

Mechanochemical endovenous ablation for the treatment of great saphenous vein insufficiency

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Objective: This study evaluated the feasibility, safety, and 1-year results of mechanochemical endovenous ablation (MOCA) of great saphenous vein (GSV) insufficiency.

Methods: A consecutive 106 patients were treated for primary GSV insufficiency with MOCA by the ClariVein device and polidocanol. The primary outcome measures were technical success, clinical success, and anatomic success after 1 year of follow-up. Secondary outcome measures were postprocedural pain, complications, general- and disease-specific quality of life, and time to return to work. Patients were evaluated with clinical examination and duplex ultrasonography at 6 weeks, 6 months, and 1 year after treatment.

Results: The technical success was 99%. The mean postprocedural pain during the first 14 days after treatment was 7.5 mm (interquartile range [IQR], 0.0-10.0 mm) per day on a 0- to 100-mm visual analog scale. The time to return to normal activities and work was 1.0 day (IQR, 0-1.0 day) and

1.0 day (IQR, 1.0-4.0 days), respectively. No major complications were recorded. At 1-year follow-up, the clinical success was 93%. The Venous Clinical Severity Score decreased significantly from 4.0 (IQR, 3.0-5.0) before treatment to 1.0 (IQR, 0-1.0) ($P < .001$) 1 year after MOCA. At 1 year, 88.2% of the treated GSVs remained occluded as measured by duplex ultrasonography. Twelve patients had a recanalization, of which eight were partial. Disease-specific quality of life and the RAND 36-Item Health Survey scores improved significantly at 1-year follow-up.

Conclusions: MOCA is a safe and effective technique in the treatment of GSV insufficiency with good clinical and anatomic success at 1-year follow-up. The technique is related to low postprocedural pain scores, low complication rate, improved quality of life, and rapid resumption of normal activities and work. (J Vasc Surg: Venous and Lym Dis 2014;2:282-8.)

Varicose veins are a widespread medical condition. In Western countries, the reported prevalence of varicose veins ranges from 20% in men to more than 25% in women.¹ The majority of patients with primary varicose veins have great saphenous vein (GSV) insufficiency. In past decades, the introduction of minimally invasive procedures considerably changed the treatment of GSV insufficiency. Randomized trials showed that endovenous treatment modalities are superior to traditional cross-section and stripping of the GSV in terms of reduced postprocedural pain, better quality of life, and faster recovery.²⁻⁵ Because of those clinical benefits, the Society for Vascular Surgery and the American Venous Forum have recommended endovenous treatment over standard surgery.⁶

Mechanochemical endovenous ablation (MOCA) is a new technique for the treatment of varicose veins that

combines mechanical damage to the venous endothelium with the infusion of a liquid sclerosant. In contrast to endothermal techniques, including endovenous laser ablation (EVLA) and radiofrequency ablation (RFA), the instillation of tumescence anesthesia is unnecessary, as heating of the vein is avoided. Studies have demonstrated that MOCA is a safe and feasible technique, with excellent short-term results.⁷⁻⁹ Moreover, MOCA was associated with lower postprocedural pain and faster recovery compared with RFA, most likely owing to the avoidance of heat-related complications.¹⁰ To date, no midterm results of MOCA with more than 100 patients are published. The aim of this study was to evaluate the 1-year results of MOCA in patients with GSV insufficiency.

METHODS

Consecutive patients referred for varicose vein treatment and diagnosed with GSV insufficiency were offered participation in this study and were included after signing the informed consent form. Patients who did not want to participate in this study were routinely offered RFA. All patients had primary GSV incompetence, as demonstrated by duplex ultrasonography performed by certified vascular practitioners. Reflux was defined as retrograde flow of ≥ 0.5 second after calf compression measured in a standing position. Patients were treated in Rijnstate Hospital, Arnhem, and in the St. Antonius Hospital, Nieuwegein, The Netherlands, by three experienced surgeons who had performed more than 50 MOCA procedures.

