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SCIENTIFIC PROGRAMME AND BOOK OF ABSTRACTS

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BOOK OF ABSTRACTS

A1 POST THROMBOTIC VEIN WALL REMODELING: PRELIMINARY FINDINGS

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Background. Post-thrombotic syndrome (PTS) is characterized by a fibrotic vein injury following deep vein thrombosis (DVT), resulting in a less compliant vein wall. We sought to quantify the change in vein wall thickness, and to determine if vein wall damage, defined as wall thickening, is worsened in patients who fail to resolve DVT by 6 months, and whether there were differences in blood or plasma levels of proteins associated with tissue remodeling.

Materials and methods. Patients presenting with suspected lower extremity DVT were evaluated. Ultrasound imaging of the lower extremity venous system was performed, and blood was collected. Patients with DVT received repeat evaluation with blood draw and ultrasound imaging at 6 months. DVT resolution was assessed using ultrasound examination. The thickness of the vein wall was quantified by ultrasound imaging in each segment affected by thrombus, and a contralateral, unaffected vein wall served as a control. mRNA was extracted from whole blood using the PAXgene system, and serum proteins were analyzed using ELISA. ANOVA or Student's t-tests were used, and a $P<0.05$ was significant.

Results. Thirty patients (10 patients with DVT resolution at 6 months, 10 patients with persistent thrombus, and 10 healthy controls) were compared. Both resolving and non-resolving DVT were associated with 1.5-1.8 fold increased vein wall thickness at 6 months (n=10-12; P=.008) as compared with non affected vein wall segments. However, the thickness of the affected segments was 1.4 fold greater in patients who had total resolution of the DVT by 6 months than in patients who had persistent chronic thrombus 6 months after presentation (N=10-12; P=0.01,). There was a 4-5 fold increased level of MMP-9 in all thrombosed groups compared with controls (n = ;$P<0.05$), while Toll like receptor-9 (TLR-9) expression was 3 fold less than controls (n = ; $P<.05$). There were no statistically significant differences in the levels of associated factors such as D-dimer, P-selectin, or inflammatory and remodeling markers such as SLC or MMP-2 by ELISA. There were no significant differences in the gene expression of CRP, MMP-2, MMP-9 or TLR-4.

Conclusions. This preliminary study suggests ongoing vein wall remodeling after DVT. At 6 months, the vein wall is markedly thickened, but this change is independent of thrombus resolution, and associated with elevated MMP-9 but not other inflammatory markers. This suggests that the vein wall damage is initiated early following thrombus formation, and persists even in the presence of total resolution.

A2 VALIDATION OF THE CAPRINI RISK ASSESSMENT MODEL IN PLASTIC AND RECONSTRUCTIVE SURGERY PATIENTS

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Background. In contrast to other surgical subspecialties, the plastic surgery literature demonstrates a paucity of research regarding the efficacy of chemoprophylaxis in venous thromboembolism (VTE) prevention. As a result, we created a consortium of three tertiary referral centers with demonstrated expertise in plastic and reconstructive surgery to perform a prospective cohort study with historic controls to examine the efficacy of low molecular weight heparin prophylaxis for VTE prevention in plastic surgery patients.

Materials and methods. A mid-term analysis of the study's control group was conducted to evaluate the incidence of VTE when chemoprophylaxis is not provided and to validate the predictive ability of the Caprini Risk Assessment Model (RAM) for VTE. Medical record review for patients undergoing plastic surgery between March 2006 and June 2008 was conducted. All patients with Caprini scores ≥ 3 having surgery under general anesthesia with post-operative hospital admission were included. Patients who received any form of chemoprophylaxis were excluded. Outcomes of interest included symptomatic DVT or PE (confirmed with imaging) within the first 60 post-operative days.

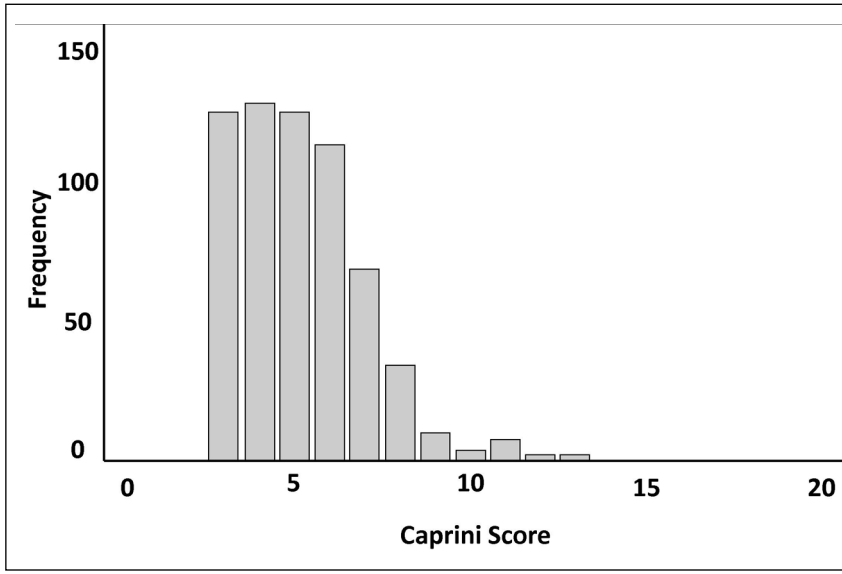

Figure 1.- Caprini Score among plastic surgery patients (N=634).

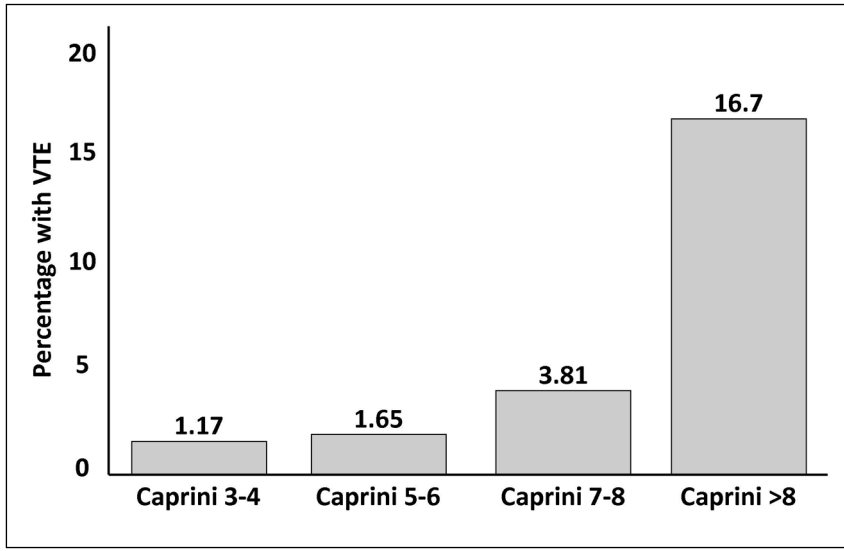

Figure 2.- Percentage of patients with VTE by Caprini Score.

Results. At present, 634 patients meeting inclusion criteria have been identified. Mean Caprini score was 5.3. VTE occurred in 16 patients (2.52%; 8 DVT, 4 PE, 4 DVT + PE) with 25% of VTE occurring between post-operative day 30 and 60. When compared to those with Caprini scores of 3-4, patients with Caprini scores of 5-6 (OR 1.41, p=.654) and Caprini scores of 7-8 (OR 3.34, p=.119) were more likely to develop VTE. Patients with Caprini scores > 8 were significantly more likely to develop VTE when compared to those with Caprini scores of 3-4 (OR 16.87, p<.001), Caprini scores of 5-6 (OR 11.95, p<.001), and Caprini scores of 7-8 (OR 5.05, p=.022). Based on preoperative risk factors, the Caprini RAM categorized 81% (13/16) patients who eventually developed VTE as "highest risk". The Caprini RAM has good discrimination for VTE in this patient population (c-statistic=0.679).

Conclusions. Plastic and reconstructive surgery patients are at notable risk for perioperative VTE and the Caprini RAM demonstrates acceptable validity in identifying those patients at greatest risk. Patients with a Caprini score > 8 are at significantly increased risk to develop VTE. A separate "maximum" risk level may be warranted for these patients in future RAMs.

A3 REQUIREMENT OF DELAYED SECONDARY PROCEDURES FOLLOWING ENDOVENOUS ABLATION

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Background. Combination endovascular laser therapy (EVL) in conjunction with phlebectomy has become the treatment of choice for superficial venous incompetence. In most cases a significant number of phlebectomies are performed to remove all visible branches. The aim of this retrospective study is to assess the effectiveness of EVL combined with minimal phlebectomies and examine the degree of patients' satisfaction with the procedure.

Materials and methods. Patients with VV initially treated with EVL and minimal additional phlebectomies (maximum 2) between January 2008 and October 2009 were retrospectively reviewed. The incidence of additional interventions was assessed. Patients were asked to subjectively rate their symptoms before and after EVL and their satisfaction with the procedure (on a scale from 1 to 5, with 5 being worse for symptoms and maximum for satisfaction.)

