View results

Respondent

138 Anonymous

15:11
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1996

## Your information

2. Name: *

Parag Sayal

3. Job title: *

Consultant Neurosurgeon

4. Organisation: *

UCLH

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BASS

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 6063410

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

## How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice**

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

## The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes I am familiar with the technology,. I am part of the SIH service at Queen square and we have a weekly MDT for which I provide surgical input and I treat CSF venous fistulae routinely, through surgery and provide into the mdt for patients who may be suitable for transvenous embolisation

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

Yes. This is done routinely in our hospital. As a Neurosurgeon with specialist interest in CSF leak disorders, I often diagnose patients with SIH / CSF venous fistulae and we discuss this at a weekly mdt and decide if embolization is appropriate and I refer the patient for Neuroradiology CSF Venous fistula embolization. These patients are admitted under my care and I supervise pre and post procedure care and follow up of these patients

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [x] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) No
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes the title reflects the procedure adequately and the indication is appropriate. The technology is an alternative to surgery and both surgery and this technology have a role in treatment of the condition

16. Does this have a multi-indication?

No

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

embolisation of CVF is an alternative to surgery and both surgery and this technology have a role in treatment of the condition

18. Which of the following best describes the procedure:

- (•) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

It will be in addition or complementary to current standard of care. Some patients will benefit from this procedure and some will need surgery

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

This will be better answered by an interventional neuroradiologist.

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

## Current management

22. Please describe the current standard of care that is used in the NHS.

Both surgery and transvenous embolisation

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

Both surgery and THIS TECHNOLOGY transvenous embolization. Can be used for treatment

## Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

This will be a potential alternative to surgery : some patients will still need surgery but others would benefit from this

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients with multiple CSF venous fistulae will benefit

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

It is in some ways less invasive treatment than surgery , particularly for patients who have multiple csf venous fistulae. However we have developed a surgical technique for treatment of csf venous fistulae which is minimally invasive and can be done as a day case with very low risks. so both these options are viable

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Existing facilities in interventional neuroradiology would be sufficient

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

interventional neuroradiologists may need short term proctoring/ mentoring but this wouldn't need much training

## Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Recurrence of the fistula at the level of treatment
Radicular pain due to nerve compression by embolic agent
Glue embolus
Groin or retroperitoneal hematoma
Infection at site of needle puncture
Pseudo aneurysm at needle puncture site
De novo development of csf venous fistulae at some other level

30. Please list the key efficacy outcomes for this procedure/technology?

Improvement in headaches/ SIH symptoms
this can be judged by specific Headache / QOL questionnaires

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

In patients with ongoing symptoms, it may be difficult to identify on repeat myelography if there is still a CSF venous fistula at the level of treatment
And it is well recognised that a proportion of patients will have ongoing symptoms after treatment of cvf. So this point is pertinent

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

no

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

## Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

not aware of a recent abstract. but many publications validating this procedure exist

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

There are plans to set up a CSF leak registry in the UK over the next year or 2

36. Please list any other data (published and/or unpublished) that you would like to share.

no

## Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

It depends on how many patients are diagnosed with CVFs . this is a hugely under diagnosed condition and with increasing number of centres doing Lateral decubitus myelograms, it is likely that more patients will be diagnosed with CVFs across the UK. If it is presumed that incidence of SIH in 5 in 100000, then across the UK, annually 3000 patietns may develop SIH and if it is presumed that 20% of SIH patients have CVF : then upto 600 patients annually may be diagnosed with CVF and may be potential candidates for this procdure. But this is only if diagnosis rates improve and that may take years

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

**Beneficial outcome measures.**

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Headache questionnaires . these should be monitored for at least 12 months post procedure

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

**Adverse outcome measures.**

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Radicular pain
Rebound high pressure headaches
Ongoing symptoms
Complications related to needle puncture site

## Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

this requires a appropriate MDT set up with Neurologists, Interventional neuroradiologists and neurosurgeons to jointly discuss all diagnosed cases of CSF venous fistulae to make an appropriate decision whether to offer surgery or this technology/ embolisation. For implementation, patient will have to admitted under the Neurosurgeon for pre and post operative care. Ideally patient should also be followed up by a specialist headache neurologist to monitor outcomes. Need for a CNS service to monitor patient in the first few weeks after procedure as unto 1/3rd of patients may get rebound high pressure symptoms

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

n/a

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.** *

- (●) I agree
- ( ) I disagree

## Signature

44. Name: *

Parag Sayal

45. Date: *

25/09/2025

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication:** **IP1996 Trans-venous foraminal vein embolisation for the treatment of Cerebrospinal fluid (CSF)-Venous fistula (CSFVF), a cause of spontaneous intracranial hypotension (SIH)**

## Your information

| | |
|---|---|
| **Name:** | Dr Lalani Carlton Jones |
| **Job title:** | Consultant Neuroradiologist |
| **Organisation:** | Guy's and St Thomas' and King's College Hospitals NHS Foundation Trusts |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | British Society of Neuroradiologists, Royal College of Radiologists<br>American Society of Neuroradiologists<br>Radiological Society of North America |
| **Nominated/ratified by (if applicable):** | Directly asked by NICE |
| **Registration number (e.g. GMC, NMC, HCPC)** | GMC: 6163850 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

X Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology? | I am a consultant neuroradiologist specialising in CSF leak care. I am neuroradiology lead for the GSTT/KCH CSF disorders multidisciplinary team meeting and SIH service, which receives referrals from across the UK. I was a neuroradiologist member of the specialist interest group who wrote the UK multidisciplinary guidelines on the diagnosis and management of SIH and I am a regularly invited expert national and international speaker on the neuroradiological aspects of the diagnosis and treatment of SIH. I have diagnosed and treated a large number of patients with all types of SIH over the last 5 years (>150) As such I am familiar with this procedure and have been involved in patient investigation and selection for it. |
| | Have you used it or are you currently using it?<br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?<br>– Is this procedure/technology performed/used by clinicians in specialities other than your own? | We have received local approval from the TRAC (trust risk and assurance committee) and new procedures committees to perform this procedure in both my sites of practice at Kings College hospital and Guys and St Thomas's hospitals NHS Trusts via the new procedures pathway.<br>Current use in the NHS is limited to just a few neurosciences centres, as there is limited UK wide neuroradiological expertise in the diagnosis and localisation of CSF-venous fistulas, which is an **essential prerequisite to the procedure.** |

| | | |
|---|---|---|
| | – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | The procedure is performed by interventional neuroradiologists and some interventional vascular radiologists. No non-radiologists perform this procedure in the UK (in the USA there are also some neurosurgeons with training in endovascular techniques who perform it).<br><br>Patients with SIH who do not have spinal epidural fluid on MRI must first undergo bilateral lateral decubitus CT myelography or digital subtraction myelography, which I perform regularly, to detect the CSF venous fistula for treatment. I have performed this technique on multiple patients referred to our centres over the last 4 years (and have been the only operator doing this regularly at both our sites). I have pioneered the technique for same day bilateral decubitus CT myelography for identifying CSF venous fistulas (Carlton Jones and Goadsby, American Journal of Neuroradiology, 2022) which is widely cited by other authors as a method for finding fistulas.<br><br>If this demonstrates a CSF-venous fistula then the patient may be selected for this procedure either as a primary treatment modality, or as a second procedure if they have not responded satisfactorily to prior treatment by CT-guided injection of fibrin glue (which I also perform regularly), or If surgical treatment is not a suitable option for them or because of patient choice. |
| **2** | – Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have done bibliographic research on this procedure and have read all currently published papers regarding this technique.<br>I present and speak regularly at international CSF leak expert meetings (Freiburg expert consensus meeting, Freiburg Germany, March 2023, Naples SIH course May 2023, Cedars Sinai SIH symposium USA July 2023, American Society of Spine Radiology, Las Vegas USA, February 2024). I am therefore well versed in the literature as well as the most up to date conference proceedings and other centre activity, through personal connections and data presented. |
| **3** | Does the title adequately reflect the procedure?<br><br>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? | Yes<br><br>This is a novel approach compared to current standard of care |

| | | |
|---|---|---|
| | Which of the following best describes the procedure (please choose one): | Novel and of uncertain safety and efficacy. |
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | This procedure would be used in addition to existing standard care, as part of a staged management programme, occupying an intermediate position between CT-guided injection of fibrin sealant and neurosurgical closure of the CSF-venous fistula. |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? | No |
| | Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | No, largely based on a large original centre experience. Further supplementary published data of small series from other centres (<10 patients at these sites).<br>Brinjikji W, Madhavan A, Garza I et al. Clinical and Imaging Outcomes of 100 Patients with Cerebrospinal Fluid-Venous Fistulas Treated by Transvenous Embolization. J NeuroIntervent Surg. 2023;:jnis-2023-021012<br>Parizadeh D, Fermo O, Vibhute P et al. Transvenous Embolization of Cerebrospinal Fluid-Venous Fistulas: Independent Validation and Feasibility of Upper-Extremity Approach and Using Dual-Microcatheter and Balloon Pressure Cooker Technique. J NeuroIntervent Surg. 2023;15(12):1234-41<br>Noufal M, Liang C, Negus J. Transvenous Embolization for Cerebrospinal Fluid-Venous Fistula. A Case Series from a Single Community-Academic Center. World Neurosurg. 2022;168:e613-20<br>Ellens N, Schartz D, Ismail R et al. Efficacy of Transvenous Embolization of CSF-Venous Fistula in Spontaneous Intracranial Hypotension: Case-Series. Interv Neuroradiol. 2023;:15910199231221449. |

