NICE National Institute for Health and Care Excellence

NICE guidance

Transvenous embolisation for spontaneous intracranial hypotension caused by a cerebrospinal fluid–venous fistula

HealthTech guidance

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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 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.

Contents

1 Recommendation

1.1 Transvenous embolisation can be used in the NHS during the evidence generation period as an option to treat spontaneous intracranial hypotension caused by a cerebrospinal fluid (CSF)–venous fistula. There must be enhanced informed consent and auditing of outcomes.

What this means in practice

There are uncertainties around the safety and efficacy of this procedure. It can be used if needed while more evidence is generated.

After this, NICE will review this guidance and the recommendation may change.

Healthcare professionals do not have to offer this procedure and should always discuss the available options with the person with spontaneous intracranial hypotension caused by CSF–venous fistula before a joint decision is made.

Hospital trusts will have their own policies on funding procedures and monitoring results. NHS England may also have policies on funding of procedures.

Enhanced informed consent

Because there are uncertainties about the procedure's safety and efficacy, there must be an emphasis on informed consent. Healthcare professionals must make sure that people (and their families and carers as appropriate) understand the uncertainty and lack of evidence around a procedure's safety and efficacy using NICE's advice on shared decision making and NICE's information for the public. Healthcare professionals must also inform the clinical governance leads in their organisation if they want to do the procedure.

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having this procedure into an appropriate registry. If there is no data collection method already available, use NICE's interventional procedure outcomes audit tool. Regularly review the data on outcomes and safety.

Who should be involved with the procedure

Patient selection and post-procedure follow-up should be done by a multidisciplinary team including a neurologist, neurosurgeon and interventional radiologist. This procedure should only be done in specialist centres by healthcare professionals (usually interventional radiologists) with specific training and experience in this procedure.

What evidence generation is needed

Healthcare professionals must collect data specifically around the safety and efficacy of this procedure.

This includes:

- patient-selection criteria, including:
  - the location of any leak
  - the number of leaks
  - which nerves are involved
  - whether alternative procedures are suitable
- evidence on procedure success, complication rates and long-term durability of repair
- comparative data on safety and efficacy between different treatment options.

Why the committee made this recommendation

Evidence on the efficacy and safety of transvenous embolisation is limited but it is already widely used for other embolisation procedures. The embolisation liquid used in the procedure has been used by healthcare professionals for a long time and its safety profile is well understood. The available evidence for the procedure has not raised any major safety concerns.

Spontaneous intracranial hypotension caused by CSF–venous fistula is a highly debilitating condition that substantially impacts quality of life. Treatment options are limited, but include more invasive surgery or off-label CT-guided fibrin glue injection. The availability of transvenous embolisation along with other alternatives would improve access to treatment. So, it can be used with evidence generation.

2 Information about the procedure

2.1 Transvenous embolisation is typically done under general anaesthesia but can also be done under local anaesthesia or conscious sedation. Venous access is achieved through the common femoral or internal jugular vein. A guiding catheter is navigated into the superior vena cava and then into the azygos vein or other relevant venous drainage pathway. Alternative pathways can include the hemiazygos vein, ascending lumbar veins or vertebral veins depending on the location of the fistula. A hydrophilic or stiff wire is often needed for access. Once the catheter has reached the appropriate venous system, a microcatheter is advanced over a fine wire to selectively catheterise the foraminal or paraspinal vein that contains the fistula.

2.2 Venography is done to confirm the location of the fistula and see the venous drainage pattern. Venography is an imaging technique that uses contrast dye to visualise the veins under X-ray. The fistula is then embolised using a liquid embolic agent. A high-viscosity formulation is injected to create a proximal plug and then a low-viscosity formulation is injected which flows across the fistula or fistulous network.

2.3 The success of the procedure is judged by clinical follow-up and imaging follow-up with MRI. A post-procedure CT myelogram or digital subtraction myelography may be done to assess the distribution of the embolic agent and the extent to which the fistula has sealed. But, this is not done routinely for this purpose, because it is invasive.

3 Committee discussion

The interventional procedures advisory committee considered evidence on transvenous embolisation for spontaneous intracranial hypotension caused by a cerebrospinal fluid (CSF)–venous fistula from several sources. This included evidence submitted by 1 company, Medtronic, along with a review of efficacy and safety evidence and responses from stakeholders. Full details are available in the project documents for this guidance.

NICE did a rapid review of the literature on the efficacy and safety of this procedure. The evidence included 1 systematic review and meta-analysis and 7 observational studies. It is presented in the summary of key evidence section in the interventional procedures assessment report.

