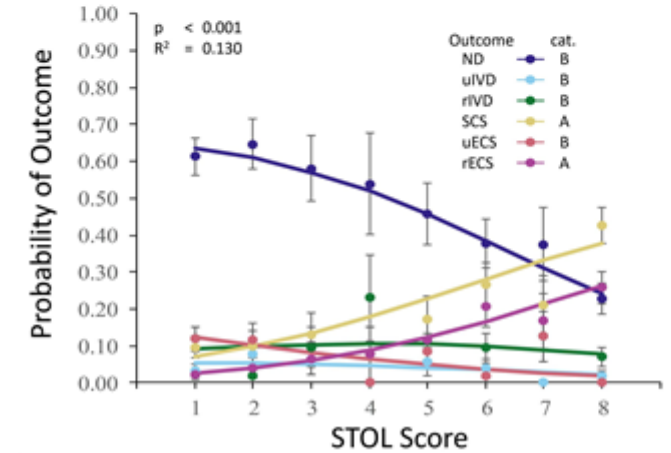
WGA: week of gestational age

HC: head circumference

Figures



a. STOL category versus outcomes



b. STOL Score vs. Outcomes

Figure 1

STOL models versus labor outcomes. We modelled the STOL categories ("favorable", "neutral", "unfavorable") and STOL score versus different birth outcomes by multinomial logistic models. R2 values are adjusted McFadden pseudo-R2s. (A) STOL categories versus outcomes. The columns represent the probabilities of each outcome versus STOL category. Error bars are standard errors calculated for ratios/probabilities. The symbols above each column indicate the degree of statistical difference of probabilities within a category (marginal means). Two outcomes that share a symbol do not significantly differ within that category. Specifically: Favorable has two statistical groups (*, †); neutral has three overlapping groups (▯, ‡, ▯); and unfavorable has two groups (¶, °). Comparisons were not made between categories. (B) STOL scores versus outcomes. The lines represent predicted probabilities of outcomes treating STOL as a continuous variable. Models of logistic, linear predictor slopes were compared by bootstrap of pairwise differences. SCS and rECS significantly increased with STOL scores versus all other outcomes, indicated as "A" vs. "B". Slopes were transformed from the model (logit) to the response scale (probability) for the figure. Points are measured outcome probabilities and error bars are standard errors for ratios/probabilities. Abbreviations and annotations: ND, normal delivery; CPD, cephalopelvic disproportion; ECS, emergency cesarean section; IVD, instrumental vaginal delivery; SCS, scheduled

cesarean section; rIVD, CPD-related IVD; uIVD, CPD-unrelated IVD; rECS, CPD-related ECS; uECS, CPD-unrelated ECS; STOL, simulated trial of labor.