Percutaneous recanalization of total occlusions of the iliac vein

Seshadri Raju, MD,[a] and **Peter Neglén, MD, PhD,**[b] *Jackson and Flowood, Miss*

Background: **Venovenous bypass has been the standard in relieving chronic total occlusions of iliac veins. The technical feasibility of percutaneous recanalization was previously reported. Routine applicability of this technique in a wide spectrum of lesions and patients, stent patency, and clinical outcome forms the basis of this presentation.**

Methods: **During a 9-year period, 167 limbs in 159 unselected patients in a consecutive series with post-thrombotic chronic total occlusions of the iliac and adjacent vein segments underwent percutaneous attempts at recanalization. Patients were not selected based on venographic appearance or extent of the lesion, or excluded because of a preemptive choice of open venovenous bypass surgery.**

Results: **Percutaneous recanalization was successful in 139 of 167 limbs (83%), including patients with bilateral occlusions and 14 patients with inferior vena cava filters incorporated in the treated occlusion. Median age was 53 years (range, 18-84 years). Thrombophilia was identified in 44 patients. Venous dermatitis/ulcer was found in 46% of the treated limbs. Recanalization involved three or more totally occluded vein segments in 42% of the limbs. The cumulative secondary stent patency rate at 4 years was 66%. The cumulative marked relief of pain and swelling at 3 years was 79% and 66%, respectively. Cumulative healing of venous ulcer at 33 months was 56%. Quality of life metrics improved significantly.**

Conclusions: **Most femoroiliocaval chronic total occlusions lesions can be successfully recanalized percutaneously with very little morbidity, minimal downtime, sustained long-term stent patency, and substantial clinical improvement. The procedure has wide applicability in a broad spectrum of symptomatic patients, including those with extensive lesions, and can be considered for routine use. (J Vasc Surg 2009;50:360-8.)**

Venovenous bypasses using the saphenous vein[1] or a prosthesis[2] have been the standard in the treatment of symptomatic iliac vein occlusions. Early results of percutaneous endovenous recanalization in 38 limbs were described in 2002.[3] Since then, procedural success has increased with experience, reducing the need for open venovenous bypass procedures. This study analyzed the success rate, stent patency rate, and clinical outcomes in patients after stent recanalization of chronic total occlusions (CTO) of femoroiliocaval vein segments.

METHODS

Patients. From 1999 through 2007, obstructive lesions of the femoroiliocaval veins segments were treated by stent placement in 1402 limbs; of these, 603 were post-thrombotic which included CTO limbs. A consecutive series of 167 limbs in 159 patients with femoroiliocaval CTO underwent attempts at percutaneous recanalization during that time. No limbs were excluded because of the extent or severity of CTO or because of a preemptive choice of venovenous bypass. In seven patients a previous venovenous bypass (3 prosthetic, 4 Palma) had been performed, and five had occluded. Two Palma bypasses had remained patent; however, the patients continued to be symptomatic. Limbs with acute or acute/chronic thromboses requiring thrombolysis before stenting were excluded because these subsets were considered different from CTO limbs. The procedure was successful in 139 limbs, representing 23% of all post-thrombotic limbs treated with stents.

Preoperative investigations, indications, technique, and follow-up protocol have been described in detail elsewhere[4-6] and are presented here in abbreviated form.

Indications. Patients with significant limb symptoms, including pain, swelling, venous dermatitis and ulcer, recurrent cellulitis, or a combination of these symptoms, who had failed conservative therapy were considered for intervention. Severity of symptom presentation, and not the venographic finding of CTO, was the determinant for intervention; some patients with extensive venographic occlusive lesions may be asymptomatic or only mildly symptomatic.

A preoperative thrombophilia workup, consisting of antithrombin 3, protein C and S, anticardiolipin antibody, lupus anticoagulant, prothrombin and Leiden gene mutations, and homocystinemia >15 mg, was routinely performed. Venous investigations included arm/foot venous pressure differential, ambulatory venous pressure measurement, air plethysmography, duplex ultrasound (DUS) examination, and ascending (pedal contrast injection) and transfemoral antegrade venography with exercise femoral pressure measurement.

After recanalization, patients were monitored by clinical examination at 6 weeks, 3 months, 6 months, and at yearly intervals thereafter. The cumulative rate of ulcer healing (100% epithelialization) was calculated. Pain was

From the University of Mississippi Medical Center, Jackson,[a] and River Oaks Hospital, Flowood.[b]

Competition of interest: none.

Reprint requests: Seshadri Raju, MD, 1020 River Oaks Dr, Ste 420, Flowood, MS 39232 (e-mail: rajumd@earthlink.net).

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evaluated using a visual analog scale (VAS)[7] from 0 to 10, wherein 10 is the most severe pain. Swelling was assessed as grade 0 (absent), grade 1 (pitting, not obvious), grade 2 (visible ankle edema), and grade 3 (gross, encompassing the entire leg) according to reporting standards. The Chronic Venous Insufficiency Questionnaire (CIVIQ) quality of life method[8] validated for chronic venous disease was used, and the latest patient response was used in outcome analysis. Contrast venography was routinely performed at 6 to 12 weeks, at 6 months after the procedure, and then yearly. DUS examination, as recently described by Labropoulos et al,[9] has been increasingly used to assess the patency of the stented iliac vein. Preliminary experience indicates the method is comparable to venography in assessing gross stent patency.

