

10<sup>th</sup> Meeting of the European Venous Forum  
Copenhagen, Denmark  
5 – 7 June 2009

**BOOK OF ABSTRACTS**

FRIDAY 5 JUNE 2009

**17:30-18.50**

**Scientific Session I:**

**Chair: Andrew Nicolaidis, Neils Baekgaard**

Paper 1.1

**DUTCH CONSENSUS ON DUPLEX GUIDED FOAM SCLEROTHERAPY IN THE LIGHT OF OTHER EUROPEAN GUIDELINES**

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Varicose veins are a common phenomenon in the general population and increase with age. Results from several epidemiological studies show that a quarter of the adult population has some type of varicose veins, in women more than in men.

Over the past few years there has been a move to different treatments for varicose veins. Besides the ligation of the SF-junction and stripping of the great saphenous vene nowadays also endovascular ablation techniques are getting more attention, such as endovascular laser or radiofrequency ablation and ultrasound-guided foamsclerotherapy. The latter technique is used frequently because of its less invasive character and highly successful occlusive percentage of the treated varicose vein.

To achieve a better understanding and standardization of the treatment, a consensus meeting was organised by Dutch experts. Based on their clinical experiences and an international literature study a Dutch consensus was drawn up. Within this consensus the different aspects of other European guidelines have been discussed and similarities as well differences have been pointed out. The consensus has been accepted for publication by a national medical journal.

Major outcomes will be discussed during the presentation.

	<b>Summary Dutch foamconsensus</b>
1	Foamsclerotherapy is an effective treatment for truncal varicositas
2	Foam is prepared following the method of Tessari
3	Foam consists of 1ml liquid and 4ml air
4	Polidocanol 1% is used for the treatment of truncal veins
5	The use of a vein catheter is advisable
6	GSV acces is at knee height, SSV acces as distally as possible
7	Minimally 10 cm between vein acces and junction
8	Max. 10 ml foam per treatment
9	slow injection
10	4 weeks compressiontherapy
11	Contra-indications same as liquid sclerosing agents

## Paper 1.2

### **FIVE-YEAR OUTCOME OF ULTRASOUND GUIDED FOAM SCLEROTHERAPY FOR SAPHENOUS TRUNKS.**

P Coleridge Smith,

*Consultant Vascular Surgeon, British Vein Institute, London, UK*

Ultrasound guided foam sclerotherapy (UGFS) is becoming more widely used in the UK, but NICE has concluded that 'current evidence of long term efficacy is limited'. The aim of the present study is to report the clinical outcome of UGFS 5 years following treatment.

During 2003 the author treated 167 patients using ultrasound guided foam sclerotherapy for truncal saphenous incompetence, recurrent following previous surgery in 30% of cases. A total of 230 saphenous trunks were treated (GSV: 184, SSV: 46). In all patients treatments were given at intervals of 2 weeks until duplex ultrasonography showed that all saphenous trunks and varices had been successfully obliterated. An average of 2.1 sessions of treatment were required per patient. Patients were invited to return after 6 months to check on completion of treatment, but only 68 came an average of 11 months following the initial course of treatment. Re-treatment for recurrent varices or re-canalisation of saphenous trunks was carried out in 9% of patients.

5 years following treatment all patients were invited for a further assessment. Only half of patients returned. Reasons for not attending included: patient not interested, moved away, not contactable. Patients who came for examination were studied by clinical examination and by duplex ultrasonography. Clinical outcome was assessed as successful if no or few varices were present, and failure where moderate or severe recurrence was present according to the method of Hobbs (1984). Duplex ultrasonography was undertaken to assess the extent of saphenous incompetence.

Results: After five years a successful clinical outcome was observed in 88 of 101 limbs (88%). Recurrent saphenous reflux was observed in 11 of 81 GSVs and 3 of 41 SSVs. Primary reflux in previously normal GSVs arose in 4 limbs.

Conclusion: Clinical recurrence 5 years after foam sclerotherapy in this series was 12%. This is comparable to or better than that reported after surgical intervention (20 – 45%). It is safe to say that long term recurrence following UGFS is no more frequent than following surgery.

## Paper 1.3

### **SEASONAL VARIATION OF SUPERFICIAL VENOUS THROMBOPHLEBITIS**

S Kakkos , G Lampropoulos, S Papadoulas, I Ntouvas, I Tsolakis.

*Department of Vascular Surgery, University of Patras Medical School, Patras, Greece*

**Background and aim:** Previous studies have demonstrated an increased frequency and severity of symptoms related with varicose veins during summer, but there is no data on the incidence of their complications, including superficial venous thrombophlebitis (SVT). The aim of the present investigation was to test the hypothesis that ST follows a similar, seasonal, pattern.

**Patients and Methods:** During the two year period between January 2007 and December 2008, inclusive, 123 patients with ST were examined at the Emergency Department. These were 60 females and 63 males, median age 55 years. In 8 patients (6.5%) an additional predisposing factor was present. On presentation, SVT was complicated by thrombus extension to the proximal deep system in 5 cases (4.1%); above knee SVT was present in 4 of these 5 cases.

**Results:** SVT occurred more often during the months of May to October (monthly incidence of 7.3 cases) compared to remaining of the year (monthly incidence of 2.9 cases). Incidence of SVT showed a peak in June and July with a monthly incidence of 20.5 cases being observed. Using time-series statistics (ARIMA) these findings showed a periodical seasonal pattern (Ljung-Box Q statistic 35.2,  $p=0.009$ )

**Conclusions:** SVT in our area showed a clear seasonal pattern of occurrence, with a significant rise during summer time. Although a possible explanation of this observation could be poor patient compliance and suboptimal usage of elastic stockings during the hot Mediterranean summer, further studies to investigate the cause, clinical significance and preventive methods of this complication are justified.

#### Paper 1.4

### EFFECTS OF TETRADECYL SULFATE ON COAGULATION PROFILE, PLATELET AGGREGATION PROFILE AND FIBRINOKINETICS: IMPLICATIONS ON SCLEROTHERAPY

E Kalodiki,<sup>1</sup> C. Adiguzel,<sup>2</sup> O. Iqbal,<sup>2</sup> G. Geroulakos.<sup>1</sup>

<sup>1</sup>Ealing Hospital & Imperial College, London, UK. <sup>2</sup>Dpt of Pathology, Loyola University, Illinois, USA.

**Introduction:** Sodium tetradecyl sulfate (STD) ( $C_{14}H_{28}NaSO_4$  - 7-Ethyl-2-methyl-4-hendecanol sulfate sodium salt) is an anionic surfactant used for endovenous chemical ablation (sclerotherapy) of varicose veins and hemorrhoids. In the UK, Ireland, Australia, New Zealand and South Africa, it is sold under the trade name Fibrovein. It is approved by the US FDA and available under the trade name Sotradecanol (Bioniche Life Sciences Inc. Belleville, Ontario) for the treatment of small, uncomplicated varicose veins of the lower extremities. Sodium tetradecyl sulfate is a potent modulator of endothelial cells and may induce a hypercoagulable state through promotion of platelet activation and selective inhibition of protein C thereby causing venous obliteration. This sclerosing venous obliteration may or may not be permanent and results in several under-reported side effects. Deep vein thrombosis and pulmonary embolism are known to occur and are reported.

**Aim:** To evaluate the effects of STD on the coagulation, platelet aggregation and fibrinokinetic profile and to assess its effect on haemostasis.

**Materials and Methods:** STD was reconstituted in saline at a concentration of 1 mg/ml. Further dilutions were made in normal human pooled plasma (NHP) to achieve concentrations in the range of 0 to 100  $\mu$ g/ml. Thirty samples (10 patients with high PT, 10 patients with high APTT and 10 patients with hictric samples) were analyzed *in vitro* to determine the coagulation profile, platelet aggregation and fibrinokinetics. Coagulation profile was determined by performing the PT, APTT, Heptest, TT (5U/ml) assays. Agonist-induced aggregation profile was determined using Collagen, ADP, Arachidonic acid, epinephrine and thrombin as agonists on the platelet aggregometers. The thrombin-induced fibrinokinetic profile of this agent was determined for a period of 30 minutes.

**Results:** Coagulation profile showed that STD does not significantly alter the coagulation parameters such as PT, APTT, Heptest and TT 5U/ml when compared to the NHP control. Agonist-induced platelet aggregation profile using STD at a final concentration of 100  $\mu$ g/ml showed approximately 80% platelet aggregation with collagen (10  $\mu$ g/ml), ADP (2.5  $\mu$ M), Arachidonic acid (500  $\mu$ g/ml), epinephrine (10  $\mu$ g/ml) and thrombin as agonists, a response similar to that of agonists with saline as controls. Fibrinokinetics profile showed no statistically significant difference in fibrin formation between different concentrations of STD and the NHP control, studied for a period of 30 minutes.

**Clinical implications:** While STD appears inert in producing any procoagulant effect in the normal individuals, its effect on patients predisposed to thrombotic risk in simulated clinical conditions including generation of the sclerosing foam need further evaluation.

09:00-10.00

Scientific Session 2: (short paper session)

Chair: Alun Davies, Anthony Comerota

### Paper 2.1

#### SURGERY OF THE SMALL SAPHENOUS VEIN; A PERSONAL SERIES

M Vandendriessche,  
*Ghent, Belgium*

Despite the introduction of many new methods of treating venous disease, the most effective management of a grossly dilated and incompetent SSV is by surgery.

Approximately 20% of primary saphenous vein incompetence involves the SSV and it has been taught that simple ligation of the terminal SSV deep to the popliteal fascia is sufficient. However there is a high recurrence rate because the anatomy of the popliteal fossa is more complex than is generally appreciated. Even in expert hands the published success rate is unacceptable (see Table).

#### Failed SSV surgery despite using Duplex Ultrasonography

		no. of legs	recurrence rate	time
Tong & Royle	1996	12	58%	1yr
Tyrell et al	2002	59	36%	6wks
Davies et al	2004	202	38%	1yr
de Cossart	2004	22	50%	6wks
Van Rij	2003	33	23%	6wks
O'Hare et al	2007	67	21%	1yr

By contrast Perrin et al (2003) in 76 legs reported a recurrence rate of 5% at 4 years.

This suggests that precise assessment of the anatomy combined with meticulous surgery is required.

We therefore undertook a detailed study of our results for surgery of the SSV. This involved 49 legs of 43 patients, 36 female and 7 male. 28 were primary and 21 were for recurrence.

A full medical history and clinical examination was carried out and if reflux was detected in the popliteal fossa on HHD the leg was examined with Duplex Ultrasound; this recorded the diameter of the SSV, the level of the S-P junction and the size and presence of reflux in other veins in the popliteal fossa (Giacomini, Gastrocnemius and vein of the popliteal fossa).

The Duplex study was made at the initial consultation, again for pre-operative marking and then repeated at 6 weeks post-op, 1 year, 3 years and to be repeated at 5 years.

All but 1 patient were treated under General Anaesthesia as Day cases.

There was a 100% follow-up. At 6 weeks there was 1 trivial recurrence detected in the lateral vein of the popliteal fossa with no signs or symptoms and it had not been detected preoperatively. At 1 year it was still the only recurrence without any signs.

The 3 year results will now be presented.

### Paper 2.2

#### CALCULATION OF ENERGY IN RADIOFREQUENCY SEGMENTAL THERMAL ABLATION OF GREAT SAPHENOUS VEIN.

C Lebard, C Daniel, F Zuccarelli

*Clinique Internationale du Parc Monceau, Paris, France*

**Background:** Radio frequency ablation procedures are now faster and occlusion rate is very high with the new CLOSURE*Fast* catheter.

The aim of this study is to appreciate the ability of RFA generator to deliver efficient energy in the great saphenous vein (GSV) and to assess the maximal amount of energy the generator is able to deliver.

**Material and methods :**

Since January 2008 to may 2008, 21 patients have been operated with the new catheter CLOSURE*Fast* for varicose vein disease with significant GSV reflux. Every limb was C2 or lower CEAP clinical class.

CLOSURE*Fast* procedure has been performed as indicated by Vnus Medical Technologies Inc.

Energy delivered by heating element during several cycles of 20 seconds was studied in 25 limbs during CLOSURE procedures. This energy displayed on the screen of the generator has been recorded on a videocamera. 154 cycles have been collected giving 3080 data and a total timing of 50 minutes of vein heating with a mean of 2 minutes for each leg (6 cycles) and the vein length treated was 33cm.

On the sapheno-femoral junction energy has been delivered twice.

Results:

There was 100% immediate vein obliteration.

Total energy delivered on the sapheno-femoral junction was near 763 joules. The average LEED delivered was 109 J/cm. The fluence calculated had an average of 47 J/cm<sup>2</sup> (range 32 to 65).

Total energy delivered on smallest saphenous segments was near 410 joules (range, 286 to 531 J). The average LEED delivered was 59 J/cm. The fluence for a simple cycle was near 30 J/cm<sup>2</sup> (range 20 to 49 J/cm<sup>2</sup>).

Third of the energy is delivered very powerfully in 4 seconds and half of the energy in 8 seconds so that temperature level is quickly at 120° and is more longer efficient.

During the second cycle, energy delivered by the heating element is lower than during the first cycle (20% less powerful). Hydratation of tissues and the amount of tumescence could explain this difference.

Tumescence could oblige the generator to deliver more energy and so become more efficient. But, the generator has upper limit and cannot deliver more than 600 J / 7 cm. So RFA is safe because its autoregulation gives enough energy to veins of 6mm but not beyond. Larger vein of 12mm requires a second energy cycle.

**Conclusion:** Radiofrequency thermal ablation is safe and very adapted to GSV.

## Paper 2.3

### CORRELATION BETWEEN CHRONIC VENOUS DISEASE AND THE STATIC FOOT DISORDERS

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**Objective :** To study the relationship between chronic venous disease (CVD) and the static disorders of the foot (SDF).

