PHLEBOLOGY PROJECT

Conservative REflux Elimination Device (CREED): The Virtual Phlebectomy

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Abstract In more than 60% of varicose subjects finger compression of the main tributary(ies) is able to eliminate the reflux in the GSV axis. This corresponds to the Reflux elimination test (RET), and in these cases a simple elimination of the tributary may be initially sufficient, if a conservative strategy is concerned. In these same cases, the positioning of a special tourniquet based on sport taping material with a thickening placed exactly over the tributary termination (CREED = Conservative REflux Elimination Device) may have the same effect than a phlebectomy. This application, easy and simple, may be useful when active treatments are not possible or need to be delayed, without any ambition of being a definitive care.

Keywords RET (Reflux Elimination Test), conservative treatments, CHIVA, phlebectomy, CREED

Introduction

Any flow (antegrade or retrograde) in veins depends upon the contemporaneous existence of a pressure (energy) gradient and a system compliance[1].

Venous Reflux is usually defined as retrograde flow in the reverse direction to physiological lasting for more than 0.5 s in the superficial network[2-4]; for the femoropopliteal veins should be greater than 1s. Outward flow in the perforating veins should be considered abnormal at greater than 350 ms [3].

A more detailed definition could be, according to C Recek: *Venous reflux in the lower extremity is a diastolic, centrifugal, pathological flow of venous blood within incompetent venous channel(s) connecting both poles of the ambulatory pressure gradient, which arises during the diastolic phase of the calf pump activity and amounts to 37.4 ± 6.4 mm Hg. The higher pole of the pressure gradient lies in the popliteal, femoral, or iliac vein, the lower pole in deep lower leg veins. Reflux takes place during the relaxation of the calf musculature, exceeds the duration of the physiological centrifugal streaming lasting 200 - 300 milliseconds, and stops as soon as the ambulatory pressure gradient has been equalized*[5].

Reflux is characterized by:

- a) an **escape point**, such as sapheno-femoral junction (SFJ) with terminal valve (TV) incompetence, a perforator, a sapheno-popliteal Junction. At times reflux can be also fed by normal tributaries, an escape pont being absent.
- b) a **pathway** of variable length distal to the escape point involving saphenous stems and/or tributaries.
- c) a **re-entry point** (for instance **a perforator**, where the pathway flow empties).

Each component is usually single but multiple escapes, pathways and perforators can be present at a time.

A venous **shunt**, sometimes with a local recirculation of blood, named by Trendelenburg “private circulation”, is then created[6].

In primary varicose veins, with pump activation (plantar, calf, thigh, gluteal, thoraco-abdominal, etc.), normal deep veins of the lower limb are submitted to pressure lowering creating the gradient for blood from superficial to deep system, and so activating the flow/reflux mechanism.

For being active, the shunt needs that all the components are present and as a consequence, it may be interrupted by eliminating one single component. Trendelenburg in 1890 for first showed that a finger's pression over the bulging Great Saphenous Vein (GSV) could avoid its sudden filling when standing (Trendenburg Test): *One lays the patient flat again, raises the leg perpendicularly, lets all the blood flow out of the saphenous field and compresses the trunk of the saphenous with the finger at a spot where it is definitely recognizable. Now one lets the patient come down from the cot cautiously, without removing the compression finger from the saphenous, we see that the whole saphenous vein now remains empty at first on standing*[6].

Perthes (1895), Trendelenburg's pupil, made the same observation using a tourniquet, a solution still in use in today hemodynamic assessment (Perthes Test). During walking, the circular compression of superficial network avoids venous refluxing, while physiologic vein drainage runs in deep veins. If a deep obstruction is present, veins (varices) are not able to empty[7].

Diagnostic tests for Venous Refilling Time calculation (plethysmography) still employ the tourniquet exclusion of superficial veins.

For clinical purposes venous reflux has been treated by trying to interrupt each component.

When an **escape point** exists, this may be treated by ligation: the source of the reflux being stopped, all the system will be freed from the blood overload coming from the reflux point. High ligation of SFJ in GSV insufficiency treatment proved to be insufficient, if performed as a single treatment, to maintain the venous system in a balance, resulting in high reflux recurrence rates. Similar results were highlighted when treating only sapheno-popliteal junction (SPJ) in small saphenous vein (SSV) incompetence. High ligation of the saphenous junction and stripping of the refluxing saphenous stem eliminates the **escape point** (when it exists) and part of **the pathway**.

