Therapeutic Hypothermia on Transport

Providing Safe and Effective Cooling Therapy as the Link Between Birth Hospital and the Neonatal Intensive Care Unit

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ABSTRACT

Therapeutic hypothermia as a neuroprotective strategy in neonates is an established standard of care for infants with hypoxic-ischemic encephalopathy (HIE) in tertiary care neonatal intensive care units (NICUs). To maximize the neuroprotective effect in infants with HIE, hypothermia is initiated as soon as possible after birth. Many infants who would benefit from therapeutic hypothermia are not born at centers that have intensive care units or offer therapeutic hypothermia and are thus transported to a tertiary care center with a NICU, offering specialty services of therapeutic hypothermia and pediatric neurology. The neonatal transport team plays a significant role in the management of these critically ill infants. Clinical research provides data for safe and effective management of these infants during therapeutic hypothermia in the NICU; however, there are no evidence-based clinical guidelines for management before and during transport. The establishment of evidence-based guidelines for cooling before and during transport will facilitate early recognition of infants who would benefit from therapeutic hypothermia therapy, and decrease delay in initiation of therapy. Careful assessment, monitoring, and intervention by the transport team are critical to provide appropriate care and ensure safe transport of these infants.

Key Words: cooling on transport, hypoxic-ischemic encephalopathy, neonatal transport, neuroprotective, therapeutic hypothermia

Therapeutic hypothermia is accepted as the standard neuroprotective therapy in infants with injury because of hypoxic-ischemic encephalopathy (HIE) in NICU. To be effective, early initiation of hypothermia therapy is critical. In large randomized controlled studies,[1-3] infants older than 6 hours were excluded, because in animal studies, therapy at this age was not beneficial. Expert opinion and studies in animal models indicate that cooling should be initiated immediately after the insult is identified[4]; the goal for therapy initiation is to achieve an infant's core temperature in the therapeutic range from 33°C to 34°C[2] within 120 minutes.[2,5] In a recent study, early initiation of therapy within 3 hours was associated with improved outcomes at 18 to 20 months in surviving infants.[6] Many infants who would benefit from therapeutic hypothermia are born in hospitals that do not offer this therapy. For these infants to benefit from hypothermia, immediate identification and intervention at the birth hospital are critical and transport to a regional center is necessary.

Cooling therapy when initiated at the place of birth and continued on transport to the regional center minimizes delay in treatment.[5] Education and

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training of the medical and nursing staff at the referral hospital facilitate appropriate care and minimize delay in treatment. Caregivers involved in resuscitation of newborns at birth hospitals must recognize infants who meet criteria for cooling (see Table 1). Once it is determined that an infant meets criteria for cooling, transfer of the infant's care should be arranged with a regional center that offers cooling therapy and the necessary supportive care, and the initiation of cooling—passive or active—at the birth hospital should be discussed.

In an effort to optimize early initiation of therapeutic hypothermia in infants, the Vermont Oxford Network Encephalopathy Collaborative recommends collaboration between the referral and accepting hospital, including timely identification of HIE, education of the referral hospital caregivers around hypothermia treatment including temperature regulation, and establishment of standards for therapeutic hypothermia on transport.[7] The total body hypothermia (TOBY) trial[2] conducted in the United Kingdom established guidelines for both referring facilities and transport. The Infant Cooling Evaluation[3] (ICE) trial from Australia evaluated the initiation of cooling with gel packs at the birth hospital by either the birth hospital staff or the transport team on their arrival. Guidelines for cooling before admission at the birth hospital from the TOBY and ICE trial were not included in the large US cooling trials and were not studied or developed as standardized clinical guidelines for current US transport practice. Recently, cooling guidelines for referral facilities prior to transport were published by Sussman and Weiss.[8] (see Table 2).

Regardless of the treatment initiated by the birth hospital, the transport team is a vital link between early identification and initiation of cooling and admission to the regional care center. Vigilant temperature management by the transport team will optimize cooling therapy and facilitate earlier time to therapeutic hypothermia goals.

