Effect of Immediate vs Delayed Pushing on Rates of Spontaneous Vaginal Delivery Among Nulliparous Women Receiving Neuraxial Analgesia
A Randomized Clinical Trial

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IMPORTANCE It is unclear whether the timing of second stage pushing efforts affects spontaneous vaginal delivery rates and reduces morbidities.

OBJECTIVE To evaluate whether immediate or delayed pushing results in higher rates of spontaneous vaginal delivery and lower rates of maternal and neonatal morbidities.

DESIGN, SETTING, AND PARTICIPANTS Pragmatic randomized clinical trial of nulliparous women at or beyond 37 weeks' gestation admitted for spontaneous or induced labor with neuraxial analgesia between May 2014 and December 2017 at 6 US medical centers. The interim analysis suggested futility for the primary outcome and recruitment was terminated with 2414 of 3184 planned participants. Follow-up ended January 4, 2018.

INTERVENTIONS Randomization occurred when participants reached complete cervical dilation. Immediate group participants (n = 1200) began pushing immediately. Delayed group participants (n = 1204) were instructed to wait 60 minutes.

MAIN OUTCOMES AND MEASURES The primary outcome was spontaneous vaginal delivery. Secondary outcomes included total duration of the second stage, duration of active pushing, operative vaginal delivery, cesarean delivery, postpartum hemorrhage, chorioamnionitis, endometritis, perineal lacerations (≥second degree), and a composite outcome of neonatal morbidity that included neonatal death and 9 other adverse outcomes.

RESULTS Among 2414 women randomized (mean age, 26.5 years), 2404 (99.6%) completed the trial. The rate of spontaneous vaginal delivery was 85.9% in the immediate group vs 86.5% in the delayed group, and was not significantly different (absolute difference, −0.6% [95% CI, −3.4% to 2.1%]; relative risk, 0.99 [95% CI, 0.96 to 1.03]). There was no significant difference in 5 of the 9 prespecified secondary outcomes reported, including the composite outcome of neonatal morbidity (7.3% for the immediate group vs 8.9% for the delayed group; between-group difference, −1.6% [95% CI, −3.8% to 0.5%]) and perineal lacerations (45.9% vs 46.4%, respectively; between-group difference, −0.4% [95% CI, −4.4% to 3.6%]). The immediate group had significantly shorter mean duration of the second stage compared with the delayed group (102.4 vs 134.2 minutes, respectively; mean difference, −31.8 minutes [95% CI, −36.7 to −26.9], P < .001), despite a significantly longer mean duration of active pushing (83.7 vs 74.5 minutes; mean difference, 9.2 minutes [95% CI, 5.8 to 12.6], P < .001), lower rates of chorioamnionitis (6.7% vs 9.1%; between-group difference, −2.5% [95% CI, −4.6% to −0.3%], P = .005), and fewer postpartum hemorrhages (2.3% vs 4.0%; between-group difference, −1.7% [95% CI, −3.1% to −0.4%], P = .03).

CONCLUSIONS AND RELEVANCE Among nulliparous women receiving neuraxial anesthesia, the timing of second stage pushing efforts did not affect the rate of spontaneous vaginal delivery. These findings may help inform decisions about the preferred timing of second stage pushing efforts, when considered with other maternal and neonatal outcomes.

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More than 3 million women give birth in the United States every year.[1] Despite the frequency of childbirth, many aspects of labor management lack an evidence-based approach. The second stage of labor, defined as the interval from complete cervical dilation through delivery of the fetus, is the most physiologically demanding period of labor for both the mother and the fetus.[2,3] Despite the effect labor management can have on mode of delivery, and the fact that operative deliveries are associated with higher risks of adverse neonatal and maternal outcomes (such as acidosis, febrile morbidities, and hemorrhage) than spontaneous vaginal deliveries,[4] the optimal technique for managing maternal pushing during the second stage of labor is unknown.

The 2 most common approaches to the second stage of labor management are to either initiate pushing with uterine contractions once complete cervical dilation occurs (immediate pushing) or to allow for spontaneous descent (delayed pushing). Both approaches are commonly used, and neither is considered the gold standard. Prior investigations regarding the optimal management strategy were conflicting regarding the effect on spontaneous vaginal delivery and maternal and neonatal morbidities.[5-9] The largest trial to date found that delayed pushing reduced the rate of deliveries using mid-pelvic forceps with an equivocal effect on neonatal outcomes. Deliveries using mid-pelvic forceps were prevalent 20 years ago when that study was conducted[10]; however, these types of deliveries are obsolete in modern obstetric practice in the United States. A subsequent systematic review and meta-analysis including that trial[10] and other trials found no differences between delayed and immediate pushing in spontaneous vaginal delivery rates when only high-quality studies were summarized.[11] Thus, the optimal second stage labor management strategy regarding the timing of pushing remains controversial.

A pragmatic, multicenter randomized clinical trial was conducted to determine the effect of immediate pushing compared with delayed pushing during the second stage of labor on rates of spontaneous vaginal delivery and maternal and neonatal morbidities among nulliparous women receiving neuraxial analgesia. It was hypothesized that the rate of spontaneous vaginal delivery would increase among nulliparous women with immediate pushing compared with delayed pushing.

Methods

Trial Design
The trial was approved by the institutional review boards at all 6 study sites prior to enrollment. All participants provided written informed consent to be included in this research study. Participants were randomly assigned to immediate pushing or delayed pushing once they reached complete cervical dilation in this open-label, pragmatic, multicenter randomized clinical trial.[12] Other than the timing of initiation of pushing, participants were managed according to usual obstetric care. The trial protocol appears in Supplement 1.

Key Points

Question What is the effect of immediate vs delayed pushing during the second stage of labor on rates of spontaneous vaginal delivery among nulliparous women receiving neuraxial analgesia?

Findings In this randomized clinical trial that involved 2414 women, immediate vs delayed pushing did not result in a significant difference in the rates of spontaneous vaginal delivery (85.9% vs 86.5%, respectively).

Meaning Among nulliparous women receiving neuraxial analgesia, the timing of pushing during the second stage of labor did not affect the rate of spontaneous vaginal delivery.

Patient Selection
Nulliparous pregnant women at or beyond 37 weeks' gestation admitted for spontaneous or induced labor with neuraxial analgesia were eligible for this trial (**Figure 1**). Women were recruited between May 19, 2014, and December 16, 2017, at 6 geographically representative academic and community medical centers across the United States (Washington University in St Louis Medical Center, Missouri Baptist Medical Center, Hospital of the University of Pennsylvania, Pennsylvania Hospital, University of Alabama, Birmingham, and Oregon Health & Science University). Multiparous patients, scheduled cesarean deliveries, multiple gestations, major fetal anomalies, and those with nonreassuring fetal status were excluded. The rate of immediate pushing across the participating centers was approximately 50% before the trial was initiated.

