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COMBINED MINIMALLY INVASIVE TREATMENT OF TROPHIC ULCERS IN RECURRENT VARICOSE VEIN

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Abstract

Introduction. Chronic venous disease of the lower extremities, particularly recurrent varicose vein disease (RVVD), is frequently complicated by venous leg ulcers. These lesions significantly impair quality of life and remain challenging to manage. Although minimally invasive endovenous techniques are increasingly applied in clinical practice, evidence regarding their role in C6 recurrent disease remains limited.

Aim. To evaluate the efficacy and safety of a combined minimally invasive approach for the treatment of active trophic ulcers in patients with recurrent varicose vein disease.

Materials and methods. A retrospective cohort analysis included 41 patients with active venous ulcers undergoing secondary interventions for recurrent disease. Treatment consisted of individualized combinations of endovenous laser ablation or radiofrequency ablation, ultrasound-guided foam sclerotherapy, and miniphlebectomy. All patients received standardized compression therapy and local ulcer care using calcium alginate dressings. Clinical outcomes were assessed using VCSS (Venous Clinical Severity Score), VDS (Venous Disability Score), VDSS (Venous Disease Severity Score), and CIVIQ-14 (Chronic Venous Insufficiency Quality of Life Questionnaire-14) before and after treatment.

Results. Significant improvements were observed across all evaluated parameters. VCSS decreased by 58.8%, VDS by 49.2%, and VDSS by 68.3%. Quality-of-life scores (CIVIQ-14) improved by 42.4%. All changes were statistically significant ($p < 0.001$), with large standardized effect sizes (Cohen's d from -1.31 to -1.75). The combined approach was associated with effective elimination of reflux sources and ulcer healing in the majority of cases.

Conclusions. An anatomically personalized combined minimally invasive strategy appears to be a safe and effective option for managing venous leg ulcers in patients with recurrent varicose vein disease. Further prospective studies are warranted to confirm these findings and to support the development of standardized treatment protocols.

Keywords: minimally invasive treatment, endovenous laser ablation, radiofrequency ablation, sclerotherapy, miniflebectomy

INTRODUCTION

Chronic venous disease (CVD) of the lower limbs persists as a formidable global health challenge, profoundly diminishing patient quality of life while placing an immense strain on medical resources [1, 2]. A particularly intricate clinical scenario arises with recurrent varicose vein disease (RVVD), which frequently resurfaces following initial interventions and is often further exacerbated by the onset of trophic ulcers [3, 4]. As one of the most severe expressions of CVD, venous leg ulcers (VLUs) are estimated to affect a significant

portion of the adult population, with incidence rates climbing sharply as populations age [5, 6]. These lesions are notoriously resistant to standard therapies and frequently recur, creating both a persistent struggle for the patient and a substantial economic burden on healthcare systems [5, 7].

The etiology and pathogenesis of RVVD are multifactorial, including disease progression, neovascularization, and suboptimal outcomes of previous interventions [4]. The emergence of VLUs in patients with RVD is fundamentally rooted in persistent venous

hypertension. This physiological strain orchestrates a cascade of inflammatory changes and skin damage that eventually culminates in ulceration [8]. For clinicians, managing these recurrences – especially when they are complicated by active wounds – remains a formidable hurdle that requires a highly nuanced approach [2].

As a result, traditional, more invasive surgeries like high ligation and stripping are rapidly making way for more refined, endovenous solutions [9, 10]. Contemporary techniques, ranging from endovenous laser ablation (EVLA) and radiofrequency ablation (REA) to ultrasound-guided foam sclerotherapy (UGFS) and mechanochemical methods, have already established a strong track record of success in resolving superficial venous insufficiency. These minimally invasive tools allow for targeted treatment with significantly less trauma, offering a more effective path for patients struggling with the complexities of RVVD [2, 11, 12]. Moreover, these methods are also applied in the treatment of VLUs, where they contribute to ulcer healing and prevention of recurrence [5, 13]. Evidence suggests that great saphenous vein ablation improves healing and reduces recurrence of VLUs in patients with post-thrombotic syndrome [14]. The efficacy of EVLA has also been demonstrated in improving outcomes for trophic ulcers in chronic venous insufficiency [15].