## Current management

| | | |
|---|---|---|
| **6** | Please describe the current standard of care that is used in the NHS. | Diagnosis of spinal CSF-venous fistulas as a cause of spontaneous intracranial hypotension is limited currently to a small number of neuroscience centres and an 'established standard of care' cannot yet be said to exist as such. Depending on local expertise patients may variably undergo a period of conservative management, non-targeted epidural blood patches, CT-guided injection fibrin sealant to occlude the fistula, this procedure, or neurosurgery. |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br>If so, how do these differ from the procedure/technology described in the briefing? | Yes – CT guided fibrin glue occlusion of the fistula. This has similar comparable success rates in the literature but is less invasive and less time consuming (up to an hour).<br>CT guided fibrin glue patching is a percutaneous technique performed under local anaesthetic and has success rates from 60- varying up to 100%. This does not require sedation or general anaesthetic unlike transvenous embolization. It is performed relatively quickly and can be performed same day as the myelogram. It is therefore less invasive than transvenous embolization with similar overall success rates with clinical and radiological end points. It can be reliably tried as a first step in treatment. Its evidence base also includes more multisite data internationally (see reference) than transvenous embolization.<br><br>Callen A, Carlton Jones L, Timpone V et al. Factors Predictive of Treatment Success in CT-Guided Fibrin Occlusion of CSF-Venous Fistulas: A Multicenter Retrospective Cross-Sectional Study. AJNR Am J Neuroradiol. 2023;44(11):1332-8 |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Relief of debilitating symptoms of SIH by means of a minimally invasive technique that avoids the risks and longer hospital stay and recovery period associated with neurosurgery. |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Patients who are unwilling to undergo neurosurgery or who are considered too high an operative risk.<br>Patients for whom CSF venous fistulas are at an eloquent nerve root level and therefore embolization would be safer than surgery. |
| **10** | Does this procedure/technology have the potential to change the current pathway or | This procedure is more invasive than image guided fibrin glue percutaneous injection but less invasive than neurosurgical treatment of CSF-venous fistulas and would be associated with a shorter hospital stay. |

| | | |
|---|---|---|
| | clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | All patients should first be discussed in a multidisciplinary team setting (including neurologist, neurosurgeon, diagnostic and interventional neuroradiologist) to discuss patient selection and suitability. Patient choice should be factored into any decision making.<br>Ability and experience to first localise CSF-venous fistula with decubitus CT myelography or digital subtraction myelography. This should only be performed by operators with the relevant level of training and experience to avoid wasted dural puncture and radiation dose if unsuccessful.<br>Interventional radiology suite for performing the embolization procedure. |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | The microcatheter skills and use of liquid embolic agents should be familiar to appropriately trained consultant interventional neuroradiologists and vascular interventional radiologists already. In person or remote proctoring of cases when learning the technique would likely be necessary for the first cases, however. Understanding of patient selection criteria, imaging already undertaken, anatomy of the fistula and discussion in MDT setting should be a prerequisite. |

## Safety and efficacy of the procedure/technology

| | | |
|---|---|---|
| **13** | What are the potential harms of the procedure/technology?<br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br>Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | Local pain at injection site (35.1%)<br>Rebound intracranial hypertension (28.6%)<br>Epidural or paraspinal vein perforation (5%)<br>Asymptomatic pulmonary emboli of liquid embolic agent (5%)<br><br>Above figures derived from:<br>Brinjikji W, Madhavan A, Garza I et al. Clinical and Imaging Outcomes of 100 Patients with Cerebrospinal Fluid-Venous Fistulas Treated by Transvenous Embolization. J NeuroIntervent Surg. 2023;:jnis-2023-021012. |

| | | |
|---|---|---|
| | | Orscelik A, Senol Y, Musmar B et al. Endovascular Embolization of Cerebrospinal Fluid-Venous Fistula: A Comprehensive Systematic Review on Its Efficacy and Safety for the Management of Spontaneous Intracranial Hypotension. Neurosurg Rev. 2024;47(1):28. |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Symptom improvement by headache scores such as HIT-6 & MIDAS<br>Improvement in brain MRI findings of SIH (as measured by the Bern score)<br>There should be whole team care including neurologist and neurosurgical input to ensure all patient treatment options are adequately explained and balanced against each other and to ensure patient outcomes are adequately assessed and recorded following interventions treatments. |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | Venous thromboembolism of embolic material may lead to pulmonary emboli (reported but rare)<br>Recurrence of CSF-venous fistulas at the treated level if all drainage is not adequately excluded. This is a known occurrence as discussed with multiple world leading centres.<br>There may be development of new CVFs at different level(s) can occur and has now been reported in the literature (Zayat R, Fermo O, Huynh T. Neurol Neurochir Pol. 2024;58(1):54-9)<br>The long-term results of this technique remain unknown as it has only been performed since 2021. |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | Patient selection needs to be rigorous. It is important to have high quality decubitus CT myelography or digital subtraction myelography that unequivocally shows a CSF-venous fistula before proceeding to treatment with this procedure.<br>Some fistulas may not be suitable for this intervention.<br>Long term outcomes e.g. recanalization of fistulas are a known occurrence and make this procedure less successful than surgical ligation. Surgical ligation after embolization remains possible however (Schievink W, Tache R, Maya M. Surgical Ligation of Spinal CSF-Venous Fistulas After Transvenous Embolization in Patients with Spontaneous Intracranial Hypotension. AJNR Am J Neuroradiol. 2022;43(7):1073-6) |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | Fewer than 5-10 specialist centres in the UK and only in centres with adequate training and experience of this procedure and of care of high volumes of CSF leak patients. There should be MDT discussion of all patients selected for the procedure between treating clinician (usually |

| | | |
|---|---|---|
| | | neurologist and neurosurgeon, diagnostic and interventional neuroradiologist to ensure patients are appropriately selected for the procedure) |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).<br><br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | Freiburg 2023 – Discussed data with world major leading SIH centres. Recurrence rates after embolization being more common in real world practice than that reported in the literature. Complete successful occlusion being reported from 50-80%.<br><br>Cedars Sinai symposium 2023<br><br>https://spinalcsfleak.org/symposia/2023-conference/ |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | A Clinical Registry of Spontaneous Intracranial Hypotension - Mayo Clinic (NCT05922514)<br><br>Cedars Sinai unit is comparing TVE and surgery for CSF venous fistulas |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | Cedars Sinai unit is comparing TVE and surgery for CSF venous fistulas<br><br>Other major high volume SIH leading centres – Freiburg, Duke will be publishing data shortly in the future |

## Other considerations

| | | |
|---|---|---|
| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | The incidence of SIH is approximately 5 per 100 000 per yr. CSF-venous fistulas account for around 25-50% of cases of SIH, so an estimate of eligible people would be 2 per 100 000 per year |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>− Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | Beneficial outcome measures:<br>HIT-6 (at 3 and 6 months)<br>MIDAS (at 3 and 6 months)<br>Patient Global Impression of Change (at 3 and 6 months)<br>EuroQol EQ-5D-5L (at 3 and 6 months)<br>Improvement in brain MRI Bern score (at 3 and 6 months)<br><br>Adverse outcome measures:<br>Occurrence of rebound intracranial hypertension (within first month)<br>Rate of procedural complications as detailed in section 13 |

## Further comments

| | | |
|---|---|---|
| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | No further comments |

NICE National Institute for Health and Care Excellence

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| ***Non-financial professional*** | Member, spontaneous intracranial hypotension UK multidisciplinary consensus guidelines special interest group | January 2021 | May 2023 |
| Choose an item. | | | |
| Choose an item. | | | |

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | Dr Lalani Carlton Jones |
| **Dated:** | 3 March 2024 |

View results

Respondent

131 Anonymous

30:34

Time to complete

1. Project Number and Name - (Can be found on email) *

Transvenous embolisation for treating cerebrospinal fluid venous fistula associated with spontaneous intracranial hypotension (IP1996)

## Your information

2. Name: *

Dr Sanjay Cheema

3. Job title: *

Consultant Neurologist

4. Organisation: *

University College London Hospitals NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Association of British Neurologists

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 7419153

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

## How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice**

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

## The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes. I have approximately 15 patients under my care who have received this treatment

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

I am involved in patient selection and MDT discussions regarding it as a treatment option
The procedure itself is done by interventional neuroradiology colleagues
I am unsure whether any other centre is currently performing this procedure, although there are 3–4 other centres who have a MDT team who treats patients with SIH
The procedure is used in several centres abroad, mainly in the USA

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) No
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. Does this have a multi-indication?

