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# Phlebolymphology

#### Editorial by

#### The Daflon International Team

#### Claudio ALLEGRA

Director of Vascular Diseases Master San Giovanni Hospital, Via S. Giovanni Laterano, 155, 00184 Rome, Italy

#### Pier Luigi ANTIGNANI

Professor of Angiology Viale Europa 55, 00144 Rome, Italy

#### Marianne DE MAESENEER

Department of Dermatology Erasmus Medical Centre, BP 2040, 3000 CA Rotterdam, The Netherlands

#### Fidel FERNANDEZ QUESADA

Senior Staff and Associated Professor in Surgery University Hospital San Cecilio, C/Oloriz, 16, 18012 Granada, Spain

#### Olivier HARTUNG

Department of Vascular Surgery Chemin des Bourrely, 13015 Marseille, France

#### Armando MANSILHA

Professor and Director of Unit of Angiology and Vascular Surgery Faculty of Medicine, Alameda Prof. Hernâni Monteiro, 4200-319 Porto, Portugal

#### Hugo PARTSCH

Professor of Dermatology, Emeritus Head of the Dermatological Department of the Wilhelminen Hospital Steinhäusl 126, 3033 Altlengbach, Austria

#### Michel PERRIN

Unit of Vascular Pathology Jean Kulin 26, Chemin de Decines, 69680 Chassieu, France

#### Attila PUSKAS

Associate Professor University of Medicine and Pharmacy of Targu Mures/Marosvasarhely, Romania

#### Karel ROZTOCIL

Department of Transplantation Surgery Institute for Clinical and Experimental Medicine, Videnska 1958, 14021 Prague, Czech Republic

#### Marc VUYLSTEKE

Vascular Surgeon Sint-Andriesziekenhuis, Krommewalstraat 11, 8700 Tielt, Belgium

#### Editorial manager

Francoise PITSCH

Servier International

#### Aims and Scope

Phlebolymphology is an international scientific journal entirely devoted to venous and lymphatic diseases.

The aim of *Phlebolymphology* is to provide doctors with updated information on phlebology and lymphology written by well-known international specialists.

Phlebolymphology is scientifically supported by a prestigious editorial board.

Phlebolymphology has been published four times per year since 1994, and, thanks to its high scientific level, is included in several databases.

Phlebolymphology comprises an editorial, articles on phlebology and lymphology, reviews, news, and a congress calendar.

#### Correspondence

Editorial Manager Françoise PITSCH

Servier International 50, rue Carnot 92284 Suresnes Cedex, France Tel: +33 (1) 55 72 68 96 Fax: +33 (1) 55 72 56 86 E-mail: francoise.pitsch@fr.netgrs.com

Publication Director Laurence ALLIOT Suresnes, France

**Publisher** 

Les Laboratoires Servier 50, rue Carnot 92284 Suresnes Cedex, France Tel: +33 (1) 55 72 60 00 Fax: +33 (1) 55 72 68 88

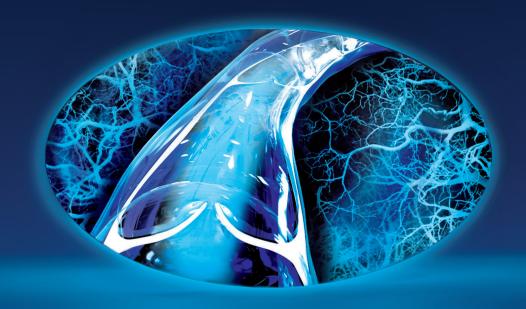
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# Medical Reporters' Academy

The reports from four recent meetings: "Controversies & Updates in Vascular Surgery" in Paris, the "Charing Cross Vascular Meeting" in London, the XVth Meeting of the European Venous Forum in Paris, and the "Paris Dermatological Meeting".

were prepared by the following members of the Medical Reporters' Academy (MRA):



José Daniel BRANDAO (Portugal)



Daciana BRANISTEANU (Romania)



Sylvain CHASTANET (France)



Fidel FERNANDEZ-QUESADA (Spain)



José Benhur PARENTE (Brazil)



Robert VLACHOVSKY (Czech Republic)



Igor ZOLOTHUKIN (Russia)

# **Editorial**

The Medical Reporters' Academy (MRA) is an international group of young specialists with a core interest in venous disease drawn from various fields including dermatology and internal medicine in addition to the more directly related areas of angiology and vascular surgery, not to mention phlebology itself. Each year, they are invited to report from international congresses of interest to venous disease specialists.

The goal of the MRA is to act as an authoritative first-hand source of state-of-the-art information for clinicians who cannot attend every international congress they would like or who miss parallel presentations at those congresses. We warmly thank the MRA members who performed a great task.

We hope this report will not only allow those who could not attend all the recent congresses to read the highlights of the meetings and benefit from the outstanding presentations and discussions held during these events, but will also facilitate the dissemination of knowledge.

Wishing you a good reading,

The Daflon International Team

# Controversies and Updates in Vascular Surgery



Paris, France, January 23-25, 2014

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# I. Arterial diseases

#### 1.1 Thoracic Endovascular Aortic Repair (TEVAR)

1.1.1 Thoracic aorta: open, endo, or hybrid

#### Can we stratify the operative risk of TEVAR?

M. Thompson

Even though thoracic endovascular aortic repair (TEVAR) presents a lower short-term mortality and morbidity than traditional open surgery, it is still associated with a high morbimortality rate (10% to 15%) and a high rate of all-cause death at follow-up. Considering these facts, the author developed a system to stratify patient-specific risk to aid in preoperative planning.

The MOTHER database (Medtronic endOvascular Thoracic Endovascular Registry) gathered data from five prospective clinical trials and a single institutional series. Rates of perioperative adverse events were calculated, as were mid-term death and reintervention rates. Different statistical tests were applied to construct models using preoperative variables to predict perioperative and mid-term adverse events as well as to determine discrimination and goodness of fit of the models.

Of 670 patients that underwent TEVAR for thoracic aneurysm, 5% died, 5% had a stroke, and 3% developed spinal cord injury (SCI) postoperatively. Independent predictors of 30-day death were age, nonelective surgery, and the need for >2 devices (C statistic=0.71). Stroke was predicted by female sex, previous stroke, coverage of the left subclavian artery, and the need for >2 devices (C statistic=0.77). SCI was predicted by female sex, smoking, previous stroke, nonelective surgery, and the need for >2 devices (C statistic=0.72). Aortic reintervention was predicted by aneurysm length, maximum diameter, and iliac tortuosity and a high-risk cohort could be identified. Patients could be successfully divided into tertiles of risk using the mid-term all-cause death model.

The study indicated that the mid-term outcomes of TEVAR are defined by associated comorbidities and mode of admission. Nonaortic mortality is high in the mid-term for patients with thoracic aortic aneurysm, and managing modifiable risk factors appears vital. The author concluded that TEVAR results in excellent mid-term protection from aortic-related mortality. Improved patient selection and better postoperative risk-factor management may help to improve the high all-cause death rate seen in aneurysm patients at follow-up.

These models predict important outcomes following TEVAR and are relatively accurate. External validation of this risk stratification system is required before it can be introduced into clinical practice.

#### Objective assessment of current stent grafts: which graft for which lesion?

L. Canaud

The first decade of thoracic endovascular aortic repair (TEVAR) has demonstrated good short- and mid-term outcomes, supporting endovascular repair as the procedure of choice for patients presenting with thoracic aortic diseases. Presently, four thoracic stent-grafts have achieved the CE (Conformité Européenne) marking: Valiant (Medtronic Vascular, Santa Rosa, CA, USA), Zenith TX2 thoracic stent-graft (Cook Medical, Bloomington, IN, USA), TAG (W.L. Gore & Associates, Flagstaff, AZ, USA), and the Relay Stent-graft (Bolton Medical, Sunrise, FL, USA). These stent-grafts have different features in terms of stent-graft design (polytetrafluoroethylene [PTFE] vs Dacron, stent framework) and delivery system. Knowledge of stent-graft conformability, radial force, and accuracy of the delivery system is crucial to prevent devastating complications such as stent-graft collapse, type I endoleak, retrograde ascending aortic dissection (RTAD), and inadvertent coverage of the supra-aortic trunks.

In this context, the author presented an experimental study performed using a benchtop pulsatile flow model and human cadaveric aortas in order to assess the conformability of the latest generation of thoracic stent-grafts as a function of oversizing and increasing aortic arch angulation. He further reported a comprehensive review of the literature combined with a review of his single center experience to identify device-related complications.

The experimental study demonstrated that the requirement for close conformability has influenced the design of next-generation devices. Manufacturers have modified devices and/or deployment systems to specifically address this problem. When compared with the results of the author's previous experimental test, these alterations have resulted in a marked improvement in the performance of commercially available stent-graft systems.

Concerning the performed literature review and regarding RTAD, inappropriate stent-graft oversizing, particularly in patients with aortic wall fragility, should be avoided. Iteration of stent-graft design will be important in reducing the incidence of RTAD, but the present study suggests that the presence of a bare proximal stent does not lead to an increased rate of RTAD. Considering the thoracic stent-graft collapse, accurate assessment of aortic arch anatomic features, as well as the choice and sizing of the device, may prevent this complication. Prevention of the risk of inadvertent coverage of the supra-aortic trunks is based on the choice of a stent-graft with a controlled delivery system.

The author concluded that improvement in the performance of commercially available stent-graft systems combined with a proper knowledge of the different features of these stent-grafts would prevent most device-related complications.

#### Ascending aorta: is the endovascular approach realistic? How I do it.

T. Kölbel

The standard treatment for pathologies of the ascending aorta is currently still open surgery; it is a dissection, aneurysm, or rupture. Meanwhile, the open approach is associated with considerable morbidity and mortality rates. Even though thoracic

endovascular aortic repair (TEVAR) is now considered the preferred approach for the descending thoracic aorta, technical and anatomical challenges persist for endovascular repair of the more proximal sections of the aorta, rendering TEVAR a more exceptional indication. Present problems of TEVAR from a downstream access for the ascending aorta include: (i) inability to advance, control, and deploy the endograft due to iliac and aortic pathology (including severe tortuosity); (ii) hemodynamic forces; (iii) the need to place a stiff guidewire into the left ventricle; and (iv) the shortness of currently available stent-graft introducing systems. To overcome these limitations, alternative retrograde access techniques have been developed including subclavian access, conduits to iliac arteries, infrarenal, and thoracic aorta. In the author's opinion, antegrade access and transapical stent-graft deployment might be an alternative access in patients unfit for or at a high risk for open surgery or retrograde access. Described originally by MacDonald et al (J Vasc Surg. 2009;49:759-762), the transapical access, through a mini thoracotomy (same approach performed for transcatheter aortic valve implantation [TAVI]), has the following potential advantages: (i) avoidance of downstream access problems; (ii) short distance with excellent trackability, pushability, and rotational control; (iii) nearly unlimited profile; (iv) instant decompression of the pericardial tamponade; and (iv) availability, as transapical access is a standard technique for TAVI in many cardiovascular centers. Meanwhile, remaining issues subsist regarding TEVAR in the ascending aorta: pulsatility of the arch, proximal seal, unknown impact on AV, selection of the patients and specifically designed grafts still to come.

#### Aortic arch: tips and tricks for total endovascular repair.

T. Resch

The author presented, in this lecture, some pertinent points that can lead to a successful endovascular repair of the entire aortic arch. He emphasized the importance of the planning in a 3D workstation, looking carefully at the ascending aorta, the coronaries, the aortic valve, the cervical vessels' landing zone, the access, the aortic tortuosity, and the presence of a previous device. He finished by stating that total endovascular arch repair is feasible, but it implies an important learning curve with regard to patient selection and stent-graft implants.

#### Hybrid techniques for the arch: are they effective and durable?

P. Cao

The author presented his group experience from 2005 to 2014 in hybrid techniques for aortic arch repair. A total of 136 patients were treated with the following landing zone distribution: Z0, 25; Z1, 60; Z2, 51. The perioperative outcome rates at 30 days were 5.1% mortality, 2.9% stroke, 2.2% spinal cord ischemia, 3.6% type I endoleak, and 3.6% retrograde type A dissection. The long-term outcomes regarding the vascular surgical reconstruction were also presented, with only 3.7% of reinterventions. As such, the author concluded that aortic arch debranching repair relies on a number of procedural options that need to be tailored to patient characteristics, mode of admission, and the center's experience. He also argued that: (i) hybrid arch procedures present a persistent high risk of perioperative mortality, mostly in landing zone 0; (ii) retrograde dissection may complicate total surgical debranching, especially in a dissected aorta; (iii) total endovascular procedures (chimney techniques) are currently subject to a high rate

of gutter type I endoleak and should be reserved for emergencies; (iv) embolization procedures are not always effective; and (v) tailored endografts seem to provide promising results.

#### 1.1.2 Controversy: Timing of TEVAR for uncomplicated acute type B aortic dissection

#### Early intervention is the best choice.

J. Brunkwall

The author started his argumentation by reminding the audience of the complications of an acute type B dissection, such as rupture, malperfusion (renals, intestines, spine, and lower limbs), uncontrolled hypertension, and aneurysm formation. He stated that malperfusion is associated with high mortality rates.

By performing thoracic endovascular aortic repair (TEVAR) in an acute setting of uncomplicated type B dissection (time from symptom onset to treatment  $\leq 14$  days), the author argued that it is possible to obtain remodeling with "restitutio ad integrum," reducing the risk of complications, the number of reinterventions, and the mortality rate at 5 years (prevention of late aortic-related death). According to the paper "The IRAD Classification System" (Booher AM et al; IRAD Investigators. Am J Med. 2013;126:730. e 19-24), an International Registry of Aortic Dissection (IRAD) with a total of 665 type B dissections, endovascular treatment provided the best cumulative survival from time of symptom onset to 60 days. Although the placement of an endograft in the acute setting increases the risk for retrograde type A dissection, distal malperfusion, stroke, and paraplegia. The interim results of the ADSORB trial (Acute Dissection Stentgraft OR Best medical treatment) further demonstrated that TEVAR is safe in the acute phase of uncomplicated type B dissection, being able to significantly reduce the mortality at 30 days in comparison with medical treatment alone. He further stressed that five treatment crossovers occurred within a few days after randomization in the medical treatment group (n=30; results not published yet).

The author concluded that acute type B dissection is life threatening, that the first 14 days are critical, and that early treatment is not dangerous, being even able to save lives.

#### Delayed TEVAR is much preferable.

M. Thompson

The author started his reply by pointing out the pitfalls of the ADSORB trial (Acute Dissection Stentgraft OR Best medical treatment), especially with regard to the way it was powered, decreasing from the 250 patients initially needed to the 60 actually recruited. He further argued that deferred thoracic endovascular aortic repair (TEVAR) resulted in fewer peridissection complications, delivering the same protection from late aortic death.

In fact, in the most recent systematic review (Canaud L et al. *Ann Surg.* 2014 Jan 16, Epub ahead of print) that gathered data from 38 reports (totaling 9594 patients), the overall incidence of retrograde type A dissection after TEVAR was 1.7%, with a mortality

rate reaching 33.6%. The odds ratio of retrograde type A dissection for an acute aortic dissection was 10.0 (95% confidence interval [CI], 4.7-21.9) and 3.4 (CI, 1.3-8.8) for chronic aortic dissection.

Additionally, he presented the results of the VIRTUE registry, describing the mid-term clinical and morphological results of TEVAR in patients with type B aortic dissection (Virtue Registry Investigators. *Eur J Vasc Endovasc Surg.* 2011;41(2):159-166). The VIRTUE registry is a prospective, multi-center clinical trial, which enrolled patients with complicated acute (<15 days), subacute (15 to 92 days), and chronic (>92 days) type B aortic dissections treated with the Valiant endograft. One hundred patients were enrolled and the clinical outcomes were described at a 3-year follow-up. 3-year all-cause mortality (18%, 4%, and 24%), dissection-related mortality (12%, 4%, and 9%), aortic rupture (2%, 0%, and 4%), retrograde type A dissection (5%, 0%, and 0%), and aortic reintervention rates (20%, 22%, and 39%) were defined for patients with acute (50), subacute (24), and chronic (26) dissections, respectively. Analysis of aortic morphology observed that patients with subacute dissection demonstrated a similar degree of aortic remodeling to patients with acute dissection. As such, retention of aortic plasticity in the subacute group appears to lengthen the therapeutic window for the treatment of uncomplicated type B dissection.

Finally, he concluded that TEVAR could be performed in a subacute setting, with similar long-term results with significantly less acute complication rates.

#### Discussion

During the discussion regarding this controversy, some argued that performing thoracic endovascular aortic repair (TEVAR) in an acute setting of uncomplicated type B dissection is similar to carotid surgery in symptomatic patients: in fact, early surgery has been shown to be essential to reduce the high risk of stroke in the first few weeks after a transient ischemic attack or minor stroke, even at the cost of a higher complication rate.

In the end, the voting was favorable to M. Thompson.

#### Malperfusion and acute type B dissection: what is the best strategy?

T. Mastracci

The publication of long-term outcomes from the INSTEAD XL trial (INvestigation of STEnt grafts in Aortic Dissection with eXtended Length of follow-up) provided adequate data to perform TEVAR in uncomplicated dissection, promoting aortic remodeling, and changing the natural history of the disease. However, complicated dissections, especially those that present with malperfusion, remain a challenging clinical problem that can be lethal very early in the presentation of the disease. In the International Registry of Aortic Dissection (IRAD) database, visceral ischemia was the cause of death in 15.9% of patients (Booher AM et al; IRAD Investigators. Am J Med. 2013;126:730.e19-24). The author stated that malperfusion can be dynamic or static, and can have a variety of etiologies including intimal dissection and complete occlusion of branch vessels, intimal tear of the dissection flap causing interrupted flow, or dissection flap collapse during systole, making the treatment of malperfusion a challenge. As such, the author argued

that endovascular surgeons must have a good understanding of the disease, as well as the likely clinical scenario based on individual patient characteristics.

The endovascular approach to malperfusion has included a variety of techniques, but most will agree that modern solutions are a combination of thoracic stenting, branch vessel stenting, and fenestration. The thirty-day mortality, in centers that have reported this, ranges from 0% to 25%, representing a heterogeneous group of patients and approaches, and making it challenging to gain insight into the best approach based on the reported literature alone. Where a good proximal landing zone exists, the author's center favors placement of a thoracic stent as the first-line approach to malperfusion. This addressed the issue of altered flow dynamics in the true lumen, which is, in the author's experience, commonly the cause of malperfusion. The author added that changing the flow dynamics between the true lumen and the false lumen, and not radial force alone, is the reason why proximal thoracic grafting is successful. When a primary thoracic stent does not completely resolve malperfusion and the large intimal tears above the celiac artery have been adequately covered, the author's group adopts an approach of selective recanalization and stenting of branch vessels. Their experience with this method describes 61 patients with malperfusion over an 11-year span (Ryan C et al. J Vasc Surg. 2013;57:1283-1290). Malperfusion in these patients occurred in at least one territory (including spinal cord, 7/61 [12%]; mesenteric, 37/61 [61%]; renal, 45/61 [73%]; and lower extremity, 38/61 [62%]), but 43/61 patients had >1 bed effected malperfusion and 54/61 patients included mesenteric or renal involvement. Most patients were treated <24 hours after presentation (36/61, 59%). Thoracic stents were used in all patients, and branch vessel stenting was also required in 41% (25/61). Mortality was inversely associated with male sex (hazard ratio [HR], 0.42; 95% confidence interval [CI], 0.18-0.96; *P*=0.04), quitting smoking (HR, 0.31; 95% Cl, 0.1-0.99; P=0.047), and positively associated with left subclavian artery occlusion (HR, 2.97; 95% CI, 1.09-8.11; P=0.034). The 30-day/in-hospital mortality was 21.3%. The 6-month, 1-year, and 5-year survival was 75% (95% CI, 65% to 87%), 71% (95% CI, 61% to 84%), and 56% (95% CI, 43% to 74%), respectively.

