

Role of Superficial Venous Therapies In Improving Venous Ulcer Healing: Choice of Techniques And Use Of Adjunctive Strategies

VEITH Symposium 2024





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Disclosures



- Medtronic PVH- Consulting and Teaching
- Shockwave Medical- Consulting and Teaching
- Endologix- Consulting and Teaching



Venous Ulcer Prevalence

- Approximately 6 million Americans have skin changes associated with CVI
- Venous stasis ulcers affect approximately 500,000 people
- Cost \$14.9 billion of annual US payor



Burden of venous ulcers in the United States. J Med Econ 2014; 17:347-56

Venous Ulceration Pathogenesis

SEMINARS IN VASCULAR SURGERY 28 (2015) 6-14

Conservative versus leg ulcers: A meta-analysis

Cost effectiveness of community leg ulcer clinics: randomised controlled trial

Abstract

Objective: To evaluate the relative cost effectiveness of conservative versus leg ulcer clinics.

Design: Randomised controlled trial.

Setting: Leg ulcer clinics in the United Kingdom.

Participants: 120 patients with leg ulcers.

Interventions: Conservative treatment (n=60) vs leg ulcer clinic (n=60).

Main results: The leg ulcer clinic group had significantly lower costs (£1,200 vs £1,800, p=0.001) and shorter time to healing (120 vs 180 days, p=0.001).

Conclusion: Leg ulcer clinics are a cost-effective alternative to conservative treatment for leg ulcers.




A Randomized Trial of Early Endovenous Ablation in Venous Ulceration

CONCLUSIONS

Early endovenous ablation of superficial venous reflux resulted in faster healing of venous ulcers compared with conservative treatment.

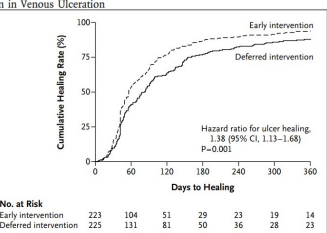




Figure 2. Kaplan-Meier Curves for Time to Ulcer Healing in the Two Treatment Groups.

Days to Healing	Early Intervention (n=223)	Deferred Intervention (n=225)
0	223	225
60	104	131
120	51	81
180	29	50
240	23	36
300	19	28
360	14	23

Hazard ratio for ulcer healing: 1.38 (95% CI, 1.13-1.68), P<0.001.

Thermal Procedures

Use vein segment treated at or below 10°C to prevent treatment. Additional vein segments treated nearby.

Use accurate catheter re-positioning between treatment cycles. No energy delivered during re-positioning.

Placement of 45 cm vein length (over 310 cm treated) lower treatment segments.

Mount Sinai Vascular Surgery
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Endovenous Laser Ablation–Induced Complications: Review of the Literature and New Cases

RENATE R. VAN DEN BOS, MD,¹ MARTINO NEUMANN, MD, PhD,²
KEES-PETER DE ROOS, MD, PhD,¹ AND TAMAR NIJSTEN, MD, PhD³

Author	Year	Limbs, n	Wave Length, nm	Skin Burns	Echymoses or Bruising	Dysesthesia	Phlebitis	Deep-vein Thrombosis	Other
Agar ⁴	2006	1076	810, 980	0.2	39	0.8	1	0	0%
De Medeiros Darwood	2005	20	810	0	100	0	0	0	0%
	2008	71	810	0	0	1.4	0	0	Pruritus 1.4%, transient discoloration 1.4%
Disselhoff	2005	93	810	0	31	0	2	0	Tightness 17%, induration 2%, pain 14%
Elmore	2008	516	810	0.4	1	2.1	0	0	0%
Gibson ⁵	2007	210	980	0	0	1.6	0	5.7	0%
Goldman	2004	24	1320	0	0	1	1	1	0%
Gonzalez-Zeh	2008	45	980	1	64.4	4.4	22.2	0	Induration 68.9%
Huang	2005	230	810	1	0	7.2	0	0	Pain +, induration +
Kabnick	2006	60	810, 980	0	0	0	22	0	Pain +, itching +
Kim 1	2006	34	980	0	24	2.9	2.9	0	Hematoma
Kim 2	2006	60	980	0	27	0	3.3	0	Hematoma, tenderness
Marston	2006	31	810	1	1	1	3.2	1	28%
Min 1	2001	90	810	0	+	1.1	0	0	0%
Min 2	2003	499	810	0	24	0	8	0	Pulling cord sensation 90%
Meyer ⁶	2006	404	810	0	+	0	1.9	0	Pulmonary embolism 0.25%, sural nerve palsy 0.25%
Navarro	2001	40	810	0	+	0	0	0	0%
Oh	2003	15	980	0	100	1	6.7	0	Induration 60%
Park ⁷	2007	21	980	0	60	0	9	0	Tightness 33.3%
Park	2008	390	980	0	83	2	2.3	0	Pain 87%
Parkowski ⁸	2004	165	940	0	+	0	0	0	0%
Plister	2008	50	980	1	1	1	0	0	0%

