Safety and Efficacy of Acute Pulmonary Embolism Treated via Large-Bore Aspiration Mechanical Thrombectomy Using the Inari FlowTriever Device

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ABSTRACT

Purpose: To report initial experience with safety and efficacy in the treatment of pulmonary embolism (PE) using the FlowTriever device.

Materials and Methods: A single-center retrospective study was performed in all patients with acute central PE treated using the FlowTriever device between March 2018 and March 2019. A total of 46 patients were identified (massive = 8; submassive = 38), all with right ventricular (RV) strain and 26% with thrombolytic contraindications. Technical success (according to SIR reporting guidelines) and clinical success (defined as mean pulmonary artery pressure intraprocedural improvement) are reported, as are major device and procedure-related complications within 30 days after discharge.

Results: Technical success was achieved in 100% of cases (n = 46). Average mean pulmonary artery pressure improved significantly from before to after the procedure for the total population (33.9 ± 8.9 mm Hg before, 27.0 ± 9.0 mm Hg after; $P < .0001$; 95% confidence interval [CI], 5.0–8.8), submassive cohort (34.7 ± 9.1 mm Hg before, 27.4 ± 9.2 mm Hg after; $P < .0001$; 95% CI, 5.2–9.5) and massive cohort (30.4 ± 6.9 mm Hg before, 25.4 ± 8.2 mm Hg after; $P < .05$; 95% CI:0.4–9.6). Intraprocedural reduction in mean pulmonary artery pressure was achieved in 88% (n = 37 of 42). A total of 100% of patients (n = 46 of 46) survived to hospital discharge. In total, 71% of patients (n = 27 of 38) experienced intraprocedural reduction in supplemental oxygen requirements. Two major adverse events (4.6%) included hemoptysis requiring intubation, and procedure-related blood loss requiring transfusion. No delayed procedure-related complications or deaths occurred within 30 days of hospital discharge.

Conclusions: Initial clinical experience using the FlowTriever to perform mechanical thrombectomy showed encouraging trends with respect to safety and efficacy for the treatment of acute central, massive, and submassive pulmonary embolism.

ABBREVIATION

PE = pulmonary embolism

Pulmonary embolism (PE) is a major cause of morbidity and mortality, estimated to affect 1–2 persons per 1,000 population annually in the United States (1,2). Massive PE is associated with persistent hypotension or cardiac arrest and has an in-hospital mortality rate as high as 33% (3,4). Submassive PE, defined as right ventricle (RV) strain without cardiogenic shock, accounts for 25%–31% of all cases of PE and is associated with in-hospital and

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EDITORS' RESEARCH HIGHLIGHTS

- In a retrospective study of 46 patients, large-bore aspiration mechanical thrombectomy led to significant reductions in mean pulmonary artery pressure in patients with massive or submassive pulmonary embolism.
- Procedure-related major adverse events were reported in 2 patients but no 30-day mortality.
- Mean aspiration-related blood loss was 280 mL, and 1 patient required packed red blood cell transfusion.
- All patients survived to hospital discharge; a 30-day mortality of 4.3% was not attributed to the procedure nor to pulmonary embolism. This promising "real-life" single-center experience builds upon the published and ongoing investigations of this technology.

90-day mortality rates of 5%–13% and 12%, respectively (4,5).

Systemic anticoagulation has long been the mainstay of treatment for PE but can require up to 24 hours to become therapeutic (6). Primary systemic anticoagulation may be tolerable for patients with low-risk PE, but those with significant RV strain or hypotension may succumb to progressive RV failure and hemodynamic collapse without additional acute treatment. Systemic thrombolysis has successfully treated such cases although with a significant risk of major bleeding (6%–10%) and intracranial hemorrhage (1%–2%) (7–9). Catheter-directed thrombolysis carries less risk of major bleeding (0.9%) and intracranial hemorrhage (10–12) but requires longer tissue plasminogen activator infusion times, ranging from 15–33 hours in a recent study (13). Additionally, such therapies may not be an option for patients with contraindications to thrombolytic medications.

Mechanical thrombectomy is a potential alternative endovascular treatment option for PE which may allow for rapid relief of RV strain without the use of thrombolytics (14). Early case reports and small studies using this technique have demonstrated promising results; however, larger and more generalizable studies are lacking.