The author concluded that understanding of this lethal disease is still limited, but it appears that endovascular techniques may improve outcomes compared with medical management.

#### Acute type B dissection. Is closure of the proximal tear sufficient?

J-M. Alsac

Thoracic endovascular agric repair became the treatment of choice for agric dissections concerning the descending thoracic aorta because of its less invasive and reproducible character. The placement of a covered stent-graft on the proximal tear of the dissection redirects blood flow in the true lumen and treats most complications that may occur during the acute phase. However, the existence of other distal entry tears often leads to reperfusion downstream of the stent-graft, which maintains a circulating flow in the false lumen of the dissection.

In case of visceral malperfusion during the acute phase of the dissection, a higher pressure in the false lumen of the dissected aorta may lead to a "dynamic" compression of the true lumen where the most collateral for visceral arteries arise. To promote the true lumen expansion and perfusion vs the false lumen pressure, the Zenith Dissection Endovascular System (Cook medical, Bloomington, IN, USA) proposes a composite device with noncovered metal stents that extend into the thoracoabdominal aorta, below the proximal thoracic aortic stent-graft. In the author's group experience in the systematic treatment for dynamic malperfusion complicating acute dissections, the Zenith Dissection Endovascular System achieved satisfactory clinical results, safely and effectively, in the short-term. However, the long-term impact of this composite treatment on aortic remodeling remains to be determined (Alsac JM et al. *J Vasc Surg.* 2014;59:645-650).

Regarding mid-term evolution of aortic dissections, a persisting circulating flow in the false lumen of the dissection often promotes aneurysmal degeneration of the thoracoabdominal aorta. To avoid distal perfusion of the false lumen, the author proposed to adjunct a retrograde endovascular fenestration of aortic dissection flap to obtain a seal at the distal portion of the aortic stent-graft using the DEFINITE technique (Distal Endovascular Fenestration INsIde Thoracic Exclusion).

The author concluded that closure of the proximal tear in type B aortic dissections is efficient, validated, reproducible, but not always sufficient (50%), especially for extensive dissections. In this setting, adjunct procedures on distal tears may be required (extensive stent-graft, spot stenting, distal stabilization with a bare metal stent, and the DEFINITE technique). These combined endovascular options could limit the frequent aneutysmal evolution of aortic dissection and its fatal complications.

### Chronic type B dissection. What is wrong with TEVAR? R. Gibbs

Chronic type B dissection is defined as a dissection lasting for more than 6 weeks. The author presented some data from the Interdisciplinary Expert Consensus Document on Management of Type B Aortic Dissection (Fattori R et al. *J Am Coll Cardiol*. 2013;61:1661-1678). As such, concerning the outcomes of endovascular treatment for chronic type B dissection, the perioperative mortality is 0% to 7.5%, and the mid-term mortality is 8%. As a result, it is advocated that interventional treatment (either endovascular or, when contraindicated, open surgery) should be reserved for recurrence of symptoms, aortic aneurysmal dilation (>55 mm), or a yearly increase of >4 mm after the acute phase. The uncomplicated chronic type B dissections should be left under medical therapy and an imaging surveillance protocol (at 6 weeks and annually thereafter).

#### 1.1.3 Thoracoabdominal segment

#### When to use branched or fenestrated stent grafts, when to use chimney?

E. Ducasse

Since its first implementation in 1999, fenestrated endovascular aortic repair (fEVAR) has demonstrated excellent early and mid-term results. Meanwhile, the author stressed that fEVAR is not for emergent cases (even if it is possible to consider homemade grafts). He added that some technical points are also required such as: adequate bilateral iliac access (18F to 24F are required in contralateral access for fenestration catheterization,

even though a double 7F puncture is possible); ostia of the target vessels are in the landing/sealing zone; targeted arteries have no important angulation, kinking, or stenosis.

Branched grafts have some advantage: the sealing zone is in the thoracic aorta, targeted arteries can be inside the aneurysm sac, and only one iliac access is needed.

The chimney technique (chEVAR) should be indicated as a bailout procedure for accidentally overstented aartic branches, adjunct to enable EVAR for a juxtarenal aneurysm in an urgent or emergency setting, and as an alternative option for patients not suitable for open repair or branched or fenestrated EVAR. It is contraindicated in aartic dissection and aartic stenosis. chEVAR has some advantages over branched or fenestrated EVAR as it is less complex, more available in smaller centers, cheaper, can be performed without previous device planning and customization, sizing is less crucial and can be an immediate solution in an acute setting. The chEVAR technique implies previous catheterization of targeted arteries before graft delivery, but allows different configurations (chEVAR juxtarenal, snorkel, and sandwich).

Subsequently, the author presented a series published in 2012 of 90 consecutive patients with juxtarenal aneurysms who were treated by fEVAR, chEVAR, or open repair, depending on the morphology and the clinical characteristics. This study demonstrated that: (i) either chEVAR or fEVAR are safe for the short-term management of juxtarenal aneurysms; (ii) chEVAR is quicker than fEVAR; and (iii) open repair is associated with longer hospital stays and higher blood transfusion requirements (Donas KP et al. *J Vasc Surg.* 2012,56:285-290).

The author concluded that fEVAR, branched grafts, and chEVAR are efficient and safe and should be adapted to each patient based on the anatomy and the setting of the presentation (elective/emergency setting).

## Paraplegia following fenestrated and branched EVAR: incidence, severity, and ways to prevent it. R. McWilliams

Spinal cord ischemia (SCI) is one of the major complications after fenestrated and branched endovascular aortic repair (EVAR). The GLOBALSTAR database (GLOBAL collaborators on advanced Stent-graft Techniques for Aneurysm Repair registry) of fEVAR in the UK records 5 cases of SCI in 318 registered patients (British Society for Endovascular Therapy; GLOBALSTAR Registry. *Circulation*. 2012;125:2707-2715). All were in grafts with four fenestrations, which is consistent with the known increased risk of SCI with greater aortic coverage. For this reason, the risk of paraplegia is much higher with thoracoabdominal branched grafts.

Strategies to reduce the risk of SCI include limitation of the reduction in the blood supply through the preservation of the left subclavian and hypogastric arteries and minimizing the length of aortic coverage, staging complex endovascular procedures, adjusting CSF and mean arterial pressures to maintain the spinal cord perfusion pressure, and using dedicated paraplegia prevention branches in endografts.

Neuromonitoring using evoked potentials has an established role in open repair of thoracoabdominal aortic aneurysms. Changes in the recorded traces are used to guide modifications to surgery and spinal cord perfusion pressure.

The author's group has started using motor evoked potential (MEP) monitoring during thoracic endovascular aortic repair (TEVAR), fEVAR, and branched EVAR. One sensor is placed in each arm (internal control) and two to three are placed in each leg. A 50% or greater loss of amplitude in the leg MEPs is considered indicative of cord malperfusion. Meanwhile, monitoring is only valuable if there is a potential response strategy if the motor evoked potentials deteriorate. Unfortunately, there are no resheathable endografts, so if the MEPs deteriorate during a procedure, then the response strategy is aimed at increasing spinal cord perfusion through changes in cerebrospinal fluid and mean arterial pressure and, if this fails, by trying to increase spinal cord perfusion directly by inducing an endoleak. MEP monitoring may also be used during a procedure to test occlusion of the last branch and decide if this should be left open as per a paraplegia prevention branch. Ischemia from large groin sheaths and arm access can complicate the interpretation of changes to MEPs.

The author concluded that prevention of SCI should be based on graft planning, optimization of spinal cord blood supply, maintenance of spinal cord perfusion pressure, and, possibly, neuromonitoring the patient to guide the procedure.

#### 1.1.4 Controversy: Off-the-shelf grafts. Are they needed and up to the job?

#### For the motion.

S. Haulon

Fenestrated and branched endografts have evolved as an effective treatment option for patients with juxtarenal, pararenal, and thoracoabdominal aneurysms. However, these technologies have required that they be specifically manufactured to fit an individual patient's anatomy. More recently, off-the-shelf technologies have emerged as an additional option. These devices simplify case planning and preparation as visceral anatomy can be simply compared with device anatomical requirements. In addition, they are available for treatment of acute or symptomatic patients. When used within their indicated anatomical requirements, short-term results for some off-the-shelf fenestrated and branch grafts are comparable with their custom-manufactured counterparts (Guillou M et al. J Vasc Surg. 2012;56:65-73).

The author concluded that if off-the-shelf grafts can apparently be suitable for more than 70% of the juxtarenal aneurysms (Sobocinski J et al. *J Endovasc Ther.* 2012;19:165-172), then its use may be more limited for pararenal and thoracoabdominal aneurysms.

#### Against the motion.

C. Bicknell

It is very hard to argue against the need for off-the-shelf grafts, but it should be kept in mind that with advances in technology, this may not be the only mechanism with which to treat urgent/emergency complex aneurysms. The technique of in-situ fenestration or rapid in-house customized manufacturing would certainly challenge the need for offthe-shelf grafts with advances in imaging and robotics.

Even if the author admitted that an off-the-shelf solution is the only viable prospect of treating this group of patients, there are many unanswered questions. The main question is regarding tolerance of different anatomical configurations. With custom-made manufacturing fenestrations/branches can be matched exactly to the required height and clock face orientation. However, if the fenestration/branch is misaligned there may be significant difficulties. Double diameter reducing ties and certainly intelligent catheter technologies will smooth the cannulation of vessels and introduction of branch stents, but the long-term durability of misaligned branches is yet to be understood due to aortic remodeling and the potential for fracture, kinking, and dislocation.

With dome shaped fenestrations, wide celiac artery scallops, and branch technology, the number of patients that may be treated with a few graft configurations is thought to be acceptable in morphological studies. However, there should be some caution because urgent and emergency cases are significantly larger with more complex anatomical configurations.

The author concluded that the range of aneurysms who can be treated with off-the-shelf grafts is limited, that data relating to the number of patients that can be treated is fundamentally flawed, that there is no data on durability and late complications, and there is no proof that these grafts are what is needed or that they are up to the job at the present time.

#### 1.2 Abdominal Aortic Aneurysms (AAA)

## Can stent graft design influence cardiac outcome? C. Liapis

Endovascular aortic repair (EVAR) is associated with lower perioperative mortality and morbidity rates compared with open surgical repair. This advantage is blunted in the long-term, mainly due to an increase in cardiovascular complications (Stather PW et al. Br J Surg. 2013;100:863-872). Arterial stiffening together with an adverse cardiac function after stent-graft implantation may explain this change in the long-term outcome. In fact, there is evidence of: (i) an increased arterial stiffness and biomarker elevation 1 year after EVAR, which is related to the endograft type (polyester more than polytetrafluoroethylene; Kadoglou NP et al. Regul Pept. 2012;179:50-54); and (ii) an increased arterial stiffness and myocardial strain after thoracic endovascular aortic repair (TEVAR). The effect of endograft type in the thoracic aorta requires further investigation.

Implantation of an endograft, although considered a minimally invasive procedure, may have serious long-term effects on the cardiovascular system and should be included in the list of risk factors. Patients with an endograft should have vigorous monitoring, control of blood pressure, lipids, and other vascular risk factors, and a life-long follow-up. Arterial stiffness should be taken into consideration by the industry when designing new endografts.

## 1.2.1 Controversy: Will current stent-grafts offer better results than those used in randomized controlled trials?

#### Yes and we have proof of that.

M. Van Sambeek

Endovascular abdominal aortic aneurysms (AAA) repair (EVAR) is continuously evolving. Next-generation devices are intended to diminish complication and reintervention rate, while broadening the applicability of EVAR. Besides randomized controlled trials (RCTs), there are registries and essential tools to monitor the performance of current devices closely in a real-world setting. Benchmarking with historic registries and RCTs might be helpful to put the early results of contemporary registries in perspective.

In this context, the author's group merged original data from 7321 EUROSTAR cases (EUROpean collaborators on Stent-graft Techniques for Abdominal aortic aneurysm Repair) with patient data from 1263 ENGAGE cases (Endurant Stent Graft Natural Selection Global Postmarket Registry) from March 2009 to April 2011 (Stokmans RA et al. Eur J Vasc Endovasc Surg. 2012;44:369-375). Groups were compared at baseline and with early outcome variables. Then, these results were compared with the published data of the EVAR I and DREAM (Diabetes REduction Assessment with ramipril and rosiglitazone Medication) trials. Perioperative conversion to open surgery occurred less often in ENGAGE (0.23% vs 0.74%, P=0.04). In the EVAR I trial, primary conversion was 1.9% and perioperative mortality rates declined significantly in ENGAGE (2.27% vs 1.27%, P=0.02). In the DREAM trial, perioperative mortality was 1.2%, and in EVAR I it was 1.6%. One-year all-cause survival curves did not differ between EUROSTAR and ENGAGE (92.2±0.3% vs 92.5±0.7%, respectively), but AAA-related mortality within 1-year decreased from 2.9±0.2% in EUROSTAR to 1.53±0.3% in ENGAGE, P<0.01. Compared with EVAR I and DREAM trials, these numbers are not significantly different. The occurrence of secondary interventions within the first year also declined in ENGAGE 1-year postoperatively, and 8.27±0.4% of patients in EUROSTAR had undergone one or more secondary interventions, whereas this was only 5.86±0.7% in ENGAGE, P=0.02. Occurrence of secondary intervention within 1 year of the EVAR I and DREAM trials was more that 10%.

As such, the author concluded that EVAR is getting better, possibly due to better insight into AAA pathophysiology and because new generation endografts seem to perform better. However, long-term follow-up is needed to confirm durability of these results.

#### No, RCT conclusions remain valid.

J. Blankensteijn

The four randomized trials on endovascular aneurysm repair (EVAR I [EndoVascular Aortic aneurysm Repair], DREAM [Diabetes REduction Assessment with ramipril and rosiglitazone Medication], ACE [Anevrysme de l'aorte abdominale: Chirurgie versus Endoprothese], and OVER [Open Versus Endovascular Repair]) have offered a wealth of evidence based on data that can be used on a daily basis to inform the patients and help chose the best treatment option for their abdominal aortic aneurysms (AAA). However, there is no question, these trials have lost some of their actuality. One important caveat when applying the data to our current practice is that the AAA-patients we

are faced with today are different from those we were treating when the trials were in progress, especially in terms of smoking habits, statins, antithrombotic medications, and along with these, their comorbidities. While this questions the generalizability of the randomized patients already, there is another factor to be considered. The trials included patients with infrarenal AAA suitable for both open and endovascular repairing that specific day and age. Consequently, with the availability of newer devices with broader inclusion criteria, the generalizability of the randomized trials further deteriorates over time.

However, according to the author, the question in debate, in clear language, is whether new device technologies have made the randomized trial outcome data obsolete. In this respect, what is needed is to assess the main outcome criteria of the trials: short- and long-term overall survival. Will the new grafts really have an impact on the operative mortality after EVAR? Short-term survival is probably driven predominantly by the shift of the operative risk status of patients included (more advanced disease), and consequently, the operative mortality is likely to increase for both open and endovascular repair (the author stressed the EVAR-2 trial data).

The trials reported a 3% short-term survival benefit, which was then lost in the subsequent 1 to 3 years. This lag-time has been reported to be also dependent on the preoperative risk status: lower surgical risks yield longer survival benefits from EVAR. The main drivers of long-term survival are patient age and risk status, not the type or brand of endograft, except for, perhaps the effect on reinterventions. However, the main driver of the reintervention rate is anatomical suitability for EVAR. While newer devices may avert the need for reinterventions, at the same time this effect may be possibly counteracted by less durable devices (lower profile, unproven technology) and the inclusion of more challenging anatomy, ie, shorter and more angulated aortic necks.

The author concluded that: (i) the short-term survival benefit of EVAR over open repair and its gradual loss over time is largely independent of endograft evolution; (ii) patient-selection drift may limit generalizability, but the risk ratio of open vs EVAR may stay the same; and (iii) device-related failures and reinterventions will decrease with better EVAR device technology, but will increase with more complex and lower profile devices and more difficult anatomy.

#### 1.2.2 Controversy: Ruptured AAA: is open surgery an outdated operation?

#### In Great Britain: Latest news from the IMPROVE RCT.

J. Powell

The IMPROVE trial (Immediate Management of the Patient with Rupture: Open Versus Endovascular repair) was a pragmatic, real-world trial that randomized 613 patients with the clinical diagnosis of abdominal aortic aneurysm rupture, before definitive imaging, and included unstable patients. Patients were randomized to endovascular procedure (n=316), and open repair (n=297) was reserved for those anatomically unsuitable for conventional EVAR. The flow of patients throughout the trial (2009-2013) with a hospital clinical diagnosis of aneurysm abdominal rupture was 1275 patients, but 652 were excluded. The average age in both groups was 76.7, with a higher prevalence of males (78% endo, 79% open). The mortality was 35% in the endovascular group and 37% in

the open repair group. Patients in the endovascular strategy group benefitted more by being discharged sooner and directly to their home, usually. Given these initial findings, it is important to follow-up patients for longer to provide cost-effectiveness evaluations.

#### Latest news from the ECAR RCT.

P. Desgranges

A study supported by the French Ministry of Health, the Endovasculaire vs Chirurgie dans les Anévrismes Rompus Protocol trial, also named ECAR, was a prospective, multicenter trial of endovascular aneurysm repair (EVAR) vs conventional surgery (CS) presenting ruptured aorta iliac aneurysms in 16 centers. One hundred and seven patients have been included. The ECAR study hypothesis was that there would be a significant decrease in mortality and morbidity in the EVAR group vs CS. Definitive results on mortality/morbidity are awaited. More than 95% of patients had a CT scan available upon arrival at the hospital (done outside the hospital).

#### 1.3 Carotid stenosis

#### Risk stratification methods for asymptomatic carotid plaques.

S. Kakkos

The incidence of stroke, in patients with asymptomatic carotid artery stenosis >60% randomized to the medical arm of the ACAS (Asymptomatic Carotid Atherosclerosis Study) and ACST (Asymptomatic Carotid Surgery Trial) studies, has been shown to be 2% per year, while in the surgical arm, carotid endarterectomy, in carefully selected patients, reduces the risk of stroke to 1% per year. Therefore, 100 surgeries are needed to prevent one stroke in one year, so up to 94% of the interventions may not benefit the patient. Additionally, the improving results of the current medical therapy have further challenged the need for intervention in asymptomatic carotid stenosis. Therefore, it is imperative to be able to identify the patients at high risk for cerebral ischemic events. Subsequently, it has found that factors associated with a high risk of stroke include clinical characteristics (hypertension, age over 70, male sex, history of contralateral neurological symptoms, and hypercholesterolemia), stenosis characteristics (increasing severity of carotid stenosis, progression of carotid stenosis over time, and contralateral carotid artery occlusion), and plague characteristics (plague ulceration, unstable carotid plaque morphology [based on ultrasound], plaque echolucency, discrete echogenic plaque components, low gray-scale median, large plaque area, discrete white areas, and juxtaluminal black areas). However, the decision to intervene should be based not only on risk stratification alone, but also on the anatomical characteristics of the stenosis, patient fitness for surgery and expected survival, the perioperative stroke and death rate of the surgeon, and the willingness to take the small short-term risk of surgery for a possible greater long-term benefit. The ACSRS study (Asymptomatic Carotid Stenosis and Risk of Stroke) has reported that the severity of stenosis and the neurological history of the contralateral carotid and ultrasonic plaque features are independent powerful predictors of plaque instability and future stroke (Kakkos S et al. J Vasc Surg. 2014;59(4):956-967). These plague features include the presence of juxtaluminal black areas and discrete white areas. High-risk groups with an annual 4% to 10% risk of stroke and a low-risk group (<1% annual risk) were identified. The latter group can be spared from carotid intervention and efforts concentrated toward aggressive medical management and patient follow-up.

The author concluded his talk suggesting, for the near future, a more common use of software for ultrasound image analysis, as this can provide not only the percentage of a carotid stenosis, but also its annual stroke risk.

