3-1-2016

Randomized controlled trial of prolonged second stage: extending the time limit vs usual guidelines.

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As submitted to:

American Journal of Obstetrics and Gynecology

And later published as:

Randomized Controlled Trial of Prolonged Second Stage: Extending the Time Limit vs Usual Guidelines

Volume 214, Issue 3, e1-6

March 2016

DOI: 10.1016/j.ajog.2015.12.042

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Disclosure: The authors report no conflict of interest.

Funding: There was no financial support for this research

This trial was registered on clinicaltrials.gov (NCT02101515).

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Abstract

Background

Guidelines for management of the second stage have been proposed since the 1800s and were created largely by expert opinion. Current retrospective data are mixed regarding differences in maternal and neonatal outcomes with a prolonged second stage. There are no randomized controlled trials that have evaluated whether extending the second stage of labor beyond current American College of Obstetricians and Gynecologists recommendations is beneficial.

Objective

The purpose of this study was to evaluate whether extending the length of labor in nulliparous women with prolonged second stage affects the incidence of cesarean delivery and maternal and neonatal outcomes.

Study Design

We conducted a randomized controlled trial of nulliparous women with singleton gestations at 36 0/7 to 41 6/7 weeks gestation who reached the American College of

Obstetricians and Gynecologists definition of *prolonged second stage of labor*, which is 3 hours with epidural anesthesia or 2 hours without epidural anesthesia. Women were assigned randomly to*extended labor* for at least 1 additional hour, or to *usual labor*, which was defined as expedited delivery via cesarean or operative vaginal delivery. The exclusion criteria were intrauterine fetal death, planned cesarean delivery, age <18 years, and suspected major fetal anomaly. Primary outcome was incidence of cesarean delivery. Maternal and neonatal outcomes were compared secondarily. Statistical analysis was done by intention-to-treat.

Results

Seventy-eight nulliparous women were assigned randomly**.** All of the women had epidural anesthesia. Maternal demographics were not significantly different. The incidence of cesarean delivery was 19.5% (n = 8/41 deliveries) in the extended labor group and 43.2% (n = 16/37 deliveries) in the usual labor group (relative risk, 0.45; 95% confidence interval, 0.22–0.93). The number needed-to-treat to prevent 1 cesarean delivery was 4.2. There were no statistically significant differences in maternal or neonatal morbidity outcomes.

Conclusion

Extending the length of labor in nulliparous women with singleton gestations, epidural anesthesia, and prolonged second stage decreased the incidence of cesarean delivery by slightly more than one-half, compared with usual guidelines. Maternal or neonatal morbidity were not statistically different between the groups; however, our study was underpowered to detect small, but potentially clinical important, differences.

Introduction

Guidelines for the management of the second stage of labor have been proposed since the 1800s and were created largely by expert opinion. The first large retrospective data collection was done by Hellman and Prystowsky[1] in 1952, which showed that women who had a second stage of labor within 2 hours had a decreased rate of postpartum hemorrhage, fever, and neonatal death. Friedman,[3] in 1955, evaluated the natural course of labor and noted that most nulliparous women without epidural anesthesia delivered within 2 hours.[2]Recent data have suggested that obstetricians may want to extend the time limit to 3 hours to achieve a vaginal delivery for nulliparous women without an epidural and to 4 hours in those with an epidural. However, current retrospective data are mixed regarding differences in maternal and neonatal outcomes with a prolonged second stage.[4, 5, 6 and 7] There are no randomized controlled trials that

have evaluated whether extending the second stage of labor beyond current American College of Obstetricians and Gynecologists (ACOG) recommendations is beneficial.[8] The aim of this study was to evaluate whether extending the time limit of second stage of labor beyond current ACOG guidelines would affect the incidence of cesarean delivery (CD). Maternal and perinatal outcomes were also assessed.

