Published in final edited form as:

BJOG. 2016 October ; 123(11): 1797–1803. doi:10.1111/1471-0528.13817.

Neonatal complications associated with use of fetal scalp electrode: a retrospective study

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Abstract

Objectives—To estimate the incidence and risk of complications associated with fetal scalp electrode and to determine whether its application in the setting of operative vaginal delivery was associated with increased neonatal morbidity.

Design—Retrospective cohort study.

Setting—Twelve clinical centers with 19 hospitals across nine American Congress of Obstetricians and Gynecologists US districts.

Population—Women in the United States.

Methods—We evaluated 171,698 women with singleton deliveries 23 weeks gestation in a secondary analysis of the Consortium on Safe Labor study between 2002 and 2008, after excluding conditions that precluded fetal scalp electrode application such as prelabor cesarean delivery. Secondary analysis limited to operative vaginal deliveries 34 weeks of gestation also was performed.

Main outcome measures—Incidences and adjusted odds ratios (aOR) with 95% confidence intervals (CI) of neonatal complications were calculated, controlling for maternal characteristics, delivery mode and pregnancy complications.

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This research was presented at the SMFM 35th Annual Meeting-The pregnancy meeting, San Diego, CA (Feb 2–7, 2015).

Contribution to authorship:

TK, UMR, and KLG conceived the idea for the study. TK wrote the article and is corresponding author of the study. CCH conducted the analyses. TK, UMR, HJL, Fetal Scalp Electrode Complications. SNI, CCH, and KLG contributed to the interpretation of the data. UMR, HJL, SNI, and KLG critically revised earlier drafts of the article for important intellectual content and gave final approval of the version to be published.

Details of ethics approval: Institutional Review Boards of MedStar Research Institute approved this study.

Disclosure of interest: The authors report no conflicts of interest. The ICMJE disclosure forms are available as online supporting information.

Results—Fetal scalp electrode was used in 37,492 (22%) of deliveries. In non-operative vaginal delivery, fetal scalp electrode was associated with increased risk of injury to scalp due to birth trauma (1.2% vs 0.9%; aOR=1.62; 95%CI=1.41–1.86) and cephalohematoma (1.0% vs 0.9%; aOR=1.57; 95%CI=1.36–1.83). Neonatal complications were not significantly different comparing fetal scalp electrode with vacuum assisted vaginal delivery and vacuum assisted vaginal delivery alone or comparing fetal scalp electrode with forceps assisted vaginal delivery and forceps assisted vaginal delivery alone.

Conclusions—We found increased neonatal morbidity with fetal scalp electrode though the absolute risk is very low. It is possible that these findings reflect an underlying indication for its use. Our findings support the use of fetal scalp electrode when clinically indicated.

Keywords

Cephalohematoma; fetal scalp electrode; scalp injury

Introduction

Fetal scalp electrode (FSE) is a spiral wire placed directly on the fetal scalp.¹ Baseline variability can be assessed more reliably with the FSE than with Doppler from external monitoring, as sometimes the signal from the latter is difficult to time accurately. Fetal scalp electrode plays a key role in intrapartum fetal surveillance when there is a non-reassuring fetal heart rate (FHR) tracing or when external FHR monitoring is difficult due to maternal body habitus or excessive fetal movement.^{2,3,4,5,6} It is estimated that FSE is used in 20% of the U.S. obstetrical population.⁷ Most of the literature on complications of FSE such as scalp laceration or abscesses is from smaller studies performed in the 1980s, when FHR monitoring was not conducted routinely.^{3,4,5,6} In addition, it is unknown whether FSE placement in the setting of operative vaginal delivery, estimated to occur in 3.4% of U.S. deliveries, is associated with excess neonatal morbidity.⁸ The aims of our study were to calculate the incidence and risk of complications associated with FSE, to determine the impact of FSE on neonatal complications in the setting of operative vaginal delivery, and to examine the risk factors for FSE associated complications.

Methods

The Consortium on Safe Labor (CSL) is a retrospective cohort study of all women delivering at 23 weeks of gestation or greater between 2002 and 2008 in 12 clinical centers with 19 hospitals across 9 American Congress of Obstetricians and Gynecologists (ACOG) US districts.⁹ All participating institutions obtained Institutional Review Board (IRB) approval.

