Eur J Vasc Endovasc Surg (2008) **36**, 485–490

Reverse Foam Sclerotherapy of the Great Saphenous Vein with Sapheno-Femoral Ligation Compared to Standard and Invagination Stripping: a Prospective Clinical Series

R. Abela*, A. Liamis, I. Prionidis, J. Mathai, L. Gorton, T. Browne, Y. Panayiotopoulos

Department of Vascular Surgery, Broomfield Hospital, Chelmsford, Essex, UK

Submitted 24 July 2007; accepted 22 June 2008
Available online 20 August 2008

KEYWORDS
Reverse foam sclerotherapy;
SFJ ligation;
Invagination stripping;
Standard stripping;
Varicose veins;
Great saphenous vein

Abstract *Objectives:* Comparison of Reverse Foam Sclerotherapy of the great saphenous vein (GSV) combed with sapheno-femoral junction (SFJ) ligation to standard (Babcock) stripping and invagination (Pin) stripping in a prospective clinical series.
Design: Prospective clinical series.
Materials and methods: 90 consecutive limbs of 82 patients with incompetence of the GSV resulting in varicose veins were prospectively randomised into 3 groups of 30, treated by SFJ ligation and either reverse foam sclerotherapy, standard stripping or invagination stripping of the GSV. Outcomes were assessed post-operatively and at 2-weeks follow-up. Peri-operative blood loss (24 hrs), analgesic requirement, bruising and residual varicosities were assessed. Bruising was assessed by both patients and independent assessors using questionnaires.
Results: SFJ ligation plus reverse foam sclerotherapy of the GSV was associated with significantly less blood loss, bruising and post-op discomfort than either of the stripping techniques. ($p < 0.001$, Mann-Whitney)
Conclusion: Standard stripping of the GSV and invagination stripping are not associated with major discomfort and problems in the early post-operative period. SFJ ligation and GSV reverse foam sclerotherapy yielded greater patient satisfaction with less post-op bruising and discomfort and reduced analgesic requirements.

* Corresponding author. Rachel Abela, Broomfield Hospital, Chelmsford, Essex CM1 7ET, United Kingdom. Tel.: +44 776 425 9385.
E-mail address: abelrachel@googlemail.com (R. Abela).

1078-5884/$34
doi:10.1016/j.ejvs.2008.06.029

Introduction

Just over 100 years ago Keller[1] described a novel method of removing the saphenous vein by using an inverting stripping method to remove the vein in segments combined with division of its tributaries. Mayo[2] introduced ring stripping in 1906. Ten years later, Homans[3] introduced the concept of flush ligation of the GSV at the sapheno-femoral junction along with all its tributaries. Intraluminal strippers were introduced by Babcock[4] in 1907 and flexible strippers by Myers[5] in 1954. GSV conservation by sapheno-femoral ligation without saphenous stripping was reintroduced in the mid 1980s and 90s in a drive to preserve the saphenous vein for arterial bypass grafts[6–8] and also because avoiding stripping decreased postoperative pain and allowed earlier functional recovery[9] after a procedure that could be done under local anaesthesia.[10] The concept of sequential avulsion of the GSV under local anaesthesia was a further attempt to minimise the consequences of saphenous stripping.[11]

The most widely used treatment in the UK for managing varices arising from incompetence of the great saphenous vein (GSV) is sapheno-femoral junction (SFJ) ligation combined with GSV stripping.[12] A number of new methods of endovenous treatment have been introduced in recent years to facilitate early ambulation and minimise postoperative discomfort. These include foam sclerotherapy, radiofrequency and laser ablation. Liquid sclerotherapy is the oldest of these treatments, first introduced around 160 years ago but when used in the traditional way is of limited efficacy in treating varices associated with incompetence of the saphenous trunk. Foam sclerosants was first described by Orbach in 1944[13] but in the era before duplex ultrasonography the advantage of these was not fully appreciated. Cabrera[14] introduced the use of ultrasound guided sclerotherapy using micro-foam in 1997 as an alternative to surgical treatment. A new technique of creating foam with small bubbles was described by Tessari in 2000[15] who used 2 syringes and a three-way tap to produce sclerosant foam.

