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Cases of Venous Stent Failure in Lower Extremities

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Iliofemoral venous outflow obstruction, arising from nonthrombotic iliac vein lesions (NIVLs) or post-thrombotic disease (PTs), is a frequent culprit behind chronic venous signs and symptoms. In response, the adoption of deep venous stenting has gained traction, demonstrating commendable technical success and acceptable complication rates in the management of both acute and chronic venous obstruction. However, the focus on venous stent failure has intensified due to concerns related to in-stent restenosis or thrombosis. Such complications elevate the risks of symptom recurrence and thrombosis relapse, necessitating a judicious approach. The identified contributors to venous stent failure encompass multifaceted factors, including insufficient coverage of the affected area, inadequate vein inflow, inappropriate stent sizing, suboptimal drug therapy, patient non-compliance, stent migration, or fracture. This paper provides a comprehensive exploration of these factors associated with venous stent failure, shedding light on the complexities surrounding the efficacy and longevity of deep venous stenting in the context of iliofemoral venous outflow obstruction. **(Ann Phlebology 2023;21:90-94)**

Key Words: Venous thrombosis, Postthrombotic syndrome, Vascular patency, Stents

Introduction

Chronic venous disease is characterized by its intricate nature, with heightened severity of symptoms in the presence of obstructive lesions within the iliac vein. Obstructions in the iliofemoral venous outflow can be attributed to nonthrombotic iliac vein lesions (NIVLs) or post-thrombotic disease (PTs). The central concern of the former is extraluminal venous compression, leading to the formation of secondary bands or webs. This compression may be induced by various factors, including the overlying iliac artery, neoplastic growth, or irradiation (*1*). For patients for whom adequate venous patency cannot be obtained with angioplasty and/or lysis due to PTs and residual intraluminal irregularities, the utilization of deep venous stenting has become increasingly prominent in addressing both acute and chronic venous obstruction (*2,3*). Venous stenting has demonstrated remarkable technical success, effectiveness in resolving venous hypertension and its related symptoms, and acceptable complication rates, regardless of the underlying cause of obstruction (*4*). However, stenting of the venous system has naturally extended from arterial stent techniques and technology, an ideal technique specifically tailored for venous pathology has not been clearly defined to date. The issue of venous stent failure has garnered attention, giving rise to concerns such as in-stent restenosis, occlusion, migration and frature (*5*). Neglén et al. (*6*) reported that the cumulative rate of severe in-stent restenosis (ISR) (>50%) occurred in 5% of limbs at 72 months (10% PTs, 1% NIVL). These complications pose the risk of symptom recurrence and thrombosis relapse, emphasizing the need for caution. Recognized contributors to venous stent failure encompass factors such as insufficient coverage of the diseased area, inadequate vein flow, inappropriate sizing (either oversizing or undersizing), insufficient drug therapy, patient non-compliance, migration, or fracture. This paper aims to thoroughly explore the factors associated with venous stent failure.

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Insufficient coverage of the lesion

Insufficiency coverage of the lesion is important factor contributing to venous stent failure (*7,8*). A study conducted by Raju et al. focused on re-interventions for non-occlusive stent malfunction, spanning a 10-year period and involving 1,085 limbs that underwent femoral-iliac-caval stenting (*9*). Among these, 577 limbs exhibited NIVL, while 508 limbs showed post-thrombotic characteristics. Of the treated limbs, 13% (137) required 177 re-intervention procedures for non-occlusive stent malfunction. Routine surveillance imaging identified stent malfunction in 31% of limbs, while 69% displayed residual/recurrent symptoms. Intra-stent lesions alone occurred in 42% of procedures, accompanied by concurrent extra-stent stenosis in 18%. Stenotic lesions beyond the original stent territory were observed in 40% of procedures, with extra-stent stenosis appearing in 58% of re-interventions overall. Differences were observed between types of extra-stent lesions when comparing NIVL limbs to post-thrombotic limbs. In NIVL limbs, outflow lesions above the stent resulted from inadequate coverage of the original NIVL lesion at the junction of the iliac vein and inferior vena cava (IVC). Lesions detected below the stent in NIVL limbs were attributed to a previously missed distal NIVL stenosis, a previously overlooked retro-inguinal stenosis, or a de novo lesion of uncertain etiology. In post-thrombotic limbs, extra-stent lesions consisted of stenosis or trabeculae in the inflow/outflow segments adjoining the stent, which were either new or missed during the original procedure. Therefore, meticulous planning and precise stent placement are imperative to mitigate such issues. When performing re-intervention, extension of the stent may be necessary to cover previously missed lesions (*7*).

Insufficient flow of the inflow veins

A critical determinant of venous stent patency is sufficient inflow (*10-13*). In cases of extensive disease, stenting across the inguinal ligament may be considered when necessary (*14*). Morris et al. (*12*) conducted a study emphasizing the significance of inflow status in patients undergoing deep vein stenting. Initially designed to compare stent performance with open-cell (OC) and closed-cell (CC) designs, the study included 207 patients (OC 100 patients, CC 107 patients). At 12 months, both primary and cumulative patency rates were similar between groups (primary: OC 63%, CC 65%; cumulative: OC 93%, CC 90%). Importantly, the sole factor significantly associated with the loss of primary patency was inflow vessel disease (hazard ratio 3.39, 95% CI 1.73～6.62, $p<0.001$). Bakas et al. (*10*) conducted another study, examining the causes of re-intervention in 129 limbs of 114 patients. The most common reasons for re-intervention were missed inflow and insufficient flow. In the context of post-thrombotic syndrome (PTS), inflow disease emerged as the strongest predictor for re-intervention (odds ratio 3.57, 95% confidence interval 1.26～10.13, $p=0.017$). To ensure adequate inflow in the common femoral vein (CFV), the lesser trochanter or femoral head is commonly used as a landmark, representing the confluence of the profunda and femoral veins forming the CFV (*15*). One of the two vessels (femoral or the deep femoral vein) have to be patent and the CFV not to be compromised when stents are placed in the iliac veins. Currently, we do not have an objective way to estimate what is an adequate inflow. However, it is easy to decide when the vessels are patent or occluded. More work is needed to determine what is adequate inflow in patients with disease at the level.

