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EDITORIAL



Hugo Partsch Editor in Chief



This beautifully illustrated issue of Phlebolymphology covers a number of interesting topics.

Dr Vasquez from Buffalo, USA, who was one of the driving forces behind the last refinement of the Venous Clinical Severity Score, gives a detailed overview of phlebological terminology, concerning both anatomical and clinical nomenclature. His article clearly shows that mutual understanding is still a problem today as it has been ever since Biblical times when the Lord confounded the tongues of the people who wanted to reach heaven by building the Tower of Babel, which was never completed.

Michel Perrin, Lyon, has written two fantastic overviews. One is a historical review of the development of venous surgery, starting with a terminological and anatomical introduction, from Aulus Cornelius Celsus to Trendelenburg, containing impressive illustrations. The other is a report of a remarkable meeting dedicated to the idea of reducing the incidence of venous leg ulcers by 50% in the next 15 years. I am confident that this goal will be achieved, unlike the aim of the 1989 St Vincent initiative to reduce the rate of amputations of diabetic feet by 50% over a five-year period. This target, unfortunately, has still not been reached.

Interesting results are reported from the DECIDE study in which 8958 consecutive patients suffering from venous symptoms associated with venous pathology (CEAP C1-C3) and treated with Daflon 500 mg for 2 months by general practitioners were questioned concerning their quality of life using the Chronic Venous Insufficiency Quality of Life Questionnaire. Symptoms like "pins and needles", night cramps, and sensation of swelling were the most valuable indications and showed improvement rates of more than 50%.

Lastly, Drs Laurian and Mallios, two highly skilled surgeons from Paris, present fascinating clinical and radiological images showing different forms of arteriovenous malformations and report spectacular therapeutic results rarely seen in non-specialized institutions.

Happy reading!



History of venous surgery (1)

This is the first of the 3 chapters that make up a "History of Venous Surgery". These chapters will be published consecutively in *Phlebolymphology*.

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Keywords:

history, venous surgery, varicose veins, thrombosis, venous valve

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INTRODUCTION

Before discussing the history of venous surgery, we thought it would be desirable to provide a short semantic and etymological review to clarify or define certain terms that we will use throughout this historical review.

SEMANTIC REVIEW

Etymologically the word <u>surgery</u> can be defined as the practice of a treatment by using one's hands. It derives from the Greek $\chi \epsilon \iota \rho o u \rho \gamma \iota \alpha$ (kheirourgia) $\chi \epsilon \iota \rho$ (kheir) [hands] and $\epsilon \rho \gamma o \nu$ (ergon) [work]. In modern language, the word surgery is used to denote any therapeutic procedure which involves one or more cutaneous incisions, or in other words, open surgery.

In this review, we will use the older definition, ie, any therapeutic intervention consisting of a manual procedure which includes all endovascular treatments that can be performed by venipuncture. Currently, such techniques are increasingly used.

To study the chronology of venous surgery, a few other terms should be explained:

<u>Chronic venous disease or chronic venous disorders</u> refer to all venous diseases of the lower limbs which progress gradually and slowly; they are the opposite of acute venous disease which is the sudden occurrence of a disorder affecting the veins. Traditionally, as we have specified, chronic venous disorders only concern the lower limbs, while the term acute venous disease can be used for all veins, whatever their location.

<u>Varicose veins</u>. These venous disorders most commonly affect the lower limb, commonly and inappropriately referred to as the "leg", even though anatomically, the leg is the region extending from the knee to the foot. Varicose veins of the lower limbs can be described as a visible dilatation of the superficial veins which most often have a tortuous appearance. Their function is altered insofar as they have lost their ability to return *venous* blood effectively to the heart. Varicose veins are classified as a chronic venous disease.

<u>A thrombosis</u> is the occurrence of a blood clot in the lumen of a vein; this term should be used instead of "phlebitis"*, which etymologically means inflammation of a vein. The terms paraphlebitis and periphlebitis, still sometimes used, should be banned because they do not correspond to any defined venous disease.

A thrombosis is an acute venous disease; it can affect the three venous systems of the lower limb, either as an isolated event or in combination, but it is deep vein thrombosis which is the most harmful. Such thrombosis quite often produces late-onset complications, in particular when it occurs in a deep vein of the lower limb, and then we refer to it as postthrombotic syndrome. Unlike acute thrombosis, postthrombotic syndrome is a chronic venous disease because, like a varicose vein, it progresses and worsens.

* Phlebitis. At that time and unfortunately even today, the difference between phlebitis—an inflammation of the walls of the vein—and venous thrombosis, is not always respected. It is true that the two events are always associated with deep veins but in this case the term deep vein thrombosis is always used, while in the superficial veins they can be separate (superficial phlebitis or "veinitis") or combined (superficial thrombophlebitis).

REVIEW OF ANATOMY AND PATHOLOGY

In the lower limb, veins are distributed into three systems.

- *The superficial venous system* (*Figure 1*), divided into two networks
 - Two collecting veins, the saphenous veins: the great saphenous vein (GSV) and the small saphenous vein, which are located in the superficial fascia.
 - The non-saphenous veins lie outside of the fascia. They drain blood from the superficial tissues into the saphenous veins; the term "collateral vein" should no longer be used to denote them, the most appropriate term is tributary vein. Therefore, there are tributary veins of the GSV and of the small saphenous vein.

The term varicose veins is reserved for abnormal veins in the superficial venous network.

• The deep venous system.





Source: Perrin M. Affections veineuses chroniques des membres inférieurs. Généralités. Rappel anatomique et physiologique. EMC (Elsevier SAS, Paris), Techniques chirurgicales - Chirurgie vasculaire, 43-160, 2006.

As its name suggests, this system is located in the deep tissues in the sub-fascia compartment and it drains 80 to 90% of venous blood. The two saphenous veins empty into the deep venous system. The GSV empties into the common femoral vein and its distal segment is called the saphenofemoral junction. The small saphenous vein most commonly ends in the popliteal vein and its distal segment is called the saphenopopliteal junction.



Figure 2a. Schematic diagram of a venous valve a. Free border of valvular cusp; b. valvular commissure; c. valvular sinus; d. Implantation of valvular cusp on vein wall.

Source: Perrin M. Affections veineuses chroniques des membres inférieurs. Généralités. Rappel anatomique et physiologique. EMC (Elsevier SAS, Paris), Techniques chirurgicales - Chirurgie vasculaire, 43-160, 2006.



Figure 2b. Valve of great saphenous vein: open. Doppler ultrasound appearance

The 2 open cusps are identified in the venous lumen and appear as 2 vertical white lines separated from each other.

Source: Perrin M. Affections veineuses chroniques des membres inférieurs. Généralités. Rappel anatomique et physiologique. EMC (Elsevier SAS, Paris), Techniques chirurgicales - Chirurgie vasculaire, 43-160, 2006.



Figure 2c. Valve of great saphenous vein: closed. Doppler ultrasound appearance The 2 valvular cusps whose free borders are in contact in the

venous lumen are identified by a circumflex

Source: Perrin M. Affections veineuses chroniques des membres inférieurs. Généralités. Rappel anatomique et physiologique. EMC (Elsevier SAS, Paris), Techniques chirurgicales - Chirurgie vasculaire, 43-160, 2006.

• The perforating vein system.

These are veins which anastomose with the deep and superficial venous systems, in addition to the saphenous junctions.

The valvular apparatus

The lower limb veins below the inguinal ligament contain valves in their lumen and along their entire



Figure 2d. Surgical view. *Femoral vein valve Courtesy; Maleti MD.*

length (*Figures 2a, 2b, 2c, 2d*) which allow blood flow only from the periphery to the heart. A valvular lesion can be of unknown or poorly identified cause (idiopathic), as is the case in so-called primary varicose veins or in primary deep vein insufficiency. Valvular lesions or abnormalities can either have a known cause (postthrombotic) or, in rare instances, be congenital.



Figure 3. Emptying of lower limb veins during muscular systole. DFV: deep femoral vein; GV: gastrocnemius vein; SV: soleal vein; IMV: intramuscular vein; PV: perforating vein; CV: communicating vein; ST: saphenous tributary.

REVIEW OF PHYSIOLOGY

In the lower limb, blood flows from the superficial veins into the deep veins at the saphenous junctions and through the perforator veins (*Figure 3*). The deep veins return blood to the heart via the iliac veins, and then the inferior vena cava. The latter ends in the right atrium after crossing through the abdomen and the thorax.

HISTORY OF VENOUS SURGERY

It might seem reasonable that venous surgery only began after scientific knowledge had been acquired on the anatomy and physiology of the veins and on their pathology and pathophysiology. There is, in fact, no truth to this, but this is not specific to veins. During each era "specialists" were persuaded that they had knowledge which in fact proved erroneous and unfounded as advances were gradually made in this field. In the 17th century, Molière had a premonition of this event by making fun of the practice of bleeding someone to treat any disease. It is possible, or even likely, that our current knowledge of venous disease and its treatment with surgery will be called into question in future decades.

For a long time, venous surgery was limited to varicose veins.

Ancient Egypt

The Ebers Papyrus (27th Pharaonic dynasty, 1580-1320 BC) clearly contraindicated surgery for varicose veins:

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Figure 4. The Eber Papyrus.

"Instruction concerning swelling of blood vessels. If thou examine a swollen blood vessel under the skin of a limb and its aspect increases, becomes sinuous and serpentine, like something swollen with air, then thou will say concerning it, it is a swollen blood vessel—Thou shall not touch something like this" (*Figure 4*).

The Greco-Roman era

Hippocrates, born in Kos (Greece), was also relatively opposed to surgery for varicose veins. At most, he recommended making punctures or tiny incisions in them once, supplemented by compression, but emphasized that the occurrence of an ulcer could be related to the incisions.

Aulus Cornelius Celsus (Rome, flourished Ist century AD) was probably one of the first to operate on varicose veins, but it is not known with certainty if he was a doctor. He performed avulsion of varicose veins with a hook-today this technique is called phlebectomy by mini-incision. He gave us a precise description: "Make an incision of the skin covering a varicose vein, spread apart the edge of the wound with a small hook and use a scalpel to detach the varicose vein from the surrounding parts, taking care not to injure them. After it has been detached, a small blunt hook is placed below it, always leaving a 4-finger interval between the incisions, and the same operation is continued on the vein. It is easy ascertain its direction by the hook method. Thus, after these varicose veins have been detached, they are removed with the hook, next to which they are cut: then the nearest hook is passed, with which the vein is removed in the same manner and is again cut at this place. Thus, after removing all varicose veins from the leg, the edges of the wound are brought close together by applying an agglutinating plaster."

Certainly, the current technique of phlebectomy is slightly different, but the principle is the same, it involves closer and closer excision of the varicose vein. What did definitely change is the pain experienced by the patient during this procedure. In fact, Caius Marius, the Roman tyrant who died in 86 BC, was very probably given a red wine "anesthetic" as pre-medication as was the custom at the time before an operation. He refused to be operated on the other side and declared that the "treatment was worse than the disease". Tumescent local anesthesia, currently used in surgery for varicose veins, is as effective as it is painless. A very complete Byzantine document was written a few centuries later by Oribasius of Pergamum (325-395?). Varicose vein surgery fills three chapters of his surgery book on this topic and some of its recommendations are still relevant:

- 1. Resection of veins is preferable to ligation, which can cause new varicose veins.
- 2. Shave and wash the limb (with hot water) before operating on it.
- 3. While the limb is still warm, mark the varicose veins on the skin with the patient in standing position.
- 4. Resect the veins of the leg before those of the thigh.
- 5. Remove blood clots (hematoma) by pressure on the operated limb.

Actius of Amida (Mesopotamia 502-575?) appears to be the first to have proposed ligation of varicose veins.

Paul of Egine, also a Greek (607-690?), provided a new approach by combining phlebectomy and ligation in treatment of the varicose GSV.

