The Effect of Deep Venous Stenting on Healing of Lower Limb Venous Ulcers

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WHAT THIS PAPER ADDS

This study reports ulcer healing outcomes following deep vein stenting. It will guide decision makers in treatment choices for venous ulcer management.

Objective: To report the outcomes of endovascular interventions on deep veins in patients with venous ulcers (C6).

Methods: This was a retrospective review of a case series. All patients with active venous ulceration who underwent endovascular interventions to the deep venous system from February 2011 to June 2013 were included. Patients with C6 disease who failed a trial of adequate compression therapy or superficial vein interventions were considered for evaluation of the deep veins. Patients with deep vein reflux or without significant venous reflux or with a previous history of deep vein thrombosis underwent computed tomographic venogram or ascending venogram. In the absence of intravenous ultrasound trial ballooning to look for a "waist" to identify subtle lesions was used. Lesions were stented with long Nitinol stents.

Results: Thirty-eight patients underwent deep vein stenting of 44 limbs with venous ulcers. The lesions were considered to be post-thrombotic in 31 limbs and non-thrombotic iliac vein lesions in 13 limbs. A mean of 1.8 stents were used per patient. There were no significant complications associated with the interventions. At a median follow-up of 15 months, the primary and assisted primary patency rates were 94% and 97%, respectively. Sustained ulcer healing was achieved in 60% of limbs. A further 20% of ulcers had reduced in size. Recurrent ulcers developed in 13% of limbs, and half of these healed with interventions for newly developed incompetence in superficial veins.

Conclusion: Endovascular interventions to the deep veins appear to be an effective adjunct in achieving the healing of recalcitrant ulcers.

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INTRODUCTION

Venous ulcers are a common and recalcitrant problem. The estimated prevalence of active venous ulcers is 0.8—1.0 per 1000 population.[1] The mainstay of management has been compression therapy with or without interventions to correct superficial venous reflux.[2,3] However, all strategies are known to be associated with a recurrence rate of 25—56% in the longer term.[4]

In the past, persistent ulcers have been addressed by repair or transposition of deep vein valves with good success.[5] The contribution of obstructive disease within the deep venous system in the development of venous stasis ulcers has been largely ignored. Work from a few centers has highlighted its relevance in the development of the features of venous insufficiency,[6,7]

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The aim of the current study was to report experience with the stenting of deep veins in patients with persistent venous ulcers.

MATERIAL AND METHODS

This was a retrospective review of prospectively collected data.

Study group

Patients with active venous ulcers attending the outpatient clinics of the Narayana Institute of Vascular Sciences during the period February 2011—June 2013 were evaluated for venous insufficiency.

Assessment

In addition to taking a thorough history and physical examination, all patients underwent duplex ultrasound (US) evaluation of the superficial and deep venous systems of the affected limb. Incompetence was defined as the presence of reverse flow in the femoral vein lasting >1 s after

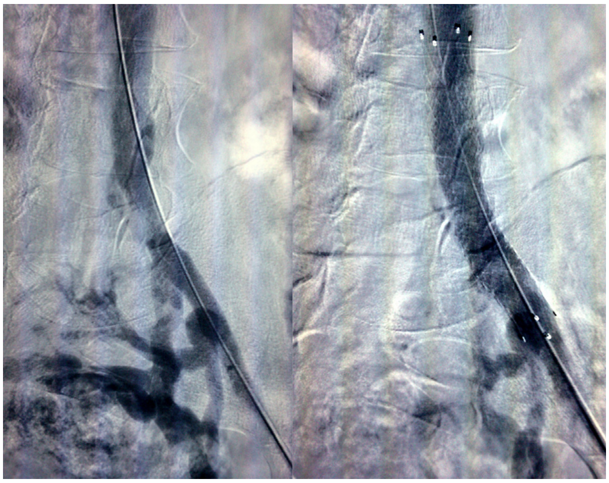

Figure 1. Non-thrombotic iliac vein lesion before and after stenting. Note degree of stent extension within the inferior vena cava.

distal augmentation, and at the saphenofemoral/saphenopopliteal junctions and saphenous trunks lasting >0.5 s.[8]

Patients with superficial reflux were offered endovenous ablation with compression therapy, and others were treated with compression therapy alone. Patients who failed an adequate trial of compression therapy or who had a persistent ulcer despite successful abolition of superficial reflux underwent assessment of the deep venous system by contrast-enhanced computed tomographic (CT) venogram.