No

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel treatment option which has only been described in the last 4-5 years.
It has some similarities to other endovascular procedures used for other conditions but as far as I am aware no other endovascular approaches are used for managing SIH.
It is offered at a similar point in the treatment pathway as treatment options which have existed for longer including surgery (which is more invasive) and targeted blood/fibrin patching (which is less effective)

18. Which of the following best describes the procedure:

- ○ Established practice and no longer new.
- ○ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ○ Definitely novel and of uncertain safety and efficacy.
- ◉ The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

As an additional treatment option

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Not as far as I am aware

21. Do you think guidance would be helpful on this topic?

- ◉ Yes
- ○ No

## Current management

22. Please describe the current standard of care that is used in the NHS.

Existing treatment options for CVFs are surgery (which is more invasive) and targeted blood/fibrin patching (which is less effective)
Transvenous embolisation for CVFs has been used in our centre in the NHS for the past two years with local governance approval

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

No

## Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

An effective treatment option (>80% according to published literature from US centres with high throughput) which has a low risk of side effects.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients with multiple CVFs, especially at non-adjacent spinal levels, as multiple fistulas can be treated at same time, whereas surgery can typically only be performed at one level at a time

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes, less invasive treatment option than surgery, and more effective than targeted patching

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Interventional neuroradiologists training in the procedure. I do not perform the procedure myself but as far as I am aware can be performed with equipment already used for other interventional neuroradiology endovascular procedures

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes

## Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

rebound intracranial hypertension (can occur with any treatment for SIH and not specific to this treatment)
local pain at the site of the embolization
recurrence of CVF at a different site
bleeding or infection at puncture site
Onyx emboli, venous perforation (both rare)

30. Please list the key efficacy outcomes for this procedure/technology?

In the largest published series of 100 patients, technical success rate was 100%. Mean post-treatment Bern SIH score was 0.9±1.6 (P<0.0001). Following treatment, 95% of patients reported significant improvement or resolution in symptoms (58 patients reporting resolution and 37 reporting improvement). 5 patients reported no improvement. There were no major procedural or periprocedural complications. 10 patients had minor procedural complications that did not result in any change in management (Onyx emboli, venous perforation). 19 patients had rebound intracranial hypertension requiring acetazolamide therapy. 7 patients had recurrent fistula at the initially treated level.

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Long term follow up and recurrence rate unknown

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Not as far as I am aware

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ○ A minority of hospitals, but at least 10 in the UK.
- ◉ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

## Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

None other than already published literature

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

Not as far as I am aware

36. Please list any other data (published and/or unpublished) that you would like to share.

In our experience in approximately 15 patients treated, the majority have had a clinical and radiological improvement of SIH, with no serious adverse events other than one patients with a pulmonary embolism a few weeks later, likely related to bed rest after the procedure rather than the procedure itself, otherwise a few patients have had rebound headache and local pain at treatment site.

## Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Difficult to reliably estimate, but:
Approximately 2500 new cases of SIH estimated per year based on incidence data from USA.
As a rough estimate 2/3 will improve spontaneously or with non-targeted blood patches leaving approx 800
As a rough estimate 1/2 of those who do not respond and have myelography will have CVFs leaving aprox 400
All patients with CVFs in theory are eligible for embolisation but in our experience about 1/2 will chose to have surgery instead leaving approximately 200 patients per year

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

**Beneficial outcome measures.**

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Best assessed at 2-3 months after treatment:

Clinical:
1. resolution/improvement of headache
2. resolution/improvement of non-headache symptoms
3. disability scores used for other headache disorders e.g. HIT-6 may be used but are not validated for this procedure
4. patient global impression of change

Radiological:
1. MRI brain with contrast to look for resolution of signs of SIH

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

**Adverse outcome measures.**

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Patients should be reviewed prior to discharge from hospital for any immediate complications related to venous puncture / spinal intervention
Rebound headache and back pain likely to become apparent within days after the procedure and typically lasts days-weeks

## Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

N/A

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [x] Indirect
- [ ] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

No financial interests.
I have published a national guideline for managing SIH (JNNP, 2023) where embolisation is recommended as one treatment option for CVFs based on published evidence.
I have provided advice to and organised a webinar series for the UK CSF Leak Association patient charity.

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.** *

- (●) I agree
- ( ) I disagree

## Signature

44. Name: *

Dr Sanjay Cheema

45. Date: *

18/06/2025

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication:** **Transvenous embolisation for treating cerebrospinal fluid venous fistula associated with spontaneous intracranial hypotension (IP1996)**

## Your information

| | |
|---|---|
| **Name:** | Dr Daniel Scoffings |
| **Job title:** | Consultant neuroradiologist |
| **Organisation:** | Cambridge University Hospitals NHS Foundation Trust |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | British Society of Neuroradiologists, Royal College of Radiologists, European Society of Radiology, American Society of Neuroradiology |
| **Nominated/ratified by (if applicable):** | N/A |
| **Registration number (e.g. GMC, NMC, HCPC)** | 4534169 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology? | I am fully familiar with the procedure as a result of my roles as:<br>• Consultant neuroradiologist lead for Cambridge spontaneous intracranial hypotension (SIH) multidisciplinary team meeting.<br>• Co-author of UK consensus guidelines on investigating and managing SIH (Cheema et al *J Neurol Neurosurg Psychiatry* 2023;94:835-843) |
| | Have you used it or are you currently using it?<br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? | We have been performing this procedure in my Trust since 2023, in each case following multidisciplinary team assessment and discussion of the patient between consultants in neuroradiology, neurology and neurosurgery. To date we have performed it in 16 patients.<br><br>Currently only a few UK centres (?fewer than 5) have used this procedure, a reflection of the small number of centres with the necessary skills and facilities to diagnose cerebrospinal fluid-venous fistulas (CVFs). |

| | | |
|---|---|---|
| | − Is this procedure/technology performed/used by clinicians in specialities other than your own?<br>− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | In the UK the procedure is performed by interventional neuroradiologists and interventional vascular radiologists. I am not aware of any other specialties that do this (in some countries there are also neurosurgeons with training to perform endovascular procedures). |
| **2** | − Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have done bibliographic research on this procedure. |
| **3** | Does the title adequately reflect the procedure? | Yes |
| | Is the proposed indication appropriate? If not, please explain. | Yes |
| | Does this have a multi-indication? | No |
| | How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? | This is an adaptation and novel application of an established existing technique used by interventional neuroradiologists and interventional radiologists elsewhere for other pathologies (vascular malformations). |
| | Which of the following best describes the procedure (please choose one): | Definitely novel and of uncertain safety and efficacy. |

| | | |
|---|---|---|
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | I think it should best be regarded as an additional treatment option within the care pathway and is unlikely to fully replace other established treatment modalities such as CT-guided fibrin sealant injection or neurosurgery. |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | Some practitioners modify the method used in the original description of the technique, by adjunctive use of coils and balloon catheters to occlude venous drainage pathways and concentrate the liquid embolic material in the foraminal and internal vertebral venous plexus veins (so-called 'pressure cooker ' technique). See Parizadeh et *al J Neurointerv Surg* 2023;15:1234-41<br><br>N/A |

## Current management

| | | |
|---|---|---|
| **6** | Please describe the current standard of care that is used in the NHS. | Current standard of care in UK neuroscience centres with the relevant expertise is to perform CT-guided injection of fibrin sealant targeting the CVF as the first line treatment. In cases where this is unsuccessful then neurosurgical occlusion of the fistula is undertaken (e.g. Wang et al. *Oper Neurosurg (Hagerstown)* 2020;18:239-45). |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br><br>If so, how do these differ from the procedure/technology described in the briefing? | CT-guided injection of fibrin sealant targeting the CVF occludes the fistula by external compression of the veins of the fistula and/or entry of sealant into the draining veins resulting in their occlusion (Mamlouk et al. *Radiology*. 2021;299:409-18)<br><br>This is a CT-guided percutaneous procedure that does not require an endovascular approach and can be performed on on a day case basis under local anaesthetic with or without sedation on the same day as the diagnostic myelogram, as soon as the sealant has been defrosted. A multicentre retrospective study of fibrin sealant injection (Callen et al *AJNR Am J Neuroradiol* 2023;44:1332-38) shows very similar efficacy to those reported for transvenous embolization, in terms of patient-reported outcomes (complete improvement in 59.7%, partial improvement in 34.5%) and changes in Bern score for brain MRI. |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Potential avoidance of requirement for neurosurgery |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Patients who are not medically fit for surgery or those whose CVF is at the level of an 'eloquent' nerve root that it would be preferable not to sacrifice |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | In cases where using this procedure resulted in the avoidance of neurosurgery then it would lead to shorter hospital stays and lower risks to patients than those associated with neurosurgery. |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | An essential prerequisite is accurate localisation of the causative CVF by decubitus CT myelography or decubitus digital subtraction myelography.<br>The procedure itself needs an angiography system with digital subtraction capabilities, catheters, guidewires and liquid embolic agent – all available in standard UK interventional neuroradiology suites. |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | In addition to standard catheter/microcatheter skills and familiarity with use of liquid embolic agents such as Onyx, practitioners would need proctoring of initial cases by an appropriately experienced expert in the technique. |