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From the Western Vascular Society

Endovenous ablation of incompetent perforating veins is effective treatment for recalcitrant venous ulcers

Peter F. Lawrence, MD, Ali Alkhatif, MD, David Rigberg, MD, Brian DeRubertis, MD, Hugh Gelabert, MD, and Juan Carlos Jimenez, MD, Los Angeles, Calif

Initial success 58%, secondary treatment 90% and eventual closure 71%

VNUS Incompetent veins treated if ulcer healing failed.

Results: Seventy-five ulcers with 86 associated incompetent perforating veins were treated with PA in 45 patients with CEAP 6 recalcitrant venous ulcers. Treated incompetent perforator veins were located in the medial ankle (61%), calf (37%), and lateral ankle (2%). Initial success of PA, assessed by postprocedure duplex ultrasound, was 58%; repeat ablation was 90% successful and 71% had eventual successful perforator closure. No complications (skin necrosis, infection, or nerve injury) occurred. Failure of ulcer healing with successful perforator closure occurred in 10% and was due to intercurrent illness, patient noncompliance, and patient death due to unrelated causes. Of patients who healed their ulcers, the healing occurred at a mean of 138 days an average PA of 1.5 incompetent veins per ulcer was required for healing. Ninety percent of ulcers healed when at least one perforator was closed; no ulcer healed without at least one perforator being closed.

Conclusions: This experience demonstrates both the feasibility and effectiveness of PA for a selected group of patients with venous ulcers who fail conventional therapy with compression. (J Vasc Surg 2011;54:37-42.)

Foam Sclerotherapy

From the Society for Vascular Surgery

Factors that influence perforator thrombosis and predict healing with perforator sclerotherapy for venous ulceration without axial reflux

Thrombosis rate of 54% with higher healing rate with IPV thrombosis

conclusion predicting IPV thrombosis and ulcer healing

Results: There were 62 patients (55% male; average age, 57.1 years) with active ulcers for an average of 28 months with compression therapy before perforator treatment, and 50% had a history of deep venous thrombosis and 38% had deep venous reflux. At a mean follow-up of 30.2 months, ulcers healed in 32 patients (52%) and did not heal in 30 patients (48%). Ulcers were treated with 189 injections, with an average thrombosis rate of 54%. Of 73 ulcers, 43 ulcers (59%) healed, and 30 (41%) did not heal. The IPV thrombosis rate was 69% in patients whose ulcers healed vs 38% in patients whose ulcers did not heal ($P < .001$). Multivariate models demonstrated male gender ($P = .03$) and warfarin use ($P = .01$) negatively predicted thrombosis of IPV. A multivariate model for ulcer healing found complete IPV thrombosis was a positive predictor ($P = .02$), whereas a large initial ulcer area was a negative predictor ($P = .06$). Increased age was associated with fewer ulcer recurrences ($P = .03$). Predictors of increased ulcer recurrences were hypertension ($P = .04$) and increased follow-up time ($P = .02$). Calf vein thrombosis occurred after 3% (six of 189) of injections.

Conclusions: Thrombosis of IPV with UCS increases venous ulcer healing in a difficult patient population. Complete closure of all IPV in an ulcerated limb was the only predictor of ulcer healing. Men and patients taking warfarin have decreased rates of IPV thrombosis with UCS. (J Vasc Surg 2014;50:1568-66.)