The CSL included a total of 228,562 deliveries with 233,736 newborns delivered at 23 weeks of gestation after excluding 106 deliveries due to errors in identification. Data from the electronic medical record were abstracted and mapped to predefined categories at the data coordinating center. Data cleaning and logic checks were performed. The data were validated for four diagnoses including cesarean delivery for non-reassuring fetal heart rate tracing, asphyxia, and neonatal intensive care unit (NICU) admission due to a respiratory diagnosis and shoulder dystocia. The variables were highly concordant with the medical

records (greater than 95% for 16 out of 20 variables and greater than or equal to 91.9% for all).⁹ We limited the current analysis to singleton gestations (Figure S1). Conditions that precluded FSE application such as prelabor cesarean delivery, maternal HIV infection, active herpes simplex virus infection, hepatitis B and C, and coagulation disorders were excluded.^{10, 11, 12, 13, 14} We also excluded major fetal anomalies, chromosomal abnormalities, and stillbirth as well as 10,777 deliveries that lacked information about FSE use. Women who underwent both vacuum vaginal delivery and forceps vaginal delivery were excluded. The final analysis was limited to 171,698 deliveries (Figure S1).

Complications of pregnancy, labor, and neonatal data as well as FSE application were derived from medical record data and supplemented with International Classification of Diseases, Clinical Modification *ICD-9-CM* codes as listed in the Supplemental table. Variables solely derived from medical records included induction of labor, PPROM (preterm premature rupture of membrane [PROM], defined by PROM <37 gestational weeks), duration of ROM (rupture of membrane), and intrapartum fever. Variables solely derived from *ICD-9* codes included injury to scalp, cephalohematoma, and cutaneous hemorrhage. Definitions of *ICD-9* codes are listed in a supplemental table (Table S1).

Information on maternal demographics and labor and delivery characteristics were evaluated. We studied the association of FSE placement in non-operative vaginal delivery with risk of the individual neonatal complications including injury to scalp due to birth trauma, cephalohematoma, cutaneous hemorrhage, and neonatal sepsis. In an analysis of 8,059 women who had operative vaginal deliveries at 34 weeks (the suggested gestational age limit for vacuum delivery¹⁵), the risk of individual complications listed above were calculated by FSE application (yes or no) and mode of delivery: vacuum assisted vaginal delivery (VVD) or forceps assisted vaginal delivery (FVD).

Lastly, we evaluated potential risk factors for composite neonatal complications that included injury to scalp due to birth trauma and cutaneous hemorrhage in non-operative vaginal deliveries where FSE was used. Risk factors that were analyzed included gestational age at delivery, birth weight, maternal GBS (group B streptococcus) colonization, and parity.

Descriptive statistics were calculated for all study variables. Univariable analyses were performed to determine associations between outcomes and the FSE application with Chi-square test, Fisher's exact test, or Wilcoxon rank-sum test. Multivariable logistic regression models were performed and adjusted odds ratios (aORs) with corresponding 95% confidence intervals (CI) were calculated, controlling for maternal age, race, maternal body mass index (BMI, kg/m²) at delivery, insurance, site, induction of labor, prior uterine scar, diabetes, hypertensive disease, PROM, gestational age at delivery, chorioamnionitis, and intrapartum fever for injury to scalp due to birth trauma, cephalohematoma, and cutaneous hemorrhage, as well as maternal GBS colonization for neonatal sepsis. All statistical analyses were performed using SAS 9.3 (SAS Institute Inc., Cary, NC).

Results

Fetal scalp electrode was placed in 37,492 (22%) of deliveries. Women with FSE application were younger, more likely to be nulliparous, non-Hispanic white, non-Hispanic black or Asian/Pacific islander, have public insurance, be overweight or obese and smoke ($p < 0.01$ for all variables, Table 1). Women with FSE application were also more likely to have comorbidities including diabetes, hypertensive disease, heart or renal disease. Women with FSE application were more likely to deliver ≥ 34 weeks of gestation by operative vaginal delivery or cesarean delivery ($p < 0.01$ for all variables, Table 2).

