

Title Ultrasound-guided transcutaneous venous occlusion of the small saphenous vein

Agency HAS (French National Authority for Health - Haute Autorité de santé)

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Reference ISBN number: 978-2-11-172066-4, link to full report in French: https://www.has-sante.fr/jcms/p 3447378/fr/occlusion-

de-la-petite-veine-saphene-par-radiofrequence-par-voie-veineuse-transcutanee-avec-guidage-echographique

Aim

The aim of this assessment was to assess the benefit-risk balance of the radiofrequency (RF) small saphenous vein (SSV) occlusion procedure, which had not previously been assessed by the French National Authority for Health (HAS), and to define its role among previously assessed techniques approved for cover. The ultimate aim was to assess whether it should be covered by National Health Insurance.

Results

The selected Clinical Practice Guidelines (CPGs) recommend RF as a first-line approach (combined with laser) for the treatment of class¹ C2S to C6 small saphenous varicose veins, with a fairly high level of evidence. The selected metaanalysis (MA), dated 2016, found that, at six or more months of follow-up, RF was 97% effective, to the same degree as laser (99%), and that these two techniques are preferable to surgery (58% effective) and to foam sclerotherapy (64%), based on indirect comparison. The MAs conducted within the scope of this assessment confirmed these efficacy findings based on more recent studies of superior methodological quality, as well as longer, more precise follow-up (97% effective at 6 months and 96% effective at 12 months). The safety data compiled and reviewed in this assessment are consistent both mutually and with previously published data, on the nature, severity and frequency of complications, which range from simple forms (ecchymosis and skin pigmentation) to moderate forms such as paraesthesia or neuropathy (generally resolving in a few weeks), up to severe, but rarer, forms such as the onset of phlebitis, thrombosis or pulmonary embolism.

These data, as well as comparative data involving other techniques, result in a favourable assessment of the benefitrisk balance of RF small saphenous varicose vein therapy, and in RF being ranked as a first-line approach, along with laser. As a whole, the two national councils for healthcare professionals consulted deemed the report to be a good representation of the data available. They were in agreement with the finding in relation to the benefit-risk balance in favour of RF SSV occlusion and its role in the therapeutic strategy.

Conclusions

Considering these data and their homogeneity, HAS deems the benefit-risk balance of RF small saphenous varicose vein therapy to be favourable. This technique is also considered to be ranked at the same level as laser therapy, as a first-line approach. This report also helps set out the conditions for the performance of this procedure, particularly in relation to patient information, preliminary examinations, the type of anaesthesia, the puncture site (above midcalf wherever possible), additional precautions, and the procedure setting.

Methods

The assessment method consisted of a critical analysis of the summarised and individual literature identified by systematic literature search for the 2012-2022 period, selected on the basis of explicit criteria, and an MA conducted with data of superior methodological quality. This analysis helped prepare a draft report which served as a basis for the consultation, through questionnaires, of the relevant professional organisations (national councils for vascular medicine, vascular and endovascular surgery healthcare professionals) in order to obtain their collective opinion

The selected literature consists of four CPGs (of good to moderate methodological quality), one MA (of moderate quality), and twenty-two observational studies (including nine of good quality).

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¹ According to the CEAP (Clinical, Etiological, Anatomical, Pathophysiological) classification