Is it necessary to dilate stents in management of nonthrombotic iliac vein lesions?

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ABSTRACT

Objective: Iliac vein stenting is an evolving treatment option for chronic venous insufficiency and management of nonthrombotic iliac vein lesions (NIVLs). Currently described protocols recommend deployed stents to be dilated with balloon venoplasty before completion of the procedure, based on previous literature established from management of arterial lesions. The objective of the study was to investigate the role of balloon venoplasty after stent deployment in the management of NIVLs.

Methods: During the course of 6 months, 71 balloon venoplasties with stenting of iliac veins (34 right and 37 left limbs) were performed. Intraoperatively, we used intravascular ultrasound to measure and to record area of iliofemoral veins. The measurement of stenosis was compared with adjacent nonstenotic iliofemoral veins. If >50% cross-sectional area or diameter reduction was found, it was treated with an appropriate balloon size (range, 10 × 40 mm to 16 × 60 mm) and Wallstent (Boston Scientific, Natick, Mass; 12-24 mm in diameter by 40-90 in mm length). All stents were dilated with a balloon after deployment. Intravascular ultrasound was used to measure the preoperative area of stenotic lesion, area of lesion after stenting, and area after balloon dilation of the stent.

Results: The mean age of the patients was 65.34 years (range, 36-99 years; standard deviation [SD], ±13.52 years), with 27 female and 20 male patients. The location of the targeted stenosis was the common iliac vein (31), external iliac vein (36), and common femoral vein (4). The mean area of the stenotic lesion was 99.06 mm^2 (range, 28-318 mm^2; SD, ±45.87 mm^2). The mean area after stenting was 151.51 mm^2 (range, 28-303 mm^2; SD, ±55.82 mm^2). The mean area after dilation of the stent was 162.72 mm^2 (range, 86-367 mm^2; SD, ±51.94 mm^2; $P = .22$). No statistically significant correlation was found between difference in areas and age of the patient, clinical class (C2-C6), sex, lesion, laterality, and location of targeted lesion. One patient developed an intraluminal partial thrombus within 30 days of intervention.

Conclusions: Our preliminary data show no significant clinical or technical benefit with use of balloon venoplasty to dilate stents after deployment in NIVLs. Postdilation should thus be limited to only those with suboptimal self-expansion of stent after initial deployment on fluoroscopic imaging. (J Vasc Surg: Venous and Lym Dis 2019;7:522-6.)

Keywords: Nonthrombotic iliac vein lesions; Iliac vein stenting; Balloon venoplasty; NIVLs; Intravascular ultrasound

During the last decade, balloon angioplasty and iliac vein stenting have become one of the treatments of chronic venous insufficiency. Iliac vein stenting has been reported to have a high cumulative patency (90%-100%), high clinical safety, and low risk of complications in patients with nonthrombotic iliac vein lesions (NIVLs) during long-term follow-up of 3 to 5 years.[1]

The role of poststenting balloon angioplasty in cases of arterial stenosis or occlusion has been previously described. Cavaye et al[2] used both in vitro and in vivo models to elaborate how arterial stenting could not only increase the cross-sectional area of the stenotic lesion but also convert its elliptical circumference to circular. This conformation change was noted to increase potential blood flow in the vessel. This suggested the role of post-stenting balloon angioplasty to extend beyond mechanical displacement of the plaque.

The use of balloon angioplasty for iliac vein stenting has been adopted after its technical success with arterial stent procedures. Raju et al[1,3,4] have suggested routine use of balloon angioplasty for post-stent dilation in all patients with iliocaval vein stenting. According to their study, redilation of the stent after deployment helps create proper stent to vessel wall apposition and prevents stent migration. Our clinical experience, however, differed in relation to utility of balloon angioplasty as we could not detect any impact of post-stent balloon angioplasty on fluoroscopy, and hence we decided to use intravascular ultrasound (IVUS) to assess whether post-stent dilation is associated with a significant increase in the targeted stenotic area.

