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ORIGINAL ARTICLE

# The transfixing endovenous thermal ablation technique in varicose vein treatment: proof of concept and multicenter case series

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ABSTRACT

BACKGROUND: The aim of this article is to describe in detail the transfixing endovenous thermal ablation (TEThA) technique in varicose collateral treatment, presenting a multicenter series of cases with mid-term outcomes.
METHODS: The study evaluated the TEThA technique for treating symptomatic varicose veins in patients. All patients suffered from saphenous trunk incompetence. Outcomes included postoperative complications and target vein occlusion rates, with follow-up via clinical assessments and Doppler ultrasound at one, three, and six months.
RESULTS: Fifty-two legs underwent saphenous endovenous ablation combined with the TEThA technique for varicose veins. The average age was 51 years, with a predominance of females (71.1%). CEAP classifications included C2 (34.6%), C3 (51.9%), C4 (9.6%), and C6 (3.8%). The great saphenous vein (GSV) was treated in 75% of patients, and the mean trunk diameter was 6.9 mm. A 1940 nm laser was used in 63.5% of cases. No complications occurred, and all the saphenous trunks were fully ablated. Follow-up showed a low recanalization rate (2.7% at three months and 10.8% at six months) for varicose collaterals treated with TEThA.
CONCLUSIONS: The TEThA technique for varicose vein tributaries treatment showed promising mid-term results in feasibility, safety, and durability of occlusion. Future studies are necessary to assess long-term outcomes and compare various treatment techniques.

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KEY WORDS: Ablation techniques; Varicose veins; Saphenous vein.

According to recent guidelines, the preferred initial treatment for incompetence of the saphenous trunks, which includes both the great saphenous vein (GSV) and/or the small saphenous vein (SSV), is endovenous ablation using laser (EVLA) or radiofrequency techniques (RFA).[1-3]

In contrast, the treatment of varicose veins (VVs), whether originating from an incompetent saphenous axis or not, remains less clearly defined, with inconsistent results reported in the existing literature. The debate continues regarding the optimal approach, whether it be surgery, sclerotherapy, or laser ablation. Historically, ambulatory phlebectomy (AP) was the only available treatment option until advancements in endovenous procedures emerged. AP remains a well-established and frequently employed procedure for addressing residual symptomatic venous disease supported by tributaries. The use of local anesthesia enhances the procedure's versatility, enabling it to be performed in various clinical settings.[4] Most patients tolerate these procedures well, and complications are rare.

With the introduction of sclerotherapy, several new techniques have been developed. Ultrasound-guided sclerotherapy (UGS) offers broad applicability in treating venous disease across all stages of clinical presentation. Different sclerosant drugs and formulations, whether liquid or foam, possess distinct properties, utilities, and side effects. Treating physicians should understand these differences and consider factors such as disease presentation, vein characteristics, and patient comorbidities when selecting the appropriate sclerosing agents. Successful outcomes depend on thorough patient evaluation and careful assessment for contraindications to sclerotherapy.[5]

The choice between AP and UGS for treating varicose tributaries largely hinges on the physician's expertise and preferences, as well as the patient's expectations and characteristics, including contraindications, comorbidities, and venous patterns.[3, 6]

In recent years, ultrasound-guided percutaneous laser ablation of tributary VVs has emerged as a potential alternative treatment, particularly for limbs with extensive VVs. In this procedure, a small laser fiber is inserted into the single tributary to ablate each VV, minimizing the number of incisions and reducing procedural time. This technique has been demonstrated to be safe and feasible for addressing VVs recurrence from the saphenous junction.[7] However, mid-term results remain controversial, showing a higher rate of recurrent VVs compared to foam ultrasound-guided sclerotherapy (UGS).[8] This discrepancy may be due to the localized damage caused by the laser, which targets a single tributary. In contrast, foam can spread through VVs, reaching areas far from the injection site. To improve coverage and ablation of all affected tributaries, some "porcupine" techniques have been adopted, but with multiple punctures.[9]

The Transfixing Endovenous Thermal Ablation (TEThA) technique combines the benefits of laser ablation for VVs while minimizing the number of punctures required. This method operates on the principle that effective treatment can be achieved not only by positioning the laser fiber within the venous lumen but also by applying it externally, both transfixing and/or penetrating the vein wall.[10]

The aim of this article is to describe in detail the TEThA technique, presenting a series of cases with mid-term outcomes.

