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Therapeutic cooling for injured newborns

Therapeutic hypothermia has become standard of care for neonates who suffer an asphyxial event near birth

Therapeutic hypothermia (whole body or head cooling) has become standard of care for neonates who have suffered perinatal asphyxia and then demonstrated encephalopathy. (Fanaroff and Martin, *Neonatal-Perinatal Medicine,* l0th ed., p. 921)

Encephalopathy for these purposes is "a clinical syndrome of disturbed neurologic function in a term or near-term infant usually manifested by decreased level of consciousness or seizures, and which may be accompanied by depressed muscle tone and reflexes and difficulty initiating or maintaining respirations."

Asphyxia in this setting implies a reduced amount of oxygen and the blood needed to deliver that oxygen to the brain and other body organs.

Human studies of hypothermia applied in this setting conducted between 1998 and 2005 have consistently shown its safety. Subsequent studies from 2005 to 2011 demonstrated its effectiveness as well.

Outcomes have now been reported for children up to 6-7 years of age and have shown improvements in both the severity of the disability and overall survival.

Post-cooling imaging studies have also documented significant changes in patterns of injury normally associated with acute hypoxic-ischemic brain injury in newborns. The frequency and severity of MRI evidence of basal ganglia and thalamic brain lesions typically associated with acute near total hypoxic-ischemic encephalopathy at birth, have been diminished in post-cooling neonates. Importantly, "normal" post-cooling MRIs do *not* exclude the presence of a prior hypoxic-ischemic injury or predict a normal long-term outcome.

The National Institute of Child Health and Human Development's Neonatal Research Network and its researchers have developed a scoring system based on MRI patterns for neonates who suffered from an asphyxial event near birth. Scores from zero to three characterize MRI patterns of injury from minimal to severe. The study concluded that there was "an excellent correlation between MRI evidence of neonatal brain injury and outcomes of death or disability at 18-22 months of age." Each point in the scoring pattern increased by twofold the odds of death or disability.

Hypothermia methods being used currently are either whole body or head cooling alone. Treatment is reserved only for term babies not preemies. Current restrictions include having the therapy start within six hours of birth, for a duration of 72 hours, with slow rewarming from a temperature of between 33.5 and 34.5 C. (92.3-94.1 F)

The most current NRP (Neonatal Resuscitation Program) guidelines (2011), a joint publication of the American Academy of Pediatrics and the American Heart Association, recommend considering therapeutic hypothermia after emergent resuscitation of an asphyxiated newborn if the gestational age is 36 weeks or more and there is evidence of an acute hypoxic-ischemic event;

If the birth hospital does not have a well-defined protocol and the ability to implement safe and effective therapeutic hypothermia, then transfer to another institution with this capability is required.

Guidelines

Guidelines for treatment with therapeutic hypothermia in newborns at two of the major children's hospitals in Southern California require:

Age 36 weeks or above at delivery

If a cord blood gas is available, a pH of 7.0 or lower *or* base deficit greater or equal to 16 mEq/L

If no cord gas is available or the pH of the cord gas is 7.01 to 7.15 or the base deficit is between 10 and 16 mEq/L, then either an Apgar score of 5 or less at 10 minutes or the continued need for assisted ventilation at birth and for at least 10 minutes afterward.

Entry criteria for cooling at these hospitals also include a history of an acute perinatal event such as an abruption, cord prolapse, or severe fetal heart rate abnormalities requiring resuscitation at birth.

Potential liability of health care providers regarding cooling includes the failure to adequately assess the neonate for therapeutic hypothermia and/ or treat appropriately and, among other things:

The failure to perform a cord gas or record one in the chart

Missing cord gas results

Failure to timely perform hypothermia

Failure to transfer to a hospital able to treat in a timely manner

Failure to develop hypothermia protocols and train staff appropriately.

