

Comparison of Four Haemodynamic Tests that Quantify Superficial Venous Insufficiency[☆]

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WHAT THIS PAPER ADDS

Currently, investigations on patients with superficial venous insufficiency are limited invariably to assessing the presence and sites of reflux. This approach is satisfactory for most patients and directs the location of treatment. However, symptoms and signs do not always improve, may not be related to clinical severity, and recurrence is common. For this reason and as in most other chronic diseases, it may be advantageous to have an objective reference standard to quantify the drainage insufficiency and then to measure its response to treatment and follow up. This study investigates four such measurement parameters and their relationships with each other.

Objectives: Reflux assessment with ultrasound (U/S) is usually qualitative. Quantitative measurements of superficial venous insufficiency (SVI) include the venous arterial flow index (VAFI), recirculation index (RCI), venous filling index (VFI), and the postural diameter change (PDC) of the saphenous trunk. The aim was to investigate their relationship.

Materials and methods: This was an observational study performed on patients with varicose veins and hospital employees. Four haemodynamic parameters were measured in 21 legs from 16 subjects. Legs were divided into no reflux ($n = 7$) and reflux ($n = 14$). The VAFI is the U/S ratio of common femoral vein volume flow divided by the common femoral artery volume flow, performed supine. The RCI is the U/S ratio of reflux volume over antegrade volume within the saphenous trunk after calf compression, standing. The VFI is the rate of calf volume increase on dependency measured in mL/s, using air plethysmography. The PDC is the percentage reduction of the saphenous trunk diameter from standing to lying, using U/S.

Results: The clinical part of the CEAP classification was: $C_0 = 3$, $C_1 = 4$, $C_2 = 5$, $C_3 = 1$, $C_{4a} = 1$, $C_{4b} = 6$, $C_5 = 1$. All four tests demonstrated significant differences between the two groups with minimal overlap (Mann Whitney U test): VAFI ($p = .028$), RCI ($p < .0005$), VFI ($p = .001$), and PDC ($p = .014$). Furthermore, significant correlations were observed with the tests: VAFI vs. RCI ($r = .532$, $p = .015$), VFI ($r = .489$, $p = .025$) and PDC ($r = -.474$, $p = .030$); RCI vs. VFI ($r = .446$, $p = .043$) and PDC ($r = -.527$, $p = .014$).

Conclusions: Superficial venous drainage insufficiency should not be confined to an U/S assessment of the presence of reflux, which is qualitative. Quantitative data may be provided using the VAFI, RCI, VFI, and PDC. Understanding why there are significant correlations among these parameters and the preferred objective reference test requires further work.

Keywords: Superficial venous insufficiency, Venous arterial flow index, Psathakis index, Recirculation index, Venous filling index, Postural diameter change

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INTRODUCTION

Ever since the phenomenon of reflux was discovered, the term superficial venous insufficiency (SVI) has become synonymous with valve reflux.^{1–4} However, the pathophysiology of SVI is more than just valve failure. The haemodynamic function of veins is drainage and other causes of drainage insufficiency include inefficiencies from a “private” circulation,⁵ rapid calf expansion on dependency, poor gravitational venous wall responsiveness, and positional

causes such as prolonged standing and sitting. Most of these can be estimated with a numerical value. This is in contrast to reflux measurements, which cannot be quantified reliably.⁶ With ultrasound, reflux quantification is an operator and manoeuvre dependent variable. However, the cut off value of >0.5 s does not necessarily depend upon these factors. This may be why its use in everyday practice is binary and limited only to establish the presence or absence of reflux.⁷ For this reason it may be advantageous to explore other parameters that quantify the degree of insufficiency.

The aim of this study was to evaluate four measurement methods in an attempt to quantify SVI and determine their relationships with each other.

MATERIALS AND METHODS

Study design

This was an observational study performed in the Phlebology Outpatient Clinic, Department of Dermatology, University Of Schleswig Holstein, Campus Lübeck, Germany, during January 2017. The haemodynamic parameters were compared concurrently in 21 legs from 16 volunteers. Legs were stratified into no reflux ($n = 7$) and reflux ($n = 14$). Patients and healthy volunteers had the four investigations explained to them and signed a consent form. All patients with primary great saphenous vein (GSV) reflux were considered, irrespective of symptoms. Exclusion criteria included evidence of a past deep vein thrombosis or deep venous reflux, past venous intervention or venous ulceration, clinical peripheral arterial disease, significant immobility, or morbid obesity.

