A Case of Left Iliac Vein Total Occlusion Presenting with Post-Thrombotic Syndrome Complicated by Mal-Deployment and Stent Fracture of a Self-Expandable Stent

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Abstract

A 69-year-old patient received endovascular treatment for an occluded left iliac vein, using a self-expandable Venovo stent, but mal-deployment of this stent occurred. The stent became completely stuck and could not be withdrawn from the patient. Balloon angioplasty was attempted to release the stuck struts of the stent but ultimately forceful manual retraction was performed, resulting in the stent fracturing and breaking. A second self-expandable stent was required to crush the fractured Venovo stent to restore vessel patency. This case highlights the bailout technique for managing mal-deployment of a self-expandable stent.

Keywords: peripheral artery diseases, self-expandable stent

Introduction

Post-thrombotic syndrome (PTS) is a common complication of deep vein thrombosis (DVT), with estimates suggesting that up to 50% of patients with iliofemoral DVT will develop PTS within two years of diagnosis.1 The severity of PTS symptoms varies depending on the location and extent of the obstruction, with common manifestations including swelling, pain, claudication, and skin changes such as discoloration or ulceration.[1] Venous recanalization and stenting have emerged as promising minimally invasive treatments for PTS, providing rapid symptom relief and long-term benefits, compared to conservative management.[2] Venous stenting boasts a high technical success rate and is associated with minimal complications both during and after the procedure. Iliac stenting, in particular, has proven highly effective in promoting ulcer healing.[3]

However, mechanical stress on stents within the venous system can occasionally lead to stent fractures. To address this, newer stents with enhanced fracture resistance, such as self-expanding nitinol stents, have been developed. Despite these advancements, many venous stents are relatively new, and long-term safety data are

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still being gathered.

Case Report

A 69-year-old man presented with a superficial wound and dark discoloration on his left leg for one year. Computed tomography revealed total occlusion of the left iliac vein, with the likely underlying pathophysiology being May-Thurner syndrome. The pre-intervention venography is shown in Figures 1a and 1b. Opening the occluded left iliac vein was indicated to relieve post-thrombotic syndrome.

We approached this case bi-directionally from the right internal jugular vein and left common femoral vein. The chronic total occlusion route was ambiguous, with no clear stump over the iliac bifurcation (Figures 1a & b), so we initiated the procedure using the knuckle wire technique. However, due to extreme vessel tortuosity, poor backup support, and the presence of multiple collateral channels, the conventional knuckle wire approach was not effective. We then employed guide extension and balloon anchoring to stabilize the guiding sheath (Figure 2a). Using the kissing wire technique and observing the wire route through orthogonal views, we were finally able to achieve bi-directional wire overlap (Figure 2b). Reverse controlled antegrade and retrograde subintimal tracking (CART) technique was performed and a retro guidewire crossed the lesion to the inferior vena cava (Figure 2c). After externalization, we performed balloon angioplasty with an 8mm balloon catheter (Figure 2d). No balloon un-dilatable lesion was noted during lesion preparation. A 12 mm*120 mm Venovo stent was deployed from the left common femoral vein. Initially, the thumbwheel allowed a smooth rotation. However, it subsequently developed an audible cracking sound on turning, and ultimately locked up completely, leading to the cessation of stent expansion (Figure 3a). To release the stuck and mal-deployed stent system, a 6-mm balloon was inserted via the right internal jugular vein and inflated near the constrained segment of the stent, but this failed to achieve full deployment. Next, we tried forceful manual retraction after adequate sedation. The distal stent struts were destroyed and became tapered like a cage (Figure 3b).

The wire was able to pass but the balloon could not cross the destroyed strut. We attempted wiring through different struts for non-compliant balloon delivery, and eventually the balloon was able to compress the damaged struts. An E-Luminexx stent (Bard Peripheral Vascular Inc., Tempe, Arizona) was then implanted over the destroyed Venovo stent (Figure 3c). The final venography showed optimal results (Figure 3d) and the patient recovered well after the procedure.

Discussion

We encountered a case in which deployment of a self-expanding stent was unsuccessful. According to previous literature, several potential mechanisms, including inadequate lesion dilatation, significant lesion calcification, highly angulated lesions and stent designs, have been associated with unsuccessful stent deployment.[4,6] In our case, there was no significant calcification within the total occlusion and the lesion preparation was optimal. However, the lesion near the CFV was highly angulated, which may have exerted excessive stress on the stent, resulting in its mal-deployment. The Venovo venous stent (Bard Peripheral Vascular Inc., Tempe, Arizona) is a nitinol, self-expanding stent designed for venous applications with high radial force. The Manufacturer and User Facility Device Experience registry has reported several Venovo stent mal-deployment cases. These reports indicated that the stent either became caught on the delivery sheath, preventing its expansion, or failed to fully expand once deployed. Bard Peripheral Vascular Inc. has acknowledged this design issue by issuing a safety notice on January 13, 2021, which emphasized that the proximal end of the stent does not expand immediately upon deployment.[5]