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METHODS

During the course of 6 months, a retrospective study was conducted to evaluate all patients who underwent venography with venoplasty and iliac vein stenting for management of NIVLs. The procedures were performed in a single office-based setting by three qualified vascular surgeons. All patients included in the study were treated with a trial of conservative management for a consecutive 3 months before venography and venoplasty were performed. Our study included only patients who had nonthrombotic lesions on venography and IVUS studies. If a patient had post-thrombotic changes of iliac veins on examination, the patient was excluded from the study. Each patient's procedure side was classified by the presenting symptoms of the Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification set by the American Venous Forum from C1 to C6.[5]

A preprocedural transcutaneous ultrasound examination was initially provided to all patients. Next, all patients included in the study were screened with contrast venography to rule out thrombotic lesions. The use of contrast material was minimal, with 20 mL used preoperatively and 20 mL used postoperatively. Intraoperatively, IVUS was used to measure and to record the area of stenotic iliofemoral veins before venoplasty. The patient was placed in supine position, and the appropriate groin side was prepared and draped in a sterile fashion. The patients then underwent ultrasound-guided venipuncture under local anesthesia with 1% lidocaine and sedation with oral medication (diazepam [Valium]) in an office-based surgical suite. Access was obtained in the ipsilateral femoral or common femoral vein (CFV) using a single-entry needle. A 10F sheath was then inserted through the femoral vein and confirmed by fluoroscopy. IVUS 15 MHz Atlantis (Boston Scientific, Natick, Mass) was used to evaluate and to measure the cross-sectional area of the veins. The iliofemoral veins were sequentially measured. We have reported the normal and stenosed aggregate mean areas of iliofemoral vein segments in a previous study.[6] A Rokitansky stenosis was uncommon in our patients as the NIVLs are more focal in nature. The measurement of stenosis noted was compared with the adjacent nonstenotic distal segment using IVUS. If >50% cross-sectional area or diameter reduction was observed, it was treated with balloon angioplasty, sized to nonstenotic distal vein segment (range, 10 × 40 mm to 16 × 60 mm), and Wallstent (Boston Scientific; 12-24 in mm diameter by 40-90 mm in length). The stents were oversized by 20% of the nonstenotic adjacent distal vein segment. All stents were dilated with a balloon after deployment. We used the Charger balloon (Boston Scientific; 10 mm and 12 mm with rated burst pressure of 12 atm) and the XXL balloon catheter (Boston Scientific; 14 mm and 16 mm with rated burst pressure of 8 atm). IVUS was used to measure the preoperative area of stenotic lesion, area of lesion after stenting, and area after balloon dilation of the stent. The locations of the stenosis were noted as distal inferior vena cava (IVC), common iliac vein (CIV), external iliac vein (EIV), and CFV. Completion fluoroscopy, angiography, or IVUS was performed to confirm that the stents were equal to normal size, with no significant stenosis.

Postoperatively, the patients were given clopidogrel 75 mg for 3 months. If they were taking any other antiplatelet drug, it was replaced with clopidogrel for 3 months. However, if they were taking an anticoagulant, they were asked to continue the same anticoagulant without any additional clopidogrel. No aspirin was prescribed after clopidogrel for 3 months. Our follow-up protocol includes a duplex ultrasound scan at 1 week to record patency of the inserted stent and to exclude any procedure-related complications. Subsequent visits are scheduled at 3 and 6 months, followed by annual visits.

The data collection and interpretation conformed to the principles set by the Declaration of Helsinki. The Institutional Review Board of Vascular Institute of New York granted a waiver for informed consent as the study is of minimal risk and the data are blinded and retrospective.

Clinical data were entered in a table after retrospective chart review of the patient's electronic medical records and procedural details, including vein measurement analysis. Statistical analysis was performed using Student *t*-test, Fisher exact test, and analysis of variance test using R version 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria). The coefficients and *P* values for each vein were also interpreted using the ordinary least squares approach to look for significant association of stenosed area response with age, sex, laterality, CEAP score, and location of targeted lesion. $P < .05$ was considered statistically significant.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective cohort study
- **Key Findings:** After Wallstent placement in 71 iliofemoral veins, intravascular ultrasound determined that mean common iliac vein (n = 31), external iliac vein (n = 36), and common femoral vein (n = 4) areas were 114.5 mm^2, 90.2 mm^2, and 59.2 mm^2, respectively. Balloon dilation after stenting did not significantly increase cross-sectional areas (116.3 mm^2, 96.1 mm^2, and 62.5 mm^2; $P = .84$, .21, and .75, respectively.)
- **Take Home Message:** The study suggests that routine postdilation of Wallstents placed for nonthrombotic iliac vein lesions is not necessary.

RESULTS

During the period of 6 months, 71 balloon venoplasties with iliac vein stenting (34 right and 37 left limbs) were performed in 47 patients. The mean age of the patients was 65.34 years (range, 36-99 years; standard deviation [SD], ±13.52 years). Among the 47 patients, there were 27 female and 20 male patients. The targeted stenotic lesions were distributed as 34 in the right lower extremity and 37 in the left lower extremity. Each patient's procedure side was classified using the CEAP classification set by the American Venous Forum as C2 (0), C3 (21), C4 (34), C5 (10), and C6 (6). The location of the targeted stenosis was CIV (31), EIV (36), and CFV (4).