The purpose of the present study was to report initial experience regarding safety and efficacy outcomes treating PE with the FlowTriever device (Inari Medical Inc., Irvine, California).

MATERIALS AND METHODS

Retrospective analysis was performed of all cases of PE treated endovascularly with the FlowTriever device at a single hospital system during the first 12 months after institutional approval of the device (March 2018–March 2019). No patients treated with the device over this initial 12-month period were excluded from the analysis. The study received expedited institutional review board approval with a waiver of informed consent and a waiver of Health Insurance Portability and Accountability authorization.

Acute technical success was the primary outcome, defined as successful delivery of the device to the site, operation of the device, and removal of the device (15). Acute clinical success was a secondary outcome, defined in this study as intraprocedural decrease in mean pulmonary artery pressure. Chart reviews of the hospitalization and the 30-day period after discharge were performed to assess for immediate and delayed procedure-related outcomes and complications. Reporting standards followed those set forth by the Society of Interventional Radiology published guidelines specific to endovascular treatment of PE (15). Patient demographics and initial imaging findings are summarized in **Table 1**.

Preprocedure computed tomography (CT) angiograms acquired within 3 days of thrombectomy were reviewed to categorize locations of clot as central (defined as thrombus within the pulmonary trunk, left/right main pulmonary artery, truncus anterior, or interlobar pulmonary artery) versus peripheral and to confirm ancillary findings of RV dysfunction, pulmonary hypertension, or pulmonary infarction. The -right ventricular to-left ventricular (RV:LV) ratio and pulmonary trunk were measured on axial CT angiography images per standard, validated technique (16). PE was classified clinically as massive or submassive based on accepted criteria (17). Those patients with PE classified as submassive were further characterized using the simplified PE severity index (sPESI) according to European Society of Cardiology guidelines (18).

Patients with acute PE were initially referred to an interventional radiologist at the discretion of their treating physician. Patients with centrally located PE that were classified clinically as massive or submassive with intermediate-high risk were offered mechanical thrombectomy. Thrombectomy was also offered to those patients whose PE were classified as submassive with intermediate-to-low risk but with other features of clinical deterioration (**Table 2**). Patients were not offered treatment if they had isolated peripheral PE, were clinically classified as low risk or intermediate-to-low risk without signs of clinical deterioration, or if they had already received systemic thrombolysis. All procedures were performed by 1 of 4 staff interventional radiologists with 7, 11, 16, or 22 years of experience.

The FlowTriever is a US Food and Drug (FDA)-approved 510K-cleared mechanical thrombectomy device used to treat PE. It consists of a compliant large-bore 20-F aspiration guide catheter (AGC), which tracks over an 0.035-inch guidewire, and a catheter system of self-expanding nitinol discs, which can be advanced through the AGC to mechanically engage thrombi and help promote release from a vessel wall during aspiration.

Systemic anticoagulation with heparin was initiated at the time of PE diagnosis and was continued throughout the thrombectomy procedure for all patients. In no cases were caval filtration devices deployed prior to thrombectomy. Moderate sedation was used in most cases, with appropriate hemodynamic monitoring. General anesthesia was used only in patients who required mechanical ventilation prior to the procedure. Vital signs were monitored and recorded by

Table 1. Baseline Patient Demographics, Risk Factors, and Preprocedure Imaging

	Total (n = 46)	Submassive (n = 38)	Massive (n = 8)
Age (y)	59.9 ± 16.4	59.1 ± 16.0	63.9 ± 18.5
Females	54%	53%	63%
Provoking factor for PE identified	57%	53%	75%
Trauma/immobility	10	7	3
Surgery	7	5	2
Active cancer	4	3	1
Hypercoagulable disorder	3	3	0
Prothrombotic medication	3	2	1
Contraindication to TPA	26%	25%	37.5%
Preprocedure echocardiography performed	32	28	4
Mild RV dysfunction	22%	18%	50%
Moderate RV dysfunction	38%	39%	25%
Severe RV dysfunction	41%	43%	25%
CT angiography findings			
Central PE	100%	100%	100%
RV:LV ratio	1.8 ± 0.5	1.7 ± 0.4	2.0 ± 0.7
Contrast reflux into hepatic veins/IVC	46%	45%	50%
Pulmonary hypertension (PA > 3.0 cm)	70%	74%	50%
Pulmonary infarction	30%	29%	38%

IVC = inferior vena cava; PA = pulmonary artery; PE = pulmonary embolism; RV:LV = right ventricular-to-left ventricular ratio; TPA = tissue plasminogen activator.