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Eligibility criteria were age older than 18 years, C2 to C6 varicose veins, GSV diameter of 3 to 12 mm, and primary GSV incompetence. Exclusion criteria included pregnancy and lactation, use of anticoagulants, previous surgical treatment of the target varicose vein, history of deep venous thrombosis, coagulation disorders, severe renal or liver insufficiency, and allergy to polidocanol.

The regional medical ethics committee approved this prospective observational study, and the trial was registered under number NCT01459263 (Clinicaltrials.gov).

Treatment. MOCA was performed under local anesthesia by a specialized team consisting of a vascular surgeon and vascular diagnostics technician. Patients were treated on an outpatient basis in daily care. No sedation or antibiotics were given. The GSV diameter just below the saphenofemoral junction was measured in the supine position with duplex ultrasound.

MOCA was performed with the ClariVein catheter (Vascular Insights, Madison, Conn), as described previously.⁷ Briefly, 2 mL of local anesthesia (lidocaine) was applied at the puncture site. By a Seldinger technique, a 4F introducer sheath was introduced into the GSV, and the ClariVein catheter was positioned with the tip of the dispersion wire 1.5 cm distal of the saphenofemoral junction under ultrasound guidance. After proper positioning of the tip, the wire was activated for a few seconds to induce spasm of the proximal vein. Then, the activated catheter with rotating tip was steadily withdrawn at 1 cm every 7 seconds, dispersing liquid polidocanol (Aethoxsclerol; Kreussler Pharma, Wiesbaden, Germany) to the damaged vein wall simultaneously. The proximal 10 cm was treated with 2 mL of polidocanol 2% and the remaining vein with polidocanol 1.5%. The total amount of liquid sclerosant used was determined by the length of the GSV and the patient's weight before treatment and monitored during the procedure.

After the procedure, patients were discharged with a compression stocking (30-40 mm Hg) continuously for the first 24 hours and during the daytime for the next 2 weeks. During the treatment, no concomitant phlebectomies or sclerotherapy was performed. Patients were instructed to use analgesics only when postprocedural pain was experienced. No standard use of analgesics was advised after the procedure.

Assessment. Patients were examined during the outpatient visit by a vascular surgeon, who recorded their Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) classification¹¹ and Venous Clinical Severity Score (VCSS).¹² Before the procedure, patients were asked to complete the RAND 36-Item Health Survey (RAND-36)¹³ and Dutch-translated Aberdeen Varicose Vein Questionnaire (AVVQ)¹⁴ to observe the general and disease-specific quality of life, respectively. The Dutch version of RAND-36 covers health status in eight dimensions: physical functioning, social functioning, role limitations due to physical health problems and emotional problems, general mental health, vitality, bodily pain, and general health perceptions. It also includes a single item

that provides an indication of perceived changes in health. A high score indicates good health status.

After the procedure, patients were instructed to complete a 14-day diary card to record the level of pain on the 100-mm visual analog scale (VAS). On the diary card, patients were also asked to provide information about returning to normal activities, and the amount of analgesics used was recorded. Patients were examined at 6 weeks, 6 months, and 1 year after the procedure, and duplex ultrasonography was performed. RAND-36 and AVVQ were completed again, and VCSS was registered by a vascular surgeon. Patients with C3 to C5 disease were not advised to wear compression stockings continuously after successful treatment.

Outcome. The primary outcome measures were (1) anatomic success, defined as occlusion of the treated vein; (2) clinical success, defined as an improvement in VCSS; and (3) technical success, defined as the ability to perform the procedure as planned without any technical problems. Failure of treatment was defined as a recanalized segment of more than 10 cm of the treated GSV.³ Secondary outcome measures included postprocedural pain, postprocedural complications, general and disease-specific quality of life, and time to return to work. Postprocedural complications were defined as any complication related to the endovenous treatment.

