AMERICAN VEIN & LYMPHATIC SOCIETY

Mechanochemical Chemically Assisted Ablation of Varicose Veins for Venous Insufficiency:

Position Statement of the American Vein & Lymphatic Society

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Abstract

Background

Mechanical occlusion chemically assisted ablation (MOCA) of incompetent saphenous veins has been utilized since its FDA approval in 2008. However, only recently have longer-term three and five year clinical follow up data become available. This updated information necessitates a societal update to guide treatment and ensure optimal patient outcomes.

Method

The American Vein and Lymphatic Society convened an expert panel to write a Position Statement with explanations and recommendations for the appropriate use of MOCA for patients with venous insufficiency.

Result

This Position Statement was produced by the expert panel with recommendations for appropriate use, treatment technique, outcomes review, and potential adverse events. These recommendations were reviewed, edited, and approved by the Guidelines Committee of the Society.

Conclusion

MOCA is effective in alleviating symptoms and a safe treatment option for venous insufficiency. It obviates the need for tumescent anesthesia, has less procedural discomfort and lower risk of thermal nerve or skin injury. It may be used in both the below knee distal GSV as well as the SSV. However, it is associated with significantly lower rates of vessel closure and higher recanalization rates compared to both RFA and EVLA and is less cost effective than thermal techniques. It is an available option for those in whom thermal ablation is not suitable.

BACKGROUND

Varicose veins and venous insufficiency are a common clinical disorder affecting a significant portion of the population. Various treatment modalities have been developed to manage varicose veins, with mechanical occlusion chemically assisted ablation (MOCA) being a non-thermal non-tumescent technique which combines mechanical and chemical methods to achieve vein closure. ClariVein® (Merit Medical; South Jordan, UT) is presently the only available MOCA treatment in the United States although elsewhere the Flebogrif® (Balton, Poland) system is available.[1]

ClariVein® was initially approved by the FDA in 2008 and specific CPT® (Current Procedural Terminology) codes for its use, 36473 and 36474, became available in 2017. It obtained the CE mark in April 2010, with a specific indication for endovascular occlusion of incompetent veins with superficial venous reflux. It is available in Europe and many countries in the world.

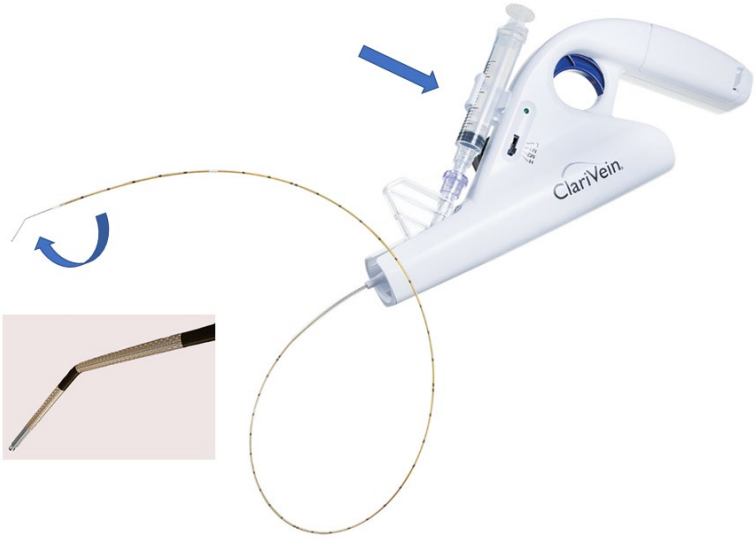

Fig 1: The mechano-chemical ClariVein® ablation catheter has a syringe attached (arrow) through which a sclerosant is injected and an angled rotating tip (curved arrow and inset).[33]

Because of the much more limited approval and published data on Flebogrif®, this position statement will focus on the ClariVein® product. This position statement will assess the appropriate use, technique, clinical outcomes and potential adverse events of MOCA ablation in the management of varicose veins and venous insufficiency.

