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Original Article

Non surgical treatment of CEAP 2 varicose veins using Flebogrif® MOCA: Series of 5 Cases at the paraguayan varicose veins center

Tratamiento no quirúrgico de varices CEAP 2 utilizando Flebogrif® MOCA: Serie de 5 casos en el centro paraguayo de varices

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ABSTRACT

Objective: To evaluate the efficacy and safety of the Flebogrif® device for mechanochemical ablation (MOCA) in treating CEAP 2 varicose veins. **Methods:** Prospective case series of five patients (four women, one man) with CEAP 2 varicose veins treated with Flebogrif® between January and July 2023. Pre-treatment evaluation with duplex ultrasound and follow-up at 1-, 3-, 6-, and 18-months post-treatment was performed. **Results:** All patients maintained complete vein occlusion at 18 months without evidence of recanalization. Significant pain reduction and quality of life improvement were observed in all cases. No major complications were recorded. **Conclusion:** MOCA with Flebogrif® proved to be a safe, effective, and economical alternative for treating saphenous insufficiency with promising short-term results.

Keywords: Varicose veins, Flebogrif, mechanochemical ablation, chronic venous insufficiency, duplex ultrasound, CEAP classification.

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RESUMEN

Objetivo: Evaluar la eficacia y seguridad del dispositivo Flebogrif® para ablación mecanoquímica (MOCA) en el tratamiento de varices CEAP 2. **Métodos:** Serie de casos prospectiva de cinco pacientes (cuatro mujeres, un hombre) con varices CEAP 2 tratados con Flebogrif® entre enero y julio de 2023. Se realizó evaluación pre-tratamiento con ecografía dúplex y seguimiento a 1, 3, 6 y 18 meses post-tratamiento. **Resultados:** Todos los pacientes mantuvieron oclusión venosa completa a los 18 meses sin evidencia de recanalización. Se observó reducción significativa del dolor y mejora en la calidad de vida en todos los casos. No se registraron complicaciones mayores. **Conclusión:** MOCA con Flebogrif® demostró ser una alternativa segura, eficaz y económica para el tratamiento de insuficiencia safena con resultados prometedores a corto plazo.

Palabras clave: Varices, Flebogrif, ablación mecanoquímica, insuficiencia venosa crónica, ecografía dúplex, clasificación CEAP.

Introduction

Chronic venous insufficiency (CVI) is a widespread condition affecting the lower extremities, with a notable prevalence of superficial venous reflux [1]. CEAP C2 varicose veins, defined as veins with a diameter of 3 mm or more according to the CEAP (Clinical-Etiology-Anatomy-Pathophysiology) classification revised in 2020 [2], represent a common manifestation of CVI that significantly affects patients' quality of life and may progress to more severe complications if not adequately treated.

The advent of minimally invasive techniques, such as mechanochemical ablation (MOCA), offers promising treatment alternatives that combine efficacy with lower morbidity compared to traditional surgical methods [3]. The Flebogrif® device (Balton, Poland) represents a new MOCA technology that combines mechanical ablation through retractable radial cutting hooks and chemical ablation via infusion of sclerosing foam [4].

Thermal endovenous procedures, such as radiofrequency and endovenous laser, are currently considered standard treatments for saphenous insufficiency. However, these techniques require tumescent anesthesia, which increases discomfort during the procedure and carries a risk of neurological and skin injury [5]. In contrast, MOCA does not require tumescent anesthesia or heat, which is associated with less pain during and after the procedure, faster return to normal activities, and a lower risk of complications [6].

This report presents the initial results of five patients with CEAP 2 varicose veins treated with the Flebogrif® device at the Paraguayan Varicose Veins Center, representing the first documented experience with this specific device in Paraguay.

Materials and Methods

A prospective case series was conducted between January and July 2023 at the Paraguayan Varicose Veins Center (CEPAVA), Paraguay. Written informed consent was obtained from all patients prior to inclusion.

CEAP Classification and Case Definition

The CEAP classification (Clinical Etiology Anatomy Pathophysiology) is an international system developed by the American Venous Forum in 1994 and updated in 2020 to standardize the description of chronic venous disorders (**Table 1**). The clinical component (C) classifies venous disease into seven categories according to the severity of visible manifestations [2,7].

Table 1. CEAP Clinical Classification for Chronic Venous Disorders.

