Perinatal morbidity among women with a previous caesarean delivery (PRISMA trial): a cluster-randomised trial

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Summary

Background Women with a previous caesarean delivery face a difficult choice in their next pregnancy: planning another caesarean or attempting vaginal delivery, both of which are associated with potential maternal and perinatal complications. This trial aimed to assess whether a multifaceted intervention, which promoted person-centred decision making and best practices, would reduce the risk of major perinatal morbidity among women with one previous caesarean delivery.

Methods We conducted an open, multicentre, cluster-randomised, controlled trial of a multifaceted 2-year intervention in 40 hospitals in Quebec among women with one previous caesarean delivery, in which hospitals were the units of randomisation and women the units of analysis. Randomisation was stratified according to level of care, using blocked randomisation. Hospitals were randomly assigned (1:1) to the intervention group (implementation of best practices and provision of tools that aimed to support decision making about mode of delivery, including an estimation of the probability of vaginal delivery and an ultrasound estimation of the risk of uterine rupture), or the control group (no intervention). The primary outcome was a composite risk of major perinatal morbidity. This trial was registered with ISRCTN, ISRCTN15346559.

Findings 21 281 eligible women delivered during the study period, from April 1, 2016 to Dec 13, 2019 (10 514 in the intervention group and 10 767 in the control group). None were lost to follow-up. There was a significant reduction in the rate of major perinatal morbidity from the baseline period to the intervention period in the intervention group as compared with the control group (adjusted odds ratio [OR] for incremental change over time, 0·72 [95% CI 0·52–0·99]; p=0·042; adjusted risk difference –1·2% [95% CI –2·0 to –0·1]). Major maternal morbidity was significantly reduced in the intervention group as compared with the control group (adjusted OR 0·54 [95% CI 0·33–0·89]; p=0·016). Minor perinatal and maternal morbidity, caesarean delivery, and uterine rupture rates did not differ significantly between groups.

Interpretation A multifaceted intervention supporting women in their choice of mode of delivery and promoting best practices resulted in a significant reduction in rates of major perinatal and maternal morbidity, without an increase in the rate of caesarean or uterine rupture.

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Introduction

Every year, more than 45 000 women in Canada[1–3] who have had a previous caesarean delivery face a difficult choice for their next pregnancy: planning another caesarean delivery, associated with a higher risk of maternal complications than a vaginal delivery;[4,5] or attempting vaginal delivery, associated with a higher risk of uterine rupture and perinatal complications particularly with unsuccessful trial of labour after caesarean.[6–16]

Several studies have identified the need to support women's decision making about mode of delivery and focus on careful monitoring of labour in order to minimise risks of adverse outcomes and uterine rupture.[17–21] Recently, clinical tools have been developed to assist women in their choice,[22–24] including an estimation of the probability of vaginal delivery based on characteristics known at the time prenatal care is initiated,[25–28] and of the risk of uterine rupture based on third-trimester ultrasound evaluation.[15,29–32] However, the effectiveness of these tools to improve person-centred decision making and outcomes remains uncertain.

This trial aimed to assess whether a multifaceted intervention, which promoted person-centred decision making and best practices, would reduce the risk of major perinatal morbidity among women with one previous caesarean delivery.[24]

Methods

Study design

The PRISMA trial was an open multicentre, cluster-randomised, parallel-group trial in which hospitals were the units of randomisation and women were the units of

Research in context

Evidence before this study

We searched PubMed for randomised controlled trials, before-and-after studies, studies that used interrupted time series analyses, observational studies, and systematic reviews published in English between Jan 1, 1990, and June 30, 2023, with the following MeSH and text searches: ("previous cesarean/caesarean" OR "prior cesarean/caesarean" OR "after cesarean/caesarean") associated with: ("uterine rupture" AND "risk") OR ("labor" OR "dystocia" AND "uterine rupture"); ("decision aid" OR "decision support" OR "decision analysis"); ("prediction/predicting" AND "vaginal birth after cesarean"); or ("prediction" AND "uterine rupture") OR ("lower uterine segment" AND "risk/evaluation/measurement"). We found two meta-analyses of 203 and 28 observational studies, 19 observational studies, and five randomised trials, that assessed the effects of a decision aid tool, the estimation of the chance of vaginal delivery, or the ultrasound assessment of the risk of uterine rupture in the setting of a trial of labour after caesarean. 12 observational studies suggested that dystocia, and particularly prolonged dystocia, was associated with an increased risk of uterine rupture. A secondary analysis of the QUARISMA trial confirmed this result in Quebec, Canada, suggesting that a standardised management of labour and dystocia could reduce perinatal and maternal risk associated with dystocia. Recently, two randomised trials in the UK and Australia suggested the potential value of clinical tools to assist in women's decision-making, which reduced anxiety and decisional conflict. However, as in the PRISMA trial, a third randomised trial in the US found a decision support tool did not alter vaginal delivery rates. Equally, six observational studies developed and validated a prediction model for vaginal birth after caesarean. Validation of this tool in the US and Quebec, Canada, suggested that a high chance of vaginal delivery was associated with a reduction in the rate of perinatal morbidity. Finally, a meta-analysis of 28 observational studies and one prospective randomised trial suggested a relationship between the lower uterine segment thickness, measured using a standardised ultrasound technique, and the risk of uterine rupture. An additional non-randomised study, based on a secondary analysis of the QUARISMA trial in Quebec, Canada, also suggested that the use of an ultrasound estimation of the risk of uterine rupture was associated with a significant reduction in major perinatal morbidity. In contrast, a recent randomised trial in France suggested that, when used alone, the estimation of the risk of rupture by ultrasound did not result in a statistically significant lower frequency of perinatal adverse outcomes or uterine rupture risk. The authors noted, however, that their study was underpowered.

