

Feasibility of the Protrieve Sheath for Embolic Protection During Venous Thrombectomy in Twenty-two Patients

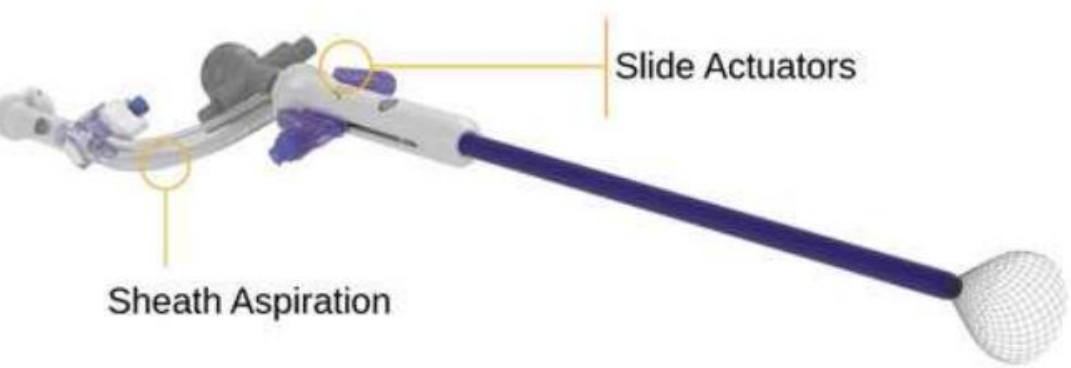
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INTRODUCTION

- Malignancy is a significant risk factor in venous thromboembolic disease that often requires mechanical thrombectomy.
- Malignant thrombus can often develop in aggressive locally invasive cancers
- The Protrieve Sheath (Inari Medical; Irvine, CA) is a thromboembolic protection device for venous thrombectomy
- An extended feasibility study was conducted for device use in deep vein thrombectomy and Inferior Vena Cava (IVC) filter removal

The Device

- The Protrieve Sheath was first released in 2022 with compatible use with the ClotTriever and FlowTriever devices.
- The sheath is 32-cm long, 20-French. The slide actuators are used to deploy and retract a self-expanding nitinol mesh funnel at the distal tip.
- The mesh is expanded until apposition to the vessel wall is achieved, with a maximum diameter of 33.5mm.
- Captured emboli can be effectively aspirated and removed via the side tube.



Patient Selection

- Performed venous thrombectomy in 22 patients with Protrieve Sheath support over 21 months (November 2022 to July 2024)
- The patient group consisted of twelve females (55.5%) and ten males 165 (45.5%), with a mean age of 55.8 ± 13.9 years (range: 28-81 years).

Clinical Presentation

clinical presentation	N	%
extremity swelling	19	86.36
pain	4	18.18
dyspnea	2	9.09
IVC thrombosis	1	4.55
pulmonary embolism	1	4.55

Thrombosed Veins

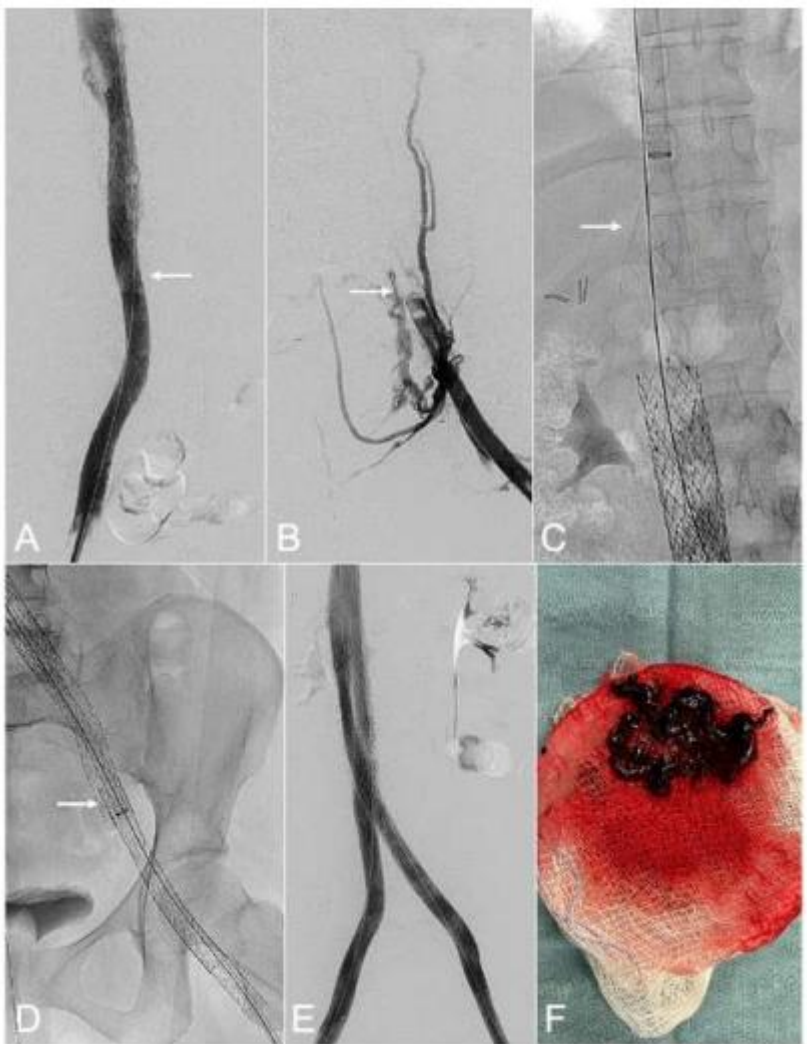
site of venous obstruction	N	%
IVC + extremity thrombus	13	59.09
extremity thrombus	4	18.18
isolated IVC	3	13.64
SVC + thoracic veins	1	4.55
isolated thoracic central vein	1	4.55
total	22	100.00