Materials and Methods

This study was conducted from March 2014 until July 2015 at Thomas Jefferson University Hospital. The protocol was approved by the institutional review board, and all women provided written informed consent before assignment. Eligible nulliparous women were at least 18 years old with singleton pregnancies of at least 36 weeks gestation, cephalic presentation, and category I or II fetal heart tracings. Exclusion criteria included category III fetal heart tracing, previous vaginal delivery at ≥24 weeks gestation, multiple pregnancy, intrauterine fetal death, trial of labor after CD, planned CD, or suspected major fetal anomaly. Women were consented well before the second stage started, either in the office during prenatal care or early on admission to labor and delivery. Participating women did not receive compensation.

This study was a randomized controlled trial. Randomization was completed by a computer-generated list that used random block sizes of 8, 10, and 12. Group assignments were made based on sequentially numbered opaque sealed envelopes. The sequence was generated by the primary investigator (A.C.G.). Participants were consented by labor and delivery providers in the office or on admission. Women were assigned randomly to either “extended care” or “usual care” groups. Randomization was

stratified by epidural status. Suggested treatment for women who were assigned randomly to the extended care group was continuing the second stage for at least 1 additional hour after reaching the ACOG prolonged second stage criteria (ie, after 3 hours in the second stage of labor with an epidural or 2 hours without an epidural). Suggested treatment for women who were assigned randomly to the usual care group was delivery soon after reaching the criteria for prolonged second stage listed by ACOG. Women were assigned randomly by labor and delivery staff at either the 3-hour mark (with epidural) or 2-hour mark (without epidural).

Except for the suggested management regarding length of the second stage as per randomization, the second stage of labor was managed according to the individual provider on labor and delivery. All patients were treated by house staff under the supervision of an attending physician. In general, on the finding of complete dilation, women without an urge to push were offered delayed pushing (ie, waiting about 1 hour before starting to push). Once pushing started, this usually was done via Valsalva maneuver. Delayed pushing was included in the total time of second stage. After reaching ACOG criteria for prolonged second stage, women in the extended care group were given at least 1 additional hour to have a spontaneous vaginal delivery (SVD) then delivered by the labor and delivery team with the option of CD, forceps-assisted vaginal delivery (FAVD), or vacuum-assisted vaginal delivery (VAVD). Women in the usual care group who reached ACOG criteria for prolonged second stage were at that point expeditiously delivered by the labor and delivery team with the option of CD, FAVD, or VAVD.

Primary outcome was CD. Maternal secondary outcome measures included incidence of: vaginal delivery (SVD and operative vaginal delivery [OVD] combined), SVD, OVD, chorioamnionitis, endometritis, postpartum hemorrhage (defined as >500 mL estimated blood loss in a vaginal delivery and >1000 mL estimated blood loss in a CD), transfusion, third- and fourth-degree laceration, and cervical laceration.

Neonatal secondary outcome measures included shoulder dystocia, birthweight, neonatal intensive care unit (NICU) admission, ventilation support with the use of continuous positive airway pressure or greater, sepsis, seizure, umbilical artery cord pH <7.10, perinatal death, and NICU length of stay.

Race/ethnicity was classified by the study participants. The classifications were non-Hispanic white, non-Hispanic black, Asian, Hispanic, or other.

A priori sample size estimation was calculated with an α of .05 and β of .20. Based on observations of successful vaginal delivery at 4-hour second stage by Mentigoglu et al,[9] and on more recent delivery rates at our institution, we estimated that the CD rate in the usual care group (ie, soon after 3 hours with an epidural or 2 hours without an epidural) would be 50%, with a reduction to 20% at 4 hours with an epidural or 3 hours without an epidural. A total sample of 78 women was estimated to provide 80% power to detect a >2-fold decrease in CD rate. A subgroup analysis was planned for women with an epidural vs women without an epidural. Potential confounders were planned to be analyzed to determine confounding vs interaction.

