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ORIGINAL ARTICLE

Comparative analysis of endovenous laser ablation versus ultrasound-guided foam sclerotherapy for the treatment of venous leg ulcers

Benedikt Weber | Elias Marquart | Julia Deinsberger | Stanislava Tzaneva | Kornelia Böhler

Department of Dermatology, Medical University of Vienna, Vienna, Austria

Correspondence
Benedikt Weber, Department of Dermatology Medical University of Vienna Waehringer Guertel 18-20 1090 Vienna, Austria.
Email: benedikt.weber@meduniwien.ac.at

Abstract

Endovenous thermal and non-thermal therapeutic approaches have become standard of care for the treatment of venous insufficiency. However, comparative studies on its use in the population of venous leg ulcer patients are scarce. The present study aimed at a comparison of the efficacy of endovenous laser ablation (EVLA) and ultrasound-guided foam sclerotherapy (UGFS) for the treatment of venous leg ulcers (VUs). We retrospectively analyzed patient records of 68 patients with active VUs (C6 of the CEAP-classification), who underwent EVLA ($n = 33$) or UGFS ($n = 35$) between January 2001 and January 2021. In 68 patients, 97 venous segments (GSV: 43, SSV: 17, NSV: 37) were treated. Ulcer surface area at initial presentation did not differ significantly between both treatment groups (EVLA: 7.7 ± 10.7 vs. UGFS: 8.5 ± 16.3 cm^2; $p = 0.73$). No significant difference regarding patient characteristics was found, with the exception of age, as patients receiving UGFS treatment were significantly older (EVLA: 61 ± 17 vs. UGFS: 70 ± 14 years; $p = 0.018$). The rate of ulcer resolution was not significantly different between EVLA and UGFS groups (97.0% vs. 85.7%; $p = 0.20$). Also, the mean time to complete ulcer healing after endovenous intervention was comparable (EVLA: 59 ± 37 vs. UGFS: 63 ± 41 days; $p = 0.68$). However, the relapse rate was significantly higher for UGFS than for EVLA treated patients (31.4% vs. 3.0%; $p = 0.002$). Taken together, rates of ulcer resolution and ulcer healing time after endovenous intervention were comparable between both treatment modalities. Nevertheless, a significantly higher relapse rate was observed in UGFS treated patients.

KEYWORDS
endovascular procedures, laser therapy, sclerotherapy, venous insufficiency, venous ulcer

Benedikt Weber and Elias Marquart contributed equally to this work.

1 | INTRODUCTION

Leg ulcers due to venous insufficiency represent the main type of all leg ulcers in the western population with the global prevalence being estimated between 0.2 and 4.5 annual cases per 1000 people.[1,2] The development of venous ulcers (VUs) is attributed to venous reflux or obstruction, whereas a combination of both leads to faster progression of the disease.[3,4] However, both conditions ultimately result in ambulatory venous hypertension, subsequently activating inflammation pathways mediated by leukocytes, chemokine as well as cytokine expression, growth factors and metalloproteinases.[5] Signs and symptoms associated with chronic venous insufficiency (CVI), include heaviness, pain, edema, hyperpigmentation, eczema, atrophy blanche, lipodermatosclerosis and, eventually, ulcer formation, entailing a considerable reduction of the affected patients quality of life.[6,7] Because of the poor healing tendency of VUs, treatment remains clinically challenging, time-consuming and cost intensive.[8,9] This can be attributed to concomitant risk factors such as old age, obesity, ulcer size, long ulcer duration and insufficient adherence to compression therapy.[10,11] Treatment of VUs includes standard wound care, compression therapy, and surgical or interventional management.[12] Compression therapy is the most commonly applied treatment and has proven effective regarding ulcer healing and ulcer recurrence.[13,14] However, early surgical intervention has been associated with an improved outcome in VU patients[15] as well as a reduction in ulcer recurrence when combined with compression therapy.[16] Surgical or interventional management involves elimination of pathological epifascial reflux by endovenous thermal or non-thermal ablation, ultrasound-guided foam sclerotherapy (UGFS) or high ligation and stripping along with skin grafting of the ulcer.[17] Recently, the use of minimally invasive endovenous interventions, including endovenous laser and foam sclerotherapy, has gained increasing attention due to the lack of open surgical incisions, the possibility to be carried out under local/tumescent anaesthesia and consequently, their lower postoperative morbidity.[12,18] So far, a large series of studies has demonstrated the efficacy of thermal and non-thermal endovenous techniques in reflux elimination in patients with axial venous reflux.[19–30] However, comparative studies on the different types of endovenous treatments in patients suffering from VUs are scarce.