In women who had non-operative vaginal delivery, FSE was associated with increased risks of individual neonatal complications including injury to scalp due to birth trauma (aOR=1.62; 95% CI=1.41–1.86), cephalohematoma (aOR=1.57; 95% CI=1.36–1.83), and neonatal sepsis (aOR=1.25, 95% CI=1.08–1.45) compared to the no FSE group (Table 3).

Of the 8,059 women with operative vaginal deliveries ≥ 34 weeks of gestation, 41% had an FSE placed. We explored the impact of FSE on neonatal complications in the setting of operative vaginal delivery (Table 4). Individual rates of each type of injury were increased in the vacuum assisted vaginal delivery with FSE compared with vacuum assisted vaginal delivery alone – injury to scalp due to birth trauma (5.8% versus 5.0%), cephalohematoma (5.4% versus 4.9%), cutaneous hemorrhage (1.1% versus 0.7%), and neonatal sepsis (1.6% versus 1.4%). However, these differences were not statistically significant after controlling for other factors ($P > 0.05$) (Table 4). FSE application in the setting of forceps assisted vaginal delivery was not associated with an increased risk of any neonatal complications compared to forceps assisted vaginal delivery without FSE use.

Nulliparity was found to be a risk factor for a composite of neonatal morbidity including injury to scalp due to birth trauma or cutaneous hemorrhage in non-operative vaginal delivery with FSE (Table S2). Preterm delivery, birth weight, and maternal GBS colonization were not independently associated with increased risk of composite neonatal morbidity in non-operative vaginal delivery with FSE use.

Discussion

Main findings

We found that 22% of all deliveries in our cohort had an FSE placed. In women who underwent non-operative vaginal delivery, FSE application was associated with a small increased risk of scalp injury due to birth trauma, cephalohematoma, and neonatal sepsis, even after adjusting for patient factors and obstetric complications including mode of delivery. We also found that while operative vaginal deliveries were more often associated with FSE application, the rates of neonatal complications were increased with FSE placement in the setting of vacuum assisted vaginal delivery although they were not statistically significant, while the rates of trauma with FSE placement were not increased beyond those associated with forceps assisted vaginal delivery itself. These data should be carefully considered since 10% of operative vaginal deliveries occurred in association with FSE application. Among non-operative vaginal deliveries with FSE application, nulliparity

was found to be an independent risk factor for a composite of neonatal complications including scalp injury due to birth trauma or cutaneous hemorrhage.

Strengths and Limitations

A limitation of our study is the lack of information on the indication and timing of FSE application. Because FSE often is used in the intrapartum period to better assess an equivocal or non-reassuring FHR tracing, it may be that the underlying reason for FSE placement was associated with higher risks of neonatal morbidity instead of the FSE use itself.² This limitation is especially important because, in our study, FSE application was associated with increased risk of operative vaginal delivery (10% versus 4%). This could be interpreted that FSE was placed in the setting of non-reassuring FHR, which resulted in operative vaginal delivery. However, we adjusted for maternal and obstetric complications that were potentially associated with certain outcomes such as neonatal sepsis. More importantly, we identified complications associated with FSE application such as scalp injury and cephalohematoma that were unlikely to be associated solely with a non-reassuring FHR tracing. Because operative vaginal delivery can be associated with increased risks of neonatal complications, we made comparisons within groups with the same mode of deliveries.¹⁵ Another potential criticism of our methods may be use of *ICD-9* codes to identify outcomes. Validity of using *ICD-9* codes to identify obstetric complications has been reported by others in studied by comparing to medical record documentation. In a retrospective study of 4253 deliveries, while *ICD-9* codes for any perineal laceration or trauma had low sensitivity when compared to medical records, *ICD-9* codes for 3rd and 4th degree perineal lacerations demonstrated a sensitivity and specificity of 1.0.¹⁶ Therefore, we argue that using *ICD-9* codes to identify clinically meaningful obstetric complications is a valid approach. Further, though we desired to know whether complications were increased with multiple FSE attempts, this information was not available. Finally, since the CSL was conducted between 2002 and 2008, we acknowledge that there might be differences in labor and delivery management.

The major strength of this study is the large cohort with clinical data from a contemporary population with the ability to study rare outcomes and to adjust for a number of confounding factors. Analysis of this large cohort supports the study of rarer outcomes such as cerebral hemorrhage and allowed the novel exploration of FSE risks in the setting of operative vaginal delivery. Since FHR monitoring is a routine procedure in current obstetrics, more recent data are valuable to examine the impact of FSE on neonatal complications.

