

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Endovenous mechanochemical ablation for varicose veins

Varicose veins in the legs are swollen and enlarged veins. They develop when the small valves inside a vein stop working properly, allowing blood to pool in the vein. This can cause pain, aching and swelling in the legs, and skin problems including inflammatory dermatitis and ulceration. In endovenous mechanochemical ablation, a tube with a hollow wire at its tip is inserted up the affected vein in the leg. The wire is rotated and a chemical is injected through the tube as it is pulled back out of the vein. This causes the vein to become inflamed, then shrivel and close.

The National Institute for Health and Care Excellence (NICE) is examining endovenous mechanochemical ablation for varicose veins and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about endovenous mechanochemical ablation for varicose veins.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of 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 the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would 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 NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 22 February 2016

Target date for publication of guidance: May 2016

1 Provisional recommendations

- 1.1 Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance. Clinicians are encouraged to collect longer-term follow-up data.

2 Indications and current treatments

- 2.1 Varicose veins are a sign of underlying venous insufficiency and affect 20–30% of adults. Most people with varicose veins have no symptoms but venous insufficiency may cause fatigue, heaviness, aching, throbbing, itching and cramps in the legs. Chronic venous

insufficiency can lead to skin discoloration, inflammatory dermatitis and ulceration. Great saphenous vein insufficiency is the most common form of venous insufficiency in people presenting with symptoms.

A NICE guideline describes recommendations for [the diagnosis and management of varicose veins](#). Many people have varicose veins that do not cause any symptoms or need treatment on medical grounds. However, some people will need treatment for the relief of symptoms or if there is evidence of skin discolouration, inflammation or ulceration. Treatment options include endothermal ablation, ultrasound-guided foam sclerotherapy and surgery (usually stripping and ligation of the great and small saphenous veins, and phlebectomies).

3 The procedure

- 3.1 Endovenous mechanochemical ablation for varicose veins combines mechanical ablation with the use of sclerosing agents to close veins without the need for tumescent anaesthesia (infusion of a large volume of dilute local anaesthetic around and along the entire length of vein to be treated).
- 3.2 The procedure is carried out using local anaesthesia at the catheter insertion site. Ultrasound imaging is used to identify the target vein, its diameter and the length of the section of vein to be treated. An infusion catheter with a motor drive is introduced percutaneously into the distal end of the target vein and, in the case of the great saphenous vein, the catheter tip is advanced to the saphenofemoral junction. A dispersion wire that extends through the catheter lumen is rotated to damage the epithelium and a sclerosant is infused simultaneously as the catheter is slowly pulled back through the vein. Patients are advised to wear compression stockings for about 2 weeks after the procedure.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 In a randomised controlled trial (RCT) of 117 patients with great or small saphenous vein incompetence treated by mechanochemical ablation or radiofrequency ablation, mean pain scores (measured on a visual analogue scale, 0–100) during the procedure were 13.4 ± 16.0 mm and 24.4 ± 18.0 mm respectively ($p=0.001$). In a non-randomised comparative study of 68 patients with great saphenous vein incompetence treated by mechanochemical ablation or radiofrequency ablation, mean pain scores (measured on a visual analogue scale, 0–100) during the procedure were 22.0 ± 16.0 mm and 27.0 ± 15.0 mm respectively ($p=0.16$). At 3 days after the procedure, mean pain scores were 6.2 ± 9.2 mm and 20.5 ± 25.5 mm respectively ($p=0.004$) and the mean postoperative pain scores per day over the first 14 postoperative days were 4.8 ± 9.7 mm and 18.6 ± 17.0 mm respectively ($p<0.001$). In a non-randomised comparative study of 147 patients treated by mechanochemical ablation, radiofrequency ablation or endovenous laser therapy, median pain scores (measured on a visual analogue scale) during the procedure were 1, 5 and 6 respectively ($p<0.01$).
- 4.2 In the RCT of 117 patients treated by mechanochemical ablation or radiofrequency ablation, complete occlusion rates were 83% and 92% (absolute numbers not reported) respectively at 1 month follow-up ($p=0.79$). In a case series of 449 patients (570 veins), occlusion rates were 89% for the great saphenous vein and 81% for the small saphenous vein (absolute numbers not reported) at 3 month follow-up. In a case series of 92 patients (106 legs) with great saphenous vein insufficiency, 88% (90/102) of veins treated

were obliterated at 1-year follow-up. In a case series of 63 patients (73 treated legs), occlusion rates were 94% (68/72), 95% (61/64) and 95% (40/42) at 6-, 12- and 24-month follow-up respectively. In a case series of 50 patients with small saphenous vein insufficiency, the occlusion rate was 94% (44/47) at 1-year follow-up.

- 4.3 In the RCT of 117 patients treated by mechanochemical ablation or radiofrequency ablation, similar venous clinical severity scores (VCSS) were reported in the 2 groups at 1-month follow-up (2.12 and 2.96 respectively, $p=0.22$, compared with 6.5 and 5.6 respectively at baseline, $p=0.086$). In the non-randomised comparative study of 68 patients treated by mechanochemical ablation or radiofrequency ablation, there were statistically significant improvements in VCSS from baseline in both treatment groups at 6-week follow-up (from 3.0 to 1.0 and from 4.0 to 3.0 respectively, $p<0.001$ for both groups). In the case series of 92 patients (106 legs), median VCSS improved from 4.0 at baseline to 1.0 at 1-year follow-up ($p<0.001$).
- 4.4 In the RCT of 117 patients treated by mechanochemical ablation or radiofrequency ablation, there were improvements in the Aberdeen Varicose Vein Questionnaire (AVVQ) in both groups at 1-month follow-up (12.7 and 15.5 respectively, $p=0.41$, compared with 22.6 and 22.7 respectively at baseline, $p=0.97$). In the non-randomised comparative study of 68 patients treated by mechanochemical ablation or radiofrequency ablation, there were statistically significant improvements in AVVQ scores from baseline in both treatment groups at 6-week follow-up (from 7.1 to 5.0, $p=0.006$, and from 9.5 to 4.5, $p=0.002$, respectively). In the case series of 92 patients (106 legs), median AVVQ improved from 11.1 at baseline to 2.4 at 1-year follow-up ($p<0.001$). In the case series of 50 patients, median patient satisfaction score (scale 0–10) was 8 (interquartile range, 8–9) at 6-week follow-up.