The Arabs

The most famous surgeon of his time was an Andalusian from Córdoba (930-1013?) Abu-Al-Qasim Khalaf Ibn'Abbas Al-Zahrawi, and thankfully posterity has retained only the last part of his name, who described stripping of the great saphenous vein in an exceptionally detailed manner.

The Middle Ages and the Renaissance

The Frenchman Guy de Chauliac (1298-1368), probably the only doctor to have treated four popes in Avignon, France, proposed a classification system of cutaneous ulcers based on their appearance (*Figures 5 a, b, c, d*) in his 4-volume treatise on surgery. He classified them as "clean and healthy, virulent and corrosive, sordid and rotten, deep and cavernous." The most common venous etiology in the lower limb would only be established much later, but the illustrious "surgeon" from Montpellier proposed treatment by cauterization of both the ulcer and the varicose veins. Ambroise Paré, a French anatomist and surgeon (1510-1590), recommended exactly the same treatment 200 years later.

The 17th and 18th centuries

Although the Englishman William Harvey was the first to correctly describe the physiology of the venous circulation in 1628 in a work entitled "Exercitatio Anatomica de Motu Cordis et Sanguini in Animalibus" (*Figures 6 a, b*), the leadership in surgery remained in continental Europe in the 17th century with the Frenchmen Pierre Dionis (1643-1718) surgeon to the Royal Family, and a contemporary of Molière and of Jean-Louis Petit (1674-1750), who was a member of the



Figure 5a. Venous ulcer. Above the ulcer, an area of pigmented skin and the dilated great saphenous vein are identified.

Figure 5b. Medial venous ulcer at the gaiter area with a necrotic zone.

Figure 5c. Large medial venous ulcer at the gaiter area.

Figure 5d. Lateral venous ulcer surrounded by lipodermatosclerosis and eczematous dermatitis.



Figure 6. The famous diagram in William Harvey's book identifying the role played by valves in the venous circulation.

Royal Academy of Surgery under Louis XV. Both Dionis and Petit advocated surgical treatment of varicose veins with no special innovative technique, although Dionis expressed the reservation that "ligation of a vein can be cruel and painful and have unpleasant effects."

Johannes Schultheiss, a German surgeon whose Latin name was Scultetus (1595-1645), developed his own hooks to perform phlebectomy.

In the 18th century, leadership in surgery crossed the English channel. John Hunter (1728-1793) a Scot, took up a range of topics, both in medicine and in surgery. In vascular surgery, in particular, he is known for having performed surgical treatment on an arterial aneurysm of the popliteal artery, but he was also interested in venous disorders and described a pulmonary embolism and differentiated septic phlebitis from traumatic phlebitis.

The 19th century

The treatment of varicose veins took a new direction with the development of sclerotherapy. The term sclerotherapy refers to injection of a sclerosing product into the lumen of a vein which gradually results in destruction of the vein. Some will object that this method is not surgery. This is incorrect if we use the definition given in the introduction, all the more so since the precursor of this method, the Frenchman Charles Gabriel Pravaz (1791-1853), although a graduate of the elite École Polytechnique, was also a surgeon. In 1841, Pravaz designed and made a syringe out of silver, 3 cm long and 5 mm in diameter, intended for injection of



Figure 7. Dr. Pravaz shown on the left. On the right, syringe with plunger and hollow needles.

ferric perchloride into an arterial aneurysm, for coagulant purposes. The plunger of the syringe descended by tightening of a screw, thus making it possible to control the quantity of substance injected. He then fitted a hollow needle on the end of this syringe (*Figure 7*) which allowed injection of the syringe contents into the vascular lumen. In fact, it was the surgeons of Lyon who lived at the same time as Pravaz, and in particular Joseph Pierre Pétrequin (1809-76), surgeon in chief of the Hôtel Dieu hospital, who deserve the credit for having applied this method to the treatment of varicose veins. But the occurrence of serious adverse events discredited this method. We can judge for ourselves: following 411 injections, Weinlechner in Germany reported 18 cases of localized gangrene.

Surgery involving removal of varicose veins saw little technical change in the 19th century. In 1884, the German Otto Wilhelm Madelung proposed making an incision along the entire length of the vein to resect it, but this was not cosmetically acceptable and was responsible for an almost 1% incidence of fatal pulmonary embolism.

In 1890, the German Friedrich Trendelenburg limited his intervention to ligation of the GSV a few centimeters from its end in patients with saphenofemoral junction reflux associated with one or more incompetent terminal valves of the GSV. It is of interest to note the following: - Such ligation of the GSV at a distance from its point of emptying into the deep vein left in place a segment of the GSV which drains a large number of tributaries above an incompetent valve (*Figure 8*). Thus, theoretically the reflux was not eliminated and it



Figure 8. A. Diagram of the saphenofemoral junction. Incompetent terminal valve of the great saphenous vein responsible for femoro-saphenous reflux during the Valsalva maneuver.

B. Ligation of the end of the great saphenous vein at a distance from where it empties into the deep vein in the same patient. The stump of the arch left in place allows persistence of reflux through the incompetent terminal valve of the great saphenous vein which will dilate the tributaries of the great saphenous vein.

Source: Perrin M. Insuffisance veineuse superficielle: notions fondamentales. EMC (Elsevier Masson SAS, Paris), Techniques chirurgicales - Chirurgie vasculaire, 43-161-A, 2007.

worsened or produced a dilatation and a reflux of the tributaries of the GSV since the filling reservoir represented by the trunk of the GSV was eliminated by its removal. In practice, this change was not constant. - Moreover, Trendelenburg performed this procedure so quickly that no anesthesia was necessary ...

In 1896 Moore, an Australian, recommended ligation of the GSV at the level where it empties into the deep vein.

The next chapter will deal with operative treatment of the 20th century.



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The Importance of Uniform Venous Terminology in Reports on Varicose Veins

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ABSTRACT

There is a need for a standardized consistent language in vascular surgery that allows easy flow of information and comparison of results among clinicians. Beginning with current nomenclature, a common language serves as a framework for more detailed efforts. Understanding the outcome assessment tools available provides the opportunity for universal outcome reporting. Data collected at widespread points can then be fairly compared, and common goals of therapy can be determined. Common outcomes that have demonstrated verifiable trends and reproducibility should be subjected to the rigors of evidence-based questioning. The resultant standards of care and expectations of therapy are then confidently presented for everyday practice and ongoing research.

INTRODUCTION

Uniform terminology and accurate nomenclature are the bedrock for valuable discourse in medicine. This common language of vascular nomenclature leads to the standardization of outcome reporting, which in turn enables the verified outcomes of evidence-based medicine. With regard to anatomy and procedural technique, nomenclature dispels gray areas in reporting and unifies treatment goals.

ANATOMICAL TERMINOLOGY

History

Vascular anatomic nomenclature is as old as the study of anatomy itself. From an ancient tablet in Athens depicting a man holding a leg with visible varicose veins¹ to the identification of blood circulation,² the advent of arteriography³ and venography,⁴ to heparin¹ and the embolectomy catheter,³ the work of past investigators has laid the foundation for the current knowledge base and for discoveries yet to come.²

Keywords:

varicose veins, venous disease, classification, outcomes, terms, consensus

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The parallel innovations of disparate physicians and surgeons was initially possible because a common anatomic language existed, namely, the nomenclature of the vascular system. One of the key issues in 21st-century discussions of vascular nomenclature is accuracy and uniformity in vessel naming. This is evidenced by support for renaming the superficial femoral vein to reflect its existence as a deep venous structure. Numerous authors have written on the potential for confusion and harm with the current name, as demonstrated in retrospective analysis of physician intent to treat when thrombus was identified in this vein on Doppler imaging.⁵⁻⁸

This issue of confusing vascular nomenclature and attempts to clarify it are not 21st-century phenomena, however. The origins of the name for the saphenous vein have been attributed to a Greek derivation of the word safaina, meaning "evident," as well as an Arabic derivation in the writings of Avicenna of the term *el safin*, meaning "concealed."9 Anatomists throughout time have tried to assign meaning to each of these derivations, summarizing that the Arabic term may refer to the proximal great saphenous vein and the Greek derivation to the palpable course of the vein on the medial thigh.9 In 2002, the saphenous vein was again the focus of a discussion, with Kakkos and Nicolaides addressing this confusion over its naming: "The knowledge of the correct etymological origin of a scientific term is valuable since this could assist its proper usage."10

In 1986, Kistner wrote about the importance of consistency in establishing diagnoses in venous disease, as well as about possible lingering ambiguity in venous nomenclature: "Historically, the venous system has not been regarded as worthy of detailed evaluation because so little could be done to repair the problems the system harbors."11 As clinicians and researchers gained knowledge on the form and function of the lower extremity vasculature, it became apparent that existing nomenclature was insufficient in its descriptions.¹² Mozes and Gloviczki proposed the framework for a new system of vascular nomenclature: "One reason to adopt a new venous terminology was to provide a system of anatomic names that are based on descriptive topographic terms rather than ill-defined eponyms. Another reason...was the goal to minimize possible errors in the management of patients with venous disease."13

Bonn wrote on the outcome of a 2001 meeting held by the International Union of Phlebology to review and address inconsistencies in anatomic terminology found in clinical use and in the literature. These included "A deficiency in the nomenclature of the veins of the lower limbs; ...the introduction and use of names of veins not present in the existing official anatomic document; ...incorrect interpretation of these names, which leads to confusion and inappropriate treatment of venous disease; inadequate listing, specifically of perforating veins, saphenous vein collateral vessels, tributary veins, and some of the deep veins."⁶

Consensus on venous anatomy

Many conventional naming methods have proven problematic in the nomenclature of the vascular tree. The importance of a common language of nomenclature has come to light, with a 2002 consensus statement written to clarify the terminology of venous anatomy for academic and clinical applications. Caggiati et al were members of this consensus committee and wrote: "Anatomy of the venous system forms the basis of clinical phlebology and is crucial to the correct evaluation and appropriate treatment of venous disorders."12 "A common anatomical terminology is the foundation for a common language in phlebologic sciences. Further, such a common language is important for investigation of the venous system and for accurate diagnosis and correct treatment of venous disorders. Universally accepted new terminology will facilitate effective international exchange of information."12

In conjunction with a 2004 international consensus committee meeting on the subject of nomenclature, Caggiati and colleagues went on to write: "Anatomic terminology is the foundation of medical communication. Effective exchange of information is possible only if a common terminology is used."14 The 2004 consensus committee "developed a refinement of the nomenclature from 2002, focusing on new terms, on the veins of the pelvis, and on practical recommendations regarding the daily clinical use of the proposed terminology."14 The committee recommendations included restricting the use of eponyms, confining them to publications with international circulation, and limiting them to "Giacomini's vein, Cockett's perforating veins and Santorini's plexus."14 Also defined were terms relating to vein size and development.

DISEASE-RELATED TERMINOLOGY

History

Another recent nomenclature clarification arose with the terms *chronic venous disease* and *chronic venous insufficiency*. Although often used interchangeably, the terms have distinct meanings.

