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## Balloon Dilation and Stenting of Chronic Iliac Vein Obstruction: Technical Aspects and Early Clinical Outcome

Peter Neglén, MD, PhD; and Seshadri Raju, MD

River Oaks Hospital, Jackson, Mississippi, USA

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**Purpose:** To describe the technical aspects of percutaneous balloon dilation and stenting for the treatment of venous outflow obstruction in chronic venous insufficiency.

**Methods:** Between March 1997 and December 1998, 94 consecutive patients (median age 48 years, range 14 to 80) with suspected iliac vein obstruction in 102 limbs were studied prospectively with the intent to treat any venous occlusion or stenosis verified during femoral vein cannulation. Data from the history, clinical examination, procedure, and follow-up were recorded. Preoperative indicators of obstruction were venographic evidence of occlusion, stenosis, or pelvic collateral vessels; increased arm-foot venous pressure differential; and abnormal hyperemia-induced venous pressure elevation.

**Results:** Cannulation and technical success rates were 98% and 97%, respectively, with 118 Wallstents deployed in 77 veins. Primary, assisted primary, and secondary patency rates at 1 year were 82%, 91%, and 92%, respectively. Clinical improvement in pain and swelling was significant.

**Conclusions:** Stenting of benign iliac vein obstruction is a safe method with good short-term results. Venous lesions should always be stented; when treating ilio caval junction lesions, stents should be inserted well into the inferior vena cava. Absence of collateral vessels does not exclude the existence of significant obstruction, and their presence may indicate an obstruction not visualized. No gold standard for accurate pre- or intraoperative patient selection is currently available.

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**Key words:** postthrombotic disease, May-Thurner syndrome, occlusion, venous pressure, intravascular ultrasound

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Chronic venous insufficiency of the lower extremity is a complex disease with several etiological factors. The most important contributors are valve incompetence with reflux, outflow obstruction, and a poor calf muscle pump. In approximately one third of limbs

with postthrombotic disease, an obstructive component is predominant.<sup>1,2</sup> A primary iliac vein obstruction, May-Thurner syndrome,<sup>3</sup> and iliac vein compression syndrome<sup>4</sup> have been described. The condition is more commonly seen in females, whose main symptoms are limb pain and swelling.

The treatment of outflow obstruction has been hampered by difficulty in identifying hemodynamically significant obstruction,<sup>5,6</sup> compounded by the fact that only invasive surgical techniques have been available.<sup>7</sup> These major surgical procedures, crossover

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Address for correspondence and reprints: Peter Neglén, MD, PhD, 1020 River Oaks Drive, Suite 480, Jackson, MS 39208 USA. Fax: 1-601-664-6694; E-mail: [pepane@hotmail.com](mailto:pepane@hotmail.com)

femorofemoral or axial ilio caval bypass grafting, are often combined with a temporary or permanent arteriovenous fistula. The necessity for long-term anticoagulation makes this treatment plan even less attractive to patients.

The development of endovascular procedures has revolutionized the diagnosis and treatment of venous outflow obstruction. In this study, we evaluated the technical aspects, immediate outcome, and complications of venous balloon dilation and stenting. We also attempted to analyze intraoperative techniques for diagnosing significant iliac outflow obstruction.

## METHODS

### Protocol and Patient Evaluation

Between March 1997 and December 1998, 94 consecutive patients (54 women; median age 48 years, range 14 to 80) with suspected iliac

vein obstruction in 102 limbs were studied prospectively with the intent to treat any venous occlusion or stenosis verified during femoral vein cannulation. A thorough history and clinical examination included the use of an analogue pain severity scale ranging from 1 to 10, in which 10 was the most severe pain. The clinical score of pain and swelling was assessed according to the guidelines of the Society for Vascular Surgery/North American Chapter of the International Society for Cardiovascular Surgery (SVS/ISCVS).<sup>8</sup>

The left lower extremity was more frequently involved (74/102, 73%). The presenting limb complaints were active (19, 19%) or healed (5, 5%) ulcer; lipodermatosclerosis, pigmentation, or dermatitis (11, 11%); swelling (65, 64%); and pain or discomfort (2, 2%). Concomitantly, 32 (34%) patients had severe pain (>5 on the analogue pain severity scale) and required analgesics. Only 12 (13%) patients denied any pain. Typically, a dependent pain was described, but 3 patients had symptoms of venous claudication. In addition, 90 (96%) patients complained of swelling.

Forty-three (42%) limbs had no history of deep vein thrombosis (DVT) nor any venographic or ultrasound findings indicating previous thrombosis. The iliac obstruction was considered the primary etiology in these patients. The remaining 59 patients had verified postthrombotic disease. Important and possibly contributory concomitant disease was found in 41 patients: thrombophilia in 12 (protein S deficiency in 5, protein C deficiency in 6, and activated protein C resistance in 1); morbid obesity in 13; lymphatic dysfunction in 8; and previous leg injury or knee surgery in 8.

Comprehensive testing prior to intervention included ascending, descending and antegrade transfemoral venography; ambulatory venous pressure measurement; hand-foot vein pressure differential at rest and after tourniquet-induced hyperemia; air plethysmography; and erect duplex Doppler investigation with standardized compression.<sup>9,10</sup>

Using the SVS/ISCVS guidelines,<sup>8</sup> the lower extremities were stratified according to clinical signs, etiology, anatomical distribution, and pathophysiological condition (CEAP classification) (Table 1). The deep system alone

Category	No. of Patients
<b>Clinical Grade</b>	
Asymptomatic	
2	0
3	8
4	0
5	0
6	0
Symptomatic	
2	2
3	57
4	11
5	5
6	19
<b>Etiology</b>	
Primary	43
Secondary	59
<b>Anatomy</b>	
Deep	60
Perforator	2
Superficial/deep	38
Unknown	2
<b>Pathophysiology</b>	
Obstruction	48
Reflux	5
Reflux/Obstruction	45
Unknown	4