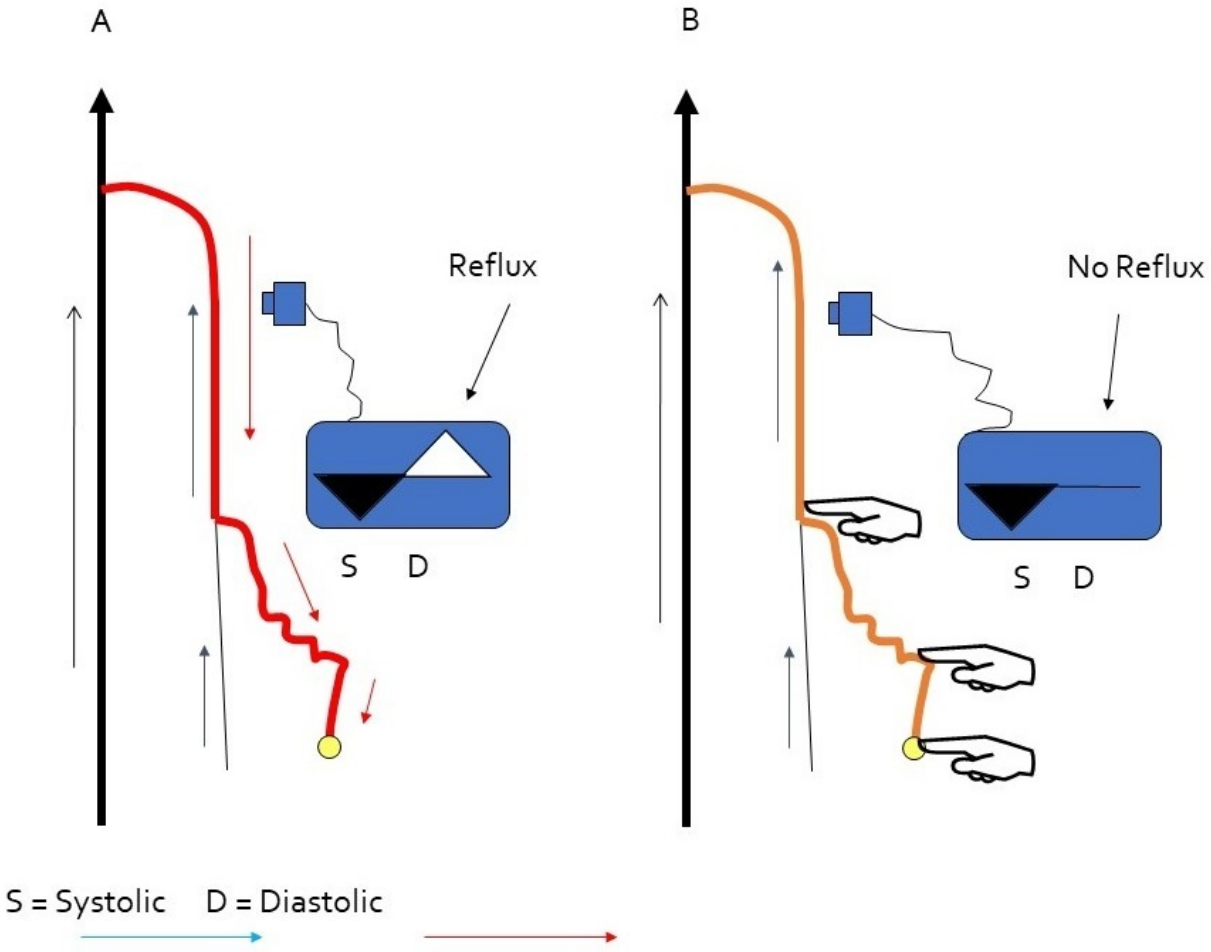


Fig 1: (re-drawn from : Zamboni P e coll :Eur J Vasc Endovasc Surg 2001;21:361–369). A) GSV reflux with re-entry perforator centred on a varicose tributary. B) Finger occlusion on the tributary (any level) eliminates the reflux: positive RET.