Table 2. Risk Stratification of Submassive PE Patients and Most Common Clinical Factors in Intermediate Low-Risk Patients Influencing the Decision to Perform Mechanical Thrombectomy

Intermediate-high risk	66% (25/38)
NT-proBNP >500	18
Troponin >0.4	12
Intermediate-low risk	34% (13/38)
Severe RV dysfunction on echocardiography	3
Respiratory failure	2
Symptomatic NSTEMI	1
Clinical judgment absent objective criteria	5
Clinical judgment plus TPA Contraindication	2

NSTEMI = non–ST-segment elevation myocardial infarction; NT-proBNP = N-terminal pro–B-type natriuretic peptide; PE = pulmonary embolism; RV = right ventricle; TPA = tissue plasminogen activator.

nurses throughout the procedure. Supplemental oxygen requirements (defined as oxygen required to maintain saturation >90%), fluoroscopy time, and procedural time were obtained from the initial and final nursing assessments performed at the start and close of the case. Hematocrit levels were obtained before the procedure and within 24 hours after the procedure.

Initial access in all cases was accomplished through ultrasound-guided puncture of the right common femoral vein, followed by insertion of a 7-F sheath, using standard technique. A 6-F Arrow (Teleflex, Wayne, Pennsylvania) balloon-tipped catheter was advanced over an 0.035-inch guidewire through the right heart and floated into the pulmonary trunk. Initial main pulmonary artery pressures were obtained (except in 4 cases of transducer failure) and an initial pulmonary arteriogram was performed through a multi-side-hole catheter. The guidewire was advanced distally into a lobar or segmental pulmonary artery and then exchanged for an Amplatz Super Stiff (Boston Scientific, Marlborough, Massachusetts) 1-inch floppy tip guidewire.

Following serial fascial dilations, the initial 7-F sheath was exchanged for a 22-F DrySeal Introducer sheath (Gore, Flagstaff, Arizona), which was advanced to the suprarenal inferior vena cava (IVC). The 20-F AGC was advanced over the wire into a main or lobar pulmonary artery containing a targeted thrombus, and the introducer was removed. Aspiration of the thrombus was performed by applying negative suction to the AGC through a 50-cm^3 locking syringe. Intermittent pulmonary arteriography was performed as deemed appropriate by the interventionalist, often through the AGC. If aspiration of the clot was unsuccessful with the AGC alone, the self-expanding nitinol discs were deployed through the AGC into the targeted thrombus. The discs were agitated to facilitate mechanical clot engagement prior to being recaptured in the AGC and removed over a wire.

Aspiration thrombectomy with or without mechanical clot engagement was repeated multiple times in different pulmonary artery branches until angiographic resolution of central clot was achieved (Fig). Repeat pulmonary artery pressures were measured, and the devices were withdrawn. Access site hemostasis was achieved either through manual pressure, purse string suture, or Perclose ProGlide suture-mediated closure system (Abbott Vascular, Abbott Park, Illinois).

Continuous variables have been summarized as mean ± SD, and categorical variables have been summarized as proportions. Acute technical success and acute clinical success have been reported as percentages, as were endpoints of in-hospital death and delayed procedure complications to 30 days after discharge. A statistician used a 2-tailed paired sample *t*-test to compare changes in mean pulmonary artery pressure before and after the procedure.