**Table 2**  
Hemodynamic Parameters of 102 Lower Extremities

Type of Investigation	All Limbs (n = 102)	Postthrombotic Disease (n = 59)	Primary Disease (n = 43)
Ambulatory venous pressure drop (%)	50 ± 17	49 ± 16	56 ± 13
Venous filling time (s)	35 ± 35	23 ± 23	54 ± 39
Venous filling index <sub>90</sub> (mL/s)	2.7 ± 2.8	3.8 ± 3.0	1.6 ± 1.4
Hand-foot pressure differential (mm Hg)	1.8 ± 1.8	1.7 ± 1.7	1.4 ± 1.4
Hyperemia pressure rise (mm Hg)	5.8 ± 6.0	6.3 ± 6.8	5.7 ± 4.5
Multisegment score (0-6)	1.6 ± 1.7	2.6 ± 1.7	0.5 ± 0.7
Axial reflux score (0-4)	1.1 ± 0.6	1.8 ± 1.6	0.0 ± 0.2

Values are mean ± SD.

was involved in 60 (59%) lower limbs; the majority of these (50/60, 83%) had only obstruction. The 10 (17%) remaining lower extremities had a combination of reflux and obstruction. Combined pathophysiology was present in 45 (44%) limbs; regardless of anatomic involvement. The results of hemodynamic testing (Table 2) reflected the higher rate of concomitant reflux observed in the postthrombotic versus primary disease limbs.

Preoperative indicators of obstruction were occlusion or obvious stenosis on ascending or antegrade transfemoral venography, increased arm-foot venous pressure differential or abnormal hyperemia-induced venous pressure elevation,<sup>11</sup> and presence of pelvic collateral vessels on venography. One or any combination of these indicators (Table 3) was justification for intervention. Positive preoperative pressure measurement was present in 42 (41%) limbs and radiological obstruction in

72 (71%). Collateral vessels were visualized in 63 (62%) limbs.

### Procedure

The authors performed all interventions in a dedicated intervention room within the surgical suite. The room was equipped with ceiling-mounted C-arm imaging equipment (International Surgical Systems, Inc., Phoenix, AZ, USA). The procedures were performed under general anesthesia or local infiltration analgesia in combination with monitored sedation. The patients received 5000 units of heparin and 30 mg of ketorolac tromethamine intravenously during the procedure.

Initially, cannulation of the femoral vein was blind, but ultrasound guidance (Site-Rite Mark II 21000 Series, Dymax Corp., Pittsburgh, PA, USA) was added later. After cannulation and insertion of a Pinnacle sheath

**Table 3**  
Indicators of Obstruction in 102 Patients

Primary Indicator	Combination
Iliac outflow occlusion (n = 5)	Alone (n = 2) With collateral vessels (n = 1) With collateral vessels/pressure positive (n = 2)
Iliac vein stenosis (n = 67)	Alone (n = 20) With pressure positive (n = 11) With collateral vessels (n = 25) With collateral vessels/pressure positive (n = 11)
Pressure positive (n = 18)	Alone (n = 6) With collateral vessels (n = 12)
Collateral vessels (n = 12)	Alone (n = 12)

(Terumo Medical Corporation, Somerset, NJ, USA), an antegrade venogram was performed. Intravascular ultrasound (IVUS) interrogation (SONOS Intravascular Diagnosis System M2400A, Hewlett-Packard, Andover, MA, USA) with a 6-F, 12.5-MHz imaging catheter (Sonicath Ultra 6, Boston Scientific Corp., Watertown, MA, USA) followed. Degree, length, and site of obstruction were recorded, and the presence and type of collateral vessels were noted.

If possible, pull-through pressure recording from the inferior vena cava (IVC) to the femoral vein was then obtained using standard equipment. Femoral pressure distal to the presumed obstruction was obtained before and after intra-arterial injection of papaverine (30 mg) to increase venous flow.<sup>12</sup> Atrial waves and respiratory variations of the pressure curve were recorded.

If a significant obstruction was found, a 12- to 20-mm  $\times$  4- to 6-cm balloon catheter (Mediatech XXL, Boston Scientific/Medi-tech, Natick, MA, USA) was delivered to the site and dilated; the degree of waisting on the balloon was noted. The venogram and IVUS were repeated to measure any recoil. No stent was inserted when (1) the stenosis was  $<25\%$  on IVUS, (2) only minimal or no waisting occurred on balloon dilation, or (3) the dilated vein did not recoil. In veins not meeting any of these criteria, a Wallstent (Schneider, [USA] Inc., Minneapolis, MN, USA) of appropriate length and diameter was delivered to the target site and deployed. The venogram, IVUS, and pressure measurements were repeated to assess the result. The sheath was removed and pressure applied for 10 minutes.

Postoperatively, a foot compression device was used; dalteparin sodium (2500 units) was administered subcutaneously twice daily, and the ketorolac injection was repeated the next morning before discharge. Aspirin (81 mg daily) was started immediately after the procedure and continued indefinitely. Only patients on warfarin preoperatively were anticoagulated postoperatively (warfarin was not routinely discontinued before the intervention). Patients were usually discharged within 24 hours. The patients were followed clinically after 6 weeks and within 12 months with as-

ending/antegrade transfemoral venography and functional studies.