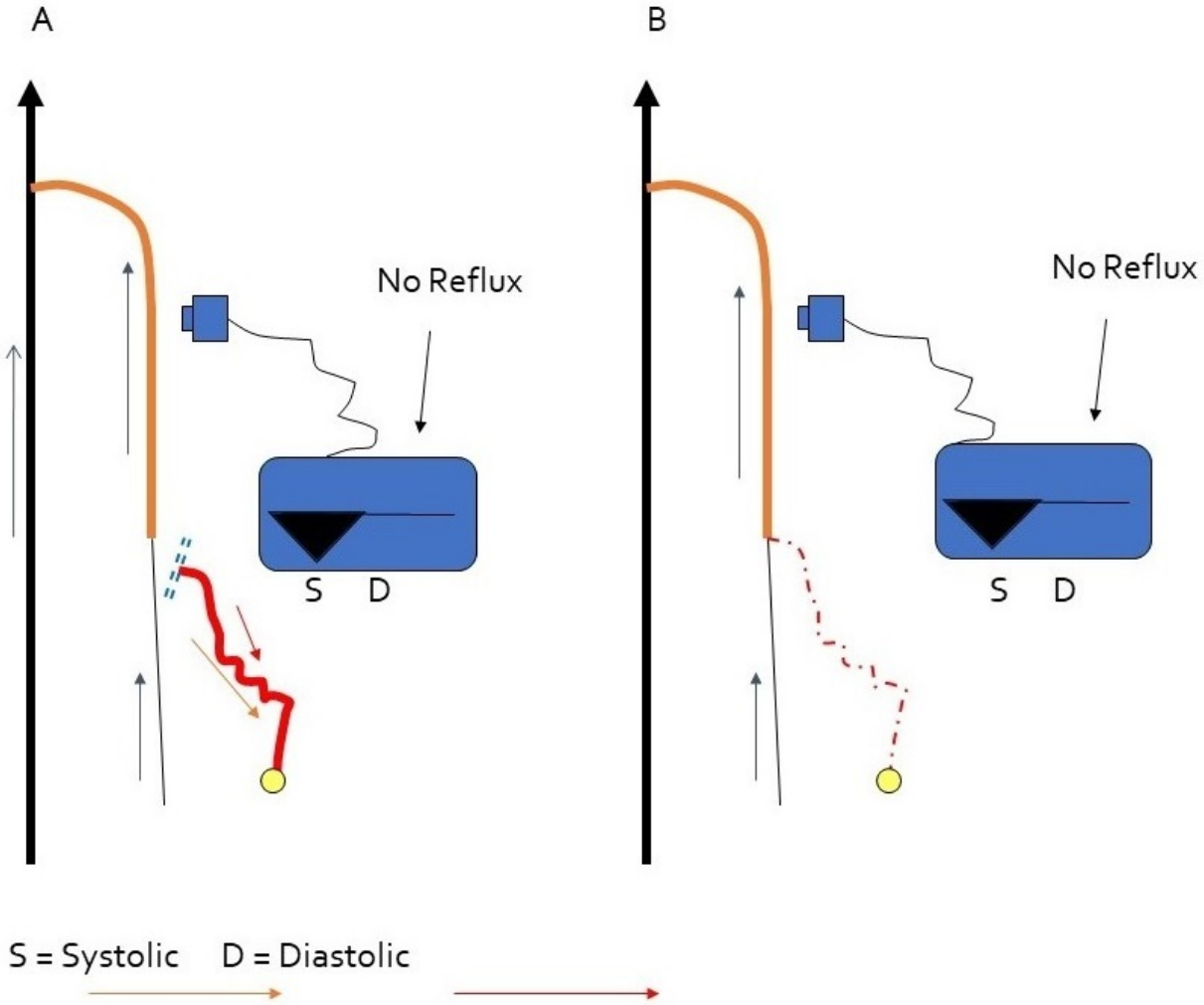


Fig 2: Reflux elimination after tributary exclusion by dis-connection (A) or phlebectomy (B).

This procedure has been considered the gold standard treatment in the last 70 years and probably it is still the most practiced method all over the world. Saphenous thermal (Laser, RF, steam) or chemical (sclerotherapy, glue) ablation would eliminate **a part (saphenous stem) of the pathway**, leaving the possible escape point untreated. Varicose veins (e.g., varicose tributaries) may be eliminated by sclerotherapy, hook phlebectomy (HP), or by laser/radiofrequency. These methods exclude **the visible pathway** of the refluxing system (the veins over the superficial fascia) anyway stopping the reflux (with exceptions). Thigh and leg **perforators** (the latter usually acting like re-entry points) are rarely treated as first choice in primary varicose veins, though any treatment on the varicose network indirectly interferes with the perforator morphology/hemodynamics. Their closure however can interrupt the shunt.

Compression bandages for ulcer treatment or more generally for CVI benefit, when effective, exclude the superficial veins network of the leg interrupting the shunt below the knee by occluding the dilated veins.

A superficial thrombophlebitis, when occluding the lumen of a refluxing GSV, stops the reflux paradoxically ameliorating the CVI (at least till the possible recanalization).

The Reflux Elimination Test

In 2001 Zamboni, et al. first named the Reflux Elimination Test (RET)[8] in a study concerning the CHIVA (Conservative Hemodynamic Insufficiency of Venuses in Ambulatory treatment)[1] method of varices correction, in a particular group of selected patients (40 cases). Inclusion needed both the presence of a GSV reflux due to SFJ incompetence, and one or more re-entry perforators located on tributary veins (Fig 1 A); excluded were the cases showing perforators centred on the GSV stem: After identification of perforators, they tested the modification

of the reflux signal on the saphenous vein after finger compression of the tributary above the opening of the perforator. When such a manoeuvre of exclusion of the perforating vein abolished and/or reduced the reflux signal in GSV such a perforator was considered as the "terminal" one, i.e., the one through which the reflux re-entered the deep system (Fig 1 B). In analogy, tributary exclusion done right at the point where it joins the GSV would eliminate the reflux in the GSV stem.(Fig 2 A,B) In fact, after 1 month follow up at ultrasound examination all cases showed centripetal flow at muscular contraction but no reflux at relaxation. At 6 months control only 6 cases showed reflux in GSV, due to formation of a new re-entry perforator on the GSV stem. Interestingly, the absence of saphenous reflux is not due to valves competence but to the absence of the pressure gradient between the GSV and the re-entry perforator or simply the absence of a path between the two points. According to Franceschi and Zamboni[1] 60% of reflux cases enter in this category.

