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Choosing wisely for Chemical or Thermal Ablation in the Treatment of incomptent Saphenous Veins and Recurrences.

Official Document of the National Professional Council of Vascular Medicine (CNPMV) recorded by the French National Health Insurance (CNAMTS) and transmitted to the National Health Authorities (HAS-Haute Autorité de Santé)

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Keywords: relevance, choosing wisely, saphenous veins, foam sclerotherapy, thermal ablation.

Preamble

This document including 10 "Choosing Wisely" and produced by French Vascular Doctors, experts from the National Professional Council of Vascular Medicine (CNPMV), was initiated following consultation with the French National Health Insurance (CNAMTS) and validated by both Instances.

The varicose veins of the lower limbs represent a major public health issue in France and the objective of this work is an improvement of their management on criteria of relevance, optimization of patient benefit and cost reduction.

Introduction

According to the French Health Authorities (HAS- Haute Autorité de Santé), "Relevance is a strategic topic that constitutes an integral part of healthcare quality and a major issue for patient safety. Any medical procedure involves risks, which are weighed against the benefits or expected outcomes of the procedure, regardless of cost."

Inspired by North Americans' choosing wisely, these tools help initiate dialogue with patients, help health professionals make decisions about care choices, harmonize practices, reduce unnecessary or at-risk treatments and procedures, and promote relevant procedures. These elements are a first step towards the necessary prioritisation of therapeutic strategies, which have recently benefited from therapeutic innovations such as foam sclerotherapy and thermal ablation by radiofrequency or endovenous laser.

The National Professional Council of Vascular Medicine has decided on two topics in vascular medicine: Duplex ultrasound examinations and therapeutic procedures, mainly the occlusion of the saphenous veins and their recurrences, which we present here. Drafted by a group of experts and submitted to a review group, they are not intended to become enforceable, but seek primarily to guide the patient and the practitioner towards the most relevant therapies in a quality and safety approach.

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These “choosing wisely” imply that the decision as to whether to treat should be taken in consultation with the patient, after weighing the pros and cons of occlusive treatment of the saphenous veins against their conservation, especially in the light of cardiovascular risk factors. The various conservative treatments are not discussed in this paper as they are not subject to it.

Finally, it should be remembered that according to the definition, the four saphenous veins (great and small) are located in the saphenous compartment, between 2 fascias. Their tributary veins are anatomically in the subcutaneous area, above the fascias. The treatments of these, be it surgical, thermal or sclerotherapy, as well as the corresponding mode of anesthesia, if any, are not part of the problem at hand. They are therefore not discussed in this document and are not concerned with the exposed criteria for the relevance of the treatment of saphenous veins.

1/ ENDOVENOUS CHEMICAL OR THERMAL TREATMENT OF A SAPHENOUS VEIN OR ITS RECURRENCE AND USE OF THE DUPLEX ULTRASOUND BEFORE, DURING AND IMMEDIATELY AFTER THE PROCEDURE.

Rationale

A varicose veins check-up of the lower limbs should always include a clinical and anatomical evaluation aswell as a hemodynamic assessment by a Duplex ultrasound.

It makes it possible to study not only the superficial venous network but also, depending on the context, more or less thoroughly the deep veins and arteries.

This assessment, including a written report, allows to make an initial evaluation of the situation.

When appropriate, and after evaluating the risk-benefit balance, a treatment can be proposed by establishing the best possible therapeutic strategy (choice of method and tactical planning), most often with a mapping as a support.

In case of treatment of saphenous vein or its recurrence by thermal or chemical ablation, the procedure itself must include the use of a Duplex ultrasound.

Before the procedure, a cutaneous marking is used to “concretize”, directly on the lower limb, key points that vary according to the technique and tactics chosen.

The treatment procedure itself always begins with a new ultrasound scan to secure and finalize the implementation of the chosen therapeutic strategy (pre-procedure ultrasound scan); then, during the procedure, in all cases, permanent ultrasound guidance is essential to perform the procedures in a safe, relevant and optimised manner during all treatment phases (per-procedure ultrasound scan).

At the end of the procedure (immediate post-procedure ultrasound examination, just after the sclerosing injections or thermal application), a final ultrasound examination ensures that the immediate therapeutic objective has been safely achieved.

Relevance of treatment - Choosing wisely N° 1

Chemical or thermal ablation of the saphenous veins or their recurrences must be performed with a Duplex ultrasound scan before, during and immediately after the procedure.

