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Selective Brain Cooling:

A New Treatment for Infants with Hypoxic-Ischemic Encephalopathy

By Patricia Sullivan

Until recently, no clinical intervention was available for babies who suffered a low level of oxygen or blood supply to the brain during birth causing a condition called hypoxic-ischemic encephalopathy (HIE).

Now, neonatologists in the Neonatal Intensive Care Unit (NICU) at Baystate Children's Hospital offer a novel treatment for HIE: Selective Brain Cooling.

The NICU at Baystate's Children's Hospital has the region's only brain cooling system. This treatment has been shown to decrease the risk of neurodevelopmental disabilities in the babies with moderate to severe HIE.

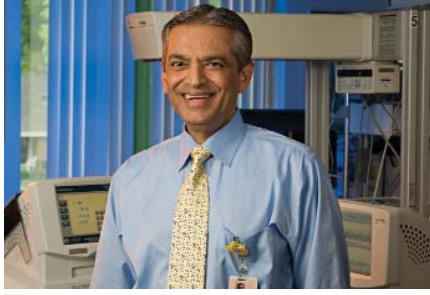
Baystate purchased Olympic Medical's Cool-Cap® System, the only FDA-approved brain cooling device, in January of this year. Before that, says Bhavesh Shah, MD, director of Newborn Services, "Treating babies with HIE was a dissatisfying experience because we could mostly only offer supportive care to the infant, and could not provide any specific therapy directed at brain injury. We are very excited to offer selective brain cooling, a promising new treatment."

The concept behind selective brain cooling is simple, yet requires a complex instrument, continuous monitoring, and close assessment of various organ systems. Full-term newborns with HIE wear a cap that circulates cooled water at carefully controlled temperatures in order to lower the baby's brain temperature. A radiant warmer maintains the infant's core body temperature within a narrow range at a safe level. Selective brain cooling slows the metabolism and reduces energy need to lessen brain injury and allow time for healing.

Rachana Singh, MD, a Baystate neonatologist, explains that the Cool-Cap® System consists of a cooling unit, a control unit, a water-filled cap and three temperature sensors – rectal, skin, and scalp. The system adjusts the water flow to maintain the infant's core temperature at 34 degrees C \pm .5 degrees. During this time, the baby's brain activity is continuously monitored with a cerebral function monitor or an amplitude electroencephalogram (aEEG).

Brain cooling should begin as soon as possible after birth, optimally within six hours, and continue for 72 hours. "Each baby responds differently to cooling and then to re-warming," says Dr. Singh. "We must find the 'sweet' point – the best temperature – for each baby. The first six hours are critical to achieve the target stable temperature."

"We're fortunate to be able to obtain this technology to support our patients, especially in these financially uncertain times," says Lindsey K. Grossman, MD, chair, Department of Pediatrics. "One of the areas of pediatrics in which we've seen dramatic improvement is in increased survival rates in the NICU. But survival doesn't mean that all babies come through unscathed. Those with HIE are at risk of life-long disabilities."



"We are entering a new era that will focus on the protection of the brain, and ultimately improve long-term neurodevelopmental outcomes in children," says Dr. Bhavesh Shah.

Implementation

During her neonatology fellowship, Dr. Singh took part in a multi-center, international clinical trial for Cool-Cap. The results of the trial, published in the *The Lancet* [2005; 365: 663-70], showed that 49 percent of infants who received cooling treatment experienced favorable outcomes, as opposed to 34 percent of the control group. No clinically significant complications resulted from head cooling. The FDA approved the Cool-Cap in 2007.

"Dr. Singh's experience has been valuable during the new treatment's implementation in the Baystate NICU," says Dr. Shah.

Susan Chamberlain, MSN, RNC, clinical nurse specialist for the NICU and Graduate Nursery at Baystate, says it took a "tremendous amount of planning and a collaborative team effort to bring selective brain cooling technology to the NICU at Baystate and get the program running."

The NICU at Baystate Children's Hospital has the only brain cooling system in western Massachusetts.

The groundwork included a site visit to learn about the system. The Cool-Cap was purchased by way of proceeds from the 2008 Max Classic Golf Tournament, an annual event supporting Baystate Children's Hospital that has raised over \$700,000 (net) over the past five years.

Once the equipment was purchased, manufacturer's representatives trained staff and physicians at Baystate. Every one of the 60-plus NICU nurses received Cool-Cap training, while a core group of "super users," including neonatologists, pediatric

neurologists, physician assistants, and neonatal nurse practitioners received additional intensive instruction.

The first baby to meet the Cool Cap criteria required resuscitation and ventilation, and was brought to the NICU and fitted with the Cool-Cap. After 72 hours of brain cooling, the baby's neurological exam was completely normal and he went home.

"We're very optimistic; however, we need to monitor these infants' long-term neurodevelopmental progress, as they are at a higher risk for consequences of brain injury," says Dr. Singh. "Everyone's great effort in the NICU contributed to an early successful outcome."



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Looking Forward

One to two babies per 1,000 births meet the current criteria for selective brain cooling. At this rate, Dr. Shah expects to treat eight to 16 babies per year, including infants born at referring area hospitals. Before Baystate Children's Hospital acquired its Cool-Cap, babies born locally were transferred to Boston for hypothermia therapy. Treating these infants at Baystate enables doctors to start cooling earlier, and decreases the family's disruption and stress by keeping their babies closer to home.

"The NICU at Baystate is a valuable resource for families in western Massachusetts," says Dr. Shah. "It is our obligation to maintain a comprehensive, ultramodern, sophisticated Level III NICU. In addition, our multi-specialty pediatric experts provide valuable support to these babies as they are at high risk for multi-organ problems frequently encountered in babies with HIE."

He continues, "I believe selective brain cooling is just a first step in the development of new treatments for infant brain injury. We are entering a new era that will focus on the protection of the brain, and ultimately improve long-term neurodevelopmental outcomes in children. This is an exciting time as new therapies and interventions on the horizon become available to reduce brain injury. The opportunities to improve in this area are unlimited."

For more information

*about selective brain cooling, contact
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Cool-Cap Criteria

Nicole Provost, RN



Selective brain cooling is indicated for use in full-term infants with clinical evidence of moderate to severe hypoxic-ischemic encephalopathy (HIE). Olympic Medical, maker of Baystate's Cool-Cap® System, provides the eligibility criteria below to define clinical evidence of moderate to severe HIE.

- A.** Infant at greater than or equal to 36 weeks gestational age and at least one of the following:
- Apgar score less than or equal to 5 at 10 minutes after birth
 - Continued need for resuscitation, including endotracheal or mask ventilation, at 10 minutes after birth
 - Acidosis defined as either umbilical cord pH or any arterial pH within 60 minutes of birth less than 7.00
 - Base deficit greater than or equal to 16 mmol/L in umbilical cord blood sample or any blood sample within 60 minutes of birth
- B.** Infant with moderate to severe encephalopathy consisting of altered state of consciousness (as shown by lethargy, stupor, or coma) and at least one of the following:
- Hypotonia
 - Abnormal reflexes, including oculomotor or pupillary abnormalities
 - Absent or weak suck
 - Clinical seizures

If the infant is paralyzed, assume an abnormal evaluation for criteria B and proceed to criteria C.

- C.** Infant has an amplitude-integrated electroencephalogram/cerebral function monitor (aEEG/CFM) recording of at least 20 minutes duration that shows either moderately/severely abnormal aEEG background activity (score of 2 or 3) or seizures.