Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins

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Objective: **Thermal ablative techniques of varicose veins carry a risk of heat-related complications, including postoperative pain. Mechanochemical endovenous ablation (MOCA) might avoid these complications and reduce postoperative pain because of the absence of thermal energy. This study evaluated postoperative pain and quality of life after radiofrequency ablation (RFA) and MOCA for great saphenous vein (GSV) incompetence.**

Methods: **Sixty-eight patients with unilateral GSV incompetence were treated with either RFA or MOCA in this prospective observational study. Patients monitored their pain for the first 14 postoperative days on a 100-mm visual analog scale (VAS). They also completed the general (RAND 36-Item Short-Form Health Survey) and disease-specific (Aberdeen Varicose Vein Questionnaire) quality of life questionnaires before and 6 weeks after treatment.**

Results: **Patients treated with MOCA reported significantly less postoperative pain than patients treated with RFA during the first 14 days after treatment (4.8 ± 9.7 mm vs 18.6 ± 17.0 mm; $P < .001$) (mean VAS over 14 days). The lower postoperative pain score was associated with a significantly earlier return to normal activities (1.2 ± 1.8 vs 2.4 ± 2.8 days; $P = .02$) and work resumption (3.3 ± 4.7 vs 5.6 ± 5.8 days, respectively; $P = .02$). At 6 weeks, patients in both groups perceived an improved change in health status and an improved disease-specific quality of life.**

Conclusions: **MOCA is associated with significantly less postoperative pain, faster recovery, and earlier work resumption compared with RFA in the treatment of GSV incompetence. MOCA and RFA are both related to a rapid improvement in quality of life. (J Vasc Surg 2013;57:445-50.)**

Varicose veins are a common medical problem with overall prevalence of 20% to 60%.[1] Chronic venous insufficiency may have a major effect on patients' health-related quality of life in advanced stages of disease, leading to significant costs in total health care resources.[2,3] With occlusion rates over 90%, as reported for endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) in prospective trials,[4-6] more emphasis is placed on secondary outcome measures, such as postoperative pain, complications, quality of life, and return to normal activities. Randomized studies have reported significantly lower postoperative pain after RFA compared with EVLA.[7,8] These studies, however, may have been biased by the choice of wavelengths and a difference in the fibers used.

Mechanochemical endovenous ablation (MOCA) is a recently introduced treatment that combines mechanical damage of the venous intimal layer with the dispersion of a liquid sclerosant. The use of tumescent anesthesia is not necessary because no heat is used. The first studies of this technique have shown that MOCA is a safe and feasible method for treating great saphenous vein (GSV) incompetence with promising short-term results.[9,10] Because heat is not used as the mechanism of action, the risk of heat-related complications, including postoperative pain is considered to be lower. The present study assessed the postoperative pain and quality of life in patients treated with RFA or MOCA.

METHODS

Patients. The study included 68 consecutive patients, treated between January and December 2011 with RFA or MOCA. All were diagnosed with unilateral symptomatic GSV incompetence, and were treated in the Rijnstate Hospital, Arnhem, The Netherlands. Patients treated with MOCA were also included in a prospective registry study (NCT01459263 at clinical.trials.gov). The regional medical ethics committee approved the study. Patients were included after signing the informed consent form in this prospective observational trial. Patients, who did not want to be treated with MOCA, were routinely offered treatment with RFA. All patients had primary GSV incompetence, as demonstrated by duplex imaging, performed by two certified vascular practitioners. Reflux was defined as a

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retrograde flow of ≥0.5 seconds after calf compression measured with the patient upright.

Eligibility criteria were age over 18 years, C_2 to C_6 varicose veins and primary GSV incompetence. Exclusion criteria included pregnancy and lactation, the use of anticoagulants, previous surgical treatment of varicose veins or history of deep venous thrombosis. Allergy to polidocanol was a contra-indication for MOCA.

Treatment. Both treatments were performed under local anesthesia by a specialized team consisting of a vascular surgeon and vascular practitioner. Patients were treated as outpatients in daily care. No sedation or antibiotics were given.

