

INTRAPARTUM FETAL/CLINICAL OBSTETRICS

Abstracts 62 – 70

Moderators: Lorraine Dugoff, MD; Michael Varner, MD

62 Randomized clinical trial for the comparison of Foley catheter and prostaglandin inserts in induction of labor at term (trial registration NTR 1646)

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OBJECTIVE: To assess the effectiveness of a transcervical Foley catheter compared to vaginal prostaglandin E2 inserts for induction of labor in term women with an unfavorable cervix.

STUDY DESIGN: We performed a randomized controlled trial in four hospitals in the Netherlands between February 2009 and May 2010. Women with a singleton pregnancy in cephalic presentation at term with an unfavorable cervix (Bishop score <6) scheduled for induction of labor were randomly allocated to either induction with a 30 cc transcervical Foley catheter or a 10 mg slow-release vaginal prostaglandin E2 insert. The primary outcome was cesarean section rate. Secondary outcomes were time from the start of the intervention to delivery and maternal and neonatal morbidity. We performed an intention to treat analysis.

RESULTS: We included 232 women. Six were excluded post-randomization due to various reasons. We randomly assigned 107 women to Foley catheter and 119 to 10 mg vaginal prostaglandin E2 inserts. Cesarean section rates were comparable in both groups (20% vs. 22%, RR 0.90, 95% CI .54-1.5). Time from start induction to delivery was not different in both groups: median time 28 hours (IQR 18-44) in the Foley group and 30 (16-51) in the prostaglandin group (p=0.96) (Figure 1). Oxytocin augmentation was needed more often after induction with a Foley catheter (78% vs. 66%, RR 1.18, 95% CI 1.00-1.40). Other secondary outcomes did not differ between groups (Table 1). We observed no serious maternal or neonatal morbidity.

CONCLUSION: In term women with an unfavorable cervix induction of labor with a Foley catheter is equally effective as induction with vaginal prostaglandin E2 inserts, with comparable maternal and neonatal morbidity.

Table 1. Primary and secondary outcomes

	Foley catheter n=107	Prostaglandin E2 insert n=119	RR (95% CI)
Cesarean section	20%	22%	0.90 (0.54-1.50)
Fetal distress	9%	10%	0.93 (0.42-2.06)
Failure to progress	10%	11%	0.81 (0.45-1.46)
Other	0	1%	Not applicable
5 min. Apgar Score <7	4%	5%	1.01 (0.96-1.07)
Umbilical cord pH <7.10	8%	10%	0.79 (0.29-2.17)
Neonatal admission	72%	68%	1.06 (0.89-1.25)
- due to suspected infection	5%	8%	0.56 (0.20-1.58)
Neonatal sepsis	1%	4%	0.22 (0.03-1.87)
Maternal fever (>38°C) during labor	5%	5%	0.93 (0.29-2.95)
Maternal post partum infection (endometritis, wound infection, UTI)	0%	1%	Not applicable
Uterine hyperstimulation	2%	2%	1.11 (0.16-7.76)
Post partum hemorrhage (>1000cc)	8%	6%	1.27 (0.48-3.39)

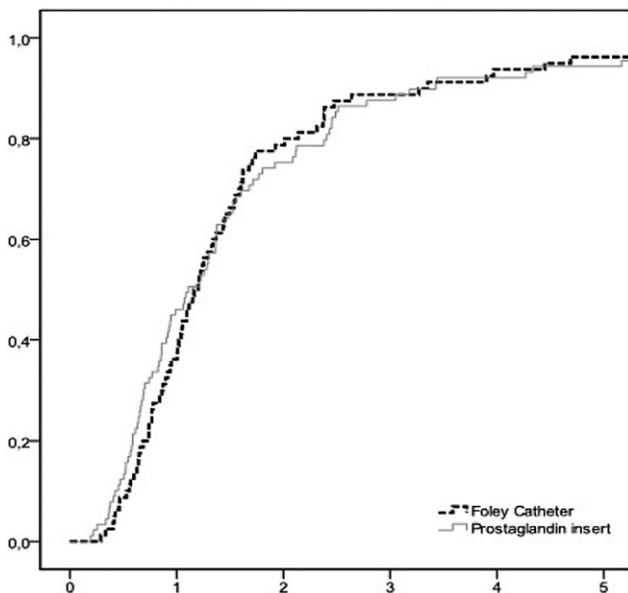


Figure 1. Kaplan Meier curve, showing the time in days on the x-axis and the proportion of women delivered on the y-axis