Varithena™

(polidocanol injectable foam) 1%



VANISH 2 Study 73% closure rate at 1 year

VIEW-VLU observational study of the effect of Varithena on wound healing in the treatment of venous leg ulcers

Michael Y. Shao, MD¹, Stuart Harlin, MD², Beverly Chen, MD³, KathyLee Santangelo, MD⁴, Er Fukaya, MD⁵, Justine Skougston, MD, and Raghav Kulkarni, MD, MSc for the VIEW-VLU Investigators, Chicago, IL; Houston, TX; Oklahoma City, OK; Palm Alto, CA; Boston, MA; Columbus, OH; and Oakville, Ontario, Canada



ABSTRACT
Objective: Chronic wound non-healing, associated by venous insufficiency and fibrosis, leads to high chronic and acute

76 patients with C6 disease with 54% healing at 12 weeks but 65% GSV closure rates

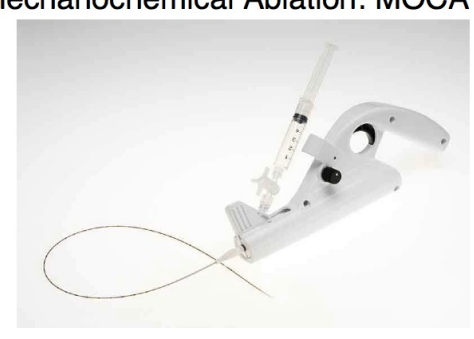
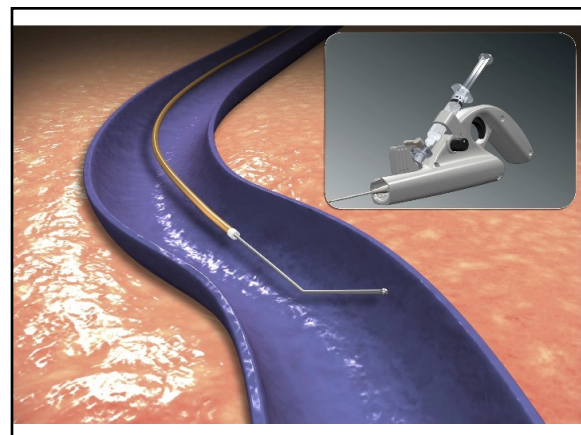
12 weeks. By 12 weeks, 53.8% of wounds (62/90) were healed. The median time to ulcer closure by Kaplan Meier analysis was 33 days (95% confidence interval, 62.0-117.0). In a Kaplan Meier analysis of initially healed ulcers, 88.9% (95% confidence interval, 76.9-94.6) remained closed at 12 weeks after closure. The mean numeric pain scores (ulcer size) improved by 41.0% and 64.1% at 12 weeks and 12 months after the procedure, respectively. The health-related quality of life (HRQL) score of 11 improved from 0.55 ± 0.27 at baseline to 0.78 ± 0.53 at 12 weeks and 0.78 ± 0.53 at 12 months. By 12 weeks after treatment, the mean target leg venous Clinical Severity Score had significantly decreased by 3.6 points, and by 12 months it had decreased by 5.0 points.

Conclusion: Treatment with 1% polidocanol microfoam was associated with promoting wound healing rates and low recurrence rates for VLU. However, a challenging patient population with recalcitrant ulcers, a large percentage of which were circumferential, in patients with high body mass indexes. © Vasc Surg Venous Lymphat Disord 2023;9:492-91

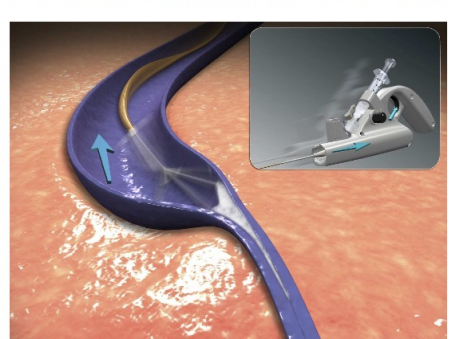
Keywords: Polidocanol sclerotherapy; Venous reflux; venous leg ulcer; Chemical ablation

Mechanochemical Ablation: MOCA

MOCA: Mechanism of action



A novel technique for closure of the perforator vein using the ClariVein® Occlusion Catheter

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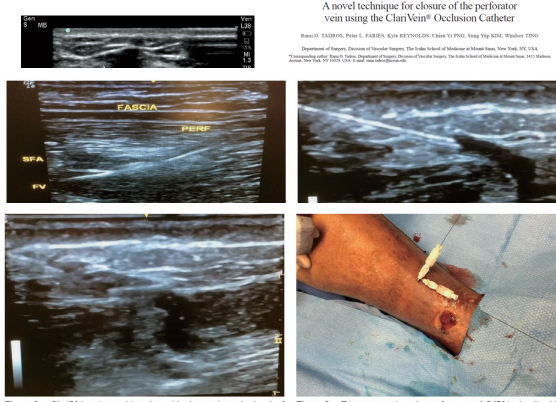
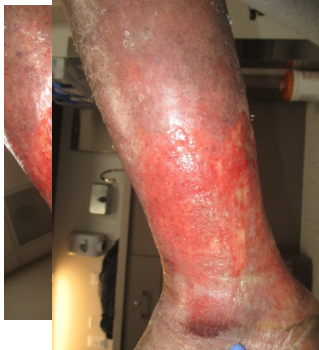


Figure 8—ClariVein wire positioned outside deep vein at the level of the fascia prior to activation.