Negative RET (30 % of cases)[1] is related to the persistence of reflux in the GSV after finger compression on tributary(ies), meaning that re-entry perforator(s) is/are centred on the saphenous stem. (Fig 3 A) In these cases the tributary elimination will not obtain the reflux cessation. (Fig 3 B)

Current strategies consists either on GSV treatment (surgical, thermal, or chemical) and phlebectomies in a single procedure[9] or GSV treatment only, awaiting diminishing of tributaries' caliber [10-14].

Starting from the empirical observations (Muller phlebectomies[15], Fegan sclerotherapy[16], Creton surgery[17]) that varices elimination may influence GSV hemodynamic behaviour, attention has been addressed to a treatment more concerned to periphery of the varicose disease with the purpose of sparing GSV partly under the influence of the so called "ascending theory" of varicose veins (''wall weakening'' is the initiating factor of primary reflux following a upward directed pattern)[18], in opposition to the classic descending pathophysiologic concept, (superficial venous insufficiency starts with valvular incompetence at an escape point and progresses downward from the main trunk to the tributaries).

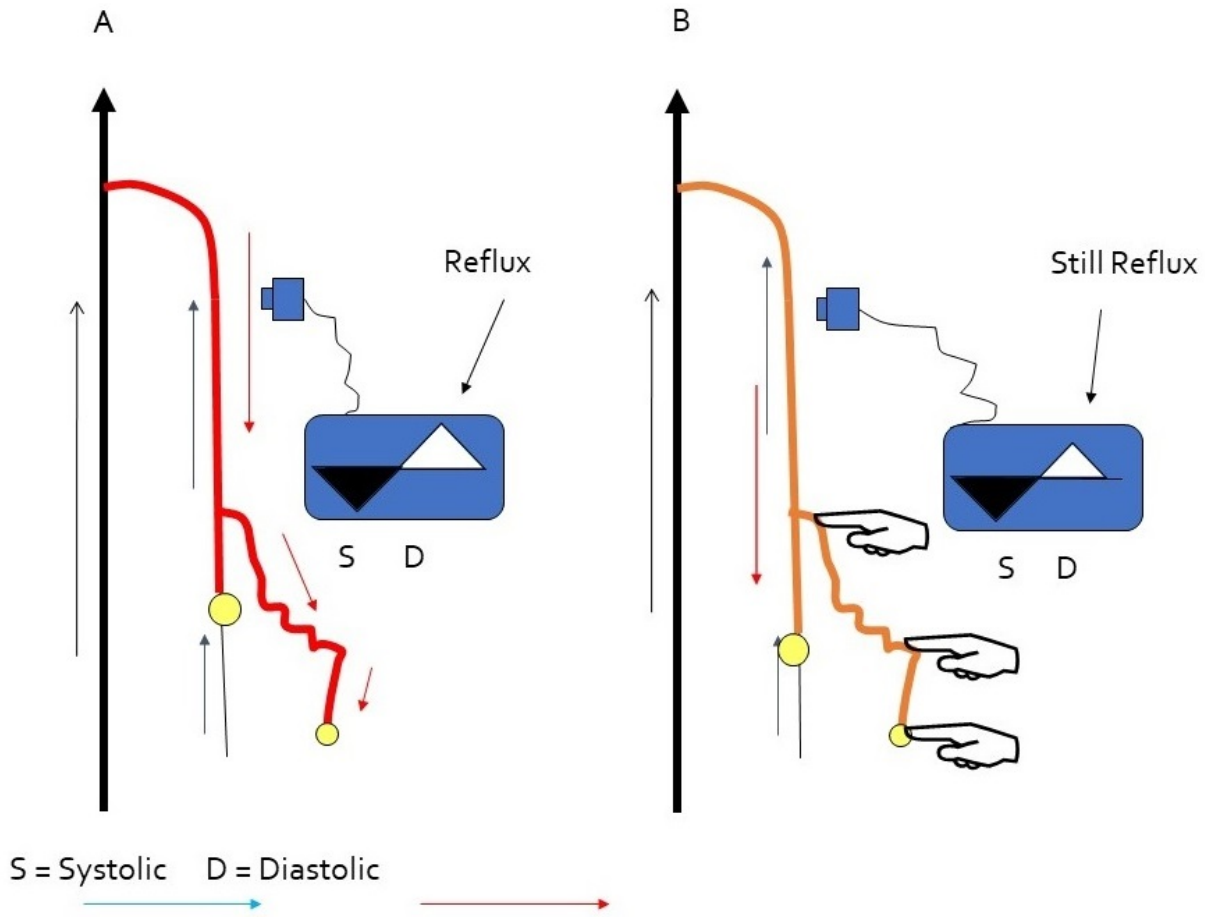


Fig 3: reflux in GSV with re entry perforator centred on the GSV stem and on tributary (A); compression of tributary does not exclude reflux in GSV: Negative Ret.