HYPOXIC-ISCHEMIC ENCEPHALOPATHY

Hypoxic-ischemic encephalopathy (HIE) is a heterogeneous syndrome characterized by dysfunction of the central nervous system in newborns.[9] The insult or injury of the brain results from a hypoxic (partial lack of oxygen) and ischemic (reduction of cessation of blood flow/circulation) event, often referred to as perinatal asphyxia. Neonatal encephalopathy may result from various conditions that may include, maternal or uteroplacental complications, or fetal complications and often remains unexplained.[9] Hypoxic-ischemic encephalopathy is characterized by 2 phases of injury, a primary and secondary phase of energy failure, separated by a short recovery phase. The primary phase of injury is the result of the hypoxic ischemic event that results in an acute energy failure necessitating resuscitation of the infant. The primary phase is followed by a recovery period of cerebral oxygenation and metabolism. The recovery period may last between 6 and 15 hours. Once the recovery phase has ended, the secondary phase of injury occurs; abnormal pathways of energy use result in free radicals and finally complex energy failure that ultimately causes irreversible neuronal injury.[10-13]

TABLE 1. Inclusion Criteria for Therapeutic Hypothermia[a]

Gestational age ≥ to 36 wks
Initiation of therapy < 6 h after birth
Presence of asphyxia: 2 of the following
Apgar score < 5 at 5 min
Resuscitation/ventilation at 10 min after birth
pH < 7 (<1 h after birth)
Base deficit >12 mmol/L (<1 h after birth)
And at least 1 of the following:
Evidence/documentation of fetal distress/acute perinatal event
Evidence of multiorgan system dysfunction
Cord blood or arterial/central venous blood >1 h after birth
Lactate >10
Signs/symptoms of moderate to severe encephalopathy

[a]Data from Shankaran et al,[1] Azzopardi and colleagues,[2] Jacobs,[3] and Task Force on Neonatal Encephalopathy.[14]

TABLE 2. Cooling Guidelines at Referring Hospitals[a]

Steps to Take
1. Turn off radiant warmer
2. Rectal temperatures every 15 min with a target temperature of 32.5°-34°C
3. If the temperature falls lower than 33.0°C, turn the radiant warmer on with the temperature set 0.5°C above current infant temperature
4. Call nearest hypothermia center for assistance and emergent transport

[a]Data from Sussman and Weiss.[8]

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TABLE 3. Criteria for Defining Moderate and Severe Encephalopathy[a]

Category	Moderate Encephalopathy	Severe Encephalopathy
Level of consciousness	Lethargic	Stupor or coma
Spontaneous activity	Decreased activity	No activity
Posture	Distal flexion, complete extension	Decerebrate
Tone	Hypotonia (focal or general)	Flaccid
Primitive reflexes		
Suck	Weak	Absent
Moro	Incomplete	Absent
Autonomic system		
Pupils	Constricted	Deviated, dilated or nonreactive to light
Heart rate	Bradycardia	Variable
Respiration	Periodic breathing	Apnea

[a]*Data from Shankaran et al.*[1]

Hypothermia decreases cerebral metabolism, allows for energy conservation, suppresses free radical activity, and prevents energy failure and cell death.[12-14] The goal of therapeutic hypothermia is to halt the progression of the injury after the primary phase of energy failure, so that there is no secondary phase of injury. There is currently no evidence that hypothermia therapy or any other therapy is effective once the infant enters the secondary phase of energy failure.

CONSIDERATIONS REGARDING ASSESSMENT AND MANAGEMENT

Infants at risk for or with encephalopathy have complex medical needs and require specialized intensive care. These infants often will require respiratory and cardiovascular support. Infants with neonatal encephalopathy will have an abnormal neurological examination[14] with signs and symptoms affecting level of consciousness, spontaneous activity, posture, tone, primitive reflexes (suck/moro), and the autonomic system (pupils, heart rate, and respiratory rate) (see Table 3).

The neurological examination of the infant will change dynamically in the first 6 hours after birth with progression of encephalopathy. Careful neurologic assessments with evaluation of encephalopathy and presence of seizures should be done soon after birth, hourly for the first 6 hours and also by the transport team upon their arrival. These infants are at risk for systemic complications including acute renal failure, myocardial dysfunction and hypotension, acute liver failure/damage, and coagulation impairment. Common metabolic complications include hypoglycemia, hypocalcaemia, metabolic acidosis, and hypomagnesaemia. Hematologic complications include anemia and abnormal coagulation.[14] Normal infant physiology is disrupted by the insult of HIE and return to homeostasis requires meticulous management by the resuscitation team and healthcare providers.[8]

The transport team must recognize and consider HIE complications during transfer of care. Careful monitoring with anticipation of complications and early intervention to correct abnormalities by the transport team are a critical element of continuation of care during transport (Table 4). The physical examination should also assess for birth injury, especially with the report of a difficult delivery or the use of instrumentation. Common birth injuries include brachial plexus palsy, phrenic nerve injury, and clavicular fracture.[14]

COOLING ON TRANSPORT

Transport is a dynamic environment; resources are often limited and environmental circumstances are uncontrolled. Temperature control of the infant is dependent on the transport team and control and efficiency of the transport isolette, which can be influenced by the temperature of the external environment. The complex medical needs and temperature regulation requirements of infants with HIE requiring cooling on transport are often a challenge for the transport team to manage.