63 Childhood lead poisoning prevention through prenatal housing inspection and remediation in St. Louis, Missouri

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OBJECTIVE: Children in St. Louis have lead poisoning rates 4 times the national average and are at risk for neurodevelopment disabilities including decreased intelligence and increased behavioral dysfunction. Current strategies to prevent lead poisoning rely on identification of poisoned children, then treating homes to prevent further damage.

Primary prevention prevents lead poisoning prior to irreparable brain damage. The Heavy Metal Project assessed the feasibility and effectiveness of screening and remediating lead hazards prenatally in a high risk population. Our hypothesis was that we could reduce average blood lead levels and the number of children poisoned by 25%.

STUDY DESIGN: 492 pregnant women were identified at prenatal visits and 152 underwent prenatal home inspections. Inspections were conducted by certified lead inspectors from the City of St. Louis in accordance with HUD regulations including a visual paint inspection, x-ray fluoroscopy and dust swipes. Upon discovery of lead hazards, the inspectors created a scope of work including paint stabilization, window replacement and cleaning. At one year of life, the children of participating women had serum lead levels drawn and those from inspected homes were compared to controls.

RESULTS: Of the 152 pregnant women whose homes were inspected, blood lead levels were obtained from 60 children. These were compared with age matched controls living in the same census tracts who had lead levels drawn in the same calendar year. The average blood lead level of children in the treatment group was 2.70 mcg/dL compared to 3.73 mcg/dL in the control group ($p=0.019$). The percentage of children who had blood lead levels greater than or equal to 10 mcg/dL in the treatment group was 0% compared to 4.2% of children in the control group ($p=0.128$).

CONCLUSION: Screening the houses of pregnant women is an effective way to reduce the average blood lead level and number of children poisoned in a high risk population. Prenatal home lead hazard screening compares favorably to other prenatal and neonatal screening tests routinely performed in the medical system.

64 RBC transfusion leads to an improvement of physical fatigue in women with acute postpartum anemia: the WOMB study (NCT00335023)

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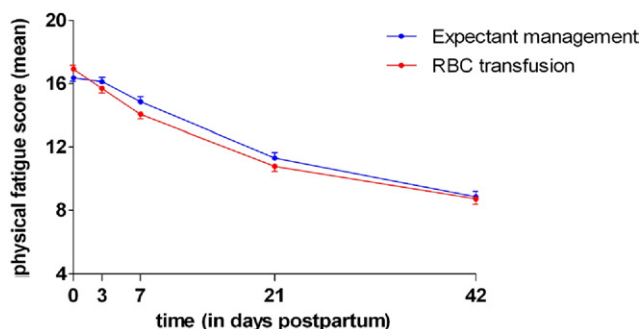
OBJECTIVE: To assess the effectiveness of red blood cell (RBC) transfusion versus expectant management on health related quality of life (HRQoL) in women with acute postpartum anemia.

STUDY DESIGN: We performed a nationwide multicentre open-label randomized study. Women suffering postpartum hemorrhage (blood loss ≥ 1000 mL or Hb decrease ≥ 1.9 g/dL) resulting in hemoglobin (Hb) between 4.8 and 7.9 g/dL, without physical complaints, were eligible. Participants were randomly allocated to RBC transfusion or expectant management. HRQoL was assessed at inclusion, three days, and one, three and six weeks postpartum with the Multidimensional Fatigue Inventory (MFI) and the ShortForm-36. Primary outcome was physical fatigue (MFI, scale 4-20, 20=most fatigue) three days postpartum. We hypothesized that there would be no important difference between study arms, using a non-inferiority margin of 1.3.

