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ORIGINAL ARTICLE

Impact of mode of delivery of twins on the pelvic floor 3 and 12 months post-partum—part II

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Abstract

Introduction and hypothesis To compare the impact of vaginal delivery (VD) versus cesarean section (CS) on the pelvic floor in twin primiparae at 3 and 12 months postpartum.

Methods This comparative multicenter prospective cohort from a large French national cohort study consisted of primiparas who gave birth to live twins after 34 weeks of gestation. The primary end point was the postnatal urinary incontinence rate 3 months postpartum. The secondary end points were the pelvic floor dysfunction (PFD) at 3 and 12 months based on PFDI-20, PFIQ-7, PISQ-12, and SF-12 responses.

Results A total of 2812 patients in 172 French maternity units were recruited between February 2014 and March 2015: 1076 (38%) responded at 3 and 12 months (61% at 3 months); 1155 were analyzed at 3 months (556 VD and 599 CS) and 800 at 12 months (394 VD and 406 CS). VD was associated with more symptoms at 3 months [median PFDI-20 score 25/300 (8–50) vs. 17/300 (4–36) after CS; $p < 0.0001$]. Vaginal bulge was more frequently reported after VD (9 vs. 4%; $p = 0.0015$). Abdnormal PFD-related quality-of-life scores (scores > 0) were more frequent after VD at 3 months (58 vs. 42%; $p < 0.0001$) and 12 months (57 vs. 43%; $p = 0.0020$), indicating greater discomfort. However, SF-12 scores were higher after VD [56 (53–59) vs. 55 (51–58)] at 12 months, indicating better general quality of life.

Conclusions Mode of delivery is significantly associated with pelvic organ prolapse symptoms 3 months postpartum, which regress by 12 months, probably because of the known spontaneous postnatal improvement of PFDs.

Keywords Pelvic floor dysfunction · Pelvic organ prolapse · Twin pregnancy · Postpartum · Risk factors · Vaginal delivery

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Introduction

Pelvic floor disorders (PFDs) are thought to be the consequence of neuromuscular injuries and loss of pelvic floor support, caused by pregnancy and vaginal delivery (VD) [1]. VD appears to increase the risk of developing combined PFDs in the long term [2], but these disorders also appear to be present in the third trimester of pregnancy and 3 months postpartum [3]. However, there is still debate concerning the protective effect of cesarean delivery [4].

Improvements and increasing use of assisted reproduction have led to a rise in the prevalence of twin pregnancies in the past 30 years (e.g., a 68% increase in France [5] and 1.9-fold increase in the USA [6]), creating a pressing need to study the impact of twin pregnancy on the pelvic floor. A pilot study showed that 3D ultrasound measurements of the hiatus as well as the sagittal and corona diameters of the levator ani are higher in twin than singleton pregnancies [7], while it has also

been demonstrated that these measurements are already higher in pregnant than non-pregnant women [8]. It appears therefore that the specific hormonal and mechanical conditions of twin pregnancy might alter the levator ani muscle anatomy and function.

In a previous study we showed that, compared with cesarean delivery, VD of twins is associated with a threefold risk of stress, urgency, or mixed urinary incontinence (UI) 3 months postpartum and a twofold risk at 12 months (Risk of new-onset urinary incontinence 3 and 12 months after vaginal or cesarean delivery of twins—Part I, in press). However, at both 3 and 12 months, only 7 to 8% of patients reported a moderate amount of leakage, with only 1% reporting a large amount.

The current study compared the onset of pelvic organ prolapse (POP) symptoms, voiding disorders (other than UI), anorectal disorders, and sexual dysfunction in women who gave birth to twins by VD versus cesarean section (CS).

Materials and methods

This study reports the results of the secondary end points of a previously published study on the consequences of mode of delivery for twin pregnancies on the onset of postpartum UI (JUMODA-CP). This study was a substudy of the French national JUMODA study [9]. The primary objective of the JUMODA study was to evaluate the impact of the planned mode of delivery on the perinatal morbidity of the second twin in twin pregnancies. All women who gave birth at or after 22 weeks of gestation to twins or triplets were eligible for inclusion, and data on several measures of mortality and severe morbidity were collected.

This study is therefore a national multicenter prospective observational epidemiological cohort study to evaluate the impact of the actual mode of delivery of twin pregnancies on pelvic floor.