## Safety and efficacy of the procedure/technology

| | | |
|---|---|---|
| **13** | What are the potential harms of the procedure/technology? | The following risks/adverse events have been reported by Orscelik et al *Neurosurg Rev*. 2024;47:28 in a systematic review of studies reporting a total of 77 patients:<br>• 27/77 (35.1%) – transient local pain at site of embolization<br>• 22/77 (28.6%) – development of rebound intracranial hypertension |

| | | |
|---|---|---|
| | Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br><br>Adverse events reported in the literature (if possible, please cite literature)<br><br>Anecdotal adverse events (known from experience)<br><br>Theoretical adverse events | In a report of the first 100 patients treated at the Mayo Clinic by this technique, the following were reported by Brinjikji et al (*J Neurointerv Surg* 2023;Oct 28: jnis-2023-021012).<br><br>• 19/100 - rebound intracranial hypertension requiring treatment with acetazolamide<br>• 7/100 - recurrence of CVF at the treated level<br>• 5/100 - perforation of foraminal veins or the internal epidural venous plexus<br>• 5/100 - pulmonary emboli of the liquid embolic agent<br><br>Most recently, Cagnazzo et al reported the following procedure-related complications in a series of 60 patients (*J Neurointerv Surg* 2025;)<br><br>• 13/60 – rebound intracranial hypertension, requiring treatment with acetazolamide in 9/13<br>• 9/60 – transient local pain at injection site<br>• 2/60 – microcatheter perforation of epidural venous plexus<br>• 2/60 – migration of Onyx into azygos venous system (asymptomatic) |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Efficacy should be assessed in terms of:<br><br>• Improvement in symptoms (which can be recorded with subjective reports from patients as well as using visual analogue pain scores and headache scales such as HIT-6)<br>• Degree of radiological improvement of brain MRI (using Bern score)<br>• Rate of treatment failure/retreatment |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | This procedure appears to be safe, based on available published data, but only a very few centres worldwide are reporting their outcomes with this procedure in the literature, the largest volume by far coming from a single centre where the procedure is performed by a single operator (Mayo Clinic, Rochester). Anecdotal evidence from discussions at SIH conferences is that 'real world' outcomes are somewhat less successful than those reported in the literature.<br><br>Recurrences of the CVF at the treated level have been reported, though it is unclear if these are true recurrences or simply persistence of the original CVF due to a failure of the cast of liquid embolic agent to penetrate sufficiently deeply into the spinal venous network at the level of the fistula. Some patients subsequently develop new CVFs at other spinal levels than the index treated level and can require retreatment. The reported retreatment/recurrence rate in a |

| | | |
|---|---|---|
| | | recent systematic review and meta-analysis (Jazayeri et al. *AJNR Am J Neuroradiol* 2025;10.3174/ajnr.A8839) was 14% but the data in the included studies was not sufficiently detailed to distinguish between recurrence/persistence at the treated level and development of new CVFs at other levels. |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | There have been multiple anecdotal reports of patients with dubious or equivocal findings at myelography, not conclusive for a CVF, being treated with the procedure without benefit and subsequently judged by expert neuroradiologists who specialise in SIH not to have had a CVF at the treated level. |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | Fewer than 10 specialist centres in the UK. |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).<br><br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | None I am aware of |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | Mayo Clinic are conducting a trial<br><br>https://clinicaltrials.gov/study/NCT05922514 |

| | | |
|---|---|---|
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | |

## Other considerations

| | | |
|---|---|---|
| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | Target population is patient with CVFs, who account for up to 40-50% cases of SIH.<br>Incidence of SIH is approx 4-5/100000/yr |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>– Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | Beneficial outcome measures:<br>*Symptomatic*<br>• Headache response (visual analogue scale, HIT-6)<br>• Patient global impression of change (PGIC)<br>• Measures of other symptoms (e.g. Tinnitus Handicap Inventory)<br>*Radiological*<br>• Bern brain MRI score<br>Adverse outcome measures:<br>• Intraprocedural complication frequency<br>• Rates of rebound intracranial hypertension requiring pharmacologic treatment or CSF drainage/diversion |

## Further comments

| | | | |
|---|---|---|---|
| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | Further research into this technique is necessary to assess the outcomes and effectiveness in multiple centres by a range of operators – much of the published data has been heavily weighted by the outcomes for a single operator in one centre.<br><br>Cases being considered for this procedure must be discussed in a multidisciplinary team meeting with representation from neuroradiology, neurology and neurosurgery who have expertise and experience in the management of SIH. The diagnosis and accurate localisation of a CVF must be secure before this procedure is undertaken, otherwise there is a risk of it being used inappropriately for myelographic findings that are not CVFs, such as irregular nerve root sleeves. | |

NICE National Institute for Health and Care Excellence

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | No conflicts of interest to declare | | |
| Choose an item. | | | |
| Choose an item. | | | |

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | **Dr Daniel Scoffings** |
| **Dated:** | **6 June 2025** |

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication:** **Transvenous embolisation for treating cerebrospinal fluid venous fistula associated with spontaneous intracranial hypotension (IP1996)**

## Your information

| | |
|---|---|
| **Name:** | Click here to enter text. Gordan Grahovac |
| **Job title:** | Click here to enter text. Consultant Neurosurgeon |
| **Organisation:** | Click here to enter text. King's College Hospital |
| **Email address:** | Click here to enter text. [redacted] |
| **Professional organisation or society membership/affiliation:** | Click here to enter text. GMC |
| **Nominated/ratified by (if applicable):** | Click here to enter text. |
| **Registration number (e.g. GMC, NMC, HCPC)** | Click here to enter text. 7473025 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology? | I am familiar with transvenous embolization (TVE) for CSF-venous fistulas (CVFs). As Spinal lead at King's College Hospital I treat on regular basis patients with spontaneous intracranial hypotension, and many of the patients have CSF-venous fistulas (CVFs). |
| | Have you used it or are you currently using it?<br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?<br>– Is this procedure/technology performed/used by clinicians in specialities other than your own? | Yes. All treatment modalities for CVFs, including transvenous embolisation as well as the other methods for treatment in my Trust and patients have been selected appropriately for these procedures through the SIH MDT.<br><br>Expert management of patient with spontaneous intracranial hypotension (SIHis limited to just a few UK centres, believe no more then 5 centres. There has not been been any randomised controlled trial to my knowledge that compares all treatment modalities for CVF's, that can clearly show which modality has better occlusion rate and safer profile.<br>The procedure is performed with interventional neuro radiologist. |

| | | |
|---|---|---|
| | – If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | I work closely with neuroradiologist and discuss every case on SIH MDT at GSTT, which intervention would be most appropriate for management patients with SIH depending on the pathology and imaging appearance and choose the most appropriate treatment modality. |
| **2** | – Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have done bibliographic research on this procedure. |
| **3** | Does the title adequately reflect the procedure?<br><br>Is the proposed indication appropriate? If not, please explain.<br><br>Does this have a multi-indication?<br><br>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?<br><br>Which of the following best describes the procedure (please choose one): | yes<br><br>n/a<br><br>no<br><br>This is a novel treatment approach for this condition but an adaptation of an existing therapeutic modality that is used for treating vascular malformations central nervous system or elsewhere in the body<br><br>Definitely novel and of uncertain safety and efficacy. |
| **4** | Does this procedure/technology have the potential to replace current standard care or | This procedure can allow additional modality of treatment, but will not replace current modalities of treatment of CVF's |

| | | |
|---|---|---|
| | would it be used as an addition to existing standard care? | |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | Not to my knowledge<br><br>NO |

## Current management

| | | |
|---|---|---|
| **6** | Please describe the current standard of care that is used in the NHS. | In the centres that have clinical expertise, patients with CVF if identified, will have CT guided injection of the fibrin glue and if this is not technically feasible or fistula is not occluded neurosurgical intervention would be offered. |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br><br>If so, how do these differ from the procedure/technology described in the briefing? | CT guided fibrin glue occlusion, during dynamic CT myelogram that serves as diagnostic modality. Procedure is done under local anaesthetic, as day procedure. |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Possibility to avoid neurosurgical intervention that potentially has higher risk associated with surgery. |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Patients with a CVF at the level of an eloquent nerve root where sacrifice of the nerve root during ligation is undesirable.<br>Patients with multiple, multilevel CVFs where surgery brings higher risk. |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | If procedure allows surgery to be avoided then hospital stays would potentially be shorter, with lower risk profile for the patient. |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | Ability to identify the patients with SIH appropriately, to have multidisciplinary team that will allow proper selection, and to have centres with higher volume to be able to gain adequate expertise in managing patients with SIH. TVE requires digital subtraction angio suite, preferably biplane but this is not essential, consumables (needles, catheters, microwire, embolic agent etc)<br>Patients should be under the relevant neurological or neurosurgical team also as will likely need admitting post procedure in the case of postoperative complications, such rebound increased intracranial pressure. |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | This disease requires working as part of a wider multidisciplinary team including diagnostic neuroradiology, neurologists and neurosurgeons.<br>The venous anatomy of the spine may not be immediately familiar to interventionists without prior experience and would require familiarisation for successful navigation of a microcatheter to the target site for embolization. Possible some proctoring might be necessary to people to familiarise with specific technical nuances of the transvenous embolization of CVF's |

## Safety and efficacy of the procedure/technology

| | | |
|---|---|---|
| **13** | What are the potential harms of the procedure/technology?<br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br>Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | Transient rebound intracranial hypertension, back pain, vascular injury, non-target embolization.<br>Pulmonary emboli around 5%<br>Venous perforation around 5%<br>CVF recurrence 7-10%<br>Rebound intracranial hypertension in 19% and headaches in 33% |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | **Clinical/symptomatic improvement and Radiological improvement** – degree of resolution/improvement in brain MRI abnormalities measured using semiquantitative scales such as the Bern score or Mayo Clinic score |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | There is relatively limited data on the effectiveness and safety of this procedure. There is no multicentre publication unlike one of the alternative treatments for the disease. |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | Recurrence rates at the site of disease and elsewhere with transvenous embolization is still not clear, due to lack of long term follow up of this patients after transvenous occlusion |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | Fewer than 10 specialist centres in the UK. |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this | The International expert SIH symposium in Amsterdam June 2025 |

| | | |
|---|---|---|
| | procedure/technology (this can include your own work).<br><br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | Mayo Clinic – 'A Clinical Registry of Spontaneous Intracranial Hypotension'<br><br>Clinicaltrials.gov ID NCT05922514 |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | N/A |