The data analysis for this study was generated with SPSS software (version 20; IBM, Armonk, NY). Statistical analysis was performed by the intention-to-treat principle. Categorical variables were compared with the use of χ^2 test or Fisher exact test.

Continuous variables were compared with the use of 2-tailed Student *t* test or Wilcoxon Rank-Sum test. A probability value of <.05 was considered statistically significant. Data were analyzed by the primary investigator (A.C.G.) with assistance from the Thomas Jefferson University Biostatistics Department.

The Consolidated Standards of Reporting Trials guidelines were followed.[10] This trial was registered on clinicaltrials.gov (NCT02101515). This study was not funded.

Results

From March 2013 through July 2015, we enrolled 78 nulliparous women, of whom 41 women were assigned to receive extended labor and 37 women were assigned to usual labor. No women were excluded or lost to follow up. All had epidural anesthesia. All women initially received the allocated intervention; however, there was a 14.1% crossover rate (extended labor, 2; usual labor, 9). Reasons for crossover in the extended labor group were maternal request (n = 1) and nonreassuring fetal heart tracing (n = 1). Reasons for crossover in the usual labor group included maternal request (n = 4) and delivery provider decision (n = 5). No women withdrew from the study. There was no loss to follow up. Figure 1 shows the trial flow diagram.

Overall, the women were 44.9% white and 25.6% African American. The average body mass index was 30.9 kg/m^2; 100% of the women had an epidural, and 48.7% of the women had labor induced. Maternal demographics were not significantly different, except for insurance type (*P* = .03) and occiput posterior presentation (*P* = .03; Table 1).

There was 1 failed OVD in the extended labor group and 4 failed OVDs in the usual labor group (*P* = .3). All failed OVDs were VAVDs.

Maternal outcome measures including chorioamnionitis, endometritis, postpartum hemorrhage, transfusion, third-- or 4th-degree perineal lacerations, and cervical lacerations, did not differ between groups (Table 2). There were no differences in neonatal morbidity outcomes between groups (Table 3).

The average time after randomization was 92 ± 65 minutes in the extended labor group and 78 ± 46 minutes in the usual labor group (*P* = 0.3).

Subgroup analysis was performed for fetal position. In the extended labor group, women with fetuses in the occiput posterior position had a similar risk of CD compared to the usual labor group (RR 1.60; 95% CI 0.92–2.81). In comparison, in the extended labor group, women with fetuses in the occiput anterior position had significantly decreased risk of CD compared to the usual labor group (RR 0.17; 95% CI 0.04–0.75).

Additionally, women in the extended labor group who underwent an induction of labor had no difference in risk of CD (RR 0.84; 95% CI 0.32–2.05) compared to the usual labor group. However, women in the extended labor group who presented in spontaneous labor had a significantly decreased risk of CD (RR 0.11; 95% CI 0.01–0.78) compared to the usual labor group.

Comment

In this trial of nulliparous women with epidural anesthesia and prolonged (≥3 hours) second stage of labor, extending the second stage of labor decreases the incidence of

CD by a significant percentage (55%) compared with usual labor guidelines, from 43.2% with usual labor to 19.5% with extended labor. Importantly, the decrease in CD was obtained without increasing maternal or neonatal morbidity. The number needed-to-treat to prevent 1 CD in this cohort of women was 4.2.

There are several strengths of this study. First, the trial was designed as a randomized controlled trial with an intention-to-treat analysis, and recruitment of the desired women was completed. Second, there are no similar trials in the literature on this subject. Third, there was no loss to follow up. Fourth, there were no changes to the protocol during the trial. Fifth, the estimated incidence of CD of the extended labor group that we used for our power calculations was very similar as in the population that was studied. Last, recruitment was relatively easy for this study; consents were obtained from 87.3% of the women who were approached, which suggests that most women are highly motivated to have an SVD.

