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Single-Center Experience Using the Inari FlowTriever for Mechanical Thrombectomy of Extrapulmonary Thrombosis: A Case Series

Achintya Patel[1,2] Adam Weekley[1] Alexey Goloubev[3] Michael Markovitz[3] Glenn Hoots[3,4]

[1] Morsani College of Medicine, University of South Florida, Tampa, Florida, United States
[2] Department of Radiology, Wake Forest University, Winston-Salem, North Carolina, United States
[3] Department of Radiology, University of South Florida, Tampa, Florida, United States
[4] Florida Interventional Specialists, Tampa General Hospital, Tampa, Florida, United States

Address for correspondence Michael Markovitz, MD, University of South Florida Integrated Interventional/Diagnostic Radiology Resident, PGY-4, 12901 Bruce B Downs Blvd, MDC 41, Tampa, FL 33612, United States (e-mail: michaelmarkovitz@usf.edu).

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Abstract

The FlowTriever Gen 1 System (Inari Medical, Irvine, California, United States) is a mechanical thrombectomy device designed to extract thrombus from the pulmonary arteries, but is U.S. Food and Drug Administration approved for use in any artery or vein. From 2019 to 2020, three consecutive patients with extrapulmonary thrombosis involving the inferior vena cava (IVC), renal, gonadal, and femoropopliteal veins were treated with the device. The FlowTriever large-bore aspiration catheter was partially successful in removing IVC, renal and lower extremity vein thrombus. Zero major or minor adverse events occurred. Several technical and therapeutic insights were gained from this preliminary experience.

Keywords
- mechanical thrombectomy
- venous thrombus

Introduction

The Inari FlowTriever system (Inari Medical, Irvine, California, United States; ►**Fig. 1**) received U.S. Food and Drug Administration clearance as the first device approved for mechanical thrombectomy of pulmonary embolism (PE) in May 2018.[1] The device consists of a large-bore aspiration catheter (LBAC) and a self-expanding nitinol mesh that forms three rings to disrupt thrombus. Its safety and efficacy for the treatment of intermediate-risk PE was demonstrated in the multicenter prospective FLARE trial, which showed significant improvement in right ventricular function with few adverse events.[2] The potential extrapulmonary applications of the LBAC have not been well explored.

Other available devices for peripheral mechanical thrombolysis include the AngioJet (Boston Scientific, Marlborough, Massachusetts, United States), the Arrow-Trerotola (Teleflex Incorporated, Wayne, Pennsylvania, United States), and the AngioVac (AngioDynamics, Latham, New York, United States).[3] The AngioVac is the most similar of the three to the FlowTriever device as it employs large-bore aspiration of thrombus in the central veins. However, the AngioVac involves extracorporeal bypass and is indicated for venous thrombectomy. This study seeks to describe novel applications of the LBAC in extrapulmonary veins and the subsequent outcomes.