Robertson et al wrote that "chronic venous disease of the legs is one of the most common diseases affecting the general adult population. It comprises a wide spectrum of clinical severity, varying from asymptomatic venous incompetence to varicose veins and, in its gravest form, trophic skin changes and ulceration."15 Bergan and colleagues wrote that "chronic venous disease encompasses the full spectrum of signs and symptoms associated with classes C0 to C6, whereas the term chronic venous insufficiency is generally restricted to disease of greater severity, ie, classes C4 to C6."16 Porter and Moneta, writing for the International Consensus Committee on Chronic Venous Disorder, wrote that "chronic venous disease is defined as an abnormally functioning venous system caused by venous valvular incompetence with or without associated venous outflow obstruction, which may affect the superficial venous system, the deep venous system, or both."17 Robertson et al commented on the confusion surrounding chronic venous disease: "the exact prevalence of chronic venous disease remains difficult to determine because of variations in study population, selection criteria and disease definition between different studies."15

Meissner et al define chronic venous insufficiency as "those manifestations of venous disease resulting from ambulatory venous hypertension, defined as a failure to reduce venous pressure with exercise."18 Thorisson and colleagues wrote: "chronic venous insufficiency (CVI) of the superficial and/or deep venous systems of the lower extremities is an extremely common condition and is estimated to occur in one of every five Americans. The most common manifestation is varicose veins...the clinical significance of CVI is not merely cosmetic because many patients experience debilitating symptoms ranging from lower extremity pain, swelling, heaviness, warmth, itching, cramping, and muscle fatigue to inflammatory dermatitis and ultimately venous stasis ulcers."19 Fowkes et al described chronic venous insufficiency as covering "a wide range of conditions, from asymptomatic incompetence of venous valves,

through varicose veins, to venous skin changes and leg ulceration,"20 while Eberhardt and Raffetto wrote that "the term chronic venous insufficiency (CVI) describes a condition that affects the venous system of the lower extremities with venous hypertension causing various pathologies including pain, swelling, edema, skin changes, and ulcerations...we will use the term CVI to represent the full spectrum of manifestations of chronic venous disease."21 Antignani wrote: "chronic venous insufficiency (CVI) is used to describe signs and symptoms of chronic venous hypertension in the lower limbs, a condition generally considered as the pathophysiological trigger of skin changes, the most serious of which is ulceration. Chronic venous disease of the lower limbs ranks as one of the most common conditions affecting humankind."22

Consensus on venous terms

The 2009 VEIN-TERM consensus document provides thorough definitions of chronic venous disease and chronic venous insufficiency and adds a third global term, namely, chronic venous disorder. Chronic venous disorder "includes the full spectrum of morphological and functional abnormalities of the venous system."23 Chronic venous disease refers to "any morphological and functional abnormalities of the venous system of long duration manifested either by symptoms and/or signs indicating the need for investigation and/or care."23 Chronic venous insufficiency (C3-C6) is "a term reserved for advanced chronic venous disease, which is applied to functional abnormalities of the venous system producing edema, skin changes or venous ulcers." The goal of the consensus committee was to agree on "a common scientific language for reports on the management of chronic venous disease."23

UNIFORM CLASSIFICATION

History

The end of the 20th century and the first part of the 21st century have been a time of compilation, contemplation, and advancement in regard to venous disease and therapy. While treatments were being offered to patients for many vascular conditions, the outcomes were only sporadically evaluated. After pioneering three valvular reconstructive procedures, Kistner found that diagnostic and reporting methods were not standardized between facilities, preventing inter-institutional trials from taking place and diluting the outcome data.⁴

Consensus

In 1994, Kistner joined with other vascular specialists to address these issues of universality on testing and reporting; this committee developed the Clinical-Etiologic-Anatomic-Pathophysiologic (CEAP) classification system for venous disease diagnosis and outcome that remains today's standard.4 Eklöf wrote that the CEAP classification was created to be a common language for venous disease, which lacked precise descriptions. The realization that diagnostic methods and treatment options cannot exist in myriad isolated incarnations has focused the attention of the scientific community on coalescing this information to provide a framework of commonality in clinical practice and research. The CEAP classification was adopted²⁴ and over time has become "the accepted standard for classifying chronic venous disorders."25 The basic design of the CEAP classification is to function as a universally accepted system for quantifying all degrees of chronic venous disease, leading to a common platform for clinical intervention and scientific inquiry.²⁴ The CEAP classification meets the desired criteria for an assessment in the range of systems and symptoms included, the nature of the severity measurements, and the inclusion of a disability score.24

TOOLS TO ASSESS TREATMENT OUTCOMES

Mozes and Gloviczki wrote that a common language in treatment and outcome, based on a common anatomic language, would lead to beneficial standardization of contributing factors to venous disease.¹³ The goal of this standardization is clarity in outcome reporting and the ability to compare results: "Outcome scoring systems have made a difference in scientific assessment of venous disease. There remains, however, the confusion over the different names used for leg veins. The confusion includes the terminology of saphenous veins (long, great or greater, small, short or lesser), the myriad of eponyms of the perforators, and, most importantly, the superficial femoral vein (a deep vein) (*Tables 1-3*)."¹³

Universal agreement on nomenclature and the anatomy of chronic venous disease will result in uniformity in reporting standards and outcome assessments. A common language must be in place for the outcome assessment to be relevant in international settings. Meissner et al wrote about the importance of evaluating outcomes: "The scientific future of studies of chronic

| Saphenous veins and their main tributaries |
|---|
| Great saphenous vein |
| Anterior and posterior accessory great saphenous vein |
| Superficial accessory great saphenous vein |
| Small saphenous vein |
| Cranial extension of the small saphenous vein |
| Superficial accessory small saphenous vein |
| Intersaphenous vein |
| Superficial inguinal veins |
| External pudendal vein |
| Superficial circumflex iliac vein |
| Superficial epigastric vein |
| Superficial veins of the foot |
| Superficial digital veins (dorsal and plantar) |
| Superficial metatarsal veins (dorsal and plantar) |
| Dorsal venous arch of the foot |
| Medial and lateral marginal veins |
| Plantar venous subcutaneous network |
| |

Table I. 2004 revised terminology for the superficial veins of the leg.¹⁴

| Deep veins of the thigh | |
|---------------------------------|--------------------------|
| Common femoral vein | |
| Femoral vein | |
| Profunda femoris or deep femo | oral vein |
| Medial and lateral circumflex f | emoral veins |
| Sciatic vein | |
| Popliteal vein | |
| Deep veins of the leg | |
| Genicular venous plexus | |
| Soleal veins | |
| Gastrocnemius veins (medial/la | teral and intergemellar) |
| Anterior tibial veins | |
| Posterior tibial veins | |
| Peroneal or fibular veins | |
| Deep veins of the foot | |
| Deep digital veins (plantar and | dorsal) |
| Deep metatarsal veins (plantar | and dorsal) |
| Pedal vein | |
| Deep plantar venous arch | |
| Medial plantar veins | |
| Lateral plantar veins | |

Table II. New terminology for the deep veins of the lower extremity.¹⁴

| | Perforators of the femoral canal |
|------|---|
| | Inguinal perforators |
| ۲ne | e perforators |
| | Medial, lateral, supra- and infrapatellar and popliteal fossa |
| | perforators |
| Leg | perforators |
| | Medial perforators (paratibial and lower, middle and upper |
| | posterior tibial) |
| | Lateral perforators |
| | Anterior perforators |
| | Posterior perforators (gastrocnemius, intergemellar and |
| | para-Achillean) |
| Ank | le perforators |
| | Medial, lateral and anterior perforators |
| Foot | perforators |
| | Medial, lateral, dorsal and plantar perforators |

Table III. New terminology for the perforating veins of the lower extremity.¹⁴

venous disease and its management depends on using proper outcome assessment methods, and this should be a major priority of all those engaged in the study of venous disease. However, measuring outcomes in CVD is complex and more difficult than most other vascular diseases."18 They also discussed what is required to achieve true standardization: "Bolstering clinical assessment by objective improvement in universally accepted venous tests could have a tremendous impact on venous outcomes assessment...[and] [r]equires that the normal range for each venous test parameter be standardized.... In addition, what constitutes a significant change in each of these parameters also needs to be established, to provide an objective basis for claiming improvement in response to an intervention. Finally, test protocols must be standardized and variability established for this approach to have universal application."18

Venous diseases, and varicosities in particular, are being diagnosed with increasing frequency worldwide, with varicosities being the most frequently diagnosed vascular anomaly.²⁶ The use of outcome assessments in venous disease has grown in importance with the explosion of technology and procedures offered for chronic venous insufficiency. To place these procedures on an

international level playing field for accurate comparison, O'Donnell wrote: "The adoption of a surgical strategy that corrects the abnormal superficial venous system alone (saphenous veins and perforators) in the face of deep venous reflux requires that the therapeutic outcomes of such a strategy be judged with objective criteria. The improved clinical status of a limb as defined by ulcer healing and by lack of ulcer recurrence, especially when expressed in a life table format, clearly is an objective outcome measurement."²⁷

After years of debate and trial-and-error attempts to identify the standard for outcome reporting, the consensus is that scoring instruments should provide uniform, accurate, reproducible measurements and be amenable to change to reflect the chosen therapy.²⁸ According to Dayal and Kent, they should "define essential terms and make recommendations regarding the following: clinical classification of disease; criteria for improvement, deterioration, and failure; a grading system for risk factors; categorization of operations and interventions; [and] complications encountered with grades for severity or outcome."²⁸ Results should be reported in a common language, which will lead to easy comparison of outcomes across studies.²⁹

Because of the variability in presentation of chronic venous disease, outcome reporting instruments have been difficult to devise. Meissner et al wrote: "The ideal clinical outcome measure for CVD would include the full spectrum of disease and be sufficiently sensitive to allow stabilization, improvement or deterioration to be precisely quantified."³⁰

One example of a useful outcome reporting method in chronic venous disease is the CEAP classification. But due to the static nature of its items, the CEAP cannot serve the purpose of assessing the treatment outcome. It only measures severity at a single time point. Like many other chronic conditions, venous disease encompasses a continuum of symptoms and severity, and change in status following therapy is an ongoing process. Some investigators have proposed combining the CEAP classification with other outcome assessment measures to increase its specificity for longitudinal assessment.^{31,32}

An assessment tool complementary to the CEAP: the VCSS

The Venous Clinical Severity Score (VCSS) is a longitudinal measure of nine categories universally

PHLEBOLOGY

| Pain | None: 0 | Mild: 1 | Moderate: 2 | Severe: 3 |
|---|---------------|--|---|---|
| or other discomfort (ie, aching, heaviness, fatigue, soreness, burning) Presumes venous origin | | Occasional pain or other discomfort (ie, not restricting regular daily activity) | Daily pain or other discomfort (ie, interfering with but not preventing regular daily activities) | Daily pain or discomfort (ie, limits most regular daily activities) |
| | | | | |
| Varicose Veins | None: 0 | Mild: 1 | Moderate: 2 | Severe: 3 |
| "Varicose" veins must be ≥3 mm in diameter to qualify | | Few: scattered (ie, isolated branch varicosities or clusters) Also includes corona phlebectatica (ankle flare) | Confined to calf or thigh | Involves calf and thigh |
| | 1 | | | |
| Venous Edema | None: 0 | Mild: 1 | Moderate: 2 | Severe: 3 |
| Presumes venous origin | | Limited to foot and ankle area | Extends above ankle but below knee | Extends to knee and above |
| | | - | | |
| Skin Pigmentation | None: 0 | Mild: 1 | Moderate: 2 | Severe: 3 |
| Presumes venous origin Does not include focal pigmentation over varicose veins or pigmentation due to other chronic diseases (ie, vasculitis purpura) | None or focal | Limited to perimalleolar area | Diffuse over lower third of calf | Wider distribution above lower third of calf |
| | | 1 | | |
| Inflammation | None: 0 | Mild: 1 | Moderate: 2 | Severe: 3 |
| More than just recent pigmentation (ie, erythema, cellulitis, venous eczema, dermatitis) | | Limited to perimalleolar area | Diffuse over lower third of calf | Wider distribution above lower third of calf |
| | | | | |
| Induration | None: 0 | Mild: 1 | Moderate: 2 | Severe: 3 |
| Presumes venous origin of secondary skin and subcutaneous changes (ie, chronic edema with fibrosis, hypodermitis) Includes white atrophy and lipodermatosclerosis | | Limited to perimalleolar area | Diffuse over lower third of calf | Wider distribution above lower third of calf |
| | 1 | | 1 | |
| Active Ulcer Number | 0 | 1 | 2 | ≥3 |
| Active Ulcer Duration (longest active) | N/A | <3 mo | >3 mo but <1 y | Not healed for >1 y |
| Active Ulcer Size (largest active) | N/A | Diameter <2 cm | Diameter 2-6 cm | Diameter >6 cm |
| | | | | |
| Use of Compression Therapy | 0 Not word | 1 | 2 Wears starkingst | 3 Full compliance: |
| | Not used | intermittent use of stockings | days | stockings |

Table IV. Revised Venous Clinical Severity Score.35

considered relevant in the diagnosis and management of chronic venous disease. This score has a strong relationship with the CEAP classification, indicating that "to some extent both scores are based on common characteristics."²⁶ That validation study by Kakkos et al²⁶ found that the VCSS and the CEAP classification were equally sensitive in outcome assessment over time. While the VCSS was determined to be useful in assessing postprocedural outcome in the short term and in the long term, the CEAP classification was found to be valuable in staging venous disease throughout the treatment period.²⁶

The VCSS has also demonstrated good correlation with the results of ultrasonography, and its simplicity makes it easy to administer and score.^{31,33} Recently, a valuable application for the VCSS has arisen in the form of its visual descriptive power. The "visual language of [the] VCSS" is a common framework for consistent physician scoring of venous disease (*Figure 1*). Similarity in scoring and in descriptions of venous sequelae adds to the structure of the language of chronic venous disease.

