Reinterventions for nonocclusive iliofemoral venous stent malfunctions

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Background: **Percutaneous iliofemoral venous stenting has been shown to be effective, safe, and durable in both nonthrombotic iliac vein lesion (NIVL) and postthrombotic disease. A small fraction of stented limbs require reintervention to correct stent malfunction. This manuscript examines the reasons for reintervention, types of procedures performed, and outcome.**
Methods: **Femoro-ilio-caval stenting was performed in 1085 limbs over a 10 year period from 1997 to 2007 (NIVL/postthrombotic limb ratio 1:1). Reinterventions were required in 137 limbs (13%) for non-occlusive stent malfunction.**
Results: **Median time of reintervention after the initial procedure was 15 months. Primary indication for reintervention was stent abnormalities discovered on routine surveillance imaging in 31% of the limbs and residual/recurrent symptoms after initial stenting in 69% of the limbs. Prevalent symptoms before reintervention were swelling (45%), pain (18%), combination of pain and swelling (33%), and venous dermatitis/ulcer (15%). Seventy-seven percent of limbs required only a single reintervention and 23% required two or more interventions. The type of reintervention could be broadly categorized into four types: (1) cephalad stent extension to correct stent outflow problems; (2) caudad stent extension to correct inflow problems; (3) balloon dilatation of stent stenoses; and (4) combinations. The types of stent inflow/outflow lesions encountered were different in NIVL and postthrombotic limbs. In both groups, the external iliac vein segment had a greater incidence of pathology than other stented venous segments during reintervention. A denovo stenotic lesion of uncertain aetiology that occurred below an existing stent was also exclusive to the external iliac vein segment. Instent restenosis (ISR) occurred in both subsets. Two types of ISR were encountered: (1) a 'soft' lesion probably due to reduced flow channel lined by thrombus within the stent from inflow/outflow problems and (2) a 'hard' lesion that occurred independently, was resistant to dilatation and tended to recur unlike the 'soft' lesion. Cumulative improvement in pain and swelling at 18 months following intervention was 67% and 72%, respectively. Complete cumulative healing of venous dermatitis/ulcer was 90% at 12 months post reintervention.**
Conclusion: **Venous stenting for chronic venous disease is largely trouble-free with only a small fraction of the stented limbs requiring reinterventions. Reinterventions were performed to correct previously overlooked or new defects in inflow, outflow and/or the stent. Reinterventions are worthwhile since they improve residual/recurrent symptoms in a durable fashion. (J Vasc Surg 2009;49:511-8.)**

Percutaneous iliofemoral venous stenting has been shown to be effective, safe, and durable in both nonthrombotic iliac vein lesion (NIVL) and postthrombotic disease.[1] The objective of this study is to analyze those patients that required reintervention after the initial procedure. This information provides a window on the types of stent malfunction that may occur, corrective actions required and steps that may be taken during the initial procedure to prevent them. The infrequency of post-stent interventions is an indication that venous stenting in chronic venous disease (CVD) is a relatively trouble-free procedure.

METHODS

A total of 1085 limbs underwent femoral-iliac-caval venous stenting for chronic venous disease over a 10-year period from 1997 to 2007. Disease was NIVL in 577 limbs and postthrombotic in 508 limbs. There were 31 (3%) stent occlusions (4 of 31 had prior reinterventions), all of which were in postthrombotic limbs; details have been described elsewhere[1] and excluded from this analysis. A total of 917 limbs (84%) had patent stents that did not require further intervention during the follow-up period. Reinterventions were required in 137 limbs (13%) for non-occlusive stent malfunction, which is the subject of current analysis.

Symptom presentation, investigations, patient selection, stenting technique, and long-term outcome have been described in detail previously.[1-4] Self-expanding braided stents were used in all but 18 limbs. Follow-up: the patients were seen in the clinic at 6 weeks, 3 months, 6 months, and yearly thereafter. Limb pain was graded on a visual analogue scale (VAS; 1-10).[5] Limb edema was graded 0 to 3; 0 = none, 1 = pitting, 2 = ankledema, 3 = gross, involving the leg or limb. Stent patency and rate of in-stent restenosis was assessed by venography[1,3] at 6 to 12 weeks post-stent and annually thereafter. Patients were also examined clinically and checked for stent patency on an ad hoc basis for persistent or recurrent symptoms. Since the last year of this study, duplex examination of the stent has been increasingly used as a screen prior to venography to assess stent patency/malfunction.