Oversizing/undersizing

In the venous system, undersizing stents will likely lead to stent failure. Given that the central veins have large diameter use of small diameter stents will compromise flow leading to stenosis and occlusion. Use of large caliber stents is recommended in the venous system to emulate normal venous anatomy. The caliber (absolute cross-sectional area) of iliac venous outflow is an important factor in controlling peripheral venous pressure (*16*). By using intravascular ultrasound (IVUS) planimetry, and Poiseuille equation in non-diseased venous segments in healthy volunteers, the stent diameters are: common iliac vein, 16 to 18 mm (area, 200 mm^2); external iliac vein, 14 mm (area, 150 mm^2); and CFV, 12 mm (area, 125 mm^2) (*17*). In contrast, oversized stent causing narrowing of the iliac vein distally (*17-19*). Other than the vein narrowing distally, large diameter stents have lower flow velocity allowing layered thrombus to develop overtime leading to stenosis and occlusion. As documented in arterial system, excessive oversizing of the stents can accelerate the development of in-stent restenosis or stent thrombosis (*20,21*). Therefore, particular attention

should be given to optimal stent sizing.

Migration

Stent migration poses a potential for significant morbidity and, in the worst cases, mortality. A systematic review conducted by Sayed et al. revealed that stent migrations often occur due to incorrect stent length and diameter selection (*22*). In fact most of the stents that migrated had a diameter of <14 mm a length of <100 mm. This issue is particularly prevalent when treating nonthrombotic iliac vein lesions (NIVLs) with focal stents, where the normal compliant vessel may not provide sufficient support to keep the stent in place. Among the 54 cases of migration, stent retrieval was achieved through either open surgery (30 cases) or an endovascular approach (16 cases). Notably, stent migration was linked to considerable morbidity or mortality. In instances where no retrieval had been attempted for 8 patients, 2 presented with cardiac arrest and failed resuscitation. Across the 31 studies, the overall mortality rate was 16.2% (6 out of 37 patients). Therefore, the authors recommended the adoption of clear strategies to prevent migration, emphasizing the importance of following these strategies to avoid the occurrence of this complication. These strategies involve placing stents with appropriate indications and proper length and sizing, employing the Valsalva maneuver in conjunction with IVUS at the vessel crossing, conducting balloon pullback, utilizing multiplanar venography to showcase significant collaterals, and adhering to the VIDIO guidelines by raising the stenting threshold to more than 60% diameter stenosis (*23,24*).

Stent fracture

Fractures are more prone to occur when extending stents into the CFV. Typically, instances of stent fractures are observed in proximity to the femoral head, approximately 1 cm below the ligament. Closed-cell stent designs or segments appear to be more prevalent in these cases, whereas open-cell or braided stents are significantly less common (*12,25*). The precise mechanism behind stent fractures remains not entirely understood, with hypotheses suggesting a potential association with crushing under the ligament or the pelvic rami due to flexion/extension movement in the region (*26*). To mitigate the risk of stent fracture, particularly when extending stents down to the confluence of the profunda vein/femoral vein, it is essential to avoid any stent overlap at the ligament or adjacent to the femoral head. Stent overlap in these areas transforms a flexible open-cell stent into a more rigid closed-cell stent, thereby elevating the risk of fracture. Furthermore, if overlap occurs on a bend, it can lead to the development of in-stent stenosis (*27*). Stent fractures have also been observed in the proximal end where compression occurs from the artery and the bone.

Insufficient drug therapy/thrombophilia/ compliance

Ensuring proper prescription and adherence to anticoagulation is crucial for upholding vessel patency (*28*). A retrospective study by Pouncey et al. (*29*) indicated that a significant number of patients required reintervention due to factors that could potentially be prevented. Out of 143 limbs (133 patients), 48 (33.6%) necessitated reintervention, with 25 experiencing reocclusion (17.4%). Noncompliance with anticoagulation was linked to an elevated risk of stenosis or reocclusion (RR, 3.26), and hematologic issues were identified in 33.3% of reintervention cases. Factors such as anticoagulation compliance, thrombus burden, and poor flow are critical considerations in patient selection. In limbs with PTS, acute DVT or combination of acute thrombosis and chronic venous obstruction the use of DOACs (direct oral anticoagulants) alone have been linked with higher thrombosis rate. Such patients now are treated with low molecular weight heparin for 4 to 6 weeks immediately after the intervention and then treatment is continued with DOACS.

Conclusion

The most cause of venous stent failure is technical issue, including inadequate coverage of the lesion or missed inflow. Venous stent failure is associated with symptom recurrence or re-thrombosis. To minimize the need for re-intervention, it is most important to perform initial stent placement appropriately. Treatment should be performed only in symptomatic individuals.

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