# The clinical impact of iliac venous stents in the management of chronic venous insufficiency

**Seshadri Raju, MD, Sam Owen, Jr, BS,** and **Peter Neglen, MD,** *Jackson, Miss*

***Purpose:*** **The purpose of this study was the presentation of the results of iliac venous stent placement in the management of chronic venous insufficiency (CVI).**
***Methods:*** **Balloon dilation and stent placement for the relief of iliac vein stenoses was performed in 304 limbs with symptomatic CVI. Sixty-one limbs had concomitant saphenous vein ablation. The median age was 52 years (range, 14 to 83 years). The ratio of postthrombotic to nonthrombotic CVI was 1 to 0.9. The CEAP classification clinical scores were: $C_2$, 24; $C_3$, 158; $C_4$, 60; $C_5$, 13; and $C_6$, 49. Associated reflux was present in 57% of the limbs. The procedure was performed on an outpatient basis. Intravascular ultrasound scanning was routinely performed because transfemoral venography had poor sensitivity for the detection of iliac vein stenosis.**
***Results:*** **The actuarial primary and secondary stent patency rates at 24 months were 71% and 90%, respectively. The median degree of swelling (graded 0 to 3, for none, pitting, ankle edema, to gross leg edema) declined from grade 2 to grade 1 after surgery ($P < .001$). The limbs without any swelling increased from 12% before stenting to 47% after stenting ($P < .01$). The pain level recorded on a visual analogue scale from 0 to 10 declined from a median level of 4 to 0 after stent placement ($P < .001$). The limbs that were completely free of pain increased from 17% before stenting to 71% after stent placement ($P < .001$). Stasis dermatitis/ulceration was present in 69 limbs. The improvement in swelling and pain was similar in ulcerated and nonulcerated limbs. The cumulative recurrence-free ulcer healing rate was 62% at 24 months. The rate of ulcer healing was similar whether or not concomitant saphenous ablation was performed. Quality of life has significantly improved.**
***Conclusion:*** **The correction of iliac vein outflow obstruction with the placement of stents results in the significant relief of major symptoms of CVI. The procedure is minimally invasive, can be performed on an outpatient basis, has minimal complications with a high patency rate, and does not preclude subsequent open surgery for the correction of restenosis or the associated reflux. If these preliminary results are sustained for a long-term period, stent placement for the correction of iliac vein stenoses may represent a useful advance in the management of CVI. (J Vasc Surg 2002;35:8-15.)**

The incidence rate of chronic venous insufficiency (CVI) in the general population is estimated to be 10% to 15%.[1] In recent years, significant advances in diagnostics, surgical technique, instrumentation, and devices have occurred. Despite these advances, the therapeutic benefit for most patients with CVI, particularly those with deep venous disease, has been limited because the more specialized techniques, such as valve reconstruction or bypass grafting procedures, are still largely confined to a few select centers. The rapid emergence of endovascular stent technology offers the prospect of quick widespread adoption for use in venous cases because the basic technique is already in broad use. Initial experience with this method indicates excellent patency and surprisingly high symptom resolution. Herein, we review our clinical experience with iliac vein stent placement. The scope of the manuscript will be restricted to the clinical outcome of the device. The aspects of patient selection, assessment, technique, hemodynamic features, and pathology have been described in detail elsewhere.[2-4] Only a brief description of some major points in these areas as relevant to the primary scope are provided where necessary in this presentation.

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Reprint requests: Seshadri Raju, MD, 1020 River Oaks Dr, Ste #420, Jackson, MS 39208 (e-mail rajumd@earthlink.net).

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## MATERIAL AND METHODS

Three hundred and four limbs (12 bilateral) in 292 patients underwent consecutive stent deployment for the correction of iliac venous stenosis at River Oaks Hospital during the period from December 1997 to November 2000. A prior group of 29 consecutive limbs underwent operation with a different stent technique and have been described elsewhere.[2] After those procedures, substantial modifications were made. Thus, those cases have been excluded from this study.

**Concurrent procedures.** Fifty-six limbs underwent stripping of the long saphenous vein (LSV) in the thigh (27 with stab avulsion of associated nontruncal varices), and five others underwent heat closure of the LSV with the radiofrequency probe. Together, these 61 limbs were grouped as a subset and designated as the stent + LSV group for outcome comparisons.