Added value of this study

To our knowledge, the PRISMA trial represents the first study to combine all these tools in a single multifaceted intervention, directed toward decision-making support and a standardised management of labour. Results showed a significant reduction in major perinatal and maternal morbidity. However, a non-significant reduction in the risk of uterine rupture was observed in both the French and PRISMA trials, by 43% and 63%, respectively. The related meta-analysis, based on a random effect, showed a significant reduction in the risk of uterine rupture (relative risk 0·38 [95% CI 0·17–0·88]; p=0·024; I^2 0%), suggesting a potential reduction in the risk of uterine rupture associated with the use of the ultrasound estimation of the risk of uterine rupture. However, this last finding should be validated in future research.

Implications of all the available evidence

The PRISMA trial confirms that the combined action of tools including in the multifaceted intervention resulted in a significant reduction in rates of major perinatal and maternal morbidity, without increasing the rate of caesarean or uterine rupture.

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analysis.[3,24] We conducted the PRISMA (process for decision making, risk assessment, and management in obstetrics) trial in 40 public hospitals in Quebec, Canada. The trial was monitored by an independent data and safety monitoring board and received approval from the CHU de Quebec-Laval University institutional review board, and institutional review board at each participating hospital. In this cluster randomised controlled trial, the term full analysis set is used to describe the analysis set which is as complete as possible and as close as possible to the intention-to-treat ideal of including randomised participants.[33] The study protocol is available online. Written institutional consent was collected from each participating hospital and written informed consent was collected from each participant who accepted to have their risk of uterine rupture assessed by ultrasonography.

Participants

To be eligible to join the trial, hospitals were required to offer trial of labour after caesarean, to have at least 300 deliveries in the year before initiation of the study, and no recent or ongoing quality-improvement programmes directed toward women with a previous caesarean or any formal evaluation of the risk of uterine rupture. Women with only one previous caesarean delivery and a singleton gestation who delivered at participating hospitals and whose newborn had a gestational age of at least 24 weeks and weighed at least 500 g at delivery were included in the analysis.

For **protocol** see *Trials* 2017; **18:** 434

Randomisation and masking

Randomisation was stratified according to level of care (community, regional, or tertiary hospital). The study included a 1 year baseline period, a 5–8 month

See Online for appendix

implementation period, and a 2 year intervention period. After the 1 year baseline period, hospitals were randomly assigned (1:1) to either the intervention group or the control group. To avoid imbalance in the size of the two groups, we used computer-generated, blocked randomisation within each stratum, with blocks consisting of four hospitals or, for strata with fewer than eight hospitals, two hospitals. Investigators at each hospital were then immediately informed of the assignment status of their hospital.

In-hospital data were abstracted by trained research nurses or medical archivists from the medical records of mothers and newborns at least 3 months after delivery. Data collectors were aware of the randomisation assignments but were not involved in quality assessment or statistical analyses.

Procedures

The PRISMA programme, which was implemented at the hospital level, consisted of professional training on best practices, and provision of tools that aimed to support women's decision making in the choice of the mode of delivery, including: first, a decision aid tool; second, an estimation of the probability of vaginal delivery; and third, an estimation of the risk of uterine rupture using ultrasound measurement of the lower uterine segment in the third trimester of pregnancy.[24]

During the implementation period, among hospitals randomised to the intervention group, health professionals in obstetrics (physicians, nurses, and midwives) were invited to participate in an onsite 1 day training workshop, provided by certified instructors from the Society of Obstetricians and Gynaecologists of Canada, on best practices regarding intrapartum care among women with one previous caesarean delivery. A half-day repeat workshop occurred in the second year of the intervention period. Finally, technicians and physicians, with expertise in sonography, were identified and invited to receive an additional 1 day training in sonographic techniques related to the evaluation of the risk of uterine rupture.

During the 2-year intervention period, following the implementation period, clinical tools of the programme were offered in each intervention hospital. Clinical algorithms and a modified partograph for the monitoring of labour were available in the delivery room. The decision aid tool was distributed to eligible women by the attending physician between 12 weeks and 0 days (12^{+0}) of gestation and 34^{+6} weeks of gestation, preferentially early in the pregnancy. Physicians asked women to read the decision-aid tool and complete the exercise section in order to discuss their preferences during their next appointment. The estimated probability of vaginal delivery, based on participant's characteristics, was calculated by the attending physician during the same period. The risk of uterine rupture was estimated by ultrasound between 35^{+0} and 38^{+6} weeks of gestation. Results were then discussed with all women during their pregnancy and upon admission for delivery (appendix pp 4–8).

No intervention was planned in the control group hospitals. In order to assess the risk of contamination bias, quality-improvement programmes were documented annually in each hospital.

Outcomes

The primary outcome was a composite risk of major perinatal complications and included death excluding lethal congenital abnormalities, Apgar score at 5 min less than 4, metabolic acidosis, major trauma, intracerebral or intraventricular haemorrhage grade 3 and 4, periventricular leukomalacia, hypoxic-ischaemic encephalopathy, seizure, invasive mechanical ventilation, major respiratory morbidity, necrotising enterocolitis, proven neonatal sepsis or infection, and hypotension requiring vasopressor support. Secondary outcomes included composite risks of minor and major maternal complications, minor perinatal complications, planned and intrapartum caesarean delivery, vaginal delivery, assisted vaginal delivery (forceps or vacuum), pharmacological induction of labour, artificial rupture of membranes, use of oxytocin during labour, epidural analgesia, and episiotomy. Composite morbidity outcomes were prespecified on the basis of literature review and expert consensus (appendix p 9).[13,16,34,35]

As initially planned in the protocol, a cost-effectiveness analysis is ongoing. Because of delay associated with the COVID-19 pandemic, results are expected for the end of 2024.[24]

Data completeness and quality were assessed continuously during the trial. Discrepancies were resolved through queries and onsite visits. Clinical cases with any uncertainty related to major perinatal or maternal morbidity were systematically assessed by a panel of experts in neonatology and obstetrics who were masked to group assignment.

