Deep axial reflux, an important contributor to skin changes or ulcer in chronic venous disease

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Objective: **We undertook this cross-sectional study to investigate the distribution of venous reflux and effect of axial reflux in superficial and deep veins and to determine the clinical value of quantifying peak reverse flow velocity and reflux time in limbs with chronic venous disease.**

Patients and methods: **Four hundred one legs (127 with skin changes, 274 without skin changes) in 272 patients were examined with duplex ultrasound scanning, and peak reverse flow velocity and reflux time were measured. Both parameters were graded on a scale of 0 to 4. The sum of reverse flow scores was calculated from seven venous segments, three in superficial veins (great saphenous vein at saphenofemoral junction, great saphenous vein below knee, small saphenous vein) and four in deep veins (common femoral vein, femoral vein, deep femoral vein, popliteal vein). Axial reflux was defined as reflux in the great saphenous vein above and below the knee or in the femoral vein to the popliteal vein below the knee. Reflux parameters and presence or absence of axial reflux in superficial or deep veins were correlated with prevalence of skin changes or ulcer (CEAP class 4-6).**

Results: **The most common anatomic presentation was incompetence in all three systems (superficial, deep, perforator; 46%) or in superficial or perforator veins (28%). Isolated reflux in one system only was rare (15%; superficial, 28 legs; deep, 14 legs; perforator, 18 legs). Deep venous incompetence was present in 244 legs (61%). If common femoral vein reflux was excluded, prevalence of deep venous incompetence was 52%. The cause, according to findings at duplex ultrasound scanning, was primary in 302 legs (75%) and secondary in 99 legs (25%). Presence of axial deep venous reflux increased significantly with prevalence of skin changes or ulcer (C4-C6; odds ratio [OR], 2.7; 95% confidence interval [CI], 1.56-4.67). Of 110 extremities with incompetent popliteal vein, 81 legs had even femoral vein reflux, with significantly more skin changes or ulcer, compared with 29 legs with popliteal reflux alone ($P = .025$). Legs with skin changes or ulcer had significantly higher total peak reverse flow velocity ($P = .006$), but the difference for total reflux time did not reach significance ($P = .084$) compared with legs without skin changes. In contrast, presence of axial reflux in superficial veins did not increase prevalence of skin changes (OR, 0.73; 95% CI, 0.44-1.2). Incompetent perforator veins were observed as often in patients with no skin changes (C0-C3, 215 of 274, 78%) as in patients with skin changes (C4-C6, 106 of 127, 83%; $P = .25$).**

Conclusion: **Continuous axial deep venous reflux is a major contributor to increased prevalence of skin changes or ulcer in patients with chronic venous disease compared with segmental deep venous reflux above or below the knee only. The total peak reverse flow velocity score is significantly higher in patients with skin changes or ulcer. It is questionable whether peak reverse flow velocity and reflux time can be used to quantify venous reflux; however, if they are used, peak reverse flow velocity seems to reflect venous malfunction more appropriately. (J Vasc Surg 2003;38:1336-41.)**

Duplex ultrasound (US) scanning is the standard for investigation of venous disease in patients with chronic venous disease, replacing venography as the method of choice for detection of reflux and obstruction.[1] How to quantify duplex US scan–derived reflux values has not been fully defined. Several reports have used reflux time (RT) in seconds and peak reverse flow velocity (PRFV) in centimeters per second for this purpose, because they are easy to measure.[2-5] Some have also advocated use of calculated flow (mL/s), with average velocity at peak reflux (cm/s) multiplied by cross-sectional area of the vein (cm^2).[6,7] Yamaki et al[7] examined 146 legs in 109 patients with isolated superficial venous insufficiency, and found PRFV (>30 cm/s) to be of greater value than RT in determining severity of disease. They showed a significant positive correlation ($r = 0.7$) between reflux flow (mL/s) measured at duplex US scanning and venous filling index measured at air plethysmography. However, the correlation was negative ($r = -0.4$) for valve closure time; increased RT was associated with a decrease in venous filling index. The explanation for these findings was that patients with relatively early disease had longer RT with lower PRFV, and that those with more advanced disease had shorter RT and higher PRFV.