The Research Committee of the AVLS recommended an expert panel of authors to develop a position statement on MOCA. These recommended panel members were reviewed and approved by the Executive Committee of the AVLS. The draft statement and its recommendations were revised and approved by the Guidelines Committee of the AVLS and represents societal endorsement of its recommendations.

Appropriate Use

Saphenous vein ablation to treat axial reflux in symptomatic patients is supported by extensive clinical experience and multiple published clinical guidelines.[2,3,4] Both thermal and non-thermal ablation technologies are recommended for saphenous vein treatment depending on the available expertise of the treating physician and the preference of the patient. Mechanochemical ablation is approved and is used for the treatment of superficial vein reflux involving the great and small saphenous veins (GSV, SSV), the anterior and posterior accessory saphenous veins (AASV, PASV), and long tributary vessels.[5] Because this is a non-thermal, non-tumescent ablation system, it may be used in the below-the-knee distal GSV and SSV segments where the risk of nerve injury is higher using thermal techniques.[6] ClariVein® can also be used in a retrograde approach to treat below venous ulcer beds.

Treatment Technique

ClariVein® is an infusion catheter system with an inner 360˚rotatable wire connected to a battery powered motor drive unit. Physician-controlled infusion of sclerosant is delivered through the catheter and exits via an opening at the distal end of the rotating dispersion wire. The mechanism of action involves both intimal disruption and medial vein wall injury by the rotating wire leading to vessel spasm and enabling better penetration of the liquid sclerosant to induce its cytotoxic effects.[7]

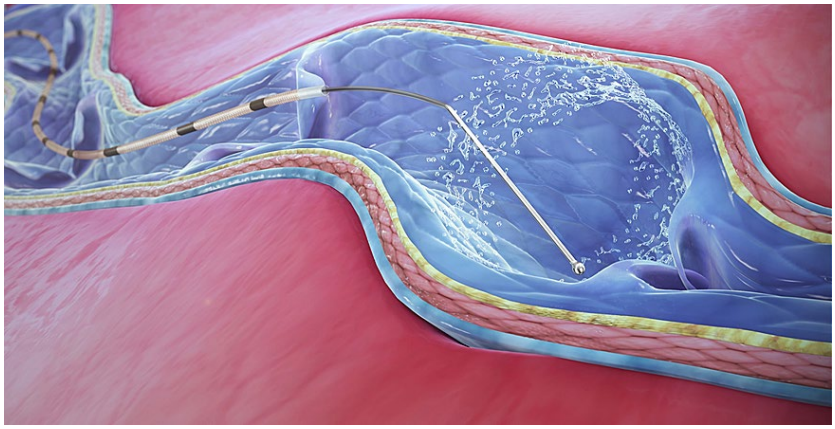

Fig 2: A drawing of the MOCA catheter tip rotating inside a model vein while the sclerosant chemical is injected from its tip.[33]

The combination of mechanical and chemical injury leads to fibrosis and obliteration of the vein lumen with better results than liquid sclerosant alone.[7] Both the rate of rotation of the dispersion wire

(2,000 – 3,500 rpm) and volume of sclerosant injection, either sodium tetradecyl sulphate or polidocanol, is physician controlled, and has not been standardized.