**Material and methods :** A retrospective study including 600 lower limbs of 300 patients with CVD in an old people's home were assessed by measurement of the Djan-Annonier angle of the foot, in order to quantify the SDF, a complete evaluation of the CEAP items (basic CEAP) and the symptoms including a scoring system of imputability.

**Results :**

a significant correlation has been found between static disorders of the foot and :

The body mass index (p<.01), the presence of symptoms (p<.001), their global score, their score of

imputability (p<.001), the CEAP clinical classes (p<.001) and the long standing position during the day.

Age and sex were not found significant.

**Conclusion :** The SDF can be considered as an important factor of worsening of the CVD.

This emphasizes the crucial importance of the correction of the foot static disorders in CVD patients: it will improve the symptoms as well as all items related to the venous stasis.

This could be easily explained by the improvement of the foot pump efficacy during walk.

## Paper 2.4

D-DIMER MEASUREMENT TO ALL SUSPICIONS OF VENOUS THROMBOEMBOLISM , INDEPENDENTLY OF PRE-TEST CLINICAL PROBABILITY ( WELLS CRITERIA), REJECT WITH SAFETY ONE OF FOUR PATIENTS AND IS ECONOMICAL FOR THE INSTITUTION, AVOIDING UNNECESSARY IMAGE EXPLORATIONS.

FJ Casals<sup>1,2</sup>, D Bernaudo<sup>1,4</sup>, N Lozano<sup>1,3</sup>, and the UFMATE Team.

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### 1.-Background

In only 13 to 25% of patients with clinical Venous Thromboembolism (VTE) suspicion, this disease is confirmed by an image study. This low efficiency in diagnosis adds a high cost to each VTE evidenced. To avoid these expenses, many Medical Societies and Consensus Groups had proposed algorithms to optimize the diagnostic explorations.

Academically is ever recommended, before practice any test, to employ the Bayes Theorem. Therefore, for each suspicion, is mandatory to proceed to a clinical stratification between likely or unlikely VTE following explicit criteria, the most employed are Wells rules. In this way the above prevalence is changed, increasing the test prediction power. So, if a patient classifies as unlikely, a normal D-Dimer value, has a high negative prediction power and rule-out the presumption diagnosis, when is measured by an evaluated test, not-necessarily a high sensitivity assay, but when the patient has a likely pre-test VTE , the D-Dimer is obviate and directly an Image exploration is ordered.

However, out of clinical trials, in general clinical practice strictly explicit rules rarely are employed.

### 2.-Aims

To prove that the diagnostic strategy to systematically measure D-Dimer levels to all suspicions of VTE, whichever the explicit criteria are, and avoiding the image determination to the patients with normal levels, it's clinically safe for them and cost-beneficial for the Institution.

### 3.-Methods

Source study design.- Observational survey and pragmatic study, watching for the VTE episodes found in a University Hospital of 800 beds.

Study period.- Twenty-two months, between December 2006 to September 2008.

Suspected VTE episodes.- From all daily D-Dimers orders and image explorations practiced, we register all suspicions of VTE consecutively raised in the Hospital, as much if one is deep vein thrombosis (DVT) or

Pulmonary Embolism (PE) suspicion, as well as in inferior as upper extremities, or inpatients as outpatients and irrespective of clinical assessment.

Physician Information.- All hospital physicians were encouraged to order D-Dimer to all VTE suspicions, by widespread distribution of an explanatory leaflet in the first semester of this study and for personalized e-mails in the second year. They applied the diagnostic methods according to their habitual clinical practice.

Image Explorations .- Deep Vein Thrombosis was diagnosed by ultrasounds ( Duplex-doppler), while Pulmonary Embolism was diagnosed by Helicoidal CT or Lung Ventilation / Perfusion Scan.

D-Dimer determination.- Blood levels of D-Dimer were measured by a quantitative ELISA by fluorescence (ELFA) rapid assay ( D-Dimer Exclusion , VIDAS, BioMerieux, Lyon, France ). A cut-off of 500 ngr / ml was chosen following main recommendations. All patients with a normal D-Dimer were intended to follow, by phone calls, for three months, asking for safety to avoid anticoagulants.

Cost-benefit analysis.- From these data, the cost for two different diagnostic strategies were compared.

A. - Cost for all VTE suspicions diagnosis without D-Dimer use

B. - Cost for all VTE suspicions diagnosis, measuring D-Dimer to all patients and rejecting VTE when normal D-Dimer values were founded, limiting the image explorations to the patients with increased D-Dimer levels

Not all suspicions are explored for VTE because in some cases an alternative diagnostic was attained before, so a weighted modulation has been introduced for this bias .

#### **4.-Results**

##### *Patient safety*

A total of 3051 suspected VTE episodes were detected. D-Dimer was measured in 2240 cases. From 529 suspicions with a normal D-Dimer value, immediately or in the follow-up, seventeen episodes of VTE were detected: In eight cases the episode was an isolated superficial vein thrombosis, other six patients were in anticoagulant treatment (a condition to preclude D-Dimer evaluation), two cases were attributed to a laboratory mistake and only one true, false-negative, result of VTE was found (a relapsed DVT).

In the carrying out of this study, clinicians progressively increase ordering of D-Dimer to all VTE suspicions, attaining at the final of the study 92 % of suspicions with D-Dimer measured or obviating it for reasoned causes (ex. anticoagulated patients or past history of VTE). No significant differences were found in VTE prevalence between the group of patients without D-Dimer measured and non explanations to obviate this test (18,42 %), and the VTE prevalence found in the group where D-Dimer was systematically ordered (19,01 %) ( $X^2 = 0,28$ ,  $p = 0,59$  Odds Ratio = 1.24 CI at 95 % = 0,56 to 2,35). Therefore, the diagnostic behaviour of the physicians when a D-Dimer is not ordered, it's not to avoid D-Dimer measurement to the patients with high probability of VTE, but is consequence of other criteria or situations.

The Negative Prediction Power of this test, for VTE diagnosis, is 99,81 % ( CI 95 % = 99,79 – 99,83 ) with a Sensitivity of 99,77 ( CI 95 % = 98,71 – 99,99 ) and a Negative Likelihood Ratio of 0,008 ( CI at 95 % = 0,001 – 0,05 ) , however the Specificity is only 29,17 % ( CI 95% = 27,32 – 31,56 ) , with Positive Prediction Power of 25,07 % ( CI 95 % = 23,03 – 27,13 % ) and a Positive Likelihood Ratio of 1,409 ( CI 95 % = 1,37 – 1,45) , for a VTE prevalence of 19,2 % and the Number of Patients to be Analyzed (NNT) to find a normal D-Dimer result is 4,2.

##### *Saving costs and application constraints*

D-dimer measurement to all suspicions of VTE is cost-benefit if  $D/I < N$  ( where N is the fraction of normal D-Dimer patients in the studied population , D the cost of D-Dimer determination and I the cost of the image exploration employed in these episodes ) ( *Blood* , 112 (11) :463, 2008). From our data and in our Institution, this strategy is cost-benefit if the prevalence of patients with normal D-Dimer levels is more than 19.7 % (0,197) for DVT or 17.5 % (0,175) in PE suspicions.

Increasing age had a lesser probability to found a normal D-Dimer value, with figures of 29%, 19% and 16% in segments of 60-69, 70-79 and 80-84 years old respectively, so the proposed strategy is cost-benefit for DVT in patients less than 70 years and for PE in patients less than 80 years old.

Cancer was found in 583 patients of D-Dimer measured group, evidencing a normal D-Dimer value in 138 cases (23,6 %), so all patients with cancer, when a VTE is suspected, could be first systematically approached, by D-Dimer measurement to reject this diagnosis, in a clinical and cost-benefit aspect.

However, a procedure could be cost-benefit but economically insignificant. To compute the net value attained (saving magnitude in Euros (S)), the following formula was computed :  $S = [ (I \times (TE/TS) \times N - D) / P$  ( Where TE/TS the fraction of explored patients from all VTE suspicions and P the prevalence of VTE in the group studied ). With the proposed strategy, to measure D-Dimer to all suspicions of VTE as a first step to screening for negative results, we compute a saving cost in image explorations, for all VTE suspected episodes in one year, between 24678 € to 47097 €, depending on the exploration used for PE diagnosis ( CT or Lung Scan ).

## 5.-Conclusions

D-Dimer determination by a High Sensitivity Assay ( Vidas Exclusion) to all patients with suspicion of VTE, independent of a pretest clinical evaluation, could reject one out of every four patients, with clinical safety for them, broadly accepted for the hospital physicians and with an important cost reduction in image explorations, provided that the local cost ratio between D-Dimer value and Image exploration, is inferior to the prevalence of normal D-Dimer levels existing in the tested population, whenever very old patients, but not cancer patients, were excluded, as well as the patients in anticoagulant treatment or relapsing episodes.

## Paper 2.5

### RESULTS OF ENDOVENOUS LASER ABLATION OF INSUFFICIENT COMMUNICANT VEINS IN THE TREATMENT OF CHRONIC VENOUS INSUFFICIENCY.

AL Sokolov, KV Lyadov, MM Loutsenko, SV Lavrenko.

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**METHOD AND MATERIALS:** Endovenous laser treatment (EVLT) of insufficient perforating veins (IPV) was performed in 383 cases of chronic venous insufficiency (C2-C6 clinical classes). The procedure was performed using diode lasers 970 nm wavelength IPG “IRE-Polus” (Russia) in constant duty on operating power 10 – 15 W with local anesthesia under ultrasound control.

At first stripping or EVLT of GSV or SSV undertaken and secondary EVLT of perforating veins was made. The effect was considered positive if the occlusion of perforating veins was constant for not less than three weeks after the EVLT. The results were evaluated from 6 to 24 months by ultrasound. Long-term results were evaluated on 485 IPV.

**RESULTS:** In most cases – 96,3%, we found abatement of chronic venous insufficiency symptoms. Ultrasound scanning corroborated that 445 perforating veins of 485 were completely occluded (91,8%). Perforating veins with diameter less than 4 mm were all occluded in clinical classes C2-C3 and in 94% of cases clinical classes C4-C6. Veins with diameter from 4 to 7 mm were occluded in 79.5% of cases. In this group patients with complicated forms of chronic venous insufficiency (C4-C6) predominated and besides recanalization of coagulated, new perforating veins were found in 6.3% of cases. Most recanalizations were registered in those cases when the diameter of perforating vein was sizeable. At the same time 75% of recanalized veins diminished there diameter to not more than 4 mm, above all vein wall thickening and decrease of reflux was mentioned. In long-term period EVLT of perforating veins was conducted for 26 patients repeatedly (33 veins recanalized or newly-appeared) combined with sclerotherapy of varicose veins and EVLT of SSV (2 patients).

Analysis of the long-term results of EVLT of perforating veins testifies high efficiency of this method. Complicated chronic venous insufficiency, venous hemodynamic disturbances create conditions for pathological reflux preservation of a different location or recanalization of IPV occluded. In those cases EVLT of IPV can be used repeatedly.

**CONCLUSION:** EVLT of perforating veins under ultrasound control is an effective method to eliminate horizontal pathological reflux caused by perforating veins insufficiency in treatment of patients with chronic venous insufficiency characterized by low invasion, aiming impact and the opportunity for repeated dispatch.

Long-term results of perforating veins EVLT proves its high reliability to eliminate horizontal pathological reflux in most cases of chronic venous insufficiency.

EVLT of IPV efficiency permit us to refuse of SEPS.

## Paper 2.6

### LOCAL ANAESTHETIC TREATMENT OF VARICOSE VEINS IN AN OUTPATIENT SETTING

MJ Metcalfe, PA Gatenby, JA Reise, JJ Franklin.

Imperial College Healthcare NHS Trust, Charing Cross Hospital, London, United Kingdom

**Objective:** To assess the effectiveness of treating varicose veins under local anaesthetic using radiofrequency ablation in a modified outpatient setting.

**Methods:** Prospective data was collected from an NHS local anaesthetic varicose vein unit between April 2007 and May 2008.

**Results:** 159 patients (67 men and 92 women) with a median age of 51 years (range 18 to 88) were treated. 48% of patients had CEAP class 4a to 6. 38 (30%) radiofrequency ablation procedures were for recurrent veins.

225 procedures were performed consisting of radiofrequency ablation (158) using VNUSClosureFAST catheters, phlebectomy (55), foam sclerotherapy (7) and perforator ablation (5) using ClosureRFS stylets. No sedation was used

126 great saphenous veins, 14 small saphenous veins and 18 accessory thigh veins underwent radiofrequency ablation. 6 (3%) procedures were abandoned due to difficult cannulation.

Follow up duplex scans performed in 104 (65%) patients demonstrated complete occlusion in 94% and near complete in the remainder. Only 28 (18%) limbs required phlebectomies following radiofrequency ablation.

An overall complication rate of 8% was observed; including neuropraxia (7), skin pigmentation (4), bruising (3), pain (3) and phlebectomy site infection (2). There were no deep vein thromboses.

Most (74%) procedures enabled the patient to return to work within 24 hours of radiofrequency ablation and 84% of patients required no analgesia 24hrs following surgery.

**Conclusions:** Office-based treatment of varicose veins produces excellent results. Less than 1 in 5 patients required phlebectomies following radiofrequency ablation. 84% of patients were successfully treated with a single visit.

10:30-12.30

**Scientific Session 3:**

**Chair: Leif Panduro Jensen, Marianne Vandendriessche**

Paper 3.1

CLINICAL RESEARCH STUDIES ON VENOUS THROMBOLYSIS AT THE NATIONAL INSTITUTES OF HEALTH, USA

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**Purpose:** Since 1994 clinical research protocols have been conducted at the National Institutes of Health, Bethesda, Md, USA with the goal of improving safety, efficacy, and affordability of thrombolytic therapy for venous thrombosis.