Valentín et al[5] reported increased reflux with increasing symptoms and signs. The saphenous vein was the main contributor to reflux in all stages of disease. RT was the least useful variable, according to the study, and the authors recommended use of PRFV. Welch et al[8] indicated the value of using total valve closure time to predict severity of deep reflux in femoral and popliteal veins, where a total value exceeding 4 seconds correlated with severe reflux (grade 3 or 4) at descending phlebography (sensitivity,

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90%; specificity, 94%; accuracy, 93%). The same group later reported the importance of deep axial reflux (continuous reflux in femoral vein through popliteal vein below knee) in patients with venous ulcer.[4] Others have had similar views regarding the importance of deep venous axial reflux, and advocate that such incompetence should be dealt with surgically in suitable patients.[9-13]

The discrepancy reported in the literature encouraged us to investigate the distribution of venous reflux and the effect of axial reflux in superficial and deep veins, and to determine the clinical value of quantifying PRFV and RT in limbs with chronic venous disease.

PATIENTS AND METHODS

Patients. Data were obtained by reviewing venous US scans obtained at the Vascular Center, Straub Clinic and Hospital, during 1999. The presence of venous reflux or obstruction (chronic venous disease) was confirmed in 401 legs (204 right, 197 left). The study group consisted of 272 patients (173 female patients), with median age 60 years (range, 14-90 years). Disease was categorized according to the CEAP classification.[14] In 129 patients, both legs were included in the study because they demonstrated bilateral symptoms and signs of venous disease. There was no correlation between left and right legs and clinical findings in these patients, and therefore each leg was regarded as an independent unit in the statistical analysis.

Methods. Two comparisons were made; legs without skin changes (C0-C3) were compared with legs with skin changes or ulcer (C4-C6), and differences in clinical presentation, according to extent of axial and segmental reflux, were compared in both the superficial and deep veins. Axial reflux was defined as reflux in the entire great saphenous vein to below the knee or in the entire femoral vein from the thigh region to the popliteal vein below the knee. The new nomenclature for veins of the lower limbs was used.[15]

Duplex US scanning. Segments in the superficial, deep, and perforator veins were examined. Scanning was performed with the patient in the 15-degree reverse Trendelenburg position, with an Ultramark-9 scanner (Advanced Technology Laboratories, Bothell, Wash). The Valsalva maneuver was used to evaluate the presence of reflux in venous segments above the knee, and manual compression or release of calf or foot was used in segments below the knee.[16]

Grading of reflux. RT and PRFV were graded on a scale of 0 to 4 in each vein segment (Table I). RT exceeding 0.5 seconds was considered pathologic. Scores were obtained from seven venous segments: four in the deep venous system, including the common femoral vein, femoral vein, deep femoral vein, and popliteal vein; and three in the superficial venous system, including the great saphenous vein at the saphenofemoral junction, great saphenous vein below the knee, and small saphenous vein. Values obtained were added to get the total RT score and PRFV score. Inasmuch as we did not regularly measure reflux in crural veins and the validity of grading perforator incompetence is unknown, we omitted these segments from calculation of the total score.

Table I. Grade of reflux time and peak reverse flow velocity

Grade	*Reflux time (s)*	*Peak reverse flow velocity (cm/s)*
0	< 0.5	—
1	$> 0.5 < 1.0$	< 10
2	$> 1.0 < 2.0$	10–20
3	$> 2.0 < 3.0$	20–30
4	> 3.0	> 30

Statistical analysis. The Mann-Whitney *U* test was used to compare measurements of legs with and without skin changes. We calculated odds ratio (OR) with 95% confidence interval (CI) as estimates of the effect on prevalence of skin changes with logistic regression analysis. All analyses were performed with software from JMP (SAS Institute, Cary, NC) and SPSS version 10.1 (SPSS, Chicago, Ill). $P < .05$ was considered statistically significant.

