Foam treatment for varicose veins; efficacy and safety

By
Dr. Tarek Hamada
Dr. Mohmed Abd El Hamid
Assistant professor vascular surgery. Al Azhar university
Assistant professor ,radiology .Al Azhar University

Abstract

Objective: To demonstrate the efficacy and safety of foam sclerotherapy in the treatment of varicose veins measured against patient satisfaction, symptom relief, clinical examination and duptex scanning.

Methods and patients: From October 2004 to October 2005,100 legs with varicose veins treated with ultrasound guided sclerosing foam prepared according toTessari method by mixing Elhanolamine Oleate (E.O) with air using 2 disposable syrings and a three way tap producing a high-quality micro foam.Every patient was studied with clinical examination and duplex scanning before and after the treatment with a mean follow up of 12 months.

Results: An average of 8 ml of E.O 5% foam were required to close incompetent varicose veins.Thirty percent of legs required a second treatment at the 3rd month of follow up.All pateints felt that their legs had treated succefully with resolution of all symptoms in 85% and resoluion of all varicosities in 92%.

Conclusion: Foam sclerotherapy is safe and effective therapy in treating varicose veins with high patient satisfaction and improvement in quality of life.

Introduction

The definition of a sclerosing foam (SF) is amixture of gas and liquid sclerosing solution (detergent type) with tensio-active properties . THE gas must be well tolerated or physiologic and the bubble size less than 100~. The behaviour of sclerosing foam is different when injected compared to the action of a liquid solution(Alessandro Frullini 2003).

The use of air and a sclerosing drug in combination was described in 1944 by Orbach: the airblock technique. The

sclerosing solution was added to air , by simply shaking the syringe or the vial to produce large bubbles which had a high air: liquid ratio and with increased efficacy only for smaller veins, this method not suitable for larger veins as saphenous trunks or larger tributaries because after injection of foam,ther air positioned itself along the upper side of the vien, Impending contat with endothelium (Orbach 1944).

Further advancement came then from subsequent innovation : Cabrera et al 1997.puplished an article about the Production of a complex foam with CO2.Monfreux 1997 described the MUS method that generated a simple foam with air by means of a glass syring: Mingo-Garcia1999 developed a special device to produce foam with compresed air; Benigni et al1999 puplished a method to produce a very short-lasting foam in a plastic syringe, and Tessari et al2000 presented an orignal method of foam formation with 2 disposable syrings and a three way-tap. Frullini 2000, puplished a different method to produce foam in a vial of sclero-sing solution, provided that the vial has a rubber cap ,the method utilizes the turbulance effect that a disposible syringe and a relatively large connector can create into the vial with a fast push on the piston.

Now several pharmaceutical campaniles have become intere-sted in foam. for example a british company is developing a fully char-acterized micro foam (Varisolve) (Alessando furllini 2003).

Patients and Methods

One hundred randomly selected legs of 60 patients (40 patients with bilateral and 20 patients with unilateral varicose veins) suferring from varicosities either long , short saphenous or both were entrolled in this study from October 2004 to October 2005.twelve legs had both long and short varicose veins.Thirty legs had post surgical recuurent varicose veins.

All patients were asked to complete a (quality of life) survey and patient satisfaction, and were revewied clinically and by duplex scanning to assess both superficial and deep venous systems . The following were criteria of exclusion: Pregnancy, breast feeding, DVT known allergy to E.O and lack of mobility. Selection criteria for the study were as follow :- [1]Pre treatment trunkal incompetence in primery long

or short saphenous veins as defined by a reflux of more than 0.5 seconds was documented by doppler/duplex scan

[2] A Tessari microfoam technique was done using Ethanolamine Oleate 5% in a ratio of 1ml sclero-sing solution to 3 ml air for saphenous trunk (s) and varying concentrations depending on the size of the saphenous branches and associated varicosities.

The foam was generated according to Tessari by using 2 disposable syrings and a three-way tap. Up to10 ml foam was produced from 2.5ml.E.O 5% and 7.5ml of air with 20 passages through the tap . This foam is very compact and with a very small bubble diameter . An other advantage of Tessari method is the ability to reconstitute the foam if the treatment session takes time to be completed.