RESULTS

Forty-six cases of mechanical thrombectomy were included in this study, with technical success achieved in 100%. Aspiration-related blood loss averaged 280 mL per case, with a maximum single case aspiration-related blood loss of 520 mL. Hematocrit dropped on average by 4.6% ± 2.8% per case. Average procedure time was 117 ± 33 minutes

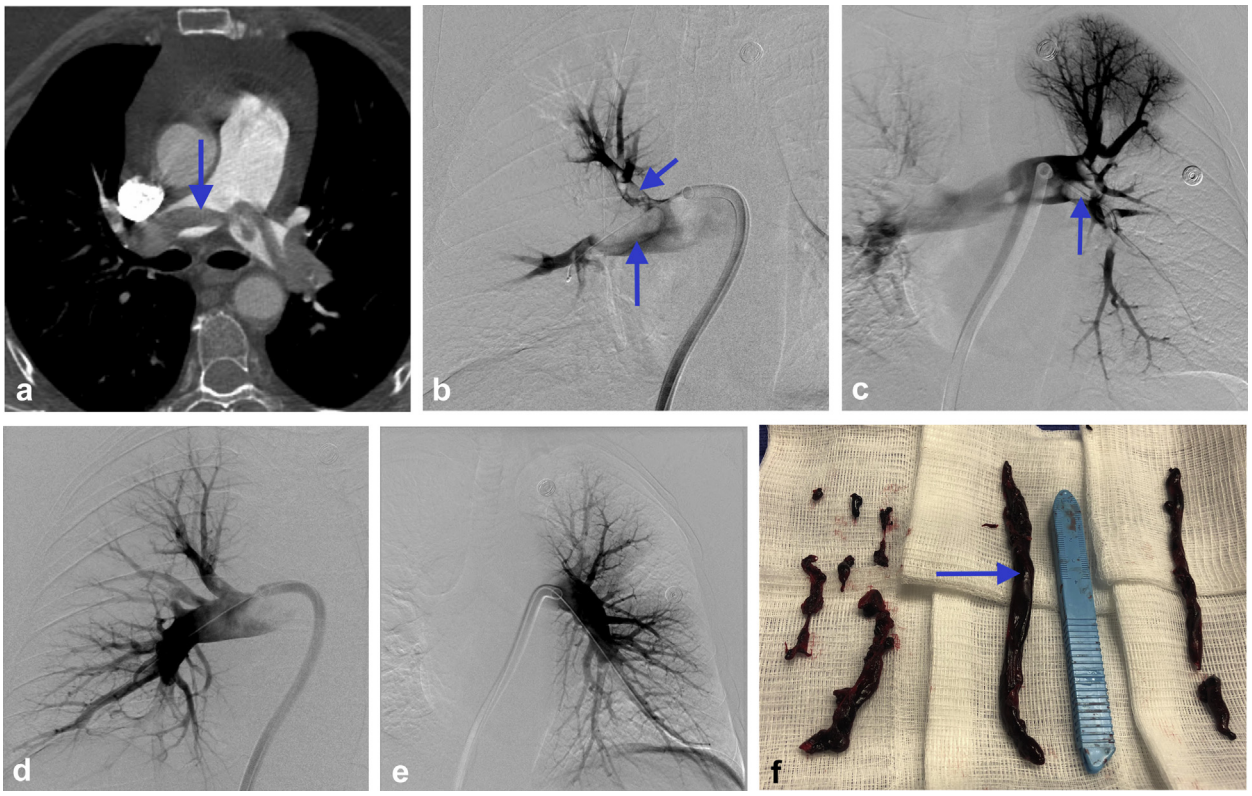

Figure. A 68-year-old female with history of ovarian cancer and brain metastases presented with acute shortness of breath and oxygen saturation of 90% on 15 L/min oxygen via nonrebreather mask. She was normotensive but tachycardic with elevated troponin of 1.4. **(a)** CT angiography revealed a saddle pulmonary embolus (arrow) and RV strain with a RV:LV ratio of 2.3. She was taken directly to the angiography suite. Initial mean PA pressure measured 37 mm Hg. **(b)** Selective right pulmonary angiography confirmed extensive endoluminal filling defects (arrows) in the right PA, truncus anterior, and interlobar PA. **(c)** Selective left pulmonary angiography revealed endoluminal filling defects (arrow) in the left PA extending into the lower lobe and abutting the upper lobe (Miller index = 28). Mechanical thrombectomy was selectively performed from the right truncus anterior and interlobar PA and left PA. Post-thrombectomy angiography revealed complete removal of central filling defects with improved filling of the peripheral right **(d)** and left **(e)** segmental and subsegmental PA branches (Miller index = 12). **(f)** Aspirated thrombus (arrow) was collected on the preparatory table and photographed. Immediately after FlowTriever mechanical thrombectomy, the final mean PA pressure measured 20 mmHg, a drop of 17 mmHg from pre-procedure measurement. Tachycardia and supplemental O_2 requirements had also resolved by the end of the procedure and the patient was discharged after 2 days. PA = pulmonary artery; RV:LV = right ventricle:left ventricle.