RESULTS

Patients. CEAP clinical class was C0 in 15 legs, C1 in 8 legs, C2 in 152 legs, C3 in 99 legs, C4 in 70 legs, C5 in 17 legs, and C6 in 40 legs. Most patients (64%) were female, and they outnumbered male patients in all clinical categories except active venous ulcer (Fig 1). There was no significant difference with regard to age between clinical class C0-C3 (59 years) and C4-C6 (62 years; Table II). Findings on duplex US scans suggested that the cause was primary in 302 legs (75%) and secondary in 99 legs (25%). The most common anatomic presentation was incompetence in all three systems— superficial, deep, and perforator—in 186 legs (46%) and in superficial or perforator veins in 111 legs (28%). Isolated reflux in one system only was rare (15%; superficial, 28 legs; deep, 14 legs; perforator, 18 legs; Table III). Perforator vein incompetence was present below the knee in 321 extremities (80%) and above the knee in 38 extremities (9.5%). Incompetent perforator veins were observed as often in patients with no skin changes (215 of 274, 78%) as in patients with skin changes or ulcer (106 of 127, 83%; $P = .25$). Deep vein incompetence was present in 244 extremities (61%). Common femoral vein reflux was noted in 35 legs, always accompanied by reflux in the great saphenous vein. If common femoral vein reflux was excluded, deep vein incompetence was present in 52% of extremities.

Quantification of duplex US scan measurements. Legs with skin changes or ulcer had a significantly higher total PRFV score ($P = .006$); however, the difference for total RT score did not reach significance, although there was a clear trend for increased RT ($P = .084$) compared with legs without skin changes.

Distribution of reflux. At analysis of the distribution of axial and segmental disease in various combinations in deep or superficial veins, the main findings were that axial deep vein incompetence with or without concomitant su-

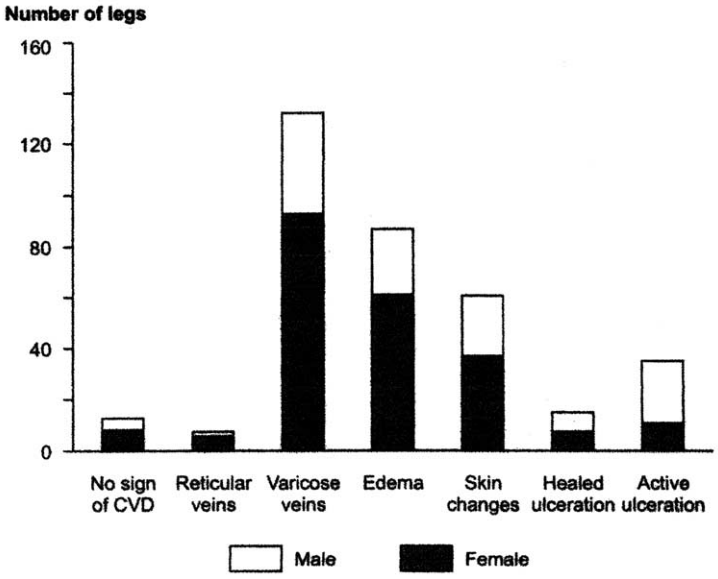

Fig 1. Clinical class in 401 legs with chronic venous disease.