The order of the study tests was as follows. Initially, patients were examined standing by ultrasound to identify GSV reflux. A point was marked 10 cm below the inguinal ligament and the antero-posterior diameter of the inner wall of the GSV was measured with ultrasound (Logiq P6, GE Healthcare GmbH, 42655 Solingen, Germany) using a 9L linear transducer (4–10 MHz). This point was also used for the recirculation index (RCI) and the postural diameter

change (PDC). A manual calf compression and release manoeuvre was performed with the probe over the GSV in pulsed wave (PW) mode. The provoked antegrade flow and resulting retrograde flow was displayed on the monitor where the calculations of the RCI were completed. Next, the subject was requested to lie on the examination couch supine where the GSV diameter was measured to complete the PDC assessment. While resting supine, the venous arterial flow index (VAFI) was performed with the probe over each of the common femoral vessels in turn while the leg was abducted slightly and externally rotated. Finally, the calibration for the air plethysmography (APG-1000, ACI Medical LLC, San Marcos, CA, USA) was performed supine and this was followed by a leg elevation and dependency test to provide the venous filling index (VFI).

VAFI

This is the ratio of venous volume flow (mL/min) out of the leg divided by the arterial volume flow into the leg. It is measured in PW mode with the ultrasound probe over the femoral vessels just below the inguinal ligament with the patient resting supine. The volume flow (VF) is calculated by time averaged mean velocity (TAMV) \times vessel cross sectional area (A), as shown in Fig. 1. Intuitively, the value should be 1 in steady state conditions. Otherwise the leg volume will increase or decrease progressively. In reality, the VAFI is 1 ± 0.12 in healthy legs and 1.36 ± 0.21 in C_2 patients with SVI.⁸ The explanation for the increase in VAFI in SVI is debatable,⁹ but a factor may be that additional recirculating venous flow is also being measured.

RCI

The recirculation index is the ratio of retrograde saphenous volume (mL) divided by antegrade saphenous volume using ultrasound with a calf compression and release manoeuvre.¹⁰ The RCI is measured in PW mode with the ultrasound probe over the saphenous trunk in the upper thigh with the patient standing. Most of the patient's body

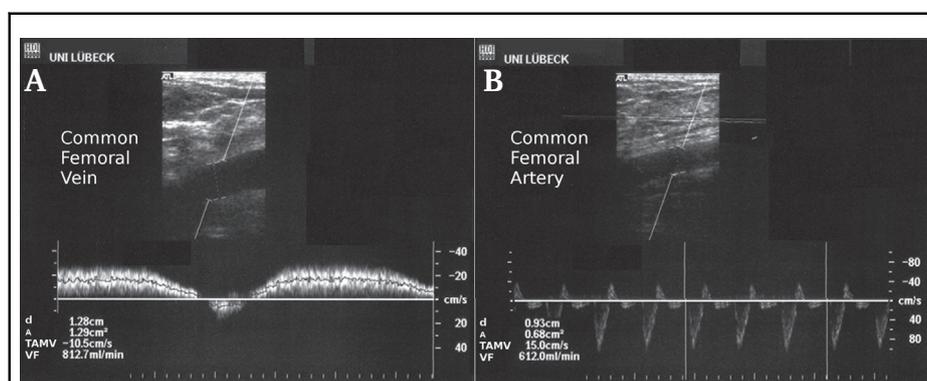


Figure 1. Venous arterial flow index (VAFI). The VAFI is calculated by venous volume flow (A) divided by arterial volume flow (B). The diameter of the vessel (d) is set by the operator and the machine calculates the area (A), time averaged mean velocity (TAMV) and then the volume flow (VF). In this example the VAFI is $812.7/612 = 1.33$.

weight is on the contralateral leg. A manual calf compression and release manoeuvre was used in the current study to induce reflux. Volume is calculated using volume flow (mL/s) \times flow duration (s). As the GSV diameter was assumed to be the same in antegrade flow and reflux, diameter was not required in the calculation of the RCI. This is because the RCI is a ratio and the diameter measurement and subsequent area calculations cancel out. The RCI is an attempt to quantify reflux by standardising the amount of reflux against the antegrade flow provocation, thereby making reflux assessments less operator dependent (Fig. 2). A significant correlation has been demonstrated earlier between the antegrade volume and the resulting reflux volume: $r = 0.76$ using manual compression, $r = .84$ using cyclical calf compression with a pump.¹⁰ A RCI >1 defines saphenous recirculation.