Conventional surgical treatment of varicose veins involves ligation of incompetent communications between deep and superficial veins. Ligation of the SFJ without stripping the GSV is not sufficient in the long term to control varices and is associated with a high rate of recurrence.[16–18] Reflux continues in the saphenous trunk following this operation due to inflow from tributaries and leads to the formation of further varicose veins. Even following apparently adequate ligation, incompetent communications between the SFJ and superficial varices arise due to recanalisation[19] and neovascularisation.[20,21] Stripping the saphenous trunk improves the outcome in patients where this vein is incompetent. Stripping of the GSV can be achieved by standard stripping using a Babcock-type flexible stripper or else by an invagination technique. This method is based on Keller's method and was introduced in 1963 by Van Der Stricht who used a strong thread to invaginate the vein. Oesch, in 1993,[22] used a metal pin stripper to facilitate inverting stripping which is reputed to be less traumatic than standard stripping. Recurrence after GSV stripping commonly arises from incompetence of the anterior accessory saphenous vein and which can be present in up to 10% of cases, a missed true duplex GSV present in 1% of cases[23] or from inadequate dissection and division of tributaries of the SFJ.

The three main drawbacks of stripping the GSV in the thigh are blood loss, bruising and post-operative pain. We have introduced the option of completing the flush ligation and division of the GSV at the SFJ with a novel technique of reverse delivery of foam sclerosant directly into the incompetent GSV to obliterate this vein rather than stripping it. The aim of our study was to measure postoperative bleeding, pain, analgesic use and thigh bruising as outcome measures to compare our method of foam sclerotherapy ablation to standard stripping and pin-stripping.

Materials and Methods

Patients

Patients undergoing treatment for varicose veins in the vascular clinics at Broomfield Hospital were considered for inclusion in this clinical series. We aimed to study 90 consecutive patients with CEAP clinical classes 2 and 3 symptomatic primary varicose veins with SFJ and GSV reflux, who agreed to accept the treatment modality chosen for them on a random basis. This would yield 3 groups of 30 procedures each. The three procedures in the study consisted of flush SFJ ligation with division of tributaries followed by either a) standard stripping of the GSV using a flexible intraluminal stripper fitted with an olive to strip the vein from groin to knee, b) GSV invagination stripping using the pin stripper according to the technique described by Oesch in 1993[22] or c) reverse foam obliteration of the GSV described below.

Ninety identical closed envelopes were prepared containing allocation instructions for 30 standard GSV stripping, 30 invagination stripping and 30 reverse foam sclerotherapy procedures. The envelopes were shuffled and patients would pick an envelope after consenting to participation. The protocol for this study was considered and approved by the local committee for medical ethics.

82 consecutive patients (32 men 50 women) presenting to our vascular clinic with symptomatic varicose veins (CEAP clinical classes 2 & 3) were included in our study. Diagnostic duplex ultrasound assessment was performed allowing us to select patients with primary SFJ and GSV incompetence as the cause of their varices. Diagnostic venous duplex scans were performed by accredited vascular technicians using the Toshiba Aplio XV using the 12 MHz linear phased array matrix transducer. Reflux duration of $\geq$0.5 seconds after a manual calf compression-release manoeuvre was used to define pathological reflux at the SFJ.[24] We included 74 patients with unilateral saphenous incompetence and bilateral incompetence in a further 8 patients. The median age for these patients was 44 years (range 18—67 years). Median height to weight ratio was 2.29 cm/kg (range 1.79—3.04 cm/kg).

All patients gave informed written consent to treatment according to random assignment into any of the three groups after being fully informed about the three

techniques. In keeping with our standard practice all patients had one leg operated at a time giving a total of 90 procedures.

