Percutaneous venoplasty for chronic cerebrospinal venous insufficiency for multiple sclerosis

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NICE interventional procedure guidance 420
www.nice.org.uk/ipg420
1 Guidance

1.1 Current evidence on the efficacy of percutaneous venoplasty for chronic cerebrospinal venous insufficiency (CCSVI) for multiple sclerosis (MS) is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.

1.2 NICE encourages further research on percutaneous venoplasty for CCSVI for MS, in the form of robust controlled clinical trials. Studies should clearly define selection criteria and patient characteristics. They should also clearly define technical success which may include measurement of pressure gradients across treated vein segments before and after venoplasty. Outcomes should include clinical and quality of life measures.

2 The procedure

2.1 Indications and current treatments

2.1.1 MS is a disease of the central nervous system, which usually starts in early adult life. It is characterised by neurological symptoms caused by episodes of inflammation and scarring in the white matter of the brain or spinal cord. Patients have a wide range of symptoms, most commonly visual disturbance with pain behind the eye, muscle spasms, pain, fatigue, and emotional problems or depression. Symptoms may vary over time and some patients become profoundly disabled. The 3 most common patterns of MS are: relapsing–remitting MS, in which periods of good health or remission are followed by sudden onset of symptoms or relapses; secondary progressive MS, in which symptoms gradually worsen and there are fewer remissions; and primary progressive MS, which involves a gradual, continuous worsening of symptoms from disease onset.

2.1.2 Current treatment for MS includes specialist neurological rehabilitation and medication aimed at symptom control and preventing disease progression.
2.2 Outline of the procedure

2.2.1 The aim of percutaneous venoplasty for CCSVI is to relieve MS symptoms by improving cerebrospinal venous drainage, although the relationships between MS, impaired cerebrospinal fluid drainage, lesions in the veins of the head, neck and chest, and their treatment by venoplasty are not well understood.

2.2.2 CCSVI is diagnosed using imaging techniques including venography, ultrasound or magnetic resonance imaging (MRI).

2.2.3 Local anaesthesia is usually used. A guidewire is advanced into the superior vena cava under fluoroscopic control using a standard needle, guidewire and catheter technique. Selective venography, and sometimes intravascular ultrasound of veins including but not limited to the internal jugular and azygous, is used to identify stenoses. If stenoses are found, the veins are dilated with an appropriate angioplasty balloon. Various angioplasty balloons can be used for this procedure. Sometimes a stent is used following the angioplasty.

2.2.4 Further imaging by venography or ultrasound, or both, is used to assess the outcome of each venoplasty. The puncture site is compressed manually.

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

2.3 Efficacy

2.3.1 A case series of 65 patients reported a significant improvement in MS Functional Composite (MSFC) score in patients with relapsing–remitting MS (n = 35) at 18 months compared with baseline (0.65 versus 5.5e-18 [less than 0], p = 0.008). There was no significant change in MSFC score at 18 months in patients with primary progressive MS (n = 10) or secondary progressive MS (n = 20).
2.3.2 A case series of 24 patients reported that 6 patients had a relapse of clinical symptoms within 1 to 2 months of the procedure, although it was reported that they felt better than they did before the procedure.

2.3.3 The case series of 65 patients reported a significant improvement from baseline to 18-month follow-up in physical health (66 versus 84, p = 0.0097) and mental health (61 versus 82, p = 0.003), as measured by the MS Quality of Life instrument (lower scores indicate lower quality of life) among patients with relapsing–remitting MS (n = 35).

2.3.4 A case series of 495 procedures in 461 patients reported restenosis requiring reintervention in 11 cases. A case series of 331 patients (344 procedures) reported that 15 repeat procedures were done for re-occlusions following balloon angioplasty. A case series of 247 procedures (229 primary procedures and 18 secondary procedures due to restenosis) in 231 patients reported that 2% (4/231) of patients had symptomatic stenosis that required retreatment within 30 days.

2.3.5 The Specialist Advisers listed key efficacy outcomes as including venography and/or ultrasound evidence of improved venous appearance, a significant change in number and character of MS lesions on MRI, a reduction in relapse rate, improvement in function and quality of life.

2.4 Safety

2.4.1 A report of 2 patients described the death of 1 patient due to a brainstem haemorrhage after insertion of 2 self-expanding stents into the right internal jugular vein (timing not stated); and another patient who required emergency open heart surgery to remove a stent that migrated to the right ventricle from the internal jugular vein.

2.4.2 A series of 18 patients reported 1 ruptured internal jugular vein during balloon angioplasty. This was treated with balloon tamponade and a bare metal stent.

2.4.3 The case series of 495 procedures in 461 patients reported acute in-stent or in-segment thrombosis in 2% (8/495) of procedures. All were treated by selective fibrinolysis, mechanical thromboaspiration and additional balloon angioplasty.
2.4.4 The case series of 495 procedures reported vein dissection in 15 procedures and vein rupture (resolved by prolonged balloon dilatation and stenting) in 2.

2.4.5 The case series of 495 procedures reported cardiac arrhythmias in 1% (6/495) of procedures. These included atrial fibrillation in 4 patients (2 resolved spontaneously and 2 resolved following treatment with amiodarone) and ventricular fibrillation (successfully treated) and ventricular tachycardia (timing not reported) in 1 patient each.

2.4.6 The case series of 331 patients (344 procedures) reported local bleeding from the groin requiring readmission to hospital in 4 patients. Two of these patients had pseudoaneurysms, which were successfully treated with thrombin injection.

2.4.7 The case series of 231 patients reported transient headache after 9% (21/247) of procedures. This persisted beyond 30 days in 1 patient. The same study also reported transient neck pain after 16% (39/247) of procedures.

2.4.8 The Specialist Advisers listed theoretical adverse events as infection, venous occlusion, air embolism, arteriovenous fistula and contrast reaction.

2.5 Other comments

2.5.1 The Committee was mindful of the distress and disability caused to patients by MS and the lack of effective treatments. Evidence that this procedure, or any other new treatment, offers clinical benefits that improve patients' quality of life would be of great value. This consideration underpinned the Committee's wish to encourage controlled research into percutaneous venoplasty for CCSVI for MS.

2.5.2 The Committee noted uncertainties about the prevalence of cerebrospinal venous stenoses in patients with MS compared with the general population, about whether such stenoses cause CCSVI, and about the relationship between CCSVI and MS. It considered that research to resolve these uncertainties would be useful.

2.5.3 The Committee noted that a number of studies included in the safety section of this guidance did not report any efficacy outcomes (see section 2.4).
2.5.4 The Committee recognised that percutaneous venoplasty can be used for other indications and that its complications are well recognised. It considered however, that judgements on the safety of any treatment can only be made in the context of evidence demonstrating efficacy for a specific indication. The Committee considered that it is difficult for any treatment to be judged as sufficiently safe in the context of substantial uncertainty about its efficacy, especially when serious side effects can occur.

2.5.5 The Committee noted many patients' commentaries and consultation responses describing their experiences of percutaneous venoplasty for CCSVI for MS, many of which described benefits and improvements to quality of life. These included reports of improved vision after the procedure, including cessation of optic neuritis. One person with MS reported being able to drive again after the procedure. Others reported improved bladder function, including better control, improvements in urgency and flow, reduced visits to the toilet and reduced incontinence. One report described a significant improvement in erectile function since having the procedure. The Committee considered that these reports added to the urgent need for robust controlled research.

3 Further information

Information for patients

NICE has produced information on this procedure for patients and carers (Understanding NICE guidance). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.
This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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