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Transfixing Endovenous Thermal Ablation (TEThA) for varicose veins treatment - A prospective single-arm study

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Nara Medeiros Cunha deMelo Vasconcelos[1,2], Marcelo Halfen Grill[1], Gabriela de Oliveira Buril[1,3], Fabrício Rodrigues Santiago[4], Renata Camila Barros Rodrigues[1], Gabriel Henrique Simoni[1], Marcela Zanoni[1], Isabela Zampirolli Leal[1], Viviane Santana da Silva[5], Walkiria Hueb Bernardi[1], Roberto Augusto Caffaro[1] and Eduardo Ramacciotti[1,5,6]

Abstract

Background: Varicose veins impact quality of life in patients with chronic venous disease (CVD), and their optimal treatment remains unclear. The Transfixing Endovenous Thermal Ablation(TEThA) technique is a procedure that consists of endovenous laser thermal ablation of varicose tributaries by combining the transfixing technique for endovenous procedure with tumescent anesthesia.

Objective: To evaluate the impact of the TEThA technique on quality of life and postoperative complications in patients with varicose veins.

Methods: This Prospective, single-arm study included 22 patients (CEAP C2–C6) treated with the TEThA technique. Quality-of-life and clinical scores (CIVIQ-14, AVVQ, rVCSS, CEAP, Caprini) were assessed at baseline, 6 weeks, and 6 months postoperative.

Results: Significant improvements were observed in CIVIQ-14 (30.95 to 22.76; p = .013), AVVQ (36.43 to 23.49; p = .012), rVCSS (7.73 to 4.18; p = .014), and CEAP (3.09 to 1.94; p = .002). No significant complications, thrombotic events, or need for reintervention occurred.

Conclusion: TEThA significantly improved clinical and quality-of-life outcomes in patients with varicose veins, with a favorable safety profile.

Keywords

chronic venous insufficiency, varicose veins, laser therapy, endovascular procedures, quality of life

Introduction

Chronic Venous Disease (CVD) is usually associated with the presence of varicose veins tributaries commonly related to the great and small saphenous veins reflux. Varicose incompetent veins also happen independently, due to structural wall changes, chronic perivenular inflammation, and segmental venous hypertension.[1,2]

The primary goal of treating varicose veins is to relieve symptoms and prevent complications, improving quality of life. For patients with indication of Saphenous veins treatment, thermoablation is the gold standard although the treatment of tributary veins remains controversial. Therapeutic options include outpatient phlebectomy, which is effective with good aesthetic and functional outcomes.[3,4] Foam sclerotherapy, a less costly method indicated for large veins, offers rapid recovery but carries risks such as hyperpigmentation and transient neurological events.[5,6] Thermoablative techniques, like radiofrequency and particularly endovenous laser, are also available.[7–9] These

[1]Vascular Surgery Department, Santa Casa de São Paulo School of Medical Sciences, São Paulo, Brazil
[2]Vascular Surgery Department, Universidade Federal do Rio Grande do Norte, Natal, Brazil
[3]Vascular Surgery Department, Universidade Federal do Pernambuco, Recife, Brazil
[4]Vascular Surgery Department, Universidade Federal de Goiás, Goiânia, Brazil
[5]Science Valley Research Institute, São Paulo, Brazil
[6]Haemostasis & Thrombosis Research Laboratories at Loyola University Medical Centre, Maywood, IL, USA

Corresponding author:
Eduardo Ramacciotti, Science Valley Research Institute, Rua Fidêncio Ramos, 302, cj. 42 – 4° andar, São Paulo CEP 04551-010, Brazil.
Email: eduardoramacciotti@gmail.com

