

Abstracts from the 2012 American Venous Forum Annual Meeting

Factors Associated With Recurrence of Varicose Veins After Thermal Ablation: 3-Year Results of the REVATA (Recurrent Veins After Thermal Ablation) Study

R.G. Bush¹, P. Bush¹, J. Flanagan², R. Fritz³, T. Gueldner⁴, J. Koziarski⁵, K. McMullen⁶, G. Zumbro⁷, ¹Midwest Vein & Laser Center, Centerville, Ohio, ²Delaware Valley Vein Center, Phoenixville, Pa, ³Advanced Vein Center of North Texas, Irving, Tex, ⁴Wisconsin Vein Center, Manitowoc, Wisc, ⁵Family Surgical, Battlecreek, Mich, ⁶Varicose Vein Clinics of Oklahoma, Oklahoma City, Okla, ⁷Vein Specialists of Augusta, Martinez, Ga

Background: Factors contributing to recurrence of varicose veins after thermal ablation are not well known. The goal of this prospective, non-randomized, multi-center trial was to determine the site, source, and contributory factors of varicose vein recurrence after radiofrequency (RF) and laser ablation.

Methods: Seven centers enrolled patients into the study during a twelve-month period, from January 1st, to December 31st, 2010. All patients underwent previous thermal ablation of the great saphenous vein (GSV), small saphenous vein (SSV) or anterior accessory great saphenous vein (AAGSV). Patients with high ligation of the GSV and/or stripping were excluded from the study. From a specific designed study tool, recurrence was identified as to site, etiology, and primary mode of treatment (RF, laser).

Results: 2,380 patients were evaluated during this time frame. A total of 164 patients, (7%), 3 with bilateral limb involvement, had varicose vein recurrence at a mean of 3 years after treatment (range, 9 months to 8 years) This group of 164 patients with varicose vein recurrence were the subjects of this study. 33% were between the age of 51 and 60, median age range was 51-60, and 83% were women. A history of deep venous thrombosis (DVT) was present in 2% of the patients and deep venous insufficiency was present in 17%. GSV ablation was the initial treatment in 159 patients (RF: 33, laser: 131, 52 of these patients had either SSV or AAGSV ablation concurrently. Total or partial GSV recanalization occurred in 47 patients (29%). Of these 47 patients, 27 had RF ablation, and 20 had laser thermal ablation. New AAGSV reflux occurred in 40 patients (24%), and new SSV reflux occurred in 24 patients (12%) Primary or associated perforator pathology was present in 64% of patients.

Conclusions: Recurrence of varicose veins at 3 years after thermal ablation was 7%. The three most important factors associated with varicose vein recurrence included new or recurrent perforating veins; recanalized GSV and new AAGSV reflux, in decreasing frequency. In this study, patients who underwent RF treatment had a higher rate of GSV recanalization than those who were treated with laser.

Cyanoacrylate Glue Great Saphenous Vein Ablation: Preliminary 180-Day Follow-Up of a First-In-Man Feasibility Study of a No-Compression-No-Local-Anesthesia Technique

J.I. Almeida¹, J.J. Javier², E.G. Mackay³, C. Bautista⁴, T. Proebstle⁵, ¹Miami Vein Center, Miami, Fla, ²Physicians Regional Vein Center, Naples, Fla, ³Mackay Vein Center, St. Petersburg, Fla, ⁴Canela Clinic, La Romana, Dominican Republic, ⁵University Clinic of Mainz, Mainz, Germany

Background: Endovenous thermal ablation is a highly effective technology for the treatment of incompetent great saphenous veins (GSVs). However, the treatment requires painful transcatheter injection of perivenous anesthetic fluids. Graduated compression hose are required postprocedure to help mitigate the inflammatory side-effects of thermal delivery. This study was conducted to demonstrate the safety and efficacy of the Saphen Closure System for chemical ablation of duplex proven incompetent great saphenous veins.

Methods: Two series of patients were treated (n=8 and n=30 follow-up of 180 and 30 days, respectively). After venous access and placement of a novel delivery system, the vein was sealed with a proprietary cyanoacrylate (CA) formulation. Perivenous tumescent anesthesia and post-procedure compression stockings were omitted.

Results: Thirty-eight patients (29 female) with a median age of 51 years (range, 26-77) and an average VCSS score of 6.0 +/-2.7 (range, 2-17) received study treatment. Average maximum saphenofemoral junction (SFJ) diameter was 8.0 +/- 2.2 cm (range, 4.1 - 12.0) before treatment. The mean length of ablated GSV segments was 33cm (range, 15-52), average treatment duration was 20.3 minutes (range, 11 - 33). The mean volume of CA delivered was a total of 1.3 ml (range, 0.63 - 2.25). Immediately postprocedure, and at 24-72 hours, 100% (38 of 38) were closed. At 30 days follow-up 97% (35 of 36) of treated GSV segments were completely closed; one limb had a 1cm segment of incomplete ablation. VCSS scores improved to a mean of 1.9 +/-2.1 (range, 0-11; P<.001 compared to baseline) at 30 days in 37 patients. Of the eight patients followed for 180 days, average VCSS improved to 1.1 +/- 1.0 (range, 0 - 3) Thirty-one of 37 patients reported no pain during the 30 days after

treatment; the remaining six were successfully treated with NSAIDs. No significant side effects or complications were observed.