Therefore, the present study aimed at evaluating the treatment outcome of patients with VUs, who underwent either EVLA or UGFS of varicose veins. A particular focus was put on the time to complete ulcer healing, the relapse rate, and potential procedural complications.

2 | MATERIAL AND METHODS

2.1 | Patient recruitment and data analysis

Study approval was obtained prior to patient recruitment from the institutional ethics committee of the Medical University of Vienna (EK-Nr: 1608/2021). Patient recruitment was performed retrospectively using the internal hospital data management tool. Patients with active VUs (C6 of the CEAP-classification), who received EVLA and/or UGFS at the Department of Dermatology, Medical University of Vienna, between January 2001 and January 2021, were eligible for subsequent analysis. All VUs of non-acute ("chronic") nature (based on the clinico-pathological definition postulated by Kyaw et al[31]) and who met the definition of the American Venous Forum[12] were included in this study. All abbreviations are summarized in Table S1. The primary purpose of this study was to evaluate and compare the effectiveness and safety of endovenous interventions for the treatment of VUs. The inclusion criteria were defined as follows: patients diagnosed with VUs without significant comorbidities potentially influencing healing times, for example, peripheral artery occlusive disease ≥ stage II according to the Fontaine classification or major wound infection. Major wound infection was classified by the following criteria: (1) elevated C-reactive protein (compared to baseline); (2) increase in (peri)ulcerative oozing, pain and wound odor and (3) necessity of antibiotic therapy because of the wound infection. Exclusion criteria included lack of documentation regarding the ulcer healing progress or outcome as well as signs of significant ulcer regression (of more than 50% reduction in ulcer size within 6 weeks) following initial treatment with standard wound care and compression therapy prior to endovenous intervention. Patients with hemodynamically relevant, postthrombotic deep venous obstruction were also excluded from analysis as this represents a contraindication for superficial truncal vein ablation. For statistical analysis, the following parameters were evaluated: sex, age, underlying pathology, medical history, use of antiplatelet or anticoagulant drugs, peripheral artery occlusive disease (<stage II), prior endovenous interventions, treated vein, additional therapy (UGFS, FS, phlebectomy), major side effects, ulcer characteristics (ulcer surface area at initial presentation, prophylactic anticoagulation, time until treatment [=ulcer duration before endovenous intervention], time to complete ulcer healing, occurrence of ulcer relapse, time until relapse and type of retreatment). Major side effects comprised post-interventional complications such as bleeding, thromboembolic events (e.g., DVT, PE), thermal injury of adjacent structures or nerve injury (all major and minor complications are summarized in Table S2). However, typical post-interventional minor side effects such as transient bruising, hyperpigmentation and transient local pain were not included in the results as in our experience they do occur in most patients and therefore are not routinely documented. Ulcer healing was defined as complete epithelialization within 150 days and assessed using photographs in addition to reports of follow-up visits. The ulcer surface area at initial presentation was determined by wound planimetry using IC Measure (The Imaging Source Europe GmbH, Bremen, Germany) which uses in-picture calibration with an object of known size (centimeter paper tape) prior to wound measurement (Figure S1). For simplicity of wording, the term of UGFS refers to ultrasound-guided sclerotherapy of truncal veins as well as sclerotherapy of non-truncal veins with or without ultrasound-guidance.

