NICE National Institute for Health and Care Excellence



Drainage, irrigation and fibrinolytic therapy (DRIFT) for post-haemorrhagic hydrocephalus in preterm infants

Interventional procedures guidance Published: 23 November 2011

www.nice.org.uk/guidance/ipg412

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment

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or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the efficacy and safety of drainage, irrigation and fibrinolytic therapy (DRIFT) for post-haemorrhagic hydrocephalus in preterm infants is inadequate in quantity. Therefore, this procedure should only be used in the context of research. Research should aim to establish the risk of secondary haemorrhage and its consequences, and the need for shunt insertion. Outcomes should include death and disability in the long-term: these should be reported separately.

2 The procedure

2.1 Indications and current treatments

Intraventricular haemorrhage is a serious complication occurring within a few 2.1.1 days of birth in a small proportion of preterm infants. It is more common and severe in infants born before 30 weeks of gestation and can be fatal. Among surviving infants, some will develop post-haemorrhagic hydrocephalus associated with varying degrees of neurodevelopmental disability.

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2.1.2 Managing post-haemorrhagic hydrocephalus in preterm infants typically involves repeated cerebrospinal fluid (CSF) drainage followed by insertion of a ventriculo-peritoneal shunt. No particular treatment has been shown to improve neurological outcomes.

2.2 Outline of the procedure

- 2.2.1 The aim of DRIFT is to reduce the risk of death, the risk of neurodevelopmental disability, and the need for shunt insertion.
- 2.2.2 The procedure is performed with the infant under general anaesthesia. Two catheters are inserted into the lateral ventricles from right frontal to left occipital or vice versa. A fibrinolytic agent is given intraventricularly with the aim of lysing thrombi in the ventricles. After 8 hours, ventricular irrigation is started by infusing artificial CSF through the frontal catheter (typically at a flow rate of 20 ml/h) and draining it through the occipital catheter to a closed drainage system. Outflow is adjusted so that intracranial pressure readings remain less than 7 mm Hg. Irrigation continues until the colour of the drained fluid becomes normal ('cola to white wine'), typically within 3 days.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 70 infants treated by DRIFT (n=34) or standard treatment (n=36) reported that DRIFT did not reduce mortality at follow-up to 6 months of age or duration of hospital stay (whichever was longer) compared with standard treatment (relative risk [RR] 0.42, 95% confidence interval [CI] 0.09 to 2.04). A second publication from the same RCT, including an additional 7 infants, reported mortality rates of 8% (3 of 39) and 13% (5 of 38) respectively at 2-year follow-up (timing of death and significance not stated).

- 2.3.2 The RCT of 70 infants treated by DRIFT or standard treatment reported that DRIFT did not reduce the use of shunt surgery compared with standard treatment at follow-up to 6 months of age or discharge (RR 0.98, 95% CI 0.54 to 1.78). The subsequent publication from the same RCT reported that permanent shunting was required in 41% (16 of 39) of infants treated by DRIFT and 40% (15 of 38) treated by standard treatment within 2 years (timing not stated).
- 2.3.3 A case series of 24 infants reported that 26% (6 of 23) of the surviving infants required ventriculo-peritoneal shunt surgery (follow-up not stated).
- 2.3.4 The second publication from the RCT (77 infants) reported on crude and adjusted odds of mental and psychomotor infant development status scores (adjusted for sex, birth weight, and intraventricular haemorrhage [IVH] grade) using Bayley Scales of Infant Development II (BSIDII; range: 0 to 100). Infants treated by DRIFT had significantly lower odds of a mental development index score of less than 55 (representing severe cognitive disability) at a mean follow-up of 25 months (crude odds ratio [OR] 0.31, 95% CI 0.11 to 0.86, p=0.024, adjusted OR 0.17, 95% CI 0.05 to 0.57). Infants treated by DRIFT had lower odds of a psychomotor development index score of less than 55 (representing severe psychomotor disability) at a mean follow-up of 25 months (crude OR 0.54, 95% CI 0.20 to 1.45, p=0.22, adjusted OR 0.21, 95% CI 0.05 to 0.85, p=0.028).
- 2.3.5 The case series of 24 infants reported that 58% (11 of 19) of infants who were evaluated at 12 months post-term had developed disability, including 21% (4 of 19) with multiple disabilities (assessment of cognitive disability based on the Ruth Griffiths Scales of Infant Development, scores not reported).
- 2.3.6 The specialist advisers listed key efficacy outcomes as reduced need for a ventriculo-peritoneal shunt and improved cognitive and motor development in the long term.

2.4 Safety

2.4.1 The RCT of 70 infants treated by DRIFT or standard treatment reported secondary IVH in 35% (12 of 34) and 8% (3 of 36) of infants respectively (p=0.014). Secondary IVH was asymptomatic in all but 1 infant who developed acute thrombocytopenia. The case series of 24 infants reported clinically significant secondary IVH in 2 infants. One was successfully treated with intravenous tranexamic acid and the other stabilised without treatment (timing not stated).

- The RCT of 70 infants treated by DRIFT or standard treatment reported mean 2.4.2 numbers of blood transfusions required in the first 7 days after randomisation of 1.7 (range: 0 to 4) and 0.8 (range: 0 to 2) respectively (p<0.001).
- 2.4.3 The specialist advisers listed anecdotal adverse events as further intraventricular bleeds after administering the thrombolytic agent. They considered theoretical adverse events to include infection, meningitis, displacement or blockage of catheters and trauma to the brain.

2.5 Other comments

2.5.1 The committee noted that there is a lack of effective treatments for posthaemorrhagic hydrocephalus in preterm infants, who may suffer severe disability as a result. The committee acknowledged that there is a reasonable conceptual basis for DRIFT, but considered the current evidence on its potential efficacy to be insufficient

3 Update information

Minor changes after publication

May 2012: Minor maintenance

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