**Clinical presentation.** All the patients were seen with one or more of the following conditions: leg swelling (eight cases with recurrent cellulitis), leg pain, stasis skin changes, or ulcer. A detailed breakdown of clinical presentation and severity represented with CEAP classification is shown in Table I, *A*. The patients in the C2 category (varices) in this series had significant associated calf or

diffuse leg pain as well. Objective swelling was graded with physical examination in the following manner: grade 0, none; grade 1, pitting, not obvious; grade 2, ankle edema; and grade 3, obvious swelling involving the limb. A subjective scoring of swelling severity obtained with patient history on the basis of the time of appearance of the swelling during the work day as recommended in the Reporting Standards[5] was also implemented after its publication last year (grades 0 to 3: no edema, evening edema, afternoon edema, morning edema). The level of pain was measured with the visual analogue scale method.[6] The patient indicated the level of pain on a visual analogue scale (0 to 10) with the markings and numbers hidden to the patient but visible to the examiner. This method has been shown to be highly reliable in tracking pain level response to therapeutic intervention in the individual patient. The patients were asked to complete a quality-of-life questionnaire validated for the assessment of CVI[7] prospectively before stent placement and again at each follow-up clinic visit. The last available completed questionnaire for each patient was used in the assessment of this outcome measure. Numerical grades (1 to 5) were provided for each question that allowed the patient to assign a numeric value to the answers.

**Preoperative work-up.** The preoperative work-up included complete duplex scan venous examination, venous functional studies (ambulatory venous pressure, air plethysmography), and transfemoral venography. A complete hypercoagulability profile was obtained as a guide to the need for postoperative warfarin therapy, its strength and duration, but patients were not excluded if the test results were positive.

**Placement of venous stent.** Stent placement was recommended for significant clinical symptoms in patients whose conditions were refractory or intolerant to conservative therapy. Fully informed consent was obtained. The details of patient selection and stent placement technique have been described in full elsewhere.[2,3] Briefly, access to the iliac venous segment was obtained through ipsilateral femoral venous puncture at the mid-thigh level with ultrasound scan guidance. A low venipuncture site assured satisfactory access to the entire iliac venous segment and the adjacent common femoral vein without restriction by the sheath. Because the sensitivity of transfemoral venography for the identification of significant iliac vein stenoses was poor, intravascular ultrasound scanning (IVUS) was used for the identification or confirmation of treatable lesions before stent placement, often at the same session. After balloon dilatation, placement of venous stent was mandatory because recoil of the dilated stenosis otherwise occurred.[2,3,8,9] A 14-mm or 16-mm stent that corresponded to the size of the healthy undiseased iliac vein was uniformly used. The extension of the iliac stent into the inferior vena cava was shown from prior experience to be important to avoid development of iliac vein ostial stenosis.[2,3] In no instance did thrombosis of the inferior vena cava or the contralateral iliac vein occurr from this practice, even when the ipsilateral stent became thrombosed or occluded. The use of an adequate length of stent to cover all stenotic lesions and to avoid interval "skip areas" of native vein between closely adjacent (<5 cm) stents was necessary to avoid recurrent stenosis. The procedure was performed percutaneously on a 23-hour admit basis. The patients in this series underwent once-a-day aspirin therapy (81 mg) after the procedure. Warfarin therapy was instituted if a clearly hypercoagulable state was present, particularly with evidence of prior venous thrombosis. Patients with marginal titer abnormalities without prior venous thrombosis did not undergo warfarin therapy. In any case, warfarin therapy was continued if the patient was already on warfarin therapy for these or other indications. In such instances, warfarin therapy was supplemented with a twice-a-week dose of 81 mg each of aspirin.

**Follow-up examination.** The patients were seen at 6 weeks after the placement of the stent for clinical evaluation, transfemoral venography for the assessment of stent patency, and repeat venous functional studies. Thereafter, the patients were seen at 4-month to 6-month intervals for follow-up clinical examination. Clinical deterioration prompted repeat venography and venous functional studies.

**Data collection and statistics.** All the clinical data, including the severity scores, were contemporaneously entered at each patient visit into a time-stamped electronic medical record database and analyzed later for this manuscript. Nonparametric Wilcoxon signed rank test was used for the comparison of preoperative and postoperative values. Actuarial data have been used where appropriate for the presentation of results. Some variations in individual values for the various parameters will be noted because relevant data were missing in some limbs or because the parameter measurement was implemented mid course during the study period.