Treatment Allocation
At complete cervical dilation (10 cm), patients were randomized centrally in a 1:1 ratio to immediate pushing or delayed pushing. A computer-generated randomization sequence was prepared using variable block sizes that were stratified according to study site by the study statistician.[13] Each woman's group assignment was obtained from a secure website only after a study number and parity were entered and locked and after complete (10 cm) cervical dilation was reached.
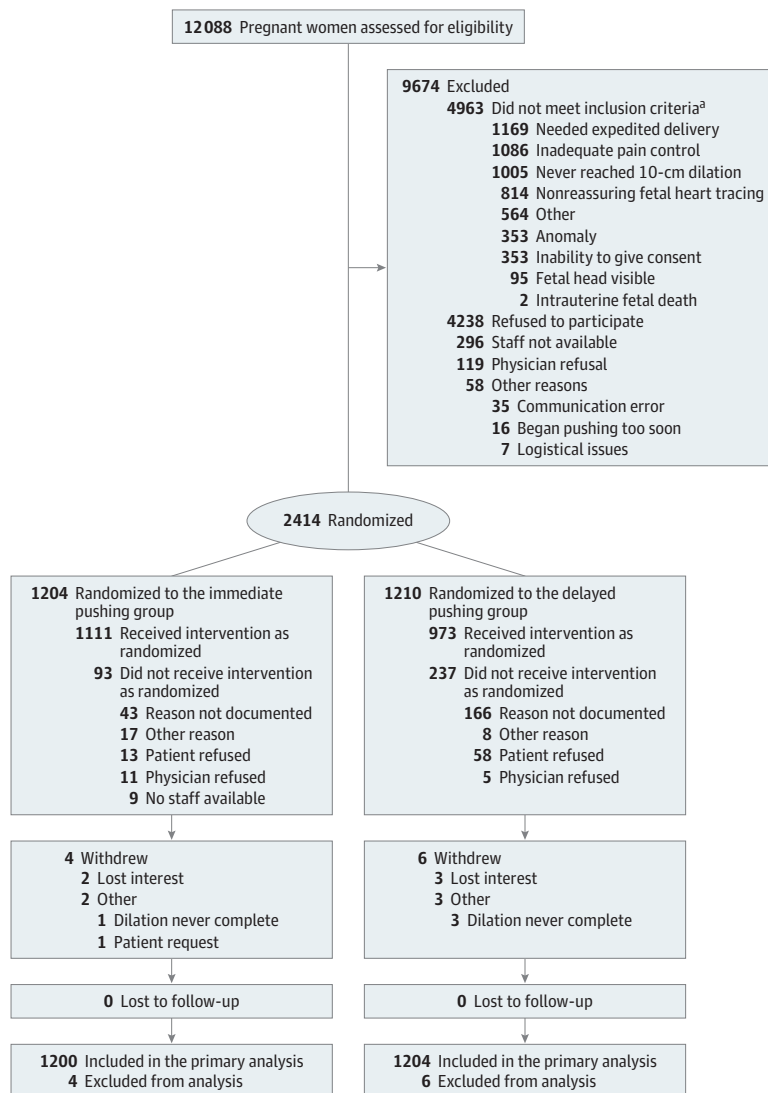
Trial Interventions
Women in the immediate pushing group were instructed to initiate pushing at randomization. Women randomized to delayed pushing were instructed to wait 60 minutes prior to initiation of pushing unless instructed to do otherwise by their clinician or unless they had an irresistible urge to push. Maternal position, technique (closed or opened glottis), and duration and frequency of maternal pushing efforts were at the discretion of each participant's nurse or clinician. Mothers and their infants were followed up through 6 weeks' postpartum.

Trial End Points
The primary end point was spontaneous vaginal delivery defined as delivery that occurred without the use of forceps, vacuum, or cesarean delivery. Prespecified secondary outcomes included total duration of the second stage of labor,

Figure 1. Recruitment, Randomization, and Flow of Participants Through the Trial

12 088 Pregnant women assessed for eligibility	

9674 Excluded
 4963 Did not meet inclusion criteria[a]
  1169 Needed expedited delivery
  1086 Inadequate pain control
  1005 Never reached 10-cm dilation
  814 Nonreassuring fetal heart tracing
  564 Other
  353 Anomaly
  353 Inability to give consent
  95 Fetal head visible
  2 Intrauterine fetal death
 4238 Refused to participate
 296 Staff not available
 119 Physician refusal
 58 Other reasons
  35 Communication error
  16 Began pushing too soon
  7 Logistical issues

2414 Randomized

1204 Randomized to the immediate pushing group
 1111 Received intervention as randomized
 93 Did not receive intervention as randomized
  43 Reason not documented
  17 Other reason
  13 Patient refused
  11 Physician refused
  9 No staff available

1210 Randomized to the delayed pushing group
 973 Received intervention as randomized
 237 Did not receive intervention as randomized
  166 Reason not documented
  8 Other reason
  58 Patient refused
  5 Physician refused

4 Withdrew
 2 Lost interest
 2 Other
  1 Dilation never complete
  1 Patient request

6 Withdrew
 3 Lost interest
 3 Other
  3 Dilation never complete

0 Lost to follow-up

0 Lost to follow-up

1200 Included in the primary analysis
 4 Excluded from analysis

1204 Included in the primary analysis
 6 Excluded from analysis

[a] Some individuals had more than 1 reason for not meeting the inclusion criteria.

duration of active pushing, operative vaginal delivery (forceps or vacuum), cesarean delivery, and several individual maternal morbidity assessments including postpartum hemorrhage (estimated blood loss >500 mL for vaginal delivery and >1000 mL for cesarean delivery), chorioamnionitis during the second stage of labor, endometritis, and perineal lacerations (≥second degree). A composite outcome of neonatal morbidity also was assessed and defined as occurrence of 1 or more of the following: neonatal death, birth injury, neonatal acidemia (umbilical cord arterial pH <7.1), respiratory distress, transient tachypnea, meconium aspiration with pulmonary hypertension, hypoxic-ischemic encephalopathy, hypoglycemia (venous blood glucose level <40 mg/dL), hypothermia treatment, or suspected neonatal sepsis.

Other prespecified secondary outcomes were occult levator ani muscle injury on 3D transperineal ultrasound, frequency and extent of signs of pelvic organ prolapse using the validated Pelvic Organ Prolapse Quantification system, and rates of patient-reported symptoms of urinary incontinence, fecal incontinence, and pelvic organ prolapse on validated quality-of-life questionnaires at 1 to 5 days, 4 to 8 weeks, and 5 to 7 months' postpartum. Data were collected for these outcomes but the findings are not reported herein.