Statistical analysis. Variables are presented in means \pm standard deviation, if distributed parametrically, or as median with interquartile range (IQR, 25th to 75th percentiles), if distributed nonparametrically. We used a repeated-measures analysis of variance (including post hoc Bonferroni correction) to evaluate differences in scores of the AVVQ, RAND-36, and VCSS before and after treatment. Analysis of postoperative pain was also performed by repeated-measurements design. Two-sided significance was set at $P < .05$.

Statistical analyses were performed with SPSS 17.0 software (SPSS Inc, Chicago, Ill). All analyses were supervised by a statistician.

RESULTS

Between December 2010 and November 2011, 92 patients (106 legs) were treated with MOCA. Patients with bilateral GSV insufficiency were treated with an interval of a minimum of 4 weeks. One procedure was terminated because of leakage of sclerosant through the ClariVein handle, and treatment was converted to RFA. The technical success rate was 99% (105 of 106). Baseline characteristics and technical data are reported in [Table 1](#). The average total procedure time, from puncturing of the vein to applying of compression stockings, was 11 minutes. At 6 months and 1 year, respectively, two and three patients were lost to follow-up. All patients lost to follow-up were contacted by phone. The reason not to present was due to lack of complaints.

Procedural pain, postprocedural pain, and return to normal activities. The median pain score during the procedure was 20 mm (IQR, 10-30 mm) on a 0- to 100-mm

Table I. Patient characteristics and technical data

	MOCA (n = 105)
Age, years	51.8 ± 14.9
Sex	
Male	30 (33)
Female	62 (67)
Bilateral	13
Body mass index	26.2 (23.3-29.7)
CEAP	
C1	1 (1)
C2	36 (34)
C3	35 (33)
C4	31 (30)
C5	2 (2)
AVVQ score	11.1 (8.0-19.2)
VCSS	4 (3-5)
GSV diameter, mm	5.5 (5.0-7.0)
Length of vein ablated, cm	45.0 (39.0-50.3)
Time of procedure, minutes	11.0 (9.0-13.5)
Pain during treatment, 0- to 100-mm VAS	20 (10-30)
Amount of polidocanol, mg	126 (115-130)

AVVQ, Aberdeen Varicose Vein Questionnaire; CEAP, Clinical, Etiologic, Anatomic, and Pathophysiologic classification; GSV, great saphenous vein; IQR, interquartile range; MOCA, mechanochemical endovenous ablation; SD, standard deviation; VAS, visual analog scale; VCSS, Venous Clinical Severity Score.

Continuous data are presented as mean ± SD or median (IQR) and categorical data as number (%).

VAS. Fig 1 shows the trend of postprocedural pain during the first two postoperative weeks. The median postprocedural pain during the first 14 days after treatment was 7.5 mm (IQR, 0.0-10.0 mm) per day on a 0- to 100-mm VAS. Information about the number of days on which patients used analgesics (mostly paracetamol or ibuprofen) was available in 75 patients (71%). The median number of days that analgesics were used was 0 days (IQR, 0.0-1.0 days).

The median time to return to normal activities was 1.0 day (IQR, 0.0-1.0 day), and the time to return to work for employees was 1.0 day (IQR, 1.0-4.0 days).

Complications. No major complications were observed. Importantly, deep venous thrombosis, saphenous nerve neuralgia, and skin necrosis did not occur. Minor complications included superficial thrombophlebitis (3%), induration along the course of the treated GSV (12%), localized hematoma (9%), and mild hyperpigmentation at the puncture site (5%). No permanent hyperpigmentation was observed after 1 year of follow-up. At 6-month and 1-year follow-up, no additional complications were recorded.