**Material and Methods:** Tissue plasminogen activator (tPA; Activase, Genentech) was chosen for study because of 2 properties: its ability to bind to fibrin and its short half-life ( $T_{1/2} \sim 5$  min.). Because of fibrin binding, tPA achieves a prolonged fibrinolytic effect after intraclot injection, without requiring prolonged or continuous infusion. Elimination of continuous infusion of tPA, reduces the duration of systemic exposure to circulating tPA, and its short half life permits rapid clearing of systemic tPA levels after "lacing" of the thrombus is completed. Initial studies reported effective thrombolysis in clearing of subclavian, jugular and central vein thrombosis (SJ-CVT) associated with use of venous access devices, and of deep vein thrombosis of the lower extremity (DVT-LE) using 20 -50 mg tPA/day given as intraclot, hand injection of tPA once a day through pulse spray catheters without continuous infusions. Despite absence of any significant bleeding complications, pharmacokinetic studies conducted during these early trials showed that these doses were excessive, but no serious bleeding complications occurred presumably because elevated tPA levels and diminished PAI-1 levels returned to normal within 2 hours as shown by pharmacokinetic studies. Low dose studies have since been conducted with treatment of SJ-CVT using  $\leq 4$ mg tPA/day and of DVT-LE with  $\leq 10$ mg tPA/day. Unless contraindicated, systemic anticoagulation was used, and low molecular weight heparin was used for 4 SJ-CVT patients who received thrombolytic therapy as outpatients. Pharmacokinetic studies were conducted in about 50% of patients receiving these lower tPA doses.

**Results:** 32 patients with SJ-CVT  $\leq 28$  days old were treated receiving an average of 2 treatments (average dose 3.4mg tPA/day) with a mean total dose of 6.9 mg achieving patency in 25 (78 %).

30 patients with DVT-LE  $\leq 14$  days old received an average of 2.6 treatments ( average dose 7.7 mg tPA/day) for average total tPA dose of 20.4 mg. Patency was restored in 29 (97%) DVT-LE patients. No significant bleeding complications occurred and pharmacokinetic data confirm expected reductions in systemic tPA levels compared to previous higher dose studies.

**Conclusions:** By taking advantage of fibrin binding and its very short half-life, the amount and duration of circulating thrombolytic can be reduced with lower doses of tPA given as intraclot injections without sacrificing efficacy. The elimination of the requirement for continuous infusions of thrombolytic and selection of lower doses of tPA improves safety and affordability, reduces the need for ICU hospitalization, makes outpatient treatment a potential option, and permits more efficient treatment of multiple thrombosed venous branches allowing a more comprehensive approach to DVT treatment than with continuous infusion regimens.

References (published work on high dose therapy):

1. Chang R, Horne MK III et al. Pulse-Spray treatment of subclavian and jugular venous thrombi with recombinant tissue plasminogen activator. *J. Vasc Interv Radiol* 1996; 7:845-851
2. Horne, MK, Mayo DJ, Cannon RO, Chen CC, Shawker TH, Chang R. Intraclot recombinant tissue plasminogen activator in the treatment of deep venous thrombosis of the lower and upper extremities. *Am J Med* 2000;108:251-5.
3. Chang R, Cannon RO, Chen CC, Doppman JL, Shawker TH, Mayo DJ, Wood B, Horne MK. Daily catheter-directed single dosing of t-PA in treatment of acute deep venous thrombosis of the lower extremity. *J Vasc Interv Radiol* 2001;12:247-52.
4. Horne MK, Chang R. Pharmacokinetics of pulse-sprayed recombinant tissue plasminogen activator for deep venous thrombosis. *Thromb Res* 2003; 111: 111-114.

- 5 Chang R, Chen C, Kam A, Mao E, Shawker TH, Horne MK. Deep Vein Thrombosis of Lower Extremity: Direct Intraclot Injection of Alteplase Once Daily with Systemic Anticoagulation –Results of Pilot Study. *Radiology* 2008; 246: 619-629.

## Paper 3.2

### THE EFFICACY OF SINGLE DAILY DOSE OF ENOXAPARIN TREATMENT IN ACUTE VENOUS THROMBOEMBOLISM: TROMBOTEK STUDY

M Kurtoglu<sup>1</sup>, et al

<sup>1</sup>*Istanbul University, Istanbul Medical Faculty, Department of General Surgery, 34390 Capa - Istanbul*

**BACKGROUND:** This local multi-center study was designed as open label, single treatment arm, prospective, observational, phase IV clinical trial. Primary objective of the study was the evaluation of the efficacy of single daily dose of enoxaparin with warfarin (three months of duration) treatment until INR reaches  $\geq 2$  in patients presenting with acute venous thromboembolism.

**METHODS:** Data of 247 patients were evaluated (ITT population) who were enrolled to the study from 14 sites. The mean age of all patients was  $52.16 \pm 16.65$  years. Percentage of male patients were slightly higher (51.8 %), where mean age of female patients were  $49.8 \pm 16.6$  years.

For all patients, enoxaparin treatment was immediately started after confirmation of diagnosis at a single dose of 1.5 mg/kg/day, sc. After 24<sup>th</sup> hour of the initiation of enoxaparin treatment, 5 mg warfarin tablet was administered for a period of minimum 3 months. Patients were followed up until the end of 18<sup>th</sup> month of the study initiation for the determination of the long term results of the study. Main efficacy procedures included; venous thromboembolic symptoms and localization of thrombus by means of doppler USG evaluations, D-Dimer and INR testing.

**RESULTS:** The most common sign and symptoms of the DVT patients at enrollment were; tenderness, edema and pain on the diseased legs present in 82.8%, 95.5% and 93.0% of enrolled patients (n=244) respectively. Significant decrease was observed in these symptoms of DVT at 1 year (p=0.000). In accordance with these symptom relief, significant decrease in the circumference of the calf and mid thigh were observed for paired samples (n=145, p=0.0000).

D-Dimer values were significantly decreased after one year follow-up (p=0.000), however, were still at 2XULN. [D-dimer evaluations were made at a central lab, by means of turbidimetric method]. Safety laboratory evaluations including ALT, AST, CK have revealed mild to moderate increases from normal levels, which returned to normal levels during the study course. There were only 3 cases in which all three parameters (ALT, AST and CK) increased, isolated ALT+AST increase were recorded in 23 cases.

INR values increased significantly in the course of treatment, mean INR values reached  $1.88 \pm 1.13$  after 5 days of treatment with enoxaparin (n=205) and to  $2.71 \pm 1.24$  for measurements performed between Day 8-10 (n=222). Due to high SD values, we have also considered percentage of patients whose INR values stayed lower than 2 and higher than 3. This evaluation revealed the fact that, between Day 8 and 22, around 55 % of all patients INR values were between 2 and 3. During the anticoagulation treatment, there were 6 cases of major bleeding [3 cases with a decrease in Hb;  $>20$  g/L, in 2 cases, transfusion with more than 2 units of whole blood, in 1 case intracranial bleeding and in one case, bleeding which required medical and/or surgical intervention] and 27 cases of minor bleeding were observed

Localization of thrombi in paired samples (n=143) revealed a thrombus tendency at left side at baseline (n=92) and the number of patients with thrombus decreased to 47 after one year follow-up

**CONCLUSIONS:** Enoxaparin treatment until patients reach  $\text{INR} \geq 2$  and addition of warfarin at least until the end of 3 months, significantly reduced the patients' physical symptoms including differences on leg circumferences. It was also shown that 90% of patients are without pain and 60% of patients are without edema at the end of one year follow-up. Thus, we can conclude that ambulatory management of DVT is an effective and safe treatment where the treatment was most effective in Common Iliac vein thrombosis with 82% complete resolution. However, the least effective treatment was observed in Femoral Vein thrombosis with 35% complete resolution.

### Paper 3.3

#### ATRESIA OF THE INFERIOR VENA CAVA AND ILIOFEMORAL VENOUS THROMBOSIS – EXPERIENCES WITH CATHETER-DIRECTED THROMBOLYSIS.

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*Department of Vascular Surgery, Department of Radiology and the Thrombosis Centre, Gentofte University Hospital, Denmark.*

**Background:** Deep venous thrombosis (DVT) in the iliofemoral segment triggered by atresia of the inferior vena cava is a known phenomenon. The conventional treatment of these patients is anticoagulation therapy. Treatment with catheter-directed thrombolysis has been described in a few cases with different treatment results and is not a standard offer. We describe the yet known largest material of patients with atresia of the inferior vena cava and iliofemoral thrombosis treated with catheter-directed thrombolysis (CDT).

**Material and methods:** Inclusion criteria were iliofemoral thrombosis with duration of symptoms of maximum 14 days, first episode of DVT, age below 60 years, and distal popliteal vein without thrombus. A multiple side-hole catheter with tip occlusion was placed in the thrombus via the popliteal vein, and pulse spray infusion with rt-PA and heparin was given. Daily venography was performed to evaluate the treatment, which was terminated when all thrombus was resolved. Patients were started on anticoagulation treatment on a life-long basis combined with long graded compression stockings for one year. Follow-up with clinical examination and ultrasonography was performed after 3, 6, and 12 months and annually thereafter.

**Results:** In the period 2001-2008, 10 patients with atresia of the inferior vena cava and iliofemoral thrombosis were included for CDT. Four women and 6 men with a mean age of 30 years (range 15-46 years) were treated for iliofemoral DVT involving 12 legs. Median follow-up was 30 months (range 2-85 months). All patients had patent iliofemoral vein segments including opened abdominal collateral veins at follow-up. One patient developed reflux in the popliteal vein after four years.

**Conclusion:** Young people with massive thrombosis of the pelvic and femoral veins or bilateral deep venous thrombosis must be considered of having atresia of the inferior vena cava. CDT can be performed in these patients with very promising results and few complications, and must be considered in all patients with this diagnosis.

### Paper 3.4

#### SHOULD RETRIEVABLE FILTERS BE RETRIEVED?

Kodati S, Patel VM, Mankanjuola J, Mobasheri M, Hussain T.

Department of Vascular Surgery, Northwick Park Hospital, Harrow, UK.

#### Background

Pulmonary emboli (PE) are a major cause of mortality and morbidity. Percutaneous insertion of Inferior Vena Cava (IVC) filters are highly effective in preventing PEs in patients with deep vein thrombosis (DVT). Indications for the insertion of IVC filters include a contraindication to anticoagulation, a reoccurrence of DVT/PE on anticoagulation, or an extensive DVT.

The aim of this study was to evaluate our experience with retrievable IVC filter insertion and retrieval. The indications for filter insertion, the type of filter inserted and retrieval data were analysed.

## Methods

A retrospective analysis involving 51 patients who had retrievable IVC filters inserted between October 2006 and January 2009 was performed.

## Results

29 Gunther Tulip and 22 Cook Celec filters were inserted. Indications for insertion included the following: reoccurrence of DVT/PEs on anticoagulation (n=9), short term contraindication to anticoagulation (n=14), long term contraindication to anticoagulation (n=12), extensive DVT (n= 6), extensive DVT + PE (n= 4), extensive DVT/PE in patients with advanced cancer (n=3) and other indications (n=1).

A total of 9 filters were retrieved in this period (16.1%), on average 48.5 days after insertion. There were no complications during insertion or retrieval and all attempts at retrieval were successful.

## Conclusions

Our results show a low retrieval rate. The permanent placement of IVC filters are associated with complications which should be avoided by the retrieval of filters in patients who do not require long term filter insertion. There is limited evidence in the literature on the optimum period for removal of filters, and the indications for permanent filter placement. Larger studies are required to explore the outcome of permanent filter insertion.

## Paper 3.5

TECHNIQUES, TREATMENTS, AND OUTCOMES OF PATIENTS WITH DELAYED INFERIOR VENA-CAVA PERFORATION FROM FILTER PLACEMENT.

RB McLafferty, C Moore, D Hood, KJ Hodgson.

*Southern Illinois University Springfield, Illinois, USA*

**Objective:** To review the techniques, treatments, and outcomes of patients presenting with delayed inferior vena-cava (IVC) perforation from placement of a filter.

**Methods:** Review was performed on a prospectively maintained vascular registry for all IVC filters placed in a tertiary university vascular surgery practice. Date beginning the review was the placement of the first retrievable IVC filter to the present. Demographics, techniques, treatment and outcomes were examined for those patients who specifically had clear evidence by computed tomography scanning of IVC perforation by a filter inserted in a previous setting.

**Results:** From Oct 2003 to Dec 2008, 227 IVC filters were inserted. Six patients (mean age: 25 years; 4 males/2 females) presented with IVC perforation on CT scan. Two patients were asymptomatic, 3 presented with abdominal pain, and one with sepsis. Indications for filter placement included trauma with contraindications to anticoagulation prophylaxis in 5 and prophylaxis during ileo-femoral mechanical thrombolysis in 1. All perforations were caused from prongs from Recovery Filters manufactured by Bard,

Inc. (54% (n=124) of all filters inserted during the study; 3.2% (n=4) of Recovery Filters). Two patients had their Recovery Filter inserted at another institution. All patients had attempt (2 with multiple attempts) of removal by percutaneous methods of which 2 patients had success. Two patients required open retrieval by laparotomy and one patient had combined percutaneous and open removal via the jugular vein (sepsis patient with prong perforation of the duodenum). One patient was lost to follow-up after two failed percutaneous attempts. In 5 patients with removal (2 percutaneous, 2 open, 1 combined), all made full recovery by 30 days with no complications.

**Conclusion:** The Bard Recovery Filter has an unacceptably high rate of prong perforation that can lead to serious complications such as sepsis. Percutaneous methods of retrieval should be attempted but failure remains. This filter was abandoned by our practice in Oct 2007 and these complications have not been observed in other types of retrievable filters used by our practice.