Prespecified exploratory outcomes included the individual components of the neonatal morbidity composite outcome and the specific degree of perineal lacerations (ie, second, third, or fourth degree). Patient satisfaction with their birthing experience was assessed using a modified Mackey Childbirth Satisfaction Rating Scale (range, 0 [worst] to 5 [best]).[14] Post hoc outcomes included estimated blood loss, blood transfusion, shoulder dystocia, severe perineal laceration (third or fourth degree), and admission to the neonatal intensive care unit.

Patient demographics, antepartum and labor course, and outcomes were extracted from the electronic medical records. Clinical outcomes were extracted by obstetric research

nurses who were blinded to group assignment. Race/ethnicity was included in this study for representativeness and generalizability, and was self-reported by the participants in response to an open-ended question. All definitions of outcome measures used in this trial appear in Supplement 2.

Trial Oversight

The trial was overseen by an independent data and safety monitoring board and a steering committee. Two planned interim analyses were conducted after 50% and 75% of the participants were randomized. The clinical investigators were not informed of the results of the prespecified interim analyses during the conduct of the trial. The Haybittle-Peto rule was designated as the guide for stopping the trial early for efficacy.[15,16] Under this rule, the prespecified interim analyses of the primary outcome had to demonstrate an extreme difference between groups ($P < .001$) to justify stopping the trial. This rule has the advantage that the overall type I error rate is preserved at 0.05.

Adverse Events

Study-defined adverse events were prespecified by the data and safety monitoring board and included neonatal acidemia (umbilical cord arterial pH <7.1), chorioamnionitis during the second stage of labor, severe postpartum hemorrhage (estimated blood loss >1000 mL for vaginal delivery and >2000 mL for cesarean delivery), and admission to the neonatal intensive care unit for longer than 12 hours. Serious adverse events were maternal death, life-threatening maternal event, maternal admission to the ICU, unplanned hysterectomy, life-threatening neonatal event, and serious neonatal birth injury including skull fracture, brachial plexus injury, and cephalohematoma.

Sample Size

The sample size was calculated based on a spontaneous vaginal delivery rate of 72% in the delayed pushing group.[9] Based on a review and meta-analysis,[11] it was estimated that a sample size of 3184 (1592 in each group) was sufficient to detect a 5% absolute difference (from a rate of 72% to ≥77%) in the spontaneous vaginal delivery rate with 90% power using a 2-tailed test and a type I error rate of 0.05.

Data Analysis

The primary data analysis followed the intention-to-treat principle in that all patients were analyzed in the group that they were randomly assigned, regardless of what intervention they received.[17] Baseline and labor characteristics were compared between the groups using the χ^2 test or Fisher exact test for categorical variables and the t test or Mann-Whitney test for continuous variables.

Rates of spontaneous vaginal delivery and other dichotomous secondary outcomes were compared using the χ^2 test or Fisher exact test as appropriate. Relative risk (RR) or risk differences and 95% CIs were calculated. Generalized estimating equations were used to account for study site and the nonindependence of participants at a given site. Continuous outcomes were tested for normality using the

Kolmogorov-Smirnov test and compared using the t test or the Mann-Whitney test as appropriate. Prespecified subgroup analyses were performed for the primary outcome using the Breslow-Day test to measure interaction and assess whether the relative effectiveness of immediate or delayed pushing differed across subgroups. Per-protocol and as-treated analyses also were performed.

There were no missing data for the primary outcome. For the other variables, there were missing data for less than 5% of the variables; thus, no imputation was used. Because there was no adjustment for multiplicity, the secondary outcomes should be interpreted as exploratory. All tests were 2-sided and the significance level was set at .05. The statistical package SAS version 9.2 (SAS Institute Inc) was used for all statistical analyses. Additional details appear in the statistical analysis plan in Supplement 3.

Results

After the second interim analysis at 75% recruitment, the data and safety monitoring board recommended recruitment be stopped due to futility and concern for increased morbidity in the delayed pushing group. The rate of spontaneous vaginal delivery was 86.0% in the immediate pushing group and 86.1% in the delayed pushing group (absolute difference, −0.2% [95% CI, −3.0% to 2.7%]; RR, 1.00 [95% CI, 0.97 to 1.04]). The estimate of the conditional power to detect a difference in the primary outcome of spontaneous vaginal delivery was 8% at most. In addition, the data and safety monitoring board was concerned about the significantly higher rate of postpartum hemorrhage in the delayed pushing group. Thus, the final sample size was 2414.

Study Participants

A total of 12 088 patients were assessed for eligibility; 9674 were excluded and the remaining 2414 women were randomized to immediate pushing (n = 1204) or delayed pushing (n = 1210; Figure 1). Most patients followed their assigned timing of pushing (92.3% in the immediate pushing group and 80.4% in the delayed pushing group). Ten patients withdrew from the study; 4 (0.3%) in the immediate pushing group and 6 (0.5%) in the delayed pushing group. No patients were lost to follow-up, leaving 2404 patients (1200 in the immediate pushing group and 1204 in the delayed pushing group) included in the primary intention-to-treat analysis. There were no significant differences in baseline maternal or pregnancy characteristics between the groups (**Table 1**). The mean time from complete cervical dilation to pushing was 18.9 minutes (SD, 15.1 minutes) in the immediate pushing group vs 59.8 minutes (SD, 21.8 minutes) in the delayed pushing group (mean difference, −40.9 minutes [95% CI, −43.1 to −38.9 minutes]).

Primary Outcome

The rate of spontaneous vaginal delivery was 85.9% (n = 1031) in the immediate pushing group vs 86.5% (n = 1041) in the delayed pushing group (absolute difference, −0.6% [95% CI, −3.4% to 2.1%]; RR, 0.99 [95% CI, 0.96 to 1.03], $P = .67$).