#### CEA versus CAS: the latest RCT evidence.

L. Bonati

Randomized controlled trials (ICSS [International Carotid Stenting Study]; EVA-3S [Endarterectomy Versus Angioplasty in Patients With Symptomatic Severe Carotid Stenosis]; SPACE [Stent-Protected Angioplasty versus Carotid Endarterectomy]; and CREST [Carotid Revascularization Endarterectomy versus Stenting Trial]) consistently demonstrated a higher risk of periprocedural nondisabling stroke with stenting than endarterectomy for treatment of symptomatic carotid stenosis. However, several factors differentially modify the periprocedural risks of the two treatments: an excess stroke risk with stenting over endarterectomy has most consistently been demonstrated for elderly patients, and more recently, patients with cerebral white matter disease and possibly those treated early after the initial cerebrovascular event. In addition, operator and procedure-related risk factors have been identified for stenting: periprocedural stroke risk is higher for stents with open-cell than closed-cell design and decreases with higher current volume of procedures performed by the operator. The clinical relevance of silent periprocedural complications is increasingly recognized: elevation of heart enzymes without other symptoms or signs of myocardial infarction, which is more common after endarterectomy, increases long-term mortality. Silent brain infarction on the other hand, which is more common in stenting, appears to increase the risk of recurrent clinically manifest cerebrovascular events in the short-term. Long-term follow-up to 10 years after randomization in the ICSS trial reveals equal efficacy of stenting and endarterectomy in preventing fatal or disabling stroke, the trial's primary outcome measure, and shows no difference in patients' functional ability between the two procedures. There is also no difference in long-term risk of severe restenosis or occlusion of the carotid artery after completed treatment between the two arms. The author concluded that the choice between the two procedures in treating patients with symptomatic carotid stenosis is therefore best guided by factors influencing periprocedural risks, like age, white matter disease, open-cell stents, and low case volume for carotid artery stenting.

#### CEA. Shunting and contralateral carotid occlusion: never, always, or in selected cases?

J. Cronenwett

The author started by placing some questions regarding carotid endarterectomy (CEA) in the setting of contralateral carotid occlusion (CCO). Is the stroke rate higher during CEA? Are shunts required more frequently? Should a shunt be placed in all patients with CCO?

Even though the stroke rate was higher for CEA with CCO in the NASCET trial (North American Symptomatic Carotid Endarterectomy Trial), in the ACAS trial (Asymptomatic Carotid Atherosclerosis Study), it was not, and multiple smaller studies showed different outcomes. Meanwhile, a meta-analysis published in 2013, gathering 25 726 patients (Antoniou GA et al. *J Vasc Surg.* 2013;57:1134-1145), verified that the stroke rate is actually 1.5 to 1.7 times higher for CEA with CCO, with important variations in shunt use between local and general anesthesia. A recent study showed that shunt requirement had an odds ratio of 4.3 in the CCO setting (Pennekamp CW et al. *Eur J Vasc Endovasc Surg.* 2013;46:631-637).

Subsequently, he presented his study that investigated the association between surgeon practice pattern in shunt placement and 30-day stroke/death in patients undergoing CEA with CCO. Among 6379 primary isolated CEAs performed in the Vascular Study Group of New England (VSGNE) between 2002 and 2009, 353 patients were identified who underwent CEA in the setting of a CCO. They examined 30-day riskadjusted stroke or death rate across the reason for shunt placement (no shunt, shunt placed routinely, and a shunt placed for an indication) as well as 2 distinct surgeon practice patterns in shunt placement (surgeons who selectively utilize a shunt (0% to 95% of their CEAs), or routinely utilize a shunt (>95% of their CEAs). Of 353 patients with CCO, 33% underwent CEA without a shunt, 49% underwent CEA using a shunt placed routinely, and 18% had a shunt placed for a specific indication. There were no significant differences in rates of 30-day stroke or death across the categories for the reason for shunt use (3.4%, no shunt; 4.0%, routine shunt; 4.8%, shunt for indication; P=0.891). However, across surgeon practice pattern in shunt use, the risk of 30-day stroke or death was higher for surgeons who selectively placed shunts and lower for surgeons who routinely placed shunts (5.6%, selective; 1.5%, routine; P=0.05). Stroke/ death rates were lowest when individual surgeons' intraoperative decisions reflected their usual pattern of practice: 1.5% stroke/death rate when "routine" surgeons placed a shunt, 3.4% when "selective" surgeons did not place a shunt, and 7.6% stroke/death rate for "selective" surgeons who placed a shunt (P=0.05 for trend; Goodney PP et al. J Vasc Surg. 2012;55:61-71).

The author concluded that shunt use for CCO during CEA is associated with fewer complications, but only if the surgeon uses a shunt as part of his or her routine practice during all CEAs under general anesthesia. When local anesthesia is applied, a shunt should only be placed for neurologic deficit.

#### CAS. My favorite stent is...?

M. Bosiers

In an endovascular treatment, the plaque is being contained by a stent and not removed as in carotid endarterectomy. At the end of the procedure, after removal of the embolic protection device (EPD), the stent is the only protector.

In this context, scaffolding (ie, plaque containment) is perhaps the most important feature of a carotid stent and an open-cell design allows higher prolapse of the plaque, especially in tortuous curvature ("fish scaling"). As a result, open-cell stents are significantly more prone to induce new ipsilateral lesions than closed-cell stents (Schnaudigel S et al. *Stroke*. 2008;39:1911-1919). For this reason, the Wallstent (Boston Scientific) and the Xact stent (Abbott Vascular) are good candidates for the treatment of (mainly symptomatic) carotid lesions because of their high scaffolding characteristics.

The choice of the stent is also determined by the arterial anatomy and the morphology of the lesion. Due to this reason, the conformability, vessel wall adaptability, and radial force are also important factors for the choice of an ideal carotid stent. Conformability is a significant feature to maintain the original anatomy. In fact, a rigid stent may cause a distal kinking. The ability to adapt to the vessel wall is also quite relevant, especially when the difference in diameter between common and internal carotid artery is high. Additionally, a carotid stent needs to have sufficient radial force to be able to resist elastic recoil and radial crush, but excessive radial force may promote intimal hyperplasia or cause plaque disruption in vulnerable lesions.

Meanwhile, new developments in carotid stent technology must combine the high scaffolding characteristics with an ideal conformability, vessel wall adaptability, and radial force. The need for flexible, maximally scaffolding stents that have the potential for reducing the late emboli, is obligatory to revive the carotid artery stenting procedure. In this context, two new stents are in the pipeline: the Terumo Roadsaver and the Gore carotid stent.

As these new devices appear to be promising tools for the treatment of carotid artery disease, the favorite stent for the author is not on the market yet.

#### 1.4 Superficial femoral artery (SFA) and stents, visceral arteries, and leg arteries

#### 1.4.1 Controversy: Do we really need a stent in long SFA lesions?

#### No: Drug eluting balloons (DEB) are the answer.

T. Zeller

The author started by presenting recent data regarding subintimal angioplasty of transatlantic inter-society consensus II class C/D lesions (TASC II C/D lesions), stressing a primary 12-month patency of 52% to 73% (Sidhu R et al. *Vasc Endovascular Surg.* 2010;44:633-637; Kim SJ et al. *Circ J.* 2010;74:1959-1964). Then, he introduced several studies and a meta-analysis concerning the results of the drug-eluting balloon (DEB) in the superficial femoral artery (SFA), showing a clear benefit of DEB compared with standard angioplasty (Cassese S et al. *Circ Cardiovasc Interv.* 2012;5:582-589). Subsequently, he compared the results of DEBs with the drug-eluting stents (DES). To do so, he proposed the Propensity Score Analysis to allow an "apples-to-apples" comparison under nonrandomized conditions and to permit the balance of covariates to make more valid inferences about treatment effects.

He concluded that: (i) DEBs potentially overcome the Achilles's heel of reduced durability of endovascular revascularization; (ii) with the limitations of a retrospective single center study, the Propensity Score statistical method adds rigor and reliability to head-to-head comparisons of real-world cohorts with approximately 90% of bias removed from confounding variables; (iii) IN.PACT Admiral (DEB) and Zilver PTX (DES) offer similar safety and efficacy outcomes to patients treated for claudication and rest pain due to long (roughly 19 cm) SFA lesions; and (iv) DEBs offer a broader anatomical applicability and bring all the advantages of a "leave nothing behind" first-line therapy.

#### Yes: Newest stents are perfect for the job.

Y. Gouëffic

The author started by affirming that, currently, endovascular treatment of femoropopliteal lesions superior to 15 cm as a first-choice treatment remains controversial. Different types of endovascular devices could be used to treat long femoropopliteal lesions such as simple balloons, bare metal or covered stents, and drug-eluting devices. Presently, nitinol self-expanding stents appear to be the gold standard of the endovascular treatment for femoropopliteal lesions inferior to 15 cm. Indeed, nitinol alloys allow scaffolding of the arterial wall in order to prevent elastic recoil, negative remodeling, and keep a greater flexibility in a tortuous physical environment. Most of these devices have been assessed in short, femoropopliteal lesions; therefore, the results cannot be generalized to longer femoropopliteal lesions.

Indeed, the treatment of long femoropopliteal lesions is still challenging for different reasons, which are especially related to the clinical status of the patients, technical factors, mechanical stress submitted to the femoropopliteal axis, and mechanical properties of the devices. Newer generations of longer nitinal self-expanding stents could allow endovascular treatment of longer femoropopliteal lesions thanks to their scaffolding properties and their resistance to compression and fracture in this tortuous physical environment. The author concluded that: stenting of trans-atlantic inter-society consensus II class C/D lesions (TASC C/D) femoropopliteal lesions appears to be a safe, efficient, and durable repair; early narrow clinical and duplex scan follow-up of long stents is mandatory to detect potential thrombosis and in-stent restenoses events; primary stenting of TASC C/D needs ongoing surveillance and longer follow-up, given the high rate of critical limb ischemia; perhaps drug-eluting stents for TASC C/D femoropopliteal lesions may be the future, pointing to STELLA-PTX trial (STEnting Long de l'Artère fémorale superficielle- Zilver PTX) results, which are going to be presented soon.

#### 1.4.2 Controversy: When a stent is needed, do you choose a bare stent or a covered stent?

#### Bare stent and I'll tell you why.

T. Zeller

The author began his presentation by stating that the superficial femoral artery (SFA) territory has much higher rates of restenosis compared with other vascular territories (coronary, carotid, iliac, renal, etc). As such, covered stent implantation in femoropopliteal artery disease is an appealing concept to prevent neointima growth into the stent lumen, which is the background of in-stent restenosis development. However, no study, so far, has shown a significant benefit for the implantation of Viabahn endoprosthesis over bare metal nitinol stent placement in lesions shorter than 20 cm. The recently published VIASTAR trial (Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease) has shown superior patency outcomes only for femoropopliteal lesions longer than 20 cm (Lammer J et al. J Am Coll Cardiol. 2013;62:1320-1327). Endograft implantation has certain limitations such as unknown duration of dual antiplatelet therapy (4 weeks for bare metal nitinol stents), occlusion of potential collateral vessels, and the higher device costs. Edge stenosis remains the Achilles's heel of endograft

implantation in peripheral arterial disease. Thus, provisional bare metal nitinol stent placement remains the therapy of choice in trans-atlantic inter-society consensus II class A/B (TASC II A/B) femoropopliteal lesions. Second and third generation bare metal stent trials have resulted in satisfying 1-year primary patency rates of approximately 80% in these lesion subcohorts (Laird JR et al; RESILIENT Investigators. *Circ Cardiovasc Interv.* 2010;3:267-276; Scheinert D et al. *J Endovasc Ther.* 2011;18:745-752). The author concluded that: (i) bare metal stents offer superior technical results over balloon angioplasty due to their better acute and mid-term performance; (ii) dedicated stent designs such as interwoven closed-cell design and 3-dimensional helical design might improve technical and clinical results of bare metal stents (1-year patency ≥80%); (iii) bare metal stents show almost no additional loss of patency after 1 year; and (iv) Viabahn endografts might improve outcomes in TASC C/D lesions, however with higher costs, coverage of collateral vessels, and an unknown duration of dual antiplatelet therapy.

#### Covered stent without any doubt.

M. Bosiers

The most common mode of failure after a technically successful stenting in the superficial femoral artery (SFA) is restenosis due to neointimal hyperplasia. Bare metal stents (BMS) are implanted in order to provide scaffolding for the plaque that is pushed aside during percutaneous transluminal angioplasty (PTA), and the chronic outward force ensures that vessel recoil is minimized. However, cells can continue to proliferate through the stent struts, eventually resulting in restenosis; the likelihood of this occurring is theoretically proportional to the length and severity of the lesion. A covered stent (CS), by contrast, provides a barrier to hyperplastic tissue ingrowth. The failure mechanism of a CS is similar to a bypass graft-edge stenosis, possibly followed by CS thrombosis, is generally the culprit. These mechanisms are theoretically much less dependent on lesion length.

Both BMS and CS for femoropopliteal occlusive disease treatment have been studied in the literature; however, lesion length and severity, term of study, and patency definitions in various studies have been different, making it hard to compare results. Luckily, we now have level-one evidence showing a difference between BMS and CS. The recently published VIASTAR study (Viabahn Endoprosthesis With PROPATEN Bioactive Surface [VIA] Versus Bare Nitinol Stent in the Treatment of Long Lesions in Superficial Femoral Artery Occlusive Disease; Lammer J et al. J Am Coll Cardiol. 2013;62:1320-1327) randomized the latest generation, heparin-bonded CS to BMS in patients with complex femoropopliteal lesions (average lesion length was 18 cm). This multicenter study showed a primary patency difference between the arms at year 1 in favor of CS (78.1% vs 53.5%, P=0.009). The VIPER study (Gore Viabahn endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease; Saxon RR et al. J Vasc Interv Radiol. 2013;24:165-173) was a single-armed, 119 limb study utilizing the newest version of CS. The patient demographics and lesion characteristics are similar to the previous study mentioned. In this study, the heparinbonded CS showed a one-year primary patency rate of 73%. Additionally, there was no difference in the patency between patients with lesions <20 cm and those with lesions >20 cm, indicating that even very long lesions could be treated successfully. The results did show that CS oversized by <20% at the proximal edge (instructions for use

recommends 5% to 20% oversizing) significantly improved the results (88% primary patency). The single-armed 25-cm VIABAHN Study enrolled lesions that are even more difficult than the lesions studied in VIASTAR and VIPER. This study, which only enrolled patients with lesion lengths greater than 20 cm, had 93% chronic total occlusions and a mean lesion length of 26.5 cm; all were treated with heparin-bonded CS. The interim 12-month primary patency was 66.7%, which is encouraging considering the extremely advanced disease of the patients studied.

Consequently, the author concluded that data for the newest generation of heparinbonded CS clearly show superior patency results to BMS when studied in difficult lesions. When a stent is required in femoropopliteal interventions, a covered stent should be chosen.

#### 1.4.3 Visceral arteries

#### Renal artery stenting: are there any indications left?

L. Mendes Pedro

Renal artery stenosis is a cause of arterial hypertension in around 1% to 4% of all hypertensive populations. There are three therapeutic options: medical treatment, conventional surgery, and endovascular stenting.

The indications for open surgery are: (i) concomitant need for aortic or visceral surgical reconstruction; (ii) distal or branch renal stenosis; (iii) very calcified lesions; (iv) endovascular surgery is not possible; and (v) complications of endovascular treatments and renal revascularization in children. The technical success in renal stenting cases are excellent (95% to 100%) with mortality <1%, restenosis between 10% and 20%, primary patency between 75% and 82% in 5 years. Accordingly, the author stated that most patients with renal stenosis may not require intervention, and therefore, should be managed medically.

In conclusion, renal "prophylactic" interventions, driven by image, are ineffective. The randomized control trial did not address severely symptomatic patients where the benefit of revascularization is usually accepted, more prospective studies with improved patient and lesion selection criteria are needed.

#### References:

Nolan et al. *J Vasc Surg.* 2005;41:46-52; Sivamurthy et al. *J Vasc Surg.* 2004;39:565-574.

#### Renal denervation: how does it work, who should be treated?

I. Baumgartner

According to the author, drugs work, but not as well as you might think. Thirty-five percent of patients treated remain uncontrolled. The contributing factors to uncontrolled hypertension include physician inertia, patient compliance, and resistant hypertension. Strong demands exist for a new and safe therapy to control resistant hypertension.

The initial proof-of-control concept study, Simplicity HTN-1, and the multi-center, prospective, randomized Simplicity HTN-2 trial investigated the effect of radiofrequency-based and catheter-based renal denervation (RND) in patients with resistant hypertension.

The catheter is introduced through the femoral artery and is threaded through the renal artery near each kidney. Once in place, the tip of the catheter delivers low-power radiofrequency energy to several locations to disable the sympathetic nerves throughout the artery. The author treated 153 patients with a 36-month follow-up. Eighty percent of patients treated had superior reduction in systolic baseline pressure up to 10 mm Hg.

In conclusion, the author suggests that transcatheter renal sympathetic denervation is safe and simple to be performed. Significant reductions in blood pressure were achieved in patients with multidrug resistant hypertension. The effect has been sustained through at least 36 months. There was no significant decline in renal function.

#### Acute visceral ischemia: how to improve survival?

Y. Castier

In a systematic review of 45 observational studies, including 3692 patients with acute mesenteric ischemia, in-hospital death rate was 70%. The first step to improve the outcome is to make the diagnosis. Only 50% of acute mesenteric ischemia is identified before surgical exploration or death. Early diagnosis makes the difference and is the major prognostic factor.

The surgeon must be aware of abdominal pain by doing a reassuring examination and also be aware of atherothromboembolism risk factors. Other nonspecific signs include nausea, vomiting, diarrhea, tachycardia, and abdominal distention.

The CT scan is the gold standard with 96% sensitivity and 94% specificity. The signs in CT include intestinal wall thickening, delayed mucosal enhancement, bowel dilatation, mesenteric vessel occlusion, ascites, and solid organ infarcts.

There are no early and specific biomarkers as hyperlactatemia is not an early biomarker. It is a multimodal and multidisciplinary management composed of gastroenterology, anesthesiology, radiology, digestive surgery, and vascular surgery.

In conclusion, early diagnosis and revascularization promotes the best survival rates.

#### 1.4.4 Leg arteries

#### What is the angiosome concept? Is it more useful than pedal arch patency?

P. Schneider

Taylor and Palmer first introduced the angiosome concept in 1987. They analyzed the blood supply to the skin and subcutaneous tissues through ink injection studies, dissection, perforator mapping, and radiographic analysis of fresh cadavers. A

3-dimensional network of vessels was identified as the blood supply source for specific blocks of tissue, further interconnected by a rescue system called "choke-vessels."

The anatomical planning of vascular reconstruction based on angiosomes involves understanding the connections among foot and ankle branches and associated angiosomes.

The angiosome strategy is less important in a fully intact pedal arch, more likely in nondiabetics, in Rutherford category 4 with no tissue loss, lesions above the ankle, and superficial ulceration (<10 mm in diameter and toe pressure ≥50 mm Hg after percutaneous transluminal angioplasty (PTA). The angiosome concept helps to guide therapy for Rutherford category 5 lesions (which tibial artery to revascularize?) and Rurtherford category 6 lesions (how many tibial arteries to revascularize?).

The angiosome concept is an opportunity for targeted therapy. Healing is more likely and is faster after direct revascularization of the correct angiosome. The angiosome concept helps explain some of the variability in revascularization results for critical limb ischemia, especially in diabetics with compartmentalized pedal circulation.