Technique of recanalization. The procedure is performed under general anesthesia for safer cardiopulmonary control and lack of adequate pain control under local anesthesia. A midthigh femoral vein access under US guidance is used. The femoral vein is found posterolateral to the artery at midthigh level. Progressive dilatation of the access needle track with over-the-wire dilators may be required in post-thrombotic veins before the introduction of the sheath. With routine use of a sealing device (VasoSeal, Datascope Corp, Montvale, NJ), access site complications are rare. With attention to depth markings on the device, inadvertent intravenous placement of the sealant is avoided (1 suspected in >1500 uses), even when large sheaths are used.

The midthigh access allows the use of shorter-length instrumentation with superior pushability compared with popliteal or internal jugular access. Sufficient space remains cephalad to the sheath (size 10-13, 13-cm length) below the inguinal ligament to deploy a stent into the common femoral vein if needed. When the femoral vein is occluded, as is frequently found, access is often possible through the upper 3 to 5 cm of the vein, which tends to remain open, or through parallel collaterals in the vicinity. The profunda femoris vein is usually open if the femoral vein is occluded and can be accessed 2 to 5 cm below the lesser trochanter. When access is possible only in the upper thigh, the sheath tip has to be withdrawn below the common femoral vein for stent deployment if needed; stent extension into the profunda femoris vein is allowed when the femoral vein is occluded.

An antegrade venogram is performed to define existing venous anatomy. A 0.035-inch soft or stiff Glidewire (Terumo Inc, Ann Arbor, Mich) is inserted up to the occlusion. Further progress into the occlusion is made with the tip of the Glidewire with straight or angled catheter support. Unlike in arterial occlusions, a leading loop is not helpful at this stage. Cutting balloons and tunneling devices (Frontrunner CTO, LuMend Inc, Redwood City, Calif) may be helpful to gain initial entry into the occluded segment. After gaining access into the occluded vein, further progress into the occlusion is made with the Glidewire tip, with or without catheter (or long sheath) support. A leading loop may be advantageous to gain passage through the external and common iliac veins if the trabeculae are not dense.

A low-profile catheter with a sharp edge (Quick-Cross catheter; Spectranetics, Colorado Springs, Colo) appears to facilitate progress, but other hydrophilic catheters, either 4F or 5F size with standard or angled tips, are helpful as well. If forward progress stalls, other Glidewires of different stiffness, caliber, or tip angle should be tried. Usually, some combination of Glidewire and supporting catheter will be found to advance progress. Passage of the Glidewire through the occluded segment meets with variable difficulty. With some experience, most occluded iliofemoral veins can be recanalized in 30 to 40 minutes and even extensive inferior vena cava (IVC) occlusions in 60 to 75 minutes. The progress is sometimes tedious and patience is necessary.

The Glidewire probably advances through small vascular channels present in the organizing fibrous tissue within the vein. Because the occluded vein segment remains invisible on venography, Glidewire passage must be guided by intuitive sense of the normal anatomic course of the vein. In the frontal projection, the left femoral vein overlies the medial third of the femoral head, coursing up to the lower pelvic brim over the pelvic tubercle, and from there bows slightly outward, moving across the sacroiliac joint joining the IVC variably between the fourth and fifth lumbar vertebral bodies at their right margin. The right femoral and iliac veins course in a straighter line (frontal projection) to their junction with the IVC. The Glidewire should track accordingly. It is useful to view progress of the recanalization intermittently by 45° or 60° oblique projections to ensure that the Glidewire initially follows the curve of the sacrum and then turns anteriorly towards the promontorium and anterior to the spine.

Progress of Glidewire passage through the occluded vein may be impeded to a variable degree by vascular and ligamentous structures compressing the vein. The post-thrombotic fibrous tissue in and around the affected vein is particularly dense at these anatomic "chokepoints," where compression occurs and post-thrombotic recanalization is known to be poor.[10-12] These sites differ between the right and left sides (Fig 1). Intermediate balloon dilatations to facilitate Glidewire passage are often counterproductive because the wire loses the support of surrounding tissue and coils in the dilated space, making further progress even more difficult. The Glidewire may be diverted into collaterals and tributaries, particularly adjacent to these chokepoints. This is easily recognized if normal anatomy is kept in mind.

An angled-tip catheter is useful in redirecting the Glidewire in the proper direction when it seems to veer off course. In a few instances, the Glidewire has passed through the vertebral veins into the vertebral canal where it is positioned in the middle of the vertebral column rather than at the right lateral edge where the IVC is situated. This is easily recognized by oblique fluoroscopic projections. The Glidewire is withdrawn and redirected with no complications.