Anatomic success. Directly after MOCA, all treated GSVs were obliterated. At 6 months, 96 of 103 treated GSVs were obliterated (93.2%). At 1 year, 90 of 102 GSVs remained obliterated, rendering the 1-year anatomic success rate 88.2%. Failure of treatment in 12 patients consisted of 4 patients with a complete recanalization of the treated GSV and 8 patients with a partial (segmental) recanalization. The mean length of the recanalized segment in patients with a partial recanalization

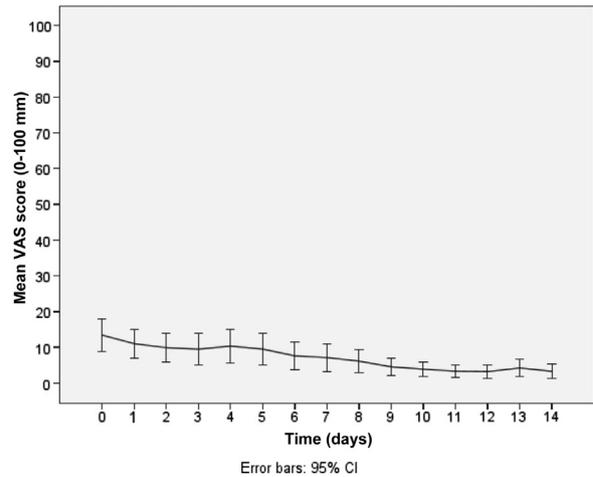


Fig 1. Mean postoperative pain scores on a 0- to 100-mm visual analog scale (VAS) for 14 days after mechanochemical endovenous ablation (MOCA). CI, Confidence interval.

was 21.0 cm (IQR, 14.3-40.8 cm). Vein diameter was not associated with increased risk of recanalization ($P = .17$). One patient with an open GSV was diagnosed with autoimmune thrombocytopenia a year after treatment and was re-treated with RFA.

Clinical outcome. At 1-year follow-up, the clinical success was 93% (86 of 92) (Fig 2). The mean VCSS significantly decreased at 6-month follow-up from 4.0 (IQR, 3.0-5.0) to 1.0 (IQR, 0-2.0) ($P < .001$). One year after treatment, VCSS was 1.0 (IQR, 0-1.0), which was significantly lower compared with the preprocedural score ($P < .001$). In patients with failure of treatment, the VCSS at 1 year was also significantly decreased from 4.0 (IQR, 3.0-6.0) to 1.0 (1.0-1.0) ($P < .001$). The change in VCSS between patients with failure of treatment and occlusion of the treated GSV was nonsignificant ($P = .47$). Although VCSS was improved in most patients, VCSS deteriorated in two patients (Fig 2). One of those patients had a recanalized GSV. The other patient decided to wear compression stockings continuously, but the VCSS deteriorated. No patients developed ulcers in follow-up.

During follow-up, 23 of 105 legs (22%) were treated with adjunctive therapy. Sclerotherapy and ultrasound foam sclerosis were used to treat reticular veins in, respectively, 19 and 2 legs. Ultrasound foam sclerosis was also used for treatment of a partial recanalized GSV in one patient and treatment of the GSV below the knee in one patient.

Quality of life. The mean AVVQ score improved significantly after 6 months from 6.6 (IQR, 4.0-11.0) at baseline to 11.1 (IQR, 8.0-19.2) ($P < .001$). One year after treatment, the AVVQ score was 2.4 (IQR, 0.5-6.2), which was significantly lower than the preprocedural score ($P < .001$). The absolute improvement in AVVQ score is shown in Fig 2.