#### 1.5 Critical limb ischemia

#### 1.5.1 Controversy: Critical limb ischemia. Endo or open first?

#### Endo is the first choice strategy.

K. Deloose

Surgical bypass has been the gold standard for revascularization in the critical limb ischemic (CLI) patient for years now. In fact, it allows a 5-year limb salvage rate >80%. However, it has a 5% mortality rate, 10% to 20% incision wound complications. In 20% to 80% of successful patent bypasses, there is a recurrent or persistent ulcer or wound at one year. It has also been shown that bypass surgery induces a 12% decline in deambulation and a 15% loss in independent living post procedure. Additionally, distal bypass surgery only allows one vessel to be revascularized and cannot be performed in infected distal areas. Moreover, many times, there are no suitable veins and these patients typically have numerous comorbidities (the "old fragile no-vein men" concept). The progress in minimally invasive, endovascular techniques and technologies, combined with the improving skills among interventionalists, is starting to shift from bypass-surgery toward using an endovascular approach first.

The BASIL trial (Bypass versus Angioplasty in Severe Ischaemia of the Leg) is the only randomized trial to compare bypass with an endovascular approach (Bradbury AW et al; BASIL trial Participants. *J Vasc Surg.* 2010;51:18S-31S). This study showed a similar amputation-free survival as well as quality of life between the two groups. However, the BASIL trial has several issues: (i) inclusion of patients with severe limb ischemia instead of CLI (inclusion ankle pressure ≥50 mm Hg); (ii) exclusion of end-stage renal disease patients; (iii) almost no below the knee lesions included; (iv) high primary procedural failure rate (20%); (v) failed angioplasties are logically doing worse; (vi) limited range of endovascular strategies (balloon angioplasty only); (vii) post hoc long-term 24-month analysis with low patient numbers (high mortality rate in the patient cohorts); and (viii) outdated because the devices and techniques for endovascular treatment have

improved substantially over the past decade. In fact, results of several high-quality, well-controlled (randomized and nonrandomized) studies and registries, using modern endovascular techniques and technologies, reveal one-year primary patency and limb salvage comparable with surgical bypass results, but with tremendously lower morbidity and mortality rates. Moreover, the vascular community has followed the evolution and, between 1996 and 2006, the number of endovascular lower-extremity interventions in the Medicare population reportedly increased by 230%, whereas the number of bypass procedures decreased by 42%.

Last, but not least, endovascular intervention, as a first approach, is also the preferred personal choice of CLI patients. Now, people prefer minimally invasive approaches with short hospital stays to huge surgical incisions with long admissions in high-dependency units

#### Surgery should be first line.

F. Mussa

The author started by saying that, according to the BASIL trial (Bypass versus Angioplasty in Severe Ischaemia of the Leg), critical limb ischemic (CLI) patients who would live more than 2 years and have a usable vein should undergo a bypass procedure. Then, he assumed that endovascular techniques have markedly evolved and showed the results from a study performed by his group reporting the fate of failed primary revascularization and their rescued approaches. In this study, a cohort of 302 patients with CLI was identified between March 2007 and December 2010. Endovascularfirst was selected if: (i) the patient had short (5 to 7 cm) occlusions or stenoses in crural vessels; (ii) the disease in the superficial femoral artery was limited to transatlantic inter-society consensus II class A, B, or C lesions (TASC II A, B, or C); and (iii) no impending limb loss. Failures were defined as recurrent clinical signs and symptoms. Criteria for reintervention were the same as for primary intervention. Regarding the results, endovascular-first was performed in 187 (62%) and open-first in 105 patients (35%). Secondary procedures (endo or open) were more common after open-first (68% vs 55%; P=0.029). Patients with above knee open-first interventions were less likely to undergo secondary interventions than those who underwent endo-first at the same location, 58% vs 40%, respectively (P=0.003). Patients treated with rest pain were more likely to undergo secondary interventions than those with ulcers, 29% vs 54%, respectively (P<0.0001). At five-years, mortality rates were higher among those without secondary interventions, 53% vs 39%, respectively (P=0.0096). However, amputation rates were higher in patients undergoing secondary interventions, 22% vs 5%, respectively (P=0.0016). There was no difference in amputation-free survival based on the need for secondary interventions, 49% vs 47%, respectively (P=0.165). Patients with an initial open intervention followed by endovascular reintervention had a trend toward the best outcome with a 70% five-year amputation-free survival. The study concluded that at 5 years, a selective revascularization strategy led to frequent reinterventions, higher in those treated with an open-first approach. While amputation rates were higher in those undergoing secondary interventions, mortality was higher among those without secondary interventions. Amputation-free survival was not different between the two cohorts and a trend toward improved outcomes was demonstrated in those undergoing an open-first followed by endovascular reintervention.

The author determined that an endovascular approach can be bad depending on the patient's issues (unreliable, renal impairment, intolerance to antiplatelet medication), anatomy (difficult access, small vessels with multilevel disease, chronic total occlusions of the popliteal artery or its trifurcation), and system limitations (poor endovascular expertise or insurance issues). He also concluded that open surgery is better for long, calcified, multilevel disease, large tissue loss, distal target adequacy, and in cases of endovascular failure (technical, nonhealing, repeated intervention, mounting cost, etc). He finished his talk by stating that: (i) he is an endovascular believer and practitioner; (ii) there are negative consequences for nonselective use of the endovascular-first approach; (iii) there is a need to make choices individually based on the patient's anatomical, wound, and functional status; (iv) patients should not be denied a highquality bypass because they are sick or the physician thinks it is a big operation.

#### 1.6 Vascular access

#### 1.6.1 Tunneled catheters

#### Prevention and treatment of sepsis.

J. Pengloan

According to the author, tunneled catheters (TCs) are essential devices for patients on hemodialysis, but are frequently associated with high levels of morbidity and mortality due to an inflammatory process or infection. Development of an intraluminal bacterial biofilm is the cause of bacteremia and abscesses may occur during the introduction of bacteria from skin flora during the connection and disconnection of TCs. The treatment is based on the association of a systemic antibiotic lock solution with a fibrinolytic treatment of TC that should be continued at least 2 weeks after the bacterial cultures are negative. Staff training is mandatory to avoid this complication.

#### When should an infected catheter be changed?

B. Canaud

Infection remains a major burden for hemodialysis patients, representing the second cause of hospitalization and mortality. There are different pathogenic pathways involved and include infected thrombus, track infection, exit skin infection, endoluminal contamination, and the catheter biofilm. The most frequent pathogen is *Staphylococcus sp* representing more than 50% of infections. Infective endocarditis is associated with high mortality in hemodialysis patients. Diagnosing catheter-related infections is very important with clinical observations, such as the presence of local or systemic symptoms, clinical vigilance, and monitoring of the catheter. In the diagnosis of microbial infections, identifying pathogenic microorganisms is mandatory through swabbing of culture skin exudates and the catheter hub, blood cultures, Gram staining, microorganism determination, and antibiotic testing.

The uncomplicated catheter (no skin exit infection, no fever, no systemic reaction, negative blood culture, no risk factor, favorable microorganism type) may be retained with local skin therapy, systemic antibiotics, and close monitoring. The complicated catheter (tunnel infection, sepsis, positive blood culture) must be removed and treated with systemic antibiotic therapy for 6 to 8 weeks with close and prolonged monitoring.

Catheter-related infections and blood stream infections should be considered as serious events in hemodialysis patients. Management of catheter-related infections should follow strict rules of the best clinical practices and close patient monitoring.

#### Difficult catheter insertions.

R. Shoenfeld

The incidence of central vein stenosis or occlusion in patients in chronic dialysis is highly significant (up to 42%). The central vein patency is a prerequisite for optimum chronic dialysis catheter tip position. Alternative cannulation may be safely performed via external jugular or other suitable collateral veins in or near the neck or by transfemoral or translumbar routes. The patent access sites include the right jugular, left jugular, right femoral, left femoral, translumbar, left subclavian, and right subclavian. The access of last resort is the transhepatic.

New and innovative endovascular recanalization techniques and devices are expanding the frontiers of end-stage vascular access. When possible, exotic central catheter insertions should serve as a pretext or bridge to recanalization and reconstruction of central veins to reclaim lost opportunities for permanent arteriovenous access and to preserve venous capital.

#### 1.6.2 Operative Techniques

#### Snuffbox fistula.

C. Gibbons

The first citation of a snuffbox fistula was over 30 years ago, but is less frequently used by surgeons than the radiocephalic arteriovenous fistula (AVF) at the wrist. However, it is the most distal fistula, giving the longest forearm cephalic access for needling. The author recommends, when performing a fistula, to stay as distal as possible, avoid grafts, and use the nondominant arm as the first option. The forearm AV fistula is easier to needle and more comfortable for the patient, reducing the incidence of steal.

The indications for snuffbox AV fistula include veins >2 mm, arteries > 1.6 mm (perhaps 2 mm for women). The snuffbox fistula is possible as a primary access in 53% of cases for indication of AV fistula.

In conclusion, snuffbox has similar patency to wrist AVF, gives longer vein length, preserves the venous "capital," and still allows wrist AVF in 45% of patients, if failure occurs.

#### References:

Shemesh D et al. *Cardiovasc Surg.* 2003;11:35-41; Biukians A et al. *J Vasc Surg.* 2008;47:415-421.

#### Middle forearm fistula.

G. Bonforte

The American and European guidelines recommend the distal wrist radial-cephalic fistula, proposed by Cimino-Brescia, as the first and best for hemodialysis access. This arteriovenous fistula requires easy placement, preservation of the patient's vascular network, and needs fewer interventions for complications (infection, stenosis, and thrombosis) compared with grafts and central venous catheters.

To avoid steal syndrome complications, the author recommends that a smaller-sized anastomosis be performed in relationship to the size of the brachial artery to limit the flow through the fistula.

In the last 30 years, the hemodialysis population has become older and sicker, comorbid factors have increased, and the life expectancy has been reduced, so nowadays, it is even more important to create a working vascular access with as few complications as possible. According to the author, several studies have shown that the classic distal radiocephalic (DRCF) fistula has an increased rate of early failure (early thrombosis or failed maturation), therefore, it is correct to wonder if the DRCF still represents the best first choice for vascular access. The middle-arm fistula (MAF) is suggested as an alternative option.

The selection criteria for MAF for primary arteriovenous fistula (AVF) include: (i) insufficient vessel diameter for successful DRCF creation; and (ii) two or more comorbid factors among: diabetes mellitus, atherosclerosis, obesity, neoplasm, coagulation disease, peritoneal dialysis failure, and >65-years-old.

In conclusion, based in the author's experience, he suggests reconsidering the current recommendations in clinical practice guidelines in an elderly population with ischemic and diabetic nephropathy, although the DRCF remains the first vascular access choice in properly selected patients. The MAF could be proposed as the primary AVF in selected patients when a DRCF is not feasible and as a second step in case of DRCF failure in all patients before attempting to place a brachial artery inflow AVF.

#### What is the least worst arteriovenous bypass for the upper limb?

M. Lazarides

Despite the fact that the European and USA guidelines recommend the increased use of an autogenous fistula because it has a more durable access once matured, almost 50% of all arteriovenous fistulas (AV) performed fail. Although prosthetic grafts are not superior to the AV fistula (AVF), they present the only choice in selected patients in whom an autogenous fistula simply cannot be constructed.

AVF and grafts are both useful in providing vascular access. An additional indication of prosthetic grafts is the use of short polytetrafluoroethylene segments in revisions of autogenous accesses, without further consumption of venous capital by harvesting veins or compromising more proximal access sites.

For elderly patients with a life expectancy < 18 months, a graft is an attractive option.

#### References:

Rooijens PP et al. *J Vasc Surg.* 2005;42(3):481-486; Staramos DN et al. *Eur J Surg.* 2000;166(10):777-781; Sgroi MD et al. *J Vasc Surg.* 2013;58(2):539-548.

#### A new sterile elastic exsanguination tourniquet.

E. Landenheim

Arterial tourniquets apply sufficient pressure on a limb to collapse the artery and block the arterial blood supply to the limb. Tourniquets have been in use in military and emergency medicine for hundreds of years. They were introduced to orthopedic surgery in 1873 by Dr Frederic Esmarch. Inflatable cuff tourniquets were adopted for orthopedics by Dr Cushing. All tourniquets are made to apply radial pressure on the circumference of the limb. There are three general types of tourniquets: (i) inflatable or pneumatic cuffs (Cushing); (ii) wrapped elastic or nonelastic bands (Esmarch); and (iii) rolling elastic rings (HemaClear). The elastic exsanguinations tourniquet was patented in 1987 by Dr Noam Graviely. Although the prototypes made by a rubber sleeve only showed some results on upper extremities, they failed to achieve their purpose on lower extremities. Development of a separate constricting element (silicone ring) was required. The elastic exsanguinations tourniquet (HemaClear) consists of a calibrated silicone ring wrapped around an elastic sleeve (stonicket) and straps with handles that are used during the application. It is not pneumatic and is significantly more narrow than a standard pneumatic tourniquet.

The author recommends special precautions to avoid twisted veins when doing vein transportations. Avoid tourniquets in patients with severely atrophic skin and release the tourniquet before closing the incision.

The advantages of a surgical exsanguination tourniquet are that the very narrow footprint expands the potential for tourniquet control, it come in 4 sizes to fit any upper limb from 14 cm to 85 cm and it leads to less blood loss from arteriovenous access procedures, which may result in fewer transfusions.

#### Reference:

Ladenheim E et al. J Vasc Access. 2013;14(2):116-119.

#### Tagliatelle technique: a revolution in vascular access to the lower limbs.

B. Boura

In cases when all options of upper vascular access are exhausted, vascular surgeons are required to consider a new lower extremity access. The author proposed the tagliatelle technique, for these cases when all attempts to create a hemodialysis access fail. This technique consists of using the great saphenous vein, harvested from the thigh and just below the knee, which is then longitudinally opened, freed from all valves, forded in 2 to create one anterior and one posterior vein panel, both with a sutured edge, as has already been described for other locations. The final result is a conduit, which doubles the initial diameter suitable for hemodialysis. This conduit is subcutaneously tunneled

and then anastomosed end-to-side with the superficial femoral artery in the mid-thigh. The author believes that this technique can be used in other anatomies, such as upper limbs in selected patients.

#### References:

Correa JA et al. BMC Surg. 2010; 10:28; Mallios A et al. Eur J Vasc Endovasc Surg Extra. 2012;23:e40-e41.

#### 1.6.3 Controversy: Small vein and forearm AVF creation

#### Peroperative technique.

P. Veroux

Ideally, every patient should initiate dialysis with a mature fistula suitable for cannulation, but in the real world, only a minority of patients has a well-functioning arteriovenous fistula (AVF) at the time of starting hemodialysis. The series reporting 1-year latency rates varies from 36% to 62.5%. The most important factors limiting the primary latency of distal autogenous AVF are quality of radial artery inflow and availability of a long patent venous segment with adequate diameter. Veins smaller than 2.5 mm in diameter have been reported to increase immediate failure and decrease the primary latency rate. The purpose of the PBA trial (Primary Balloon Angioplasty) was to evaluate the safety and efficacy of a new technique, the Primary balloon angioplasty, used to increase the cephalic vein diameter at the time of AVF creation, compared with the standard hydrostatic dilation technique. The inclusion criteria were a radial artery with normal duplex ultrasound parameters and a cephalic vein with a diameter less than 2 mm. The exclusion criteria were segmental cephalic vein occlusions and no compliance with antiplatelet therapy. A total of 40 patients were randomized on a 1:1 basis into two groups according to the technique used to increase the vein caliber: hydrostatic dilatation (HD) group (21 patients) and primary balloon angioplasty (PBA) group (19 patients).

The results demonstrated an immediate success in 67% of patients in the HD group and 100% in the PBA group. The mean maturation time was 55 days in the HD group and 33 days in the PBA group.

In conclusion, PBA of very small cephalic veins performed before the creation of a distal AVF for hemodialysis, is a safe and feasible procedure. PBA is associated with excellent latency and maturation.

#### Postoperative balloon angioplasty.

A. Raynaud

The maturation of a fistula requires arteries to be able to provide a flow of at least 500 mL/min, superficial veins able to develop and to be punctured 3 times a week, and normally patent central veins. Preoperative assessment of artery and vein patency is required before the creation of an access (clinical examination, artery and vein ultrasonography, venography).

A radiocephalic fistula is the first-choice access. When radial arteries or cephalic veins are not suitable, other sites should be considered for access creation, mainly ulnobasilic or a more proximal access. When possibilities of access creation are very limited, the creation of distal access should be considered, despite nonoptimal radial artery or cephalic veins. This is the case when the cephalic veins are small.

When a surgeon creates a fistula, he avoids traumatizing the vein because he knows that a tiny trauma often engages a process leading to stenosis. He takes care to obtain a harmonious and regular anastomosis because he knows that turbulences will traumatize the venous wall and will cause a postanastomotic stenosis. Dilatation causes major parietal damages.

The peroperative dilatation of a vein whose diameter is underestimated is not only useless, but is also deleterious. Dilation causes major parietal damages leading to a risk of rupture, a high risk of early thrombosis, and a very high risk of delayed stenosis (80%). Compared with postoperative dilatation, the risk of complications appears higher with the venous wall not being developed at all; therefore, the access flow is lower and the vein is more prone to spasm.

The postoperative dilatation is achieved only when necessary, and is safer because it is achieved on partly developed veins. There are fewer risks of ruptures if the dilatation is performed on somewhat enlarged venous walls. There are fewer risks of early thrombosis because of the higher flow, which favors venous wall remodeling and the risks of spasms are lower.

In conclusion, the author considers peroperative dilatation seldom evoked, because when a doubt exists about the abilities of a cephalic vein to mature, the access is created on another site. The peroperative dilatation of a small vein along its entire length is inconceivable for the author for several reasons including: (i) the vein could be large enough, but its diameter may be underestimated by ultrasonography in which case a peroperative dilatation is useless and deleterious; (ii) a small, but normal vein will maturate alone only requiring a little more time; and (iii) dilatation of a thin vein wall has a high risk of rupture, early occlusion, and secondary stenosis.

Postoperative dilatations are performed only when needed. The maturation failure is due to insufficient flow (due to overlooked preexisting venous or artery lesions) and lesions occurring after the fistula creation. Postoperative dilatation is safer when attempted on a partly mature fistula with a larger diameter, more resistant wall, higher flow, and less risks of spasm.

#### 1.6.4 Lecture

#### Vascular steal and ischemia after vascular access creation.

P. Bourquelet

The ischemia after arteriovenous fistula (AVF) creation results from the association of high pressure arterial flow (not only retrograde flow coming from the distal artery, but also cut from the proximal artery) and a low-pressure vein. The clinical grading includes

cyanosis, mild coldness, pain during dialysis sessions, rest pain, motor dysfunction, limited ulceration or necrosis, and irreversible tissue loss in the hand.

Treatment algorithms for cases of coldness, cyanosis, and pain during dialysis require conservative treatment. In cases of rest pain, motor dysfunction, and limited necrosis, duplex/angiography is mandatory in order to look for artery stenosis. In case of distal necrosis, fistula ligation is necessary.

In conclusion, distal ischemia occurs in 5% to 10% of AVF cases in the elbow. The treatment consists of angioplasty, flow reduction, and AVF ligation.

#### Puncture ultrasound guidance: to decrease access site complication.

P. Schneider

The author started by presenting the rationale for puncture by ultrasound guidance. In fact, it appears to reduce access site complications (lower risk of hematoma, bleeding, and arteriovenous fistula) by allowing single-wall punctures and first pass, as well as avoiding branches, calcifications, and lesions. It is also optimal for the use of closure devices such as for those used for percutaneous EVAR, as it permits an optimal puncture site placement. Subsequently, the author corroborated these statements by presenting the results of several studies (Gedikoglu M et al. Catheter Cardiovasc Interv. 2013;82:1187-1192; Seto AH et al. JACC Cardiovasc Interv. 2010;3:751-758; Lamperti M et al. Intensive Care Med. 2008;34:2100-2105). He further introduced some tips like: (i) placing the needle 1 to 2 cm above the femoral bifurcation, after finding the profunda; (ii) using imaging to avoid small common femoral artery branches and calcific patches; (iii) placing the needle at a steeper angle in a more calcified or scarred artery; (iv) obtaining a spot film with the needle in place to confirm that the puncture site is below the top of the femoral head to avoid retroperitoneal hematoma.