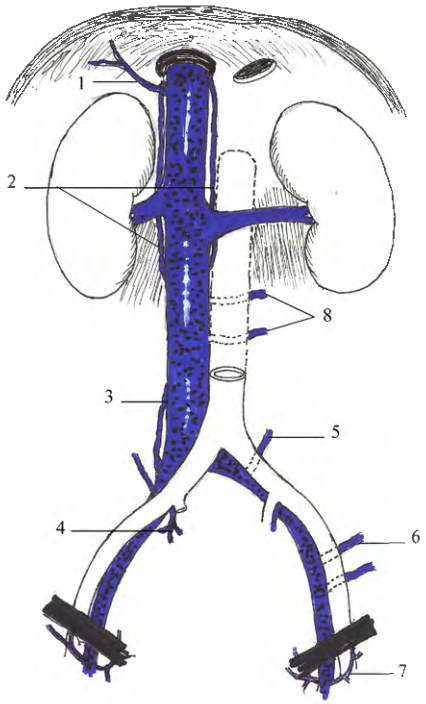

Fig 1. The Glidewire passage during recanalization procedure commonly meets resistance at several anatomic chokepoints where the iliac or the hypogastric artery crosses the vein; the inguinal ligament and the diaphragmatic hiatus may also prevent passage. Relevant arterial crossover levels differ slightly between the right and left side, as shown. The Glidewire can veer off course from the main vein through tributaries and collaterals (shown numbered) when meeting resistance. On the right side, the Glidewire may enter medial or lateral collaterals because the iliac vein runs a straighter course to the inferior vena cava. The left iliac vein has a convex curvature, and the Glidewire tends to enter lateral tributaries, usually the ascending lumbar vein. When the suprarenal vena cava is occluded, the azygos and hemiazygos collaterals are enlarged and the Glidewire enters them frequently. *1,* Phrenic vein; *2,* azygos/hemiazygos complex; *3,* prevertebral plexus; *4,* hypogastric vein; *5,* ascending lumbar vein; *6,* tributaries from the iliopsoas muscles; *7,* femoral vein tributaries; *8,* lumbar veins.

Passage of the Glidewire away from the expected course of the vein with sudden ease denotes perforation. The Glidewire can be withdrawn and usually manipulated in the proper direction without sequelae. Withdrawal of blood through the catheter may or may not be possible during the recanalization process and has no particular significance (procedure may not be aborted) as long as the Glidewire tracks approximate to normal anatomy.

Approaching the IVC, the Glidewire can track parallel to the vena cava, possibly within the vasa vasorum in its wall, for 3 to 5 cm before entering the proper lumen of the IVC. This is not harmful. Interval contrast injections into the track are usually not helpful, and pooling of the dye into lakes can be misleading and should not suggest that the procedure be aborted.

Entry into the IVC is verified by further easy passage of the wire or catheter along the normal course of the vessel into the right atrium. This should be confirmed by fluoroscopy, contrast injection through a catheter placed in the IVC, and intravascular US (IVUS). From this stage of the recanalization procedure, the use of IVUS[13] becomes crucial to assure integrity of the recanalized channel, to select optimal proximal and distal landing sites preferably free of post-thrombotic disease, to ensure proper deployment and expansion of the stents, and to minimize radiation exposure. Venography alone is distinctly inferior in these respects, and exclusive dependence on it may result in an inferior outcome with poor patency.

The recanalized channel may be dilated in a single step to the ultimate desired size after IVUS examination. Predilatation up to 10 mm may be necessary, starting with smaller-sized (3-mm) balloons and matched guidewires in some cases to gain easy passage of a 6F IVUS catheter and large-caliber balloons. By IVUS, the Glidewire is invariably found to lie within the confines of the recanalized occluded vein (Fig 2).

Repeated balloon dilatation at the anatomic chokepoints may be necessary. It is useful to use high-pressure balloons (16 to 18 atm) and keep the balloon expanded at maximum level for at least a minute until the balloon pressure stabilizes at this level. Overdilatation and oversizing of the stent diameter by 2 to 4 mm for the anatomic location is recommended to compensate for the variable recoil of the recanalized channel. Oversizing the vena caval stent is important to facilitate later contralateral stenting if required. Optimal stent diameters after recoil are 20 mm for the IVC, 16 to 18 mm for the common iliac vein, 14 to 16 mm for the external iliac vein, and 12 to 14 mm for the common femoral vein in normally sized adults.

Self-expanding woven braided stainless stents (Wallstent, Boston Scientific, Nantucket, Mass) in series with 3- to 5-cm overlap to minimize shelving along the complex course of the iliac vein were used in most patients (Fig 3). A smooth transition at overlaps is facilitated by using stents with the same diameter (used for the largest segment) through all of the recanalized segments, but limiting postdeployment balloon dilatation to the size appropriate for each segment. This results in oversizing of the stents, which is an advantage during later interventional corrections, if needed.

Because multiple stents are typically required, the maximum manufactured length for the various diameter sizes (typically 7- to 9-cm length) should be used, restricting shorter lengths for use at either end of the stack to tailor length. Unless the recoil is severe (>40%), dilatation after deployment should be delayed until all of the stents are in place. This speeds up restoration of flow through the stent assembly and helps to reduce the chances of thrombus nidus formation. A completion IVUS examination and venogram terminate the procedure after noted defects are corrected by repeat ballooning. Patients can be discharged after an overnight stay.