RESULTS: We randomized 494 patients of which 247 were allocated to expectant management and 247 to RBC transfusion. Mean Hb at inclusion was comparable between groups (both 7.2 g/dL, $P=.98$), as was mean Hb six weeks postpartum (11.8 g/dL, 11.9 g/dL resp., $P=.66$). Seven patients allocated to RBC transfusion did not receive transfusion, whereas 31 women allocated to expectant management received RBC transfusion, mainly because of anemic complaints. The mean physical fatigue score on day three postpartum was 0.9 higher in women allocated to expectant management (95% CI: 0.2-1.6, $P=.010$, Repeated Measurements ANOVA). After one, three and six weeks, this score was respectively 1.3 (95% CI 0.5-2.0, $P=.002$), 0.8 (95% CI -0.1-1.7, $P=.082$) and 0.4 (95% CI -0.5-1.3, $P=.436$) higher (Fig 1). The differences between study arms were not dependent on mode of delivery or Hb at study entry.

CONCLUSION: In women with acute postpartum anemia, RBC transfusion leads to a small statistically significant decrease in physical fatigue during the first weeks after birth.

Figure 1: Mean physical fatigue score postpartum (ANOVA estimates, error bars represent SEM)



65 Neonatal outcomes associated with intended place of birth: birth centers and home birth compared to hospitals

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OBJECTIVE: To examine whether neonatal outcomes differ in women who intended home births, and births that occurred at birthing centers compared to hospitals.

STUDY DESIGN: This was a retrospective cohort study of singleton live births that occurred in 2008 in the U.S. that had specified birthing facility information. Deliveries were categorized by location of occurrence: hospitals, birthing centers, or intended home births. Neonatal outcomes were compared using chi-square test and potential confounders adjusted for by multivariable logistic regression.

RESULTS: There were 2,296,953 singleton, live, term births meeting study criteria; of these, 10,726 (0.47%) delivered at birthing centers and 12,433 (0.54%) had intended home births. While the risk of cesarean delivery was much lower for women who delivered/or intend to deliver outside of hospitals (0.02-4% vs. 24%, p<0.001), the odds of 5-minute Apgar score<7 and neonatal seizure was significantly higher for intended home births compared to hospital birth (see Table).

CONCLUSION: The risk of cesarean delivery is significantly lower for women who had or intend to have births outside of hospitals; however, the risk of lower 5-minute Apgar score and neonatal seizure was higher for intended home births. This trade-off between maternal benefit and neonatal risk of deliveries outside of hospital should be weighed in the decision regarding birthing facility preferences.

	5min Apgar<7 %	Neonatal seizure %
	aOR 95%CI	aOR 95%CI
Hospital	1.23% referent	0.03 % referent
Birthing center	0.99% 0.82 0.68-0.99	0.04 % 1.33 0.42-4.15
Intended home births	2.51% 2.08 1.68-2.34	0.08% 2.83 1.40-5.71

Compare to deliveries in hospitals

66 Obstetric outcome in singletons after in-vitro fertilization with frozen-thawed embryos

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OBJECTIVE: Cryopreservation of embryos is an established method within assisted reproduction technique with satisfactory pregnancy- and live birth rates. The increasing use of single embryo transfer (SET) results in more embryos available for freezing. For IVF children in general, also singletons, higher rate of preterm birth (PTB) and low birth weight (LBW) have been reported. The aim of this study was to compare obstetric outcome for singleton children born after cryopreservation of embryos with singletons born after fresh IVF and singletons born after spontaneous conception.

STUDY DESIGN: This was a retrospective cohort study, including data from all IVF clinics in Sweden for IVF treatment during the years 2002-2006. All singletons from frozen/thawed IVF cycles (n=2348; 1533 SET and 815 double embryo transfers (DET)) and singletons from fresh IVF cycles (n=8944; 6047 SET and 2897 DET) were included. Data were cross-linked with the Swedish Medical Birth Registry and compared with all non-IVF singletons born during the same time period (n=571 914). Outcome measures were: PTB (<28w, <32w, <37w), very LBW <1500g and LBW (<2500g), small for gestational age, peri/neonatal mortality, Apgar score, caesarean section, preeclampsia, gestational diabetes, placenta previa, placental abruption. Crude and adjusted OR were calculated. Adjustment was made for maternal age, parity, smoking, BMI, years of involuntary childlessness and year of birth.

