

Venous stenting across the inguinal ligament

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Background: Arterial stenting across joints is not recommended because of increased risk of in-stent focal neointimal hyperplasia and compression or fracture of the stent by joint motion with decreased long-term patency. The aim of this study was to assess the risk of placing stents in the venous system across the inguinal ligament.

Materials and Methods: From 1997 to 2006, 177 limbs with chronic non-malignant obstructive lesions had stents placed in the iliofemoral venous outflow across the inguinal ligament into the common femoral vein. Transfemoral venograms and duplex ultrasound scans to assess cumulative patency rates, cumulative rates, site of in-stent restenosis (ISR), and structural integrity of the stents were performed during follow-up. The results were compared to the findings in 316 limbs with stents terminating cephalad to the inguinal ligament.

Results: Overall cumulative secondary patency (CSP) rate at 54 months was greater in the limbs with cephalad than in those caudad stent termination in relation to the inguinal ligament (95% and 86%, respectively; $P = .0001$). Although CSP of limbs with non-thrombotic obstruction was 100% regardless of the site of stent termination, that of the limbs stented for thrombotic obstruction was greater for stents terminating cephalad than for those caudad to the ligament (90% and 84%, respectively; $P = .0378$). However, a comparison of CSP rates between limbs treated for thrombotic occlusion and those with thrombotic non-occlusive obstruction at 32 months revealed no difference whether or not the stent was placed across the inguinal ligament (occlusion 77% and 77%, $P = .7540$, non-occlusive obstruction 96% and 95%, $P = .7437$). Severe ISR ($\geq 50\%$) were rare, 5%. The cumulative rate was, however, not significantly different in limbs stented cephalad and caudad to the inguinal ligament (7% and 11%, respectively, $P = .6393$). Focal in-stent recurrent stenosis at the site of the inguinal ligament occurred in only 7% of limbs (all $< 50\%$). None of the braided stainless steel stents were compressed or fractured.

Conclusion: Contrary to arterial stenting, braided stainless stents can be safely placed in the venous system across the inguinal crease with no risk of stent fractures, narrowing due to external compression, focal development of severe in-stent restenosis, and no effect on long-term patency. The patency rate is not related to the length of stented area or the placement of the stent across the inguinal ligament, but is dependent upon the etiology and whether the treated postthrombotic obstruction is occlusive or non-occlusive. (*J Vasc Surg* 2008;48:1255-61.)

Venous stent placement in chronic femoro-ilio-caval venous outflow obstruction has been shown to be a safe and efficacious procedure.¹⁻³ Long-term studies have shown a high patency rate, low rate of in-stent restenosis, and limited need for re-interventions. The clinical outcome after stenting is excellent with good symptom relief, low recurrence rate of healed venous ulcerations, and marked improvement of quality of life.⁴ Although technically a rather simple procedure, attention to details is vital to achieve an optimal result. Experience obtained from arterial stenting may not necessarily be transferable to the venous system. Stenting of arteries across moving joints, for example, is not recommended because of damage to the stents and more frequent development of intimal hyperplasia resulting in poorer patency.⁵⁻⁷ There is a fear that this would also apply to venous stenting. Several factors affecting stent-outcome have been analyzed and reported in previous studies.^{4,8} In the most recent study, proportional hazard expressed as odds ratios and effect were calculated. Significant factors associated with stent occlusion were younger age, chronic

thrombotic disease, occluded vein segment, and stent extension into the common femoral vein; sidedness, gender, and thrombophilia were not associated with stent thrombosis or severe in-stent recurrent stenosis ($> 50\%$). The worse stent-related outcome observed when the venous stenting was carried underneath the inguinal ligament into the common femoral vein has lead many to conclude that stents should not be placed at this site. The aim of this study is to contest this conclusion by further assessment of the patency, in-stent recurrent stenosis rate, and structural integrity of venous stents placed across the inguinal ligament.