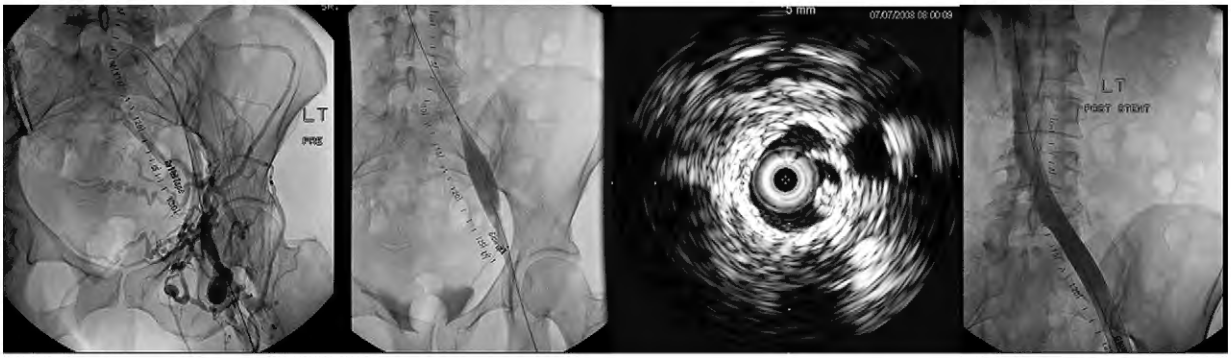

Fig 2. Recanalization of an occluded iliac vein. **Left panel,** Initial venogram. **Second panel,** Aggressive dilatation of the occluded vein and deployment of a slightly oversized stent is required to achieve a recanalized lumen approximating normal anatomy. This poses no bleeding risk (see text). **Third panel,** Intravascular ultrasound examination of the recanalized channel after maximal balloon dilatation invariably shows the Glidewire in the middle of the venous channel with intact thick walls. **Right panel,** Completion venogram shows a stented channel of adequate lumen without residual stenoses, good flow, and absence of previously visualized collaterals.

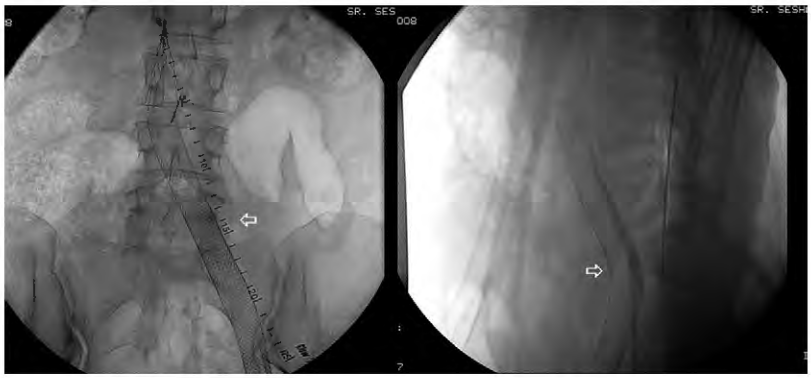

Fig 3. Left, Frontal projections obscure the complex course of the iliac vein through the pelvis. **Right,** A 50° turn occurs at the L5-S1 vertebral junction (arrow, **Left** and **Right**), evident on lateral projection. "Shelving" of stent ends, compromising effective in-stent lumen, may occur if stent overlaps are placed near this location. A strategy to avoid this problem is to center a long (9-cm) stent initially over L5-S1 junction and add proximal and distal stents with overlaps situated away from this point.

Previously placed IVC filters incorporated in the occluded caval segment or present above the occlusion in a patent segment pose a special technical problem. In the former instance, the filter must be displaced sideways or remodeled/fractured by repeated high-pressure balloon dilation to allow stent placement.[14] In the latter case, the filter implantation site must be assessed for significant associated stenosis. If present, the IVC filter should be disrupted or displaced for placement of the stent across the stenosis; otherwise, it is left alone (Fig 4). Balloon dilatation of filter-associated stenoses has been surprisingly easy with routine technique; there is little recoil, probably because the stenosis is predominantly intraluminal with little perivenous component.

Bilateral iliofemoral vein recanalizations are performed at the same session or staged, depending on the duration and difficulty of the initial procedure. The right and left stent assemblies are connected through a fenestration created in the side of the initial stent assembly.[14] The technique is described in detail elsewhere.[15]

Anticoagulation. Bivalirudin (50 mg) or unfractionated heparin (5000 U) is administered intravenously during the procedure. Low-molecular-weight heparin (dalteparin, 2500 U subcutaneously) is administered before the procedure, afterwards in the recovery room, and daily thereafter for 3 to 5 days. Earlier in this experience, only aspirin was used empirically for long-term stent maintenance, except in cases of thrombophilia when warfarin was instituted or continued after recanalization. Currently, fondaparinux sodium is used in all patients for 4 to 6 weeks after recanalization. A prophylactic dosage is used except in cases of long recanalizations (≥3 segments), suprarenal stent placements, thrombophilia, or in patients receiving long-term anticoagulation; in these patients, the therapeutic dosage is used. Long-term warfarin is indicated in most of these patients.

