Percutaneous thrombectomy of upper extremity and thoracic central veins using Inari ClotTriever System: Experience in 14 patients

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ABSTRACT

Objective: In the present report, we have described the technical and clinical outcomes of percutaneous thrombectomy in the deep veins of the upper extremity and thorax using the ClotTriever system (Inari Medical, Irvine, CA).

Methods: Fourteen patients with symptomatic deep venous occlusive disease in the upper extremity deep veins and thoracic central veins who had undergone thrombectomy using the ClotTriever system between October 2020 and January 2022 were reviewed. The technical results, adverse events, imaging follow-up data, and clinical outcomes were recorded.

Results: Fourteen patients (seven men and seven women; mean age, 53.6 ± 13.3 years) constituted the study cohort. Of the 14 patients, 9 (64.3%) had had DVT due to intravascular invasion or external compression from known malignancy, 2 (14.3%) had had infected thrombi and/or vegetation due to *Staphylococcus aureus* refractory to intravenous antibiotic therapy, and 3 (21.4%) had had a benign etiology for thrombus formation. The presenting symptoms included upper extremity and/or facial swelling (n = 14), upper extremity pain (n = 6), fever (n = 2), and dyspnea (n = 1). Thrombectomy with the ClotTriever system was successfully completed in all 14 patients. Seven patients (50.0%) had required additional venous stent reconstruction after thrombectomy to address the underlying stenosis. No major adverse events were noted. All the patients had experienced resolution of the presenting symptoms.

Conclusions: For the management of symptomatic deep venous occlusive disease of the upper extremity deep veins and thoracic central veins, thrombectomy using the ClotTriever system was feasible with excellent technical and clinical success. (J Vasc Surg Cases Innov Tech 2023;9:1-7.)

Keywords: ClotTriever; Superior vena cava syndrome; SVC syndrome; Thoracic central venous occlusive disease; Upper extremity DVT

Upper extremity deep vein thrombosis (DVT) accounts for ~10% of all cases of DVT.[1] The etiology of upper extremity and thoracic central venous thrombosis can be either primary (20% of cases), such as that occurring with venous outlet syndrome and Paget-Schroetter syndrome, or secondary (80% of cases), including catheter-associated, cancer-associated, postoperative, and pregnancy- or hormone-related thrombosis.[2] At present, no treatment algorithms have been established for upper extremity DVT. Patients will generally be treated with anticoagulation and removal of the offending central venous device, if applicable.[1,3] Other treatment options include catheter-directed thrombolysis and percutaneous mechanical thrombectomy.

The ClotTriever thrombectomy system (Inari Medical, Irvine, CA) offers an endovascular treatment option for peripheral and central DVT.[4-6] The application of this device has been focused on the removal of iliocaval and iliofemoral DVT. The system allows for single-session thrombectomy for patients with contraindications to pharmacologic thrombolytic therapy. In the present report, we have described a single-center experience for ClotTriever-mediated venous thrombectomy in the upper extremity and thoracic central veins.

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METHODS

Study design. The institutional review board approved the present single-center, retrospective, descriptive study, which complied with the Health Insurance Portability and Accountability Act, and waived the requirement for patient informed consent owing to the retrospective study design. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Patient selection and diagnostic imaging studies. From October 2020 to January 2022, 14 patients had undergone endovascular intervention for symptomatic deep venous occlusive disease of the upper extremity deep veins and thoracic central veins using the ClotTriever system. All the patients had undergone preprocedural computed tomography venography (CTV) of the chest and/or upper extremity duplex venous ultrasound. None of the 14 patients had undergone prior interventions.

Procedural technique. Intervention was performed with the patient under either general anesthesia or moderate sedation. Intraprocedural heparin was administered with an initial bolus of 100 U/kg, followed by intermittent bolus doses of 2000 to 3000 U at the operator's discretion. Venous access (brachial vein or internal jugular vein) was obtained under ultrasound guidance. The choice of brachial vein vs basilic vein access was by physician preference. No basilic vein access was used for any of the 14 cases. Thoracic central venous recanalization was performed using either a blunt or sharp technique, as previously described.[7-13] Subsequently, wire access was established to the inferior vena cava. Over the wire, mechanical thrombectomy was performed using the ClotTriever system (Inari Medical). One to four thrombectomy sweeps were made via each access site. Each mechanical thrombectomy sweep was performed over a stiff wire access into the infrarenal inferior vena cava. The coring element was opened within the right atrium and then slowly pulled back across the superior cavoatrial junction along the length of the affected vessel toward the ClotTriever sheath under fluoroscopic guidance.