MATERIALS AND METHODS

A review of a venous stent database of 1,085 limbs with chronic non-malignant venous outflow obstruction collected prospectively from 1997 to 2006 revealed 177 limbs that had an iliofemoral stenting extending from the inferior vena cava beneath the inguinal ligament into the common femoral vein. The inguinal ligament cannot be visualized radiologically. Its course is represented by a line between the *pectin ossis pubis* close to the symphysis on the superior pelvic ramus to the *spina iliaca anterior superior* of the iliac bone on an anterior-posterior abdominal plain x-ray (Fig 1). In practice, the stenting is directed by intravascular ultrasound (IVUS) performed during the procedure. Stents extended into the common femoral vein were reaching the inflow of the profunda or circumflex veins and were, therefore,

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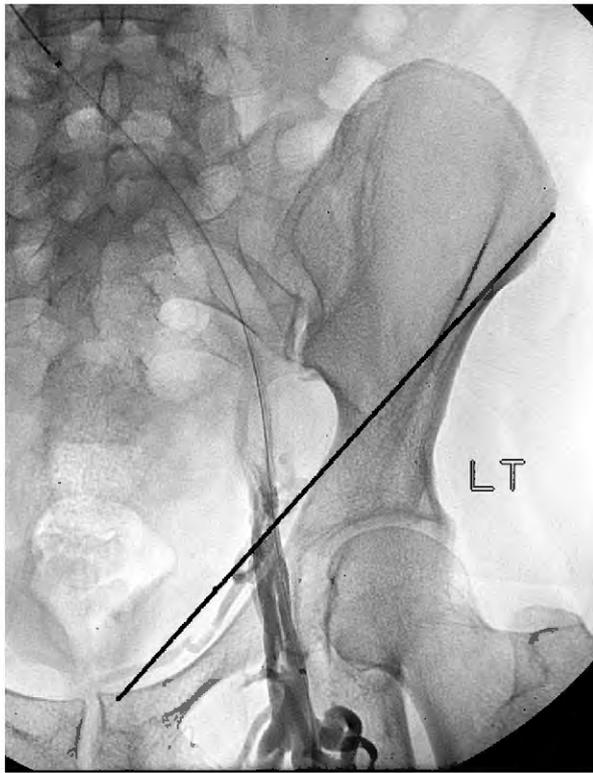


Fig 1. Anterior-posterior view of a transfemoral antegrade venogram including the left half of the pelvis. The line indicates the course of the inguinal ligament (see text).

placed well caudad to the level of the line representing the inguinal ligament. Stenting placed cephalad to the inguinal ligament were placed above this line and usually terminated in the middle or upper lower third of the external iliac vein (Figs 2 and 3).

The intervention was performed for chronic non-thrombotic iliac vein lesions (NIVL), so-called compression lesions (all non-occlusive) in 38 limbs, and for chronic postthrombotic obstruction in 139 limbs (non-occlusive obstruction in 78 limbs and occlusion in 61 limbs). The obstructive lesion was considered thrombotic when the patient had a known history of previous deep vein thrombosis (DVT) or when postthrombotic changes in the lower extremity were found on venogram, duplex scan, or intravascular ultrasound scan. Limbs treated by thrombolysis prior to stenting were excluded. The female/male ratio was 2.8/1 and left/right limb involvement was 1.9/1. The median age was 55 years (range, 22-91) (Table). The diagnosis of obstruction, indications for iliofemoral stenting, technical details of endovenous stenting, and perioperative anticoagulation treatment have been described previously.^{2,9-11} Braided stainless steel stents (Wallstents Boston Scientific, Natick, Mass) were most frequently used, but in 18 limbs (10%) nitinol mesh stents were placed.

Limbs stented to a level cephalad to the inguinal ligament were selected from the same database for comparison.

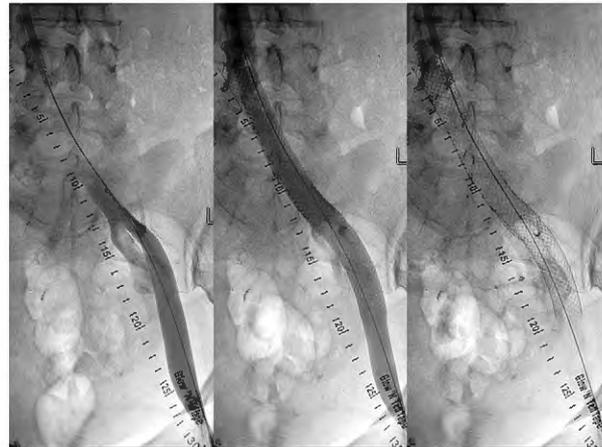


Fig 2. Transfemoral venograms showing an obstruction of the common and proximal external iliac vein (left) and the outflow after placement of braided stainless steel stents (middle) (plain x-ray; right). The stented area terminates well above the inguinal ligament and the distal external iliac vein is normal.