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2/ ULTRASOUND-GUIDED SCLEROTHERAPY OF A SAPHENOUS VEIN OR ITS RECURRENCE: REPORT OF THE PROCEDURE AND ICONOGRAPHY OF THE TARGET VEIN.

Rationale

Ultrasound-guided sclerotherapy (USGS) of a saphenous vein is a therapeutic procedure whose results depend on a number of factors, including the injection site, the sclerosing product used, its form (liquid or foam), its concentration and the volume injected.

All these parameters must be recorded for two main reasons, the first being the traceability of these elements in the event of side effects or complications, enabling precise notification to pharmacovigilance in order to better identify the event and its cause.

The second reason is the possibility, by the same or a different operator, of complementing or secondarily adapting the treatment according to the doses previously used, which must therefore be perfectly known.

The availability of a photo of the Duplex ultrasound scan of the target vein before performing the procedure and another, once the foam injection completed, attests to the technical quality of the procedure.

[These photos provide very useful information and should be part of the available material, especially in the event of a case transfer].

The foam sclerosing agent can be traced in Duplex ultrasound (B-Mode) just after injection and the comparison of the two photos makes it possible to evaluate the immediate impact of the therapeutic procedure and the reaction of the venous wall (spasm).

Relevance of treatment - Choosing wisely N° 2

Ultrasound-guided sclerotherapy of a saphenous vein or its recurrence must be accompanied by a report of the procedure including: injection site(s), type and form of the sclerosing agent with concentration(s) used and volume(s) of foam injected, and by an iconography of the target vein just before the procedure and just after injection

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3/ CHOICE OF THE SAPHENOUS VEIN TREATMENT FOR THE LARGE DIAMETERS (> 8 MM*).

Rationale

The large diameters of saphenous veins are mainly associated with terminal valve insufficiency and are correlated with more advanced CEAP stages of venous disease.

Several studies have shown that the results of sclerotherapy in terms of occlusion or persistence of occlusion were less good on large diameter saphenous veins as of 6 mm and especially beyond 8 mm, as the product could not fully penetrate the wall thickness for these large diameter veins.

Therefore, after foam sclerotherapy, the occlusion rate for large saphenous veins after 1 year would be less than 40% for diameters of 9 mm and larger, and 75% for diameters of less than 6 mm.

The occlusion rate decreases at 5 years, possibly requiring iterative retreatments.

* *Measurement of internal diameter taken (patient standing) in a transverse ultrasound cross-section at mid-thigh for the great saphenous vein and at mid-calf for the small saphenous vein, excluding ectasia.*

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On the other hand, the use of large volumes of foam to try to occlude large diameter veins is likely to increase the risk of complications.

Finally, if only partial occlusion is obtained, the performance of a second-line thermal procedure may be more difficult to achieve or even compromised.

Relevance of the treatment - Choosing wisely N° 3

If saphenous vein treatment is considered, for a diameter greater than 8 mm*, thermal ablation must be proposed as a first-line treatment if achievable; ultrasound-guided foam sclerotherapy remains a possible option depending on the context, but with a lower definitive occlusion rate.

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4/ TREATMENT OF A SAPHENOUS VEIN INSUFFICIENCY OR ITS RECURRENCE BY MEANS OF A LIQUID OR FOAM SCLEROSING AGENT.

Rationale

The superiority of the foam form compared to liquid in sclerotherapy of saphenous veins is no longer debatable. It has been proven in many randomised studies and is widely accepted, with a European grade 1A recommendation in favor of foam.

For recurrences, while there are fewer specific studies, the use of foam rather than liquid in this indication is recommended in grade 1C; moreover, for recurrences indication, foam sclerotherapy is recommended as a first-line treatment before thermal ablation and surgery (grade1B UIA/EVF recommendations).

In case of a contraindication to foam, rather than sclerotherapy with liquid on saphenous veins or their recurrences, it is preferable to consider thermal ablation if this is feasible.

Relevance of the treatment - Choosing wisely N° 4

Except in special cases and contraindications, the foam form of a sclerosing agent should be used rather than the liquid form for the sclerotherapy treatment of a saphenous vein insufficiency or its recurrence.

In case of contraindication to foam, thermal ablation is recommended if feasible.