Table II. Comparison of reflux values in individual veins

	With skin changes (C0–C3; 274 legs)	*Without skin changes (C4–C6; 127 legs)*	*P*
Age (y)	59 ± 15.0	62 ± 15.5	NS
Sum of reflux time score for all veins	7.6 ± 4.8	8.8 ± 5.4	NS
Sum of peak reverse flow velocity score for all veins	5.5 ± 3.7	6.9 ± 4.4	.006
GSV reflux time*	1.9 ± 1.8	1.4 ± 1.7	.018
GSV peak reverse flow*	1.3 ± 1.4	1.1 ± 1.4	NS
SSV reflux time*	0.33 ± 1.0	0.64 ± 1.4	.041
SSV peak reverse flow*	0.14 ± 0.4	0.32 ± 0.8	.036
CFV reflux time*	1.17 ± 1.5	1.38 ± 1.6	NS
CFV peak reverse flow*	1.16 ± 1.4	1.44 ± 1.5	NS
DFV reflux time*	0.29 ± 0.8	0.37 ± 0.9	NS
DFV peak reverse flow*	0.27 ± 0.7	0.31 ± 0.7	NS
FV reflux time*	0.9 ± 1.5	1.4 ± 1.6	<.0001
FV peak reverse flow*	0.5 ± 0.9	1.0 ± 1.3	<.0001
PV reflux time*	0.57 ± 1.3	1.1 ± 1.6	<.0001
PV peak reverse flow*	0.28 ± 6.3	0.58 ± 0.9	<.0001

Values represent mean ± SD.
C0–C3, C4–C6, CEAP classification; *GSV,* greater saphenous vein; *SSV,* small saphenous vein; *CFV,* common femoral vein; *DFV,* deep femoral vein; *FV,* femoral vein; *PV,* popliteal vein.
*Sum of grades from Table I.

perficial venous reflux was the most common denominator for CEAP 4-6. Compared with patients with segmental deep vein incompetence, patients with axial deep vein incompetence had an almost threefold increased prevalence of skin changes or ulcer (OR, 2.7; 95% CI, 1.56-4.67). The prevalence of skin changes or ulcer was twice as high (although not reaching significance) in patients with axial deep vein incompetence alone (28 legs) compared with patients with segmental deep vein incompetence alone (51 legs; OR, 2.06; 95% CI, 0.8-5.3; Table IV). The same was apparent for patients with axial deep vein incompetence combined with superficial axial reflux (21 legs) compared with patients with superficial axial reflux alone (39 legs; OR, 1.785; 95% CI, 0.57-5.56; Table IV). Of 110 extremities with incompetent popliteal veins, 81 legs had femoral vein reflux, with significantly more skin changes or ulcer, compared with the 29 legs with popliteal reflux alone ($P = .025$). Other combinations did not increase prevalence of skin changes or ulcer. Superficial venous incompetence in the great saphenous vein at the saphenofemoral junction and below the knee (axial) did not increase prevalence of skin changes compared with segmental superficial venous

Table III. Clinical class and reflux pattern in superficial and deep veins (number of legs in each category)

	No skin changes (C0–C3)	*Skin changes (C4–C6)*		
		n	*%*	*Total*
Sa	29	10	26	39
Ss	60	19	24	79
Da	14	14	50	28
Ds	35	16	31	51
DaSa	13	8	38	21
DaSs	10	18	64	28
DsSa	50	15	23	65
DsSs	50	22	30	72
IPV only	13	5	28	18
Total	274	127		401

S, Superficial venous incompetence; *D,* deep venous incompetence; *s,* segmental incompetence; *a,* axial incompetence; *IPV,* incompetent perforator vein.

reflux (OR, 0.73; 95% CI, 0.44-1.2). Thirty-three of 127 legs (26%) with skin changes or ulcer had axial reflux in the great saphenous vein. Superficial segmental reflux was the most common anatomic finding (Table IV). The prevalence of skin changes or ulcer and of segmental and axial reflux in superficial and deep veins is shown in Fig 2.