Patients were admitted on the morning of surgery and operated under general anaesthesia on a morning list. For the sake of the study, patients were discharged 1 day post-operatively to allow uniform management of dressings and assessment and removal of drains. Observation for complications including the occurrence of rashes, allergic reactions, cough, malaise and headache in patients receiving foam sclerotherapy was recorded by recovery nurses prior to transfer from the theatre recovery area and by ward nurses while routine post-op observations were being recorded. The standard stripping group was made up of 13 men and 17 women with a mean age of 46yrs (18–66 yrs). The invagination stripping group was made up of 15 men and 15 women with a mean age of 47 yrs (25–67 yrs). The Reverse foam sclerotherapy group was made up of 8 men and 22 women with a mean age of 45 yrs (22–66 yrs).

Reverse foam sclerotherapy

The patient's leg and groin were prepped with aqueous povidone iodine and draped with the entire leg exposed from above the groin to just above the ankle. After groin dissection, division of tributaries and flush ligation of the SFJ, the GSV was divided and canulated distally using a 5 Fr angiography catheter at a point approximately 10 cm distal to the knee. Ultrasound imaging (Sonosite 180®, Sonosite Inc, Bothell, WA, USA) was used to position the catheter and subsequently to guide tumescent infiltration of local anaesthetic (40 mls 0.5% Bupivacaine with adrenaline diluted in 500 ml of 0.9% Saline solution) along the length of the GSV/catheter. This achieved the dual effect of compressing the vein and decreasing its capacity as well as post operative analgesia.

The foam was then prepared mixing 3 ml of 1% STS (Sodium Tetradecyl Sulphate/ Fibrovein®) and 3 ml of air using Tessari's technique; two 10 ml syringes and a three-way tap. The resulting 6 ml of foam was injected into the collapsed vein via the angiography catheter as this was withdrawn along the length of the vein (hence the term *reverse foam*).The proximal GSV was tied 5 cm distal to its cut end and the redundant few cm of vein were excised. Complete filling of the vein with foam was checked by ultrasonography.

To ensure uniformity between the procedures, tumescent anaesthesia was also applied along the length of the GSV prior to stripping in both the Standard stripping technique and the Invagination technique. Associated varicosities were removed by multiple phlebectomies through small incisions with local anaesthetic infiltration in all cases prior to the tumescent anaesthetic along the GSV.

In all techniques a size 10 Fr suction drain was placed in the groin wound with the distal end of the drain inserted along the proximal GSV track. All legs were dressed post-operatively with foam strip padding applied externally over the length of the GSV track which was secured using an elastic adhesive bandage (Panelast®). At one day post-op drains were removed and drained volumes were recorded; leg dressings were taken down and replaced by Class II graduated compression stockings which were worn continuously until follow-up at 15 days. All patients were prescribed 75 mg diclofenac bd as post-op analgesia and were asked to keep a diary of consumption of this and other analgesia used post-op.

Follow-up

Thigh bruising, residual varicosities, post-op discomfort and analgesic use were assessed at the 15-day post-op clinic visit. Patients completed questionnaires dealing with analgesic use, post-operative discomfort and thigh bruising (absent, moderate, severe) prior to being seen by medical staff. A surgeon and a vascular nurse specialist measured the extent of thigh bruising (cm^2) and recorded the patients' satisfaction with the results and residual varicosities. Bruising was assessed in the thigh along the stripping or ablation line and not in the calf where any bruising would be related to the avulsions. Bruising involving $<15\ cm^2$ was described as moderate and $>15\ cm^2$ as severe. Patients who had undergone foam sclerosis of the GSV underwent duplex ultrasonography to ensure complete obliteration of the GSV and were also assessed for the presence of skin pigmentation and thrombophlebitis. The patients in the other 2 groups were not scanned at this point.

Results were analysed using SPSS®11. Data were assumed to be of non-normal distribution so the descriptors used are the median and inter-quartile range and significance testing for differences between groups was assessed by a Mann-Whitney u test.

Results

Technical results

There were 9 technical failures. In 2 patients undergoing standard stripping and 1 patient undergoing invagination stripping it was impossible to pass the stripper to below the knee. In 3 patients undergoing invagination stripping the GSV tore before an adequate length was stripped. In 3 patients undergoing reverse foam it was not possible to pass the catheter to the desired level. Duplex scanning of the GSV in patients who had been treated by foam sclerotherapy group at the 15-day post-op assessment showed that 26 out of the 27 GSVs were completely obliterated and the remaining 1 had a patent segment related to incompetent perforators above the knee.