Additionally, a post hoc analysis was performed in which the major respiratory morbidity component was excluded from the perinatal composite. This was undertaken given that during the study, 32 (80%) of 40 hospitals in the trial (16 in the control group and 16 in the intervention group) developed an increased capacity, due to a provincial policy change in 2017 after the baseline period, to perform non-invasive mechanical ventilation. A second post hoc analysis was performed in which the internal organs injuries component was excluded from the major maternal composite. This was undertaken mainly because this component was accounting for a major proportion of the overall composite.

Statistical analysis

The sample size was calculated to maximise statistical power while minimising the number of hospitals (clusters).[3,36] To account for clustering by hospital, we

assumed an intraclass correlation coefficient of 0·001, estimated from the QUARISMA trial data.[3] We calculated that we would have to enrol 40 hospitals with an expected total of 7360 women with one previous caesarean delivery per year, to achieve a power of 80% to detect a 25% relative reduction in the rate of major perinatal morbidity with the intervention, assuming a baseline rate of 4·5% at a two-sided alpha level of 0·05.[3,37]

In the primary full analysis set, we assessed the effect of the intervention on the rate of major perinatal morbidity using the multivariable generalised-estimating-equations extension of logistic regression, with an exchangeable covariance matrix, to account for both clustering of women within hospitals and baseline imbalances.[38] Changes in the risk of major perinatal morbidity in the two study groups between the 1 year baseline period and the 2 year intervention period were compared with the use of an adjusted odds ratio (OR; with 95% CIs) for the interaction between group (intervention *vs* control) and time (intervention period *vs* baseline).[3,36] The adjusted OR for interaction was estimated with the use of data from women who delivered during the baseline or the intervention periods and measured the intervention effect with the difference-in-differences approach,[3,39] which was adapted for generalised-estimating-equations analyses of clustered binary outcomes (appendix pp 17–19).[24,36] Two-tailed p values of less than 0·05 were considered to indicate statistical significance.

All primary analyses were adjusted for prespecified maternal, perinatal, and institutional risk factors potentially associated with major perinatal morbidity. These factors included parity, smoking, assisted reproductive technology, maternal age, any pathology during pregnancy, previous vaginal delivery, birthweight, gestational age, presentation, level of care, and academic status of hospital (appendix pp 17–19).[24] To conform as closely as possible to the intention-to-treat approach, all eligible women who delivered at participating hospitals were included in the analyses. For adjustment variables for which less than 1% of the data were missing, we used random imputation based on highly correlated covariates.[3,24] Variables for which more than 1% of the data were missing were excluded from the analyses. No data were missing for primary and secondary outcomes. To assess whether the intervention effect varied according to the level of care used in the stratified randomisation, we tested the corresponding three-way interactions: level of care×intervention×time. Subgroup-specific intervention effects were reported for outcomes with significant three-way interactions.[3,39] Separate subgroup analyses were also conducted with women stratified by whether they underwent labour and whether they had a term delivery.

Secondary outcomes were analysed using a multivariable generalised-estimating-equations extension of logistic regression, with an exchangeable covariance matrix. If the generalised-estimating-equations models did not converge, the intervention effect was estimated with the use of a multivariable logistic model, which did not account for within-hospital clustering; to correct for the resulting underestimation of the standard errors, a conservative p value of less than 0·001 was used.[3,38]

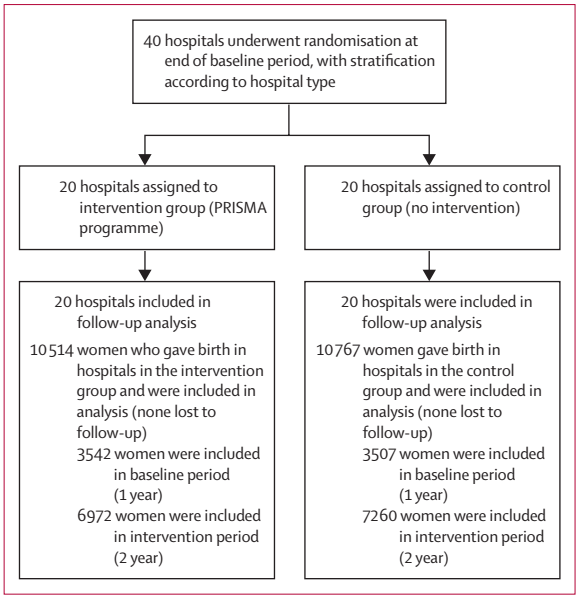

Figure: **Trial profile**

Adherence to the protocol was assessed in each intervention hospital through an implementation score derived from clinical data and onsite visits conducted during the intervention period (appendix pp 4–7). Hospitals with a score of less than 70% were excluded from the intervention group per protocol analyses. All analyses were performed with the use of SAS software, version 9.4, by an independent team whose members were unaware of the group assignments. A data monitoring committee oversaw the study.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Among 45 eligible hospitals, 44 agreed to participate and 40 were randomly selected for inclusion in the trial in April 1, 2016 (four community, 28 regional, and eight tertiary hospitals). Between April 1, 2016 and Dec 13, 2019, 21 281 women with a previous caesarean delivered during the study period (10 514 in the intervention group and 10 767 in the control group) and contributed to the estimation of the intervention effect. No hospital or woman who gave birth among participating hospitals was lost to follow-up (figure). Baseline characteristics were similar among hospitals and among women, with the exception of a significant between-group difference in maternal age

