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Case Report

Treating hemodialysis access thrombosis with the InThrill Thrombectomy System: Technique and case report $^{\star, \star \star}$

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ABSTRACT

The purpose of this report is to describe via a case example an efficient mechanical thrombectomy technique for hemodialysis access thrombosis using the InThrill Thrombectomy System (Inari Medical, Irvine, CA). A man in his late 60s with end-stage renal disease and a thrombosed femoral arteriovenous graft (AVG) underwent a thrombectomy procedure to remove all thrombotic material including the arterial plug and restore use of the graft for hemodialysis. The InThrill Thrombectomy System used in this procedure consists of a mechanical thrombectomy catheter with a wall-apposing coring element and a sheath with a retractable funnel and aspiration port. The technique starts with gaining wire and sheath access towards the venous outflow. The InThrill Thrombectomy catheter is deployed proximal to the sheath to sequentially remove small segments of thrombus thus avoiding sheath obstruction. A locking syringe is used for rapid aspiration, reducing or eliminating the need to remove the InThrill sheath with every mechanical thrombectomy pass. Finally, the arterial plug is pulled using a Fogarty balloon sheath (Edwards Lifesciences, Irvine, CA) and extracted using the InThrill catheter, removing what may be the nidus for recurrent AV access thrombosis. The technique described here provided a means to remove all thrombotic material including the arterial plug in a planned, sequential manner, without the need for thrombolytics. Patency was restored to the patient's femoral AVG within 60 minutes, and hemodialysis resumed shortly thereafter. Further studies are needed to support long-term efficacy of this thrombolytic-free treatment option.

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Introduction

Hemodialysis access thrombosis is a leading cause of dialysis failure. Many of these patients experience up to 2 thrombotic events annually [1]. The long-term outlook for dialysisdependent patients is concerning, as up to 42% develop heart failure and pulmonary hypertension [2,3], a bleak prognosis that is further amplified by a 12.2-fold increase in mortality risk due to pulmonary embolism (PE) [4]. The survival rate for these patients hovers around 40% at 5 years [5].

Most treatment options for thrombosed AV access, including balloon angioplasty and existing mechanical thrombectomy devices, can disrupt thrombus but do not have the ability to extract it, risking thrombus migration to the distal arterial or pulmonary circulation. While continuous aspiration thrombectomy devices can remove thrombus, they cannot extract organized thrombus, or lack effectiveness in doing so. The InThrill Thrombectomy System (Inari Medical, Irvine, CA) addresses the unmet need for a mechanical thrombectomy device that emphasizes the capture and removal of acute to chronic thrombus to restore AV access. It is an over-the-wire 8-French (F) system consisting of a sheath with a recapturable funnel and a catheter with a nitinol element for wall-to-wall thrombus capture in 4-10 mm vessels (Fig. 1). Here we describe a simplified procedural workflow using InThrill to restore flow to a thrombosed dialysis circuit in an end-stage renal disease (ESRD) patient (Fig. 2).

Technique

A 67-year-old man with ESRD presented to the emergency department with hypotension and a thrombosed left femoral arteriovenous graft (AVG). He was referred to interventional radiology.

After pre-procedure imaging diagnosed the location and extent of the thrombus (Fig. 3A), the diseased vessel was mapped into segments. Using ultrasound guidance, access was gained toward the venous outflow, 10 cm from the arterial anastomosis (Fig. 2, Step 1). The wire was advanced distally, beyond the existing femoral venous stent, and a catheter placed over the wire. A pull-back venogram demonstrated patency of the central veins and occlusion of the stent (Fig. 3B).

The access was dilated, and the InThrill sheath was advanced safely into the vessel. The InThrill catheter was advanced into the segment most proximal to the sheath, and the InThrill funnel was deployed. Segmental thrombectomy was performed, removing the most proximal thrombus segment first (Fig. 2, Step 2). Briefly, the InThrill catheter was advanced until the deployed coring element was fully within the nearest thrombus segment. The catheter was then slowly retracted over the wire until the dark purple marker on the outer catheter exited the sheath.