In complex cases of RVVD with VLUs, a combined approach is often required [9, 10]. This may involve a combination of thermal ablation, sclerotherapy, miniphlebectomy, and other adjunctive techniques to eliminate reflux sources and treat skin changes [9, 11, 12]. The aim of such integrated management is not only reflux elimination but also acceleration of ulcer healing, pain reduction, and improvement of patients' overall quality of life [6].

Even though minimally invasive treatments for varicose veins have advanced tremendously, there is still a clear shortage of evidence concerning their use in recurrent cases complicated by VLUs. While the general success of endovenous methods is well-established, we still lack a definitive, standardized protocol for choosing the right technique when a recurrence occurs alongside active ulceration [4]. This specific gap in our current understanding makes further, more targeted research essential for developing the reliable treatment strategies these patients need.

AIM

To evaluate the efficacy and safety of a combined minimally invasive approach for the management of trophic ulcers in patients with RVVD of the lower extremities.

MATERIALS AND METHODS

Study design. This was a single centre, single operator, retrospective cohort study of patients with recurrent varicose veins of the lower limbs presenting with active venous leg ulcers (CEAP C6).

Eligibility criteria. Inclusion. Adults with symptomatic recurrent varicose veins and open trophic ulcers (clinical class C6r according to the 2020 CEAP update). *Exclusion.* Acute deep vein thrombosis, uncontrolled local infection, pregnancy, decompensated cardiopulmonary disease, or inability to complete follow up.

Patients. Between 2020 and 2024, 41 consecutive patients underwent secondary interventions for recurrent disease complicated by trophic ulceration and were included in the analysis. Baseline characteristics are summarised in Table 1.

Table 1

Consecutive Patients Underwent Secondary Interventions for RVVD Complicated by Trophic Ulceration

Variable	Value
Age, years (mean ± SD)	56.85 ± 11.43
Age range, years	30-76
Female, n (%)	28 (68.3)
Male, n (%)	13 (31.7)
BMI, kg/m ² (mean ± SD)	31.76 ± 6.19
BMI range, kg/m ²	20.2-44.9
Time since first intervention, years – median [IQR]	11 [7-25]
Time since first intervention, years – range	1-50
Time since first intervention, years – mean ± SD	16.1 ± 11.9

*Note. «Time since first intervention» is presented as median [IQR] and range; the mean ± SD is also reported for completeness.

Prior interventions. The surgical history of the patient cohort reflected the ongoing challenge of managing RVVD, with 32 patients having previously undergone conventional open venectomy, while others had been treated with EVLA – 3 cases, RFA – 3 cases, or miniphlebectomy – 3 cases. The presence of such recurrences following primary interventions highlights the

persistent difficulty in achieving long-term hemodynamic stability in advanced venous disease.

Clinical assessment and duplex ultrasound mapping. To establish a rigorous baseline for our study, all participants underwent a standardized clinical evaluation that confirmed an active CEAP C6 status. We utilized

several validated instruments – specifically the Venous Clinical Severity Score, the venous disability score (VDS), venous disease severity score (VDSS), and the CIVIQ-14 quality-of-life questionnaire – to quantify the degree of functional impairment and clinical severity in each case. This evaluation was integrated with meticulous duplex ultrasound mapping, which remains the fundamental diagnostic step for identifying the specific anatomical sources of pathological reflux and guiding the planning of subsequent interventions.

Spectral Doppler settings included an insonation angle < 60°, 2 mm sample volume, low wall filter, and sweep speed sufficient for accurate timing of reflux. Provocative manoeuvres were: Valsalva or cough at the saphenofemoral junction (SFJ); distal manual compression-release for superficial trunks/tributaries; active calf raises at the saphenopopliteal junction (SPJ)/small saphenous vein; targeted compression for perforators; and proximal thigh compression (or Valsalva) for deep veins. Reflux was defined as a duration of at least 0.5 s in superficial segments, 0.35-0.5 s in perforating veins, and 1.0 s or longer in the deep venous system. All measurements were obtained in orthostasis with minimal probe pressure.