Although we reached our pretrial goal for sample size, a potential limitation of this study was the relatively small number of women who were included. Although no maternal morbidity differences were found, postpartum hemorrhage, endometritis, and third- and fourth-degree lacerations all had wide confidence intervals. This study was underpowered to determine differences in these outcomes. Additionally, the time difference between the 2 groups was not statistically significantly different 92 ± 65 minutes vs 78 ± 46 minutes; $P = .3$). The lack of time difference was contributed by several factors that included the 14.1% overall crossover, time spent waiting for operating rooms to be available, and time waiting to set up for an OVD. Nevertheless, the lack of time difference and the presence of crossover strengthen our results

because of the analysis as intention-to-treat. It was the intention of extending the second stage of labor to at least 4 hours that seemed to have contributed to the results. The generalizability of this study was limited by the fact that no women without an epidural were assigned randomly. Out of the entire cohort of nulliparous women who presented to labor and delivery during the study time period and did not have an epidural, only 4 of 107 women (3.7%) had prolonged second stage >2 hours. Of these 4 women, none was consented for the trial. This is an important finding because it supports previous studies that suggest that epidural anesthesia is a significant contributor to a prolonged second stage.[11 and 12]

There were differences in insurance type and fetal position between groups. We analyzed both of these possible confounders and found that they had no interaction with the results. The effects were in different directions for each insurance type and fetal position. Thus, there does not appear to be confounding, but this is more likely effect modification. The safety and effectiveness of prolonged second stage has been evaluated previously only in retrospective studies. There are only 2 studies that specifically report outcomes for nulliparous women with epidural anesthesia.[7 and 9] In 1 retrospective review that included 548 nulliparous women with prolonged second stage and an epidural who were allowed to labor longer, the CD rate (17.9%) was comparable with our extended labor results (19.5%). A second larger retrospective study of 3533 nulliparous women with prolonged second stage plus epidural who were allowed to labor longer also confirmed a similar CD rate of 20.0%. In terms of maternal and neonatal morbidities, this study showed rates of third- and fourth-degree laceration of 8.8%, postpartum hemorrhage of 7.3%, chorioamnionitis of 11.1%, endometritis of

1.2%, and a NICU admission rate of 7.1%. Importantly, our maternal and neonatal complication incidences did not differ by group. However, our incidences of chorioamnionitis and NICU admission in general were higher across both the extended labor and usual labor groups than those found by prior studies, although the findings were similar for the other outcomes. These findings could be explained by differences in our study populations, but possibly they also reflect underreporting in retrospective data vs our prospective data. Other retrospective studies of prolonged second stage are difficult to compare with our data because the results are not stratified by epidural status.

Extending the length of labor in nulliparous women with singleton gestations, epidural anesthesia, and a prolonged second stage decreased the incidence of CD by slightly more than one-half, compared with usual labor. Maternal or neonatal morbidity were not statistically different between the groups, but our study was underpowered to detect small but potentially clinical important differences. A larger trial would be necessary to address further the safety of the extended protocol.

Acknowledgments

We acknowledge Sidney Kimmel Medical College at Thomas Jefferson University Labor and Delivery staff, attending physicians, and residents who helped with recruitment of women and who did not receive funding or compensation and Ben Leiby, PhD, Division of Biostatistics, Department of Pharmacology and Experimental Therapeutics, Sidney Kimmel Medical College at Thomas Jefferson University, who contributed to the data analysis and did receive financial compensation from the Division of Maternal Fetal Medicine.

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The authors report no conflict of interest.

