165 RANDOMIZED DOUBLE-BLINDED TRIAL OF INDOMETHACIN TOCOLYSIS VERSUS EXPECTANT MANAGEMENT IN PATIENTS WITH PREMATURE RUPTURE OF MEMBRANES AT 24-32 WEEKS OF GESTATION

VINEET SHRIVASTAVA[1], ROBERT EHSANIPOOR[1], RICHARD M. LEE[2], KENNETH CHAN[3], ANNA GAYLEAN[1], THOMAS GARITE[1], PAMELA RUMNEY[1], DEBORAH WING[1], [1]University of California, Irvine, Orange, California, [2]University of California, Irvine, OB/Gyn Maternal Fetal Medicine, Orange, California, [3]Long Beach Memorial Medical Center, Maternal-Fetal Medicine, Long Beach, California

OBJECTIVE: Preterm premature rupture of membranes (PPROM) represents 1-2% of all pregnancies and results frequently in preterm birth. To date, studies on the use of tocolytic agents in PPROM are limited and have had relatively small sample sizes. The objective of this study is to determine if subjects with PPROM between 24-32 weeks gestation benefit from a 48 hour course of indomethacin.

STUDY DESIGN: This was a double-blinded randomized controlled trial. Consenting subjects with confirmed preterm premature rupture of membranes between 24-32 weeks gestation were included. All subjects received corticosteroids and antibiotic therapy and were randomized to receive indomethacin or placebo for 48 hours. The primary outcome was to determine if a course of indomethacin will increase the proportion of subjects between 24-32 weeks gestation beyond 48 hours. Both maternal and neonatal outcomes were also examined. A sample size of 65 subjects in each arm was needed for 80% power to detect a reduction in the percentage of women delivering within 48 hours from 50% to 25%

RESULTS: This study was concluded prematurely due to a lack of enrollment. A total of 49 subjects met inclusion and exclusion criteria and were enrolled in the study. With regard to the primary outcome of this study, there were no differences in the proportion of subjects pregnant beyond 48 hours (indomethacin 56% vs placebo 44% $p=0.58$) or in the latency period (indomethacin 337+500 hrs vs 372+485 hrs, $p=0.41$). There were also no differences in the frequency of subjects with chorioamnionitis ($p=0.74$) or endometritis ($p=0.99$). In terms of neonatal outcomes, there was no differences noted in respiratory distress ($p=0.55$), intraventricular hemorrhage ($p=0.22$), necrotizing enterocolitis ($p=0.99$), retinopathy of prematurity ($p=0.39$), patent ductus arteriosus ($p=0.99$) or death ($p=0.99$).

CONCLUSION: This limited study demonstrates no benefits for the use of indomethacin as a tocolytic agent in subjects with PPROM over placebo in terms of extending the length of gestation or with neonatal outcomes.

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166 MATERNAL FETAL MEDICINE SPECIALIST DENSITY AND STATE SPECIFIC MALPRACTICE ACTIVITY

SCOTT SULLIVAN[1], ELIZABETH PLATZ[1], ROGER NEWMAN[2], CHARLES RITTENBERG[1], GREER ALBERGOTTI[1], [1]Medical University of South Carolina, Charleston, South Carolina, [2]Medical University of South Carolina, Mount Pleasant, South Carlina

OBJECTIVE: To determine if there is an association between Maternal-Fetal Medicine (MFM) specialist density and state specific malpractice activity.

STUDY DESIGN: This was a cross-sectional, observational study of MFM specialist density and malpractice activity in the United States from 2000 to 2007. Individual state provider density data were obtained directly from the membership department of the Society for Maternal-Fetal Medicine. Fellows in training and honorary/affiliate members were not included in this analysis. State demographic data including population density and income was obtained from the US Census Bureau. State specific malpractice activity data was obtained from the National Practitioner Databank. Provider density was calculated for each state as MFM per 10,000 live births to control for differences in birthrate. Pearson correlations and multiple linear stepwise regression models were constructed for both absolute and relative changes in MFM density.

RESULTS: The national MFM density in 2007 was 4.0 providers per 10,000 live-births. The median state MFM provider density is 3.9 / 10,000 live-births with a range of 0 to 9.1. Pearson correlations demonstrated that population density ($p<.0001$), mean income ($p<.001$), presence of a fellowship program ($p<.005$) are positively associated with MFM density while number of malpractice judgements ($p<.02$) and median malpractice payout amounts ($p<.04$) are negatively associated. A multi-variable stepwise linear regression including these variables explains a reasonable amount of the variability in the MFM density model ($R = 0.68$), however none of the variables reflecting malpractice activity retained their significance in the final model. Variables that retained their significance in the model are population density ($p<.0001$) and presence of a fellowship program ($p<.01$).

CONCLUSION: The density of practicing MFM specialists does not appear to be associated with state specific malpractice activity. The strongest predictors of state MFM provider density are population density and the presence of a fellowship training program.

