Journal of Phebology and Lymphology

Hybrid endoluminal treatment of incompetence of the great saphenous vein with radiofrequency and foam sclerotherapy: initial experience

Authors: Jorge Hernando Ulloa, MD, FACS. Heinz Hiller, MD, FRCS. Samira Alí, MD, Jairo Ramírez, MD, FACS.

Adress: Fundación Santa Fé de Bogotá Universidad El Bosque -Bogotá – Colombia

E-mail: cirugiavascular@yahoo.com*corresponding author

Published: November 2013
Journal Phlebology and Lymphology 2013; 6:14-18

Received: August 2013
Accepted: 20 October 2013

Abstract

Background: The treatment of incompetence of the great saphenous vein (GSV) by radio frequency (RF) or laser has been associated with neuralgia and other complications due to the extension of thermal injury. These techniques require anesthesia and have a major disadvantage in the management of tortuous trunks due to the stiffness of the catheter or optical fiber used in the treatment. Foam sclerotherapy is a new option to treat larger veins, painlessly reaching varicosities, however the treatment of the GSV raises the possibility of a sudden reopening of the saphenofemoral junction (SFJ). Our group developed an approach that combines the benefits of thermal ablation and foam sclerotherapy.

Methods: Forty-six patients (39 female) classified as C2-C4 (CEAP classification) with a mean age of 58.4 years and incompetence and tortuosity of the GSV as seen by duplex ultrasound where included in this study. Two patients were lost during follow-up. The hybrid procedure was performed using ultrasound guided percutaneous access of the GSV with a new short RF catheter (VNUS ClosureFAST) two centimeters distal to the SFJ under local anesthesia. Thermal occlusion of the saphenofemoral junction (SFJ) and the subjacent segment of the GSV were achieved. Before retracting the device, 8 mL of 1% Lapidium Chloride foam (Sklerol, ICV Pharma, Colombia) was injected using physiological gas (70% CO_2/30% O_2); the region was gently massaged with the transducer to spread the foam distally. The patient was followed-up for 6 months which including duplex ultrasound to check the ligation of the GSV and SFJ.

Results: Forty-four patients completed the follow-up period. There were no major complications. Seven patients reported pain in the groin region immediately after the procedure. Two cases presented with superficial phlebitis in the calf due to lack of compression and required microthrombectomy. At six months, the GSV and SFJ were occluded in forty-one patients as demonstrated by duplex ultrasound but the other three required a second dose of foam in the recanalized segment.

Conclusions: This is a preliminary report of a hybrid procedure that involves the use of heat to completely ligate the SFJ and, at the same time, foam to treat the GSV and associated varicosities, without the need of further thermal ablation of the venous trunk or the use of phlebectomy. This hybrid procedure combines the best of two techniques, minimizing their disadvantages and potentiating their advantages. The occlusion rate seems promising but further studies should evaluate the true effectiveness over time.

Key words: varicose veins, foam, saphenous vein, radiofrequency

Introduction

Venous surgery has undergone a transformation over the last 15 years, leaving behind the traditional saphenectomy for varicose veins which had been the therapy of choice for 100 years [1]. At the end of the last century, new techniques based on endoluminal thermal ablation using radiofrequency (RF) and laser were created to occlude circulation to the affected venous trunk using minimally invasive surgical procedures [2,3].

These new techniques increase the treatment options for venous disease after a long time without novelties. Soon other forms of treatment began to appear such as foam sclerotherapy, the injection of cyanoacrylate or steam at the saphenofemoral junction which, when introduced through a catheter guided by ultrasound, generates chemical injury resulting in occlusion [4,16,26].

With minimal manipulation of the tissue and little injury, there will be low angiogenic response after the intervention thus the probability of relapse will be lower than in surgical procedures that have rates that exceed 50% of cases in 5 years [17,21]. Moreover, the outpatient nature of endovascular interventions reduces costs, allows the patient to return to his normal activities promptly and drastically reduces morbidity [10].

Laser and RF are the most popular of the endoluminal techniques and are established as the gold standard to treat incompetence of the GSV according to the American Venous Forum [22] and the German Vascular Surgery Society. However, the catheter or the optical fiber used to transmit thermal energy has a certain degree of rigidity that does not allow easy navigability in tortuous segments of veins. Additionally if the saphenous trunk is significantly dilated, the temperature used varies and the rate of occlusion tends to be lower [23,24,32].