Results. One thousand and six limbs with VV were initially treated in 714 patients. In 811 limbs the great saphenous vein (GSV) was ablated, in 93 the small saphenous vein (SSV), in 79 an accessory vein (AV) and in 23 GSV and AV. The incidence of any additional interventions was 6.4% (65/1006 limbs.) Regarding additional procedures, in 19 cases additional EVL was performed: in 17 the SSV was ablated and in 2 EVL of the GSV was repeated because of incomplete occlusion. Forty six patients were treated with ultrasound guided sotradecol (STS) foam sclerotherapy, 72% glycerine with lidocaine and epinephrine 1:100,000, sclerotherapy, surface laser or a combination of these (17 foam, 10 foam and glycerine, 9 foam, glycerine and surface laser, 5 surface laser, 2 surface laser and glycerine, 2 glycerine and 1 phlebectomy and glycerine). In 46 cases the main reason for additional interventions was remnant veins (70% of additional interventions, 4.5% of the treated limbs) and in 19 cases it was mainly cosmetic (30% of additional interventions, 1.9% of the treated limbs). Self reported severity of symptoms was 3.9±1 and 1.7±1 before and after the procedure respectively ($p < .0001$), and reported satisfaction with the procedure was 4.6±0.3.

ConclusionS. EVL and minimal phlebectomies is an effective treatment for varicose veins. The incidence of secondary interventions is 6.4%. Reasons for reintervention are remnant veins, SSV incompetence and cosmetic. Patients report significant amelioration of the symptoms and high satisfaction with the procedure.

1.1 SURGICAL TREATMENT FOR VARICOSE RECURRENCE: IS INGUINAL REDO SURGERY JUSTIFIED?

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Background. Surgical treatment for varicose recurrence (STVR) traditionally involves removing all sources of reflux from the deep venous network to the superficial venous network. STVR is usually more complex and aggressive than first line treatment by means of stripping, particularly for inguinal redo surgery (IRS). The aim of this study is to compare the results of traditional STVR to the results of a less aggressive surgical approach focusing on treatment of the varicose reservoir (VR) avoiding IRS as often as possible.

Materials and methods. This study was a retrospective study comparing two successive periods of STVR after great saphenous vein (GSV) stripping: the first period (T1) involved traditional STVR and the second period (T2) involved STVR focusing on the VR. We reviewed postoperative complications and studied the haemodynamic and clinical results for both periods.

Results. During the entire period of the retrospective study (T1+T2), we operated on a total of 473 legs to treat varicose recurrence after GSV stripping. Overall, we operated on 288 patients (236 women and 52 men) aged between 28 and 88 (mean age 57). We operated on 137 patients during T1 and 151 during T2. There was no significant preoperative difference between T1 and T2 in terms of demographic data, CEAP classification and the Venous Disability Score. There was inguinal reflux in 73.9% of cases during T1 and in 74.4% of cases during T2. We performed IRS in 69% of cases during T1 and in only 2.6% of cases during T2 ($P<0.05$). We did not use foam sclerotherapy in addition to STVR in any cases during T1 and T2. The postoperative complications rate was higher during T1 than during T2 (4% versus 0.5%, $p<0.05$), particularly due to the frequency of inguinal complications. After 3 years of follow-up, there was no significant difference for patients operated on during T1 or T2 with regard to the rate of iterative varicose recurrence (9.6% versus 8.6%), the absence of inguinal reflux (90.4% versus 91.7%) and levels of patient satisfaction (85.5% versus 93.5%). On the other hand, patients operated on during T2 had better results in terms of the Venous Disability Score (0.36 versus 0.57, $p=0.02$) and cosmetic improvement (93.5% versus 81.3%, $p<0.05$).

Conclusion. STVR focusing on the VR and avoiding IRS led to a reduction in postoperative complications with good clinical and haemodynamic results in the medium term, particularly in terms of improvements to symptoms and cosmetic appearance, compared to traditional STVR with IRS.

1.2 QUALITY ASSURANCE OF VENOUS DUPLEX SCANS PERFORMED BY A VASCULAR SURGEON

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Background. Duplex scanning is recognised as the 'gold standard' method of investigating venous reflux and ideally should be performed pre-operatively in all patients with varicose veins. Traditionally, Duplex scanning is performed by vascular technologists, but increasingly UK vascular surgeons are performing Duplex scans themselves. Vascular technologists are trained over a three year period during which they follow a defined curriculum and undergo regular competency assessments. The training period for surgeons is, by necessity, much shorter and usually takes the form of intensive training courses. Clearly, the quality of venous scans performed by surgeons should be comparable to those performed by the technologists. To our knowledge there has been no data published analysing the accuracy of consultants' scans.

Aims. This study aims to compare venous Duplex scans performed by one consultant vascular surgeon with those performed by clinical vascular scientists.

Materials and methods. We prospectively assessed 50 legs with symptomatic varicose veins. Each patient underwent two lower limb venous Duplex scans; one performed by a consultant vascular surgeon in the outpatients clinic and one by a vascular technologist in the vascular laboratory. The scan results were randomly assigned to report 1 or report 2 for each patient. The results were sent to two consultant vascular surgeons along with information about age, comorbidities, symptoms and previous varicose vein surgery. They recommended treatment based on each separate report. For each assessor, a kappa score was calculated to measure the level of agreement between the two sets of scans.

Results. 44 patients were enrolled in the study and 30 (68%) were female. The mean age of the patients was 47.7 years (range 16-81). All varicose veins were C1-C6 (CEAP classification). The mean interval between Duplex scans was 37.5 days. Maximum unweighted kappa scores were 0.68 (substantial agreement) for the first assessor and 0.81 (almost perfect agreement) for the second assessor.

Conclusions. In this instance, the lower limb venous Duplex scans performed by the consultant were comparable to those performed in the laboratory. The study needs to be expanded to involve other vascular surgeons in order for more generalised conclusions to be drawn. In this era of competency based assessments, we propose standardisation of training for vascular surgeons wishing to perform Duplex scans to ensure the highest level of care is delivered to patients.

1.3 ANALYZING EXHALED BREATH DURING ENDOVENOUS LASER ABLATION OF VARICOSE VEINS USING AN ELECTRONIC NOSE AND GAS CHROMATOGRAPHY-MASS SPECTROMETRY

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Background. Endovenous Laser Ablation (EVLA 980nm) is a common therapy for the treatment of varicosis veins. During this procedure the temperature of the tissue and blood remaining in the vein can reach temperatures of over 800°C. This causes release of steam bubbles and gases. Notably, during and after EVLA most patients described a barbeque-like taste. Also the surgeon can smell an indistinct odour although the endovenous treatment is inside the patient.

Objective. We hypothesized that the exhaled breath molecular profile changes during the EVLA procedure. Exhaled breath contains thousands of volatile organic compounds (VOC's) in gaseous form. The electronic nose (Cyranose 320) can distinguish VOC mixtures in exhaled breath by pattern recognition, called a "breathprint." Specific analysis using gas chromatography-mass spectrometry (GC-MS) can identify and quantify the individual VOC's.

Materials and methods. In twelve patients the EVLA 980nm was performed. (M/F 2/10, age 36/74 and CEAP (C2-C3). Fifteen minutes before the EVLA, patients were asked to breath for five minutes through a non-rebreathing valve with nose clip. One final single vital capacity manoeuvre was done to collect an exhaled air sample in a Tedlar bag. The same procedure was repeated during the actual EVLA procedure. In two patients, GC-MS was performed in exhaled breath samples collected from the Tedlar bags before and during the treatment. Patients recorded their taste during the procedure. Breathprints were analysed by principle component reduction followed by paired t-testing.

Results. Breathprints differed between samples obtained before and during EVLA ($p=0.02$). However there was no relationship between detecting a barbeque-like taste and analyzing a difference between de paired samples ($p>0.09$). The GC-MS results showed a difference in VOC profile; 16 compounds were identified that showed a concentration elevation of at least a factor of two.

Conclusion. Electronic nose assessment detects a difference in exhaled breath molecular profile before and during the EVLA procedure. Compounds identified during EVLA by GC-MS were mainly unsaturated hydrocarbons and a few aromatics.

Clinical implication. This small pilot study suggests that EVLA produces pyrolysis products that can be captured in exhaled air. The health implications of such compounds are as yet unknown.

1.4 PHARMACODYNAMIC DIFFERENCES BETWEEN BIOSIMILAR AND BRANDED ENOXAPARINS WITH REFERENCE TO THEIR IMMUNOGENIC PROFILE

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Background/aims. Low molecular weight heparins are complex mixtures of sulfated oligosaccharides produced by depolymerization of porcine mucosal heparin. The depolymerization process inflicts a variety of structural modifications, which are process-dependent. The objective of this study was to compare branded enoxaparin with bio-similar enoxaparin in healthy human volunteers for pharmacodynamic equivalence.

Materials and methods. Individual groups of volunteers (n=110) were administered test agent at doses of 40 mg OD SC for 10 days and blood samples were collected at baseline and after 1, 3, 7, and 10 days. Hemostatic parameters such as aPTT, anti-Xa, anti-IIa and TFPI release were measured. In addition, anti-heparin-PF4 antibodies were measured using two commercially available assays (GTI and Hyphen Biomedical). The antibody subtype (IgG, IgA, IgM) was determined using an assay from Hyphen Biomedical.

Results. No significant differences in the various hemostatic parameters were noted. The prevalence of positive antibody titers was different between assays, but not between treatment groups. The titer of anti-heparin-PF4 IgG antibodies was higher following bio-similar enoxaparin treatment (0.37 ± 0.21) compared to following branded enoxaparin treatment (0.21 ± 0.11). The relative proportion of IgG positive samples was also different in the two groups.