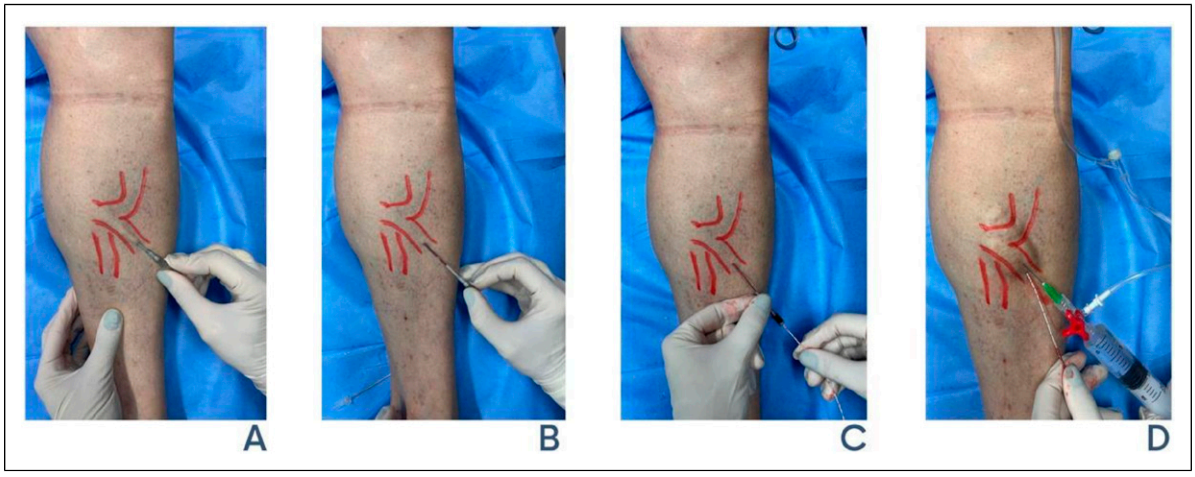

Figure 1. Treatment of varicose tributaries with the Transfixing Endovenous Thermal Ablation (TEThA) technique. (A) Puncture with a 16G catheter in the center of the previously marked perivenous region. (B) Catheter retraction until venous return. (C) The optical fiber is pushed through the catheter. (D) Tumescence with an orange-peel appearance.

approaches are often combined with the treatment of saphenous reflux, optimizing both clinical and aesthetic results.[1,2]

To date, the recommendation of varicose vein endovenous ablation (EVA) has been to precisely insert the 1470 nm laser fiber into the lumen of the veins, to avoid skin burns and nerve damage. When torturous, multiple punctures have been recommended, avoiding "perforation" whenever possible.[10] Before EVA, tumescence is necessary to protect the skin and perivenous structures, confining the thermal effects to the vein wall.[11]

The Transfixing Endovenous Thermal Ablation (TEThA) technique consists of endoluminal and extraluminal vein treatment by a transfixing approach with 1470 nm radial laser application combined with tumescence. It promotes effective fibrosis and minimizes the need for multiple punctures or additional procedures. Its potential benefits include less surgical aggressiveness, reduced sclerosing use, and rapid functional recovery. However, scientific evidence on TEThA is limited, being based primarily on case reports.[12]

This study aimed to explore the efficacy of the TEThA technique by evaluating prospectively the quality of life of patients with CVD undergoing this treatment for varicose veins.[13–15]

Methods

Study design and oversight

This prospective, single-center, single-arm clinical trial was conducted at the Hospital das Clínicas of the Federal University of Pernambuco, Brazil.

All study data were collected using a pre-established clinical recording file (CRF) within the REDCap® platform (Research Electronic Data Capture, Redcap Consortium, Vanderbilt University Medical Center, Tennessee, USA), capturing demographic information and clinical characteristics related to patient comorbidities. Clinical evaluations were conducted by a trained team member employing standardized assessments, including imaging when clinically indicated.

Eligible participants were aged ≥18 years old, with CVD CEAP (clinical, etiological, anatomical, and pathophysiological) classification C2 to C6, with incompetence of the saphenous trunk and tributary veins ≥ diameter, who were willing to sign the informed consent form (ICF). Exclusion criteria included individuals with CVD CEAP 1, age under 18 years, and those who did not provide an ICF.