Table 1. Baseline Participant and Labor Characteristics

	Immediate Pushing (n = 1200)	Delayed Pushing (n = 1204)
Maternal age, mean (SD), y	26.5 (5.9)	26.6 (6.2)
Gestational age, mean (SD), wk	39.5 (1.2)	39.4 (1.2)
Body mass index (BMI) at delivery, mean (SD)[a]	30.8 (6.2)	30.7 (6.2)
Obese (BMI >30), No./total No. (%)	557/1182 (47.1)	559/1188 (47.0)
Race, No. (%)		
White	566 (47.2)	538 (44.7)
Black	516 (43.0)	535 (44.4)
Other or mixed[b]	118 (9.8)	131 (10.9)
Not Hispanic or Latina, No./total No. (%)	1136/1193 (95.2)	1131/1191 (95.0)
Marital status, No. (%)		
Single	689 (57.4)	706 (58.6)
Married	500 (41.7)	488 (40.5)
Other	11 (0.9)	9 (0.7)
Employment status, No./total No. (%)		
Employed	611/1021 (59.8)	611/1012 (60.4)
Unemployed	328/1021 (32.1)	321/1012 (31.7)
Student	82/1021 (8.0)	80/1012 (7.9)
Insurance, No. (%)		
Private	603 (50.2)	621 (51.6)
Government	534 (44.5)	513 (42.6)
Other or mixed	36 (3.0)	45 (3.7)
Uninsured	27 (2.2)	25 (2.1)
Type of drug use, No./total No. (%)		
Tobacco	67/1185 (5.6)	54/1191 (4.5)
Alcohol	44/1186 (3.7)	39/1194 (3.3)
Recreational	68/1188 (5.7)	70/1194 (5.9)
Positive for group B Streptococcus, No./total No. (%)	399/1155 (34.5)	350/1163 (30.1)
Medical comorbidities, No./total No. (%)		
Asthma	193/846 (22.8)	189/853 (22.2)
Chronic hypertension	26/846 (3.1)	25/853 (2.9)
Diabetes (type 1 or 2)	50/844 (5.9)	56/853 (6.6)
Obstetric complications		
Gestational hypertension, No./total No. (%)	97/846 (11.5)	96/852 (11.3)
Preeclampsia or eclampsia, No. (%)	25 (2.1)	23 (1.9)
Fetal growth restriction, No. (%)	60 (5.0)	62 (5.2)
Oligohydramnios, No. (%)	29 (2.4)	35 (2.9)
Spontaneous labor, No. (%)	642 (53.5)	652 (54.2)
Oxytocin use, No./total No. (%)	956/1199 (79.7)	963/1201 (80.2)
Magnesium sulfate use, No./total No. (%)	29/1200 (2.4)	29/1199 (2.4)
Amnioinfusion, No./total No. (%)	64/1198 (5.3)	65/1201 (5.4)
Support person during labor, No./total No. (%)	1160/1171 (99.1)	1155/1163 (99.3)
Fetal station at complete dilation <2 cm, No./total No. (%)[c]	869/1178 (73.8)	863/1185 (72.8)
Fetal position at complete dilation, No./total No. (%)[d]		
Occiput anterior	784/907 (86.4)	769/881 (87.3)
Occiput posterior	108/907 (11.9)	91/881 (10.3)
Occiput transverse	15/907 (1.7)	21/881 (2.4)
Type of personnel delivering the fetus, No. (%)		
Attending physician	581 (48.4)	586 (48.7)
Resident physician	503 (41.9)	516 (42.9)
Physician in fellowship	23 (1.9)	18 (1.5)
Midwife	82 (6.8)	78 (6.5)
Nurse	8 (0.7)	3 (0.2)
Student	3 (0.2)	2 (0.2)

(continued)

Table 1. Baseline Participant and Labor Characteristics (continued)

	Immediate Pushing (n = 1200)	Delayed Pushing (n = 1204)
Birth weight, mean (SD), g[e]	3285.7 (438.7)	3262.0 (418.4)
Apgar score at 1 min, median (IQR)[f,g]	8 (8-9)	8 (8-9)
Apgar score at 5 min, median (IQR)[f,h]	9 (9-9)	9 (9-9)
Fetal sex female, No. (%)	639 (53.2)	623 (51.7)
Approach to pushing, No./total No. (%)		
Guided	805/1137 (70.8)	783/1122 (69.8)
Spontaneous	223/1137 (19.6)	231/1122 (20.6)
Both	109/1137 (9.6)	108/1122 (9.6)

Abbreviation: IQR, interquartile range.

[a] Calculated as weight in kilograms divided by height in meters squared. There were missing data for 18 participants in the immediate pushing group and 16 in the delayed pushing group.

[b] Includes American Indian or Alaskan Native, Asian, Hawaiian or Pacific Islander, or other race.

[c] Position of the leading portion of the fetal head relative to maternal pelvic anatomy in centimeters on a scale of −5 (highest) to 5 (lowest).

[d] The direction of the fetal head relative to the maternal position.

[e] There were missing data for 3 participants in the immediate pushing group and 2 in the delayed pushing group.

[f] Summarizes the condition of the newborn after birth. Neonates are given a score of 0, 1, or 2 (best) for 5 items: color, tone, breathing, heart rate, and grimace resulting in a score from 0-10.

[g] There were missing data for 6 participants in the immediate pushing group and 2 in the delayed pushing group.

[h] There were missing data for 6 participants in the immediate pushing group and 5 in the delayed pushing group.

Prespecified Secondary Outcomes

Women in the immediate pushing group had a significantly shorter mean duration of the second stage of labor (102.4 minutes) vs women in the delayed pushing group (134.2 minutes) (mean difference, −31.8 minutes [95% CI, −36.7 to −26.9 minutes], $P < .001$; Table 2). The immediate pushing group had a significantly longer mean duration of active pushing (83.7 minutes) vs the delayed pushing group (74.5 minutes) (mean difference, 9.2 minutes [95% CI, 5.8 to 12.6 minutes], $P < .001$).

Rates of operative vaginal delivery and cesarean delivery were low and did not differ significantly between the groups (Table 2). Specifically, immediate pushing was not associated with a significant decrease in operative vaginal deliveries (6.3% in the immediate pushing group vs 5.9% in the delayed pushing group; absolute difference, 0.4% [95% CI, −1.5% to 2.4%]; RR, 1.1 [95% CI, 0.7 to 1.7], $P = .75$) or cesarean deliveries (7.8% vs 7.6%, respectively; absolute difference, 0.2% [95% CI, −1.9% to 2.3%]; RR, 1.0 [95% CI, 0.9 to 1.1], $P = .55$). There were no significant differences in the distribution of indications for operative vaginal deliveries and cesarean deliveries (eTable 1 in Supplement 2).

The rate of postpartum hemorrhage was significantly lower among women in the immediate pushing group compared with those in the delayed pushing group (2.3% vs 4.0%, respectively; absolute difference, −1.7% [95% CI, −3.1% to −0.4%]; RR, 0.6 [95% CI, 0.3 to 0.9], $P = .03$). In addition, rates of chorioamnionitis during the second stage of labor were significantly lower among women in the immediate pushing group compared with the delayed pushing group (6.7% vs 9.1%, respectively; absolute difference, −2.5% [95% CI, −4.6% to −0.3%]; RR, 0.70 [95% CI, 0.66 to 0.90], $P = .005$; Table 2). Rates of endometritis were low and not significantly different between groups (0.6% in the immediate pushing group vs 0.3% in the delayed pushing group; absolute difference, 0.3 [95% CI, −0.3 to 0.8]; RR, 1.8 [95% CI, 0.6 to 5.1]).