After thrombectomy, some of the patients had required venoplasty and stent reconstruction to address the underlying venous stenosis. In these cases, Viabahn VBX balloon-expandable stent grafts (W.L. Gore & Associates, Inc, Flagstaff, AZ) or Abre self-expanding venous stents (Medtronic, Dublin, Ireland) were deployed simultaneously in a kissing fashion, extending from the brachiocephalic veins (BCVs) to the superior vena cava (SVC). The choice of a covered vs an uncovered stent was driven by physician preference, related, in part, to the patient's clinical and intraprocedure imaging findings. At the end of the intervention, completion venography and intravascular ultrasound (IVUS) were performed to demonstrate the final technical outcomes. Temporary purse-string sutures were used for access site hemostasis and were removed within 24 hours.

Postprocedure management and follow-up. All 14 patients received intravenous heparin after the procedure and were observed overnight. For all but one patient, who continued with intravenous heparin because of known renal failure requiring dialysis, the patients were transitioned on postprocedure day 1 from intravenous heparin to 1 mg/kg enoxaparin twice daily to be continued for 6 to 12 months. The patients who had undergone thrombectomy and venous reconstruction with stenting started enoxaparin 1 mg/kg twice daily with the addition of 81 mg of aspirin daily, to be continued indefinitely. Alterations to the anticoagulation regimen were dictated on a case-by-case basis.

Technical success was defined as the placement and use of the ClotTriever system with extraction of thrombotic materials on visual inspection and a reduction of the thrombus burden found on repeat venography. Clinical success was defined as patient-reported improvement of the presenting symptoms on postprocedure follow-up. Clinical follow-up was obtained by in-person or telephone visits, and all 14 patients had undergone bilateral upper extremity venous duplex ultrasound with or without CTV.

RESULTS

Patient demographics and presenting symptoms

A total of 14 patients (7 men and 7 women; mean age, 53.6 ± 13.3 years) had undergone thrombectomy of the upper extremity deep veins and thoracic central veins using the ClotTriever system for management of symptomatic deep venous occlusive disease. The presenting symptoms included upper extremity and/or facial swelling (n = 14), upper extremity pain (n = 6), fever (n = 2), and dyspnea (n = 1). Of the 14 patients, 9 (64.3%) had had DVT due to intravascular invasion or external compression from a known malignancy, including lung adenocarcinoma (n = 3), small cell lung cancer (n = 1), squamous cell lung carcinoma (n = 1), metastatic micropapillary carcinoma (n = 1), metastatic papillary thyroid carcinoma (n = 1), metastatic breast adenocarcinoma (n = 1), and acute T-cell lymphoblastic leukemia (n = 1). Two patients (14.3%) had had infected thrombi and/or vegetation due to *Staphylococcus aureus* refractory to catheter removal and intravenous antibiotic therapy. These cases were confirmed by pathologic analysis of the aspirated thrombi. Three patients (21.4%) had had a benign etiology for thrombus formation. The patients with noninfectious thrombi were

Table. Baseline demographics and clinical characteristics

Characteristic	Total (n = 14)	Benign (n = 3)	Infectious (n = 2)	Malignant (n = 9)
Age, years	53.6 ± 13.3	51.7 ± 7.2	36.5 ± 31.8	58 ± 12.2
Sex				
Male	7 (50)	1 (7.1)	1 (7.1)	5 (35.7)
Female	7 (50)	2 (14.2)	1 (7.1)	4 (28.6)
Presenting symptoms				
UE with or without facial swelling	14 (100)	3 (21.4)	2 (14.2)	9 (64.3)
Pain	6 (42.9)	1 (7.1)	2 (14.2)	3 (21.4)
Fever	2 (14.2)	0	2 (14.2)	0
Dyspnea	1 (7.1)	0	0	1 (7.1)
Diseased venous segments				
Bilateral UE DVT + SVC	5	1		4
RUE DVT only	3	1	1	1
LUE DVT only	2			2
SVC + LUE DVT	2		1	1
SVC	1	1		
SVC + RUE DVT	1			1

DVT, Deep vein thrombosis; *LUE,* left upper extremity; *RUE,* right upper extremity; *SVC,* superior vena cava; *UE,* upper extremity.
Data presented as mean ± standard deviation, number (%), or number.

found to have either subacute or chronic thrombus. Detailed patient demographics are presented in Table.