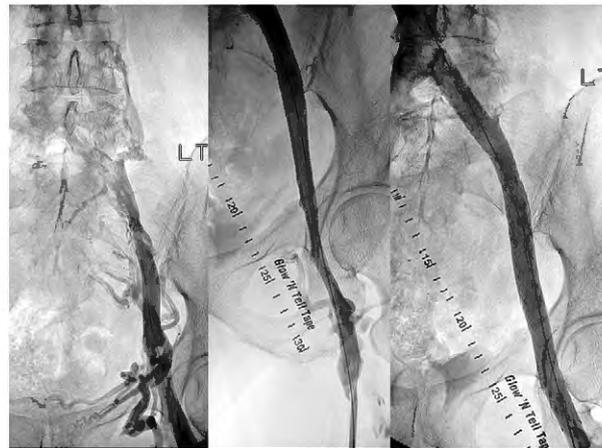


Fig 3. Transfemoral venogram showing an extensive postthrombotic iliofemoral venous obstruction (left). The proximal nitinol stent is placed, but there is a remaining stenosis of the common femoral vein (middle). The stenting is extended underneath the inguinal ligament covering the entire common femoral vein (right). The upper and lower ends of the nitinol stent are shown by radiopaque markers (*line of dots*).

Selection criteria were (1) termination of the iliac vein stent system cephalad to the inguinal ligament as described above and (2) first stent patency test performed by venogram 4 months or later following the intervention (stent may have been checked previously by duplex ultrasound scanning). These criteria were met by 316 limbs, which reflected the patient characteristics and stent outcome of the entire group of the 916 limbs in the database with stenting terminating above the inguinal ligament.

All limbs were classified using the CEAP classification according to the Reporting Standards of International So-

Table. Characteristics of groups of limbs with stenting terminated cephalad and caudad to the inguinal ligament. Basic CEAP classification is given (see text)

	<i>Caudad to inguinal ligament</i>	<i>Cephalad to inguinal ligament</i>	<i>P value</i>
Number of limbs	177	316	
Median age, years	55 (range, 22-91)	53 (range, 15-81)	.099
Female/male ratio	2.8/1	3.2/1	.653
Left/right limb ratio	1.9/1	3.0/1	.024
C ₂	8 (5%)	29 (9%)	.088
C ₃	75 (42%)	149 (47%)	.353
C ₄	42 (24%)	79 (25%)	.837
C ₅	8 (5%)	17 (5%)	.839
C ₆	44 (25%)	42 (13%)	.002
E _{primary}	38 (21%)	191 (60%)	.000
E _{secondary}	139 (79%)	125 (40%)	
A _{deep}	65 (37%)	158 (50%)	.006
A _{superficial/deep}	112 (63%)	158 (50%)	
P _{obstruction}	46 (26%)	136 (43%)	.000
P _{reflux/obstruction}	131 (74%)	180 (57%)	

ciety of Cardiovascular Surgery/Society of Vascular Surgery (ISCVS/SVS)^{12,13} based on duplex Doppler scan study with standardized compression^{14,15} and transfemoral antegrade and descending venography.^{16,17} The patients were followed with transfemoral or ascending venography and duplex Doppler ultrasound scan to assess patency, degree of in-stent recurrent stenosis (ISR), and stent integrity at 6 weeks, 4 and 9 months post-intervention, and then annually. ISR was assessed as percentage diameter reduction of patent lumen of the stent on a face view venogram. The degree of stenosis was measured using an electronic caliper and calculated thusly: diameter of stent – diameter of patent area/diameter of stent × 100 (%). Cumulative patency rates were calculated for limbs stented across the inguinal ligament to compare groups of limbs with non-thrombotic and thrombotic obstruction, and groups of thrombotic limbs with varying degrees of obstruction (non-occlusive and occlusive). In addition, cumulative patency rates were compared for groups of limbs with the same etiology and degree of obstruction, but with stent termination cephalad and caudad of the inguinal ligament as determined by the extent of the obstruction. Secondary patency rates are presented, since the main endpoint is thrombotic occlusion of the stent in this study. An evaluation and comparison of the cumulative rate of ISR was possible in limbs which had transfemoral venograms during follow-up.