Calculation of the number of subjects required

To calculate the number of subjects required, it was hypothesized that 60% of twin pregnancies would be delivered by CS [10], that the absolute difference in the prevalence of UI at 3 months to be demonstrated was 10%, and that the prevalence of UI at 3 months in the VD group would be 50% [11]. To obtain a power of 90% with an alpha error of 5%, 1080 returned questionnaires would be required. Assuming that 50% of women would not respond or would be lost to follow-up, 2160 women needed to be recruited.

Study population

The population included all the primiparous adults in a large national cohort of women pregnant with twins who gave birth to two live infants after 34 weeks of gestation [8], unless they chose to opt out.

The attending obstetrician enrolled patients prospectively, immediately after delivery, using a web-based questionnaire.

The two groups were defined by the actual route of delivery (VD or CS). The VD (exposed) group comprised women who gave birth vaginally to at least one twin, and the CS (non-exposed) group comprised women who had an elective CS or an emergency or non-emergency CS during labor, provided both twins were born by CS.

Data collection methods

Each patient received five questionnaires at 3 and 12 months postpartum (a total of 69 questions per session and 207 questions per patient), including:

- PFDI-20 (Pelvic Floor Distress Inventory-Short Form 20) and PFIQ-7 (Pelvic Floor Impact Questionnaire-Short Form 7). These self-administered questionnaires evaluate all the patient's urinary, anorectal, and perineal/vaginal symptoms. They take into account the functional aspect of the various forms of PFDs and generate easily interpretable scores [12] that correlate with the physical examination [13].
- PISQ-12 (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire). This self-administered questionnaire evaluates the impact of PFDs on sexual function, encompassing behavioral, emotive, physical, and partner-related aspects. The data from this questionnaire were only analyzed 12 months postpartum since the responses pertained to the patient's sexuality during the previous 6 months [14].
- SF-12 (Medical Outcomes Study Short Form 12) [15], a shortened version of SF-36, for assessing mental, social, and physical quality of life.

All these questionnaires were adapted for use by French speakers. Although PFDI-20, PFIQ-7, and PISQ-12 were initially intended for a target population with PFDs, we used them here in the absence of pregnancy-specific questionnaires.

Factors studied

UI before or during pregnancy, smoking status, body mass index (BMI) in early pregnancy, total weight gain during pregnancy, and the presence or absence of gestational diabetes were also recorded. We chose, post hoc, to exclude all patients who had UI before or during pregnancy in order to focus on the effects of delivery on urinary disorders and eliminate as far as possible any symptoms provoked by the pregnancy itself.

For the 3-month postpartum outcomes, only answers provided between 2 and 4 months postpartum were analyzed

(based on the reported questionnaire completion date). For the 12-month postpartum outcomes, only answers provided between 6 and 24 months postpartum were analyzed (again, based on the reported questionnaire completion date).

We also studied a number of secondary outcomes, based on patient reports.

Anorectal and perineal symptoms were determined using two PFDI-20 subscales: POPDI-6 (Pelvic Organ Prolapse Distress Inventory) and CRADI-8 (Colorectal-Anal Distress Inventory). Each of these scores range from 0 to 100, with high scores indicating more severe PFDs. PFDI-20 scores range from 0 to 300.

The impact of anorectal and perineal symptoms on quality of life was determined using two PFIQ-7 subscales: CRAIQ-7 (Colorectal-Anal Impact Questionnaire) and POPIQ-7 (Pelvic Organ Prolapse Impact Questionnaire). Again, these subscale scores range from 0 to 100, and the PFIQ-7 score ranges from 0 to 300. The higher these scores are, the greater the impact of these PFDs on quality of life.

The symptoms and quality-of-life questionnaires were also used to determine the percentage of women whose scores were 0 or greater than 0, indicating the absence or presence of symptoms or impact.

The sexual impact of PFDs was determined using the total score calculated from PISQ-12, with low scores indicating greater sexual impact.

The impact of PFDs on general quality of life was determined using the physical and mental composite scores calculated for the SF-12 questionnaire, with norm-based scoring. Low scores indicate greater impact. The questions pertain to the 4-week period prior to completion of the questionnaire.