After injection of a local anesthetic, ultrasound-guided access into the target vein is attained. The 3 Fr catheter can be inserted through either a 4 or 5 Fr vascular sheath or an 18-gauge short peripheral catheter. According to the manufacturer's Instructions for Use, the catheter is advanced under ultrasound guidance placing the visible tip of the rotating wire 2 centimeters from the junction of the target vein and the deep vein (saphenofemoral or saphenopopliteal junctions)[8] in order to lessen the risk of ablation-related thrombus extension (ARTE).[9] After activation of the angled rotating wire, adjustable to variable speeds but most frequently used at its maximal setting of 3,500 rpm, the wire is pulled back at a rate of 1.5mm/sec (7 secs/cm) for the first centimeter, without any sclerosant being infused, in order to induce spasm of the proximal segment of the vein. After this first centimeter of pullback, the sclerosant infusion begins. The catheter is thereafter slowly pulled back at the same rate of 1.5 mm/second. Simultaneously with the withdraw, a liquid sclerosant (sodium tetradecyl sulfate or polidocanol, at the physician's discretion) is infused. The first treatment area of 10cm is checked and, if not closed, it should be re-treated.[10] The amount and concentration of sclerosing agent depends on the ultrasound assessment of the length and diameter of the vein requiring treatment. Reported concentrations used in the GSV have been of 1.5 - 2.0% liquid sodium tetradecyl sulphate and 1.5 - 3% of polidocanol, with some practitioners using higher concentrations in the proximal portion of the vein.[11-13] Average volumes of sclerosant used are 7-10 ml for the GSV and 4-6ml for SSV treatment. Sodium tetradecyl sulphate and polidocanol have different properties and are not equivalent at similar concentrations. The higher concentration of 3% polidocanol may be more effective with better early closure results.[14] Initial purging of the device should be done with sclerosant rather than saline so that a full dose of the sclerosant is injected at the beginning.[10]

Efficacy and Outcomes

Clinical efficacy data for ablation procedures performed with MOCA include both prospective and retrospective studies – some RCTs and some observational – that demonstrated early occlusion rates comparable to radiofrequency (RFA) and laser ablation (EVLA), as well as a reduction in pain (Visual Analog Scale), symptomology (Venous Clinical Severity Score, VCSS), and days until return to normal function return to work.[15-17] Systematic literature reviews have been performed.[6,18] Because it is minimally invasive, performed under local anesthesia and requires only a small incision for the catheter insertion, it results in less pain and a quicker recovery period compared to surgical stripping.[19]

The initial pivotal trial of thirty GSVs documented a primary closure rate of 97% at six months.[20] A subsequent randomized, controlled trial of GSV treatment in 119 limbs demonstrated similar occlusion rates, less intra-procedural pain, equivalent improvement in clinical and patient-reported quality of life measures at one month, and a faster return-to work, with MOCA as compared to RFA.[21] Reflecting no need for the additional injections of tumescent anesthesia as needed with thermal ablation techniques, similarly decreased levels of procedural pain with MOCA was found when compared in a blinded fashion with EVLA.[22] A prospective multicenter randomized clinical trial of 167 patients directly compared non-tumescent ablation techniques of MOCA and endovenous cyanoacrylate closure (CAC) of the GSV and SSV.[11] Both groups demonstrated significant and comparable improvement in pain severity, generic and disease-specific quality of life scores, and vein occlusion rates at one year. This indicates that the decreased procedural pain scores are due to the avoidance of the injections of tumescent anesthetic and endovenous thermal application.

Ozen et al reported on the 2-year results for MOCA treatment of the refluxing great saphenous vein with a vein closure rate of 95% and a significant decrease in the physician derived VCSS score.[23] In a larger multicenter prospective randomized controlled trial of 231 patients comparing MOCA with radiofrequency, the 2-year outcomes were lower with an 80% occlusion rate for MOCA as compared to 88% with RFA.[13] A randomized study was performed to compare MOCA with endovenous laser ablation and radiofrequency ablation for great saphenous vein insufficiency in combination with