VFI

This is the rate of gravitational calf expansion in mL/s on dependency, measured by air plethysmography (APG) (Fig. 3). Following calibration in the supine position, the leg is drained by elevation. The measurement starts when the subject stands, bearing weight on the contralateral leg, while the test leg fills. The technique was described in detail by Allan in 1964 who standardised the manoeuvre using a tilt table.¹¹ Over half a century later, venous filling time has been validated as a measure of reflux duration in SVI patients using simultaneous recordings with ultrasound and APG.¹² The significant correlation observed in that study was very strong ($r = 0.93$). In health the VFI should be less than 2.4 mL/s.

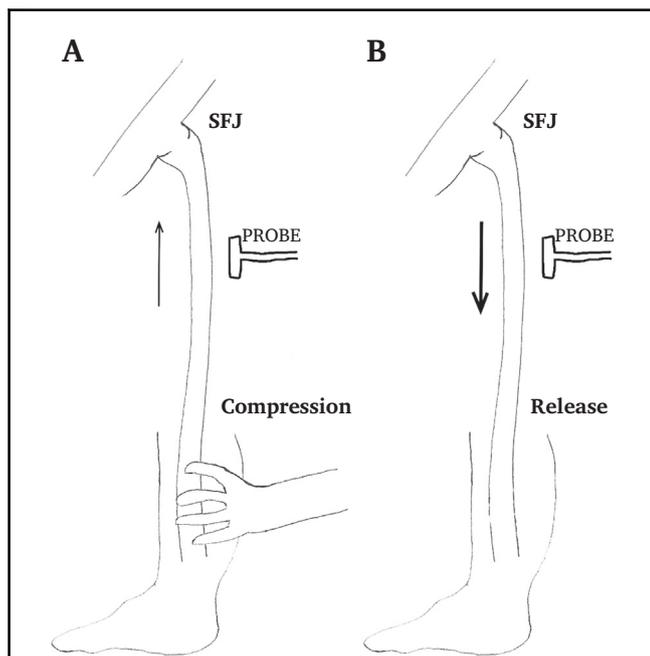


Figure 2. Recirculation index (RCI). On calf compression there is antegrade flow up the saphenous trunk (A). On relaxation there is more reflux flow down (B). The RCI is reflux volume/antegrade volume. SFJ = sapheno-femoral junction.

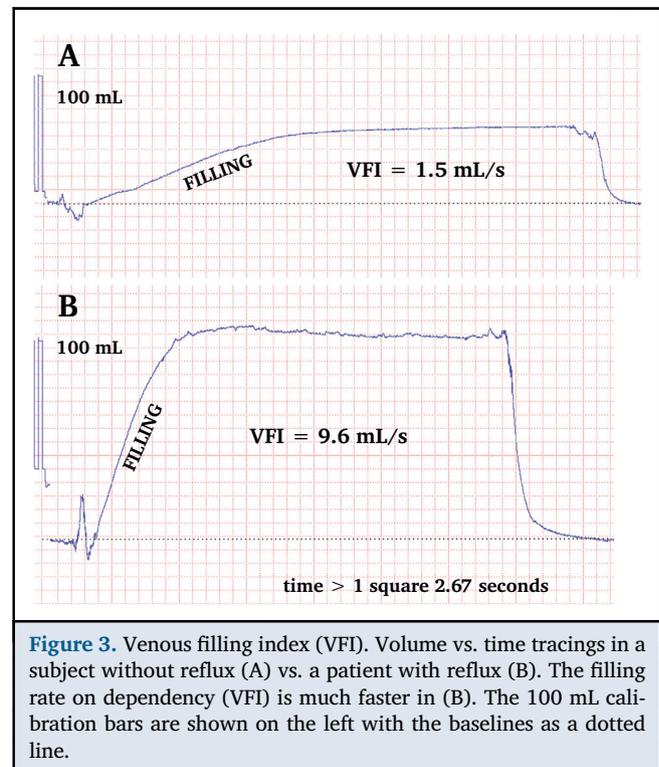


Figure 3. Venous filling index (VFI). Volume vs. time tracings in a subject without reflux (A) vs. a patient with reflux (B). The filling rate on dependency (VFI) is much faster in (B). The 100 mL calibration bars are shown on the left with the baselines as a dotted line.