All these analyses were performed at 3 and 12 months, apart from those for PISQ-12, which were only analyzed at 12 months because the responses provided pertain to the previous 6 months. By analyzing the same patients at two time points, we were able to assess the dynamics of these disorders.

A number of secondary analyses were also performed. The presence of POP and how bothersome it was to the patient were defined by the answer to PFDI-20 question 3: "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" The presence of obstructed defecation was defined by a positive response to at least one of the following PFDI-20 questions: "Do you ever have to push on the vagina or around the rectum to have or complete a bowel movement?", "Do you feel the need to strain too hard to have a bowel movement?", or "Do you feel you have not completely emptied your bowels at the end of a bowel movement?" (questions 4, 7, and 8). Anal incontinence was defined by at least one positive response to the following PFDI-20 questions: "Do you usually lose stool beyond your control if your stool is well formed?", "Do you usually lose stool beyond your control if your stool is loose?", or "Do you usually lose gas from the rectum beyond your control?" (questions 9, 10, and 11). Finally, we determined the presence of pain and the impact of this pain by the answer given to PFDI-20 question 20, "Do you usually experience pain or discomfort in the lower abdomen or genital region?", as well as the presence of dyspareunia, defined by the answer to the PISQ-12 question, "Do you feel pain during sexual intercourse?"

Statistical methods

The population was described by the number and percentage of patients for categorical variables and mean and standard deviation or median and quartiles for continuous variables, depending on their distribution.

The baseline comparability of the groups was checked and outcomes compared using the chi-square test or Fisher's exact test for qualitative variables and Student's t test or the Wilcoxon-Mann-Whitney test for quantitative variables.

Data analysis was performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA), with an alpha level of 5% for all tests.

Results

Flow chart of study participants

Although 2904 patients were eligible for inclusion in this study, 34 (1%) were not sent questionnaires because notification of their inclusion was not received, and 58 were excluded post hoc because of a history of UI before pregnancy (2 women), UI during pregnancy (13 women), or lack of information concerning their UI history (43 women). Of the 2846 patients eligible for analysis, 1734 (61%) returned at least one set of questionnaires at 3 months or 12 months and 34% returned both sets.

Characteristics of the patients included

Patients were recruited between February 10, 2014, and March 01, 2015, in 172 French maternity units with facilities for moderate- or high-risk pregnancies that performed more than 1500 deliveries per year.

The average age of the patients was 32 years [17–51], the average gestational age at delivery was 37 weeks, the average BMI in early pregnancy was 22, and 1297 (46%) gave birth vaginally versus 1549 (54%) by CS. The mean intrauterine weight was 4885 g ± 724 g; 27% of these patients (758) had a BMI > 25 in early pregnancy.

Comparability of the various groups

After post hoc exclusion of 58 patients due to the presence of UI before delivery, 2846 patients were potentially

analyzable. Of these, 1734 returned at least one questionnaire, 458 of whom returned only the 3-month questionnaire and 318 only the 12-month questionnaire. The characteristics of responders and nonresponders were similar in terms of the frequency of diabetes, episiotomy and perineal injury, fetal weight, maternal BMI, mode of delivery, and other factors, except maternal age at delivery, which was 31 years for nonresponders versus 32 years for responders ($p < 0.001$).

We only analyzed the responses of the 1155 patients who were analyzable for the primary end point of the study (presence or absence of UI). A further 1691 eligible patients could not be analyzed for this end point.

We also compared the characteristics of the analyzable patients delivered vaginally versus those who underwent CS. The two groups were comparable regarding gestational age at delivery, combined fetal weights, smoking status, endometriosis, and antenatal pelvic floor muscle training, but differences were observed in maternal age at delivery (31 years in the VD group versus 33 years in the CS group; $p > 0.001$), the proportion of patients over the age of 25 (89% in the VD group and 94% in the CS group; $p = 0.0045$), and the proportion of women with a BMI greater than 25 in early pregnancy (23% in the VD group and 30% in the CS group; $p = 0.0115$). As expected, a difference was found in the presentation of the first twin (97% were cephalic in the VD group versus only 58% in the CS group), a difference that is directly related to the decision to perform CS.

Among these analyzable patients, 249 had an instrumental delivery for the first twin and 152 for the second. Two fetuses had shoulder dystocia, one of which was a first twin and the other a second twin. Bladder injury occurred in three patients during CS.