Conclusion. These studies suggest that bio-similar enoxaparin produces a different immunogenic profile than branded enoxaparin. These studies warrant larger trails to establish differential behavioral bio-similar/ branded LMWHs.

1.5 MICROFOAM SCLEROTHERAPY AS A PART OF MULTIMODALITY TREATMENT IN PATIENTS WITH VENOUS MALFORMATIONS

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Objective. To assess the efficacy of multimodality treatment in patients with venous malformations.

Materials and methods. The study included 96 patients with venous malformations (VM) of different localization: head and neck lesion (18.2%), upper (20.9%) and lower (46.4%) limbs lesions, body lesions (4.5%), pelvis and pudenda lesions (1.8%) and of mixed localization (8.2%). 72 patients underwent surgical treatment and in 24 cases surgical treatment was combined with sclerotherapy. When appropriate compression was not possible (face, neck) we helped with absolute alcohol obliteration of the lesions. Cabrera technique (3% ethoxisclerol solution) was used for limbs and body veins. Compression adhesive bandaging was applied to all patients. Patients having signs of lower limbs chronic venous insufficiency were assessed in terms of CVI stage (CEAP) before and after such treatment.

Results. Multimodality treatment provided immediate success in 92.6%. New foamform medication allowed to increase both the efficacy and safety of sclerotherapy in consequence of significant decrease of medication quantity used. Surgical treatment combined with minimally invasive techniques (sclerotherapy mainly) provided 1.5 fold increase of positive long-term outcomes rate in multimodality treatment group in comparison with surgical treatment group (62.5% and 38.9% relatively, p=0.04, chi-square test).

Conclusion. Sclerotherapy provides safe and effective obliteration of residual caverns despite surgery excellence in malformed tissue removal. It is necessary to use absolute alcohol for obliteration when appropriate compression is not possible. Foam sclerotherapy is considered to be safe and effective method of superficially located malformed vessels and caverns treatment.

2.1 REPRODUCIBILITY OF LOWER LIMB VENOUS REFLUX ASSESSED BY ULTRASOUND DUPLEX SCANNING USING MANUAL AND PNEUMATIC CUFF COMPRESSION IN PATIENTS WITH CHRONIC VENOUS DISEASE AND CONTROLS

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Purpose. The objective was to evaluate the reproducibility of deep venous reflux assessed by duplex ultrasound, using either manual or pneumatic cuff compression in the standing position. Furthermore, the two methods were compared to each other by either using immediate 'eyeballing' or direct measurements of reflux time from Doppler flow curves. Reproducibility of examination of different vein segments was assessed.

Materials and methods. Between April 2008 and July 2009 deep venous valve function was studied in 40 individuals, 20 patients with a previous history of deep venous thrombosis (DVT) treated with warfarin and 20 healthy persons with no prior history of venous disease. Both limbs were examined at the common femoral vein (CFV), the femoral vein (FV), and at the popliteal vein (PV). Examination was performed by two investigators using both manual calf compression and pneumatic cuff compression. A reflux time above 0.5 seconds in the FV and PV was pathological whereas the cut off value was 1 second in the CFV. At every examination, the investigator made an immediate estimate ('eyeballing') of whether reflux was present or not. Additionally, every Doppler curve was analysed more thoroughly after the clinical examination, measuring the exact reflux time and this was compared to the 'eyeballing' result. The inter-observer agreement was expressed as the Cohen's kappa-coefficient.

Results. As every person was examined in 3 venous segments bilaterally (CFV, FV, and PV) with two different methods (manual and pneumatic cuff) by two investigators, a total of 960 measurements of reflux time were recorded. The overall inter-observer agreement between the two investigators using manual compression was 0.76 [CI: 0.64;0.88] and 0.81 [CI: 0.71; 0.91] when using the pneumatic cuff. Comparing manual and cuff compression resulted in a Kappa-coefficient of 0.83 [CI: 0.77; 0.89]. 'Eyeballing' compared to direct measurements of reflux time from Doppler flow curves showed a high level of reproducibility with a Kappa-coefficient of 0.92 [CI: 0.89; 0.95]. At the common femoral vein, the inter-observer agreement was 0.77 [CI: 0.62; 0.92], at the femoral vein it was 0.67 [CI: 0.52; 0.82], and at the popliteal vein it was 0.88 [0.80; 0.96].

Conclusion. No significant difference between manual and cuff compression was found in diagnosing reflux in the deep veins in the standing position. Reproducibility was similar between two experienced ultrasound investigators. Immediate 'eyeballing' provides a quick subjective evaluation of reflux but may underestimate reflux duration. The inter-observer agreement of reflux measurements with regard to anatomical variation demonstrated the highest level of agreement at the popliteal vein.

2.2 PERFORATOR INCOMPETENCE AND ASSOCIATED PATTERNS OF SAPHENOUS REFLUX IN PRIMARY CHRONIC VENOUS DISEASE

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Objective. To determine the relationship between perforator incompetence and patterns of reflux in saphenous and deep veins in patients with primary chronic venous disease (CVD).

Materials and methods. Venous duplex ultrasonography reports of all patients presenting with signs/symptoms of CVD between 1st January 2000 and 31st August 2009 in a single Vascular unit were reviewed. Limbs with evidence of secondary CVD (congenital, recurrent, or post thrombotic), no abnormal findings, or incomplete data were excluded. The presence of venous reflux at saphenofemoral or saphenopopliteal junctions, great saphenous vein (GSV), small saphenous vein (SSV), thigh and calf perforator veins was recorded. Venous incompetence was defined as retrograde flow >0.5s after calf compression. Patients were classified as having no perforator incompetence (PI), calf PI, thigh PI or calf and thigh PI.

Results. Over the study period, 8654 legs were scanned, of which 4020 were eligible for inclusion and analysed (2888 patients; 1084 male, 1804 female; mean limb age 54 years, range 12-101). PI was present in 1042/4020 (25.9%) of legs, the majority of which had calf PI alone (820/1042, 78.7%). Thigh PI was seen in 145/1042 (13.9%) and both thigh and calf PI was present in 77/1042 legs (7.4%). Deep venous incompetence was present in 1146/4020 (28.5%) and the incidence of PI was significantly greater in these patients compared to patients with competent deep veins (769/1146 *versus* 273/2874, $p<0.001$, Chi Square test). The majority of patients with PI had incompetence of the GSV (904/1042, 86.8%).

Conclusions. Perforator incompetence is more likely in the presence of deep vein reflux and is associated with GSV reflux in the vast majority of patients with primary CVD. Further studies are needed to define which of these patients would benefit from perforator procedures, rather than GSV ablation alone.

2.3 LOWER LIMB VENOUS BLOOD FLOW BY MAGNETIC RESONANCE IMAGING DURING INTERMITTENT PNEUMATIC COMPRESSION OF THE CALF AND FOOT

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Aim. To investigate the potential of magnetic resonance imaging (MRI) for measuring venous flow and velocity. Also to establish the contribution of each of the foot and calf components of an intermittent pneumatic compression (IPC) device and their combination to the venous flow per IPC cycle.

Background. Venous velocity and flow measurements can predict the optimal stimulus for devices preventing venous thromboembolism (VTE). The real-time MRI venous flow imaging was validated against a standard clinical flow sequence in deep calf veins in normal subjects. We present the first direct MRI venous flow measurements during Intermittent Pneumatic Compression (IPC) [ArtAssist AA-1000e®, ACI Medical, USA].

Materials and methods. Normal subjects (6 male, 6 female, ages 28 – 82) lay supine for MR scanning (1.5T Siemens Avanto). The foot and calf cuffs of the ArtAssist were applied to the right leg and a receiver coil was wrapped lightly above the knee. Venous flow imaging (range ±10 cm/s) measured baseline flow before starting IPC. Imaging during three compression cycles (200 images each 310 ms at 1mm resolution) was repeated with velocity ranges ±30, ±60, ±90 cm/s, repeated again with only calf compression and finally only foot compression. The venous flow driven by each IPC cycle was summed from 25 images, starting 10 images before the peak.

Results and discussion. In two subjects, large secondary veins diverted flow from the measured vein, and a potential advantage of MRI is that all flow through the slice could be analysed from these images. A complex spatial distribution of flow over the venous area was sometimes seen, which may affect ultrasound flow accuracy. The wide range of velocities between subjects could be handled efficiently in future using software available for MRI-guided surgery. In some cases, arterial blood flow was reversed briefly by the calf cuff inflation.

Table I.- Median flow volume per IPC cycle, and the peak pixel velocity in the vein.

	IPC off	*IPC both cuffs*	*IPC calf cuff*	*IPC foot cuff*
Flow per IPC cycle (ml/cycle)	4.1	16.7	16.6	6.9
Range (min, max) (ml/cycle)	1.5-9.1	9.5-41.4	9.2-44.5	4.6-18.6
Peak velocity (cm/s)	3.7	66.6	63.9	12.0
Range (min, max) (cm/s)	2.3- 6.2	36.0-90.5	39.4-102.0	5.3-25.1

Conclusions. This first demonstration of venous flow MRI during IPC showed that the foot cuff delivered ≈25% of the supine flow. The foot and calf compression in combination had no improvement of the venous flow versus the calf compression on its own. These findings may have implications on the design of the IPC

2.4 TISSUE PRESSURES IN VENOUS DISEASE

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Background. Raised venous pressure directly influences the microcirculation and leads to increased vessel wall permeability resulting in extravasation and increased interstitial tissue pressure. Since both primary and secondary varicose vein disease as well as chronic venous obstruction leads to increased venous pressure this study was undertaken to evaluate the relationship between tissue pressures and various venous pathologies and their severity.