RESULTS: Singletons from frozen SET/DET had higher rates of PTB <28w and peri/neonatal mortality as compared with the general population (Table). Singletons from frozen SET/DET had lower rates of LBW (aOR 0.76; 95% CI 0.60-0.95) but higher rates of peri/neonatal mortality (aOR 1.90; 1.03-3.54) as compared with singletons from fresh SET/DET. Placenta previa was less common in pregnancies from frozen SET/DET as compared with pregnancies from fresh SET/DET.

CONCLUSION: Singletons born after cryopreservation had increased peri/neonatal mortality as compared with singletons born after fresh IVF cycles and after spontaneous conception, however, the absolute risk was low (4.3/1000).

Outcome	Frozen SET/DET vs general population Crude OR (95% CI)	Frozen SET/DET vs general population Adjusted OR (95% CI)
< 28 weeks	2.84 (1.74-4.63)	1.92 (1.12-3.93)
< 32 weeks	1.96 (1.40-2.75)	1.20 (0.83-1.74)
< 37 weeks	1.37 (1.16-1.60)	1.05 (0.88-1.25)
< 1500 g	2.04 (1.42-2.95)	1.28 (0.87-1.88)
< 2500 g	1.22 (0.99-1.51)	0.88 (0.71-1.1)
SGA	1.09 (0.85-1.41)	0.80 (0.62-1.05)
Apgar score < 7 at 5 min	1.65 (1.23-2.22)	1.30 (0.94-1.81)
Peri/neonatal mortality	2.12 (1.16-3.91)	2.00 (1.02-3.92)
Caesarean section	1.90 (1.74-2.08)	1.12 (1.01-1.23)
Preeclampsia	1.96 (1.64-2.34)	1.25 (1.03-1.51)
Gestational diabetes	0.95 (0.66-1.38)	0.95 (0.66-1.38)
Placenta previa	2.32 (1.42-3.81)	1.22 (0.73-2.04)
Placental abruption	1.45 (0.84-2.50)	1.21 (0.69-2.11)

67 Single nucleotide polymorphisms (SNPs) in endothelial nitric oxide synthase (eNOS) gene and unexplained stillbirth

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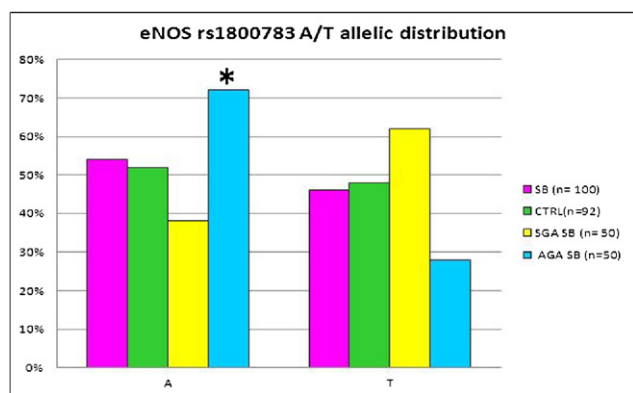
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OBJECTIVE: Altered utero-placental perfusion has been implicated in the pathogenesis of unexplained stillbirth (SB). We previously reported that genetic polymorphisms of VEGF affecting placental vasculogenesis are associated with unexplained SB. Nitric oxide (NO) plays a critical role in regulation of uterine perfusion, and eNOS is the rate limiting enzyme in the NO production cascade. Previous studies suggest that eNOS gene SNPs may be associated with preeclampsia and idiopathic recurrent pregnancy loss. Our objective was to evaluate the presence and distribution of eNOS gene SNPs between unexplained SB and controls in a well-characterized cohort.

STUDY DESIGN: Placentas were obtained from 50 unexplained SB and 46 livebirth controls. Classification of “unexplained” stillbirth was by Wigglesworth and Aberdeen criteria and included both appropriate (AGA-SB) and small for gestational age (SGA-SB, <10th%) SB. Placental DNA was extracted (Qiagen) and evaluated for 4 eNOS SNPs (rs1007311 A/G, rs891512 A/G, rs1800779 A/G and rs1800783 A/T) by real time PCR using specific taqman probes. The genotype and allelic distributions were compared between the groups using Chi-square (significance: $p < 0.05$).