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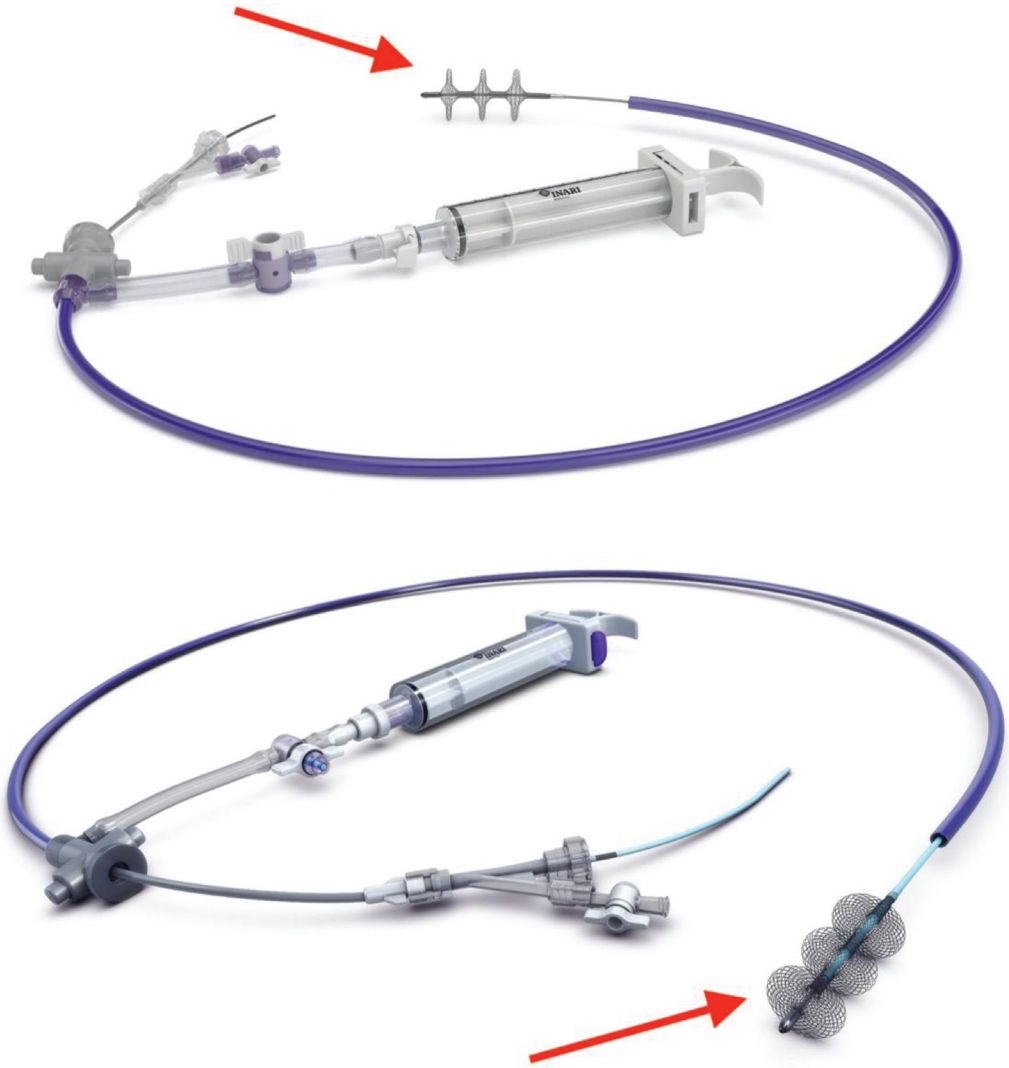

Fig. 1 The FlowTriever System (Inari Medical, Irvine, California, United States), including the nitinol mesh (red arrow) and the large-bore aspiration catheter. The nitinol mesh was not used in any of the three cases. (Reprinted with permission from Inari Medical, Inc. *Form 10-K 2020.* Irvine, CA: Inari Medical, Inc; 2020.)

Case Report

Appropriate Institutional Review Board (IRB) approval was obtained prior to accessing patient information for research purposes. A total of three consecutive patients underwent extrapulmonary, venous mechanical thrombectomy with the 20 French LBAC between April 2019 and March 2020 (►**Table 1**). The decision to use the LBAC was based on clinical judgement at the time of the procedure. The LBAC was used without the self-expanding nitinol mesh.

Case 1

A 71-year-old female with a history of stage IV squamous cell lung carcinoma presented with hemoptysis, shortness of breath, and abdominal pain. Computed tomography (CT) angiogram showed no evidence of acute PE. Contrast-

Table 1 Patient demographics and case summaries

Case	Age	Sex	Thrombus location	Access site	Accessory devices used	Complications
1	71	Female	IVC, bilateral renal, right ovarian veins	Right IJV	IVC filter	None
2	27	Male	IVC, left common iliac, external iliac, femoral, and popliteal veins	Right IJV		None
3	39	Female	IVC	Bilateral CFV	PTA	None

Abbreviations: CFV, common femoral vein; IJV, internal jugular vein; IVC, inferior vena cava; PTA, percutaneous transluminal angioplasty.

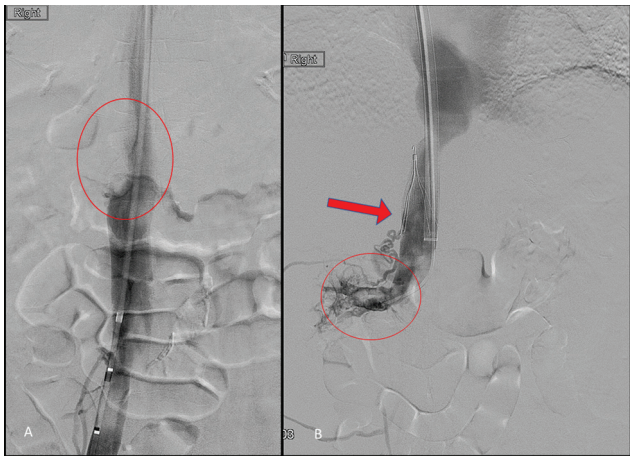

Fig. 2 Case 1—(**A**) Venacavogram with filling defect representing thrombus in inferior vena cava (IVC) prior to intervention. (**B**) Right renal venogram demonstrating nearly occlusive thrombus with IVC filter in place (red circle) and resolution of filling defect seen in (**A**) (red arrow).