Newly issued recommendations by the Society for Vascular Surgery and American Venous Forum include the use of CEAP in both clinical and research applications. Revised VCSS is recommended for assessment of therapeutic results in all levels of venous disease.³⁴

Revision of the VCSS

In 2007, through the American Venous Forum, an international ad hoc working group was created to revise the VCSS.35 (Table 4). The intention was to update the terminology, simplify the application, and clarify ambiguities. The additional objective was to protect the strengths of the VCSS, while acknowledging the limitations. Revisions to each of the clinical descriptors were made using, where applicable, quality of life language to address patients at the lower end of the disease spectrum. The pain component now contains common patient symptoms (aching, heaviness, fatigue, soreness, and burning) that establish a venous origin. The effect on different types of daily activities is clarified. The varicose vein component has modified the vein size criteria to greater than three mm to maintain consistency with the revised CEAP. Telangiectasias and reticular veins remain without a score; however, corona phlebectatica (ankle flare) has been added to the mild category. The edema component presumes a venous origin and now

reflects anatomic distribution and extent. Skin pigmentation has guideline criteria for anatomic distribution and extent and excludes non-venous causes. Inflammation has been expanded to include more than just recent pigmentation changes or underlying infection. Erythema, cellulitis, venous eczema, and dermatitis have been incorporated, as well as anatomic distribution and extent. Induration has been modified to reflect more severe venous disease. Chronic edema, with fibrosis, hypodermitis, white atrophy and lipodermatosclerosis, has been added. The ulcer categories have been refined to include size and duration to reflect the largest and longest active ulcers. The compressive therapy category led to the most discussion and has now eliminated leg elevation to reflect that the category comprises only the wearing of compression garments. This revised VCSS is currently undergoing validation testing internationally.

Another assessment tool complementary to the CEAP: the REVAS scale

Another outcome assessment used in conjunction with the CEAP classification is REVAS (recurrent varices after surgery). While the CEAP classification alone is effective in staging chronic venous disease, there is a need for a tool specifically designed to score and assess recurrent varicosities after therapy. Although useful in following the course of venous disease after therapy, the VCSS is not designed to specifically address factors important in scoring recurrent varicosities, including the effect of initial treatment and the type of follow-up provided.³⁶

The use of REVAS and the CEAP classification together provides the type of information that is necessary for a complete picture of the nature of recurrent varicosities in the context of chronic venous disease. This allows for clearer, more accurate reporting of this common postprocedural problem.³⁶

Eklöf wrote a commentary on REVAS in which he explained that the goal was "to create a classification for REVAS to be used as a complement to [the] CEAP [classification], which was expanded to define the sites, nature, and sources of recurrence, as well as the magnitude of the reflux and possible contributory factors. Factors responsible for recurrence and recommendations for primary prevention were debated."³⁶

| Attribute | Absent (0) | Mild (1) | Moderate (2) | Severe (3) |
|---------------------------------------|------------|-------------------------------|--|--|
| Pain | None | Occasional | Daily | Daily limiting |
| Varicose Veins | None | Few | <u>Confined to calf or</u> <u>thigh</u> | Involves calf and thigh |
| Venous Edema | None | Limited to foot/ankle | <u>Extends above</u> ankle/below knee | Extends to knee and above |
| Skin Pigmentation | None | Limited, to perimalleolar | Diffuse over lower 1/3 of calf | Wider distribution above lower 1/3 calf |
| Inflammation | None | Limited, to perimalleolar | Diffuse over lower 1/3 of calf | Wider distribution above lower 1/3 calf |
| Induration | None | Limited, to perimalleolar | Diffuse over lower 1/3 of calf | Wider distribution above lower 1/3 calf |
| No. Active Ulcers | None | 1 | 2 | >3 |
| Active Ulcer Size (largest active) | None | Diameter <2 cm | Diameter 2-6 cm | Diameter >6 cm |
| Ulcer Duration (longest active) | None | <3 months | >3 mo but <1 yr | Not healed for >1 year |
| Compression Therapy | None | Intermittent use of stockings | <u>Wears stockings most</u> <u>days</u> | Fully compliance: stockings |



Fig 1a – Leg Pre RFA. Pain=2, VV=2, Edema=2, Pigmentation=0, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2. Total VCSS =8

| Attribute | Absent (0) | Mild (1) | Moderate (2) | Severe (3) |
|---------------------------------------|------------|---------------------------------|--|--|
| Pain | None | Occasional | Daily | Daily limiting |
| Varicose Veins | None | <u>Few</u> | Confined to calf or thigh | Involves calf and thigh |
| Venous Edema | None | <u>Limited to</u> foot/ankle | Extends above ankle/below knee | Extends to knee and above |
| Skin Pigmentation | None | Limited, to perimalleolar | Diffuse over lower 1/3 of calf | Wider distribution above lower 1/3 calf |
| Inflammation | None | Limited, to perimalleolar | Diffuse over lower 1/3 of calf | Wider distribution above lower 1/3 calf |
| Induration | None | Limited, to perimalleolar | Diffuse over lower 1/3 of calf | Wider distribution above lower 1/3 calf |
| No. Active Ulcers | None | 1 | 2 | >3 |
| Active Ulcer Size (largest active) | None | Diameter <2 cm | Diameter 2-6 cm | Diameter >6 cm |
| Ulcer Duration (longest active) | None | <3 months | >3 mo but <1 yr | Not healed for >1 year |
| Compression Therapy | None | Intermittent use of stockings | <u>Wears stockings most</u> <u>days</u> | Fully compliance: stockings |



Figure 1b – Leg Post RFA alone. Pain=0, VV=1, Edema=1, Pigmentation=0, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2. Total VCSS =4

Figure 1. The "visual language" of VCSS. Consistency in physician scoring and reporting allows a common language of venous disease to emerge. Basic Clinical CEAP 3, VCSS 8 (pre) - CEAP 3, VCSS 4 (post).

A NEED FOR COMMON OUTCOME MEASURES

Progression to the next step in assessment involves having common outcome measures that can be subjected to rigorous examination. According to Meissner et al, "An evidence-based approach to the treatment of any disease requires a mechanism for ensuring that patient populations are comparable and a means of quantifying outcome."³⁰

Regardless of the instrument chosen for outcome assessment, the manner in which results are tabulated and presented is of paramount importance in determining the effect of therapy. Rutherford wrote: "Results mean everything.... The results of therapy for vascular diseases have little meaning if presented in isolation, no matter how uniform and valid the criteria used for reporting them.... So the proper comparison of outcomes goes much farther than standardized reporting practices, as essential as these are. It requires not only reporting outcomes in a standard fashion but including comparable data on all factors known to affect those outcomes."

The journey from an assessment instrument to a standardized reporting practice to a universal results measurement that is useful in clinical practice and research methods is a long exacting process. Along the way, there are key elements to consider to ensure reliability and a clear focus on the desired objectives.

Several categories of assessment tools are now in use, including physician- and patient-completed surveys, disease-specific and generic surveys, and tools that measure quality of life or that grade objective changes following intervention.³⁵ The choice of instrument is based on the focus of the assessment, whether a straightforward measure of success or failure following an intervention or a detailed analysis of patient perception of change over time. Recently, the case has been made for inclusion of physician- and patient-generated measures to assess the full effect of treatment for chronic venous disease.^{35,37}

CONCLUSION

Consistent nomenclature provided the language foundation that has allowed communication to progress in a common direction. This communication later focused on the development and achievement of common therapeutic goals, which over time manifested as the reporting of outcomes. When results could be stratified in a universal format, these findings then could be subjected to the rigorous scrutiny of evidence-based medicine. This process is the seed for future therapies and continued conversations.

In his presidential address to the Midwestern Vascular Surgical Society, Glover spoke about the potential influence of this generation of vascular surgeons on the next. He articulated the value of future research, emphasized the inevitability of change in vascular surgery, and quoted one of his mentors, Vanderbilt anatomy professor Sam Clark: "Come, let us work, and in this little time do some new thing that no one on this earth has ever thought to do. Split from the world's eternal truth some atom of the everlasting! Then let us die, and leave for coming generations one bit of knowledge by which we'll be remembered until some later one shall show the truth we found was but a grain gleaned from some vast store we'd hardly touched and we shall be forgot and he remembered-but we, out where absolute is near, shall smile, seeing how little a beach of sand resembles the granite cliff from which it weathered."38



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Results of the DECIDE survey: appraisal of the predictive value for chronic venous disease of a symptom checklist

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Keywords:

Symptoms, epidemiology, chronic venous disease, CIVIQ

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ABSTRACT

Objectives: The main objective of the DECIDE study was to evaluate the predictive value of a symptom checklist for chronic venous disease (CVD) in patients seen by general practitioners. The secondary objectives were to assess the relationship between the checklist data and the patient's quality of life evaluated using the Chronic Venous Insufficiency Questionnaire (CIVIQ), and to monitor the medium-term evolution of this relationship amongst patients prescribed a venoactive drug.

Method: Consecutive patients in general practice presenting symptoms that could be ascribed to CVD were included. Patients with an advanced form of CVD, ie, skin changes and a history of venous ulcers, were excluded.

Results: A total of 13131 patients were included by 1323 general practitioners, whose acceptance of the symptom checklist was good, since the completion rate was high. Of the 2104 patients referred to venous specialists, 2080 were confirmed as suffering from CVD. The correlation between a positive diagnosis of CVD and positive answer to the symptom checklist was 98.9% (95% confidence interval [CI]: 98.3%-99.3%), indicating that the symptom checklist is of predictive value for CVD. The CIVIQ-20 was of discriminatory value since there was a 12-point difference between patients with and without CVD (64.4 ±17.9 vs 76.2±16.4, respectively; P<0.001). Of 9953 patients followed up for an average of 63 days, 88.7% received Daflon 500 mg, 5.1% received another venoactive drug, and 3.5% were left untreated. After the 63-day follow-up, a significant decrease in CVD symptoms was observed in all patients treated with Daflon 500 mg. Amongst the 7103 patients to whom the CIVIQ-20 was readministered, a significantly greater improvement in quality of life was seen in the Daflon 500 mg group compared with the other treatment groups.

Conclusion: This symptom checklist may be used as a predictive tool for CVD in general practice. Data from the present survey show that CVD has a negative impact on patients' quality of life. Finally, a 63-day treatment with Daflon 500 mg rapidly alleviated symptoms of CVD and significantly improved the quality of life of CVD patients.