### Paper 3.6

#### VENOUS THROMBOEMBOLISM IN PATIENTS WITH IVC APLASIA

AP Gasparis, N Labropoulos P Lebda, G Spentzouris, L Leon, M Borge, AK Tassiopoulos, PJ Pappas.  
*Stony Brook University Medical Center, Loyola University Medical Center, University of Medicine and Dentistry of New Jersey, USA*

**Objective:** To determine the prevalence and clinical significance of the inferior vena cava (IVC) aplasia.

**Design:** Prospective collection of data with retrospective analysis

**Methods:** Patients with IVC aplasia identified during imaging were included in the study. The clinical presentation, prevalence of venous thromboembolism (VTE) and follow-up data were collected. Diagnosis of IVC aplasia was always confirmed by CT and selective phlebography. The IVC segment and extent of aplasia and the collateral pathways were recorded in detail. VTE events were documented by duplex ultrasound, d-dimer, CTA and phlebography. The status of the lower extremities at presentation and follow-up were graded with the CEAP system. Data were collected from three institutions in a sequential manner of 14 years (10, 2 and 2). The prevalence of IVC aplasia was estimated from a prospective analysis of a group of 300 consecutive patients that underwent an abdominal examination. The prevalence of VTE and hypercoagulability was compared to another group of consecutive patients that were examined for VTE prospectively.

**Results:** There were 16 patients identified with IVC aplasia 10 of which were males with a mean age of 28 years, range 12 to 63. Eleven patients presented with VTE, 1 with hematuria and limb swelling, 1 with hypertension, 1 with bilateral chronic venous disease and 2 had mild swelling. There was one patient with aplasia (0.3%) and one with hypoplasia (0.3%) of IVC in the prospective study group. Complete IVC aplasia was found in 5 patients, infrahepatic interruption in 3, hepatic interruption in 2, infrarenal aplasia in 2, segmental aplasia at renal level in 2 with segmental infrahepatic hypoplasia, aplasia of the suprarenal segment in 1 and severe hypoplasia of duplicated IVC to the renal level in 1. Thrombophilia was detected in 4 patients of the 14 patients tested (28.6%) compared to 19% in the prospective VTE group (p=0.82). Patients with IVC aplasia were younger than the VTE group (31 vs. 52, p<0.0001). VTE recurrence was also more prevalent in patients with IVC aplasia compared to VTE group (4/11 vs. 11/100, p=0.06). Thrombosis of the iliac veins was more common in the aplasia group (9/11 vs. 17/100, p< 0.001). At presentation and follow-up the clinical status of the lower extremities were worst in the patients with IVC aplasia.

**Conclusion:** IVC aplasia should be suspected if thrombosis involving the iliac veins is seen in younger patients. Recurrent VTE may be higher and postthrombotic syndrome more severe in such patients.

13:15-15.15

Scientific Session 4:

Chair: Arkadiusz Jawien, Olle Nelzen

#### Paper 4.1

### THE INCIDENCE OF MALIGNANT DISEASES AMONG PATIENTS WITH DEEP VEIN THROMBOSIS AND DEEP VEIN THROMBOSIS RECURRENCES IN THESE PATIENTS DURING AND AFTER ANTICOAGULANT TREATMENT

DJ Milic, SS Zivic, DC Bogdanovic.

*Clinic for Vascular Surgery, University Clinical Centre Nis, Nis, Serbia*

**Background:** It is well known that patients with malignant disease have increased hypercoagulability (Trousseau syndrome). However, the true incidence of deep vein thrombosis (DVT) in patients with malignant disease is unknown because most DVT episodes remain clinically silent.

**Methods:** The aim of our study was to establish the incidence of malignant diseases among patients with deep vein thrombosis and to determine DVT recurrences in these patients during the 24 months follow-up period after the initial anticoagulant treatment.

Also, in the follow up period of 24 months patients with DVT and without established malignancy were regularly checked up in order to determine the appearance of malignant disease.

All patients included in the study were anticoagulated with low molecular weight heparin (LMWH) during the 5-10 days period followed by a six months of anticoagulation with warfarin.

**Results:** Overall, 382 patients with DVT verified by ultrasonography were included in the study. Fifty-five patients were lost during the 24 months follow-up period and 327 patients completed the study.

During the initial treatment of DVT, eighteen patients (5.5%) already had verified malignant disease. The diagnosis of lymphoma and retroperitoneal tumor was established in two more patients (0.61%) after performing additional diagnostic procedures making overall incidence of malignant diseases in patients with newly diagnosed DVT of 6.11%.

In the follow up period of 24 months, the malignancy was established in 17 patients (5.20%). Six patients (1.83%) were diagnosed with cancer in the first year and 11 patients (3.36%) were diagnosed with cancer in the second year of the follow up period.

Overall, 37 patients (11.31%) included in the study developed DVT as a result of increased hypercoagulability due to presence of malignant disease.

Colorectal cancer and prostate cancer were the most often seen malignancies in patients during the initial treatment of DVT while in the follow up period lung cancer had the highest incidence.

Twenty-nine out of 37 patients with malignancy (78.4%) had DVT recurrences with 61 episodes. Nine patients (24.3%) had DVT recurrences while on anticoagulant treatment and 20 patients (54.1%) had DVT recurrences after discontinuation of anticoagulant treatment.

On admission, International Normalized Ratio (INR) in patients who were on anticoagulant treatment was in range from 1.21 to 2.35.

During the follow-up period, 11 out of 37 patients (29.7%) with malignancy died, four of them (10.8%) with symptoms of VTE.

**Conclusions:** The results obtained in our study indicate that the presence of DVT might be an early sign of malignant disease and that the patients with idiopathic DVT should be carefully monitored for malignancy especially if recurrent DVT occur.

It may be prudent to maintain a higher INR values (2.5-3.5) in patients with DVT and concomitant malignant diseases. Life long anticoagulation should be considered in these patients especially if risk of bleeding is low.

## Paper 4.2

### EVOLVING ALGORITHM FOR THE TREATMENT OF COMPLEX CHRONIC VENOUS DISEASE

P Neglén, R Darcey, S Raju.

*River Oaks Hospital, Flowood, MS, USA*

**Background:** An evolving paradigm of treatment of complex multisystem chronic venous disease (CVD) is to initially correct venous outflow obstruction and superficial reflux by minimally invasive endovenous interventions. The aim of this study is to evaluate the clinical outcome in the presence of untreated deep venous reflux.

**Methods:** Between 1997 and 2008, 242 limbs in 237 patients had percutaneous iliofemoral venous stenting for outflow obstruction combined with great saphenous vein (GSV) procedures to control superficial reflux. Clinical severity (C-class of CEAP) was C<sub>3</sub> with a swelling grade of 3 (0-3) and/or pain  $\geq 5$  (visual analogue scale, VAS, 0-10) in 73 limbs, C<sub>4</sub> (hyperpigmentation, LDS, dermatitis) in 86 limbs, C<sub>5</sub> (healed ulcer) in 15 limbs, and C<sub>6</sub> (active ulcer) in 68 limbs. Median age: 57 years (range, 19-87); left/right limb 2.2:1; female/male ratio 2:1; primary/secondary etiology 1.6:1. Perioperative data included VAS, degree of swelling; quality of life assessment (CIVIQ); venous filling index (VFI<sub>90</sub>, ml/s), venous filling time (VFT, s), ambulatory venous pressure drop (AVP, %), duplex Doppler scanning, and radiologic studies. The following 3 groups of stented patients were identified: Group A - Reflux in the superficial system alone, 107 limbs (44%); Group B – combined with deep segmental reflux, 73 limbs (30%); Group C – combined with deep axial reflux, 62 limbs (26%). Group C had a greater ratio of secondary etiology and C<sub>6</sub> limbs as compared to Group A and B (2:1, 1:3.5, 1:1.7 and 42%, 24%, 22%, respectively). VFI<sub>90</sub> was greater, VFT shorter and AVP drop less in the Group C limbs pre-intervention ( $p < 0.05$ ).

**Results:** 229 limbs (95%) were followed for median 12 months (range: 1-117). The GSV remained closed in 85-87% in all groups. Cumulative primary, assisted-primary, and secondary stent patency rates at 3 years were Group A 81%, 98%, and 98%, Group B 73%, 100%, and 100%, Group C 56%, 76%, and 85%, respectively. Median VFT and VFI<sub>90</sub> normalized in Groups A and B (17 to 25s and 18 to 23s; 2.6 to 1.6 ml/s and 3.0 to 1.5 ml/s, respectively) and median AVP remained normal. Group C limbs significantly improved VFI<sub>90</sub> (4.3 to 3.4 ml/s) and AVP (49 to 54% drop) and VFT trended towards improvement (7 to 5.5 s,  $p = 0.0942$ ), no value was normalized. Cumulative complete relief of pain and swelling at 3 years was in Groups A, B, and C 87%, 73%, and 93% (logrank test, no significance) and 60%, 48%, and 35% (logrank test, Group A better), respectively. Cumulative ulcer healing at 3 years was in Groups A, B, and C 94%, 92%, and 63%, respectively. Total CIVIQ score improved significantly in Group A and B, and trended towards improvement in Group C ( $p = 0.065$ ).

**Conclusion:** The treatment of limbs with multisystem reflux and outflow obstruction by percutaneous stenting and endovenous ablation has excellent clinical outcome. Surprisingly, limbs with remaining untreated deep reflux and worse hemodynamics are *completely* relieved of pain in 93% and of swelling in 35% of limbs, 63% of leg ulcers are healed, and quality of life is substantially improved. These results justify the initial treatment with endovenous stenting and control of superficial reflux in complex severe CVD. When clinically unsuccessful, repair of the axial deep reflux may be considered. The results also suggest that leg pain is mainly due to obstruction, and swelling more related to reflux.

## Paper 4.3

### DOES IT MAKE SENSE TO APPLY TWO LIGHT STOCKINGS OVER EACH OTHER?

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<sup>1</sup>Private practice, Vienna, Austria, <sup>2</sup>Salzmann Medico Laboratory, Wald, Switzerland

#### **Background:**

Donning of strong compression stockings is frequently difficult for the patient which limits the compliance.

**Aim:**

To compare pressure and stiffness of two light compression stockings (European class I) applied over each other with class III stockings.

**Material and methods:**

In 12 healthy volunteers interface pressure and stiffness of the following stockings and stocking-combinations were assessed at different points of the leg using in vivo measurements (Picopress, MST tester) and textile laboratory tests (wooden leg model, Hosy, MST-Professional): A) class I, B) class I silver, C) class III, D) A+A, E) B+B, F) A+B. Stiffness as defined by the pressure increase achieved by an increase of the leg circumference of 1 cm was measured using the new MST-Professional and compared with the static stiffness index assessed by in vivo measurements.

**Results:**

The superposition of two light stockings (group D, E, F) revealed higher values of interface-pressure and of stiffness than a class III stocking (group C), demonstrated by in vivo and by in vitro measurements. Friction between the stocking layers increases stiffness depending on the gliding property of their surfaces. There is a good agreement between the pressure values measured in vivo and in vitro.

**Conclusions:**

Two class I stockings applied on top of each other reveal higher interface pressure and stiffness than one class III stocking (I+I>III). This amazing result has practical importance when stronger compression stockings are indicated, especially for patients who have difficulties to put them on.

[Paper 4.4](#)**A VALIDATION STUDY OF A RETROSPECTIVE VENOUS THROMBOEMBOLISM RISK SCORING METHOD**

V Bahl, HM Hu, P Henke, TW Wakefield, DA Campbell, JA Caprini

*Department of Surgery, North Shore University Health System, Evanston, Il, USA*

**Background** Venous thromboembolism (VTE), a disease which includes deep vein thrombosis and pulmonary embolism, results in significant mortality and morbidity among surgical patients. Despite strong evidence that VTE prophylaxis reduces the incidence of VTE, numerous studies show that prophylaxis is underutilized or inadequate for patients at risk. To measure prophylaxis practices at our academic medical center, a retrospective risk scoring method based on a published VTE risk assessment model was developed. The objectives of this study were to validate this method and assess the confounding effects of provider adherence to VTE prophylaxis guidelines.

**Methods** A total of 8,216 inpatients from the private sector National Surgical Quality Improvement Program discharged between July 2001 and January 2008 were selected for study. The VTE risk category (low, moderate, high and highest) for each patient was assigned using the retrospective scoring method, which is based on data from electronic sources. Logistic regression was used to calculate odds ratios (OR) for VTE within 30 days after surgery of individual risk factors and the four risk categories. A bivariate probit model was applied to estimate the effects of the risk category while controlling for adherence to prophylaxis guidelines.

**Results** The distribution of the study population by risk was: highest: 51.5%, high: 36.1%, moderate: 10.2%; low: 2.1%. The incidence of acquired VTE within 30 days was: overall: 1.4%; by risk category: highest: 1.9%; high: 0.9%; moderate: 1.1%; low: 0%. Controlling for length of hospitalization (>2d) and fiscal year, pregnancy or postpartum (OR = 8.3; 1.0 – 68, p<.05), recent sepsis (4.0; 1.4 – 10.9, p<.01), malignancy (2.3; 1.5 – 3.3, p<.01), history of

VTE (2.1; 1.1 – 4.1,  $p < .05$ ) and central venous access (1.8; 1.1 – 3.0,  $p < .05$ ) were associated with VTE. Age, varicose veins, and Factor V Leiden were marginally significant, at  $! = 0.1$  level. The four risk categories were significantly associated with the likelihood of acquiring a VTE (1.7; 1.3 – 2.3,  $p < .01$ ). The bivariate probit model demonstrated a significant association between the probability of acquiring VTE and lack of adherence to prophylaxis guidelines ( $\beta = 0.331$ ,  $p = 0.006$ ). When recommended prophylaxis is not given, the marginal effect of an increase in patient risk from moderate to high on the mean probability of VTE was an increase of 0.3% ( $p < .05$ ). The marginal effect of an increase from high to highest risk was a growth 0.7% ( $p < .0001$ ).

**Conclusion** An internally-developed retrospective VTE risk scoring system, coupled with data about length of hospitalization, produced a valid method for identifying patients at risk for VTE within 30 days after surgery. Validation of a prospective scoring system will further refine VTE risks in surgical patients.

