NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

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

A cerebrospinal fluid (CSF)–venous fistula is an abnormal connection that develops between the space surrounding the spinal cord and nearby veins. The fistula allows CSF to leak into the veins. The loss of CSF can cause pressure in the brain to drop (spontaneous intracranial hypotension).

In this procedure, a small tube (catheter) is inserted through the femoral vein (transvenous) at the top of the leg and guided to the fistula. A liquid is then injected to seal the fistula (embolisation). The aim is to prevent further CSF leaks.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and effective these procedures are. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on transvenous embolisation for spontaneous intracranial hypotension caused by a cerebrospinal fluid–venous

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fistula in the NHS in England. The interventional procedures advisory

committee has considered the evidence and the views of clinical and patient

experts.

This document has been prepared for consultation with the

stakeholders. It summarises the evidence and views that have been

considered and sets out the recommendations made by the committee. NICE

invites comments from the stakeholders for this evaluation and the public.

This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

Has all of the relevant evidence been taken into account?

Are the summaries of clinical effectiveness reasonable interpretations of

the evidence?

Are the recommendations sound and a suitable basis for guidance to the

NHS?

Are there any aspects of the recommendations that need particular

consideration to ensure we avoid unlawful discrimination against any group of

people on the grounds of age, disability, gender reassignment, pregnancy and

maternity, race, religion or belief, sex or sexual orientation?

After consultation:

Based on the consultation comments received, the committee may meet

again.

• If committee meets again it will consider the evidence, this evaluation

consultation document and comments from stakeholders.

The committee will then prepare the final draft guidance, which will go through

a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on transvenous

embolisation for spontaneous intracranial hypotension caused by a

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cerebrospinal fluid-venous fistula. The recommendations in section 1

may change after consultation.

More details are available in NICE's interventional procedures programme

manual.

Key dates:

Closing date for comments: 25 November 2025

Second committee meeting: 22 January 2026

1 Recommendations

1.1 More research is needed on transvenous embolisation for

spontaneous intracranial hypotension caused by a cerebrospinal

fluid (CSF)-venous fistula before it can be used in the NHS.

1.2 This procedure should only be done as part of formal research and

a research ethics committee needs to have approved its use.

What this means in practice

There is not enough evidence to know if this procedure is effective.

Transvenous embolisation for spontaneous intracranial hypotension

caused by a CSF-venous fistula should only be done as part of formal

research.

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

and regularly review the data on outcomes and safety.

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Who should be involved with the procedure

Patient selection should be done by a multidisciplinary team. This procedure should only be done in specialist centres by healthcare

professionals with specific training and experience in this procedure.

What research is needed

More research, including randomised controlled trials or a registry, is needed.

The research should:

• report patient-selection criteria, including the location of any leak, the

number of leaks, which nerves are involved, and whether alternative

procedures are suitable.

include UK-based evidence on procedure success, complication rates and

long-term durability of repair.

Why the committee made these recommendations

Evidence on the efficacy and safety of this procedure comes from small

observational studies done in the US and France. The evidence shows that

transvenous embolisation can relieve symptoms of spontaneous intracranial

hypotension and prevent future episodes. But there is no evidence directly

comparing transvenous embolisation with any other procedure for closing a

CSF-venous fistula. There is also not enough evidence on its long-term

effectiveness and no published evidence from the UK.

The available evidence has not raised any major safety concerns with the

procedure.

2 Information about the procedure

2.1 Transvenous embolisation is done under local or general

anaesthesia. Venous access is achieved through the common

femoral or internal jugular vein. A guiding catheter is navigated into

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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.

- 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 highviscosity 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 procedure does not offer a way to check that the fistula has successfully sealed. So, the success of the procedure is judged by symptom resolution. A post-procedure CT scan may be done to view the distribution of the embolic agent and assess the extent to which the fistula has sealed.

3 Committee discussion

NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 6 sources, which was discussed by the committee. The evidence included 1 meta-analysis and 5 observational studies. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

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The condition

- 3.1 A cerebrospinal fluid (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.
- 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 injections, which are usually done as a day-case procedure under local anaesthesia and may be offered immediately after the scan, or surgical ligation.

Unmet need

3.4 Existing treatment options may not always be feasible or suitable. 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. Existing treatments can also fail, risking recurrence or the development of new CSF-venous fistulas. Transvenous embolisation offers an

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alternative treatment option. It 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. Although the procedure is more invasive than CT-guided fibrin glue injection, it is less invasive than surgery and may reduce hospital length of stay and overall patient risk.

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 existing treatments.

Clinical effectiveness

- 3.6 The professional experts and the committee considered the key efficacy outcomes to be: symptom resolution, headache resolution, success rate and 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 and 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. Its diagnosis is often complex and delayed. The diagnosis needs myelography which is invasive,

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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 There are several treatment options for spontaneous intracranial hypotension caused by a CSF–venous fistula. These include surgery, CT-guided fibrin glue injections and transvenous embolisation. Surgery may have a lower recurrence rate, but it may not be suitable for people with multiple fistulas. CT-guided fibrin glue injection is less invasive and is typically done under local anaesthesia. Whereas transvenous embolisation is usually done under general anaesthesia.
- 3.11 Transvenous embolisation for spontaneous intracranial hypotension caused by a CSF–venous fistula is a highly specialised procedure. It is done in a limited number of specialist centres by healthcare professionals with specific training and experience in the procedure. The procedure is evolving as centres adapt it to meet the needs of their patients.
- 3.12 Current evidence is limited and comes from single-centre studies, although the results appear consistent. There are no major safety concerns. It is not known how well these findings translate to real-world practice. Given the availability of alternative treatment options, comparative randomised controlled trials should be done to better assess the efficacy and safety of the procedure.
- 3.13 The patient population is not homogenous, with some people experiencing recurrent fistulas despite treatment, and other people having resolution of their fistula with treatment. Transvenous embolisation could be a useful option for people with spontaneous intracranial hypotension caused by a CSF–venous fistula when other treatment options have failed.

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3.14 Digital subtraction myelography or dynamic CT myelography is essential for precise targeting of the fistula. This is because closure cannot be directly confirmed during the transvenous embolisation

procedure.

Equality considerations

3.15 The procedure is offered in a limited number of 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 <u>NICE's interventional procedures advisory</u> 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 <u>minutes of each committee meeting</u>, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock

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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