PLETIX

Screening of Vascular Circulation of the Legs

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Magnitude of a problem[1]

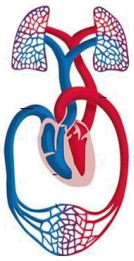
Chronic Venous Insufficiency (CVI) has a considerable socioeconomic impact in the world due to its high prevalence, cost of investigations and treatment, and loss of working days. In Europe over 70% of the population suffers from blood circulation problems in the legs. For example, varicose veins are present in the Western countries in 33% of female and 20% of male adults.
In the Framingham study, the incidence of varicose veins per year was 2.6% in women and 1.9% in men. The prevalence of edema and skin changes such as hyperpigmentation and eczema due to CVI is up to 12% of the population.
The overall prognosis of venous leg ulcers is poor: only 50% heal at 4 months, 20% remain open at 2 years, and 8% remain open at 5 years. The annual recurrence rate varies from 6% to 15%.
In 1 study, 12.5% of patients with ulcers took early retirement because of continued disability.
Data from the Brazilian Security System show that CVI is the 14th most-frequently quoted disease for temporary work absenteeism and the 32nd most frequent cause of permanent disability and public financial assistance. The annual cost of venous ulcers has been estimated to be £400 to 600 million for the United Kingdom and $1 billion for the United States.
The total cost of CVI to society, both direct and indirect, is estimated to be $1 billion (US dollars) in each of 3 European countries (Germany, France, and the United Kingdom)

What is the venous insufficiency?

Veins are the blood vessels of the body that return blood from the arms, legs, and organs back to the heart.

The heart pumps oxygen-rich blood to all tissues through the arteries. Veins transport exhausted blood to the heart again. During this process, the arteries contain about 15% of total blood volume, while the veins contain more than 80%.

If the heart works like a pump to transport blood into the arteries, veins of the calf are like a "**muscle pump**" which forces the blood to go to the heart by counteracting the force of gravity.



Veins return blood to the heart in two ways. Either the force of the heart pumping fresh blood pushes blood back to the heart, or blood flows to the heart from the force of gravity. When blood has to fight gravity and flow upstream back to the heart, as it does through the deep veins in the legs, the leg muscles contract to pump blood back toward the heart.

Vein walls are elastic, and they have small valves that only allow blood to flow in one direction. When leg muscles contract, they push inward against the elastic vein walls. This squeezes blood upward, opens the valves, and moves blood toward the heart. When leg muscles relax, the vein wall also relaxes and the valves inside the vein close to prevent blood from flowing backward. This method of pumping blood out of the legs is called **venous pump**.

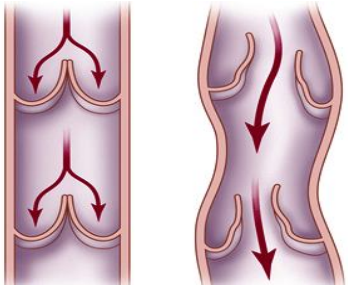
The venous pump is most effective when a person is walking and leg muscles are contracting. But when a person sits or stands, blood pressures in leg veins can build. Deep veins are usually able to withstand short periods of inactivity, but extended periods of increased pressure can stretch and weaken vein walls.

Increased blood pressure can stretch and damage vein walls. The veins may no longer be able to pump blood back to the heart.

Venous insufficiency is a condition in which the flow of blood through the veins is impaired. Venous insufficiency can be caused by a number of disorders of the veins, particularly deep vein thrombosis (blood clot) or varicose veins.

What are the causes of venous insufficiency?

In healthy veins, there is continuous flow of blood from the limbs back toward the heart. There are valves within the veins of the legs that prevent the backflow of blood. Venous insufficiency occurs when forward flow through the veins is obstructed, as in the case of a blood clot, or if there is backward leakage of blood flow through damaged valves.



In many cases of venous insufficiency, patients have both obstruction of forward flow and backward leakage of the veins.

The most common causes of venous insufficiency are previous cases of blood clots and varicose veins. In some cases, weakness of the leg muscles that help squeeze blood forward may also contribute to venous insufficiency.

What are the symptoms of venous insufficiency?

Symptoms of venous insufficiency include:

- Vericose veins
- Skin ulcers
- Edema (swelling)
- Skin discoloration
- Prominent varicose veins or ropy veins
- Aching, burning, or throbbing sensations in the legs and feet
- Cramping
- Leg weakness
- Cellulite and water retention

Medications and immobility can also affect the muscles and veins of the legs. Patients should also consider signs and symptoms of venous insufficiency before traveling or having surgery and early diagnosis helps to delay the onset of this condition.

What are the risk factors for venous insufficiency?

Some of the risk factors that can contribute to venous insufficiency are:

- Older age
- Varicose veins
- Previous deep vein thrombosis (blood clot)
- Family history (other members of the family suffer from the disorder)
- Obesity
- Inactivity
- Muscle weakness
- Pregnancy
- Injury to the legs
- Cancer

How is venous insufficiency treated?