Materials and methods. Tissue pressures were measured in both subcutaneous and intramuscular compartments of the lower limb in 10 healthy legs, Group A, 18 legs with primary varicose veins (C 2-4), Group B, 45 legs with primary varicose veins (C 5-6), Group C, 12 limbs with secondary varicose veins, PTS (C 2-4),Group D, 26 limbs with secondary varicose veins, PTS (C 5-6), Group E, and 8 legs with chronic iliac vein obstruction, Group F, prior to any treatment. Measurements were performed in standing position and in the non-weight bearing limb. A 19-gauge needle was connected via a saline-filled tubing to a pressure transducer and recorder. The needle was first introduced into the subcutaneous tissue, 25 cm below the knee joint. Pressures were measured at rest during 4 minutes (steady state) and thereafter pushed into the posterior muscle compartment and intramuscular tissue pressures were recorded.

Results: Results are shown in the Table I. Subcutaneous tissue pressures were higher in all groups compared to healthy limbs, $p<0.001$. The more severe the disease the higher was the s.c. tissue pressure. The intramuscular tissue pressure was significantly higher in Group C-F, $p<0.001$ and Group E had significantly higher i.m. pressures compared to Group C. Group F had the highest i.m. pressures of all groups.

Table I.- Results.

Groups/Tissue pressure	*A Normal limbs*	*B Primary VV (C 1-4)*	*C Primary VV (C 5-6)*	*D Secondary VV (C 2-4)*	*E Secondary VV (C 5-6)*	*F Chronic iliac Vein obstruction*
N. limbs	10	18	45	12	26	8
Subcutaneous tissue pressure, mmHg Mean ± SD	0.2±1.2	7.8±3.2	9.4±2.7	14.2±4.3	17.2±9.1	15.6±8.1
Intramuscular tissue pressure, mmHg Mean ± SD	9.2±4.9	12.2±4.2	21.0±4.0	15.9±4.9	28.4±6.2	34.1±8.1

Conclusions. The subcutaneous tissue pressure is significantly elevated in limbs with symptomatic varicose veins, and increases with disease severity. The highest i.m. tissue pressure was seen in obstructive venous disease, but was also significantly increased in C 5-6 patients more importantly in the C5-6 post-thrombotic limbs. An excellent correlation between tissue pressures and disease severity was documented.

2.6 STEAM ABLATION OF SAPHENOUS VARICOSE VEIN: A PROMISING NEW ENDOVENOUS THERMAL THERAPY

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Introduction. Over the last decade, thermal ablation techniques such as endovenous laser ablation have been challenging the position of traditional surgery for the treatment of saphenous varicose veins. The newest method of thermal ablation is steam, which works by heating the vein with high-pressure steam at 120° Celcius.

Aim. To assess the effectiveness of endovenous steam ablation of varicose veins in animal and human subjects.

Materials and methods. In sheep, the safety of the procedure was assessed by cardiovascular monitoring during treatment. We used ultrasound to examine occlusion of the veins, and changes in treated veins were examined microscopically. In a pilot study, 20 human patients with insufficiency of the great or the small saphenous vein were treated with steam ablation. Anatomical success, patients' satisfaction and complications were investigated 1 week and 3 months after the procedure.

Results. All veins in the sheep were occluded; there were no cardiovascular changes during treatment. Histological examination of treated veins showed typical changes of the vein wall, such as disappearance of the endothelial layer, fibrotic thrombosis, and major alterations in collagen fibers in the media. In the 20 patients the steam ablation was successful; all veins were completely closed after 3 months of follow-up. Nine of 20 patients had some ecchymoses at the puncture site, 1 patient had a transient superficial phlebitis, and a mean maximal pain score of 2,1 (0-10) was reported. No serious side-effects such as deep vein thrombosis, nerve injury, skin burns, or infections were reported. Patients were very satisfied about the treatment with a mean satisfaction score of 9,1 (0-10).

Conclusions. In this study, steam ablation was a safe and effective treatment for saphenous varicose veins and was highly appreciated by patients. Steam ablation is promising, but should be compared in a prospective randomized trial with the common endovenous thermal therapies, such as EVLA, which is the new gold standard, or radiofrequency ablation.

3.1 PERIOPERATIVE BRIDGING THERAPY IN SURGICAL PATIENTS WITH HIGH RISK OF THROMBOEMBOLIC AND HAEMORRHAGIC COMPLICATIONS ON LONG TERM ACENOKUMAROL THERAPY

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Patients with mechanical valve, chronic atrial fibrillation, thrombophilia with high risk of thromboembolic complications require long term anticoagulant therapy. Perioperative bridging therapy reduces the risk of thromboembolic and haemorrhagic complications. In some European countries, Poland included, the drug used in secondary antithrombotic prophylaxis is acenokumarol (not considered in ACCP guidelines). The aim of the study is to present our own experience in perioperative bridging therapy for surgical patients at high risk of thromboembolic complications on long term acenokumarol therapy (AK).

Materials and methods. Within the period 2002-2009, the following patients, all on long term AK, underwent elective surgery: 42 patients with inherited thrombophilia (IT), 21 with antiphospholipid syndrome (APS), 17 with chronic atrial fibrillation, 9 with mechanical valve. All were on long term acenokumarol doses which maintained INR values within 2,0-3,5. Two days prior to elective surgery AK was interrupted and since that day half of the individual therapeutic dose of LMWH was administered. On surgery day, the therapeutic dose was divided into two parts. The first part was administered 2 or 12 hours prior to surgery, the second 6-12 hours following surgery (depending on the type of anesthesia). Starting with first day after surgery, the patient was given half of the individual dose of LMWH every 24 hours. On post operation day four, AK was additionally included. Both drugs (LMWH and AK) were administered until stabilization of INR values within 2,0-3,5 for two consecutive days. LMWH was then interrupted while AK continued. In the perioperative period all patients used pneumatic sleeves with gradual pressure release and/or elastic bands; following discharge, antithrombotic knee-socks or tights were recommended.

Results. In the 6 month observation period no symptoms or episodes of VTE were reported in physical examination or in color Doppler imaging. No perioperative or postoperative haemorrhagic complications were observed.

Conclusions. Results suggest that the our perioperative bridging therapy is safe and effective for prevention of thromboembolic and haemorrhagic complications in patients with high risk of thromboembolism on long term acenokumarol therapy.

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

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Aim: The purpose of this study was to evaluate whether 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.

Materials and methods: In this trial, 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 recanalized when it was compressible with gentle transducer pressure. The incidence of symptomatic recurrent venous thromboembolism (VTE) and major bleeding were also analysed. Statistical analysis (SPSS v.11): Chi-square o Fisher test for categorical variables and the log-rank test were 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.

3.3 A TEN YEAR EXPERIENCE OF RETRIEVABLE INFERIOR VENA CAVA FILTERS

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Objectives: To review a single centre experience with retrievable inferior vena cava filters (IVC) over a 10 year period.

Materials and methods. A retrospective database of all IVC filters inserted between 1998-2008 was analysed. Patient demographics, indications for filter insertion, complications, use of anticoagulants and retrieval times were recorded. A literature search was performed for recommendations and guidelines regarding management of patients with IVC filters.

Results. The Gunther Tulip (Cook) IVC filter was used in a total of 112 patients (median age 66 (range 22-91), 58 females: 54 males). Median follow up was 60 (range 6-120) months. Indications for use of a filter included: (i) in patients with established venous thromboembolism (VTE) and a contra-indication or complications to anticoagulation (n=105, 94%) or (ii) in patients considered high risk for VTE despite adequate anticoagulation (n=7, 6%). The majority of filters (n=109, 97%) were placed in the infra-renal vena cava. Tilting of the filter at the time of insertion was the most common complication (n=7). In 45(40%) patients, filters were inserted for peri-operative cover and would all have been suitable for removal post-operatively. Filters were only retrieved in 6(13%) of these patients at a median time of 19 (7-42) days after insertion. Two of the temporary filters could not be retrieved due to difficulty while attempting to retrieve them. There were, however, no reports of adverse events associated with leaving filters in situ. Recommendations are published by the (ACCP) American College of Chest Physicians (8^{th} Edition) and the British Committee for Standards in Haematology (BCSH) regarding indications, contraindications and use of concomitant anticoagulants with IVC filters. These suggest the use of IVC filters when anticoagulation is not possible. Patients with acute deep vein thrombosis or pulmonary embolism with IVC filters are recommended to receive a conventional course of anticoagulant therapy as soon as the risk of bleeding resolves. There are however no guidelines available for the follow up of IVC filters to monitor complications and the recommended times of filter retrieval. The recommendations for uncommon but critical groups of patients e.g. the pregnant patients who may need IVC filters are still weak.

Conclusions. Only a small proportion of IVC filters were removed in the present series. Failure to retrieve "temporary" IVC filters appears to be low-risk. There was however no long-term follow-up plans to monitor patients who still had filters in situ. Closer follow-up of patients is required to determine whether removal should be mandatory. Although broad guidelines for the use of IVC filters are available these need to be expanded.

3.4 TOWARDS A BETTER UNDERSTANDING OF INFERIOR VENA CAVA ATRESIA

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Introduction. Inferior vena cava atresia (IVCA) is a rare vascular anomaly. In literature only case reports or small series have been published on this subject.