Interventional strategy. Management was minimally invasive and tailored to the anatomic distribution of reflux and the individual risk profile. All procedures were performed in an office based surgical suite under tumescent local anaesthesia with continuous ultrasound guidance.

EVLA. Diode laser (Biolitec Ceralas) with the ELVeS® Radial® 2ring Pro fiber.

– power 6-7 W; automated pullback 0.7 mm/s; typical linear endovenous energy density (LEED) 70-90 J/cm.

– REA. Closure Fast catheter; heating cycle 20 s at 120 °C.

– UGFS. Polidocanol 1-3%, 1-3 mL per injection; foam prepared by Tessari or double syringe technique (~ 1 mL sclerosant with 2-3 mL air, agitated 20-30 times). UGFS was used specifically for varicoangiomas and varices located within areas of induration.

– Miniphlebectomy. Excision of tributaries through micro incisions (Varady technique) performed only outside the zone of induration.

Compression therapy (primarily class II, escalated to class III when indicated) was initiated on day I and continued until stable epithelialisation.

Local ulcer care and adjunctive pharmacotherapy. Topical management of venous leg ulcers was based on calcium alginate dressings, adjusted according to the phase of healing (Figure 1). All patients received a venoactive agent – micronised purified flavonoid fraction – in standard dosing. Peri-operative thrombotic risk was stratified using the Caprini score; individuals at increased risk received pharmacologic thromboprophylaxis with anticoagulants in prophylactic doses for an individualised duration.

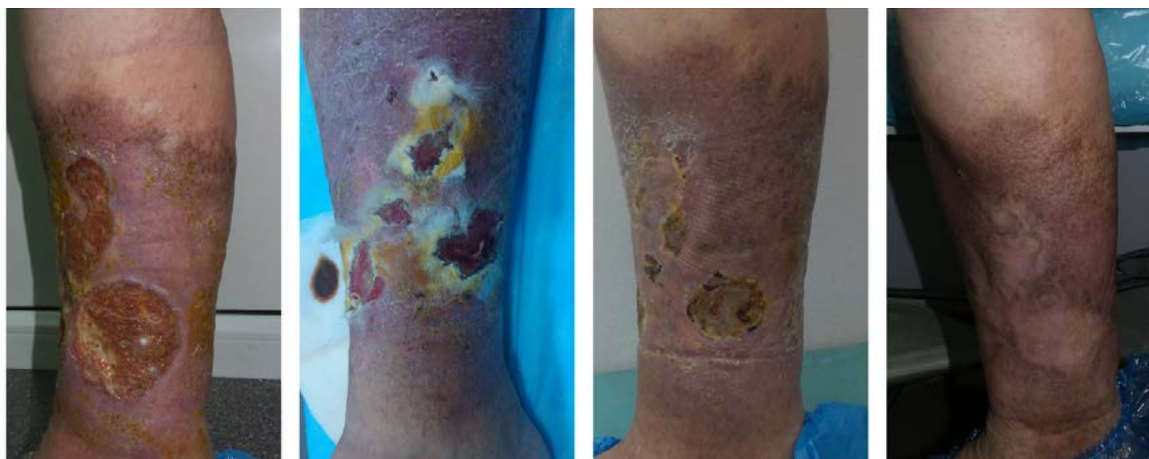


Figure 1. Application of calcium alginate dressings as part of local wound management in a patient with a large venous leg ulcer. Sequential images illustrate the dressing effect on wound bed preparation and subsequent healing.

Endpoints. Primary endpoints. 1) Duplex confirmed occlusion or absence of reflux in the treated segment; 2) ulcer closure (complete epithelialisation); 3) serious adverse events (EHIT > II, deep vein thrombosis, pulmonary embolism, full-thickness burns, clinically relevant neuropathy). *Secondary endpoints.* Change from baseline to the first post-treatment visit in VCSS, VDS, VDSS, and CIVIQ 14, and the need for re-intervention.