PDC

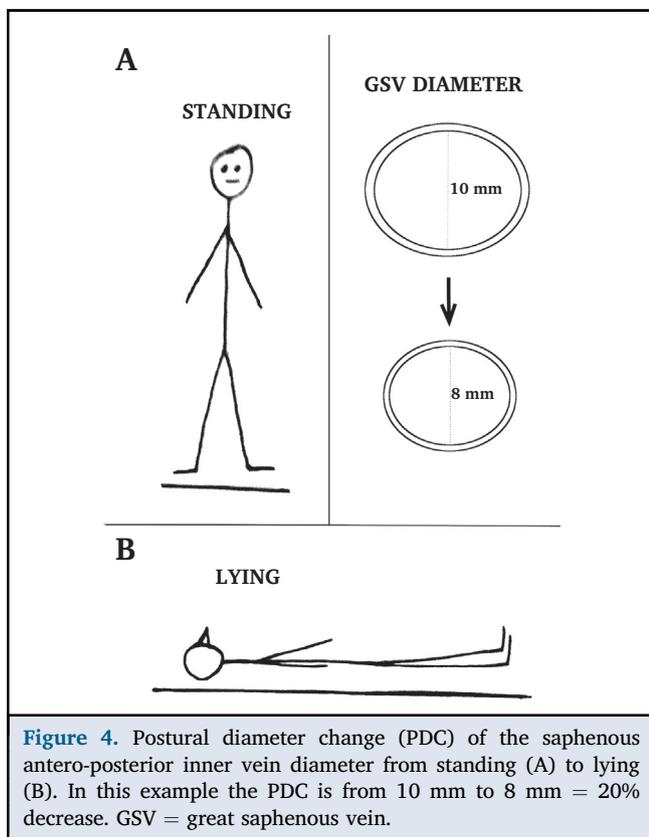
This is the percentage reduction of the inner diameter of a named saphenous trunk from standing to lying (Fig. 4). It is measured with the ultrasound probe over the same saphenous point as the RCI. The median PDC has been shown to be significantly lower in C₄₋₆ limbs than in C₂₋₃ or C₀₋₁ at 16%, 21%, and 23%, respectively ($p = .016$).¹³ The explanation may be a decrease in the elastic properties of the venous wall in diseased refluxing veins. Elevated venous pressure in superficial veins while supine may also hamper their responsiveness to collapse. A PDC $>22\%$ was used to define a healthy responsive vein.

Statistical analysis

The data were entered onto spreadsheets and analysed with the IBM SPSS statistics package version 24 (IBM Corporation, USA). Non-parametric statistics were used with median, interquartile range [IQR] and range to define the datasets. Box plots were used to illustrate the differences between refluxing and non-refluxing legs with the Mann Whitney *U* test to determine statistical significance. Scatter plots were used to display the individual data points and the correlations. The correlations between each of the four haemodynamic parameters were performed using the Spearman rho test. A $p < .05$ defined statistical significance.

Ethical approval for research

The University of Lübeck ethics commission, Ratzeburger Allee 160, Building 21, 23562 Lübeck, Germany, approved the study (Ethics number: 16–340).



RESULTS

General

The median [interquartile range] age, BMI, and venous clinical severity score (VCSS) were 52 [37–69], 25.7 [24.5–30.9], and 4 [1–6], respectively. There were 13 right legs

and 11 male legs. The clinical part of the CEAP classification was $C_0 = 3$ and $C_1 = 4$ in the healthy volunteers ($n = 7$ legs). In the patients ($n = 14$ legs) it was $C_2 = 5$, $C_3 = 1$, $C_{4a} = 1$, $C_{4b} = 6$, and $C_5 = 1$. All participants completed the required tests during the same session.

The haemodynamic data of the participants' legs are shown in Table 1 where they have been stratified into no reflux vs. GSV trunk reflux.

Differences

There were significant differences between the no reflux and the reflux group on nearly all the measurements despite the small numbers in this study (Table 1). Also, there were significant differences between the two groups with all four tests. This is seen graphically in Fig. 5 with the numerical data in Table 1. The box plots demonstrate discriminative values ranging from no overlap with the RCI, minimal overlap with the VFI and VAFI, and mild overlap of the interquartile ranges with the PDC.

Correlations

Significant but moderate correlations were observed when all four tests were correlated with each other (Fig. 6). In addition, a positive relationship with increasing haemodynamic severity was noted, irrespective of the test used. The highest correlation was between the VAFI and the RCI (Fig. 6A). This may imply that both VAFI and RCI are in some way related in the assessment of recirculation.

DISCUSSION

Each of the four tests for SVI has been evaluated in relationship to clinical features, and each merited an individual

Table 1. Haemodynamic characteristics of the two study groups with the four study parameters in bold face.

