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Research article

## TITLE PAGE

# Morbidity associated with planned cesarean deliveries performed before the scheduled date: a cohort study

### Authors:

Nicolas SANANES, MD MPH PhD<sup>a, b</sup>, Laure HALLER, MD<sup>a</sup>, Floriane JOCHUM, MPH<sup>a, c</sup>,  
Antoine KOCH, MD<sup>a</sup>, Lise LECOINTRE, MD MPH<sup>a, e</sup>, Patrick ROZENBERG, MD<sup>d, f</sup>

### Department affiliations:

<sup>a</sup> Department of Obstetrics, Strasbourg University Hospital, Strasbourg, France

<sup>b</sup> INSERM UMR-S 1121 "Biomaterials and Bioengineering", Strasbourg University, France

<sup>c</sup> Department of Public Health, Strasbourg University Hospital, Strasbourg, France

<sup>d</sup> Department of Obstetrics, Poissy-Saint-Germain-en-Laye Hospital Poissy, France

<sup>e</sup> I-Cube UMR 7357, Strasbourg University, France

<sup>f</sup> Research Unit EA 7285, Versailles St-Quentin University, Montigny-le-Bretonneux, France

**Corresponding author:** Nicolas Sananès, MD MPH PhD

Work address: Hôpitaux Universitaires de Strasbourg, service de gynécologie obstétrique,  
avenue Molière, 67200 Strasbourg, France

Email: [nicolas.sananès@chru-strasbourg.fr](mailto:nicolas.sananès@chru-strasbourg.fr) / Tel: +33 3 69 55 33 97

## **ABSTRACT**

### **Objective:**

Women with planned cesareans can require delivery before the scheduled date. However, data describing the morbidity associated with planned cesarean deliveries performed before the originally scheduled date is lacking.

The objective of this study was to compare the morbidity associated with planned cesarean delivery performed before compared with on the scheduled date.

### **Study design:**

This retrospective single-center cohort study included all 3595 women with singleton pregnancies and cesarean deliveries after 36<sup>+6</sup> weeks. All cases were reviewed individually to identify the initial intended mode of delivery, determined before 37 weeks. We excluded the 2145 (59.7%) unplanned cesareans initially planned as vaginal deliveries. Finally, the analysis included 1450 women with planned cesareans: 1232 (85.0%) performed as scheduled, and 218 (15.0%) before that date. The composite outcomes of maternal morbidity was one or more of the morbidity measures, including surgical complications, postpartum hemorrhage, infection and thrombo-embolism. Neonatal morbidity measures included 5 minute Apgar score <7, arterial cord blood pH <7.00, and admission to the neonatal intensive care unit (NICU).

### **Results:**

Reasons for performing planned cesarean delivery before the scheduled date were as follows: onset of labor (n=109; 50.0%), rupture of membranes (n=85; 39.0%), preeclampsia (n=9; 4.1%), scar pain in women with a previous cesarean (n=6; 2.8%), unexplained vaginal bleeding (n=5; 2.3%), and nonreassuring fetal heart rate (n=4; 1.8%).

Mean gestational age for planned cesarean deliveries before the scheduled date was 38.7 weeks  $\pm$  0.8 versus 39.2 weeks  $\pm$  0.7 for those performed when scheduled ( $P < .0001$ ).

The maternal morbidity composite outcome rate was significantly higher among planned cesareans performed early compared with those on the scheduled date: 18.3% vs 9.7%, respectively,  $P = .0002$ . It was still higher in the multivariable analysis: aOR 2.17, 95% CI 1.46–3.21,  $P = 0.0001$ . The neonatal composite outcome did not differ significantly between the two groups.

**Conclusion:**

In planned cesarean deliveries, maternal morbidity is higher for cesareans performed before rather than on the scheduled date. Studies without accurate intent-to-treat analyses underestimate the morbidity associated with planned cesareans. Accordingly, medical records must make it possible to distinguish planned cesarean deliveries performed before the scheduled date from those performed as planned.

**Key words:**

Planned cesarean delivery, elective cesarean delivery, cesarean performed on the scheduled date, cesarean performed before the scheduled date, maternal morbidity, neonatal morbidity

**Funding:**

None

**Conflict of interest:**

The authors have no conflict of interest to declare.

## INTRODUCTION

The Royal College of Obstetricians and Gynecologists and the American College of Obstetricians and Gynecologists recommends that elective cesarean deliveries (CDs) not be performed before a gestational age of 39 weeks [1-3]. A principal purpose of this recommendation is to reduce the risk of neonatal respiratory complications, especially as several studies have shown that early term delivery before 39 weeks is at higher risk of poor neonatal outcomes [4], such as neonatal pulmonary disease, particularly in cases of elective CDs [5, 6].