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Competition of interest: none.
Presented at the Twentieth Annual Meeting of the American Venous Forum, Charleston, SC, February 20-23, 2008.
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0741-5214/$36.00

doi:10.1016/j.jvs.2008.08.003

Table I. Details of 177 reintervention procedures in 137 limbs

Reintervention procedure	*NIVL (n = 61 limbs)*	*Postthrombotic (n = 76 limbs)*	*Total*
Balloon dilation	29	46	75
Caudad stent extension	4	8	12
Cephalad stent extension	25	20	45
Caudad + cephalad stent extensions	5	7	12
Balloon dilation + caudad stent extension	1	6	7
Balloon dilation + cephalad stent extension	11	9	20
Balloon dilation + caudad + cephalad stent extensions	5	0	5
Correct stent separation	1	0	1
Total	81	96	177

NIVL, Non-thrombotic iliac vein lesion.

Stent imaging. Duplex imaging of iliofemoral stents was carried out according to the technique described by Labropoulos.[6] Briefly, stents were visualized in the recumbent position through the abdominal 'window' with ipsilateral arm raised over the head. Stents were examined for flow and velocities measured along the length of the stent. Visible narrowing of the flow lumen and localized increase in flow velocities were indicative of in-stent restenosis. Because this technique of stent imaging was recently introduced and has not been fully validated, pre-reintervention assessment in the majority of cases in this series was based on venography.

Ascending venography via pedal injection of contrast was considered acceptable if adequate visualization of the entire stent length was obtained. Otherwise transfemoral venography was obtained for stent visualization. Visible in-stent stenosis (>50%), collaterals, and inflow or outflow abnormalities were all considered evidence of stent malfunction.

Intravascular ultrasound (IVUS)[3,7] was the final diagnostic arbiter and was carried out if prior stent imaging revealed evidence of stent malfunction, if limbs were symptomatic, or both. Appropriate reintervention in the 137 limbs described herein was based on IVUS findings and was carried out concurrently with IVUS.

Reintervention technique. A mid-thigh ipsilateral antegrade femoral vein access[2] under ultrasound guidance with routine use of a sealant device (Vasoseal) at termination is employed. After an initial on-table venogram, IVUS is used to examine the stent and adjoining inflow and outflow segments. In-stent restenosis (ISR) is corrected by high pressure (16 atm) balloon dilatation to appropriate size, generally to the original nominal diameter of the deployed stent. Overdilatation is discouraged to avoid fracture (laser cut mesh stents) or foreshortening that may result in stent separation at stent overlaps (braided stents). Recoil of ISR and external compressions of the stent occur to a variable degree following quick inflation/deflation of the balloon and may be minimized by sustained pressure dilatation for a minute or more until the balloon pressure stabilizes at 16 atm without noticeable decay.

Any defects in inflow or outflow segments to and from the stent are corrected by additional stent deployment and extension of the original stent assembly without skip areas.

Data analysis. Clinical features, operative details, and follow-up data were contemporaneously entered into a time-stamped electronics medical records program. Current material is extracted from this database. A commercially available statistical program (Graph Pad Prism for Windows [version 3.0], GraphPad Software, San Diego, Calif) was used for statistical analysis. Categorical variables were analyzed by χ^2 test. Clinical outcome analysis was plotted according to the Kaplan-Meier method. Log rank test was used to compare cumulative curves. Results are reported using P values. A P value of less than .05 was considered significant.

RESULTS

A total of 76 of 577 (13%) postthrombotic limbs and 61 of 508 (12%) of NIVL limbs required reintervention (P = ns). Median age was 50 years (range, 15 to 83 years), female to male ratio was 2.5:1, and left to right ratio was 3:1. Median time of first intervention after initial stent deployment was 15 months (range, 2 to 84 months). There was no difference in these demographics between NIVL and postthrombotic limbs. Primary reason for reintervention was stent malfunction discovered on routine surveillance imaging in 31% of limbs and residual/recurrent symptoms in 69% of limbs. Presenting symptom prompting reintervention in the latter subset was: pain (10%), swelling (39%), combined pain/swelling (36%), and venous dermatitis/ulcer (15%).