In our experience, it is very common to find saphenous trunks presenting tortuosity or major dilation, especially in patients who consult late and treatment often requires a second or even a third insertion of a catheter guided by ultrasound. Ambulatory phlebectomy is used as an adjunct therapy in more severe cases, especially for infragenicular segments where derivations are more common and in failure of one or more epifascial leg veins [14,31]. It is in these cases that foam sclerotherapy has an important role. This technique evolved from traditional sclerotherapy, which uses liquid for sclerotherapy, to a new pharmaceutical foam that offers advantages in vessels larger than telangiectasias, with independence from the vessel diameter and the concentration of the sclerosing agent [35,30]. This allows foam sclerotherapy to be used as a therapeutic tool in large trunks [1,2]. The scientific literature reports interesting findings in this regard, although a doubt still remains as to whether this conduct is enough or whether there will be a recurrence rate similar to techniques that are a little more aggressive such as RF which affects the media and adventitia layers by thermal ablation [8,20].

Our group has been working since the appearance of ultrasound-guided thermal ablation and chemical ablation techniques at the end of the 20th century. An interesting idea is that we can easily associate the advantages of both techniques to maximize their individual effects. This study presents our experience using RF and foam sclerotherapy in one intervention. The thermal ablation of the SFJ and the immediately subadjacent GSV, followed by an ultrasound-guided injection of foam along the same via in the rest of the GSV and associated epifascial veins, enabling a more effective occlusion of the affected saphenous trunk, without the use of tumescent anesthesia in the saphenous fascia or the transmission of heat to the GSV trunk which could potentially affect adjacent nerve structures or add discomfort to the procedure [11,5,6,27,29,34]. The difficulties of tortuosity and greatly dilated segments of vessels are easily manageable with foam sclerotherapy which is applied through the same catheter prior to its retraction. Foam acts independently of the diameter of the vessel, and is not impeded by tortuosity; the vessel is filled without difficulty by a single injection [33,28,7].

Materials and methods

During the first half of 2012, 46 patients were included in this case study. The inclusion criteria were age between 25 and 80 years, of both genders, with the capability to sign an informed consent form. Exclusion criteria were previous venous surgery, use of oral anticoagulants, previous deep vein thrombosis, trauma to the legs, and absence of venous reflux and dilatation of the GSV.

The study prospectively documented data over 6 months for each patient. Follow up ultrasounds were performed after two weeks, 3 months and 6 months. All complications were noted. The frequency and presentation of complications were analyzed case by case and the procedure was performed in the same way for all 46 patients.

Using the Seldinger technique and local anesthesia, the SF was channeled at the knee using a 7-F introducer to avoid damage to the saphenous nerve that emerges at this point. The RF catheter was advanced guided by ultrasound to a point 2 cm distal to the SFJ. Tumescent anesthesia was injected around the GSV to isolate the GSV along its entire bed using ultrasound. Thermal ablation was applied along the canalized vein following the instructions of the manufacturer. Prior to the retraction of the introducer, the rest of the GSV was infiltrated with 8 mL of 1% Lapidium Chloride foam (Sklerol, ICV Pharma, Colombia) which spread distally to penetrate into the distal GSV and its tributaries.

The introducer was retracted, micropore tape was used to protect the puncture site and the patient used elastic compression class II stockings for 48 consecutive hours. In addition, the patients were requested to walk around for 20 minutes immediately after the procedure and to perform day-to-day activities normally.

Ultrasound monitoring was carried out by the same surgeon who evaluated the patient in the second post-operative week and third and sixth months. The purpose of this follow-up was to verify the presence or absence of occlusion of the SFJ and the treated GSV.

Results

A total of 46 patients were recruited, but two patients were lost to follow-up because of difficulty in monitoring as they lived far from the clinic.

Two cases of groin pain were reported along the route of the GSV in the thigh which warranted single-doses of non-steroidal intramuscular painkillers on the second and third postoperative days. At the first follow-up visit, seven cases of superficial phlebitis were reported without disabling pain, with erythema and a lump in the plexus of epifascial veins of the medial side of the leg in all cases; all were submitted to thrombectomy in the clinic.

Forty-one patients had occlusion of the GSV and SFJ in the sixth postoperative month. Three cases required a second procedure just with foam which was injected in a similar manner to the first procedure but without the use of thermal ablation.

Discussion

The RF has proven to be an excellent method to treat venous disease associated to truncal saphenous insufficiency [(15)]. Its use, similar to other thermal ablative techniques, offers easy and safe occlusion of the GSV. Among its disadvantages is the indiscriminate burning of the adventitia and occasionally of the adjacent nerve structures as it requires tumescent or another type of anesthesia [(25)]. It is important to remember that the venous intima does not have innervation and therefore the presence of pain is explained by alterations in the outermost layer of the vessel, an undesired result for the vascular surgeon. Although costs are dropping, they still are an item tof concern. Comparative studies show that RF is as good as or better than conventional surgery; as it is an endoluminal technique, the concept of neophlebogenesis is void and therefore relapse should be minimal. Thus this procedure has become the gold standard in the management of incompetence of the GSV by the American Venous Forum [(22)].