Several papers have been devoted to study if simple phlebectomy could satisfy varicose veins treatment, compared to the standard treatments[19-26]. GSV reflux cessation after phlebectomy has been described in 50 [19], 66 [20], 69.9 [21] % of the cases at 1 year, 85% at three years[21], 66.3% at 4 years[22], 64.4 % at ten years[23], although data concerned selected populations (i.e. C2 cases, thigh tributaries, GSV smaller diameter and short reflux length, younger, competent SFJ). Constant decrease in GSV calibre has been typically and constantly observed[24].

The RET showed a strongly significant positive correlation with GSV reflux free, the chance of treatment success being >65%[19], independently from C class of CEAP classification, extent of reflux, diameter of GSV, or tributary. According to Pittaluga, the positive predictive value of the test for the abolition of reflux of the GSV was 95.7% and 94.7% at 1 and 2 years[25]. Interestingly in contrast, Escribano[26] assessed reflux in the GSV system in 53 (91%) of 58 operated limbs originally with a positive RET, recurring in the great majority of limbs (88%) quite early (within 6 months). This discrepancy has been explained by different criteria for defining the terminal perforator[27].

Furthermore, a positive RET test associated to a competent SFJ gave 85% of positive result on GSV compared to 18 % when the junction was incompetent[21].

RET is frequently cited in specific papers; however, a real analysis of this correlation was rarely assessed[19,21,25], with only in one instance obtaining the true significance of the finding[8] based on CHIVA philosophy. Passariello proposed an interesting particular CHIVA flow chart based on RET[28].

In summary, if the test is positive (re-entry on tributary), tributary ablation makes disappear the GSV reflux, while if negative (re-entry on saphenous), the reflux will remain. The duration of no- reflux state is related to the formation of a new re-entry perforator either through a new tributary or directly on the GSV stem. The new tributary may be eliminated again, while if the GSV finds a new perforator allowing re-entering the reflux, the SFJ may be successfully interrupted (achieving a draining system = 2° stage of CHIVA 2 strategy[1]) or the GSV eliminated[29], thus giving up conservative therapy.

"Tributary First" VV treatments

Ambulatory phlebectomy (AP) was conceived and introduced[15] in the sixties of last century, when full GSV avulsion tendency was still at its maximum; its efficacy was easily perceived by Muller's followers although initially opposed by establishment; it was counter intuitive compared to surgical rule because GSV treatment was not the centre of the solution: it was avulsed only when clearly "perceived" by clinical examination ("Muller positive" according to the Author's anecdotical definition) mostly spared even if (doppler) incompetent. The diffusion of Duplex facilities at the turn of the century revealed why AP had so good results: patients with (hypothetic) positive RET were mostly cured, those with (hypothetic) negative RET could have local recurrences and could need GSV treatment. This same strategy was called ASVAL (Ablation Sélective des Varices en Anesthésie Locale) by the French Author Pittaluga[30].

In 1988 C Franceschi expounded the theory called CHIVA – Cure Conservative Hemodynamique de l' Insuffisance Veineuse en Ambulatoire[31] – devoted to the conservation of the venous capital, especially of the saphenous vein, based on the modulation of venous drainage through targeted ligatures of the reflux leaking points and based on an accurate ultrasound study of the re-entry points. CHIVA deals with tributary disconnection and RET just when the saphenous junction reflux is deviated into an incompetent tributary, i.e., realizing what in venous hemodynamic is called a Shunt III. Tributaries being dis-connected from the GSV stem (and in part avulsed by many) behave like a phlebectomy effect, and when a RET is positive (shunt III), no other procedure is needed initially[32]. When RET is negative (shunt I), tributary de connection is accompanied by a Junction crossotomy. It is interesting to remember that RET concept has been described in 2001 by Zamboni[8], a CHIVA follower and that the true explanation of its meaning is due to this Author.

For the sake of history, in 1967 G Fegan (one of the "Fathers" of sclerotherapy) described a sort of proto- RET test by finger placement over the superficial fascia orifices: *As Many of the likely sites of retrograde filling as possible are compressed with the tip of doctor's fingers and the patient then stands up. With the compression maintained, the limb is watched for filling of superficial vein. If this occurs, the test is repeated with pressure placed on different sites. Once filling of the superficial vein is controlled by the pressure of fingertips on a few sites, the fingers are removed one by one. When a finger is withdrawn from an orifice which is transmitting a perforating vein, the superficial vein slowly fills*. Without ultrasound assistance Fegan looked for varicose feeding point, starting the sclerotherapy from the most distal leaks. *Even large saphena varices often disappear within a few weeks of treatment of perforating veins in the calf*[16].

The "Virtual Phlebectomy": the CREED system

If a finger placement on the leg skin like in RET is able to mimic the result of a phlebectomy, the positioning of a tourniquet, producing a similar compression, could be let in place for a variable time obtaining the same result: the elimination (reduction) of the refluent volume and the consequent reduction of the saphenous calibre.

