JACC: CASE REPORTS VOL. 3, NO. 3, 2021

MINI-FOCUS ISSUE: CORONARY & STRUCTURAL INTERVENTIONS

INTERMEDIATE

CASE REPORT: CLINICAL CASE SERIES

Single-Session Thrombolysis-Free Treatment of Deep Vein Thrombosis With a Novel Mechanical Thrombectomy Device

Adam Raskin, MD, Amitesh Verma, Timothy D. Brennan, MD

ABSTRACT

Catheter-directed thrombolysis of iliofemoral deep vein thrombosis (DVT) carries an increased risk of major bleeding and may fail to rapidly remove thrombus or prevent post-thrombotic syndrome. We describe an alternative, thrombolysis-free, advanced DVT treatment strategy with rapid single-session percutaneous mechanical thrombectomy using the ClotTriever system. (**Level of Difficulty: Intermediate.**) (J Am Coll Cardiol Case Rep 2021;3:415–20) © 2021 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

INTRODUCTION

Deep vein thrombosis (DVT), commonly associated with severe swelling, can lead to post-thrombotic syndrome (PTS) and poor quality of life (1). Endovenous therapy with catheter-directed thrombolysis (CDT) can decrease thrombus burden, alleviate symptoms, and reduce PTS risk (2,3). However, it carries an increased risk for major bleeds, requires an intensive care unit (ICU) stay, and is not successful in all cases (4,5). Alternatively, the ClotTriever (Inari Medical, Irvine, California), a novel percutaneous stand-alone mechanical thrombectomy system, can remove significant amounts of thrombus without thrombolysis, thus minimizing bleeding risk and ICU need. The ClotTriever system comprises the ClotTriever specialty sheath and ClotTriever catheter (**Figure 1**). The sheath features an expandable nitinol funnel to maximize thrombus capture. The catheter, with a nitinol coring element and attached collection bag, is designed to mechanically separate thrombus from the vein wall and extract it. After obtaining access and placing the ClotTriever sheath, the catheter is introduced over an 0.035-inch guidewire under fluoroscopic or intravascular ultrasound guidance and deployed beyond the occlusion. Subsequent retraction toward the sheath allows continuous

LEARNING OBJECTIVES

- To illustrate interventional decision making in different symptomatic DVT settings.
- To adopt treatment of DVT with the ClotTriever system because it minimizes bleeding complications and ICU need.
- To demonstrate rapid reduction in symptoms after thrombectomy with the ClotTriever system.

From the Division of Endovascular Cardiovascular Medicine, Mercy Heart Institute, Cincinnati, Ohio, USA.
The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

Manuscript received November 2, 2020; revised manuscript received December 14, 2020, accepted December 17, 2020.

ISSN 2666-0849 https://doi.org/10.1016/j.jaccas.2020.12.049

ABBREVIATIONS AND ACRONYMS

CDT = catheter-directed thrombolysis

DUS = Doppler ultrasound

DVT = deep vein thrombosis

ICU = intensive care unit

LE = lower extremity

PMT = percutaneous mechanical thrombectomy

PTS = post-thrombotic syndrome

coring and capturing of thrombus. The catheter is then collapsed and removed, and can be prepared for additional passes. In this report, we document our initial experience with the ClotTriever System in treating DVT.

CASE 1

A 50-year-old white woman developed left lower-extremity (LE) swelling and pain after prolonged immobility secondary to heart failure-related complications. Doppler ultrasound (DUS) revealed extensive DVT of the left LE. Venography confirmed complete occlusion of the left iliac and femoral veins (**Figure 2**, Video 1). CDT with an EkoSonic (Boston Scientific, Marlborough, Massachusetts) catheter via left popliteal vein access was performed. After 24 h of thrombolysis, a repeated venogram revealed inadequate thrombus resolution, prompting the decision to perform percutaneous mechanical thrombectomy (PMT) with ClotTriever, which fully restored venous blood flow (**Figure 2**, Video 2) without any complications. After successful thrombectomy, the patient was discharged on oral anticoagulation with apixaban and was symptom free at 3-month follow-up.