	Intervention group		Control group	
	Hospitals (n=20)	Patients (n=3542)	Hospitals (n=20)	Patients (n=3507)
Hospitals				
Type of hospital				
Community	2	80 (2·3%)	2	69 (2·0%)
Regional	14	2074 (58·6%)	14	2072 (59·1%)
Tertiary	4	1388 (39·2%)	4	1366 (39·0%)
Academic hospital	8	2035 (57·5%)*	7	2428 (69·2%)*
Patients				
Maternal age at delivery, years				
Mean	..	32·3 (4·7)	..	33·2 (4·7)*
Range				
≤17 years	..	1 (<0·1%)	..	0
18–34 years	..	2521 (71·2%)*	..	2224 (63·4%)*
≥35 years	..	1020 (28·8%)*	..	1283 (36·6%)*
Parity				
1	..	2914 (82·3%)	..	2849 (81·2%)
2	..	441 (12·5%)	..	444 (12·7%)
≥3	..	187 (5·3%)	..	214 (6·1%)
Previous vaginal delivery				
0	..	2944 (83·1%)	..	2878 (82·1%)
1	..	423 (11·9%)	..	424 (12·1%)
≥2	..	175 (4·9%)	..	205 (5·8%)
Gestational age at delivery				
<37 weeks	..	209 (5·9%)	..	213 (6·1%)
37–41 weeks	..	3329 (94·0%)	..	3287 (93·7%)
≥42 weeks	..	4 (0·1%)	..	7 (0·2%)
High-risk pregnancy†	..	2157 (60·9%)	..	2109 (60·1%)
Presentation of infant				
Cephalic	..	3343 (94·4%)	..	3313 (94·5%)
Breech	..	182 (5·1%)	..	178 (5·1%)
Transverse	..	17 (0·5%)	..	16 (0·5%)
Neonatal birth weight				
<1500 g	..	18 (0·5%)	..	19 (0·5%)
1500–2499 g	..	142 (4·0%)	..	140 (4·0%)
2500–3999 g	..	3023 (85·3%)	..	3011 (85·9%)
≥4000 g	..	359 (10·1%)	..	337 (9·6%)

Data are n (%) or mean (SD). There were no significant between-group differences at baseline except with regard to academic status of the hospitals, previous vaginal birth after caesarean, and maternal age. *p<0·05 for the difference between groups. The p value was calculated by means of a univariate model with the use of generalised estimating equations in which the structure for patient characteristics was exchangeable or independent. †A pregnancy was considered to be low risk if the woman gave birth to a single baby in cephalic presentation, had not used assisted reproductive technology, was between 18 and 39 years of age, had a BMI before pregnancy between 17 and 29, had no previous vertical caesarean section, no previous or current stillbirth, no transfer to another hospital during pregnancy, no other pathological condition or complication during the current pregnancy or a previous pregnancy, and if the gestational age was between 37 and 41 weeks. A pregnancy was considered to be at high risk if any of these conditions were not met. See appendix p 10 for further details.

Table 1: **Baseline characteristics of hospitals and patients**

and academic status of hospitals (table 1), for which adjustments were made in multivariable analyses.

Changes in maternal characteristics were also detected from the baseline period to the intervention period. The frequency of women with a BMI over 30 kg/m² increased from 1216 (17·3%) of 7049 women during the baseline period to 2785 (19·6%) of 14 232 during the intervention period, and the frequency of women with a high-risk pregnancy increased from 4266 (60·5%) of 7049 women to 9117 (64·1%) of 14 232 women (appendix p 25).

During the study period, the rate of major perinatal morbidity increased in the control group from 110 (3·1%) of 3507 women at baseline to 309 (4·3%) of 7260 women during the intervention period. Conversely, this rate decreased in the intervention group over the same time-period from 141 (4·0%) of 3542 women to 265 (3·8%) of 6972 women (table 2).

In the between-group comparison of the change from the baseline period to the intervention period, there was a reduction in the rate of major perinatal morbidity in the intervention group compared with the control group (adjusted OR 0·72 [95% CI 0·52 to 0·99]; p=0·042; adjusted absolute risk difference –1·2% [–2·0 to –0·1]; table 2). The intervention effect was similar regardless of the level of care of the hospital (p=0·27 for the three-way interaction). The reduction in the rate of major perinatal morbidity was mostly due to the effect of the intervention on metabolic acidosis and major trauma (table 2).

Among the 20 hospitals in the intervention group, 19 (95%) met the prespecified criteria for adherence to the protocol. Non-adherence was primarily due to the low amount of uptake of ultrasound estimation of the risk of uterine rupture and tools related to the management of labour. The per protocol analysis, which included 19 adherent hospitals, yielded a greater intervention effect for the primary outcome (adjusted OR 0·69 [95% CI 0·50–0·95]; p=0·024) than that of the full analysis set (table 2).

Centre-specific results are shown in the appendix (pp 11–16). No substantial heterogeneity across hospitals was found in either the control or intervention group (p=0·41 and p=0·32, respectively).

The intervention group, compared with the control group, had a reduction in the rate of major maternal morbidity from the baseline period to the intervention period (adjusted OR 0·54 [95% CI 0·33 to 0·89]; p=0·016; adjusted absolute risk difference –1·1% [–1·6 to –0·3]; table 3). This reduction was mostly due to the effects of internal organ injuries. Internal organ injuries increased in both groups (table 3), but the increase was smaller in the intervention group (adjusted OR 0·52 [0·30 to 0·90]; p=0·019). The intervention did not significantly affect the rates of minor perinatal and maternal morbidities, uterine rupture, elective repeat caesarean delivery, trial of labour, or vaginal delivery (tables 3 and 4).

Among women who attempted labour, both major perinatal and maternal morbidity decreased in the intervention group compared with the control group (perinatal: adjusted OR 0·52 [95% CI 0·31–0·89], p=0·017; maternal: 0·43 [0·23–0·80], p=0·0081), whereas no significant effect was observed among women with an elective repeat caesarean delivery (appendix p 23).