#### Paper 4.5

##### EFFECT OF THE ANTICOAGULANT THERAPY IN THE THROMBUS REGRESSION: A PROSPECTIVE DUPLEX ULTRASOUND STUDY.

A Romera-Villegas, M Cairols, R Vila- Coll, X Martí-Mestre, S Riera-Batalla, H Ballón –Carazas  
*Dept of Vascular Surgery, Hospital Universitari de Bellvitge, Barcelona, Spain*

**AIM:** The purpose of this study was to evaluate if long-term low-molecular-weight heparin (LMWH) in patients with lower limb deep vein thrombosis (DVT) increases the thrombus regression as compared to oral anti-vitamin-K agents (AVK)

**DESIGN:** A randomised, open-label trial.

**MATERIAL AND METHODS:** 241 patients with symptomatic proximal DVT of the lower limbs confirmed by duplex ultrasound scan were included. After initial LMWH (Tinzaparin), patients received 6 months of treatment with full therapeutic dosage of Tinzaparin or acenocoumarol. The primary outcome was the 12-month degree of thrombus regression and venous reflux. Duplex scans were performed at 6 and 12 months. The compression method was used to assess thrombus resolution. The vein segment under examination was classified as recanalised when it was compressible with gentle transducer pressure. The incidence of symptomatic recurrent venous thrombo-embolism (VTE) and major bleeding were also analysed. Statistical analysis (SPSS v.11): Chi-square or Fisher test for categorical variables and the log-rank test was used to compare both treatments

**RESULTS:** During the 12-month period, the venous re-canalisation increased significantly (91.5% vs. 69.2%) in the LMWH group,  $p < 0,001$ . The venous reflux is lesser in the LMWH group 41 % than in AVK group 81,6%,  $p < 0,001$ . Six patients (5%) of 119 who received LMWH and 13 (10.7%) of 122 who received AVK had recurrent VTE ( $p = 0.11$ ). One major bleeding occurred in the LMWH group and three in the AVK group.

**CONCLUSIONS:** Tinzaparin was more effective than AVK in achieving re-canalisation of leg thrombi. Long-term Tinzaparin was at least as efficacious and safe as AVK for preventing recurrent VTE.

#### Paper 4.6

##### A CA AND CB FOR EACH C CLASS OF THE CEAP CLASSIFICATION

A Cornu-Thenard, JF Uhl, PH Carpentier. Saint-Antoine Hospital - Paris France

##### BACKGROUND

The CEAP classification is a great tool to appreciate the state of chronic venous patients. The ‘C’ clinical classes permit to describe the symptoms and the signs [1]. The different scores system allows us to follow the severity of the disease and so the evolution [1,2].

In 2001 it has been decided to divided C4 in 2 subgroups, C4a and C4b [1].

### OBJECTIF

To propose the same subdivision Ca and Cb for each ‘C’ class in order to have a similar organization at all levels.

### METHOD

A publication in which it was proposed a similar idea has been studied [3]. We tried to see if it was possible to find 2 items in each class with respect to the clinical severity.

### RESULTS

- C1 got already two items in itself: Telangiectasias and Reticular blue veins [1].
  - C2 could be divided in two: Primary Varicose Veins (VV) and recurrent VV (REVAS) which are more difficult to treat [4].
  - For C3, a work showed that Corona Phebectatica is a clinical sign sandwiched between Edema and C4a [5]. Other works going to the same way are in press.
  - C4 is already cut in two. C4a: Eczema-Pigmentation and C4b: Lipodermatosclerosis-Atrophie Blanche (AB).
  - Obviously for C5 and C6 the “recurrences” are ‘b’ because they are more severe.
- So the propositions could be:

‘C’ classes	Currently	Propositions:	
		a	b
C1	Telangiectasies, Rb veins	Telangiectasies	Reticular blue veins
C2	Varicose Veins	VV	REVAS
C3	Edema	Edema	Corona Phlebectatica
C4	a : Eczema-Pigmentation b : Lipodermatosclerose - AB	Eczema-Pigmentation	Lipodermatosclerose-Atrophie Blanche
C5	Healed Venous Ulcer	Healed Venous Ulcer	Recurrences
C6	Venous Ulcer	Venous Ulcer	Recurrences

### ADVANTAGES

Inclusion of REVAS and Corona in the ‘C’. It brings a better description of the clinical severity in the C class system. This improvement of CEAP is done without any change.

1- Eklöf B, Rutherford RB, Bergan JJ et al. Revision of the CEAP classification. J Vasc Surg 2004;40:1248-52

2- Meissner MH, Natiello C, Nicolls SC. Performance characteristics of the VCSS. J Vasc Surg 2000;31:1307-12

3- Cornu-Thenard A, Uhl J-F, Carpentier PH. Do we need a better classification than CEAP? Acta Chir Belg 2004;104:276-82

4- Perrin MR, Guex JJ, Ruckley CV, Royle JP, Eklöf B, et al. Recurrent varices after surgery (REVAS): a consensus document. Cardiovasc Surg 2000;8:233-45

5- Carpentier Ph, Cornu-Thenard A, Uhl J-F. Appraisal of the Information Content of the C. J VascSurg 2003;37:827-33

16.30-18.30

Scientific Session 5:

Chair: Bo Eklöf, Michel Perrin

Paper 5.1

THE EFFECTS OF ISOLATED PHLEBECTOMY ON REFLUX AND DIAMETER OF THE GREAT SAPHENOUS VEIN : A PROSPECTIVE STUDY

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*1 Riviera Veine Institut, Nice, France*

**Background:**

A new pathophysiological concept in primary varicose disease suggests ascending or multifocal progression from the suprafascial venous network to the saphenous vein (SV). Ablation of the suprafascial varicose reservoir could therefore improve or eliminate reflux in the SV.

**Objective :**

To evaluate the effect of isolated phlebectomy on the duration and velocity of reflux, as well as on the diameter of the SV.

**Method:**

We included patients presenting reflux in the great saphenous vein (GSV) and who were treated with isolated phlebectomy in a prospective study. We measured reflux duration (RD) and peak reflux velocity (PRV) using duplex ultrasound when patients were standing up and including a manual compression/release manoeuvre in the calf, preoperatively and then 1 month after surgery. We also measured the diameter of the GSV at the same time when patients were standing up using ultrasound.

**Results:**

We included 55 legs in 54 patients (24 women and 30 men) aged from 37 to 83 (mean age 62.6). We reviewed all of the legs 1 month after the isolated phlebectomy treatment.

	Preoperative	1 month postop	P
Mean RD (sec)	1.53	0.81	< .0001
Mean PRV (ms)	248.6	119.5	< .0001
Mean GSV diameters (mm)			
Ostial	6.7	5.6	< .01
Preostial	5.4	4.8	< .05
Thigh mid third	5.0	4.2	< .001
Knee	5.3	4.0	< .001
Leg mid third	4.0	2.7	< .0001

**Conclusions:**

We noted a change to reflux in the GSV after isolated phlebectomy with a significant reduction in RD and PRV. Isolated phlebectomy also led to a significant reduction in GSV diameter. These data suggest that the SV can be improved from a haemodynamic and anatomical point of view by using treatment focusing on the suprafascial venous network.

## Paper 5.2

### THE RISK OF SAPHENOFEMORAL RECURRENCES WITHOUT HIGH LIGATION

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**OBJECTIVE** To evaluate if a novel pre-operative duplex protocol could predict the need of high ligation (HL) in varicose veins surgery.

For this purpose we propose to utilize the combination of the reflux elimination test (RET) and the assessment of the terminal sapheno-femoral valve (TV) competence.

RET is performed by finger-compression of the incompetent collaterals and is considered positive when demonstrates great saphenous veins (GSV) reflux disappearance.

The analysis of the sapheno-femoral junction (SFJ) is performed by placing the Doppler PW sample on the femoral side of the TV, investigating reflux by means of two different manoeuvres: squeezing (SQ) and Valsalva (VAL).

We hypothesized that the combination of a positive RET and of a competent TV could represent the pre-operative duplex indication of varicose veins surgery without HL.

**DESIGN OF THE STUDY:** Case control study.

**SETTING:** Vascular Diseases Center, University of Ferrara, Italy; Teaching Hospital, Institutional Practice.

**SUBJECTS** We compared 100 consecutive patients, affected by CVI (CEAP Clinical Class C2-6), presenting a RET + and an incompetent TV both at VAL and SQ (Group A), with 100 patients presenting a RET+ and a competent TV (Group B) both at VAL and/or SQ. The two groups were matched for age, gender, clinical class and disease duration.

**INTERVENTIONS** We operated both Group A and B patients by means of flush ligation and proximal avulsion of the incompetent tributaries from the GSV trunk (the so-called Chiva 2 procedure).

**MAIN OUTCOME MEASURE** Recurrence rates assessed with clinical and ECD evaluation at 3 y f. up.

**RESULTS** The risk of recurrences was almost 32 times higher in the group A, confirming that TV incompetence assessed according to the experimented protocol is the main predictive factor (OR 31.5; 14.4-68.6, CI 95%). Moreover, these recurrences were mainly localized at the SFJ, exactly in 71% of group A vs 3% of group B (OR 79.2; 23.2-270.2;  $p < .0001$ ).

**CONCLUSIONS** Our results demonstrate how patients with a competent TV at the preoperative duplex analysis can be successfully treated by a minimally invasive and cheap surgery, without the need of high tie.

## Paper 5.3

### POPLITEAL VEIN REFLUX IS FREQUENT IN HARD-TO-HEAL VENOUS LEG ULCERS

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**Aim:** To assess whether the difference in reflux profile, size and duration of ulcer and other factors could predict the healing of a chronic venous leg ulcer.

**Methods:** Consecutive patients with chronic leg ulcers referred to an outpatient clinic in Tampere University Hospital. The patients with venous ulceration underwent a three-month intensive treatment period including optimal local therapy and compression. Colour flow duplex imaging (CFDI) was done to assess venous reflux in superficial and deep veins. Venous clinical score system was observed.

**Results:** 110 chronic leg ulcer patients were screened. 50 patients with venous ulcers were found. Of them, 28 healed during a three-month conservative treatment (clinical class C5), and 22 remained open (clinical class C6). There was a significant difference in ulcer size between healed and hard-to-heal venous ulcers (5.0 cm<sup>2</sup> versus 11.2 cm<sup>2</sup>). Duration of ulceration was markedly longer in hard-to-heal ulcers (7 versus 26 months). Age, gender, smoking and medication did not demonstrate any significant difference between these groups, but popliteal vein reflux showed a high Odds Ratio (OR=3.8; CI95 1.24-12.0).

**Conclusions:** Popliteal vein reflux may predict poor outcome in hard-to-heal ulcers. Size and duration of venous ulcer may have a major prognostic role, and therefore all delays regarding proper diagnosis and treatment of these ulcers should be avoided.

#### Paper 5.4

SAPHENECTOMY OF THE GSV WITHOUT CROSSECTOMY: 6 YRS FOLLOW UP IN A RANDOMIZED STUDY IN 124 LEGS WITH TERMINAL VALVE REFLUX..

P Casoni.

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The inguinal flush ligation with tributaries ligation far from the femoral vein is the standard procedure to treat varicose veins of the GSV. Recanalization of missed little veins, or previous lymphatic reflux or others unknown factors are the origin of the so called "neoangiogenesis" in more than 50%. Aim of this study is to show that the inguinal dissection can be avoided in more than 90% of cases.

1200 legs were submitted to vv surgery (same surgeon with pre operative echo-guided mapping : 833 (69.4%) primary vv and 367 (30.6) were recurrence of which 658 (79%) were submitted to minimally invasive surgery without inguinal dissection and saphenectomy when necessary. 124 legs were randomized in two groups and entered the study: (A) flush ligation with inguinal dissection (61 cases) and (B) with GSV ligation 2 cm. below the SFJ (61 cases). In all cases saphenectomy of the great saphenous vein was performed (short or long) plus phlebectomies. Inclusion criteria were: varicose vein disease with SFJ incompetence, competent SSV and absence of other refluxes. All cases were echographically mapped from the same surgeon and digitally recorded. The follow up included an echo guided study of the groin every year for five yrs. 99% of patients were detected at the end point. Any case who presented inguinal reflux was recorded as positive for recurrence. In conclusion 119 legs were detected at the end of the study. Previous reports at 24 and 36 months showed no difference between the groups, while in the last year the comparison showed the presence of inguinal reflux in 20% patients of group A and 8% patients in group B. The study of the terminal valve with echo duplex was performed in all legs and in the Group B only 1,6% (n=1) presented a reflux at Valsalva manouvre. Interesting and casual feature The whole group of patients operated without inguinal dissection (658 groins checked) presented the same incidence (6 reflux= 1,6%) .

The Authors discuss any correlation in order to avoid standard procedures in favour of a more satisfactory personalized surgery avoiding in 98% of cases groin dissection, with less complication rate, time wasting and costs.

## Paper 5.5

### SAPHENOUS SURGERY IS NOT A RELIABLE CURE FOR INCOMPETENT PERFORATORS IN PATIENTS WITH VENOUS ULCERS

O Nelzén for the SWESEPS study group

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**Objective:** There have been reports claiming that incompetent perforators (IP) often become competent as a result of superficial venous surgery alone. Whether this is true or not is the subject of this report.

**Method:** Within a Scandinavian randomized multicenter study to study perforator interruption with SEPS that enrolled 72 patients, 37 were randomized to the no-SEPS group and 35 in the SEPS group. All patients had a median of 2 incompetent medial perforators visualized by a duplex scan prior to enrollment and in addition all had incompetent saphenous veins. Patients in the no SEPS group were treated with saphenous surgery without interfering with the perforators and in the SEPS group SEPS was added to interrupt IP. The result was assessed by a repeat duplex scan 6-9 months following surgery.