Figure 9—Direct access into the perforator and GSV in the distal leg


Patient #1

Pre-Op Photo taken on 10/5/15. Ulcer measured approximately 10.0 cm x 5.0 cm. Ulcer was active for six months before patient decided to seek vascular surgery intervention.




Patient #1

- Intra-operative Photo on 10/17/15
- GSV treatment
- Dual puncture




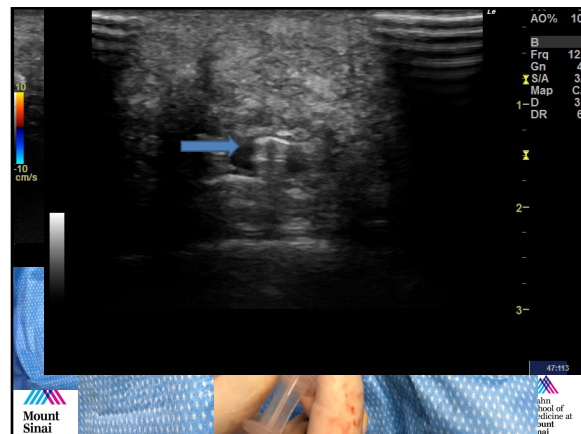
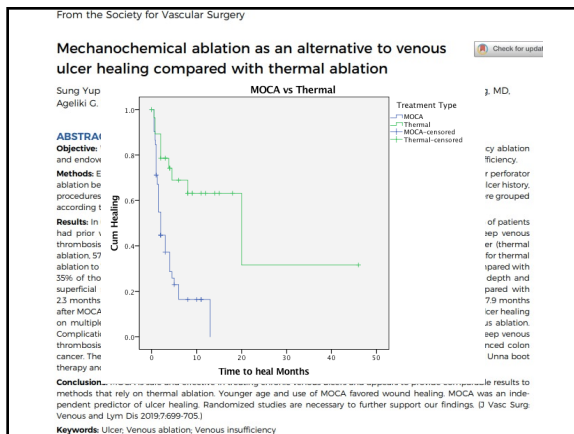
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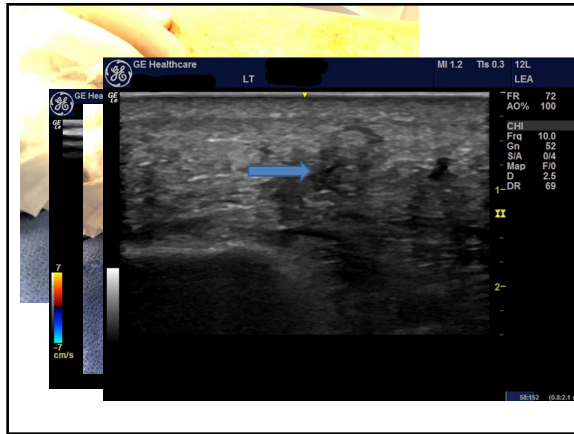
- Intra-operative Photo on 11/14/15
- SSV treatment



Patient #1

- 3/12/16 Patient had undergone 5 months of Unnaboot, 4 months status post left leg small saphenous vein treatment with Clarivein



Results: Procedural Characteristics & Outcomes

	Thermal Ablation	Non-Thermal Ablation	P value
Ulcer Healed, %	34.5% (10/29)	69% (38/55)	0.002
Time to Heal, months	4.4 (0.5-20)	4.8 (0.5-19)	0.87
Length of follow-up, months	12.8 (0-46)	19.6 (1-68)	0.052
Multiple Segments Treated, %	17%	95%	<0.05
Recurrence, %	0%	45%	<0.05

- On logistic regression, only treatment modality (thermal v non-thermal) and preoperative duration of ulcer presence had an independent impact on ulcer healing rate
- Complications: 3 non-access related infections, two hospital admissions for antibiotics/wound debridement, and one late, unrelated death
- Recurrent ulcers were effectively rehealed with Unna-Boot therapy & compression