2.2 | Preintervention and postintervention treatment protocol

Prior to EVLA and/or UGFS treatment, ultrasound examination was performed in order to determine refluxive superficial veins (truncal and side branches) on the leg that affected the ulcer. Prophylactic anticoagulation with weight-adapted enoxaparin was used in patients with risk factors (e.g., previous DVT or SVT, positive family history, immobilization, etc.) and continued for 1 week after EVLA and/or UGFS treatment. In patients already receiving oral anticoagulation, no additional anticoagulation was installed. After EVLA and/or UGFS treatment, ultrasound examination of the treated veins was performed and thigh-length graduated compression stockings class II were routinely applied. Another postinterventional ultrasound examination of the treated vein was performed after 7–14 days to confirm vein occlusion. In the case of not fully occluded veins, retreatment sessions with UGFS were performed until full venous occlusion was achieved. Patients experiencing ulcer relapse were reexamined using ultrasound and retreated with UGFS if possible.

2.3 | Endovenous laser ablation

EVLA was performed using either a Diomed 810 nm diode system (Diomed, Inc., Andover, MA, USA) or a Leonardo Dual 15 system (1470 nm diode laser/radial fiber system; Biolitec, Inc., Jena, Germany) under general or tumescent anaesthesia. The target vein was cannulated with a 18G (or 16G) needle under ultrasound-guidance with subsequent insertion of a 6-Fr introducer sheath in conjunction with a guide wire. Afterwards, the guide wire and dilator were removed and in case of using an 810 nm diode system a sterile 600 μm bare laser fiber (KHP-GmbH, Grieskirchen, Austria) or the ELVeS® Radial® 2ring Pro Fiber (Biolitec, Inc., Vienna, Austria) was inserted into the target vein placing the laser tip 1–2 cm distal to the saphenofemoral junction (SFJ). Power was delivered in a 13-W pulsed mode (1 s pulse duration, 1 s interval) drawing the laser fiber manually at a retraction speed of 2 mm/s (810 nm diode system). When using the 1470 nm laser and a radial fiber, the distance of the laser tip to the SFJ was <1 cm. The power was adjusted to 10 Watt and the energy to 70–80 J/cm. If required, surgical removal or foam sclerotherapy or UGFS of varicose side branches was performed in the same surgical session (additional treatment).

2.4 | Ultrasound-guided foam sclerotherapy

UGFS of truncal veins was performed without any kind of local or systemic anaesthesia using different concentrations of polidocanol (Aethoxysklerol®, Kreussler Pharma, Wiesbaden, Germany) depending on the vein diameter. For the treatment of truncal veins only concentrations of either 2.0% or 3.0% Aethoxysklerol® were used. In the case of retreatment of periulcerative side branches, lower concentrations of either 0.5% (reticular veins) or 1.0% (larger periulcerative veins) were used. Foam was prepared according to the Tessari-method (one part polidocanol, four parts air) and subsequently injected under ultrasound-guidance using 18-22G needles or peripheral venous catheters. Side branches were injected either under direct vision or ultrasound-guidance with 0.5% or 1.0% foam. A maximum volume of 10–15 ml foam was injected in one session.

2.5 | Statistical analysis

For statistical testing SPSS® software (SPSS-24; SPPS-Inc. Chicago, IL, USA) and Excel-2016, macOS-software (Microsoft Corp., Redmond, WA, USA) were used. If required, imputation of missing values was performed prior to statistical analysis. For comparison of patient and treatment characteristics, chi-square-tests, Fisher-exact-tests and Mann–Whitney *U* tests or unpaired *t*-tests were used depending on the distribution of the data. A p-value ≤ 0.05 was considered statistically significant.