With the sheath remaining in place, a locking syringe was placed on the side arm. The catheter was then removed, and the stopcock was opened, filling the syringe with blood, and extracted thrombus via aspiration through the sheath. The ex-

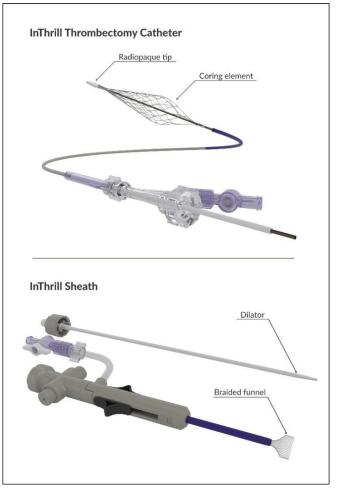


Fig. 1 – InThrill Thrombectomy System. Images courtesy of Inari Medical.

tracted thrombus was acute to chronic on visual inspection (Fig. 3C).

The catheter was advanced again, and the process repeated 4 times, with each pass removing another segment of thrombus. The InThrill catheter was passed through the exposed stent, with caution as damage or dislodgment of the stent or damage to the coring element may occur. Once all segments had been extracted, angioplasty was performed within the stent (Fig. 3D), followed by another thrombectomy pass to ensure the graft and venous outflow were clear of thrombus.

For the arterial plug, retrograde access was gained (Fig. 2, Step 3). A 6F sheath was placed, and a wire was advanced upstream to the arterial outflow (Fig. 3E). From the original access, the InThrill catheter was advanced into the venous outflow and positioned beyond the graft, where the element was then expanded (Fig. 2, Step 4).

The InThrill funnel was collapsed into the sheath while a 4 mm Fogarty balloon catheter was advanced over the secondary access wire and beyond the arterial plug (Fig. 2, Step 4 and Fig. 3F). Following standard techniques, the balloon was then retracted through the anastomosis, pulling the arterial plug along with it into the venous outflow, and the InThrill

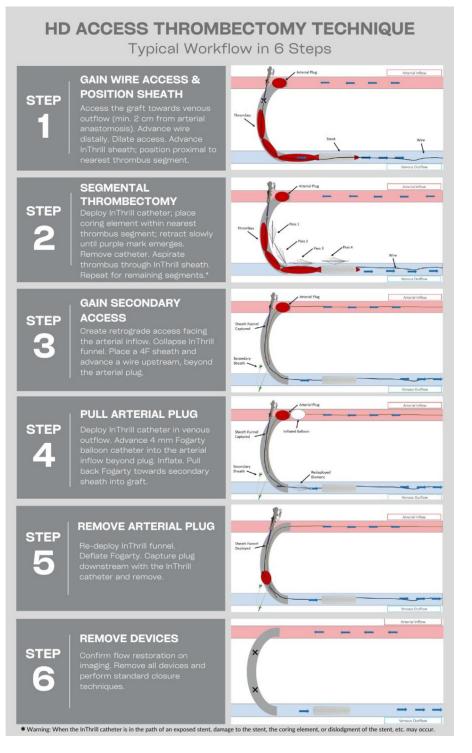


Fig. 2 - Thrombectomy technique workflow, illustrated.

