2021 in Review: Key Papers in Venous Surgery

An overview of notable articles related to venous disease published in the recent literature and summaries of their impact on superficial venous disease.

By Nicole D'Ambrosio, MD; Bianca Cutler, FNP; and Misaki Kiguchi, MD, MBA, FACS

Management and Outcomes of Patients With Isolated Superficial Vein Thrombosis Under Real Life Conditions (INSIGHTS-SVT)

Bauersachs R, Gerlach HE, Heinken A, et al. Eur J Vasc Endovasc Surg. 2021;62:241-249. doi: 10.1016/j.ejvs.2021.04.015

SUMMARY/TAKEAWAY POINTS

This paper reports the results of a prospective observational study investigating significant health trends in the management of superficial vein thrombosis (SVT) (INSIGHTS-SVT). The primary outcome detailed SVT complications, including symptomatic deep vein thrombosis (DVT), pulmonary embolism, and extension or recurrence of SVT at 3 months. Incidence of clinically relevant bleeding was also measured. The review included 1,150 patients (mean age, 60.2 ± 14.7 years; 64.9% women; mean body mass index, 29.4 ± 6.3 kg/m^2) with presence of isolated SVT in the lower extremity, classified anatomically as below knee, above knee, or above and below knee. Patients received a variety of treatments at baseline, including a combination of pharmacologic treatment with either anticoagulants (fondaparinux, heparins, direct oral anticoagulants) and/or analgesics (93.6%), compression (77%), surgery (1.9%), and nonpharmacologic treatment (6.4%). The primary outcome occurred in 5.8% of patients and was adjusted by propensity score and treatment duration. A multivariable analysis was performed identifying associated factors influencing the primary outcome, including a previous SVT event, age per year, thrombus length, and duration of drug treatment. Complete clinical recovery of SVT was achieved in 708 (62.4%) patients. In total, 7.4% of patients with SVT did not improve or worsened after 3 months. The study concluded that patients with isolated SVT are at continued risk of thromboembolic complications at 3-month follow-up, particularly those with recurrent or extended SVT, despite anticoagulation. The article identifies the need for better standardization of treatment and guideline adherence for SVT patients, with an overall recommendation for extended anticoagulant therapy in this patient population. However, the study recognizes the need for further randomized controlled trials (RCTs) with expanded demographics to elucidate more specific treatment recommendations.

WHY THIS ARTICLE IS IMPORTANT

Isolated SVT is a common venous condition that is widely influenced by a variety of factors. Although it is well known that SVT may be bothersome and uncomfortable, current treatment guidelines are inconsistent, and long-term complications are less well studied than those of DVT. Perhaps underestimated in the past, INSIGHTS-SVT demonstrates that SVT portends significant risk of thromboembolic events and recurrent or extended SVT, despite initial anticoagulation within a high-risk group. Through the exploration of risk profile heterogeneity, clinical presentation, complications, and various treatments, this study importantly delineates factors that are associated with a higher risk of SVT complications. These data can be further evaluated and researched to develop better risk stratification and more standardized treatment guidelines in the management of SVT. The study identifies an important need for ongoing research and standardization within a common but impactful superficial venous condition.

Reducing Hyperpigmentation After Sclerotherapy: A Randomized Clinical Trial

Gonzalez Ochoa AJ, Carrillo J, Manríquez D, et al. J Vasc Surg Venous Lymphat Disord. 2021;9:154-162. doi: 10.1016/j.jvsv.2020.06.019