The author concluded his talk by stating that ultrasound-guided access provides added safety and reduces the most common complications, is readily available, allows a more ideal needle puncture placement, enhances use of closure devices, and brings an opportunity for quality improvement.

#### 1.7 Imaging and navigation tools

#### How accurate is intraoperative overlay imaging?

H. Kobeiter

The author started by defining accuracy as the quality or state of being correct or precise, and, technically, it is the degree to which the result of a measurement, calculation, or specification conforms to the correct value or the standard.

Next, he stated that in the last decade, there have been significant improvements and new developments in image guidance. Two-dimensional (2D) angiography has developed into three-dimensional (3D) rotational angiography, and more recently, C-arm cone-beam computed tomography (CBCT) has enabled 3D volumetric imaging. These recent image acquisition capabilities have been developed to assist clinicians

in performing procedures that could not be easily done with traditional fluoroscopy or digital subtraction angiography alone. CBCT can be used to guide catheter placement for intra-arterial therapy, stent positioning in arterial or venous disease, needle placement, and coil placement. In addition to image acquisition development, significant achievements have been seen in intraprocedural guidance software advancement that enables the use of multimodality image fusion to guide procedures. Image fusion and coregistration bring different imaging modalities together for targeting a specific location. The image fusion guidance has been reported to be accurate and useful for multiple applications in interventional radiology and endovascular procedures.

Subsequently, he presented several studies and concluded that all aortic parts and vessels are not equal to deformations; technology is accurate, but errors can be induced (vessel shifts, patient movements, or errors in overlay, for instance, as a result of a delay between diagnostic imaging and treatment), even though the majority can be corrected; 3D/3D fusion appears to be more precise than 2D/3D fusion; this technology is sufficient for current clinical requests, but for future applications (eg, robotics and automatic navigation) more accuracy may be needed.

#### Endovascular navigation: pros and cons of the Magellan system.

F. Cochennec

The Magellan robotic system combines a 9F OD robotically steerable guiding catheter 3D with a distal bend up to 90 degrees, a 6F OD robotically steerable leader catheter 3D with a distal bend up to 180 degrees, and 0.014" to 0.035" guidewires with full-roll capability. Approximately 300 cases were performed worldwide. The author presented the experience of his center from February 2013 to October 2013, totaling 28 cases. Most of them represented complex aortic aneurysms in which a total of 34 vessels were cannulated, with a mean cannulation time of 4 min 10 s, with no target vessel injury. The author concluded that the Magellan robotic system improves stability and pushability, facilitates navigation in complex anatomies, may reduce x-ray exposure and trauma, and has an acceptable learning curve. However, he also highlighted that the device is expensive, cumbersome, and not readily accessible.

# II. Venous diseases

#### 2.1 Deep vein and perforator

#### Deep venous reconstructive surgery for CVI. New procedures and tricks.

O. Maleti

Postthrombotic deep vein incompetence is an incapacitating disease, which, in most cases, can lead to severe chronic venous insufficiency.

The author proposed a question: What do we mean by deep venous reconstructive surgery for chronic venous insufficiency (CVI)? In answering, surgery aimed at repairing one or more venous valves, or aimed at reconstructing a nonrefluxing segment. Repair is frequently possible in CVI due to primary reflux, rarely possible in secondary reflux, never possible in valve agenesis. Reconstruction is possible in secondary reflux and valve agenesis. The main repair technique is valvuloplasty, which consists of shortening the free edge of the cusps. The modified technique is lifting the free edge of the cusps. In the secondary reflux, postthrombotic syndrome (PTS) valvuloplasty is rarely feasible because the cusps are ticketed and the sinus is modified. In such cases, the creation of a new nonrefluxing segment is preferable. We have several options; the first option is transposition, meaning to transpose a devalvulated segment into a valvulated segment, using various techniques (transposition on the profunda vein, saphenous vein, or distal femoro-profunda vein).

The neovalve is the second preferable option. This technique has been submitted for improvement. Neovalves create a competing flow. The advantage is to create a wash action into the pocket and a mobile flap.

The reconstruction in valve agenesis (absence of the valves affects the femoral and the profunda district. In these cases, the author prefers the endophlebectomy (removing the fibrosis that determines an obstruction) associated with stent insertion.

In conclusion, the author reminded the audience that severe CVI is an incapacitating disease and has a high social cost. Patients with a Clinical, Etiologic, Anatomic, and Pathophysiologic classification of  $\rm C_3\text{--}C_6$  must be investigated due to the limits of the US in making an exhaustive diagnosis. Additional investigations (air plethysmography, venography, and intravascular ultrasound, are needed. When a proximal obstruction is detected it must be treated first, and if the re-equilibrium of the leg is obtained, our mission is accomplished, if not, open surgery can be advisable to correct possible obstruction at the common femoral level and to correct noncompensated obstruction at the femoral level. Regardless of technique, we must abolish the reflux.

#### Do we need to treat lea perforator veins? Pros.

O. Nelzen

According to the author, incompetent perforators (IPs), together with superficial venous insufficiency (SVI) and deep venous insufficiency (DVI), contribute to global venous

incompetence. The number of IPs increases with the amount of reflux. Perforator incompetence is an independent factor contributing to venous disease severity.

The author related the myth that IPs are of importance only if combined with DVI; that would perhaps be true if we were standing still like statues, but we do walk, which changes the situation. In fact, IPs are connected more to SVI rather than DVI.

Most IPs are found in association with superficial venous reflux; if the venous reflux is left untreated, new IPs may develop. Missed IPs are strongly correlated with nonhealing or recurrent leg ulcers.

The second myth is that IPs become competent because of superficial vein surgery in ulcer patients? Only one out of three IPs normalize, thus, two out of three remained incompetent.

In series of a hard to heal venous ulcers, unresponsive compression, and 76 ablations of superficial venous incompetence, 66 IP treatments with radiofrequency (RF) ablation were additionally performed with a 6-month healing rate of 76%. Ablation of all refluxing superficial or perforating veins was recommended.

The indications are venous ulcer disease or eczema/sclerosis, size of perforator >3 mm, number of IPs, inflammation in the area of the perforator and severe edema.

In conclusion, the author proposes treating IPs in patients with: (i) Clinical, Etiologic, Anatomic, and Pathophysiologic classification (CEAP) classes  $C_4$ - $C_6$ ; (ii) in certain cases, with severe edema ( $C_3$ ) or recurrent varicose veins with several IPs; and (iii) clinical observation in patients with primary varicose veins ( $C_2$ - $C_3$ ).

#### Reference:

Harlander-Locke et al. J Vasc Surg. 2012;55:458-464.

#### Do we need to treat leg perforator veins? Cons.

J-J. Guex

The author proposed that we do not need to treat medial leg perforator veins (MLPVs), but that we do need to treat other incompetent perforator veins (IPVs) and to do something.

The reasons for not treating MLPVs are because they are a phenomenon of great saphenous vein (GSV) insufficiency, they usually disappear after treatment of the GSV, they are not usually responsible for skin changes, their treatment does not improve clinical results or reduce recurrences and are not satisfactory. The criteria for possible treatment of MLPVs are a diameter >5 mm, reflux >0.5 sec, or the reflux of MLPVs that is not accompanied by an incompetent GSV and is above a significant varicose cluster.

The possible treatments are ultrasound-guided foam ablation (not in PVs since a small collateral artery may be injected), thermal ablation with special probes under ultrasound guidance, in selected cases after treatment of a superficial network in IPVs remain.

In conclusion, the author proposed treating the superficial network, defering treatment of incompetent MLPVs, evaluating outflow obstruction, and considering iliocaval angioplasty and deep valve repair.

#### 2.2 Iliofemoral vein

#### Acute thrombosis for iliofemoral veins: thrombolysis or pharmaco-mechanical thrombolysis?

A. Camerota

Acute iliofemoral deep vein thrombosis (DVT) is associated with the most severe postthrombotic morbidity when treated with anticoagulation alone.

According to the author, patients submitted to thrombectomy compared with anticoagulation alone have improved latency, lower venous pressures, less leg swelling, and fewer postthrombotic symptoms. Catheter directed thrombolysis (CDT) has been shown to reduce postthrombotic morbidity, improve quality of life, and reduce recurrent DVT

The addition of external pneumatic compression devices to the leg being treated with CDT has been shown to accelerate lysis to noncompressed limbs.

In conclusion, both methods improve outcomes compared with anticoagulation alone, pharmacomechanical thrombolysis improves efficacy, speeds lysis, shortens treatment time, and causes no adverse effects on valve function.

#### 2.3 Venous Malformation

#### Vascular malformation classification: Hamburg or ISSVA classification?

A. Bisdorff Bresson

According to the author, the term "angioma" is often incorrectly used in literature to name both vascular tumors and vascular malformations. Vascular malformations are congenital developmental errors concerning the lymphatic, arterial, and/or venous system. They might be present at birth, but are not always seen. They can appear in childhood, adolescence, or adulthood, but will never disappear.

The Hamburg classification (1993) classifies the vascular malformations according to the type of predominant vessel. This classification system is used mainly by vascular surgeons. The classification differentiates between truncular and extratruncular lesions as well as between localized (limited) and infiltrating lesions.

The ISSVA classification (International Society for the Study of Vascular Anomalies) is the clinical classification that differentiates vascular tumors (hemangioma and others) from vascular malformations (Slow-flow: capillary malformation, venous malformation, lymphatic malformation; and Fast-flow: arteriovenous fistula, arteriovenous malformation).

In conclusion, both classifications are complementary, the ISSVA classification is a very simple binary classification with accurate clinical diagnosis, whereas the Hamburg

classification is more complicated, but helpful for a better understanding and accurate treatment decision.

#### Embolic agents to treat venous and lymphatic malformations: an overview of the past 10 years.

A. Bisdorff Bresson

Venous malformations and lymphatic malformations are slow-flow malformations based on the ISSVA classification (International Society for the Study of Vascular Anomalies). Sclerotherapy is used to treat slow malformations and is most frequently performed by a direct puncture technique. We have liquid agents (foam, ethanol (ETOH), Bleomycine, A5, and Doxycycline), semiliquid agents (glue, Onyx, and Ethanol gel), permanent agents (plug and coils), and both endovenous thermal ablation and radiofrequency ablation. The choice of agent depends on lesion type, location, and extension.

In conclusion, sclerotherapy is an efficient treatment tool in venous malformations (VM) and lymphatic malformations (LM). Bleomycine seems to be promising agent in VM and LM, even though recurrence has been observed. The ethanol gel efficiency must be confirmed (high price and quantity issue). The endovenous laser treatment technique is an effective modality in small (<2 cm) skin and mucosal VM and can be associated with sclerotherapy. VMs and LMs require a Vascular Anomalies Center multidisciplinary approach (dermatologists, interventional radiologists, anesthesists, vascular surgeons, nurses, etc).

#### 2.4 Sclerotherapy

#### Sclerotherapy treatment of telangiectasies by ultrasound guidance.

C. Hamel Desnos

The author started by stressing the importance of a right initial mapping to ensure the success of the treatment. To perform this mapping, according to the author, an adequate clinical examination with careful observation (frequently using cold light) and ultrasound imaging are necessary. In fact, insufficient or no treatment of the underlying reflux is the cause, in many cases, of matting. Even if it can be difficult to perform sclerotherapy treatment of small and very superficial veins under ultrasound imaging guidance, the use of an adequate technique can be the key for success. For these purposes, the equipment to be used should have a high frequency probe (13 to 16 MHz). Assessment is carried out with the patient in the standing position, then with the patient in the lying position. Sclerotherapy is always performed with the patient in the lying position. In conclusion, as for any sclerotherapy treatment, the success of sclerotherapy for reticular varices and telangiectases is achieved through careful initial examination, making it possible to establish which sources of the disorder may be involved. The author finished her talk stating that, in sclerotherapy treatment, it is important to know exactly how to inject, but just as important to know exactly where to inject.

## LAFOS: a mix between laser and foam sclerotherapy without tumescent anesthesia. Short-term follow-up results.

A. Frullini

In order to enhance the treatment of insufficient saphenous veins with sclerosing foam, the author presented a new technique called LAFOS (Laser Assisted Foam Sclerotherapy) in which a new specifically designed Holmium:YAG laser has been used to reduce the vein diameter immediately before foam sclerotherapy. This laser pretreatment is capable of shrinking the vein lumen by converging on the type III collagen fibers of the tunica media, resulting in a reduction in the foam volume needed without affecting the intima, which is essential for an effective sclerosis. As such, the author stated that this technique allows the ablation of the vein with lower chances of complications (no risk of perivenous damage, no pain). This method can be performed as an office-based procedure as anesthesia is not required. The technique consists of gaining access to the vein with a simple cannula (17 g) or with a sheath, placing the laser fiber, retrieving the fiber while the vein diameter is reduced, and immediate foam injection in the same cannula.

Subsequently, the author presented the short-term results of the first 50 cases treated by LAFOS. The laser system used had a 5W max average power with a maximum of 500 mJ/pulse. The treatment was performed on 38 patients with an insufficient greater saphenous vein (GSV) and on 12 patients with lesser saphenous vein (LSV) insufficiency. The mean maximum diameter of the GSV was 9.17 and 7.91 for the LSV. Two GSVs were previously treated twice unsuccessfully with two sessions of echo-guided foam sclerotherapy. Vein shrinkage was easily achieved and the internal lumen diameter was reduced in association with thickening of the vein wall. Complete occlusion was always observed at one month, even in the two cases resistant to conventional treatment with sclerosing foam. No complications due to foam sclerotherapy were observed with the exception of minor bruising that resolved uneventfully. As a result, the author concluded that this new technique is less expensive than surgery or thermal ablation, can be performed in an office setting with no anesthesia and no pain, is a faster procedure with immediate return to family activities and work, makes sclerotherapy more technologically advanced, and uses a lower volume of foam. He added that the media pretreatment could possibly result in a better late outcome and that the vein shrinkage permits larger vein treatment (>2 cm).

#### 2.5 Thermal ablation

#### Endovenous therapies of saphenous veins, the evidence.

R. van den Bos

Endovenous thermal ablation (EVTA) techniques are commonly used and very effective for saphenous vein insufficiency and are recommended as first-choice treatments in several national guidelines (UK, USA, and Holland). The author presented the first large meta-analysis on great saphenous vein (GSV) treatment from randomized controlled trials (RCTs) only (Siribumrungwong et al. *Eur J Vasc Endovasc Surg.* 2012;44:214-223). This study analyzed the efficacy, complications, postoperative pain, time to return to normal activities, and QOL scores.

Endovenous laser ablation (EVIA), radiofrequency ablation (RFA), and surgery were equally effective. Ultrasound-guided foam sclerotherapy (UGFS) was 10% to 15% less effective than surgery and EVTA EVTA has less postoperative complications than surgery (less wound infections, less hematoma, lower pain scores, quicker return to work, and no difference in venous thromboembolism). The short saphenous vein is best treated with EVTA or UGFS (complex treatment because of anatomy; more sural nerve injury after surgery than after EVTA; the puncture site in EVTA should be in the upper half of the calf). There is no evidence that EVLA wavelength matters. There is evidence that the fiber tip influences postoperative pain and bruising by perforations. Less perforations and less pain are seen with a tulip tip compared with the bare tip. After RFA, there seems to be less pain than after EVIA.

The author concluded that: (i) EVTA is the first choice for GSV; (ii) EVTA and UGFS are the first choice for the small saphenous vein (SSV); (iii) wavelength does not matter; (iv) tulip tip is less painful than bare tip; (v) RFA is less painful than EVLA; and (vi) there is no evidence from RCTs regarding mechanicochemical ablation (MOCA), glue, and steam, yet.

## Medium-term follow-up after the different techniques: RCT comparing surgery, chemical, and thermal ablation.

L. Rasmussen

The author presented his study comparing the 3-year outcomes after treatment of varicose veins by radiofrequency ablation (ClosureFast, CLF), laser ablation (EVLA), ultrasound-guided foam sclerotherapy (UGFS), or high ligation and stripping. A total of 500 patients (580 legs) were randomized to one of the treatments. Results: At 3 years, 8 (Kaplan-Meier (KM) estimate, 7%), 8 (KM estimate, 6.8%), 31 (KM estimate, 26.4%), and 8 (KM estimate, 6.5%) of the GSVs were recanalized or had a failed stripping procedure (P<0.01) from treatment with CLF, EVLA, UGFS, and high ligation and stripping, respectively. In addition, 17 (KM estimate, 14.9%), 24 (KM estimate, 20%), 20 (KM estimate, 19.1%), and 22 (KM estimate, 20.2%) legs developed recurrent varicose veins from treatment with CLF, EVLA, UGFS, and high ligation and stripping, respectively (NS). The patterns of reflux and location of recurrent varicose veins were not different between the groups. Within 3 years after treatment, 12 (KM estimate, 11.1%), 14 (KM estimate, 12.5%), 37 (KM estimate, 31.6%), and 18 (KM estimate, 15.5%) legs were retreated in the CLF, EVIA, UGFS, and stripping groups, respectively (P<0.01). Venous Clinical Severity Score (VCSS), 36-Item Short Form Health Survey (SF-36), and Aberdeen QOL scores improved significantly in all groups with no difference between the groups. He concluded that all treatment modalities were efficacious and resulted in a similar improvement in VCSS and QOL. However, more recanalization and reoperations were seen after UGFS.

## Quality of life after varicose vein surgery. Does the current evidence favor one method over another? A. Mansilha

Quality of life (QOL), internationally defined by the World Health Organization as "the product of the interplay between social, health, economic, and environmental conditions, which affect human and social development," has gradually increased

its importance, once it reflects the patient's perspective and sensitivity regarding the influence of the disease in daily life.

Nowadays, there is a growing interest for patient-reported outcomes and the use of QOL questionnaires in patients suffering from CVD, which can provide important information regarding burden of illness that otherwise would not be able to be obtained. The association established between QOL (based on QOL questionnaires) and the severity of disease progression, highlights the importance of patients' QOL assessments.

Despite all this growing interest in the patient's perspective and the large number of surgeries performed every year, there is a deficiency in the published data regarding QOL life assessments in patients with varicose veins. Several physician-generated measurements tools have been used, such as the Clinical, Etiologic, Anatomic, and Pathophysiologic classification (CEAP classification) and the Venous Severity Scoring System (VSSS). Nevertheless, patient-generated QOL tools have gained significant relief, which enables monitoring disease progression and response to treatment, as well as assessing quality of care provided and allowing the provision of important information not properly expressed by the statistical values of morbidity and mortality that physicians traditionally use.

Among the patient-generated measurement tools, generic instruments, such as the 36-Item Short Form Health Survey (SF-36) or Nottingham Health Profile (NHP), allow comparisons across populations of patients with different diseases, while diseasespecific instruments, such as the Chronic Venous Insufficiency Questionnaire (CIVIQ), Venous Insufficiency Epidemiological and Economic Study—Quality of Life questionnaire (VEINES-QOL), the Aberdeen Varicose Vein Questionnaire (AVVQ), or Charing Cross Venous Ulceration Questionnaire (CXVUQ), are more sensitive to key dimensions of quality of life that are affected by specific diseases.

