ROYAL HOSPITAL FOR WOMEN Approved by
LOCAL OPERATING PROCEDURES Quality & Patient Safety Committee
CLINICAL POLICIES, PROCEDURES & GUIDELINES MANUAL 18/8/11

COOLING FOR HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE) IN INFANTS ≥ 35 WEEKS GESTATION

This LOP is developed to guide clinical practice at the Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this LOP.

Aim

- To select appropriate babies for cooling to improve neurological outcomes
- To cool babies in a safe, timely and appropriate fashion

Patient

- Infants born at **≥35 weeks** gestation and who meet the eligibility criteria.
- (Refer to inclusion and exclusion criteria in next section)

Staff

- Neonatal Nurses & Medical staff in Newborn Care Centre.

Equipment

Cool Packs from fridge (not frozen)
Cotton bags for Cool packs
Rectal Thermistor Probe
Cardiorespiratory Monitor
Ventilation support equipment
Saturation Monitor
Open Bed
Body Temp Probe
Temp probe cover

Clinical practice

Eligibility Criteria

All four criteria must be met before cooling is commenced

1. Newborn Infant born ≥ 35 weeks gestation:
2. < 6 hrs post birth
3. Evidence of asphyxia as defined by the presence of **at least 2 of the following 4 Criteria**:
    a. Apgar scores < 6 at 10 min or continued need for resuscitation with positive pressure ventilation +/- chest compressions at 10min after birth
    b. Any acute perinatal event that may result in HIE (ie. Placental abruption, cord prolapse, severe FHR abnormality etc)
    c. Cord p H < 7.0 or base deficit of -12 or more
    d. If cord pH is not available, arterial pH <7.0 or BE > - 12mmoL/L within 60 min of birth
4. The baby has the evidence of moderate or severe HIE. This is defined as seizures or presence of signs in at least 3 of the 6 following categories:

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Category	Moderate encephalopathy	Severe encephalopathy
1. Level of consciousness	Lethargic	Stupor/coma
2. Spontaneous activity	Decreased activity	No activity
3. Posture	Distal flexion, full extension	Decerebrate
4. Tone	Hypotonia	Flaccid
5. Primitive reflexes	Weak suck, incomplete Moro	Absent suck, absent Moro
6. Autonomic system Pupils Heart rate Respirations	 Constricted Bradycardia Periodic breathing	 Dilated /non - reactive Variable heart rate Apnoea

NB: Most eligible babies will need or be receiving respiratory support

Exclusion Criteria

- Oxygen requirement > 80% that is not responsive to treatment
- Major fatal congenital abnormalities – such as Trisomy 13 or 18, severe inoperable congenital heart disease (babies with anomalies such as Down Syndrome and Tracheo-esophageal fistula may be considered for cooling after discussion with parents)
- Severe clinical coagulopathy (including low platelet counts) not responsive to treatment
- Baby unlikely to survive. This should be discussed with and decided by the neonatologist.

Additional information from aEEG (amplitude-integrated EEG) criteria

Amplitude integrated EEG (a-EEG) / Cerebral Function Monitor (CFM) may be used to gain further early information regarding the severity of the encephalopathy.[10-12] See aEEG Nicolet LOPS for more information.

The following findings on aEEG are relevant to HIE: [10-12]

A. Normal amplitude, where the upper margin of the aEEG band was > 10µV and the lower margin > 5 µV.

B. Moderately abnormal amplitude, where the upper margin of the aEEG band was > 10µV and the lower margin = 5 µV

C. Suppressed amplitude where the upper margin of the aEEG band was < 10µV and the lower margin < 5 µV, usually accompanied by bursts of high voltage activity ("burst suppression).

When to start cooling

- Cooling should be started as soon as possible after resuscitation is completed.
- Current evidence suggests that cooling is unlikely to be beneficial if started more than 6-8 hours after birth.

