From the American Venous Forum

Thirty-sixth-month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence

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ABSTRACT

Objective: The objective of this study was to evaluate the long-term safety and effectiveness of endovenous cyanoacrylate (CA)-based closure of incompetent great saphenous veins.

Methods: This was a prospective, single-arm, single-center feasibility study conducted at the Canela Clinic (La Romana, Dominican Republic) to assess the effectiveness and safety of a CA-based adhesive for great saphenous vein closure at 36 months after treatment. Thirty-eight subjects were treated by injection of small boluses of CA under ultrasound guidance and without the use of perivenous tumescent anesthesia or postprocedure graduated compression stockings. Periodic scheduled follow-up was performed during 36 months.

Results: At month 36, there were 29 subjects who were available for follow-up. Complete occlusion of the treated veins was confirmed by duplex ultrasound in all subjects with the exception of two subjects showing recanalization at month 1 and month 3. Kaplan-Meier analysis revealed an occlusion rate at month 36 of 94.7% (95% confidence interval, 87.9%-100%). The mean Venous Clinical Severity Score (VCSS) improved from 6.1 ± 2.7 at baseline to 2.2 ± 0.4 at month 36 ($P < .0001$). Pain, edema, and varicosities (VCSS subdomains) improved in 75.9%, 62.1%, and 41.4% of subjects, respectively, at month 36. Overall adverse events were mild or moderate and self-limited.

Conclusions: CA adhesive appears to be an effective and safe treatment for saphenous vein closure, with long-term occlusion rates comparable to those of other thermal and nonthermal methods and with no reported serious adverse events. (J Vasc Surg: Venous and Lym Dis 2017;■:1-9.)

Chronic venous disease (CVD) in its advanced form can affect primarily the lower extremity and lead to chronic venous insufficiency (CVI),[1] which causes hyperpigmentation and lipodermatosclerosis and, if left untreated, can lead to a number of complications, including venous ulceration and thrombosis.[1,2] CVI is also associated with decreased quality of life.[3]

A common manifestation of CVD is varicose veins, which are dilated superficial veins that become increasingly enlarged and tortuous.[2] Cross-sectional population-based studies have shown that 21% of adults have some form of varicose veins, with a higher prevalence in women.[4-6] The condition worsens when venous pressure increases and blood return is compromised.[2] The most frequent cause of CVD is incompetence of the great saphenous vein (GSV).[7]

Traditionally, varicose veins were treated with surgical ligation and stripping, which requires general anesthesia. However, the management of varicose veins has changed in the past 15 years, and minimally invasive techniques have largely supplanted these surgical procedures.[8] Endovenous thermal ablation (EVTA), which includes endovenous laser ablation and radiofrequency ablation, has demonstrated occlusion rates of >90% at up to 2 and 5 years of follow-up.[9-13] These techniques have been endorsed by the Society for Vascular Surgery and the American Venous Forum as well as by the UK National Institute for Health and Care Excellence over traditional surgical procedures.[14,15] Compared with standard surgery, EVTA has fewer complications, reduced

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need for postoperative pain relief, and improved quality of life and cosmetic outcomes.[16] However, EVTA requires tumescent anesthesia and carries a small risk of thermal-related complications, such as paresthesia, prolonged pain, and skin burn. The insertion of the tumescent fluid can also be painful.[17,18]

Because of these drawbacks, interest in nonthermal alternatives has increased. Foam sclerotherapy has become a popular nonthermal alternative because of its low cost and treatment flexibility. However, success rates for foam sclerotherapy appear to be lower than for other methods, and reintervention to maintain vein closure is common.[10,19,20] Complications associated with foam sclerotherapy include phlebitis and skin pigmentation.[8] In addition, foam sclerotherapy has been associated with a risk of paradoxical intracerebral gas emboli, resulting in stroke, migraine headache, and visual disturbances.[21,22] Other nonthermal nontumescent techniques are commercially available in the United States. These include mechanochemical ablation, which uses an infusion catheter that mechanically scores the inner lining of the vein while injecting a sclerosant. An injectable polidocanol endovenous microfoam has also been introduced.

A new procedure using endovenous delivery of a cyanoacrylate (CA) has been developed to address these drawbacks. CA can be formulated for rapid polymerization and high tissue affinity in the presence of blood, which causes target vein closure by a secondary inflammatory reaction and encapsulation that leads to fibrosis.[23,24] The CA closure device (VenaSeal Closure System; Medtronic, Dublin, Ireland; formerly Sapheon Closure System) is commercially available in the United States (indicated for the permanent closure of lower extremity superficial truncal veins), European Union, and other countries (for the permanent, complete, endovascular adhesive closure of the GSV and associated varicosities in the treatment of venous reflux disease).[25]

The first-in-human study was initiated to determine the feasibility of treating incompetent saphenous veins using an endovenous delivery of CA, and outcomes from the 12- and 24-month follow-ups were previously reported.[26,27] Herein the effectiveness and safety results of the 36-month follow-up are reported.

METHODS

Study design and enrollment. This was a prospective, single-arm, single-center feasibility study conducted at the Canela Clinic (La Romana, Dominican Republic) to assess the 36-month effectiveness and safety of CA closure for GSV closure. The study enrolled 38 subjects beginning in December 2010 and with consent for up to 36 months of follow-up. Results of the 12- and 24-month follow-ups have been previously published[26,27]; this paper reports the results of the 36-month follow-up.

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective single-center uncontrolled study
- **Take Home Message:** At 36 months after treatment of 38 patients with a cyanoacrylate-based adhesive, 27 of the 29 patients available for follow-up had occluded great saphenous vein (94.7%; 95% confidence interval, 87.9%-100%). The mean Venous Clinical Severity Score (VCSS) improved ($P < .0001$), and adverse events were mild or moderate and self-limited.
- **Recommendation:** The authors suggest that cyanoacrylate adhesive is an effective and safe treatment for saphenous vein closure, with 3-year occlusion rates comparable to those of other thermal and nonthermal methods and with no reported serious adverse events.

Ethics. Before commencement of the study, the protocol was approved by the local Ethics Committee and the Dominican Republic's National Council on Bioethics in Health (CONABIOS). Potential patients meeting initial eligibility criteria after screening provided informed consent before any study-specific activities were performed.

Inclusion and exclusion criteria. The target patient population was adults with venous reflux disease in the GSV with Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification between C2 and C4 and the ability to walk unassisted. Subjects were examined by the investigator and evaluated according to medical history, physical examination, and surgical clearance evaluation. Initial screening included a complete history and physical examination and duplex ultrasound evaluation to assess venous reflux and affected veins. Study eligibility of patients was determined by defined inclusion and exclusion criteria (Table I).

Study treatment and plan. Before treatment, the investigator completed the Venous Clinical Severity Score (VCSS) for the index leg. Baseline limb characteristics were scored using the CEAP classification. After treatment, subjects were seen at 24 to 72 hours after the procedure and then at clinic visits at 1, 3, 6, 12, 24, and 36 months after the procedure. A complete duplex ultrasound evaluation of the deep and superficial systems was performed at each follow-up visit. In addition, the VCSS and CEAP evaluations were completed by the investigator at each follow-up visit.

Study procedure. The closure system (VenaSeal Closure System) has been described previously.[26,27]

Similar to EVTA, the patient's vasculature was mapped under ultrasound guidance, and the GSV was accessed with a Micro Introducer Kit followed by insertion of a 0.035-inch J guidewire (Cook, Bloomington, Ind). Under

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