There were a total of 177 interventions in 137 limbs; 81 interventions in 61 NIVL limbs, and 96 reinterventions in 76 postthrombotic limbs, respectively (P = ns). Seventy-seven percent of limbs required only a single reintervention, 18% two, and 5% three interventions each. There was no difference in the single/multiple reintervention ratio between NIVL and postthrombotic limbs. The type of reintervention could be categorized into four types: (1) cephalad stent extension; (2) caudad stent extension; (3) balloon dilatation of stent stenoses; and (4) combinations.

Table II. Lesion frequency by segment (n = 128)*

	Extrastent		*Intrastent*		*Total*	
Inferior vena cava	17	10%	5	8%	22	9%
Common iliac vein	54	31%	28	48%	82	35%
External iliac vein	78	45%	21	36%	99	43%
Common femoral vein	24	14%	5	8%	29	13%
Total	173	100%	59	100%	232	100%

*Data missing in 9 of 137 limbs.

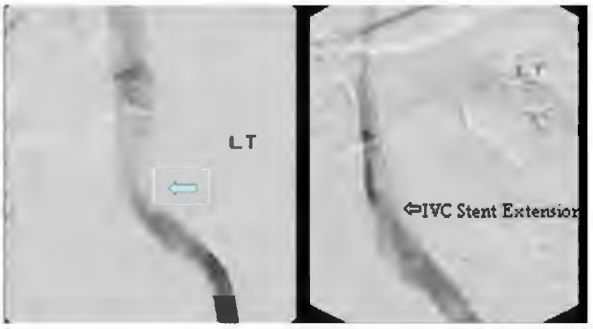

Fig 1. Distal migration of braided stent **(left)** because the stent was not extended adequately into the inferior vena cava. The stent is gradually "squeezed" distally by the constricting lesion, resulting in recurrence. The stent should be extended well into the vena cava to avoid this problem **(right)**.

Stent extensions were required to treat new or missed lesions beyond the original stent. Reintervention procedure detail for NIVL and postthrombotic limbs is shown in Table I.

Lesion types encountered during reintervention. Intrastent lesions alone (ISR and stent compressions) occurred in 75 of 177 (42%) reintervention procedures, with concurrent extrastent stenoses in 32 (18%). Stenotic lesions outside of the original stent (cephalad and/or caudad) alone without stent involvement were seen in 70 of 177 (40%) reintervention procedures. Overall, extra stent stenoses occurred in 102 of 177 (58%) reinterventions. Segment distribution of lesion types encountered is shown in Table II. The external iliac vein was most commonly involved; IVC lesions including ISR of IVC stent extensions were rare.

There were differences in the type of missed and new extra-stent lesions between NIVL and postthrombotic limbs. Because several specific lesion types in these two subsets were recognized as such at variable times during this experience, relative incidence data for individual lesion types described below is not available.

In NIVL limbs, outflow lesions above the stent were due to inadequate stent coverage of the original NIVL stenosis at the junction of the iliac vein and inferior vena cava. Reintervention was necessitated due to distal migration or 'squeezing' of the braided self-expanding stent by