Venography

The diseased venous segments shown on intraprocedural venography included bilateral upper extremity deep veins and SVC (n = 5), right upper extremity deep vein only (n = 3), left upper extremity deep vein only (n = 2), left upper extremity deep vein and SVC (n = 2), SVC only (n = 1), and right upper extremity deep vein and SVC (n = 1).

Procedural details

The ClotTriever sheath (13F) venous access sites included the right brachial (n = 7), bilateral brachial (n = 2), left brachial (n = 3), and right internal jugular (n = 2) veins. One to four thrombectomy sweeps were made via each access site. Technical success was obtained for all 14 patients. No intraprocedural adverse events occurred, including no clinically significant arrhythmia or cardiac tamponade.

Of the 14 patients, 7 (50.0%) had undergone additional venous stent reconstruction after thrombectomy to address the underlying venous occlusive disease. For the patients who had undergone stent reconstruction, the mean number of stents deployed was 3.4 (range, 2-6). The mean stent diameter was 11.8 ± 1.6 mm (range, 10-14 mm). No patient had required thrombolytic infusion or intensive care unit admission.

Imaging and clinical outcomes

All the patients had undergone follow-up bilateral upper extremity venous duplex ultrasound examinations inclusive of the access site at a mean of 31.6 ± 21.1 days (range, 7-97 days) after the procedure. One patient (7.1%) was found to have an acute but asymptomatic brachial vein thrombosis of one of the paired brachial veins on follow-up. No additional treatment of this asymptomatic thrombosis was provided beyond the routine postprocedure anticoagulation regimen. No brachial sheath hematoma or median nerve neuropraxia was identified in any of the patients immediately after the procedure or at follow up. Clinical success, defined as patient-reported improvement of the presenting symptoms, was achieved for all 14 patients. A representative subset of patients are presented in Figs 1-4.

Case report

Patient 1. Patient 1 was a 43-year-old woman with acute T-cell lymphoblastic leukemia and bilateral upper extremity swelling (Fig 1). CTV of the chest revealed acute thrombosis of the bilateral BCVs and SVC that was superimposed on diffuse chronic stenosis due to surrounding confluent masses. After initial venography, the ClotTriever thrombectomy system was placed sequentially via the bilateral brachial veins to perform mechanical thrombectomy sweeps from the right atrium to the sheath. Post-thrombectomy venography confirmed the restored inline patency along the bilateral thoracic central veins. Two 14-mm × 100-mm Abre stents (Medtronic) were then deployed in a kissing configuration, extending from the SVC to the bilateral BCVs. Completion venography demonstrated wide inline patency with no residual stenosis or thrombus burden. The patient experienced resolution of her presenting symptoms.

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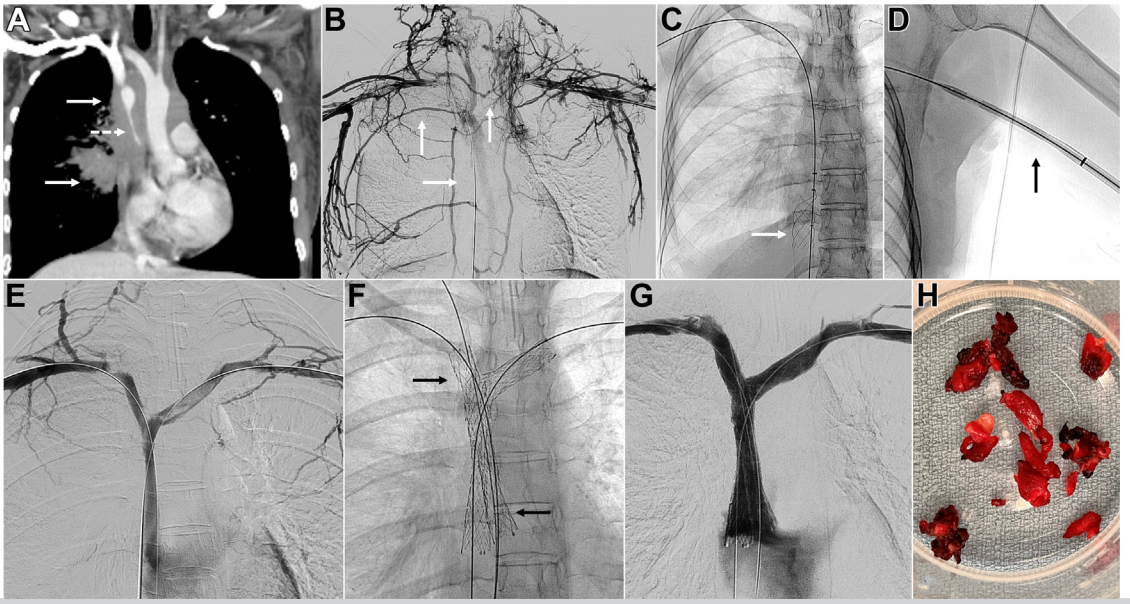