Nevertheless, among the women for whom a CD is planned, it can sometimes become necessary to perform it before the scheduled date, because of the onset of labor, premature rupture of membranes, or intercurrent obstetric complications. In a randomized controlled trial comparing planned CDs at 38 weeks versus 39 weeks, spontaneous labor began for 12.9% of the women in the 39-week group before the scheduled cesarean date [7].

Scheduling a CD does not necessarily result in a planned CD performed on the scheduled date. According to the intention-to-treat principle, planned CDs are a mix of CDs performed before and on the scheduled date. Therefore CDs performed before the scheduled date should be included in reports of outcomes for women with planned CDs.

It is well known that both maternal and neonatal morbidity are higher in case of emergence CDs [8]. However, most of these emergence CDs result from a failed trial of labor (because of fetal distress or arrest of dilatation for example) and can't be compared with planned CDs performed before the scheduled date (because of onset of labor or rupture of membrane for example).

Published data on the proportion of women requiring CDs before the scheduled date, and on their outcomes compared to those with planned CDs on the scheduled date are limited. The objective of this study was to compare the maternal and neonatal morbidity associated with planned CDs performed before, compared with on, the originally scheduled date.

## MATERIAL AND METHODS

This retrospective single-center cohort study took place at the level II maternity unit of the Medical-Surgical and Obstetrical Center (CMCO), part of Strasbourg University Hospitals. We included all cases of CDs in singleton pregnancies after 36<sup>+6</sup> weeks' gestation during the years 2010–2017. During the study period, the rate of CD was 16.8%. All cases were reviewed individually to identify the initial intended mode of delivery, and the planned vaginal deliveries which resulted in an unplanned CD were excluded.

Finally, we analyzed all planned CDs. Indications for CDs were discussed between 36 and 37 weeks in a labor and delivery medical staff meeting. If there were multiple indications for cesarean, only the primary one was reported. During the study period, the rate of trial of labor after a previous CD (TOLAC) was 79.1%. No TOLAC was offered in case of 2 or more CDs. The rate of planned CDs in case of noncephalic presentation was 50.9%. We indicated planned CD in case of estimated fetal weight > 5000g for non-diabetics and > 4500g for diabetics. All planned CDs were scheduled after 39<sup>+0</sup> weeks. Cesarean procedure was standardized and did not change during the study period. It included skin preparation with povidone-iodine, prophylactic antibiotics (cephalosporins), bladder catheter, sequential compression stockings before surgery, and deep venous thromboembolism pharmacological prophylaxis.

We divided the planned CDs into two comparison groups: (i) planned CDs performed on the scheduled date; (ii) planned CD that took place before the scheduled date, regardless of the reason (onset of labor, premature rupture of membranes, or intercurrent obstetric complications).

All data were collected from an electronic medical record system (DIAMM®, Micro6, Villers-Lès-Nancy, France). Every individual patient file was reviewed, in particular to identify the initial intended mode of delivery: planned CD or planned vaginal delivery.

Maternal characteristics included maternal age, parity, tobacco use during pregnancy, body mass index, previous abdominal surgery, coagulopathy or thrombophilia, diabetes mellitus, hypertensive disease, and previous CD.

Maternal morbidity measures included intraoperative surgical complications (accidental extension of the uterine incision into the lower uterine segment, and incidental cystotomy), bowel or vascular laceration, uterine dehiscence (incomplete uterine scar separation with intact serosa), uterine rupture (complete scar separation), postpartum hemorrhage greater than 1000 mL of blood, need for blood transfusion, puerperal febrile morbidity (greater than 38°C on two or more occasions in any 48-hour period excluding the first 24 hours after delivery), wound infection with a need for antibiotics and/or drainage, evacuation of hematoma, venous thrombosis, pulmonary embolism, and need for hospital readmission within 2 months postpartum.

Neonatal morbidity measures included a 5 minute Apgar score <7, arterial cord blood pH <7.00, need for resuscitation after delivery, need for assisted ventilation with the use of an endotracheal tube, neonatal infection (diagnosed clinically with or without confirmation by blood culture), admission to the neonatal intensive care unit (NICU) within 7 days of birth, and neonatal death within 28 days.

The composite outcomes of maternal and neonatal morbidity were any one or more of the morbidity measures.

