Venous outflow obstruction: An underestimated contributor to chronic venous disease

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Objective: **To assess the importance of iliac venous outflow obstruction in limbs with and without concomitant deep or superficial reflux, we performed a retrospective analysis of data contemporaneously entered into a set time-stamped electronic medical records program.**

Material and method: **Four hundred forty-seven limbs underwent iliac vein stenting of chronic, nonmalignant obstruction when greater than 50% morphologic stenosis was found at transfemoral venography or intravascular ultrasonography. Group 1 (female-male ratio, 3.4:1; left limb–right limb, 2.7:1; nonthrombotic-thrombotic, 1.8:1) included 187 stented limbs in 176 patients with absence of deep and superficial reflux as identified at erect duplex Doppler scanning. Group 2 (female-male, 1.7:1; left-right, 1.9:1, nonthrombotic-thrombotic limb, 1:2.1) included 260 limbs in 253 patients with combination obstruction and reflux. Reflux was left untreated during the observation period. Clinical outcome (ulcer healing and recurrence rate, degree of pain per visual analog scale, swelling grade) and hemodynamic effects (ambulatory venous pressure, venous refilling time, venous filling index at 90 seconds) of iliac venous stenting were assessed.**

Result: **Patients with reflux and obstruction had more severe disease (clinical class 4-6, 53% in group 2 vs 24% in group 1; $P < .001$). Similarly, rate of active ulcer was low in limbs with obstruction only (3% vs 24%, groups 1 and 2, respectively). Mean clinical follow-up was 13 ± 12 months (SD) in 86% of limbs. Because of the presence of reflux in group 2, venous pressure was higher, venous filling time was shorter, and venous filling index at 90 seconds increased, compared with group 1. Multisegment scores were 2.6 ± 1.6 and 0, respectively. Of greater interest, there was no deterioration in venous hemodynamics in group 2 after stenting. There was substantial clinical improvement in both groups after stenting. Approximately half of patients were completely relieved of pain after stenting, and a third were completely relieved of swelling. In addition, 55% of ulcerated limbs healed.**

Conclusion: **Iliac venous outflow obstruction appears to have an important role in clinical expression of chronic venous insufficiency, particularly in producing pain, and is easily overlooked, mainly because of diagnostic difficulty. The combination of reflux and obstruction is seen more frequently with severe clinical disease than is obstruction alone. Ulcer prevalence is clearly associated with reflux, with a low incidence in patients with obstruction alone. Removal of iliac vein outflow obstruction does not result in increased axial reflux, with clinical deterioration in limbs with combined reflux and obstruction. (J Vasc Surg 2003;38:879-85.)**

Treatment of chronic venous disease has been focused mainly on controlling axial deep or superficial reflux caused by incompetent valves. The pathophysiology of chronic venous disease is complex, and many aspects, such as obstruction to outflow, poor calf muscle pump, low venous compliance, and geometric changes in flow channels, have largely been ignored, in part because of lack of means to properly assess the importance of these components and their specific contribution to the disease. At venous ultrasonography, a morphologic obstructive component is predominant in approximately one third of post-thrombotic limbs. Obstruction is found in combination with reflux in 55% of symptomatic limbs.[1,2] The combination of reflux and obstruction results in more symptoms and higher venous ambulatory pressure than either entity alone.[3,4] Despite this observation, the fear persists that relief of proximal blockage will increase distal reflux; that is, it is thought that proximal obstruction is in some way protective. No accurate noninvasive or invasive test is available for evaluation of the hemodynamic significance of venous outflow obstruction.[5-7] In fact, the degree at which venous stenosis should be considered hemodynamically "critical" is unknown. Despite these shortfalls, venous stenting of iliac vein obstruction on the basis of degree of morphologic obstruction is beneficial.[7-11]

The purpose of this study was to assess the importance of venous outflow obstruction by evaluating clinical outcome and hemodynamic effect of iliac venous stenting in limbs with and without concomitant axial deep or superficial reflux.