### Is Endothermal Heat Induced Thrombosis (EHIT) depending on the learning curve? L. Kabnick

L. NUDITICK

Endothermal Heat Induced Thrombosis (EHIT) of the great saphenous vein is an expected outcome after endovenous ablation, but what remains unclear is the clinical outcome of patients who present with this entity in close proximity to, or with an extension into, the common femoral vein. With an incidence in the literature ranging from 0% to 16% (1 to 3), this has gained the attention of physicians treating this disease process. The following is the description for EHIT Classification: Class 1, venous thrombosis to the superficial-deep junction (ie, saphenofemoral junction or saphenopopliteal junction, but not extending into the deep system); Class 2, nonocclusive venous thrombosis, with an extension into the deep system of a cross-sectional area less than 50%; Class 3, nonocclusive venous thrombosis into the deep venous system, with an extension into the deep system of a cross-sectional area more than 50%; and Class 4, occlusive deep vein thrombosis of the common femoral vein. The author presented the experience of his center regarding EHIT, examining the extent of echogenicity within the thermally induced thrombosis, and comparing it with de novo thrombosis seen within a typical deep venous thrombosis (DVT). From October 2007 to December 2010 at the New York University Vein Center, 2672 procedures (Endovenous laser ablation [EVLA], 662; radiofrequency ablation [RFA], 2010) were performed. There were 78 EHIT II (EVLA, 21 vs RFA, 57) resulting in a total of 2.9%. Of note, there was a diminishing trend among interventionalists: first year, 5.2%; second year, 1.8%; and third year, 0.4%. He concluded that EHIT II rates may differ in patients treated using EVLA as compared with RFA and that frequency of EHIT II may diminish with increasing institutional experience. He finished by stating that, in his opinion, the presence of EHIT II will not reach 0.

## When can the treatment of venous reflux for open ulcers (C6) be justified? M. Gohel

The author started by stating that venous ulcers are a distressing and expensive condition, which is increasingly common as the population aged more than 65-years-old is estimated to grow in the next twenty years. Then, he described the different forms of reflux: (i) isolated superficial reflux (50% to 60%); (ii) superficial and segmental deep reflux (25% to 30%); and (iii) superficial and total deep reflux (10% to 15%).

In fact, the importance of treatment of venous reflux in patients with chronic venous ulceration was demonstrated unequivocally in the ESCHAR trial (Effect of Surgery and Compression on Healing And Recurrence; Gohel MS et al. *BMJ.* 2007;335:83). Superficial venous surgery resulted in a significantly lower ulcer recurrence rate at 4 years. However, no healing benefit was seen, resulting in the perception among many clinicians that there is no role for treating superficial reflux in patients with C6 disease.

However, there are many reasons to challenge this dogma. The influence of treating superficial reflux is likely to have been significantly underestimated in the ESCHAR trial. Twenty percent of patients in the surgery group refused to have surgery (but were analyzed on intention to treat). The median delay to surgery was 7 weeks and surgical interventions would be considered suboptimal by modern endovenous standards, with residual reflux frequently seen (a quarter of the procedures were saphenofemoral junction [SFJ] or saphenopopliteal junction [SPJ] ligations alone). Moreover, the rapid and widespread adoption of office-based, endovenous interventions has meant that many patients are now entirely suitable and willing to undergo minimally invasive endovenous ablation procedures. In addition, it is unreasonable to extrapolate the findings of a study where patients were generally compliant with compression, to the overall leg ulcer population, where compression therapy is often poorly tolerated. In fact, the author suggested that superficial reflux should be treated if effective compression is not achieved.

Recent nonrandomized studies have proposed that excellent venous ulcer healing rates can be achieved by aggressive ablation of superficial reflux with ultrasound-guided foam sclerotherapy, far higher than published healing rates with compression alone (Kulkami et al. *Phlebology.* 2013;28:140-146). For these reasons, the Early Venous Reflux Ablation ulcer study (EVRA) was planned. Recently, researchers have started recruiting patients at six centers in the UK. The study aims to evaluate the role of early endovenous ablation of superficial reflux (within 2 weeks), in addition to compression bandaging in patients with chronic venous ulceration. The primary outcome is time to ulcer healing.

The author concluded that the perception that there is no benefit in treating superficial venous reflux in patients with active venous ulceration (C6) is probably not justified.

There is strong rationale for reflux ablation in patients who have poor compliance with compression. The results of the EVRA ulcer study should help clarify whether early superficial venous intervention should become an early part of treatment for all patients with venous ulcers.

## Is it safe to treat varicose veins by thermal ablation below the knee? P. Gloviczki

Thermal injuries to the saphenous or sural nerves have been major concerns that limited widespread use of endovenous thermal ablations below the knee (BK). Incidence of nerve injuries as high as 39% have been reported with stripping of the BK segment of the great saphenous vein (GSV). Meanwhile, BK-GSV reflux is reported in up to 81% of patients, increasing to 91% at 2 years following above the knee (AK) GSV ablation.

Ignoring the refluxing BK-GSV is reported to result in residual symptoms and a need for reintervention in nearly half of the patients.

The author's group recently presented results of patients treated with thermal ablation of the BK-GSV (Gifford et al. J Vasc Surg: Venous Lymph Dis. 2013;1:112). The study included 387 patients treated between January 2010 and August 2012. Results of 38 patients who underwent thermal ablation of the BK-GSV on 47 limbs were retrospectively reviewed. There were 22 females and 16 males, with a mean age of 51 years. Twentyseven limbs were treated for simple varicose veins (Clinical, Etiologic, Anatomic, and Pathophysiologic classification (CEAP) of C<sub>1</sub>-C<sub>3</sub>) and 20 for advanced insufficiency  $(C_4-C_6)$ . Ablation was performed in 45 limbs (97%) utilizing the VenaCure EVLTM laser vein treatment (AngioDynamics, Queensbury, NY) and 2 limbs using radiofrequency ablation (RFA) with the ClosureFAST system (VNUS Medical Technologies, San Jose, CA). Mean GSV length ablated was 51.6 cm (range, 26 to 65 cm). Ambulatory stab phlebectomies of branch varicosities were performed simultaneously in 37 (79%) limbs. All patients had tumescent anesthesia with circumferential injection immediately around the saphenous vein. All limbs were evaluated with ultrasound within 24 hours. There were no skin burns or evidence of endovenous heat-induced thrombosis. Transient hyperesthesia occurred in one patient (2.1%), which resolved in two weeks. Reinterventions were not needed during follow-up, despite two early recanalizations.

Excellent results of small saphenous vein endovenous thermal ablations have been reported in the literature, with minor sensory deficits in 2.2% to 7.5%, with a lower chance of nerve injury when the vein was punctured at the mid-calf level and using large amounts of tumescent infusion, without an effect on recanalization rates. Routine visualization of the nerve using ultrasound was also reported. Paresthesia rates as high as 8% to 13% were observed after thermal ablation of the BK-GSV.

The author concluded that endovenous ablation below the knee can be performed safely, with a low rate of minor complications. Neuralgia cannot be completely excluded with thermal ablations of below the knee saphenous veins; however, evidence in the literature suggests that puncturing at mid-calf level and using large amount of tumescent anesthesia will result in a lower probability of nerve injury. Nevertheless, further studies are needed to investigate the benefit of routine duplex scanning of the

sural or saphenous nerves and to determine what type of anesthesia can or cannot be used for these patients.

#### Clarivein: the answer to avoiding heat treatment?

A. Davies

Ablation of truncal varicose veins has undergone significant changes in the last 10 years. The development of endothermal techniques (ET) to ablate truncal veins has led ET to replace classic surgery. Meanwhile, ET generally involves the use of tumescent anesthesia. However, even less invasive techniques are being developed. Clarivein is a mechanical and chemical technique that does not require tumescent anesthesia. Clarivein has a rotating tip that agitates and sensitizes the endothelium. Simultaneously, a sclerosant drug is sprayed from the tip of the catheter ensuring precise longitudinal and radial drug delivery, occluding the vein. The early outcomes show similar results at year 1 compared with ET (Elias S et al. *Phlebology.* 2013;1:10-14). It would seem, on basic modeling, that it is as cost-effective as ET. Techniques of retrograde ablation may have a particular role in the management of patients with venous ulceration.

The author concluded that Clarivein is a novel technique that has many potential benefits over endothermal ablation and the results of ongoing randomized controlled trials will help determine whether potential benefits exist.

#### 2.6 Other

#### Behcet disease: an atypical DVT. Diagnosis and treatment.

M. Bouayed

Behcet's disease (BD) is a primitive multisystematic vasculitis nonautoimmune disease of unknown etiology. It is exceptional after the age of 60 and common in the Mediterranean basin and in Japan.

The International Clinical Criteria from 1990 are recurrent oral ulcers, recurrent ulcers more than three times in 12 months, and two of the following: recurrent genital ulcerations, eye-injury, skin-lesions, and a positive pathergy test (sensitivity, 91% and specificity, 96%).

The vascular lesions are highly suggestive of an attack on the arteries and veins of any caliber. In the vascular lesions, the great majority is deep venous thrombosis (DVT; 90%). Superficial venous thrombosis (SVT) is a major criterion according to the Japan Committee for Behcet's disease.

The new criteria for the classification of BD is according to points attributed to clinical conditions: oral ulcers (1 point), genital ulceration (2 points), skin lesions as pseudofolliculitis or erythema nodosum (1 point), ocular involvement (2 points), vascular disease as superficial thrombophlebitis, DVT, arterial thrombosis, aneurysm (1 point), and positive pathergy test (1 point). The diagnosis is made if there are  $\geq 3$  positive points.

The treatment recommendation for vascular involvement is corticosteroids and immunosuppressants, but with formal proof; no formal proof exists regarding the effectiveness of anticoagulants or antiplatelet agents on vascular thrombosis of the BD. In DVT, anticoagulants are essential, used long-term, sometimes for life after repeated offenses. An immunosuppressant bolus limits thrombus extension and prevents recurrence.

#### Reference:

International Study Group for Behcet's Disease. Criteria for diagnosis of Behcet's disease. *Lancet*, 1990:335:1078-1080.

## Does long-term follow-up confirm that high ligation and stripping is an obsolete procedure? O. Pichot

Saphenofemoral junction (SFJ) residual stump and neovascularization are considered to be the main causes of recurrence after surgery; that is why surgeons have emphasized the necessity of performing an extended high ligation, even if no artifice has been demonstrated to effectively avoid SFJ neovascularization. Thermal ablation introduced the concept based on trunk ablation alone with preservation of the SFJ. Mid-term follow-up already demonstrated that this approach significantly decreases the incidence of neovascularization.

The author concluded that there is no inferiority of endogenous procedures compared with surgery in the long-term follow-up. Clinically significant reflux in the residual great saphenous vein stump is rare. Valsalva-induced reflux into lymph node veins is frequent, is different from neovascularization seen after surgery, and appears to stay quiescent over time. High ligation is definitely an obsolete procedure.

# Charing Cross Vascular Meeting



London, UK, April 5-8, 2014

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# Treatment of varicose veins

#### 1. Guidelines

NICE guidelines and comparative effectiveness in the treatment of chronic venous disease.

A. Davies

The National Institute for Health and Care Excellence (NICE) in the UK analyzes and assesses the treatment for varicose veins. In 2010, it was shown that day-case procedures were all cost-effective with surgery being the most cost-effective, but the guidelines have also shown that despite modern advances and day-case surgery, patients expect an extended period off work!

The progression of the disease is still poorly understood. Body mass index, female sex, and increased age were associated with increased rates of disease progression and a weaker association was found for subjective sensations of leg heaviness, leg swelling, and leg tension. The rate of disease progression to ulceration increased with male sex and history of serious leg injury.

It was difficult to determine key factors for outcomes postintervention, but being female did confer a risk for a higher rate of complications after foam sclerotherapy. A raised body mass index was associated with greater reflux recurrence.

Patients with symptomatic varicose veins, active or healed ulceration, or superficial venous thrombosis should be referred to a specialist's vascular service. Patients do not have to wait as long for a referral. As venous intervention is cost-effective, the compression hosiery should not be a holding measure unless the patient is unsuitable for treatment. A full duplex ultrasound venous mapping should be done because it has been shown to reduce recurrence rates and improve short-term disease specific quality of life measures. Endovenous thermal ablation is the first-line treatment. The important message delivered in this communication is that, nowadays, no patient with varicose vein disease should be without a treatment option.

#### 2. Pelvic and vulvar varicose veins

Debate: Pelvic vein reflux must be treated before addressing leg veins

#### For the motion.

J. Brookes

In males, varicocele of the gonadal veins is a relatively common occurrence that is easily recognized by clinical examination. The same occurs in the gonadal veins of women, but the deep ovaries hide the presence of varicosities to external examination. The deep iliac veins have three fields of drainage and may be incompetent alone or in combination with gonadal veins. They may drain to the leg directly or via pudendal tributaries.

Diagnosis of pelvic venous insufficiency is clinical and is confirmed with imaging. Dynamic contrast venography should be done to obtain a complete examination of the deep venous pathways and to allow for the appropriate and selective treatment by transcatheter embolization at the same time.

#### Against the motion.

J. Earnshaw

Only 2% of lower limb varices in women are due to isolated incompetent pelvic veins. Pelvic venous incompetence may be diagnosed using ultrasound imaging, transvaginal ultrasonography, venography, and magnetic resonance imaging (MRI). Ovarian vein embolization was first described in 1993, but most reported series in the literature are small with numerous biases.

Treating pelvic vein incompetence first before varicose veins of the lower limbs in a two-stage session has not shown any evidence for improving the symptoms of pelvic reflux or preventing varicose vein recurrence. In addition, some complications such as coil migration have been reported. Concomitant foam sclerotherapy could be an alternative solution to this infrequent problem, but controlled studies are required.

#### How to treat vulvar veins after pelvic embolization.

B. Price

Vulval varices are common and do not disappear after delivery. These kinds of varices should not be considered as a separate entity and they should be treated in the context of a complete plan with other sources of reflux.

Surgical avulsion is a good technique, but it could be difficult to perform in certain locations. Foam sclerotherapy combined with compression seems to be the treatment of choice, but few data are available.

#### Pelvic venous congestion causes hemorrhoids.

J. Holdstock

No high-quality studies are available on this topic.

#### 3. Thermal ablation

#### Is all heat the same and does catheter design matter?

M. S. Whiteley

Endothermal ablation is less invasive than traditional surgery with reduced side effects and a faster recovery period. Many different devices have been developed by different companies, but questions remain regarding whether the heat produced differs between different devices and how the catheter design influences the energy distribution to the vein wall

The linear endovenous energy density (LEED) is a measure of the heat energy delivered to the vein wall in Joules (J)/cm of vein treated. The power of the device is measured in watts (W) and one W is defined as one J/sec. So the LEED could be adapted by setting the power of the device or the time of the withdrawal.

Some devices (radiofrequency and steam) use direct heating by transmitting the thermal energy by direct conduction to the vein wall. Others (lasers) use indirect heating by transferring electromagnetic energy into thermal energy. Some of these devices require direct contact with the vein wall to have their effect (radiofrequency) and others that do not need any contact (laser and steam) to deliver the energy to the wall. It seems that to achieve better results, blood should be absent from the section of vein being treated, otherwise the heat energy will be used to heat the blood and not the vein wall.

Successful thermoablation requires transmural death of all layers of the vein wall to ensure complete fibrosis and permanent ablation. To achieve this goal, the thermal energy should be spread radially and deeply, avoiding a high power with a fast pullback.

From these arguments, it is suggested that bare-tip laser fibers are more likely to cause perforation and inadequate treatment of vein sections, and that devices requiring direct contact with the vein wall may get inadequate thermoablation results in case of aneurysmal or thrombotic veins.

The direct contact devices and the radial lasers do not spread thermal energy, thereby restricting the thermoablative effects to extend no more than 1 to 2 mm proximal from the tip.

In conclusion, the heat used to ablate veins can be applied directly to the vein wall, or not, with the same effect because the effect of the heat on the vein wall depends only on the LEED delivered and transferred. Catheter design plays an important role for the technical success of the procedure and ensures the optimal transfer of thermal energy to the vein wall.

#### Endovenous laser treatment (EVLT) never touch.

L. Kabnick

The laser side effects are most likely caused by laser-induced vein wall perforation with extravasation of blood into the surrounding tissue. These perforations are more common with a higher power and greater linear endovenous energy density (LEED). The hemoglobin-based wavelengths produce more short-term side effects than longer wavelengths. There are fewer side effects in terms of pain and bruising with 980 nm than 810 nm at the same power and with 1320 nm at 5 W compared with 8 W. The New York University (NYU) pilot studies is an observational nonrandomized study that compares 810 nm, 980 nm, and 1470 nm lasers using bare-tip vs the NeverTouch fiber. The conclusion is that water-based lasers (1470 nm) allow decreased power and energy to be delivered, and more importantly, that covered fibers allow decreased power density leading to less vein perforations.

#### EVLT for perforating veins with NeverTouch Direct Laser (NTDL).

M. Whiteley

The diagnosis and treatment of incompetent perforating veins (IPV) are controversial. The author argues that some patients with varicose veins only have IPVs, some varicose veins go away after an IPV treatment, some IPVs are associated with the recurrence of varicose veins, and that IPVs are regularly found to be the cause of the recurrence. Many treatments have been used to treat IPVs such as open surgery with the Linton and Cockett technique, subfacial endoscopic perforator surgery (SEPS) described by Hauer, and more recently the transluminal occlusion of perforators (TRLOP) technique reported by Whiteley. TRLOP now uses a laser fiber with water as the chromophore. TRLOP using the NeverTouch Direct Laser (NTDL) seems to offer many advantages: it is a safe and quick procedure if used at 10 W where the same device could be used for truncal veins and there is no risk of needle damage.

#### **EVLT Biolitec.**

M. Cough

For the author, the best results with endovenous laser treatment (EVLT) are obtained with standardization of the procedure and by using a linear endovenous energy density (LEED) of 70 J/cm (which means a power of 14 W/cm for 5 seconds). Using a 1470 nm radial fiber, Pannier reported no pain, no need for analgesia, no ecchymosis in 44%, 50%, and 80% of patients, respectively (Pannier et al. VASA. 2013;39(3):249-255). Schwars compared radial fiber with bare fiber lasers and found fewer ecchymosis (P<0.0001) and less analgesia (P>0.04) with radial fibers. For the author, his 1470 nm radial fiber is equivalent to VNUS Closure. The 1470 nm radial fiber with 2 rings gave more homogeneous energy distribution, less sticking, less postoperative pain, ecchymosis, and paresthesia in the series by Maurins (Maurins et al. Int Angiol. 2009;28(1):32-37). Approximately 78% of patients do not need analgesics and it seems there is no benefit of compression post-EVIA. In conclusion, the 1470 nm radial fiber is equivalent to VNUS Closure fast on pain, bruising, paresthesia, and outcome. The laser could be useful for tortuosity and junctional treatment with the possibility of using a guidewire. In addition, 1470 nm fibers have also a lower cost than VNUS closure fast fibers.

#### **CLASS** trial.

J. Brittenden

The primary objectives of the CLASS (Comparison of LAser, Surgery and foam Sclerotherapy as a treatment for varicose **veins**) study was to compare surgery, ultrasound-guided foam sclerotherapy (UGFS), and endovenous laser ablation (EVLA) combined with foam to residual nontruncal varicosities for the treatment of varicose veins. The quality of life at 6 months was assessed through the Aberdeen Varicose Veins Questionnaire (AVVQ), EuroQOL five dimensions questionnaire (EQ-5D), and 36-Item Short Form Health Survey (SF-36) questionnaires, and the cost-effectiveness was evaluated as the cost per quality adjusted life year (QUALY) gained. The CLASS conclusions were that UGFS is associated with significantly lower improvement in quality of life, more complications compare with EVLA, reduced ablation rates at 6

months, and, on modeling, was not cost-effective at 5 years compared with either EVLA or surgery. EVLA had fewer complications and less cost-effectiveness compare with surgery with the same efficacy.

#### 4. Mechanoablation

#### CLARIVEIN.

M. Reijnen

Mechanicochemical ablation (MOCA) is a new technique for saphenous vein treatment. It combines mechanical endothelial damage using a rotating wire with the infusion of a liquid sclerosant. Heating the vein and tumescent anesthesia are not required, only local anesthesia is used at the insertion site. As MOCA generates no heat, it is related to a very low incidence of major complications. It is a fast and safe technique for both great saphenous vein (GSV) and small saphenous vein (SSV) insufficiency. The early results are promising with acceptable closure rates (88% at 1 year with three partial recanalizations and one complete recanalization). There is a learning curve, which seems to be less forgiving than laser or radiofrequency ablation. We have no data concerning the optimal dose of sclerosant and the pullback rate that should be apply. We also need results about long-term and comparative data from randomized controlled trials (RCTs); the Maradona trial compares MOCA and ClosureFast for GSV insufficiency.