SUMMARY/TAKEAWAY POINTS

This article reports results of a prospective, multicenter RCT with a parallel group design to compare rates of hyperpigmentation after sclerotherapy with use of a venoactive drug, sulodexide. The study included 720 patients without deep venous reflux but with varicosities amenable to sclerotherapy. Group A (354 patients) received twice-daily sulodexide 7 days prior to and 3 months after sclerotherapy with polidocanol. Group B (366 patients) underwent sclerotherapy with polidocanol without taking sulodexide. Photographs were taken at baseline and at 1- and 3-month follow-up. Computer software analyzed the degree of hyperpigmentation and improvement in treated varicosities. Incidence of major bleeding was also examined. A total of 609 out of 720 patients completed the 3-month follow-up. Patients treated with sulodexide had significantly less degree of hyperpigmentation (10.7% vs 18.2%; *P* = .01). The skin tone of the hyperpigmented area was also lower in the sulodexide-treated group compared to the nontreated group, but this significant difference was not maintained after 3 months. The overall aesthetic disappearance rate was similar between the two groups. No adverse events were reported, but 20 patients who developed residual thrombus needed thrombectomy. These patients all developed hyperpigmentation.

WHY THIS ARTICLE IS IMPORTANT

This study advances our attempts to minimize one of the most minor but dreaded complications of sclerotherapy. As sclerotherapy treatment is often cosmetic, hyperpigmentation, as a consequence, is suboptimal and is contrary to the objective of sclerotherapy. Sulodexide is a venoactive drug that regulates endothelium–blood cell interactions, counteracts vascular inflammatory changes, and protects the endothelium. Its pleiotropic properties may reduce the inflammatory response, which causes hyperpigmentation prior to initiation of sclerotherapy by mitigating venous hypertension and during and after sclerotherapy by limiting inflammation. Although the study population was not divided according to types of veins treated (telangiectasias, varicose), the large number of patients suggests a real-world experience.

A Randomized Controlled Trial of Endovenous Laser Ablation Versus Mechanochemical Ablation With ClariVein in the Management of Superficial Venous Incompetence (LAMA Trial)

Mohamed AH, Leung C, Wallace T, et al. Ann Surg. 2021;273:e188-e195. doi: 10.1097/SLA.0000000000003749

SUMMARY/TAKEAWAY POINTS

This single-center, nonblinded RCT compared clinical, technical, and quality-of-life (QOL) outcomes after endovenous laser ablation (EVLA) versus mechanochemical ablation (MOCA) in the treatment of symptomatic, unilateral superficial venous incompetence. The study included 150 patients, equally distributed between the two treatment groups. Outcomes included patient-reported periprocedural pain and technical efficacy at 1 year. Secondary outcomes included QOL measures, complications, and procedural details. Both groups reported a low intraprocedural pain score (EVLA, 22 [9-44] vs MOCA, 15 [9-20]; *P* = .210). However, at 1 year, occlusion rates after EVLA were significantly higher as compared with MOCA (91% vs 77%; *P* = .02). QOL scores improved significantly in both groups, but there was no significant QOL score difference between treatment groups. One patient in the MOCA-treated group experienced a DVT.

WHY THIS ARTICLE IS IMPORTANT

Nonthermal venous closure techniques have reported an advantage to thermal venous closure techniques with a lower periprocedural pain profile due to the

lack of tumescence needed. However, there has been no significant difference in periprocedural pain with newer laser technology, despite the use of tumescence with EVLA. This challenges a previous notion that laser venous closures are associated with increased pain compared to those of other endovenous closure modalities, especially nonthermal. These data may ultimately influence clinician recommendations and patient decisions to proceed with certain vein treatments. Both MOCA and EVLA techniques are highly efficacious in the treatment of venous reflux, with significant improvement in QOL measures; however, a significantly higher rate of recanalization after MOCA was observed at 1 year compared with EVLA, and thus, EVLA carries a technical advantage over MOCA. Further research on the clinical sequelae of lower occlusion rates with MOCA treatment after 1 year, as compared to EVLA treatment, would also help in deciding between treatments.