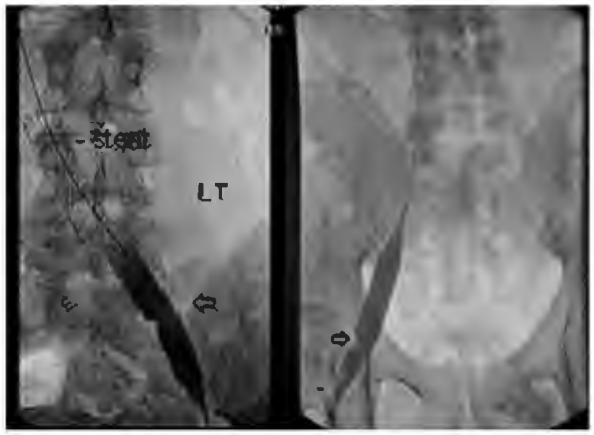

Fig 2. Reintervention in a limb that continued to be symptomatic following correction of proximal NIVL with a stent **(left)**. A distal lesion was discovered and stented. The distal lesion may be obscured even on IVUS as it sits close to the hypogastric vein orifice. Routine balloon 'sizing' (1 atm) of the entire iliac-femoral segment is recommended in all cases. A retroinguinal lesion **(right)** uncovered by balloon 'sizing.' Venography alone is unreliable as retroinguinal narrowing may be normally present in some patients due to collapse of the vein in recumbent position in this location.

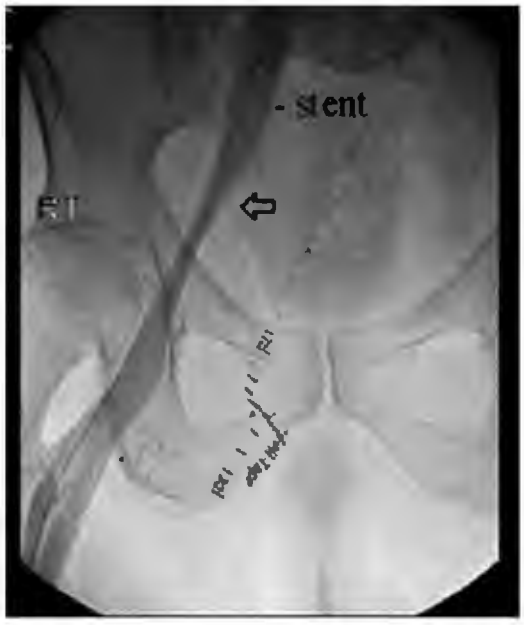

Fig 3. The nature of the denovo lesion is obscure but is exclusively confined to the external iliac vein and occurs below a previously placed stent after a period of time. It presents as a smooth, tapered stenosis with no special characteristic features on IVUS examination.

the lesion resulting in recurrence (Fig 1). Lesions detected below the stent in NIVL limbs were one of three types: (1) a previously missed distal NIVL stenosis (Fig 2, *left*); (2) a previously overlooked retroinguinal stenosis (Fig 2, *right*); and (3) a denovo lesion of uncertain etiology (Fig 3).

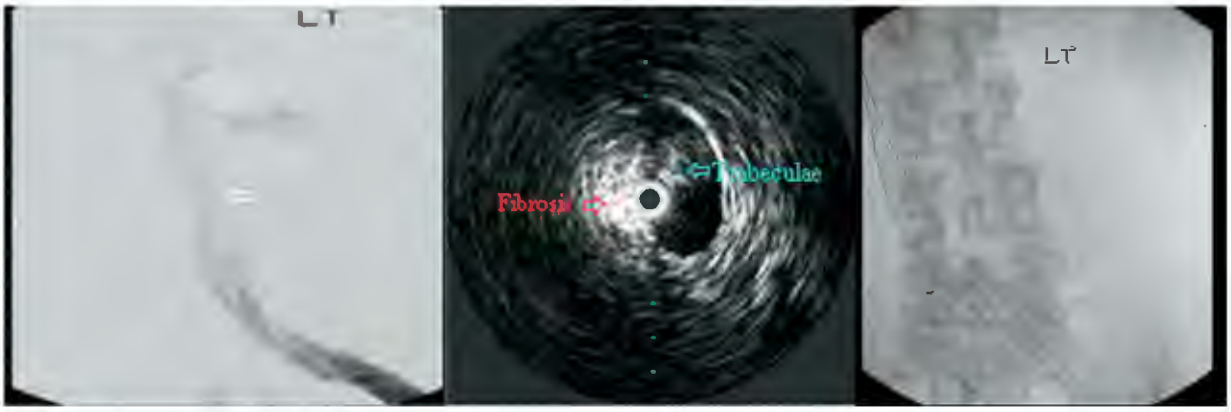

Fig 4. Reintervention for residual symptoms in a postthrombotic limb. On table venography appeared unremarkable **(left)**. A postthrombotic stenosis of the inferior vena cava with fibrosis and trabeculae above the stent was found on IVUS examination **(middle)**. A stent was placed extending up to the renal vein orifice **(right)**.