MOCA was performed using the ClariVein catheter (Vascular Insights, Madison, Wisc), as previously described.[9] Briefly, a Seldinger technique was used to introduce a 4F introducer sheath into the GSV, and the ClariVein catheter was positioned with the tip of the dispersion wire 0.5 cm distal of the saphenofemoral junction (SFJ) under ultrasound guidance. After the tip was properly positioned, 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, simultaneously dispersing liquid polidocanol (Aethoxysklerol; Kreussler Pharma, Wiesbaden, Germany) to the damaged vein wall. The proximal 10 to 15 cm was treated with 2 mL polidocanol 2% and the remaining vein with polidocanol 1.5%. The total amount of liquid sclerosant used was determined by the diameter of the varicose vein near the SFJ and length of GSV.

In patients treated with RFA, a 6F introducer sheath was inserted in the GSV under ultrasound guidance using a Seldinger technique. Then, the VNUS ClosureFAST-catheter (VNUS Medical Technologies, Sunnyvale, Calif) was introduced with the tip of the catheter located 2 cm below the SFJ. Subsequently, tumescent anesthesia was applied using normal saline containing 1% lidocaine with epinephrine. After proper positioning of the catheter tip was confirmed, the GSV was ablated in 7 cm segments during a 20-second treatment cycle. The temperature was maintained at 120° during withdrawal of the catheter by using a feedback system at the heating source.

After the procedures, patients were discharged with instructions to wear a compression stocking (30-40 mm Hg) for 2 weeks. Patients were instructed to use analgesics only when they experienced postoperative pain. No standard analgesics were prescribed. No concomitant phlebectomies or sclerotherapy were performed. Treatment time was defined as duration of the treatment starting with puncturing the vein and ending with removal of the catheter.

Assessment. Patients were examined during the outpatient visit by a vascular surgeon, who recorded their CEAP classification[11] and Venous Clinical Severity Score (VCSS).[12] Before the procedure, patients were asked to complete the Dutch versions of the RAND-36-Item Short-Form Health Survey (RAND-36)[13] and the 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. Also included is one item that provides an indication of perceived changes in health. A high score indicates good health status.

At the end of the procedure patients marked their pain perception on a 100-mm visual analog scale (VAS). Procedural pain was defined as the amount of pain patients experienced during the procedure. Afterward patients were instructed to complete a 14-day diary card to record the level of pain on a 100-mm 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. The dosage of medication was not listed. At the 6-week follow-up, RAND-36 and AVVQ were completed again, and a vascular surgeon assessed the VCSS.

Statistical analysis. The primary end point of this study was postoperative pain. A sample size calculation was performed based on the assumption that MOCA would reduce postoperative pain during the first 3 days by 50% compared with RFA. To describe a significant difference, 34 patients were necessary in each group.

Intergroup analysis was done using the Student *t*-test or Mann-Whitney *U* test for continuous data and the χ^2 or Fisher exact test for categoric data. Variables are presented as means ± standard deviation (SD) if distributed parametrically, or as median with interquartile range (IQR, 25th to 75th percentiles) if distributed nonparametrically. Two-sided significance was set at $P < .05$. The primary end point was analyzed using the Mann-Whitney *U* test. Analysis of pain was performed using repeated measurements design. Differences in scores of the AVVQ, RAND-36, and VCSS before and at 6 weeks after treatment were tested using the Wilcoxon signed-rank test, for single group analysis. The Mann-Whitney *U* test was used to test differences in change between both groups.

Statistical analyses were performed using SPSS 15.0 software (SPSS Inc, Chicago, Ill). A statistician supervised all analyses.

RESULTS

During the study period, 68 patients (25 men, 43 women) were treated, 34 in each group, and all completed their 6-week follow-up assessment. Patients were a mean age of 58 ± 17 years. Patient characteristics are summarized in Table I. There were no significant differences between the groups regarding demographic data, CEAP classification, preoperative VCSS, and initial AVVQ. The treated GSV was significantly wider at the SFJ in the RFA group than in the MOCA group ($P = .03$). Treatment time was significantly shorter in the MOCA group ($P = .02$). No major complications occurred in either group, and there was no difference in the incidence of minor complications between the two groups (Table II).

