

## **Brain Cooling in Neonates: The Medical-Legal Implication**

*By Bruce G. Fagel, MD, JD*

Cerebral palsy can be the outcome of either negligent or non-negligent obstetrical care. However, regardless of the cause, a child diagnosed with cerebral palsy faces a lifetime of required medical and attendant care. Such care places an emotional and financial burden on both the family and society. Where there is sufficient evidence of negligent obstetrical care, such "brain-injury baby" cases can result in a financial recovery that at least provides some assistance to a family faced with the lifetime care of such a child.

Until recently such financial assistance through the legal system was the only hope that could be offered to the family of a child with negligently-caused cerebral palsy. However, within the last 10 years a new treatment has been developed which may change the long-term outcome for such a "brain-injured baby." This treatment is called brain cooling, and it is based on scientific research showing that injury to a neonatal brain from hypoxia and ischemia during the birth process does not occur immediately, but occurs over several hours. The initial lack of oxygen (hypoxia) and/or lack of blood supply (ischemia) to the brain kicks off a series of other events, as the body tries to repair itself. This natural approach may be effective when the Hypoxic-Ischemic Encephalopathy (HIE) is mild, but in moderate or severe cases the body's desperate attempts to heal can cause more brain damage.

Brain cooling interrupts the evolution of progressive damages to the baby's brain that are thought to be caused by a complex biochemical cascade. Brain cooling is performed over a 72-hour period, but it must be started within six hours of delivery. The body temperature of the infant is reduced 3 to 4 degrees Celsius from a normal of 37 degrees to 33.0 to 34.5 degrees. The Food and Drug Administration (FDA) has approved the Olympic Cool-Cap System for selective head cooling treatment of neonatal HIE. The first studies on brain cooling were focused on the risks of brain cooling, and they showed that brain cooling was a safe procedure, but more recent studies have shown that induction of moderate hypothermia for 72 hours in infants who had perinatal asphyxia did not significantly reduce the combined rate of death or severe disability, but "resulted in improved neurologic outcomes in survivors." The most recent literature reviewed the status of multiple studies which have looked at brain cooling and neurologic outcomes, and concluded that "in infants with hypoxic-ischemic encephalopathy, moderate hypothermia is associated with a consistent reduction in death and neurological impairment at 18 months."

Brain cooling treatment for neonates with HIE has progressed to the point that major neonatal centers throughout the U.S. have developed specific policies and protocols for this treatment. In California, there are currently 14 hospitals that provide this treatment, all of which have Level III Neonatal Intensive Care Units. Each of these hospitals have developed specific requirements

and eligibility criteria for patients. Since many neonates who qualify for brain cooling are delivered at other hospitals and must be then transported to a hospital that offers brain cooling within 6 hours of birth, the eligibility criteria are basically clinical features that would lead to a diagnosis of hypoxic-ischemic encephalopathy.

Not surprisingly, these criteria are similar to the ACOG criteria for a diagnosis of perinatal asphyxia and include low Apgar scores, evidence of metabolic acidosis on a cord blood gas, and neonatal symptoms including early onset seizures.

The basic eligibility criteria includes evidence of an acute perinatal event, such as a placental abruption, cord prolapse, or severe fetal heart rate (FHR) abnormalities indicative of fetal distress; an Apgar score of less than five at 10 minutes of age; a pH on a cord or subsequent blood gas that is less than or equal to 7.0, or a base deficit of 16 mEq/L or greater; and continued need for ventilation.

Although the written protocols for brain cooling are very detailed with regard to both eligibility and the details of treatment, they are relatively devoid of any specifics about informed consent. Since brain cooling must begin within six hours of birth, and many infants require transfer from the birth hospital to another hospital with a brain cooling program, there is often little time to discuss the details of brain cooling with the parents. Upon being offered the only treatment that offers the possibility of neurologic improvement, it is highly unlikely that any parent would refuse to consent to such treatment, but the written information given to parents is generally highly optimistic about the potential benefit of such treatment, and confirms that it is a safe procedure. Although neither the American Academy of Pediatrics (AAP) nor the American College of Obstetricians and Gynecologists (ACOG) have yet recommended brain cooling as the standard of care for a child diagnosed with HIE at birth, this lack of recommendation is based on the fact that the studies conducted have only shown improvement at 18 months of age, and there are no studies on long term outcome. However, in light of the studies that show no harm from this treatment, and the evidence of improved neurologic outcome at 18 months, the failure to offer such brain cooling treatment to a child who meets the eligibility criteria would certainly be a strong issue before any jury. In situations where there is insufficient evidence of negligent care in the treatment of an acute cord prolapse or placental abruption, a failure to offer brain cooling to a child may be a sufficient basis for recovery in a medical malpractice action, without the need to prove that the initial HIE was preventable. The studies that show a significant improvement in outcome, even at 18 months, should be sufficient to prove causation in a case where brain cooling was not offered for treatment after a clear diagnosis of HIE was established at birth.

Beyond offering an additional legal basis for liability in cases where brain cooling was not provided, the use of brain cooling may have a dramatic effect on the damages aspect of all cases involving brain injured infants. In the typical brain injury baby case, most of the economic damages relate to future medical care costs, which are in turn affected by the projected life expectancy of the child. The defense in many such cases will routinely use both neurology opinions and statistical evidence on the life expectancy of individuals with severe neurologic impairments. All of this evidence is based on data from years ago, much of it before the use of gastrostomy tubes for feeding, and all of it before the use of brain cooling. Thus, in addition to

affecting the validity of such older data on life expectancy, the use of brain cooling with evidence of improved outcome, may affect the use of such statistical evidence of life expectancy of children with HIE.

Since the studies on brain cooling show a statistically significant reduction in neurologic impairment, at least at 18 months, it is quite likely that children who suffered HIE at birth, but then had brain cooling, will be shown to have enough improvement of function that their needs for therapy and other long-term treatments will also increase. Although anecdotal evidence is not sufficient for any statistical significance, in the last several years, we have seen several cases of infants with severe HIE at birth, who show remarkable function at age 2 in comparison to other children who had similar evidence of HIE at birth, but did not get brain cooling because they were born in the 1990's. In one very dramatic case, a child who was born with a severe metabolic acidosis (pH 6.6) and a five minute Apgar score of 0, and such a severe neurologic picture that life support was withdrawn upon the recommendations of the neonatologist and neurologist, even after brain cooling was administered. Yet, at 2 years of age, the child was able to show significant motor function and near normal cognitive function. As a result, his future care costs were significantly higher than they would have been for a child with no motor or cognitive function, and his life expectancy was also dramatically increased.

Since brain cooling is the first treatment that has actually been shown to show statistically significant improvement in neurologic outcome, this treatment will become an important focus for both the families of children with brain injuries from birth and their attorneys. Since the scientific basis for the success of brain cooling is related to the metabolic and chemical processes that cause brain injury over time, after the acute hypoxic event, in the future brain cooling may be applied to adults who suffer from an acute hypoxic event following a cardiac arrest which usually results in brain injury in those patients who survive. This treatment may thus improve the outcome of patients at all ages who suffer from an acute hypoxic event, and the failure to provide such treatment may prove to be an important issue in future medical legal cases involving brain injured individuals.

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