	Intervention group			Control group			Crude difference in rate change (95% CI)†	Effect of intervention		
	Baseline period (n=3542)	Intervention period (n=6972)	Percentage difference	Baseline period (n=3507)	Intervention period (n=7260)	Percentage difference		Adjusted absolute risk difference (95% CI)‡	Adjusted odds ratio (95% CI)§	p value
Full analysis set										
Major perinatal morbidity	141 (4·0%)	265 (3·8%)	−0·2%	110 (3·1%)	309 (4·3%)	1·1%	−1·3 (−2·4 to −0·2)	−1·2 (−2·0 to −0·1)	0·72 (0·52 to 0·99)	0·042¶
By type of complications										
Intrapartum or neonatal death	9 (0·3%)	10 (0·1%)	−0·1%	12 (0·3%)	13 (0·2%)	−0·2%	0·1 (−0·2 to 0·3)	0·1 (−0·1 to 0·8)	1·47 (0·39 to 5·52)	0·57
Apgar 5 min (<4)	21 (0·6%)	17 (0·2%)	−0·3%	20 (0·6%)	37 (0·5%)	−0·1%	−0·3 (−0·7 to 0·1)	−0·2 (−0·4 to 0·1)	0·52 (0·23 to 1·19)	0·12
Metabolic acidosis	15 (0·4%)	17 (0·2%)	−0·2%	17 (0·5%)	53 (0·7%)	0·2%	−0·4 (−0·8 to −0·0)	−0·4 (−0·6 to −0·2)	0·41 (0·22 to 0·76)	0·0047¶
Major trauma‖	5 (0·1%)	8 (0·1%)	−0·0%	1 (<0·1%)	12 (0·2%)	0·1%	−0·2 (−0·3 to 0·0)	−0·1 (−0·2 to 0·1)	0·13 (0·01 to 1·38)	0·090
Intraventricular haemorrhage**	2 (0·1%)	3 (<0·1%)	−0·0%	0	3 (<0·1%)	0·0%	−0·1 (−0·2 to 0·0)	..	..	..
Periventricular leukomalacia**	1 (<0·1%)	3 (<0·1%)	0·0%	0	1 (<0·1%)	0·0%	0·0 (−0·1 to 0·1)	..	..	..
Seizure**	4 (0·1%)	6 (0·1%)	−0·0%	0	9 (0·1%)	0·1%	−0·2 (−0·3 to 0·0)	..	..	..
Invasive mechanical ventilation	32 (0·9%)	43 (0·6%)	−0·3%	26 (0·7%)	57 (0·8%)	0·0%	−0·3 (−0·8 to 0·2)	−0·2 (−0·4 to 0·2)	0·76 (0·46 to 1·27)	0·30
Major respiratory morbidity	108 (3·0%)	233 (3·3%)	0·3%	83 (2·4%)	243 (3·3%)	1·0%	−0·7 (−1·6 to 0·3)	−0·6 (−1·5 to 0·7)	0·81 (0·54 to 1·22)	0·32
Necrotising enterocolitis‖	1 (<0·1%)	2 (<0·1%)	0·0%	1 (<0·1%)	2 (<0·1%)	−0·0%	0·0 (−0·1 to 0·1)	−0·0 (−0·0 to 0·5)	0·54 (0·01 to 21·02)	0·74
Hypoxic-Ischemic encephalopathy‖	4 (0·1%)	5 (0·1%)	−0·0%	5 (0·1%)	7 (0·1%)	−0·0%	0·0 (−0·2 to 0·2)	−0·0 (−0·1 to 0·4)	0·96 (0·17 to 5·53)	0·97
Proven neonatal sepsis‖	12 (0·3%)	17 (0·2%)	−0·1%	6 (0·2%)	13 (0·2%)	0·0%	−0·1 (-0·4 to 0·2)	−0·0 (−0·1 to 0·3)	0·74 (0·21 to 2·50)	0·63
Hypotension requiring vasopressor‖	2 (0·1%)	2 (<0·1%)	−0·0%	6 (0·2%)	3 (<0·1%)	−0·1%	0·1 (−0·1 to 0·3)	0·1 (−0·0 to 1·3)	2·84 (0·25 to 33·05)	0·40
Post hoc analysis										
Major perinatal morbidity excluding major respiratory morbidity	74 (2·1%)	98 (1·4%)	−0·7%	61 (1·7%)	153 (2·1%)	0·4%	−1·1 (−1·8 to −0·3)	−0·8 (−1·2 to −0·3)	0·59 (0·41 to 0·86)	0·0060¶
Per protocol analysis††										
Total	3147	6212		3507	7260					
Major perinatal morbidity	135 (4·3%)	245 (3·9%)	−0·3%	110 (3·1%)	309 (4·3%)	1·1%	−1·5 (−2·6 to −0·3)	−1·3 (−2·1 to −0·2)	0·69 (0·50 to 0·95)	0·024¶

Data are n (%) unless otherwise indicated. GEE=generalised-estimating-equations. *Events that determined major perinatal morbidity included in utero death, intrapartum death, and neonatal death, APGAR score of less than 4 at 5 min after birth, metabolic acidosis, major trauma, intraventricular haemorrhage (grade 3 and 4), periventricular leukomalacia, seizure, invasive mechanical ventilation, major respiratory morbidity, necrotising enterocolitis, hypoxic-ischemic encephalopathy, proven neonatal sepsis or infection, and hypotension requiring vasopressor. For complete definitions of major perinatal morbidity, see appendix p 9. †The unadjusted crude difference in rate change was calculated as follows: (intervention rate – baseline rate in intervention group) – (intervention rate – baseline rate in control group). ‡The adjusted absolute risk difference represents adjusted differences between group-specific changes over time and was estimated with the use of the GEE model (see appendix pp 17–19). §The adjusted odds ratios for the interaction between groups (intervention *vs* control) and time (intervention period *vs* baseline period) were estimated with the use of the GEE model. ¶In the GEE model, p values of less than 0·05 were considered to indicate statistical significance, and p values of less than 0·06 were considered to indicate marginal significance. ‖A logistic model was used because the calculations for the GEE model did not converge. For this model, p values of less than 0·001 were considered to indicate statistical significance and p values of less than 0·003 were considered to indicate marginal significance. **When no event was observed for at least one group, the effect of intervention was not possible to calculate and was replaced by a "··" in the table. ††For the per protocol analysis, one hospital with a low level of adherence to the protocol was excluded from the intervention group.