3 | RESULTS

3.1 | Patient characteristics

In total, 68 patients with VUs were eligible for retrospective data analysis. 33 patients (48.5%) initially received EVLA and 35 (51.5%) UGFS. In these 68 patients, 97 refluxive venous segments (great saphenous vein (GSV): 43, small saphenous vein (SSV): 17, and non-saphenous veins (NSV) including anterior and posterior accessory saphenous veins: 37) were treated whereas in one UGFS patient a recurrent GSV after EVLA was treated. Additionally, deep venous reflux was seen in 7 (21.2%) EVLA and 11 (31.4%) UGFS treated patients and 4 (11.4%) UGFS patients had a combination of deep venous reflux and postthrombotic wall changes. The ulcer surface area at initial presentation

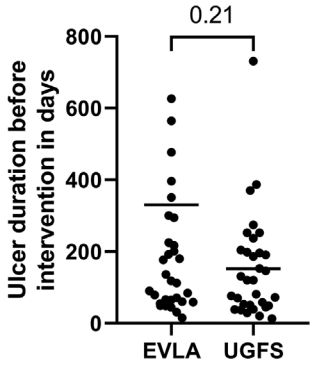

FIGURE 1 Ulcer duration before endovenous intervention with EVLA or UGFS. For better graphical depiction, three outliers with a disease duration of 1480, 1483, and 2556 days where excluded. EVLA, endovenous laser ablation; UGFS, ultrasound-guided foam sclerotherapy

TABLE 1 Patient characteristics

Patients ($n = 68$)	EVLA ($n = 33$)	UGFS ($n = 35$)	p-value
Male (%)	12 (36.4%)	17 (48.6%)	0.31
Female (%)	21 (63.6%)	18 (51.4%)	0.31
Mean age (age range) in years			0.018
• Male	54 (18–83)	70 (47–97)	
• Female	65 (40–89)	66 (39–92)	
Additional deep vein pathologies			
• Reflux	7 (21.2%)	11 (31.4%)	0.34
• Reflux and post-thrombotic wall changes	-	4 (11.4%)	0.18
Treated Leg, mean ABI (range)	0.98 (0.84–1.12)	1.02 (0.77–1.33)	N/A
Ulcer surface area at initial presentation (±SD) in cm^2	7.7 (±10.7)	8.5 (±16.3)	0.73
Medical history			
• Diabetes mellitus Type II (NIDDM)	6 (18.2%)	4 (11.4%)	0.43
• Arterial Hypertension (AHT)	11 (33.3%)	14 (40.0%)	0.57
• Smoking	10 (30.3%)	8 (22.9%)	0.49
• Peripheral occlusive disease (POAD)	3 (9.1%)	1 (2.9%)	0.28
Use of antiplatelet drugs	8 (24.2%)	10 (28.6%)	0.67
Use of anticoagulant drugs	6 (18.2%)	10 (28.6%)	0.31
Prior interventions			
• Crossectomy	2 (6.1%)	-	0.14
• Stripping	4 (12.1%)	3 (8.6%)	0.63
• UGFS	8 (24.2%)	9 (25.7%)	0.89
• EVLA	1 (3.0%)	3 (8.6%)	0.33
Ulcer location Left lower leg			N/A
• Lateral	1 (3.0%)	4 (11.4%)	
• Medial	14 (42.4%)	13 (37.1%)	
• Ventral	-	3 (8.6%)	
• Dorsal	1 (3.0%)	-	
Right lower leg			
• Lateral	2 (6.1%)	2 (5.7%)	
• Medial	11 (33.3%)	12 (34.3%)	
• Ventral	4 (12.1%)	1 (2.9%)	
• Dorsal	-	-	

Abbreviations: EVLA, endovenous laser ablation; UGFS, ultrasound-guided foam sclerotherapy.

showed no statistically significant difference between both treatment groups (EVLA: 7.7 ± 10.7 vs. UGFS: 8.5 ± 16.3 cm^2; $p = 0.73$). Overall, the most common ulcer location was the medial malleolar region in both groups. Mean ulcer duration prior to treatment was comparable for both treatment groups (EVLA: 330 ± 532 vs. UGFS: 152 ± 146 days; $p = 0.21$; Figure 1). However, patients receiving UGFS were significantly older compared to EVLA treated patients (mean age in years EVLA: 61 ± 17 vs. UGFS: 70 ± 14; $p = 0.018$). No statistically significant differences regarding sex, use of antithrombotic medication, medical history (AHT, NIDDM, smoking), ulcer location, or prior venous interventions between both treatment groups were found. All patient characteristics are summarized in Table 1.