MATERIAL AND METHOD

Between October 1996 and August 2002 at our institution, balloon angioplasty and stenting of the venous outflow tract—that is, common femoral vein, external and common iliac veins, or inferior vena cava—were performed in 613 limbs. During this time, approximately 2621 new patients were examined for venous disease. Considering an additional number of stented limbs in existing, reexamined patients, the rate of venous stenting was approximately 20%

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Table I. Characteristics of patients with obstruction only (group 1) compared with patients with combined obstruction and reflux (group 2)

	Obstruction only (N = 176)		*Obstruction plus reflux (N = 253)*		
	n	*Range*	*n*	*Range*	P
Median age (y)	49	15-78	52	14-87	.017
Female/male ratio	3.4/1	136/40	1.7/1	160/93	.001
Left limb/right limb ratio	2.7/1	136/51	1.9/1	169/91	.104
Limb nonthrombotic/thrombotic cause	1.8/1	120/67	1/2.1	84/176	.000

Table II. Clinical CEAP class for limbs with obstruction only (group 1) compared with limbs with combined obstruction and reflux (group 2)

Clinical class	*Obstruction only (N = 187)*			*Obstruction plus reflux (N = 260)*			P
	n	*%*	*Pain (%)*	*n*	*%*	*Pain (%)*	
2	15	8	100	14	5	100	.357
3	128	68	77	110	42	75	.000
4	37	20	85	56	22	84	.740
5	2	1	100	19	7	89	.004
6	5	3	100	61	24	77	.000

in our patient population with venous disease, and was performed in approximately 25% of venous surgeries (613 of 2381).

Two groups of limbs stented because of chronic nonmalignant obstruction were identified and analyzed. Group 1 included 187 stented limbs in 176 patients with absence of deep and superficial reflux as identified at erect duplex Doppler scanning. Group 2 comprised 260 limbs in 253 patients with a combination of obstruction and reflux diagnosed before stenting. Only outflow blockage was treated in these limbs; reflux was left untreated. No subsequent reflux surgery was performed during follow-up. The obstructive lesion was considered thrombotic if the patient had a history of previous deep venous thrombosis or if post-thrombotic changes in the lower extremity were found on venograms (61% of limbs) or duplex ultrasound scans (39% of limbs). Prevalence of thrombotic disease was 54% in the study population.

Group characteristics are shown in Table I. Median age was slightly higher in patients with combined obstruction and reflux (group 2), and female-male ratio was higher in patients with an isolated iliofemoral outflow obstruction (group 1). Patients in group 1 had more frequent involvement of the left leg compared with patients in group 2. Conversely, thrombotic obstruction was significantly more frequent in limbs with reflux (67% vs 36% in groups 2 and 1, respectively; $P = .000$). Clinical class of disease (CEAP classification according to the Reporting Standards of the International Society for Cardiovascular Surgery and the Society for Vascular Surgery) is shown in Table II.[12] Patients with reflux and obstruction had more severe clinical findings of chronic venous disease than did patients with obstruction only (clinical grade 4-6, 53% vs 24% in group 2 and group 1, respectively; $P = .000$). Consequently, the primary complaint of swelling was more often seen in group 1 (68% vs 42%, groups 1 and 2, respectively; $P = .000$). Similarly, the rate of active ulcer was low in limbs with obstruction only (3%) compared with limbs with combined obstruction and reflux (24%).

Median duration of nonhealing ulcer before stenting was 14 months (range, 1-102 months), and for all complaints was 15 months (range, 1 month–30 years). Half of patients (51%) wore compression stockings regularly before intervention. Preoperative ulcer care and compression therapy continued postoperatively until healing of the ulcer.

The technical details of percutaneous stenting of the iliofemoral venous outflow tract have been outlined.[7-11] The indication for stenting was the finding of more than 50% morphologic stenosis at transfemoral venography or intravascular ultrasonography. Crosscut area of the stenosis was measured at intravascular ultrasonography and compared with the area of the normal vein below the stenosis. The presence of collateral vessels was noted on venograms before and after stenting. Air plethysmography (APG-1000; ACI Medical, Sun Valley, Calif), duplex Doppler scanning with standardized compression, and ascending and transfemoral venography were performed, and arm-foot pressure differential, dorsal foot venous hyperemia pressure, and ambulatory dorsal foot venous pressure were measured before intervention. Venous function studies were repeated at follow-up. The methods used have been described.[13-15] Before and after stenting, ambulatory venous pressure with venous refilling time was determined in 79% (351 of 447) and 35% (155 of 447) of all studied limbs, respectively; venous filling index in 89% (399 of 447) and 41% (182 of 447), respectively; and grade of obstruc-