At this time there are no evidence-based clinical guidelines for management of cooling for the infant requiring transport in the United States. Published reports of practice before and during transport vary but commonly include passive cooling (elimination of a heat source either with initiation at the birth hospital or by the transport team) and active cooling (initiation of cool gel packs or ice packs by the birth

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TABLE 4. Guidelines for Neonatal Assessment and Management by Transport Team[a]

Respiratory
Obtain ABG within the first hour after birth or on arrival to birth hospital *eligibility for therapeutic hypothermia*
Provide oxygenation and ventilation support as indicated in Neonatal Resuscitation Program guidelines[22]
Monitor PaO_2 and $PaCO_2$—avoid hyper oxygenation PaO_2>100 mmHg and $PaCO_2$< 35 mmHg[8,14]
Hyperoxia results in free oxygen radical production and increased oxidative stress[8,14]
Hypocapnia leads to decreased cerebral perfusion and decreased oxygen release of oxygen[8,14]
If FiO_2 requirement > 50% monitor pre- and postductal saturations as *assessment of presence of pulmonary hypertension*
Cardiovascular
Monitor blood pressure: continuously via UAC or peripheral pressures at minimum every 15 min
Provide inotropic support: Dopamine 2-20 mcg/kg/min or epinephrine 0.01-1 mcg/kg/min to maintain mean arterial pressures > 40 and/or systolic pressures > 55[8,9]
Fluid and glucose management
Restrict total fluids to 50-70 ml/kg per day *to decrease risk of cerebral edema and risk of acute renal failure*
May need to concentrate glucose (D12-D15) *to meet needs glucose needs and avoid fluid overload*
Use concentrated drips (inotropic/sedation) *to minimize fluid overload*
Obtain magnesium level,[b] goal 2.5 mg/dL, replacement magnesium sulfate 25 mg/kg *at risk for hypomagnesemia*[14]
Obtain calcium level normal levels > 8 mg/dL or Ionized Ca^{++} level > 1.1 mmol/L, treat with calcium gluconate 50-100 mg/kg per dose *at risk for hypocalcemia*[14]
Infant at risk for hypo- and hyperglycemia[14]
Monitor glucose levels, maintain > 60 mg/dl
Maintain GIR of 4-6 g/kg per minute
If hyperglycemic present give insulin 0.1 U/kg while maintaining GIR, *glucose necessary as substrate for cerebral metabolism to prevent brain injury*[8]
Hematologic
Infant at risk for anemia and coagulopathy[14]
Obtain coagulation studies[b]: PT, PTT, INR, Fibrinogen
Obtain hematocrit
Kidneys/liver
Obtain baseline liver function levels[b] *evidence of organ insult/injury*[9]
Obtain baseline creatinine level[b] *evidence of organ insult/injury*[9]
Neurologic
Monitor for seizures
Phenobarbital and Ativan (lorazepam) administration for control of seizures
Phenobarbital loading dose 20 mg/kg per dose Ativan 0.1 mg/kg per dose[8,9]
Monitor for shivering[2,15] as a result of hypothermia-magnesium administration and morphine[2] are current unstudied therapies for shivering, initial dose of morphine 0.1 mg/kg followed by morphine 0.05 mg/kg per dose
Temperature
Goal 33-34°C < 2 h
Monitor core temperature–rectal

Italics indicate rationale.
Abbreviations: ABG, arterial blood gas; GIR, glucose infusion rate; INR, international normalized ratio; PT, prothrombin time; PTT, partial thromboplastin time; UAC, umbilical arterial catheter.
[a]Azzopardi and colleagues,[2] Sussman and Weiss,[8] Wu,[9] Task Force on Neonatal Encephalopathy[14] and Robertson and colleagues.[15]
[b]Not usually available for evaluation on transport, the transport team should verify whether labs were drawn before their arrival and when not, obtain and send to lab at birth hospital. Timing is critical and should not be delayed.

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hospital or by the transport team). More recently active cooling devices were used on transport.