Table I. Patient characteristics and technical data

	MOCA (n = 34)	*RFA (n = 34)*	P *value*
Age, years	57.2 ± 15.2	58.0 ± 17.8	.85[a]
Sex			
Male	12 (35%)	13 (38%)	.80[b]
Female	22 (65%)	21 (62%)	
BMI	25.6 ± 3.9	26.6 ± 4.1	.33[a]
CEAP			
C1	1 (3%)	0 (0%)	.31[b]
C2	16 (47%)	9 (26%)	
C3	8 (23.5%)	10 (30%)	
C4	8 (23.5%)	14 (41%)	
C5-6	1 (3%)	1 (3%)	
AVVQ	7.1 (5.3-9.2)	9.5 (4.5-16.4)	.17[c]
VCSS	3.0 (2.75-5.25)	4.0 (3.0-7.0)	.09[c]
GSV diameter, mm	5.7 ± 1.6	6.8 ± 2.4	.03[a]
Length of vein ablated, cm	45.3 ± 9.7	46.8 ± 10.1	.54[a]
Time of procedure, minutes	13.0 (10.0-15.0)	14.5 (12.0-17.3)	.02[c]
Procedural pain (0-100 mm VAS)	22 ± 16	27 ± 15	.16[a]
Number RFA cycles	—	7.7 ± 1.4	
Amount of polidocanol, mg	118 ± 22	—	
Total volume of polidocanol, mL	6.9 ± 1.9	—	

AVVQ, Aberdeen Varicose Vein Questionnaire; *BMI,* body mass index; *CEAP,* Clinical Etiologic Anatomical Pathophysiological classification; *GSV,* great saphenous vein; *MOCA,* mechanochemical endovenous ablation; *RFA,* radiofrequency ablation; *VAS,* visual analog scale; *VCSS,* Venous Clinical Severity Score.
[a]Student *t*-test.
[b]χ^2 test.
[c]Mann-Whitney *U* test.

Table II. Complications in the first 6 weeks after MOCA and RFA

	MOCA (n = 34)	*RFA (n = 34)*	P *value*
Major complications			
Deep venous thrombosis	0	0	
Pulmonary embolism	0	0	
Skin burn	0	0	
Minor complications			
Hematoma	2 (6%)	4 (12%)	.67[a]
Paresthesia	0	0	
Thrombophlebitis	0	2 (6%)	.49[a]
Induration	4 (12%)	8 (24%)	.20[b]
Hyperpigmentation	3 (9%)	3 (9%)	1.0[a]

MOCA, Mechanochemical endovenous ablation; *RFA,* radiofrequency ablation.
[a]Fisher exact test.
[b]χ^2 test.

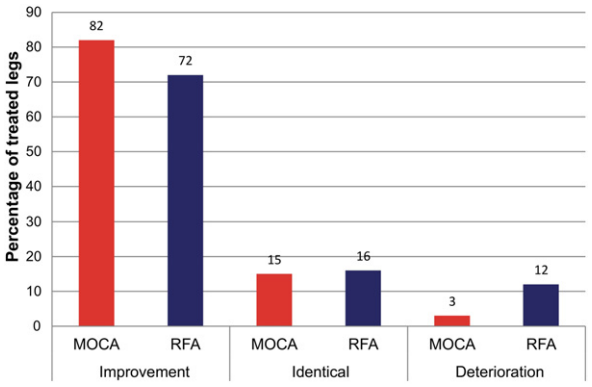

Fig 1. Assessment of the Venous Clinical Severity Score (VCSS) 6 weeks after treatment with mechanochemical endovenous ablation (*MOCA*) and radiofrequency ablation (*RFA*).