RESULTS: All SNPs were in Hardy-Weinberg equilibrium. None of the SNPs were associated with SB overall. However, significant different genotype distribution emerged for eNOS-SNP rs1800783 A/T when comparing the subgroups of SGA-SB and AGA-SB to controls ($p = 0.004$). Allele-A carriers of rs1800783 were more frequent in AGA-SB compared to both controls ($p = 0.003$) and SGA-SB ($p = 0.001$) (Fig. 1).

CONCLUSION: This is the first study to report on placental eNOS polymorphisms and unexplained SB. Importantly we found that Allele A of rs1800783 eNOS SNP might play a role in the occurrence of unexplained stillbirth in the setting of adequate growth. Our results warrant further population-based analysis.



* allele A in AGA-SB vs SGA-SB vs CTRL, $K^2 p = 0.003$
 allele A in AGA-SB vs CTRL, $K^2 p = 0.003$, OR = 0.36, 95% CI: 1.1-5.3
 allele A in AGA-SB vs SGA-SB, $K^2 p = 0.001$, OR = 0.24, 95% CI: 9.4-0.6

68 The influence of a mediolateral episiotomy during an operative vaginal delivery on the risk for Obstetric Anal Sphincter Injuries (OASIS)

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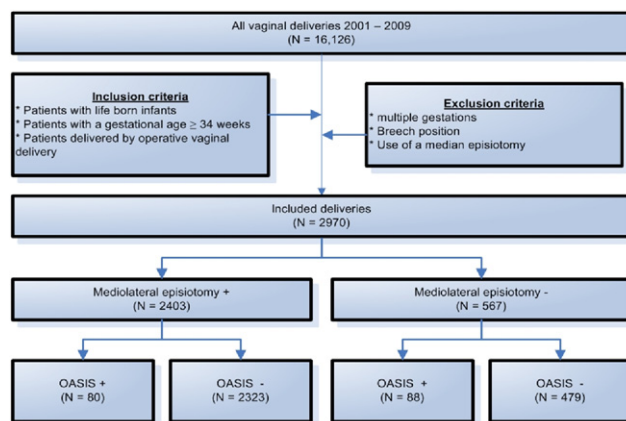
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OBJECTIVE: Operative vaginal delivery is associated with an increased risk of Obstetric Anal Sphincter Injuries (OASIS). It's unclear if structural use of a mediolateral episiotomy at operative vaginal delivery will decrease this risk. The aim of our study was to evaluate the incidence of OASIS in women with operative vaginal delivery, and to assess if a mediolateral episiotomy is preventive for OASIS in these deliveries.

STUDY DESIGN: A retrospective cohort study was performed using the obstetric-database of the Amphia Hospital, The Netherlands of deliveries from 2001 up to 2009. All patients with live born infants delivered by an operative vaginal delivery at a gestational age ≥ 34 weeks were included. Exclusion criteria were: multiple gestations, breech deliveries and the use of a median episiotomy. Continuous variables were compared using the Students t test or Mann-Whitney U test, the χ^2 test for categorical variables. Continuous variables were summarized as means with standard deviations, or medians with interquartile ranges. A logistic regression model was used for the risk assessment for OASIS when a mediolateral episiotomy was performed. Treatment effect was presented as adjusted odds ratio with 95% confidence interval.

RESULTS: There were 2970 operative vaginal deliveries in the study period meeting the inclusion and exclusion criteria (Figure 1). The prevalence of OASIS was 5.7%. The absolute risk was 3.3% in the MLE+ group, compared to 15.5% in the MLE- group (OR 0.19; 95% CI: 0.14-0.26). The risk estimation for OASIS remained similar (adjusted OR 0.20; 95% CI: 0.12-0.34), after logistic regression analysis with correction for gestational age, parity, birth weight, maternal age, use of epidural analgesia, indication for operative vaginal delivery, cephalic fetal position, and duration of the second stage.

CONCLUSION: The use of a mediolateral episiotomy in operative vaginal delivery is associated with a fivefold decreased risk for developing OASIS. Therefore we advocate the structural use of a mediolateral episiotomy during an operative vaginal delivery in order to prevent OASIS.