INTRODUCTION

Chronic venous disease (CVD) of the lower limbs is defined as "morphological and functional abnormalities of the venous system of long duration manifest either by symptoms and/or signs indicating the need for investigation and/or care",¹ while "chronic venous insufficiency" is the term reserved for more severe forms of the disease (from C3 to C6 of the CEAP classification).¹ Varicose veins are one of the most common manifestations of CVD.²

Symptoms related to CVD include tingling, aching, burning, pain, muscle cramps, sensation of swelling, of throbbing, of heaviness, itching, restless legs, leg tiredness, and fatigue.¹ CVD can lead to acute (rupture of varicose veins, venous thrombosis) or chronic complications (dermatitis, lipodermatosclerosis, chronic leg ulcers).^{3,4}

The impact of CVD is substantial.⁵⁻⁹ Both symptoms and visible varicose veins, even in the absence of complications, lead many patients to seek medical advice. Although uncomplicated varicose veins have little functional impact, they nonetheless affect quality of life, mainly in social terms.^{2,10} At the other end of the spectrum, the most serious manifestations of CVD, such as venous leg ulcers, are a major medical problem. Venous ulcers have a poor prognosis, and delayed healing and recurrences are very frequent.¹¹⁻¹³

Apart from general and physical measures,^{2,14} venoactive drugs are of proven efficacy in alleviating symptoms. A recent review of available clinical data¹⁵ has made it possible to assign a high level rating (grade 1B according to Guyatt's recommendations)¹⁶ to clinical evidence of symptom relief for a few active substances, such as Daflon 500 mg.¹⁷⁻²⁰

Apart from advanced stages of the disease, it is often difficult to recognize CVD, for two main reasons: the symptoms are not related solely to CVD^{1,2,21} and are not

always associated with signs in patients designated C_0 in the CEAP classification, who account for up to 15% of the general population. But, the venous nature of symptoms is suggested by their worsening during the day, after a prolonged period of standing or sitting, on exposure to heat, and during the premenstrual period in women, and their improvement in response to cold, lower limb elevation, and exercise.

To help physicians identify the venous origin of CVD, a symptom checklist was designed *(Table I)*. It contains the most commonly reported symptoms of CVD and allows assessment of their worsening and/or improvement in 4 cases. If such a change is observed for at least two of the cases, the venous origin of these symptoms is considered highly likely.

The checklist has not yet been evaluated in a prospective study to assess its utility in everyday medical practice. Evaluation of this utility is based primarily on confirmation of its positive predictive value, and on assessment of its ability to identify patients in whom symptoms have a high impact and for whom an active therapeutic strategy would be the most beneficial.

A non-interventional evaluation of the checklist was conducted in a population of patients seen by general practitioners. The checklist was used if the general practitioner decided to advise the patient to start treatment with a venoactive drug because of symptoms suggestive of CVD. The Chronic Venous Insufficiency Questionnaire (CIVIQ) was used to assess the impact of CVD on the patient's quality of life. It consists of 20 questions designed to assess four dimensions (physical, psychological, social, and pain) and has been widely validated in various stages of CVD.^{17,22-25} This questionnaire is sensitive in the short and medium term to changes in symptoms that occur spontaneously or following initiation of treatment.^{23,24}

METHODS

Objectives

The primary objective of this prospective, noninterventional survey was to evaluate the predictive value of a symptom checklist for CVD in patients seen by general practitioners. The secondary objectives were to assess the relationship between the checklist data and the patient's quality of life evaluated using the CIVIQ,

| Does the patient have the following leg problems? | Presence of t | he symptom | Expression of the sym | ptom | |
|---|---------------|------------|---|------|--|
| Heavy legs | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| Pain in the legs | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| Pain along the course of leg vein | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| Sensation of swelling | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| Sensation of burning | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| Itching | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| Sensation of 'pins and needles' in the legs | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| Night cramps | Yes No | | Spontaneous complain On questioning only | t 🗆 | |
| And when are the leg problems most severe? | | | | | |
| Exacerbated after prolonged standing, but diminish after rest, and/or exacerbated at the end of the day, but disappear in the morning N | | | | | |
| Exacerbated by warmth, but less severe in winter and/or with cold temperatures | | | | | |
| Exacerbated by standing around, but improve or disappear on walking No | | | | | |
| <i>For women only:</i> Exacerbated before menstrual period or occur with your hormonal therapy, but disappear with discontinuation of Normonal therapy, but discontinuation d | | | | | |

Please report the number of situations in which your patient's symptoms are exacerbated: If symptoms are exacerbated in at least 2 of these situations your patient is most probably suffering from chronic venous disease–related symptoms.

Table I. Symptom checklist.

and to monitor the medium-term evolution of this relationship in patients prescribed a venoactive drug.

Patients

Adult subjects, with no upper age limit, seen in general medical practice and presenting with symptoms suggestive of CVD, confirmed by use of a symptom checklist. On the day of the visit these patients were not receiving medical therapy of CVD, and did not present with skin changes or a history of venous ulcers. The CEAP international classification, with which general practitioners too often are still not very familiar, was not used in this study, but "purists" can note that all patients were rated Cos, $C_{1s'}$, $C_{2s'}$, or C_{3s} .

Methodology

Starting with the date when the survey was set up, in a given medical practice, the first ten patients seen successively and who met the inclusion criteria were enrolled. Treatments of venous disease initiated were recorded. In particular, the general practitioner noted if he/she referred the patient to a specialist for an opinion on venous disease. The patient was informed of the objectives of the survey and then completed a CIVIQ. If the patient was seen again at a follow-up visit 3-6 months later, the general practitioner used the symptom checklist to assess any changes in symptoms. The patient's compliance with any treatment of CVD was assessed and another CIVIQ was filled out. If a specialist's

opinion was requested, any laboratory findings were reported along with the specialist's conclusions.

Statistical analysis

Statistical analysis was conducted with l SPSS 13.0 software.

The total population was classified into several subgroups, taking into account sex, age category and type of venoactive treatment prescribed (Daflon 500 mg or another).

The positive predictive value of the checklist was calculated based on the subpopulation of patients with available specialized laboratory data.

Categorical variables were compared between the different subgroups using a chi-square test. Univariate or multivariate analyses were used for quantitative variables.

Data are presented as means \pm the standard error (SEM) or as a percentage. 95% confidence intervals (95% CI) were calculated using a normal approximation for quantitative variables and the Clopper-Pearson method for nominal or ordinal variables.

For quality of life results, the global index score of CIVIQ was used, and for convenient reading of results, a score of 0 was considered the worst possible, while 100 was the best possible.

Ethical and regulatory context

In this non-interventional survey, no data obtained directly or indirectly from visits was collected.

The essential documents of this survey were submitted for approval to the National Board of the French General Medical Council (*Conseil National de l'Ordre des Médecins*) before it was initiated.

Patients concerned received an information leaflet informing them that their doctor was participating in a national survey and that their personal medical data, from which their names had been removed, would be computer processed, and that they were entirely free to agree to participate in the survey or not.

RESULTS

Population enrolled

A total of 1323 general practitioners throughout metropolitan France enrolled 13 131 patients between June 2008 and July 2009. This predominantly female (83.0% women, 60.5% of whom were multiparous) population (*Table II*) had a mean age of 53.3 ± 15.0 years, the women being younger than the men on average (45% of women were under 50 years of age vs 26.5% of the men). Mean BMI was 25.7 ± 4.9 kg/m². A BMI >30 kg/m² was noted in 22% of patients, most often men. In 61.4% of cases the patient's mother or father or both had a history of CVD, 9.6% of patients had a history of phlebitis, and 69.6% of patients reported a sedentary lifestyle.

In the physical examination, telangiectases and varicose veins were observed in 70.3% of patients, most often men. Conversely, edema was more common in women (68.2% vs 57.3%).

Use of the checklist for detection of CVD

Use of the checklist for detection of CVD in this population never posed a problem in terms of filling out the questionnaire in routine visits. Of the eight symptoms routinely sought, sensation of heaviness in the legs, swollen legs, and painful legs were by far the most prevalent in both men and women (greater than or equal to 70% in patients reporting these symptoms), but with a higher incidence in women (Table II). These three symptoms were spontaneously reported by patients in 56.7%, 41.8%, and 38.9% of cases, respectively. Pruritus was the symptom least frequently reported (21.4% of men vs 17.1% of women). Patients had 4.2 ± 1.5 symptoms on average, with no clinically relevant difference according to sex. However, the number of symptoms rose significantly with age, from 3.8 ± 1.5 in patients under 40 years of age to 4.4 ± 1.5 in patients aged over 70 (P<0.001).

Worsening was almost always observed (94.6% of cases) in patients in the standing position, with an improvement or disappearance of symptoms at rest. The effect of warmth and of standing was also dominant, while an effect associated with menstruation was only observed in 25% of women.

PHLEBOLOGY

| Variable | Women | Men | P value | Total (N=13 131) |
|--|--|--|----------------------------|---|
| Gender % | 83.0% | 17.0% | | |
| Age (years) % • >70 • Between 60 and 69 • Between 50 and 59 • <49 | 52.5+15.3 16.0% 17.2% 21.6% 45.2% | 57.4+12.5 18.5% 23.8% 31.2% 26.5% | <0.001 | 53.3+15.0 |
| BMI (Kg/m²) % | 25.4+5.0 | 27.1+4.2 | <0.001 | 25.7+4.9 |
| BMI>30 Kg/m ² % | 21.2% | 25.4% | | 21.9% |
| Family history of CVD % | 62.1% | 57.7% | | 61.4% |
| Personal history of venous thrombosis % | 9.5% | 10.0% | | 9.6% |
| Given birth to >1 child % | 60.5% | | | |
| Presence of edema % | 68.2% | 57.3% | | 66.2% |
| Presence of varicose veins % | 69.1% | 77.0% | | 70.3% |
| Presence of symptoms - Heavy legs - Sensation of swelling - Pain in the legs - Night cramps - Sensation of 'pins and needles' - Pain along the course of vein - Sensation of burning - Itching | 94.2% 76.5% 74.6% 50.9% 41.0% 32.8% 32.0% 17.1% | 89.3% 66.1% 68.8% 53.1% 41.2% 34.6% 32.4% 21.4% | <0.001 <0.001 <0.001 | 93.4% 74.8% 73.7% 51.3% 41.1% 33.1% 32.1% 7.9% |
| Mean number of symptoms | 4.2+1.5 | 4.1+1.5 | | 4.2+1.5 |
| Exacerbated after prolonged standing | 94.9% | 93.5% | | 94.6% |
| Exacerbated by warmth | 87.6% | 82.8% | | 86.8% |
| Exacerbated by standing around | 71.8% | 76.1% | | 72.5% |
| Exacerbated before menstrual period | 25.5% | | | |
| Probability that a CVD is present | 97.7% | 95.4% | | 97.3% |

Table II. Patient characteristics at the inclusion visit.

In summary, based on the checklist data, CVD was considered likely in this population.

Impact of symptoms on quality of life

A CIVIQ was filled out at visits by 9848 patients (75.0% of those included). The most altered dimension in the CIVIQ was pain (50.7% of men and 58.0% of women had a score of 50 or lower), while the psychological dimension was the least altered. An overall score of 50 or lower, indicating a major alteration in quality of life, was observed in 15.6% of men and 23.5% of women. Overall, total CIVIQ score and that of its dimensions, with age being constant, were very significantly lower in women (*Figure 1*). Except for pain, whose mean score was stable, these scores decreased with increasing age, regardless of sex (*Figure 1*).

This score was also positively and significantly correlated with the number of symptoms in the checklist, decreasing from 85.0 ± 13.5 when a single symptom was observed to 53.8 ± 17.9 (r=0.462; *P*<0.001) when all eight symptoms were reported. (*Figure 2*). The CIVIQ-20 was of discriminatory value since there was a 12-point difference between patients with and without CVD (64.4 ± 17.9 vs 76.2 ± 16.4 , respectively; *P*<0.001) (*Figure 3*).