Table III. Clinical result of degree of pain (visual analog scale, 0-10) and swelling (grade 0-3) before and after stenting in limbs with obstruction only (group 1) and combined obstruction and reflux (group 2)

		Obstruction only		*Obstruction plus reflux*	
		Pre-stent	*Poststent*	*Pre-stent*	*Poststent*
Pain	No. of limbs	177	152	244	196
	Prevalence (n; %)	135 (76)	41 (27)	186 (77)	58 (30)
	Score (median; range)	4 (0-9)	0 (0-9)*	4 (0-9)	0 (0-9)*
Swelling	No. of limbs	187	152	249	200
	Prevalence (n; %)	170 (91)	91 (60)	207 (83)	94 (47)
	Grade (median; range)	2 (0-3)	1 (0-3)*	1 (0-3)	0 (0-3)*

*$P < .001$.

tion in 78% (347 of 447) and 34% (156 of 447), respectively.

The stented limb was followed up clinically. The study end point of legs with stasis ulceration was healing, that is, complete epithelialization. Any breakdown of the ulcer after healing was considered a recurrence. Degree of pain was evaluated with a visual analog scale of 0 to 10, with 10 indicative of the most severe pain.[16] Swelling was assessed as grade 0, absent; grade 1, pitting, not obvious; grade 2, visible ankle edema; and grade 3, massive, encompassing the entire leg. A single-plane transfemoral venogram was obtained early (2-3 months) after stenting, again 9 months later, and annually thereafter for routine surveillance. If the patient returned with recurrence of symptoms, transfemoral venography was always performed to assess patency of the venous outflow tract. In-stent recurrent stenosis, if present, was assessed as percentage diameter reduction of patent lumen of the stent as observed on the venogram.

Clinical data were entered prospectively into a time-stamped electronic medical records program for retrospective analysis. Nonparametric Wilcoxon rank test for paired and unpaired data and χ^2 analysis were used for statistical analysis, as appropriate. Commercially available statistical programs (GraphPad Prism for Windows, version 3.0, and GraphPad StatMate, version 1.01i; GraphPad Software, San Diego, Calif) were used for analysis and power calculation. $P < .05$ was considered significant.

RESULTS

Intraoperative observations and procedure outcome. Intravascular ultrasonography, performed in 402 limbs, revealed greater than 70% stenosis in 72% of limbs and 50% to 70% stenosis in the remaining limbs. Intraoperative venograms obtained before stenting demonstrated collateral vessels in 66% (287 of 434) of limbs. After stenting, the collateral vessels disappeared completely in 60% (116 of 287) of limbs and decreased substantially in 21% (59 of 287) of limbs. There was no mortality and low nonthrombotic complication rate after venous stenting. Retroperitoneal hematoma requiring blood transfusion, and deep venous thrombosis in the contralateral leg developed in one patient each; and in one patient the guide wire was caught in the stent, and was removed through a small groin incision. No late nonthrombotic complications occurred.

Transfemoral venography was performed in 266 of 447 limbs during follow-up. Thirteen stented veins became occluded, four early (<30 days postoperatively) and nine late (2-15 months after stenting). In-stent recurrent stenosis greater than 50% was noted in 11 stented limbs. Repeat dilation was successful in 6 limbs, and no additional intervention was performed in 5 limbs. Typically, patients with symptom relief after stenting had symptom recurrence when the stent became occluded or significantly narrowed. No patient had worse symptoms after stenting than before stenting.

Clinical outcome. Mean clinical follow-up was 13 ± 12 (SD) months (range, 1-66 months) in 172 of 187 (92%) limbs with obstruction only and 214 of 260 (82%) limbs with combined obstruction and reflux. Clinical results (degree of pain and swelling) are shown in Table III. There was substantial, statistically significant improvement in both groups after stenting. Improvement in pain relief was most impressive, with 73% and 70% of patients completely free of pain after stenting, compared with 24% and 23% before stenting, in groups 1 and 2, respectively. Improvement in pain and swelling was similar in both groups. Complete relief of pain and swelling was observed in one half and one third of the limbs, respectively, after venous stenting.