On the other hand, foam sclerotherapy, a highly cost-effective method that is affordable to patients in South America, has become more common in the treatment of incompetence of the GSV; this is an alternative to other expensive endoluminal techniques [(3)]. Possible thrombotic and embolic complications, as well as the release of inflammatory endothelial factors, are its biggest disadvantage [(12)]. It must be used with extreme caution by qualified professionals capable of solving any complications that may occur; we emphasize that this is a technique that must be performed only by vascular surgeons.

The use of physiological gas has given a substantial reduction in the adverse reactions of sessions; this is the reason that our group uses a special mixture of CO_2 (70%) and O_2 (30%) which minimizes the phosphenes, coughing, chest tightness, and other phenomena that appear more frequently with ambient air [(19)]. Currently Interleukin-6 and C-reactive protein are being analyzed to objectively understand these phenomena.

The synergy of these two techniques, thermal ablation of the GSV by RF in an attempt to guarantee a perfect seal of the SFJ combined with foam sclerotherapy of the tortuous and dilated tributaries where access using a catheter is cumbersome and pointless, allows us to perform both procedures in a single session without losing the minimally invasive character in the outpatient clinic as preferred by the patient today.

Postoperative pain continues to be a source of discomfort of RF and even though it is substantially less than the pain using other endoluminal thermal ablative techniques, it merits further studies.

Phlebitis is a variable to take into account in the management of foam sclerotherapy. Phlebitis is very dependent on the use of and the quality of elastic compression stockings. Our group found a greater adherence to treatment and therefore a lower rate of complications when microfiber pressure gradient class II stockings were used up to the thigh as they are very tolerable in a predominantly hot country, are relatively easy to put on and are more in line with the stature of the average Colombian, short with large hips and thighs.

A 93% occlusion rate at 6 months is attainable and extremely desirable. Obviously such a short follow-up is not proof of the outcome in 5 or 10 years, forcing us as a research group to continue monitoring.

Even though 6.8% of the patients required a second session of ultrasound-guided foam sclerotherapy in the outpatient clinic, this is an easily performed procedure which is very well tolerated by the patient. Occlusion after this procedure is demonstrated by an intraluminal hypoechoic image of the GSV with the presence of heterogeneous echoes within two weeks of the procedure, no pain on exerting compression on the vessel and without fluids (evaluated using contrast).

By combining these two ultrasound-guided endoluminal techniques, the margin of safety is greater for the vascular surgeon with the occlusion rate being high. Further monitoring is necessary and studies on larger samples are necessary to determine the true value of this association.

Conclusion

Low elastic compression sleeves have a synergistic effect with controlled exercising to reduce the volume of lymphedematous limbs.

References

1. Colt GH. Babcock´s Extraction Operation for Varicose Veins. Br J Surg. 1920; 32(8): 486-492.

2. Chandler JG, Schuller- Petrovicc S, Sessa C. Treatment of Primary Venous Insufficiency by Endovenous Saphenous Vein Obliteration. Vasc Endovasc Surg. 2000; 3(34) 201-214.

3. Min RJ, Zimmet SE, Isaacs MN. Endovenous Laser Treatment of the Incompetente Greater Saphenous Vein. J Vasc Interven Radiology. 2001; 10(12):1167-1171.

4. Frullini A, Cavezzi A. Echosclerose par Mousse de Tetradecyl-sulfate de Sodium et de Polidocanol: Deux annes déxperience. Phlebologie. 2000; 4(53): 442-467.

5. Min RJ, Almeida JI, McLean DJ. Novel Vein Closure Procedure Using a Proprietary Cyanoacrylate Adhesive: 30-day Swine Model Results. Phlebology. 2012; 6(1): 3-6.

6. Milleret R. Obliteration of Varicose Veins with Superheated Steam. Phlebology. 2011; 19(4):174-181.

7. Jones L, Braithwaite BD, Selwyn D. Neovascularization is the Principal Cause of Varicose Vein Recurrence: Results of a Randomised Trial of Stripping the Long Saphenous Vein. Eur J Vasc Endovasc Surg. 1996; 12(4): 442-445.

8. Nyamekye I, Shephard NA, Davies B. Clinicopathological Evidence that Neovascularization is a Cause of Recurrent Varicose Veins. Eur J Vasc Endovasc Surg. 1998; 5(15):412-415.

9. Gohel MS, Epstein DM, Davies AH. Cost Effectiveness of Traditional and Endovenous Treatments for Varicose Veins. Br J Surg. 2010; 97(12):1815-1823.

10. Gloviczki P, Comerota AJ, Dalsing M, Gillespie D. The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. Journal of Vascular Surgery. 2011 May; Volume 53, Issue 5, Supplement: p. 2S-48S.

11. Proebstle TM, Gül D, Lehr HA. Infrequent Early Recanalization of Greater Saphenous Vein After Endovenous Laser Treatment. J Vasc Surg. 2003; 3838(3): 511-516.