The protocol of the treatment included the following; For treat-ment of the saphenous trunk (s) injection of 6 ml to 10 ml foam (average 8 ml) depending on the diameter of the saphenofemoral junction. Because of the echo-visibility of the foam , the injection was Duplex guided , when the foam reached the sapheno-femoral or sapheno-popliteal junction compression was done .An other visit was done within a week to confirm closure of the saphenous trunk(s) and to treat the visible varicosities if was not closed.

For treatment of associated varicosities and saphenous tribu-taries lower concentraion and less volume of the foam was used ranging from 2 ml to5 ml of 0.5% to 3% E.O .Perforators especially Cockett often need further treat-ment at the second visit , and this involves injection at least from 2 ml to 4 ml proximal or distal to the perforator,of varying concentration dependent on the size of the perforator.

For patients with bilateral varicose veins, the saphenous trunk (s) of one leg treated as previousely mentioned, the second leg treated 2days later and a third treatment to the visible varicosities and /or distal perforators being treated 5days later, so that for the majority of those patients the treatment of the 2 legs was completed in three visits over one week.

All patients were left laying for about 5 minutes after the treatment in order to keep the foam in contact with the wall of the vein and to possibly decrease its migration , and then they asked to walk for 15 minutes and 1hour per day.

All legs were placed in (class 2

) 30-40mmHg graduated and elastic stocking for 2 week(1 week all the time and 1week during day only).

Every patient was advised to:

[1] Avoid straining, strenuous physical activity or Valsala maneu-vers for the frist month because they may contribute to early recanalisation.

[2]Avoid prolonged car or plane travel of more than 4 hours during the frist month after treatment to decrease the incidence of the thromboembolic events

All patients were reviewed for occurance of complication: the complications were classified as systemic(plumonary embolism-drug reaction-transient transient cofus-ional status) and visual distur-bance, local (DVT, phlebitis,skin pigmention, skin necrosis).

Follow-up was provided for every patient: Every patient was reveiwed every month for 1 year to assess closure of incompetent saphenous trunks, incompetent branches and all associated varicosities by duplex and clinical examinations well as patient satisfaction and improve-ment of qualty of life .

Results: One hundred legs were studied.Males represented 32%, and females represented 68% (an average of age 52]. There were 55 left and 45 right legs.Seventy seven legs had the greater saphenous vein , and 23 legs had the short saphenous vein , 12 legs of them having both greater and short saphenous veins .

Seventy-three percent were CEAP class 2. 8%CEAP class 3. 18%CEAP class 4. And 1%CEAP class 6 (Fig 1).

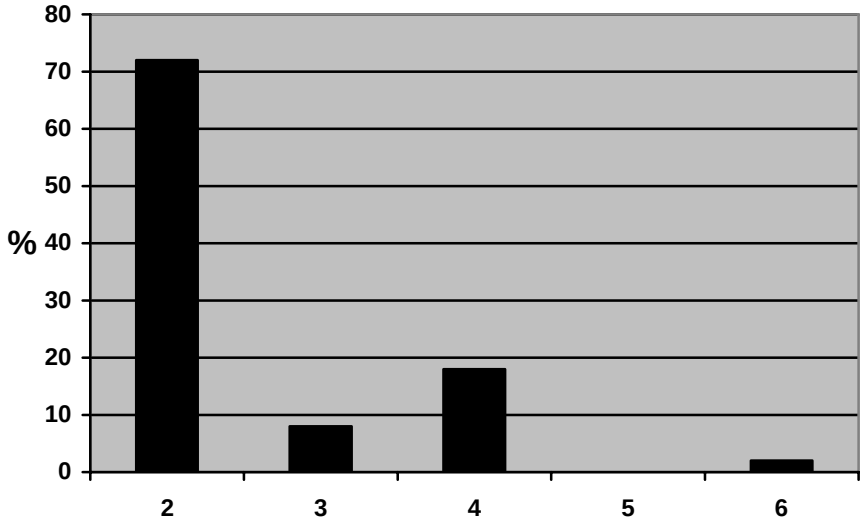

Figure 1-CEAP classification class 1: reticular and spider veins:

excluded from study .class 2:varicose veins. Class3: varicose veins with edema.Class4: varicose veins with skin changes. Class 5:varicose veins with healed ulcer: Class 6 active varicose ulcers. The total volume of Ethanolamine oleate (E.O) 5% foam used for completion of all treatments totally 8 ml [range from 2 to 25ml (fig 2), thirty percent of legs had required varying concentration of E.O to visible varicosities dependent on the size of the varicositie(o.5 % to 3 %].