Aim. The aim of the study is to better understand pathophysiology, clinical presentation and complications of IVCA in view of optimizing detection, diagnostic work-up and treatment of these patients.

Material and methods. A retrospective cohort study was performed in 2 stages. First, a review of the literature was performed by means of a computerised Medline search of English-language reports on IVCA published during the period 2000 – 2010. Second, a questionnaire was sent to all members of the Benelux Society of Phlebology and the Belgian Society of Vascular Surgery to collect data about their patient(s) with IVCA. Data on age, gender, medical history, thromboembolic complications, clinical presentation of venous insufficiency, diagnostic tools and strategy, presence of underlying thrombophilia and actual treatment were collected and compared between groups.

Results. Data of 64 patients were collected. The literature search resulted in 39 included cases (group A) and the survey in the Benelux in 25 cases (group B). In total 73% of patients were male (n=47). The mean age was 26 ± 12 yr in group A and 39 ± 15 yr in group B *(p=0.001)*. At the time of diagnosis of IVCA, the mean age was 26 ± 12 yr in group A and 35 ± 14 yr in group B *(p=0.009)*.

Diagnosis of IVCA was made at the occasion of a DVT (unilateral or bilateral) in 83% of cases. Pulmonary embolism was rare (n=3). Diagnostic work up included duplex sonography (75%) or phlebography (34%) and CT scan (88%) in most cases. Magnetic resonance angiography was more frequently used in published cases (41% in group A). Thrombophilia was diagnosed in 28% of patients in group A and in 44% in group B *(n.s.)*. In total 14 patients of 64 (22 %) underwent invasive treatment (thrombolysis and/or stenting). At the moment of the survey in group B 12 of 25 patients (48 %) suffered from advanced clinical stage (C4-C6), whereas in group A there were only 2 patients with C4-C6 *(p=0.0001)*. Compression stockings were used in 72% and long-term oral anticoagulant drugs in 76% of patients of group B.

Conclusions. IVCA is a rare disease affecting predominantly male patients. Diagnosis is usually made at young age, at the occasion of a DVT, often in association with thrombophilia. Follow-up of IVCA patients in 'real life' reveals an unfavourable evolution towards severe chronic venous insufficiency. Early diagnosis, not only by means of duplex ultrasound but by using additional diagnostic tools and invasive treatment of iliofemoral DVT as well as adequate surveillance is very important in these patients.

3.5 STENTING FOR CHRONIC POSTTHROMBOTIC VENA CAVA AND ILIOFEMORAL VENOUS OCCLUSIONS. MIDTERM PATENCY AND CLINICAL OUTCOME

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Objectives: The aim of this study was to determine the mid-term patency and the clinical outcome after stenting chronic occluded caval and iliofemoral venous segments.

Design: an observational study.

Material and methods. Between 2000 and 2009, 2 400 patients with severe CVI were initially evaluated with colour duplex ultrasound (CDU) and ambulatory venous pressure measurement. Fifty nine patients with severe symptoms including venous claudication, oedema, pain and leg ulcer suggesting venous outflow impairment were further investigated with ascending venography (AV), venous occlusion plethysmography (VOP), venous pressure gradient (VPG) and CT venography or transfemoral/popliteal venography. The severity of these symptoms rendered these patients incapable of functioning at work and/or in other physical activities, representing a clear indication to attempt endovascular treatment. Twenty five patients were found unavailable to endovascular treatment due to the extension of the postthrombotic occlusion to the popliteal level that precluded adequate inflow possibilities. The other 34 patients showed to have chronic venous occlusions after DVT with open popliteal and caudal superficial femoral veins, and were chosen for treatment. This group that constitutes the material of our study was then categorized according to the CEAP (clinical-etiological-anatomical-pathophysiological) classification for chronic venous insufficiency. And the severity of symptoms quantified by using the VCSS (venous clinical severity score). The median age was 41 years (15-63) and 19 were females. The time elapsed after the last DVT episode varied with a median of 108 months (9-420). Seventeen patients (50 %) had a thrombophilia (APC resistance, protein C or S deficiency and homocysteinemi). The major symptoms were: venous claudication in 27 patients, oedema in 24, pain in 21 and leg ulcer in seven.

All patients were treated with stenting. Self-expanding stents were deployed in 22 iliofemoral, nine iliac and one caval-iliac-femoral. Twenty one procedures required stenting across the inguinal ligament.

Results: Primary recanalisation was accomplished in 32/34 (94%). The median follow-up was 33 months (1-96) with clinical examination, CDU and VOP. Two year primary patency was 14/21(67%) primary-assisted patency 16/21 (76 %) and secondary patency was 19/21 (90 %). Venous claudication and oedema resolved in those successfully recanalized. Four of seven ulcers healed.

Conclusions: Stenting to treat venous claudication, oedema and recurrent venous ulcer caused by postthrombotic chronic venous occlusions has positive clinical outcome and good mid-term patency.

3.6 ANATOMICAL VARIATIONS OF THE FEMORAL VEIN

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Background. The venous anatomy is highly variable. This is due to possible venous malformations (minor truncular forms) occurring during the late development of the embryo.

They are producing several anatomical variations in the number and caliber of the main venous femoral trunks at the thigh level.

Aims. To study the prevalence of the different anatomical variations of the femoral vein at the thigh level.

Material and methods. 336 limbs of 118 fresh, non embalmed cadavers were used for this study.

The technique used washing of the whole venous system, latex injection,anatomical dissection and then painting of the veins.

Results. The modal anatomy of the femoral vein was found in 308 / 336 limbs (88%).

Truncular malformations were found in 28/336 limbs (12%): Unitruncular configurations in 3% (axo femoral trunk 1% and deep femoral trunk 2%). Bitruncular were found in 9% (Bifidity of the femoral vein 2%, femoral vein with axio-femoral trunk 5%, femoral vein with deep femoral trunk 2%)

Conclusion. Truncular venous malformations of the femoral vein are not rare (12%).

Their knowledge is important for the investigation of the venous network, particularly the venous mapping of patients with CVD. It is also important to recognize a bitruncular configuration to avoid potential errors for the diagnosis of deep venous thrombosis of the femoral vein, in the case of an occluded duplicated trunk.

4.1 A PROPSPECTIVE RECOVERY STUDY AFTER HIGH LIGATION AND STRIPPING OR ENDOVENOUS TREATMENT OF THE INSUFFICIENT GREAT SAPEHNOUS VEIN USING LOCAL ANAESTHESIA

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Background. High ligation and stripping (HL/S) is considered to be the 'gold standard' in the treatment of the incompetent great saphenous vein (GSV). During the last decade endovenous treatments, such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA), have become popular alternatives. In our clinic a RCT, comparing HL/S with EVLA ELVeS® 980nm, showed equal efficacy after both treatments but also significantly more pain after EVLA at day 7, 10 and 14. From our experience we hypothesized that VNUS ClosureFast and EVLA ELVeS® RADIAL 1470nm would be less painful and show less hindrance postoperative.

Objectives. The aim of this study was to compare prospectively postoperative pain and quality of life after HL/S, EVLA ELVeS® 980nm, EVLA ELVeS® RADIAL 1470nm, and VNUS ClosureFast, using local anaesthesia only.

Materials and methods. Consecutive patients completed questionnaires immediately after treatment. Pain was scored at day 1, 2, 3, 7, 10 en 14 in a visual analogue scale (VAS 1-10). Quality of life was scored at the same days in a 0-2 score, using the EuroQuol5 questionnaire. Inclusion criteria were: insufficient GSV, length of the GSV >15 cm, diameter GSV ≤1,5 cm, CEAP 2-5. Statistical analysis was performed using ANOVA, Mann-Whitney, and t-tests.

Results. Three hundred and ten questionnaires were distributed, 266 (86%) were completed: 68 HL/S , 62 EVLA ELVeS® 980 nm, 51 EVLA ELVeS® RADIAL 1470 nm, 85 VNUS ClosureFast. Groups were homogenous for demographic characteristics such as age, gender, length of treated vein and CEAP. All procedures were performed under local tumescent anaesthesia and were well tolerated. Postoperative pain was significantly less after the VNUS ClosureFast procedure compared to the other treatments. The intensity of postoperative pain was significant and most explicit in the second week after the EVLA ELVeS® 980nm procedure. QoL results were most favourable in the VNUS ClosureFast group. After VNUS ClosureFast as well as after EVLA ELVeS® RADIAL 1470 nm patients resumed daily activities after ±1.4 days (mean). After HL/S and EVLA ELVeS® 980 nm the interval was ±3,2 days (mean). Return to work was significantly faster after VNUS ClosureFast and EVLA ELVeS® RADIAL 1470nm (mean ±2,9 days) compared to ±4,2 days after HL/S and EVLA ELVeS® 980nm. In each group ±80% of the patients were willing to undergo the same treatment again if necessary.

Conclusions. Treatment of the insufficient GSV using the VNUS ClosureFast procedure and the EVLA ELVeS® RADIAL1470 nm cause less postoperative pain and better QoL results compared to HL/S and EVLA ELVeS® 980 nm.

4.2 ENDOVENOUS LASER TREATMENT: IS THERE A DIFFERENT CLINICAL AND MORPHOLOGICAL OUTCOME USING A 1500NM LASER VERSUS A 980 NM DIODE LASER? A MULTICENTRIC RANDOMISED COMPARATIVE TRIAL

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Objective. In this trial we compared the use of two different laser wavelengths in the treatment of great saphenous vein(GSV) reflux: the 1500nm versus the 980nm diode laser. We studied the occlusion rates at one month and six months postoperatively and noted possible side-effects.