A Comparison of Cyanoacrylate Glue and Radiofrequency Ablation Techniques in the Treatment of Superficial Venous Reflux in CEAP 6 Patients

O'Banion LA, Reynolds KB, Kochubey M, et al. J Vasc Surg Venous Lymphat Disord. 2021;9:1215-1221. doi: 10.1016/j.jvsv.2020.12.082

SUMMARY/TAKEAWAY POINTS

This article reports the results of a multi-institutional retrospective review of all patients with CEAP (clinical, etiologic, anatomic, pathophysiologic) class 6 who had undergone closure of their truncal veins from 2015 to 2020 with either ClosureFast radiofrequency ablation (RFA) or VenaSeal adhesive closure (both Medtronic). The study included 119 patients with CEAP 6 disease, 68 of whom were treated with RFA and 51 with VenaSeal. Patients were included if they had CEAP class 6, documented superficial venous reflux > 0.5 seconds, and vein diameters > 3 mm. Patients whose wounds had healed at the time of first ablation were excluded. The procedure choice was left to the physician, taking into account the patient's discretion and insurance approval. All procedures were performed according to instructions for use; follow-up ultrasound examination to ensure vein closure and the absence of DVT was performed for all patients within 1 week after the procedure. The primary endpoint was the time to wound healing. The secondary endpoints included the ulcer recurrence and infection rates.

Overall median wound size was 3 cm^2. No patient presented with an active wound infection at the initial visit. The technical success rate was 100%, confirmed by postprocedural duplex ultrasound. On univariate analysis examining the risk factors for an increased time to wound healing, use of RFA and a history of DVT were significantly associated with an increased time to wound healing. The median time to wound healing was 64 days (interquartile range, 29-166 days) but was significantly shorter for the VenaSeal-treated cohort as compared with the ClosureFast-treated cohort (43 vs 104 days; $P = .001$). The overall ulcer recurrence rate was 19.3% and did not differ between the two treatment arms (22.1% for RFA vs 13.7% for VenaSeal; $P = .25$). The infection rate was not significant between the two groups but only occurred in the RFA-treated group (two patients).

WHY THIS ARTICLE IS IMPORTANT

This study advances our knowledge of nonthermal treatment options for patients with CEAP 6 disease by evaluating their efficacy in healing venous ulcers and recurrence rates as compared to the thermal treatment options. Venous leg ulcers are the most advanced form of chronic venous hypertension and affect 1.5% of the population, accounting for > 1 million people in the United States.[1] These patients often experience pain, immobility, and overall decreased QOL.

Prior to this study, results from the ESCHAR and EVRA studies revealed superior wound healing rates for patients who had undergone early endovenous intervention. However, these studies predate the nonthermal endovenous ablative techniques such as VenaSeal. In this study by O'Banion et al, the use of cyanoacrylate glue closure via VenaSeal decreased wound healing time compared to ClosureFast RFA. One of the primary advantages of VenaSeal ablation in CEAP 6 patients is the elimination of the thermal element, which allows for access to the target vein at or below the ankle and closure of the entire segment of the refluxing vein from the junction to the ankle. In thermal ablation, treat-

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ment of refluxing distal calf saphenous veins is avoided due to risk of thermal nerve injury. Therefore, in theory, nonthermal endovenous closure may allow for more elimination of venous hypertension in the leg and thus may expedite venous ulcer healing.

The study also stratified the wounds based on median wound size and eliminated ulcer size as a bias. This stratification still revealed that VenaSeal closure healed all wounds, regardless of size classification, quicker than ClosureFast RFA. The treatment options for patients with CEAP 6 disease have expanded with development of nonthermal endovenous techniques, and this study may strengthen the use and efficacy of VenaSeal over ClosureFast RFA as an optimal endovenous closure technique across all wound sizes for patients with venous ulcers. ■

1. O'Donnell TF Jr, Passman MA, Marston WA, et al; Society for Vascular Surgery; American Venous Forum. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery ® and the American Venous Forum. J Vasc Surg. 2014;60(2 suppl):3S-59S. doi: 10.1016/j.jvs.2014.04.049

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