**Results:** The repeat duplex scan showed significantly fewer IP in the SEPS group compared with the no-SEPS group, 23 vs. 56. In the no-SEPS group 40/56 was remaining original IP and 16 new IP had developed while 7 legs were free from IP. In the SEPS group 9/23 was “missed” original perforators and 14 new perforators had developed while 20 legs were free from IP. Based on the original perforators significantly fewer legs in the no-SEPS group were cured 8/36 (22%) compared with 26/34 legs (76%) in the SEPS group.

**Conclusion:** When patients with venous ulcers are concerned only a minority of IP is likely to normalize as a result of saphenous surgery alone. Saphenous surgery is not a reliable cure for IP.

## Paper 5.6

### NEW PAPER 5.6

#### THIGH COMPRESSION WITH DIFFERENT COMPRESSION DEVICES AFTER GREAT SAPHENOUS VEIN SURGERY

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##### *Introduction*

Aim of our work was to study the clinical effectiveness and tolerability of different compression devices after great saphenous vein (GSV)- surgery depending on the exerted pressure.

##### *Materials and methods*

54 patients (21 males, 33 females aged 57.6±10.2 years), treated by vein surgery because of massive GSV-insufficiency (CEAP C2-C5) were randomly assigned to receive 3 different compression devices after the

procedure, 18 patients for every compression system. The patients were fully informed on the procedure and gave their consent to take part in this study.

Group 1: thigh length natural rubber stocking exerting at the B point 23-32 mm Hg (Gloria 261®; Menaggio; Italy); Group 2: the same stocking on top of a newly developed eccentric compression device (ECD) (Medi postop®, Medi Bayreuth, Germany) fixed at the skin by crosswise applied tapes; Group 3: inelastic bandage made up of Porelast® on the lower leg and the thigh and Panelast® on the knee area (Por-Pan-Por; Lohmann & Rauscher GmbH & Co KG, Rengsdorf; Germany) applied to exert  $\geq 40$  mm Hg at thigh level in the standing position.

All the devices were left in place for 7 days. The interface pressure was measured immediately after application and before removal by means of Picopress® (Microlab, Padua; Italy) with the probe on the medial aspect of the thigh halfway between the groin and the knee. At compression removal the patients were checked for severe adverse events based on the following definitions: pain when VAS evaluation exceeded 8 and when analgesics were required; haematoma when a tissue hemorrhagic area more than 10cm<sup>2</sup> was measured; external bleeding when the stocking was significantly stained with blood; bruising when it was diffused in all the medial aspect of the thigh. Tolerability and discomfort of the compression system were evaluated as well.

## Results

Median values and ranges for the sub-bandage pressures (mm Hg) after application and 6 days later are given in the Table1:

	Sub-bandage pressure (thigh)		Before removal after 6 days	
	Lying	Standing	Lying	Standing
Elastic stocking (n=18)	14 (12-18)	16 (14-20)	12 (8-17)	14 (9-21)
ECD (n=18)	68 (44-100)	98 (72-128)	36 (22-54)	59 (36-72)
Por-Pan-Por (n=18)	47 (29-65)	67 (42-42)	17 (11-30)	31 (15-40)

Severe reactions (n) are reported in Table 2:

	Pain	Haematoma	External bleeding	Bruising
Elastic stocking (n=18)	7	2	1	3
ECD (n=18)	0	0	0	0
Por-Pan-Por (n=18)	1	0	0	0

ECD was better tolerated than Por-Pan-Por.

## Conclusions

The results support the use of high pressure compression devices, at least in the first week post-op, to minimize the post-surgical sequelae. An eccentric compression device fixed by tapes and topped by a stocking seems to offer the best outcome.

08.50-11.30

Scientific Session 6:

Chair: Morten Stahl Madsen, Marianne de Maeseneer

### Paper 6.1

## FOLLOW-UP OF RADIOFREQUENCY SEGMENTAL THERMAL ABLATION (RTFA) OF GREAT SAPHENOUS VEINS

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### Background:

Radiofrequency segmental thermal ablation has been introduced recently and shown its feasibility in occlusion of incompetent great saphenous veins (GSV).

### Methods:

N – 295 GSVs in 225 patients were treated by RTFA under local anesthesia in a prospective multicentre trial. Duplex-ultrasound control visits were performed after 3 days, 3, 6, 12 and 24 months. Clinical data was obtained at the same time.

### Results:

Of 225 patients n = 166 (73.8%) were female with a mean age of 50.5 years (range 18 – 79). All GSVs were treated per protocol with double cycle treatment at the first segment with an average length treated of 36.9 cm. Concomitantly performed procedures were phlebectomy in 164 legs (55.6%) and sclerotherapy in 38 legs (12.9%). During follow-up, one vessel was open at 3 days but occluded thereafter. Treatment failures or recanalizations of the once occluded GSVs were n = 2 of 290 at 3 months, n = 4 of 289 at 6 months and n = 9 of 292 at 12 months and n = 6 of 101 at 24 months after the intervention. Inner diameters of n = 292 GSVs followed for 1 year measured 3 cm distal to the sapheno-femoral junction were reduced from an average of  $5.4 \pm 2.0$  mm pre treatment to  $4.5 \pm 1.7$  mm at 3 days, to  $2.4 \pm 1.5$  mm at 6 months, to  $1.2 \pm 0.9$  at 1 year afterwards. **Reflux was reported in n = 0 of 290 at 3 month (no reflux), n = 1 of 289 at 6 months (0.3% reflux) and n = 4 of 292 at 12 months (1.4 % reflux) and n = 3 of 101 at 24 months (3.0 % reflux) after the intervention.** 50 % of veins were sonographically non visible at mid thigh level by 1 year. The average VCSS score improved from  $3.9 \pm 2.1$  before treatment to  $3.5 \pm 1.2$  at 3 days, to  $0.9 \pm 1.5$  at 3 months,  $0,7 \pm 1.2$  at 6 months,  $0,6 \pm 1.2$  at 12 months and  $0,2 \pm 0.8$  at 24 months thereafter. Presence of any pain in the treated limb improved from 58.6 % before treatment to 48.5 %, 33.3 %, 12.5 %, 3.1 % and 2.0 % at the same follow-up intervals. Likewise, presence of leg swelling improved from 52.9 % to 6.4 %, 8.3 %, 8.3 %, 4.5 % and 3.0 %. Side effects noticed at any time during follow-up in the RSTA-treated area were ecchymosis (5.8 %), paresthesia (3.4 %), erythema (2.0 %), skin pigmentation (3.1 %), hematoma (1.4 %) and phlebitis (1.0 %).

### Conclusion:

RSTA showed a high success rate and durability of the once achieved occlusion of treated GSVs together with a moderate side-effect profile. A remarkable subsequent improvement of clinical symptoms was noted.

## Paper 6.2

### INTRALUMINAL FIBRE-TIP CENTERING CAN IMPROVE ENDOVENOUS LASER ABLATION: A HISTOLOGICAL STUDY.

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(d) *INSERM U 703, Lille University Hospital, 59037 Lille, France (SM).*

#### **Objective:**

In this histological study we analysed the use of a new tulip-shaped self-expandable catheter fixed to the fibre for ELT in an animal model (goats). Can the avoidance of the direct contact between the fibre tip and the vein wall prevent vessel wall ulcerations and perforations and perivenous tissue destruction? We were looking for the difference in destruction between veins treated with a normal bare fibre and veins treated with this new catheter fixed to the fibre.

#### **Materials and Methods:**

In 10 goats, 20 lateral saphenous veins were treated with ELT. In 10 veins we used the tulip-shaped catheter fixed to the fibre (Fig 1). With a 980nm diode laser (Inter-Medic<sup>o</sup>, Barcelona, Spain) 62,1J/cm on average were administered.

Postoperatively the veins were removed at different stages and sent for histological examination. The pathologists measured the diameter of the ulcerations, as well as the depth of penetration in the vein wall. A score to measure the perivenous tissue destruction was used (see below).

#### **Description of the fibre-tip catheter: “Tulip-catheter”**

To prevent the direct contact of the fibre tip with the vein wall, a fibre-tip centering catheter was designed. It consists of a tube fixed to the fibre, with a tulip-shaped self-expandable end at the fibre tip (Tobrix, Waarle, The Netherlands). This tube is folded in an outer guiding catheter. The fibre tip is covered by the tulip. The material is thermoresistant (up to 200°C). When withdrawing the outer guiding catheter (pullback), the tulip-shaped end of the catheter expands and pushes away the vein wall. With this manoeuvre the intraluminal centering of the fibre tip is obtained and avoiding a direct contact with the vein wall. (Fig 1).

#### **Perivenous tissue destruction scale (Fig 2):**

The lateral saphenous vein in a goat is surrounded by a triangular shaped fascia. At three different points at the edge of the vein, located at a distance of 120° from each other, the perivenous tissue destruction is measured. The distance between the vein wall and the surrounding fascia is divided into three equal layers. Extent of necrosis was graded following the scale: 0=no necrosis, 1=necrosis. Consequently, at each location, if the 3 layers were involved extent of necrosis was graded 3, if the necrosis was seen in all 3 positions, the maximum necrosis score could reach 9. We count one point for each part where necrosis is seen.

The perivenous tissue destruction was measured at different stages after ELT (immediately, 10 days and 3 weeks).

#### **Measurements of perivenous temperature:**

Peroperatively the temperature in the perivenous liquid collection was measured using thermocouples (Thermocouple type K). One needle was inserted at the proximal and another at the more distal part of the vein. The needle location in the perivenous liquid in the immediate proximity to the vein wall was controlled by peroperative ultrasound. The probes for temperature readings were connected to a digital thermometer.

(Pronto tc ,Thermo-Electric ,Balen, Belgium). Temperature was measured during fibre withdrawal in order to determine the maximum temperature for both groups (with and without tulip-catheter).

**Results:**

A temperature increase around the treated vein (in the tumescent liquid) was observed during fibre pullback. On average the maximum temperature was 50°C (min:32,3°C ; max:68,3°C) without using the catheter and 47°C (min: 34,1°C; max: 80°C) using the tulip-catheter . These differences were not statistical significant ( $p > 0,05$ ).

Veins removed immediately after ELT (without catheter) (n=6, 78 sections) show an uneven destruction of the vein wall with ulcerations and perforations. Using the catheter these ulcerations were avoided. In veins removed 10 days after treatment (n=8, 99 sections), we found a much more extended vein wall destruction. Using the tulip-shaped catheter we obtained a significant higher circumferential total vein wall necrosis (79,8 versus 64,4%) ( $p=0,001$ ) and a reduced perivenous tissue destruction rate ( $p < 0,001$ ). Veins removed three weeks (n=6, 88 sections) after treatment still show a higher circumferential vein wall necrosis (97,6 versus 79,1%) ( $p < 0,001$ ) but the difference in perivenous tissue destruction disappeared due to inflammatory regression and healing of the damaged tissue ( $p=0,47$ ).

**Conclusion:**

The use of a new tulip-shaped self-expandable catheter fixed to the fibre for ELT avoids the usual ulcerations and perforations of the vein wall , results in a more even vein wall destruction with necrosis of a higher percentage of the circumferential vein wall. The perivenous tissue destruction and reactive inflammatory reaction is significantly lower . This can clinically correlate with less postoperative pain and periphlebitis. The direct contact between the fibre tip and the vein wall should be avoided if possible.

**Figures:**

Figure 1: Tulip-shaped self-expandable catheter fixed to the fibre

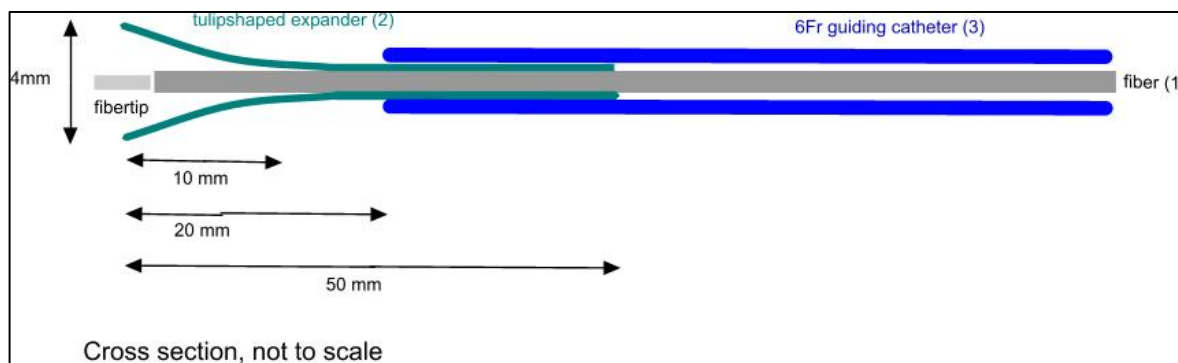
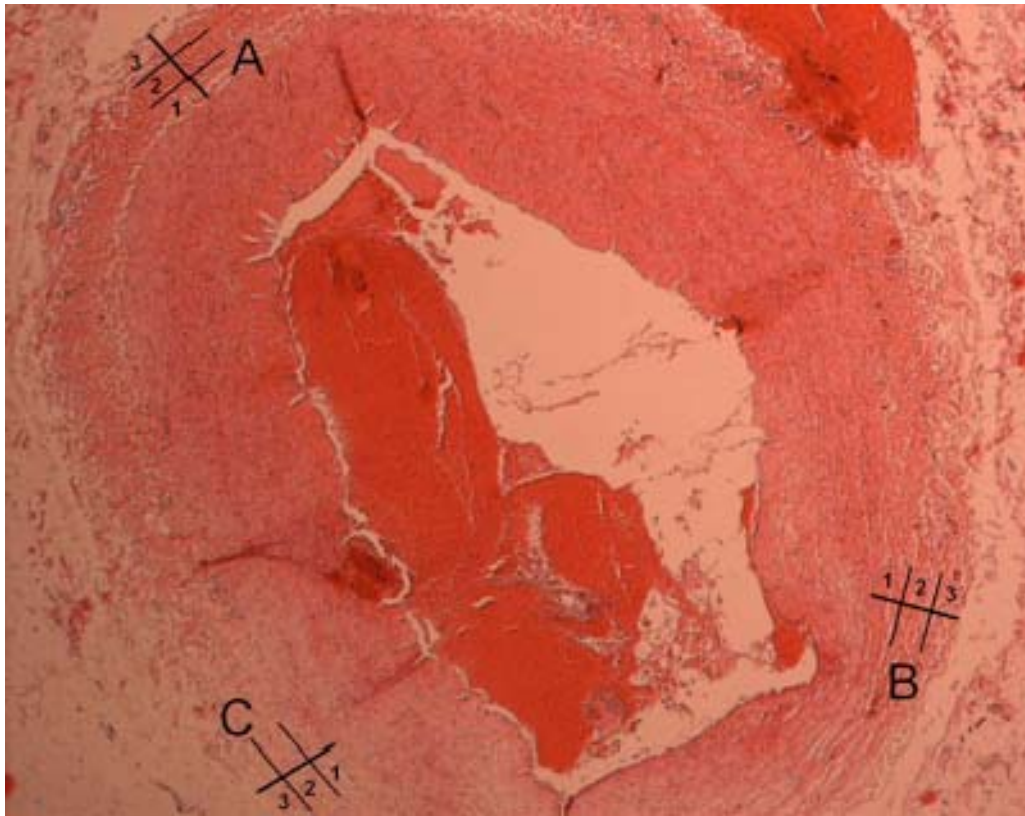


Fig 2: Perivenous tissue destruction scale: at three points (A,B,C) the perivenous destruction is measured. The distance between the edge of the outer vein wall and the surrounding fascia is divided in three parts (1,2,3).