	No reflux ($n = 7$)	Reflux ^a ($n = 14$)	<i>p</i> value ^b
Common femoral vein (CFV) \emptyset , mm ^c	10.8 [8.2–11.9] 8–13.3	12.4 [10.3–14.3] 9.5–14.7	.039
Common femoral artery (CFA) \emptyset , mm ^d	9.2 [7.8–10.7] 6.9–11.4	9.2 [8.3–10.8] 7.9–12.9	.478
Venous arterial flow index (VAFI)	0.92 [0.87–1.33] 0.52–1.76	1.34 [1.21–2.13] 0.76–3.0	.028
Volume _R , mL ^e	0.07 [0.06–0.09] 0–0.3	14.34 [9.06–19.69] 4.2–101.9	<.0005
Volume _A , mL ^f	1.16 [0.6–1.9] 0.2–3.1	3.78 [2.44–4.85] 0.3–52.4	.006
Recirculation index (RCI)	0.1 [0.02–0.15] 0.02–0.35	3.47 [2.38–6.1] 1.75–15.5	<.0005
Working venous volume (wVV), mL ^g	77.4 [44.4–88.7] 42.1–116.8	111.8 [97.9–149.6] 63.8–175.8	.017
Venous filling index (VFI), mL/s	0.9 [0.7–1.5] 0.6–1.7	4.0 [2.1–7.2] 0.9–10.9	.001
Great saphenous vein (GSV) _S \emptyset , mm ^h	3.9 [3.0–4.7] 2.5–5.2	5.7 [4.7–6.3] 3.9–8.3	.004
GSV _L \emptyset , mm ⁱ	2.8 [2.5–3.1] 1.8–3.4	4.6 [4.0–5.7] 2.8–7.0	.001
Postural diameter change (PDC), %	28 [17.1–35.9] 16.7–40.4	12.2 [8.4–23.6] 5.2–28.2	.014

Data are expressed as median [interquartile range] and range. CFA: common femoral artery; CFV: common femoral vein; GSV: great saphenous vein; PDC: postural diameter change; RCI: recirculation index; VAFI: venous arterial flow index; VFI: venous filling index; wVV: working venous volume.

^a Defined as reflux duration >0.5s on release of manual calf compression.

^b Mann Whitney *U* test. Significance is illustrated in bold.

^c Diameter of CFV supine.

^d Diameter of CFA supine.

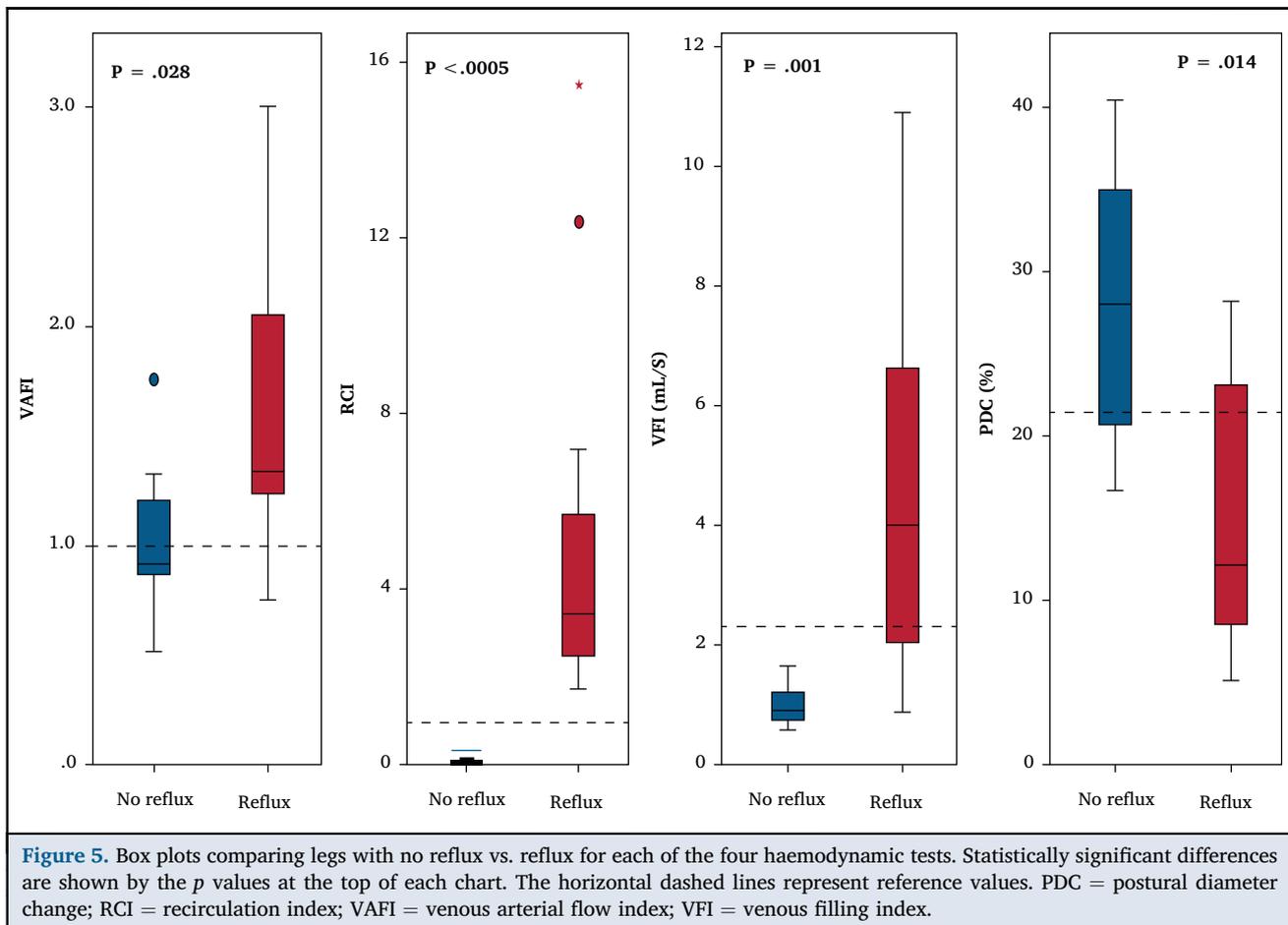
^e Volume displacements over the GSV in reflux (R) standing.