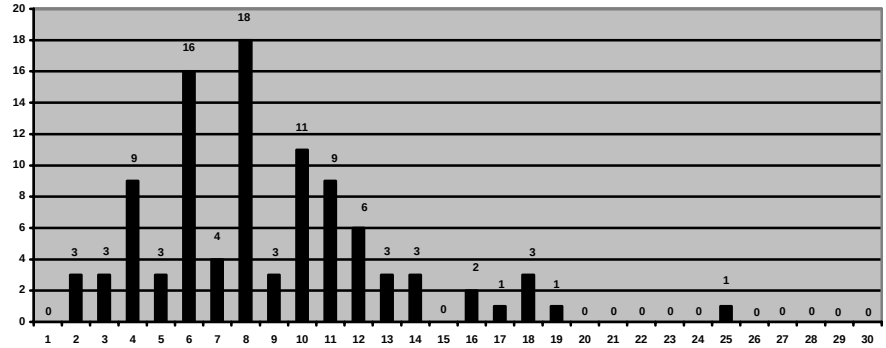

Figure 2 :volume of E .O 5% foam

Thirty percent of legs required a second treatment at the 3rd months of follow up(doses included in the previousely mentioned totals).

Such treatments were generally for a small segment in the saphenous trunk , a small feeding vessel , a perforator or minor residual varicosities. The majorityof these legs were presented with post surgical recurrent varicose veins (multiple sources of refluxes).

The success of foam treatment was analyzed from 4 perspectives: Patient satisfaction , Quality of life improvement , Clinical assessment, and Duplex assessment

Pateint Satisfaction

There was exetermely high patient satisfaction .One handerd percent of patients felt that foam injections had been successful for treating their varicose veins and releated symptoms. Eighty five percent registered compelete success, and 15 % felt that foam had been partialy successful (not all symptoms had completely resolved).No body rated the treatment as a failure(fig. 3).

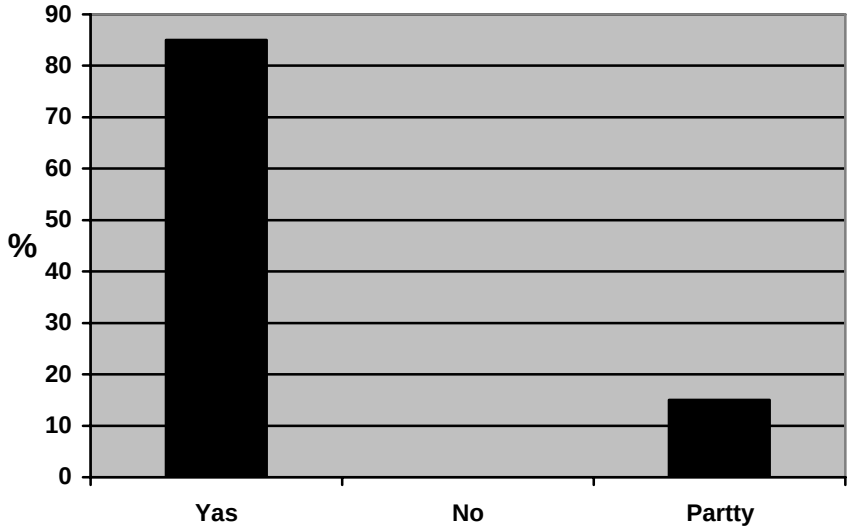

Figure 3 :Foam successes

Quality of Life Questionnaire

Ninety four percent of patients felt that their quality of life had improved after treatment[78% complete and 16% partial] (fig. 4).