The rate of the composite outcome of neonatal morbidity was 8.1% (194/2404), and there was no significant difference between the groups (7.3% in the immediate pushing group vs 8.9% in the delayed pushing group; absolute difference, −1.6% [95% CI, −3.8% to 0.5%]; RR, 0.8 [95% CI, 0.6 to 1.1]; Table 2). Perineal lacerations were common and there was no significant difference in the overall rates between the groups (45.9% in the immediate pushing group vs 46.4% in the delayed pushing group; absolute difference, −0.4% [95% CI, −4.4% to 3.6%]; RR, 0.99 [95% CI, 0.95 to 1.04]; Table 2).

Prespecified Subgroup Analyses

In prespecified subgroup analyses, there were no significant differences in the rates of spontaneous delivery by study site, fetal station at randomization, fetal occiput position, or duration of delay prior to pushing (Figure 2). Similarly, there were no significant differences in the rates of spontaneous vaginal delivery by maternal age or race, maternal obesity, low birthweight, fetal sex, or pushing technique.

Prespecified Exploratory Outcomes

For components of the composite outcome of neonatal morbidity, there was a significantly decreased risk of neonatal acidemia in the immediate pushing group compared with the delayed pushing group (0.8% vs 1.2%, respectively; absolute difference, −0.4% [95% CI, −1.2% to 0.4%]; RR, 0.7 [95% CI, 0.5 to 0.9]). There were no neonatal deaths in either group. Compared with the immediate pushing group, there was a significantly higher rate of suspected sepsis in the delayed pushing group (3.2% vs 4.4%, respectively; absolute difference, −1.2% [95% CI, −2.8% to 0.3%]; RR, 0.7 [95% CI, 0.6 to 0.9]; Table 2). Risk of third-degree perineal laceration was significantly higher in the immediate pushing group compared with the delayed pushing group (5.3% vs 4.3%, respectively; absolute difference, 0.9% [95% CI, −0.8% to 2.6%]; RR, 1.2 [95% CI, 1.0 to 1.4], $P = .02$).

Table 2. Primary and Exploratory Secondary Efficacy Outcomes

	No. (%)[a]		Absolute Risk Difference (95% CI)[b]	Relative Risk (95% CI)[c]	P Value
	Immediate Pushing (n = 1200)	Delayed Pushing (n = 1204)			
Primary Outcome					
Spontaneous vaginal delivery	1031 (85.9)	1041 (86.5)	−0.6 (−3.4 to 2.1)	0.99 (0.96 to 1.03)	.67
Prespecified Secondary Outcomes					
Total duration of the second stage of labor, min					
Median (IQR)	79 (45 to 134)	113 (84 to 167)			
Mean (SD)	102.4 (79.6)	134.2 (76.3)	−31.8 (−36.7 to −26.9)		<.001
Duration of active pushing, min[d]					
Median (IQR)	58 (29 to 114)	49 (25 to 100)			
Mean (SD)	83.7 (76.8)	74.5 (70.7)	9.2 (5.8 to 12.6)		<.001
Type of delivery					
Operative vaginal	76 (6.3)	71 (5.9)	0.4 (−1.5 to 2.4)	1.1 (0.7 to 1.7)	.75
Vacuum-assisted vaginal	55 (4.6)	56 (4.7)	−0.1 (−1.8 to 1.6)	1.0 (0.7 to 1.4)	.93
Forceps-assisted vaginal	21 (1.8)	15 (1.3)	0.5 (−0.5 to 1.5)	1.4 (0.7 to 3.0)	.38
Cesarean	93 (7.8)	91 (7.6)	0.2 (−1.9 to 2.3)	1.0 (0.9 to 1.1)	.55
Postpartum hemorrhage	27 (2.3)	48 (4.0)	−1.7 (−3.1 to −0.4)	0.6 (0.3 to 0.9)	.03
Chorioamnionitis	80 (6.7)	110 (9.1)	−2.5 (−4.6 to −0.3)	0.70 (0.66 to 0.90)	.005
Endometritis	7 (0.6)	4 (0.3)	0.3 (−0.3 to 0.8)	1.8 (0.6 to 5.1)	.29
Composite outcome of neonatal morbidity[e]	87 (7.3)	107 (8.9)	−1.6 (−3.8 to 0.5)	0.8 (0.6 to 1.1)	.16
Perineal laceration (≥second degree)	551 (45.9)	558 (46.4)	−0.4 (−4.4 to 3.6)	1.0 (0.9 to 1.0)	.69
Prespecified Exploratory Outcomes					
Components of neonatal morbidity					
Neonatal death	0	0			
Major birth injury	6 (0.5)	3 (0.3)	0.3 (−0.2 to 0.7)	2.0 (0.7 to 5.5)	.18
Acidemia (umbilical cord arterial pH <7.1)	9 (0.8)	14 (1.2)	−0.4 (−1.2 to 0.4)	0.7 (0.5 to 0.9)	.01
Respiratory distress	30 (2.5)	25 (2.1)	0.4 (−0.8 to 1.6)	1.2 (0.8 to 1.8)	.36
Transient tachypnea	8 (0.7)	9 (0.8)	−0.1 (−0.8 to 0.6)	0.9 (0.3 to 2.7)	.84
Meconium aspiration with pulmonary hypertension	0	2 (0.2)	−0.2 (−0.4 to 0.1)		
Hypoxic-ischemic encephalopathy	3 (0.3)	2 (0.2)	0.1 (−0.3 to 0.5)	1.5 (0.4 to 6.5)	.57
Hypoglycemia	28 (2.3)	26 (2.2)	0.2 (−1.0 to 1.4)	1.1 (0.6 to 1.9)	.79
Hypothermic treatment (cooling)	1 (0.1)	3 (0.3)	−0.2 (−0.5 to 0.2)	0.3 (0.1 to 2.1)	.24
Suspected sepsis	38 (3.2)	53 (4.4)	−1.2 (−2.8 to 0.3)	0.7 (0.6 to 0.9)	.003
Degree of perineal laceration					
Second	483 (40.3)	503 (41.8)	−1.5 (−5.5 to 2.4)	1.0 (0.9 to 1.0)	.12
Third	63 (5.3)	52 (4.3)	0.9 (−0.8 to 2.6)	1.2 (1.0 to 1.4)	.02
Fourth	5 (0.4)	3 (0.3)	0.2 (−0.3 to 0.6)	1.7 (0.4 to 6.8)	.44
Post Hoc Outcomes					
Estimated blood loss, mL[f]					
Median (IQR)	350 (300 to 450)	350 (300 to 450)			
Mean (SD)	419.0 (252.8)	424.4 (298.2)	−5.2 (−24.7 to 14.4)		.60
Blood transfusion	14 (1.2)	15 (1.3)	−0.1 (−1.0 to 0.8)	0.9 (0.5 to 1.8)	.84
Shoulder dystocia	40 (3.3)	27 (2.2)	1.1 (−0.2 to 2.4)	1.5 (0.9 to 2.5)	.12
Third- or fourth-degree laceration	68 (5.7)	55 (4.6)	1.1 (−0.7 to 2.9)	1.2 (1.1 to 1.5)	.01
NICU admission	63 (5.3)	78 (6.5)	−1.2 (−3.1 to 0.6)	0.8 (0.6 to 1.1)	.21