phlebectomy. At 3 years, the occlusion rate was significantly lower with MOCA than with either EVLA or RFA (82% vs 100%).[24] Quality of life was similar between the groups. In the MOCA group, GSVs that were larger than 7 mm in diameter preoperatively were more likely to recanalize during the follow-up period with only 75% occlusion at 3 years.[24] Another prospective study, however, did not find this correlation with vein diameter.[10] Similarly, a recent meta-analysis restricted to randomized controlled trials comparing MOCA to RFA and EVLA, showed significantly lower occlusion rates with MOCA at 1, 2 and 3 years while they had similar procedural pain and clinical outcomes.[12] Anatomical success has been found to progressively deteriorate after the first year and by five years had decreased to 81% due to recanalization.[10] The odds of recanalization (partial or complete) after treatment with MOCA are higher than after treatment with either RFA or EVLA.[25] Recent five year results from the prospective LAMA trial similarly showed significantly lower anatomical occlusion rates compared to laser ablation, 47% versus 91%, respectively.[26] In addition, At five years, Lim et al reported 21% reintervention for symptomatic clinical recurrence for MOCA as compare to 8% for EVLA.[26] There has been only one prospective trial directly comparing vein closure rates between non-tumescent ablation techniques of MOCA versus cyanoacrylate adhesive (CAC).[11] The vein closure rates at one year were 89% and 91% for MOCA and CAC, respectively. However, the reported 5 year vein closure rate for CAC is higher at 91% [27] as compared to the 81% for MOCA. Successful treatment with MOCA of the small saphenous vein (SSV) has also been reported without any major complications and a 93% one year occlusion rate.[28] Three or five year follow-up results have not been reported for use of MOCA in the SSV.

Although short-term results within the first year were promising, long-term durability at two, three and five years indicates that mechanical occlusion chemically assisted ablation are inferior to other endovenous treatments in terms of maintenance of vein occlusion. However, European practice guidelines state that MOCA is a reasonable alternative and may be considered for patients preferring non-thermal non-tumescent treatment, even if the occlusion rates are inferior to that of thermal

ablation (recommendation Class IIb - usefulness/efficacy is less well established by evidence/opinion; Level of evidence A - data derived from multiple randomized

clinical trials or meta-analyses).[4] Similarly, American recommendations do not indicate a preference between thermal and non-thermal procedures (Strong recommendation with moderate evidence).[2,9] However, it is worth noting that both of these clinical guidelines were reported before the five year results of MOCA were published. Therefore, because of the associated successful symptom relief, this treatment modality may be useful in selected patients.

Adverse Events

The MOCA procedure has a low risk of complications when performed by physicians trained and experienced with performing minimally invasive endovenous interventions. This approach has been associated with a reduced risk of complications compared to traditional surgical saphenous vein ligation and stripping.[19] Similarly, as a non-thermal non-tumescent intervention, the risk of nerve injury and skin burns are lower compared to RFA and EVLA and less than 0.2% with MOCA.[12,16,24,29,] Furthermore, as an endovenous occlusion procedure, no major differences are expected in the incidence of superficial thrombophlebitis or DVT as compared to other procedures.[12] Complications that do occur are generally mild, transient and include temporary discomfort, skin discoloration, and bruising at the injection site (Table).[17] A phenomenon specific to the MOCA procedure is when the rotating wire “snags” on the vein wall at a tributary branch or at valve cusps and causes pain. This is more likely in smaller caliber veins or veins in spasm.Therefore, MOCA is not well suited for veins with prior thrombus or recanalization/synechiae because of risk of snagging. Should snagging occur, the rotational motor should be shut off and the catheter jerked to free the wire tip. If it does not easily loosen, the procedure should be stopped and the wire and sheath removed.[30]

Complication	Incidence
Hyperpigmentation	7-27%
Superficial thrombophlebitis	4- 9%
Ecchymosis	2-10%
Skin Infection	1-4%
Hematoma	0-24%
Deep venous thrombosis / ARTE	0 - 2.7%
Pulmonary embolism	0 – 0.5%

CONCLUSIONS and RECOMMENDATIONS

Mechanical occlusion chemically assisted venous ablation is effective in alleviating symptoms and a safe treatment option for venous insufficiency. As a non-thermal ablation method, MOCA obviates the need for tumescent anesthesia and thus results in less procedural discomfort and risk of thermal nerve or skin injury. It may be used in both the below knee distal GSV as well as the SSV with no risk of thermal injury to the adjacent nerves. However, it is associated with significantly lower rates of vessel closure and higher recanalization rates when followed for more than one year compared to both RFA and EVLA. It is also less cost effective than thermal techniques. [27,31] It is an available option for those in whom thermal ablation is not suitable.[32]

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