

Endovenous mechanochemical ablation for varicose veins

Interventional procedure guidance

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nice.org.uk/guidance/ipg435

1 Guidance

- 1.1 Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to undertake endovenous mechanochemical ablation for varicose veins should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand that there is a lack of long-term efficacy data and that the procedure has potential side effects (particularly venous thromboembolism). They should be provided with clear written information, including details of other treatment options available to them. In addition, the use of NICE's [information for the public](#) is recommended.
 - Report adverse events and review and audit clinical outcomes (including long-term efficacy) for all patients having endovenous mechanochemical ablation for varicose veins (see [section 3.1](#)).
- 1.3 Patient selection should be carried out by clinicians who can offer a range of treatment options.

1.4 This procedure should only be carried out by clinicians with specific training in this technique.

1.5 NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 *Indications and current treatments*

2.1.1 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. Long saphenous vein insufficiency is the most common form of venous insufficiency in people presenting with symptoms.

2.1.2 Because most varicose veins do not cause serious health problems, treatment is not usually needed on medical grounds. Conservative methods such as compression hosiery (support stockings or tights) may help people with symptomatic varicose veins. If symptoms are severe the main treatment options include sclerotherapy, endovenous laser treatment, radiofrequency ablation and surgery (usually stripping and ligation of the long and short saphenous veins, and phlebectomies).

2.2 *Outline of the procedure*

2.2.1 Endovenous mechanochemical ablation combines mechanical and chemical ablation to close varicose 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).

2.2.2 The procedure is carried out using local anaesthesia at the catheter insertion site. Ultrasound imaging is used to identify the target vein (usually the long saphenous vein), its diameter and the treatment length, which depends on perforators and tributaries. An infusion catheter with a motor drive is introduced percutaneously into the distal end of the target vein and, in the case of the long 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. After the procedure, ultrasound may be used to check for target vein occlusion and patency of the common femoral vein. Patients are advised to wear compression stockings for approximately 2 weeks after the procedure.

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 29 patients reported a primary closure rate of 97% (29/30 veins) at a mean follow-up of 260 days (assessed by ultrasound). A case series of 25 patients reported complete occlusion in 87% (26/30) of veins at 6-week follow-up (assessed by duplex ultrasound). In this case series, 3 patients had a partial recanalisation and 1 patient had a total recanalisation (which was successfully treated by a repeat procedure 7 weeks after the initial procedure). It should be noted that the 2 case series used different sclerosants.
- 2.3.2 The case series of 25 patients reported a statistically significant reduction in median venous clinical severity score (scale 0–30, higher scores indicating more severe disease) from 3 (interquartile range 2–5) at baseline to 1 (interquartile range 0.3–3) at 6-week follow-up ($p < 0.001$).
- 2.3.3 The case series of 25 patients reported a median patient satisfaction score of 8.5 (scale 0–10, higher scores indicating increased patient satisfaction).
- 2.3.4 The Specialist Advisers listed key efficacy outcomes as including vein occlusion (up to 5 years after treatment), absence of full or partial recanalisations after the treatment (seen on duplex scan but not necessarily clinically apparent), length of treated truncal vein occluded by initial treatment, reduction of clinical symptoms, improved peri- and post-procedural pain scores and improved quality of life.

2.4 *Safety*

- 2.4.1 Deep vein thrombosis after the procedure was reported in 4 patients (reports submitted to the Food and Drug Administration [FDA] manufacturer and user facility device experience [MAUDE] database); 3 of these thromboses occurred after treatment of the short saphenous vein. All 4 patients were asymptomatic and were treated conservatively.
- 2.4.2 Pulmonary embolism after the procedure was reported in 1 patient (report submitted to the FDA MAUDE database). After treatment, the patient was discharged from hospital with a good prognosis.
- 2.4.3 Minor thigh ecchymosis was reported in 10% (3/30) of limbs in the case series of 29 patients. Localised ecchymosis at the puncture site was reported in 30% (9/30) of limbs in the case series of 25 patients.
- 2.4.4 Transient superficial phlebitis of distal tributaries was reported in 13% (4/30) of limbs in the case series of 25 patients.
- 2.4.5 The Specialist Advisers listed theoretical adverse events as including visual and neurological disturbance, allergy to sclerosant, haemorrhage, infection, embolisation, vein wall perforation and skin pigmentation.

2.5 *Other comments*

- 2.5.1 The Committee noted that deep vein thrombosis appeared to be more commonly reported following treatment of short saphenous vein varicosities.

3 **Further information**

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an [audit tool](#) (which is for use at local discretion).
- 3.2 For related NICE guidance see the [NICE website](#).

Information for patients

NICE has produced information on this procedure for patients and carers ([Information for the public](#)). 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](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

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 have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