We experienced our complicated case before the recall of Venovo stents in 2021. Bundy et al. reported several cases of Venovo stent deployment failure and proposed various bailout techniques.[4] First, if the stent does not fully expand, slightly rotating the deployment handle may help release the constrained stent links. Second, balloon dilation can be attempted near or within the constrained stent segment from an alternative access point to achieve full expansion and ensure smooth removal of the deployment device. Another possible bailout technique is the 'cut and peel' method.[6] The Venovo stent is deployed using an over-the-wire, triaxial delivery system consisting of (a) an inner catheter, (b) a stent delivery sheath, and (c) a system stability sheath. Stent deployment is initiated by rotating a thumbwheel on the handle, which retracts the stent delivery sheath into the system stability sheath. The author proposed that by removing the system stability sheath and pulling back the stent delivery sheath, the stent might be successfully released.

In our case, however, the stent mal-deployment could not be resolved using these recommended methods. Manual retraction became our last resort, although it carried significant risks, including vessel rupture or stent migration. Additionally, an extra stent was required to cover the damaged one, potentially increasing the future risk of in-stent restenosis.

Conclusions

Awareness of potential Venovo stent deployment failures, along with an understanding of salvage techniques tailored to specific failure mechanisms, is crucial for the effective use of this device.

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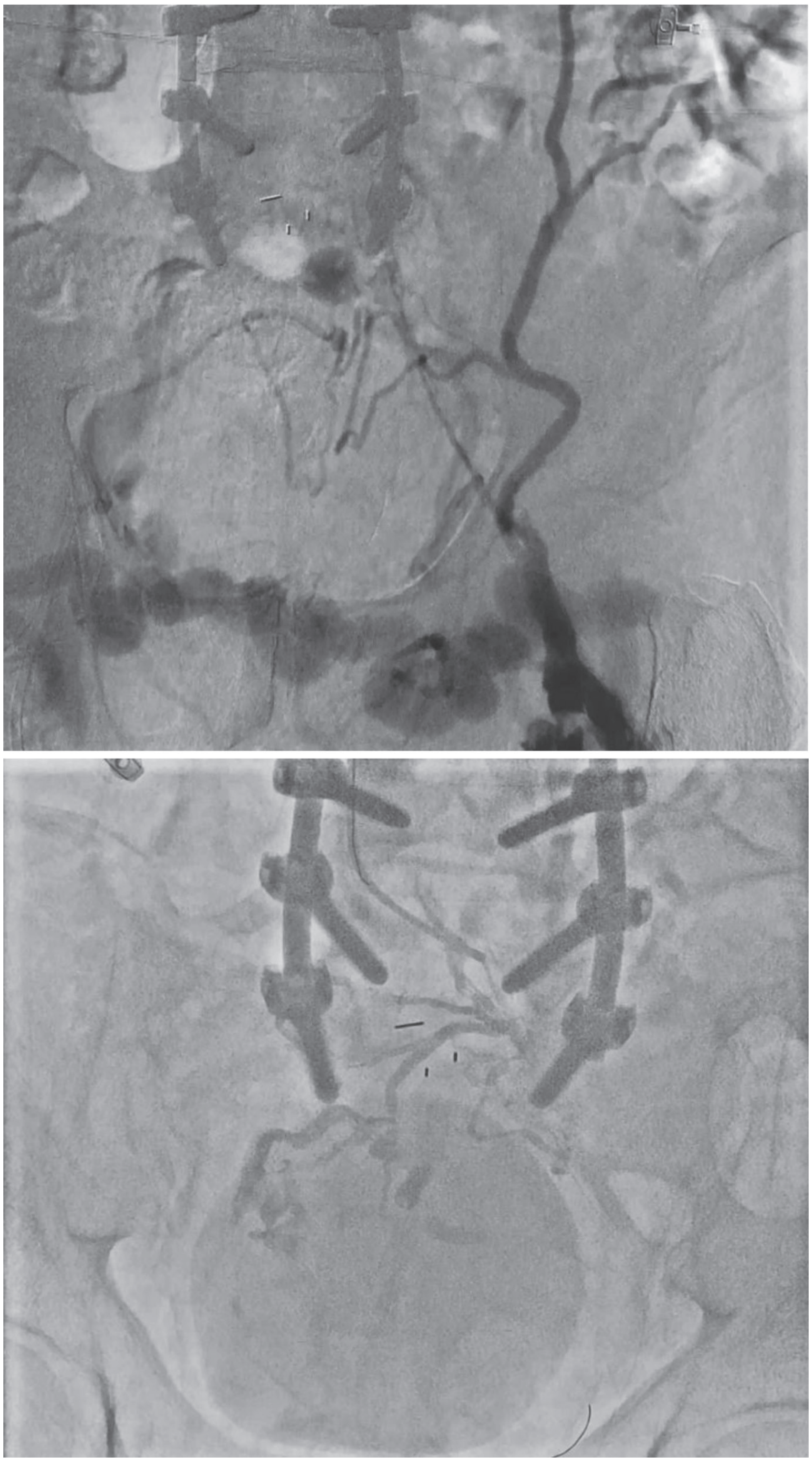