Specialist's opinion requested on treatments

The opinion of a venous specialist or a vascular specialist was requested for 2475 patients (18.8% of the total population), mainly regarding treatment in 56.2% of them. This population was characterized by a higher mean number of visits (4.6 \pm 1.5 vs 4.1 \pm 1.5 in the population for whom no opinion was requested;



Figure 1. CIVIQ-20 global score according to sex and age.



Figure 2. CIVIQ-20 global score according to mean number of symptoms.

P<0.001) and a lower quality of life (with a global CIVIQ score of 64 on average).

At the end of the first visit, Daflon 500 mg was prescribed in 90% of patients, another type of venoactive drug in 8%, and no treatment in 2%.

Positive predictive value of the symptom checklist

Of 2475 patients for whom a specialist's opinion was



Figure 3. CIVIQ-20 global score according to the probability that chronic venous disease is present.



Figure 4. Prevalence of symptoms before and after 2-month treatment with Daflon 500 mg.

requested, 2155 were seen again at a follow-up visit. In 85% of these patients, the results of duplex ultrasound scanning were available.

Superficial venous disease was seen in 48.8% of patients and, in terms of pathophysiology, reflux was noted in 54% of these patients, 42% of whom were treated by the specialist (sclerotherapy in 54% of cases). In 2104 patients who likely have CVD based on the symptom checklist, confirmation or not of CVD was clearly documented. CVD was confirmed by a specialist in 2080 cases, and the positive predictive value of the symptom checklist was 98.9% (95% CI: 98.3%-99.3%).

Patients seen again and compliance with therapy

A total of 9954 patients were seen again at a follow-up visit. Median follow-up was 63 days; 8834 (88.7%) patients were receiving Daflon 500 mg, 511 (5,1%) were treated with another venoactive drug, and 260 (2.6%) were not receiving any type of treatment. In 349 cases (3.5%), there was no record of whether or not a venoactive drug was used.

In the general practitioner's opinion, compliance with the recommended venoactive drug therapy was very good in 62.7% of cases (63.6% in patients receiving Daflon 500 mg and 49.6% in those on another venoactive drug), acceptable in 33.8%, and mediocre or poor in 3.5% of patients.

Symptoms at the follow-up visit

Prevalence of all eight symptoms on the checklist decreased markedly. In patients receiving Daflon 500 mg, prevalence decreased by 26% for sensation of heaviness in the legs, 59% for sensation of swelling, and 62% for painful legs (*Figure 4*). The number of symptoms present at the follow-up visit per patient treated with Daflon 500 mg decreased by 2.1 ± 1.5 on average, vs baseline visit (*P*<0.001). This decrease was significantly lower in patients treated with another type of venoactive drug (-1.7 \pm 1.5; *P*<0.001).

Based on their overall impression scored on an 8-point rating scale, the general practitioners reported good or very good improvement in symptoms in 66.3% of patients who received Daflon 500 mg vs 38.7% in those receiving another type of venoactive drug (*P*<0.001).

Quality of life at the follow-up visit

A CIVIQ was filled out for 7103 patients at the baseline visit and during monitoring. All dimensions of the CIVIQ improved very significantly at the second evaluation, the greatest improvement being in pain. Overall quality of life score increased by 15.8 ± 12.5 in patients treated with Daflon 500 mg and by 10.3 ± 10.4 in those treated with another venoactive drug (*P*<0.001).

DISCUSSION

The purpose of this observational survey was to evaluate whether a symptom checklist would help non-specialist physicians diagnose CVD when suggestive symptoms are present. This checklist incorporates the eight most commonly reported symptoms in CVD, and, in particular, the evaluation of four situations in which these symptoms are worsened or improved depending on the presence or absence of the triggering factor (prolonged standing, exposure to warmth, standing about, and the pre-menstrual period in women). When at least two of these situations have an effect, CVD can be considered likely. Thus, it is not the symptoms themselves, whatever their severity, which guide the diagnosis, but solely the change in their severity in the situations evaluated. In at least two cases, both worsening and relief must be noted, depending on whether or not the situation occurs.

Very few instruments of this type, with a purely diagnostic purpose, have been developed. In this regard, the efficacy of routine screening is undergoing evaluation. Such screening programs are conducted by specialized centers and include noninvasive investigations. Although the first results are promising, these programs cannot be applied to conditions of general medical practice where the diagnosis will be based mainly on the clinical interview and a physical examination of the patient.

A checklist relatively similar to the one used in this study was developed by Carpentier et al,²⁶ who also considered above all the effect of triggering factors. Based on a 54item questionnaire, these authors selected 6 items which when combined showed very good sensitivity and specificity. But this questionnaire requires cautious interpretation and may not be suitable for routine visits in general practice. This is why the checklist used in our study was developed and designed to enable rapid completion and immediate use in guiding in the diagnosis.

The results of this survey in a very large sample of general practitioners clearly demonstrate that the objective of a simple-to-use checklist was achieved. The likelihood of a patient presenting with CVD when the checklist results were positive (positive predictive value) was very high (99%) in a highly diversified population. However, this value must be interpreted with caution, insofar as diagnostic confirmation was requested mainly in those patients who tended to have many symptoms and therefore were at high risk of actually presenting with CVD. Nevertheless, in the case of a positive test result, overall the patients concerned had more symptoms and a lower quality of life, which is evidence of the utility of this type of instrument in everyday practice.

In summary, this survey demonstrates that patients in whom a general practitioner must decide whether to initiate treatment with a venoactive agent are those in whom there is an impact, sometimes severe, of CVD. Assessed by means of the CIVIQ, this impact relates particularly to pain, as more than half of the patients have a score of 50 or more (100 being the worst), which is indicative of a major impairment of quality of life. This high score is found whatever the patient's sex and age. However, in spite of this reduced quality of life, a specialist's opinion is sought in very few cases (19%), even though venous investigations would undoubtedly be useful in assessing the hemodynamic impact, locating the lesions, and initiating the most effective treatment.

Nevertheless, initiation of a venoactive treatment, in particular with a drug of proven efficacy such as Daflon 500 mg, alleviates symptoms quickly and improves quality of life. This effect is that much greater when compliance with therapy is good. This improvement is also better than that observed with other venoactive drugs not recommended as grade 1, an observation which supports the recommendations of consensus conferences in their classification of venoactive drugs. However, insofar as this study was not randomized, this observation should be interpreted cautiously. In conclusion, this survey demonstrates that a simple symptom checklist can be used in general medical practice to simplify the decisions of general practitioners regarding CVD. The aim was not to validate this checklist in the detection of CVD, but the survey nevertheless confirms its high positive predictive value and shows that it deserves to be used by vascular specialists.

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Congenital arteriovenous malformations: what are the perspectives?

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arteriovenous malformations, surgical treatment, embolization, sclerotherapy

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SUMMARY

Arteriovenous malformations (AVMs), irrespective of their localization, are a therapeutic challenge. Available imaging modalities permit complete identification of lesions and definition of their relation to adjacent tissues. Conventional arteriography is now replaced by noninvasive techniques, mainly the CT scan. Duplex scan provides a variety of information and confirms the diagnosis of AVM, pointing to the AV shunts by localizing the zones of shunts within the tissues, and by showing the main feeding arteries and draining veins. Flow measurement and its comparison between the limbs can also help in the determination and follow-up of hemodynamic changes. CT scan with contrast enhancement can identify precisely the zone of shunts within the tissue (intramuscular localization, intra-articular, or in the cellular space, most often around a joint). The 3D reconstruction visualizes the feeding arteries, the zones of shunt, and the draining veins better than arteriography.

Therapeutic protocols require a multidisciplinary approach involving interventional radiologists, vascular surgeons, and plastic or orthopedic surgeons. Therapeutic approaches may differ a lot depending on the diversity of the lesions that must be treated and also to the diverse backgrounds of treating specialists. Procedures have improved, thanks to embolization techniques and surgical approaches combined with sclerotherapy procedures. Arterial selective embolization may be used to control the incapacitating symptoms, but is always palliative and is usually reserved for hemorrhagic complications. Nowadays, it is rarely indicated before surgery because it provides few benefits in controlling bleeding. Retrograde percutaneous venous embolization may be complementary to the arterial approach with a bigger risk of pulmonary embolism. Some forms of vascular architecture may be more indicated for such procedures (Rose's vascular architecture, pelvic AVM). Percutaneous sclerotherapy with direct puncture has not been much used for these lesions. Intraoperative sclerotherapy is applicable for the venous compartment. It controls perioperative bleeding or is the complementary treatment of incomplete surgical excision.

The difficulty in assessing the results stems from variability in the therapeutic aims that may be adopted. These aims may include complete excision, partial excision supplemented by reconstructive surgery, or treatment of vascular complications of the AVM, leaving the malformation itself aside.

INTRODUCTION

Irrespective of their localization, AVMs are a rare and serious condition. Therapeutic approaches may greatly differ and this can be related to the diversity of the lesions and also the different backgrounds of treating specialists.

In this review, we consider malformations of the limbs and, of the thoracoabdominal wall and pelvic AVM.

ANATOMY – ANGIOARCHITECTURE

The arteriovenous shunts (or nidus) of the AVM are well individualized within a tissue or vascular region.

Proximal to the shunts, the high arterial flow may cause aneurysms or heart failure (proximal AVM of the limbs or pelvic AVM)

The nidus may present in two ways: either as multiple arteriovenous shunts well identified within the tissues (often around the knee joint in the lower limb)



Figure 1. A. Arteriography diagnosis of AVM B. CT scan localization of the AVM in the medial gastrocnemius muscle.

(*Figure 1*) or as arteriovenous shunts within the wall of a congenital venous ectasia. The latter is currently better recognized and has been reported intracranially (arteriovenous fistulas of the lateral sinus or the vein of Galen) and extracranially in the parametrium. These arteriovenous fistulas constitute what we call the rose angioarchitecture (*Figure 2*).



Figure 2. Pelvic AVM: A. 3D CT scan of AVM in the parametrium. B. Axial view of arteriovenous shunts around an ectasia of the iliac internal vein (rose architecture).

The draining veins, downstream of the AVM, form pulsatile ectasias responsible for the swelling. The superficial localization of the AVM (in the distal part of the limbs) may be because of skin manifestations and hemorrhagic complications.

Imaging studies (CT scan) distinguish the various anatomic details.

Soft tissue AVMs can be separated into three categories:

- Localized AVMs within a well-defined structure (subcutaneous cellular tissue, intramuscular, intraarticular, or cellular spaces). The consequences of surgical excisions are relevant to the localization of the lesion.
- Regional AVMs involve a larger area of tissue. Treatment is palliative and is indicated only for complications.
- Diffuse or extensive AVMs where current modalities are not successful.

Truncal AVMs with a high flow are exceptional and difficult to identify.

CLINICAL PRESENTATION

Symptoms may vary according to the subject and the localization. We will limit our presentation to AVMs of the limbs, thoracoabdominal region and pelvic region. The most frequent localization is the **limbs** where 4 clinical features may lead to the diagnosis:

- a pulsatile tumor of some part of the limb responsible for functional limitation or pain
- pulsatile veins, mainly in the extremities (hand, foot), may be the weakness of an underlying AVM
- a flat warm angioma corresponding to a superficial AVM
- complications of the AVM may necessitate some form of treatment (management of trophic problems such painful ulcer, or bleeding complications requiring emergency hemostasis procedures) (*Figure 3*).



Figure 3. Trophic lesions and hemorrhagic complications: A. Hand. B. Forefoot. C. Abdominal wall.

Thoracoabdominal AVMs are more often limited in parietal structures, while the localization of **pelvic AVMs** may be visceral (uterine) or extravisceral within the parametrium.

NONINVASIVE IMAGING

Many advances in the understanding of arteriovenous malformations have been possible by progress in imaging techniques, which are now sufficient for making the diagnosis. **Bone radiography** of the region of concern, in the search for osseous or periosteal reaction or a cortical fracture often indicative of bone destruction by draining veins.

