1 IMPACT OF A "RESCUE COURSE" OF ANTENATAL CORTICOSTEROIDS (ACS): A MULTI-CENTER RANDOMIZED PLACEBO CONTROLLED TRIAL

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OBJECTIVE: Previous studies using scheduled repetitive courses of ACS have demonstrated limited benefit and concern over potential risk. We present the first study evaluating the impact of a single "rescue course" of ACS on neonatal outcome.

STUDY DESIGN: A multi-center, randomized, double blind, placebo controlled trial was performed. Eligible patients with singletons or twins were < 33 weeks (wks), had completed a single course of betamethasone before 30 wks and at least 14 days prior, and were judged to have a recurring threat of preterm delivery in the coming week. Patients were randomized to receive a single "rescue course" of ACS or placebo. Exclusion criteria included: PROM, advanced dilation (> 5 cm), chorioamnionitis, and other steroid use. The primary outcome was composite neonatal morbidity at < 34 wks.

RESULTS: 437 patients were randomized (223 study group, 214 placebo group). 55% of patients in each group delivered at < 34 wks. The groups were similar in gestational age (GA) at randomization (29.4 wks) and at delivery (33.0 wks), proportion of twins, delivery route, delivery indications, APGAR scores, cord pH, birth weight, and head circumference. There was a significant reduction in composite neonatal morbidity < 34 wks in the "rescue steroid" group vs. placebo (42.5% vs. 63.3%, RR 0.67, 0.54.-0.83, p=0.0002) as well as significantly decreased RDS, ventilator support, and surfactant use. Perinatal mortality and other morbidities were similar in each group. When all 578 neonates were included in the analysis (regardless of GA at delivery), a significant reduction in composite morbidity in the "rescue steroid" group was still demonstrated (30.3% vs. 41.7%, RR 0.73, 0.58-0.91, P=.0055) as well improvement in other respiratory morbidities, but no other differences in outcome including head size and birth weight were evident.

CONCLUSION: Administration of a single "rescue course" of ACS before 33 wks improves neonatal outcome without apparent increased risk.

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2 A PROSPECTIVE MULTICENTER RANDOMIZED TREATMENT TRIAL OF MILD GESTATIONAL DIABETES (GDM).

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OBJECTIVE: To evaluate if treatment of mild GDM reduces perinatal morbidity.

STUDY DESIGN: Women underwent a blinded OGTT(24-31 wks gestation). Those meeting criteria for mild GDM(abnormal OGTT with fasting<95mg%)were randomized to usual prenatal care(untreatedGDM)or dietary intervention,self blood glucose monitoring,and insulin if necessary(treatedGDM).A cohort of women with normal OGTT were also enrolled to mask the status of the untreated GDM group.The primary outcome was a composite of neonatal morbidity:stillbirth/perinatal death, hyperbilirubinemia, hypoglycemia,hyperinsulinemia,birth trauma.

RESULTS: 958 women were enrolled (485 treated, 473 untreatedGDM).There was no difference in composite morbidity in treatedGDM(32.4%)vs untreatedGDM(37.0%) (p=0.14).Neonatal hypoglycemia, hyperbilirubinemia, birth trauma, and hyperinsulinemia(cord c-peptide>90%)were not different. However, mean BW (3302±502g vs3408±589g, p=.0005), neonatal fat mass (427±198g vs 464±222g, p=.003), BW>4000g,LGA, shoulder dystocia,and c-section were reduced with treatment.

CONCLUSION: Whereas treatment of mild GDM does not reduce the frequency of several commonly observed neonatal morbidities associated with diabetic pregnancy,it does lower the risk for fetal overgrowth,shoulder dystocia,and cesarean delivery.

	Treated GDM	Untreated GDM	RR (95%CI)	p-value
1° Comp Outcome	149/460 (32.4%)	163/440 (37.0%)	0.87 (0.73, 1.05)	0.143
Hypoglycemia	62/381 (16.3%)	55/357 (15.4%)	1.06 (0.76, 1.47)	0.747
Hyperbilirubinemia	43/450 (9.6%)	54/418 (12.9%)	0.74 (0.51, 1.08)	0.116
Hyperinsulinemia	75/423 (17.7%)	92/403 (22.8%)	0.78 (0.59, 1.02)	0.068
Birth Trauma	3/476 (0.63%)	6/455 (1.32%)	0.48 (0.12, 1.90)	0.332
Shoulder Dystocia	7/476 (1.5%)	18/455 (4.0%)	0.37 (0.16, 0.88)	0.019
Cesarean Section	128/476 (26.9%)	154/455 (33.8%)	0.79 (0.65, 0.97)	0.021
LGA	34/477 (7.1%)	66/454 (14.5%)	0.49 (0.33, 0.73)	0.0003
BW >4000g	28/477 (5.9%)	65/454 (14.3%)	0.41 (0.27, 0.63)	0.0001

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3 MATERNAL ORAL THERAPY TO REDUCE OBSTETRIC RISK (MOTOR): A REPORT OF A MULTI-CENTERED PERIODONTAL THERAPY RANDOMIZED-CONTROLLED TRIAL ON RATE OF PRETERM DELIVERY.

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OBJECTIVE: Maternal periodontal disease has been identified as a potential risk factor associated with an increased risk for preterm delivery. However, relatively few randomized controlled trials have explored the effects of treating periodontal disease on rates of prematurity.

STUDY DESIGN: A randomized, controlled clinical trial among pregnant mothers with periodontal disease was conducted to assess the effects of periodontal therapy consisting of scaling and root planing and oral hygiene instructions completed prior to GA 23w6d on the rate of preterm delivery at GA<37 weeks, compared to delayed treatment group. Study design required complete obstetric and dental examinations, periodontal treatments, with periodontal and obstetric follow-up of 1800 pregnant women, (600 at each clinical performance sites: University of North Carolina/ Duke Medical Center, University of Alabama, and University of Texas Health Science Center at San Antonio) employing trained and calibrated obstetric and dental investigators. [Details at ClinicalTrials.gov number NCT00097656]. Statistical testing for treatment vs non-treatment was performed by Chi Square.

RESULTS: The study completed maternal therapy and obtained primary outcome data on 1806 deliveries, 903 in the treatment and 903 in the delayed treatment group. Randomization resulted in an equal balance of relevant co-morbid risk factors including smoking, history of preterm delivery and race. In an intent-to-treat analysis, the rate of preterm deliveries <37 weeks was not significantly different between groups. Further, the therapy did not reduce the incidence of secondary outcomes: preterm delivery at 35 and 32 weeks gestational age, weight for gestational age, or neonatal morbidity.

CONCLUSION: Periodontal therapy did not reduce the incidence preterm delivery at less than 37 weeks gestation. Periodontal therapy consisting of a single treatment of scaling and root planing was ineffective in resolving gingival inflammation and preventing disease progression in a substantial portion of these pregnant women. Supported by NIDCR U01-DE-014577.

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