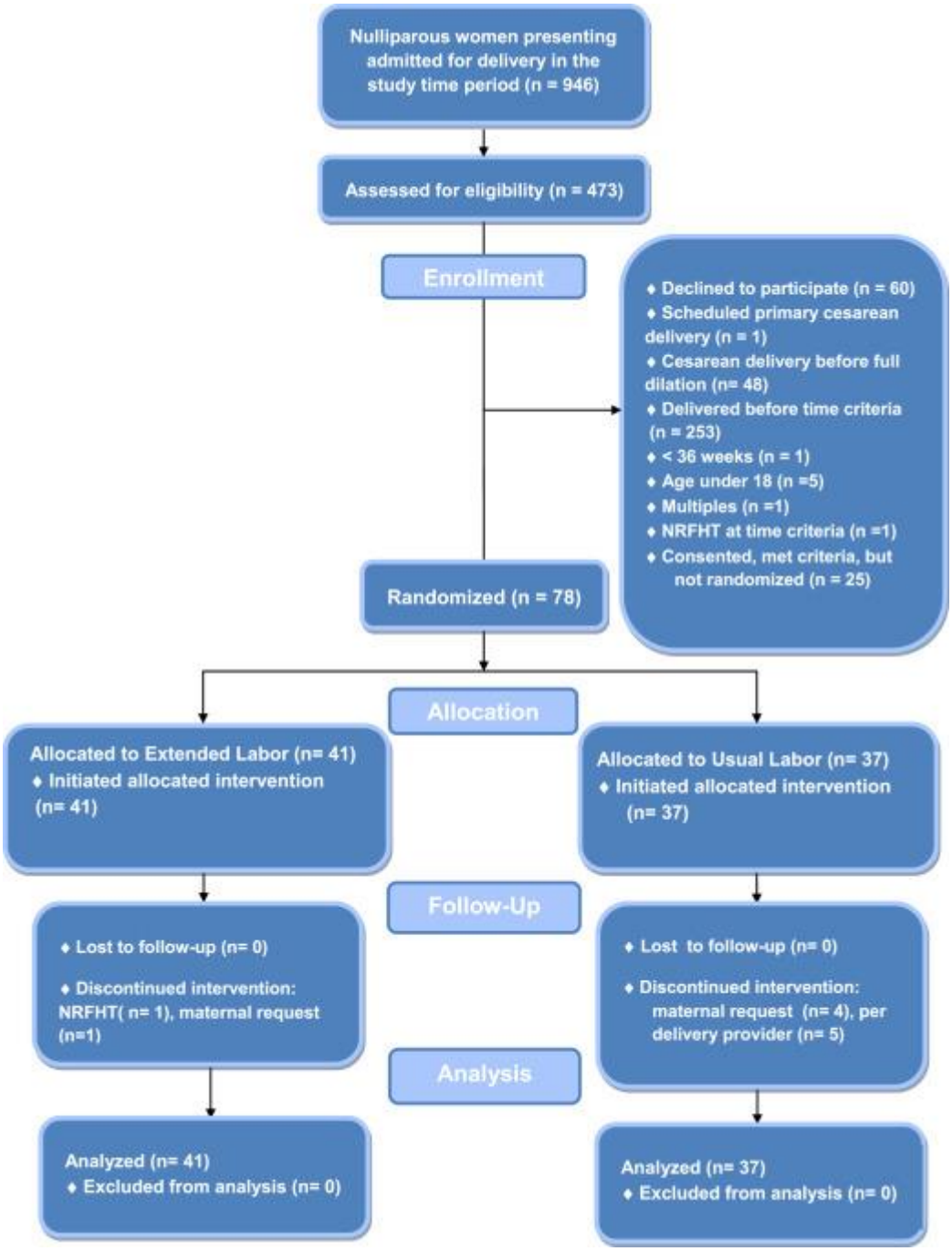

Figure 1.

Consolidated Standards of Reporting Trials flow diagram

Flow diagram of study participants.

NFRHT, nonreassuring fetal heart tracing.