Before Cooling

- Ensure adequate resuscitation and support for the neonate including airway, breathing, circulation and dextrose.
- Inform parents and provide them with the parent information sheet (at back of this LOPS)
- The ability to commence cooling of neonates should NOT influence decisions to cease resuscitation attempts at birth or to consideration for withdrawal of intensive care at a later point
- Avoid **hyperthermia** (temp > 37ºC - this can increase the risk of adverse outcome)[13]

COOLING FOR HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE) IN INFANTS ≥ 35 WEEKS GESTATION cont'd

Cooling Procedure

Our initial preferred cooling method is passive cooling.

Passive Cooling

This is a process of allowing the infant to cool down of their own accord through the removal of the usual interventions undertaken to keep infants warm.

Aims

- To achieve an axillary temperature between 33.5^{0}C and 34.5^{0}C or rectal temperature between 33^{0}C and 34^{0}C.
- To achieve the target temperature within 60 minutes of commencing cooling.
- To target hypothermia initially with passive cooling
- If rectal temperature remains > 35ºC or axillary temp >35.5^{0}C within 60 minutes of starting, then active cooling should be commenced
- To cool baby for 72 hrs then rewarm slowly over 12 hours

Procedure

- **Infant must be nursed on open bed with warmer off (DO NOT nurse infant in incubator)**
- Do not nurse the infant on a sheep skin.
- Nurse infant naked: **NO** clothes, hats or any wraps (plastic or cloth)
- Leave nappy unfastened
- Full cardiopulmonary monitoring and O_2 saturation monitor
- If ventilated or on CPAP, use normal humidity settings
- **Record:** Time of commencement of passive cooling and **rectal (**wherever possible) or axillary temperature every 15min
- If rectal temperature drops < 33.5^{0}C(axillary temperature below 34^{0}C) set radiant warmer on manual mode gradually adjust heater output to maintain axillary temp at 33.5-34.5^{0}C or rectal temp at 33.0 – 34.0^{0}C

Active Cooling:

Active cooling must only be started if passive cooling has been underway for one hour and the infant's rectal or axillary temp is still over 35^{0}C or 35.5^{0}C.

Aims:

- To achieve target temperature range within 1 hour
- Continue to manage Airway, Breathing, Circulation

Procedure

- Use cool packs from the fridge, NEVER frozen. Always wrap cool packs in cotton bags. They should never be applied directly to the skin.
- Cold packs can be placed under the shoulders/upper back under the head and/or across the chest/body but not in the axilla where the accuracy of temperature monitoring.
- Follow the algorithm below:
- **Rectal temperature algorithm for application of cool packs: Aim for 33 - 34^{0}C within the first hour of cooling. For axillary temp, aim for 33.5 – 34.5^{0}C**

COOLING FOR HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE) IN INFANTS ≥ 35 WEEKS GESTATION cont'd

Rectal Temperature algorithm (Axillary temp in brackets)	Number of cool packs to be applied	Areas to apply
≥ 35.50C(≥35.5)	2*	under shoulders, along sides
34 – 35.50C(34.5 -35.5)	1	along sides
<34.0(<34.5)	0	Nil

NB: *Having more than 2 packs prevents radiant loss of heat into the environment and makes it more difficult to cool the baby*

- **Record** time of initiating active cooling and monitor temperatures every 15 minutes.
- If rectal temp drops to <33.5^{0}C(axillary temp <34^{0}C), remove all cool packs and repeat temperature in 15 minutes. If the temperature continues to fall, set radiant warmer on manual and gradually adjust heater output to maintain rectal temp at 33-34^{0}C (axillary temp 33.5-34.50C).

Application of Rectal Thermistor Probe

- Insert **Rectal Thermistor/Probe** at least 5cm into anus.
- Secure the probe at the 10cm (first marking) measurement with tape to the upper inner thigh
- **Note:** The probe must be at least 5cm into the anus to accurately measure the baby's core temperature (The probe is soft and should not cause mucosal trauma). The probe does not require to be removed for cleaning (when removed after completion of Cooling Procedure, discard thermistor, keep and clean cable and monitor).
- Connect rectal probe to cable, temperature module and monitor
- Set temperature alarm limits at 33°C (low) and 34°C (high) during the cooling period.
- Record time of initiating *Active Cooling* and monitor Rectal Temperatures every 15 minutes.