In almost all physical domains of RAND-36, there was a significant improvement 12 months after MOCA

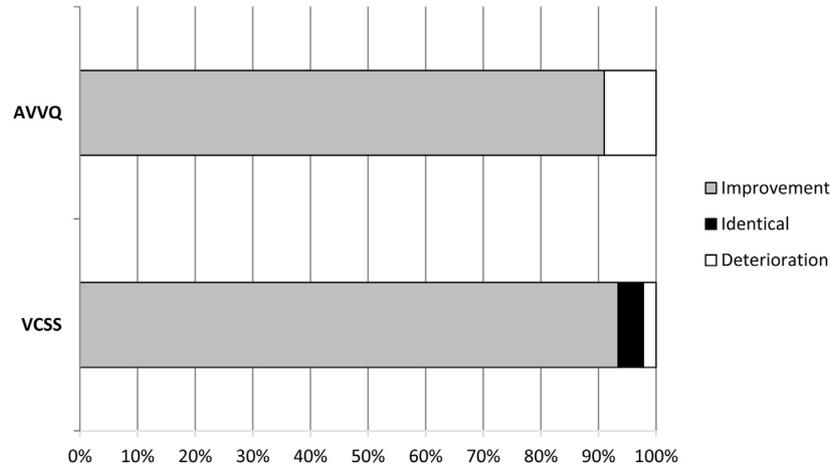


Fig 2. The impact of mechanochemical endovenous ablation (MOCA) on the Venous Clinical Severity Score (VCSS) and Aberdeen Varicose Vein Questionnaire (AVVQ) 12 months after treatment.

compared with baseline (Table II). Improvement was also seen in perceived change of health. The greatest improvement was seen in the domain of bodily pain.

DISCUSSION

Given the high success rates of current endovenous ablation techniques, the aim of new techniques is focused on the establishment of a more tolerable, less painful, but still highly effective treatment. MOCA is a recently developed technique that combines mechanical damage of the venous endothelium with the infusion of a liquid sclerosant. This is the first study with more than 100 patients describing 1-year outcome of MOCA in the treatment of GSV insufficiency. At 1 year, the anatomic success, measured by duplex ultrasonography, was 88.2%.

Results from this have shown that MOCA is a highly effective method, considering the clinical outcome of patients. The clinical disease severity, measured as VCSS, was significantly improved at 6 and 12 months. Moreover, the disease-specific quality of life, measured by the AVVQ, improved significantly 1 year after treatment. In addition, an improvement in almost all domains of the general quality of life questionnaire, the RAND-36, was observed

1 year after MOCA. These data emphasize the impact of venous disease on the quality of life of the patient. Whether these clinical outcomes are better than those with EVLA and RFA has to be evaluated in a comparative study. At present, comparison of clinical outcome would be misleading because outcome parameters are defined in various ways in the literature.

Since the introduction of EVLA in 1999, the treatment of varicose vein incompetence has changed dramatically.¹⁵ Several randomized trials showed the superiority of endovenous procedures to conventional surgery in terms of postprocedural pain and complications.^{2-5,16} Therefore, high ligation of the saphenofemoral junction, with or without surgical stripping of the GSV, has almost been abandoned from surgical practice. A randomized study comparing EVLA, RFA, ultrasound-guided foam sclerotherapy (UGFS), and surgical stripping reported 1-year success rates of 94.2%, 95.2%, 83.7%, and 95.2%, respectively.³ In our study, anatomic success of MOCA measured by duplex ultrasonography at 6 months was 93.2% in 103 patients. After 1 year, 88.2% of the treated veins (90 of 102) remained occluded. These 1-year occlusion rates may be lower compared with those of endothermal

Table II. Median (IQR) health status scores for patients before and 6 and 12 months after treatment with MOCA (RAND-36)

	Preprocedural status	6 months	12 months	P value
Physical functioning	90 (75-100)	100 (89-100)	100 (87-100)	.02
Social functioning	100 (84-100)	100 (88-100)	100 (88-100)	.14
Role—physical	100 (75-100)	100 (100-100)	100 (100-100)	.02
Role—emotional	100 (100-100)	100 (100-100)	100 (100-100)	.15
Mental health	84 (72-92)	84 (76-92)	88 (76-92)	.52
Vitality	70 (60-80)	80 (63-88)	75 (60-85)	.45
Bodily pain	80 (67-94)	100 (80-100)	100 (80-100)	.003
Health perception	70 (55-90)	75 (60-95)	73 (60-85)	.64
Health change	50 (50-50)	50 (50-75)	50 (50-50)	.009