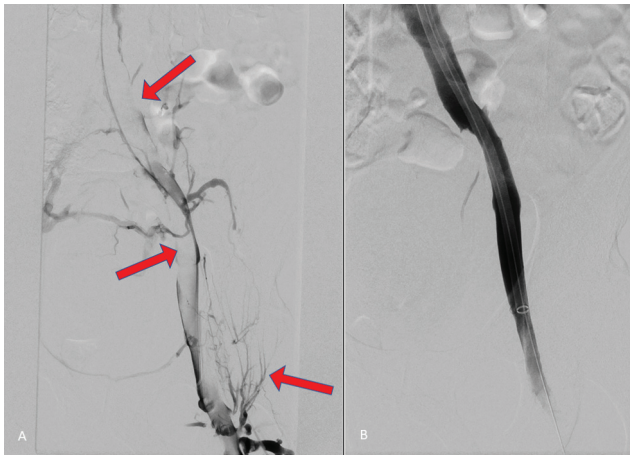

Fig. 3 Case 2—(**A**) Left iliac and common femoral venogram demonstrating extensive pre-procedure thrombus burden and collateral formation (red arrows). (**B**) Left femoral and iliac venogram demonstrating significant resolution of thrombus post-thrombectomy.

enhanced CT (CECT) of the abdomen and pelvis revealed occlusive thrombus of the right gonadal and renal veins extending into the suprarenal inferior vena cava (IVC; ►**Fig. 2A**).

Via right internal jugular vein (IJV) access, an inferior venacavogram confirmed thrombus extending from the right renal vein orifice into the suprarenal IVC. A Gunther tulip IVC filter (Cook Medical Inc, Bloomington, Indiana, United States) was placed superior to the thrombus. Suction thrombectomy of the IVC thrombus was performed using the LBAC. Subsequent right renal venogram demonstrated nearly occlusive thrombus remaining in right renal vein, but resolution of the IVC filling defect was noted (►**Fig. 2B**). Multiple attempts to maneuver the LBAC into the right renal vein were unsuccessful and the procedure was terminated. The patient was transitioned from intravenous (IV) heparin to subcutaneous enoxaparin upon discharge 5 days later. She experienced no complications during or in the early postintervention period.

Case 2

A 27-year-old male with a history of stage IV melanoma complicated by brain metastases with recent hemorrhagic conversion, recurrent deep vein thrombosis (DVT) with PE, and IVC filter presented with 2 days of worsening left lower extremity pain and swelling. CECT of the abdomen and pelvis demonstrated new thrombus in the left femoral and common iliac veins with extension into the IVC. He was started on weight-based heparin infusion.

The patient was not a candidate for tissue plasminogen activator given his recent cerebral hemorrhage, so the decision was made to proceed with mechanical thrombectomy. Via right IJV access, left lower extremity venography demonstrated occlusive thrombus extending from the left popliteal vein to the patient's indwelling IVC filter (►**Fig. 3A**). Suction thrombectomy was performed with the LBAC. Multiple thrombectomy passes were performed yielding complete clearance of thrombus in the left popliteal, superficial femoral, and common iliac veins (►**Fig. 3B**). A small residual thrombus remained in the IVC filter, which was left in place. The patient experienced no immediate postintervention complications and was transitioned from IV heparin to oral apixaban.

Case 3

A 39-year-old female presented with 4 days of severe, progressive bilateral lower extremity edema and pain. This patient has a history of end-stage renal disease on hemodialysis via left groin tunneled catheter, systemic lupus erythematosus, and recurrent DVT treated with warfarin and an IVC filter. Ultrasound evaluation in the emergency department showed nonocclusive common femoral vein (CFV) thrombus. She was admitted to the intensive care unit secondary to hypertensive urgency. A CECT abdomen/pelvis demonstrated a poorly opacifying IVC suspicious for chronic occlusion.