Materials and methods. In 3 centers 180 great saphenous veins were treated with endovenous laser ablation (EVLA). Randomly half of the patients were treated with a 980nm laser and half with a 1500nm laser. They were treated according to the same continuous retraction protocol. The difference was the applied laser wavelength and the delivered energy. A duplex-scan was scheduled at one month and six months postoperatively. Ecchymosis was measured at one week using a calculated scale. Further the need for analgetics, the induration around the treated vein and patient satisfaction rate were noted. At two week postoperatively a quality of life score (CIVIQ2) was done.

Results. The used energy was on average 48 J/ cm and 72.2 J/ cm respectively using a 1500 nm and 980 nm laser. The complete occlusion rate at 6 months was 95,5% (980 nm) and 93,1%(1500 nm) which means no statistical significant difference between both groups. Most of the non-occluded veins had a filiform internal lumen and didn't show reflux while performing a Valsalva-maneuver. There was no significant difference in the postoperative appearance of ecchymosis (p=0,09). Veins treated with a 980 nm laser had more induration around the treated vein (p=0,002). Patients treated with a 1500 nm laser had less need to take analgetics (1,8 days versus 2,9 days) and had a better postoperative quality of life(p=0,018). The patient satisfaction rate was not different in both groups.

Conclusions. Using a 1500nm diode laser in the treatment of an incompetent GSV, compared to the use of a 980 nm laser, results in similar occlusion rates at six months. Patients have less need to take analgetics and have a better postoperative quality of life.

4.3 RANDOMISED CLINICAL TRIAL COMPARING VNUS CLOSURE FAST VERSUS LASER FOR VARICOSE VEINS (VALVV): DUPLEX AND QUALITY OF LIFE OUTCOMES AT 6 MONTHS.

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Objective. Early results from the VALVV trial showed that outcomes after segmental radiofrequency ablation (RFA) and laser ablation (EVLA) were comparable at 6 weeks. The aim of this study was to compare technical success, quality of life outcomes and disease severity at 6 months following RFA and EVLA.

Materials and methods. Consecutive patients with great saphenous vein (GSV) reflux were randomised to receive EVLA or RFA. Patients were reviewed at 6 months when clinical disease severity was assessed using the VCSS and quality of life was evaluated using the Aberdeen Varicose Vein Questionnaire (AVVQ).). Abolition of reflux was assessed using colour duplex by an accredited vascular scientist. Great saphenous veins were classified as: Complete ablation; ablated above the knee only or failed ablation. Veins successfully ablated above the knee were ultimately considered successes. Analysis was on intention to treat. (ISRCTN66818013).

Results. Of 131 randomised patients, duplex scans performed at a median (IQR) of 27 (25-29) weeks following the procedure were available for 107 patients (81%) (RFA n=55, EVLA n=52). There were a total of 9 treatment failures (RFA n=6, EVLA n=3) either due to recanalisation of the above knee segment of the GSV (RFA n=5, EVLA n=1) or failure to ablated the refluxing GSV segment above the knee (RFA n=1 EVLA n=2). No significant difference was observed in the overall technical success rates between the groups [RFA 49/55 (89% success) EVLA 49/52 (94% success) p= 0.490 *Chi Squared analysis*]. Completely ablated veins were found in 24/55 patients in the RFA group and 30/52 in the EVLA. 25/55 and 19/55 patients had either residual or new below knee (BK) GSV reflux in the RFA and EVLA groups respectively. 1 patient in the RFA group developed substantial neovascularisation in the groin and new varicosities. Improvements in quality of life and clinical disease severity seen at 6 weeks were maintained at 6 months in both groups. Mean (SD) scores from 6 weeks- 6 months were: AVVQ 10.9(9.2)-10.2(9.4) and VCSS 1.7(1.7)-1.4(1.8) in the RFA group and AVVQ 10.8(8.9)-10.8(8.7) and VCSS 1.5(1.8)-1.4(1.7) in the EVLA group. There were no significant differences at 6 months between the RFA and EVLA groups for the AVVQ (p=0.286), and the VCSS p=(0.239) respectively, *(ANCOVA).*

Conclusions. Both RFA and EVLA resulted in good technical success rates at 6 months. Improvements in quality of life and clinical disease severity were maintained from the 6 week results and comparable between the two groups.

4.4 COMPARISON OF RADIOFREQUENCY AND LASER TREATMENT IN THE SAME SAPHENOUS VEINS OF THE SAME PATIENT

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Problem. Endovenous radiofrequency (RF) and Laser (L) are competing in the treatment of saphenous veins. We performed a newly designed study comparing both modalities in the same vein of the same patient.

Materials and methods: 38 patients with "symmetric" saphenous veins (6/08-1/09, f: 46, m: 29, 28 – 81 yrs., vein diameter 4.8 – 22.5 mm), meeting the criterion of diameter variance < 20% were included. The target veins were divided into two segments of same length, these were randomized to RF (Celon 18 W) or L (810 nm, 12 W, 50 – 200 J/ cm; total: 152 segments). All patients received coaxial perivenous tumescence anaesthesia (CPTA) according to angioclinic®-standards, postinterventional excentric compression for 4 days and follow-up examinations including ultrasound after treatment, one week, eight weeks and 2, 6 and 12 months.

Results: Both methods were applicable without pain (n = 0) during or after intervention, there was no use or prescription of analgetics. Only few segments showed had lesser complaints below pain level (RF: 18%, L: 13%). Ultrasound comparison showed similar shrinking and similar patterns, with slightly lesser echo intensity for RF. The intended morphology of junction closure (at femoral vein level or below epigastric) was accomplished in 48/76 (RF) resp. 73/76 cases (L). The primary success rate (elimination of reflux) was 98% with RF and 100% with laser. Mean application time (puncture to termination) was 16.8 min. (RF) versus 12.7 min. (L).

Complications: Hematoma < 20 ml (28% RF, 35% L). During 12 months follow-up, recanalization was present in 5/76 cases of RF and 1/76 cases of laser treated segments, all successfully retreatable using microfoam sclerotherapy.

Conclusions. The results of RF and laser, when performed under identical conditions in comparable objects, are very similar. Laser-induced obliteration could be performed with higher precision, due to ultrasound-based criteria, than RF (Celon) with its power management using acoustic feedback.

4.5 DUPLEX GUIDED FOAMSCLEROTHERAPY VS SURGERY FOR THE INCOMPETENT GREAT SAPHENOUS VEIN: A RANDOMISED CONTROLLED TRIAL

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Background. Varicose veins due to insufficiency of the great saphenous vein (GSV) are often treated by surgery. In the last years, new minimally invasive treatment modalities, such as ultrasound guided foam sclerotherapy, have become available and are increasingly used. The purpose of this study was to compare efficacy and direct health care costs of ultrasound guided foamsclerotherapy and surgery.

Materials and methods. Between October 2005 and February 2008, 460 consecutive patients with primary varicose veins of the GSV were randomly assigned either to 1) ultra-sound guided foamsclerotherapy or 2) surgical stripping with high ligation. Included were patients with a reflux in the GSV including the saphenofemoral junction, a normal deep venous system and a general good health. The primary outcome measure was recurrence of reflux in combination with venous complaints. Reflux was evaluated using color duplex scanning, which was performed by an ultrasound technician before treatment, at 3 months at 1 year and 2 years after treatment.

Findings. In the final patient group 227 patients were treated by foam and 198 patients by surgery. A total of 394 completed 3 months of follow-up (217 in foamsclerotherapy group and 177 in surgery group), 499 patients completed 1 year of follow up (221 in foamsclerotherapy and 188 in surgery group) and a total of 391 completed 2 years follow-up (213 in foamsclerotherapy group and 178 in surgery group). The primary outcome, recurrence of reflux in combination with venous complaints, occurred after 3 months in 5.1% (11/217) in the foamsclerotherapy group and in 0.6% (1/177) in the surgery group. After 1 year it was detected in 19.5% (43/221) in the foamsclerotherapy group and in 26.6% (50/188) in the surgery group. Suprisingly the primary outcome decreased to 3.3% (7/213) in the foamsclerotherapy group and in 0% (0/178) in the surgery group. This differences were not significant (p=0.15, 0.98, 0.17). Absence of reflux was detected by colour duplex scanning after two years in 64.8% (138/213) of the patients in the foamsclerotherapy group and in 81.5% of the patients in the surgery group. In the foam sclerotherapy group two thrombo-embolic events occurred: deep venous thrombosis in one patient and pulmonary embolism in another patient. Thrombo-phlebitis was observed in 17 patients treated with foamsclerotherapy. In the surgery group groin infection and paraesthesia was observed in 10 patients. Mean hospital costs were € 592,13 (sd: € 137.48) per patient for duplex-guided foam sclerotherapy and € 1715,61(sd: € 82.02) for stripping.

Interpretation. Foamsclerotherapy is comparable in efficacy with surgery in treating reflux of the GSV. It is easy to perform, non-invasive and lower in costs than surgery.