IQR, Interquartile range; MOCA, mechanochemical endovenous ablation; RAND-36, RAND 36-Item Health Survey.

techniques. However, the previously shown lowered post-procedural pain and the earlier resumption of normal activities and work might justify this possible difference.⁹ Randomized controlled clinical trials, such as the ongoing MOCA Versus RFA in the Treatment of Primary Great Saphenous Varicose Veins (MARADONA) trial (NCT01936168), will finalize the answer on 1-year outcome of both techniques.¹⁷

Our results at 6-month follow-up are consistent with those of other studies evaluating MOCA. Elias and Raines⁸ showed an excellent success rate at 6 months of 96.7% (29 of 30) in the first human study. Another multicenter study evaluating results of 126 patients reported 6-month success rate of 94%.¹⁸ However, the success rate after 1 year decreased from 93.2% to 88.2%. This phenomenon is also seen with other endovenous modalities, such as RFA and UGFS.¹⁹ It is likely that recurrences will vary among different endovenous procedures as recanalization is the mechanism by which recurrence develops. However, in a recent publication of the first human MOCA study, the success rate of 96.4% (27 of 28) remained equal at 2 years of follow-up.²⁰

Interestingly, we found no difference in clinical outcome between patients with a successful treatment and those with failure of treatment. As eight patients (of 12 patients with failure of treatment) had a partial recanalization, which resulted in improvement of VCSS, the most common explanation is that a segmental occlusion of the GSV also results in decrease of VCSS and patient complaints. One patient with a complete recanalization of the treated GSV had deterioration of VCSS after 1 year and was re-treated with RFA. This patient was diagnosed with autoimmune thrombocytopenia. Hypothetically, patients with autoimmune thrombocytopenia have low levels of platelets, which can impair clot formation in the MOCA-treated GSV.

Combining adjunctive therapies, such as sclerotherapy or phlebectomies, with primary treatment of GSV reflux has been conducted in several studies.^{3,21,22} The ability to resolve varicose veins in one stage, leading to good cosmetic outcome, benefits a combined approach. We considered that one of the advantages of MOCA is that the sclerosant enters branch varicosities in the area of the treated GSV, which do not have to be treated with adjunctive therapy. Moreover, many branch varicosities diminish in size or resolve completely once GSV reflux has been eliminated.²³ No adjunctive procedures were performed in this study. After GSV ablation, adjunctive procedures up to 50% are necessary for satisfactory results to be obtained in patients with varicose veins.²³⁻²⁵ At 1-year follow-up, only 22% of the patients were adjunctively treated with sclerotherapy or UGFS. However, long-term follow-up is needed to observe the additional effect of MOCA on branch varicosities as they can increase in time.

In most studies evaluating results of MOCA, sodium tetradecyl sulfate (Sotradecol) was used as the sclerosant to treat the vein. In this study, polidocanol was used as

this is the only registered sclerosant available in The Netherlands. Contraindications to treatment with a sclerosant are a known allergy, pregnancy or lactation, immobility, coagulation disorders or increased risk of thromboembolic complications, use of anticoagulants, and severe renal insufficiency. Studies with use of foam have shown that endothelial cell loss and damage to the media are significantly greater with sodium tetradecyl sulfate compared with polidocanol.²⁶ We used 2 mL of polidocanol 2% to treat the proximal 10 cm of the GSV and polidocanol 1.5% for the remaining segment of the vein. Although a higher concentration of polidocanol was used in the proximal GSV, all the partial recanalizations were seen in the proximal segment. Whereas partial recanalizations can finally result in an open and recurrent GSV, treatment of the proximal GSV is essential for long-term success. Therefore, the authors suggest the use of 2 mL of polidocanol 3% in the proximal segment of the GSV to optimize outcome of MOCA. This statement is supported by the results of a previous study of our group.⁹ In this observational study of 50 patients with short saphenous vein insufficiency, anatomic success after MOCA at 1 year was 94%. Interestingly, a difference in anatomic success of, respectively, 87% and 97% was seen between patients treated with polidocanol 1.5% and polidocanol 2%.