Fig 1. A 43-year-old woman with acute T-cell lymphoblastic leukemia and bilateral upper extremity swelling. **A,** Coronal computed tomography of the chest demonstrating a confluent right hilar and mediastinal mass (*solid white arrows*) encasing the superior vena cava (*dashed white arrow*). **B,** Bilateral upper extremity venography showing acute-on-chronic thrombotic occlusion of the bilateral brachiocephalic veins (BCVs) and superior vena cava (SVC; *solid white arrows*). **C,** The ClotTriever thrombectomy system was advanced via the right brachial vein, with the coring element opened within the right atrium (*solid white arrow*) to perform mechanical thrombectomy sweeps. **D,** The ClotTriever thrombectomy system (*solid black arrow*) was then used via the left brachial vein. **E,** Post-thrombectomy bilateral upper extremity venography demonstrating restored inline patency of the thoracic central veins with a residual thrombus burden. **F,** A kissing brachiocephalocaval stent reconstruction was performed using two 14-mm Abre stents (*black arrows*). **G,** Completion bilateral upper extremity venography demonstrating brisk flow through the stent constructs to the right atrium with no residual thrombus or stenosis. **H,** Photograph of gross specimens of the removed thrombus.

Follow-up CTV performed at 7 days demonstrated continued wide patency of the stent constructs.

Patient 2. Patient 2 was a 40-year-old man with a history of non–small-cell lung cancer, who had presented with right upper extremity swelling and pain (Fig 2). Thrombectomy was performed via right brachial vein access using the ClotTriever system, as described. On completion, an 11 × 59-mm VBX stent graft (W.L. Gore & Associates) was deployed at the upper-to-mid SVC and dilated ≤16 mm. Subsequently, two 14 × 80-mm Abre stents were deployed from the upper SVC into the bilateral BCVs in a kissing fashion. The right stent construct was extended with a 12-mm × 120-mm Abre stent, and the left stent construct was extended with a 14 × 80-mm Zilver self-expanding stent (Cook Medical Inc, Bloomington, IN). Although two 10-mm or 11-mm stents, in a double-barrel fashion, would fit the SVC better, for the extension to each BCV, a 12-mm or 14-mm uncovered self-expanding stent was typically used to fit the usual BCV caliber with the VBX stent graft in the SVC overdilated ≤16 mm. Such overlapping and tapering constructs have worked well in our experience. Venography and IVUS were used to confirm wide patency. Because of the resolved facial swelling but persistent left arm swelling, a short-term follow-up CTV was obtained, which demonstrated poor expansion of the BCV end of the left stent. On postprocedure day 4, the patient underwent relining of the existing left brachiocephalocaval stent. The double-barrel SVC construct was again dilated using two 10-mm balloons simultaneously to optimize stent expansion. CTV performed 169 days later demonstrated patency of the affected segments.

Patient 3. Patient 3 was a 47-year-old man with a history of metastatic small cell lung cancer, who had presented with head pressure, plethora, and chest pain (Fig 3). Thrombectomy was performed via right brachial vein access using the ClotTriever system, as described. Two 10-mm × 79-mm VBX stent grafts were then deployed bilaterally across the brachiocephalic confluence in a kissing fashion. Venography and IVUS were performed to confirm proper placement. His presenting symptoms had resolved, and CTV performed at 30 days demonstrated continued stent patency.