Blood loss at 18–24 hrs

Median values for blood loss were 25 ml (Interquartile range, IQR, 25–35 ml) for standard stripping, 25 mls (IQR 20–35 ml) for the invagination group and 15 mls (IQR 10–20 mls) for the reverse foam group. (Fig. 1). The difference between the first 2 groups was non statistically significant but there was significantly less blood loss for the reverse foam group compared to the other two techniques ($p < 0.001$, Mann Whitney).

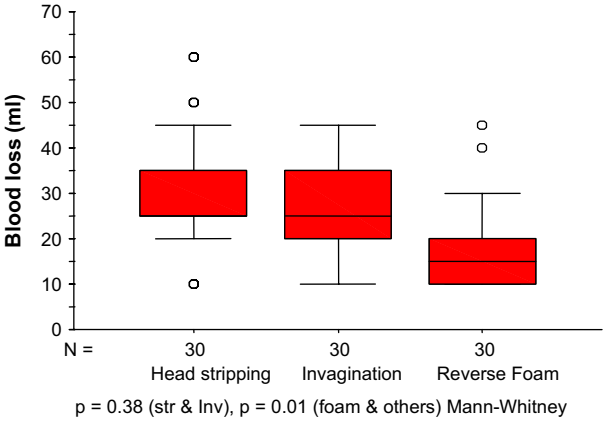

Figure 1 Blood loss at 18—24 hours. Box and whisker plot shows the median, inter-quartile range with maximum and minimum values.

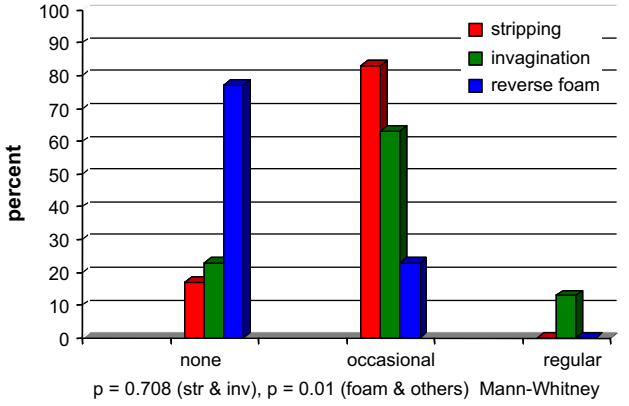

Figure 2 Use of analgesia. Consumption has been classified as none, occasional and regular.

Analgesic use post-op

77% of patients in the reverse foam group used no analgesia and the remaining 23% used it occasionally. Only 23% of invagination patients needed no analgesia; 63% needed it occasionally and 13% regularly. In the standard stripping group, 17% used no analgesia and 83% used it occasionally (Fig. 2). Again significantly fewer patients in the reverse foam sclerotherapy group required analgesia and these only needed it occasionally ($p < 0.001$, Mann Whitney).

Thigh bruising

There was significantly less thigh bruising reported by patients ($p = 0.005$) and also observers ($p < 0.001$) in the reverse foam group. The difference in thigh bruising between the standard stripping and invagination techniques was not significant as reported by both the patients ($p = 0.187$) and observers ($p = 0.575$). Questionnaires showed that only 13% of patients who underwent standard GSV stripping and GSV invagination assessed themselves as having no bruising. In the reverse foam sclerotherapy group 67% thought that they had no bruising (Table 1). The observations the patients and the assessors are shown in Fig. 3.

Adverse effects of foam sclerotherapy

No clinically detectable adverse effects attributable to the use of foam sclerotherapy were reported post-operatively or during the follow-up period.

Discussion

Since the late nineties, minimal access techniques have become well established in the management of varicose veins in the United States, Europe and Australia. The primary appeal of radiofrequency, laser and chemical ablation is the significant reduction in post procedural morbidity and pain compared to conventional surgery. An added benefit is that most varicose veins can be treated using these techniques with local anaesthetic within a clinic setting. This results in a low-cost treatment with minimal post-operative consequences.