Statistical analysis. Statistical analyses were performed in R (version 4.3.x; R Foundation for Statistical Computing, Vienna, Austria). Continuous variables are presented as mean ± SD or median [IQR] (distribution assessed by the Shapiro-Wilk test). Categorical variables are reported as n (%). Pre- versus post-treatment comparisons for VCSS, VDS, VDSS, and CIVIQ 14 used paired t tests or Wilcoxon signed rank tests as appropriate;

effect sizes were expressed as Cohen's *d*z with 95% confidence intervals. For categorical data, comparisons were performed using the chi-square test or, when appropriate, Fisher's exact test. Statistical significance was defined at a two-sided *p* level of 0.05.

RESULTS

Combinations of reflux sources were detected on duplex ultrasonography (Table 2). Categories were non-mutually exclusive.

Table 2

Duplex Ultrasound-Identified Sources of Reflux (n = 41)

Segment	n (%)
Great saphenous vein (GSV)	30 (73.2)
Small saphenous vein (SSV)	25 (61.0)
Anterior accessory saphenous vein (AASV)	9 (22.0)
Calf perforators	29 (70.7)
Thigh perforators	5 (12.2)
Varicoangiomas at the SFJ	8 (19.5)
Total reflux sources	106 (258.5)

Note: Categories were non-mutually exclusive. A total of 106 reflux sources were identified in 41 patients (mean 2.58 sources per patient). Therefore, percentages exceed 100%.

Secondary interventions. Across our cohort of 41 patients with active CEAP C6 ulcers, a total of 87 secondary procedures were carried out. This high intervention rate highlights the complex nature of recurrent disease, which often demands a multi-staged or combined surgical strategy to achieve clinical success. Endovenous thermal ablation, specifically EVLA and RFA, was the most frequently utilized technique for neutralizing primary reflux sources. For more localized issues, such as varicoangiomas

or diseased tributaries, we selectively employed UGFS and ambulatory miniphlebectomy. The infrequent use of traditional venectomy in this study reflects a broader clinical shift toward minimally invasive standards. The specific distribution of these procedures is detailed in Table 3.

Clinical outcomes. Among 41 patients with CEAP C6 disease, clinical parameters were compared before and after treatment. The results are summarized in Table 4.

Table 3

Distribution of Secondary Interventions (CEAP C6, n = 41)

Intervention type	Number of procedures (n)	% of total
EVLA	30	34,5
RFA	14	16,1
UGFS	12	13,8
Miniphlebectomy	31	35,6
Total	87	100,0

Note: Percentages are calculated relative to the total number of interventions (n = 87); several patients underwent >1 procedure.

Table 4

Clinical Outcomes Before and After Treatment

Metric	n	Before (mean ± SD)	After (mean ± SD)	Mean diff (95% CI)	Cohen's <i>d</i> z	<i>p</i> -value
VCSS	41	10.12 ± 3.66	4.17 ± 2.89	-5.95 (-7.03; -4.87)	-1.69	1.88×10 ⁻¹³
VDS	41	2.54 ± 0.55	1.29 ± 0.81	-1.24 (-1.47; -1.02)	-1.69	1.75×10 ⁻¹³
VDSS	41	4.42 ± 1.71	1.40 ± 1.60	-3.02 (-3.74; -2.31)	-1.31	4.21×10 ⁻¹⁰
CIVIQ-14	41	54.88 ± 13.08	31.63 ± 11.53	-23.24 (-27.32; -19.17)	-1.75	6.89×10 ⁻¹⁴

Note: Values are mean ± SD. Mean diff reported with 95% CI; *p* values from paired *t*-tests; Cohen's *d*z denotes standardized within-subject effect size.

The observed changes corresponded to large within-subject effect sizes (Cohen's *d*z from -1.31 to -1.75). The applied treatment combined thermal ablation of incompetent trunks (EVLA or RFA),

UGFS for varicoangiomas in indurated areas, and miniphlebectomy outside zones of induration. Improvements in VCSS, VDS, and VDSS were accompanied by parallel improvement in CIVIQ-14 scores.

