

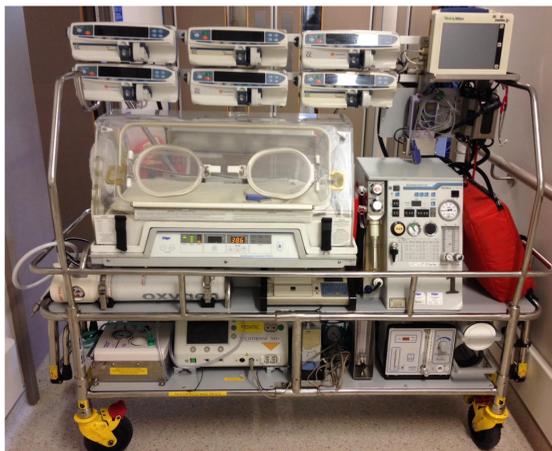
Neurological assessment in infants referred for therapeutic hypothermia: a need for more structured assessment and /or pragmatic criteria?

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INTRODUCTION

- Therapeutic hypothermia improves neuro-developmental outcomes in moderate to severe hypoxic ischaemic encephalopathy.
- Identification of suitable infants requiring hypothermia needs careful clinical assessment. The major cooling trials that informed clinical practice had specific entry criteria to select infants, before recruitment into the study occurred.
- With proven efficacy of hypothermia, there is a concern that in everyday clinical practice there may be a ‘therapeutic drift’ and clinicians may choose to start treatment in borderline cases where the ‘trial criteria with proven benefit’ are not fulfilled.
- The long term effects and risks or benefits of cooling outside the published trial criteria are not yet known.



METHODOLOGY

- Retrospective data collection and analysis: on all infants referred for therapeutic hypothermia between July 2011 to June 2013 to the London Neonatal Transfer Service.
- The neurological state of the baby documented by the referring centre and / or evaluation by the transfer team, prior to administration of sedative or muscle relaxant, were reviewed.

AIMS

- To assess if infants referred for therapeutic hypothermia meet the published criteria for encephalopathy, as used by either the TOBY study or Shankaran et al study (References 1, 2)

RESULTS

- 156 infants were transferred to a cooling centre (data available on 145 infants). The documentation of neurological assessment for encephalopathy prior to cooling treatment is shown in Figure 1.
- Hypertonia was more commonly used as referral criteria rather than the trial criteria of hypotonia.
- Suck reflex as not mentioned in 50% of ventilated babies as compared to 25% of non-ventilated babies.
- When reviewed for encephalopathy assessment criteria as published by the TOBY group (1), only 86/145 infants fulfilled the criteria. The remained 59/145 (40%) infants did not have documented evidence of moderate to severe encephalopathy (Table 2). Normal neurological examination was documented in 36/145 (24.8%) and in 23/145 cases, there was only evidence of mild encephalopathy.
- Similarly reviewing cases to check if encephalopathy assessment criteria as published by the Shankaran et al group – 24/145 infants did not meet the criteria and 36 others had normal neurology.
- Cerebral function monitoring (CFM) was available at the referral centre in 47/145 (32%) cases. The CFM trace was documented as normal in 14/47, of which 8 had normal neurology as well, while 6 had abnormal tone with no seizure activity.

Figure 1. Encephalopathy assessment in babies referred for cooling

	Documented	Abnormal	Normal
Posture	69.6%	24.1%	47.6%
Spontaneous activity	68.9%	Decreased or none 44.8%	24.1%
Tone	97.2%	Hyper – 36.5% Hypo – 29.6%	31%
Suck	54.4%	26.9%	27.6%
Pupillary reflex	73.1%	8.9%	64.1%
Seizure		30.3%	69.7%

Figure 2. Documentation of neurological assessment in babies who did not meet the criteria used by the TOBY study group {Azzopardi *et al* (1)}

Abnormal Posture	Decreased or no activity	Alertness*	Hypotonia	Hypertonia	Abnormal Suck	Abnormal pupils	No. of babies
✓	✓			✓			5
✓							1
	✓			✓			5
		✓					2
✓	✓						1
				✓			4
		✓		✓			5
-	-	-	-	-	-	-	36
						TOTAL	59

* hyperalert/irritable

CONCLUSIONS

- In 40% of infants referred for cooling the documentation of neurological assessment did not show any evidence of moderate to severe encephalopathy as defined in therapeutic hypothermia trial criteria.
- This has important clinical and medico-legal implications and may represent a significant additional workload.
- There is a need for structured neurological examination training with appropriate documentation for referring clinicians, along with pragmatic guidance for referring infants for cooling treatment.

REFERENCES

1. Azzopardi DV, Strohm B, Edwards AD, et al. TOBY Study Group. Moderate hypothermia to treat perinatal asphyxial encephalopathy. N Engl J Med. 2009 Oct; 361(14):1349-58.
2. Shankaran S, Laptook AR, Ehrenkranz RA, et al. National Institute of Child Health and Human Development Neonatal Research Network. Whole-body hypothermia for neonates with hypoxic-ischaemic encephalopathy. N Engl J Med. 2005 Oct 13; 353(15):1574-84.