Few patients in group 1 had a history of ulcer (7 limbs, 5 with active ulcer). Three limbs with active ulcer were followed up, and healed. One of 2 limbs with healed ulcer demonstrated ulcer recurrence during follow-up. In group 2, 41 of 61 limbs with active ulcers were observed over 15 ± 14 months (range, 1-53 months) after stenting. About half (51%) healed and remained healed during this period, and half (49%) did not heal. Of this latter group, 9 remained virtually unchanged, whereas 11 improved but never healed completely.

Hemodynamic outcome. Hemodynamic findings in obstructive limbs with and without reflux before and after stenting are shown in Table IV. Various hemodynamic investigations after stenting were performed in 35% to 51% of limbs with test results available before stenting. The power to show a change greater than 8% decrease in ambu-

Table IV. Hemodynamic results before and after stenting in limbs with no reflux* and limbs with combined obstruction and reflux†

	Obstruction only				*Obstruction plus reflux*			
	Pre-stent	*n*	*Poststent*	*n*	*Pre-stent*	*n*	*Poststent*	*n*
AVP (% drop)	71 ± 17	138	70 ± 15‡	60	58 ± 19§	213	57 ± 20‡	95
Venous filling time (s)¶	57 ± 35	138	54 ± 34‡	60	27 ± 29§	213	26 ± 27‡	95
Venous filling index (mL/s)‖	0.9 ± 0.7	168	1.1 ± 0.8‡	69	3.0 ± 2.4§	231	3.3 ± 3.9‡	113
Obstruction grade, Raju test	1.4 ± 0.7	139	1.3 ± 0.7‡	49	1.5 ± 0.8#	208	1.4 ± 0.6‡	107

AVP, Ambulatory venous pressure, normal value >50% drop.
*Multisegment score, 0; group 1.
†Multisegment score, 2.6 ± 1.6 (SD); group 2.
‡No statistical significance, post-stent vs pre-stent values.
§$P < .001$ group 2 vs. group 1 before stenting.
‖Normal, <2 ml/s.
¶Normal, <20 s.
#No statistical significance, group 2 vs group 1 before stenting.

Table V. Comparison between limbs with obstruction grade 2-4 and limbs with no hemodynamic obstruction (grade 0-1) according to Raju test

	Obstruction grade ≥2			*Obstruction grade ≤1*		
	Pre-stent	*Poststent*	P	*Pre-stent*	*Poststent*	P
AVP (% drop)	59 ± 20 (n = 108)	62 ± 20 (n = 45)	.4913*	65 ± 18 (n = 235)	65 ± 18.59 (n = 92)	.7637*
Swelling grade	1.8 ± 1.0 (n = 115)	1.0 ± 1.1 (n = 88)	<.0001*	1.6 ± 1.0 (n = 229)	0.9 ± 1.1 (n = 192)	<.0001*
Pain scale	4.3 ± 2.8 (n = 112)	1.8 ± 2.6 (n = 91)	<.0001*	4.0 ± 2.9 (n = 223)	0.89 ± 1.8 (n = 183)	<.0001*
Ulcer healing		6/13			15/23	.771†

AVP, Ambulatory venous pressure.
*Post-stent vs pre-stent values within same group.
†Group 1 vs group 2.

latory pressure and greater than 0.3 mL/s change in venous filling index was 85% to 100%. This indicates that the sample size was large enough to ensure adequate statistical comparison. As expected, there were clear between-group differences before stenting. Because of the presence of reflux in limbs in group 2, venous pressure was higher, venous filling time was shorter, and venous filling index at 90 seconds increased in this group, compared with group 1. Isolated deep and superficial reflux was observed in 37% and 23% of limbs, respectively. A combination of reflux in both systems was noted in the remaining 40% of limbs. The multisegment score was 2.6 ± 1.6 (SD) and 0 in groups 2 and 1, respectively. The maximum multisegment score is 7 (1 point each for incompetence of superficial femoral, profunda, popliteal, posterior tibial, long and short saphenous, and perforator veins). Of greater interest was that there was no deterioration in reflux parameters (venous filling time, venous filling index) or change in ambulatory venous pressure after stenting in group 2. There was no difference in degree of obstruction, per Raju test,[17] between the two groups before stenting, and neither group showed improvement in mean obstruction grade after insertion of the stent.

Positive Raju test results (obstruction grade ≥2) were seen before stenting in 27% and 38% of patients in groups 1 and 2, respectively ($P = .046$). Limbs with obstruction grade 2 did not behave differently from those with lower obstruction grades with regard to clinical response. Ambulatory venous pressure was not affected in either group after stenting (Table V). A small but statistically significant decrease in mean hand-foot pressure differential and obstruction grade was observed between limbs in which both pre-stenting and post-stenting pressure tests were obtained (Table VI).