Fig 4. Staged bilateral recanalization. The left iliac vein and the infrarenal vena cava with an inferior vena cava filter incorporated in the occlusion were recanalized first. The filter was ballooned and stented across. The right iliac vein was recanalized a few weeks later, connecting the two sides through a fenestration (see text). Bilateral excoriative dermatitis with lymph leak healed soon thereafter. This 92-year-old patient was not a candidate for open surgery.

Table I. Basic CEAP classification of 139 recanalized limbs

CEAP classification	*No.*
Clinical	
C_2: varicose veins	3[a]
C_3: edema	71
C_{4a}: pigmentation or eczema	14
C_{4b}: lipodermatosclerosis or white scar	8
C_5: healed venous ulcer	11
C_6: active venous ulcer	32
Etiologic	
E_p: primary	0
E_s: secondary	139
Anatomic[b]	
A_d: deep veins	39
$A_{s,d}$: superficial and deep veins	76
$A_{d,p}$: deep and perforator veins	3
$A_{s,d,p}$: superficial, deep, and perforator veins	19
Pathophysiologic[b]	
P_o: obstruction	26
$P_{r,o}$: reflux and obstruction	111

[a]All had severe limb pain.
[b]Anatomic and pathophysiologic classes are missing for two patients.

Data analysis. Continuous and categoric variables were analyzed by paired nonparametric Wilcoxon signed rank test and χ^2 test, respectively. Primary, assisted-primary, and secondary patency rates, as well as clinical outcome were calculated using survival analysis with the Kaplan-Meier method. Prism 3 software (GraphPad, San Diego, Calif) was used for analysis. A value of $P < .05$ was considered significant.

RESULTS

The procedure was successful in 139 of 167 limbs in 131 of 159 patients. Median age was 53 years (range, 18-92 years). Female to male ratio was 2:1, and left to right limb ratio was 4:1. Bilateral occlusions were present in 14 patients, and recanalization was successful in both limbs in eight patients (simultaneously in 4 and staged in 4) and in one of the two limbs in three patients, but failed in three patients. Significant thrombophilia was found in 44 stented patients (34%). CEAP classification of recanalized limbs is

Table II. Anatomic distribution of recanalized vein segments in 139 limbs[a]

Recanalized Segment	*No.*	*Recanalized Segment*	*No.*
CFV	4	IVCir, CIV, EIV, CFV	10
EIV, CFV	5	IVCsr, IVCir	1
CIV	27	IVCsr, IVCir, CIV	2
CIV, EIV	36	IVCsr, IVCir, CIV, EIV	3
CIV, EIV, CFV	32	IVCsr, IVCir, CIV, EIV, CFV	1
IVCir	4	IVCth, IVCab, CIV	1
IVCir, CIV	4	IVCth, IVCab, CIV, EIV, CFV	1
IVCir, CIV, EIV	7	IVCat, IVCsr, IVCir, CIV, EIV	1

CFV, Common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein; *IVC,* inferior vena cava; *IVCat,* inferior vena cava-atrial junction; *IVCir,* infrarenal vena cava; *IVCsr,* suprarenal vena cava; *IVCth,* thoracic vena cava; *IVCab,* abdominal vena cava.
[a]Of the 139 limbs, 35 (25%) had recanalization of one segment; 46 (33%) had recanalization of two segments; 58 (42%) had recanalization of three or more segments.

Table III. Procedure success in 139 recanalized limbs by number of attempts at recanalization[a]

Attempt	*No.*	*%*
First	121	87
Second	10	8
Third	6	4
Fourth or more[b]	2	1

[a]Recanalization was ultimately successful in 139 of 167 limbs (83%).
[b]1 limb on the fifth attempt; 1 limb on the sixth attempt.

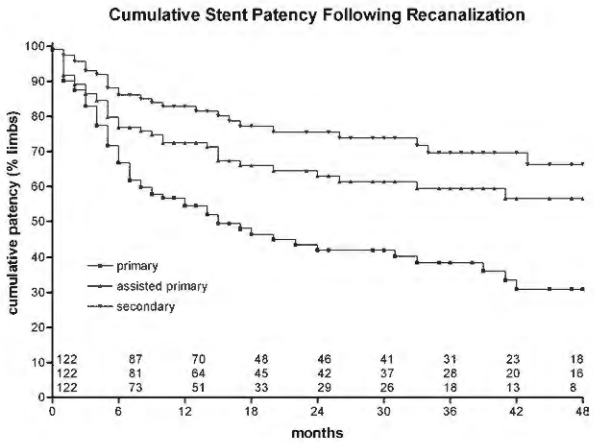

Fig 5. Cumulative primary, assisted-primary, and secondary patency rates of femoroiliocaval stents placed in recanalized occluded limbs. The lower numbers represent limbs at risk for each time interval (all standard error of the mean <10%).