## Other considerations

| | | |
|---|---|---|
| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | 2-2.5 people per 100 000 population per year (based on CVFs accounting for 40-50% cases SIH and estimated incidence of SIH being 4-5/100 000/yr) |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br><br>– Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement | **Beneficial outcome measures:**<br><br>- Headache scores (HIT-6, MIDAS)<br>- Other symptomatic scales (THI, vertigo symptom scale etc)<br>- PGIC, SF36<br>- Bern score and/or Mayo Clinic score for brain MRI<br><br>**Adverse outcome measures:** |

| | | |
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| | for each and the timescales over which these should be measured.<br><br>– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | - Intraprocedural complications (puncture site haematoma, venous perforation, non-target embolization inc. PE)<br>- Rebound intracranial hypertension within first 2 months<br>- Treatment failure rate: residual/recurrent CVF at treated level and frequency of new CVFs at non-treated levels |

## Further comments

| | | |
|---|---|---|
| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | This is still regarded as a relatively new entity and as such the efficacy of ANY treatment does require further long term clinical data. |

NICE National Institute for Health and Care Excellence

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | nil | | |
| Choose an item. | | | |
| Choose an item. | | | |

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | **Click here to enter text. Gordan Grahovac** |
| **Dated:** | **Click here to enter text. 18.6.2025** |

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication:** **Transvenous embolisation for treating cerebrospinal fluid venous fistula associated with spontaneous intracranial hypotension (IP1996)**

## Your information

| | |
|---|---|
| **Name:** | Hiren Patel |
| **Job title:** | Consultant Neurosurgeon |
| **Organisation:** | Salford Royal Hospital |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | Society of British Neurological surgeons |
| **Nominated/ratified by (if applicable):** | Click here to enter text. |
| **Registration number (e.g. GMC, NMC, HCPC)** | C4182775 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

*☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

| |
|---|
| Click here to enter text. |

## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology? | I am familiar with the procedure but I have never performed it and neither have any members of the department I work in. |
| | Have you used it or are you currently using it?<br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?<br>– Is this procedure/technology performed/used by clinicians in specialities other than your own? | I hear or see lectures advertised about the use of this procedure but I do not feel that this is a procedure that is widely used in the NHS.<br><br>This procedure is mainly performed by interventional neuroradiologists. |

| | | |
|---|---|---|
| | − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | As a neurosurgeon I would be involved in looking after patients with csf fistulae leading to cerebral hypotension |
| **2** | − Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have done bibliographic research on this procedure.<br><br>I have had no involvement in research on this procedure.<br><br>I have seen colleagues from the US present their experience with this at meetings |
| **3** | Does the title adequately reflect the procedure?<br><br>Is the proposed indication appropriate? If not, please explain.<br><br>Does this have a multi-indication?<br><br>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?<br><br>Which of the following best describes the procedure (please choose one): | Yes<br><br>Yes<br><br>The title does not suggest multi-indication<br><br>Standard of care is identification of the fistula, use of epidural blood patch and if persistent identification using myelography/non invasive imaging prior to surgical repair.<br><br>Definitely novel and of uncertain safety and efficacy. |

| | | |
|---|---|---|
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | This procedure does have the potential to replace standard care but in the initial stage likely to be used in addition to existing standard care. |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | I don't know<br><br>There is a better reporting of the venous anatomy and tips and tricks for access. The safety and efficacy of the procedure is limited to single centre series or a systematic review of these reports. |

## Current management

| | | |
|---|---|---|
| **6** | Please describe the current standard of care that is used in the NHS. | I think that the standard of care is as outlined above that is identification of the fistula, use of epidural blood patch and if persistent identification using myelography/non invasive imaging prior to surgical repair. |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br><br>If so, how do these differ from the procedure/technology described in the briefing? | no |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Non invasive, more effective than blood patching |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Patients that have ongoing symptoms following a blood patch |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | Yes<br>yes |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | No need to change facilities as existing facilities exist. |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | Increased understanding of the venous anatomy would be necessary. There would be an understanding of how to identify leaks |

## Safety and efficacy of the procedure/technology

| | | |
|---|---|---|
| **13** | What are the potential harms of the procedure/technology?<br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: | Rebound intracranial hypertension transient local pain at the site of the embolization. Orscelik, A., Senol, Y.C., Musmar, B. *et al.* Endovascular embolization of cerebrospinal |

| | | |
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| | Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | fluid-venous fistula: a comprehensive systematic review on its efficacy and safety for the management of spontaneous intracranial hypotension. *Neurosurg Rev* **47**, 28 (2024). https://doi.org/10.1007/s10143-023-02264-1 |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Improvement of headache and quality of life scores. |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | Main concern with regard to efficacy is whether the endovascular approach is better than current best practice which is epidural blood patch +/- surgery |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | No big controversy apart from the level of efficacy |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | Fewer than 10 specialist centres in the UK. |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).<br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help | Orscelik, A., Senol, Y.C., Musmar, B. *et al.* Endovascular embolization of cerebrospinal fluid-venous fistula: a comprehensive systematic review on its efficacy and safety for the management of spontaneous intracranial hypotension. *Neurosurg Rev* **47**, 28 (2024). https://doi.org/10.1007/s10143-023-02264-1 |

| | | |
|---|---|---|
| | us if you list any that you think are particularly important. | |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | no |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | n/a |

## Other considerations

| | | |
|---|---|---|
| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | I don't know |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>− Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | Beneficial outcome measures:<br>I don't have the experience for this and would need to do a literature search<br><br>Adverse outcome measures:<br>As above |

## Further comments

| | | |
|---|---|---|
| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | |

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## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | | | |
| Choose an item. | | | |
| Choose an item. | | | |

* ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | **HC Patel** |
| **Dated:** | **0406/2025** |

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication:** **Transvenous embolisation for treating cerebrospinal fluid venous fistula associated with spontaneous intracranial hypotension (IP1996)**

## Your information

| | |
|---|---|
| **Name:** | Rukhtam Saqib |
| **Job title:** | Consultant Interventional Neuroradiologist |
| **Organisation:** | Salford Royal Hospital |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | GMC, RCR |
| **Nominated/ratified by (if applicable):** | Click here to enter text. |
| **Registration number (e.g. GMC, NMC, HCPC)** | 7408909 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

: Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

| |
|---|
| Click here to enter text. |

## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

| | | |
|---|---|---|
| 1 | Please describe your level of experience with the procedure/technology, for example:<br>Are you familiar with the procedure/technology? | I have not performed this procedure. I am aware of the procedural technique and have done background research on the topic. At our Trust, I perform myelograms to assess for CSF leaks since starting in July 2024. The volume of referrals is currently low, and the technique is being developed to identify a CSF-venous fistula. Once one is identified, this procedure would be a potential method of treatment. |
| | Have you used it or are you currently using it?<br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?<br>– Is this procedure/technology performed/used by clinicians in specialities other than your own?<br>– If your specialty is involved in patient selection or referral to another specialty for this | No, I have not performed this procedure. It has previously been performed in other neuroscience centres in the UK, such as Royal London Hospital. The procedure is usually performed by Consultant Interventional Neuroradiologists in the UK. The referral for assessment and treatment of CSF leaks usually comes via neurosurgery or neurology at our Trust. |

| | | |
|---|---|---|
| | procedure/technology, please indicate your experience with it. | |
| **2** | – Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have had no involvement in research on this procedure. |
| **3** | Does the title adequately reflect the procedure? | Yes |
| | Is the proposed indication appropriate? If not, please explain. | Yes |
| | Does this have a multi-indication? | No |
| | How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? | Within interventional neuroradiology, we routinely perform embolisation of dural arteriovenous fistulas or arteriovenous malformations using embolic material such as Squid, Onyx or glue. The principle of this procedure is similar, blocking the abnormal fistulous connection between the CSF and venous system. This procedure is more commonly performed in the United States in institutions such as the Mayo Clinic and Duke University Medical Center. The other invasive treatment options for CSF venous fistulas include surgical ligation and blood patch/fibrin. |
| | Which of the following best describes the procedure (please choose one): | Established practice and no longer new. |
| **4** | Does this procedure/technology have the potential to replace current standard care or | CSF-venous fistulas were first described in 2014 and are increasingly being recognised as a cause of spontaneous intracranial hypotension over the last few years. There is a guideline on spontaneous intracranial hypotension management (Multidisciplinary consensus guideline for the diagnosis and management of spontaneous intracranial hypotension) which states “If a CVF is |

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| | would it be used as an addition to existing standard care? | shown on myelography, then endovascular treatment may also be considered as a first-line treatment (along with targeted patching and surgery).” I would therefore say it is already part of the standard of care. |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | No. The procedure utilises equipment and embolic material that we routinely use in interventional neuroradiology for other procedures.<br><br>No. |