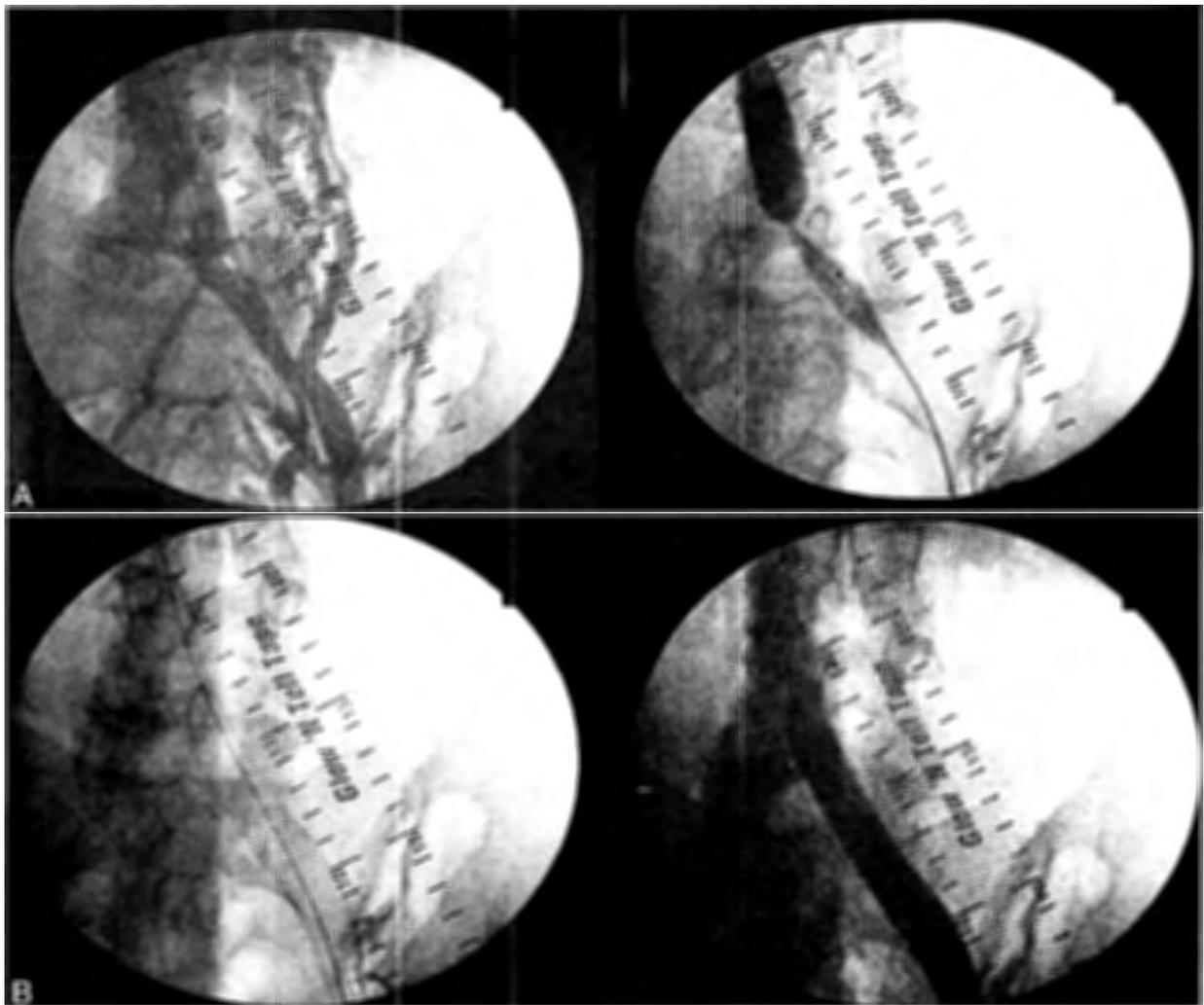
### Definitions and Statistical Analysis

Acute treatment success was defined as residual stenosis  $<25\%$  and abolition of the pressure gradient. Clinical failure was defined as occlusion or restenosis  $>50\%$  on venography. Continued clinical success was freedom from occlusion, restenosis, or worsened clinical status. Wilcoxon rank sum paired and unpaired nonparametric tests were used in the appropriate setting to evaluate statistical significance. A  $p$  value  $<0.05$  was considered significant. Primary, assisted primary, and secondary patency rates were calculated using survival analysis with the Kaplan-Meier method. Values are presented as the mean  $\pm$  standard deviation unless otherwise noted.

## RESULTS

The femoral vein of all 102 lower extremities was cannulated, but in 2 limbs, the guidewire could not traverse the occlusion to reach the IVC, so the procedure was abandoned (98% cannulation success). The intraoperative venogram, IVUS images, and pressure measurements were completely normal in 13 (13%) limbs; no obstruction could be identified. Balloon dilation alone was performed in 10 (10%) lower extremities, while balloon dilation was combined with stent implantation in 77 (75%) limbs (Fig. 1). From 1 to 6 stents (total 118) were deployed in the 77 vessels (Table 4). The median length of the stented area was 8 cm (range 4 to 25); the median stent diameter was 16 mm (range 10 to 20). The most common site for stent implantation was the common iliac vein.

Among the 87 treated limbs, 3 (3%) had a residual partial narrowing of a tight stenosis at the ilio caval junction with a pressure gradient after stenting, giving a technical success rate of 97%. In 7 patients, the dilation and stenting was combined with stripping of the long saphenous vein. One patient had the procedure with an adjuvant temporary arteriovenous fistula.



**Figure 1** ♦ (A) Venogram and balloon dilation of a postthrombotic iliac vein. Left: generally narrowed iliac vein with ill-defined multiple stenoses. Several collateral vessels are seen. Right: definite waisting of the balloon showing tight stenosis at the iliocaval junction. (B) Left: the stent after deployment and secondary balloon dilation. Right: completion venogram shows no outflow obstruction nor filling of previously visualized collateral vessels.

### Intraoperative Observations

In 12 limbs, no venographic narrowing was identified, typically when there was a broadening of the common iliac vein at the arterial crossing on the left side. Intravascular ultrasound, however, detected a very tight, short narrowing in all cases (Fig. 2). The mean stenosis measurement by venography was  $50\% \pm 36\%$ , compared to  $68\% \pm 23\%$  with IVUS ( $p < 0.0001$ ). Obvious waisting of the balloon on inflation, indicating resistance at the narrowed portion of the vein, was found in 80

(92%) of the 87 limbs. Minimal change was observed in 3 (3%) and no waisting in 4 (5%).