Gestational age at delivery was expressed as a quantitative variable in both groups. It is presented as means ± standard deviations and then compared with Student's t test. All other

variables were expressed in binary form by using relevant thresholds determined a priori from the literature. Categorical variables are presented as numbers and percentages and then compared between groups with Pearson's  $\chi^2$  test or Fisher's exact test, as appropriate.

Multivariable logistic regression models were then built to predict maternal and neonatal composite outcomes. The predictors were selected with a backward stepwise procedure ( $P$ -value  $\leq .20$  for entry and  $P$ -value  $\geq .05$  for removal). Adjusted odds ratios (aORs) and their 95% confidence intervals (95% CIs) were computed for each predictor.

A  $P$ -value  $< .05$  was defined as statistically significant. The statistical software package SAS 9.3 (SAS Institute Inc., Cary, NC, USA) was used for all data analyses.

The National Data Protection Authority (n° 2001404v0, Commission Nationale de l'Informatique et des Libertés) approved the study and the database. Because the dataset contained no information enabling patient identification and all women received standard care, the study was exempt from informed consent requirements.

## RESULTS

During the study period, 3595 women with singleton pregnancies had a CD after 36<sup>+6</sup> weeks. We excluded 2145 (59.7%) unplanned CDs that had initially been planned as vaginal deliveries. Finally, the analysis included 1450 women with planned CDs: 1232 (85.0%) planned CDs performed on the scheduled date, and 218 (15.0%) planned CDs performed before then. Figure 1 presents the flow chart of study participants, and Table 1 the indications for the planned CDs in each group.

Reasons for performing planned CDs before the scheduled date were as follows: onset of labor (n=109; 50.0%), rupture of membranes (n=85; 39.0%), preeclampsia (n=9; 4.1%), scar pain in women with a previous cesarean (n=6; 2.8%), unexplained vaginal bleeding (n=5; 2.3%), and nonreassuring fetal heart rate (n=4; 1.8%). Mean gestational age for planned CDs performed before the scheduled date was 38.7 weeks  $\pm$  0.8 versus 39.2 weeks  $\pm$  0.7 for those performed as scheduled ( $P < 0.0001$ ).

Women's baseline characteristics by group are reported in Table 2, maternal morbidity outcomes in Table 3, and neonatal morbidity outcomes in Table 4. The maternal morbidity composite outcome was significantly more frequent for the earlier-than-planned CDs compared with those performed as scheduled, at 18.3% and 9.7%, respectively ( $P = .0002$ ), while the neonatal composite outcome rate did not differ between the groups, at 4.1% vs 3.3% ( $P = .55$ ).

For the multivariable analysis, maternal baseline characteristics that differed between the two study groups by a  $P$ -value  $\leq 0.20$  were entered into the model (maternal age  $\geq 40$  years, parity  $\geq 1$ , BMI  $\geq 30$ , previous abdominal surgery, diabetes mellitus, hypertensive disease, previous CD, and noncephalic presentation) and then removed from the model if the  $P$ -value  $\geq .05$ , according to a backward stepwise procedure. The risk of composite maternal

morbidity remained higher for the planned CDs performed before compared with on schedule (aOR 2.17, 95% CI 1.46–3.21,  $P=0.0001$ ), after adjustment for maternal age  $\geq 40$  years (aOR 1.42, 95% CI 1.02–1.99,  $P=0.036$ ). The multivariable model for neonatal morbidity had no variables, because no variable, in particular, CD before the scheduled date, was significantly associated with the composite neonatal outcome (OR 1.25, 95% CI 0.60–2.61,  $P=.55$ ).

## **DISCUSSION**

### **Main findings**

This cohort study showed that when a CD has been planned, maternal morbidity is higher when it is performed before rather than on the scheduled date. Neonatal morbidity did not differ between the groups. In all, 15% of women with a planned CD eventually had a CD before its scheduled date.

### **Strengths and Limitations**

This is the first study to evaluate the maternal morbidity associated with planned CDs performed before the scheduled date. Strengths of this study include the individual review of each file to identify the initial intended mode of delivery. Baseline characteristics of patients from both study groups (CDs performed before and at the scheduled date) differed for some of the variables, although they both come from the same group of planned CDs. Accordingly, we conducted a multivariable analysis to adjust for potential confounders.