4.6 RANDOMIZED TRIAL COMPARING RF, LASER, FOAM SCLEROTHERAPY AND STRIPPING IN VARICOSE VEINS

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Background: Endovenous ablation of the saphenous veins are in many places replacing high ligation and stripping (HL/S) as the standard treatment of varicose veins due to GSV insuficiency. The new treatments, radiofrequency ablation (RF), endovenous laser ablation (EVL) and ultrasound guided foam sclerotherapy (UGFS) are thought to minimize postoperative morbidity and reduce time off work compared to conventional surgery. However, no randomized trials comparing the new treatment modalities with surgery have been performed so far. We undertook such trial.

Materials and methods: 500 patients (575 legs) with GSV insufficiency and varicose veins were randomized to treatment with RF (ClosureFast), EVL (ELVES), UGFS (Polidocanol) or HL/S. Miniphlebectomies were also performed. The patients were examined clinically and with duplex, preoperatively, 3 days and 1 month postoperatively and yearly thereafter. Follow-up will continue for 5 years.

Results: At one-year follow-up, 5,7%, 5,4%, 15% and 4% of the GSV´s were open and refluxing in the RF, EVL, UGFS and HL/S group respectively (P<0.01). One patient developed a DVT after UGFS. No other major complications were recorded. The pain score for the first 10 days were significantly lower in the patients treated with RF and UGFS. The time to normal function was 1(0-30), 5(0-46), 1 (0-30) and 4 (0-39) days in the RF, EVL, UGFS and HL/S group respectively (P<0.0001). The days off work were 4 (0-14), 5 (0-46), 4 (0-33) and 6 (0-42) respectively (P<0.01). Varicose veins severity score and Aberdeen clinical severity score improved similarly in all the groups. In the SF-36 quality of life scores, domains bodily pain and physical functioning the RF and UGFS groups performed better than the other groups. Within two years follow-up, the distribution of new varicose veins (REVAS), were not different between the groups.

Conclusions: All treatments are efficacious, but the technical failure rate is higher after foam sclerotherapy. RF and UGFS leads to faster recovery, less postoperative pain and superior quality of life scores than EVL and HL/S. Longer follow-up (5 years) is mandatory to evaluate recurrence rates. Safety aspects should be followed in registries of larger groups of patients as phase IV.

5.1 HOW WELL INFORMED ARE YOUR PATIENTS? ASSESSING THE QUALITY OF VARICOSE VEIN INFORMATION FOR PATIENTS ON THE INTERNET

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The use of the Internet has become increasingly popular with patients to seek medical advice and information. By 2001, 52 million adults had used the internet to obtain health and medical information.[1] Concerns have been raised regarding website reliability and a systematic review in 2002 found that quality was a problem in 70% of health websites.[2] The Health On the Net Foundation (HON) have devised the HONcode certification to improve the quality of online health information to promote useful and reliable information.[3] This study assesses the quality of medical websites with information on varicose veins accessible on the web.

Materials and methods. We searched the keywords "varicose veins" in the most popular three search engines: Google, Yahoo and MSN/Bing.[4] The search was restricted to English Language websites and exact phrase setting. The top 50 websites were evaluated from each search engine (Total=150). Exclusion criteria were irrelevant information, repetition in the search or inaccessibility. Readability of the websites was assessed using the Gunning-Fog Index (GFI, measure of years of schooling needed to understand content) and the Flesch Reading Ease Score (FRES, index rating – score/100). We then used the LIDA tool to evaluate the accessibility, usability and reliability of medical information websites.[5]

Results. 59 out of 150 websites were analysed. Websites were excluded due to irrelevant information (28), repetition of the same website (61) and inaccessibility

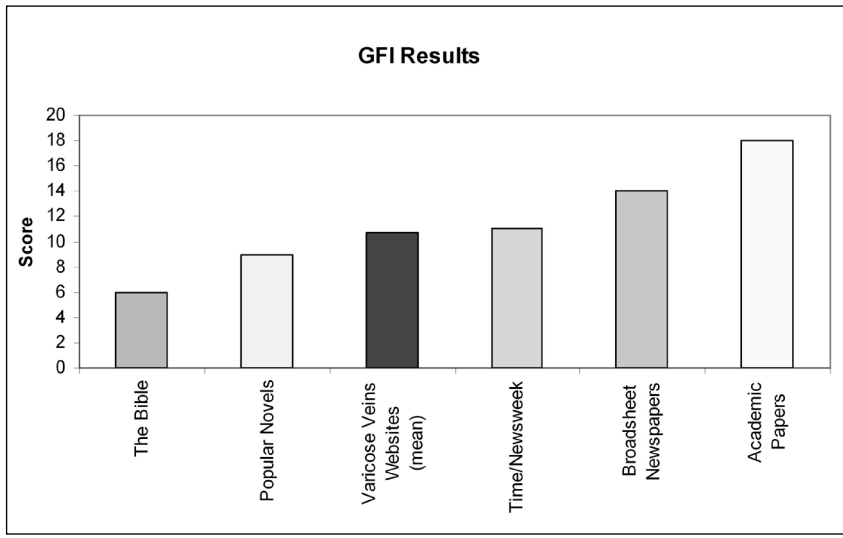

Figure 1.

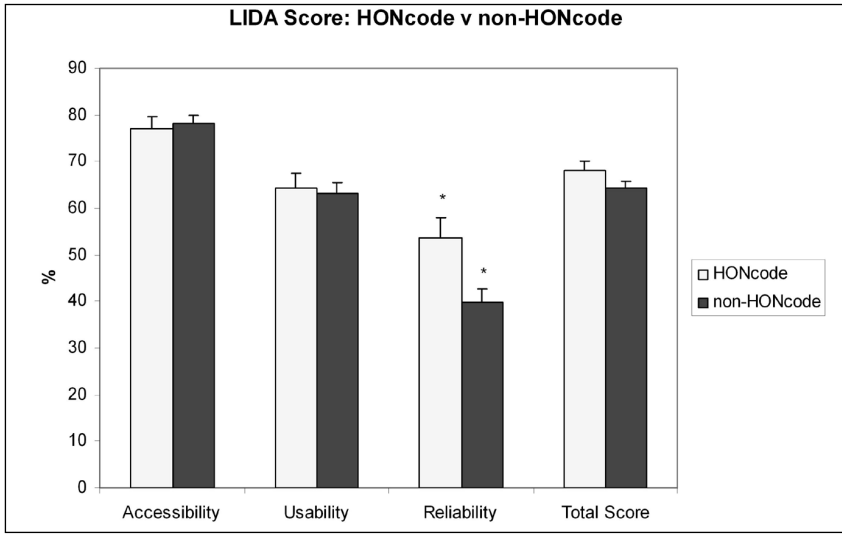

Figure 2.

(2). The GFI results showed the average varicose veins website was similar to reading Time/Newsweek magazines (mean GFI=10.69.S.D:2.03). The mean FRES was 58.59 (S.D: 12.03), slightly below the universally encouraged target of 60-70.

The results of the LIDA medical website validation tool were as above. The HON websites were statistically more reliable than those without HON-code accreditation (53.6% v 40.0% p = 0.005). However, there was no statistically significant difference in readability, accessibility or usability.

Discussion. Our study has assessed the quality of varicose vein information online, which in today's society has an important bearing on patient choice, and ultimately their safety. The best resources are those belonging to recognised medical institutions (often online leaflets), as well as those without financial interests in this field (newspapers). The reliability of medical information on HON-accredited websites is better than those without such accreditation. However, the readability is akin to an intellectual magazine(which many would consider too complicated), and there is generally poor reliability of information. In conclusion, varicose veins patient decisions are likely to be influenced by the internet. As clinicians, it is essential that we guide and help patients identify reliable sources of information.

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5.2 VALIDATING VEINS QOL/SYM: MEASURING CHANGES FOLLOWING ENDOVENOUS MICROFOAM ABLATION OF THE GREAT SAPHENOUS VEIN.

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Background: Measuring patient perceived benefit is the gold standard for clinic trial endpoints. There are now more than five disease specific quality of life instruments for measuring the impact of venous disease on patients. Best known are Aberdeen (AVSSS), CIVIQ, VCSS and more recently SQOR-V. VEINES QOL, which was developed to measure change in symptoms following deep vein thrombosis, has been validated to some degree. None of the current instruments, however, meet the current FDA standards for patient reported outcomes (PRO). One common failing with these instruments is that physicians not patients have evolved the questions. To rectify this problem, group and individual patient interviews were completed and the questions analyzed psychometrically to determine their validity.

Materials and methods.The study design was a multicenter randomized control trial, in which seventy-seven patients (age 18-65) with great saphenous incompetence were treated with endovenous microfoam ablation or agitated saline control. Patients were blinded to treatment assignment. VEINES QOL/Sym, patient global assessment, CIVIQ 2 and VCSS were completed before, and then 8 and 12 weeks after treatment. Duplex examinations were performed at each time point to assess for elimination of reflux or occlusion of the GSV.

Results. Patients treated with endovenous microfoam had significantly increased clinical improvement on patients' global assessment of symptoms at four, eight, and twelve weeks ($p < 0.0001$). VEINES-Sym scores improved in both those getting saline injection, and those treated with endovenous microfoam, but the improvement in scores was statistically greater in the microfoam group at eight ($p=0.0006$) and twelve weeks ($p<0.0001$). In comparison of the different instruments, CIVIQ-2 correlates well with VEINES sym, and VEINES QOL. Both patients found to have elimination of reflux (duplex responders) and those who did not have elimination of reflux (duplex nonresponders) showed improvement in symptoms, with the least amount of improvement in the nonresponder group.