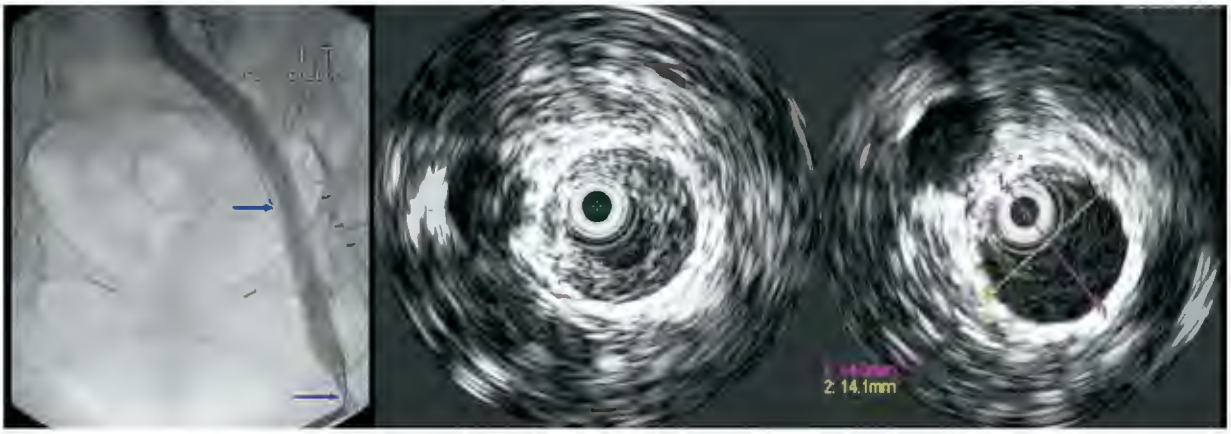

Fig 5. Layering of thrombus within the stent due to stenosis of inflow below the stent **(left)**. This type of soft instent lesion **(middle)** responds well to balloon dilatation **(right)**, but requires simultaneous correction of associated inflow/outflow problems for maintenance.

In postthrombotic limbs, extra-stent lesions were stenoses or trabeculae in the inflow/outflow segments adjoining the stent that were new or missed during the original procedure (Fig 4).

Intra-stent lesions were of similar type in NIVL and postthrombotic disease: three distinct types of were found: (1) a 'soft' ISR lesion (Fig 5); (2) a 'hard', more fibrous ISR lesion (Fig 6); and (3) external compression of the stent from inadequate ballooning or recoil of previously dilated stenoses (Fig 7). The soft ISR lesion occurred in association with inflow/outflow restriction into the stent and is likely to be layered thrombus within the stent due to stagnant flow. It was easily dilatable with near complete lesion elimination and did not recur with correction of the flow restricting lesion into or out of the stent. The hard ISR lesion was more echogenic, often occurred independently, was hard to dilate leaving considerable residue even after repeated dilatations, and tended to recur.

Outcome. There was no mortality or stent occlusion (excluded) in this series. Deep vein thrombosis occurred in seven limbs after reintervention (<30 days for two limbs; >30 days for five limbs), all involving the venous tree contralateral to the stented side.

Reinterventions improved presenting symptoms significantly (Table III) and was durable; cumulative improvement in pain, swelling, and healing of venous dermatitis/ulceration are shown in Table IV. There was no significant difference between NIVL and postthrombotic subsets in these cumulative results.