Figure 1. (1a) (upper) Antegrade venography showed left iliac vein total occlusion with misty channels inside and prominent femoral to femoral sausage-like collateral. **(1b)** (lower) Retrograde venography showed ambiguous entry of total occlusion and very complex collateral connections to the right common iliac vein.

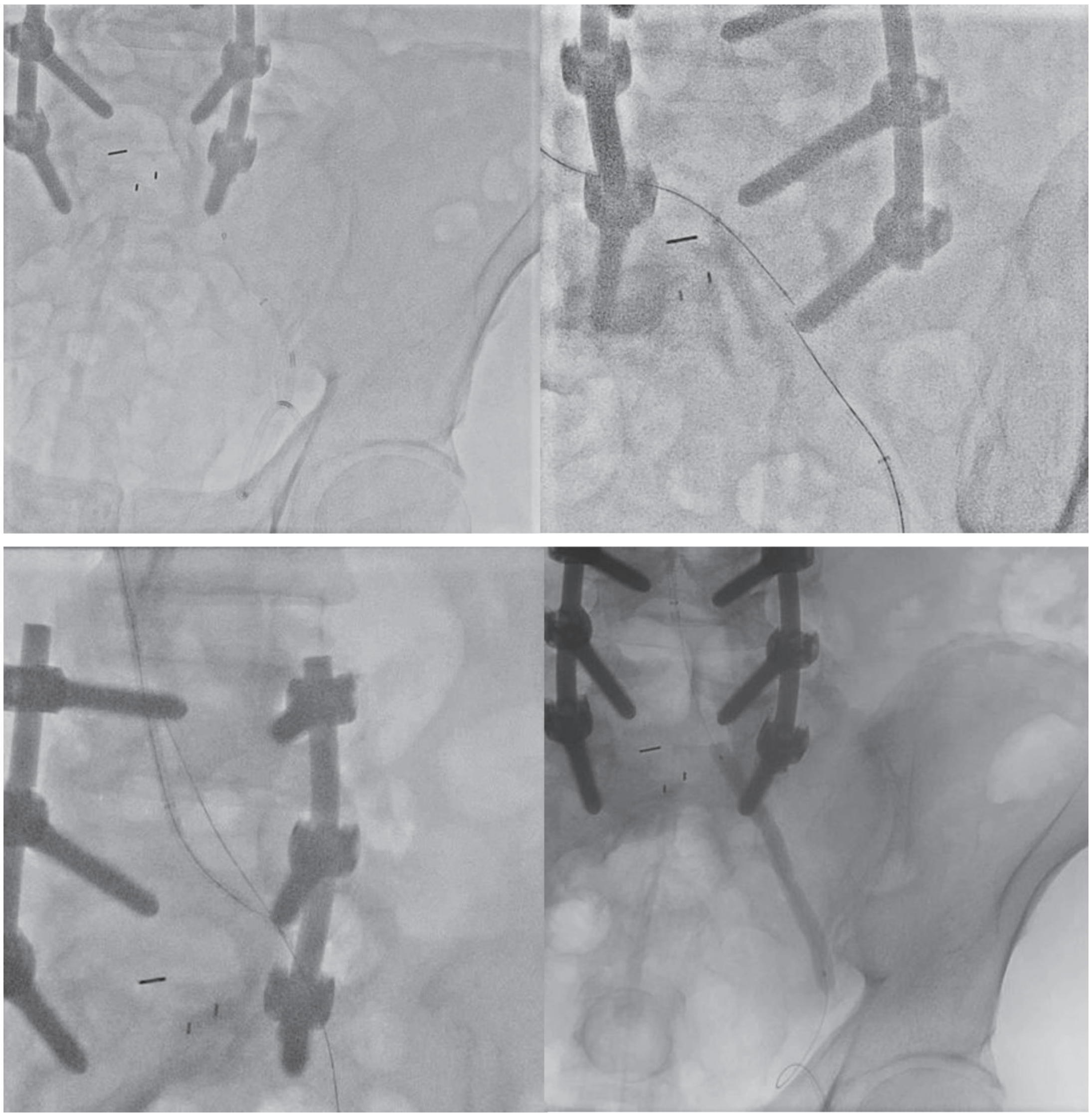

Figure 2. (2a) (left upper) Very tortuous vessel course from the left common femoral vein to the left external iliac vein; the guide sheath in the common femoral vein bent into a loop. **(2b)** (right upper) Kissing wire came closer. **(2c)** (left lower) Antegrade wire crossed into inferior vena cava. **(2d)** (right lower) 8mm balloon angioplasty.