Symptom questionnaires

Table 1 shows the results obtained with the PFDI-20 and PFIQ-7 questionnaires at 3 months and 12 months postpartum. The median scores and 1st and 3rd quartiles are reported, and, where helpful, we have provided the proportion of scores greater than 0 to indicate the proportion of patients in each group with symptoms or whose symptoms impaired their quality of life.

Sexual function questionnaire

No significant difference was found between the two groups studied regarding the potential impact of delivery mode on sexual function, based on the women's responses to the PISQ-12 questionnaire. The median scores were 38.59 [35–42] after VD and 39 [35–42] after CS ($p = 0.7486$).

General quality-of-life questionnaire

There was no significant difference between the groups in the impact these PFDs had on general quality of life 3 months postpartum. At 12 months, the aggregated physical scores obtained with SF-12 were statistically significantly higher in the VD group, indicating a better general physical quality of life (Table 2).

Analyses of other pelvic floor disorders at 3 and 12 months

The results of these analyses are shown in Table 3.

Discussion

The quality and validity of the study methods were discussed in our previous article (Risk of new-onset urinary incontinence 3 and 12 months after vaginal or cesarean delivery of twins-Part I, in press) on UI, where we pointed out that established questionnaires, adapted for French speakers were used to assess the prevalence and impact of pelvic, intestinal, and sexual symptoms, but that they are usually reserved for women with PFDs. However, in the absence of an alternative validated method, we extrapolated their use to a population who do not necessarily have PFDs.

We found significantly higher PFDI-20 scores 3 months postpartum among the women who delivered twins vaginally, indicating a higher prevalence of PFDs in this group. Analysis of the subscales showed a higher proportion of women at 3 months with anorectal symptoms after VD (67% versus 61.2% after CS), but no difference was observed between the two delivery modes for individual anorectal symptoms (obstructed defecation, anal incontinence, etc.). These results are consistent with those of the Twin Birth Study, which found no difference in anal incontinence rates [16]. An Israeli study [3] reported an obstructed defecation rate at 3 months postpartum of 31.5%, which is lower than the 40% rate in our study, suggesting that the prevalence is higher after twin pregnancy but unaffected by delivery mode.

Patients who delivered vaginally were more likely to experience POP symptoms than those who underwent CS, as indicated by the greater proportion of patients in the VD group with a POIQ-7 score > 0 and the difference in their total PFIQ-7 scores. Analysis of individual POP symptoms showed that significantly more patients reported vaginal bulging 3 months postpartum in the VD group. Similar findings were reported in 2002 by Sze et al. [17], but in their study the risk factor for POP appeared to be specifically the first stage of labor. However, our study found much lower rates of POP 3 months postpartum, probably because we measured the patients' perception of POP, whereas Sze

Table 1 Symptomf scores and symptom-related quality of life scores

	At 3 months $n = 1117$*				Score > 0 (%)			At 12 months $n = 779$*			Score > 0 (%)		
	Median score [1st quartile–3rd quartile]							Median score [1st quartile–3rd quartile]					
	Either mode	VD	CS	p	VD	CS	p	Either mode	VD	CS	p	VD	CS	p
PFDI-20	20.8 [6.3–43.8]	25 [8.3–50.0]	16.7 [4.2–35.9]	< ***0.0001*****	67	57.8	***0.0425*****	16.7 [4.2–39.6]	16.7 [4.2–40.6]	14.6 [4.2–37.5]	0.4648	–	–	–
CRADI-8	6.3 [0–18.8]	9.4 [0–18.8]	6.3 [0–18.8]	0.0689				6.3 [0–18.8]	6.3 [0–12.5]	6.3 [0–15.6]	0.1024	–	–	–
UDI-6	4.2 [0–16.7]	8.3 [0–20.8]	4.2 [0–12.5]	< ***0.0001*****	44.1	39.5	0.1152	8.3 [0–16.7]	8.3 [0–20.8]	4.2 [0–16.7]	***0.0274*****	–	–	–
POPDI-6	0 [0–8.3]	0 [0–12.5]	0 [0–8.3]	0.0749				0 [0–8.3]	0 [0–8.3]	0 [0–8.3]	0.7819	–	–	–
	At 3 months $n = 1127$*							At 12 months $n = 801$						
	Median score [1st quartile–3rd quartile]				Score > 0 (%)			Median score [1st quartile–3rd quartile]				Score > 0 (%)		
	Either mode	VD	CS	p	VD	CS	p	Either mode	VD	CS	p	VD	CS	p
PFIQ-7	0 [0–14.3]	0 [0–14.3]	0 [0–9.5]	< ***0.0001*****	48.4	33.5	< ***0.0001*****	0 [0–4.8]	0 [0–4.8]	0 [0–4.8]	***0.012*****	34.5	26.6	***0.0131*****
CRAIQ-7	0 [0–0]	0 [0–0]	0 [0–0]	0.2837				0 [0–0]	0 [0–0]	0 [0–0]	0.2852			
UIQ-7	0 [0–0]	0 [0–4.8]	0 [0–0]	< ***0.0001*****	28.6	13.5	< ***0.0001*****	0 [0–0]	0 [0–0]	0 [0–0]	***0.0124*****	22.9	16.3	***0.0156*****
POPIQ-7	0 [0–0]	0 [0–4.8]	0 [0–0]	***0.002*****	27.6	19.7	***0.0019*****	0 [0–0]	0 [0–0]	0 [0–0]	***0.0101*****	15.6	9.4	***0.0067*****