The intraoperative venogram showed venous collateralization in 63 (72%) treated limbs. Transpelvic collateral vessels were most common (57 patients, 66%), followed by a visualized ascending lumbar vein (14, 16%) and paravertebral (8, 9%) or axial collateral (8, 9%) vessels. After balloon dilation, stenting, or both, the collateral vessels disappeared completely in 54 (62%), substantially decreased in 17 (20%), and remained un-

changed in 16 (18%) limbs. A subgroup of 11 (13%) limbs with diffuse iliac vein narrowing but no collateral formation was identified (Fig. 3). Comparison of the preoperative hemodynamics and intraoperative pressure findings in the obstructed limbs with and without collateral formation showed no statistically significant differences.

In most cases, after balloon dilation the vessel recoiled by varying degrees toward the original dimension. The mean percentage of recoil was 76% ± 36. The recoil was complete in 55 (63%) of the 87 limbs; 69 (79%) limbs had >50% recoil following balloon dilation.

Atrial waves were substantially dampened or completely absent in the femoral vein compared to the IVC in 17 (20%) limbs; similarly, respiratory variations were either not found (20 limbs, 23%) or were severely dampened (3 limbs, 3%). No pressure curve changes oc-

curred in patients with obvious venographic obstruction and did not contribute to the diagnosis of a significant stenosis. No pressure gradient was observed in the majority of limbs during intraoperative measurement. A resting gradient ≥2 mm Hg was seen in 12 (15%) of the 80 limbs tested. This rate increased to 35% (28/80) after papaverine injection (Table 5).

### Complications

The early (<30-day) complication rate was low (10%); there was no mortality. One patient developed retroperitoneal bleeding from a high cannulation site and was conservatively treated with blood transfusion. One patient sustained an arterial injury during cannulation that required open repair with an interposition graft. These 2 cases occurred early in our series when the vein was cannulated blindly. Under the direction of ultrasound guidance, single-wall puncture was performed with ease, minimizing cannulation complications. In another patient, the guidewire was caught in the stent, which was pulled to the femoral vein and then successfully removed through a groin incision. One patient developed postoperative swelling of unknown etiology; the stent was patent on venography and the swelling subsided within weeks.

Thrombosis of the stented area was encountered in 5 (6%) limbs, all within 3 weeks of the surgery in patients with postthrombotic disease. Only 1 patient had a known thrombophilia (protein S deficiency). Thrombectomy was performed in 1 patient, but the vein rethrombosed after 3 weeks and was treated conservatively. Two limb occlusions were treated with urokinase; 1 was successful. This patient had a remaining partial stenosis that could not be dilated even during a repeat attempt. A Palma femorofemoral procedure was performed in the second patient. The remaining 2 patients required only anticoagulation.