The utility of endovenous cyanoacrylate glue ablation for incompetent saphenous veins in the setting of venous leg ulcers

Sally Shin Jia Chan, MBBS, MRCS, Chary Jia Qi Yap, BSc, Seck Guan Tan, MBBS, FRCS (Glas), FAMS, Edward Tieng Chek Choke, MBBS (Surg), PhD (Lond), FRCS (Eng), Tee Tec Chong, MBBS, FACS, RPVI, and Tun Yip Tang, MA (Cantab), MD, FRCS (Gen), FAMS, Singapore

ABSTRACT

Objective: Patients with venous leg ulcers (VLU) represent the worst spectrum of chronic venous insufficiency (CVI). The Early Venous Reflux Ablation (EVRA) landmark trial published in 2018 demonstrated that early endovenous intervention results in faster healing of VLU. We describe our post-EVRA experience using endovenous cyanoacrylate glue ablation (ECA) to treat superficial venous reflux on an early basis and assess its efficacy and safety in the setting of VLU.

Methods: There were 37 patients (39 legs, 43 truncal veins) with 43 discrete venous ulcers who underwent ECA for CVI symptoms and VLU. They received compression therapy and regular dressing for the VLU postoperatively and were reviewed at 1 week, 3 months, 6 months, and 12 months after the procedure. Postoperative healing time for VLU and complications were recorded along with the patient's satisfaction and postoperative pain scores.

Results: The venous ulcers were all <30 cm² before ECA. The mean time for VLU healing from operation was 73.6 ± 21.8 days, and the primary occlusion rate of the CVI at both 1 week and 3 months was 100%. No major adverse events were observed except for one case of deep venous thrombosis. There was significant improvement in the revised Venous Clinical Severity Score postoperatively from 11 ± 1.63 (baseline) to 5.6 ± 1.37 (P < .001) at 3-month follow-up on a scale of 0 to 27, with the severity of symptoms at a maximal 27. The visual analog scale score for pain were low postoperatively, decreasing from a preoperative score of 6.8 ± 1.42 to 2.7 ± 1.59 (P < .001) at the 3-month follow-up on a scale of 1-10, with 10 being the most severe pain. The median time to return to normal activities was 7 days (interquartile range, 5-9 days).

Conclusion: ECA together with compression therapy for VLU is both safe and effective in this population of Asian patients. ECA for patients with VLU has excellent patient acceptability, minimal morbidity, and low re-occlusion rates at 12 months. Larger extensive studies and longer follow-up periods are required to validate the preliminary outcomes of this paper, and if it is proven to significantly improve ulcer healing rates, this will change the way we approach chronic venous ulceration. © Yoon Sung Venous and Lim Dis. 2020;8(04):8.

Keywords: Cyanoacrylate glue, Endovenous, Venous, vein, Venous leg ulcer, Venous ulcer, Venous closure system

A comparison of cyanoacrylate glue and radiofrequency ablation techniques in the treatment of superficial venous reflux in CEAP 6 patients

Liqin Ann O'Banion, MD, FACS, Kyle B. Reynolds, MD, Marlysa Kochubey, MD, Bianca Cutler, MSN, FNP, C, Eshetu A. Tefera, MS, Rachel Dirks, PhD, and Misaki M. Kiguchi, MD, MBA, FACS, Fresno, Calif and Washington, D.C.

CME Activity

Abstract: The Society for Vascular Surgery is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. Society for Vascular Surgery.

Objectives: After reading this article, the participant should be able to: 1. Compare the efficacy and safety of cyanoacrylate glue ablation (ECA) and radiofrequency ablation (RFA) in the treatment of superficial venous reflux in CEAP 6 patients. 2. Discuss the role of ECA and RFA in the management of VLU. 3. Evaluate the impact of ECA and RFA on patient satisfaction and postoperative pain scores.

Keywords: Cyanoacrylate glue, Endovenous, Venous, vein, Venous leg ulcer, Venous ulcer, Venous closure system

Fig. 1. Time to wound healing stratified by ulcer size. RFA, Radiofrequency ablation.

Future Improvements for cyanoacrylate glue in C6 Treatment

- Medtronic Spectrum trial
 - Prospective arm 125 C6 patients
 - 12-month healing time
- C6 cyanoacrylate glue treatment kit
- Insurance coverage

Thank you!

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