Table 2: **Primary outcome: composite risk of major perinatal morbidity***

Among women who delivered at term, major perinatal morbidity decreased in the intervention group compared with the control group (adjusted OR 0·64 [95% CI 0·42–0·98]; p=0·042), whereas no significant effect was observed among women who had preterm birth (adjusted OR 0·90 [0·58–1·41]; p=0·66, appendix p 24).

In the first post hoc analysis, exclusion of major respiratory mortality from the perinatal composite led to an observed temporal increase in major respiratory morbidity (table 2), because neonates who received non-invasive mechanical ventilation instead of low-level oxygen supplementation could now be categorised as having major perinatal morbidity. This change occurred in both study arms. Nevertheless, the intervention was associated with a decrease in major perinatal morbidity after the exclusion of major respiratory morbidity component from the perinatal composite (adjusted OR 0·59 [95% CI 0·41 to 0·86]; p=0·0060; table 2).

In the second post hoc analysis, after removing the internal organ injuries component from the major

	Intervention group			Control group			Crude difference in rate change (95% CI)†	Effect of intervention		
	Baseline period (n=3542)	Intervention period (n=6972)	Percentage difference	Baseline period (n=3507)	Intervention period (n=7260)	Percentage difference		Adjusted absolute risk difference (95% CI)‡	Adjusted odds ratio (95% CI)§	p value
Major maternal morbidity	70 (2·0)	125 (1·8)	−0·2%	52 (1·5)	179 (2·5)	1·0%	−1·2 (−1·9 to −0·4)	−1·1 (−1·6 to −0·3)	0·54 (0·33 to 0·89)	0·016¶
By type of complications										
Maternal death (per 100 000)‖	0	1 (14·3)	14·3	0	0	0·0	14·3 (−13·8 to 42·5)	..	..	..
Hysterectomy	7 (0·2%)	9 (0·1%)	−0·1%	6 (0·2%)	7 (0·1%)	−0·1%	0·0 (−0·2 to 0·2)	0·0 (−0·1 to 0·4)	1·23 (0·31 to 4·88)	0·77
Thromboembolic disease**	6 (0·2%)	6 (0·1%)	−0·1%	2 (0·1%)	8 (0·1%)	0·1%	−0·1 (−0·3 to 0·1)	−0·1 (−0·1 to 0·1)	0·26 (0·04 to 1·77)	0·17
Admission to ICU (≥ 4 days)**	3 (0·1%)	2 (<0·1%)	−0·1%	2 (0·1%)	3 (<0·1%)	−0·0%	−0·0 (−0·2 to 0·1)	−0·0 (−0·0 to 0·2)	0·47 (0·04 to 5·92)	0·56
Acute pulmonary oedema**	2 (0·1%)	2 (<0·1%)	−0·0%	3 (0·1%)	9 (0·1%)	0·0%	−0·1 (−0·2 to 0·1)	−0·1 (−0·1 to 0·4)	0·37 (0·03 to 3·88)	0·40
Cardiogenic shock‖	1 (<0·1%)	1 (<0·1%)	−0·0%	0	0	0·0%	−0·0 (−0·1 to 0·0)	..	..	..
Sepsis‖	6 (0·2%)	4 (0·1%)	−0·1%	0	5 (0·1%)	0·1%	−0·2 (−0·3 to −0·0)	..	..	..
Internal organ injuries	50 (1·4%)	104 (1·5%)	0·1%	36 (1·0%)	148 (2·0%)	1·0%	−0·9 (−1·6 to −0·3)	−1·0 (−1·4 to −0·2)	0·52 (0·30 to 0·90)	0·019¶
Uterine rupture**	7 (0·2%)	5 (0·1%)	−0·1%	7 (0·2%)	14 (0·2%)	−0·0%	−0·1 (−0·4 to 0·1)	-0·1 (−0·2 to 0·1)	0·37 (0·09 to 1·62)	0·19
Post hoc analysis										
Major maternal morbidity excluding Internal organ injuries	27 (0·8%)	25 (0·4%)	−0·4%	18 (0·5%)	41 (0·6%)	0·1%	−0·5 (−0·9 to −0·0)	−0·3 (−0·4 to −0·1)	0·44 (0·23 to 0·81)	0·0088¶
Minor perinatal morbidity	876 (24·7%)	1675 (24·0%)	−0·7%	908 (25·9%)	1901 (26·2%)	0·3%	−1·0 (−3·5 to 1·5)	−0·9 (−4·4 to 2·9)	0·95 (0·78 to 1·16)	0·63
Minor maternal morbidity	335 (9·5%)	715 (10·3%)	0·8%	322 (9·2%)	677 (9·3%)	0·1%	0·7 (−1·0 to 2·3)	0·6 (−0·8 to 2·3)	1·08 (0·90 to 1·28)	0·41