DISCUSSION

Venous stenting for symptomatic CVD has excellent long-term patency and symptom relief.[1] Reintervention is infrequently required and when needed, appears to be useful in maintaining patency and symptom relief. This resulted in an astonishing 100% cumulative secondary stent

Fig 6. A 'hard' instent lesion without evident inflow/outflow problems has a prediclection for the external iliac vein. The common iliac vein and the femoral vein are less frequently involved and less profusely; the inferior vena cava portion of the stent is seldom affected.

patency in NIVL disease and 84% in postthrombotic disease in a total of 982 limbs at six years as previously reported.[1] The difference between the two subsets is due to stent occlusions. Though the overall incidence of stent occlusions in the entire group of stented limbs is small (31 of 1085 or 3% non-cumulative), occlusions occur exclusively in postthrombotic limbs (31 of 508 or 6%, non-cumulative), two-thirds of them after recanalization of totally occluded postthrombotic veins. About a quarter of occluded stents (23% [n = 7]) were opened up by lysis, others remained occluded because stent occlusion was not detected in a timely fashion for successful lysis. It is now possible to image iliac vein stents with duplex, allowing easy surveillance and replacing the need for repetitive venography. We currently perform routine stent surveillance in all stented limbs the day after stent placement, at 6 weeks, and yearly thereafter. A more frequent schedule in the early poststent period (3, 6, and 10 weeks) in vulnerable postthrombotic stents (ie, stents with poor inflow/outflow or after recanalization) may be warranted. Stents should also be checked for patency/malfunction when symptoms recur or when residual symptoms persist. When stent imaging reveals inflow, outflow or in-stent abnormalities in such cases, the need for intervention is clear. Experience indicates that both venography and duplex imaging may be unrevealing in some cases of stent malfunction. Our rec-

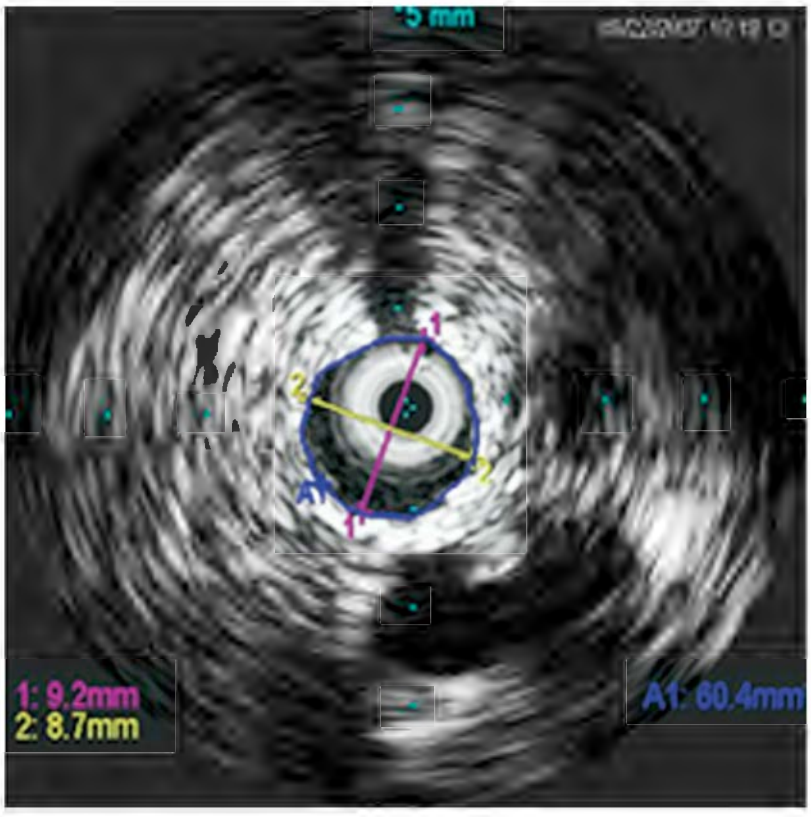

Fig 7. External compression of the stent by recoil/recurrent fibrosis of the lesion. A 16 mm diameter stent has been compressed to about 9 mm. Note the absence of ISR within the stent itself.

Table III. Symptom improvement following reintervention

Relief of symptoms	*Pre-intervention* *Median (range)*	*Post-intervention* *Median (range)*	P *value*
Pain (VAS scale)* (n = 26)	6 (0-9)	0 (0-8)	.0004
Swelling Grade** (n = 69)	3 (0-3)	1 (0-3)	<.0001

VAS, visual analog scale.
*15 of 26 limbs had complete relief of pain.
**26 of 69 limbs had complete relief of swelling.

