

T-053

**Quantifying Cervical Stiffness in Patients with a Short Cervix.**

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**Introduction:** Premature cervical remodeling is implicated as a mechanism for spontaneous preterm birth (PTB). Aspirated cervical stiffness (aCS) characterizes the softening phase of cervical remodeling. A novel device quantifies aCS via cervical aspiration. This study assessed aCS for patients at high and low-risk of PTB.

**Methods:** This prospective cohort study was ancillary to a randomized-control trial. Patients with no history of PTB, non-anomalous singleton pregnancy and diagnosed with a short cervix, were randomized to vaginal progesterone (VP) versus pessary placement with VP. Visit 1 occurred between 16<sup>0</sup> and 23<sup>6</sup> and Visit 2 between 26<sup>0</sup> and 29<sup>6</sup>. The primary outcome was aCS (unit: mbar | higher mbar = stiffer). Patients at low-risk for PTB with normal cervical length composed the control arm. aCS data from 18<sup>0</sup>-19<sup>6</sup> and 24<sup>0</sup>-25<sup>6</sup> visits were used. Welch's t-tests were performed to compare the average aCS between studies and timepoints. We hypothesized patients with a short cervix would have lower aCS values compared to controls.

**Results:** Of 36 patients with a short cervix, 19 (53%) completed two study visits. Of 39 control patients, 24 (62%) completed two study visits (Table 1). There was no significant difference in the average aCS at Visit 1 between the short cervix (76.8 mbar) and control (98.56 mbar | t-value = -1.8, p-value = 0.08). For pessary patients with a short cervix who completed two study visits, there was no significant difference in average aCS between visits (t-value = -0.37, p-value = 0.07). Patients in the short cervix arm who delivered prior to Visit 2 (n = 6) had significantly lower average aCS (47.4 vs. 82.9 mbar) at Visit 1 as compared to patients in the study arm who completed both visits (t-value = 2.8, p-value = 0.02).

Table 1: Study Characteristics

	Control   N = 39	Short Cervix (Study Arm)   N = 36
Received pessary	N/A	18 (50%)
Completed 2 or more study visits	24 (62%)	19 (53%)
Average Gestational Age at Visit 1 (weeks)	19.18	21.4*
Average Cervical Stiffness at Visit 1 (mbar)	98.56 SD (40.0)	Overall 76.82   SD 38.75 Pessary 77.33   SD 40.0
		No Pessary 76.33   SD 38.65
Average Gestational Age at Visit 2 (weeks)	25.11	28.23*
Average Cervical Stiffness at Visit 2 (mbar)	82.77 SD (37.13)	Overall 83.68   SD 46.69 Pessary 87.29   SD 44.27
		No Pessary 78.25   SD 52.7

SD = standard deviation  
\*Significant difference between control and study arm (p-value <0.01)

**Conclusion:** Aspirated cervical stiffness was significantly lower for patients with a short cervix who delivered before Visit 2. Pessary placement did not significantly change cervical stiffness in cases of short cervix. Patients with short cervix trended toward lower average cervical stiffness, a potential new marker for PTB, than control counterparts.

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**Perinatal Outcomes of Early Preterm Pregnancies: An Obstetrical Perspective.** George Saade\*. Eunice Kennedy Shriver National Institute of Child Health and Human Development, Fetal Medicine Units Network, Bethesda, MD, United States.

**Introduction:** Published reports on determinants of neonatal outcomes often exclude neonates that were not born alive, focus on post-birth measures, such as birthweight, and lack adequate contemporary assessment of obstetrical contributions. Our aim was to develop a multicenter registry of early preterm birth from an obstetrical perspective, and to use the data to develop a risk-stratification tool based on obstetrical determinants.

**Methods:** This was a retrospective cohort study. All singleton and twin deliveries between 16 0/7 and 34 6/7 weeks' gestation occurring at 34 hospitals across the US between 1/1/2019 and 8/31/2019 were reviewed. Data were abstracted by certified research coordinators using predefined criteria and definitions. The primary outcome was neonatal morbidity defined as any one of the following: fetal or neonatal death, severe bronchopulmonary dysplasia (BPD) grade 3, intraventricular hemorrhage (IVH) grades III-IV, necrotizing enterocolitis (NEC; proven - Bell Stage 2A or greater), periventricular leukomalacia (PVL), retinopathy of prematurity (ROP) stage III-V, or proven sepsis (early and late). Obstetrical factors likely to influence neonatal outcomes were predefined. Associations between these factors and the primary outcome were evaluated using univariable and multivariable analyses.