DISCUSSION

This study was designed to investigate the value of duplex US scan measurements in routine clinical practice to enable prediction of chronic venous disease clinical class. The role of duplex US scanning has been well established for confirmation of reverse flow in venous segments, although the value of quantifying the findings is less defined. Vasdekis et al[6] examined 46 patients with chronic venous disease and used duplex US scans to calculate PRFV, and found that reflux great than 10 mL/sec was associated with a high incidence of skin changes, whereas there was no significant difference in ambulatory venous pressure in patients with or without skin changes. Two publications from 1993 reported the value of RT for judging severity of chronic venous disease.[2,3] Weingarten et al[2] found that total limb RT greater than 9.66 seconds was predictive of ulceration and that reflux in the common femoral vein was significantly associated with wound area and duration of ulcer. They also noted a high incidence of multiple segment reflux (superficial and deep), as opposed to single segment reflux, in patients with ulcer. They did not differentiate between reflux in the common femoral vein, femoral vein, or deep femoral vein, nor did they report concomitant incompetence in the great saphenous vein. The same group later (1996) reported a correlation between limb RT and venous filling index as measured at air plethysmography, and concluded that the validity of total limb RT in quantification of chronic venous insufficiency was confirmed.[17] Rodriguez et al[18] could not confirm these findings when analyzing the correlation between total limb RT and venous filling index measured at air plethysmography, and concluded that valve closure time should not be used to quantify degree of reflux.

Our findings indicate that PRFV is significantly higher in legs with clinical class C4-C6 disease compared with legs with clinical class C0-C3 disease. In addition, presence of axial reflux in deep veins contributes significantly to increased prevalence of skin changes or ulcer compared with segmental deep reflux only. Several recent reports have demonstrated the importance of superficial veins in all stages of venous disease, and the role of deep veins in the discussion has diminished.[19,20] Our findings emphasize the importance of axial deep vein incompetence, and it might be inferred that deep venous reconstruction has a role in management in a substantial number of patients with skin changes or ulcer. The effect of axial reflux in the great saphenous vein on prevalence of skin changes or ulcer cannot be determined from our findings. Even if the presence of axial great saphenous vein reflux did not indicate increased prevalence of skin changes or ulcer (OR, 0.73; 95% CI, 0.44-1.2), the validity of these findings is uncertain, because some information about former surgical treatment of the great saphenous vein might be missing from this analysis.

Deep reflux in the common femoral vein only was always accompanied by reflux in the proximal portion of the great saphenous vein. A possible interpretation of the findings is that common femoral vein reflux is caused by overloading venous volume from the proximal portion of the great saphenous vein, and should not be considered important deep vein incompetence. Ablation of the great saphenous vein has been reported to revert deep vein reflux.[21,22] Studies from our group indicate that femoral vein reflux is seldom corrected in limbs with axial reflux compared with those limbs with segmental reflux.[23]

The objective of our study was to observe the prevalence of axial reflux in superficial and deep veins and how it is linked to clinical class of disease. We did not include perforator vein incompetence in scoring reflux measurements, because standardization of measurement and interpretation of findings is unclear. The hemodynamic importance of perforator vein incompetence in the pathogenesis of venous skin changes and ulcer has also been questioned.[24,25] We did note their presence, based on bidirectional flow with manual compression of the foot or leg. Crural veins were not included, because we did not measure reflux below the popliteal vein in 1999. The recently proposed venous severity scoring system allots higher scores to reflux in popliteal and crural veins, because it is thought to be more important than deep vein incompetence above the knee.[26] Our findings indicate that the presence of axial deep vein incompetence (gravitational reflux) should also be noted in the scoring system. Even if valve competence in the popliteal vein is crucial, our results indicate that valve repair in a femoral vein with reflux might be indicated in a substantial number of patients with skin changes or venous ulcer. The value of treatment remains to be proved in randomized controlled studies with hemodynamic evaluation of treatment effect.[27]