## RESULTS

There were no technical failures in stenotic lesions because all such lesions were successfully crossed and treated. Seventeen totally occluded iliac venous segments were successfully recanalized (included in this series), but four others were technical failures during the same time period (excluded from this series). There were no procedure-related complications, and the 6-week mortality rate was nil. Reintervention was required in 44 limbs because of restenosis (>50% stenosis with transfemoral venography/IVUS) in 39 limbs and occlusion in five limbs. Two limbs in the latter group (included in analysis as failed stents) subsequently underwent a Palma procedure for salvage after reintervention failed to restore patency.

The mean follow-up period was 9 months, and the range was 1 to 41 months. Follow-up data were available in 87% of the limbs.

The median age of the patients was 52 years (range, 14 to 83 years), the male to female ratio was 1:2, and the left to right ratio was 2:1. Hypercoagulability was present in 48 patients (16%) with the following conditions: protein C (14 cases, eight severe), protein S (16 cases, six severe), antithrombin III (14 cases, three severe), lupus

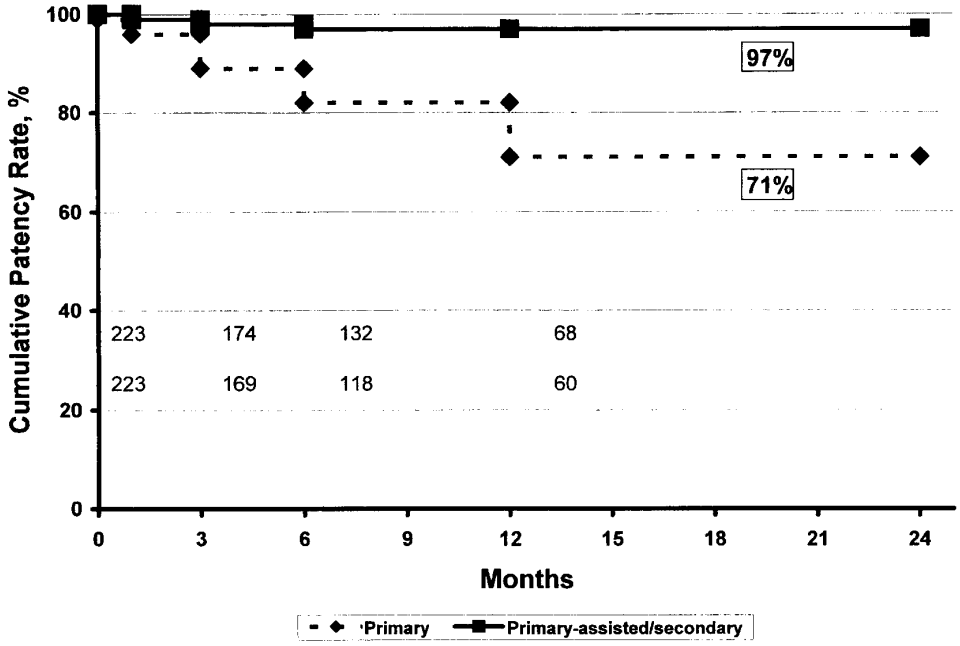


**Fig 1.** Actuarial patency rate (primary and primary assisted/secondary) of iliac venous stents. Limbs at risk at each interval for two categories are shown in *lower panel.*

anticoagulant (three cases), anticardiolipin antibody Igg (seven cases, three severe), anticardiolipin antibody Igm (six cases, three severe), factor V mutation (11 cases), homocysteinemia (eight cases, one with homocysteine gene), and prothrombin gene mutation (one case). In 32 patients, more than a single factor was involved. The common combinations were: anticardiolipin antibody and others, factor V mutation and others, and combinations of protein C, protein S, and antithrombin III deficiencies. The venous lesion was considered nonthrombotic (web, stricture, or May-Thurner syndrome) in 142 cases. A postthrombotic cause was apparent with venographic or IVUS examination results in 162 limbs (ratio, 0.9:1). Only one stent was needed in 61% of the limbs, two stents were needed in 27% of the limbs, and three or more stents each were needed in 11% of the limbs. One hundred and thirty-two patients had isolated obstruction, and 172 (57%) had associated reflux (deep system alone in 9% [n = 15], deep and perforators in 1% [n = 2], superficial system alone in 38% [n = 65], and a combination in 52% [n = 90]; Table I, *B*). Deep reflux thus was present in 35% of the entire group of 304 limbs. Forty-nine patients had open ulcers (C6), and in 13 cases, the recurrent ulcer was closed (C5) at the time of stent placement (Table II). There were seven additional limbs with stasis dermatitis/eczema included with C4 classification in Table IA as well. Associated reflux was present in 91% (63 of 69) of these limbs with various forms of venous stasis skin changes.