Ethical approval and registration

The National Research Ethics Committee (CONEP) of the Brazilian Ministry of Health approved the study protocol under the ethical appraisal number 7.112.732 (CAAE 81917424.2.0000.8807). The study is registered at www.clinicaltrials.gov (NCT06669260).

Study procedures

Patients underwent a clinical consultation and provided a written ICF before enrollment. Baseline clinical data were collected. Participants underwent systematic clinical data collection, including evaluation with Doppler ultrasound (DUS), physical examination, and photographic recording using a mobile device (iPhone 14®). The short Chronic Venous Disease Quality of Life Questionnaire (CIVIQ-14),[14] Aberdeen Varicose Vein Questionnaire (AVVQ),[15] Revised Venous Clinical Severity Score (rVCSS),[13] and the CEAP classification data were collected under the coordination of the principal investigator and administered by co-

Table 1. Demographic data.

Variable	n (%) or mean (SD)
Sex	
Male	4 (18.2%)
Female	18 (81.8%)
Age (years)	50.6 (9.6)
BMI (kg/m^2)	31.4 (6.8)
Caprini score	4.68 ± 2.34
CEAP clinical class	
C0	0 (0.0%)
C1	1 (4.5%)
C2	7 (31.8%)
C3	8 (36.4%)
C4	3 (13.6%)
C5	1 (4.5%)
C6	2 (9.1%)
Previous varicose vein surgery	
No	14 (63.6%)
Yes	8 (36.4%)

BMI: body mass index; CEAP: Clinical, Etiologic, Anatomic, and Pathophysiologic.

investigators from the Federal University of Pernambuco (UFPE).

The tributary veins were marked with the patient standing, under the guidance of a phleboscope (Medic®, M3DIC Healthcare Technologies, Natal, RN, Brazil) and a DUS device. The treatment was performed on an outpatient basis under regional anesthesia and sedation. A 1470 nm laser with a 400 or 600 µm radial fiber was used, applying the TEThA technique, with endo- and perivenous ablation using tumescent infiltration. A single treatment session was performed, followed by two in-person evaluations: the first at 6 weeks and the second at 6 months.

TEThA technique description

EVLA of the saphenous trunk was first performed, using a 1470 laser with the 400 and 600 µm radial fiber, followed by sequential punctures of the varicose veins (veins above 3 mm diameter were treated, with no predefined maximum size; some occasionally exceeded 10 mm) with 16- or 14-gauge catheters. DUS guidance was used in two approaches: the short-axis or the long-axis. The punctures were performed one by one, at an average distance of 5 to 10 cm, with the transfixion of the tributary wall, using the laser fiber passed inside. The catheter was removed and followed by generous tumescent anesthesia with 0.08% lidocaine diluted in saline solution. To confirm that sufficient anesthesia has been infiltrated between the skin and the varicose tributary, creating an adequate distance, was observed with the naked eye, whether an "orange peel" appearance has formed on the skin, or with DUS if the optical fiber inside the vein is at least 5 mm away from the skin. The thermal ablation by the TEThA technique was performed with laser settings between 5-7 W of power and a linear endovenous energy density (LEED) of 25-49 J/cm. The optical fiber was retracted 1 cm every 5-7 s and was removed from the puncture site (Figure 1).

Postoperatively, compression stockings (20-30 mmHg) were applied for 24 h, along with restrictions on physical activity and sun exposure for 7 days. No routine analgesia was prescribed. Clinical reevaluations were performed at 45 and 180 days (6 weeks and 6 months), including physical examination, Doppler ultrasonography, reapplication of clinical and quality of life scores, and assessment of potential local complications.

Objectives

The study aimed to assess the impact of the TEThA (Transfixing Endovenous Thermal Ablation) technique on quality of life in patients with lower limb varicose veins, along with technical and clinical outcomes.