CT venogram images were reviewed for telltale signs of deep venous pathology. CT characteristics of deep venous obstruction were the absence or narrowing of the vein, and discrepancy in bilateral vein diameters. A reduced diameter was considered suggestive of fibrosis and an increased diameter was suggestive of pre-stenotic dilatation, the presence of significant pelvic or axial collaterals, or visible compression of the iliac vein by overlying arterial structures. Enlargement and prominence of the deep femoral vein, especially in comparison with the opposite side, was assessed at the same time. Patients with the features of deep vein obstruction on CT venogram underwent ascending venography and intervention, if appropriate.

Interventional techniques

All procedures were performed under local anesthesia supplemented with intravenous analgesia and sedation when required. This was most often at the time of trial ballooning or therapeutic angioplasty or stenting.

Ascending venogram was performed by US-guided percutaneous puncture of a normal segment of vein caudad to the presumed site of disease, most commonly the common femoral vein through a 6-Fr sheath. Images were acquired with a contralateral 20° oblique view for the iliacs and 20° ipsilateral oblique view for the femoral vein. If normal, images were acquired in a projection of 90° to the original plane.

When the common femoral vein (CFV) was assessed as being disease-free it was the preferred site for access. For patients with diseased femoral veins but well developed deep femoral veins, access was obtained through the normal section of femoral vein or popliteal or small saphenous vein (SSV). Where the deep femoral vein was not well developed, access was always obtained through the popliteal or SSV with the patient prone.

Compression or narrowing is not considered to be the only sign of venous obstruction; other features were also considered.[9] Features suggestive of iliac vein obstruction were occlusion, stenosis, abnormal collaterals, layering of contrast, holdup and non-clearance of contrast, filling defects, and axial or cross-pelvic collaterals. Fig. 1 shows the venographic appearance of an NIVL lesion before and after stenting

Lesions were classified as being likely post-thrombotic or non-thrombotic iliac vein lesions (NIVL) according to their venographic features. Discrete areas of abnormality at sites described for proximal and distal NIVL were classified as NIVL. Non discrete lesions and lesions in patients with a history of deep vein thrombosis (DVT) were classified as post-thrombotic.

Unfractionated heparin (80 IU/kg) was administered and the lesion crossed using a combination of an angled catheter with a 035′ hydrophilic wire. Once across the lesion, the hydrophilic wire was exchanged for a stiff J tip 035′ guidewire (Emerald; Cordis, Bridgewater, NJ, USA).

In the absence of clearly visualized occlusions or stenosis, "trial angioplasty" was performed. The 6-Fr sheath was exchanged for a 9-Fr one compatible with 12—14-mm balloons (Atlas, Bard Peripheral Vascular, Tempe, AZ, USA; and Maxi LD, Cordis). A 14-mm (common iliac vein [CIV]) or a 12-mm balloon (external iliac vein [EIV]) was inflated until it achieved a smooth cylindrical shape or a pressure of 1 atmosphere. under fluoroscopic guidance. The presence of a "waist" during this process was considered to be diagnostic of a stenosis.

All stenotic and occlusive lesions were treated by stenting. For significantly stenotic or occlusive lesions predilation with smaller diameter balloons was performed first. Self-expanding Nitinol stents were used preferentially. For inferior vena cava (IVC) lesions, large-diameter (16—24 mm) Niti stents (Taewoong Medical, Seoul, Korea) were used. E-Luminexx stents (Bard Peripheral Vascular) were used for common iliac lesions of 12—14 mm diameter, external iliac lesions of 10—12 mm, common femoral lesions of 8—10 mm diameter, and femoral vein lesions of 6—8 mm diameter. Where multiple stents were used extensive overlap was avoided ensuring that no areas were left uncovered.

Long stents were used with the aim of covering the visible lesion and also a minimum of 2—3 cm proximal and distal to the lesion. For common iliac lesions the cranial end of the stent was extended well into the IVC.

In the case of bilateral disease, the stents were deployed by a kissing technique with the creation of a double barrel of stents in the IVC. If required, the external iliac stent was extended across the inguinal ligament to reach a healthy inflow segment. All stents were post-dilated to their nominal diameters and checked via venograms to confirm an