## Current management

| | | |
|---|---|---|
| **6** | Please describe the current standard of care that is used in the NHS. | Patients with clinically suspected spontaneous intracranial hypotension would have MR imaging of the brain and spine, and if this shows signs of intracranial hypotension and along with clinical symptoms, then at least one non-targeted blood patch would be performed. If this fails, invasive myelography would be considered to identify the site of leak. There are different types of leaks, including ventral leaks which have different aetiologies to CSF venous fistulas. There is a guideline on spontaneous intracranial hypotension management (Multidisciplinary consensus guideline for the diagnosis and management of spontaneous intracranial hypotension) which states “If a CVF is shown on myelography, then endovascular treatment may also be considered as a first-line treatment (along with targeted patching and surgery).” I would therefore say it is already part |

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| | | of the standard of care. I have referenced this below. |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br><br>If so, how do these differ from the procedure/technology described in the briefing? | As above, conservative management and non-targeted blood patches are trialled first as per current guidelines for spontaneous intracranial hypotension. In terms of specific invasive procedures for CSF venous fistulas, the options would be surgical ligation, transvenous embolisation of targeted blood/fibrin patch. A recent systematic review published May 2025, showed both surgical and endovascular treatment modalities led to over 90% partial or complete headache response, with no significant difference between embolisation and surgical ligation. Epidural blood patch outcomes have been reported as having poor outcomes in literature for CSF venous fistulas (2.5-14%). I am not aware of any other endovascular approach to treatment CSF venous fistulas at present. |

## Potential patient benefits and impact on the health system

| | | |
|---|---|---|
| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | This would be a minimally invasive treatment method for CSF-venous fistulas, providing relief from the debilitating symptoms of intracranial hypotension. |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Patients with a CSF venous fistula identified CSF venous fistula on myelography with clinical symptoms / signs of intracranial hypotension. This would not benefit patients with other types of CSF leaks, such as those with dural tears. There is no restriction in terms of patient demographics etc. There is a radiation dose involved which could be focussed on the abdominal region (depending on where the fistula is) – risk/benefit to considered especially in pregnant patients. |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | Yes. This procedure offers an alternative to surgical management of CSF venous fistulas, with a recent systematic review showing similar outcomes. The recovery time would likely be reduced compared to open surgery. |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | This procedure would be performed in existing biplane suites in neuroscience centres. The equipment and embolic material are the same which would be used for existing other intracranial endovascular procedures. It may potentially add extra burden to the interventional neuroradiology department caseload if the number of procedures were to keep increasing. |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | The basic skills are the same we use for procedures in interventional neuroradiology. In the first few cases, it would be best to have an experienced colleague present who has done the procedure, whether from within the Trust or brought in externally for the case. The main challenge would be identifying the correct fistulous point in anatomy which is less familiar. |

## Safety and efficacy of the procedure/technology

| | | |
|---|---|---|
| **13** | What are the potential harms of the procedure/technology? | Specific risks of this procedure include rebound intracranial hypertension, technical failure, need for re-treatment / recurrence (5-15%), small amount of Onyx/Squid emboli in the lungs, intramuscular extravasation, or unintended extensive Onyx/Squid embolisation of the venous |

| | | |
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| | Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br>Adverse events reported in the literature (if possible, please cite literature)<br>Anecdotal adverse events (known from experience)<br>Theoretical adverse events | plexus near the CSF venous fistula (but there is usually extensive collateral pathways), transient local pain at the level of embolization. Other general risks of endovascular procedures include bleeding, infection, risk of general anaesthesia, vessel injury. |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Resolution of clinical symptoms and radiological evidence of intracranial hypotension. Previous studies have used the HIT-6 (Headache Impact Test) and Bern spontaneous intracranial hypotension score pre- and post-treatment as a quantitative method of evaluation. |
| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | There is little long-term data available as this is procedure that is fairly new and does not have vast case numbers. There is no randomised control trial at present and most of the data is based upon case series and recent systematic reviews. |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | Besides little long-term data, nothing specific I am aware of. |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | Fewer than 10 specialist centres in the UK (neuroscience centres with interventional neuroradiology, neurosurgery and neurology). |

## Abstracts and ongoing studies

| | | |
|---|---|---|
| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). | 1. Cheema S, Anderson J, Angus-Leppan H, Armstrong P, Butteriss D, Carlton Jones L, Choi D, Chotai A, D'Antona L, Davagnanam I, Davies B, Dorman PJ, Duncan C, Ellis S, Iodice V, Joy C, Lagrata S, Mead S, Morland D, Nissen J, Pople J, Redfern N, Sayal PP, Scoffings D, Secker R, Toma AK, Trevarthen T, Walkden J, Beck J, Kranz PG, Schievink W, Wang SJ, Matharu MS. Multidisciplinary consensus guideline for the diagnosis and management of spontaneous intracranial hypotension. J Neurol Neurosurg Psychiatry. |

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| | Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | 2023 Oct;94(10):835-843. doi: 10.1136/jnnp-2023-331166. Epub 2023 May 5. PMID: 37147116; PMCID: PMC10511987.<br>2. Brinjikji W, Garza I, Whealy M, et al Clinical and imaging outcomes of cerebrospinal fluid-venous fistula embolization Journal of NeuroInterventional Surgery 2022;14:953-956.<br>3. Kranz PG, Amrhein TJ The promise and challenges of CSF-venous fistula treatment Journal of NeuroInterventional Surgery 2022;14:951-952.<br>4. Jazayeri SB, Eraghi MM, Ognard J, Ghozy S, Kadirvel R, Brinjikji W, Kallmes DF. Transvenous Embolization vs. Surgical Intervention for cerebrospinal fluid Venous Fistulas: A Systematic Review and Meta-analysis. AJNR Am J Neuroradiol. 2025 May 16:ajnr.A8839. doi: 10.3174/ajnr.A8839. Epub ahead of print. PMID: 40379458.<br>5. Amrhein TJ, Williams JW Jr, Gray L, Malinzak MD, Cantrell S, Deline CR, Carr CM, Kim DK, Goldstein KM, Kranz PG. Efficacy of Epidural Blood Patching or Surgery in Spontaneous Intracranial Hypotension: A Systematic Review and Evidence Map. AJNR Am J Neuroradiol. 2023 Jun;44(6):730-739. doi: 10.3174/ajnr.A7880. Epub 2023 May 18. PMID: 37202114; PMCID: PMC10249694.<br>6. Kissoon NR, Huynh TJ. Treatment of Spinal CSF Leaks and Fistulas. Continuum (Minneap Minn). 2025 Jun 1;31(3):688-708. doi: 10.1212/CON.0000000000001568. PMID: 40459310.<br>7. Zayat R, Fermo OP, Huynh TJ. Recurrence of cerebrospinal fluid-venous fistulas at different spinal levels following transvenous embolisation or blood/fibrin glue patching. Neurol Neurochir Pol. 2024;58(1):54-59. doi: 10.5603/pjnns.97522. Epub 2024 Jan 31. PMID: 38294430.<br>8. Goapper M, van Dokkum LEH, Costalat V, Risi G, Corti L, Portalier O, Lonjon N, Le Bars E, Ducros A, Cagnazzo F. The impact of CSF venous fistula embolization on patient's quality of life, a longitudinal clinical-radiological exploration. J Headache Pain. 2025 May 19;26(1):120. doi: 10.1186/s10194-025-02056-6. PMID: 40389826; PMCID: PMC12087204. |
| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | I am not aware of specific ones in the UK. |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | None |

## Other considerations

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| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | Spontaneous intracranial hypotension has an approximate incidence of 3.7 per 100 000, with some papers citing up to 5 per 100 000. There is a large variation in the proportion of which the aetiology would be a CSF venous fistula, with some papers citing up to 25%. It is difficult to predict how many of these would potentially need treatment via transvenous embolisation. |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>− Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured: | Beneficial outcome measures:<br>Examples of scores used in literature are:<br>1. HIT-6 (Headache Impact Test) score<br>2. Bern spontaneous intracranial hypotension score<br>3. Visual Analog Scale (VAS-QoL)<br>4. SF-36<br>These scores should be performed before and post procedure, as has been done in the reported literature looking at the outcomes of CSF venous fistula treatments.<br><br>Adverse outcome measures:<br>Incidence of complications as listed above. Long term data looking at recurrence rates of clinical symptoms or radiologically. |

## Further comments

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| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | None |

NICE National Institute for Health and Care Excellence

## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | I have no conflict of interest. | | |
| Choose an item. | | | |
| Choose an item. | | | |

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

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| **Print name:** | **RUKHTAM SAQIB** |
| **Dated:** | **13/06/2025** |

NICE National Institute for Health and Care Excellence

# Professional Expert Questionnaire

**Technology/Procedure name & indication:** **Transvenous embolisation for treating cerebrospinal fluid venous fistula associated with spontaneous intracranial hypotension (IP1996)**

## Your information

| | |
|---|---|
| **Name:** | Dr Sean T. O'Reilly |
| **Job title:** | Consultant Diagnostic and Interventional Neuroradiologist |
| **Organisation:** | Royal Victoria Hospital, Belfast |
| **Email address:** | [redacted] |
| **Professional organisation or society membership/affiliation:** | Royal College of Radiologists (FRCR) |
| **Nominated/ratified by (if applicable):** | Dr Owen Thomas, on behalf of the British Society of Neuroradiologists. |
| **Registration number (e.g. GMC, NMC, HCPC)** | GMC: 7073192 |