Primary efficacy outcome. Quality of life of treated patients, assessed by the specific quality of life questionnaires CIVIQ-14, AVVQ, and the VCSS, administered preoperatively and 6 weeks and 6 months postoperatively.

Primary safety outcome. Potential skin alterations: redness, swelling, temporary changes in skin pigmentation (hyper or hypopigmentation), scarring, or burns. Venous thromboembolism, with DUS when necessary, superficial venous thrombosis, and fibrotic cords clinical evaluation.

Statistical analysis

Data were analyzed using descriptive statistics (frequencies, mean, median, standard deviation, and interquartile ranges). Normality was assessed using the Shapiro-Wilk test. For nonparametric variables, the Friedman test was applied, followed by Dunn's post hoc test when necessary. For parametric variables, repeated measures ANOVA was used, with Bonferroni correction for multiple comparisons. Generalized estimating equations (GEE) with robust variance were employed to estimate changes in scores over time. A significance level of 5% ($p < .05$) was adopted, and analyses were performed using GraphPad Prism software.

Results

Between September 2024 and July 2025, a total of 114 patients met formal eligibility criteria, with 22 patients with CVD, classified between CEAP C2 and C6, included in the study. Of these, 81.8% were female, with a mean age of 50.6 years. Baseline Caprini score was 4.68 ± 2.34 with CEAP clinical staging showed predominance of C2 (31.8%) and C3 (36.4%), followed by C4 (13.6%), C5 (4.5%), and

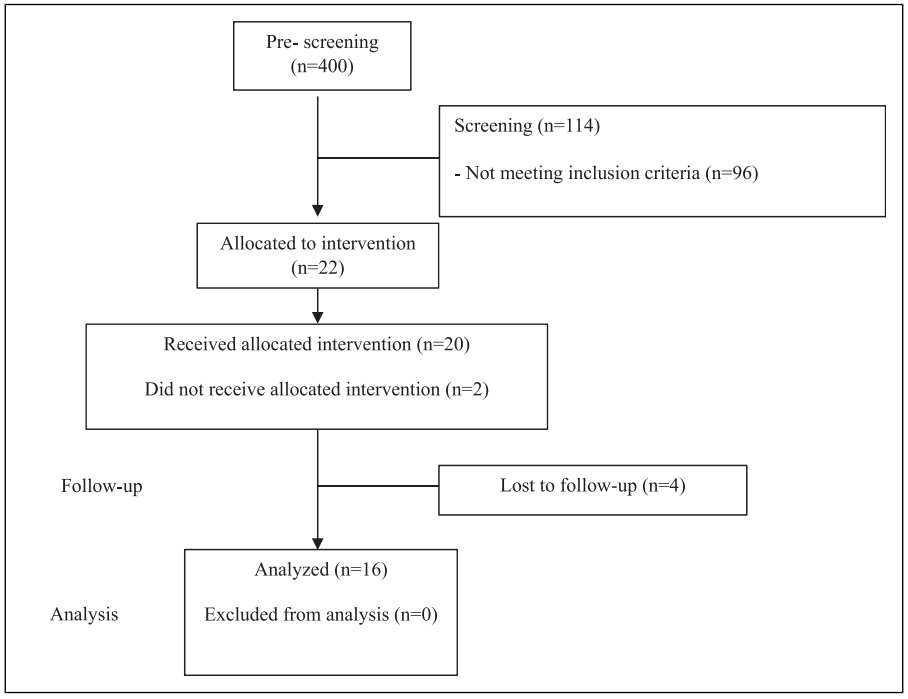

Figure 2. CONSORT flow diagram.