After 6 weeks, the median VCSS significantly decreased in both groups, from 3.0 (IQR, 2.75-5.25) to 1.0 (IQR, 1.0-2.0) in the MOCA group ($P < .001$) and from 4.0 (IQR, 3.0-7.0) to 3.0 (IQR, 1.25-3.75) in the RFA group ($P < .001$). VCSS improvement was similar between groups ($P = .21$). Although the VCSS improved in most patients, VCSS deteriorated in five patients at 6 weeks after treatment; one in the MOCA group and four in the RFA group (Fig 1). There were three patients with reported postoperative pain after 2 weeks, one patient with a thrombophlebitis, and one patient with induration. The median deterioration in VCSS was 1.0 (IQR, 1.0-2.0).

Postoperative pain. The mean procedural pain during treatment was 22 ± 16 mm for MOCA and 27 ± 15 mm for RFA ($P = .16$) on the 0 to 100-mm VAS. The progress of postoperative pain is shown in Fig 2. At each postoperative day, the difference between groups was statistically significant. Patients receiving MOCA reported less pain over the first 3 days, with mean pain of 6.2 ± 9.2 mm for MOCA and 20.5 ± 25.5 mm for RFA ($P = .004$). The mean postoperative pain per day during the first 14 days after treatment was 4.8 ± 9.7 mm in the MOCA group and 18.6 ± 17.0 mm in the RFA group ($P < .001$). Thrombo-

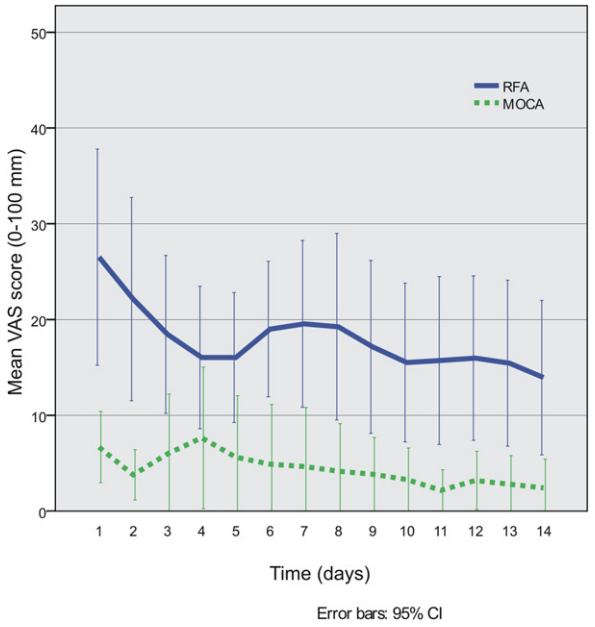

Fig 2. Mean postoperative pain scores on a 0 to 100 mm visual analogue scale for 14 days after mechanochemical endovenous ablation (*MOCA*) and radiofrequency ablation (*RFA*). *CI,* Confidence interval; *VAS,* visual analog scale.

phlebitis and induration were associated with more postoperative pain in both groups.

Information about the number of days, in which patients used analgesics (mostly paracetamol or ibuprofen), was available in 60 patients (88%). Patients in the MOCA group used postoperative analgesics for a mean of 0.5 ± 1.5 days compared with 2.8 ± 4.2 days in had significantly less days, in which postoperative analgesics were used than in the RFA group, which was a significant difference (P = .008).

Quality of life. Six weeks after treatment, the AVVQ improved significantly in both groups, from 7.1 (IQR, 5.3-9.2) to 5.0 (IQR, 3.0-8.5) in the MOCA group (P = .006) and from 9.5 (IQR, 4.5-16.4) to 4.5 (IQR, 1.5-11.2) in the RFA group (P = .002). The difference in AVVQ change between the groups was not statistically significant (P = .17).

Comparison of RAND-36 scores before and at 6 weeks after treatment with MOCA and RFA showed that health status significantly improved in two dimensions for MOCA (physical functioning and role limitations physical). For RFA there was an improvement in bodily pain after 6 weeks. No deterioration in quality of life was observed. Patients in both groups perceived an improved change in health status (Table III).

Return to normal activities. The time to return to normal activities was 1.0 day (IQR, 0-1.0) in the MOCA group and 1.0 day (IQR, 1.0-3.0) in the RFA group, which was significantly longer (P = .01). The median time to work resumption for employees was significantly shorter in the MOCA group than in the RFA group (P = .02), respectively, 1.0 days (IQR, 1.0-3.75) vs 2.0 days (IQR, 2.0-7.0).