An elastic stocking compression can partly achieve a similar result, but is rarely accepted by patients, especially in the hot season, it does not achieve sufficient pressure at the required point and it has a relatively high cost.

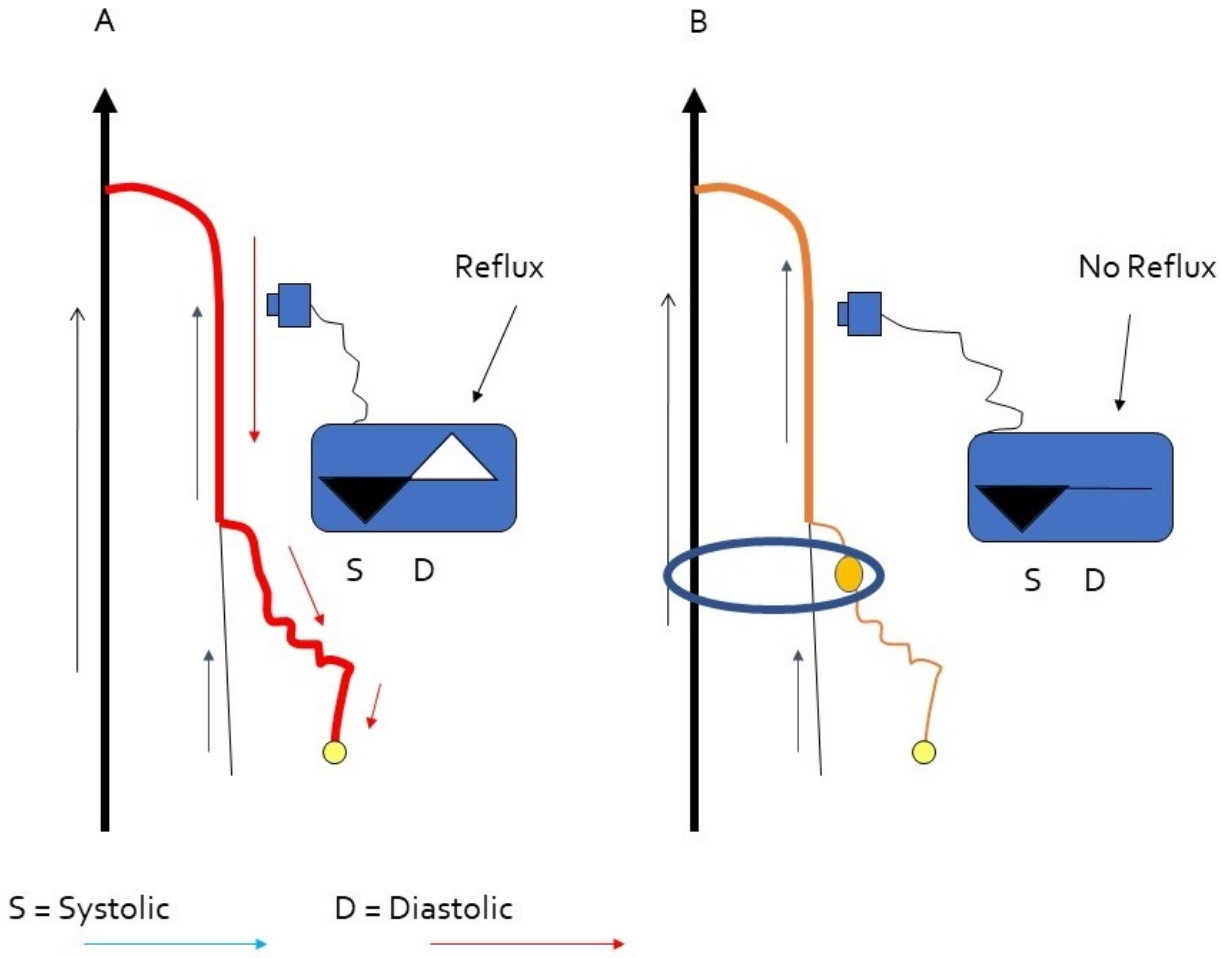


Fig 4: When a varicose tributary is related to a perforator (A), a tourniquet with a thickness (CREED) to precisely close the vein (B) would have the same hemodynamic effect of a phlebectomy (virtual phlebectomy).

A limited compression done at the site of the passage of reflux from the saphenous to the collateral with a stable tape (CREED: Conservative REflux Elimination Device- Fig 4), will be better accepted by the patient. It is in fact effective in closing the dilated vein, it is not very visible (Fig 5) especially if a skin-coloured "taping" is used, nor very aggressive especially in summer; easily manageable by the patient once the principle has been explained, inexpensive, highly appropriate if surgery should be delayed (i.e.: hot weather, waiting list, inflammation, infection).

Such a solution would be optimal for C2 cases. In presence of oedema (C3), however, nothing prevents from using this selective compression under a stocking, perhaps lighter than that otherwise required. Even C4-6 cases would still benefit from the method, as long as they are associated with traditional compression.