Duplex scanning is involved at several stages of the diagnosis:

- it helps locate arteriovenous shunts within the tissues,
- it can identify the main feeding pedicles and draining veins preoperatively (in well-defined AVMs),
- it permits a skin marking of the lesion in order to accomplish a well-targeted surgical approach
- it can identify residual shunts and assess the comparative flow rates in the limbs in postoperative monitoring and follow-up.

CT scanning. With axial acquisitions, CT scanning is the most efficient exploration of AVMs. Without contrast it gives an image of bone lesions. With contrast it defines the topography of the malformation in relation to surrounding tissues. Three-dimensional reconstruction defines the location of the nidus better than arteriography.

Arteriography has restricted indications. There is a place for it before attempts at embolization or at control of bleeding.

Coagulation control is usually normal: AVMs are not associated with hemolytic anemia. There is no need for coagulation factor therapy.

Cardiac flow measurement may be restricted to high-flow AVMs (proximal part of limb, or pelvis)

THERAPEUTIC PROCEDURES

There has been significant progress thanks to new pretreatment investigations.

Embolization and sclerotherapy

Few embolization agents are applicable to AVMs:

• *Ethanol* is not often used as there is a risk of migration or tissue ischemia. Combination of ethanol with coils has reduced this risk. Gelified ethanol, which is not yet commercially available, might also reduce this risk.

- *Cyanocrylate agents* (Glubran) or *ethylene alcohol copolymer* (Onyx) are most often used during arteriography. Ethiboc is no longer available: its poor resorption can create a mass effect.
- *Cement* can be injected percutaneously in areas of bone destruction. Its efficacy is often incomplete because of technical problems in controlling the draining veins.
- *Ethylene glycol (bone wax)* may be used exclusively perioperatively. It helps achieve hemostasis in difficult cases or occludes the venous compartment in some forms of AVM.

The injection site of these products can be discussed according to the surgical approaches used and the type of lesions: arterial or venous retrograde embolization, percutaneous or perioperative sclerotherapy.

Surgical procedures must be adapted to lesion localization. There are three strategies:

• *Complete surgical excision* for well-localized AVMs (seen on CT scan), in well-defined tissue (cellular space or subcutaneous, muscle or joint tissues). It is a complex procedure that often requires associated reconstructive procedures (*Figure 4*).



Figure 4. AVM of the digit:*A.* Extensive trophic lesions.*B.* CT scan of AVM in P1-P2 segments.

- C. Amputation with muscle free flap.
 - *Partial excision* may be the only feasible approach in order to preserve function (hand, foot). Hybrid methods are possible combining excision with reconstructive procedures or sclerotherapy.
 - *The treatment of complications* of AVMs may require specific skills: vascular surgery for proximal arterial aneurysms, orthopedic surgery for bone or joint lesions (arthroplasty combined with sclerotherapy)

(*Figure 5*), reconstructive surgery (tissue expansion, tendon transfer, free tissue flap).



Figure 5. TAVM of the knee hybrid procedure:

- A. AVM of the knee and ankle.
- B. Preoperative 3D CT scan.
- *C. Postoperative CT scan of arthroplasty of the knee and perioperative sclerotherapy.*

THERAPEUTIC INDICATIONS

The main thing is to avoid proposing treatment for an asymptomatic and uncomplicated AVM and in the absence of functional or significant cosmetic problems. Any mistake in the treatment may lead to detrimental complications. The indications are based on the anatomic and clinical data of each case.

- AVMs in the limbs

The main problems occur in the extremities (hands and fingers, ankles and feet). Intra-arterial embolization is not effective. Hybrid surgical procedures are used for hemorrhagic complications or trophic lesions.

- AVMs in the thoracoabdominal wall

Parietal lesions (subcutaneous, intramuscular) may be treated with extensive resection as reconstructive surgery has extensive possibilities in these cases.

- Pelvic AVMs

Visceral (uterine) or extravisceral (parametrium) AVMs pose complex therapeutic problems. Intra-arterial embolization is most often palliative. Surgery combined with intra-operative embolization of the venous compartment (ethylene glycol) may permit a definitive treatment.

CONCLUSION

Good information from the patient and on his or her environment is needed to determine the significance of an AVM. Advances in noninvasive imaging techniques (CT scan) have led to new treatment strategies. The complex nature of the lesions requires the involvement of multidisciplinary teams including radiologists, surgeons, in particular vascular surgeons, and reconstructive and orthopedic surgeons.

READING MORE

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Review of proceedings

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VU: venous ulcer DVT: deep venous thrombosis PTD: postthrombotic disease or postthrombotic syndrome

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In November 2009, a meeting at Big Island (HI), USA was attended by 60 invited international experts on venous disease, wound care, internal medicine, nursing, vascular technology, epidemiology, health care management, insurance industry, public policies, marketing, industry research and development, and government relationships. Most participants were US citizens, but experts from other countries were also present.

The aim of the meeting was not to provide an update on venous ulcer (VUs), but the experts used the latest results in making their recommendations for reducing the prevalence of VUs by 50% over the next 10 years. To achieve this aim, the participants were divided into 4 working groups:

Group I: Deep venous thrombosis (DVT) and postthrombotic disease (PTD).* *Leaders: P. Henke and T. Wakefield*

Group II: Primary chronic venous disease *Leaders: P. Neglen and B. Eklof* Group III: Ulcer healing and recurrence prevention *Leaders: D. Gillespie and B. Kistner*

Group IV: Nonmedical issues Leaders: M. Passman and S. Elias

Their task was to list the critical issues to be addressed, which afterwards were presented and discussed in the plenary session chaired by A. Comerota. The four groups then worked separately to prioritize the critical issues and actions required, landmark measures and the timeline. Their proposals were again discussed in depth at a plenary session.

* Postthrombotic disease. In English and American English the term most commonly used is postthrombotic syndrome, but in this document both postthrombotic syndrome and disease are used. It is generally admitted that disease is the appropriate term for describing clinical features, ie, symptoms and signs related to a single known etiology, which is the case when dealing with sequelae of DVT. Conversely, syndrome applies to symptoms and signs that may be related to various etiologies. Confusion between disease and syndrome is attributed to Copland when he translated Galen's works in 1541. The leaders of each group then summarized their conclusions, and this document was reviewed various times by the group members before submission to the Journal of Vascular Surgery, knowing that P. Henke was editor.

The Journal of Vascular Surgery supplement is divided into seven parts. The first two describe in detail why this topic was chosen as well as the symposium's goal, while the next four describe recommendations and actions for reducing the prevalence of VU. The last one is devoted to the presentation of 13 selected abstracts.

A - VENOUS ULCER DIAGNOSIS, TREATMENT, AND PREVENTION OF RECURRENCE (GROUP III)

- 1. Recommendation and actions regarding the diagnosis of VU. An educational program should be developed to help primary care physicians classify leg ulcer as venous, nonvenous, or of mixed etiology. Public awareness is also needed to convince people to consult their general practitioner.
- 2. Recommendation and actions regarding VU treatment. Definitive care of VU can be divided into two parts: ulcer healing and recurrence prevention.
 - 2-1. VU healing. Compression is the key factor. Nevertheless, there is no consensus regarding multilayer bandages or stockings, knowing that the main problem with compression remains compliance. Evidence-based studies are not available to show whether corrective operative procedures should be done while the ulcer is active or healed.
 - 2-2. Recurrence prevention. Compression, correction of the underlying venous disease and surveillance are the three key actions. To fulfill these actions the medical profession and the public alike need to be educated.
 - 2-2-1. Effective compression must be maintained on the extremity as long as the underlying cause of VU remains uncorrected and as long as swelling persists.
 - 2-2-2. Correct axial superficial reflux and other readily correctable sources of reflux obstruction in all cases at during treatment of the first VU.
 - 2-2-3. Develop guidelines for ongoing surveillance of patients presenting an ulcer.

B - PREVENTION AND TREATMENT OF VENOUS ULCERS IN PRIMARY CHRONIC VENOUS INSUFFICIENCY (GROUP II)

Four critical issues were identified.

- 1. Standardization of diagnostic testing, especially ultrasound scanning for chronic venous disease and criteria for interpretation of the results. There are no known hemodynamic methods to identify which patients with primary chronic venous disease and limbs with C-class 2 to 4 will develop VU. To achieve this goal, other hemodynamic tests in addition to ultrasound scanning should be developed. Finally, it is possible to develop a practical protocol for chronic venous disease investigations for clinical practice and then to introduce a more sophisticated protocol for longitudinal research into chronic venous disease
- 2. Identification of factors (other than hemodynamic) to identify patients with primary chronic venous disease C-class 2-4 limbs who are at risk of progression to active leg ulcer. This approach was particularly innovative and the possible risk factors were listed. Some of them—age, "feeling of swelling", hypertension, obesity, pregnancy, smoking, use of hormones-are known as varicose vein risk factors, but they need to be correlated with progression of the disease. Mechanical dysfunction of the calf muscle pump may enhance the development of VU. It may be of value to identify genetic factors, biomarkers of venous endothelium dysfunction, imbalance of humoral mediators of vasoconstriction and venous dilatation, differences in skin type/metabolism/race.
- 3. Identification of treatment that may prevent progression in patients with C2-C4 limbs to VU (C6). There is no study on the efficacy of compression therapy, venoactive drugs, or endovenous (thermal chemical ablation, stenting)/open surgery in preventing chronic venous disease progression. Such studies may be difficult to perform adequately, since it will be hard not to intervene in symptomatic patients with clinical classes below C6.
- 4. Calculation of the number of C2-C4 patients needed to treat to prevent VU. Based on C4-C6 the outcome of critical issues 1-3, it may be possible to acquire the information needed to perform a cost-benefit analysis.

C - PREVENTION AND TREATMENT OF POSTTHROMBOTIC SYNDROME (GROUP I).

Six topics were identified.

- 1. Prevention of DVT recurrence. Knowing that recurrent ipsilateral DVT is probably the most important factor in the development of PTD, practical measures to prevent recurrence are crucial. They include the best practices in the American College of Chest Physicians guidelines, which are presented in Table I. To promote use of guidelines it is recommended to provide the patient with a DVT information card to be given to their physicians, and to package it with compression stockings.
- 2. Compression/ambulation compliance. The benefits of elastic compression stockings after acute DVT have been well described in randomized controlled trials in the prevention of PTD. Additionally, when elastic compression stockings are combined with early ambulation, rates of PTD are decreased. Nevertheless, some ambiguity persists concerning the effectiveness of elastic compression stockings. First, it is unknown how long elastic compression stockings need to be

worn to provide the prescribed amount of compression before they wear out. Second, it is not known whether elastic compression stockings are effective in patients with symptomatic distal DVT. Third, the compression strength (high or low) that prevents VU is not clearly established, given that lighter stockings are easier to apply than heavier ones (compression strength of 30 to 40 mm Hg). Fourth, it is unknown how long elastic compression stockings need to be worn.

Various actions may be recommended. The most applicable worldwide is to ensure that patients treated in emergency rooms as well as in an ambulatory setting wear appropriate stockings in addition to taking their anticoagulants. Further studies could be directed to the use of dynamic pulse compression as adjunctive therapy, and in developing microchips embedded in stockings for the measurement of pressure and compliance.