## Materials and methods

### Patients

The research included non-consecutive patients ranging from 18 to 90 years of age who had symptomatic moderate to severe VVs, as classified by the Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) system, with a symptomatic C2-C6 disease. Three skilled for venous interventions clinicians performed the technique in three centres (Hospital Dia Anjos Vasculares, Natal, RN, Brasil, AngioCor Clinic, Palermo, Italy and Clínica Metier Vasculare, Mogi das Cruzes, São Paulo, Brasil), in an outpatient setting, from January 1, 2024, to January 1, 2025.

### The TEThA technique

Contraindications for TEThA technique were life expectancy <2 years, pregnancy or breastfeeding, prior tributaries laser ablation, severe comorbidities with an augmented operative risk. Also, patients with recurrent VVs could be included if eligible.

Before the procedure, the VVs to be treated are marked on the skin. A pathway is drawn alongside the varicose tributaries, either outlining their borders or placing the vein's path between parallel lines. This marking process is facilitated by a vein viewer and/or augmented reality device, supplemented by Doppler ultrasonography (DUS) while the patient is in a supine position. Accesses to the VVs are achieved sequentially after treating the saphenous trunk responsible for the reflux in the tributaries. In case of non-saphenous VVs, the treatments starts where the reflux start as escape point. Since the treatment of the venous axis is not the aim of this article, we refer to a previous publication for its analysis.[10] Tributary varicose veins intended to be treated are punctured with a 16 G peripheral catheter. The number of punctures ranging according to the number, degree and diameter of target VVs, starting from the most distal segments (near their drainage points) to the most proximal areas (where reflux originates). The procedure utilizes a laser with a wavelength of 1470 nm or 1940 nm. With the 1940 nm laser, a 16G slim fiber catheter and a power of 2-4W was used, while with the 1470 nm a 16G slim fiber with power of 5W was employed; the fiber is pulled-back at a rate of 1 mm/second. The fiber is advance through the needle (Figure 1A) and then through the VVs, piercing them several times (Figure 1B). Once the needle is removed (Figure 1C), thermal ablation starts when the fiber is advance enough, pulling it back. All procedures were conducted under tumescence anaesthesia – performed just before the "thermal phase" with 0.08% lidocaine in saline solution to protect neighbouring structures and, primarily, the skin. A skin-fiber distance more than 5 mm was considered enough for avoiding surrounding burns damage. As results, thermal damage affects both internal and external vein wall, creating a double "perivenous-endovenous" injury pattern (Figure 1D). Sclerotherapy foam injection was used for completing the procedure.

The patients were discharged around 2 hours after the procedure, walking, and wearing 35 mmHg compression hosiery for 24 hours. Follow-up analysis includes both a