Table IV. Cumulative relief of presenting symptom following reintervention

Symptom	*Cumulative relief (n = limbs at risk)* *6 months*	*12 months*	*18 months*
Pain* (n = 26)	100% (22)	75% (17)	67% (12)
Swelling** (n = 69)	90% (68)	80% (57)	72% (48)
Dermatitis/ulcer*** (n = 24)	90% (18)	90% (12)	70% (7)

Limbs at risk at various intervals are shown in parenthesis.
*Complete relief or improvement of 3 or more grades of VAS scale.
**Improvement of 1 or more swelling grade.
***Complete healing of dermatitis/ulcer.

ommendation is therefore to consider a diagnostic IVUS in symptomatic limbs even if imaging results are negative. Some clinical judgment is required in deciding when to perform IVUS/reinterventions when symptoms are slow to resolve after initial stenting and imaging results are negative. Noticeable improvement in symptoms, particularly that of pain indicating satisfactory stent function, is apparent within days after stent deployment. Most ulcers and dermatitis are resolved by 6 to 8 weeks after stenting. Swelling may be slower to resolve, sometimes taking up to 6 months for complete resolution particularly (counterintutively) in NIVL limbs. The reason for tardy resolution of swelling in this subset is not clear. Such limbs with slow clinical resolution may be watched for a period of time, provided duplex imaging reveals a patent stent free of lesions. A treadmill or stationary bicycle exercise program (alternate days), with instructions to exercise the limb gradually to the point of limb tiredness, appears to be helpful in speeding resolution of symptoms. IVUS examination is scheduled if symptoms are not largely resolved by 6 months after initial stent placement, even if imaging results at the time are non-revealing.

Ultrasound access for entry and routine use of a sealing device at termination virtually eliminates access site complications. Mid-thigh entry provides for superior endovenous maneuverability (torque and push) than other more distant access locations (popliteal, contralateral femoral, internal jugular), use of shorter length implements, and reduced procedure times while leaving room above the tip of the sheath to deploy stents in the femoral vein below the inguinal ligament.

Lesions encountered during intervention were either lesions missed during the original procedure or had developed since. Most encountered in this experience appeared to belong to the former category. Greater attention to detail and proper technique during the original procedure could have avoided many of them. Intravascular ultrasound has an essential role in the initial stenting and in reinterventions. Reliance on venography alone would have been deficient as shown in the many illustrated examples.

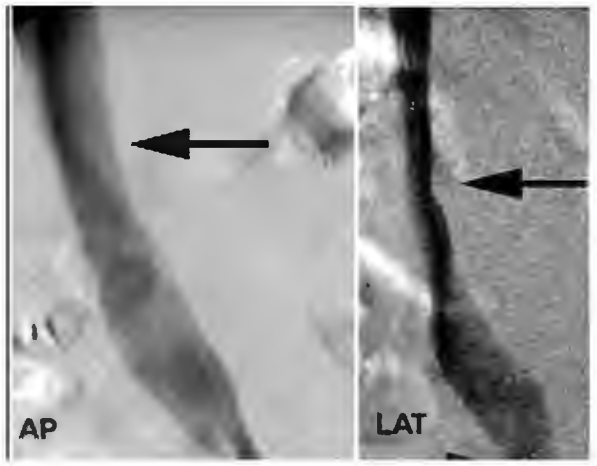

Fig 8. The proximal NIVL can involve the distal end of the inferior vena cava which can be masked in frontal projection **(left)** but evident in lateral projection **(right)**. IVUS is more reliable in uncovering such lesions while minimizing radiation exposure.