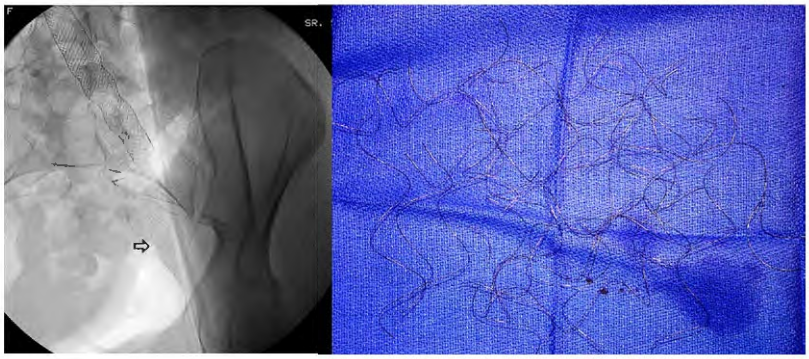

Fig. 6. Removal of an occluded Wallstent through a limited transverse venotomy. **Left,** Steady pull on one of the strands under fluoroscopy *(arrow)* will result in unraveling of the stent weave and **(Right)** serial removal of all of the strands. The technique may allow repeat recanalization in selected cases.

reported in Table I. Distribution of recanalized venous segments of the limbs is summarized in Table II. A total of 14 IVC filters of various types were remodeled and stented through, without any apparent complications. No associated stenosis was found in two other limbs, and the filter was left undisturbed above the stent. No pararenal or suprarenal filters were encountered in this experience.

The upper and lower landing sites of the stents commonly extended one or more segments beyond the recanalized section to cover adjoining nonocclusive stenoses. The lower landing site of the stent was below the inguinal ligament (common femoral vein) in 65 limbs (47%), in the external iliac vein in 42 (30%), and in the common iliac vein in 32 (23%). The upper landing site was in the IVC in all but two limbs for previously described technical reasons.[4] These two limbs had distal external iliac vein occlusion, and the upper landing site was in the common iliac vein.

Procedural success. The overall recanalization success rate was 83% (139 of 167 limbs), and most procedures were successful on the first attempt (Table III). Recanalization failed in two of five patents with occluded venovenous bypasses performed earlier because the prior venotomy site could not be traversed. Endophlebectomies[16] of the femoral vein were performed in seven limbs that were impervious to percutaneous entry into the occluded femoral vein segment. Subsequent recanalization was attempted in five limbs, but succeeded only in two limbs, both of which later occluded.

Morbidity. There was no 30-day mortality. There was no clinically apparent procedurally related bleeding. (A contained pelvic hematoma requiring transfusions occurred in one patient in 2008 who was not included in this series.) No access complications occurred that required intervention. About 25% of the patients reported back pain, which was limited (commonly days, occasionally up to 2 weeks) and easily controlled with ibuprofen. No patient required hospitalization for pain. One patient had a contrast-related transient rise in the serum creatinine concentration. Early thrombotic events (<30 days after stenting) occurred in 10 limbs, all associated with concurrent thrombosis of the stent. Late thrombotic events (>30 days after stenting) occurred in 32 limbs (ipsilateral, involving the stent in 29; contralateral nonstented limbs in 3 patients).

Table IV. Details of reintervention procedures in 38 recanalized limbs

Reintervention procedure	*No. (n = 38)*
Balloon dilation	22
Plus add proximal stent	2
Plus add distal stent	8
Plus add proximal and distal stents	1
Plus add stent separation stent	2
Add proximal stent	1
Removal of Wallstent; restented	2

Stent patency. Long-term primary, assisted-primary, and secondary patency rates are shown in Fig 5. During the follow-up period, 39 stents (28%) occluded, including one patient in whom the lower portion (common femoral inflow) has occluded and only the upper part of the stent stack is open (hypogastric inflow through the stent weave). Stent thrombosis was unrelated to preexisting thrombophilia ($P = .68$). Pharmacomechanical thrombectomy or catheter-directed thrombolysis, or both, were attempted in 23 limbs with occluded stents. This was successful in restoring stent patency in 17 limbs; 10 remained patent, but seven later occluded. One occluded stent spontaneously lysed after having been occluded for 3 years, and both occurrences were confirmed by transfemoral venography. An adjunctive arteriovenous fistula to improve inflow after thrombectomy was used in one patient, but the stent rethrombosed. In two limbs, the occluded iliac stent was removed (Fig 6) through a limited transverse venotomy. One limb was recanalized and restented later, but thrombosed ≤6 weeks.

Other reinterventions. Precautionary reinterventions were completed in 38 recanalized limbs (27%; Table IV). Indication for reintervention was the presence of significant (>50%) in-stent restenosis or residual or recurrent symp-

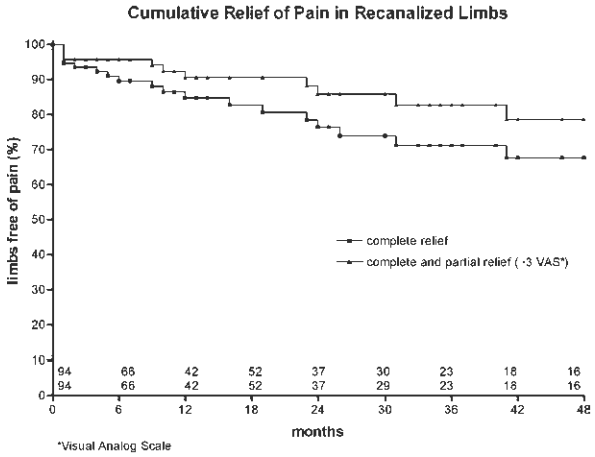

Fig 7. Cumulative partial, defined as ≥3 of 10 on the visual analog scale *(VAS)*, and complete relief of pain after recanalization and stenting. The lower numbers represent limbs at risk for each time interval (all standard error of the mean <10%).