**Results:** 6506 mother/newborn dyads were included. The distribution of the composite varied by gestational age (100% < 22 weeks, 95% 22-23 weeks, 79% 24-25 weeks, 51% 26-27 weeks, 30% 28-29 weeks, 18% 30-31 weeks, 10% 32-33 weeks and 5% 34 weeks). Deliveries before 22 weeks represented 9.4% (95%CI 8.7-10.1%) of the total population and were excluded from the analysis since all participants met the neonatal composite criteria. There were significant associations between obstetrical determinants and the primary outcome for deliveries between 22 0/7 and 34 6/7 weeks (Table 1). Using a backwards logistic regression, 8 remained associated with the primary outcome. A prediction model based on these variables resulted in a ROC with AUC of 88.3 (95%CI 87.2, 89.4).

**Conclusion:** We have successfully implemented a multisite registry of early preterm deliveries with thorough ascertainment of obstetrical data. Even in the periviable period, mortality and morbidity remains high. Obstetrical variables, such as estimated fetal weight, fetal growth restriction and reasons for delivery, significantly impact neonatal outcomes and their inclusion in tools for patient counseling may enable more precise estimation of risk.

Table 1: Obstetrical determinants for neonatal morbidity and mortality composite for deliveries between 22 0/7 and 34 6/7 weeks' gestation

Obstetrical determinant	Neonatal composite (n/N)	No neonatal composite (n/N)	OR or Mean Difference (95% CI)	Adjusted OR or Mean Difference (95%CI)*
Gestational age at delivery	26.7 (24.3, 30.6)	33.3 (31.3, 34.1)	5.0 (4.8, 5.1)	4.9 (4.8, 5.1)
Length of time from hospital admission to delivery (days)	0.7 (0.3, 2.4)	1.1 (0.5, 4.8)	2.2 (1.6, 2.8)	2.7 (1.8, 3.5)
Estimated fetal weight, %ile (continuous) <sup>†</sup>	29.0 (9.3, 82.6)	38.0 (17.6, 58.6)	5.5 (3.4, 7.5)	Unfit category
Estimated fetal weight, %ile category				
No ultrasound EFW within 1 week	5/9 (14.9%)	14/37 (32.2%)	3.76 (1.55, 8.80)	3.43 (1.16, 11.20)
< 5%	1/1 (0.0%)	2/6 (6.8%)	2.16 (1.74, 2.74)	1.74 (1.26, 2.34)
5-9%	7/7 (8.9%)	2/4 (5.2%)	1.42 (1.08, 1.87)	1.36 (0.98, 1.88)
≥ 10%	2/6 (6.3%)	2/6 (6.3%)	Reference	Reference
Maternal BMI at delivery (continuous) <sup>†</sup>	29.2 ± 7.7	29.2 ± 8.2	0.95 (0.96, 0.96)	NA
Prior preterm births				
None	441 (30.2%)	1331 (29.7%)	0.97 (0.97, 1.00)	0.97 (0.71, 1.08)
≥ 1	607 (48.3%)	3392 (45.9%)	Reference	Reference
≥ 2	211 (16.5%)	774 (17.2%)	0.88 (0.76, 1.00)	0.77 (0.61, 0.97)
≥ 3	40 (6.0%)	206 (7.3%)	0.86 (0.73, 1.00)	0.58 (0.44, 0.77)
1st gestation	174 (12.6%)	653 (13.9%)	0.90 (0.76, 1.08)	NA
Premature ROP <sup>‡</sup>	261 (18.9%)	1372 (20.9%)	0.53 (0.46, 0.62)	0.53 (0.43, 0.66)
Placental abruption	188 (12.2%)	301 (7.4%)	1.76 (1.44, 2.14)	NA
Chorioamnionitis	103 (7.8%)	64 (2.4%)	3.77 (2.66, 5.08)	3.26 (1.87, 5.74)
Hypertensive disorders				
None	647 (41.3%)	2355 (51.2%)	Reference	Reference
Chronic HTN only	53 (3.8%)	137 (3.1%)	1.98 (0.81, 4.33)	1.19 (0.68, 1.62)
GHTN or PREGN without SF	198 (14.2%)	841 (18.2%)	0.86 (0.77, 1.01)	1.10 (0.88, 1.48)
SPE with SF, Preeclampsia with SF, HELLP, eclampsia	294 (20.6%)	1416 (21.6%)	0.82 (0.55, 0.70)	1.2 (0.58, 0.88)
Use of antenatal corticosteroids				
None	600 (43.4%)	1032 (22.9%)	Reference	Reference
Partial course <sup>†</sup>	344 (24.9%)	1413 (31.4%)	0.50 (0.48, 0.80)	0.28 (0.20, 0.31)
1 or more courses	438 (31.7%)	2053 (45.6%)	0.48 (0.43, 0.53)	0.28 (0.21, 0.32)

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