Mechanical damage of the endothelial vein wall is a crucial component of MOCA. Treatment of GSV insufficiency with only a liquid sclerosant results in a disappointing outcome. In a meta-analysis, anatomic success of liquid sclerotherapy was 39.5% vs 76.8% for UGFS.²⁷ An *ex vivo* histologic study evaluated the effect of mechanical damage of the ClariVein system.²⁸ Only the mechanical portion causes subtle, incomplete destruction of the endothelium without damage to the media and adventitia. Moreover, adding mechanical balloon catheter injury to standard UGFS increases endothelial cell loss.²⁹ As endothelial cell loss is incomplete after liquid sclerotherapy and residual islands of endothelium may cause recanalization, both components of MOCA could lead to the desired complete destruction of the venous endothelium.²⁰ Further *in vivo* studies are needed to evaluate the impact of MOCA on endothelial cell loss.

Serious complications, such as pulmonary embolism, deep venous thrombosis, nerve injury, and skin burns, are uncommon with all endovenous treatment modalities for varicose veins,³⁰ although the nature of different techniques can cause specific complications. Endothermal techniques depend on heat to obliterate the vein and require tumescence anesthesia. Segmental RFA causes venous closure by venous wall denaturation at 120°C, whereas EVLA causes thrombotic occlusion with temperatures of 1200°C to 1400°C at the tip.^{31,32} Perforation of veins and heating of surrounding tissue are thought to be associated with hematoma and prolonged postprocedural pain. Significantly less postprocedural pain was reported after MOCA compared with RFA.¹⁰ The postprocedural pain scores in this study were also considerably low and mirror results in previous MOCA studies.^{7,10} No standard

analgesics were advised after MOCA. This advice can probably influence the perception of postprocedural pain.

Return to normal activities and work is influenced negatively by postprocedural pain. The median time to return to normal activities and work was 1.0 day in this study, which is very low compared with the results of Rasmussen.³ Time to resume work was 3.6, 2.9, 2.9, and 4.3 days for, respectively, EVLA, RFA, UGFS, and surgical stripping. The potential implications on societal costs should be emphasized in considering optimized endovenous treatment for varicose veins. Those costs were not assessed in this study but require further attention. Localized hematoma were seen in 9% of the treated patients. This finding may be explained by the mechanical catheter, which tears out a valve, leading to injury of the vein wall and a localized hematoma around the vessel.

A consideration of this study is that MOCA with the ClariVein system is a first-generation technique. Adaptation of the technique based on clinical studies and histologic experiments must lead toward a standard and optimized protocol to treat varicose veins. Recommendations on optimizing MOCA, learned from personal experiences, are summarized by Elias et al.²⁰ Second, the initial learning curve to acquire competency is not yet determined for MOCA. Assessment of the learning curve was not an objective of this study, but it is important in adopting a novel endovenous technique.

CONCLUSIONS

MOCA is a safe and effective technique in the treatment of GSV insufficiency with good clinical and anatomic success at 1-year follow-up. The technique is related to low postoperative pain scores, low complication rate, improved quality of life, and rapid resumption of normal activities and work. Randomized studies and long-term follow-up studies are needed to compare the long-term success of MOCA with other endovenous techniques.

AUTHOR CONTRIBUTIONS

Conception and design: RE, DB, JV, MR

Analysis and interpretation: RE, SH, MR

Data collection: RE, SH, DW

Writing the article: RE

Critical revision of the article: RE, DB, SH, DW, JV, MR

Final approval of the article: RE, DB, SH, DW, JV, MR

Statistical analysis: RE, SH

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Overall responsibility: MR

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