69 Prophylactic arterial catheterization may improve operative morbidity in suspected placenta accreta and reduce the need for hysterectomy

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OBJECTIVE: The optimal operative approach to placenta accreta (PA) is not well defined. We evaluated whether prophylactic arterial occlusion (CATH) techniques can decrease the need for routine cesarean-hysterectomy and improve operative outcomes in patients with suspected PA.

STUDY DESIGN: Retrospective study of all antenatally diagnosed PA at our institution from 1995-2011. Data regarding maternal demographics, operative procedure, EBL, PRBC, use of other blood products (FFP, cryo, or platelets), OR time, length of stay (LOS), and need for hysterectomy were collected. Cases with CATH, either Avitene embolization(UAE) or hypogastric balloon(BAL) were compared to controls without CATH. Data were analyzed using Fisher's-exact and t-test.

RESULTS: Of 78 identified PA, 63 had an antenatal diagnosis (Mean GA del 36wks); of these 39 had CATH, and 24 had no arterial occlusion. Maternal demographics were similar in both groups. CATH had significantly less EBL (2.0 vs.3.6l; $p = 0.0012$), less PRBC (2.5 vs. 4.5U; $p = 0.0006$), less need for additional blood products (15% vs. 42%; OR 0.25 [CI 0.07-0.84]; $p = 0.04$) with no difference in OR time or LOS. In a subgroup analysis of CATH, 26 had intraoperative UAE immediately post delivery of infant while 13 had BAL. UAE vs. no occlusion also had decreased EBL and less PRBC transfusion ($p < 0.01$). However, this reduction was not seen with BAL. 56 of 63 had attempt at uterine preservation; 35% in the CATH group required a hysterectomy vs. 88% without CATH ($p < 0.001$). When the patient did have a hysterectomy, those that had CATH had similar EBL (3.0 vs.3.8l; $p = 0.41$), and no significant differences in PRBC, use of other blood products, OR time, or LOS. When analyzed by type of CATH, there was a trend for lower EBL and PRBC vs. BAL, but this was nonsignificant. In the CATH group, only one complication (axillary hematoma) was observed.

CONCLUSION: This is one of the largest series to date in the US that looks at the management of PA. Our findings suggest that a protocol that includes CATH may improve the likelihood of uterine conservation and reduces operative morbidity.

70 Predicting acidemia with intrapartum electronic fetal monitoring (EFM) patterns

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OBJECTIVE: To estimate the predictive ability of EFM patterns prior to delivery for acidemia at birth in term infants using standard nomenclature and novel features.

STUDY DESIGN: A 5-year retrospective cohort study of all singleton, non-anomalous gestations in the second stage of labor and delivered at ≥ 37 weeks. The primary exposure, the 30 minutes of EFM immediately prior to delivery, was interpreted by 2 dedicated and formally trained and re-trained obstetric research nurses, blind to clinical and outcome data. EFM patterns were interpreted using the NICHD nomenclature, as well as novel measurements of deceleration features reflecting severity. A novel measure of decelerations, called debt-time, was calculated by the sum of depth x width of all decelerations in the final 30 minutes. Women were excluded for insufficient EFM (< 10 minutes) or lack of umbilical cord gas (UCG), though both are universal at our institution. The primary outcome was UCG pH ≤ 7.10 . Extensive chart extraction allowed for robust assessment of prediction co-factors. Logistic regression and receiver-operator curve (ROC) analyses were used to model and compare predictive ability of EFM parameters for acidemia. Prediction models included: labor type, fever, preeclampsia, protracted first stage, obesity.

RESULTS: There were 57 (1.1%) cases of acidemia (pH ≤ 7.10) among 5,388 term births. Four NICHD-defined EFM features within the 30 minutes prior to birth demonstrated greatest association with acidemia: number of prolonged decelerations (model 2), number of late decelerations (model 3), minimal variability (model 4), tachycardia (model 5), were compared to debt-time (model 1) in their ability to predict acidemia. Debt-time demonstrated superior predictive ability for acidemia (AUC 0.83, $p = 0.04$).

CONCLUSION: A novel measure of deceleration frequency and severity prior to delivery in the second stage performed superior to 4 NICHD EFM features for the prediction of acidemia, and all models performed better than previously published data. While promising, much work needs to be done to properly utilize EFM at the bedside.