12. Proebstle TM KFGDea, Proebstle TM, Krummenauer F, Gül D. Nonocclusion and Early Reopening of the Great Saphenous Vein After Endovenous Laser Treatment is Fluence Dependant. Dermatol Surg. 2004; 30(2):174-178.

13. Theivacumar NS, Dellagrammaticas D, Bealex RJ. Factors Influencing the Effectiveness of Endovenous Laser Ablation in the Treatment of Greater Saphenous Vein Reflux. Eur J Vasc Endovasc Surg. 2008; 35(1):119-123.

14. Oguzkurt L. Ultrasonographic Anatomy of the Lower Extremity Superficial Veins. Diag Interv Radiol. 2012; 18:423-430.

15. Suzi Su-Hsin C, Shri Kumar P. Long Saphenous Vein and its Anatomical Variations. Aust J Ultras Med. 2009; 12(1): 28-31.

16. Yamaki T, Nozaki M, Sakura H. Prospective Randomized Efficacy of Ultrasound-Guided Foam Sclerotherapy Compared with Ultrasound-Guided Liquid Sclerotherapy in the Treatment of Symptomatic Venous Malformations. J Vasc Surg. 2008; 47(3): 578-584.

17. Stücker M, Kobus S, Altmeyex P. Review of Published Information on Foam Sclerotherapy. Dermatol Surg. 2010; 36(52): 983-92.

18. Ulloa JH. Occlusion Rate with Foam Sclerotherapy for the Treatment of Greater Saphenous Vein Incompetence: A Multicentric Study of 3170 Cases.. J Vasc Surg. 2012; 55(1): 297.

19. Bradbury AW, Bate G, Oang K. Ultrasound-Guided Foam Sclerotherapy is a Safe and Clinically Effective Treatment for Superficial Venous Reflux. J Vasc Surg. 2010; 52(4):939-945.

20. Geroulakos G. Foam Sclerotherapy for the Management of Varicose Veins: A Critical Reapprisal. Phlebolymphology. 2006; 13(4):202-207.

21. Nyamekye I, Shephard NA, Davies B. Clinicopathological Evidence that Neovascularization is a Cause of Recurrent Varicose Veins. Eur J Vasc Endovasc Surg. 1998; 5(15)412-415.

22. Hinchliffe RJ, Beech A. A Prospective Randomized Controlled Trial of VNUS Closure versus Surgery for the Treatment of Recurrent Long Saphenous Varicose Veins. Eur J Vasc Endovasc Surg. 2006; 31(2): 212-218.

23. Das SK, Shanaz M, Sahoo N. Experience with Radiofrequency Closure of Varicose Veins (VNUS). Phlebology. ; 20(2): 82-86.

24. Fassiadis N, Holdstock JM, Whiteley MS. Endoluminal Radiofrequency Ablation of a Long Saphenous Vein (VNUS Closure): A Minimally Invasive Management of Varicose Veins. Min Invas Ther. 2003; 12(1):91-94.

25. Puggion A, Karla M, Carmo M. Endovenous Laser Therapy and Radiofrequency Ablation of the Great Saphenous Vein: Analysis of Early Efficacy and Complications. J Vasc Surg. 2005; 42:488-493.

26. Shepherd AC, Gohel MS, Brown LC. Randomized Clinical Trial of VNUS Closure FAST Radiofrequency Ablation versus Laser for Varicose Veins. Br J Surg. 2010; 97(6): 810-818.

27. Van den Bos R, Arends L, Kockaert M. Endovenous Therapies of Lower Extremity Varicosities: A Meta-Analysis. J Vasc Surg. 2009; 49(1):230-239.

28. Ulloa J, Ulloa JH. Escleroespuma.: Distribuna ; 2007.

29. Simkin R. Tratado de Patología Venosa y Linfática. Medrano; 2008.

30. Kabnick LS. Rutherford's vascular surgery. 7th ed. Saunders; 2010.

31. Proebstle TM VBAJGOLCPOea, Proebstle TM, Vago B, Alm J, Göckeritz O, Lebard V. Treatment of the incompetent great saphenous vein by endovenous radiofrequency powered segmental thermal ablation: first clinical experience. J Vasc Surg. 2008; 47:151-6.

32. Breu FX, Guggenbichler S, Wollmann JC. 2nd. European Consensus Meeting on Foam sclerotherapy 2006,Tegernsee, Germany. Vasa. 2008; 37(suppl 71):1-29.

33. Bergan JJ. The Vein Book. Elsevier Academic Press; 2007.

34. Morrison N, Neuhardt DL, Rogers CR, McEownr J. Comparisons of side effects using air and carbondioxide foam for endovenous chemical ablation. J Vasc Surg. 2008; 47: 830-6.

35. Guex JJ. Complications and side-effects of foam sclerotherapy. Phlebology. 2009; 24: 270-4.