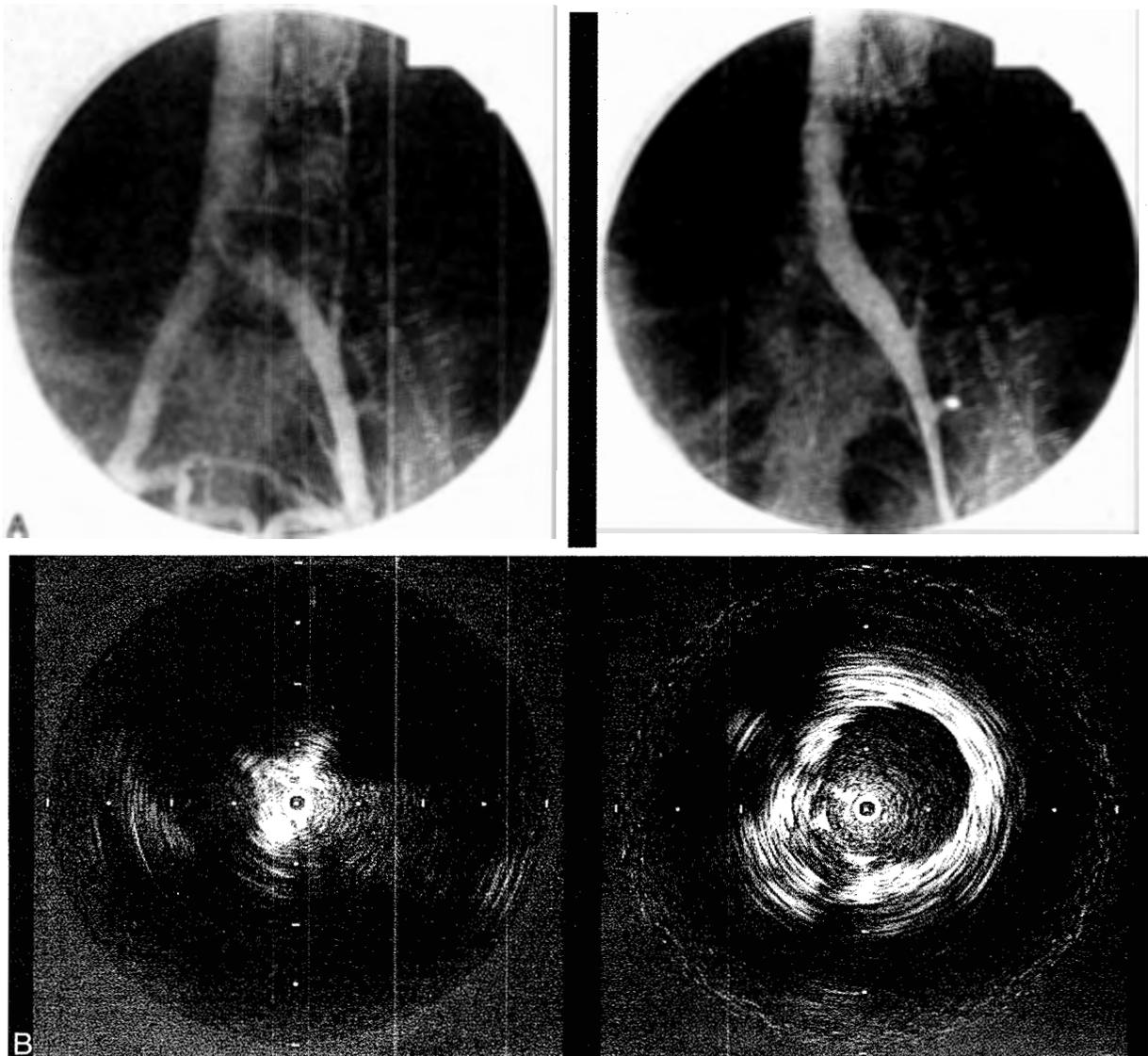
### Clinical Outcome of Stented Cohort

The median follow-up in 70 (91%) of the 77 stented limbs was 12 months (range 1 to 21);

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**Table 4**  
Stent Parameters in 77 Patients

<b>Number of Stents</b>	
1	48
2	22
3	4
4	2
5	0
6	1
<b>Length of Stented Area (cm)</b>	
4	14
6	20
8-10	22
12-16	17
20-25	4
<b>Diameter of Stent (mm)</b>	
10	4
12	9
14	15
16	34
18	14
20	1
<b>Site of Stenosis</b>	
IVC occlusion	2
IVC + CIV stenosis	2
CIV, short	24
CIV, long	20
Mid iliac vein	4
CIV + EIV	25
EIV	3

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IVC = inferior vena cava, CIV = common iliac vein, EIV = external iliac vein

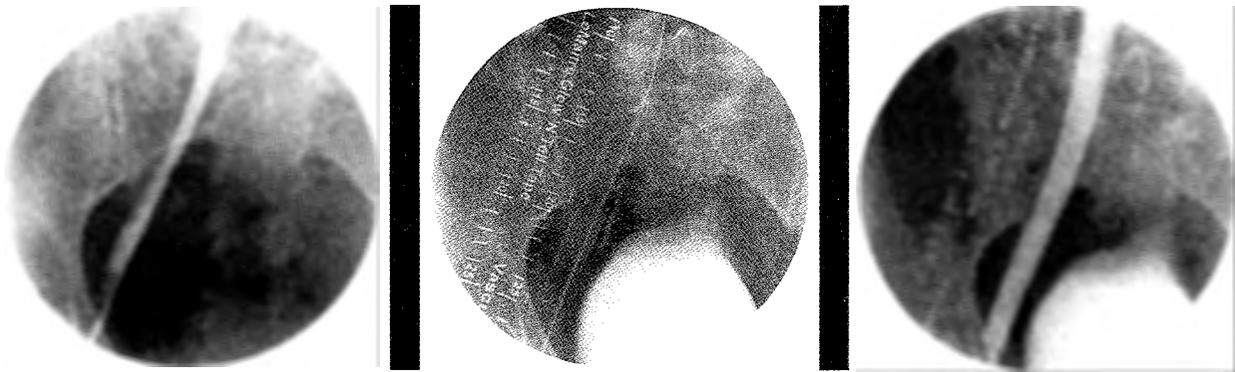


**Figure 2** ♦ In the patient with iliac vein compression syndrome, the transfemoral venogram (A) and IVUS images (B) acquired before (left panel in A and B) and after (right panel in A and B) balloon dilation and stenting. Note the severe stenosis on IVUS, which cannot be visualized on the venogram, although the collateral vessels suggest an outflow obstruction.

primary, assisted primary, and secondary patency rates at 1-year were 82%, 91%, and 92% respectively (Fig. 4). There was substantial pain relief after surgery. The rate of patients free from pain increased from 13% to 68% postoperatively. The mean value of the pain intensity scale decreased from  $4.6 \pm 3.0$  before intervention to  $1.3 \pm 2.3$  ( $p < 0.001$ ) on follow-up. Leg edema also improved. Before surgery, 96% of patients complained of varying degrees of swelling; this rate was reduced

to 35% after the procedure. The clinical score of swelling decreased from  $1.4 \pm 0.6$  to  $1.0 \pm 0.8$  ( $p < 0.001$ ).

To assess the characteristics of limbs that did well after the endovascular procedure, the data on preoperative hemodynamics, intraoperative pressure gradients, collateral vessels, and degree of stenosis were analyzed to identify predictive factors. Disappointingly, no correlation was found between any of these parameters and clinical outcome as measured



**Figure 3** ♦ Transfemoral venogram before (left panel) and after (right 2 panels) balloon dilation and stenting of a postthrombotic, generally narrowed vein with no developed collateral vessels.

by pain scale, decrease of swelling, or a combination of both objective data and subjective symptomatic relief.

Nineteen limbs had active ulcer before intervention. Three limbs were not treated (2 had no stenosis and the other had an iliac occlusion that could not be negotiated), leaving 16 limbs for follow-up. In 6 patients, the ulcer healed after stenting before additional reflux surgery was performed (38%). The ulcer healed in 2 additional patients, but recurred quickly; 8 venous ulcers never healed.

Of 66 patients available for imaging follow-up, antegrade transfemoral or ascending venography was performed in 53 patients; 49 (92%) stents were patent (4 failed due to early thrombosis). Three limbs had irregularities within the stent, indicating hyperplasia or partial rethrombosis but no obstruction to flow. The remaining 13 patients were examined with duplex sonography, which showed no iliac vein obstruction. The repeated hemodynamic studies show no significant statistical

improvement except that the hand-foot vein pressure differential decreased from  $1.4 \pm 1.5$  to  $0.8 \pm 1.3$  ( $p < 0.05$ ).