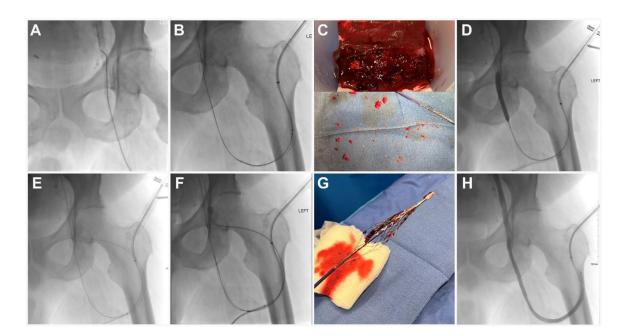


Fig. 3 – Pull-back venogram indicates location of the central thrombotic occlusion (A). Device placement, stent visible. Passes performed with the InThrill catheter starting proximal to the sheath (B). Extracted thrombus. Appears to be acute material only; once dissolved in heparinized saline, chronic thrombus is revealed (C). Balloon advanced through the stent followed by a full pass with the InThrill catheter (D). A smaller French sheath is introduced through the second access point and a wire is placed into the arterial inflow. A Fogarty balloon was introduced and inflated. Wire is placed in the arterial inflow (E). InThrill is placed downstream then the arterial plug is pulled (F). Arterial plug captured in InThrill element and extracted (G). Final venogram confirms restoration of flow through the vessel and stent. No thrombus seen downstream (H).

funnel was redeployed behind it (Fig. 2, Step 5). After balloon deflation, the InThrill catheter was slowly retracted, capturing, and removing the arterial plug (Fig. 3G). Final venography demonstrated 100% thrombus removal and restored flow (Fig. 3H).

All devices were removed, and access sites were closed (Fig. 2, Step 6). Hemostasis was achieved with purse-string sutures and manual compression. Total procedure time was 60 minutes. Estimated blood loss was approximately 70 mL. The patient returned to dialysis that evening without incident.

Discussion

Rapid thrombus clearance and flow restoration are key to maintaining viability of an ESRD patient's vascular access and ensuring prompt resumption of dialysis treatment [6–9]. With the high comorbidity rate and low cardiac reserve in this patient population, it is also vital to minimize risks and potential cardiac strain [2,10]. In this procedure, we expeditiously removed all acute to chronic thrombus from an occluded AVG using InThrill, without the need for thrombolytics and without releasing macerated thrombus into the central venous system. The described technique helped to maximize procedural efficiency with InThrill while safely restoring flow and holds promise in treating hemodialysis access thrombosis in upper or lower extremities.

InThrill has the potential to address various limitations encountered with other treatment options. Thrombolytics are commonly used to salvage a thrombosed AV access but are limited by lengthy dwell times and the inability to treat more organized thrombus. The associated bleeding risks also hamper their use in the vulnerable ESRD population. Endovascular treatments that employ only the thrombus maceration technique release thrombus fragments into the central venous system where it can travel to the pulmonary arteries. Dialysisdependent patients typically have poor cardiac health and are at a higher risk for PE mortality, further escalating the potential harm from such treatments [2–4]. Rheolytic and continuous aspiration thrombectomy techniques are often dependent on adjunctive thrombolytics [7] and can result in uncomfortable side-effects such as chest pain [11]. Furthermore, these treatments do not have a mechanism to remove walladherent or organized thrombus, a significant limitation as complete thrombus removal is essential to improve treatment durability [12]. As demonstrated here, InThrill was able to rapidly remove all acute to chronic thrombus without thrombolytics.

InThrill functions similarly to the ClotTriever System (Inari Medical) [13]. However, InThrill is smaller and better suited for AV access thrombosis. Additionally, the ClotTriever catheter is advanced distal to the thrombus before deployment of the coring element and retraction of the device through the entire thrombus. With InThrill, a different approach of advancing the catheter proximal to the thrombus and deploying the coring element into the nearest thrombus segment before retracting is utilized here [13]. By removing segments of thrombus sequentially with each pass followed by rapid aspirations, sheath obstruction was avoided.

In Thrill also facilitated arterial plug removal. Extracting the arterial plug is a critical step with the potential to delay the need for reintervention and may contribute to sustained patency. The patient has not returned for additional thrombectomy as of 1-year postprocedure.

The use of the InThrill system and described thrombolyticfree technique allowed for the efficient and complete removal of acute to chronic thrombotic material, successfully salvaging the AVG, and resuming hemodialysis treatment.

Conclusion

The example case and described technique demonstrate the potential of the InThrill Thrombectomy System to remove acute to chronic thrombus safely, effectively, and efficiently from AV accesses in a single session, without the use of thrombolytics. Further studies are needed to support these findings and establish long-term effectiveness.

Patient consent

Written informed consent for the publication of this case report was obtained from the patient.

Ethical approval

For this type of study, formal consent is not required.

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