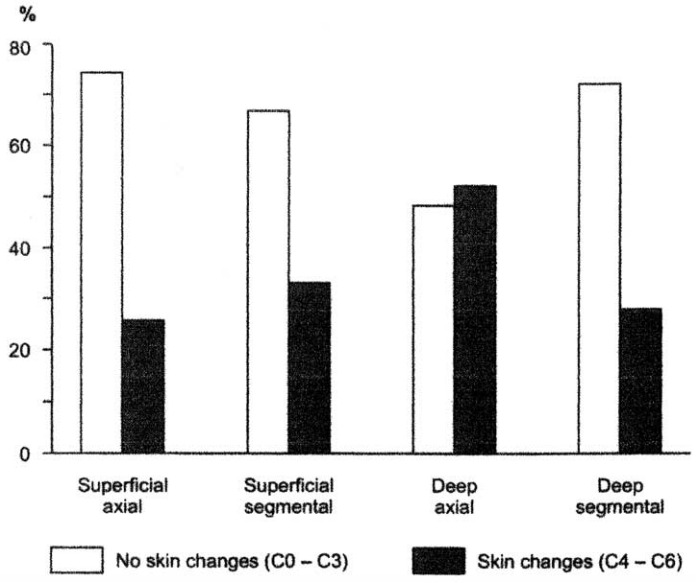

Fig 2. Prevalence of skin changes or ulcer and of axial or segmental reflux in superficial and deep veins.

This is a cross-sectional study, and the possibility of bias must be considered. Inasmuch as all patients with all categories of chronic venous disease routinely undergo duplex US scanning before or during their first visit to the Straub Clinic and Hospital, there should be no selection bias between clinical classes. The high proportion of obese patients in our study is another factor that should be taken into account. We have previously reported our finding of overweight as a risk factor for increased prevalence of skin changes or ulcer in this same patient population.[28] Whether this population is representative of patients with chronic venous disease in another geographic area or at another clinic is unknown.

CONCLUSION

The importance of axial deep vein incompetence, as opposed to segmental deep vein incompetence, is confirmed. Restoration of deep vein valve function might have a role in skin changes or ulcer in a number of patients. PRFV is significantly higher in extremities with skin changes or ulcer compared with those without skin changes or ulcer. It is highly questionable that summation of PRFV or RT is useful in judging overall venous function of the leg. We recommend that, in future studies with duplex US scanning, PRFV rather than RT should be used to quantify venous incompetence.

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REFERENCES

1. Neglen P, Raju S. A comparison between descending phlebography and duplex Doppler investigation in the evaluation of reflux in chronic venous insufficiency: a challenge to phlebography as the "gold standard." J Vasc Surg 1992;16:687-93.
2. Weingarten MS, Branas CC, Czeredarczuk M, Schmidt JD, Wolferth CC Jr. Distribution and quantification of venous reflux in lower extremity chronic venous stasis disease with duplex scanning. J Vasc Surg 1993;18:753-9.
3. Neglen P, Raju S. A rational approach to detection of significant reflux with duplex Doppler scanning and air plethysmography. J Vasc Surg 1993;17:590-5.
4. Welch HJ, Young CM, Semegran AB, Iafrati MD, Mackey WC, O'Donnell TF Jr. Duplex assessment of venous reflux and chronic venous insufficiency: the significance of deep venous reflux. J Vasc Surg 1996;24:755-62.
5. Valentin LI, Valentin WH. Comparative study of different venous reflux duplex quantitation parameters. Angiology 1999;50:721-8.
6. Vasdekis S, Clarke H, Nicolaides AN. Quantification of venous reflux by means of duplex scanning. J Vasc Surg 1989;10:670-7.
7. Yamaki T, Nozaki M, Sasaki K. Quantitative assessment of superficial venous insufficiency using duplex ultrasound and air plethysmography. Dermatol Surg 2000;26:644-8.
8. Welch HJ, Faliakou EC, McLaughlin RL, Umphrey SE, Belkin M, O'Donnell TF Jr. Comparison of descending phlebography with quantitative photoplethysmography, air plethysmography, and duplex quantitative valve closure time in assessing deep venous reflux. J Vasc Surg 1992;16:913-9 ; discussion 919-20.
9. Kistner RL. Deep venous reconstruction (1968–1984). Int Angiol 1985;4:429-33.
10. Eriksson I, Almgren B, Nordgren L. Late results after venous valve repair. Int Angiol 1985;4:413-7.
11. Raju S, Fredericks R. Valve reconstruction procedures for nonobstructive venous insufficiency: rationale, techniques, and results in 107 procedures with two- to eight-year follow-up. J Vasc Surg 1988;7:301-10.
12. Welch HJ, McLaughlin RL, O'Donnell TF Jr. Femoral vein valvuloplasty: intraoperative angioscopic evaluation and hemodynamic improvement. J Vasc Surg 1992;16:694-700.
13. Sottiurai VS. Surgical correction of recurrent venous ulcer. J Cardiovasc Surg (Torino) 1991;32:104-9.
14. Kistner RL, Eklof B, Masuda EM. Diagnosis of chronic venous disease of the lower extremities: the "CEAP" classification. Mayo Clin Proc 1996;71:338-45.
15. Caggiati A, Bergan JJ, Gloviczki P, Jantet G, Wendell-Smith CP, Partsch H. Nomenclature of the veins of the lower limbs: an international interdisciplinary consensus statement. J Vasc Surg 2002;36:416-22.