The actuarial patency rate of the stents is shown in Fig 1. Proof of patency/occlusion was on the basis of initial post-stent transfemoral venographic results (n = 223) and subsequent duplex scan/venographic follow-up examination results.

Primary and primary assisted/secondary patency rates (corrective intervention for stenosis/thrombosis) were 71% and 97%, respectively, at 24 months. There was no correlation between hypercoagulable state and stent occlusion/stenosis.

The incidence rate of ulcer healing after stent placement is also shown in Table II and in actuarial form (62% at 2 years) in Fig 2. None of the closed ulcers recurred during the follow-up period. Seven limbs with venous dermatitis/eczema included with C4 classification had their skin lesions resolved.

Swelling and pain severity scores improved significantly after stent placement (Tables III and IV).Both the subjective and objective severity scores for swelling improved. Of note, limbs that were free of any objective swelling increased from 12% to 47% ($P < .001$) and limbs that were totally free of pain increased from 17% to 71% ($P < .001$) after stent placement. Recurrent cellulitis resolved in all eight limbs with this type of primary presentation.

Because a stasis ulcer by itself can be the source of pain and local swelling apart from that caused by the iliac vein stenosis, these outcome measures were separately analyzed for ulcerated and non-ulcerated limbs (Table V). These outcome measures improved significantly ($P < .001$) after stent placement in both subsets. It is noteworthy that pain severity was the same and swelling was actually worse in the non-ulcerated limbs as compared with the ulcerated limbs. This highlights the important

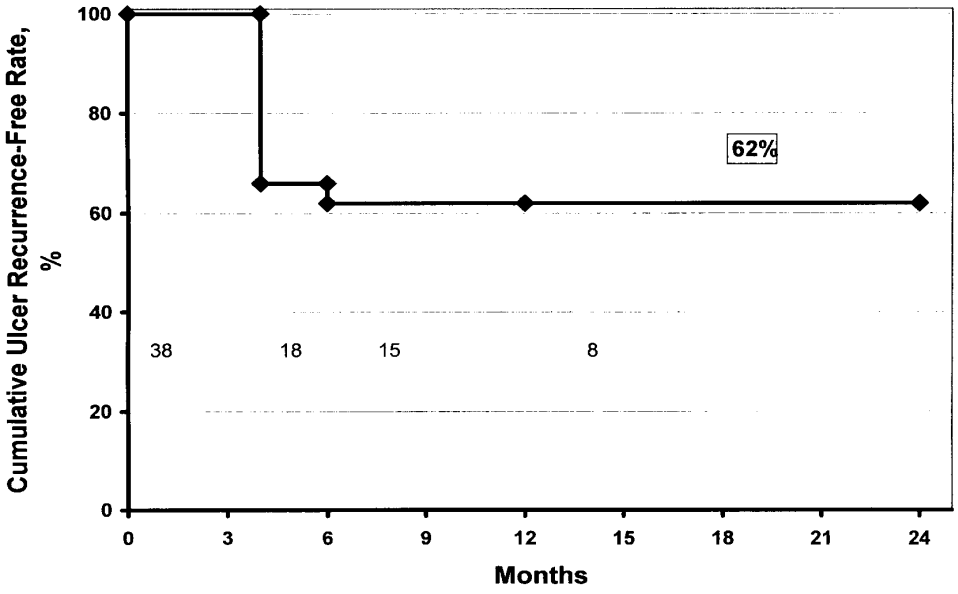


**Fig 2.** Actuarial ulcer-free interval after stent placement. Only ulcers that were active (C6) at time of stent insertion are included. Grace period of 4 months for ulcer healing was allowed in constructing curve. Ulcers that did not heal within time period were scored as unhealed for first time at 4 months. Limbs at risk at each interval are shown at *lower panel.* See Table II for data on all limbs with severe skin changes (C4, C5, and C6).

**Table I, *A*.** Clinical severity (CEAP classification) of symptoms in 304 limbs with CVI

| | *Clinical severity* | | | | |
|---|---|---|---|---|---|
| | *C2* | *C3* | *C4** | *C5* | *C6* |
| Asymptomatic | 3 | 29 | 1 | 1 | 4 |
| Symptomatic | 21 | 129 | 59 | 12 | 45 |
| Total number | 24 | 158 | 60 | 13 | 49 |

*Includes 53 limbs with hyperpigmentation and seven limbs with stasis dermatitis/eczema.