3.2 | Treatment characteristics

Ulcer healing was observed in 32 (97.0%) EVLA and in 30 (85.7%) UGFS treated patients ($p = 0.20$). One patient not responding to UGFS treatment was switched to EVLA and subsequently also achieved ulcer healing. Time to complete ulcer healing was comparable for both treatment groups (EVLA: 59 ± 37 vs. UGFS: 63 ± 41 days; $p = 0.68$; see Figure 2) with 7 (21.2%) EVLA and 8 (22.9%) UGFS treated ulcers showing complete healing within 1 month. On average, patients in UGFS group required 1.9 ± 0.9 treatment sessions for initial ulcer healing. As 3 (9.1%) EVLA patients received concomitant split-thickness skin grafting, a subanalysis excluding these patients

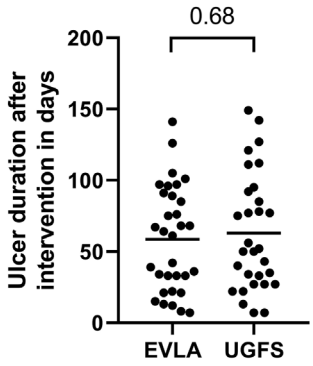

FIGURE 2 Time to complete ulcer healing after endovenous intervention with EVLA or UGFS. EVLA, endovenous laser ablation; UGFS, ultrasound-guided foam sclerotherapy

regarding the rate of ulcer healing and time until ulcer healing was performed, which showed no statistical difference ($p = 0.21$ and $p = 0.48$, respectively). In the EVLA group, treatment success could be confirmed in all but one case as proximal advancement of the tip of the laser probe was not possible due to anatomical reasons. Postinterventional complications occurred in 2 (6.1%) EVLA patients, in which minimal bleeding from the puncture site occurred, however without the need for reintervention. No complication was seen in UGFS treated patients. Ulcer relapse occurred in 1 (3.0%) EVLA and 11 (31.4%) UGFS treated patients ($p = 0.002$). Time until ulcer relapse was comparable for EVLA and UGFS treated patients (238 ± 0 vs. 617 ± 434 days; $p = 0.50$). In case of relapse, 5 (41.7%) patients received a duplex re-examination, which showed venous occlusion of the previously treated vein in 20.0%, venous reflux in a previously not treated vein in 20.0% and reflux of the previously treated vein in 60.0% (all UGFS group). The remaining patients either continued treatment in the extramural setting, were lost for follow up or refused a further duplex exam. Retreatment was performed with UGFS (3/12) and/or standard wound care only (9/12). After retreatment, ulcer resolution was seen in four patients, while the remaining patients were lost to follow up. All treatment characteristics are summarized in Table 2.

4 | DISCUSSION

Current clinical guidelines support the elimination of superficial venous reflux in affected patients using surgical or interventional approaches.[12] Given the minimally invasive nature of endovenous therapeutic approaches in comparison to open surgery, their use has significantly increased over the last two decades and endovenous surgical approaches have even been favored by several authors.[18] EVLA and UGFS represent commonly used endovenous therapeutic approaches, also in the treatment of active VUs.[32–40] However, comparative studies on these techniques in VU patients are scarce. Hence, our study aimed at evaluating and comparing the treatment outcome of these two endovenous interventions in this specific patient population. In particular, in the often multimorbid, old aged patient population affected by VUs, the low postoperative morbidity associated with endovenous therapeutic approaches may represent a major advantage over conventional open surgical techniques. Interestingly, in the present study patients were significantly older in the UGFS versus the EVLA group. This may be due to a selection bias as multimorbid patients with a higher perioperative risk profile will rather be selected for the less invasive UGFS approach. In the contrary, younger, less morbid patients would rather be selected for the more invasive EVLA procedure. This implies that in the setting of VU patients, comorbidities in combination with the invasiveness of the procedure may represent central factors influencing treatment selection.