Statistics. Categorical variables were analyzed by χ^2 test. Primary, assisted-primary (patency after preemptive intervention) and secondary patency rates (patency after intervention for occlusion) as defined by the reporting standards of the ISCVS/SVS¹² were calculated using survival analysis with the Kaplan-Meier method. Log-rank test was used to compare cumulative curves. Commercially available statistical programs (Graph Pad Prism for Windows, version 3.0) were used for analysis. Results are reported using *P* values. A *P* value of less than .05 was considered significant.

RESULTS

The characteristics of the groups of patients with stenting reaching caudad and cephalad to the inguinal ligament are shown in the Table. The age and gender distribution were the same in both groups. The left leg dominated in both groups, although it was more pronounced in the comparison group. The distribution of the clinical severity of the limbs in C-class 2-5 was not significantly different in the two groups, but there were relatively more limbs with leg ulcers (C-class 6) in those with stenting caudad to the inguinal ligament. There was a significantly greater rate of postthrombotic limbs, limbs with combined deep and superficial disease, and limbs with combined reflux and obstruction among the patients with extensive stenting as compared to those with stents terminating cephalad to the inguinal ligament. These findings reflect that these limbs had more complex, extensive, and severe infra-inguinal venous disease. Transfemoral antegrade venograms of typical obstructions of varying extent are shown in Figs 2 and 3. When the obstruction involves the distal external iliac vein (EIV) and proximal common femoral vein (CFV), there is no alternative but to extend the stenting caudally. If the full lesion is not treated the stent will most often occlude.

A total of 163 limbs (92%) limbs with stenting caudad to the inguinal ligament were followed for 19 months (median; range, 1-95). Twenty-eight stent systems placed in limbs treated for thrombotic obstruction occluded during the observation period after 11 months (median; range, 1-66). Eleven limbs had successful thrombolysis and two limbs failed removal of the thrombus; 15 limbs had no intervention. Intervention of patent stents was performed in 29 limbs. The majority (26 limbs, 90%) had balloon venoplasty of in-stent restenosis, in three limbs combined with distal stent extension, and in two limbs combined proximal and distal stent extensions. Three limbs had stent-

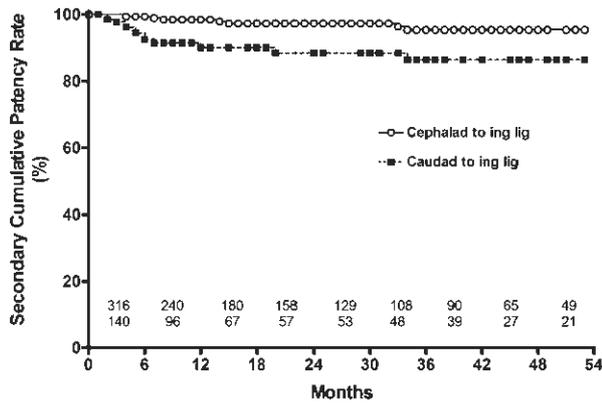


Fig 4. Secondary patency rates in all limbs with iliofemoral stenting terminating cephalad and caudad to the inguinal ligament (ing lig). The lower numbers represent total limbs at risk for each time interval (SEM <10%).