The main limitation is the small number of women with planned CDs performed before the scheduled date. Larger studies are necessary to evaluate the perinatal outcome because our study was underpowered to accurately assess the perinatal morbidity. Moreover, in our study, we evaluated the morbidity associated with earlier-than-planned CDs. However, it must be noted that outcomes are influenced by multiple confounders, notably the reason for performing the CD before the scheduled date. Therefore it would be also interesting to study the attributable morbidity of such a CD, rather than the associated morbidity. This would require focusing only on a low-risk population, such as noncephalic presentations with no

previous CD and no comorbidity and excluding CDs performed before the scheduled date for intercurrent obstetric complications. Again, a larger cohort would be necessary.

## **Interpretation**

Publications assessing the rate of planned CDs performed earlier than scheduled are scarce. Glavind et al. conducted a randomized controlled multicenter open-label trial comparing perinatal outcomes after CDs scheduled at a gestational age of 38 weeks and 3 days versus 39 weeks and 3 days ( $\pm 2$  days in both groups) [7]. Of the 526 women in the 39-week group, 97 (18.4%) had an unscheduled CD, including 82 (12.9%) with spontaneous onset of labor. In a population-based study reporting 700,878 ongoing pregnancies after 37 weeks, Smith et al. showed that 123,408 (17.6%) women gave birth before 39 weeks [9]. In all, around 15% to 18% of pregnancies ongoing at 37 weeks are delivered before 39 weeks. This means that a significant number of women scheduled for a planned CD at 39 weeks will give birth before then, in an unscheduled CD. Moreover, the incidence of maternal morbidity associated with planned CDs increases with the rate of these CDs performed before the scheduled date. It is therefore important to know the rate of earlier-than-planned CDs, especially when morbidity and other outcomes of the planned CDs are compared with planned vaginal deliveries. Just as the maternal morbidity of planned vaginal delivery depends mainly on the risk of CD during labor, as Allen et al. showed, the maternal morbidity of the planned CD depends on the risk of planned CD performed before the scheduled date [10]. In addition, another cohort study showed that increasing cervical dilation at the time of the intrapartum CD is an independent risk factor for maternal morbidity [11]. Nonetheless, the risk of an intrapartum or emergency CD also exists when the initial plan was a planned CD, since these risks may also occur before the scheduled CD date. We found that composite

maternal morbidity is approximately twice as high for planned CDs performed before compared to on the scheduled date. However, we found no significant difference for composite neonatal morbidity, consistent with the results reported by Riskin et al. in a retrospective cohort study [12].

Therefore, a planned CD performed before the scheduled date should not be considered comparable to a planned CD performed at the scheduled date, especially for comparisons with planned vaginal deliveries. An example of avoiding such a biased study design can be seen in the prospective observational study by Landon et al., which compared maternal and perinatal outcomes between women who underwent a trial of labor and women who had an elective repeated CD without labor. The authors excluded from their analysis the women who presented in early labor and subsequently had a CD, due to the difficulty of distinguishing between a failed trial of labor and a planned elective repeated CD [13]. The authors stated that the exclusion from the study of these women probably lowered the risk of complications in the group of women undergoing elective repeated CDs.

There is a need for a data entry system and a classification of planned CDs that enables better compliance with the intention-to-treat principle: the population of planned CDs should necessarily include both planned CDs performed as scheduled and those performed before that date. This is especially necessary given that the failure to do so may well introduce a severe misclassification bias, by considering CDs performed before the scheduled date as CDs during labor instead. The risk associated with planned CD would thus be underestimated and that associated with planned vaginal delivery overestimated.

This error appears to underlie most of the retrospective cohort studies evaluating mode of delivery, especially registry-based studies. They do not include an appropriate intention-to-treat analysis. For example, in a Dutch population-based cohort study of breech deliveries,

Vlemmix *et al.* defined the planned vaginal delivery group as the combination of actual vaginal deliveries and ‘emergency’ CDs, whereas the planned CD group comprised only women who actually had an elective CD without labor; all emergency cases were treated as planned vaginal deliveries [14]. The authors acknowledge in the discussion the misclassification bias due to incomplete intention-to-treat analysis for mode of delivery. Under those circumstances, they reported no perinatal deaths among the 30,503 planned CDs. In the PREMODA study, on the other hand, an observational prospective study with an intention-to-treat analysis that used antenatal decisions to determine "planned" mode of delivery, Goffinet *et al.* reported a perinatal mortality rate of 0.14% (8/5573) for planned CDs for breech presentation [15]. Similarly, in the randomized controlled trial by Hannah *et al.*, the perinatal mortality rate in the planned CD group was 0.3% (3/1041) [16].

Finally, patient counselling about elective CD should include in the discussion information about the possibility that the CD may need to be performed before the scheduled date and the risks associated with it.