Patient Intervention and Outcomes

- Large-bore thrombectomy devices utilized
 - ClotTriever System (Inari Medical, Irvine, CA) in 18 patients (81.8%)
 - InThrill Thrombectomy System (Inari Medical) in 4 (18.2%)
 - Lightning Flash 16 Aspiration System (Penumbra; Salt Lake City, UT) in 3 (13.6%)
 - FlowTriever System (Inari Medical) in 2 (9.1%)
 - RevCore Thrombectomy System (Inari Medical) in 2 (9.1%)
 - Cleaner Rotational Thrombectomy System (Argon; Plano, TX) in 1 (4.5%)
 - Lightning 12 Aspiration System (Penumbra) in 1 (4.5%)
- Four of the thrombectomy procedures required the removal of previously placed IVC filters
 - Two Bard G2 (C. R. Bard, Inc; Murray Hill, NJ)
 - One Celect (Cook Medical; Bloomington, IN)
 - One Gunther Tulip (Cook Medical)
- Ten (45.5%) patients required stent reconstruction following thrombectomy.
- Histopathological analysis of removed thrombi
 - Acute thrombus (n=11; 50.0%)
 - malignant thrombus (n=4; 18.2%)
 - Chronic thrombus (n=1; 4.5%)
 - Large neuroendocrine tumor (n=1; 4.5%)
 - Not performed (n = 5, 22.7%)
- Outcomes
 - Technical success (n=22; 100%)
 - There was no acute hemorrhagic or hematoma formation associated with use. No PE post-procedural pulmonary embolism documented.
 - All patients were followed with bilateral lower extremity duplex ultrasounds and CT venogram abdomen and pelvis at 1, 3, 6, and 12 months and in clinic at 1, 3, 6, and 12 months.
 - During the study period, nine (40.9%) patients expired due to non-procedure-related disease,