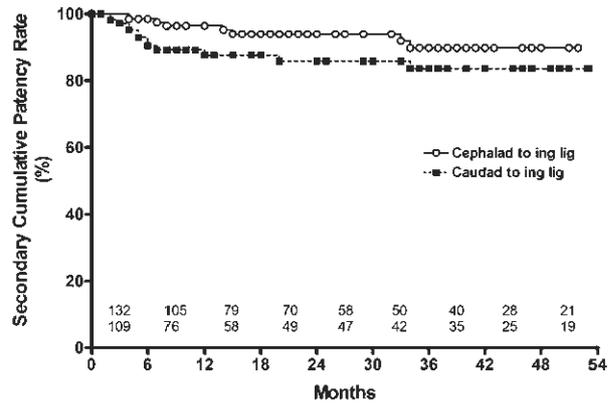


Fig 5. Secondary patency rates in limbs treated for thrombotic obstruction with iliofemoral stenting terminating cephalad and caudad to the inguinal ligament (ing lig). The lower numbers represent total limbs at risk for each time interval (SEM <10%).

ing alone; of these, one had distal stent extension, one had proximal extension, and one had a combined procedure.

All 316 limbs with stents terminating above the inguinal ligament were followed (a selection criterion for the comparison group of limbs) for a median duration of 23 months (range, 2-103 months). Only five limbs had nitinol mesh stents placed, while the remaining limbs were stented with braided stainless steel stents. Nine of the latter stents placed in limbs treated for thrombotic obstruction occluded during the observation period after 14 months (median; range 2-66). Thrombolysis was successful in three, failed in three, and was not attempted in three limbs. Interventions for patent stents were performed in 68 limbs. Additional stenting was performed more often in this group of limbs (53 limbs, 78%). Most frequently, the stent was extended caudally (38 limbs), in a few the direction was in cephalad (5 limbs) or in both directions (7 limbs). Stents bridging the gap between two stents were placed in 3 limbs. Venoplasty of in-stent restenosis was combined with the stent extension in 9 limbs, while it was the sole procedure in 15 limbs.

Cumulative secondary patency at 54 months was significantly greater in the limbs with cephalad as compared to caudad stent termination in relation to the inguinal ligament, regardless of etiology of the treated obstruction (95% and 86%, respectively; $P = .0001$) (Fig 4). None of the stents placed in limbs with non-thrombotic obstruction occluded during the observation period. Therefore, secondary patency in this group of limbs was 100% regardless of the site of stent termination. In contrast, when limbs stented for thrombotic obstruction were analyzed the patency was greater for stents terminating cephalad rather than caudad to the inguinal ligament (90% and 84%, respectively; $P = .0378$) (Fig 5). A comparison of cumulative secondary patency rates at 32 months between limbs treated for thrombotic occlusion (requiring a recanalization procedure) and those with thrombotic non-occlusive obstruction revealed no difference whether or not the stent

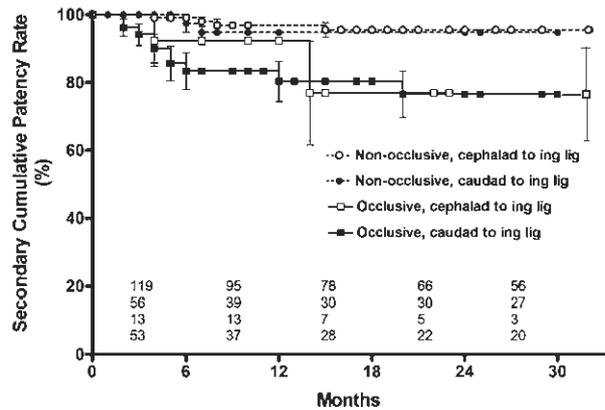


Fig 6. Secondary patency rates of stents placed in thrombotic limbs for non-occlusive obstruction and occlusion with stenting terminating cephalad and caudad to the inguinal ligament (ing lig). The lower numbers represent total limbs at risk for each time interval (\pm SEM).

was placed across the inguinal ligament (non-occlusive obstruction 96% and 95%, $P = .7437$, and occlusion 77% and 77%, $P = .7540$, stent termination cephalad and caudad to inguinal ligament, respectively) (Fig 6). On the other hand, comparing the limbs treated for non-occlusive obstruction and occlusion with stents placed cephalad and caudad to the ligament showed significant differences ($P = .0010$ and $P = .0188$, respectively). It is evident that the patency rate was not related to the length of stented area or the placement of the stent across the inguinal ligament, but dependent upon the etiology and whether or not the treated postthrombotic obstruction was occlusive or non-occlusive.