Temperature measurement also varies; the most common methods are axillary or rectal. Axillary temperatures in newborns do not accurately reflect rectal or core temperatures based on systemic reviews[15] and may be 2°C to 4°C different from core temperatures. In cold environments, the difference in axillary and core temperature increases. Case studies by Hallberg, O'Reilly, Fairchild, O'Reilly, Chaudhary, Hobson, and a collaborative database report from Akula in California reported their experiences with therapeutic hypothermia before and during transport. In the current transport literature, whole-body cooling was the preferred cooling strategy by either passive or active cooling, selective head cooling is not identified in any of the transport literature.

The ICE trial[3] used 2 gel packs applied to the chest/head and or shoulders if temperature was higher than 35.5°C, temperature was monitored every 15 minutes and gel packs were removed when temperature dropped lower than 35°C, the radiant warmer/isolette temperature was turned on and adjusted every 15 to 30 minutes when infant temperature was lower than 33.5°C. Gel packs were used on 93 infants during the first 6 hours of life. Infants reached the goal temperature of 33°C to 34°C at a mean time of 2 hours. During the 72 hours of therapy, they reported overshooting of temperature, with 64 infants having at least 1 temperature lower than 33°C.

In the report from Fairchild, of 35 infants passively cooled by the birth hospital and then actively cooled with gel packs during transport, 34% experienced overcooling with rectal temperature lower than 32°C and 66% of the infants maintained a temperature between 32°C and 35°C.[16] O'Reilly and colleagues[17] recently published their experience in a retrospective review from Boston Children's Hospital (BCH), of 43 newborns transported for therapeutic hypothermia, 27 were passively cooled prior to transport and all were passively cooled by the transport team. On arrival to BCH, 74% of the passively cooled infants had temperatures 32.5°C to 34.5°C, only 1 infant had a temperature lower than 32.5°C and 22% had temperatures higher than 34.5°C.[17]

Akuna's analysis of 223 infants revealed that 69% were cooled during transport (active or passive) and the target temperature of 33°C to 34°C was achieved in only 44% of the infants.[18] In the United Kingdom, O'Reilly et al,[19] in a prospective study to compare cooling methods of 46 infants, reported greater control of temperature within the therapeutic range with an active purpose built cooling machine (84%) compared with adjunct cooling (ice or gel packs) (47%) and passive cooling (20%). In Sweden, Hallberg et al[20] reported that of the 18 infants transported with passive induction of hypothermia, 6 infants had temperatures lower than 33°C on arrival to the regional center.

Hobson et al[21] presented 3 case studies, using an active cooling device, not specifically designed for transport. Ground, rotor wing, and fixed wing transport cases are reviewed and lessons learned were shared. In 2 of the 3 cases, infants were overcooled before transport, and thus the cooling device was used to warm infants to appropriate temperature. The admission temperature in the 3 cases presented were 33.5°C, 34.1°C, and 33.3°C.[21] The active cooling device did not stay connected to the transport isolette to provide cooling during transfers from vehicles or vehicles to buildings because the cooling device weight was approximately 70 lb and not practical for transfer to and from vehicles by the transport team.[21]

In a study from Chaudhary and colleagues,[5] comparing active versus passive cooling in the United Kingdom, 73% of the infants passively cooled reached therapeutic hypothermia temperature prior to admission, and all of the infants actively cooled reached the target temperature. In the passive group, 34% were overcooled. Another report from Hallberg et al[20] found that infants overcooled during transport experienced temperature instability once placed on active cooling. To decrease overcooling, the transport team at BCH turns on the isolette for warming and sets the servo-controlled isolette temperature at 34°C for all infants with a temperature lower than 33°C. The isolette temperature is maintained at 34°C and the infant's temperature is monitored every 15 minutes until the infant's temperature is within the therapeutic range of 33°C to 34°C.[17]

DISCUSSION

Therapeutic hypothermia is the only known therapy available for neuroprotection in infants with risk for or evidence of HIE. Case reports, collaborative data analysis, and studies from the United Kingdom[3,16-21] reveal that passive cooling is safe and, when compared with no cooling, facilitates the infant's reaching target temperature for hypothermia therapy within the therapeutic 6-hour window. However, passive cooling is not without the risk of overcooling and in some cases fails to achieve temperatures in the therapeutic range for neuroprotection. In the report from O'Reilly at BCH, overcooling can be minimized with guidelines for care and management during transport. The ICE trial[3] from Australia establishes the safety and effectiveness of the use of gel packs with achievement of goal temperature within 2 hours. To minimize the risk of overcooling with gel or ice packs, practice guidelines for temperature management are essential.