#### 5. Glue

#### Glue.

K. Gibson

There are many opportunities to improve current treatments for varicose veins: eliminate need for tumescent anesthesia, eliminate the need for compression stockings, significantly reduce postprocedure pain and bruising, and improve current treatment closure rates to >90%. The VenaSeal Sapheon Closure system is a new device using cyanoacrylate adhesive to embolize the saphenous veins safely and effectively through a catheter and a dispenser gun. The catheter is engineered to be inert to adhesive and to not stick, and the dispenser gun is designed to deliver a precise amount of glue into the vein. A feasibility study, a European multicenter study (eSCOPE), has been done and a US pivotal study (VeClose) is ongoing. The results of the first study showed that the Venaseal sapheon closure system offers a tumescent-free solution for treating symptomatic venous reflux disease. The closure rate of this new device is very high (96.2% at 2 years) and similar to current treatment technologies. It is safe and postprocedure compression stockings are not mandatory. In the last study, the primary end point is to be noninferior to radiofrequency (RF) on great saphenous vein closure and the secondary end point is to be superior to RF in reducing postprocedural pain and bruising.

#### 6. Sclerotherapy

#### Catheter-directed foam with tumescence.

A. Cavezzi

Using foam sclerotherapy on larger saphenous diameters results in a higher recanalization rate. Larger veins require higher doses, which increases the deep vein thrombosis rate and the risk of cerebral complications. Moreover, stagnating and inflowing blood within veins neutralizes foam in a few seconds. To reduce the diameter of the vein and the blood inflow, the author describes a new foam sclerotherapy approach using a perisaphenous tumescence infiltration with an intrasaphenous flushing with saline solution through a long catheter. After using this technique for refluxing great saphenous veins (GSV) with concomitant phlebectomies on varicose tributaries in a prospective study, the author concludes that this technique is an effective, extremely cheap, and safe treatment for overall GSV reflux. Larger diameters can also be treated with good efficacy and safety.

#### The difference in wall penetration between STS and polidocanol.

M. Cough

A 3% sodium tetradecyl sulphate (STS) and polidocanol foam are widely used for treating incompetent truncal veins. However, few data are available concerning the half-life of the products as well on the damages inflicted upon the vein wall. No comparison between STS and polidocanol, in vivo, on human veins has been published and we do not know precisely why there are relatively high recanalization rates following foam sclerotherapy. Polidocanol foam exhibits superior stability to STS, but endothelial cell loss and medial injury were significantly greater with STS.

It seems that permanent venous ablation probably requires complete endothelial denudation and collagen denaturation. The greater injury inflicted by STS should make it a more potent sclerosant. The persistent islands of endothelial cells combined with a minimal media injury may explain the high recanalization rates after foam sclerotherapy.

#### Sclerosant selection.

P. Coleridge-Smith

For the author, not all foams are the same, and it is impossible to compare clinical results unless characteristics of the patients and foam are known and are reproducible. Air foams have good performance, but they have associated risks with some persistent bubbles in the circulation. The small bubbles and narrow bubble distribution, along with a slow drainage and separation times improves foam performance by enhancing stability of the foam.

#### Debate: Air is the best gas for making foam

#### For the motion.

K. Darvall

#### Against the motion.

A. Cavezzi

Air is free and readily available. Air-based foam seems to be more stable and easier to use. There is no evidence that air-based foam is less safe or less effective and the minor side effects are unaffected by the gas used. We do not need to use a large volume of foam to improve efficacy and there is no huge difference in efficacy according to the gas used.

The vote was for the motion.

#### 7. CX Office-based Vein Practice Course

The CX Office-based Vein Practice Course was led by Ian Franklin (Imperial College, London, UK) and it covered a wide range of techniques and procedures. Over the two days, the course welcomed more than 700 participants. We were granted the unique opportunity to view demonstrations and try office-based venous devices and procedures with the guidance of experienced tutors. The course was set up in a very flexible format so we could go to the training stations we were interested in (we could have one-on-one or small group interactions with world experts).

The Day 1 practice course strongly emphasized practical skills with simulators and equipment provided for attendees to learn ultrasound-guided cannulation, catheter positioning, and tumescent anesthesia. Other stations included: virtual ultrasound training with the Axiom simulator; deep vein thrombosis interventions including Trellis, Angiojet, suction thrombectomy, and Ekos; leg ulcers and skin grafting under local anesthesia; steam thermotherapy; ambulatory phlebectomy; deep vein thrombosis prophylaxis in the thrombophilic patient; microsclerotherapy for thread veins; Norseld laser treatment for thread veins; and marketing and social media for doctors.

This year, the course featured a very large section on acute venous thrombosis and acute deep vein thrombosis and interventional techniques for treating deep vein thrombosis. Additionally, for the first time ever, the course featured four different lasers, three different radiofrequency catheters, endovenous glue, mechanicochemical ablation, and steam thermotherapy.

We could go from station to station and discover nuances that we had never seen other people do and bring that back to our practice, so the course is good not only for people with basic knowledge, but it is also good for people with advanced skills.

Day 2 of the CX Office-based Veins Practice Course offered CHIVA (Cure Conservatrice et Hemodynamique de l'Insufficience Veineuse en Ambulatoire); diagnostic ultrasound training; lymphedema and compression therapy; foam sclerotherapy; microsclerotherapy for thread veins; ASVAL (Ablation Sélective des Varices sous Anésthesie Locale); pin

stripping under local anesthesia; Norseld laser for thread veins; surgical deep vein reconstruction; deep venous stenting; endovenous valves; pelvic vein treatments and pelvic congestion syndrome; case presentations; and website design and search engine optimization for doctors.

#### 8. Other

#### Duplex scanning is not mandatory after treatment for saphenous reflux.

L. Kabnick

The goal of routinely performing a postoperative duplex scan after endothermal ablation of the saphenous, veins is to detect endovenous heat-induced thrombosis and to evaluate the treatment's efficacy.

In the USA, greater than 300 000 endovenous procedures are performed annually. The overall incidence of endothermal heat-induced thrombosis is 3% to 4% and if we exclude thrombosis class 1, which are out of clinical significance, the overall rate falls to 1% to 2%. The majority of these thrombi will disappear within 7 to 10 days with no additional sequelae. The incidence of pulmonary embolism after radiofrequency ablation is, at most, 0.03%, probably less than 0.01% and with no sequelae in Kabnick's report.

The rate of saphenous vein closure in the immediate postoperative period is reported to be high, close to 99%, and it is obvious that assessing the efficacy of the treatment during a 3-month period with a duplex scan is not of interest.

In terms of a financial point of view, performing a duplex ultrasound during the postoperative period of each endovenous procedure costs \$150 000 000 per annum for a wasteful and unnecessary healthcare test: the postoperative morbidity and mortality rates would not be affected.

#### The place of concomitant phlebectomy.

T. Lane

Clinical experience shows that treatment of the truncal vein does not necessarily resolve varicosities and so the need for a treatment pathway is vital. The principle behind a single treatment is clear and a deferred treatment of the tributaries provides the opportunity for varicose veins to dwindle once the venous hypertension has been resolved. Despite the question about a need for additional procedures, what are the quality of life, clinical outcomes, and safety when looking at the two options? In the randomized controlled study by Carradice, there is clearly clinical evidence for an additional procedure on tributaries combined with the endovenous laser. Three studies also show an improved outcome in early disease quality of life as well as for clinical outcomes as measured by the Vein Clinical Severity Score (VCSS) for patients treated with simultaneous endovenous ablation and varicosity treatment. These treatments are very safe and no cases of deep vein thrombosis (DVT) have been reported.

Improvement in early symptom outcomes and early clinical outcomes are reported in the literature and it is established that patients treated with endovenous ablation alone have a 43-fold relative risk of requiring further procedures. The conclusion of the author is that concomitant phlebectomy has multiple benefits, is appropriate, and should be considered as was suggested recently in the NICE guidelines.

#### Pneumatic pressure device for prevention of deep vein thrombosis (DVT).

M. Dennis

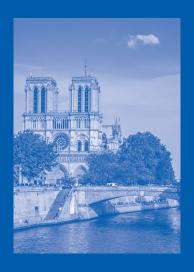
Heparin and low-molecular-weight heparin (LMWH) reduce asymptomatic, but not symptomatic, deep vein thrombosis (DVT) and they both increase major bleeding. They do not have significant effects on survival as reported by Lederle et al in 2011. The graduate compression stocking does not reduce DVT and may cause skin problems (CLOTS 1 trial [Clots in Legs Or Stockings after Stroke], 2009). Intermittent pneumatic compression (IPC) is an effective form of venous thromboembolism (VTE) prophylaxis. For the author, it is feasible and safe. IPC probably improves overall survival even if no data are available and it is effective in ischemic and hemorrhagic stroke. In conclusion, IPC should be used when lowering the risk of death is considered worthwhile.

#### EHIT, EFIT, EGIT: a new word is needed for therapy induced thrombosis.

J. Lawson

James Lawson has found an acronym for an unstable clot extension occurring after classic surgery, thermal ablation, and future developments in ablation of superficial veins: it is PACE (Post Ablation Clot Extension). A precise anatomic classification is useless because it is not related to thrombotic events. PACE forces us to find out what the characteristics of the clot extension are using duplex scanning or to find other risk factors like thrombophilia, which are prone to thromboembolic events.

# XV<sup>th</sup> Annual Meeting of the European Venous Forum



Paris, France, June 25-28, 2014

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# 1. Generalities

Evolution of chronic venous disorders (CVD) from 18 to 88 years according to parental heredity. About 21 318 patients.

V. Crébassa

Data from a large French prospective, observational, multicentric study that involved 21 318 consecutive adult patients were presented. Some of the conclusions drawn from the data are unexpected. The odds ratio of chronic venous disease (CVD) is 8.6 if the patient has paternal heredity, while it is 5.0 when it is a maternal. CVD was also shown to be more frequent and symptomatic for women.

#### Chronic venous disease: Inherited or acquired?

P-L. Antignani, N. Labropoulos, E. Bouskela

Despite being studied for many years, the etiology and pathogenesis of chronic venous disease (CVD) remains an interesting and controversial topic for discussions. This session provided an update on the genetic and biological mechanisms of CVD, make an analysis of current knowledge on the pathways involved in the pathogenesis, and provide targets for pharmacological treatments.

The session was opened with the presentation of P-L. Antignani (Italy) entitled "Population prevalence of chronic venous disease: A question of lifestyle or valves?" The real prevalence of CVD is quite difficult to determine because the previous studies were performed in different geographical areas, they often used a nonepidemiological mode of patient recruitment, and, of course, the definition of the disease may vary especially if the Clinical, Etiologic, Anatomic, and Pathophysiologic classification (CEAP classification) was not used. Despite these issues, we know a lot about the risk factors that influence CVD manifestation. For example, we know from the Vein Consult Program that age, being overweight, and having an individual and/or family history of vein thrombosis are the risk factors in both sexes. Menopause and multiple childbirths are additional risk factors for women.

N. Labropoulos (USA) presented "Is chronic venous disease an inherited or acquired phenomenon?" and stressed the importance of epigenetic factors in CVD. There is no doubt about the role of genetic predisposition, but it cannot explain why some patients without a family history have chronic venous insufficiency that can be severe. To identify the polymorphism that is responsible, we need information from genomewide association studies, but they are expensive and have to be large enough and accurately planned.

To review the known targets of pharmacological treatments and to map out the ways of future research was the goal of E. Bouskela's (Brazil) presentation "Therapeutic targets for chronic venous disease." Some brilliant experimental studies from the last decade showed that the micronized purified flavonoid fraction (MPFF) is able to decrease capillary leakage, prevent remodeling of the venous wall and valves, and reduce inflammation in venous valves. These effects, resulting in clinical consequences, were

confirmed in many trials. Venoactive drugs improve venous signs, such as pain, and MPFF reduces edema and the healing rate of leg ulcers. However, many details of CVD mechanisms are still poorly investigated. For this reason, E. Bouskela and her colleagues are going to perform a new study to create an experimental model of long-lasting venous hypertension.

A summary was made by A. Nicolaides, the chairperson of the session. Modern consensus statements recommend MPFF with grade 1B because the benefits clearly outweigh the risks for relief of symptoms associated with CVD.

# 2. Treatment of saphenous veins

#### Management of saphenous reflux in 2014

#### Comparative efficacy of different methods of treatment.

M. de Maeseneer

This was an excellent summary on the current situation with comparative efficacy of different methods of saphenous reflux treatment. While endovenous thermal ablation is recommended by several international guidelines as a first-choice treatment, no strong data exist supporting that those methods can get better results than surgery. Modern phlebectomy is as effective in terms of recurrence and quality of life as thermoablation.

#### In our daily practice: which technique for which patient?

C. Hamel-Desnos

Ultrasound-guided foam sclerotherapy might be the most used technique in France. It is preferably used by vascular practitioners, especially in cases of recurrent varicose veins, if the saphenous trunk is less than 5 mm in diameter, and if important obstructive sequalae of superficial vein thrombosis exists. Patients prefer sclerotherapy to other methods because it is faster, less aggressive, cheaper, and can be reimbursed.

#### Recent improvements in foam sclerotherapy techniques.

A. Cavezzi

The rationale for the use of tumescent anesthesia in foam sclerotherapy was discussed. If we treat large saphenous veins, we need higher doses of sclerosants; therefore, it results in higher risks of deep venous thrombosis or cerebral complications. Cavezzi and colleagues performed a small, nonrandomized, comparative study on three patient groups treated with tumescence, echo-guided tumescence, or no tumescence. The occlusion rate was significantly better with echo-guided tumescence at a median 14-month follow-up with no clinical recurrence in this group.

# Randomized trial comparing thermoablation, foam sclerotherapy, and stripping in GSV varicose veins. Outcome after 5 years.

L. Rasmussen, M. Lawaetz, The Danish Vein Centers.

One of the most known randomized controlled studies comparing different ways of saphenous ablation is by L. Rasmussen. He published one-year results in 2011. Now his team has 5-year results that confirmed previous data. No differences in recurrence rate, great saphenous vein reflux, needs in the new procedure, quality of life, and venous clinical severity scoring were found between laser, radiofrequency ablation, stripping, and ultrasound-guided foam sclerotherapy.

#### Sclerotherapy

Feasibility of a new system of standardized foam fabrication and comparison with Tessari's method.

E. Roche, R. Pons, A. Puig, J. Puig

One problem of sclerosing treatment with foam is a great variability in the devices used, the exact ratio between the sclerosant and gas, temperature, etc. A new system of standardized foam fabrication was invented by E. Roche (Spain) and his team. The foam from this system is less heterogeneous than the classic Tessari's foam, but it is >5 times more stable when using air and 2 times more stable when using a mixture of oxygen and carbon dioxide.

Vein wall penetration of detergent sclerosants: an in vitro study using immunohistochemistry.

C. T. D. Lee, M. S. Whiteley, J-M. Li

The authors investigated vein wall penetration by detergent sclerosants using immunohistochemistry in vitro. They found that endothelial cell damage is incomplete and to get an effective damage of the wall, penetration into the media may be needed. The greater damage was obtained with 10 min exposure of sodium tetradecyl sulfate. Using a shorter time or polidocanol led to lower reduction in damage.

#### Consequences of population aging in the management of varicose veins by sclerotherapy.

J. Gillet, C. Hamel Desnos, M. Lausecker, C. Daniel, J-J. Guex, F. Allaert

The presentation pointed out the problems coming from the aging populations because 176 out of 418 patients who were included were older than 75 years. Compared with younger patients, this subgroup was more often treated for "curative" rather than "symptomatic" or "cosmetic" indications. However, large veins were treated as often in the elderly as in the control group. Lower amounts of foam were injected in older patients. No complications or needs for special precautions were observed.

#### Thermal ablation

The European study of radiofrequency segmental thermal ablation (RSTA) of the great saphenous vein: five year follow-up.

T. M. Proebstle, O. Pichot

The authors presented the five-year results of the European study of radiofrequency segmental thermal ablation (RSTA) of the great saphenous vein on 295 limbs. An immediate success rate (occlusion of the GSV) was 99.7% at 3 days. A total of 91.9% of veins remained occluded after 5 years, but about one-third of the legs were with a Clinical, Etiologic, Anatomic, and Pathophysiologic classification (CEAP) of  $C_2$ . This means a high frequency of recurrent varicose veins.

#### Compression therapy

#### Sport stockings using stiff material increases the ejection fraction of the calf pump.

H. Partsch, G. Mosti

The question of whether sport stockings using stiff material increases the ejection fraction of the calf pump was addressed. The authors used magnetic resonance imaging (MRI) for this purpose and found that conventional sport stockings do not increase calf pump function, but when wrapped with stiff bands, it expels more blood volume with exercise.

#### Compression treatment for superficial vein thrombosis. An RCT.

K. Boehler, H. Kittler, S. Stolkovich, S. Tzaneva

The objective of the study was to evaluate the treatment effect of compression stockings on the acute stage of superficial vein thrombosis (SVT) compared with no compression. A total of 73 patients with symptomatic SVT, with a thrombus extent of at least 5 cm, and with the upper level no closer than 2 cm to the saphenofemoral or saphenopopliteal junction were randomized. The primary outcome was pain. No differences were found at 3 weeks between wearing compression stockings or not. This finding contradicts the traditional view on compression as a key point of SVT treatment, but there are many limitations of the study (sample size, use of painkillers, and absence of compliance assessment with stockings) that are keeping the question open.

#### Compression therapy by stocking and epifascial veins.

D. Rastel

The pressure performed by elastic compression (with medical compression stockings [MCS]) in the lower limb follows a Laplace-type MCS (different due to curves) more than a fluid-type MCS. There are two different methodological approaches: (i) measuring the changes in epifascial and great saphenous veins, and its effect in curvature radius and area in 5 patients with a Clinical, Etiologic, Anatomic, and Pathophysiologic classification (CEAP) of C2 in 12 varicose leg areas with and without compression type 2 MCS; and (ii) using a numerical model of qualification of physical properties of leg components to make a simulation of biomechanical responses to varicose veins with elastic compression.

The conclusions were that, in the standing position, MCS does not reduce epifascial vein calibers significantly; MCS, even at a medium range pressure ≈20 mm Hg, decrease transmural pressure; external pressure is modulated by the fat tissue behavior; and skin inflammations following foam sclerotherapy are more frequently seen for epifascial veins than for saphenous veins. Therefore, they hypothesized that MCS, which increases perivenous pressure, could create a protective environment against local side effects of foam sclerotherapy.

## Impact of compression stockings on the cutaneous microcirculation as assessed by skin thermal conductivity. J. P. Gobin

The instantaneous local physiological effect of compression stockings on skin microcirculatory activity by an original device (Hematron ) based on the thermal conductivity of tissues was studied. The thermal conductivity of tissues is a physiological variable, an indicator of metabolic and microcirculatory activity, and increases linearly with skin blood flow in the capillary network. The device is an ambulatory miniaturized system that measures the effective skin thermal conductivity in real time monitoring (wireless) and with local data storage in the memory card. In this study, they measured the calf in the supine position in 30 male patients with a medium age of 42 (age range, 25 to 55), 11 patients with Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) class of  $C_0$  and 19 patients with CEAP class of  $C_1$ . Subjects were explored in the supine position with and without elastic compression stockings with a pressure of 13 mm Hg at the ankle. The data analysis was the calculation of the relative difference (%) between the value of skin thermal conductivity measured with and without stockings. They found significant improvements in skin microcirculatory activity with elastic compression (7.6% improvement, P < 0.0001 and an 83% rate of earning of the investigated population).

In conclusion, the Hematron device is suitable to measure the evolution of microcirculatory activity under compression stockings and the use of compression stockings provides a benefit on the skin's physiological properties with a significant improvement in skin perfusion. Further studies can explore the effects of medical compression stockings in other positions of daily life (sitting, standing, and walking) and the outcomes of other levels of compression (8, 10, 20, 30, and 40 mm Hg).