DISCUSSION

This study evaluated a combined minimally invasive approach for the treatment of venous leg ulcers in patients with RVVD. Clinically relevant changes were observed across all assessed outcome measures. VCSS decreased by 58.8%, VDS by 49.2%, and VDSS by 68.3%. Quality-of-life assessment showed a 42.4% reduction in CIVIQ-14 scores. Effect sizes were large, with Cohen's *d* ranging from -1.31 to -1.75. These findings are consistent with other studies underscoring the effectiveness of minimally invasive interventions in promoting ulcer healing and improving quality of life [5, 13, 16]. Previous studies have reported improvements in VCSS after radiofrequency ablation in patients with venous ulcers [13]. Comparable findings have been described for endovenous laser ablation and foam sclerotherapy in the treatment of active ulcers [5, 9].

In the present cohort, treatment combined thermal ablation of incompetent trunks with UGFS for varicoangiomas in indurated areas and miniphlebectomy outside zones of induration. This combination allowed elimination of multiple reflux sources in patients with recurrent disease [10, 16]. This approach is consistent with contemporary clinical practice guidelines [17], which emphasize comprehensive management of reflux and consideration of the multifactorial nature of recurrent CEAP C6 disease. Combined treatment approaches have been reported previously [9]. In our cohort, reflux was identified in multiple venous segments, including the GSV (73.2%), SSV (61.0%), and calf perforators (70.7%).

Most patients had undergone conventional venectomy (82.9%), with a mean interval of 16.1 ± 11.9 years since the primary intervention. Recurrence after traditional surgery has been associated with neovascularization and disease progression [4, 18]. Our strategy directly targeted these secondary reflux pathways.

Nevertheless, this study has certain methodological limitations. The retrospective design may have influenced patient selection. In addition, the absence of a control group does not allow direct comparison with alternative interventional or conservative approaches.

The sample included 41 patients. Although statistically significant changes were observed, studies with larger populations are needed to confirm these results. Data on adverse events and repeat interventions were not analyzed in detail, which limits assessment of safety and long-term outcomes.

Follow-up was limited to short- and mid-term observation. Extended follow-up is required to evaluate ulcer durability and recurrence rates [19].

Further investigation using prospective controlled designs would help clarify the role of combined

minimally invasive treatment in this patient population. Further exploration of ulcer-healing mechanisms and the molecular impact of various combinations of minimally invasive procedures also offers promising opportunities [20]. The potential role of biophysical and cell-based therapies in the treatment of difficult-to-heal venous ulcers warrants further investigation [7, 21].

In summary, our study demonstrates the high efficacy of an anatomically personalized combined minimally invasive strategy for venous ulcer management in RVVD. The present results contribute to the existing evidence on the management of VLUs. Additional studies are needed to confirm these observations and address the limitations of the current design.

CONCLUSIONS

In patients with RVVD complicated by active VLUs (CEAP C6r), comprehensive DUS mapping enables precise identification of multiple sources of pathological reflux, which determine the strategy of secondary intervention.

The combined use of minimally invasive techniques – EVLA or REA in conjunction with UGFS and miniphlebectomy provides effective elimination of hemodynamically significant reflux in patients with active ulceration.

In the studied cohort, treatment was associated with statistically significant reductions in clinical severity scores (VCSS, VDS, VDSS) and improvement in quality of life (CIVIQ-14), reflecting regression of chronic venous insufficiency manifestations in the presence of active ulcer disease.

The obtained results support the application of combined minimally invasive interventions as a justified therapeutic strategy for patients with RVVD complicated by active VLUs, provided that individualized planning and appropriate postoperative management are ensured.

Perspectives for further research. Future research in the management of venous leg ulcers associated with RVVD should prioritize prospective randomized controlled trials with larger patient cohorts. Further controlled studies with increased sample sizes are needed to confirm the safety and effectiveness of combined minimally invasive treatment in RVVD. Standardization of treatment protocols may improve comparability of outcomes between centers.

Additional research may also address molecular aspects of ulcer healing and the influence of different endovenous modalities on the local wound environment.

The role of adjunctive therapies, including biophysical and cell-based approaches, requires further evaluation.

Long-term follow-up studies are necessary to assess durability of healing and recurrence rates.