DISCUSSION

In patients with combined reflux and obstruction, demographic, clinical, and hemodynamic features differed from those in patients with obstruction alone. Although severity of obstruction was the same in the two groups, as measured with current techniques, more than half of limbs with combined outflow obstruction and reflux had severe

Table VI. Pre-stent and poststent values for hand-foot pressure differential,* dorsal foot venous hyperemia pressure,† and obstruction grade (according to Raju) in limbs with tests performed before and after stenting

	Pre-stent	*Poststent*	P
Hand-foot pressure differential (mm Hg)	1.4 ± 1.7 (n = 144)	0.8 ± 1.4 (n = 144)	<.0001
Hyperemia pressure increase (mm Hg)	6.1 ± 5.6 (n = 137)	6.3 ± 4.4 (n = 137)	<.5933
Obstruction grade	1.3 ± 1.1 (n = 149)	0.9 ± 1.1 (n = 149)	<.001

*Normal, <4 mm Hg.
†Normal, <8 mm Hg.

clinical chronic venous disease, with hyperpigmentation, lipodermatosclerosis, or healed or active ulcer (C_{4-6}), compared with one fourth of limbs with obstruction alone. This finding is in agreement with the previous observation that combined reflux and obstruction are more frequently seen with severe clinical disease than either entity alone.[3,4] Ulcer prevalence is clearly associated with reflux, with a low rate of 5% in patients with obstruction alone, compared with 24% in patients with reflux also. It is not understood whether this is due to reflux per se or to associated hemodynamic deterioration.

Percutaneous iliac venous stenting is a safe and efficient method to correct pelvic venous outflow obstruction.[18] Mortality is null, and morbidity is less than 1%. Similar results were achieved in this study. After stent placement only a small number of limbs demonstrated late occlusion. Development of severe in-stent recurrent stenosis creating greater than 50% obstruction is infrequent. In this study, 9 stented limbs became occluded, and in 11 greater than 50% in-stent recurrent stenosis developed during follow-up. These findings are in line with those of previous reports that showed cumulative secondary patency rate of 93% at 4 years, and cumulative rate of 85% at 42 months for freedom from in-stent recurrent stenosis greater than 50%.[19] Thus it appears that balloon venoplasty and stenting of the iliac vein in limbs with chronic obstruction is a safe, minimally invasive method with minimal complication rate, no mortality, and acceptable 4-year patency rate. A smaller number of patients have been followed up for 5 years or longer, without precipitous deterioration of clinical efficacy and stent patency.

The clinical results of this study indicate that iliac venous outflow obstruction is important and that disobliteration alone results in substantial clinical improvement in most limbs with or without remaining concomitant axial deep or superficial vein incompetence. Significant femoroiliocaval outflow obstruction is probably a commonly overlooked contributing factor in limbs with chronic venous disease. It was observed and treated in approximately 23% of our patients during the study, and venous stenting accounted for 25% of venous surgeries performed at our institution. Traditionally, diagnosis of venous obstruction has been made on the basis of outflow plethysmography and femoral venous pressure measurement with exercise. Determination of outflow resistance and arm-foot venous pressure has also been used. None of these tests have proved adequately accurate in borderline obstruction, and are flawed by poor sensitivity.[5-7] Proximal outflow obstruction does not influence ambulatory venous pressure,[20] and normal ambulatory venous pressure does not exclude pressure increases in the proximal venous system of the lower extremity.[21,22] Therefore, ambulatory venous pressure is not a suitable diagnostic tool for detection of obstruction. In this study, ambulatory venous pressure was not affected by iliac stenting, even in limbs positive for obstruction before stenting. Lack of appropriate physiologic tests probably reflects poor understanding of the underlying pathophysiologic processes. The degree at which venous stenosis is hemodynamically "critical" is unknown. Experience from the arterial system may not be applicable in the venous system because of several fundamental differences.[18] In this study, detection and treatment of obstruction relied on significant clinical symptoms and signs, combined with the finding of more than 50% morphologic stenosis. Intravascular ultrasonography and multiplane transfemoral venography remain the methods of choice for visualization of iliac venous obstruction.[23] Greater than 70% stenosis was found in 72% of limbs with intraoperative intravascular ultrasonography. Despite lack of pressure correlations, presence of physiologic obstruction and its relief after stent placement is strongly suggested by disappearance or substantial decrease in pre-stenting collateral vessels in 81% of limbs. The degree of hemodynamic improvement, as measured by decrease of average hand-foot pressure, although statistically significant, cannot be used for identification of hemodynamic improvement in individual limbs. A more sensitive physiologic test to identify venous stenosis in individual limbs is sorely needed.