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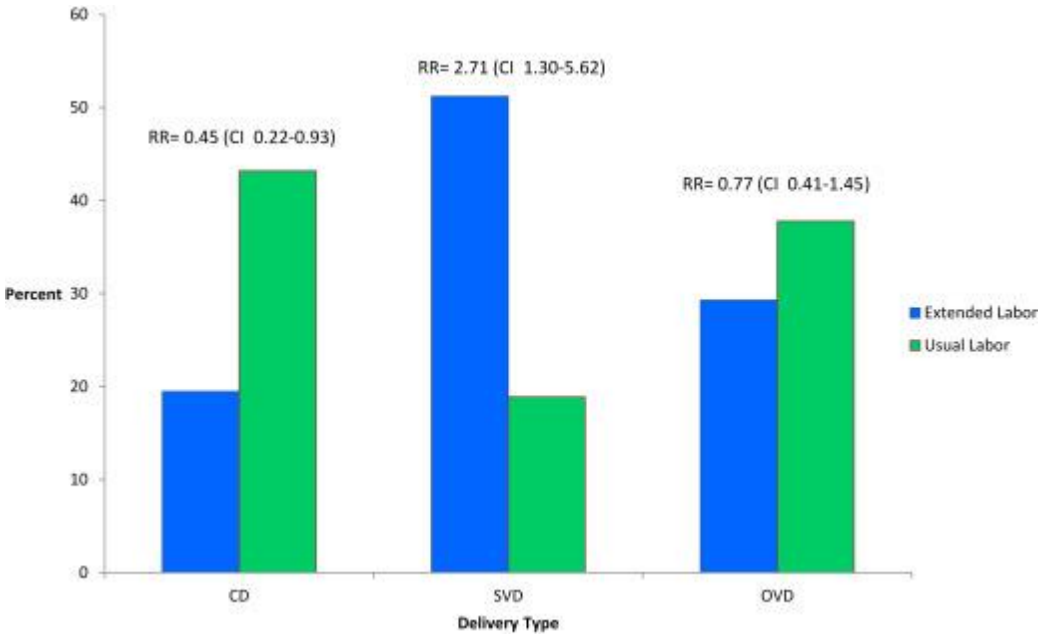

Figure 2.

Delivery outcomes

Type of delivery by group.

CD, cesarean delivery; *CI*, confidence interval; *OVD*, operative vaginal delivery; *RR*, relative risk; *SVD*, spontaneous vaginal delivery.

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Table 1.

Maternal, obstetric, and neonatal characteristics

Characteristics	Extended labor (n = 41)	Usual labor (n = 37)
Maternal age, y[a]	27.6 ± 4.7	28.7 ± 5.4
Epidural anesthesia, n (%)	41 (100)	37 (100)
Ethnicity (non-Hispanic), n (%)	37 (90.2)	36 (97.3)
Race, n (%)		
Non-Hispanic white	18 (43.9)	17 (45.9)
Non-Hispanic black	11 (26.8)	9 (24.3)
Asian	11 (26.8)	11 (29.7)
Other	1 (2.4)	0
Insurance type, n (%)[b]		
Private	21 (51.2)	28 (75.7)
Public or self pay	20 (48.8)	9 (24.3)
Pregnancy complications, n (%)		
Gestational diabetes mellitus	4 (9.8)	3 (8.1)
Pregestational diabetes mellitus	0	1 (2.7)
Hypertensive disorder, n (%)		
Chronic hypertension	0	2 (5.4)
Gestational hypertension	6 (14.6)	2 (5.4)
Preeclampsia	3 (7.3)	3 (8.1)
Body mass index at delivery, kg/m^2[a]	32.1 ± 6.2	29.5 ± 4.8
Prenatal weight gain, kg[a]	15.2 ± 5.6	14.1 ± 6.2
Gestational age at delivery, wk[a]	40.4 ± 0.9	40.0 ± 1.3
Induction of labor, n (%)	22 (53.7)	16 (43.2)
Cervical ripening, n (%)	11 (26.8)	8 (21.6)
Dilation on admission, cm[a]	3.0 ± 1.8	3.8 ± 1.7
Oxytocin use, n (%)	34 (82.9)	30 (81.1)
Artificial rupture of membranes, n (%)	28 (68.3)	17 (45.9)
Contraction frequency in 2nd stage, min[a]	2.9 ± 1.0	3.3 ± 1.4
Supine position in 2nd stage, n (%)	38 (92.7)	36 (97.3)
Delayed pushing, n (%)	34 (82.9)	30 (81.1)
Patient willing to do operative vaginal delivery, n (%)	36 (87.8)	27 (73.0)
Fetal position, n (%)[c]		
Occiput anterior[d]	34 (82.9)	20 (54.1)
Occiput posterior[e]	7 (17.1)	15 (40.5)
Occiput transverse	0	2 (5.4)
Male fetus, n (%)	28 (68.3)	19 (51.4)