These tables present and compare the results obtained respectively by the cesarean section and vaginal delivery group. The first table groups symptom scores (general then separately digestive, urinary, and pelvic perineal symptoms). The second group includes quality of life scores related to symptoms (general and then separately digestive, urinary, and pelvic perineal symptoms). Higher scores represent more symptoms and greater discomfort

*n = Number of patients who responded to the survey

**Statistically significant results (values in bold are statistically significant)

et al. defined POP through clinical diagnosis, and included stage 2 POP, which is often asymptomatic. These disorders had regressed by 12 months, probably because of the known phenomenon of spontaneous postnatal improvement of PFDs.

The notion that POP-related disorders in particular improve between these two time points is very useful for reassuring patients, but longer term studies would be useful to determine whether POP of early postnatal onset correlates with its re-emergence in the long term. A large Swedish study suggests this might be the case [2] and also found a higher prevalence of PFDs 20 years after a VD than after a CS, including a higher proportion of women in the VD group with combined POP symptoms and urinary symptoms or even symptoms involving all three compartments.

Regarding sexual function in women who gave birth to twins, not only did we find no significant difference between the PISQ-12 scores of each group (58.6 in the VD group and 59.0 in the CS group), but also the scores were relatively high, indicating rather satisfactory sexual function in both groups. This is consistent with the findings of the Twin Birth Study [16], in which 85% of patients expressed satisfaction with their partner relationship. In our study, 81% had resumed sexual activity 3 months postpartum, although about one quarter of patients reported dyspareunia (29% in the VD group and 25% in the CS group). However, only 6.1% of the patients who delivered vaginally and 5.9% who underwent CS reported severe pain, which did not therefore appear to be related to the mode of delivery.

Despite the results presented above, these anorectal and perineal disorders appeared to have little impact on the women's general quality of life. Mode of delivery had no statistically significant effect on the SF-12 score at 3 months, and at 12 months the scores for the VD group were actually higher (indicating a better quality of life) than in the CS group (56 versus 55). Although a one-point difference in mean scores is not clinically meaningful, other studies have confirmed this difference: one found that CS was associated with more pain or discomfort and poorer general quality of life than VD at 12 months, using a different questionnaire (EQ-5D) [18], and another found a better score at 2 and 4 months after VD than after CS using the SF-36, which contains the SF-12 [19]. Finally, the Twin Birth Study [16] found no difference between the SF-36 scores of the groups. In addition, abdominal weakness created at the abdominal level can be the origin of an impossibility to carry out elementary basic child care or household tasks, which can impact the well-being of the patients in general.

