# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Interventional procedures consultation document

# Percutaneous venoplasty for chronic cerebrospinal venous insufficiency in multiple sclerosis

It has been suggested that multiple sclerosis symptoms may be caused, or made worse, by blocked veins in the neck or chest (chronic cerebrospinal venous insufficiency). This procedure involves inserting an inflatable balloon to widen veins in the neck and chest. The aim is to improve blood flow and symptoms.

The National Institute for Health and Care Excellence (NICE) is looking at percutaneous venoplasty for chronic cerebrospinal venous insufficiency in multiple sclerosis. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the <u>Interventional Procedures Programme process</u> guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of

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discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 29 October 2018

Target date for publication of guidance: January 2019

# 1 Draft recommendations

1.1 Current evidence on percutaneous venoplasty for chronic cerebrospinal venous insufficiency in multiple sclerosis shows there are serious complications. The evidence also shows that it provides no benefit. Therefore, this procedure should <u>not be used</u> in the management of multiple sclerosis.

# 2 The condition, current treatments and procedure

## The condition

- 2.1 Multiple sclerosis 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
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white matter of the brain or spinal cord. It causes a range of symptoms including problems with vision, arm or leg movement, sensation or balance. Muscle spasms, pain, fatigue, and emotional problems or depression may also occur. Symptoms may vary over time and some people become profoundly disabled. The 3 most common types of multiple sclerosis are: relapsing–remitting, in which periods of good health or remission are followed by sudden onset of symptoms or relapses; secondary progressive, in which symptoms gradually worsen with fewer remissions; and primary progressive, which involves a gradual, continuous worsening of symptoms.

### **Current treatments**

2.2 Current treatment for multiple sclerosis includes specialist neurological rehabilitation, and medication aimed at symptom control and preventing disease progression (see NICE's clinical guideline on <u>multiple sclerosis in adults: management</u>).

## The procedure

- 2.3 The aim of percutaneous venoplasty for chronic cerebrospinal venous insufficiency is to relieve multiple sclerosis symptoms by improving cerebrospinal venous drainage. However, the full mechanism of action is not currently understood.
- 2.4 Percutaneous needle puncture of the femoral vein is done under local anaesthesia and a vascular sheath inserted using a standard needle, guidewire and catheter technique. The guidewire is advanced into the superior vena cava under fluoroscopic control. Selective venography of veins, including but not limited to the internal jugular and azygos, is used to identify any abnormal luminal narrowing and collateral circuits. Intravascular ultrasound may also be used. Abnormally narrowed segments are dilated with a standard angioplasty balloon. Sometimes a stent is left in place

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after the angioplasty. Further venography or ultrasound, or both, are used to assess the outcome of the intervention before the guidewire and sheath are removed.

# 3 Committee considerations

## The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials (one of which also reported a case series), 3 further case series (1 of which is also included in the systematic review), 1 nonrandomised comparative study, 1 systematic review, and 1 registry report, and is presented in table 2 of the <u>interventional procedures</u> <u>overview</u>. Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, relapse rates, and measures of disability and disease progression.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: vascular rupture or dissection, venous thrombosis or occlusion, neurological damage including stroke, cardiac arrhythmia and stent fracture (if a stent is inserted after venoplasty).
- 3.4 Submissions were received from 2 patient organisations, which were discussed by the committee.

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3.5 This guidance is a review of NICE's interventional procedures guidance on <u>percutaneous venoplasty for chronic cerebrospinal</u> venous insufficiency for multiple sclerosis.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee August 2018

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