^f Volume displacements over the GSV antegrade (A) standing.

^g wVV of air plethysmography.

^h GSV diameter standing (S).

ⁱ GSV diameter lying (L).

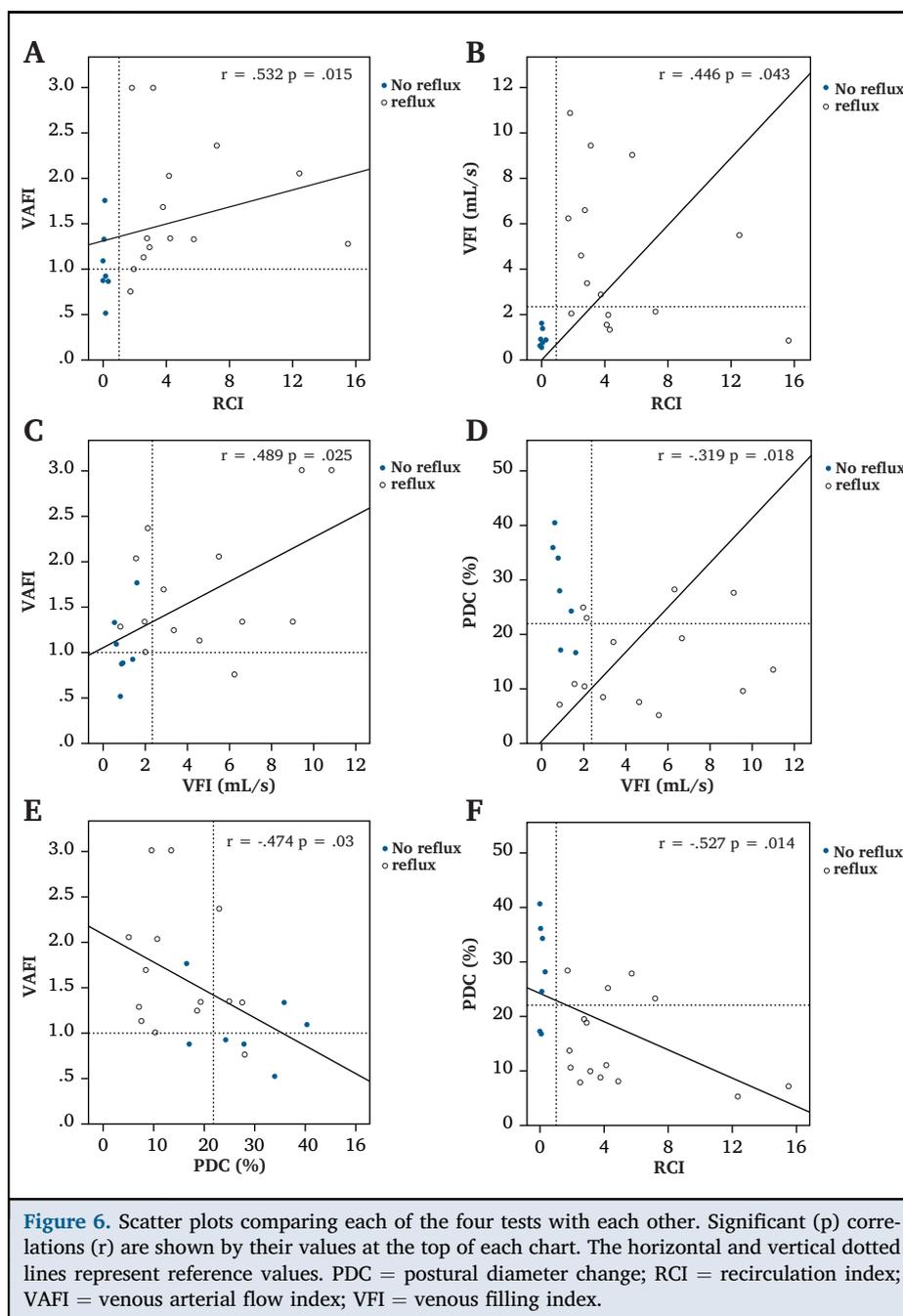


publication.^{10,13–15} However, this is the first time these tests have been performed concurrently and compared with each other from a haemodynamic standpoint. The results demonstrated that all four tests were able to identify patients with reflux from volunteers with good discriminative ability. Furthermore, there were statistically significant correlations in every test when they were compared with each other. This indicates that all four tests appear to be measuring venous insufficiency at a similar level of severity. This is in contrast to the relationship between clinical symptoms and signs when there is often an inverse association. For example, every phlebologist is aware that pain and the extent of varicose veins may not be a feature of late disease with skin changes. Furthermore, venous leg ulcers may not be associated with varicose veins and a few are painless. The lack of a strong relationship between clinical symptoms and signs makes the task of SVI severity assessment very difficult. Also clinical assessments of severity are qualitative because they attempt to scale biological units in steps using numbers. For this reason an objective reference value may help to quantify the amount of insufficiency present which is hampering the venous drainage mechanism.

Haemodynamic evaluations have always taken second place behind clinical assessments. Current practice relies on identification of the site and presence of reflux with ultrasound to direct treatment. The expectation is that once the disease is treated then the symptoms and signs improve.

Although this works for the majority of patients with SVI, clinical outcomes may not reflect the anticipated treatment success. For example, patients may deteriorate despite a successful ablation and vice versa. Causes of a discordant outcome may be that the leg pain is non-venous in origin or high observer variability in questionnaire completion. It is in these circumstances that an objective reference value may help to determine how well the leg has been treated. This is in contrast to traditional teaching in which haemodynamic parameters are considered surrogate endpoints.¹⁶ The aim of this study was to compare four potential reference values that may be of value in quantifying haemodynamic severity.