Patient 4. Patient 4 was a 47-year-old woman with oral contraceptive use who had presented with right upper extremity pain and swelling (Fig 4). CTV and right upper extremity venography confirmed the presence of axillosubclavian DVT. Thrombectomy was performed via right

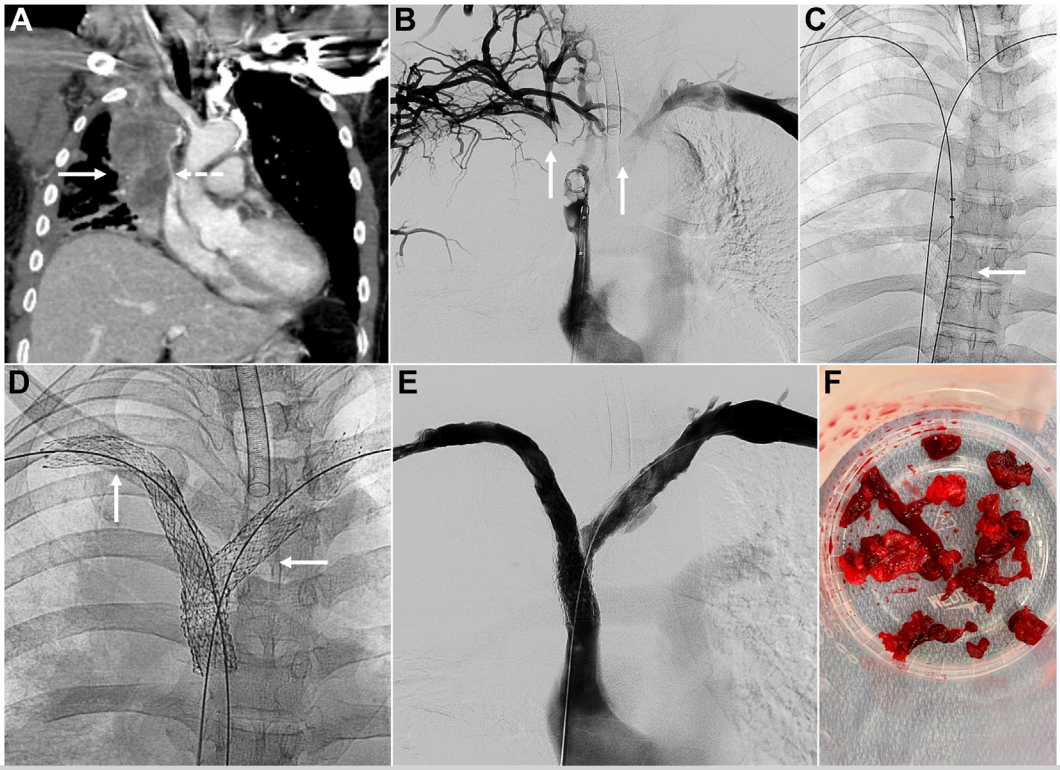

Fig 2. A 40-year-old man with right upper extremity swelling, pain, and known metastatic non–small-cell lung carcinoma. **A,** Coronal enhanced computed tomography of the chest demonstrating a right lung mass (*solid white arrow*) extending to the mediastinum and obliterating the superior vena cava (SVC; *dashed white arrow*). **B,** Bilateral upper extremity venography showing thrombotic occlusion of both brachiocephalic veins (BCVs; *solid white arrows*) and the upper SVC. **C,** Thrombectomy was performed using the ClotTriever system via right brachial vein access (*solid white arrow*). Additional thrombectomy was performed via left brachial vein access (not shown). **D,** Kissing brachiocephalocaval stent reconstruction was performed using VBX and Abre stents (*white arrows*). **E,** Completion bilateral upper extremity venography demonstrating brisk flow through the stent constructs to the right atrium with no residual thrombus or stenosis. **F,** Photographs of gross specimens of the removed thrombus.

brachial vein access using the ClotTriever system, as described. Post-thrombectomy angioplasty was performed using a 12-mm high-pressure balloon. Completion venography demonstrated restored patency. The patient reported symptom resolution at the 2-week follow-up visit with no residual or recurrent thrombus found on CTV at 26 days. The patient underwent right transaxillary first rib resection at 106 days.

Adverse events

No intraprocedural adverse events occurred, including no clinically significant arrhythmia or cardiac tamponade. After the procedure, all the purse-string sutures had been removed within 24 hours of the procedure with no occurrence of clinically significant hematoma (eg, requiring transfusion, intervention, or a prolonged length of hospital stay).