** Measurement of internal diameter taken (patient standing) in a transverse ultrasound cross-section at mid-thigh for the great saphenous vein and at mid-calf for the small saphenous vein, excluding ectasia.*

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5/ CHOICE OF A SAPHENOUS VEIN TREATMENT FOR THE SMALL DIAMETERS (< 4 MM*).

Rationale

Ultrasound-guided sclerotherapy is versatile with very few technical limitations for feasibility, including for small diameter veins (≤ 4 mm).

For these small diameters, thermal ablation by an experienced operator, using suitable equipment, is delicate but also technically feasible.

However, several studies have shown that on small venous diameters, chemical ablation, with a lighter technical platform, allows good results in terms of venous occlusion and clinical scores, at a lower cost.

The medical service provided in this context is therefore in favor of the ultrasound-guided foam sclerotherapy option.

A survey of many international experts on their practices showed that they reserved the indication of thermal ablation for veins of at least 4 mm in diameter.

Relevance of the treatment - Choosing wisely N° 5

If saphenous vein treatment is considered, for a diameter of less than 4 mm*, an ultrasound-guided foam sclerotherapy must be proposed as a first-line treatment if it is achievable; thermal ablation remains a possible option depending on the context, but with a significant cost increase compared to that of foam sclerotherapy.

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** Measurement of internal diameter taken (patient standing) in a transverse ultrasound cross-section at mid-thigh for the great saphenous vein and at mid-calf for the small saphenous vein, excluding ectasia.*

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6/ CHOICE OF A TREATMENT FOR A SAPHENOUS VEIN INSUFFICIENCY IN A HIGH-RISK THROMBOTIC PATIENT.

Rationale

An acute or recent episode of deep vein thrombosis or pulmonary embolism is an absolute contraindication to performing chemical or thermal ablation on a saphenous vein or its recurrence.

After an acute episode (> 3 months), high thrombotic risk (repeated thromboembolic episodes, severe known thrombophilias, hypercoagulability, active cancer) remains a relative contraindication for sclerotherapy according to European recommendations.

While the individual risk-benefit ratio of saphenous insufficiency treatment must be assessed with particular attention regardless of the treatment considered, the high thrombotic risk is not a contraindication for thermal ablation (HAS report- French Health Authorities).

Thermal ablation must be performed under thromboprophylaxis and allows the occlusion of the saphenous vein to be obtained in a single step and with greater certainty.

However, ultrasound-guided foam sclerotherapy remains a possible option depending on the context and must also be performed under adapted thromboprophylaxis.

Relevance of the treatment - Choosing wisely N° 6

If the treatment of saphenous vein insufficiency in a patient at high thrombotic risk (repeated thromboembolic episodes, known severe thrombophilias, hypercoagulability, active cancer) is decided, it is preferable, except in special cases, to propose thermal ablation as a first line of action, if this is feasible. However, ultrasound-guided foam sclerotherapy remains a possible option depending on the context. In all cases, the individual risk-benefit ratio must be assessed and an appropriate thromboprophylaxis performed.

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7/ TREATMENT OF SAPHENOUS VEIN INSUFFICIENCY OR RECURRENCE BY CONVENTIONAL OPEN SURGERY (HIGH LIGATION AND STRIPPING).

Rationale

"Conventional" open surgery of saphenous vein is an old technique involving a high ligation of the saphenofemoral or saphenopopliteal junction associated with trunk stripping (by pin-stripper or a similar Babcock device) often complemented by phlebectomies.

In France, this surgery is still largely performed under general anaesthesia, with significant co-morbidity, particularly during surgical procedures for recurrences of varicose veins in the territory of a previously operated saphenous vein. In addition, it results in an average work stoppage of 26 days.

Its outcomes are not better than those of the endovenous techniques such as thermal or chemical ablations, which are less invasive and preferred to surgery in the international recommendations.

Indeed, the first-line treatment for saphenous veins is thermal ablation (maximum recommended grades), which can give way to foam sclerotherapy for recurrences.

As a result, and with very rare exceptions (such as very large dysmorphic ectasia of the saphenofemoral or saphenopopliteal junction or of the saphenous trunk), conventional surgery should not be proposed for the treatment of saphenous veins or their recurrence.

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Relevance of the treatment - Choosing wisely N° 7

Once the decision to treat a saphenous vein or its recurrence has been made, conventional open surgery (high ligation and stripping) should not be proposed, except in very rare cases (such as very large dysmorphic ectasia of the junction or trunk).