- 4.5 In the RCT of 117 patients treated by mechanochemical ablation or radiofrequency ablation, the mean times to return to usual activities were 3.5 days and 4.8 days respectively ($p=0.235$). In the case series of 92 patients (106 legs), the median time to return to usual activities was 1.0 day (interquartile range, 0.0–1.0).
- 4.6 The specialist advisers listed the following key efficacy outcomes: successful closure, ideally after 1-year minimum follow-up; quality of life (specific and generic); postoperative pain; and resolution of symptoms relating to venous incompetence.

5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 In a randomised controlled trial (RCT) of 117 patients, no patients treated by mechanochemical ablation and 1 patient treated by radiofrequency ablation had deep vein thrombosis. In a case series of 449 patients, 1 patient had deep vein thrombosis, diagnosed in the popliteal vein 3 weeks after treatment. The patient was treated with coumarins for 3 months and, at 6-month follow-up, the popliteal vein was no longer occluded. In the same study, pulmonary embolism was reported in 2 patients, 1 week postoperatively in 1 patient and 1 month postoperatively in the other. This patient also had a deep vein thrombosis in the popliteal and femoral vein of the treated limb. Both patients were admitted overnight and treated with coumarins. Neither patient had any sequelae.
- 5.2 Sural nerve injury resulting in transient hyperaesthesia was reported in 1 patient in the case series of 449 patients. The patient already had sensory sural neuropathy after previous

saphenopopliteal junction ligation, which was aggravated by the mechanochemical ablation.

- 5.3 Thrombophlebitis of the treated limb was reported in 2% (12/558) of limbs in the case series of 449 patients. Thrombophlebitis was reported in 0% (0/34) of patients treated by mechanochemical ablation and in 6% (2/34) of patients treated by radiofrequency ablation in a non-randomised comparative study of 68 patients ($p=0.49$). Thrombophlebitis was reported in 0% (0/60) of patients treated by mechanochemical ablation and in 3% (2/59) of patients treated by radiofrequency ablation in the RCT of 117 patients. Superficial thrombophlebitis was reported in 3% of patients (absolute numbers not reported) and 13% (10/73) of legs in 2 case series of 92 patients and 63 patients respectively. Transient superficial thrombophlebitis of the treated vein was reported in 14% of patients (absolute numbers not reported) in a case series of 50 patients. Thrombophlebitis was reported in 10% of patients (absolute numbers not reported) in a case series of 126 patients. Pain and erythema were reported in 1% (6/558) of limbs in the case series of 449 patients. Hardening and pain at the injection site was reported in 18% (13/73) of legs in the case series of 63 patients. Induration was reported in 12% (4/34) of patients treated by mechanochemical ablation and in 24% (8/34) of patients treated by radiofrequency ablation in the non-randomised comparative study of 68 patients ($p=0.20$). Induration along the course of the treated vein was reported in 12% of patients (absolute numbers not reported) in the case series of 92 patients.
- 5.4 Abscess at the puncture site was reported in 1 patient in the case series of 449 patients. A superficial wound infection was reported in 1 patient treated by mechanochemical ablation in a non-randomised comparative study of 147 patients.
- 5.5 Haematoma at the puncture site was reported in 1 patient in the case series of 449 patients. Haematoma was reported in 6% (2/34)

of patients treated by mechanochemical ablation and in 12% (4/34) of patients treated by radiofrequency ablation in the non-randomised comparative study of 68 patients ($p=0.67$). Localised haematoma was reported in 9% of patients (absolute numbers not reported) in the case series of 92 patients. Localised ecchymosis was reported in 12% of patients (absolute numbers not reported) and 8% (6/73) of legs in the 2 case series of 50 and 63 patients respectively. Ecchymosis was reported in 9% of patients (absolute numbers not reported) and haematoma in 1% of patients (absolute numbers not reported) in the case series of 126 patients.

- 5.6 Hyperpigmentation was reported in 9% (3/34) of patients treated by mechanochemical ablation and in 9% (3/34) of patients treated by radiofrequency ablation in the non-randomised comparative study of 68 patients. Mild hyperpigmentation at the puncture site was reported in 5% of patients (absolute numbers not reported) in the case series of 92 patients.
- 5.7 Retrograde inversion stripping of a small saphenous vein was reported in 1 patient in a case report. During the ablation procedure, the catheter got stuck and the motor was shut off. The catheter was pulled out and the entire small saphenous vein was also extracted, having been inversion stripped. The tip of the catheter was found to be fixed to a small calcified tributary. The patient was asymptomatic and pain free at the 6-week and 6-month follow-up. There was no recurrence, no sign of revascularisation and no neurological compromise.
- 5.8 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not identify any additional anecdotal adverse events. They considered

that the following were theoretical adverse events: vein perforation, migraine, visual disturbance and stroke.

6 Committee comments

- 6.1 The committee was informed that the procedure might be particularly useful for treating short saphenous veins and in patients with venous leg ulcers.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance is a review of NICE's interventional procedure guidance on [endovenous mechanochemical ablation for varicose veins](#).

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