C6 (9.1%), reflecting the varied severity of CVD among participants (Table 1). By the 6-weeks follow-up, 20 patients had completed the assessment, and by 6 months, 16 patients remained in active follow-up, with no significant complications related to the technique (Figure 2, CONSORT diagram). The CIVIQ-14 score decreased from a mean of 30.95 at baseline to 26.38 at 6 weeks and 22.76 at 6 months ($p = .013$), while the AVVQ score decreased from 36.43 to 35.77 and 23.49, respectively ($p = .012$). The rVCSS score declined from 7.73 to 6.10 and 4.18 ($p = .014$), and the CEAP score dropped from 3.09 to 2.33 and 1.94 ($p = .002$), indicating clinical improvement of the disease. GEE analysis confirmed a statistically significant decrease in β coefficients over time between baseline and the 6-months follow-up for the following scores: CIVIQ-14 ($\beta = 0.31$; 95% CI: 0.03–0.59; $p = .032$), CEAP ($\beta = 0.40$; 95% CI: 0.12–0.69; $p = .006$), AVVQ ($\beta = 12.94$; 95% CI: 4.20–21.67; $p = .004$), and rVCSS ($\beta = 0.49$; 95% CI: 0.08–0.90; $p = .020$) (Table 2). Figure 3 depicts examples of pre- and post-treatment cosmetic results.

Postoperative complications were infrequent and generally mild. There was a significant reduction in lower limb pain between the preoperative period and 6 months ($p = .001$), while a transient increase in itching was noted at 6 weeks ($p = .020$), with resolution thereafter. Skin pigmentation remained absent or focal in most cases, with only one instance of severe pigmentation (4.5%) reported at 6 months. No cases of clinical thrombophlebitis or ultrasound-confirmed thrombophlebitis were observed after the procedure. A palpable fibrotic cord was present in 31.8% of patients at 6 weeks but decreased to 4.5% at 6 months. No cases of ultrasound-confirmed troncular fibrotic cord were observed after the procedure (Table 3). No significant changes were found in skin staining over time, and no active wounds were documented postoperatively.

Discussion

In this study, there was a significant improvement in clinical and quality of life scores, with sustained improvement observed up to 6 months of follow-up, and a reduction in CEAP clinical classification was observed after the procedure, reflecting meaningful functional and anatomical improvement in chronic venous disease.

Significant reductions in CIVIQ-14, AVVQ, and rVCSS scores supported clinical improvements. The Generalized Estimating Equations (GEE) analysis confirmed a progressive decline in beta coefficients over time, with

Table 2. Quality-of-life scores at baseline and at 6 weeks and 6 months postoperatively.

Score	Preoperative	6 weeks	6 months	p-value
CIVIQ-14, mean	30.95	26.38	22.76	0.013
AVVQ, mean	36.43	35.77	23.49	0.012
rVCSS, mean	7.73	6.10	4.18	0.014

CIVIQ-14: Chronic Venous Insufficiency Quality of Life Questionnaire; AVVQ: Aberdeen Varicose Vein Questionnaire; rVCSS: revised Venous Clinical Severity Score.