Conclusion: Endovenous ablation of incompetent GSVs with a CA-based glue is feasible. Procedure times are short, tumescent anesthesia is unnecessary as are postprocedure compression stockings. Lack of significant side-effects and an initial success rate of 100% with significant, long-standing, improvement of clinical symptoms support further clinical studies.

The Long-Term Effect of Foam Sclerotherapy On Chronic Venous Leg Ulcers With Superficial Venous Reflux

F.J. Slim, S.R. Kulkarni, L.G. Emerson, C. Davies, R.A. Bulbulia, M.R. Whyman, K.R. Poskitt, Cheltenham General Hospital, Cheltenham, United Kingdom

Background: The ESCHAR trial showed that superficial venous surgery and compression in chronic venous ulcers achieved a 24 week healing rate of 65%, 12 month recurrence rate of 12% and 4 year recurrence rate of 31%. Foam sclerotherapy may be an attractive alternative to surgery. The aim of this study is to assess the effect of foam sclerotherapy on ulcer healing and long term recurrence in chronic venous leg ulcers. This is an expanded study of the abstract presented at the Royal Society of Medicine Venous Forum reporting long term recurrence data.

Methods: Chronic venous leg ulcers (CEAP 5 and CEAP 6) with superficial venous reflux were treated between March 2006 and August 2011 with ultrasound guided foam sclerotherapy and compression. Venous duplex was performed on all legs before and one week after treatment. 24-week ulcer healing and 1 and 4 year ulcer recurrence rates were analysed using Kaplan-Meier survival analysis.

Results: Two hundred and fourteen legs (199 patients) with chronic venous ulcers (CEAP 5: n=173, CEAP 6: n=41) were treated with foam sclerotherapy. Median age was 73 years (range, 29-92, M:F = 87:112). Complete occlusion was achieved in 195/214 (91.1%) legs, short segment occlusion in 16/214 (6.5%) legs and 3/214 failed to occlude. One patient suffered nonocclusive DVT diagnosed on duplex scan at 1 week and one presented with an occlusive DVT at 3 weeks following a normal scan at 1 week. One patient developed asymptomatic occlusive DVT at two weeks following a nonocclusive DVT diagnosed on initial 1 week scan. Eighteen patients were lost to follow up (3 moved away and 15 died of unrelated cause). Twenty four week healing rate was 70.7% and 1 and 4 year recurrence rate were 4.7% and 28.1% respectively.

Conclusion: Foam sclerotherapy is effective in abolition of superficial venous reflux contributing to favourable ulcer healing and long term recurrence rates. Foam sclerotherapy is an attractive alternative to superficial venous surgery in this group of patients.

Occlusion Rate With Foam Sclerotherapy For the Treatment of Greater Saphenous Vein Incompetence: A Multicentric Study of 3170 Cases

J.H. Ulloa, Jr, Clinica de Venas, Bogota, Colombia

Background: Foam sclerotherapy using direct access under guided ultrasound, has been the method of choice of our group for the treatment of greater saphenous vein (GSV) incompetence for the last 8 years. The practicality of this approach, low costs, no anesthesia requirement and repeatability, has encouraged other groups in Latin America to follow our example. We organized a multicentric international group in order to get mutual feedback to improve our technique and establish the potential hazards we may encounter.

Methods: We present a prospective multicentric study where 2674 patients, 3170 limbs, C2-6, Ep,As,Pr, diagnosed with duplex scanning and operated between June 2007 and June 2011. All cases were treated with foam sclerotherapy with no other treatment associated. Lapidium clohidrate was the sclerosant of choice due to its increased foam stability. Foam was delivered into the vein via a 21-gauge needle just below the knee; an average of 3cc (12cc of foam) per patient was used. Compression stockings (22mmHg) were used in all cases. Follow-up visits were scheduled at the first week, first,3rd,6th and 12th months and included ultrasound surveillance to assess the occlusion of the treated vein.

Result: Occlusion of the GSV was achieved in 96.2% of limbs studied and 93.7% remain occluded at 12months after treatment. Among the complications we had three DVT, one of them subclinical. Superficial thrombophlebitis in 17, induration in 390 and dyschromia in 46 cases. We had one major incident: a neutomonitis that required ICU hospitalization for 5 days and were successfully discharged.

Conclusions: Foam sclerotherapy is a safe method that showed a high occlusion rate. The possibility of adverse effects has to be taken into account in order to minimize risks and be prepared to handle unavoidable complications.