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167 RACIAL DISPARITIES IN PREMATURE DELIVERY FOR WOMEN UNDERGOING ULTRASOUND OR PHYSICAL EXAMINATION INDICATED CERCLAGE

ELIZABETH PLATZ[1], SCOTT SULLIVAN[1], ROGER NEWMAN[2], MYLA EBELING[1], CHARLES RITTENBERG[1], [1]Medical University of South Carolina, Charleston, South Carolina, [2]Medical University of South Carolina, Mount Pleasant, South Carolina

OBJECTIVE: To determine if there is a difference in premature delivery (PTB) between African-American and Caucasian women who have undergone an ultrasound or physical exam indicated (rescue) cervical cerclage.

STUDY DESIGN: This was an IRB approved, retrospective cohort study of African-American (AA) and Caucasian women who underwent ultrasound and exam-indicated cervical cerclages. The study subjects were identified from a research quality perinatal database. All subjects received a vaginal cerclage utilizing a McDonald technique between 16 - 23 weeks of gestation. The primary outcome was spontaneous PTB; subdivided by gestational age as $<$ 20 weeks, 20-23 weeks, 24-27 weeks, 28-31 weeks, 32-34 weeks and 35-36 weeks. Gestational age specific incidence of PTB was reported. Multivariable logistic regression was used to control for demographic and clinical differences between groups.

RESULTS: A cohort of 325 women was identified from 1997 to 2008; 215 African-American women (study group) and 110 Caucasian women (control group). AA women were significantly more likely to be obese ($p<.0001$), have Medicaid insurance ($p<.01$), a previous preterm delivery ($p<.01$) and be diagnosed with bacterial vaginosis ($p<.05$) or Chlamydia cervicitis ($p<.05$). There was no difference in the odds of delivery prior to 24 or 28 weeks of gestation between cohorts. The AA women were at significantly decreased risk of delivery prior to 28-31 weeks (19.5% vs.28.9% adj OR 0.53 [0.27 – 0.92]), 32-34 weeks (17.7% vs. 43% adj OR 0.29 [0.15 – 0.56]) and 34-36 weeks of gestation (28.4% vs. 43.2% adj OR 0.46 [0.27 - .79]) compared to the Caucasian women. The overall rate of preterm delivery was also significantly lower for the AA women. (66% vs. 81% adj OR 0.45 [0.27-0.8]

CONCLUSION: African-American women undergoing ultrasound and physical exam indicated cerclages experienced significantly lower rates of preterm birth less than 32, 34 and 37 weeks of gestation when compared to Caucasian women. This unexpected outcome was observed despite the number of risk factors for preterm birth in the African-American cohort.

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168 IMPAIRED ANTI-INFLAMMATORY RESPONSE IN WOMEN WITH A PRIOR SPONTANEOUS PRETERM BIRTH

LUISA WETTA[1], ALICE GOEPFERT[1], ELENA LOBASHEVSKAYA[1], SUZANNE CLIVER[1], JOSEPH BIGGIO[1], WILLIAM ANDREWS[1], [1]University of Alabama at Birmingham, Birmingham, Alabama

OBJECTIVE: To examine whether differences in host immune response to antigen stimulation may explain risk for prior spontaneous preterm birth (SPTB).

STUDY DESIGN: Peripheral blood mononuclear cells (PBMC) were isolated from non-pregnant women enrolled in a follow-up study of maternal-infant dyads 5-8 years after a SPTB ($n=39$) or indicated preterm birth (IPTB, $n=26$) at 23-31 6/7 weeks and term birth at 37 weeks ($n=11$). Cells were stimulated with LPS (1.0 μg/ml), incubated 24 hours, and supernatant assayed for cytokines using Luminex x100 (Luminex Corp, Austin, TX) including: Th1 (IFN-, IL-2, IL-12p70); Th2 (IL-4, IL-5, IL-10); general pro-inflammatory (IL-1, IL-6, IL-8, TNF-). Cytokines were considered elevated if $>$75%ile for the term (control) group.

RESULTS: The cohort was 65% black and 34% white. The mean maternal age at delivery was 24$\pm$5 yrs; at follow-up 30$\pm$3 yrs. The mean GA at delivery was 29$\pm$2 in the SPTB, 29$\pm$2 in the IPTB, and 40$\pm$1 wks in the term group. No differences were noted in median levels of individual cytokines among birth groups except IL-4 (0.7 vs 1.8 pg/ml, $p=0.02$) and IL-5 (1.97 vs 2.5 pg/ml, $p=0.03$) levels were lower in the SPTB vs IPTB group. When evaluating the panel of Th1 or Th1+general pro-inflammatory cytokines, there were no differences among birth groups in the proportion with elevated levels. For the Th2 panel (generally considered anti-inflammatory), women with a prior SPTB were more likely to have none (0/3) of the cytokine levels elevated when compared to IPTB and term (none of Th2 cytokines $>$75%ile: SPTB 69.2 vs IPTB 34.6 and term 27.3%, $p=0.005$).

CONCLUSION: In this cohort of women followed-up 5-8 years after delivery, a prior SPTB was associated with less anti-inflammatory cytokine response after antigen stimulation when compared to women with a prior IPTB or term birth. These findings suggest an altered ability to regulate inflammation in women with a prior SPTB.

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