Class	Description	Characteristics
C0	No visible venous disease	No visible or palpable signs of venous disease
C1	Telangiectasias or reticular veins	Spider veins or superficial reticular veins
C2	Varicose veins	Dilated veins 3 mm or more in diameter
C3	Edema	Swelling of venous origin
C4a	Pigmentation or eczema	Early skin changes
C4b	Lipodermatosclerosis or white atrophy	Advanced skin changes
C4c*	Corona phlebectatica	Fan-shaped pattern of small intradermal veins
C5	Healed venous ulcer	Previously present venous ulcer, currently healed
C6	Active venous ulcer	Open and active venous ulcer

**Added in the 2020 revision. Each class may be symptomatic (s) or asymptomatic (a). The modifier "r" indicates recurrence.*

Patients included in this study presented CEAP C2, that is, visible varicose veins defined as dilated superficial veins with a diameter equal to or greater than 3 mm, distinguished from smaller reticular veins. These varicose veins may be symptomatic (C2s) when they cause discomfort such as pain, heaviness, or cramps, or asymptomatic (C2a) when they do not generate symptoms.

Case Presentation

Five patients (four women and one man) diagnosed with symptomatic CEAP C2 varicose veins were included after signing informed consent. Inclusion criteria were: confirmed diagnosis of superficial venous insufficiency by duplex ultrasound, presence of CEAP C2 varicose veins with symptoms attributable to venous disease, age over 18 years, ability to provide informed consent, and acceptance of the follow-up protocol. Patients with a history of deep vein thrombosis, veins with severe tortuosity preventing treatment, mild venous disease (CEAP C0–C1), pregnant or breastfeeding women, and patients with contraindications to elastic compression were excluded.

Procedure

The procedure was performed in the operating room under local anesthesia after detailed explanation and signing of specific informed consent for the procedure. Using the Seldinger technique, a 6F vascular sheath was placed in the great saphenous vein (GSV) or small saphenous vein (SSV) under ultrasound guidance. The Flebogrif® device was advanced to 2-3 cm below the saphenofemoral or saphenopopliteal junction. During catheter withdrawal, the radial cutting hooks caused mechanical endothelial damage while 3% polidocanol foam was simultaneously infused for chemical ablation. The procedure was completed with external compression and compressive bandaging. All patients received standardized postoperative instructions and were scheduled for outpatient follow-up.

Pre-treatment evaluations included duplex ultrasound to measure venous diameters, reflux times, and complete anatomical mapping. Clinical severity was documented using the CEAP classification and symptom scales. Outcome variables included venous occlusion, absence of reflux, reduction in venous diameter, symptomatic relief, time to return to normal activities, complications, and patient satisfaction.

Follow Up

Follow up evaluations were conducted at 1, 3, 6, and 18 months post-treatment to assess venous occlusion, evaluate recurrence by duplex ultrasound, and document clinical evolution. At each visit, physical examination, duplex ultrasound, and quality-of-life assessment were performed.

Results

Baseline Patient Characteristics

The first case corresponded to a 32-year-old woman who presented with varicose veins and moderate pain in the right leg. Duplex ultrasound showed a GSV with a diameter of 6.5 mm and a reflux time of 0.8 seconds, indicating significant valvular incompetence with thickened venous walls and valves that failed to coapt properly, resulting in retrograde flow during the Valsalva maneuver.

The second patient was a 37-year-old woman with a history of varicose veins and severe pain in the left leg. Ultrasound findings revealed a prominent GSV with a diameter of 7.2 mm and prolonged reflux time of 1.5 seconds, suggesting severe valvular insufficiency with an irregular venous lumen and continuous retrograde blood flow confirmed by color Doppler.

The third case included a 41-year-old woman with visible varicose veins and intermittent leg cramps. Evaluation showed a small saphenous vein (SSV) with a diameter of 7.8 mm and an extended reflux time of 2.3 seconds. The vein demonstrated tortuosity and valvular dysfunction, resulting in venous hypertension that significantly contributed to the patient's symptoms.

The fourth case corresponded to a 30-year-old woman with primary varicose veins and mild leg pain. Ultrasound findings indicated a dilated GSV with a diameter of 6.0 mm and reflux time of 2.0 seconds. Valvular insufficiency was evident, and Doppler study showed a retrograde flow pattern during compression and release maneuvers.

The fifth patient was a 45-year-old man with symptomatic varicose veins and a sensation of leg heaviness. Ultrasound examination highlighted an enlarged GSV with a diameter of 6.5 mm and substantial reflux of 2.7 seconds. The vein presented irregular luminal contours and non-functioning valves, causing increased venous pressure and development of symptomatic varicose veins.

Treatrment Outcomes

All patients successfully completed the procedure and the 18-month follow-up. Technical efficacy was 100%, with complete occlusion of all treated veins maintained throughout the follow-up period. No recanalization was observed in any case, and complete elimination of reflux was achieved in all treated veins.

Clinical outcomes were consistently favorable. All patients reported significant pain improvement, with pain scores decreasing from moderate to severe preoperative levels to minimal or absent levels at follow-up. One hundred percent of patients experienced improvement in quality of life, with return to normal activities within the first days post-procedure. No significant mobility restrictions were documented, and all patients expressed high satisfaction with the results.