The use of foam sclerotherapy in the UK seems to have lagged behind that in Europe, the US and Australia. NICE guidelines were issued in June 2006 while the German Society of Phlebology had published guidelines in 2004[25,26] issued from the 2nd European Consensus Meeting on Foam Sclerotherapy, April 2003. The recurring exhortation in these and other reviews and guidelines is that the conversion of Polidocanol or Sodium Tetradecyl Sulphate into foam by any method represents 'off-label' use of the sclerosants. Commercial preparations such as Varisolve® (British Technology Group PLC, London, UK) and lauromacrogol 400 microfoam have not yet gained approval necessitating the continued use of home made foam.

Early comparisons of the results of sclerotherapy and surgery have shown better long-term results for surgery[27,28] however this has been changing since the replacement of liquid sclerotherapy with foam.[29] Foam sclerotherapy has clear advantages over liquid in the treatment of larger varices and saphenous trunk incompetence,[30,31] and is maximally effective when ultrasound-guided treatment is given. One draw-back is the need for close follow-up and

Table 1 Two week post-op bruising reported by patients and observers

Bruising	Stripping		Invagination		Reverse Foam	
	Patients%	Observers%	Patients%	Observers%	Patients%	Observers%
None	13	20	13	13	67	77
Moderate	50	73	70	80	30	23
significant	37	7	17	7	3	0

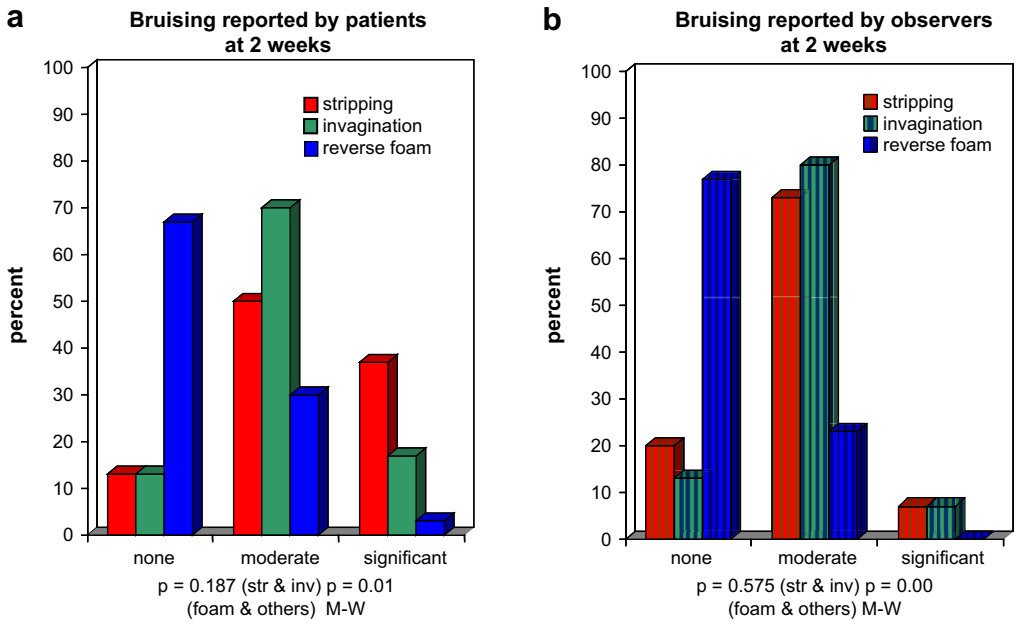

Figure 3 Percentage of a) patients and b) observers reporting no, moderate or significant bruising at two weeks post-op.

the need for repeated injection for treatment of recurrence.[32] It is hoped that this combination of modalities in a single treatment session will offer long term results which will avoid the need for further intervention.