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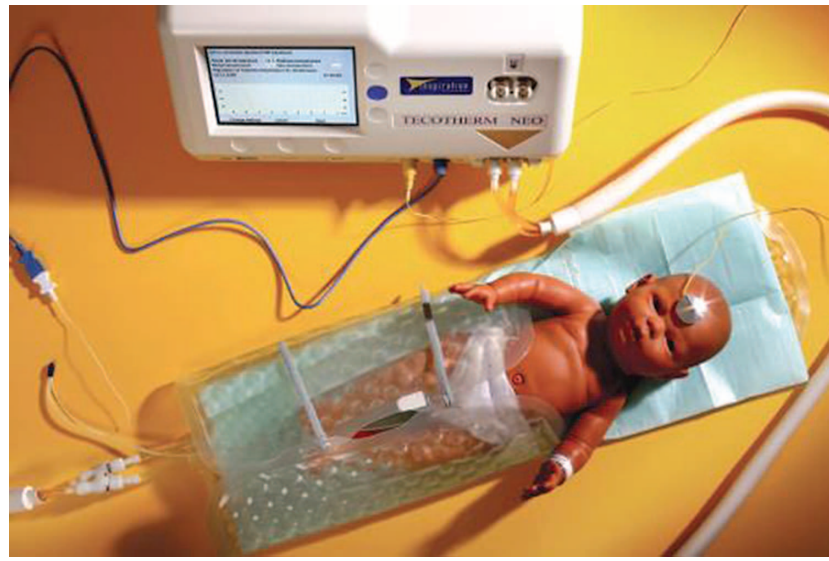
FIGURE 1.



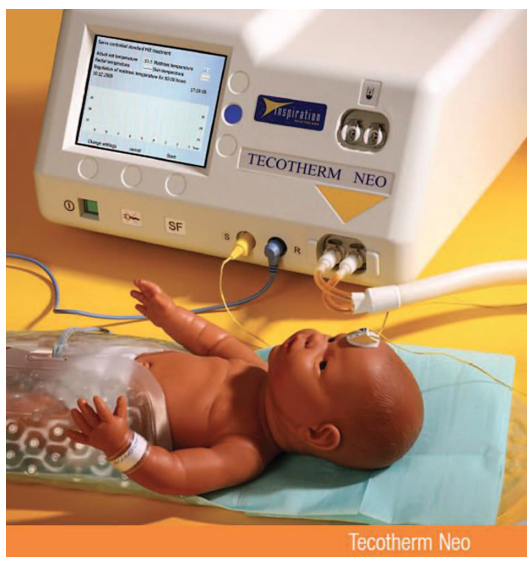
Tecotherm Neo cooling device.

The complications related to overcooling are unknown but, as observed in the study by Hallberg et al,[20] may lead to temperature instability, with unknown consequence, during the initial day of active cooling. Active cooling by the transport team with a specific cooling device designed for transport appears ideal for patient care and neonatal outcome. An active cooling device optimizes the control of cooling and delays time to reach therapeutic hypothermia temperatures.[5,19]

In the transport environment, space and weight are often at a premium and additional hypothermia equipment will present a challenge for transport teams. Equipment must be properly secured during every transport, on ground and in air. Depending on the size of the equipment, specialized mounting may be required and in rotor wing and fixed wing must be approved by the Federal Aviation Administration.

A recent study by Akula et al[23] with the California Transport Cooling Trial compared active cooling during transport using the Tecotherm Neo (Inspiration Medical LTD, Leicester, England) with standard cooling practices—passive cooling or the use of ice/gel packs. In the California Transport Cooling Trial study, 100 infants were randomized, and the target temperature was 33° to 34°C. They found that 80% of infants in the device cooling group reached the target temperature range compared with only 49% in the standard cooling group. They also found that 72% of the infants in the device cooling group reached the target temperature range by 1 hour of age compared to only 20% with standard cooling. The Tecoterm Neo is promising compared with other cooling devices for transport. Tecotherm Neo has dimensions of 31 cm × 37 cm ×19 cm and has a total weight of 7.2 kg (see Figures 1 and 2), making it the most practical active cooling device available for neonatal transport. The Tecotherm Neo is a product from the United Kingdom and at this time is not approved by the Federal Drug Administration for use in the United States.

FIGURE 2.



Tecotherm Neo cooling device.