The academic exercise of correlating clinical severity with haemodynamic severity is of limited clinical value. This is because clinical severity is a term that is not well defined and there are a plethora of variables present to confuse a severity assessment. Several questions arise. Knowing that symptoms do not correlate well with clinical signs, which is more important as a treatment objective? Should venous disease be treated as a lesion like an ulcer, varicose vein, or a plaque of lipodermatosclerosis or as a haemodynamic insufficiency of drainage? How much of the multidisciplinary nature of leg symptoms is attributed to venous disease?¹⁷ For these reasons, and in common with most other diseases, a numerical value of drainage severity could be important as a reference. This is a growing field in venous research that the current study attempts to address.



A summary comparing the strengths and weaknesses of the four tests is shown in Table 2. For the purposes of response to treatment and follow up, only the VAFI and VFI are applicable. Once the GSV has been removed or ablated the RCI and PDC cannot be performed. However, the RCI could be done on incompletely obliterated saphenous segments to determine whether the reflux is significant. This is not possible with the PDC because the GSV wall after treatment cannot be compared to the original wall behaviour. The RCI and PDC could be performed also on any distal GSV post ablation as well as on ultrasound detectible tributaries. In European centres that practice saphenous sparing surgery, either by reflux source elimination¹⁸ or through the reduction of superficial volume load,¹⁹ special situations may arise. After a

crossotomy the RCI is still possible if the reflux source is not fully interrupted because of missed pelvic sources, a slipped ligature, or from a groin recurrence. With a complete interruption of reflux the RCI should be ≤ 1 because the volume displaced upwards should be equal or more than the volume downwards. Nevertheless, in common with reflux assessments using ultrasound, the main weaknesses of the RCI and PDC are that they are performed on individual veins and that may not reflect the global venous haemodynamics.