Interpretation

Our results support the findings of previous smaller studies. Ashkenazi et al. performed a study of 535 infants in 1985 and found that FSE was associated with a 1.3% rate of scalp ulcers which is similar to the 1.2% rate in our cohort.³ These authors reported a high incidence of scalp laceration associated with FSE (41%).³ However, most of the lacerations were described as transient superficial (21%) or superficial laceration present at discharge (19%), and severe laceration (scalp ulcer) occurred only in 1.3%.

We also found that FSE application was associated with an increased risk of neonatal sepsis after adjusting for confounders although the rate was lower in FSE group. A published case series and a case-control study suggesting an increased risk of neonatal sepsis with FSE application.^{2, 17} In the case series of 15, Yancey et al reported that prolonged duration of FSE use (defined as more than 12 hours) was associated with an increased risk of neonatal sepsis.¹⁷ In a small study of 40 women by Nakatsuka et al, a weak association was found between FSE application and neonatal sepsis.² In a study of 3,944 women by Harper et al, maternal fever prior to delivery was increased both in FSE only group (aOR=1.8; 95%CI=1.0–3.2) and FSE and IUPC group (aOR=2.0; 95%CI=1.3–3.0), although neonatal sepsis was not investigated.¹⁸ Our data do not permit ascertainment of the timing of when FSE placement occurred in the setting of clinical infection, and therefore, we cannot ascertain whether FSE caused an increased risk of neonatal sepsis, or whether FSE was more likely to be placed during labor in fetuses at higher risk for neonatal sepsis. It may be the latter given that FSE placement occurred more frequently in labors with longer rupture of membranes.

In investigating risk factors that were more likely to be directly associated with FSE, injury to scalp due to birth trauma or cutaneous hemorrhage, we found a trend in increased risk that was not statistically significant when FSE was used in earlier deliveries before 37 weeks of gestation. Previous case reports have described complication of FSE use in preterm infants is associated with higher risk of complications resulting from more fragile scalp tissue, immature immune system, and wider separation of skull bones.^{19–20}

Conclusion

Our study found a slightly increased risk of neonatal complications associated with the application of FSE. The risks were reassuringly very low, and were not increased with operative vaginal delivery. Our findings support the use of FSE when it is clinically indicated.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The Consortium on Safe Labor was funded by the Intramural Research Program of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, through Contract No. HHSN267200603425C. Institutions involved in the Consortium include, in alphabetical order: Baystate Medical Center, Springfield, MA; Cedars-Sinai Medical Center Burnes Allen Research Center, Los Angeles, CA; Christiana Care Health System, Newark, DE; Georgetown University Hospital, MedStar Health, Washington, DC; Indiana University Clarian Health, Indianapolis, IN; Intermountain Healthcare and the University of Utah, Salt Lake City, Utah; Maimonides Medical Center, Brooklyn, NY; MetroHealth Medical Center, Cleveland, OH; Summa Health System, Akron City Hospital, Akron, OH; The EMMES Corporation, Rockville MD (Data Coordinating Center); University of Illinois at Chicago, Chicago, IL; University of Miami, Miami, FL; and University of Texas Health Science Center at Houston, Houston, Texas. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health.

Funding: The data included in this paper were obtained from the Consortium on Safe Labor, supported by the Intramural Research Program of the NICHD, NIH through contract number HHSN267200603425C. This project

was funded in part with Federal funds (Grant # UL1TR000101 previously UL1RR031975) from the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), through the Clinical and Translational Science Awards Program (CTSA), a trademark of DHHS, part of the Roadmap Initiative, “Re-Engineering the Clinical Research Enterprise.”

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Table 1

Demographic data by application.