Strong evidence of the presence of symptomatic obstruction and its relief with stenting is provided by impressive clinical relief of pain and swelling, and high rate of ulcer healing. Approximately one third of limbs were completely relieved of swelling objectively after stenting, and significant improvement was noted in others. Improvement in degree of swelling is probably underestimated, because of poor resolution in the grading system. Considerable decrease in gross limb swelling with symptomatic improvement was observed after stenting, but the limbs still had grade 3 disease. The visual analog scale is valid and recognized as a reliable tool for measurement of pain. Although certainly not free of placebo effect, the high degree and consistency of pain improvement and concurrent improvement in objective measurement of swelling and ulcer healing after stent placement suggest a true therapeutic effect

rather than placebo effect. This is also supported by the observation that patients with recurrent obstruction had recurrence of symptoms after a symptom-free period. About 50% of patients in both groups had complete relief from pain after venous stenting. Pain is a frequent symptom, and is poorly represented in the clinical component of the CEAP classification. Clinical improvement frequently occurred even when associated reflux was left untreated. Therefore, obstruction appears to have an important role in clinical expression of chronic venous insufficiency, particularly in production of pain.

Of interest, half of limbs with active ulcer healed after iliac vein stent placement alone. Median duration of venous stasis ulcer disease was 14 months. Most patients had exhausted conservative treatment, such as ulcer dressings, compression stockings, and Unna boot application, before stenting, without healing of the ulcer. The same treatment continued postoperatively. It is unlikely that continued treatment alone would lead to ulcer healing without stenting. Why ulcers heal and other symptoms abate after stent placement alone, despite untreated residual reflux, is unknown. There was no measurable hemodynamic improvement with present techniques to explain this outcome.

It has been perceived that when proximal outflow obstruction is relieved, axial retrograde reflux through the distal incompetent valves increases. However, ambulatory venous pressure, venous refilling time, and venous filling index did not worsen after stent insertion in patients with preoperative reflux. Although reflux remained, symptoms improved. Thus removal of iliac vein outflow obstruction did not result in increased axial reflux with clinical deterioration in this patient cohort.

It would be preferable to direct treatment with physiologic testing, but inasmuch as such testing is unavailable, diagnosis and treatment must be based on morphologic investigations. Gratifying clinical results, relative simplicity and minimal invasiveness of stent placement, negligible morbidity, and improvement in quality of life[10] after stenting, in our opinion, justify a more aggressive approach toward diagnosis and treatment of morphologic iliac venous outflow obstruction. Duplex Doppler ultrasound scanning has become the mainstay and often the sole diagnostic method for chronic venous insufficiency in most centers. As currently used, however, it is insensitive to the diagnosis of iliac vein obstruction. Awareness and a high index of suspicion of iliac venous obstruction, combined with generous use of transfemoral venography and intravascular ultrasonography, are necessary for detection of borderline obstruction. The target population includes patients with clinical features (especially pain) out of proportion to detectable disease, patients with no other detectable basis for their symptoms, patients with symptoms with visualized pelvic collateral vessels, and patients with a history or ultrasound scan or venogram evidence of previous deep vein thrombosis. Venous stenting is evolving as the initial procedure of choice for treatment of morphologic iliac venous obstruction, with or without associated reflux. Open procedures such as bypass grafting and valve reconstruction may be considered as second-stage interventions in patients in whom stenting fails. Stent placement does not preclude subsequent open surgery. If superficial axial long saphenous vein reflux is present, percutaneous venous stenting may be combined with minimally invasive sealing of that vein with radiofrequency or laser therapy at one visit.[24,25] Any associated deep reflux is ignored pending clinical response to intervention. Although clinical stage is more severe with combined reflux and obstruction, correction of obstruction alone results in substantial clinical improvement, even with remaining reflux.

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