DISCUSSION

This study has demonstrated that postoperative pain is significantly lower after MOCA compared with RFA, corresponding to a 74% reduction in pain for the first 14 postoperative days. MOCA was also associated with a significantly faster return to normal activities and work resumption.

Whereas occlusion rates over 90% are constantly reported after endovenous treatment, secondary outcome measures of treatment, such as postoperative pain, return to normal activities and health-related quality of life become more important to determine the optimal endovenous treatment for patients with varicose veins.[15,16] Several studies have analyzed postoperative pain after thermal endovenous ablation, foam sclerotherapy, and surgical stripping. Rasmussen et al reported significantly less postoperative pain in patients treated with RFA (1.21) and foam sclerotherapy (1.60) than those treated with EVLA (2.58) and surgical stripping (2.25).[16] The observed pain was presented as mean pain during the first 10 days on a 0 to 10 cm VAS. Other randomized studies also confirmed the superiority of RFA over EVLA in postoperative pain.[7,8,17] The postoperative pain in patients treated with RFA in this study is consistent with those reports. However, results of postoperative pain are difficult to compare, while outcomes of postoperative pain have been valued in various ways. Most reports on postoperative pain after varicose vein treatment use a VAS to evaluate postoperative pain, but a validation study of different pain rating scales has never been performed for this specific subject. Evidence supports the reliability and validity of most pain intensity scales.[18] The authors advocate a uniform use of outcome measures for postoperative pain.

The postoperative pain in patients treated with MOCA was consistent with our previous report. In a safety study, we found that the mean postoperative pain on the first day was 9 mm on a 0 to 100 mm VAS.[9] The score decreased to a mean of 2 mm, 7 days after MOCA. The main objective of this study was to evaluate postoperative pain and early quality of life, not to observe anatomical success. However, larger comparative studies are needed to assess the long-term efficacy of MOCA. Elias et al reported a 96.7% occlusion rate at 260 days in patients treated with MOCA.[10] The observed differences in postoperative pain in the present study may be explained by the different mechanisms of action. Heating the vein and its surrounding tissue with RFA causes endothelial denudation, collagen denaturation, and vein closure at temperatures of 120°C.[19] Perforation of veins and heating of surrounding perivenous tissue is thought to be associated with (prolonged) postoperative pain.

MOCA combines mechanical damage to the endothelium of the vein wall with the infusion of a sclerosant. The liquid sclerosant produces irreversible damage to the ve-

Table III. Median (IQR) health status scores for patients before and 6 weeks after treatment with MOCA and RFA (RAND-36)

	Preoperative status	*6 weeks*	P *value*[a]	P *value intergroup*[b]
Physical functioning				
MOCA	87.5 (71.3-100)	95 (80-100)	.02	.21
RFA	80 (57.5-95)	80 (57.5-95)	.83	
Social functioning				
MOCA	93.8 (78.1-100)	100 (75-100)	.77	.72
RFA	87.5 (62.5-100)	87.5 (75-100)	.56	
Role - physical				
MOCA	100 (50-100)	100 (100-100)	.046	.48
RFA	75 (0-100)	75 (25-100)	.875	
Role - emotional				
MOCA	100 (100-100)	100 (100-100)	.1	.46
RFA	100 (66.7-100)	100 (83.3-100)	.68	
Mental health				
MOCA	84 (70-92)	84 (68-92)	.49	.37
RFA	76 (64-90)	80 (66-90)	.88	
Vitality				
MOCA	70 (45-85)	75 (60-85)	.14	.42
RFA	65 (47.5-80)	65 (55-77.5)	.66	
Bodily pain				
MOCA	84.7 (67.3-100)	89.8 (67.4-100)	.3	.34
RFA	67.3 (39.7-79.6)	69.4 (51-89.7)	.025	
Health perception				
MOCA	70 (55-90)	75 (60-95)	.3	.89
RFA	65 (50-75)	70 (52.5-80)	.52	
Health change				
MOCA	50 (50-50)	50 (50-75)	.015	.69
RFA	50 (25-50)	50 (50-75)	.035	