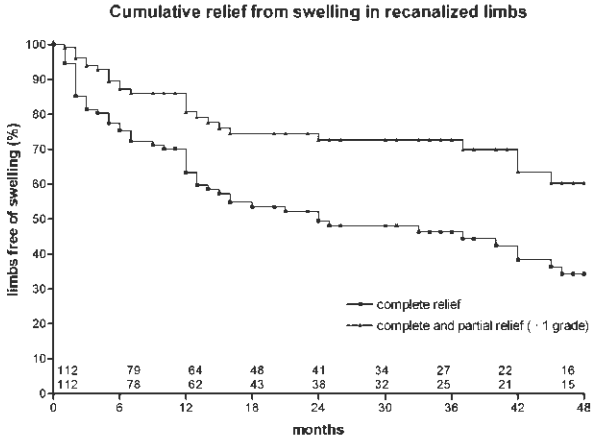

Fig 8. Cumulative partial (≥1 grade) and complete relief of swelling after recanalization and stenting. The lower numbers represent limbs at risk for each time interval (all standard error of the mean <10%).

toms, or both. Types and details of reintervention techniques performed in stented patients, including the recanalized CTO subset, are described elsewhere.[17]

Clinical outcome. Cumulative curves representing symptom relief (pain, swelling, skin changes) are shown in Figs 7-9. Quality of life metrics before and after recanalization are reported in Table V**.** Significant improvement was seen in all categories. Six patients in whom recanalization failed or occluded later underwent a venovenous bypass, and the others either declined the procedure or were not considered appropriate candidates for the open procedure.

Hemodynamics. Hemodynamic parameters before and after recanalization and stenting are summarized in Table VI. No improvement was noted. No hemodynamic values deteriorated, including reflux parameters.

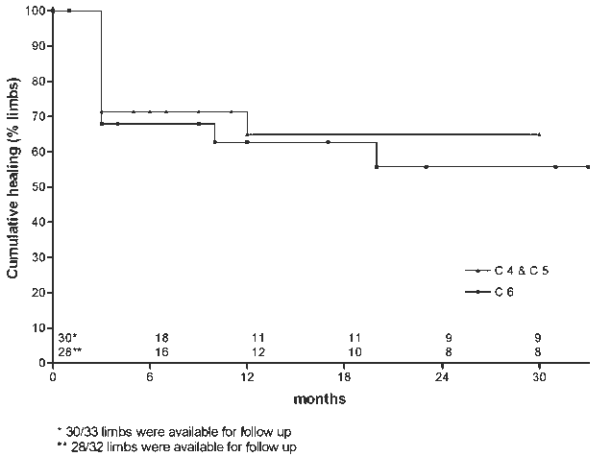

Fig 9. The upper curve shows cumulative freedom from dermatitis/ulcer in limbs with clinical severity *(C)* class 4 and 5 by CEAP after recanalization and stenting. The lower curve shows cumulative rate of healed leg ulcers (C6 in CEAP) after recanalization and stenting. Limbs with ulcers that never healed after stenting were censored at the 3-month follow-up. Ulcers that healed and subsequently recurred were censored at the time of recurrence. The incidence of recurrence is very low after primary healing, resulting in a flat curve. The lower numbers represent limbs at risk for each time interval (all standard error of the mean <10%).

Table V. Quality of life assessment values (Chronic Venous Insufficiency Questionnaire) before and after recanalization in 128 limbs

	Total score (mean ± SD)	
Value	*Before*	*After*
Leg pain (none = 1, max score, 5)	3.5 ± 1.3	2.6 ± 1.3[a]
Work-related leg problem (not bothered = 1; max score, 5)	3.7 ± 1.3	2.9 ± 1.2[a]
Sleep disturbance due to leg problems (never = 1; max score, 5)	3.2 ± 1.3	2.5 ± 1.3[a]
Effect on social activities (none = 8; max score, 40)	26.8 ± 8.8	21.3 ± 8.7[a]
Effect on morale (none = 9; max score, 45)	26.4 ± 11.1	21.6 ± 8.8[a]

[a]$P < .001$.

DISCUSSION

Current endovascular techniques are largely derived from arterial experience. The venous system obviously differs from the arterial system in many respects. Prevailing pressure is low, although flow is high due to larger conduit size; obstructive lesions result from post-thrombotic fibrosis both inside and around the vein, quite different from atherosclerotic lesions; and extravenous compressive bands and associated enhanced perivenous fibrosis contribute to the obstructive pathology. The response of large venous conduits to prosthetic metal is also different from arterial experience. The incidence of in-stent restenosis is less,[18]