In the first 25 patients in this study, care was taken not to insert any stent into the IVC but to place it just slightly beyond the stenosis, even when the narrowing was at the ilio-caval junction. Nine (36%) of these patients had full relief of symptoms after treatment but returned with symptomatic recurrence 6 to 8 months later (Fig. 5). Repeat venography showed restenosis proximal to the stent. None had thrombosis of the narrowed area. All but 1 limb was restented successfully with placement of the stent well into the IVC. The remaining patient did not accept any further procedure. When this late complication of stenting was realized, all subsequent stents (52 limbs) were placed well into the IVC. Neither deep vein thrombosis of the contralateral limb nor any restenosis of the common iliac vein has been seen since the technique was altered (Fig. 6).

**Table 5**

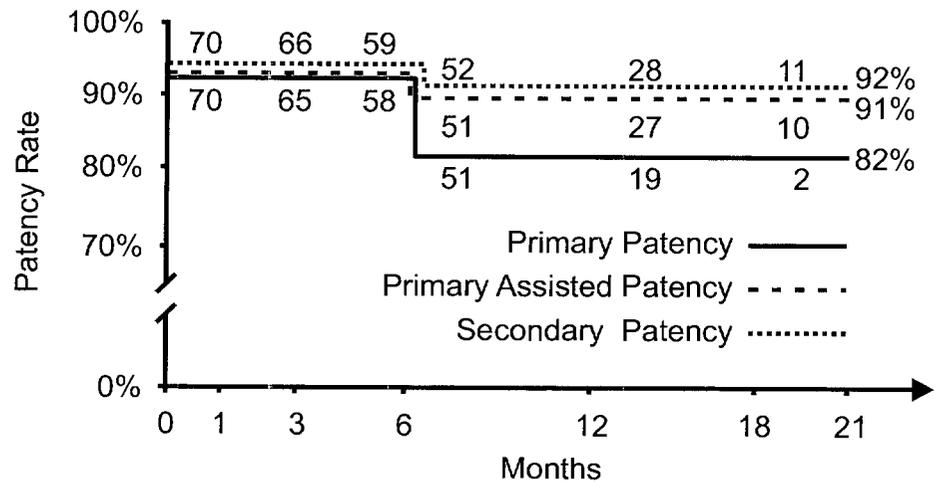
Comparisons of Venous Pressure Gradients With and Without Intra-Arterial Papaverine

	Baseline at Rest	Gradient	
		At rest	With papaverine
Femoral vein Pressure (mm Hg)	$12.6 \pm 4.3$	$0.6 \pm 1.3^*$	$2.0 \pm 3.5^*$

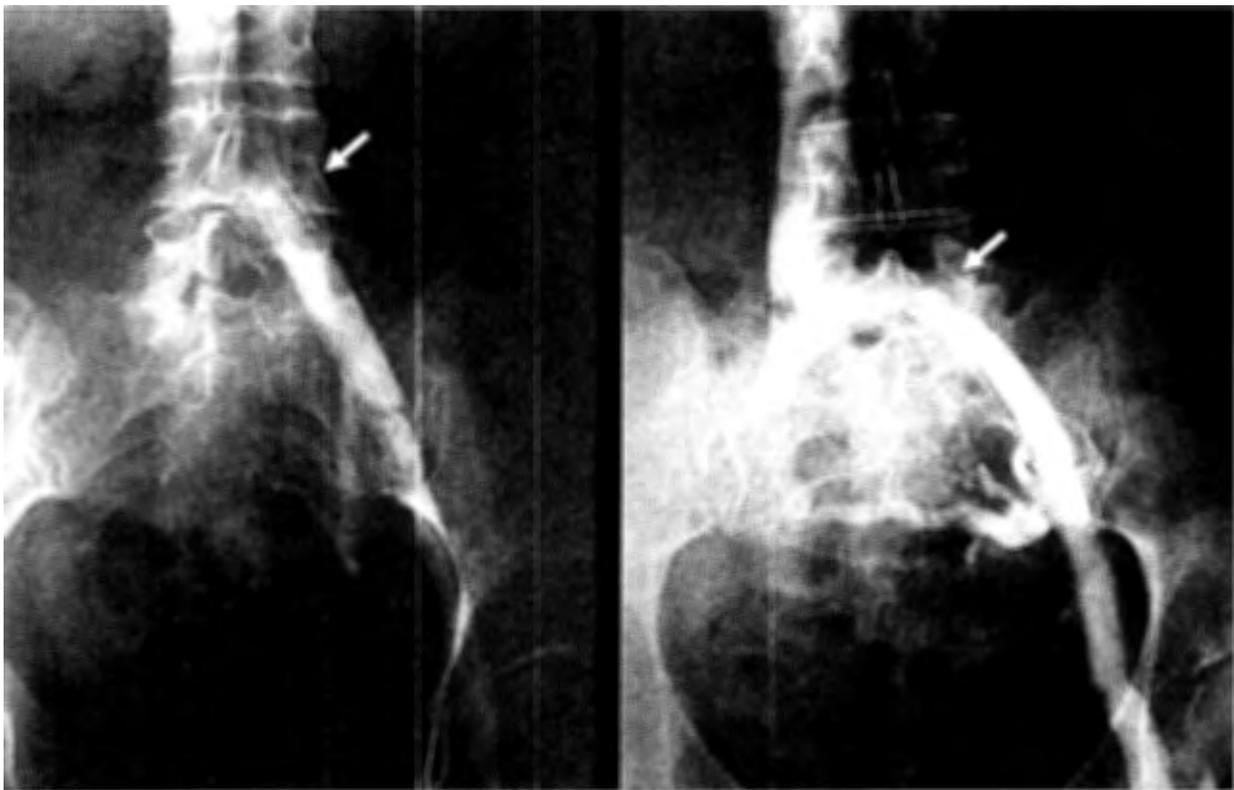
Values are mean  $\pm$  SD. \*  $p < 0.001$ .