**Table I, *B*.** Anatomy involvement and type of pathology

| | *Deep system* | *Super/deep system* | *Deep/perforator* |
|---|---|---|---|
| Reflux/obstruction | 15 | 155 | 2 |
| Obstruction only | 132 | 0 | 0 |
| Total number | 147 | 155 | 2 |

contribution of non-ulcer pain and swelling in symptomatic iliac vein obstruction.

**Concurrent long saphenous vein stripping (stent + long saphenous vein).** Improvement in swelling, pain, or ulcer healing was similar and significant in this group after stent placement, whether or not an ulcer was present, and there was no difference in these outcome measures when stent placement was performed alone without LSV ablation (Table VI). Notably 58% of ulcers healed after stent placement alone as compared with 54% in the stent + LSV group (*P* value was not significant).

**Quality of life.** After stent placement, patients (n = 136) experienced improved quality of life in all major categories addressed in the questionnaire. The categories were subjective pain, sleep disturbance, morale, and social activities, routine and strenuous physical activities ($P < .025$ or better for each category).

## DISCUSSION

Approximately 17% of all the limbs evaluated for CVI in our clinic currently undergo stent placement.[4] It appears that the real incidence rate of obstructive lesions in CVI

**Table II.** Limbs (n = 62) with active ulcer or healed previous ulcer (C5 + C6)

| | *Active ulcer (n = 49)* | *Healed ulcer (n = 13)* |
|---|---|---|
| Median follow-up period (months) | 7 (range, 2 to 35) | 9 (range, 2 to 23) |
| Number of limbs for follow-up examination | 41 (84%) | 12 (92%) |
| Healed | 28 (68%)* | – |
| Improved | 8 (16%)* | – |
| Recurred | 2 (4%)* | 0 |
| Unchanged | 5 (12%)* | – |

Seven other limbs with stasis dermatitis/eczema (included in C4) healed after stent placement.
*Percentage of limbs that underwent follow-up examination.

**Table III.** Improvement in swelling after stent placement

| *Parameter* | *Grade* | *Before stent placement* | *After stent placement* |
|---|---|---|---|
| Objective swelling | Grade 0 (no swelling) | 36 of 297 (12%) | 124 of 264 (47%)* |
| | Grades 1 to 3 (swelling; median) | 2 (range, 0 to 3) | 1 (range, 0 to 3)† |
| Subjective swelling | Grades 0 to 3 | n = 62 | n = 62 |
| | Median | 2 (range, 0 to 3) | 1 (range, 0 to 3)† |

See text for description of grades 1 to 3.
Grade 0: no swelling for both subjective and objective swelling.
*$P < .01$.
†$P < .001$.

**Table IV.** Level of pain before and after stent placement

| *Pain severity* | *Before stent placement* | *After stent placement* |
|---|---|---|
| Limbs with no pain | 49 of 291 (17%) | 185 of 261 (71%)* |
| Limbs with pain (pain level, 0 to 10; median) | 4 (range, 0 to 9) | 0 (range, 0 to 9)* |

See text for description of pain level.
*$P < .001$.

may be much higher than generally suspected because the traditional diagnostic techniques, such as ascending phlebography, are poorly sensitive in the identification of these lesions. The current trend towards increasing reliance on duplex scanning to the exclusion of phlebography in the investigation of CVI is likely to further worsen the already low detection rate of these lesions. A high index of suspicion along with the complete investigation of patients with CVI, including use of relevant invasive diagnostic techniques when appropriate (patients with significant pain, swelling, or stasis skin changes), is responsible for the noted high detection rate of obstructive pathology in our own practice. Patients with CVI, particularly those with postthrombotic variety, are seen with symptom severity that is often disproportionately high as compared with the meager clinical signs present. It is easy to underestimate the morbidity in terms of pain and limb discomfort experienced by these patients unless a targeted history with a severity scale is used for assessment(Table V). For the same reasons, workplace disability from this affliction is much higher than generally recognized.[10]

The relief of iliac venous obstruction with balloon dilation and stent placement clearly relieves in the short term the major symptoms of CVI, with significant resolution of pain, swelling, stasis dermatitis, and even ulceration. Quality of life is improved. Stent placement is a minimally invasive procedure performed on a short hospital stay basis, and the recuperative time is negligible. Stent patency rate is high, and the morbidity rate is low. For these reasons, it is a superior choice over open surgery, such as a veno-venous bypass grafting, when either choice is available in the clinical setting. Furthermore, subsequent open bypass grafting surgery is not precluded if the stent were to fail with thrombosis or development of restenosis. Valve reconstruction can be performed, as well, for the correction of associated reflux. Because of its relative simplicity as compared with invasive surgery, venous stent placement has the potential to reach and benefit a larger group of patients with CVI, particularly those with postthrombotic disease, than is currently the case with the more complex bypass grafting or valve reconstruction techniques. Some caveats, however, are in order. Because the technology is new, the cost of endovascular supplies, particularly that of the stent, is relatively high; moderation of costs as the result of an increase in the number of supply sources and other factors is expected in the near future.