Inadequate stent coverage of the NIVL lesion at the junction of the iliac vein and inferior vena cava invariably results in recurrence at this site (Fig 1).[8] The proximal NIVL[3] can sometimes involve the lower end of the inferior vena cava itself from a high aortic bifurcation,[9] a feature often masked in frontal venographic projections (Fig 8). We have routinely extended the stent for 3-5 cm into the vena cava to minimize this problem.[8] In 1085 limbs stented during a 10-year period, problems with contralateral limb flow were rare (1%) and were successfully corrected when they occurred.[1] ISR of IVC stent extension was documented in only one limb included in this series. Distal NIVL stenoses occur in as many as 64% of NIVL cases,[3] and can be impervious to even IVUS in some cases (Fig 2). Compressive lesions of the ilio-femoral vein behind the inguinal ligament in NIVL as well as postthrombotic disease have been known for some time[10] and are easily missed as well. The genesis and nature of the denovo external iliac vein stenosis is unknown.

Fig 9. Placement of undersized stents can result in persistent symptoms due to inadequate decompression of the limb **(left)** or outright stent occlusion **(right)**. In both cases, 10 mm stents were placed in the common iliac vein (desirable size 16).

In postthrombotic veins that have recanalized, diffuse residual stenosis may be present with no visual focal cues to indicate its presence on venography. Routine IVUS measurement of the venous lumen may help identify diffuse lesions. A lumen size (maximum diameter) less than 20 mm for the infrarenal vena cava, 16 mm for the common iliac vein, 14 mm for the external iliac vein, and 12 mm for the femoral vein in normal-sized adults are alertive of diffuse stenoses. In combined NIVL/postthrombotic disease, excessive focal stenoses may develop at proximal, distal, or retroinguinal NIVL locations in addition to postthrombotic stenoses elsewhere in the segment(s).[10]

Intra-stent lesions can occur in isolation or in combination with inflow/outflow problems. Like diffuse stenotic lesions, external compressions of the stent from lesion recoil are easily missed unless IVUS measurements are taken. External compression of the stent by unrelieved stenoses at the first instance is more common in postthrombotic limbs, particularly after recanalization of totally occluded veins. We are currently evaluating overdilation of tough stenotic lesions and over sizing stents by one or two sizes in an effort to minimize this problem. Rupture and clinical bleeds are not a concern in venous stenting.[1,11] Initial oversizing may be helpful in later aggressive dilatation beyond resident size if stenoses were to recur. A generous overlap of successive stents during the initial deployment will help prevent foreshortening and stent separation during such maneuvers. Initial deployment of undersized stents for fear of rupturing the vein segment is misguided and may result in poor symptom relief or worse (Fig 9).

Though forming a large fraction in this reintervention series, overall incidence of significant ISR is quite low in veins (<5%)[1] compared with its high occurrence in the arterial system. Significant ISR is nearly exclusive to postthrombotic limbs and the incidence is negligible (<1%) in NIVL pathology.[1] It is not known whether the ISR lesions are the same or similar in the two systems. The soft ISR lesion is probably unique to venous stents. The advent of large caliber high pressure balloons (16 to 18 atm) has improved the outlook for treating stent stenoses whether internal or external to the stent. Response to standard pressure balloons (6 to 8 atm) was unsatisfactory.

The inclination to restrict stent assembly length to the bare minimum to correct only major lesions is intuitive but is counterproductive in the long run. The degree of metal load per se does not seem to lead to vein occlusion in case of stents[11] and even from flow trap (filter) devices deployed in thrombogenic limbs.[12] The propensity to understent is particularly strong when there is reluctance to extend the stent into the inferior vena cava or below the inguinal ligament into the femoral vein even when indicated. Stent extensions in either direction is safe.[13]

The external iliac vein segment appears to be a weak link in venous outflow of the limb with a propensity to develop denovo stenoses, soft or hard in-stent stenoses, and mask lesions that may pose potential problems. We have become progressively more aggressive to extend the stent from vena cava to the femoral vein to treat major and minor lesions in both NIVL and postthrombotic cases at the initial procedure. Partial correction of lesions in iliac vein stenting may result in residual or recurrent symptoms.

AUTHOR CONTRIBUTIONS

Conception and design: SR, PN
Analysis and interpretation: SR, PN
Data collection: SR, PT, PN
Writing the article: SR, PN
Critical revision of the article: SR, PN
Final approval of the article: SR, PN
Statistical analysis: SR, PT, PN
Obtained funding: Not applicable
Overall responsibility: SR

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Submitted May 27, 2008; accepted Aug 6, 2008.