Failure to recognize the need for hypothermia

Plaintiffs' attorneys should be aware that failure to properly assess and/or treat asphyxiated newborns with hypothermia exposes the health-care providers to liability and, secondly, that a "normal" post-cooling MRI does not rule out an asphyxial injury.

Philip Michels has practiced trial law for over 30 years. He is a California State Bar recognized specialist in Medical Professional Liability; CAALA Trial Lawyer of the Year-2003; and voted by the American Trial Lawyers Association as one of theTop 100 Trial Lawyers in California. His firm handles a broad range of catastrophic injuries, especially birth and brain injuries. He is a past-president of the Consumer Attorneys of Los Angeles.

Editor's Note:

See illustrations next three pages.

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OLYMPIC COOL-CAP® SYSTEM

CHANGING THE STANDARD OF CARE IN THE NICU FOR INFANTS WITH HIE

The only FDA approved device for the treatment of hypoxic-ischemic encephalopathy (HIE) in term infants, the Olympic Cool-Cap System is a unique and complete system utilizing a special cooling cap to provide selective brain cooling while maintaining core temperature at safe levels through the use of a radiant warmer.

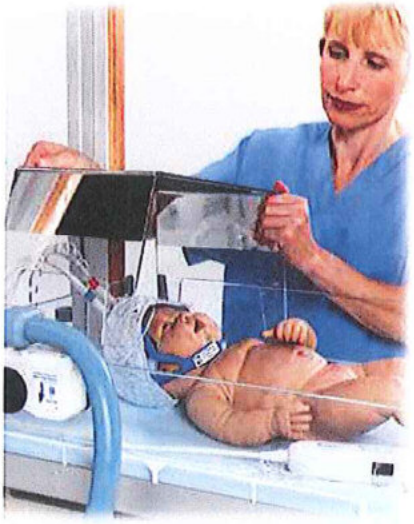
Administered to newborns within the first six hours of life, treatment with the Olympic Cool-Cap System can prevent or significantly reduce the severity of neurologic injury associated with HIE.

CLINICAL BENEFITS

- Provides neuroprotection while minimizing the side effects due to hypothermia
- Allows infant brain cooling while maintaining infant core temperature at safe levels
- Results in meaningful improvements in neurodevelopmental outcome and survival rates at 18 months of age
- Improved outcome for babies with early intervention

BETTER TREATMENT THROUGH BETTER DIAGNOSIS

- The Olympic CFM 6000 cerebral function monitor helps assess extent of HIE to determine if cooling is indicated



- When used in conjunction with the Cool-Cap System, the CFM 6000 provides greater confidence in diagnosing & treating babies in the first few hours of life

PROVEN SAFE & EFFECTIVE

In a randomized-controlled, multi-center, international clinical trial, the Olympic Cool-Cap was shown to reduce or prevent neurological damage associated with HIE in some infants[1].

[1]References available upon request.