DISCUSSION

In the present report, we have described the use of the ClotTriever system for thrombectomy of the upper extremity and thoracic DVT, establishing its feasibility and clinical efficacy. Although well-established for lower body venous thrombectomy via femoral and popliteal access points, a paucity of experience and data is available on the use of this large-bore device via upper extremity venous access. Only two case reports were found that had described the use of the ClotTriever in the upper extremities: one case of a patient with left arm swelling and a history of breast cancer receiving chemotherapy via a left-sided central venous catheter[3] and the second case of a patient with right upper extremity swelling associated with a peripherally inserted central catheter.[14]

The technical and clinical success rates in our study were both 100%, with no immediate major adverse events. Although a larger sample size is required to establish generalizability, the results from our initial experience suggest the feasibility, safety, and usefulness of the device in this anatomy. Because of the device caliber, the manufacturer has recommended accessed vein diameters of ≥6 mm, and extended experience is

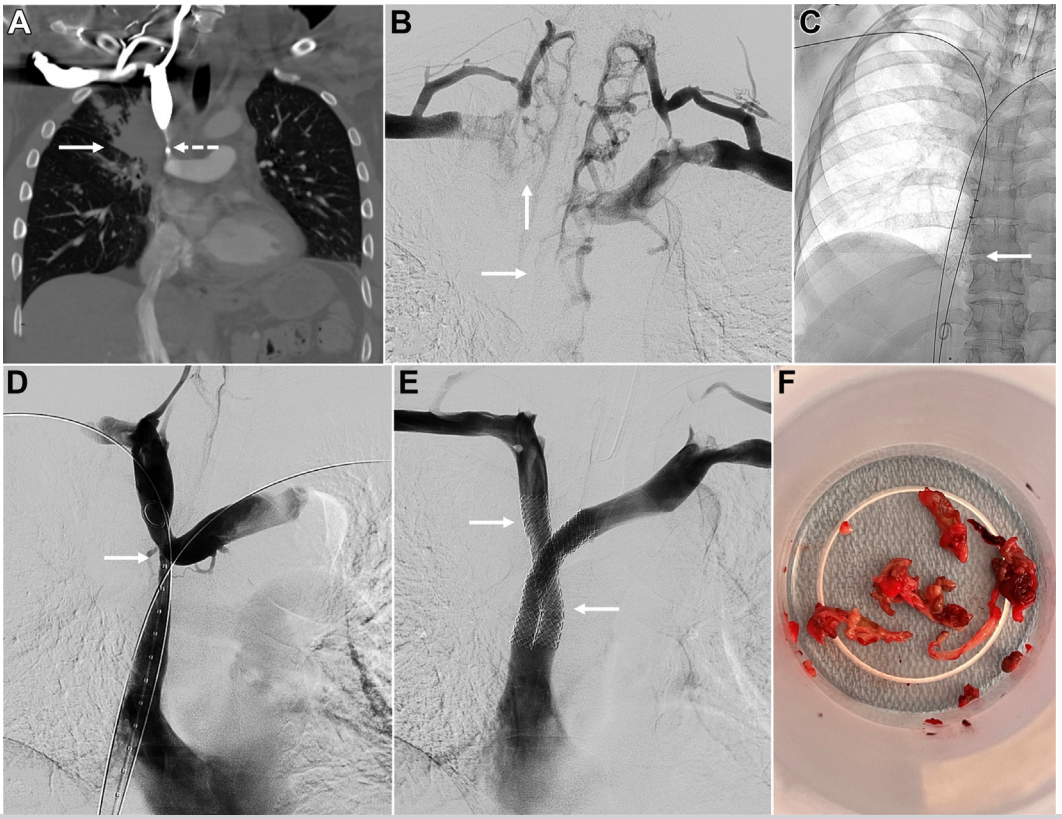

Fig 3. A 47-year-old man with head pressure, plethora, and chest pain likely due to known metastatic small cell lung carcinoma. **A,** Coronal enhanced computed tomography of the chest demonstrating a right lung mass (*solid white arrow*) that had obliterated the superior vena cava (SVC; *dashed white arrow*). **B,** Bilateral upper extremity venography showing thrombotic occlusion of the right brachiocephalic vein (BCV) and SVC (*solid white arrows*). **C,** The ClotTriever thrombectomy system was advanced via a right brachial vein and the coring element opened within the right atrium (*solid white arrow*) to begin a mechanical thrombectomy sweep. **D,** Bilateral upper extremity venography demonstrating clearance of thrombus burden, which revealed extrinsic compression at the confluence of the BCVs and SVC (*solid white arrow*). **E,** Brachiocephalocaval stent reconstruction was performed using two 10-mm VBX stent grafts (*solid white arrows*). **F,** Photograph of gross specimens of the removed thrombus.

needed to determine the rates of access site thrombosis as those thresholds are approached or exceeded, which could be the case with upper extremity venous applications.

