



NEURODIAGNOSTIC EVALUATIONS THAT ASSIST IN THE PREDICTION OF ADVERSE OUTCOMES FOLLOWING ACUTE PERINATAL ASPHYXIA

OBJECTIVE: 1) To compare the test characteristics (sensitivity, specificity, ROC, and likelihood ratios) of the 4 lead aEEG with the neurological examination obtained in infants with moderate or severe encephalopathy within 6 hours of age as predictors of death or disability at 18 months of age (either singly or in combination). 2) To examine the relationship between the aEEG and MRI in neonates with moderate or severe encephalopathy. 3) To evaluate the sensitivity, specificity, ROC, and likelihood ratio of the ability of the MRI obtained at discharge or at 44 weeks of age to predict outcome at 18 months.

ORGANIZATION

Clinical Centers: University of Alabama, Brown University, University of California at San Diego, Case Western Reserve University, University of Cincinnati, Duke University, Emory University, Indiana University, University of Miami, University of Rochester, Stanford University, University of Texas (Dallas), University of Texas (Houston), Wake Forest University, Wayne State University, Yale University

Subcommittee chair: Seetha Shankaran, MD

ELIGIBILITY

Inclusion criteria: Infants will be evaluated by clinical and biochemical criteria (step A), followed by neurological exam (Step B)

Step A Infants must meet criteria in either section A1 or section A2 depending on availability of blood gases:

| A1. IF BLOOD GAS IS AVAILABLE: | A2. IF BLOOD GAS IS NOT AVAILABLE, OR pH 7.01 to 7.15, OR BASE DEFICIT 10 to 15.9mEq/L |
|---|---|
| <ul style="list-style-type: none"> • Cord pH or first postnatal blood gas pH ≤ 7.0 <li style="text-align: center;">or • Base deficit on cord pH or first postnatal blood gas is ≥ 16 mEq/L | <ul style="list-style-type: none"> • Acute perinatal event and either An Apgar score ≤ 5 at 10 minutes <li style="text-align: center;">or • Continued need for ventilation initiated at birth and continued for at least 10 minutes |

Step B Infants must present with moderate/severe encephalopathy defined as seizure or exhibit neurological signs as specified in the study protocol.

Exclusion criteria

- Inability to obtain aEEG recording by 9 hours age
- Presence of known chromosomal anomalies
- Presence of major congenital anomalies
- Severe intrauterine growth restriction (weight ≤ 1800 g)
- Infants in extremis for which no additional intensive therapy is offered
- Parents refuse consent
-

SAMPLE SIZE

- 100 infants who received whole body cooling for HIE as part of standard care

SCHEDULED EVALUATIONS

- Eligibility
- Neurologic examination
- Repeat neurologic examination within 3 days of discharge
- 18 month follow-up

PROTOCOL MANAGEMENT

- Whole body cooling to 33.5°C initiated within 6 hours of age
- aEEG completed at ≤ 9 hours of age
- MRI of the brain obtained at discharge or 44 weeks of age if reached before discharge

OUTCOME MEASURES

Primary outcome:

The primary outcome is the combined endpoint of death or moderate to severe disability at 18 months of age. Infants will be assessed at 18 to 22 months of age. Growth parameters, a neurologic examination, psychometric testing and vision and audiometry evaluations will be performed.

TIMETABLE

Enrollment: 06/2005 – 10/2006

CONCLUSIONS

Shankaran S; Pappas A; McDonald SA; Laptook AR; Bara R; Ehrenkranz RA; Tyson J; Goldberg RN; Donovan EF; Fanaroff AA; Das A; Poole WK; Walsh MC; Higgins RD; Welsh C; Salhab WA; Carlo WA; Poindexter BB; Stoll BJ; Guillet R; Finer NN; Stevenson DK; Bauer CR; for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Predictive Value of an Early Amplitude Integrated Electroencephalogram and Neurologic Examination. *Pediatrics*. 2011 Jul;128(1):e112-e120. Epub 2011 Jun 13. PMID21669899; PMCID3124102.

DATA CENTER

RTI International