## **Conclusion**

In conclusion, among women with planned CDs, maternal morbidity is higher when the CD is performed before rather than on the scheduled date. Studies without accurate intent-to-treat analyses substantially underestimate the morbidity associated with planned CDs. Classification of planned CDs in studies (and therefore in data collection forms) must be able to distinguish planned cesarean deliveries performed ahead of schedule.

Larger studies are necessary to evaluate perinatal outcomes, and the attributable morbidity of cesareans performed before the scheduled date, rather than the associated morbidity of these CDs.

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**Figure 1: Flow chart of patient selection**

**Table 1: Indications for planned cesarean delivery**

<b>Indications for planned CD</b>	<b>CD on the scheduled date</b> (n = 1232)	<b>CD before the scheduled date</b> (n = 218)	<b><i>P</i></b>
Prior cesarean section	774 (62.8%)	112 (51.4%)	.0018
Noncephalic presentation	372 (30.2%)	97 (44.5%)	<.0001
Macrosomia	17 (1.4%)	4 (1.8%)	0.83
Others	69 (5.6%)	5 (2.3%)	0.081

**Table 2: Patient characteristics at baseline**

<b>Patient characteristics</b>	<b>CD on the scheduled date</b> (n = 1232)	<b>CD before the scheduled date</b> (n = 218)	<b><i>P</i></b>
Maternal age $\geq$ 40 years	452 (36.7%)	64 (29.4%)	.037
Parity $\geq$ 1	795 (64.1%)	125 (57.3%)	.042
Tabaco use during pregnancy	168 (13.6%)	33 (15.1%)	.55
BMI $\geq$ 30	249 (20.2%)	33 (15.1%)	.081
Previous abdominal surgery	153 (12.4%)	20 (9.2%)	.17
Coagulopathy or thrombophilia	25 (2.0%)	4 (1.8%)	.85
Diabetes mellitus	181 (14.7%)	24 (11.0%)	.15
Hypertensive disease	45 (3.7%)	20 (9.2%)	.0003
Previous CD	774 (62.8%)	112 (51.4%)	.001
$\geq$ 2 previous CDs	284 (23.1%)	44 (20.1%)	.98
Noncephalic presentation	372 (30.2%)	97 (44.5%)	<.0001

**Table 3: Maternal outcomes**

<b>Morbidity</b>	<b>CD on the scheduled date (n = 1232)</b>	<b>CD before the scheduled date (n = 218)</b>	<b><i>P</i></b>
Bladder laceration	9 (0.7%)	1 (0.5%)	1
Bowel laceration	0 (0%)	0 (0%)	1
Vascular laceration	6 (0.5%)	5 (2.3%)	0.016
Unintended uterine tear	3 (0.2%)	1 (0.5%)	0.479
Uterine dehiscence	11 (0.9%)	7 (3.2%)	0.011
Uterine rupture	0 (0%)	1(0.4%)	0.150
Postpartum hemorrhage >1 L	62 (5.0%)	15 (6.8%)	0.252
Blood transfusion	16 (1.3%)	3 (1.4%)	1
Puerperal febrile morbidity	12 (0.9%)	7 (3.2%)	0.016
Wound infection	11 (0.9%)	7 (3.2%)	0.011
Evacuation of hematoma	6 (0.5%)	5 (2.3%)	0.016
Venous thrombosis	1 (0.1%)	0 (0%)	1
Pulmonary embolism	0 (0%)	0 (0%)	1
Readmission to hospital	7 (0.6%)	3 (1.4%)	0.180
<b>Maternal composite outcome (one or more of the above)</b>	<b>119 (9.7%)</b>	<b>40 (18.3%)</b>	<b><i>P=0.0002</i></b>

**Table 4: Neonatal outcomes**

<b>Morbidity</b>	<b>CD on the scheduled date (n = 1232)</b>	<b>CD before the scheduled date (n = 218)</b>	<b><i>P</i></b>
Apgar score <7 at 5 min	6 (0.5%)	1 (0.5%)	1
Arterial cord blood pH <7	6 (0.5%)	1 (0.5%)	1
Resuscitation after delivery	25 (2.0%)	4 (1.8%)	1
Intubation and ventilation	2 (0.2%)	0 (0%)	1
Neonatal infection	1 (0.1%)	1 (0.5%)	0.278
Admission to NICU	12 (1.0%)	3 (1.4%)	0.483
Neonatal death	0 (0%)	1 (0.5%)	0.150
<b>Neonatal composite outcome (one or more of the above)</b>	<b>41 (3.3%)</b>	<b>9 (4.1%)</b>	<b><i>P</i>=0.55</b>