Although catheter-directed thrombolysis has been used for severely symptomatic acute thrombosis, especially for patients with good functional status and a low bleeding risk,[15] catheter-directed thrombolysis can be offered only in the absence of contraindications to the use of thrombolytic agents. Furthermore, rheolytic devices have, in general, been avoided in cases of infected thrombi owing to the potential for septic emboli and/or induction of septic shock. Few series have reported the feasibility of pharmacomechanical thrombectomy and mechanical aspiration in this region and were generally limited to small-bore devices. The ClotTriever system allows for single-session thrombectomy for patients with contraindications to pharmacologic thrombolytic therapies and those with chronic thrombus for which thrombolytic therapy could be futile.

The limitations of the present study included its retrospective nature, single-arm design, and small sample size. One half of the cohort had undergone venous stenting at the same treatment session, introducing heterogeneity in the technique and clinical outcomes.

CONCLUSIONS

In the present report, we have described our single-center experience using the ClotTriever system in the upper extremity and thoracic central veins for benign, infectious, and malignant DVT of various chronicity. The device was used successfully to debulk the thrombus burden in these anatomic sites without immediate adverse events and allowed for effective stent reconstruction when indicated. Further studies are warranted to determine the scope of the application of the

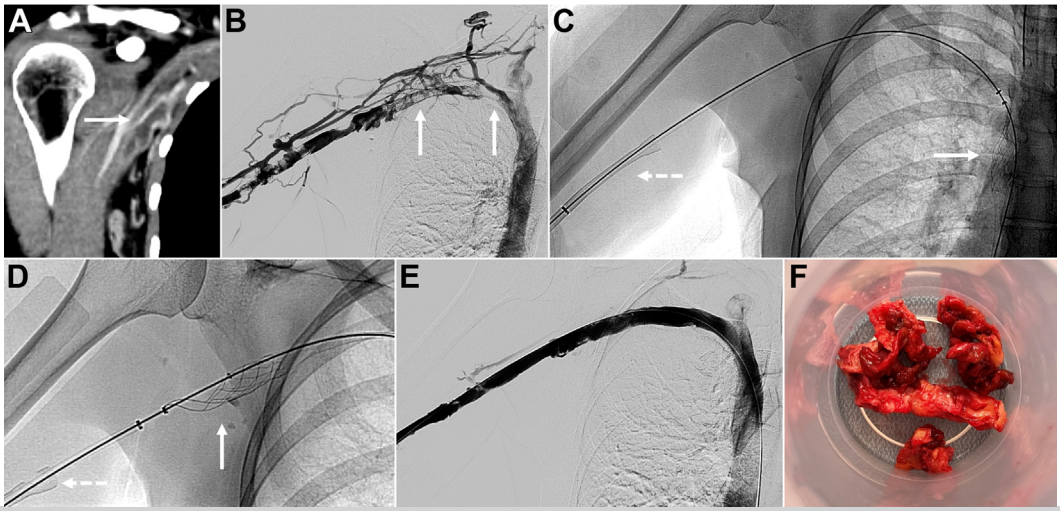

Fig 4. A 47-year-old woman with oral contraceptive use, who had presented with right upper extremity pain and swelling. **A,** Coronal enhanced computed tomography of the chest demonstrating axillosubclavian thrombosis (*solid white arrow*). **B,** Right upper extremity venography showing thrombotic occlusion of the axillary and subclavian veins (*solid white arrows*). **C,** The ClotTriever sheath (*dashed white arrow*) was placed into a right brachial vein. The ClotTriever catheter was advanced and its coring element (*solid white arrow*) as opened within the right atrium. **D,** Thrombectomy of the right upper extremity was performed as the coring element (*solid white arrow*) was pulled toward the sheath (*dashed white arrow*). **E,** Post-thrombectomy right upper extremity venography demonstrating unobstructed inline flow from the right brachial vein to the right atrium with no residual thrombus burden. **F,** Photograph of gross specimens of the removed thrombus.

ClotTriever system and long-term outcomes for treating symptomatic upper extremity DVT.

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