Post-treatment ultrasound findings demonstrated anatomical changes consistent with successful ablation. At 18 months, venous diameters were significantly reduced: the first patient showed GSV reduction to 2.1 mm with a fibrotic appearance; the second patient presented reduction to 2.5 mm without evidence of recanalization; the third patient showed a completely occluded SSV with diameter reduced to 2.3 mm; the fourth patient presented an occluded GSV with reduction to 2.0 mm and no retrograde flow; and the fifth patient showed a completely occluded GSV with diameter decreased to 2.7 mm without evidence of reflux.

Safety Profile

The procedure demonstrated a high safety profile. All treatments were well tolerated with no major complications. No cases of deep vein thrombosis, pulmonary embolism, puncture site infection, significant nerve injury, or permanent hyperpigmentation were observed. Patients experienced minimal discomfort

during the procedure, with mean intraoperative pain scores of 2/10 on the visual analog scale. No prolonged hospitalizations or additional treatments for complications were required.

Discussion

The results of this case series suggest that MOCA with Flebogrif® is an effective and safe alternative for the treatment of CEAP C2 varicose veins. The findings are consistent with previous studies reporting satisfactory venous occlusion rates with MOCA devices, including series with Flebogrif® showing occlusion rates of 92–97% at 12 months of follow-up [8,9]. A multicenter study including 348 procedures with Flebogrif® reported anatomical success rates of 95% at 3 months and 92% at 12 months [10].

The absence of recanalization at 18 months in our series is satisfactory, considering that previous studies have shown that recurrences typically occur within the first 12 months post-treatment [11]. This durability may be attributed to the dual mechanism of action of Flebogrif®, which combines direct mechanical endothelial damage via radial cutting hooks with chemical ablation through polidocanol, resulting in more complete venous wall injury compared to techniques using only one of these mechanisms [12].

The symptomatic improvement observed in all patients is comparable to that reported with other endovenous ablation techniques, including laser and radiofrequency [13]. The advantage of MOCA lies in the absence of perivenous tumescent anesthesia, which may reduce procedural discomfort and allow faster return to normal activities. Comparative studies have suggested that patients treated with MOCA may experience less intraoperative and postoperative pain compared to thermal techniques [14].

The mechanism of action of Flebogrif® presents theoretical advantages over other MOCA devices. While ClariVein® uses a rotating wire for mechanical damage, Flebogrif® employs retractable radial cutting hooks that provide more direct and uniform endothelial injury. This mechanical difference may explain the favorable results observed, although direct comparative studies are required to confirm this hypothesis.

The concentration of polidocanol used (3%) in this study aligns with manufacturer recommendations and previous studies. Research evaluating different polidocanol concentrations with Flebogrif® suggests that 3% concentrations may be superior to 1.5% in terms of occlusion rates, although differences do not always reach statistical significance due to small sample sizes [4].

Limitations and Strengths

The main limitations of this study include the small sample size (n=5), which limits the ability to detect statistically significant differences and generalize the results. The 18-month follow-up, while adequate for short- to mid-term efficacy evaluation, is insufficient to determine long term durability. The absence of a control group prevents direct comparisons with other ablation techniques. Additionally, the single-center design may introduce biases related to operator experience and patient selection.

Among the strengths, this represents the first documented experience with Flebogrif® in Paraguay, providing important initial evidence for adoption of this technology in the region. Systematic follow-up with duplex ultrasound at multiple time points allows objective evaluation of anatomical outcomes. The comprehensive assessment including technical, clinical, and quality-of-life outcomes provides a holistic perspective of treatment efficacy. The standardized protocol and detailed documentation facilitate reproducibility of the results.

Clinical Implications

The results suggest that MOCA with Flebogrif® may be considered a first-line option for patients with CEAP 2 varicose

veins, particularly in cases where avoidance of tumescent anesthesia is desired or where contraindications to thermal techniques exist. The technique may be particularly valuable in patients with superficial veins close to neural structures, where thermal techniques carry a higher risk of injury. Additionally, the outpatient nature of the procedure and rapid return to normal activities make it attractive from cost effectiveness and patient satisfaction perspectives.

Conclusions

MOCA with Flebogrif® proved to be a safe and effective alternative to standard methods in the treatment of CEAP C2 varicose veins with favorable short-term results. All patients maintained complete venous occlusion with elimination of reflux and symptomatic improvement throughout the 18-month follow-up period. The favorable safety profile, absence of major complications, and high patient satisfaction support consideration of this technique in the treatment of varicose veins.

Prospective controlled studies with larger patient numbers, long-term follow-up, and direct comparisons with standard thermal techniques are needed to validate these preliminary findings and establish standardized treatment protocols. Future studies could include cost-effectiveness analyses, evaluation of predictive factors for success, and development of patient selection criteria to optimize outcomes with this technique in the Paraguayan and Latin American population.

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