(range, 51–210 minutes) with average fluoroscopic time of 20 ± 9.2 minutes (range, 5–38 minutes).

Average mean pulmonary artery pressure improved significantly from before to after the procedure for the total population (33.9 ± 8.9 mm Hg before, 27.0 ± 9.0 mm Hg after; 6.9-mm Hg decrease; $P < .0001$; 95% confidence interval [CI], 5.0–8.8), as well as for the massive cohort (30.4 ± 6.9 mm Hg before, 25.4 ± 8.2 mm Hg after; 5.0-mm Hg decrease; $P < .05$; 95% CI, 0.4–9.6) and the submassive cohort (34.7 ± 9.1 mm Hg before, 27.4 ± 9.2 mm Hg after; 7.4-mm Hg decrease; $P < .0001$; 95% CI, 5.2–9.5) separately. Intraprocedural reduction in mean pulmonary artery pressure was achieved in 88% of cases (n = 37 of 42). Of the 38 patients who required preprocedure supplemental oxygen, 71% (n = 27 of 38) experienced intraprocedural reduction in oxygen requirements. A total of 100% of patients (n = 46 of 46) survived to hospital discharge.

There were 2 major procedure-related complications. One was a case of self-limited hemoptysis, which led to intubation for airway protection. This patient was extubated within 24 hours and discharged within 48 hours. The second complication was a single outlier maximum hematocrit drop of 15% that resulted in transfusion of 2 units of packed red blood cells. Two patients died within 30 days of discharge, 1 from widely metastatic pancreatic cancer and the other from severe anoxic brain injury related to prolonged out-of-hospital cardiac arrest, which occurred prior to the thrombectomy procedure. There were no delayed procedural complications or procedure-related deaths in the 30 days following hospital discharge. Procedure-related key results are summarized in Table 3.

DISCUSSION

The initial, single-institution 12-month experience using the Inari FlowTriever device presented here yielded 100% technical and 88% clinical success. The average drop in mean pulmonary artery pressure was statistically significant, both when it was evaluated in aggregate and for the massive and submassive cohorts separately. Improvement in

Table 3. Summary of Procedure-Related Information and Key Results

	Total (n = 46)	Massive (n = 8)	Submassive (n = 38)
Procedure time (min)	114 ± 34.7	111 ± 17.7	114 ± 37.5
Fluoroscopy time (min)	20 ± 9.2	17 ± 6.0	20.4 ± 9.7
FlowTriever catheter component used	45%	50%	45%
Hematocrit drop (%)	4.6 ± 2.8	6.0 ± 4.9	4.3 ± 2.1
Improved O_2 requirements	71% (27/38)	88% (7/8)	67% (20/30)
Improved mean PA pressure	88% (37/42)	88% (7/8)	88% (30/34)
Average before	33.9 ± 8.9	30.4 ± 6.9	34.7 ± 9.1
Average after	27.0 ± 9.0	25.4 ± 8.2	27.4 ± 9.2
Average drop (mm Hg)	6.9* (95% CI: 5.0-8.8)	5.0‡ (95% CI: 0.4-9.6)	7.4* (95% CI: 5.2-9.5)
Survival to hospital discharge	100%	100%	100%
Major complications	4.3%	12.5%	2.6%
Hemoptysis requiring intubation	1	0	1
Hematocrit drop requiring transfusion	1	1	0
30-Day mortality	4.3%	12.5%	2.6%
Device- or procedure-related	0	0	0
PE-related†	1	1	0
Other§	1	0	1

CI = confidence interval; PA = pulmonary artery; PE = pulmonary embolism.
*$P < .0001$.
†Anoxic brain injury from prolonged out of hospital cardiac arrest triggered by PE but occurring prior to procedure.
‡$P < .05$ by parametric paired *t*-test and nonparametric Wilcoxon signed ranks test.
§Widely metastatic pancreatic cancer.

supplemental oxygenation requirements also trended toward improvement (71%). The rate of major procedure-related adverse events was 4.3%. No delayed complications were observed in the 30 days after discharge. Although there were 2 deaths during this post-discharge period, neither death was related to the device or procedure.