Data are n (%) unless otherwise indicated. GEE=generalised-estimating-equations. *Events that determined major maternal morbidity included maternal death, hysterectomy, proven thromboembolic complications, admission to intensive care unit for 4 days or more, acute pulmonary edema, cardiogenic shock, sepsis with proven bacteremia (septicemia), injury or lacerations to internal organs requiring surgical repair, and uterine rupture. Events that determined minor neonatal morbidity included minor cardiorespiratory complications, non-invasive mechanical ventilation, admission to intensive care unit for less than 4 days, oxygen therapy, suspicion of neonatal infection, APGAR score between 4 and 6 at 5 min after birth, moderate acidosis, minor trauma, blood transfusion, and a weight loss of more than 10% in the first 10 postnatal days. Events that determined minor maternal morbidity included blood transfusion, postpartum haemorrhage, perineal tear (grade 3–4), cervical lacerations, dehiscence of skin wound, puerperal fever, postpartum infection, major gastrointestinal complications, obstetric anaesthesia complications, postpartum hospital stay of 7 days or more; admission to intensive care unit for less than 4 days, and readmission to hospital within 40 days of childbirth. For complete definitions of major maternal morbidity and minor perinatal and maternal morbidity, see appendix p 9. †The unadjusted crude difference in rate change was calculated as follows: (intervention rate – baseline rate in intervention group) – (intervention rate – baseline rate in control group). ‡The adjusted absolute risk difference represents adjusted differences between group-specific changes over time and was estimated with the use of the GEE model. §The adjusted odds ratios for the interaction between groups (intervention *vs* control) and time (intervention period *vs* baseline period) were estimated with the use of the GEE model. ¶In the GEE model, p values of less than 0·05 were considered to indicate statistical significance, and p values of less than 0·06 were considered to indicate marginal significance. ‖When no event was observed for at least one group, the effect of intervention was not possible to calculate and was replaced by a ".." in the table. **A logistic model was used because the calculations for the GEE model did not converge. For this model, p values of less than 0·001 were considered to indicate statistical significance and p values of less than 0·003 were considered to indicate marginal significance.

Table 3: **Secondary outcomes: composite risk of major maternal morbidity and minor perinatal and maternal morbidity***

	Intervention group			Control group			Crude difference in rate change (95% CI)†	Effect of intervention		
	Baseline period (n=3542)	Intervention period (n=6972)	Percentage difference	Baseline period (n=3507)	Intervention period (n=7260)	Percentage difference		Adjusted absolute risk difference (95% CI)‡	Adjusted odds ratio (95% CI)§	p value
All deliveries										
ERCD	2432 (68·7%)	4705 (67·5%)	−1·2%	2200 (62·7%)	4493 (61·9%)	−0·8%	−0·3 (−3·0 to 2·4)	−1·0 (−5·6 to 3·3)	0·96 (0·79 to 1·15)	0·65
TOLAC	1110 (31·3%)	2267 (32·5%)	1·2%	1307 (37·3%)	2767 (38·1%)	0·8%	0·3 (−2·4 to 3·0)	1·0 (−3·3 to 5·6)	1·05 (0·87 to 1·26)	0·65
Intrapartum caesarean delivery	320 (9·0%)	602 (8·6%)	−0·4%	315 (9·0%)	690 (9·5%)	0·5%	−0·9 (−2·6 to 0·7)	−0·9 (−2·9 to 1·6)	0·89 (0·67 to 1·18)	0·43
VBAC	790 (22·3%)	1665 (23·9%)	1·6%	992 (28·3%)	2077 (28·6%)	0·3%	1·3 (−1·2 to 3·7)	2·4 (−0·8 to 5·7)	1·12 (0·96 to 1·30)	0·15
Women who attempted labour										
Total	1110	2267		1307	2767					
Intrapartum caesarean delivery	320 (28·8%)	602 (26·6%)	−2·3%	315 (24·1%)	690 (24·9%)	0·8%	−3·1 (−7·4 to 1·2)	−3·3 (−7·6 to 1·7)	0·83 (0·63 to 1·09)	0·18
Vaginal delivery	790 (71·2%)	1665 (73·4%)	2·3%	992 (75·9%)	2077 (75·1%)	−0·8%	3·1 (−1·2 to 7·4)	3·3 (−1·7 to 7·6)	1·21 (0·92 to 1·59)	0·18
Pharmacological induction of labour	189 (17·0%)	596 (26·3%)	9·3%	264 (20·2%)	741 (26·8%)	6·6%	2·7 (−1·3 to 6·6)	4·3 (−0·6 to 9·7)	1·23 (0·97 to 1·57)	0·088
Artificial rupture of membranes	656 (59·1%)	1363 (60·1%)	1·0%	689 (52·7%)	1567 (56·6%)	3·9%	−2·9 (−7·7 to 1·9)	−2·9 (−8·4 to 2·4)	0·89 (0·71 to 1·10)	0·28
Assisted vaginal deliveries	151 (13·6%)	283 (12·5%)	−1·1%	158 (12·1%)	347 (12·5%)	0·5%	−0·3 (−0·8 to 0·2)	−1·7 (−4·4 to 1·9)	0·85 (0·62 to 1·17)	0·32
Use of oxytocin during labour	363 (32·7%)	769 (33·9%)	1·2%	410 (31·4%)	837 (30·2%)	−1·1%	2·3 (−2·2 to 6·9)	1·8 (−2·9 to 6·9)	1·09 (0·87 to 1·37)	0·45
Epidural analgesia	836 (75·3%)	1761 (77·7%)	2·4%	981 (75·1%)	2187 (79·0%)	4·0%	−1·6 (−5·8 to 2·5)	−1·3 (−6·4 to 3·2)	0·93 (0·70 to 1·22)	0·59
Episiotomy	94 (8·5%)	189 (8·3%)	−0·1%	142 (10·9%)	291 (10·5%)	−0·3%	0·2 (−2·6 to 3·1)	−0·2 (−3·2 to 3·8)	0·98 (0·68 to 1·42)	0·92

Data are n (%) unless otherwise indicated. In the GEE model, p values of less than 0·05 were considered to indicate statistical significance, and p values of less than 0·06 were considered to indicate marginal significance. ERCD=elective repeat caesarean delivery. GEE=generalised-estimating-equations. TOLAC=trial of labour after caesarean delivery. VBAC=vaginal birth after caesarean. *Rate of ERCD is the number of elective caesarean deliveries divided by the total number of women with one previous caesarean delivery. Rate of TOLAC is the number of women attempting a vaginal delivery divided by the total number of women with one previous caesarean delivery. Rate of VBAC is the number of vaginal deliveries divided by the total number of women with one previous caesarean delivery. †The unadjusted crude difference in rate change was calculated as follows: (intervention rate – baseline rate in intervention group) – (intervention rate – baseline rate in control group). ‡The adjusted absolute risk difference represents adjusted differences between group-specific changes over time and was estimated with the use of the GEE model. §The adjusted odds ratios for the interaction between groups (intervention *vs* control) and time (intervention period *vs* baseline period) were estimated with the use of the GEE model.