#### Enhancement of body balance. Another benefit of compression.

R. Lepers

Another benefit of medical compression stockings (MCS) to the usually accepted enhancement of venous return in subjects with chronic venous insufficiency-preventing occupational leg swelling at the end of the day-is the potential benefits for physical performance and recovery in athletes. The study was aimed to answer two questions: (i) do compression garments influence the balance during dynamic exercise such as jumping?; and (ii) do compression garments reduce muscle vibrations while running?

They studied 15 physically active male subjects using the Sigvaris Run sleeves Pulse Road. Balance ability was measured with a counter movement jump platform and they found that stability after landing improves with compression. They found no differences in reaction time, movement duration or duration for stabilization after landing, and it may be beneficial for injury management and injury prevention of lesions caused by jumping.

To measure calf vibrations, the calf movements were studied in three different points with accelerometers—one in the anterior tibial cell beside the anterior tibial crest and two in the posterior part of the calf. They studied the calf vibrations at slow and medium running speed, with and without compression (20 mm Hg). They found no improvement in the anterior tibial cell, but compression garments reduced tricep sural vibrations while running. It may reduce muscle damage during prolonged running exercises and provide faster recovery of neuromuscular function with lower limb compression.

# 3. Treatment of perforating veins

#### Which perforating veins should be treated?

J-J. Guex

The role of perforating veins in the pathogenesis of chronic venous disease (CVD) is controversial. Now the question being debated is: should we treat perforators and if so, which perforator(s)? The usual attitude is to not treat medial leg perforating veins, irrespective of whether they are incompetent or not. That is why their incompetence in primary disease is a consequence of great saphenous vein (GSV) reflux, which is shown by their disappearance after GSV ablation. No data was published on the efficacy of dissecting perforators in terms of clinical results or recurrences. The treatment of medial leg perforating veins can be of value if they have a diameter more than 5 mm, reflux more than 0.5 seconds, if they remain large and refluxing after GSV ablation, if there is no incompetent GSV, or if there is a significant varicose cluster above the perforating veins.

#### Foam or endovenous laser?

E. Rabe

Both methods are safe and effective, but no randomized controlled trials were conducted to compare them. Both methods have theirs pros and cons. The laser method delivers defined energy into the targeted vein, however, it is expensive and there may be problems with access to the vein. Sclerotherapy is cheap, the vein can be easily accessed, but there is no defined concentration of sclerosing agent, which can also migrate into the deep vein.

#### Subfacial endoscopic perforating vein surgery: is there still a place in 2014?

P. Gloviczki

As a previous supporter of subfascial endoscopic perforator surgery (SEPS), the author presented a view on the place of this method in phlebology today. He concluded that the role of SEPS is limited to rare and refractory cases of venous ulcers, cases of short and large perforators, and if percutaneous techniques, such as thermoablation or sclerotherapy, are not available.

# 4. Treatment of iliac and caval veins

Morphologic changes in iliac veins and inferior vena cava in patients with primary varicose veins.

L. Dzieciuchowicz

During high ligation and stripping in 20 patients with primary varicose veins, the author used intravascular ultrasound to detect nonthrombotic stenosis of iliac veins and the inferior vena cava. No intraluminal lesions were detected, but stenosis of the iliac veins seemed to be common in patients with primary varicose veins.

# 5. Thromboembolic diseases

#### Venous thromboembolism

## Factors affecting long-term outcome in patients with iliofemoral DVT treated with catheter directed thrombolysis.

P. Foegh, L. P. Jensen, L. Klitfod, S. Just, R. Broholm, N. Baekgaard

The Danish team investigated factors affecting long-term outcomes in patients with iliofemoral deep venous thrombosis (DVT) treated with catheter-directed thrombolysis. This method is not widely used because of its cost, but also because its effectiveness is questionable. The team achieved very good results on 203 limbs with iliofemoral DVT. Median follow-up was 5 years and the rate of reocclusion was only 13%. The factors in favor of good outcomes were female sex, type of thrombolytic administration (infusion is better than pulse), duration of symptoms less than 14 days, and absence of a previous DVT on the same leg.

#### The impact of international VTE guidelines on hospital performance.

A. N. Nicolaides

Despite many efforts of medical specialists all over the world, venous thromboembolism (VTE) prophylaxis in hospitals is still far from ideal. A good one-third of high-risk patients do not receive appropriate prophylaxis. There are many reasons for that, such as lack of awareness with the guidelines, lack of agreement between different expert recommendations, fear of bleeding while using anticoagulants, improper estimation of risk, lack of hospital policies and protocols. Many tools are available to improve this situation from pocket guidelines for doctors and printed guidelines for patients to educational campaigns. Appropriate estimation of the risk of VTE is the key point of effective prevention.

#### Validation of the Caprini risk score for venous thromboembolism (VTE) in high-risk surgical patients.

K. Lobastov, V. Barinov, L. Laberko, V. Boyarintsev

The attempt to distinguish subgroups of extremely high-risk surgical patients in whom standard measures were insufficient was difficult. The authors followed up 140 patients defined as high risk with a Caprini score and received prophylaxis with compression and low-dose unfractionated heparin (LDUH). In patients with Caprini scores of 5 to 8, the deep venous thrombosis (DVT) rate on prophylaxis was 1.9%; with Caprini scores of 9 to 11, the DVT rate was 26.1%; and with Caprini scores of 12 to 15, the DVT rate was 65%. Authors concluded that patients with Caprini scores ≥11 must be identified as extremely high-risk patients.

#### What is new in the treatment of acute vein thrombosis?

#### Recommendations on Superficial Vein Thrombosis.

J-L. Gillet

In contrast with deep venous thrombosis (DVT), no high-grade recommendations for superficial venous thrombosis (SVT) exists. SVT is not a benign disease because it is associated with DVT in 23% to 26% of cases, pulmonary embolism in 4%, and a recurrence rate up to 20% within 2 years. Now, anticoagulant therapy is widely used, but the level of evidence for low-molecular-weight heparin in intermediate doses is moderate according to the International Consensus Statement. Only fondaparinux has a high-level of evidence, but it is an expensive treatment. Further research is needed to define subgroups of patients with a higher incidence of venous thromboembolism after SVT where the benefits of anticoagulants would outweigh the costs.

#### Thrombolysis.

G. O'Sullivan

The author presented his remarkable experience in thrombolysis in phlegmasia cerulea dolens. He outlined that phlegmasia is not comparable to venous gangrene since clinical symptoms and signs are very different. Thrombolysis was performed in 21 patients using a Trellis device. He achieved a high success rate with no lost limbs and no mortality.

# 6. EVF prizes

#### **American Venous Forum**

Ovarian vein thrombosis (OVT) rarely occurs, so data on clinical presentation, natural history, and treatment outcomes are lacking. RD. Malgor and colleagues (USA) presented their own data in the lecture titled "The natural history and treatment outcomes of symptomatic ovarian vein thrombosis." They examined 23 patients with symptomatic OVT (mean age, 44). The most frequent causes of OVT were postpartum depression and cancer, and the most frequent symptoms were abdominal and flank pain. Location was mostly on the right. Intravenous heparin leads to complete recanalization in 62% of patients and incomplete recanalization in 15% of patients, while 23% of veins remained occluded. Long-term follow-up (median of 27 months) revealed four recurrent deep vein thrombosis (DVT) and four deaths (all of them in cancer patients).

A. C. Ring and colleagues (USA) in the lecture "Enough of EMR based VTE risk scores – we need to implement VTE prophylaxis based on these alerts!" showed an effect of venous thromboembolism (VTE) prophylaxis with electronic medical records. With electronic alerts in 24 960 consecutive hospital patients, both surgical and medical, the VTE rate was 0.7% during the hospital stay.

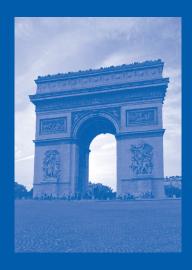
#### **American College of Phlebology**

Awaited results of superglue treatment of saphenous reflux were presented by T. Proebstle (Germany). A 12-month follow-up of the European multicenter study on cyanoacrylate revealed that 92.9% of patients were free of reflux in the great saphenous vein in the legs. The superglue treatment was announced to be a slight killer of thermoablation due to no necessity to use anesthesia, no postprocedure compression, and no paraestesias. The ultrasound results are similar to thermoablation, the new method also has complications such as thrombophlebitis (11.4%), pain (8.6%), and thrombus extension to the deep vein (0.7%). Thus, it can be noted that no miracle happened. The new method must have more scientific support that takes into account its cost, which is evidently the highest of nearly all the competitive methods.

#### Japanese Society of Phlebology

Two very interesting and original topics were delivered by Japanese colleagues. In the first one by H. Ohmori ("Deep vein thrombosis in patients with severe motor and intellectual disabilities"), the very rare cohort of patients became a subject of investigation. Severely handicapped persons are usually not of interest to vascular specialists. Ohmori and colleagues examined 28 such patients (median age, 44.5) and found signs of a previous deep vein thrombosis in 12 of the patients. Another topic by N. Sakakibara ("Micropulsation as a key factor for endovenous pulsed laser ablation") was experimental with the objective to observe the phenomenon of micropulsed laser emission in water and blood as a model of endovenous laser ablation.

# Paris Dermatological Meeting 2013



Paris, France, December 10-14, 2013

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# 1. Hemangiomas

Propranolol in the treatment of infantile hemangiomas: Results from an international randomized, placebo-controlled, multidose, adaptive phase 2/3 study.

C. Leaute-Labreze, J. Mazereeuw-Hautier, L. Guibaud et al.

The study was conducted at the suggestion of the European Medical Association (EMA) and the Food and Drug Administration (FDA) and was an international, multicenter, randomized, double-blind, adaptive phase 2/3 study. The authors presented the results of this study, which was conducted at 56 centers in 24 countries on 460 children aged 1 to 5 months, who were treated for infantile proliferative hemangioma with a pediatric formulation of oral propranolol for 24 weeks.

The purpose of this study was to assess the optimal daily propranolol dosage (3 or 6 mg/kg/day), treatment duration (3 or 6 months), and the superiority of propranolol vs placebo in complete or nearly complete resolution of infantile proliferative hemangiomas. Another parameter assessed was the safety and tolerability of propranolol, especially the cardiovascular, respiratory, metabolic, and behavioral adverse events.

As a result of an interim analysis of the results obtained in the first 188 patients, the 3 mg/kg/day regimen for 6 months was selected for the next step of the study. At the end of the 24-week study, the results in the 55 children treated with placebo and 101 children treated with propranolol were analyzed. A pediatric oral solution of propranolol demonstrated statistically significant efficacy vs placebo (P<0.0001) as complete or nearly complete resolution of infantile proliferative hemangiomas were recorded in 61 patients in the propranolol group (60.4%) compared with only 2 patients in the placebo group (3.6%).

As for tolerability, no unexpected side effects related to propranolol were found. The reported adverse effects were not dose-dependent. Bronchial hyperreactivity and diarrhea occurring in some children were not severe and had no consequences.

This multicenter international study concludes that the new formulation of oral propranolol is effective and well tolerated in the treatment of infantile proliferative hemangioma in children aged 1 to 5 months.

#### Late recurrences of infantile hemangiomas after propranolol discontinuation.

I. Dreyfus, C. Frisch, A. Maza et al

This paper discusses the characteristics of infantile hemangioma recurrences after the discontinuation of propranolol. This phenomenon is recognized to occur in about 25% of cases within 5 months after discontinuation of the drug, especially when propranolol is not administered until the end of hemangioma growth. The recurrence of hemangioma means its recoloration or increase in size, sometimes exceeding its initial size.

The results of a single-center retrospective study conducted between January 2010 and June 2013 in 29 children with hemangiomas are presented. Children were followed

up for at least 8 months after propranolol discontinuation. Treatment with propranolol at doses of 1 to 3 mg/kg/day was started at an average age of 138 days and continued until the average age of 361 days. Sixty-nine percent of hemangiomas were located in the head and neck, and 9 were periocular hemangiomas (67% deep and 33% mixed).

Four hemangioma recurrences were identified, all were deep and located periocularly, and the increase in size after discontinuation of propranolal ranged between 40% and 150% of the initial volume. These cases required therapeutic reintervention.

The authors concluded that these relapses were due to the deep and periocular location of hemangiomas. In these cases, propranolol could reduce or suppress the tumor mass of hemangiomas.

# Assessment of the antalgic methods used during treatment with pulsed dye laser (PDL) in infantile flat hemangiomas.

L. Lagier, G. Georgescu, M. Berton et al.

The authors presented the results of a standardized questionnaire on analgesia during pulsed dye laser (PDL) treatment in infantile flat hemangiomas. This questionnaire was filled in by members of the Pediatric research group of the French Society of Dermatology and Laser Group Scientific Committee of the French Society of Dermatology.

The questionnaire contained questions about the use of PDL in private or hospital practice for flat hemangiomas, PDL treatment under general anesthesia, with local anesthetic cream, use of nitrogen oxide, and oral analgesics. There were also questions related to the feeling that these types of anesthesia may or may not reduce the efficacy of PDL therapy for infantile hemangioma.

Responses to the questionnaire show that pain treatment during PDL procedures for hemangioma in children is very heterogeneous. The most commonly used analgesic was an anesthetic cream (56%) with a variable duration of application. However, the effectiveness of anesthetic creams in PDL treatment was not proven by clinical trials and it causes a degree of hemangioma vasoconstriction that may decrease the efficacy of PDL. Fifty-four percent of physicians believe that these anesthetic creams reduce the efficacy of PDL.

The authors concluded that randomized clinical trials are needed to determine the most effective type of anesthesia for PDL in infantile hemangioma.

# 2. Venous malformation

#### Characteristics and monitoring of venous malformations in children.

C. Boulard, Y. Surlemont, E. Clavier et al

The study is focused on the characteristics and the way of monitoring venous malformations in children. These malformations are general vascular congenital anomalies with a slow flow developing in parallel with the child's growth.

The study presents the results of an observational retrospective analysis developed at the CHU-Hospital of Rouen, in consultations covering several medical areas over the year 2000. There were 23 girls and 22 boys with venous malformations included, with the average age of 7 (3 months to 18 years old), who were under medical investigation for an average of 4.5 years (2 months to 12 years). The clinical, evolutional, and therapeutic characteristics of the studied venous malformations were very diverse. Regarding the localization: 35.5% were on the legs; 22% were on the arms; 16% were on the face; and 6.5% were on the body.

The venous malformation dimension was greater than 15 cm³ in 28% of the cases, and 91% of the venous malformations were symptomatic: functional discomfort (23 patients), inequality of legs and arms (2 patients), and pain in 50% of the cases. Pain was more frequent in cases of associated muscular touch, extended venous malformations, puberty, or venous malformations associated with phleboliths. In six cases, venous malformations developed into complications of relapsing venous thrombosis, treated with low-molecular-weight heparin (LMWH) in curative doses for about 15 days.

The therapeutic behavior was different: elastic compression was used in 17/26 children with venous malformations of the legs (good tolerance in 73% of the cases); curative sclerotherapy was used in 3 cases of venous malformations of the face; sclerotherapy in an antalgic scope was used in 3 cases of venous malformations of the arms and legs (50% relapse rate in 5 years); and surgical treatment was used and showed improvement in 6 cases of venous malformations of the face. The authors consider that it is the first study demonstrating that, although congenital, venous malformations are diagnosed late in about 51% of the cases.

Painful venous malformations are associated with muscular touch, extended venous malformations, and the existence of phleboliths. This study confirms the results of two other prospective studies sustaining that there is localized intravascular coagulation in venous malformations. The pain in venous malformations associated with the increase in D-dimers can be treated with LMWH, even if it does not have market authorization for children, but the degree of relapses when stopping the treatment is large.

The conclusion of the authors is that monitoring children with venous malformations is difficult because of its evolution in parallel with their growth and when suggesting a therapy, the benefits and the risks must be considered.

# 3. Venous leg ulcer

#### Retrospective study assessing the efficacy of electrical stimulation on leg ulcer pain.

P. Leloup, P. Toussaint, J. P. Lembelembe et al

The authors presented the results of the first study on the efficacy of electrostimulation in leg ulcer pain, demonstrating that this method may improve pain control as assessed by the evolution of a subjective criterion (visual numeric scale) and a target (reduced consumption of analgesics).

Several clinical studies have demonstrated the efficacy of electrostimulation in chronic wound healing by applying an electric current directly to the ulcer. Electrostimulation increases angiogenesis as well as migration and proliferation of macrophages, fibroblasts, and keratinocytes in ulcers.

This retrospective study included 73 patients (43 women and 30 men) with leg ulcers, mean age of 75.2 years, assessed between 2011 and 2013. The etiology of leg ulcers varied: 31 venous ulcers, 21 mixed arteriovenous ulcers, 2 arterial ulcers, 17 necrotic angiodermatites, 1 amputation stump ulcer, and 1 ulcer due to Hydrea. Patients were assessed by conventional or home follow-up. Pain medication administered to each patient was closely monitored.

The results were interpreted using, as tools, the visual numeric pain scale (VNS) and the Student test for the statistical interpretation of data (significant P<0.05). Patients were treated with electrostimulation, and pain was assessed on days 0, 3, and 7.

The study showed a statistically significant decrease in pain between day 0 (VNS 5.3) and day 7 (VNS 2.2), accompanied by reduced consumption of pain medication. In necrotic angiodermatitis, a hyperalgesic condition, VNS decreased from 6.88 on day 0 to 2.82 on day 7 (*P*=0.001). The consumption of pain medication and the number of morphine derivatives used for pain relief also decreased.

Leg ulcer pain is difficult to control. The study showed that electrostimulation is an easy treatment that does not require hospitalization, favors leg ulcer closure, and significantly reduces pain.

#### Contact sensitivity to modern wound dressings: study in 345 patients with chronic leg ulcer.

A. Valois, M. Avenel-Audran, F. Truchetet et al.

Modern wound dressings for leg ulcers are effective, but failed to solve the problem of contact sensitivity. The authors started by presenting the results of a recent study in 423 patients with chronic leg ulcers, which showed that a high number of cases (73%) developed contact sensitivity to the components of topical treatments. After, the authors presented the results of a new French multicenter study conducted in 354 patients with chronic leg ulcers that evaluated contact sensitivity to modern wound dressings. The study was conducted over a period of 4 years (2009-2013) in patients with at least a one-month-old chronic leg ulcer of well-documented cause and course.

Patients were subjected to epicutaneous tests with the European standard battery (containing 27 molecules) and a "special" leg ulcer battery. The latter contained 26 allergens present in modern wound dressings, antiseptics, dermatocorticosteroids, and 11 different types of modern wound dressings. Of the total number of patients included in the study, 59.6% (211 patients) had at least 1 positive epicutaneous test and 32.8% (116 patients; 32.8%) had positive epicutaneous tests to modern wound dressings.

Modern wound dressings that caused contact sensitization were: laluset cream in 45 patients (12.5%), hydrocellular dressings in 28 patients (7.9%), hydrocolloid dressings in 17 patients (4.8%), hydrogels in 7 patients (2%), alginate (Algosteril) in 6 patients (1.6%), hydrofibers in 5 patients (1.4%), and interface dressings in 8 patients (2.2%). The constituents of modern wound dressings responsible for contact sensitivity were colophane (4.2%), amerchol L 101 (6.8%), sodium metabisulfite (4.8%), propylene glycol (1.4%), carboxymethyl cellulose (0.8%), and ibuprofen (0.3%).

There is a direct association between the ulcer's age and an increasing rate of contact sensitivity to modern dressings. There is no direct correlation between the occurrence and intensity of contact sensitivity and association of chronic leg ulcers with periulcerous eczema, erythema, or chronic ulcer etiology, contrary to some literature data.

The authors suggested that the packages of modern dressings should specify the presence of the allergenic components detected in this study (eg, colophane derivatives, perfume, etc).

# Phlebolymphology...



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