The condition

3.1 A CSF–venous fistula is an abnormal connection between the CSF space surrounding the brain and spinal cord, and the venous system. This abnormal connection allows CSF to leak into the venous system, causing spontaneous low pressure in the brain, a condition called spontaneous intracranial hypotension. CSF–venous fistula was first described and recognised as a cause of spontaneous intracranial hypotension in 2014.

3.2 Spontaneous intracranial hypotension can present with a variety of symptoms. These include orthostatic headache, which typically worsens upon standing and gets better when lying down; neck stiffness; nausea; vomiting; vertigo; tinnitus; visual disturbances; dizziness and imbalance.

Current practice

3.3 Initial management may include bed rest, hydration, and oral or intravenous caffeine. If symptoms persist then non-targeted epidural blood patching may be offered. If this fails, advanced imaging such as digital subtraction myelography or dynamic CT myelography is done to locate the CSF–venous fistula. Once the fistula is located, targeted treatments are considered. These may include CT-

guided fibrin glue injection, surgical ligation or transvenous embolisation.

Unmet need

3.4 When a fistula is located near an eloquent or functional nerve root, surgery may not be the best option. This is because it can damage nerves and cause muscle weakness in the arms and legs. Transvenous embolisation could be particularly useful when nerve root ligation cannot be done, when people are unfit for or decline surgery, or when there is treatment failure or recurrence after a CT-guided fibrin glue injection.

Innovative aspects

3.5 Transvenous embolisation adapts established endovascular techniques for treating spontaneous intracranial hypotension caused by a CSF–venous fistula. By accessing and occluding the fistula within the venous system, it provides a less invasive targeted alternative to surgery.

Clinical effectiveness

3.6 The professional experts and the committee considered the key efficacy outcomes to be:

- symptom resolution including headache resolution
- technical success of the procedure
- long-term durability of repair.

3.7 The professional experts and the committee considered the key safety outcomes to be:

- post-treatment rebound intracranial hypertension or rebound headache
- pain

- persistent leak
- inadvertent embolisation (movement of embolic agent), failure of procedure
- need for retreatment.

3.8 Fifteen commentaries from people who have had this procedure were discussed by the committee.

Committee comments

3.9 Spontaneous intracranial hypotension caused by a CSF–venous fistula is a debilitating condition impacting people's quality of life. Its diagnosis is often complex and delayed. The diagnosis needs myelography which is invasive, difficult to interpret and needs expert evaluation. People may have more than one fistula. If the leak can be stopped, it can dramatically improve quality of life.

3.10 Current treatment options for spontaneous intracranial hypotension caused by CSF–venous fistula are limited. Using transvenous embolisation while further evidence is generated would provide people with an additional treatment option alongside surgical repair (which is more invasive) and CT-guided fibrin glue injection (which is currently off label for this indication). People with the condition may benefit from the availability of all 3 treatment options. They should be fully informed about each option, including the potential benefits and risks.

3.11 While transvenous embolisation is an emerging treatment for spontaneous intracranial hypotension caused by CSF–venous fistula, the material used in the procedure to seal the leak is widely used in other endovascular procedures. Healthcare professionals have used it for a long time, so they understand how to handle it and its safety profile. So, this procedure is an incremental adaptation of an existing technique to address a specific condition, and it is still evolving.

3.12 This procedure is usually done by interventional radiologists. The procedure requires involvement of a multidisciplinary team in patient selection and follow-up. Healthcare professionals with neurology or neurosurgery expertise need to be part of the multidisciplinary team in the immediate post-procedure follow-up

period. This is in case of rebound intracranial hypertension requiring a lumbar puncture or drain, although this can usually be managed with medicines in most cases.

3.13 Current evidence is limited and comes from single-centre studies, although the results appear consistent. The additional data on the procedure provided at consultation gives incremental support to the evidence base on efficacy but does not fulfil the evidence gaps.

3.14 There is a need for data on long-term outcomes on both efficacy and safety, and to understand which patients benefit most from the procedure. It is also important to generate comparative data between different treatment options. While the committee acknowledges that randomised controlled trials may be challenging to conduct, they remain the gold standard and should be done where feasible.

3.15 Data should be collected in an appropriate registry that meets NICE registry standards. The data must be accessible to the NHS.

Equality considerations

3.16 The procedure is only offered in specialist centres in the UK. This may create challenges in accessibility and geographic equity. Delays in diagnosis and treatment may also further widen disparities in care.

4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chairs

Rick Body
Chair, interventional procedures advisory committee

Tom Clutton-Brock
Former chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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