**How NICE will use this information:**

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see our privacy notice.**

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

## Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

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| 1 | Please describe your level of experience with the procedure/technology, for example:<br><br>Are you familiar with the procedure/technology?<br><br>Have you used it or are you currently using it?<br><br>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?<br><br>– Is this procedure/technology performed/used by clinicians in | I learned about this procedure whilst on international fellowship in Interventional Neuroradiology in the Toronto Western Hospital (University Health Network) in Canada, from September 2021 to August 2022.<br><br>To date, I have personally performed this procedure 5 times as primary operator and assisted as an outside proctor for 2 cases performed in Preston, England.<br><br>The technology involved; in terms of x-ray guidance, guide catheters, microcatheters and embolic material used (EVOH liquid embolics), should be familiar to any trained interventional neuroradiologist in the UK from our current practice, for example when embolising dural arteriovenous fistulas or AVMs.<br><br>To my knowledge this procedure would be performed exclusively by trained interventional neuroradiologists, although I do know in Toronto a surgical approach to clip the recipient vein of the CSF venous fistula was reserved for a very small minority of cases in which endovascular treatment failed.<br><br>Patient selection for this procedure should be done in a multidisciplinary fashion, with discussion primarily between Neurologists and Neuroradiologists to confirm both the clinical syndrome of SIH and the subsequent imaging findings confirming a CSF leak (involving Bern scoring on MRI and dynamic myelographic techniques, using CT or Fluoroscopy, to identify the source of leak). |

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| | specialities other than your own?<br>– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it. | The journal of Neurology, Neurosurgery and Psychiatry published a useful consensus guideline for the investigation and management of SIH, which includes this procedure for those with confirmed CSF venous fistula. https://jnnp.bmj.com/content/94/10/835<br>I have attached the published algorithm from this paper for suggested management of these patients below: |

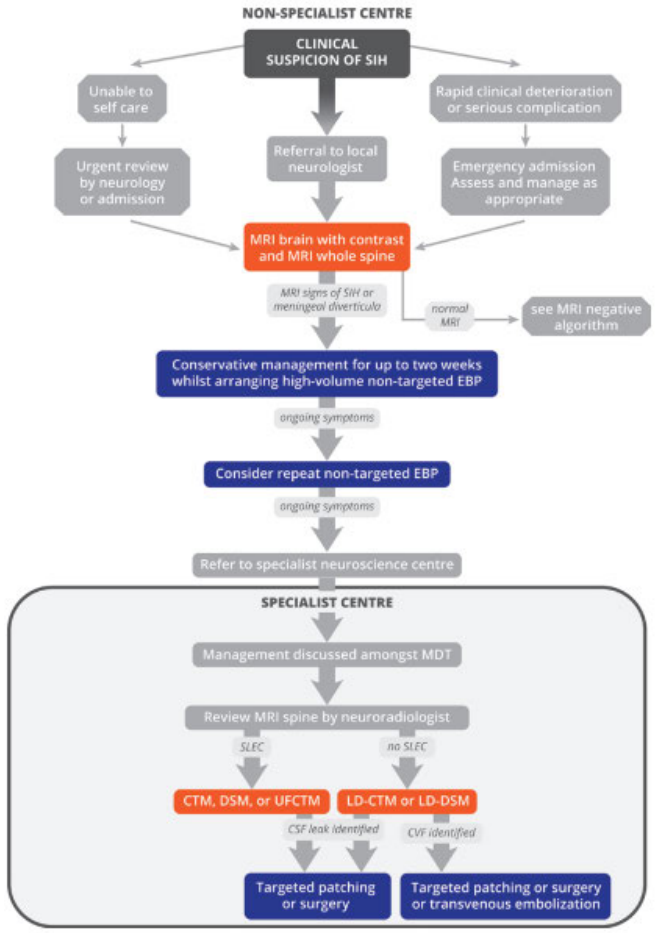


**Figure 3** Algorithm for MRI-positive patients. This algorithm is designed to show the recommended pathway for most patients rather than capture every single possible situation which may occur in the management of a patient with spontaneous intracranial hypotension (SIH). CSF, cerebrospinal fluid; CTM, CT myelography; CVF, CSF-venous fistula; DSM, digital subtraction myelography; EBP, epidural blood patch; LD-CTM, lateral decubitus CT myelography; LD-DSM, lateral decubitus digital subtraction myelography; MDT, multidisciplinary team; SLEC, spinal longitudinal epidural collection; UFCTM, ultrafast CT myelography

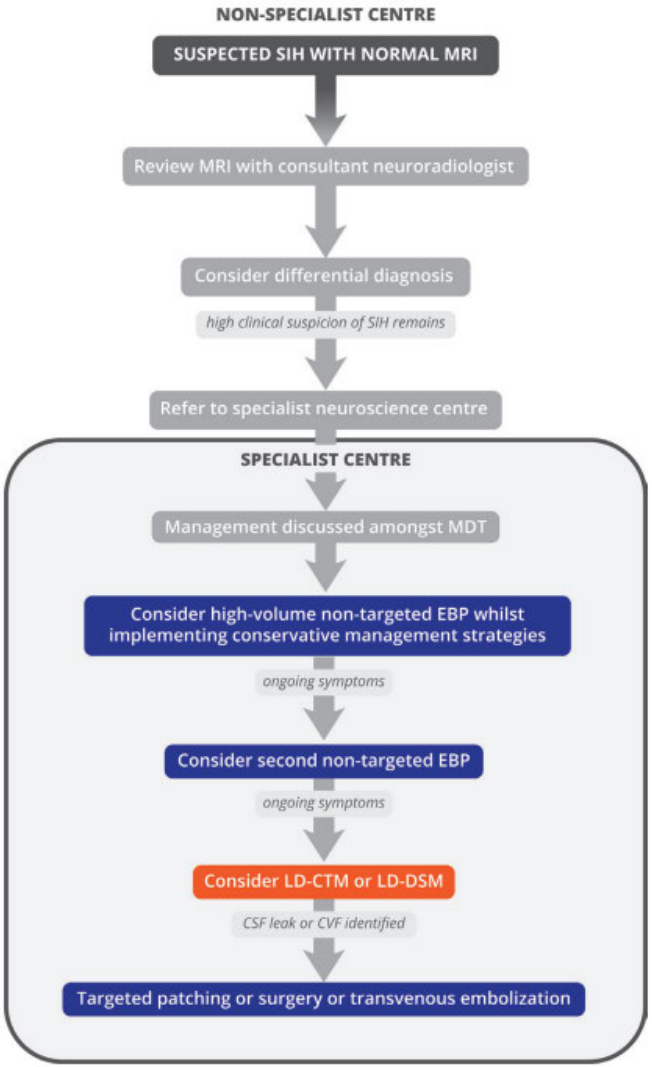


**Figure 4** Algorithm for MRI-negative patients. CSF, cerebrospinal fluid; CVF, CSF-venous fistula; EBP, epidural blood patch; LD-CTM, lateral decubitus CT myelography; LD-DSM, lateral decubitus digital subtraction myelography; MDT, multidisciplinary team; SIH, spontaneous intracranial

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| | | In my centre these patients are usually identified and managed primarily by the neurology team, often presenting via their Headache clinic.<br>In those who are unresponsive to blood patching, MRI investigation is performed. If this confirms appearances concerning for CSF leak (objective Bern scoring) they may then proceed to dynamic myelography.<br>Patients are then offered transvenous embolisation if a CSF venous fistula is identified (performed by a trained interventional neuroradiologist).<br><br>Bern Score for SIH - Dobrocky T, Grunder L, Breiding PS, et al. Assessing Spinal Cerebrospinal Fluid Leaks in Spontaneous Intracranial Hypotension With a Scoring System Based on Brain Magnetic Resonance Imaging Findings. JAMA Neurol. 2019;76(5):580–587. doi:10.1001/jamaneurol.2018.4921 |
| **2** | − Please indicate your research experience relating to this procedure (please choose one or more if relevant): | I have done bibliographic research on this procedure and presented on the imaging investigation and management of spontaneous intracranial hypotension (including use of this procedure); at regional (NI Headache Meeting December 2024), national (UK Neurovascular Group meeting June 2024) and international meetings (Irish Society of Neuroradiology meeting May 2023).<br><br>I have been involved in clinical research on this procedure involving patients during my fellowship in Canada.<br><br>I have published this research:<br><br>Farb RI, O'Reilly ST, Hendriks EJ, et al. Spontaneous intracranial hypotension due to CSF–venous fistula: Evaluation of renal accumulation of contrast following decubitus myelography and maintained decubitus CT to improve fistula localization. Interventional Neuroradiology. 2023;0(0). doi:10.1177/15910199231172627 |
| **3** | Does the title adequately reflect the procedure?<br><br>Is the proposed indication appropriate? If not, please explain.<br><br>Does this have a multi-indication? | Yes, I think the title adequately reflects the procedure the proposed indication is appropriate.<br><br>I do not know of any other indication for this procedure. |