Initial venography via right CFV access demonstrated IVC stenosis superior to the indwelling filter with intraluminal thrombus. Using the patient's existing left groin dialysis catheter site, angioplasty with 20 mm Bard ATLAS (Bard

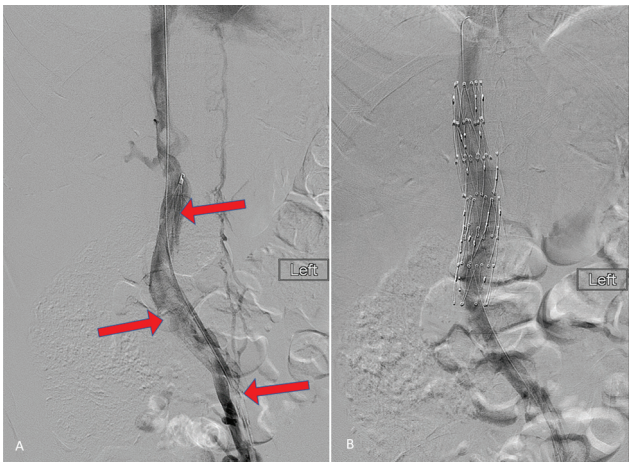

Fig. 4 Case 3—(**A**) Left common iliac vein and inferior vena cava (IVC) venogram with chronic thrombus burden (red arrows). (**B**) IVC and left common iliac venogram demonstrating resolution of stenosis and 25 mm Gianturco Z-stents (Cook) in place and IVC filter removal.

Peripheral Vascular, Inc, Tempe, Arizona, United States) was performed (►**Fig. 4A**). Venography showed improvement in IVC stenosis but persistence of the intraluminal thrombus. The LBAC was introduced using the right groin access and mechanical thrombectomy was performed. Minimal thrombus was retrieved suggesting chronic thrombus adherent to the vessel wall. The IVC filter was removed via the right groin with forceps. Gianturco Z-stents (25 mm, Cook Medical, Bloomington, Indiana, United States) were deployed from the intrahepatic IVC to the iliac confluence with restored patency of the IVC (►**Fig. 4B**). The patient was discharged 1 week later with near resolution of lower extremity pain and edema. She experienced no complications during the procedure or in the early postintervention period. Her IVC has remained patent on catheter exchange venograms for 1 year postintervention.

Discussion

The armamentarium possessed by interventional radiologists to treat both arterial and venous thrombus is ever expanding. The LBAC is yet another option available when faced with large, complex thrombus burden, as demonstrated in each of the three cases discussed. The catheter itself is appealing in the extrapulmonary setting as, in the authors' experience, it tracks well over a wire and provides a large lumen for suction thrombectomy.[4,5]

This single-center experience with the device in the treatment of extrapulmonary thrombus yielded mixed results. Its demonstrated utility is clear when systemic fibrinolysis is contraindicated (Case 2).[6] It also appears to have a role in treating acute thrombi in large veins such as the IVC, iliac, and femoral veins but without complete success (cases 1 and 2). Its benefit appears limited, though, in treating chronic thrombus adherent to vessel walls despite appropriate device positioning and making multiple aspiration attempts (Case 3). In our experience, the device can also be relatively difficult to properly manipulate into the optimal position. For example, it was unable to make the acute angles required to perform thrombectomy of the renal veins (Case 1). The device has also been utilized comparably as a protective shield, using the nitinol mesh to prevent embolization of an existing IVC thrombus during percutaneous drainage of a hepatic hematoma that was compressing the patient's IVC.[7]

Despite the mixed efficacy results, the LBAC proved reasonably safe in this small case series. Zero major or minor adverse events, technical complications, delayed procedure-related complications, or deaths within 30 days of hospital discharge occurred. Further studies may involve more patients in a prospective manner to better characterize the safety profile and efficacy of the device.

Conclusion

Several technical and therapeutic insights were gained from our center's preliminary experience. Based on a small number of patients, the LBAC appears to be a viable option in the treatment of large, acute venous thrombi. However, its difficult maneuverability may preclude its use in locations with sharp angles such as the renal veins. Further study is required to extrapolate safety and efficacy to comparable patients with different presentations or comorbidities.

Compliance with Ethical Standards

1. This study was not supported by any funding.
2. The authors declare that they have no conflict of interest.
3. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.
4. This study has obtained IRB approval and the need for informed consent was waived due to the retrospective nature of the study.
5. For this type of study consent for publication is not required.
6. The material was presented as a poster presentation for the cancelled 2020 SIR Annual Scientific Meeting.
7. This material will not be submitted for another publication while it is under consideration with JCIR ISVIR.

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Conflict of Interest
None declared.

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