**Table V.** Objective swelling and pain severity in limbs with and without ulcer

| | *Before stent placement* | | *After stent placement* | |
|---|---|---|---|---|
| | *Objective swelling* | *Pain* | *Objective swelling* | *Pain* |
| Limbs with ulcer (n = 62) | | | | |
| Severity, grade/level (median) | 1 (range, 0 to 3) | 4 (range, 0 to 9) | 0 (range, 0 to 3) | 0 (range, 0 to 10) |
| Limbs with no pain or objective swelling | 14 of 62 (23%)* | 13 of 62 (21%) | 31 of 53 (58%) | 39 of 51 (76%) |
| Limbs without ulcer (n = 242) | | | | |
| Severity, grade/level (median) | 2 (range, 0 to 3) | 5 (range, 0 to 9) | 1 (range, 0 to 3) | 0 (range, 0 to 9) |
| Limbs with no pain or objective swelling | 24 of 237 (10%)* | 39 of 232 (17%) | 93 of 211 (44%) | 146 of 210 (70%) |

See text for description of severity levels.
Limbs without ulcer had significantly higher median grade of swelling and less number of limbs with no swelling (10% versus 23%) before stent placement than did ulcerated limbs ($P < .001$), and pain level was same. Both outcome measures improved significantly in both groups after stent placement ($P < .001$).
*$P < .001$.

**Table VI.** Outcome measures when stent placement was performed with or without long saphenous vein ablation

| | *Before stent placement* | | *After stent placement* | | |
|---|---|---|---|---|---|
| | *Objective swelling* | *Pain* | *Objective swelling* | *Pain* | *Ulcer* |
| Limbs with ulcer | | | | | |
| Stent + LSV (n = 12; severity grade/level [median]) | 1 (range, 0 to 3) | 3 (range, 0 to 8) | 0 (range, 0 to 1)* | 0 (range, 0 to 0)‡ | 6 of 12 (50% healed) |
| Stent only (n = 37; severity grade/level [median]) | 1 (range, 0 to 3) | 4 (range, 0 to 9) | 0 (range, 0 to 3)* | 0 (range, 0 to 10)‡ | 22 of 37 (59% healed) |
| Limbs without ulcer | | | | | |
| Stent + LSV (n = 49; severity grade/level [median]) | 1.5 (range, 0 to 3) | 5 (range, 0 to 8) | 0.5 (range, 0 to 3)† | 0 (range, 0 to 8)‡ | |
| Stent only (n = 190; severity grade/level [median]) | 2 (range, 0 to 3) | 5 (range, 0 to 9) | 1 (range, 0 to 3)‡ | 0 (range, 0 to 9) ‡ | |

Addition of long saphenous vein ablation does not appear to influence objective swelling grade or pain level outcome in limbs with or without stasis ulcer. Ulcer healing also appears unaffected. See text for description of severity/grade level.
*$P < .05$.
†$P < .01$.
‡$P < .001$.
*LSV,* Long saphenous vein.

The high cost of interventional therapy has to be balanced against the comparatively low but recurrent and on-going costs cumulative over the long term of medications, supplies, and healthcare personnel involved in conservative therapy, including the management of complications and the staggering indirect costs of work hours lost.[10] The long-term (>10 years) effects of stents in the venous system are not known. The follow-up period is short, and many more years of monitoring are required for the assessment of the efficacy of this therapeutic method in CVI. The results presented in this study can be considered only preliminary. However, follow-up periods for cases in the early part of this series have now extended beyond 3 years and the clinical benefits appear to have been maintained without precipitous degradation. Cautious optimism for this technique therefore appears to be warranted. Regarding the concern for long-term effects, the experience with vena cava filters may be relevant. These devices are not opitimized for laminar flow (unlike the stents), with most designs presenting a chunk of metal to central flow, creating flow turbulence; they have little prospect of endothelial coverage, and they are often inserted in the context of ongoing thrombotic event with simultaneous stoppage of heparin therapy. Yet the patency rate of the filter insertion site has exceeded 90% up to years.[11]