Abbreviations: IQR; interquartile range; NICU, neonatal intensive care unit.

[a] Unless otherwise indicated.
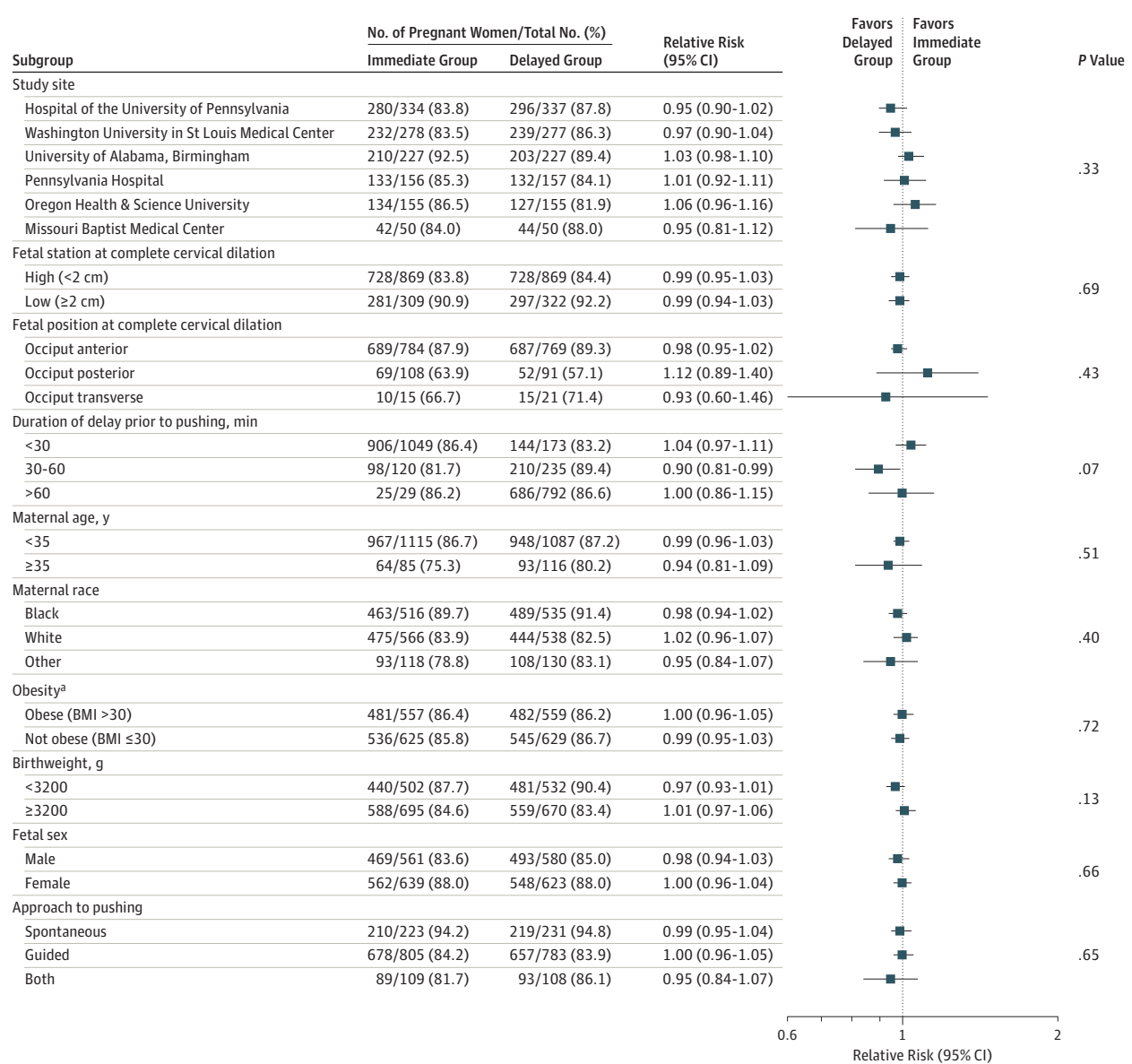
[b] Calculated from binomial distribution.

[c] Obtained from generalized estimating equations models, which were used to account for study site.

[d] There were missing data for 2 participants in the immediate pushing group and 4 in the delayed pushing group.

[e] Defined as occurrence of 1 or more of the following: neonatal death, birth injury, umbilical cord arterial acidosis, respiratory distress, transient tachypnea, meconium aspiration with pulmonary hypertension, hypoxic-ischemic encephalopathy, hypoglycemia, hypothermia treatment, or suspected neonatal sepsis.

[f] There were missing data for 37 participants in the immediate pushing group and 30 in the delayed pushing group.

Figure 2. Prespecified Subgroup Analysis of the Primary Outcome of Spontaneous Vaginal Delivery