There are many treatment options for venous insufficiency, depending upon the condition that is causing it. The most common treatment for venous insufficiency is **prescription-wear compression stockings.** These special elastic stockings apply pressure at the ankle and lower leg and improve venous blood flow and reduce leg swelling.

Compression stockings are available in a range of prescription strengths and in different lengths (such as knee-high or thigh-high stockings). In some cases when a non-healing ulcer (sore) is present, a physician may prescribe special **medicated wraps** (such as an Unna boot) to reduce swelling and treat the skin ulcer.

To further help with the leg swelling caused by venous insufficiency, your doctor may also tell you to keep your legs elevated above your heart when you are lying down. He or she may also suggest that you **get more exercise**; for example, **walking** can improve your circulation. **Weight loss** can also be very helpful for treatment of venous insufficiency for patients who are overweight.

For patients with venous insufficiency caused by blood clots, doctors commonly prescribe **anticoagulants or blood thinners**. This treatment works on existing blood clots and also prevents additional clots from forming.

Phytomedicines and antioxidants are also very useful for the treatment of this disease. The most important active principles are:

1. Centella
2. Blueberry
3. Red grape-vine
4. Escina
5. Hamamelis
6. Melilot
7. Equisetum
8. Rusco

The use of **creams and gel with refreshing, linfo-draining and hydration action** can be also very important in order to improve the elasticity of the skin so reducing the possibility of ulcers, and to reduce the water retention reinforcing the walls of the veins.

How can venous insufficiency be prevented?

Prevention of venous insufficiency is important, especially if there is a strong family history. **Hence early diagnosis is essential**. Strategies for prevention of blood clots can help you avoid chronic venous insufficiency. Prevention methods for each patient may be different; therefore, a physician should discuss and design a personal program for each situation.

You can help prevent venous insufficiency with the following steps:

- Maintain a healthy body weight; lose weight if you are overweight.
- Exercise regularly.
- If you smoke, try to quit. Smoking is harmful to the circulation.
- Protect your legs from injury.
- Do not stand or sit in one place or position for very long; get up and move.

Diagnosis

A careful clinical history and examination should reveal the patient's symptoms, their severity, and whether they are due to venous disease rather than to coexisting nonvenous musculoskeletal, arterial, or neurological pathology. Subsequent noninvasive or, in some cases invasive, investigations may be required to confirm the clinical assessment.

Pletix: the Point of Care (or near patient) testing Solution

Plethysmography is a well-known and consolidated (See *Bibliography of the method* at the end of the guide) non invasive method utilized to screen and monitor vascular circulation.

Plethysmography measures changes in blood volume in a given area of the body. It measures these changes with a photometric sensor. Plethysmography is especially effective in detecting changes caused by blood flow.

Pletix is a point of care medical device developed to support operators in the prevention (**preliminary screening**) of chronic venous insufficiency, employed at a global level.
The Pletix measures the **Venous Refilling Time (RT)**. This refers to the time is takes for blood to return to the point of measurement on the calf after forced movement (e.g. tapping of the foot).

It therefore demonstrates, in a non invasive way, a problem in the venous down flow of the leg, and the condition of the venous reflux or altered functionality of the muscular pump of the calf.

Plethysmography with reflected light or photoplethysmography[2, 3] is based on the principle that the degree of reflected light from the cutis is in respect to the quantity of hemoglobin. The reflection of the light will result minimal in conditions of maximum capillary filling up and the same reflection will be at its maximum in conditions of maximum capillary emptying.

How to perform testing with Pletix

Sit the patient comfortably, with feet firmly on the floor, and with the leg bent at about 100-110° degree so to avoid any compression and awkward angles of the veins.

The probe is positioned on the internal part of the calf, at about 10 cm above the ankle.

Once the test has started, the patient should remain still until the base signal is stable (signaled by the instrument via a beep).

The patient then performs a program of 10 foot taps following the beep sounds emitted by the unit itself. Ensure that the heel of the subject is firmly placed on the floor and is not lifted during this procedure.

The patient then is to sit still, whilst the instrument registers a progressive return of the tracing to the base line, due to the filling up of the cetaceous venous plexus. This interval of time is called **Refilling Time (RT)**.

In normal subjects, the RT expressed in seconds is equal or greater to 25 seconds. In subjects that may have CVI, results are lower than 25.

They results are divided in 4 classes:

- normal	> 24 seconds
- insufficiency of pump degree 1	light: from 24 to 20 seconds
- insufficiency of pump degree 2	moderate: from 19 to 10 seconds
- insufficiency of pump degree 3	severe: < 10 seconds

The instrument delivers the result and recommendations as well as further consultation and investigation. Products advised following screening range from graduated tights, creams, supplements with ingredients such as vitamins and anti-oxidants with the aim to increase the strength of the vein walls and reduction of problems associated with poor blood and vein circulation.

Pletix aids the practice of prevention of CVI by offering on the spot screening. The instrument is designed for healthcare operators ranging from specialists in clinics, to health and wellness operators at point of care sites.

Bibliography of the method

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[5]. *The Journal of Investigative Dermatology, 73: 13-19, 1981* **– The optics of human skin.**

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