## DISCUSSION

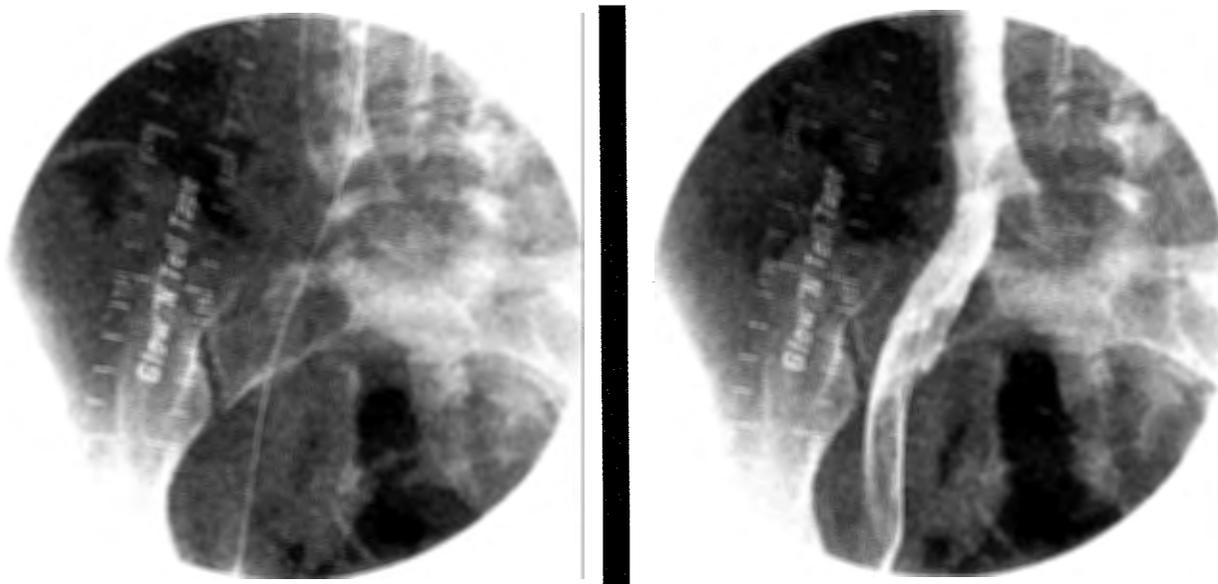
Before the development of venous balloon dilation and stenting, obstructions of the venous circulation were corrected by surgical bypass reconstruction. Iliac vein obstruction was usually managed by a Palma femorofemoral bypass or unilateral bypass between the femoral vein distal to the obstruction and the contralateral iliac vein or IVC.<sup>7</sup> These major surgical procedures usually necessitate



**Figure 4** ♦ Cumulative primary, primary assisted, and secondary patency rates following iliac vein balloon dilation and stent insertion in 70 lower limbs.



**Figure 5** ♦ Two examples of recurrent proximal narrowing (arrows) in a previously stented iliac vein. These stents were not inserted into the IVC and appear to have been squeezed distally by a severe ilio caval junction stenosis.



**Figure 6** ♦ Contralateral transfemoral venogram 6 months postoperatively in a patient who had stenting of the left iliac vein with the stent inserted well into the IVC. No outflow obstruction is seen.

lifelong anticoagulation, and a temporary or continuous adjunctive arteriovenous fistula is often necessary to keep the bypass open. Due to the magnitude of the intervention, only patients with the most severe postthrombotic syndrome were selected. While reports on the crossover bypass technique claim durable symptomatic relief,<sup>13,14</sup> most studies lack consistent follow-up with venography, which appears to be the only reliable method to show patency.

Our experience indicates that balloon dilation and stenting may be superior to conventional surgical treatment and possibly the "method of choice." Long-term follow-up, however, is necessary to validate this opinion. Endovascular treatment is much less invasive and has a high technical success rate (97%) with minimal complications in our experience. The procedure can be performed as a  $\leq 1$ -day admission with the patients returning to work immediately following discharge.

Nazarian et al.<sup>15</sup> reported a 1-year assisted primary patency rate of 66% for 29 iliac obstructions, decreasing to 37% when both femoral and iliac veins were stented. This differs significantly from our 1-year 91% assisted primary patency rate, but the difference in pa-

tient selection readily explains the discrepancy. In their study, 13 of the 29 iliac veins were completely occluded; the other 16 lesions were caused by malignancy. Few occlusions occurred after 6 months, however, and patency rates remained the same at 1-year and 4-year follow-up intervals.

Semba and Dake<sup>16</sup> reported better results (92% patency at 3 months) for iliofemoral thrombosis when stenting was performed after thrombolysis uncovered a common iliac vein stenosis. While these outcomes are comparable to ours, their follow-up is disappointingly short.

Early experience with simple venous angioplasty following iliofemoral thrombectomy was poor.<sup>17</sup> In various locations, early recurrence followed balloon venoplasty if stent implantation was not performed.<sup>18,19</sup> In our study, 79% of the dilated veins recoiled by at least 50% immediately following dilation. In contrast to the arterial system, mandatory stenting after venoplasty appears prudent.

When the stenosis was near the ilio caval junction, the stent was initially placed at the junction or only slightly into the IVC. More than a third of limbs thus treated restenosed within 6 to 8 months. It is likely that the stent

was squeezed distally by pressure from the stenosis, which is possible because of the Wallstent's spiral configuration. When the stent was inserted several centimeters into the IVC astride the narrowing, no restenosis occurred. This positioning of the stent did not appear to impede outflow of the contralateral iliac vein, as no contralateral thrombosis was encountered. Therefore, it appears safe to recommend that the stent be placed well into the IVC when obstruction occurs close to the ilio caval junction, as in May-Thurner syndrome.<sup>3</sup>

Postoperative thrombosis following stent implantation occurred in 5 patients. All of these limbs had postthrombotic disease, and 4 had occlusion of the vein at the time of the endovascular procedure. The diameter of the stents in these patients was smaller and the stented area longer compared to the corresponding measurements in the total patient population ( $\leq 14$ -mm diameter versus median 16 mm; 13- to 25-cm length versus median 8 cm). Larger stent diameters, at least 14 mm and preferably 16 to 20 mm, may be desirable. Although it may seem important to keep the stented area to a minimum, stent implantation should extend to cover all identified stenoses, leaving no residual lesion if possible. Since the Wallstent is flexible, it is considered safe to cross the inguinal ligament. However, few patients in this study had such extensive stent placement, so no conclusion on this issue is possible. In an effort to keep the stented segment open, Nazarian et al.<sup>20</sup> have used a temporary arteriovenous fistula in selected limbs with some success.