Subgroup	No. of Pregnant Women/Total No. (%) Immediate Group	Delayed Group	Relative Risk (95% CI)	Favors Delayed Group / Favors Immediate Group	P Value
Study site					
Hospital of the University of Pennsylvania	280/334 (83.8)	296/337 (87.8)	0.95 (0.90-1.02)		
Washington University in St Louis Medical Center	232/278 (83.5)	239/277 (86.3)	0.97 (0.90-1.04)		
University of Alabama, Birmingham	210/227 (92.5)	203/227 (89.4)	1.03 (0.98-1.10)		.33
Pennsylvania Hospital	133/156 (85.3)	132/157 (84.1)	1.01 (0.92-1.11)		
Oregon Health & Science University	134/155 (86.5)	127/155 (81.9)	1.06 (0.96-1.16)		
Missouri Baptist Medical Center	42/50 (84.0)	44/50 (88.0)	0.95 (0.81-1.12)		
Fetal station at complete cervical dilation					
High (<2 cm)	728/869 (83.8)	728/869 (84.4)	0.99 (0.95-1.03)		.69
Low (≥2 cm)	281/309 (90.9)	297/322 (92.2)	0.99 (0.94-1.03)		
Fetal position at complete cervical dilation					
Occiput anterior	689/784 (87.9)	687/769 (89.3)	0.98 (0.95-1.02)		
Occiput posterior	69/108 (63.9)	52/91 (57.1)	1.12 (0.89-1.40)		.43
Occiput transverse	10/15 (66.7)	15/21 (71.4)	0.93 (0.60-1.46)		
Duration of delay prior to pushing, min					
<30	906/1049 (86.4)	144/173 (83.2)	1.04 (0.97-1.11)		
30-60	98/120 (81.7)	210/235 (89.4)	0.90 (0.81-0.99)		.07
>60	25/29 (86.2)	686/792 (86.6)	1.00 (0.86-1.15)		
Maternal age, y					
<35	967/1115 (86.7)	948/1087 (87.2)	0.99 (0.96-1.03)		.51
≥35	64/85 (75.3)	93/116 (80.2)	0.94 (0.81-1.09)		
Maternal race					
Black	463/516 (89.7)	489/535 (91.4)	0.98 (0.94-1.02)		
White	475/566 (83.9)	444/538 (82.5)	1.02 (0.96-1.07)		.40
Other	93/118 (78.8)	108/130 (83.1)	0.95 (0.84-1.07)		
Obesity[a]					
Obese (BMI >30)	481/557 (86.4)	482/559 (86.2)	1.00 (0.96-1.05)		.72
Not obese (BMI ≤30)	536/625 (85.8)	545/629 (86.7)	0.99 (0.95-1.03)		
Birthweight, g					
<3200	440/502 (87.7)	481/532 (90.4)	0.97 (0.93-1.01)		.13
≥3200	588/695 (84.6)	559/670 (83.4)	1.01 (0.97-1.06)		
Fetal sex					
Male	469/561 (83.6)	493/580 (85.0)	0.98 (0.94-1.03)		.66
Female	562/639 (88.0)	548/623 (88.0)	1.00 (0.96-1.04)		
Approach to pushing					
Spontaneous	210/223 (94.2)	219/231 (94.8)	0.99 (0.95-1.04)		
Guided	678/805 (84.2)	657/783 (83.9)	1.00 (0.96-1.05)		.65
Both	89/109 (81.7)	93/108 (86.1)	0.95 (0.84-1.07)		

Relative Risk (95% CI) — axis: 0.6 — 1 — 2

The P values were calculated using the Breslow-Day test and indicate the interactions between the treatment groups and the subgroup variables.

[a] Body mass index (BMI) calculated as weight in kilograms divided by height in meters squared.

Patients rated their experience highly during the second stage of labor, and there was no significant difference between the immediate and delayed pushing groups on the Mackey Childbirth Satisfaction Rating Scale (median score, 5 vs 5; mean difference, 0.01 [95% CI, −0.04 to 0.06]). Patients in both groups reported feeling in control of their labor management during the second stage of labor, with no significant difference between the groups (median score, 5 vs 5; mean difference, 0.01 [95% CI, −0.03 to 0.05]; eTable 2 in Supplement 2). There was no significant difference in patient preference for the same second stage management plan in a subsequent delivery (91.3% in the immediate pushing group vs 91.0% in the delayed pushing group; absolute difference, 0.3% [95% CI, −1.9% to 2.7%]; RR, 1.1 [95% CI, −0.9 to 1.3]).

Post Hoc Outcomes

There were no significant differences between the groups in either estimated blood loss (419.0 mL in the immediate pushing group vs 424.4 mL in the delayed pushing group; mean difference, −5.2 mL [95% CI, −24.7 to 14.4 mL], P = .60) or rate of blood transfusions (1.2% vs 1.3%, respectively; absolute difference, −0.1% [95% CI, −1.0% to 0.8%]; RR, 0.9 [95% CI, 0.5 to 1.8], P = .84). There was no significant difference in the rates of shoulder dystocia or neonatal intensive care unit admission between the groups (Table 2). Risk of severe perineal laceration (third or fourth degree) was significantly higher in the immediate pushing group compared with the delayed pushing group (5.7% vs 4.6%, respectively; absolute difference, 1.1% [95% CI, −0.7% to 2.9%]; RR, 1.2 [95% CI, 1.1 to 1.5], P = .01).

Table 3. Study-Defined Adverse Events and Serious Adverse Events

	No. (%)		Absolute Risk Difference (95% CI)[a]	Relative Risk (95% CI)[b]	P Value
	Immediate Pushing (n = 1200)	Delayed Pushing (n = 1204)			
Any adverse event	169 (14.1)	209 (17.4)	−3.3 (−6.2 to 0.4)	0.8 (0.7 to 0.9)	.001
Any serious adverse event	13 (1.1)	9 (0.8)	0.3 (−0.4 to 1.1)	1.4 (0.7 to 2.8)	.29
Type of maternal adverse event					
Chorioamnionitis	80 (6.7)	110 (9.1)	−2.5 (−4.6 to −0.3)	0.7 (0.6 to 0.9)	.005
Severe postpartum hemorrhage[c]	21 (1.8)	32 (2.7)	−0.9 (−2.1 to 0.3)	0.6 (0.4 to 1.1)	.11
Death	0	0			
Life-threatening event	3 (0.3)	1 (0.1)	0.2 (−0.2 to 0.5)	2.9 (0.5 to 16.2)	.23
Intensive care unit admission	1 (0.1)	2 (0.2)	−0.1 (−0.4 to 0.2)	0.5 (0 to 8.2)	.61
Unplanned hysterectomy	0	1 (0.1)	−0.1 (−0.3 to 0.1)		
Type of neonatal adverse event					
Acidemia (umbilical cord arterial pH <7.1)	9 (0.8)	14 (1.2)	−0.4 (−1.2 to 0.4)	0.7 (0.5 to 0.9)	.01
NICU admission	63 (5.3)	78 (6.5)	−1.2 (−3.1 to 0.6)	0.8 (0.6 to 1.1)	.22
Serious neonatal birth injury	9 (0.8)	7 (0.6)	0.2 (−0.5 to 0.8)	1.3 (0.6 to 2.7)	.52

Abbreviation: NICU, neonatal intensive care unit.

[a] Calculated from binomial distribution.

[b] Obtained from generalized estimating equations models, which were used to account for study site.

[c] Defined as >1000 mL for vaginal delivery and >2000 mL for cesarean delivery.