Combination of treatment modalities has been common practice in the treatment of varicose veins. This most frequently took the form of liquid sclerotherapy of residual varicosities after definitive surgical treatment of varicose veins. Combinations have also been used in stepped protocols and also as primary interventions. The combination of liquid sclerotherapy with high saphenous vein ligation[33] in an attempt to minimize the recurrence rate has not been uniformly successful.[29,34] The combination of foam sclerotherapy and high ligation was addressed in a recent study[35] where patients were transferred to the ultrasound suite immediately post-operatively for ultrasound-guided foam injection of the GSV through an access point at below-knee level. This study has eliminated the need for transfer since ultrasound imaging can easily be used in operating theatre whilst maintaining sterility of the operative site. The use of high ligation and division of the SFJ and division of tributaries was used to try to minimize future recurrence of varicosities by recruitment of these tributaries.

The procedure of reverse foam sclerotherapy introduced in this paper addresses a number of loop-holes in the treatment of varicose veins. Though for the purposes of this study and to allow comparison with the stripping procedures, the procedure was performed under general anaesthetic, it would be equally feasible under local anaesthetic subject to patient preference.

Complementing flush ligation at the SFJ with foam sclerotherapy to decrease post-operative recurrence rates, is expected achieve a superior effect to the previously reported use of liquid sclerosant. Also when compared to closed procedures, since the GSV has been dissociated from the deep femoral vein, the head of foam in the proximal vein is not subject to back pressure from the column of blood in the femoral vein at the SFJ and the risk of spillage of foam into the deep system at this point is removed though seepage through perforators remains a concern.

Open cannulation of the GSV under direct vision with ultrasound confirmation allows accurate delivery of foam along the full length of the vein allowing evident proximal displacement of blood from the lumen as the catheter is withdrawn. Completion of filling of the vein is evident as foam will leak from the proximal open end of the vein though this was further confirmed using ultrasound prior to dressing the leg. Resection of a proximal 5 cm length of vein after injection also ensures completion and distances the cut ends to decrease the likelihood of neovascularisation. Ultrasound can also be used during this procedure to locate perforators and allow the application of pressure at their communication points to decrease passage of foam into the deep veins.

This paper addresses blood-loss, post-operative pain/use of analgesics and extent of thigh bruising as a measure of immediate procedural success as well as patient satisfaction, cosmesis and quality of life. Long-term follow-up of this series will be forthcoming to allow us to confirm whether long-term results confirm expectations.

References

1 Keller W. A new method of extirpating the internal saphenous and other similar veins in varicose conditions. A preliminary report. *NY Med J* 1905;**2**:385—8.
2 Mayo C. Treatment of varicose veins. *Surg Gunecol Obstet* 1906;**2**:385—8.
3 Homans. Operative treatment of varicose veins and ulcers. *Surg Gynecol Obstet* 1916;**22**:143—58.
4 Babcock W. A new operation for extirpation of varicose veins of the leg. *NY Med J* 1907;**86**:153—6.
5 Myers T. Varicose vein surgery in the management of the postphlebitic limb. *Surg Gynecol Obstet* 1954;**99**:733—44.