In our study, the criteria for iliac vein stenosis were the presence of complete occlusion, narrowing, collateral vessels, or a preoperative pressure increase. However, preoperative diagnosis of hemodynamically significant venous outflow obstruction is difficult.<sup>5</sup> No relationship has been shown between morphological findings and plethysmographic or venous pressure changes. Although the hand-foot venous pressure differential combined with an elevated hyperemic dorsal foot venous pressure is considered the best available test, it did not correspond to IVUS findings or clinical outcome in this study.

Intraoperatively, attempts to accurately describe the hemodynamic effect of the outflow obstruction were generally disappointing with the several methods employed. The measurement of the pull-through pressure gradient, the femoral pressure response to intra-arterial papaverine, and the absence of atrial waves or respiratory variations in the femoral pressure curve were not helpful in determining whether a borderline obstruction was hemodynamically significant.

In this study, IVUS was superior to the venogram in identifying not only the presence of stenosis but also the degree and extent of narrowing. The venogram underestimated the stenosis by more than one third on average. In many cases, IVUS showed a short stenosis or intraluminal web that could not be identified on the venogram. However, this situation was sometimes suspected because of left common iliac vein broadening with central translucence at the vessel crossing or the presence of transpelvic collateral vessels. Some iliac veins may be diffusely narrowed without any focal stenosis and are mistakenly read as "normal" by the radiologist, especially when no collateral vessels are present.

Intravascular ultrasound offered other valuable assistance during the procedure. Trabeculation and axial collateral vessels were well elucidated on the IVUS image, which also provided accurate measurements of vessel diameter for stent sizing. Intravascular ultrasound accurately displayed postdilation flaps or vein wall irregularities and confirmed complete apposition of the stent to the vein wall at the end of the procedure.

Venous collateral vessels, initially seen in 72% of limbs with stenosis, completely disappeared or substantially decreased in 82% after treatment. Persistent collateral vessels could indicate that partial outflow obstruction remained despite stenting. Another possible explanation is that the collateral vessels might be large and compliant veins easily visualized due to low resistance. According to most investigators, collateral circulation appears to be the best indicator of a significant stenosis. Even tight stenosis, however, is not always accompanied by collateralization, and the absence of collateral vessels does not ex-

clude the possibility of a significant obstructive lesion.

Why and how venous collateralization occurs is not clear, but the existence of a subgroup of postthrombotic limbs with noncollateralizing obstruction and diffuse iliac vein narrowing has not been emphasized before. The 11 limbs identified in this study presented no specific symptomatology and did not differ hemodynamically from collateralizing obstructed limbs. Their venographic appearance is easily mistaken as normal unless compared to the contralateral side. At surgery, these veins also display significant resistance to dilation. The lack of collateralization and increased stiffness could result from postthrombotic periphlebitis, which can produce scarring and a fibrous sheath surrounding the vein (phlebosclerosis), preventing distension and collateral formation. Although there is no focal obstruction, the decreased compliance due to the encompassing sheath results in outflow obstruction when flow increases.

At this time there is no gold standard for selection of patients who need treatment for significant iliac outflow obstruction. Preoperative pressure measurement and transfemoral pressures with hyperemia may be helpful, but our results are disappointing. Venographic evidence of collateral vessels may be more reliable, but significant lesions can be present without collateralization. IVUS investigation is highly accurate and should probably be more liberally used, especially in patients in whom there is clinical suspicion of outflow obstruction with symptoms of pain and swelling and a history of DVT.

Treated patients showed significant symptomatic improvement after balloon dilation and stenting. Although pain and swelling is difficult to assess objectively, we used an analogue pain scale and the clinical outcome classification recommended by the SVS/ISCVS to assess symptomatic improvement. Although imperfect, these tools are probably the best available at this time. The rates of complete relief of pain (68%) and swelling (65%) after the procedure were impressive compared to before treatment (13% and 4%, respectively). More than a third of stasis ulcers healed after correction of the outflow obstruction, although venous reflux persisted.

In patients with reflux, timing of repair procedures is open to discussion. Raju and Hardy<sup>21</sup> showed that surgical correction of the reflux (e.g., valve repair or subfascial endoscopic perforator vein interruption) can be performed with excellent results despite outflow obstruction. However, the relief of pain and swelling after endovascular treatment of venous stenosis has been so obvious that patients may experience more symptom resolution when stenting is performed before reflux procedures. The lack of improvement in reflux after stenting suggests that reflux control will be required later in many of these patients, especially those in CEAP clinical classes 4 to 6.

In conclusion, balloon dilation and stenting is a safe treatment for chronic benign obstruction of the iliac vein. While short-term results are good, only longer follow-up will determine if the hyperplasia observed in the stented area will progress to late venous obstruction. Significant venous lesions should always be stented, and the stent should be inserted well into the IVC when an ilio caval junction stenosis is treated. No gold standard test for selecting the appropriate patient for intervention is presently available. Intravascular ultrasound should probably be used more frequently in diagnosis and is a vital intraoperative tool. The absence of venographically documented collateralization does not exclude a significant obstructive lesion; on the other hand, collateral vessels might indicate a significant stenosis that is not visualized. In postthrombotic limbs with severe symptoms and a combination of reflux and outflow obstruction, stenting to correct the venous stenosis should probably be done before attempts are made to control reflux.

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