IQR, Interquartile range; *MOCA,* mechanochemical endovenous ablation; *RAND-36,* RAND-36-Item Short-Form Health Survey; *RFA,* radiofrequency ablation.
[a]Wilcoxon signed-rank test.
[b]Mann-Whitney *U* test.

nous endothelium. The cellular membranes of the endothelium are damaged, creating denudation of the endothelium and endofibrosis. Finally, this causes venous obliteration and thrombus development.[20] Damage of the endothelium depends on the concentration of sclerosant. The purpose of the mechanical damage is fourfold: (1) promoting the coagulation activation by minimal mechanical damage to the endothelium, (2) inducing a vasospasm that reduces the diameter of the vein, (3) increasing the action of sclerosant by an increase in surface, and (4) ensuring an even distribution of the sclerosant at the endothelium. A recent study showed that adding mechanical balloon catheter injury to standard foam sclerotherapy increased endothelial cell loss.[21] No (in vivo) histologic studies on MOCA are to date, but the authors hypothesize that the rotating wire also increases endothelial cell loss. Moreover, endothelial cell loss and damage to the media are significantly greater with sodium tetradecyl sulfate compared with polidocanol.[22] In this study polidocanol was used as single sclerosant registered in The Netherlands.

Although the VAS was threefold lower in the MOCA group, the procedural pain was not significantly different between the groups. This may have been caused by the small sample size, because the study was powered a reduction of 50% in the postoperative course. Previous studies have not assessed procedural pain as an outcome measure. Adding tumescence anesthesia to a standard treatment, however, does not seem to contribute to a clinically relevant increase in procedural pain. In addition, tumescence anesthesia is time-consuming, as reflected by the significantly longer treatment time with RFA. In the present study, tumescence anesthesia was widely applied before the RFA treatment was initiated. Because insufficient tumescent anesthesia may contribute to increased pain, the adequacy was assessed by duplex ultrasound imaging and by controlling the temperature of the catheter on the monitor.

Patients treated with MOCA needed significantly less time to return to normal activities, and the time to resume work was also significantly shorter. The observation that patients treated with MOCA resume their work 1 day earlier than patients treated with RFA might have a significant effect on the total health care burden of varicose vein treatment. This observation urges the initiation of further randomized studies to confirm the observation.

As assessed by the RAND-36 results, the health status of patients was improved 6 weeks after MOCA in the dimensions of physical functioning and role limitations physical. This suggests that these patients perceived fewer problems with their daily physical activities, also related toward employment. Both groups, however, had a significant improvement in perceived health change. In addition, the disease-specific quality of life improved in both groups,

without differences between groups. These results regarding quality of life are in line with existing reports. However, differences in quality of life are usually observed 1 year after treatment.[16]

The present trial had some limitations. First, the study has a small population, although the expected 50% reduction in postoperative pain was achieved. Second, the study did not document other variables that can be associated with postoperative pain, such as depth of the vein from skin level, amount of tumescence fluid, quality of tumescence anesthesia, and incidence of perforation of the treated vein. The quality of tumescence anesthesia, in particular, is a complex parameter to observe, whereas we presume this parameter is the most important factor of pain after endothermal ablation. Finally, as with all nonrandomized studies, results are more susceptible to selection and measurement biases.

In conclusion, MOCA is associated with significantly less postoperative pain and a faster recovery and work resumption, compared with RFA in the treatment of great saphenous incompetence. These observations should be confirmed in a randomized controlled trial. Outcomes of postoperative pain after endovenous ablative techniques for varicose veins may be helpful for clinicians in the decision making for optimal treatment.

AUTHOR CONTRIBUTIONS

Conception and design: RE, DB, VK, JV, MR
Analysis and interpretation: RE, MR
Data collection: RE, VK
Writing the article: RE
Critical revision of the article: DB, VK, JV, MR
Final approval of the article: RE, DB, VK, JV, MR
Statistical analysis: RE
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Overall responsibility: MR

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