### Paper 6.3

#### MEDIUM-TERM FOLLOW-UP OF A RANDOMIZED TRIAL COMPARING LASER ABLATION WITH STRIPPING OF THE GSV. RECURRENCE RATE AND – PATTERN AFTER 2 YEARS.

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**BACKGROUND:** Endovenous laser ablation (EVLA) has gained increasing popularity as a tool for treating incompetent great (and small) saphenous veins (GSV). Follow-up studies have shown a durable occlusion of the GSV in more than 93% of cases after 2 years. Whereas previous studies have focused on the efficacy of EVLA in eliminating the GSV from the circulation, the actual recurrence of varicose veins has only been described to a limited extent, and not previously in randomized trials when compared with stripping.

**METHODS:** Patients with varicose veins due to GSV insufficiency were randomized to either EVL (980 nm, Biolitec) or high ligation and stripping (HL/S) in tumescent anaesthesia. Miniphlebectomies were also performed. Examinations and duplex scan were performed preoperatively and subsequently at 12 days, 1, 3 and 6, 12 and 24 months postoperatively. Sick leave, time to normal physical activity, pain score, use of analgesics, Aberdeen score, SF-36 quality of life score, VCSS and complication rates were investigated. The total cost of the procedures, including work loss and equipment was calculated.

**RESULTS:** One hundred and twenty-one patients with 137 legs have been followed for up to 24 months. Two HL/S procedures failed while 3 GSV's recanalized in the EVLA group. The groups experienced similar improvement in quality of life scores and VCSS score. Complications were rare and minor. Postoperative morbidity, improvements in quality of life, venous clinical severity score and costs were similar in the 2

groups. Twenty-three (33%) and 18 (26%) of the HLS and EVLA group respectively developed new varicose veins (ns). The distribution of the recurrent varicose veins was not different between the groups; new incompetent femoral perforators being the most frequent finding at follow up. A total of 11% were re-operated within 2 years (ns between groups).

**CONCLUSIONS:** This study suggests that the medium term efficacy and safety of EVLA and HL/S are similar. Except for slightly increased postoperative pain and bruising in the HL/S group, no differences were found between the 2 treatment modalities. The treatments were equally safe and efficient in eliminating GSV reflux, alleviate symptoms and signs of GSV varicosities and improve quality of life. The recurrence rate was disappointingly high in both groups, as seen in other studies. Longer term outcomes, particularly with respect to recurrence rates shall be investigated in future studies including the continuation of the present.

## Paper 6.4

### A RANDOMIZED TRIAL OF ENDOVENOUS THERMAL ABLATION FOR SUPERFICIAL VENOUS INSUFFICIENCY OF THE GREAT SAPHENOUS VEIN: RADIOFREQUENCY ABLATION VERSUS ENDOVENOUS LASER THERAPY

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#### **Background**

Great saphenous vein (GSV) incompetence is the most common cause of superficial venous insufficiency. Randomized trial results show that endovenous ablation with a radiofrequency catheter (RFA) is superior to the conventional surgical procedure of ligation and stripping. Techniques of endovenous laser treatment (EVL) have emerged as an effective alternative to RFA, but have not been studied in a randomized fashion. This study presents the early and one-year results of a randomized trial of RFA versus EVL of the GSV for superficial venous insufficiency.

#### **Methods**

Following informed consent, 119 patients with superficial venous insufficiency due to GSV incompetence were randomized to RFA or EVL. RFA was performed with the ClosurePlus system (VNUS Medical Technologies, Sunnyvale CA). EVL was performed with the EVLT<sup>®</sup> system (AngioDynamics Inc., Queensbury NY). Early (one-month) postoperative results of pain, bruising, erythema, and hematoma were recorded. In addition, Venous Clinical Severity Scores (VCSS), CEAP scores, quality-of-life (QOL), GSV recanalization, and recurrent reflux were evaluated at one year.

#### **Results**

Fifty-four patients were randomized to RFA and 65 to EVL. At one week, one patient in the RFA group had an open GSV and was deemed a failure. There was more bruising in the EVL group ( $P=.0123$ ) at one week, and 2 RFA and 5 EVL patients had symptomatic erythema ( $P=NS$ ). At one month there was no difference in bruising. At one year, 104 patients (47 RFA, 57 EVL,) have been evaluated with duplex ultrasound and leg assessments. Eleven RFA and 2 EVL patients demonstrated recanalization of one or more vein segments ( $P=.002$ ). Mean VCSS scores improved in both groups, from 6.74 preoperatively to 1.57 at one year for RFA and from 5.95 to 1.26 for EVL ( $P=NS$ ). CEAP scores improved from 2.87 to 1.78 in RFA and 2.88 to 1.79 in EVL ( $P=NS$ ). Mean QOL score also improved in both groups, from 48.41 to 27.52 for RFA to 48.89 to 25.28 for EVL ( $P=NS$ ).

#### **Conclusion**

Both methods of endovenous ablation effectively reduce symptoms of superficial venous insufficiency. Although it is associated with greater bruising and discomfort in the periprocedural period, EVL may provide a more secure closure over the long term when compared with RFA.

## Paper 6.5

### INCIDENCE OF US VISUALISATION OF THE SURAL NERVE AND ECHO-ANATOMICAL ASPECTS

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**Background and Objective:** Lesions of Sural Nerve (or Small Saphenous Nerve) (SN) have been reported to complicate surgical or thermal avulsion of SSV. Although there is no consensus on their incidence, their occurrence is a major concern in SSV treatments. We aim to visualize the SN and its spatial relationship with SSV.

**Type of study.** Ultrasound anatomical research in normal subjects and in SSV dilatation cases

**Method:** SN is easily identified with high definition 15 Mhz probe. Moving the probe up and down alternatively in a transverse section is always well visible within the Saphenous compartment and in proximity to the SSV only in the distal third of the limb, where the two components of the Nerve (the Saphenous Tibial Nerve-STN (branch of the Tibial Nerve) and the Saphenous Peroneal Nerve- SPN(branch of the Common Peroneal Nerve)) join together. In a transverse scan the nerve appears then like a round echogenic formation containing small anechogenic spots (the nerve's fibers). The relationship with the SSV is variable, the nerve running separately or in strict contact with the vein for different lengths, all the combinations being possible. Once the nerve has been identified, proceeding proximally, the point of separation of the two components is often (50%) detectable. It is then possible to follow the two different nerves observing the STN (inside the "triangle" of connective tissue below the SSV) joining the tibial nerve and the SPN joining the STN running inside a tiny fascial duplication (and thus more difficult to be followed). When the SSV is dilated, the nerve is still well visible unless the vein is tortuous, duplicated or aneurismatic. In these instances the nerve must be visualised more distally and followed upwards "by continuity".

**Conclusions:** The SN visualisation is possible and may be clinically useful to define pre-operatively the "dangerous" point of contact between the nerve and the SSV, when this vein must be avulsed or thermally occluded.

## Paper 6.6

### SUPERFICIAL VENOUS REFLUX IS A POOR PREDICTOR OF THE IMPACT OF VENOUS DISEASE AND SUBSEQUENT TREATMENT OUTCOMES

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#### **Aims**

Numerous tools are available for the assessment of disease severity for patients with venous insufficiency. This study investigates the relationship between patterns of venous reflux with haemodynamic function, disease specific quality of life and clinical scoring systems pre and post operatively

#### **Methods**

Patients referred with symptomatic superficial venous reflux (without deep reflux) were prospectively studied. Pre-operative colour venous duplex, digital photoplethysmography (a measure of venous refill time, VRT), CEAP grade and Aberdeen Varicose Vein Questionnaire (AVVQ) scores were recorded. Legs were stratified according to the pattern of reflux, into those with reflux of the great, small or both saphenous veins.

AVVQ scores and VRTs were also recorded at 6 weeks following endothermal ablation therapy.

## Results

Over a 12 month period, 177 patients with varicose veins were studied, of which 123 completed all pre operative investigations. 90/123 patients were female, the mean age was 50 years (range 22-88) and median pre op AVVQ score was 16.52 (range 1.31-71.5/100). CEAP scores were C2 (n=83), C3 (n=45), C4(n=36), C5(n=4) and C6(n=9). Median AVVQ scores were 14.4 (range 1.3-71.5) for patients with unilateral disease (n=80) compared to 19.1 (range 4.2-34.3) for those with bilateral disease (n=43)  $p=0.047$ , Mann Whitney U, however there was no significant correlation between AVVQ score and the number of refluxing veins ( $p=0.124$  Spearman Rank). Pre operatively VRTs were significantly worse in patients of CEAP class 5 and 6 compared to those classed as 2, 3 or 4 (mean VRTs 9.6 and 6.8. versus 20.8, 21.5, 15.0, seconds respectively,  $p=0.021$  Mann Whitney U test). Mean VRTs for legs with great saphenous, small saphenous or combined reflux were 18.8, 16.0 and 17.0 seconds respectively,  $p=0.80$  Kruskal Wallace).

At 6 weeks the median AVVQ score was 11.25 (range 0-53) with an average improvement of 4.9 points (range -9-32) There was no significant difference in the degree of improvement in AVVQ score between those who underwent bilateral treatment compared to unilateral ( $p=0.723$  Mann Whitney U), However, those who had received treatment for bilateral disease still had significantly worse scores than those were treated for unilateral disease at 6 weeks (median 14.0 versus 8.28 respectively,  $p=0.37$  Mann Whitney U)

At 6 weeks VRTs improved by a mean of 6.8 seconds (range -38 to 48). There was no correlation between improvement in quality of life and improvement in venous refill times ( $p=0.078$  and  $0.142$  right and left leg respectively Spearman Rank) or between the number of refluxing veins treated and the improvements in AVVQ at 6 weeks ( $p=0.583$  Kruskal Wallace). Improvements in VRTs at 6 weeks did not differ depending on pre operative CEAP class ( $p=0.376$  Kruskal Wallace)

## Conclusions

The pattern of superficial venous reflux appears to be a poor indicator of disease severity, although patients with bilateral disease report poorer quality of life scores pre and post operatively. Assessment of haemodynamic function and quality of life may be important when evaluating and managing patients with chronic venous disease.

## Paper 6.7

### FACTORS AFFECTING POST OPERATIVE PAIN FOLLOWING ENDOVENOUS ABLATION OF VARICOSE VEINS

AC Shepherd, MS Gohel, CS Lim, M Hamish, AH Davies

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## Objectives

A variety of endothermal treatments are currently available for the treatment of varicose veins, offering the prospect of less discomfort and quicker return to normal activities compared to traditional surgery. The aim of this study was to evaluate which factors may contribute to post-operative pain following endothermal ablation procedures.

## Methods

Patients treated with endovenous laser ablation (EVLA) or radiofrequency ablation (RFA) completed the Aberdeen Varicose Vein Questionnaire (AVVQ) before surgery and a 100mm visual analogue diary card to record post-operative pain scores. Initial VCSS and CEAP scores were assessed by a clinician and recorded along with demographic and operative details. Independent risk factors for post-operative pain were identified using a multivariate linear regression model.

## Results

Over a 6 month period, 75 patients completed diary cards. RFA was performed in 43/75 and EVLA in 32/75. The median (range) age was 48 years (27-78) and 57/75 were female. Median (range) AVVQ and VCSS scores were 17.59 (2.47-74.3) and 4 (0-13) respectively. Age, sex, AVVQ, VCSS and CEAP scores were comparable between the treatment groups ( $p=0.528, 0.862, 0.186, 0.930$  &  $0.240$  respectively, Mann Whitney U test). Overall median (range) pain scores after 3 and 10 days were 20mm (1-81mm) and 17mm (1-85mm). Pain scores were significantly higher after EVLA compared to RFA after 3 days (31mm (2-80mm) versus 16mm (1-81mm)  $p=0.016$  Mann Whitney U) and after 10 days (24 mm (1-85mm) versus 13mm (1-68mm),  $p=0.003$  Mann Whitney U). Using a multivariate analysis, we found that none of the other factors assessed predicted post operative pain score at 3 days or at 10 days.