In light of these results, CS cannot reasonably be considered a satisfactory solution for preventing the development of these postnatal anorectal and POP-related disorders. When weighed against the additional morbidity and mortality associated with CS, due in particular to anesthetic,

Table 2 General quality of life scores

	SF-12 at 3 months				SF-12 at 12 months			
	Total $n = 1108$	Cesarean section $n = 572$	Vaginal delivery $n = 536$	p	Total $n = 769$	Cesarean section $n = 389$	Vaginal delivery $n = 380$	p
Physical score	53.3 [46.4–57.4]	53.2 [45.7–57.2]	53.5 [47.2–57.5]	0.17	55.9 [51.6–58.6]	55.1 [50.9–58.3]	56.1 [52.7–58.9]	**0.0104***
Mental score	42.5 [33.8–51.1]	42.4 [34.7–51.4]	42.7 [33.0–50.6]	0.3101	41.7 [33.7–50.1]	41.5 [33.8–51.2]	41.8 [33.5–49.6]	0.6963

*Values in bold are statistically significant

infective, or thromboembolic complications, the differences demonstrated between the two delivery modes are not clinically sufficient to recommend systematically delivering twins by CS [20]. It is likely that the abdominal surgical incision of the cesarean section itself may have a detrimental impact on the pelvic floor. This aspect of this delivery mode should not be neglected. It may be interesting for future studies to measure the true impact of CS on quality of life and overall health.

The main strengths of our study are its prospective design and large sample size. Furthermore, because it was a national multicenter study that encompassed all the regions of metropolitan France, maternity units providing various levels of care, and both public and private hospitals, the study sample was representative of the general population, thus reducing selection bias. The use of validated, standardized questionnaires made the study reproducible and limited classification bias. In addition, patients were unaware of the study's precise objective.

One weakness of the study was that anorectal and pelvic floor disorders were not the primary end point, and the results should therefore be interpreted accordingly. It might also have been preferable to conduct a randomized study. However, since the actual rather than planned modes of delivery were analyzed, this would not have had a major influence and would have slowed recruitment, as it did for the Twin Birth Study [16]. The strict inclusion criteria of our study limited recruitment, and we therefore have no data on women who delivered before 34 weeks' gestation or on triplet births. The inclusion of triplets may well have introduced in imbalance between the groups because they would have been delivered far more frequently by CS. Unfortunately, data on Cesarean indication during labor or duration of the first phase of labor before Cesarean were not available, inducing bias by decreasing the difference in the effect on pelvic floor disorders of Cesarean versus vaginal delivery. Similarly, we have no data on multiparous women.

Moreover, our study was not able to evaluate the effects of pelvic floor muscle training, particularly in the case of vaginal delivery. That point should be taken into account in future study.

Conclusion

Mode of delivery appears to be significantly associated with POP symptoms 3 months postpartum, which regress by 12 months, probably because of the known spontaneous postnatal improvement of PFDs. Long-term data on twin

Table 3 Results of other pelvic perineal disorders at 3 and 12 months

Variable	n	Total population	Vaginal delivery	Cesarean section	p	n	Total population	Vaginal delivery	Cesarean section	p
Vaginal bulge n (%)	1150	71 (6)	47 (9)	24 (4)	***0.0015****	811	37 (5)	23 (6)	14 (3)	0.1133
Obstructed defecation n (%)	1148	455 (40)	225 (41)	230 (39)	0.4819	809	257 (32)	119 (30)	138 (34)	0.2229
Voiding dysfunction n (%)	1148	212 (18)	109 (20)	103 (17)	0.2699	809	183 (23)	86 (22)	97 (24)	0.4982
Anal incontinence n (%)	1149	433 (38)	218 (39)	215 (36)	0.242	812	255 (31)	122 (30)	133 (32)	0.5523
Well-formed stool n (%)	1149	31 (3)	13 (2)	18 (3)	0.4841	811	19 (2)	8 (2)	11 (3)	0.5173
Loose stool n (%)	1146	54 (5)	28 (5)	26 (4)	0.5788	811	38 (5)	18 (4)	20 (5)	0.7931
Gas n (%)	1149	415 (36)	210 (38)	205 (34)	0.207	812	242 (30)	114 (28)	128 (31)	0.3978
Pelvic floor pain or discomfort n (%)	1154	282 (24)	140 (25)	142 (24)	0.5485	812	163 (20)	71 (18)	92 (22)	0.1033

*Values in bold are statistically significant

pregnancies are be required to conclude definitively which delivery mode is preferable.

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Compliance with ethical standards

Details of ethics approval This study was approved by the Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé and by the Commission Nationale de l'Informatique et des Libertés (autorization no. 913448).

The study was recorded on Clinicaltrials.gov at no. NCT02059746.

Conflicts of interest None.

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