COMPLIANCE WITH ETHICAL REQUIREMENTS

The study was performed in accordance with the Declaration of Helsinki and current national regulations. The protocol was approved by the Local Bioethics Committee of Bogomolets National Medical University (Protocol № 186, 24 June 2024).

All participants were informed about the aims and procedures of the study before inclusion. Written informed consent was obtained prior to data collection. Participants could withdraw at any stage without consequences. Data were anonymized before analysis and handled according to applicable data protection regulations, including General Data Protection Regulation requirements. Results are presented in aggregated form.

This research is part of a broader scientific project registered under the State Registration Number 0124U001673 (Development of new methods of reconstructive and restorative operations in patients with surgical diseases and lesions as a result of military actions, registered on 11 February 2024).

No artificial intelligence was used in this work to generate text, analyze data, or create images. All content was prepared independently by the author, who is fully responsible for the accuracy and originality of the data and compliance with ethical norms and standards.

FUNDING AND CONFLICT OF INTEREST

No external funding was received. The author declares no conflicts of interest.

AUTHOR CONTRIBUTIONS

Shchukin S. P.^{A-F}

The author was responsible for study design, data collection, analysis, interpretation of results, and manuscript preparation. The final version was reviewed and approved by the author. Language editing and statistical consultation were obtained.

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Резюме**КОМБІНОВАНЕ МІНІІНВАЗИВНЕ ЛІКУВАННЯ ТРОФІЧНИХ ВИРАЗОК ПРИ РЕЦИДИВНІЙ ВАРИКОЗНІЙ ХВОРОБІ**
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Вступ. Рецидивна варикозна хвороба нижніх кінцівок нерідко ускладнюється формуванням венозних трофічних виразок. Такі ураження суттєво знижують якість життя пацієнтів і потребують тривалого лікування. Попри активне впровадження малоінвазивних методів, питання оптимальної тактики при рецидиві захворювання, ускладненому виразкою (CEAP C6), залишається дискусійним.

Мета. Проаналізувати клінічні результати застосування комбінованого малоінвазивного підходу у пацієнтів із рецидивною варикозною хворобою, ускладненою активними трофічними виразками.

Матеріали та методи. У дослідження включено 41 пацієнта з активними венозними виразками (CEAP C6), яким виконували повторні втручання з приводу рецидиву варикозної хвороби. Лікувальна тактика визначалась індивідуально за даними ультразвукового картування та передбачала поєднання ендовенозної лазерної або радіочастотної абляції, ехокерованої пінної склеротерапії та мініфлебектомії. Усім пацієнтам призначали компресійну терапію та місцеве лікування із застосуванням альгінатних пов'язок. Динаміку оцінювали за шкалами VCSS (Venous Clinical Severity Score – шкала клінічної тяжкості венозного захворювання), VDS (Venous Disability Score – шкала венозної інвалідизації), VDSS (Venous Disease Severity Score – шкала тяжкості венозного захворювання) і CIVIQ-14 (Chronic Venous Insufficiency Quality of Life Questionnaire-14 – опитувальник якості життя при хронічній венозній недостатності) до втручання та після лікування.

Результати. Після усунення джерел патологічного рефлюксу відзначено зменшення вираженості клінічних проявів: показник VCSS знизився на 58,8 %, VDS – на 49,2 %, VDSS – на 68,3 %. Покращення якості життя за шкалою CIVIQ-14 становило 42,4 %. Виявлені зміни були статистично значущими ($p < 0,001$) та характеризувалися великим розміром ефекту (Cohen's d_z від -1,31 до -1,75). Отримані дані свідчать про ефективність комплексного усунення різних анатомічних джерел рефлюксу в пацієнтів із рецидивом захворювання.

Висновки. Індивідуалізована комбінація малоінвазивних методів може розглядатися як ефективний варіант лікування трофічних виразок при рецидивній варикозній хворобі нижніх кінцівок. Подальші проспективні дослідження необхідні для уточнення довгострокових результатів і формування уніфікованих клінічних рекомендацій.

Ключові слова: трофічна виразка, рецидивна варикозна хвороба, малоінвазивне лікування, ендовенозна лазерна абляція, радіочастотна абляція, склеротерапія, мініфлебектомія

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