The present retrospective study on 68 patients positively corroborates the prominent role of axial reflux elimination by EVLA and UGFS for the treatment of venous leg ulcers, as both treatment modalities showed a high rate of ulcer resolution, namely 97.0% and 85.7%, respectively. Although the healing rate was higher in the EVLA group, the difference was not statistically significant. In previous studies, VUs treated with sclerotherapy showed a 24-week healing rate ranging from 53% to 95%.[32–35] For EVLA, the observed healing rates ranged between 45% and 95% within varying follow-up times of 13–46 weeks[37–39] and ulcers continuing to improve even 1 year after the intervention.[40] When EVLA is combined with UGFS or phlebectomy, healing rates of 93% after a mean of only 55 days have been observed.[41] However, healing rates of only 45% after an average of 3.4 months have also been described by others.[37] Our study found no significant difference between both treatment modalities regarding postinterventional ulcer healing time. This might be due to our strategy to thoroughly eliminate all refluxive veins, independent of the treatment modality used. However, the EVLA group showed a (statistically insignificant) tendency toward a shorter time until ulcer resolution than the UGFS group. In the present study, no difference was found in terms of ulcer outcome when comparing the time until treatment (=ulcer duration before endovenous intervention) between EVLA and UGFS patients ($p = 0.21$). A previous randomized controlled trial found that particularly early endovenous ablation of superficial reflux results in a faster ulcer healing time than deferred endovenous ablation, whereas ulcer relapse rates were comparable within the first year after intervention.[15] Therefore, delayed referral of VUs toward treatment eventually results in an increase of resource usage and delayed ulcer healing.[42]

When evaluating the relapse rates of the present study, it becomes evident that the UGFS treatment group had a significantly higher rate of relapses compared to patients receiving EVLA (31.4% vs. 3.0%; $p = 0.002$). This is in line with randomized trials in CVI patients without leg ulceration, where UGFS turned out to be less efficient than endothermal techniques.[23,24,43] In a randomized study involving 580 legs with GSV insufficiency, Rasmussen[43] and Lawaetz[24] found that the 5-year occlusion rate was 25% lower in the UFGS group. These observations are consistent with several other reports on VU patients, where relapse rates in the treatment of VUs with UGFS ranged between 5% and 13% within a year,[8–32] whereas

TABLE 2 Treatment characteristics

Patients ($n = 68$)	EVLA ($n = 33$)	UGFS ($n = 35$)	p-value
Treated vein (left/right)			N/A
• GSV	13/13	7/10	
• SSV	6/3	4/4	
• NSV[a]	1/0	21/15	
Mean vein diameter of truncal veins in cm (±SD)			N/A
• GSV	0.9 (±0.4)	0.7 (±0.4)	
• SSV	0.7 (±0.3)	0.6 (±0.2)	
Prophylactic anticoagulation with weight-adapted enoxaparin	28 (84.8%)	9 (25.7%)	<0.001
Patients with already installed oral anticoagulation	3 (9.1%)	9 (25.7%)	0.07
Patients with no anticoagulation	2 (6.1%)	17 (48.6%)	<0.001
Type of anaesthesia			N/A
• General	14 (42.4%)	N/A	
• Tumescent	18 (54.5%)	N/A	
• Local	1 (3.0%)	N/A	
Additional therapy of side branches			N/A
• UGFS	12 (36.4%)	10 (28.6%)	
• Miniphlebectomy of side branches	4 (12.1%)	-	
Concomitant split-thickness skin grafting	3 (9.1%)	-	N/A
Mean ulcer duration in days (±SD) before intervention	330 (±532)	152 (±146)	0.21
Time to complete ulcer healing in days (±SD) after intervention	59 (±37)	63 (±41)	0.68
Initial ulcer resolution			0.20
• Yes	32 (97.0%)	30 (85.7%)	
• No	1 (3.0%)	5 (14.3%)	
Ulcer relapse	1 (3.0%)	11 (31.4%)	0.002
Time until ulcer relapse (±SD) in days	238 (–)	617 (±434)	0.50
Retreatment for ulcer relapse			N/A
• With UGFS • With standard wound care only	- 1 (100.0%)	3 (27.3%) 8 (72.7%)	
Ulcer resolution after retreatment			N/A
• Yes	-	4 (36.4%)	
• Lost to follow up	1 (100.0%)	7 (63.6%)	