The results indicate also that the RCI and VFI have the best discriminative value in identifying significant reflux, but it is the VFI that has the lion's share of publications (Table 2). Unfortunately, APG is not yet readily available. If there were excellent correlations between the four tests it

Table 2. Comparative evaluation of the usefulness of the four haemodynamic tests in quantifying superficial venous insufficiency.

	Pre and post treatment	Global assessment	Manoeuvre independent	Discriminative value	Readily available	Extensive validation
Venous arterial flow index (VAFI) ^a	√	√	√	X	√	X
Recirculation index (RCI) ^b	X	X	X	√	√	X
Venous filling index (VFI) ^c	√	√	X	√	X	√
Postural diameter change (PDC) ^d	X	X	X	X	√	X

√: true most of the time and in most situations. X: false most of the time and in most situations. PDC: postural diameter change; RCI: recirculation index; VAFI: venous arterial flow index; VFI: venous filling index.

^a VAFI (ratio).

^b RCI (ratio).

^c VFI (mL/s).

^d PDC (% change).

could be possible to use them indiscriminately so that the one more available at that institution could be used.

Quantifying reflux has been the aim of many investigators with limited success. Studied parameters include peak reflux velocity,²⁰ flow volume at peak reflux (mL/s),² and duration of reflux.^{12,21} Reflux volume may be more representative as indicated in a recent publication on quantifying reflux.⁶ However, antegrade saphenous volume has been shown to be a determinant of the resulting reflux volume. For this reason the RCI may be an improvement in quantification of reflux.¹⁰ This was appreciated by D.N. Psathakis and N.D. Psathakis, originators of the concept of measuring antegrade flow and reflux with a ratio, named the Psathakis index (PI). However, they used this to test deep venous valve function before and after reconstructive surgery.²² The RCI attempts to standardise reflux measurements by benchmarking against antegrade flow.¹⁰ This can be improved further by automated cyclical compression pumps which standardise the refilling time, thereby making reflux less operator dependent.¹⁰

Regarding the definition of recirculation, Trendelenburg described a “private circulation” because not all venous blood leaves the leg in one pass.⁵ In reflux disease, some of this blood circulates again around the private circulation. The extra saphenous volume load that circulates again has been termed “recirculation.” This definition of recirculation differs from its use in other fields in which assessments are made by isotope injection. There, marked compounds can be measured passing the same point of the circulation using scintigraphy.

In 2016, a UIP venous haemodynamic consensus document of 116 pages was published to express the experience from over 70 phlebologists from around the world.¹⁶ The VFI was discussed as an index of clinical severity^{15,23,24} and so was its response to intervention.^{25–28} The RCI was mentioned as a way of quantifying saphenous recirculation with implications that it may quantify reflux. The GSV diameter was presented in the context of clinical severity,²⁹ clinical C class,³⁰ and reflux.³¹ However, the response of the GSV to gravitational manoeuvres was not discussed as a parameter of venous disease and the PDC was not included in the document. Furthermore, the VAFI was not acknowledged, as it has been shown to be responsive to

intervention only in 2014.¹⁴ The UIP consensus was almost complete in 2013 when the VAFI was not widely known. The current study was undertaken to fill in some gaps of the consensus in light of recent studies, especially in relation to the VAFI and the PDC. As the ESVS guidelines (2015) on the management of chronic venous disease excluded all references beyond Jan 1, 2013 in their search criteria, only the VFI is mentioned. However, it is anticipated that the other three tests will be included in the next revision.³²

An interesting finding from the current study was a significant increase in the diameter of the common femoral vein (CFV) in the patients compared to the controls. This difference was not observed in the common femoral artery (Table 1). These results are in agreement with the observation that the CFV significantly reduces in diameter following interventional treatment.³³ As the CFV was measured below the sapheno-femoral junction (SFJ), it is believed that the extra venous volume comes from a recirculation. However, this explanation may not be true for the VAFI because the CFV was measured above the SFJ, which is therefore outside of the recirculation.⁸ This leads to a scientific contradiction worthy of further studies. The use of the CFV diameter as an index of haemodynamic severity is easy to perform and its responsiveness to treatment is also worthy of further evaluation.

CONCLUSIONS

This work compared four haemodynamic tests for SVI in patients and healthy controls. All tests were able to discriminate patients with reflux from volunteers without reflux, with minimal overlap. Each test correlated significantly with the others in quantification, thereby validating them as an assessment of venous drainage impairment.

Once reflux has been identified, it is recommended that it is quantified by an appropriate test providing an objective reference value independent of the complex and subjective nature of clinical assessments.

CONFLICTS OF INTEREST

None.

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