Table 1. Results of multivariate linear regression analysis (outcome – average post-operative pain score over 3 days)

Risk factor assessed	HR	95% CI	P value
Male sex	-0.064	(-16.702-10.620)	0.657
Patient age	-0.063	(-0.532-0.346)	0.672
Pre-op AVVQ	-0.040	(-0.707-0.558)	0.814
Pre-op VCSS	0.256	(-1.059-6.529)	0.154
Pre-op CEAP grade	0.066	(-6.311-8.978)	0.728
Bilateral surgery	0.008	(-12.564-13.217)	0.960
Total length of vein ablated	-0.072	(-0.284-0.180)	0.657

Table 2. Results of multivariate linear regression analysis (outcome – average post-operative pain score over 10 days)

Risk factor assessed	HR	95% CI	P value
Male sex	-0.065	(-13.143-8.196)	0.644
Patient age	-0.225	(-0.610-0.075)	0.123
Pre-op AVVQ	-0.071	(-0.601-0.387)	0.666
Pre-op VCSS	0.310	(-0.295-5.632)	0.077
Pre-op CEAP grade	0.064	(-4.927-7.015)	0.727
Bilateral surgery	-0.070	(-12.350-7.786)	0.651
Total length of vein ablated	-0.130	(-0.256-0.106)	0.410

## Conclusions

Pain scores were lower after RFA compared to EVLA, however, sex, age, AVVQ, VCSS, CEAP score, bilateral intervention or the length of vein ablated were not predictive of post operative pain.

## Paper 6.8

### PROTEOMIC COMPARISON OF VARICOSE VEINS IN HUMANS AND IN THOSE THAT DEVELOP IN A NEW PORCINE MODEL OF VARICOSE VEINS

AM van Rij, LV Philips, E Bateman, D Madut, T Kleffmann<sup>†</sup> and G Jones

Departments of Surgery and Biochemistry,<sup>†</sup> University of Otago, Dunedin, New Zealand

**Aim.**

This study aimed to examine the protein profile associated with varicose veins, in both humans and a novel porcine model of superficial venous disease.

**Methods.**

Varicose and control veins were collected from human subjects. Two-dimensional gel electrophoresis and mass-spectroscopy was used to identify differentially expressed proteins. The same process was used to compare varicose and control superficial thigh vein samples from a porcine model of superficial venous disease.<sup>1</sup> Written informed consent was obtained from all patients and the relevant institutional Human and Animals Ethics Committees approved the study.

**Results.**

The proteomic profiling revealed changes in a range of proteins not previously considered in the study of varicose vein pathogenesis. Proteins significantly up regulated (>2 fold) in human varicose veins included cytoskeletal and contractility related proteins (actin, tropomyosin, desmin and vimentin), heat shock protein (HSPB1), thioredoxin peroxidase 1 and serine proteinase inhibitor. In the porcine model similarly cytoskeletal and contractility related proteins (actin, tropomyosin, desmin and vimentin), heat shock proteins (HSPB1, HSP70, HSP 60) and ATP synthase were up regulated. Taken together, these profiles suggest a similar process of mild inflammatory induced fibrosis and tissue remodelling in both the human and porcine varicose vein.

**Conclusion.**

These observations are encouraging as they indicate a similar molecular pathology between human disease and experimentally induced porcine varicose veins. Moreover they appear consistent with independently reported gene expression profiles of human primary varicose veins.<sup>2</sup> Proteomic analysis has identified new proteins not previously recognised to be involved in the development of varicose veins. These may point to other approaches to treatment and prevention.

*\*This study was supported by the Union Internationale de Phlébologie Research Fellowship 2005.*

1. Jones GT, Grant MW, Thomson IA, Hill BG, van Rij AM. Characterization of a Porcine Model of Chronic Superficial Varicose Veins. *J Vasc Surg.* 2009;In Press.
2. Lee S, Lee W, Choe Y, Kim D, Na G, Im S, Kim J, Kim M, Kim J, Cho J. Gene expression profiles in varicose veins using complementary DNA microarray. *Dermatol Surg.* 2005;31(4):391-395.

**11:30-12.10 Presentations from American Venous Forum (Servier Award Travelling Fellowship Winners.  
Chair: Joe Caprini, Jawed Fareed**

**Paper 7.1****PHARMACOMECHANICAL THROMBECTOMY FOR DEEP VENOUS THROMBOSIS: AN ALTERNATIVE FOR HIGH RISK PATIENTS**

S Rao, G Konig, SA Leers, JS Cho, LK Marone, RY Rhee, MS Makaroun, RA Chaer  
*University of Pittsburgh Medical Center, Pittsburgh, PA, USA*

**Background:** venous lysis is usually reserved for symptomatic patients with acute DVT and low risk for bleeding. This study reports on the use of pharmacomechanical thrombectomy (PMT) in high risk patients traditionally considered unsuitable for this therapy.

**Methods:** a retrospective review of all patients with symptomatic DVT treated between 2007 and 2008 with PMT was performed. All patients were treated by a combination of local TPA with the Angiojet or Trellis device. TPA drip was used sparingly.

**Results:** 28 patients with mean age  $50.4 \pm 16.8$  presented with symptoms averaging  $15.6 \pm 9.2$  days in duration. 16(57%) had symptoms for more than 14 days and 11 (39%) had a contraindication for lysis (Table 1). Symptomatic subclavian thrombosis occurred in 4(14%), and 24 (86%) presented with disabling lower extremity DVT (3 phlegmasia) despite anticoagulation. Ten patients had a thrombosed indwelling permanent filter (9 TrapEase, 1 Greenfield). 81% were treated in one session but 3 patients required a TPA drip following suboptimal PMT. Iliac stenting was required in 30%. Successful lysis (>50%) was achieved in 89% of patients, and symptom resolution in 97%. All patients became ambulatory with no or minimal limitation. There were no major systemic bleeding complications but access site hematoma occurred in 2 patients, and worsening of preexisting rectus sheath hematoma requiring transfusion occurred in another 2 patients. Limb salvage was maintained in 100%. Mean follow up was  $4.3 \pm 2.6$  months. Freedom from DVT recurrence and reintervention was 96% at 9 months by life table analysis.

**Conclusions:** PMT can be safely and effectively used for sub-acute ilio caval and iliofemoral DVT and in patients with contraindications for lytic therapy resulting in improved functional outcomes.

Contraindication to Thrombolysis (N=11/28)						
	Renal/Liver Failure	Recent Minor Surgery	PUD/GI Bleed	Major Surgery/Trauma	Organ Biopsy	Active Bleeding
Number of Patients	3	2	2	4	2	5

## Paper 7.2

### ABSORBABLE INFERIOR VENA CAVA FILTERS (VCF): AN IN-VIVO PORCINE MODEL

A Thors, P Muck.

*Good Samaritan Hospital, Cincinnati, OH, USA*

**BACKGROUND:** The use of vena caval filters (VCF) in the acute care surgical patient continues to expand. This increased use has led to further product development and options pertaining to the type of device that is inserted. This study is the first of a multi-part series to determine the efficacy and feasibility of an absorbable VCF in an in-vivo porcine model.

**METHODS:** A total of 10 hand-made, dual filtration level, absorbable VCF's were produced and gas sterilized. Operative insertions using paramedian incisions, infra-renal vena cava dissection, venotomy, and device insertion using 8F rigid sheath was performed on 10 pigs (>50lbs). Six-weeks after implantation, the VCF's were operatively removed en-bloc and the pigs euthanized. The filters were grossly inspected for measure of absorption, retained residual material, migration, and clot burden. Subsequently the inferior vena cava (IVC) specimens were examined under microscopy to assess for degree of inflammatory response to the present foreign body.

**RESULTS:** All 10 retrieved devices were completely dissolved (100%), with no signs of migration, residual material, or clot burden. The non-absorbable Z-stent portion of the design was completely incorporated into

the vena cava wall with complete neointimalization of the vena cava lumen. There was no evidence for residual knots or strands in the caval wall, nor was there evidence of IVC narrowing. One pig (10%) developed a post-operative wound infection requiring treatment. Filter and vena cava specimens were preserved in formaldehyde and sent for histology.

**CONCLUSIONS:** To date there are no commercially available absorbable VCF devices, nor has this concept been published in the medical literature. The application of such a device could fit a specific subset of patients.

**12:10-12.50                      Presentations from winners of the EVF Pump Pring Grant**  
**Chair: Mehmet Kurtoglu, Marianne Vandendriessche**

[Paper 8.1](#)

THE ROLE OF DYSREGULATED APOPTOSIS AS A CELLULAR RESPONSE TO HYPOXIA IN THE PATHOGENESIS OF VARICOSE VEINS

CS Lim

Department of Vascular Surgery, Charing Cross Hospital, London, UK

**Introduction**

Hypoxia has been postulated to contribute to varicose vein formation by regulating vein wall remodelling. The identification of hypoxia-inducible factors (HIF) in varicose veins recently suggested that the HIF pathway may be involved in varicosity pathogenesis. Dysregulated apoptosis observed in varicose veins may also be regulated by hypoxia since cell cycle and apoptosis are known downstream targets of HIFs.

**Aims**

The aim of the study is to assess if hypoxia regulates varicose vein wall remodelling and dysregulation of apoptosis through the HIF pathway and its downstream targets.

**Methods**

Human varicose and non varicose veins obtained from surgery were stained with special stains (haematoxylin and eosin, Masson's trichrome and elastic van Gieson). Semi-quantitative histomorphological assessment was performed by two independent reviewers to assess for variations between varicose and non varicose veins. A varicose vein organ culture model was also set up. Cell death of the varicose veins cultured in different conditions including with and without regular culture medium change, with and without foetal bovine serum, with and without sodium azide 10mM, in hypoxia and normoxia, and of different time length were measured using the Cell Death Detection ELISA Plus® to determine if the tissue culture was alive.

**Results**

Special stains demonstrated significantly more smooth muscle cells (SMC) and less elastin in the tunica media of varicose compared to non varicose veins ( $P=0.0155$  and  $P=0.0433$ , respectively). There was also significantly more connective tissue observed in the intimal hyperplasia in varicose compared to non varicose veins ( $P=0.0474$ ). No significant differences were seen in the severity of intimal hyperplasia, and its SMC and elastin content between varicose and non varicose veins. No significant differences were also noted in terms of the constituents of the tunica adventitia and the elastic laminae between the two types of veins. Meanwhile, relatively high amount of cell death was observed between day 0 and day 2 of the varicose vein tissue culture, likely to be due to trauma from tissue preparation. Less cell death in the organ culture was measured when the culture medium was changed regularly than when it was not replaced at all. The presence of sodium azide 10mM in the culture medium caused the cell death to continue to increase to a significantly higher level after day 2 compared to when there was no sodium azide ( $P=0.0253$ ). No significant differences were observed in the cell death of the varicose veins when cultured with and without foetal bovine serum, and when exposed to hypoxia and normoxia.

## Conclusions

The histomorphological features between varicose and non varicose veins including the increase of SMC and decrease of elastin in the tunica media of the former were consistent with the findings from previous studies. The vein organ culture model that involved regular culture medium change was shown to be alive for up to 27 days. The model will be used to assess the *in vivo* effects of normoxia and hypoxia to varicose and non varicose veins.

## Future works

Immunohistochemistry of markers of hypoxia (carbonic anhydrase ix and glucose transporter-1) and intrinsic pathway of apoptosis (caspase 9 and bax) will be performed on the varicose and non varicose veins. Any correlation between the expressions of these markers in the veins will be sought. Using the vein organ culture model already set up, the effects of hypoxia and normoxia, with and without the presence of micronised purified flavonoid fraction (MPFF) and doxycycline, on the expressions of the apoptosis pathway genes in varicose and non varicose vein organ cultures will be assessed using polymerase chain reaction superarray.

## Paper 8.2

### THE ROLE OF DYSREGULATED APOPTOSIS AS A CELLULAR RESPONSE TO HYPOXIA IN THE PATHOGENESIS OF VARICOSE VEINS

CS Lim

Department of Vascular Surgery, Charing Cross Hospital, London, UK

## ABSTRACT

### Introduction

Hypoxia has been postulated to contribute to varicose vein formation by regulating vein wall remodelling. The identification of hypoxia-inducible factors (HIF) in varicose veins recently suggested that the HIF pathway may be involved in varicosity pathogenesis. Dysregulated apoptosis observed in varicose veins may also be regulated by hypoxia since cell cycle and apoptosis are known downstream targets of HIFs.

### Aims

The aim of the study is to assess if hypoxia regulates varicose vein wall remodelling and dysregulation of apoptosis through the HIF pathway and its downstream targets.

### Methods

Human varicose and non varicose veins obtained from surgery were stained with special stains (haematoxylin and eosin, Masson's trichrome and elastic van Gieson). Semi-quantitative histomorphological assessment was performed by two independent reviewers to assess for variations between varicose and non varicose veins. A varicose vein organ culture model was also set up. Cell death of the varicose veins cultured in different conditions including with and without regular culture medium change, with and without foetal bovine serum, with and without sodium azide 10mM, in hypoxia and normoxia, and of different time length were measured using the Cell Death Detection ELISA Plus® to determine if the tissue culture was alive.

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were observed in the cell death of the varicose veins when cultured with and without foetal bovine serum, and when exposed to hypoxia and normoxia.

### **Conclusions**

The histomorphological features between varicose and non varicose veins including the increase of SMC and decrease of elastin in the tunica media of the former were consistent with the findings from previous studies. The vein organ culture model that involved regular culture medium change was shown to be alive for up to 27 days. The model will be used to assess the *in vivo* effects of normoxia and hypoxia to varicose and non varicose veins.

### **Future works**

Immunohistochemistry of markers of hypoxia (carbonic anhydrase ix and glucose transporter-1) and intrinsic pathway of apoptosis (caspase 9 and bax) will be performed on the varicose and non varicose veins. Any correlation between the expressions of these markers in the veins will be sought. Using the vein organ culture model already set up, the effects of hypoxia and normoxia, with and without the presence of micronised purified flavonoid fraction (MPFF) and doxycycline, on the expressions of the apoptosis pathway genes in varicose and non varicose vein organ cultures will be assessed using polymerase chain reaction superarray.