[a]Including perforating veins, anterior and posterior accessory saphenous veins as well as recurrent varicose veins.

Abbreviations: EVLA, endovenous laser ablation; GSV, great saphenous vein; SSV, small saphenous vein; UGFS, ultrasound-guided foam sclerotherapy.

relapse rates of studies involving EVLA were ranging between 0% and 9%.[37–40] In a study by Wysong et al,[41] in which 30 patients were treated with EVLA in combination with foam sclerotherapy and/or phlebectomy of incompetent tributaries, no ulcer reoccurrence was observed within a median follow-up time of 448 days. After a long-term follow-up period of 4 years Kulkarni et al[32] report a relapse rate of 28% in UGFS treated patients. These findings support endothermal techniques, such as EVLA, as the treatment of choice, particularly in younger patients, where interventional management is not contraindicated due to possible comorbidities.

Since this was a retrospective data analysis, the results of this study have to be seen in the light of several major limitations. No patient randomization could be performed due to the retrospective nature of the study. Given the significantly lower mean age in EVLA patients in our study, a selection bias toward younger, less multimorbid patients might have occurred. This might have resulted

in heterogeneous study populations and might have influenced the study outcome. In order to minimize selection bias and heterogeneity of the study population regarding ulcer severity, the wound surface area at initial presentation was compared using IC Measure. Given the commercial nature of the tool and the accuracy in the sub-millimeter range, the reliability of this method is deemed to be high. However, a potential source of a measurement error might be the differences in the convexity of the surface on the lower leg, resulting in potential underestimation of the actual ulcer size. Concerning the limitations of the treatment outcome, no standardized duplex examinations at defined time points in the years after both interventions have been performed due to the retrospective nature of the study. Only on the short-term, 1–2 weeks after the interventional procedure, a standardized duplex examination was performed confirming the principal technical success of the procedure. Likewise, UGFS in the present study was performed using needles or cannulas which might have resulted in a lower occlusion rate due to the lack of uniform foam delivery with skipped treated areas and dilution of the sclerosant with blood when compared to currently available catheter-directed foam sclerotherapy procedures.[44–48] Therefore, it is not possible to adequately correlate venous occlusion rates and ulcer relapse rates. Additionally, even if—to our best knowledge—this represents the largest comparative analysis between UGFS and endothermal interventions in VU patients published so far, the number of patients is still very limited and larger, ideally prospective studies are mandatory.

5 | CONCLUSION

Taken together, the results showed no significant difference regarding the ulcer healing time between EVLA and UGFS treated patients. In addition, the rate of ulcer resolution was not significantly different between both groups. However, the relapse rate was significantly higher for UGFS than for EVLA treated patients. Therefore, although these results indicate an equivalent short-term efficacy of both treatments, these results also suggest a higher sustainability of the EVLA approach versus UGFS in this specific indication.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Benedikt Weber and Elias Marquart contributed to data collection. Benedikt Weber and Elias Marquart and Kornelia Böhler contributed to study design. Benedikt Weber, Elias Marquart, Julia Deinsberger and Kornelia Böhler contributed to data analysis. All authors contributed to data interpretation/revision/final approval.

ETHICS STATEMENT

This study was approved by the institutional ethics committee from the Medical University of Vienna, Austria (EK-Nr: 1608/2021).

DATA AVAILABILITY STATEMENT

Data available from the corresponding author on request due to privacy/ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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