Demographic data and pregnancy outcomes	No FSE (n=134206)	FSE (n=37492)	p - value ^e
Mean maternal age, y - mean (SD)	27.28 (6.07)	26.77 (6.01)	<.01 ^f
Race/ethnicity, % (n)			<.01
Non-Hispanic white	50.70 (68044)	50.87 (19073)	
Non-Hispanic black	20.75 (27848)	22.46 (8422)	
Hispanic	17.68 (23732)	16.67 (6249)	
Asian/Pacific islander	3.90 (5230)	4.00 (1501)	
Other, multiracial, unknown	6.97 (9352)	5.99 (2247)	
Prepregnancy BMI (kg/m ²), % (n) ^a			<.01
Underweight/Normal	62.54 (56682)	53.13 (14928)	
Overweight	21.97 (19910)	23.32 (6552)	
Obese	15.49 (14034)	23.56 (6619)	
BMI (kg/m ²) at admission, % (n) ^a			<.01
Underweight/Normal	16.33 (17709)	11.56 (3680)	
Overweight	40.22 (43607)	34.52 (10985)	
Obese	43.44 (47098)	53.92 (17157)	
Nulliparous, % (n)	38.95 (52271)	53.25 (19963)	<.01
Prior uterine scars, % (n)	8.70 (11671)	6.16 (2310)	
Health insurance, % (n)			<.01
Private	56.49 (75808)	56.26 (21092)	
Public or self-pay	31.34 (42066)	35.33 (13246)	
Other, unknown	12.17 (16332)	8.41 (3154)	
Any maternal disease, % (n) ^b	13.82 (18548)	19.23 (7208)	<.01
Any Diabetes, % (n) ^c	5.17 (6941)	6.65 (2492)	<.01
Preexisting diabetes, % (n)	1.57 (2104)	2.67 (1001)	<.01
Gestational diabetes, % (n)	3.60 (4837)	3.98 (1491)	<.01
Chronic hypertension, % (n)	2.46 (3307)	3.57 (1339)	<.01
Pregnancy related hypertensive disease, % (n) ^d	7.65 (10268)	12.02 (4505)	<.01
Smoking, % (n)	5.71 (7660)	6.82 (2558)	<.01

FSE group: Any neonates who had FSE application regardless of mode of delivery

No FSE group: Any neonates who did not have FSE application regardless of mode of delivery

^aMaternal BMI (body mass index) is categorized as underweight if BMI is <18.5 kg/m², normal weight if BMI is 18.5 to 24.9 kg/m², overweight if BMI is 25.0 to 29.9 kg/m², obese if BMI is 30.0 to 34.9 kg/m², and morbidly obese if BMI is ≥35.0 kg/m²

^bAny maternal disease includes any diabetes, any hypertensive disease, heart and renal disease.

^cAny diabetes includes preexisting diabetes and gestational diabetes

^dAny hypertensive disease includes gestational hypertension, pre-eclampsia, and eclampsia

^eP-value from Chi-square test unless specified.

f Student's t test

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Table 2

Labor and delivery characteristics by application.

Pregnancy outcomes	No FSE (n =134206)	FSE (n=37492)	p - value ^b
Gestational age at delivery, weeks - mean (SD)	38.77 (2.00)	39.02 (1.69)	<.01 ^c
Gestational age group % (n)			<.01
< 34 weeks	2.60 (3492)	1.39 (523)	
34 weeks	97.40 (130714)	98.61 (36969)	
Birth weight (gram), mean +- SD	3281 (542)	3278 (514)	0.24 ^c
Birth weight group % (n)			0.11
Birth weight < 2500 g	6.33 (8408)	6.20 (2304)	
Birth weight 2500 – 4000 g	86.56 (114913)	86.96 (32307)	
Birth weight > 4000 g	7.11 (9441)	6.84 (2540)	
Mode of delivery % (n)			<.01
Vaginal delivery	78.36 (105163)	67.92 (25464)	
Operative vaginal delivery	4.40 (5901)	10.53 (3949)	
Vacuum delivery	62.99 (3717)	54.11 (2137)	
Forceps delivery	18.10 (1068)	30.03 (1186)	
Vacuum + forceps	0.39 (23)	0.35 (14)	
Not specified	18.52 (1093)	15.50 (612)	
Cesarean delivery	17.24 (23142)	21.55 (7079)	
Induction of labor, % (n)	35.81 (48057)	49.13 (18418)	<.01
Intrauterine pressure catheter use, % (n)	10.91 (14643)	52.85 (19816)	<.01
Maternal GBS colonization, % (n)	22.44 (30116)	22.62 (8481)	0.46
PROM or PPROM, % (n) ^a	7.33 (9837)	7.07 (2649)	0.08
Duration of rupture of membrane (min), median(10th,90th)	209 (8,776)	367 (101,949)	<.01 ^d
Duration of ROM group, % (n)			<.01
< 12 hours	88.41 (94731)	81.31 (28523)	
12 to < 24 hours	9.00 (9643)	15.45 (5418)	
> 24 hours	2.59 (2777)	3.24 (1138)	
Intrapartum fever, % (n)	5.00 (6711)	6.69 (2508)	<.01
Postpartum fever, % (n)	2.18 (2921)	4.09 (1532)	<.01
Chorioamnionitis, % (n)	2.69 (3612)	5.28 (1980)	<.01
Endometritis, % (n)	0.47 (631)	1.20 (449)	<.01