6 Large J. Surgical treatmentof saphenous varices, with preservation of the main great saphenous trunk. *J Vasc Surg* 1985;**2**:886—91.
7 Hammarsten J. Long saphenous vein saving surgery for varicose veins. A long-term follow-up. *Eur J Vasc Surg* 1990;**4**:361—4.
8 Fligelstone L. Flush sapheno-femoral ligation and multiple stab phlebectomy preserve a useful greater saphenous vein four years after surgery. *J Vasc Surg* 1995;**22**:588—92.
9 Munn S. To strip or not to strip the long saphenous vein? A varicose veins trial. *Br J Surg* 1981;**68**:426—8.
10 Francois P. Ambulatory ligation of the sapheno-femoral junction. Complement of Dr Muller's ambulatory phlebectomy technique. *Phlebologie* 1991;**44**:693—5.
11 Khan B. Prospective randomised trial comparing sequential avulsion with stripping of the long saphenous vein. *Br J Surg* 1996;**84**:1559—62.
12 Dwerryhouse S. Stripping of the long saphenous vein reduces the rate of reoperation for recurrent varicose veins: five year results of a randomised trial. *J Vasc Surg* 1999;**29**:589—92.
13 Orbach E. Sclerotherapy of varicose veins: utilisation of an intravenous air-block. *Am J Surgery* 1944;**66**:362—6.
14 Cabrera-Garrido J. Elargissement des limites de la schlerotherapie:nouveaux produits sclerosants. *Phlebologie* 1997;**50**:181—8.
15 Tessari L. Nouvelle technique d'obtention de la sclero-mousse. *Phlebologie* 2000;**53**:339—42.
16 Sarin S. Stripping of the long saphenous vein in the treatment of primary varicose veins. *Br J Surg* 1994;**81**:1455—8.
17 Dwerryhouse S. Stripping the long saphenous vein reduces the rate of reoperation for varicose veons: five-year results of a randomizer trial. *J Vasc Surg* 1999;**29**:589—92.
18 Tong Y. Recurrent varicose veins following high ligation of long saphenous vein; a duplex ultrasound study. *Cardiovasc Surg* 1995;**3**:485—7.
19 Wajeh YE. Sapheno-femoral venous channels assocoated with recurrent varicose veins are not neovascular. *Eur J Vasc Endovasc Surg* 2004;**28**:590—4.
20 Winterborn R. Causes of varicose vein recurrence: late results of a randomized controlled trial of stripping the long saphenous vein. *J Vasc Surg* 2004;**40**:634—9.
21 Rij Av. Neovascularization and recurrent varicose veins: more histologic and ultrasound evidence. *J Vasc Surg* 2004;**40**: 296—302.
22 Oesch A. 'Pin stripping': a novel method of atraumatic stripping. *Phlebology* 1993;**8**:171—3.
23 Ricci S. Does a double long saphenous vein exist? *Phlebology* 1999;**14**:59—64.
24 Evans C. Prevalence of venous reflux in the general population on duplex scanning: the Edinburgh Vein Study. *J Vasc Surg* 1998; **28**:767—76.
25 Breu FX. *Consensus Conference on Foam Sclerotherapy at the 2nd International European Symposium on Sclerotherapy (April 4—6, 2003, Tegernsee, Germany)* 2004;**33**:97—104.
26 Rabe F. Guidelines for sclerotherapy of Varicose Veins (ICD 10: 183.0, 183.1, 183.2 and 183.9). *Dermatol Surg* 2004;**30**:687—93.
27 Belcaro G. Endovascular sclerotherapy, surgery and surgey plus sclerotherapy in superficial venous incompetence: a randomized 10-year folllow-up trial — final results. *Angiology* 2000;**41**:529.
28 Hobbs J. Surgery and sclerotherapy in the treatment of varicose veins. A random trial. *Arch Surg* 1974;**26**:19—23.
29 Belcaro G. Foam-sclerotherapy, surgery, sclerotherapy and combined treatment for varicose veins: a 10-year prospective, randomised controlled trial (VIDECO trial). *Angiology* 2003;**54**: 307—15.
30 Yamaki T. Comparative study of duplex-guided foam sclerotherapy and duplex-guided liquid sclerotherapy for the treatment of superficial venous insufficiency. *Dermatol Surg* 2004;**30**: 718—22.
31 Hamel-Desnos C. Evaluation of the efficacy of pilodocanol in the form of foam compared with liquid form in sclerotherapy of the greater saphenous vein: initial results. *Dermatol Surg* 2003;**29**: 1170—5.
32 Myers K. Outcome of ultrasound-guided sclerotherapy for varicose veins; medium-term results assessed by ultrasound surveillance. *Eur J Vasc Endovasc Surg* 2007;**33**:116—21.
33 Ishikawa M. Treatment of primary varicose veins: an assessment of the combination of high saphenous ligation and sclerotherapy. *Surg Today* 1998;**28**:732—5.
34 Rutgers P. Randomized trial of stripping versus high ligation combined with sclerotherapy in the treatment of the incompetent greater saphenous vein. *Am J Surgery* 1994;**168**:311—5.
35 Bountouroglou D. Ultrasound-guided foam sclerotherapy combined with Sapheno-femoral ligation compared to surgical treatment of varicose veins: early results of a randomized controlled trial. *Eur J Vasc Endovasc Surg* 2006;**31**:93—100.