Abstracts 1-9

1 Randomized Trial of Maternal Hyperimmune Globulin to Prevent Congenital Cytomegalovirus (CMV): 2 year outcomes
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OBJECTIVE: To evaluate whether CMV hyperimmune globulin (HIG) administered to women with primary CMV during pregnancy reduces adverse childhood outcomes at age 2 years.

STUDY DESIGN: Multicenter randomized double-masked trial of women with a singleton gestation < 24 weeks with primary maternal CMV infection defined by the presence of either CMV IgM and IgG with low avidity, or IgG seroconversion, as assessed by a central reference laboratory, without evidence of fetal infection. Monthly infusions of CMV HIG (100 units/kilogram) or placebo were given until delivery. At the time of delivery, congenital CMV infection or death did not differ between the HIG and placebo groups (22.7% vs. 19.4%). The primary composite 2-year child outcome included: death, sensorineural hearing loss (unilateral and bilateral), chorioretinitis, seizure disorder, or developmental delay (defined as cognitive score < 70 or motor score < 70 on the Bayley III).

RESULTS: At 17 centers from 2012 to 2018, 206,111 pregnant women were screened; 712 had primary CMV infection (0.35%), of whom 399 (56%) were enrolled and 78 infants (19.5%) had congenital CMV. 90% of children had data collected for the 24-month visit and 75% had complete 2-year outcomes available. The rate of the child primary composite outcome in the CMV HIG group was 13.4% compared with 10.1% in the placebo group (Relative Risk 1.3; 95% confidence interval (0.7, 2.5)). The proportion of children with CMV infection and severe disability was similar between the groups (4.1% vs. 4.7%, p=0.69) and there was no improvement in neuro-developmental outcomes or in the percentage of children whose weight was < 10th percentile at 2 years (Table).

CONCLUSION: CMV HIG did not decrease adverse two year outcomes among children born to women with primary CMV infection in early pregnancy.

2 Randomized Clinical Trial Comparing Group vs. Traditional Prenatal Care for Improving Equity in Birth Outcomes
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OBJECTIVE: The traditional model of individual prenatal care (IPNC) has not appreciably changed in more than a century and is associated with high rates of preterm birth (PTB) and low birthweight (LBW), the burden of which disproportionately affects Black women and infants. Innovative group prenatal care (GPNC) models may reduce the risk of PTB, especially for Black women. We sought to test whether GPNC compared to IPNC reduced rates of PTB and LBW, and if GPNC reduced the racial disparity among Black, White and Hispanic women.

STUDY DESIGN: This was a randomized clinical trial in which medically low-risk pregnant women were allocated 1:1 between GPNC and IPNC stratified by self-identified race/ethnicity at a single study site. Primary outcomes were PTB (< 37 weeks gestational age) and LBW (< 2500 grams). Comparisons were made using three analytic approaches: intent-to-treat (ITT) including all randomized participants, modified intent-to-treat (mITT) including participants attending at...
least one visit in the assigned study arm, and a per compliance (PC) including those receiving at least five visits in the assigned study arm.

RESULTS: 2350 participants were enrolled with 1176 in GPNC and 1174 in IPNC. The study arms were balanced by race/ethnicity, with 40.6% Black, 36.9% White and 21.2% Hispanic women. Compared with IPNC, GPNC did not have lower rates of PTB in ITT (10.4% vs. 8.7%), mITT (10.0% vs. 8.5%), or PC (7.8% vs. 7.3%), p > 0.05 for all. Rates of LBW were also not statistically different between care groups. The racial disparities in PTB and LBW, especially between Black and White women, were smaller for GPNC in all analytic approaches. Additionally, the more GPNC sessions women attended, the smaller the difference in the rate of PTB and LBW between GPNC and IPNC.

CONCLUSION: Although there was no significant difference in overall PTB or LBW rates between GPNC and IPNC, GPNC was effective for reducing racial disparities in both PTB and LBW and women had better outcomes with increased exposure to GPNC. Future research warrants development of interventions for promoting GPNC attendance and reach.

**3. EMG provides insights into preterm birth:**

**Mid-trimester cervical shortening is associated with abnormal myometrial activation**

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OBJECTIVE: Risk of preterm birth (PTB) increases with shortening cervical length (CL) in the mid-trimester; yet, pathophysiology is poorly understood. Uterine electromyography (uEMG) is a novel technology, which offers nuanced assessment of myometrial signaling, not observable with legacy tocodynamometry. We aimed to characterize uterine bioelectrical activity in pregnant patients with short cervical lengths (CL) in the mid-trimester.

STUDY DESIGN: Prospective cohort study of singleton, non-anomalous pregnancies from 16-22 wks. Subjects with normal CL (≥ 3.0 cm) were compared to subjects with short CL (< 2.5 cm) and further stratified by history of PTB. Multi-channel uEMG recordings were obtained for ~60 min. Primary outcome was median percentage of spike, short-burst, and burst signals. Secondary outcomes included linear regression analysis of signal percentage by CL and median signal percentage by PTB history.

RESULTS: 28 subjects were included, 10 with normal CL and 18 with short CL (9 with history of PTB). Spikes were the most commonly recorded signals and were higher in the normal CL cohort (96.3% [IQR 93.1-100.0%]) compared to the short CL cohort (75.2% [IQR 66.7-92.0%], P=0.001). In contrast, median percentages of short-bursts and bursts were significantly higher in subjects with short CL (17.3% [IQR 13.6-23.9%] vs 2.5% normal CL [IQR 0-5.5%], P=.001). The same was true for bursts (6.6% [IQR 0-13.4%] vs 0% normal CL [IQR 0-2.8%], P=.014). In assessing secondary outcomes, CL was inversely proportional to the percentage of observed short-bursts (P=.013) and bursts (P=.014). When accounting for PTB, subjects with short CL and history of PTB had higher burst percentages (12.8% [IQR 9.0-15.7%]) compared to those with short CL and no history of PTB (3.3% [IQR 0-5.0%], P=.003). See Figure 1.

CONCLUSION: Short-burst and burst uEMG signals are observed more frequently in mid-trimester patients with short CL. The presence of these signals confirms that abnormal myometrial activation is present in mid-trimester patients at risk for PTB and may provide a plausible bio-physiologic basis for cervical shortening.