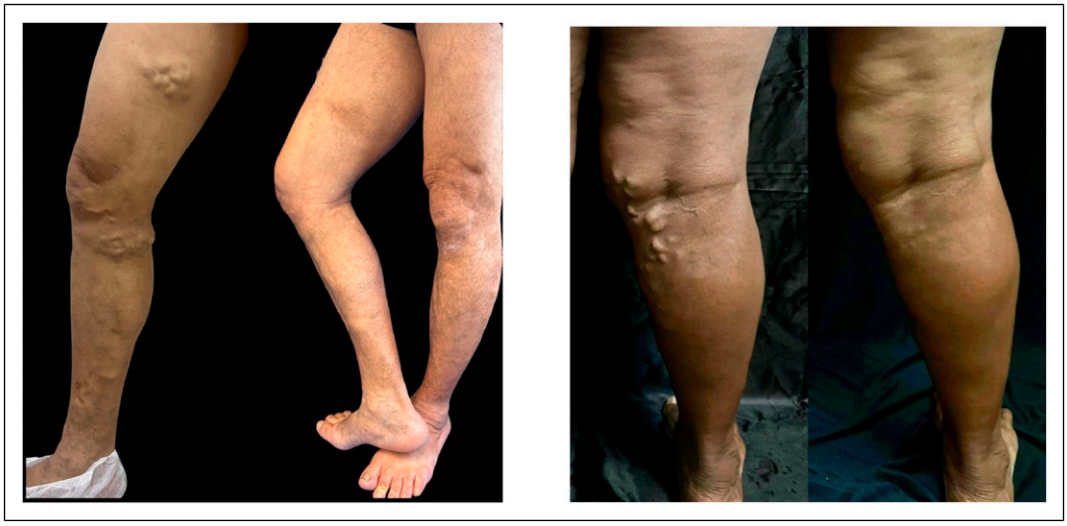

Figure 3. Examples of pre and post treatment results.

statistically significant differences primarily between the preoperative period and 6 months. These results suggest that the TEThA technique offers acceptable clinical benefits in reducing the burden of venous disease.

The CEAP score showed a statistically significant decrease ($p = .002$), with clinically relevant changes in classification. Patients initially classified as C6 (active ulcer) improved to C5 (healed ulcer), and others classified as C3 (edema) were reclassified as C1 (telangiectasias). These findings indicate not only symptomatic relief but also functional and anatomical improvement in chronic venous disease.

EVLA is well established as the reference treatment for great saphenous vein insufficiency.[16] However, the optimal management of varicose tributary veins remains under discussion. While phlebectomy continues to be a valid option,[17,18] there is growing interest in less invasive approaches, such as sclerotherapy and direct EVLA of the tributaries.[17,18] The TEThA technique emerges in this context as a promising alternative, particularly due to its ability to access tortuous veins through transfixing punctures, minimizing incisions, and improving procedural accessibility.[7,19]

Table 3. Adverse events.

Adverse event	Preoperative	6 weeks	6 months
Bruising, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Fibrous cord, n (%)	0 (0.0)	7 (31.8)	1 (4.5)
Itching, n (%)			
Right	3 (13.6)	8 (40.0)	5 (29.0)
Left	3 (13.6)	10 (47.6)	5 (29.4)
Pain, n (%)			
None	2 (9.1)	6 (28.6)	8 (47.1)
Mild	3 (13.6)	7 (33.3)	5 (29.4)
Moderate	9 (40.9)	7 (33.3)	3 (17.6)
Considerable	4 (18.2)	0 (0.0)	1 (5.9)
Intense	4 (18.2)	1 (4.8)	0 (0.0)
Edema, n (%)	13 (59.1)	13 (61.9)	10 (58.8)
Severe pigmentation, n (%)	0 (0.0)	0 (0.0)	1 (4.5)
Skin burns, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Thrombophlebitis, n (%)	1 (4.5)	0 (0.0)	0 (0.0)
Deep vein thrombosis, n (%)	1 (4.5)	1 (4.5)	0 (0.0)
Infection, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Allergy, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Optical fiber damage, n (%)	0 (0.0)	0 (0.0)	0 (0.0)

In addition to its clinical advantages, the procedure was shown to be feasible in an outpatient setting and safe with a low complication rate. The use of standardized photographic documentation and validated clinical scoring systems enhanced the reliability of the reported outcomes.

The TEThA technique was associated with a low rate of postoperative complications, which were mostly mild and self-limited, such as transient fibrotic cord and minor pigmentation changes. The pigmentation rate of 4.5% found in this study is well below that of foam, which reaches up to 10-30%.[6] No cases of thrombophlebitis or wound complications were observed. Patients did not complain of paresthesia or worsening of edema in the lower limbs. Some CEAP C3 patients progressed to C1, showing improvement in edema. This may suggest the absence of neurological and lymphatic lesions even with extraluminal ablation, which is expected when using an adequate tumescence that promotes thermal confinement in the vein, limiting temperature change, and protecting the structures around.[11] These findings suggest a favorable safety profile for the procedure.