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| | How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?<br><br>Which of the following best describes the procedure (please choose one): | Definitely novel and of uncertain safety and efficacy.<br><br>In the UK I feel this procedure remains novel, although there is an increasing volume of literature regarding its safety profile and efficacy.<br><br>Brinjikji W, Garza I, Whealy M, et al Clinical and imaging outcomes of cerebrospinal fluid-venous fistula embolization Journal of NeuroInterventional Surgery 2022;14:953-956. |
| **4** | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care? | CSF venous fistulas are a relatively recently discovered entity, the first ever case report on their existence being published in 2014, https://doi.org/10.1212/wnl.0000000000000639<br><br>With this method of treatment first described in 2021. https://doi.org/10.3174/ajnr.A7014<br><br>In the recent past these patients would likely have been managed the same as others with SIH, using non-targeted blood patching in the first instance or subsequent 'targeted' blood patching at the site of leak. Surgical ligation was also previously described.<br><br>Blood patching in the management of CSF venous fistulas has been shown to have a reduced effectiveness versus other causes (eg dural tear or post LP), therefore it is my view that this procedure would likely replace the current standard of care for this subset of SIH patients. |
| **5** | Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?<br><br>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance? | The procedure technique utilises equipment and technology which is familiar to interventional neuroradiologists from our current practice. The difference is the indication for embolisation (CSF venous fistula) and the target of embolisation (recipient foraminal vein of the CSF venous fistula).<br><br>No guidance currently exists on use of this procedure for the UK, however there is an international multidisciplinary guidance on management of CSF leaks which does mention its use for those patients with SIH who are found to have CSF venous fistula. https://jnnp.bmj.com/content/94/10/835 |

## Current management

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| **6** | Please describe the current standard of care that is used in the NHS. | Spontaneous Intracranial Hypotension (SIH) is managed by trained neurologists in the UK, as such I am not an expert on management being a neuroradiologist.<br><br>To my knowledge, current standard of practice is the use of autologous blood patching, with potential 'targeted' blood patching used in those patients who are non-responsive to initial non-targeted patch, or those with an objective site of CSF leak identified. |
| **7** | Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?<br><br>If so, how do these differ from the procedure/technology described in the briefing? | No. To my knowledge the standard practice of care in the management of SIH in the UK remains blood patching, with surgical options reserved for severe cases not responding to blood patching with objective evidence of leak (eg spontaneous dural tear, post surgery or post trauma). |

## Potential patient benefits and impact on the health system

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| **8** | What do you consider to be the potential benefits to patients from using this procedure/technology? | Published case series to date have shown promising results in terms of improvement in patient symptoms, with a good safety profile.<br><br>The largest published case series to date (Brinjikji W, Garza I, Whealy M, et al Clinical and imaging outcomes of cerebrospinal fluid-venous fistula embolization Journal of NeuroInterventional Surgery 2022;14:953-956) describes 90% of patients showing clinical improvement post treatment, and more than 90% showing improvement in their MRI findings post procedure.<br><br>For comparison, blood patching for this condition has been found to show permanent improvement in <15% of patients, with only ~45% showing temporary relief.<br>Shlobin NA, Shah VN, Chin CT, et al. Cerebrospinal fluid- venous fistulas: a systematic review and examination of individual patient data. Neurosurgery 2021;88:931–41. |
| **9** | Are there any groups of patients who would particularly benefit from using this procedure/technology? | Those with spontaneous intracranial hypotension which has been found to be secondary to CSF venous fistula. |
| **10** | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br><br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | YES. Patients with SIH often find it a very debilitating condition, having difficulty getting out of bed as their symptoms are usually relieved by lying down. They can wait years for thorough investigation and diagnosis leading to treatment.<br><br>This procedure, for patients with SIH caused by CSF venous fistula, has been shown to be very effective in improving symptoms (90% of patient in largest study). This is significantly more effective than other treatment methods such as autologous blood patching, arguably less invasive than autologous blood patching and certainly less invasive than surgical approaches. |
| **11** | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely? | None. This procedure utilises equipment and technology already available to centres with interventional neuroradiology. |
| **12** | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety? | Yes, the part of this procedure that is most novel to interventional neuroradiologists is navigating through the veins, from the groin access site in the common femoral vein to the recipient foraminal vein of the fistula which requires embolisation.<br><br>The training required is not felt to be a significant hurdle however, with competency likely to be achieved after seeing several cases and study of the relevant venous anatomy. |

## Safety and efficacy of the procedure/technology

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| **13** | What are the potential harms of the procedure/technology?<br><br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:<br><br>Adverse events reported in the literature (if possible, please cite literature)<br><br>Anecdotal adverse events (known from experience)<br><br>Theoretical adverse events | The largest case series published to date involved 40 patients<br><br>Brinjikji W, Garza I, Whealy M, et al Clinical and imaging outcomes of cerebrospinal fluid-venous fistula embolization Journal of NeuroInterventional Surgery 2022;14:953-956.<br><br>They describe harms such as:<br>- Localised site injection pain in ~30%, usually self limiting<br>- Rebound intracranial hypertension in 17.5%, usually self limiting, but some requiring medical treatment<br>- Clinically asymptomatic pulmonary embolism of embolic material was observed in 7.5%<br><br>In my own clinical experience, pain localised to the site of injection was observed in 30-50% of patients, which was self-limiting, settling within a few days. |
| **14** | Please list the key efficacy outcomes for this procedure/technology? | Primary outcomes:<br>- Occlusion of the CSF venous fistula<br><br>Secondary outcomes:<br>- Reduction in severity or frequency of headaches (with use of objective scoring systems such as HIT-6)<br>- Improvement in MRI imaging findings (with use of objective scoring systems such as Bern Score)<br>- Improvement in other symptoms patient may describe, such as tinnitus, hearing loss, ‘brain fog’ etc. |

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| **15** | Please list any uncertainties or concerns about the efficacy and safety of this procedure/? | As stated, this is a relatively novel procedure. Therefore, more data and studies are required to be able to make strong predictions about its efficacy and safety profile, however the data available to date seems very promising. |
| **16** | Is there controversy, or important uncertainty, about any aspect of the procedure/technology? | Outwith this procedure being a relatively novel procedure for a relatively recently described disease, there are no great controversies that I know of. |
| **17** | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | Fewer than 10 specialist centres in the UK.<br>This procedure will likely be performed by trained interventional neuroradiologists so will be confined to specialist centres which already have those services available.<br>Given the relatively rare incidence, this procedure may be confined to only a few centres in the UK with regional interest. |

## Abstracts and ongoing studies

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| **18** | Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).<br>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important. | I have listed several studies throughout this form to provide the evidence base for my figures, most of which I predict would be found on literature search so I won't repeat myself here. |

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| **19** | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | Not that I know of. |
| **20** | Please list any other data (published and/or unpublished) that you would like to share. | |

## Other considerations

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| **21** | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)? | The understood incidence of spontaneous intracranial hypotension is approximately 3.7 cases per 100,000 per year. Of those with SIH, CSF venous fistula is felt to represent the cause in 25% of cases.<br><br>Cheema, S., Anderson, J., Angus-Leppan, H. et al (2023). Multidisciplinary consensus guideline for the diagnosis and management of spontaneous intracranial hypotension. Journal of Neurology, Neurosurgery & Psychiatry, jnnp-2023-331166. https://doi.org/10.1136/jnnp-2023-331166<br><br>Orscelik A, Senol YC, Musmar B, Kobeissi H, Bilgin GB, Zandpazandi S, Bilgin C, Pakkam M, Brinjikji W. Endovascular embolization of cerebrospinal fluid-venous fistula: a comprehensive systematic review on its efficacy and safety for the management of spontaneous intracranial hypotension. Neurosurg Rev. 2024 Jan 2;47(1):28. doi: 10.1007/s10143-023-02264-1 |
| **22** | Please suggest potential audit criteria for this procedure/technology. If known, please describe:<br>– Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.<br>– Adverse outcome measures. These should include early and late complications. Please state the post | Beneficial outcome measures:<br><br>Short-term (within 1 month)<br>- Reduction of headache frequency/severity<br>- Improvement in quality of life related to being able to remain in a non-recumbent state (numbers of hours spent upright before needing to lie down)<br>- Improvement in other symptoms (dizziness, nausea, disequilibrium, tinnitus/hearing loss etc)<br><br>Medium-term (~3 months)<br>- Improvement in MRI imaging findings (reduced Bern score)<br><br>Long-term (>3 months)<br>- Stability of treatment (no recurrence of symptoms) |

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| | procedure timescales over which these should be measured: | Adverse outcome measures:<br>Short-term (within 1 month)<br>- Procedural complications (failure of treatment, adverse incidents)<br>- Localised injection site pain<br>- Iatrogenic pulmonary embolism secondary to treatment<br>- Rebound intracranial hypertension<br>Medium to long-term<br>- Rebound intracranial hypertension (do they settle with time, do patients require long-term acetazolamide or even surgical shunt placement)<br>- Unknown adverse outcomes within the first year |

## Further comments

| | | |
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| **23** | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | |

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## Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

| Type of interest * | Description of interest | Relevant dates | |
|---|---|---|---|
| | | Interest arose | Interest ceased |
| Choose an item. | No conflicts of interest to declare. | | |
| Choose an item. | | | |
| Choose an item. | | | |

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

**Please note, all declarations of interest will be made publicly available on the NICE website.**

| | |
|---|---|
| **Print name:** | **Sean Thomas O'Reilly** |
| **Dated:** | **04/06/2025** |