Communication to parents

Advise/reassure parents re: baby's skin appearance, Baby will be cool to touch and occasionally babies may shiver

Slowing down Active Cooling

- Reduce *Active Cooling* when the rectal temperature falls below 34.5^{o}C.
- When rectal temperature < 34.5°C – reduce active cooling by removing one/some 'Cool Packs'.
- When rectal temperature < 34.0°C - stop *Active Cooling* by removing all 'Cool Packs'.
- If rectal temperature falls < 33.5°C - Commence Servo Control. Set Servo Temperature control at the lowest temperature to maintain target rectal temperature at around 33.5°C.

COOLING FOR HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE) IN INFANTS ≥ 35 WEEKS GESTATION cont'd

Duration of therapeutic cooling.

Normal cooling should be continued for 72 hrs from the commencement of cooling.

Consider stopping cooling early if there is:

1. Persistent hypoxemia in 100% oxygen
2. Life- threatening coagulopathy despite treatment
3. An arrhythmia requiring medical treatment (not sinus bradycardia), or
4. After mutual discussion between parents and senior clinicians

Rewarming:

Aim: To rewarm slowly over about 12 hours and to avoid making the baby hyperthermic.

Method:
1. Apply skin probe and turn the radiant warmer on with the servo set at 34.5ºC.
2. Increase the set temperature by 0.5ºC every 2 hours until reach 36.2 to 36.5ºC and rectal temperature is 37ºC. (It should take up to 12 hours for rewarming)**.
3. Monitor axillary temperatures frequently as the rectal temperature approaches the target range. Monitor infant's temperature carefully for 24 hours after normothermia has been achieved to prevent rebound hyperthermia.

****NB:** **Experience to date has shown rewarming can occur too rapidly so babies need close monitoring**
If baby is rewarming too rapidly increase set temp by 0.5C every 4 hrs instead of 2 hrly
Avoid hyperthermia [13]

Ongoing Monitoring:

- Continuous rectal temperature
- Continuous arterial blood pressure wherever possible or at least 4 hrly non-invasive blood pressure monitoring.
- aEEG monitoring as indicated clinically by HIE.
- Blood Gas (arterial access is usually obtained); 4 hourly at least initially then as required by clinical state (includes glucose and lactate and ionised calcium)
- Electrolytes; 8-12 hourly initially then as required by clinical state but at least daily until day 3-5
- Full Blood count; 12 hrly initially then as required by clinical state but at least daily until day 3-5
- INR and APPT clotting studies; on day 1 and then, if abnormal, daily until day 5.
- LFT on day 1 and if abnormal daily until day 5. If normal on day 1, repeat LFT on day 2 and 5.
- **Hypotension**: Treatment with volume replacement and/or inotropes should be considered if the mean arterial blood pressure is less than 40 mm Hg. A bolus of 10-20 ml/kg of normal saline may be given initially and if the BP remains low, consider using inotropes (either dopamine or dobutamine)

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COOLING FOR HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE) IN INFANTS ≥ 35 WEEKS GESTATION cont'd

- **Renal Impairment**: As a guide infants with history of perinatal hypoxia will require about 40-60 ml/kg/day. Infants in renal failure should receive a total of 30 ml/kg/day plus any measured losses. Boluses of 0.9% saline may be required to avoid hypovolaemia if diuresis occurs in the infant or if vasodilation occurs during rewarming.

- **Enteral Feeding**: Enteral feeding can be cautiously introduced once the initial biochemical and metabolic disturbance are corrected, usually after about 24 hours.

- **Sedative Therapy**: Signs of distress include tachycardia, facial grimacing and irritability. A heart rate consistently above 110 bpm in cooled infants suggests that infant may be distressed. Ventilated infants may be sedated with morphine infusion 10-20 µg/kg/hr. Morphine may be discontinued after 24-48 hours to lessen the risk of accumulation and toxicity.