Table I depicts the mean cross-sectional area measurements of stenosed vein segments before and after stent balloon dilation based on type of vein segment treated. The mean area of the targeted stenotic lesion was 99.06 mm^2 (range, 28-318 mm^2; SD, ±45.87 mm^2). The mean area after stenting increased to 151.51 mm^2 (range, 28-303 mm^2; SD, ±55.82 mm^2). The mean area after dilation of the stent with balloon venoplasty was 162.72 mm^2 (range, 86-367 mm^2; SD, ±51.94 mm^2; $P = .22$). Table II shows the mean increase or decrease in area after stent balloon dilation based on specific vein segments.

In addition, this cross-sectional area response was correlated with the patient's age ($P = .49$), sex ($P = .34$), laterality ($P = .1$), presenting symptoms of CEAP score ($P = .92$), and location of targeted lesion ($P = .87$); no statistically significant difference was observed. One patient developed an intraluminal partial thrombus within 30 days of intervention. Clinical improvement, stent patency, and complications at follow-up have been reported previously.[7,8]

DISCUSSION

Virchow[9] in 1851 observed higher predilection of chronic venous insufficiency in the left lower extremities and attributed it to compression of the left iliac vein by crossing of the right common iliac artery. Since then, clinical experience with diagnosis and management of NIVLs has become prevalent. Studies have established other frequent causes of NIVLs including intraluminal web, band, or strut formation (22%-33%) and varying degrees of external compression of the iliac vein (66%-88%) by different adjacent structures in symptomatic patients with chronic venous insufficiency.[10-13]

Table I. Mean area of vein segments after balloon dilation in nonthrombotic iliac vein lesions (NIVLs)

Vein type	No.	Before stent dilation, mm^2		After stent dilation, mm^2		*P* value
		Mean	SD	Mean	SD	
CIV	31	114.5	59.3	116.3	66.6	.84
EIV	36	90.2	25.2	96.1	39.1	.21
CFV	4	59.2	30.6	62.5	40.7	.75

CFV, Common femoral vein; *CIV*, common iliac vein; *EIV*, external iliac vein; *SD*, standard deviation.

Table II. Effect of balloon dilation on area of stenosed vein after stenting

Vein type	Increase in area (>10%)	No change in area	Decrease in area after dilation (<10%)	*P* value
CIV	32.3 (10)	29 (9)	38.7 (12)	.87
EIV	38.9 (14)	33.3 (12)	27.8 (10)	
CFV	50 (2)	25 (1)	25 (1)	

CFV, Common femoral vein; *CIV*, common iliac vein; *EIV*, external iliac vein.
Values are reported as percentage (number).

These NIVLs have been considered "permissive lesions" by Raju et al[14,15] as the symptoms tend to be precipitated in the presence of concomitant reflux or other pathologic processes, including trauma, cellulitis, distal thrombosis, and secondary lymphatic obstruction. Excellent clinical outcomes have been noted in approximately 75% of legs with NIVLs treated with balloon dilation and stent placement, with 67% showing healed ulcers even after 2.5 years. In a review article,[1] cumulative patency of 90% to 100% was reported after iliac stenting and angioplasty of NIVLs at 3 to 5 years, with pain relief in 86% to 94% and relief from swelling and ulcers in 66% to 89% and 58% to 89%, respectively.

Previous studies have thus established iliac vein stenting with balloon angioplasty as the primary treatment of choice for NIVLs (Grade 1B).[1,16,17] Stenting guided by IVUS to identify stenotic lesions has been shown to improve symptoms in patients who exhibit lower extremity edema and pain.[3,18,19] The use of IVUS technology not only allows judgment of the extent and severity of the lesion preoperatively but also helps determine the area reduction and diameter of the stenosed iliac vein segment with exquisite detail and compares it with the area after stent deployment and balloon angioplasty.[20-22]

The venous physiology differs from the arterial lesions. Endovascular management of iliac vein stenosis has been largely derived from treatment of arterial lesions; however, there are differences in stenting techniques due to differences in vessel reactions.[15] First, a ≥50% reduction in cross-sectional area is considered significant per venous standards.[23] Also, the purpose of arterial stenting is to increase flow, whereas vein stenting is performed to decompress and to relieve peripheral venous pressure. The importance of appropriate balloon dilation with stent to vessel wall apposition has been previously demonstrated in both coronary and peripheral vessels.[20] In our experience, we use the same size of balloon before and after dilation. The role of balloon angioplasty before stenting, however, has been discussed in a separate

abstract. A highly variable response with increase or decrease or no change in cross-sectional area of the stenotic NIVL was noted with angioplasty before stenting.[24]