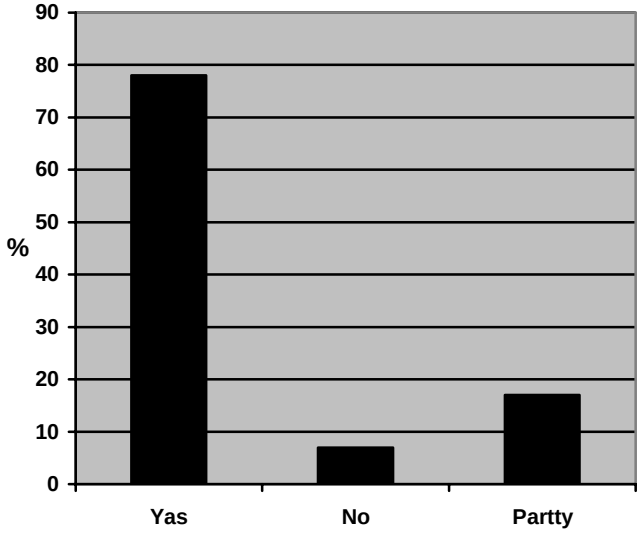

Figure 4 : Quality of life Improved .

Clinical Outcomes Of Foam Treatment

Ninety two percent of legs had symptoms before treatment.The size of varicosities and the degree of reflux were not accurate predictors of symptoms (fig. 5)

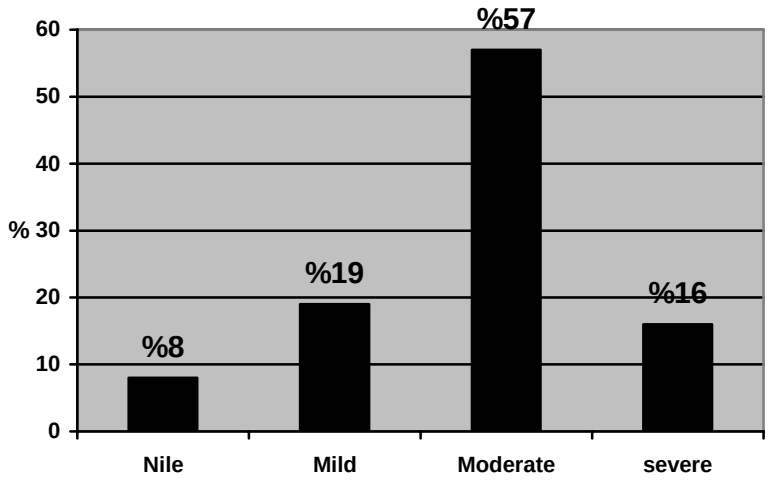

Figure 5 : Symptoms Pretreatment.

After treatment , 86% showed improvement in symptoms symptom relief 38%,symptom improvement 48%). Fourteen percent showed no change,the majority of the this group(57%)did not have symptoms before treatment (fig. 6).

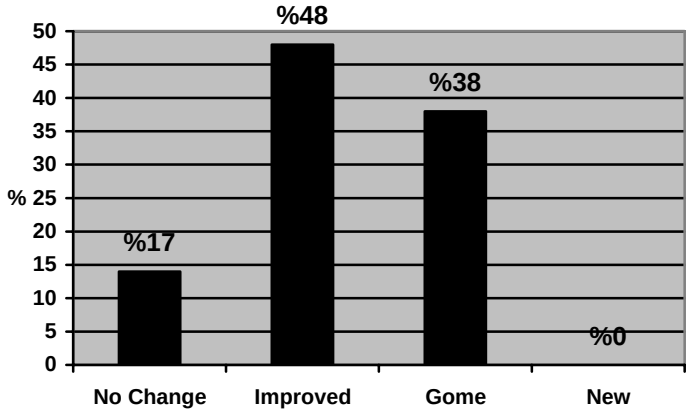

Figure 6 : symptom post treatment

(Fig.7) demonstrates the percentage of patients with symptoms in each class before and after the treatment. The difference reflects those patients who had shown either some improvement , much improvement or complete relief.