This does not apply to the so-called "modern" or "minimally invasive" surgery performed under strict local tumescent anaesthesia.

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8/ FAILURE OF AN INITIAL TREATMENT OF A SAPHENOUS VEIN BY ULTRASOUND-GUIDED FOAM SCLEROTHERAPY.

Rationale

Without prejudging the remote retreatment that may be necessary in the event of subsequent recanalisation, studies on foam sclerotherapy of the saphenous veins show that during initial treatment, venous occlusion can often be obtained in 1 to 2 sessions for the great saphenous vein and in a single session for the small saphenous vein, for moderate to medium calibre veins.

If, in the face of an occlusion failure, more sessions seem necessary, the relevance of the choice of this technique can be questioned, particularly in relation to the benefit-risk balance (especially if the doses must be increased significantly).

A new individual assessment is then required to reconsider, in consultation with the patient, whether another option can be considered.

Relevance of the treatment - Choosing wisely N° 8

Two consecutive failures of an initial treatment of the great saphenous vein with ultrasound-guided foam sclerotherapy or a failure on the small saphenous vein should lead to a reassessment of the situation and alternative therapeutic solutions, taking into account the balance between benefit and risk.

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9/ ANESTHESIA IN THE TREATMENT OF THE SAPHENOUS VEIN BY THERMAL ABLATION.

Rationale

The standard method for anaesthesia during endovenous thermal ablation of a saphenous vein is a strict local tumescent anaesthesia (LTA), performed under ultrasound guidance to ensure its quality.

LTA seeks not only to provide local analgesia, but also to empty the vein of its blood, thus improving the contact of the probe or fibre with the venous wall, and to protect the perivenous structures, in particular cutaneous and nervous structures, from heat.

Safety requires that in the event of a nerve heating, the patient can immediately report any painful signals to the practitioner so that the practitioner can immediately stop the application of energy.

The maintenance of a patient's vigilant state is therefore essential and is respected by the LTA; however, this is not compromised by the possible combination of hypno-sedation, Entonox gas or neurolept-analgesia, provided that the patient's vigilance is checked before and during the application of the energy.

In contrast, general, spinal or femoral-block anaesthesia do not meet safety criteria and potentially increase the risk of co-morbidity and the risk of neurological and skin complications.

Relevance of the treatment - Choosing wisely N° 9

During treatment by thermal ablation (laser or radiofrequency) of a saphenous vein, local tumescent anaesthesia is mandatory. General, spinal or femoral-block anaesthesia is contraindicated except in very rare cases, for which ultrasound-guided tumescence remains mandatory.

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10/ CHOICE OF TREATMENT FOR THERMAL ABLATION OF THE SMALL SAPHENOUS VEINS.

Rationale

The small saphenous vein (SSV) is a short vein that runs in areas close to the nerves.

Compared to surgery, the thermal endovenous techniques can significantly reduce the rate of side effects, especially neurological complications (4.8% for laser versus 19.6% for surgery).

During the thermal ablation of an SSV, it is essential to perform a quality tumescence under ultrasound guidance and the patient's vigilous state must be maintained; these conditions make the procedure safer and minimize the neurological risk.

In addition, for ease of handling and safety, the active tip of a radial laser fibre with millimetre firing is better suited to a short vein than the 7-cm heating element of the segmental radiofrequency.

In addition, the thermal inertia of the segmental resistance if this radiofrequency device is absent for the laser, which constitutes for the latter an additional safety guarantee.

A review of the literature on the treatment of the SSV, with meta-analysis, shows that studies carried out with endovenous laser (EVL) significantly outnumber those carried out with radiofrequency (RF) (2950 SSV treated by EVL, 386 by RF) with very good occlusion rates in both cases (98.5% for EVL,

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97.1% for RF) and very good safety (4.8% for neurological events for EVL and 9.7% for RF) (1).

A 3-cm segmental RF probe has been marketed but has not been studied extensively in this indication.

The same is true for bipolar and monopolar radiofrequency systems, whose very short active segment appears to meet safety criteria, but evaluation studies are still needed.

Relevance of the treatment - Choosing wisely N° 10

Whenever a thermal ablation of a small saphenous vein is chosen, it is preferable to propose an endovenous laser ablation as a first-line treatment.

The 3-cm segmental radiofrequency, bipolar and monopolar radiofrequency are possible options, but the 7-cm segmental radiofrequency is not recommended.

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