16. Masuda EM, Kistner RL, Eklof B. Prospective study of duplex scanning for venous reflux: comparison of Valsalva and pneumatic cuff techniques in the reverse Trendelenburg and standing positions. J Vasc Surg 1994;20:711-20.
17. Weingarten MS, Czeredarczuk M, Scovell S, Branas CC, Mignogna GM, Wolferth CC Jr. A correlation of air plethysmography and color-flow-assisted duplex scanning in the quantification of chronic venous insufficiency. J Vasc Surg 1996;24:750-4.
18. Rodriguez AA, Whitehead CM, McLaughlin RL, Umphrey SE, Welch HJ, O'Donnell TF. Duplex-derived valve closure times fail to correlate with reflux flow volumes in patients with chronic venous insufficiency. J Vasc Surg 1996;23:606-10.
19. Labropoulos N, Leon M, Geroulakos G, Volteas N, Chan P, Nicolaides AN. Venous hemodynamic abnormalities in patients with leg ulceration. Am J Surg 1995;169:572-4.
20. Bello M, Scriven M, Hartshorne T, Bell PR, Naylor AR, London NJ. Role of superficial venous surgery in the treatment of venous ulceration. Br J Surg 1999;86:755-9.
21. Walsh JC, Bergan JJ, Beeman S, Comer TP. Femoral venous reflux abolished by greater saphenous vein stripping. Ann Vasc Surg 1994;8:566-70.
22. Sales CM, Bilof ML, Petrillo KA, Luka NL. Correction of lower extremity deep venous incompetence by ablation of superficial venous reflux. Ann Vasc Surg 1996;10:186-9.
23. Puggioni A, Lurie F, Kistner RL, Eklöf B. How often is deep venous reflux eliminated after saphenous vein ablation? J Vasc Surg 2003;38:517-21.
24. Danielsson G, Eklof B, Kistner RL. What is the role of incompetent perforator veins in chronic venous disease? J Phlebol 2001;1:67-71.
25. Ruckley CV, Makhdoomi KR. The venous perforator. Br J Surg 1996;83:1492-3.
26. Rutherford RB, Padberg FT Jr, Comerota AJ, Kistner RL, Meissner MH, Moneta GL. Venous severity scoring: an adjunct to venous outcome assessment. J Vasc Surg 2000;31:1307-12.
27. Stacey MC. Investigation and treatment of chronic venous ulcer disease. Aust N Z J Surg 2001;71:226-9.
28. Danielsson G, Eklof B, Grandinetti A, Kistner RL. The influence of obesity on chronic venous disease. Vasc Endovasc Surg 2002;36:271-6.

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