Raju and Neglén[15] have suggested that recoil of lesions after balloon dilation is common with iliac veins, and hence stenting is required for iliac vein stenosis. In the article, use of hyperdilation, large balloons, and oversized stents was recommended in iliac vein stenosis because of the low risk of rupture and hemorrhage compared with arterial lesions. A high-pressure balloon (16-18 atm) was suggested to be employed and kept expanded at its maximum level for at least a minute to allow balloon stabilization. This was recommended to be followed in an oversized and overdilated stent diameter by 2 to 4 mm to account for the variable recoil of the recanalized vein.

The physiology of each vein is unique. In supine position, although the IVC collapses, the CIV, EIV, and CFV do not tend to collapse. As described by Raju et al,[25] these vessels are externally supported to maintain shape by surrounding structures. The optimal stent diameters after recoil, however, have been noted to be 20 mm for IVC, 16 to 18 mm for CIV, 14 to 16 mm for EIV, and 12 to 14 mm for CFV in normal-sized adults. It is also suggested that post-stent balloon dilation should be limited to a size appropriate per segment when it is performed in patients with multiple stents. However, repeated ballooning is suggested to ensure complete recanalization and overdilated stents to ensure long-term patency.[15,26]

Experience with angioplasty and stent placement in medium-sized arteries has suggested recurrent stenosis in 15% to 30%.[27] Mild in-stent restenosis (ISR) is also a known complication encountered in up to 20% of stented limbs with iliac vein stenosis; however, severe ISR is rare (5%) and noted generally after stenting of thrombotic lesions compared with NIVLs.[28] Reintervention using high-pressure balloons is suggested to clear and to correct ISR in symptomatic patients, with reports showing up to 100% secondary patency rate in NIVLs.[4] Raju et al have thus suggested that oversizing of stents during the initial procedure facilitates later interventional corrections when necessary in a future course of treatment.

In our study, this role of balloon venoplasty after stent deployment was tested by measuring cross-sectional area using IVUS before and after balloon dilation; however, no significant difference was noted in stent-vessel wall apposition with or without additional dilation after the procedure. Our study results suggest that post-stent balloon dilation is useful only in cases of suboptimal stent deployment. No role relating to better stent area was noted. Also, discontinuation of post-stent balloon dilation has possible implications of shorter operative time and less radiation exposure, and it is cost-effective while providing equivalent technical success.

Our study, however, has limitations. The study was a retrospective analysis limited to a single center. Furthermore, the sample size of the population of patients considered for the study is small. Also, our study hypothesis has been restricted to stents placed after NIVLs only, not post-thrombotic lesions. It is also essential to note that we used the Charger (10-12 mm) and the XXL balloon (14-16 mm), available at our center, for post-stent dilation with maximum rated burst of 8 to 12 atm in contrast to the Atlas 16- to 18-mm balloon (CR Bard Inc, Covington, Ga). Another limitation of the study is that our experience is only with Wallstents; no other types of stents were used. Also, a cost analysis or analysis of fluoroscopy time was not conducted in this study. However, we do not expect a significant decline in cost from discontinuation of balloon alone. Although our study suggests that there is no benefit short term with immediate post-stent dilation, there may exist a long-term advantage with need for reintervention in this subset of patients. Hence, long-term studies are necessary to determine and to confirm the utility of balloon dilation after stent deployment. To validate this in practice, there currently is ongoing data collection at our center for long-term patency rates, patients' symptoms, quality of life scores, and pressure measurements at follow-up.

CONCLUSIONS

Our preliminary data show no significant clinical or technical benefit with use of balloon venoplasty to dilate stents after deployment in NIVLs. Post-stent dilation may thus be limited to only those with suboptimal self-expansion of stent after initial deployment on fluoroscopic imaging.

AUTHOR CONTRIBUTIONS

Conception and design: AfA, AH
Analysis and interpretation: AfA, AH
Data collection: YO, HN, AhA, NM, SR, AH, EA
Writing the article: AfA, AH
Critical revision of the article: AfA, YO, HN, AhA, NM, SR, AH, EA
Final approval of the article: AfA, YO, HN, AhA, NM, SR, AH, EA
Statistical analysis: YO
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Overall responsibility: AfA

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