Table VI. Hemodynamic parameters before and after recanalization

Variable	*No.*	*Before*	*After*	P[a]
		Median (range)	*Median (range)*	
Hand-foot pressure differential, mmHg	33	2 (0-22)	1 (0-8)	.0688
Ambulatory venous pressure				
% drop	37	63.5 (0-100)	61 (19-97)	.8044
Venous filling time, s	36	17 (1-336)	18 (1-120)	.1199
APG				
$VFI_{90,}$ mL/s	58	2.7 (0.4-16.6)	2.3 (0.04-12.2)	.4326
Ejection fraction, %	55	47 (11-100)	44 (5-100)	.7445
RVF, %	49	32 (0-100)	28 (0-100)	.6386

APG, Air plethysmography; *RVF*, residual volume fraction; *VFI_{90}*, venous filing index.
[a]None of the values for *P* are significant.

and large metal loads are surprisingly well tolerated.[19] Braided venous stents can be extended across flexion creases.[20] Stent fractures and erosions are rare, probably because pulsatile flow causing intravessel stent motion and metal fatigue is absent.

These differences pose advantages as well as challenges in adapting endovascular techniques to venous use. For example, deep veins can be directly accessed nearer the lesion without fear of hemorrhage, and the midthigh access resulted in successful recanalization of CTO lesions after attempts through traditional access points had failed. Aggressive balloon dilatation and overdilatation can be performed safely.

Extraluminal excursions of the guidewire, limited perforations, and leaks during recanalization maneuvers need not abort the procedure prematurely. On the other hand, undersizing of stents and residual stenoses at the inflow or outflow portions of the stented conduit are less well tolerated (poor symptom relief) than in the arterial system. Modifications of standard technique, as suggested in the previous section, may increase procedure success, stent patency, and clinical outcome in treating iliac vein CTO lesions.

Most femoroiliocaval CTOs, even if extensive, can be successfully recanalized percutaneously. Repeat attempts are warranted if the initial recanalization fails. Some short lesions may be surprisingly difficult or impossible to traverse, particularly those involving occlusion of the common femoral vein. Stenting across previously placed IVC filters, even when incorporated in the occluded vein segment, can be successful.[14,21]

The stented recanalized channel must be of adequate caliber, approximating normal anatomy, to provide unrestricted flow and decompress the limb to relieve symptoms and maintain long-term patency. Stenotic lesions adjacent to the recanalized segment should be stented without concern for the ensuing length of the stent assembly. The stent may be safely extended across the groin crease in pursuit of this objective.[20] The metal load is seldom the cause of stent thrombosis, even in thrombophilic patients. The use of IVUS is critical to ensure a satisfactory technical outcome, minimize the need for reinterventions, and maximize symptom relief when venous lesions are treated.[17]

Some inflow problems may be impossible to correct because of the severity of post-thrombotic disease involving the femoral and profunda femoral vein segments. Currently, there is no reliable way to assess preoperatively the potential adequacy of inflow. Several patients with severe post-thrombotic disease of the inflow tract in this study have had good clinical outcome, with long-term stent patency. Inflow can be grossly assessed intraoperatively by the speed of contrast clearance during completion venography.

Although rapid clearance is reassuring, the opposite does not necessarily warn of failure. The large sheath used during the recanalization procedure may itself impede inflow into the stent in some cases. When clearance is slow, adequate postoperative anticoagulation and close stent surveillance must be ensured. More frequent surveillance is now possible with DUS imaging.

The perioperative anticoagulation protocol is empiric. Risk of hemorrhage has to be balanced with the desire to maintain stent patency during and after the procedure. Full anticoagulation during the procedure has not been found to be necessary, and no stent thromboses during the procedure have occurred. There is room for improvement in the postoperative anticoagulation protocol to reduce delayed stent thromboses. We have not routinely used arteriovenous fistulas[22,23] to assist stent patency.

Open venovenous bypasses are major procedures, and application has been limited by age or other comorbidities. The resulting scar (Palma procedure) in the thigh is a disadvantage. Reported patency of venovenous bypass procedures has been variable.[23-27] Symptoms may persist despite a patent Palma bypass, as occurred in some patients in this series, because of the restricted size of the saphenous conduit.

CONCLUSIONS

Percutaneous recanalization is minimally invasive, safe, efficacious, and associated with negligible morbidity and downtime; therefore, it can be used in a broad spectrum of patients in whom an open bypass procedure will be precluded or inappropriate because of age (the oldest in this series was 92), symptom severity, and comorbidities. These advantages place the procedure as the first choice in treating

symptomatic femoroiliocaval vein occlusion. If stenting were to fail, subsequent open surgery would not be precluded. The open vein segment below the occluded stent or the occluded femoral vein after endovenectomy, combined with partial resection of the occluded stent, can then be used for inflow to the bypass. Conversely, prior failed open surgical interventions in the groin area (venovenous bypass) and the resulting dense fibrosis may render the percutaneous recanalization technically impossible.

A current deficit is the absence of a reliable tool to assess hemodynamic severity.[6,12] If available, such a metric would be expected to be grossly abnormal in CTO lesions. None of the currently available techniques are useful in this respect. Selection of patients for intervention continues to be based on symptom severity and morphologic assessment of obstruction.

AUTHOR CONTRIBUTIONS

Conception and design: SR, PN
Analysis and interpretation: SR, PN
Data collection: SR, PN
Writing the article: SR, PN
Critical revision of the article: SR, PN
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