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Original article

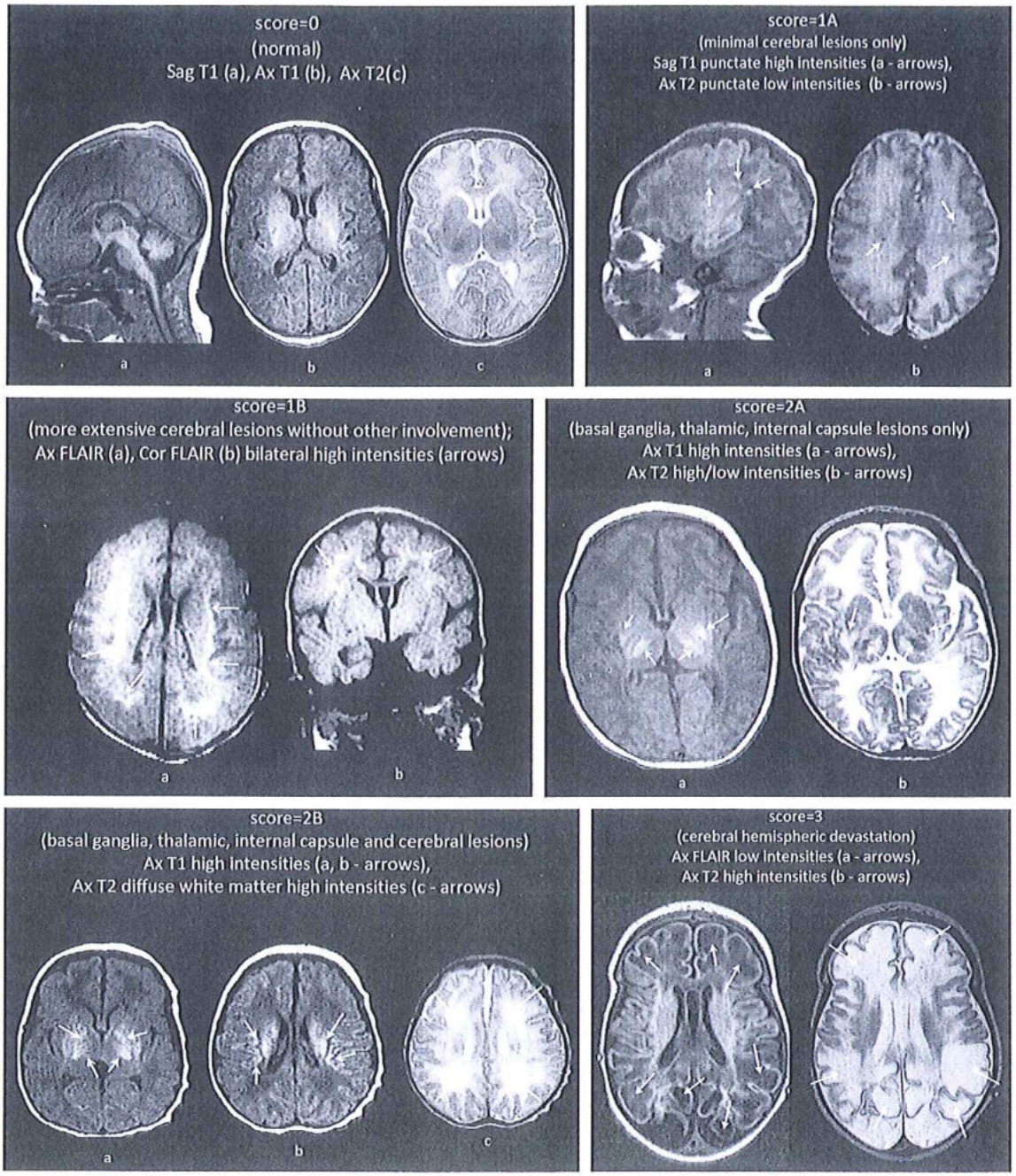

Figure 1 (A) National Institute of Child Health and Human Development Neonatal Research Network score=0; (B) score 1A: lesions in frontal and parietal subcortical areas; (C) score 1B: more extensive cerebral lesions in frontal, parietal and occipital subcortical areas; (D) score 2A: lesions in the basal ganglia and thalamic area (BGT) and internal capsule (IC); (E) score 2B: lesions in the BGT, IC and cerebral areas; (F) score 3: cerebral hemispheric devastation.

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Sources

Neonatal encephalopathy

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Outcome [not all or none]: *Marlow N, et al. . *Arch Dis Child Fetal Neonatal Ed* 2005;90:F330
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Hypothermia

Review — *Committee on Fetus and Newborn. *Pediatrics* 2014:133:1146

Outcome — *Azzopardi D, et al. *NEJM* 2014;371:140

MRI — * Shankaran S, et al. *Arch Dis Child Fetal Neonatal Ed* 2012;97:F398
* Rollins et al. *Pediatr Neurol* 2014;50:447