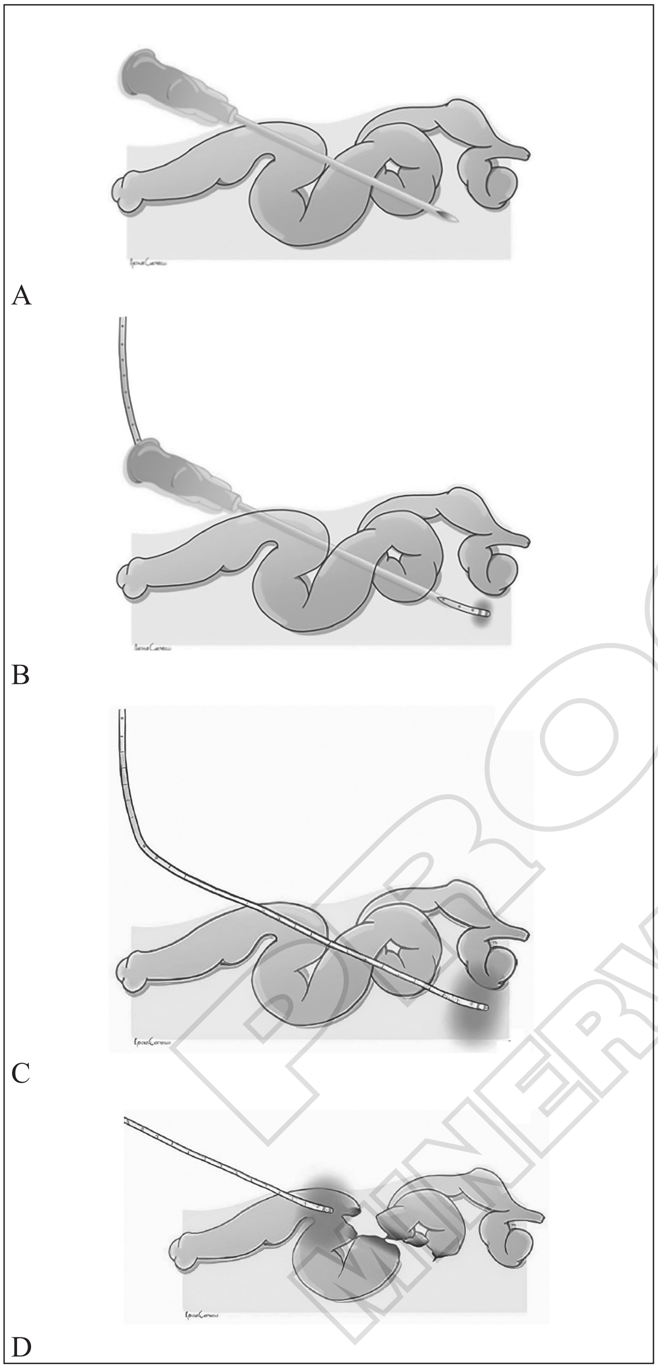

Figure 1.—Transfixing endovenous thermal ablation (TEThA) technique steps: the fiber is advanced through the needle (A) and into the varicose veins, piercing them multiple times (B). After needle removal (C), thermal ablation begins as the fiber is retracted. Procedures were performed under tumescent anesthesia using 0.08% lidocaine in saline to protect surrounding structures, particularly the skin. This results in thermal damage to both the internal and external vein walls, creating a dual “perivenous-endovenous” injury pattern during the fiber pull-back (D).

clinical and DUS evaluation at one, three and six months after TEThA.

### Outcomes

The primary outcome was the postoperative complication rate. Postoperative complications were classified as minor (transient [<30 days] discomfort, bruising, ecchymosis and/or nerve damage), moderate (transient superficial vein thrombosis [SVT] <10 cm in length, transient neurological deficit) or severe (permanent [>30 days] minor or moderate complications, SVT >10 cm in length, deep vein thrombosis, pulmonary embolism, any permanent neurological deficit).

Secondary outcomes were the target vein occlusion rate and target vein competent rate during the follow-up. Occlusion was defined as the absence of color and Duplex signals during follow-up DUS evaluation; competency was defined as the absence of reflux during follow-up DUS evaluation after reflux evocative maneuvers.

Each patient signed a consent document for clinical and scientific purposes, according to Helsinki declaration.

### Statistical analysis

Clinical data were recorded and tabulated in a Microsoft Excel (Microsoft Corp., Redmond, WA, USA) spreadsheet; statistical analysis was performed with JMP 16.0 (SAS Institute Inc., Cary, NC, USA). Missing data were reported during data extraction and flagged as such (-). Categorical / nominal variables were presented using frequencies and percentages, while continuous variables by mean (μ) and standard deviation, or median with interquartile range (IQR) and ranges, according to data distribution. Due to the pivotal nature of the manuscript, only descriptive analysis was performed, with no group comparison. The Kaplan-Meier method was employed to estimate the probability of an event (*e.g.* occlusion/reflux rate) occurring at a specific time point among subjects who have not already experienced that event during the follow-up.

## Results

During the study period, 52 legs in 36 patients were treated with saphenous endovenous ablation + TEThA for varicose collaterals.

Mean age was 51±13 years; females were 71.1%. Right and left lower limb were treated quite similarly (46.1% and 53.8%, respectively). CEAP classes were represented as follows: C2, 34.6%; C3, 51.9%, C4 9.6% and C6, 3.8%. In 75% of patients the GSV was treated, in 9.6% the SSV