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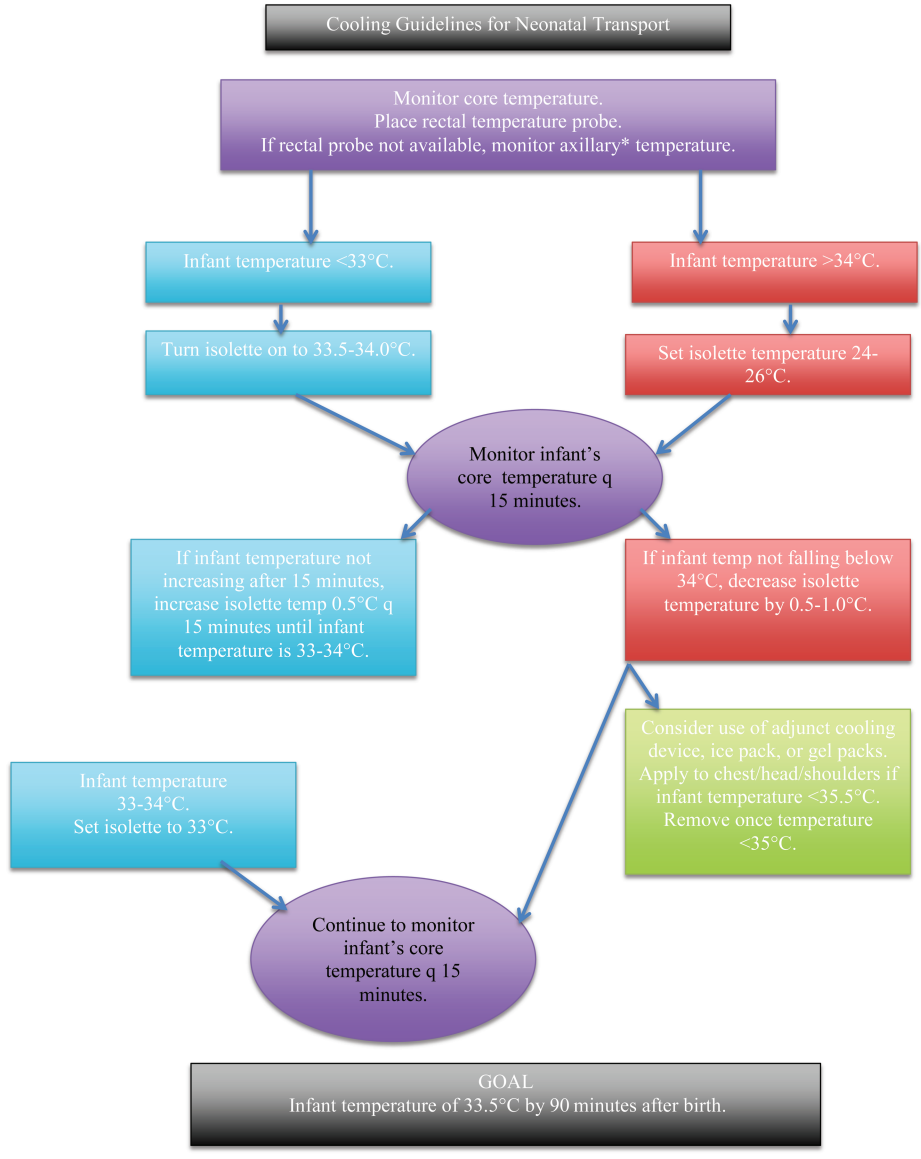
FIGURE 3.



Data from Azzopardi et al,[2] Jacobs et al,[3] O'Reilly et al,[17] Kendall et al.[24]
*Axillary temperature not a reliable reflection of core temperature, especially in cold environments.[15]

Guidelines for cooling during neonatal transport.

CONCLUSION

Therapeutic hypothermia has been established as the only known therapy available for neuroprotection in the infant with neonatal encephalopathy. The goal is to facilitate treatment for infants at risk for encephalopathy to decrease brain injury. Any delay in initiating cooling therapy should be avoided. The sooner hypothermia is initiated and the infant reaches goal therapeutic temperature, the greater chance for optimal benefit for neuroprotection. An active cooling device may be ideal; however, there are no Food and Drug Administration–approved devices for use in the United States and the research is limited. Future research should evaluate active and passive cooling devices on transport and provide evidence-based guidelines for transport cooling. Guidelines for cooling during neonatal transport are presented (see Figure 3) on the basis of current literature and evidence from the TOBY and ICE trials. With evidence-based guidelines, early therapeutic hypothermia therapy by birth hospitals and transport

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teams can be more effective for infants with neonatal encephalopathy.

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