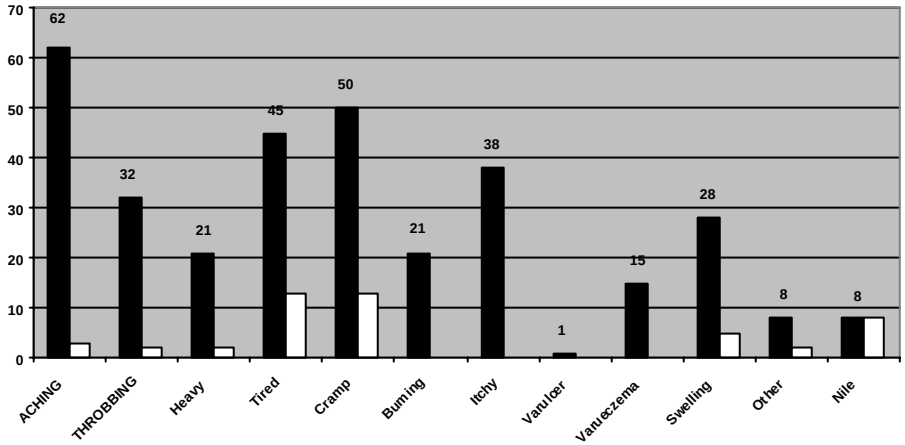

Figure 7 : symptom pre and post treatment, before treatment in black and after treatment in white.

Table[1] shows a decrease of the number of legs versus degree of improvement in each symptom group after treatment culminating with the precentage improvement in each group.[other group] includes, bleeding, heat sensation, tenderness and tingling .

Abble 1. improvement by Symptom Class

	Ache	Throbbing	Heavy	Tired	Cramp	Suming	Itchy	Varicose Uker	Varicose Echema	Swelling	Other	Nile
Worse	**0**	**0**	**0**	**0**	**2**	**0**	**0**	**0**	**0**	**0**	**1**	**0**
No Change	**4**	**2**	**2**	**5**	**12**	**0**	**0**	**0**	**0**	**4**	**1**	**8**
Some Improvement	**4**	**5**	**4**	**5**	**4**	**4**	**2**	**0**	**0**	**2**	**0**	**0**
Much Improvement	**23**	**10**	**3**	**12**	**15**	**6**	**10**	**1**	**8**	**9**	**0**	**0**
No longer Occurs	**31**	**15**	**12**	**22**	**17**	**11**	**18**	**0**	**7**	**10**	**3**	**0**
Total Improved	**58**	**30**	**19**	**39**	**36**	**21**	**30**	**1**	**15**	**21**	**3**	**8**
Before Treatment	**52**	**32**	**21**	**44**	**50**	**21**	**30**	**1**	**15**	**27**	**5**	**8**
% Improved	**93.5**	**93.8**	**95**	**88.6**	**72**	**100**	**100**	**100**	**100**	**70.4**	**60**	**0**

One handerd percent of visible varicosities related to treated saphenous veins were successfully treated clinically(92% completely removed,8% significantly improved) .4% had developed some minor new varicosities unrelated to the treated saphenous veins(fig.8).

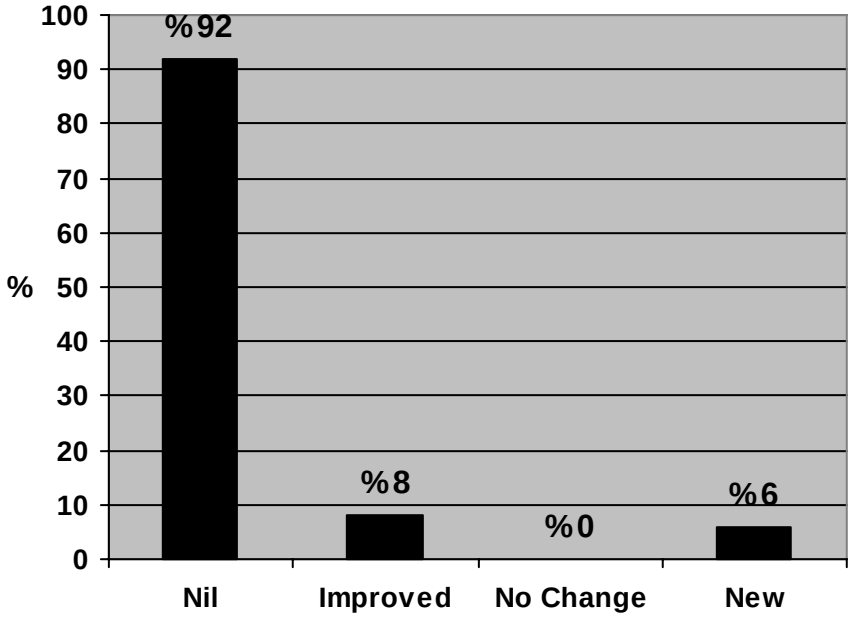

Figure 8 :visible varicosities post treatment

Duplex Scaning Assessment

One hundred legs were treated ,twelve of them had both short and long saphenous veins , giving a total of 112 saphenous veins treated.