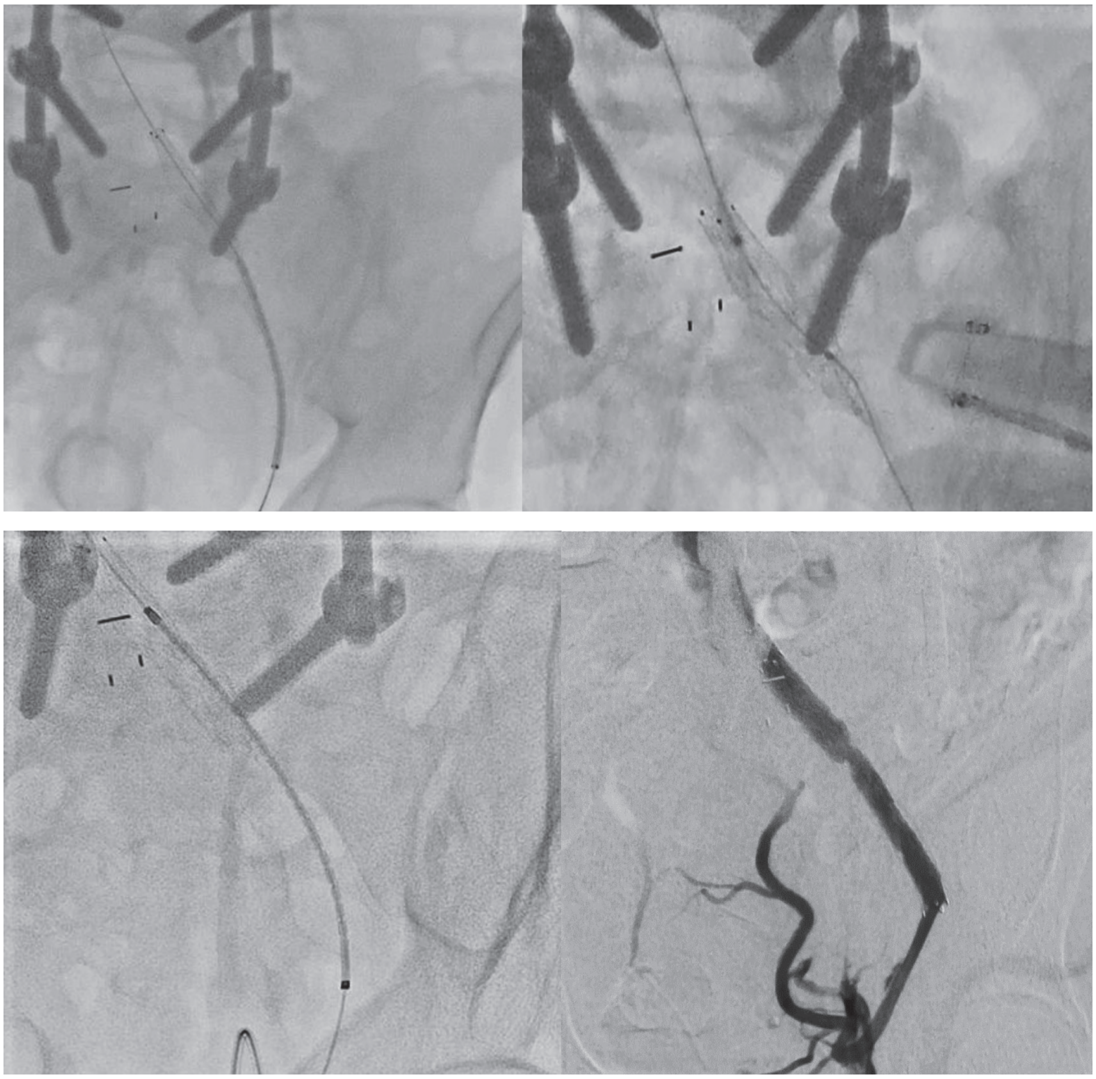

Figure 3. (3a) (left upper) Mal-deployment and stuck Venovo stent system. **(3b)** (right upper) After manual retraction of stent, the distal stent struts were destroyed and narrowed like a cage. **(3c)** (left lower) After balloon angioplasty crushed the destroyed struts, the E-Luminexx self-expandable stent covered the lesion and destroyed stent. **(3d)** (right lower) After stenting, the venography showed good flow from the common femoral vein to the inferior vena cava.