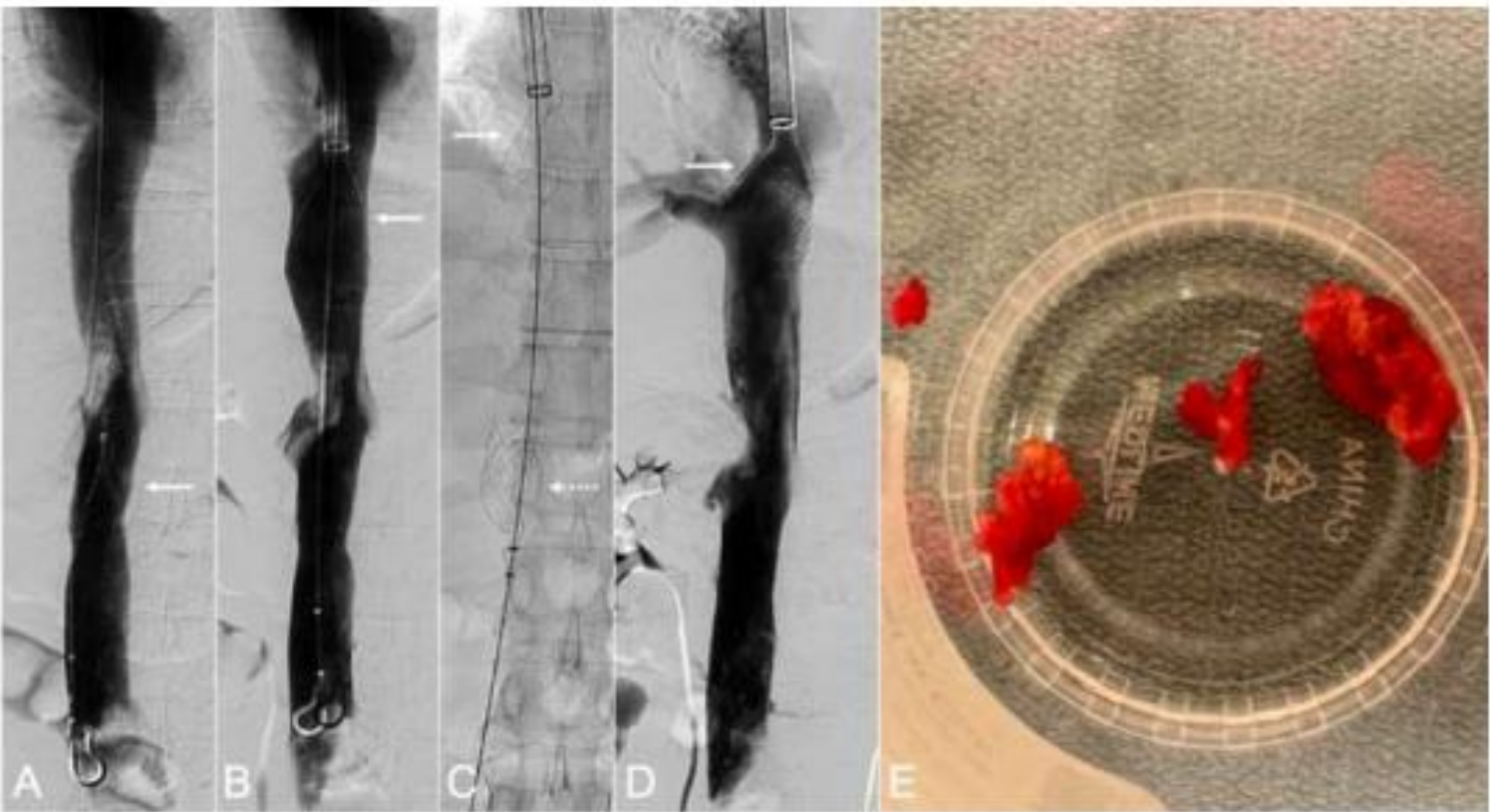
Case 1: Thrombosed Iliocaval IVC and Left Common Iliac Vein

- 43-year-old female with hypercoagulability and prior caval and bilateral ilioacaval
- (A) Normal right lower extremity ascending through the stent reconstruction, to the right atrium (solid arrow).
- (B) Left lower extremity ascending venography demonstrated total chronic (solid arrow).
- (C) The Protrieve Sheath was placed and the funnel deployed in the intrahepatic inferior vena cava (solid arrow).
- (D) FlowTriever T20 thrombectomy of the left lower extremity was performed (solid arrow).
- (E) Completion bilateral lower ascending venography demonstrated brisk in-line
- (F) Histologic thrombus analysis, from both the FlowTriever System and Protrieve Sheath, was consistent with bland thrombus.



Case 2: Thrombosed IVC for retrieval

- (A) IVC venography demonstrated a tip-centered Gunther Tulip IVC filter (solid arrow) with a cranial non-occlusive thrombus.
- (B) The Protrieve Sheath was placed and the funnel deployed in the intrahepatic inferior vena cava (solid arrow) IVC filter was removed.
- (C) The ClotTriever System (dashed arrow) was then advanced into the Protrieve Sheath (solid arrow) and large-bore thrombectomy of the IVC was performed.
- (D) IVC venography demonstrated removal of thrombus. The Protrieve sheath remained in placed (solid arrow). Histologic thrombus analysis was consistent with bland thrombus.



CONCLUSIONS

- The Protrieve Sheath was effective at the capture of emboli in complex venous thrombectomy with 100% clinical and technical success.
- There were not documented acute complications associated with the use of the device in 22 patients.
- Larger cohorts would need to be studied to capture PE, device malfunction, or operator error that would impact patient morbidity or mortality.
- Study shows the feasibility of the standardized use of the large bore device in thrombectomy for further investigation.
- Cases provided demonstrate the importance of embolic protection to significantly reduce the risk of pulmonary embolism.

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CONTACT

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