The Theta technique was not designed to substitute phlebectomy. Just a single method for treating varicose veins above 3 mm is not ideal. We believe different techniques should be complementary. In the case of the TEThA Technique, its puncture-based approach—which can be ultrasound-guided—becomes an option for treating deeper veins prior to phlebectomy, such as in obese patients. Furthermore, being less invasive and utilizing tumescence makes it an interesting approach for patients with stasis dermatitis and CEAP C6.

The main limitations of the study include the small sample size and the absence of a control group, which limit the generalizability of the findings and prevent direct comparisons with established techniques. Nevertheless, the prospective design, standardized protocol, and longitudinal follow-up provide methodological strength to the study.

In summary, the findings of this exploratory study suggest that the TEThA technique is a safe and effective minimally invasive treatment of tributary varicose veins, with a positive impact on both clinical outcomes and quality of life. Larger multicenter studies with control groups are needed to validate these results and define the role of TEThA in future venous treatment guidelines.

Conclusions

The TEThA technique improved clinical and quality of life scores, with sustained improvement observed up to 6 months of postoperative follow-up, with no significant complications.

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ORCID iDs

Isabela Zampirolli Leal https://orcid.org/0009-0009-6803-9060
Eduardo Ramacciotti https://orcid.org/0000-0002-5735-1333

Ethical considerations

This study was conducted in compliance with the principles of the Declaration of Helsinki and applicable national regulations. The National Research Ethics Committee (CONEP) of the Brazilian Ministry of Health approved the study protocol under the ethical appraisal number 7.112.732 (CAAE 81917424.2.0000.8807). The authors declare that the procedures followed complied with the ethical standards of the responsible human experimentation committee and adhered to the World Medical Association and the Declaration of Helsinki. The procedures were approved by the institutional Ethics Committee. The authors have obtained approval from the Ethics Committee for the analysis of routinely obtained and anonymized clinical data, so informed consent was not necessary. Relevant guidelines were followed.

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Declaration of conflicting interests

ER reports grants and consulting fees from Novartis and personal fees from Aché Pharma, Novartis, and EMS outside the submitted work—no conflict of interest to disclose for the remaining authors.

Data Availability Statement

Anonymized participant data can be made available upon requests directed to the corresponding author. Proposals will be reviewed based on scientific merit. After a proposal is approved, data can be shared through a secure online platform after signing a data access agreement.

Trial registration

The study is registered at www.clinicaltrials.gov/ (NCT06669260).

Contributorship

NMCMV, ER, MHG, FRS, WHB and RAC conceived the trial and wrote the initial proposal. All other authors contributed intellectually relevant content. ER and NMCMV estimated the sample size and drafted the statistical analysis. NMCMV, GOB, GHS, IZ, MHG, MZ actively enrolled patients for the trial, NMCMV and MHG performed all the treatments. NMCVM performed the imaging exams. RK and FRS participated on the core laboratory. ER checked the performed statistical analysis, that was carried out by EF (acknowledgments). The initial draft of the manuscript was written by ER, NMCMV, RAC, WHB, FRS who had full access to

and verified all the data underlying the study. All authors had access to the data, contributed to the manuscript, agreed to submit for publication, and vouch for the integrity, accuracy, and completeness of the data and for the fidelity of the trial to the protocol.

Declaration on the use of artificial intelligence

During the preparation of this work, the author(s) used ChatGPT, OpenAI, Grammarly, and Grammarly Inc. to improve the text"s clarity and grammar. The authors carefully reviewed the output and are solely responsible for the manuscript"s content. After using this tool/service, the author(s) reviewed and edited the content as needed and took full responsibility for the content of the publication.

Guarantor

The guarantor is Eduardo Ramacciotti, MD, Ph.D, who is the senior author of the paper. Dr Ramacciotti holds important global publications, is a professor of Health Sciences at Santa Casa School of Medicine and professor of Thrombosis and Hemostasis at Loyola University Medical Center, Maywood, IL, USA. The current paper is a master thesis (MPH) of the principal author (AFL) under the formal mentorship of Dr. Ramacciotti.

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