

NICHD Neonatal Research Network
Prediction of Jaundice in Term Infants

OBJECTIVE: To use end tidal Co concentration (Etcoc), an Index of bilirubin production, to develop criteria to identify infants who are at low risk of developing significant jaundice, defined as a serum bilirubin > 13 Mg/Dl

ORGANIZATION

Clinical Centers: Brown University, Case Western Reserve University, University of Cincinnati, Emory University, Indiana University, University of Miami, University of New Mexico, Stanford University, University of Tennessee-Memphis, University of Texas-Dallas, Wayne State University, Yale University

Subcommittee chair: David K. Stevenson, MD

DESIGN

Type:

- Prospective cohort study

Major inclusion criteria:

- Well baby delivered by cesarean section
- Birth weight > 2500 grams
- Gestational age > 37 weeks

Sample size

- Goal = 4,000 infants
- Assumption:
 - 7.5% will develop bilirubin > 13 mg/dl
 - 300 infants with bilirubin > 13 mg/dl will be enough to estimate the sensitivity with a 90% confidence interval of ± 0.02

SCHEDULED EVALUATIONS

Prior to discharge:

- ETCO at 2 to 8 hours of age
- ETCO and bilirubin at 72 ± 12 hours of age

After discharge:

- Maximum bilirubin
- Treatment for bilirubin

OUTCOME MEASURES

Primary:

- Development of bilirubin > 13 mg/dl

Secondary:

- Development of bilirubin > 20 mg/dl
- Evaluation of predictors other than ETCO
- Comparison of center differences

TIMETABLE (as designed)

Recruitment

- 11/4/91 – 11/30/92 (13 months)

Data collection

- 1/1/91 – 12/31/92 (14 months)

Closeout/final analysis

- 1/1/93 – 9/30/93 (9 months)

CONCLUSIONS

ETCOc measurements may be helpful in understanding the mechanisms of jaundice in healthy term infants in a variety of conditions (*Clin Chem* 1994;40;10:1934-1939)

Bilirubin measurements differed significantly from established target values at most of the participating laboratories (*Clin Chem* 1996;42;6:869-873)

DATA CENTER

George Washington University Biostatistics Center