3. Early thrombus removal in patients with iliofemoral DVT. Thrombus removal with catheter-based procedures is likely an important component to reduction of PTD in DVT involving the iliocaval

| Factors | Evidence level | Tools to facilitate | Gaps in knowledge |
|---|----------------|--|---|
| Maintain adequate level of AC | I C | AC clinical services | Type of AC and effect on recurrence |
| Proper prophylaxis for high-risk patients | IA | ACCP guidelines risk strata and reminders | Group versus individual prophylaxis prolonged prophylaxis |
| Type of AC | II B | Education | New agent effects on PTD LMWH versus VKA for PTD prevention |
| Maintain adequate duration of AC | ١C | Duplex US, d-dimer measurement, Education | Biomarkers to better determine risk of recurrence |
| Compression | IA | Rapid placement | Compliance Duration of compression and PTD incidence |

 Table I. Prevention of DVT recurrence

Abbreviations: AC anticoagulation; ACPP American College of Chest Physicians; LMWH low-molecular-weight heparin; PTD postthrombotic disease; US ultrasound; VKA vitamin K antagonist.

| Methods | Evidence | Gaps in data |
|----------------------|----------|---|
| Open thrombectomy | I B | Who is best treated? |
| Pharmacological | II A | Timing? |
| Catheter mechanical | II A | Sequential levels of thrombus clearance for best outcome? |
| Angioplasty/stenting | II B | |

Table II. Early DVT removal techniques.

segment, although is not a strong recommendation in the American College of Chest Physicians 2008 guidelines. One practical measure to achieve this objective is to ensure early referral of patients with iliofemoral and extensive thrombosis to venous specialists. It is worth noting that the present classification of DVT as proximal and distal is not satisfactory and it seems appropriate to promulgate a more precise anatomical classification. Other points to be clarified are shown in *Table II*.

- 4. Elimination of postthrombotic iliofemoral venous obstruction. Chronic obstruction of the iliofemoral segment, independent of reflux, is the principal cause of PTD in approximately one-third of postthrombotic cases. This pathophysiological component is underdiagnosed, as various imaging techniques (ascending venogram, computed tomography, and magnetic resonance venography) do not provide reliable information on the degree of compression or on the hemodynamic significance of such lesions, given that the contribution of vein wall stiffness is unknown. Intravenous ultrasound scanning seems more reliable, but is invasive. Ballooning and stenting procedures that are presently the first-line operative treatment need to be evaluated using a dedicated registry so that best practice recommendations can be made.
- 5. Stratification of patients with acute DVT who are at risk of developing severe PTD.

Although it is not possible to foresee the development and course of PTD in the individual patient, some clinical predictors of PTD are identifiable at the time of acute DVT. DVT involving the iliac and common femoral veins, elevated body mass index, previous ipsilateral DVT, older age, and inadequate anticoagulation have been associated with the development of PTD. Furthermore, patients who show symptoms of PTD one month after acute DVT have been found to develop PTD at 2 years.

A DVT PTD risk prediction score including symptoms, etiology, and anatomy components has been proposed but needs to be validated (Table III). Also needed is a review of the PTD literature with regards to factors that predict ulcer progression, so as to define better the variables associated with PTD development and severity.

6. Pharmacological management of PTD.

Venoactive drugs such as micronized purified flavonoid fraction (MPFF) and horse chestnut seed extract (HCSE) are used worldwide, except in the USA, as adjuvant therapy in the management of chronic venous insufficiency and VU. The peerreviewed literature contains a large body of evidence on the effectiveness of such venoactive drugs. As the PV6 group was set up by members of the majority AFV (see remark at the end of the review), they recommended conducting randomized controlled trials in an American population to support legal acceptance by their governing bodies.

Nevertheless some grade recommendations as mentioned in *Table I* and *II* should be debated.

D - NONMEDICAL INITIATIVES TO DECREASE VENOUS ULCER PREVALENCE (GROUP IV)

The goal of this group was to identify and prioritize critical issues and how to address them. Some of the group's actions and recommendations are applicable only in the USA, others worldwide, and we will focus on the latter.

| Symptoms | Etiology | Anatomy | Р |
|----------------------|----------------|----------------------------|---------------|
| 1 = None | 1 = Provoked | 1 = Calf vein | 1 = Primary |
| 2 = Mild | 2 = Unprovoked | 2 = Femoral / Popliteal | 2 = Recurrent |
| 3 = Moderate | | 3 = Iliofemoral | |
| 4 = Severe | | $4 = Multi-segments \ge 2$ | |
| 5 = Limb-threatening | | | |

Table III. Risk classification for PTD related to acute DVT: "SEAP".

| 7/2010 | | 2/2011 | 6/2011 |
|--------|---|--|---|
| | Standard test for CVD dx(2A - C) Create responsible overseeing organization. Empower organization for fundraising (5A,C) Develop program to determine VU prevalence (4A) | Creation and dissemination of prevention programs for (1A,B) providers Educational for PTD (3A - D) prevention | Initial health care and insurance policy (5B) Initial research programs for prevention and treatment of VU (4A - C) |
| 7/2013 | | 2/2015 | Ongoing |

Figure 1. Projected timeline to accomplish the overarching goal of UV reduction. Abbrevations: CVD: chronic venous disease; dx: diagnosis; PDT: postthrombotic disease; VU: venous ulcer.

- Lack of awareness of VU recognition, diagnosis, and prevention at all levels of the health care system. Recommendations: Develop educational programs targeting all levels of the care system, especially at the patient and primary care levels.
- 2. Variable quality of care for VU because of the poor coordination of care within all levels of the health care systems and lack of standard guideline implementation and compliance.

Recommendations: There are too many guidelines from different sources, and a unified evidence base is critical in facilitating guideline implementation. Evidence-based guidelines need to address all levels of health services.

3. Poorly substantiated economics of prevention and treatment of VU leading to problems in determining cost-effective quality care and optimal reimbursement. High-quality data assessing the total economic burden of VU are lacking.

Recommendations: Gather unbiased economic data by justifying health services and other health care payers of the value equation involved in VU prevention and quality care.

4. Funding for research in VU prevention and treatment is currently limited and studies on comparative effectiveness are lacking. Funding opportunities from national institutes of health for VU prevention and treatment have been limited in the past, with ongoing clinical trials funded mostly by other organizations. Recommendations: Develop a strong centralized foundation to promote research and education through national institutes of health, industry, and other alternative sources for studies of the comparative effectiveness of VU prevention and treatment.

- 5. Improving the care of VU requires development of governmental relationships and advocacy in order to provide input into health care policies addressing venous ulcer prevention and treatment goals.
- 6. Need for a strong central organization to promote all necessary elements requiered for prevention and treatment of VU.Recommendations for issues 5 and 6 mainly involved the AVF and consequently will not be described in this

The 5th part of this J Vasc Surg supplement summarizes the major proposals (*Figure 1*) including a projected timeline for the overarching goal of VU reduction.

review (see remark at the end).

In the last part, 13 selected extended abstracts are presented.

- 1. O Nelzen, Uppsala, Sweden. Fifty percent reduction in venous ulcer prevalence is achievable - Swedish experience.
- 2. GL Moneta, Portland, Ore USA. Decreasing venous ulcers by 50% in 10 years: five critical issues in the diagnosis and investigations of venous disease.
- 3. JD Raffetto, Boston, Mass USA. The definition of the venous ulcer.
- 4. AH Davis, et al, London, UK. Natural history and progression of primary chronic venous disorder.
- 5. M Perrin, Lyon, France. Management of primary venous disorders in C6 patients.
- 6. W Marston, Chapel Hill, NC USA. Summary of evidence of effectiveness of primary chronic venous disease treatment.
- 7. S Vedantham, St Louis, Mo USA. Definition of postthrombotic disease.
- 8. SR Kahn, Montreal, Canada. Natural history of postthrombotic disease: transition from acute to

chronic disease.

- 9. JA Caprini, Chicago, Ill USA. Critical issues in deep vein thrombosis prevention.
- 10. MH Meissner, Seattle, Wash USA. The effectiveness of deep vein thrombosis prevention.
- 11. S Raju, Flowood, Miss USA. Critical issues in ulcer prevention in postthrombotic disease.
- 12. RB McLafferty, Springfield, Ill USA. Evidence of prevention and treatment of postthrombotic syndrome.
- 13. P Pappas. Newark, NJ USA. Critical issues in prevention of postthrombotic re-ulceration.

To support the recommendations, 564 references are listed.

I am grateful to A. Comerota B. Eklöf, RL. Kistner, F. Lurie, and T. Wakefield that accepted to amend the manuscript and honored with their final comment:" We have reviewed this synopsis of the detailed Journal of Vascular Surgery report with care and believe it clearly and succinctly reflects the content of the PVS-6 meeting. Dr. Perrin's effort to promulgate this conference's intent to improve the care of the venous ulcer patient and ultimately to decrease the incidence of its occurrence is greatly appreciated."

NB. It should be borne in mind that the most active members of the American Venous Forum initiated the meeting. Consequently, some recommendations and actions are specific to the USA, and not applicable to other countries, and so will not be developed.



The sixty venous experts.



The PV6 organizers From left to right Thomas Wakefield, Fedor Lurie, Bo Eklöf, Robert Kistner.

| Congress and co | nference | calendar |
|------------------------|----------|----------|
|------------------------|----------|----------|

| DATES | CONGRESS | COUNTRY | CITY |
|----------------------------------|---|-----------------|----------------------|
| 9-11 September 2011 | MAYO CLINIC INTERNATIONAL VASCULAR SYMPOSIUM | France | Paris |
| 15-17 September 2011 | INTERNATIONAL CONGRESS OF THE UNION INTERNATIONALE DE PHLEBOLOGIE (UIP) EUROPEAN CHAPTER MEETING | Czech Republic | Prague |
| 22-25 September 2011 | THE EUROPEAN SOCIETY FOR VASCULAR SURGERY | Greece | Athens |
| 29 September - 1 October 2011 | VASCULAR SOCIETY OF INDIA | India | Mumbai |
| 29 September - 1 October 2011 | 15° CONGRESSO NAZIONALE COLLEGIO ITALIANO FLEBOLOGIA - CIF | Italy | Ferrara |
| October 2011 | XIX. CONGRESS OF SLOVAK SOCIETY OF ANGIOLOGY WITH INTERNATIONAL PARTICIPATION | Slovak Republic | Tatranská Lomnica |
| 6-8 October 2011 | 20TH EUROCHAP | Slovenia | Ljubljana |
| 11-15 October 2011 | ANGIOLOGY AND VASCULAR SURGERY BRASILIAN CONGRESS – SÃO PAULO - CBACV | Brazil | São Paulo |
| 20-22 October 2011 | BUDAPEST ANGIOLOGY DAYS 2011 (COMMON CONGRESS OF HUNGARIAN ANGIOLOGY AND VASCULAR SURGERY SOCIETY AND INTERVANTIONAL RADIOLOGY SOCIETY WITH INTERNATIONAL PARTICIPATION) | Hungary | Budapest |

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|---------------------------------|--|-------------|--------------------|
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| 29 October - 2 November 2011 | XLIII NATIONAL CONGRESS OF ANGIOLOGY & VASCULAR SURGERY | Mexico | Aguascalient es |
| 9 November 2011 | SCLEROTHERAPY IN CHRONIC VENOUS DISEASE | Croatia | Zagreb |
| 9-11 November 2011 | 12TH ANNUAL CONGRESS OF THE UNION OF SWISS VASCULAR SOCIETIES | Switzerland | Baden |
| 16-18 November 2011 | CONGRESO NACIONAL DE LA SOCIEDAD VENEZOLANA DE FLEBOLOGIA Y LINFOLOGIA | Venezuela | Caracas |
| 17-19 November 2011 | MEETING SFP- ACP, PARIS | France | Paris |
| 23-26 November 2011 | XXXIII CONGRESSO NAZIONALE SOCIETÀ ITALIANA DI ANGIOLOGIA E PATOLOGIA VASCOLARE - SIAPAV | Italy | Roma |
| 1-3 December 2011 | MEET 2011 MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY | Italy | Roma |
| 10-11 December 2011 | 1ST LISBON INTERNATIONAL FORUM ON VASCULAR DISEASES | Portugal | Lisbon |
| 19-21 January 2012 | CONTROVERSIES & UPDATES IN VASCULAR SURGERY | France | Paris |
| 21-23 January 2012 | 3RD ANNUAL MEETING OF THE BALKAN VENOUS FORUM | Turkey | Istanbul |

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