CREED Compression tools and application

Taping is commonly used in sports medicine/ rehabilitation as an external reinforcement to the muscle-tendon action of a specific muscle group that needs support. In any sporting event it is common to see athletes with coloured patches on joints or muscle groups; these remain stable during the activity even in water or after shower: they are made of inelastic synthetic material with hypoallergenic acrylic glue. The one suggested here is flesh-coloured, 2.5 cm wide (Cure Tape®). The tape must be applied to site needing compression in two or three layers with limited traction avoiding any obstruction effect on superficial circulation; subsequently in the specific point of compression (identified by US) a thickness is inserted (compressed cotton, latex, neoprene) which will exert, only at that point, a stronger effective compression verified by ultrasound. This thickness can be removed at night when the hydrostatic pressure has no effect on the venous system.

The tape can be placed in any site of the limb, wherever the varicose tributary merge; it is not strictly necessary that the tributary is compressed exactly at the point of separation from the GSV stem; even some distance may be taken in account if the site fits better to the CREED system; the best place is under the knee (fig 5), where a bony substrate (tibia) is present, and by the way most of the varices are present. Furthermore, it is considered a strategic site conditioning the dividing line of the ambulatory pressure gradient from below the knee into the thigh[33].

The taping is not reusable but can be maintained for several days without being removed. Its repositioning requires adequate learning on the part of the patient, although easily acquired. A mobile Velcro tape could be used instead, after exact calibration. (Fig 5, left leg)

An adapted sub patellar support commercially available may also be employed (fig 5 right). It is easy to replace once the correct measure has been fixed, limited by that it can be placed only below the knee. Adaptation consists of placing or arranging the compression element on the vascular compression site and not on the patellar tendons.

As a curiosity, in 1894 a "Bandage for varicose veins" has been patented, aimed "to reduce the enlargement of the vein, without interfering with the circulation of the blood" (Fig 6 a). It didn't gain popularity, but stimulated further patent subscription more than 100 years later in 2007 (Starkey et al. *Method and device for treatment of varicose veins* – Patent N. US 7,297,094 B2), with a kind of valvular solution intended allowing centripetal flow while stopping reflux, however not having any practical success at all. CREED is similar (although much simpler), but based on different hemodynamic mechanisms, (not simply compressing the saphenous stem, but trying to select the tributary involved in RET).

Indications for CREED

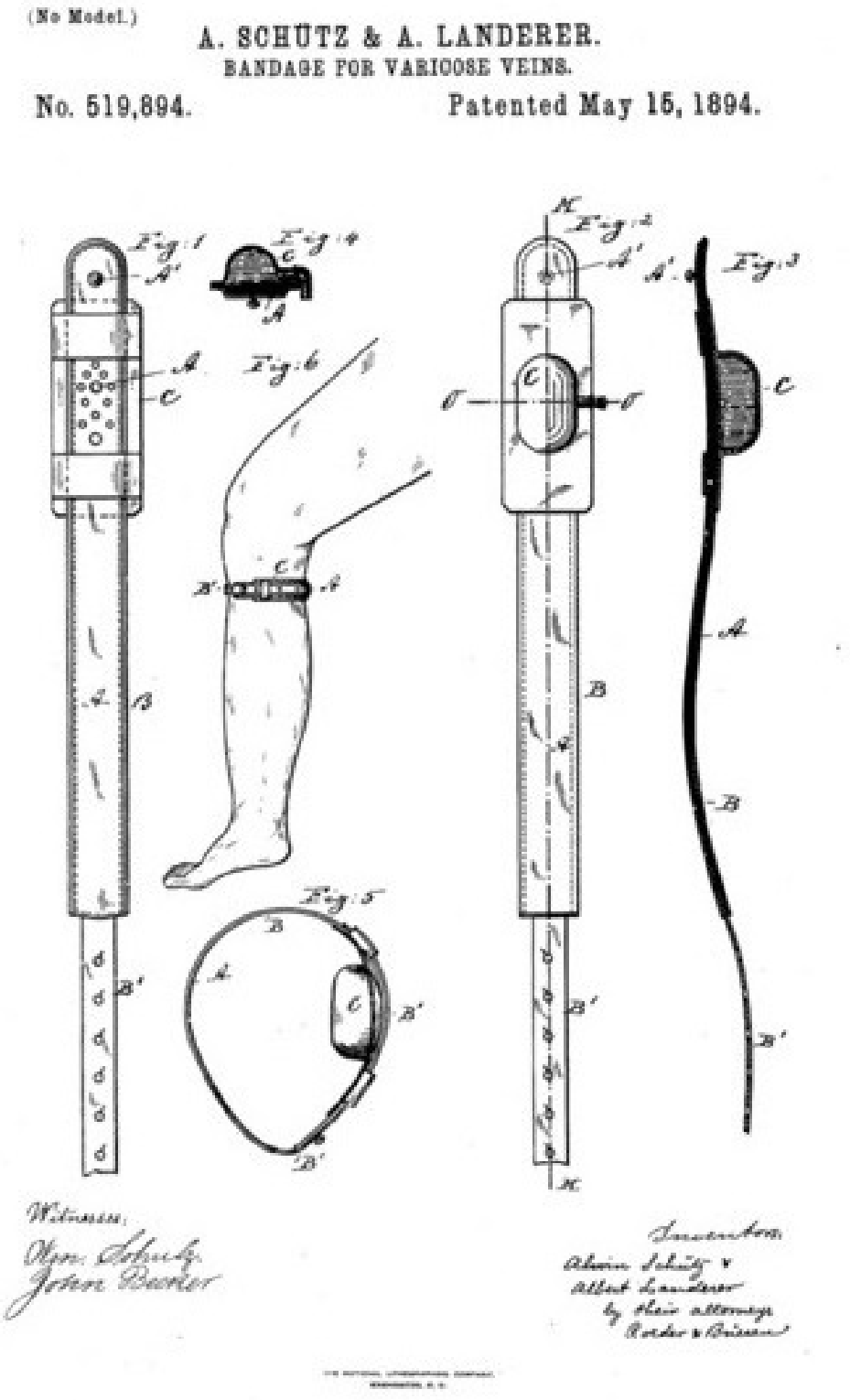
This Compression REflux Elimination Device (CREED) may be employed every time the VV correction procedure is not feasible (old age, comorbidities, acute disease, fear, refusal, logistics deficiency) or must be delayed (hot weather, waiting list, inflammation, infection).