Although the technique is minimally invasive, it is not implied that it is simple. Our technique, as briefly summarized here and described in greater detail elsewhere,[2,3] was empirically derived from an initial experience of 29 limbs[2] with more complications and a markedly higher restenosis rate than in subsequent series. Some of the complications in the earlier series were undoubtedly related to the learning curve; substantial technical modifications since have been made in placement of the stent. Morbidity rates and technical outcomes have greatly improved since. It is not known for certain which of these modifications are central to the improved outcome. The use of ultrasound scan guidance for femoral vein access has eliminated complications related to inadvertent arterial puncture. Use of a large stent (14-mm to 16-mm), extension of the stent into

the vena cava, and use of intraoperative IVUS for the detection and treatment of all stenotic areas in the iliac venous segment are believed to be important technical details in the reduction of the incidence rate of restenosis. IVUS is invaluable both in diagnosis and as an intraoperative tool in stent placement because contrast venography even with the transfemoral approach has poor sensitivity in the assessment of the iliac venous segment.

Thirty-six percent of the limbs in this series had associated deep reflux with the obstruction. Relief of obstruction did not worsen clinically manifested reflux by opening up the axial channel as has been feared. On the contrary, healing occurred in the vast majority of cases in this series with stasis dermatitis or ulceration commonly attributed to the reflux component. Ninety-one percent of the limbs with ulcers/dermatitis reported here had associated reflux. We speculate that the correction of the proximal outflow obstruction in combined obstruction/reflux allows for the residual reflux to be more easily tolerated. It remains to be seen if the initial ulcer healing seen in this series will be durable over time without the need for additional valve reconstruction. Our clinical impression is that swelling and pain of CVI resolve more rapidly and thoroughly than with valve reconstruction. For the time being, the use of valve reconstruction procedures in our own practice have sharply declined since the adoption of stent placement in eligible limbs when either choice is available.

Surprisingly, nearly half the cases in this series were classified as nonthrombotic in cause on the basis of intraoperative IVUS findings. It appears that strictures, webs, membranes obstructions, and May-Thurner syndrome are more common causes of venous obstructive symptomatology than generally believed. These lesions have been implicated in the preponderance of the left lower limb in acute and chronic venous pathology.[12-14] Better diagnosis of these high-grade short length obstructive lesions is dependent on the use of IVUS because traditional contrast venography has poor sensitivity in the assessment of the iliac venous segment for these lesions.[4] On the basis of this preliminary experience, iliac venous stent placement appears to be a useful method in the management of patients with CVI.

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## DISCUSSION

**Dr Thomas F. O'Donnell, Jr** (Boston, Mass). Thank you, Dr Raju, for e-mailing the various iterations of your manuscript, which presents the largest experience in the literature on the treatment of iliac vein occlusive lesions. I think that in this series you've shown that about half were due to standard postthrombotic occlusion, the type that we generally treat surgically with a saphenofemoral or Palma procedure.

The high symptomatic relief of swelling and pain and the overall low morbidity for stent placement are quite attractive for this technique. As you emphasized, however, about 14% of your stent placements required reintervention. By contrast, venous stenting is a procedure that doesn't burn any bridges. I have several comments and questions.

As you presented, you are appropriately cautious in recommending this form of therapy as the be-all and end-all for iliac vein lesions. I would echo this caution, but, like you, am intrigued with your early good results. I have some concerns, however, about the brevity of the follow-up period, which averaged only 9 months. In addition 13% of the limbs were lost to follow-up, which is another factor that could bias results. Do you have the following data not available in the manuscript: (1) the median follow-up time and (2) reasons for the loss of 40 limbs to follow-up in such a short period of time.

Secondly, for a group that has championed the hemodynamic evaluation of iliac vein obstruction, and indeed have developed a specific objective test for it, the "Raju test," I was really surprised not to see any mention of preoperative hemodynamic values in this manuscript. All of us appreciate that patients with leg "pain" are the most difficult ones to sort out. With a catheter in place in the iliac vein, did you obtain baseline and post-hyperemic pressures?

Finally, you appear to have mixed apples and oranges in your manuscript. The iliac vein occlusion patency data were presented with the iliac stenosis data. Do you have data specifically on the limbs with postthrombotic occlusion alone?

I enjoyed your conclusions, with which I agree; the follow-up is short, and time will tell.