Adverse Events

The risk of any study-defined adverse event was significantly lower in the immediate pushing group compared with the delayed pushing group (14.1% vs 17.4%, respectively; absolute difference, −3.3 [95% CI, −6.2 to 0.4%]; RR, 0.8 [95% CI, 0.7 to 0.9], P = .001; **Table 3**). Of the individual adverse events, the rates for neonatal acidemia were significantly lower in the immediate pushing group compared with the delayed pushing group (0.8% vs 1.2%, respectively; absolute difference, −0.4% [95% CI, −1.2 to 0.4%]; RR, 0.7 [95% CI, 0.5 to 0.9]) and for chorioamnionitis (6.7% vs 9.1%; absolute difference, −2.5% [95% CI, −4.6 to −0.3%]; RR, 0.7 [95% CI, 0.6 to 0.9]). The study-defined adverse event of severe postpartum hemorrhage (>1000 mL for vaginal delivery and >2000 mL for cesarean delivery) did not differ significantly between the groups (1.8% in the immediate pushing group vs 2.7% in the delayed pushing group; absolute difference, −0.9% [95% CI, −2.1 to 0.3%]; RR, 0.6 [95% CI, 0.4 to 1.1]). There were no significant differences in the rates of any other individual serious adverse events between the groups.

Additional Analyses

Predominantly similar results were seen in the per-protocol and as-treated analyses (eTable 3 and eTable 4 in Supplement 2).

Discussion

In this pragmatic, multicenter randomized clinical trial, there was no significant difference in the rate of spontaneous vaginal delivery among women randomized to immediate pushing compared with delayed pushing. Women who delayed pushing had a longer second stage of labor by more than 30 minutes compared with those who pushed immediately, and pushed for a mean of 9 minutes less. Among the prespecified

secondary outcomes, rates of postpartum hemorrhage and chorioamnionitis were significantly higher among women in the delayed pushing group, but there was no significant difference in the rate of the composite outcome of neonatal morbidity or the overall rate of perineal laceration between groups. Among the prespecified exploratory outcomes, the rates of neonatal acidemia and suspected neonatal sepsis were significantly higher in the delayed pushing group. In contrast, the rate of third-degree perineal lacerations was significantly higher in the immediate pushing group.

The findings in this trial are consistent with the results of a meta-analysis by Tuuli et al[11] of prior randomized clinical trials that found no differences in spontaneous vaginal delivery rates with delayed or immediate pushing among high-quality studies. In contrast, they differ from the results of a meta-analysis that included randomized clinical trials without regard to study quality and found delayed pushing to be a superior strategy to immediate pushing.[18] Many of the original randomized clinical trials lacked applicability to current obstetric practices given the historically high rates of operative vaginal deliveries. The present study provides contemporary evidence from a multicenter randomized clinical trial to guide evidence-based management of the initiation of pushing during the second stage of labor among nulliparous women with neuraxial anesthesia. The results from this pragmatic trial conducted in a modern obstetric cohort are more appropriate to guide clinical practice.

The finding of no effect on spontaneous vaginal delivery for pushing timing during the second stage of labor, and the evidence suggesting increased maternal and neonatal complications in the delayed pushing group, support the view that women immediately pushing after complete cervical dilation may be preferred because women without neuraxial analgesia reflexively push immediately. The prior trial by Fraser et al[10] found that women reported being more satisfied with their birthing experience when pushing was delayed. In contrast,

no significant difference was found in satisfaction scores with delayed pushing compared with immediate pushing, suggesting that patient satisfaction is not a reasonable basis for clinicians to choose delayed pushing over immediate pushing. Because the planned subgroup analyses demonstrated no evidence of any interaction, suggesting that delayed pushing was not superior to immediate pushing in any subgroups, nulliparous patients should not be instructed to delay pushing based on those characteristics.

An important and consistent finding in this and prior trials is that delayed pushing was associated with prolongation of the second stage of labor. A growing body of observational data has suggested that every additional hour spent during the second stage of labor compared with the first hour, regardless of an immediate pushing vs delayed pushing management strategy, is associated with an increase in maternal and neonatal morbidity.[19-23] Specifically, a longer second stage of labor has been associated with an increase in the risks of maternal hemorrhage, infection, severe perineal laceration, as well as neonatal acidemia and neonatal intensive care unit admission. Thus, the current finding that delayed pushing prolonged the second stage of labor without increasing spontaneous vaginal delivery rates further argues against routine use of delayed pushing.

This multicenter trial was regionally representative of obstetric patients in the United States, and enrolled patients from both tertiary care and community-based obstetric programs to enhance external validity and generalizability. The pragmatic design of the trial also facilitates generalizability because labor and delivery management (with the exception of the timing of pushing) was at the discretion of the patient's clinician. The primary analysis adhered to the intention-to-treat principle, producing findings that reflect anticipated outcomes with a strategy of immediate or delayed pushing.

The trial was stopped following a planned interim analysis after 2414 of the planned 3184 patients were recruited, raising the possibility that it is underpowered. However, the decision by the data and safety monitoring board to stop the trial for futility was based on a conditional power analysis showing only an 8% probability of detecting a significant difference in the primary outcome if the total planned sample size was recruited. This suggests that the lack of difference observed is likely due to a true absence of effect on spontaneous vaginal delivery for pushing timing. In addition, the narrow 95% CI (0.96 to 1.03) around the primary outcome effect size of 0.99, suggests that a clinically important effect for pushing timing on the rate of spontaneous vaginal delivery is unlikely. A higher than expected spontaneous vaginal delivery rate in both groups also was observed, which further increased the power of the study to detect a true difference if one existed. Moreover, this study is, to our knowledge, the largest randomized clinical trial of labor management to date, including the second stage.

Limitations

This trial has several limitations. First, the study could not feasibly be blinded, raising the possibility of bias. It is possible that these biases might have influenced individual patient management or clinical diagnoses. However, there were no between-group differences in the management of labor or in the technique of pushing measured in the study. In addition, any bias may likely have been nondirectional because the prestudy rate of delayed pushing at the study centers was about 50%, demonstrating equipoise. However, it is possible that this equipoise overall does not reflect the biases of individual clinicians. To further reduce the potential for bias, data extraction also was performed masked to group assignment.

Second, no adjustment was made for multiple comparisons, raising the possibility that some significant differences in the secondary and exploratory outcomes could have occurred by chance. Third, the study was stopped early, and despite the large sample size, the study may have been underpowered to detect clinically important differences in some of the secondary and exploratory outcomes.

Conclusions

Among nulliparous women receiving neuraxial anesthesia, the timing of second stage pushing efforts did not affect the rate of spontaneous vaginal delivery. These findings may help inform decisions about the preferred timing of second stage pushing efforts, when considered with other maternal and neonatal outcomes.

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