Published reports highlight the importance of acutely treating PE to improve hemodynamic flow, decrease pulmonary hypertension and RV strain, and minimize thrombus volume (11,14,19,20). Studies have also highlighted negative clinical outcomes associated with PE, including relatively high 30-day mortality (21,22), association with the development of chronic thromboembolic pulmonary hypertension, and "post-PE syndrome" (23,24). Treatment of massive and submassive PE can present a clinical challenge in patients who have acute clinical deterioration or contraindications to thrombolytic medications. Mechanical thrombectomy may be of particular interest in such cases because it can be performed in less than 2 hours and without the use of thrombolytics. A total of 26% of patients treated in this study had a contraindication to tissue plasminogen activator. Avoidance of thrombolytic medications enabled treatment of these patients, enlarging the overall pool of patients amenable to endovascular treatment of PE. Additionally, the major risks of hemorrhage associated with thrombolytic medications were also avoided. Another potential advantage was the fact that the large bore of the thrombectomy device permitted aspiration of organized and fibrotic venous thromboemboli.

Concerns specific to large-bore aspiration devices include aspiration-related blood loss, injury to cardiac structures, rupture of thin-walled pulmonary arteries (19), and distal embolization of thrombus-in-transit, which can potentially worsen the condition of a stable patient with submassive PE. Aspiration-related blood loss in this study did result in 1 patient requiring post-procedural transfusion. In the present study, the maximum single-case of blood loss occurred during an operator's initial use of the device and decreased with operator experience. Cardiac trauma can occur during advancement of devices through the right heart. For example, the larger AngioVac cannula (AngioDynamics, Latham, New York) has caused severe RV/tricuspid valve injury requiring open surgical repair (25). Although risks of cardiac injury remain present, this study experienced no such complications. One patient in this study did complain of increasing intraprocedural chest pain, however, the patient's pain resolved following completion of the procedure and her vital signs remained stable throughout the case.

Use of the FlowTriever device has been reported in several other published case reports and series (26–28) including the FlowTriever Pulmonary Embolectomy Clinical Study (FLARE; NCT02692586) (29), a multicenter single-arm trial treating 106 intermediate-risk PE patients without thrombolytics. No intracranial hemorrhage, access site complication, device-related cardiac or pulmonary injury, or death was reported, but 4 major adverse events (3.8%) occurred. These included 2 cases of respiratory deterioration, 1 case of ventricular fibrillation leading to emergent intubation, and 1 episode of pulmonary vascular injury requiring lower lobectomy. Although FLARE complications limited to an intermediate risk population could be interpreted as significant, it is notable that a similar complication rate occurred in our study despite the additional inclusion of patients with massive PE. Future studies such as the ongoing FlowTriever All-Comer Registry for Patient Safety and Hemodynamics (FLASH; NCT03761173) or other future comparisons between mechanical thrombectomy and alternate available therapies (30) may address the possibility of using large-bore mechanical thrombectomy devices in larger and more generalizable patient populations.

The major limitation of this study was its retrospective nature, potentially confounding data. Also, this study population was small, nonrandomized, and from a single center, which can introduce selection bias and limit the ability to extrapolate outcomes to a generalized population. Small

sample size also limits the ability to detect infrequent but potentially significant complications. Additionally, this study contains no comparison of thrombectomy versus systemic anticoagulation, systemic thrombolysis, or alternative available endovascular treatment options or devices.

In conclusion, a retrospective review of an initial single-institution clinical experience treating acute central massive and submassive PE with mechanical thrombectomy by using the FlowTriever device shows encouraging trends with respect to safety and efficacy. Prospective and randomized studies are needed to validate these initial observations as well as to assess the potential long-term impact on the development of post-PE syndrome.

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