

BRITISH ASSOCIATION OF PERINATAL MEDICINE

Position Statement on Therapeutic Cooling for Neonatal Encephalopathy

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BAPM Position Statement on Therapeutic Cooling for Neonatal Encephalopathy

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BAPM Position Statement on Therapeutic Cooling for Neonatal Encephalopathy

Perinatal asphyxia severe enough to cause neonatal hypoxic-ischaemic encephalopathy (HIE) occurs in approximately 3/1000 births in the UK¹. The risk of death or severe handicap in survivors of moderate or severe HIE is approximately 25 and 75% respectively, and children without motor impairments have lower cognitive scores on long term follow-up, poorer scholastic attainment in independent National Attainment Tests, and often need educational support^{2,3}. Perinatal asphyxia thus creates a major burden for the individual, the family and for society.

Until recently no specific treatment for HIE was available. However the results of three randomised controlled trials, including the UK total body cooling trial (TOBY), confirm that 72 hours of cooling to a core temperature of 33-34°C started within six hours of birth reduces death and disability at 18 months of age and improves a range of neurodevelopmental outcomes in survivors⁴⁻⁶. A meta-analysis of these data⁷ and an economic evaluation (Regier et al, Value in Health in press) shows that the treatment is cost effective in the context of the National Health Service⁸.

1. We recommend that babies presenting with moderate to severe neonatal encephalopathy within the first few hours after delivery should undergo therapeutic cooling.
2. (i) Evidence suggests this treatment is effective in infants of thirty-six weeks gestation and more. For these infants treatment should be initiated within six hours of birth.
(ii) No data currently supports the use of cooling for neuroprotection in infants of lower gestational age or for other conditions such as sudden postnatal collapse or seizures thought to be due to acute cerebral infarction. Clinicians who choose to cool in these situations should be aware of the weak evidence basis for treatment in these circumstances and parents should be informed of this before treatment is started.
3. Patients should be identified by using approaches compatible with the published trial data. This includes (i) evidence of obstetric problems suggesting intrauterine hypoxia-ischaemia, (ii) their condition at birth, and (iii) ongoing encephalopathy following physiological stabilisation.
4. Amplitude integrated EEG (aEEG or CFM) is also a helpful though not essential tool for obtaining evidence of cerebral depression and in the ongoing management of these infants, including prognostication and recognition of seizures. Initiation of cooling should *not* be delayed awaiting aEEG data and indeed could be initiated in infants showing poor response to resuscitation at an early stage while they are being evaluated further.
5. All infants who are cooled should be entered on to the TOBY registry
6. All paediatricians having any responsibility for the evaluation and resuscitation of babies at birth should be capable of recognising babies in need of cooling and the instigating treatment.
7. Units initiating cooling (either active or passive) should do so in accordance with their network guideline/care pathway and after discussion with their network neonatal intensive care unit (previously called level 3 units)
8. Therapeutic hypothermia is an intensive care treatment which is delivered by either selective head, or total body cooling. This would normally be expected to be delivered in a neonatal intensive care unit (previously called level 3 units): Networks need to ensure that babies receive their continuing care in units which are supported by a multidisciplinary team experienced in intensive care, neonatal electrophysiology (such as CFM and EEG), and neuro MR imaging. Their care should be directed by clinicians experienced in the diagnosis and prognosis of perinatal brain injury. This level of multidisciplinary expertise is rarely available outside Neonatal Intensive Care Units (NICUs)⁹.

9. To enable transfer of infants to the appropriate centre for ongoing cooling Networks should ensure that a 24-hour, seven-day-a-week transport service is available. The transport team should have equipment and expertise to initiate and/or continue cooling during transportation.
10. Centres providing therapeutic hypothermia should ensure they follow their Local Trust's clinical governance procedures and the policy for consent for treatment should be followed.
11. Research into further ways to improve the outcomes for babies who suffer perinatal brain injury continues. We recommend that as new therapies or indications arise, these should be carefully evaluated in clinical trials. Clinicians should actively support these trials by referring babies to evaluation centres following parental agreement.

PRACTICAL CONSIDERATIONS:

1. Hyperthermia particularly induced by external heating should be categorically avoided in these patients.
2. The initiation of cooling will often take the form of switching off external heat sources as a first step pending evaluation. Where appropriate this would be followed by a more active cooling process using specific cooling apparatus.
3. During any form of cooling, including eliminating heat sources, the baby should have their rectal temperature continuously monitored.
4. Those babies whose initial assessments suggest they are candidates for cooling but who show initial improvement, should be maintained at 33-34⁰C during further assessment. Any decision to stop cooling in an infant who previously met appropriate criteria for cooling requires expert assessment, most likely including aEEG, because encephalopathy can be progressive. E.g. infants who have a normal amplitude integrated EEG (aEEG or CFM) throughout the first six hours and are showing no ongoing signs of encephalopathy could be actively re-warmed. This re-warming should be closely monitored with on going rectal temperature measurement.
5. We would recommend that this therapy be incorporated where appropriate into resuscitation algorithms and training of medical and midwifery staff.
6. We would suggest that all infants who undergo therapeutic cooling should have a formalised developmental assessment at two years of age.

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