Univariate and multivariable analysis of SSI risk

	SSI (row n, %)	Unadj OR (95% CI)	*Adjust OR (95% CI)
Mean ± s.d. age, yr	26.6 ± 6.3	0.95 (0.93-0.98)**	0.95 (0.93-0.98)
Hispanic /Other (n=623) Black (n=692) White (n=698)	53 (8.5) 81 (11.7) 43 (6.1)	1.4 (0.9-2.2) 2.0 (1.4-3.0) Ref	1.4 (0.9-2.2) 1.8 (1.2-2.8) Ref
BMI > 30 (n=1473) BMI 25-30 (n=438) BMI < 25 (n=98)	145 (9.8) 28 (6.4) 4 (4.1)	2.7 (1.0-7.4) 1.7 (0.6-4.9) Ref	2.1 (0.7-5.8) 1.4 (0.5-4.1) Ref
ROM duration < 6 hours (n=641) < 12 hours (n=653) < 18 hours (n=398) < 24 hours (n=192) 24+ hours (n=118)	33 (5.1) 60 (9.2) 43 (10.8) 28 (14.6) 13 (11.0)	Ref 1.9 (1.2-3.0) 2.3 (1.4-3.6) 3.2 (1.9-5.5) 2.3 (1.2-4.6)	Ref 1.9 (1.2-3.0) 2.4 (1.4-3.9) 3.4 (2.0-6.0) 2.7 (1.3-5.4)
Surgery duration < 38 minutes (n=555) < 49 minutes (n=488) < 60 minutes (n=469) 60+ minutes (n=497)	35 (6.3) 39 (8.0) 50 (10.7) 52 (10.5)	Ref 1.3 (0.8-2.0) 1.7 (1.1-2.7) 1.7 (1.1-2.6)	Ref 1.4 (0.9-2.3) 1.9 (1.2-3.0) 1.9 (1.2-3.0)
IUPC (n=1284) No IUPC (n=728)	140 (10.9) 37 (5.1)	2.3 (1.6-3.3) Ref	-
Vertical skin (n=77) Transv skin (n=1936) Vertical uterine (n=81) Transv uterine (n=1932)	13 (16.9) 64 (8.5) 11(13.6) 166 (8.6)	2.2 (1.2-4.1) Ref 1.7 (0.9-3.3) Ref	- - -
Private insurance (n=629) Other/none (n=1384)	36 (5.7) 141 (10.2)	0.5 (0.4-0.8) Ref	-
Induced labor (n=1094) Spont labor (n=919) 1st cesarean (n=1523) Repeat cesarean (n=490)	116 (10.6) 61 (6.6) 144 (9.5) 33 (6.7)	1.7 (1.2-2.3) Ref 1.4 (0.98-2.1) Ref	-
Pregest DM (n=83) Gestational DM (n=205) No DM (n=1725)	11 (13.3) 14 (6.8) 152 (8.8)	1.6 (0.8-3.0) 0.8 (0.4-1.3) Ref	1.6 (0.8-3.2) 0.7 (0.4-1.3) Ref
Smoker (n=219) Non smoker (n=1794)	22 (10.1) 155 (8.6)	1.2 (0.7-1.9) Ref	-
Azithromycin (n=1019) Placebo (n=994)	60 (5.9) 117 (11.8)	0.5 (0.3-0.6) Ref	0.4 (0.3-0.6)
Preterm (n=226) GBS positive (n=515) Amnioinfusion (n=317) Steroids (n=161)	19 (8.5) 36 (7.0) 29 (9.2) 16 (10.0)	0.95 (0.6-1.6) 0.7 (0.5-1.1) 1.1 (0.7-1.6) 1.2 (0.7-2.0)	P>.05 therefore not included in final model

* adjusted for variables that remained significant (age, race/ethnicity, BMI, ROM duration, surgery duration, azithromycin) or were clinically relevant (DM)
- nonsignificant with backward elimination
** mean ± s.d. maternal age in women without SSI is 28.4 ± 6.3

193 Verification of a proteomic serum-based classifier to predict spontaneous preterm birth in asymptomatic patients

Kim Boggess, George Saade, Scott Sullivan, Glenn Markenson, Jay Iams, Dean Coonrod, Leo Pereira, M. Sean Esplin, Larry Cousins, Garrett Lam, Matthew Hoffman, Angela Fox, Chad Bradford, Tracey Fleischer, Ilia Ichetovkin, Ashoka Polpitiya, Paul Kearney, Durlin Hickok, Jay Boniface