**Dr Seshadri Raju.** We started performing iliac venous stents 4 years ago. As the initial results were good, the volume has increased substantially in the last 2 years. This skewed distribution has resulted in a short median follow-up. Many of the earlier patients are now beyond 3-year follow-up. It appears that there is no precipitous degradation of the early good results. We are cautiously optimistic that the long-term results of the entire series will mirror the experience in the early subset. The follow-up rate is 87%. Unfortunately, the percutaneous nature of the procedure in an outpatient setting has engendered the feeling in some patients that the procedure was minor. This misconception combined with speedy resolution of symptoms has resulted in follow-up delinquency.

We have reported on the hemodynamic aspects of the procedure, including intraoperative femoral pressure measurements and pull through gradients in detail elsewhere. These tests are positive in only about a third of patients. It appears that this is a reflection of the poor sensitivity of these pressure-based tests to identify significant outflow obstruction. Criteria validated in the arterial system may not apply in the venous circuit. For example, the contralateral iliac vein flow certainly tends to neutralize or mask the gradient of iliac vein stenosis. We do not know what a flow limiting or critical venous stenosis is and if such a concept is even valid in the venous system.

Seven percent of limbs in this series (17 limbs) had total iliac occlusions; the rest were stenoses. There were some minor differences between these two subsets, but overall the clinical results appear to be substantially similar.

**Dr Harry R. Schanzer** (New York, NY). The question that I have has to do with selection. It's well known, at least from bypass venous surgery, that in order to have good results you need really obstructive pattern. I am sure that what you call obstructive/refluxive are patients that have reflux, but they still also have obstruction in terms of high pressure distally, low pressure proximally, so that blood flow can go through the stent and not thrombose. Did you see any difference in results between those obstructive/ refluxive and the poor obstructive cases?

Second, have you used any ancillary method like AV fistula to improve patency?

And lastly, are bypasses, like the Palma procedure, out?

**Dr Raju.** We did not see any difference between pure obstruction and combined obstruction/reflux limbs.

Palma type of veno-venous bypasses have precipitously declined in our practice. They are now used only as salvage procedures when the initial stent procedure had failed. As the patency rate of iliac venous stent is very high, we have not felt the need to use adjunctive AV fistula. Among the small number of stents that have occluded, we have not been able to identify any specific predictive factors to consider selective use of AV fistula.

**Dr Ali F. AbuRahma** (Charleston, WVa). We presented our experience in the Southern Surgical last January and it appears in the *Annals of Surgery* just this month. It's not as large a series as yours, but our cumulative patency rate of a series of iliac vein PTA stenting was 69% over 5 years. It's much longer duration than yours. But our series was much shorter. We also were somewhat selective. What I have not seen in your presentation, which you might have it in your manuscript, have you compared the preoperative clinical severity score with the postoperative score? I think that's more objective data we could rely on.

**Dr Raju.** The data presented pertained to severity scores for specific clinical features such as pain, edema, etc. Overall clinical severity score and outcome based on reporting standards also significantly improved.

**Dr Frank T. Padberg, Jr** (Newark, NJ). I have two questions for you. The first has to do with your quality-of-life measures, of which there are four fairly well validated instruments available for use: The CIVIQ from Europe; the Aberdeen varicose vein questionnaire; one from this country presented to this Society 2 years ago by Tony Comerota which had to do with iliofemoral thrombolysis; and another, specifically dealing with the ulcer and its effect on quality of life. Were any of these used? And if so, which?

The second question has to do with ulcer evaluation during follow-up. While ulcer healing is often a function of attention to dressings and compliance with local care, the real key is prevention of recurrence! And here, even with a very short follow-up, a mean of 9 months, you've shown us a 64% recurrence rate. Unfortunately, your slide flashed by so fast I couldn't see at what interval of time the ulcer recurrence was noted; however, I would note that that 60% is similar to the 5-year results reported for compliant patients with elastic compression stockings. Thus, I would ask you to compare recurrence of ulcer rather than healing, since that probably is a more meaningful measurement of successful management options.

**Dr Raju.** We used the CIVIC quality of life questionnaire. This was among the first such questionnaires to be validated for use in chronic venous insufficiency and was approved by the European Consensus Conference headed by Nicolaides. We started using it routinely 5 years ago before others you referred to became available.

The cumulative ulcer-free rate—not recurrence—was 64% at 2 years. The stent procedure was not specifically directed toward the ulcer, but rather the companion symptoms of pain and swelling. The high ulcer healing rate was therefore quite a surprise and a pleasant byproduct. We have stopped prescribing new stockings if the patient was not already wearing them, and we encourage patients to abandon restrictive support use after the stent procedure if they can tolerate it. The majority are free of stockings.