Duplex confirmed 97% succe-ssful treatment (88 saphenous veins complete sclerosis, 20 with fibrosed veins of less than 2 to3 mm and minimal flow)of the saphenous veins .Four saphenous veins had reduced diameter but persistent reflux and require further treatment if recurrence occurred.

(Fig .9) shows the precentage of veins diameter at the junction :34%of veins had diameter 0-5 mm,65% of veins had diameter 5-10 mm, 11.6% of veins had diameter 10-15 mm , 2% of veins had diameter more than 20 mm.

Results for the group of veins which had dimeter at the junction more than 10 mm(13

of 112 saphenous veins). were as better as for the 0-10 mm dimeter group.

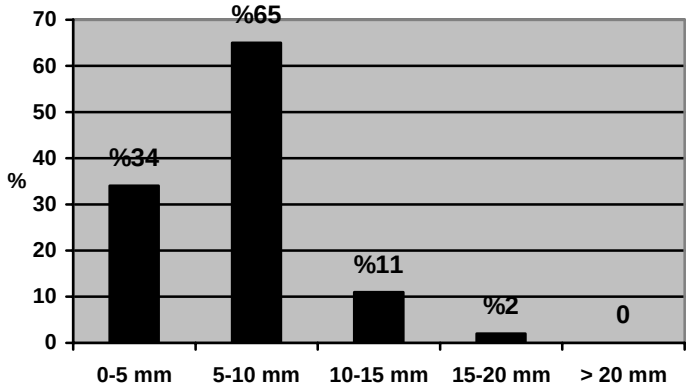

Figure 9 : vein diameter pre treatment

Table [2]shows the complication which had occured . No major complication . 3% of legs (3 of 100) had minor complications :2 legs had superficial phelbitis and1 leg had partial soleal DVT .

Complication	No. legs
Phlebitis.	2
Minor DVT.	1
Drug reaction .	0
Transient visual disturbance	0
Transient confusional status.	0
skin pigmentation	0
skin necrosis	0
Pulmonary embolism	0
Neurasthenia	0

Table 2.complications of foam sclerotherapy

Two patients had superficial phlebitis evidenced by local eryth-ema and edema and confirmed by increased echo genicity surro-unding the treated vein on duplex and they treated by local application of anti inflammatory agent and

hygroscopic agents as kaolin, lead subacetate and glycerin. One had partial throm-bosis of one of the soleal veins, diagnosed clinically by edema and calf tenderness and by duplex scanning , he treated by rest, leg elevation graduated elastic stocking and subcutaneous unfra-ctionatd heparin in the hospital, was followed up till complete recovery.

Discussion.

This study demonstrates a high patient satisfaction with improve-ment of the quality of life and a high rate of closure of the saphenous trunks and visible varicosities with foam therapy**.**

Results achieved in this study are comparable wih other reports (Brrett et al 2004,Hamel Desnos et al 2003,Rybak 2003,Wright 2003, Frullini and Cavezzi 2002,Frullini et al 2000 and Cabrera et el 2000). But in the VEDICO trial comparing the treatment of varicose veins using several techneques inclu-ding sclerotherapy, surgery and foam sclerotherapy, the study demon-sterated elimination of reflux in all patients with10 years follow up.(Belcaro et al 2003)

There are 2 established appro-ches for foam sclero therapy :low concentration\ high volume and high concentration \ low volume.

The former group used low concentration of the sclerosing foam with volumes often in excess of 15 ml per treatmen visit. The later group used a high concen-tration of the sclerosing foam with lower volumes typically less than 10ml\visit (Breu and Guggenbichler 2004). We have adapted the latter technique because we believe that ,the lower the concentrations tended to lead to more treatment sessions and higher volumes inevitably lead to the deep venuos system being exposed to more sclerosant.

To decrease the incidence of passage of the foam to the deep system by leg elevation during the treatment, we elevte the legs because on leg elevation the lighter foam will move upward, and also leg elevation impedes the fast penteration into the deep system.