FSE group: Any neonates who had FSE application regardless of mode of delivery

No FSE group: Any neonates who did not have FSE application regardless of mode of delivery

^aPremature Rupture of Membrane (PROM) or Preterm Premature Rupture of Membrane (PPROM)^bP-value from Chi-square test unless specified^cStudent's t test d Wilcoxon rank-sum test

Table 3

Neonatal complications by FSE application in non-operative vaginal delivery.

Neonatal complications	NOVD ^a , No FSE (n=105163) % (n)	NOVD ^a , FSE (n=25464) % (n)	Adjusted OR (95%CI)
Injury to scalp due to birth trauma	0.92 (972)	1.17 (299)	1.62 (1.41–1.86)^b
Cephalohematoma	0.86 (908)	1.03 (262)	1.57 (1.36–1.83)^b
Cutaneous hemorrhage	0.56 (592)	0.47 (119)	0.91 (0.74–1.12) ^b
Neonatal sepsis	1.26 (1327)	1.04 (264)	1.25 (1.08–1.45)^c

Any gestational age with non-operative vaginal delivery.

^aNon-operative vaginal delivery (NOVD)^bAdjusted for maternal age, race, maternal BMI at delivery, insurance, site, induction of labor, prior uterine scar, diabetes, hypertensive disease, PROM or PPROM, and gestational age.^cAdjusted for maternal age, race, maternal BMI at delivery, insurance, site, induction of labor, prior uterine scar, diabetes, hypertensive disease, PROM or PPROM, gestational age, chorioamnionitis, intrapartum fever, and maternal GBS colonization.

Table 4

Neonatal complications by FSE application in operative vaginal deliveries.

Neonatal complications	No FSE, VVD ^a (n = 3689) % (n)	FSE + VVD ^a (n = 2135) % (n)	Adjusted OR (95%CI) ^b	No FSE, FVD ^e (n = 1060) % (n)	FSE + FVD ^e (n = 1175) % (n)	Adjusted OR (95%CI) ^f
Injury to scalp due to birth trauma	4.99 (184)	5.76 (123)	1.20 (0.94–1.52) ^c	3.96 (42)	3.32 (39)	0.90 (0.56–1.44) ^c
Cephalohematoma	4.88 (180)	5.43 (116)	1.16 (0.90–1.48) ^c	3.49 (37)	2.98 (35)	0.91 (0.55–1.51) ^c
Cutaneous hemorrhage	25 (0.68)	23 (1.08)	1.54 (0.86–2.75) ^c	2.08 (22)	1.96 (23)	0.89 (0.49–1.63) ^c
Neonatal sepsis	50 (1.36)	35 (1.64)	1.20 (0.76–1.88) ^d	1.13 (12)	1.28 (15)	1.13 (0.50–2.55) ^d

Gestational age at delivery 34 weeks of gestation with operative vaginal delivery.

^aVVD (vacuum vaginal delivery)^bReference No FSE, VVD.^cadjusted for maternal age, race, maternal BMI at delivery, insurance, site, induction of labor, prior uterine scar, diabetes, hypertensive disease, PROM or PPRM, and gestational age.^dAdjusted for maternal age, race, maternal BMI at delivery, insurance, site, induction of labor, prior uterine scar, diabetes, hypertensive disease, PROM or PPRM, gestational age, chorioamnionitis, intrapartum fever, and maternal GBS colonization.^eFVD (forceps vaginal delivery)^fReference No FSE, FVD.