SIDE EFFECTS/COMPLICATIONS/PRECAUTIONS

- Side Effects of hypothermia: (see also consider stopping section above)

  A. Sinus bradycardia-usually transient and reversible.

  B. Decreased blood pressure - usually transient and reversible

  C. Increased oxygen requirement

  D. Low pCO2 (check arterial or capillary pCO2 on ventilated babies regularly and put in the low temperature when putting a gas into the blood gas machine) – babies pCO2 can be up to 20% lower at 33.5ºC than at 37ºC

  E. Mild thrombocytopenia (50,000- 80,000)

  F. Prolonged drug half-life - morphine (only need half the amount) and phenobarbitone

  G. Increased bleeding tendency

- **Too rapid rewarming** – this has occurred with the current rewarming protocol above (see rewarming section)

  - Rapid rise in body temperature may cause **hypotension** by inducing peripheral vasodilatation.

DOCUMENTATION

Integrated Notes
Whole Body Cooling Therapy special Observation Chart
Problem Sheet
Neonatal Care Plan
Discharge Summary
NICUS follow-up at 1 yr & 2 yrs

RELATED POLICIES/ PROCEDURES/CLINICAL PRACTICE GUIDELINES/LOCAL OPERATING PROCEDURES

- aEEG Nicolet Set-up & Monitoring

COOLING FOR HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE) IN INFANTS ≥ 35 WEEKS GESTATION cont'd

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……/Parent Information Sheet

Cooling Treatment for Babies to Help Protect their Brains

Parent Information Sheet

Your baby needed a lot of help to breathe at birth. He/she appears to have suffered from the effects of a lack of oxygen and blood supply to the brain. This is called moderate to severe encephalopathy and your baby, may be at high risk of permanent brain damage.

You have been given this information sheet because your doctor recommends COOLING your baby to help his/her problem. This will provide you with more information about your baby's treatment and his/her condition.

What does encephalopathy mean?
Encephalopathy means a "global brain dysfunction." About two in a thousand newborn babies suffer from the effects of reduced oxygen supply to their brain around the time of birth and this can result in an encephalopathy. Babies can recover from an encephalopathy but when it is severe, it can result in brain damage and a high chance of disability and death. For example, around 40% of babies who survive with a moderate to severe encephalopathy will develop long-term disabilities like cerebral palsy and mental retardation.

Moderate encephalopathy is where baby has reduced activity and is floppy with a weak suck and weak reflexes. Babies with an encephalopathy may also have seizures (fits). Severe encephalopathy is where baby has very little activity and is very floppy with absent reflexes and seizures.

In the past, there was no treatment to reduce the severity of brain damage for these newborn babies. Recently evidence from high quality research studies in Australia, NZ, Europe and the USA has shown that cooling babies, ie reducing their body temperature, may be a safe treatment to reduce the risk of future brain damage. Cooling also increases the chances of survival and reduces the severity of possible long-term disability by between 10-35%.

What is Cooling?

Cooling means that a baby is cooled from the normal body temperature of 37ºC down to a temperature of 33-34ºC. The baby is kept cool for 3 days (72 hours). This cooling is achieved by turning off any warming devices, having your baby naked and using cold packs. Cooling is started as soon as possible after birth (best if before 6 hours of birth). After the 72 hrs your baby would be gradually re-warmed to normal temperature of 37 ºC.

There have been no severe lasting side effects in babies who have been cooled. Side effects include cooling of the skin, a mild slowing of the heart rate, mildly reduced blood pressure, clotting problems and a slight increase in the amount of oxygen your baby requires. These have not usually required any change in the cooling treatment. The doctors and nurses looking after your baby are aware of these side effects and your baby will be monitored for any signs of these. Reversing the cooling can reverse side effects if they occur. Your baby's doctors can decide to stop the cooling early if they consider this to be best for your baby.

How will my baby be treated when he/she is cooled?

Your baby will receive standard intensive care during cooling. You will be able to touch your baby as you would normally if he/she was receiving intensive care.

Your baby will be followed up for neurodevelopment at 1 year and 2 years of age following discharge from hospital. If you decide not to have your baby cooled your baby will be treated the same as any other baby and will not receive any different treatment. If you have any further questions or require any further information regarding your baby and the cooling process please ask the medical and nursing staff caring for your baby.

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