Further support for this conclusion was found by analysis of the limbs with stenting performed across the inguinal ligament only. The cumulative primary, assisted primary, and secondary patency rates for all these limbs at 42 months

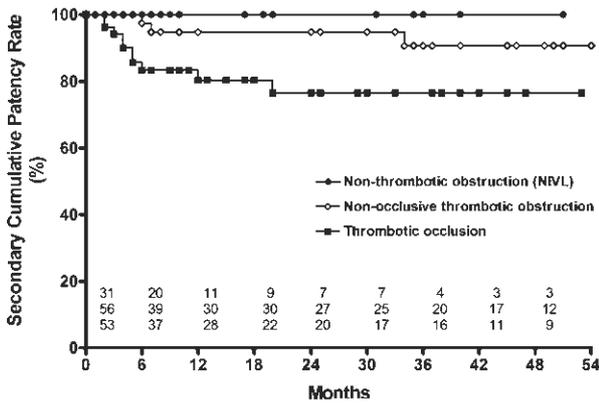


Fig 7. Secondary patency rates in limbs stented across the inguinal ligament for nonthrombotic obstruction, non-occlusive thrombotic obstruction, and thrombotic occlusion. The lower numbers represent total limbs at risk for each time interval (SEM <10%). NIVL, non-thrombotic iliac vein lesion.

were 52%, 80%, and 86%, respectively. Cumulative secondary patency rates after stratification into groups of limbs with NIVL, non-occlusive thrombotic disease, and thrombotic occlusion at 42 months show deterioration of the patency rate with more severe disease (100%, 91%, and 77%, respectively) (Fig 7).

Transfemoral venogram was performed at least once during the observation period in 351 limbs (median 8 months after stenting; range, 1-86), allowing assessment of the rate of ISR (289 limbs and 62 limbs with stenting terminating cephalad and caudal to the inguinal ligament, respectively). Limbs with re-occlusion of the stent system were excluded in this analysis. During the follow-up, 115 limbs (115/351, 33%) developed $\geq 20\%$ ISR, but only a few (19/351, 5%) had severe ISR ($\geq 50\%$). The cumulative rates of in-stent recurrent stenosis at 48 months are given in Figs 8 and 9. Some degree of ISR ($\geq 20\%$) developed more frequently in limbs stented across the inguinal ligament than in those with stent termination above the ligament (60% and 37%, respectively; $P < .0001$). A similar result was found when limbs with thrombotic obstruction were compared with those with non-thrombotic obstructions (50% and 34%, respectively; $P = .0016$). The cumulative rate of severe ISR ($\geq 50\%$) was, however, not significantly differently in limbs stented cephalad and caudal to the inguinal ligament (7% and 11%, respectively, $P = .6393$). Contrarily, the rate was lower in limbs stented for non-thrombotic obstruction than for thrombotic obstructions (1% and 14%, respectively; $P = .0003$). The development of severe in-stent recurrent stenosis, like stent patency rates, appeared to be more related to the treatment of thrombotic obstructions rather than to extension of the stenting across the inguinal ligament.

Focal in-stent recurrent stenosis occurred at the site of the inguinal ligament in 7% of limbs stented across the ligament and were not severe (<50%). ISR extended throughout the entire stent in half of the limbs (52%),

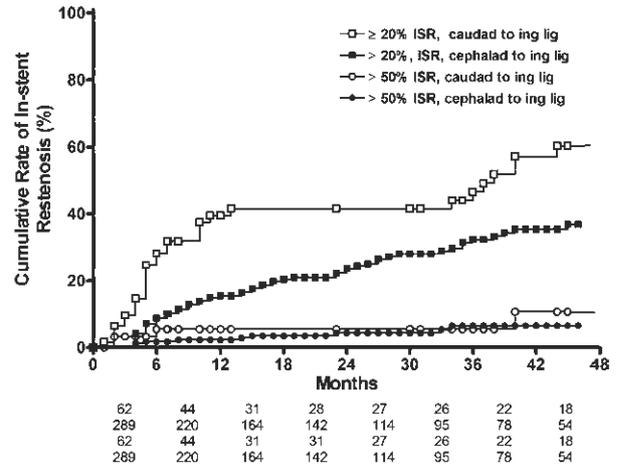


Fig 8. Cumulative rate of in-stent recurrent stenosis ($\geq 20\%$ and $\geq 50\%$) in limbs with stenting terminating cephalad and caudal to the inguinal ligament (ing lig). The lower numbers represent total limbs at risk for each time interval (SEM <10%).