In addition, in:

- Patients with trophic ulcer with saphenous incompetence

During ulcer treatment with multilayer bandage, discontinuation of saphenous reflux below the knee by selective suspended compression could be a hemodynamic advantage. The presence of an adhesive taping below the knee would also have the function of anchoring the bandage avoiding its (frequent) sliding downwards[34].

Fig. 5: Three operational proposals: one with a pink physiotherapy/sport's "tape" (not reusable) (right leg), one with Velcro webbing (reusable) (left leg) and one using an adapted sub patellar support (right).


(No Model.)

A. SCHÜTZ & A. LANDERER.

BANDAGE FOR VARICOSE VEINS.

No. 519,894. Patented May 15, 1894.

Fig 6: Bandage for varicose veins: 1894 patent: " The spring A supports the hollow sliding pad C adapted to be filled with air or water and which will bear upon the vein when the spring is secured in place". SPECIFICATION forming part of Letters Patent No. 519,894, dated May 15, 1894, USA. Application filed January 2, 1894. Serial No. 495,302- (No model). Already patented in Germany April 19, 1890, No. 56,336.

- Patients with indication for CHIVA 2 (two-stage intervention in shunt III carriers)[1,31,32]

In CHIVA strategy, shunt III (saphenous reflux with re-entry into perforator not located along the saphenous axis- fig 1 a) patients are submitted to a two staged procedure (CHIVA 2) for avoiding GSV thrombosis: 1° disconnection of the tributary from the saphenous axis; 2° SFJ crossotomy, when a new perforator develops on the GSV stem[28]. This event is not time foreseeable, so that 2° stage may be delayed for months/years. CREED could substitute the first stage favoring the perforator development and directly allowing the second stage

- Large-caliber incontinent perforator

The direct compression of the perforator site[35], highlighted by the glaring gap appreciable with digital palpation, can be useful to conservatively eliminate the negative effect of valve insufficiency. At Doppler, in fact, the reflux distally disappears at the treated point. Insufficient perforators generally have a circumscribed indurative infiltration that disappears with this treatment providing the indication for surgical interruption of the perforator.

- Directly over the GSV stem instead over tributary

The reflux is stopped (or reduced) in the trunk, together with the centripetal flow, producing a "Perthes Test" situation, i.e., the same haemodynamic effect of a GSV interventional interruption.

Clinical evaluation

CREED is a theoretical hypothesis that was tried just in a few patients.

Further trials will be needed to confirm its effectiveness, better if by different observers, this paper acting as a Project proposal.

Conclusions

In varicose veins patients, when RET is positive (more than 60% of the cases) the exclusion of the involved tributary/ies makes the GSV reflux disappear. This exclusion may be done by surgery (phlebectomy, dis-connection), sclerotherapy, thermal ablation. When treatment cannot be done (old age, comorbidity, acute disease, logistics deficiency, fear) or needs to be delayed (hot weather, ulcer presence, inflammation, skin infection, contemporary treatments), simple positioning of a tape in strategic site (that was called CREED - Conservative REflux Elimination Device) could be applied with positive haemodynamic effect similar to active tributary elimination. In selected cases CREED could be employed directly over the refluxing GSV, in this case with a different haemodynamic effect (direct occlusion).

This conservative solution, inspired by the CHIVA theory, is obviously temporary (with rare exceptions) and has no intention to substitute a final treatment, but has the advantage to be easy to apply, costless, repeatable, non-invasive. Its effectiveness, empirically observed, must be confirmed by clinical trials.

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