[1]University of North Carolina at Chapel Hill, Chapel Hill, NC, [2]University of Texas Medical Branch, Galveston, TX, [3]Medical University of South Carolina, Charleston, SC, [4]Baystate Medical Center, Springfield, MA, [5]Tufts University, Springfield, MA, [6]The Ohio State University, Columbus, OH, [7]Maricopa Integrated Health System / District Medical Group, Phoeniz, AZ, [8]University of Arizona College of Medicine, Phoenix, AZ, [9]Oregon Health & Science University, Portland, OR, [10]Intermountain Healthcare, Salt Lake City, UT, [11]University of Utah, Salt Lake City, UT, [12]San Diego Perinatal Center, San Diego, CA, [13]Regional Obstetrical Consultants, Chattanooga, TN, [14]University of Tennessee College of Medicine, Chattanooga, TN, [15]Christiana Care Health System, Newark, DE, [16]Sera Prognostics, Inc, Salt Lake City, UT, [17]Integrated Diagnostics, Inc., Seattle, WA

OBJECTIVE: To discover and confirm a proteomic serum-based classifier predictive of spontaneous preterm birth (sPTB) using a novel analytical approach.

STUDY DESIGN: A quantitative proteomics study analyzed 148 sPTB candidate biomarkers in serum from 312 subjects (104 sPTB cases <37 weeks, 208 term controls) drawn during gestational age (GA) weeks 17-25. Performance was assessed separately from 7 overlapping 3-week windows. Classifiers were formed from the ratio of the normalized intensity of up- vs down-regulated analytes. These "reversals" amplify diagnostic signal and normalize pre-analytical and analytical variability. Top performing reversals defined as those with highest AUC from each GA window were identified in a training set and tested in an independent and blinded verification set. A post-verification Monte Carlo Cross Validation (MCCV) study was conducted using a combination of the 2 sample sets and additional filtering to elect a classifier for clinical validation.

RESULTS: 61 of 148 proteins satisfied initial quality filters with 38 demonstrating differential expression between cases and controls. Blinded testing identified classifiers with similar or improved performance relative to training, with best performance in GA weeks 19-21 and 23-25. Blinded verification and post-verification studies identified 18 proteins from high performing reversals in the most diagnostic GA period (weeks 19-21). The classifier, consisting of up-regulated insulin-like growth-factor binding protein 4 (IBP4) and down-regulated sex hormone binding globulin (SHBG), had an AUC of 0.74, 0.77 and 0.75 in the training, blinded verification and post-verification studies, respectively.

CONCLUSION: This independent and blinded study verified a powerful multi-analyte classifier predictive of sPTB. Our novel analytic approach found that IBP4/SHBG is a candidate classifier for clinical validation. These findings support etiologies of inflammation, steroid metabolism, and placental/fetal development in sPTB and provide direction for future intervention studies.

194 Impact of chlorhexidine-alcohol versus iodine-alcohol skin antisepsis on methicillin-resistant staphylococcus aureus infection after cesarean

Molly J. Stout, Shannon Martin, Alison G. Cahill, George A. Macones, Methodius G. Tuuli

[1]Washington University in St. Louis, Saint Louis, MO

OBJECTIVE: Results of our recent randomized trial showed that preoperative skin antisepsis with chlorhexidine-alcohol is superior to iodine-alcohol for preventing surgical site infection (SSI) after cesarean. The superiority of chlorhexidine-alcohol has been attributed in part to its efficacy against methicillin-resistant staphylococcus aureus (MRSA). We tested the hypothesis that chlorhexidine-alcohol will have a greater impact on the rate of positive wound cultures and prevalence of MRSA than iodine-alcohol.

STUDY DESIGN: This was a planned secondary analysis of a randomized trial in which pregnant women undergoing cesarean were randomly assigned to preoperative skin preparation with either chlorhexidine-alcohol or iodine-alcohol. Treating physicians were encouraged to send aerobic and anaerobic wound cultures from subjects presenting with suspected SSI. The outcome measures for this analysis were rates of pathogenic bacterial growth and presence of MRSA. Analysis was by intention-to-treat.

RESULTS: 1082 subjects (538 in the chlorhexidine-alcohol group and 544 in the iodine-alcohol group) were included in the intention-to-treat analysis. In all, 65 (6.0%) subjects developed SSI; 45 superficial and 20 deep. Wound cultures were sent for 32 subjects with suspected SSI and 84.4% (27/32) showed pathogenic bacterial growth. There was no significant difference in rates of pathogenic bacterial growth between the two groups (6/8 [75.0%] in the chlorhexidine-alcohol group vs 21/24 [87.5%] in the iodine-alcohol group, RR 0.86 [95%CI 0.56, 1.31). In all, 15.6% (5/32) of the cultures were positive for MRSA. There was no significant difference in the prevalence of MRSA in the two groups (1/8 [12.5%] vs 4/24 [16.7%], RR 0.75 [95%CI 0.10, 5.8).

CONCLUSION: MRSA is present by culture in a significant proportion of SSI after cesarean and was not impacted by chlorhexidine-alcohol antisepsis. MRSA is an important cause of clinically meaningful morbidity and should be targeted in measures of prevention and treatment of SSI after cesarean.(ClinicalTrials.gov: NCT01472549)