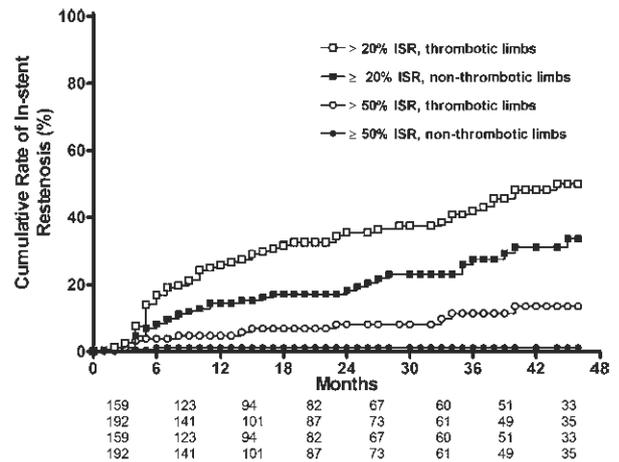


Fig 9. Cumulative rate of in-stent recurrent stenosis ($\geq 20\%$ and $\geq 50\%$) in limbs treated for non-thrombotic and thrombotic obstructions. The lower numbers represent total limbs at risk for each time interval (SEM <10%). ISR, in-stent recurrent stenosis.

which developed $\geq 20\%$ stenosis. Focal stenosis was more common in limbs with stenting across the inguinal ligament than those with stenting terminating cephalad to the inguinal ligament (68% and 39%, respectively; $P = .005$). The most common site was the external iliac vein in the former limbs (68%), while in the latter limbs it was the common iliac vein (66%). Nevertheless, the overall rate of severe ISR ($\geq 50\%$) was so low that no site analysis for these can be performed confidently.

None of the braided stainless steel stents were compressed or fractured. One of the nitinol stents was crushed at the inguinal ligament (1/18, 6%). This required treatment by insertion and venoplasty of a braided stainless stent placed inside the nitinol stent.

DISCUSSION

Arterial stenting across joints is not recommended. Motion of the joint has been shown to enhance formation of focal intimal hyperplasia in the stent at the joint sites, which may decrease the long-term patency.⁵ Stents may also be compressed, kinked, penetrate the vessel wall, or fracture by the joint motion, especially if they are not self-expandable.^{7,18-19} There is a fear that similar events would occur when stents are placed in the same position in the venous system and, thus, negatively affect outcome. Therefore, many interventionists have refrained from stenting underneath the inguinal ligament from the iliac vein to the common femoral vein, even in instances in which the common femoral vein is obviously involved in the disease process. It is vital to ensure a sufficient in- and outflow of the stent for long-term patency by covering the entire obstructive lesion with stent. The length of stenting is determined by the extent of the lesion as determined by IVUS rather than to avoid crossing the inguinal ligament. This study shows that it is safe to extend stenting across the inguinal ligament when the obstructive lesion involves the common femoral vein. Failure to do so will, almost without exception, result in early occlusion of the stent.

The mechanism behind venous recurrent in-stent restenosis is not well known and probably is different from formation of "neointimal hyperplasia" in arterial stents. Occlusion of venous stents has never been shown conclusively to occur by an evolving progression of in-stent restenosis. It is more likely to be caused by a novel thrombotic event with acute thrombosis of the stent.⁸ Significantly increased odds ratios for factors possibly contributing to stent occlusion in an unselected material, have shown these factors to be treatment for occlusion (9.0) and stenting across the inguinal ligament (odds ratio 3.8), but not thrombophilia (1.2). However, stent occlusion occurred only when stents had been placed in limbs with previous thrombosis.⁴ The group of limbs with stenting across the inguinal ligament in this study had higher prevalence of previous thrombosis (79%) than those with stents terminating above the inguinal ligament (40%). In addition, occlusions, which were stented, were only found in limbs with previous thrombosis. These limbs also appear to have a more extensive postthrombotic disease with involvement of the femoro-popliteal and profunda veins. The infra-stent postthrombotic disease may result in a poor venous outflow of the limb, decreasing the flow into the stent, and contribute to thrombosis of the stent. Layering of thrombotic material along the stent has been observed immediately after stent placement in a few cases with poor inflow. Whether or not there is a sufficient inflow to sustain stent patency is not presently possible to determine. The relationship of decreased inflow and stent thrombosis was not assessed in this paper.