Table 4: **Secondary outcomes: rates of obstetrical interventions***

maternal composite, the intervention was associated with a decrease in major maternal morbidity compared with the control group (adjusted OR 0·44 [95% CI 0·23 to 0·81]; p=0·0088; table 3).

Discussion

A multifaceted intervention, designed to promote person-centred decision making and best practices for pregnant women with one previous caesarean delivery, led to a statistically significant reduction in the rate of major perinatal morbidity. This reduction was driven by the effect of the intervention among women who delivered at term, and who attempted labour. Equally, no difference was observed among women who had preterm delivery. Furthermore, the intervention was associated with a significant reduction in major maternal morbidity, while no difference was observed in the rates of uterine rupture and caesarean delivery. These results might reflect improvements in the estimation of risks and benefits associated with mode of delivery and in intrapartum care.

Recently, randomised and non-randomised studies suggested the potential value of clinical tools to assist in women's decision making,[22–24,40] to help estimate the probability of vaginal delivery and delivery-related morbidity,[25–28,41,42] and to help estimate the risk of uterine rupture.[15,22–31,43,44] As in our trial, a previous randomised trial found a decision support tool did not alter vaginal

delivery rates. Nevertheless, the trial was not powered to detect differences in perinatal or maternal morbidity.[45] A non-randomised study also suggested that the use of an ultrasound estimation of the risk of uterine rupture was associated with a significant reduction in major perinatal morbidity.[32] By contrast, a recent randomised trial suggested that, when used alone, the estimation of the risk of rupture by ultrasound did not result in a statistically significant lower frequency of maternal and perinatal adverse outcomes.[46] The authors stated, however, that their study was underpowered.[46]

Our trial represents the first study to combine these tools in a single multifaceted intervention, directed toward decision making support and a standardised management of labour. Equally, this trial had one of the largest samples, including more than 90% of women with one previous caesarean who delivered in Quebec province during the study period. The PRISMA programme consisted of provision of tools available during the pregnancy and delivery. The first components of the program, provided during pregnancy, were first, a decision aid tool available at the first visit; second, an estimation of the probability of vaginal delivery conducted between the first and the second trimester; and third, an estimation of the risk of uterine rupture using ultrasound measurement of the lower uterine segment in the third trimester of pregnancy. The second components of the programme, provided during delivery, were: first, Society of Obstetricians and Gynaecologists of Canada clinical practice guidelines and algorithms on best practices regarding intrapartum management and labour dystocia, associated with an increased risk of uterine rupture;[11,14,21,47–55] and second, the use of a partograph to manage labour and dystocia (appendix p 8).

The implementation of the PRISMA programme consisted of a 1 day training workshop, including a half-day repeat workshop after the first year of the program, from the Society of Obstetricians and Gynaecologists of Canada on best practices in intrapartum care, and provision of tools that aim to support women's decision making in the choice of mode of delivery. The implementation analysis of the programme showed a high level of adherence to the protocol for 19 hospitals out of 20, with an implementation score of more than 70%. Only the ultrasound estimation of the risk of uterine rupture presented challenge in the implementation, with an additional 1 day training in sonographic techniques and the availability of an ultrasound platform, and trained health professionals in each hospital. The observed non-adherence was primarily due to the low amount of uptake of ultrasound estimation of the risk of uterine rupture. However, among the 20 hospitals of the intervention group, more than 75% of women eligible to an estimation of the risk of uterine rupture, with one previous caesarean delivery, were assessed during the trial, suggesting a good level of adherence to the protocol. The reduction in the rates of major perinatal and maternal morbidity observed in this trial confirm the benefit of the programme and suggest that a similar intervention could be beneficial in other countries or regions with similar settings.

Our study had some limitations. Since hospitals were the unit of randomisation and the number of deliveries varied across hospitals, there were differences in the distribution of some hospital characteristics across groups at baseline. These differences were adjusted for, as planned a priori, in multivariable analyses. Furthermore, the rate of major perinatal morbidity increased from the baseline period to the intervention period in the control group. This may be explained by an increase in major respiratory morbidity due to a provincial policy change in 2017 that allowed greater access to mechanical ventilation. The results of the post hoc analysis confirmed that this change in practice did not influence the primary findings of the trial. It should be noted that, compared with the primary analysis, a higher decrease in the rate of major perinatal morbidity was observed in the intervention group, and an attenuated increase was detected in the control group. However, this increase could be attributed to the changes observed in maternal characteristics over time. Equally, the trial was not designed to detect any difference based on race or ethnicity, and data on self-reported race and ethnicity were not available in medical records. Finally, because we tested a multifaceted intervention, it is not possible to determine which of its components were primarily responsible for the observed effect.

PRISMA trial research group

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Contributors

NC and EB designed the study, with advice from BM regarding statistical issues; ED and SB gathered the data; TD and NC carried out the analyses, under the supervision of BM; NC and EB vouch for the data, while NC, BM, EB, WDF, and WAG all vouch for the analyses; all authors contributed to the writing of the manuscript; and NC was the primary author responsible for writing and publishing the manuscript. This manuscript has been read and approved by all the authors. Each author believes that the manuscript represents honest work. All authors were permitted access to all the data in the study, and all authors accept responsibility for the decision to submit the manuscript for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit the manuscript for publication. NC, ED, and TD verified all the raw data in the study.

Declaration of interests

We declare no competing interests.

Data sharing

The data that support the findings of this study are available from the corresponding author, NC, upon request.

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