Conclusions. Existing symptom measures as reported by patients were seen to change with treatment, and to correlate with each other. Disease specific quality of life instruments are a sensitive and reproducible method to detect symptom change in patients undergoing treatment for varicose veins. As a result of this trial, a complete PRO dossier has been submitted with anticipated approval of a simplified symptom questionnaire, responsive to change in varicose veins and validated to current standards acceptable to the FDA as a primary endpoint.

5.3 VARICOSE VEIN RECURRENCE AND PATIENT SATISFACTION 10-15 YEARS FOLLOWING SAPHENOUS AND PERFORATOR SURGERY

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Objective: To look at long term varicose vein recurrence and patient satisfaction within a prospective study of patients who had subfacial endoscopic perforator surgery in 1993-1998. Saphenous surgery was performed in addition to SEPS in 93% of the legs.

Materials and methods.: From an original cohort of 104 operated patients with Varicose veins (C3-C4) 93 patients were still alive in 2008 and were invited to a Colour Doppler Ultrasound (CDU) scanning and received a questionnaire regarding long term patient satisfaction. In around 70% the index procedure regarded primary varicose vein surgery and the rest was repeat surgery. Altogether 71 were examined with CDU and responded to the questionnaire and an additional 12 responded only to the questionnaire.

Results: The follow-up was 12 years in median (range 10-15). No patients had required repeat procedures during the period. Following groin surgery 28/53 (53%) showed no recurrence. Neovascularisation grade 1 was responsible for about half (12/25) of the CDU-detected recurrences, 8 had neovascularisation grade 2 and five had remnant incompetent saphenous stumps. The most common cause for recurrence in the popliteal fossa was a politeal perforator (5/7 following 13 op). Recurrence of incompetent perforators was noted 18/71 limbs (25%). New deep vein incompetence was in 21/71 (30%), mostly segmental. The lowest recurrence rate 33% was noted in the subgroup that had primary GSV surgery (37/71). The correlation between CDU-detected recurrence and symptoms was low, 13/25 with groin recurrence, 3/7 with popliteal recurrence and 11/18 with IP recurrence reported total symptom relief. Equally the cosmetic result was considered excellent by the majority of patients with CDU-detected recurrence, 15/25 with groin recurrence, 4/7 with popliteal recurrence and 13/18 with IP recurrence. The overall satisfaction was high, 45/81 (56%) was fully satisfied and 24/81 (30%) was fairly satisfied. Only 5 patients were not satisfied with the outcome and 6 were undecided.

Conclusions. Despite a fair number of CDU-detected recurrences following VV surgery the overall long term result from the patients' point of view was surprisingly favourable. The correlation between symptoms cosmetic result and CDU detected recurrence seem low. Few recurrences could be considered as surgical mistakes in this series. The long term result following open venous surgery appears surprisingly durable both from a clinical point of view as well as from the patients´ point of view. Whether endovascular treatments can match these results long term is still unknown.

5.4 HOSPITAL ADMISSION FOR VENOUS ULCERS: WHAT IS IT WORTH?

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Background. The majority of patients with chronic venous ulcers are treated in an outpatient setting. On average 50% of these ulcers heal within 12 weeks, but it may take over 10 years for some ulcers to heal. There is a high recurrence rate of up to 70%. A minority of patients are admitted because of leg ulceration, most frequently because of non-healing tendency.

Objective. The aim of this study was to investigate time to ulcer recurrence after in hospital treatment of venous leg ulceration.

Materials and methods. A multicenter, retrospective cohort study of patients admitted for leg ulceration between 1996 and 2003, or between 2002 and 2007, was conducted. Patients with venous leg ulceration were collected from four hospitals and identified from hospital coding. The following main data were collected: sex, date of birth, year of admission, length of hospital stay, cause of ulceration (primary or secondary), therapy, percentage of ulcer closure at discharge, time to ulcer recurrence. Mann-Whitney U and Kruskal-Wallis tests were used.

Results. Of 111 patients (84 women; median age 76 years; range 30-92 years) most data could be collected. Median admission time was 31 days (range 1-364), median percentage of closure at discharge was 95 (range 0-100), and median recurrence time 60 days (IQR 19-338). Patients were divided in three main treatment groups (conservative treatment (n = 27; e.g. local wound management, bed rest, pain management), surgical treatment (n = 29; e.g. split thickness skin graft, pinch grafting), and vacuum assisted closure (VAC) in combination with surgical treatment (n = 19). Mann-Whitney U test showed significant differences between the conservative treated group and the surgical treated group, in favour of the surgical treated patients, length of hospital stay ($P<0.0001$), percentage of ulcer closure ($P<0.0001$), but not for ulcer recurrence time ($P=0.273$). Comparable differences were demonstrated between the conservative group and the VAC® plus surgical treated group for length of hospital stay ($P < 0.0001$), percentage of ulcer closure ($P < 0.0001$), and ulcer recurrence time ($P = 0.790$). No significant differences could be demonstrated between the surgical patients and the patients treated by VAC® and surgery. Data comparing primary (n = 44) to secondary (n = 61) causes of venous ulceration showed no significant differences for length of hospital stay, percentage of ulcer closure at discharge and time to ulcer recurrence.

Conclusions. In this study two months after hospital discharge most venous leg ulcers had recurred. Recurrence of venous leg ulcers after hospital admission is independent of treatment and cause of ulceration.

5.5 CAN SAPHENOUS AND SURAL NERVE PARAESTHESIA BE PREVENTED DURING ELT?

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Aim: To determine if it is possible to minimize the risk of thermal injury to the saphenous and/or sural nerves during the performance of ELT.

Materials and methods. Using a Siemens Accuson X300 ultrasound machine with a 5-13MHz transducer the zone of contact (ZOC) between the distal GSV and the saphenous nerve and the SSV and the sural nerve were seen. The ZOCs were determined by observing the upper and lower points of contact (POCs) between the great and small saphenous veins and the corresponding nerves. The saphenous nerve POCs were measured from the central prominence of the medial malleolus. The sural nerve POCs were measured from the floor.

Results. The saphenous ZOC was measured in 297 consecutive legs undergoing ELT of the GSV. The sural ZOC was measured in 83 consecutive legs undergoing ELT of the SSV. The range of the saphenous upper POC was 7.0-29.0 cm above the medial malleolus (Average: 18.4 cm, Median: 18.0 cm, S.D.: 4.7 cm). The ZOC range was 2.0-22.5 cm below the upper POC (Average: 11.6 cm, Median: 11.0 cm, S.D.: 4.6 cm). The range of the sural upper POC was 18.5-34.0 cm (Average: 26.2 cm, Median: 26.5 cm, S.D.: 3.5 cm). The ZOC range was 4.0-11.5 cm below the upper POC (Average: 6.3 cm, Median: 6.0 cm, S.D.: 2.2 cm). There were no complaints of parasthesias after any of these procedures.

Conclusions. Identification of the saphenous and sural nerve ZOCs with the GSV and SSV is easily accomplished with only minor practice. If the desired result is to lase as much of the GSV or SSV as possible, the safest approach would be to introduce the fiber at a location determined by ultrasound visualization of the pertinent nerve. Without ultrasound nerve identification, insertion of the fiber should be 18 cm (2 S.D. = 27 cm) above the medial malleolus for the GSV and 26 cm (2 S.D. = 33 cm.) above the floor for the SSV.

5.6 THE COST EFFECTIVENESS OF THE TRELLIS PERIPHERAL INFUSION SYSTEM ("TRELLIS") COMPARED WITH CATHETER DIRECTED THROMBOLYSIS OR TREATMENT WITH STANDARD ANTICOAGULATION THERAPY FOR PATIENTS WHO ARE POOR RESPONDERS TO ACT: AN EXPLORATORY MARKOV ANALYSIS

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Objectives. The treatment of Deep vein thrombosis (DVT) has evolved significantly over the last 60 years from systemic to clot-specific modalities. However, only a small proportion of patients are treated by the more recent interventional therapies while the majority are treated by anticoagulation therapy (ACT). Anticoagulation therapy attempts only to prevent the propagation of the clot and minimize the risk of Pulmonary Embolism (PE) but does not remove the thrombus that has caused the DVT, and is therefore inadequate to retard the long term complication of Post Thrombotic Syndrome (PTS) and recurrent venous thromboembolism (VTE).

The purpose of our study is to assess the cost effectiveness in terms of the cost per life year gained and the cost per quality adjusted life year (QALY) gained in the treatment of DVT with the Trellis Peripheral Infusion System ("Trellis") compared with treatment with Catheter Directed Thrombolysis (CDT) or treatment with standard anticoagulation therapy (ACT) for patients who are poor responders to ACT.

Materials and methods. We performed a Markov model based cost utility and cost effectiveness analyses comparing treatment for DVT with Trellis, CDT and ACT. The analysis was conducted from the perspective of the National Health Service in England. Utility estimates based on published utilities were used. Parameter variables were drawn from the literature where available, Covidien registry data and author assumptions where no data were available.

Results. Trellis is dominant (i.e. lower cost and better outcomes) compared with CDT whether the outcomes are measured in life years gained or QALYs gained). Versus ACT the extra cost to gain one extra year of life for Trellis is £5,059 and the extra cost to gain one extra QALY is £6,090.

Conclusion. Initial treatment costs with Trellis are lower than CDT and long term costs and health outcomes are superior. Against ACT, health outcomes are also superior and the higher initial treatment costs are partially recouped by lower future treatment costs for recurrent DVT and PE.

AUTHOR'S INDEX

(Surname/Paper Number)