Analysis was made to further elucidate the previously reported risk factors since there is obviously an intimate relationship between limbs treated for thrombotic occlusion, stenting across the inguinal ligament, and stent pa-

tency. Cumulative secondary patency analysis of all limbs in this study, regardless of etiology, showed a significantly lower patency rate in limbs with stenting caudad than cephalad to the inguinal ligament. This observation seems to support the notion that there is a risk of extending the stent into the common femoral vein across the hip joint. Even when stents placed in limbs with non-thrombotic lesions which had 100% patency, were excluded, this decreased patency rate was observed. Further analysis of the stented thrombotic limbs revealed, however, that the patency rate was dependent on whether or not the treated thrombotic vein was occluded. The extent of stenting appeared not to influence stent patency outcome in these limbs. The patency rate was not related to the placement of the stent across the inguinal ligament but was dependent upon the etiology, and whether or not the treated post-thrombotic obstruction was occlusive (requiring recanalization) or non-occlusive, ie, degree, not extent, of the postthrombotic obstruction. This observation was also supported by the fact that the secondary patency rate in limbs stented across the inguinal ligament was progressively less in limbs treated for non-thrombotic obstruction, non-occlusive thrombotic obstruction, and thrombotic occlusion (100%, 91%, and 77%, respectively).

Previously, a higher rate of severe in-stent recurrent stenosis in iliofemoral venous stents has been associated with the presence of thrombophilia, long stents, and stents crossing the inguinal ligament.⁸ This may have been explained by an over-representation of limbs with thrombotic obstruction in these groups, which probably resulted in a more severe and extensive obstructive disease. Recently, the odds ratio for possible factors contributing to the development of severe ISR in an unselected material was high for limbs with thrombotic obstruction (26.7), occlusion (8.3), and stenting caudad to the inguinal ligament (5.5), but not associated with thrombophilia (1.2).⁴ This study showed a greater development of in-stent recurrent stenosis ($\geq 20\%$) in limbs with the stent terminating caudad to the inguinal ligament rather than in those with thrombotic obstruction. Although some degree of ISR was present in many cases, severe ISR ($\geq 50\%$) was found in only 19 limbs (5%) during the observation period. The extent of the stenting in relationship to the inguinal ligament had no influence on the cumulative rate of severe ISR, which appeared to be dependent mainly on whether or not a thrombotic obstruction was stented. Focal stenosis at the level of the inguinal ligament was rare (7%) and none of these were severe. Significant in-stent restenosis occurred rarely in venous stents and no increase of focal stenosis was found at the site of stent crossing the inguinal ligament.

In this study, the stent structure was intact in all braided stainless steel stents placed in the venous system, while one nitinol mesh stent was compressed at the level of the inguinal ligament. No stent fracture or vessel erosion occurred in any case. Thus, the structural integrity of the venous stent is maintained despite movement of the hip joint.

In sum, contrary to arterial stenting, braided stainless stents can be safely placed in the venous system across the inguinal crease with no risk of stent fractures, narrowing due to external compression, or focal development of severe in-stent restenosis. Patency of these stents is not associated with the sub-inguinal site of placement, but is related to the etiology of the obstruction with secondary patency depending on the presence and severity of postthrombotic obstructions. It is vital to ensure adequate in- and outflow of the stented vein by covering the entire iliofemoral obstructive lesion as outlined by IVUS, even though this may entail crossing the hip joint. Failure to extend the stent under these circumstances creates a higher risk of stent occlusion than does the stent extension itself.

AUTHOR CONTRIBUTIONS

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

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