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a. Data are given as mean ± standard deviation

b $P = .03$

c Across all 3 fetal positions, $P = .015$

d $P = .01$

e $P = .03$.

Incidence of CD was 19.5% in the extended labor group and 43.2% in the usual labor group (relative risk [RR], 0.45; 95% confidence interval [CI], 0.22–0.93; Table 2, Figure 2). The number needed to treat to prevent 1 CD was 4.2. SVD was significantly increased in the extended labor group (RR, 2.71; 95% confidence interval [CI], 1.30–5.62); OVD was not significantly different between groups (RR, 0.77; 95% CI, 0.41–1.45). When we analyzed FAVD (n = 5 in extended labor group and n = 3 in usual labor group) and VAVD (n = 7 in extended labor group and n = 11 in usual labor group) separately, there was also no difference between groups (FAVD: RR, 1.50; 95% CI, 0.39–5.86; VAVD: RR, 0.57; 95% CL, 0.25–1.32). Results were similar when adjusted for confounders.

Table 2.

Maternal outcomes

Outcome	Extended labor (n = 41), n (%)	Usual labor (n = 37), n (%)	Relative risk	95% Confidence interval
Cesarean delivery	8 (19.5)	16 (43.2)	0.45	0.22–0.93[a]
Vaginal delivery	33 (80.5)	21 (56.8)	1.42	1.03–1.95[a]
Spontaneous vaginal delivery	21 (51.2)	7 (18.9)	2.71	1.30–5.62[a]
Operative vaginal delivery	12 (29.3)	14 (37.8)	0.77	0.41–1.45[a]
Chorioamnionitis	11 (26.8)	13 (35.1)	0.76	0.39–1.49[a]
Endometritis	1 (2.4)	1 (2.7)	0.90	0.06–13.92[b]
Postpartum hemorrhage	8 (19.5)	3 (8.1)	2.41	0.67–8.40[b]
Transfusion	1 (2.4)	0	Not estimable	Not estimable
Third-/fourth-degree perineal laceration	6 (14.6)	1 (2.7)	5.41	0.68–42.90[b]
Cervical laceration	0	0	—	—

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a. Chi-square test

b. Fisher's exact test.

Table 3.

Neonatal outcomes

Outcome	Extended labor (n = 41)	Usual labor (n = 37)	Relative risk	95% Confidence interval	*P*value
Shoulder dystocia, n (%)	1 (2.4)	0 (0)	Not estimable	Not estimable	—
Birthweight, g[a]	3437 ± 527	3506 ± 534	—	—	.6[b]
Neonatal intensive care unit admission, n (%)	13 (31.7)	14 (37.8)	0.8	(0.46–1.54)	
Continuous positive airway pressure or greater, n (%)	1 (2.4)	3 (8.1)	0.3	(0.03–2.77)	
Sepsis, n (%)	0	0	—	—	—
Seizure, n (%)	0	0	—	—	—
Umbilical artery cord pH <7.10, n (%)	0	0	—	—	—
Perinatal death, n (%)	0	0	—	—	—
Neonatal intensive care unit length of stay, d[a]	2.66 ± 1.02	4.03 ± 5.67	—	—	.3[c]

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a Data are given as mean ± standard deviation

b Two sample *t*-test

c Wilcox Rank-Sum test.