In January and November 2004,2 reports by Barrett et al showing a similar results to our study. They used the same techneque to obtain high success with low incidenc of complication.

Althoug all pateints who needed further treatment were during the first 3months of follow up ,we believe that the 1

year follow up provides an sufficient time to assess the development of early recanalization.Barrett et al 2004had reported that, 3 months follow up were enough but others (Hamel Desnos et al 2003 , Rabee et al 2004 and Breu and Guggenbichler 2004) did not accept that because this peroid was too short to establishment of alterntive venous path-way .

Over 100 legs treated with sclerosing foam we had no serious complications (in particular , no plumonary embolism, no major DVTor nerve injury).But Hamel Des nos et al 2003, reported 2 of 80 patients had popliteal D VT after Polidocanol l3 % foam sclero-therapy. This may be explained by : the difference in the nature between the Polidocanol which used in their study and the Ethanolami ne oleate which used in our study, the high concenteration they used or the dependence leg position vs the elevation leg position in our study. We had 1 case (1%) of minor DVT in a soleal vein with complete resolution over three months, but Barrett et al 2004 reported 3% of their cases had minor DVT. Phlebitis which was a sequale of excessive inflame-matory reaction of the sclerosing foam had-occurred in 2% of legs (2 different patients), while Frullini and Cavezzi 2002 and Rabee et al 2004 reported only 1% of phlibitis. no Skin pigmentation, skin necrosis, sclerosant induced ulcer , wound infection or neurasthenia.

Surgery carries a significantly high risk of DVT, nerve injury and wound infection especially grion incision, plus risk of general anesthesia and the time of work off. Surgery is not more effective than foam sclero-therapy for 1ry truncal saphenous vein treatment but less so for recrrent varicose veins (**Gerou-lakos 2005**) . So we believed that, it is difficult to justify a procedure that has increased patient morbidity and mortality and no increase in safety.

Endovenous laser ablation and radiofrequency closure in compe-rasion to foam require tumescent anesthesia and can only be used for relatively striaght saphenous trunks and the tributaries need multiple phlebectomies, these tenquics also require expensive instruments and result in release of uncontrolled volume of smoke produced by laser in the venous system . (Teruya and Ballard 2004) .

CONCLUSION:

We believe that foam is a safe and effective treatment for varicose veins wthout serious side adverses. It can be used for all age groups, and all varicosities (saphenous trunks, tributaries, perferators and complicated post surgical recurence where multiple sources of recurrent reflux).patient safety is a prime indication for foam therapy
(no general anesthesia and low risk of DVT because of the immediate mobility.

Foam has the added benefit of high patient satisfaction and impro-vement of quality of life.

Foam sclerotherapy is a simple procedure (no anesthesia,no hospi-tal lization, can be done in out patient clinic,takes about 10 minutes per cession and the patient
can return to home after 15 minutes and no work off peroid.

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دراسة كفاءة وأمان رغاوى عقار الأيثانولامين في علاج مرضى دوالي الساقين

طارق حمادة – محمد عبد الحميد
من أقسام الجراحة ، والأشعة – كلية طب – جامعة الأزهر

الهدف من هذه الدراسة هو تقييم كفاءة الرغوة الناتجة من خلط الهواء مع عقار الايثانولامين في علاج دوالي الساقين و كذلك معرفة إذا كانت هذه الطريقة آمنة لهؤلاء المرضى .

أجريت هذه الدراسة في مستشفى الحسين الجامعي علي 100 ساق مصابة بدوالي الساقين و قد تم تحضير هذه الرغوة عن طريق خلط الهواء مع عقار الايثانولامين مستخدما سرنجتين بينهما صمام .

وتعتمد هذه الطريقة على حقن الوريد الصافين الأعظم أو الأصغر بهذه الرغوة مستدلا بجهاز تصوير الأوردة بالموجات فوق الصوتية (الدوبلكس).

وأدت هذه الطريقة إلى نتائج هائلة في علاج معظم دوالي الساقين دون أى أعراض جانبية على المرضى الذين أجريت عليهم هذه الدراسة.

ويمكن أن نستنتج أن طريقة علاج دوالي الساقين عن طريق الحقن بالرغوة طريقة فعالة وآمنة .