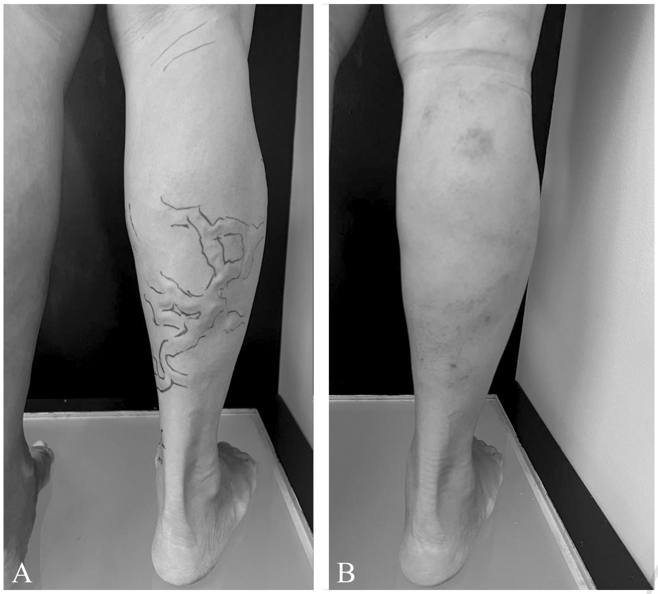


Figure 2.—Preoperative varicose veins evaluation in 43-year-old women with great saphenous vein (GSV) incompetence (A). Results at 30 days after endovenous GSV laser ablation and transfixing endovenous thermal ablation (TEThA) technique for posterior varicose tributaries.

and in the 1.5% both GSV and anterior accessory saphenous vein. All patients underwent concomitant TEThA technique. Mean saphenous trunk diameter was 6.9±2.2 mm.

In 63.5% of patients the 1940 mm laser was used while in the remaining 1470 laser was employed. The mean operating time was 31±9 minutes. Neither minor nor major complications were detected, perioperatively and during the follow-up period. The percentage of patients that completed the follow-up at 1 months, 3 months and 6 months was 100%, 100% and 71.2%, respectively. All saphenous trunks were totally ablated during follow-up controls. Regarding collaterals treated with the TEThA technique, only one recanalization was detected at the 3-month follow-up control (1/36, 2.7%). At the 6-month follow-up, three more cases were detected as open (4/33, 10.8%). No intraoperative and postoperative differences were detected between the use of 1940 mm or 1470 mm lasers. An example of clinical results is presented in Figure 2A, B.

## Discussion

In recent years, there has been a growing interest in the use of lasers for the treatment of varicose tributary veins using laser technologies. The primary advantage of laser lies in its ability to combine the minimally invasive nature of endovenous procedures with the safety and effectiveness of its application. While optimal outcomes for treating the saphenous trunk with EVLA have been well-documented and included in clinical guidelines,[1-3] there remains a need for further investigation and evidence regarding the treatment of tributaries.

A recent clinical practice guideline focused on endovenous thermal ablation for varicose veins emphasizes EVLA for varicose tributaries, outlining total endovenous techniques that primarily achieve damage to the internal venous wall.[11] In contrast, the TEThA technique offers both internal and external damage to the vein, presenting a potentially more comprehensive approach to treatment. Moreover, the TEThA technique optimally utilizes laser ablation for VVs tributaries while significantly reducing the number of punctures needed, if compared with totally endovenous collaterals laser ablation. This innovative approach is based on the concept that effective treatment can be accomplished by positioning the laser fiber not only inside the vein but also externally, allowing it to penetrate or transfix the vein wall. The TEThA technique offers several advantages, particularly since it utilizes lasers that have previously been effective on the saphenous axis. Moreover, one key benefit is the elimination of incisions required for phlebectomies, which can lead to discomfort and can decrease aesthetic patients' expectations. The double "perivenous-endovenous" injury pattern should be deeper analyzed but, according to these preliminary results, lead to a concomitant intima and adventitia contraction, maximizing the tributary collapse and irreversible closure. Perivenous tissue remain unaltered despite the injury provided by the laser pull-back, with no nerve or lymphatic registered damage in this patients' cohort.

Despite the primary aim of this study was to present encouraging mid-term outcomes achieved by a pivotal three-centers experience, the purpose of the article was to present the technique, describing it and evaluating the feasibility and safety. Limitations derive from the retrospective and preliminary nature of the cohort assessed. Further study should evaluate quality of life and long-term outcomes of the TEThA technique, providing useful insight regarding intraoperative tips and tricks, and comparing TEThA with AP and UGS.

## Conclusions

TEThA technique for VVs tributaries provided encouraging results in the mid-term outcomes analysis, regarding feasibility, safety and durability in tributaries occlusion.

Future studies are needed to implement and provide long-term outcomes, as well as a direct and random comparison between different collaterals treatment techniques.

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*Conflicts of interest*
The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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