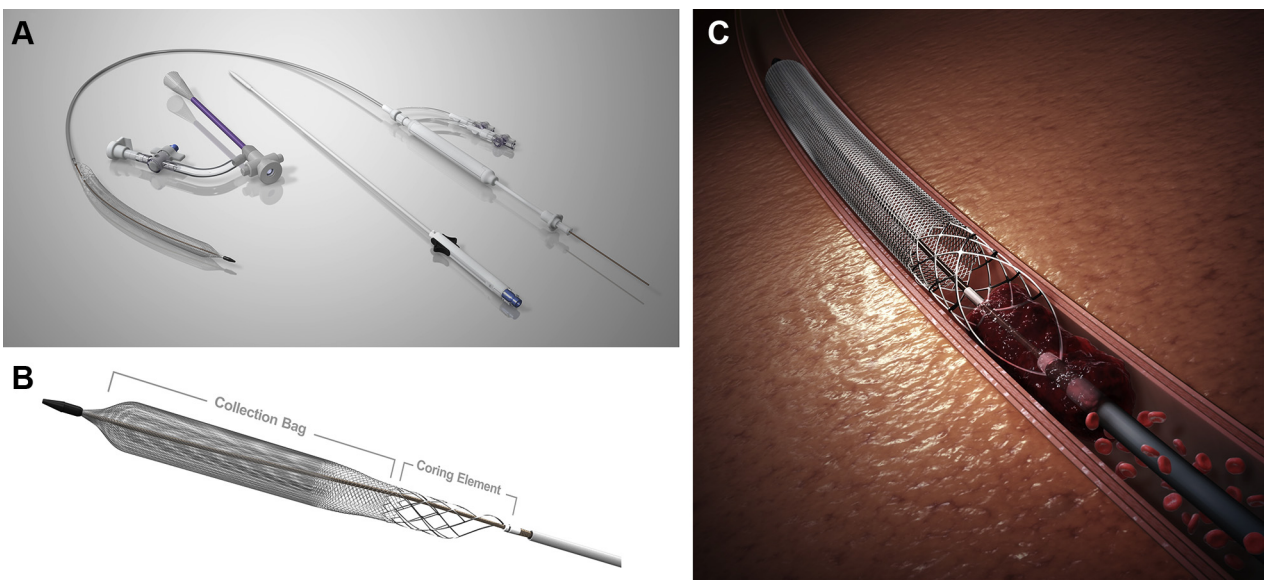
CASE 2

A 64-year-old black man with a history of chronic DVT was admitted to our hospital with phlegmasia cerulea dolens after discontinuing oral anticoagulation on his own. DUS of the right LE revealed extensive DVT. Venography performed from right popliteal vein access showed complete occlusion of the iliac and femoral veins with extensive collaterals. We performed PMT with ClotTriever to restore flow. That was followed by balloon angioplasty of the right iliac vein with the use of 10 mm × 80 mm and 12 mm × 40 mm balloon catheters to target tight stenoses and optimize flow in the right femoral and iliac veins and inferior vena cava. The patient was discharged the next day on oral anticoagulation with apixaban. At 2-month follow-up, the patient had no leg pain or phlegmasia.

CASE 3

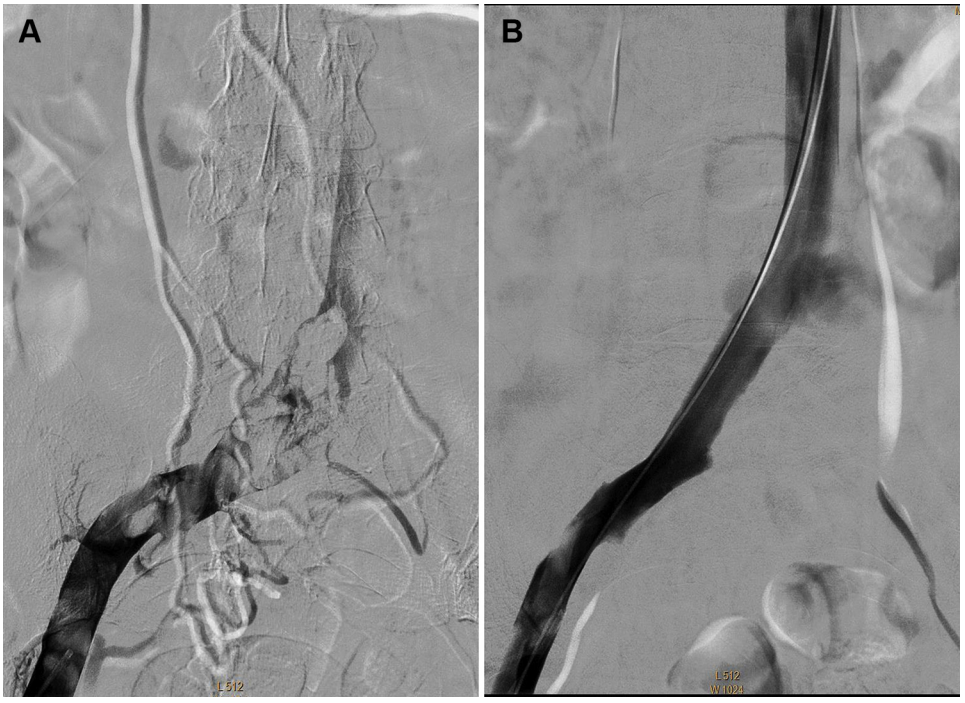
A 64-year-old man with a history of chronic DVT presented with right thigh pain, swelling, and recurrent DVT of the right LE by DUS. He had no clear etiology for DVT. A venogram was performed from right popliteal vein access, confirming a complete occlusion of the right femoral and iliac veins with extensive collaterals. After crossing the occlusion with an 0.035-inch angled Glidewire Advantage (Terumo Interventional Systems, Somerset, New Jersey), guidewire position in the femoral vein was confirmed with the use of intravascular ultrasound owing to the extensive collateralization, and chromoflow showed arterial flow alongside the wire, confirming femoral vein location before intervention. Initial balloon angioplasty of the

FIGURE 1 ClotTriever System



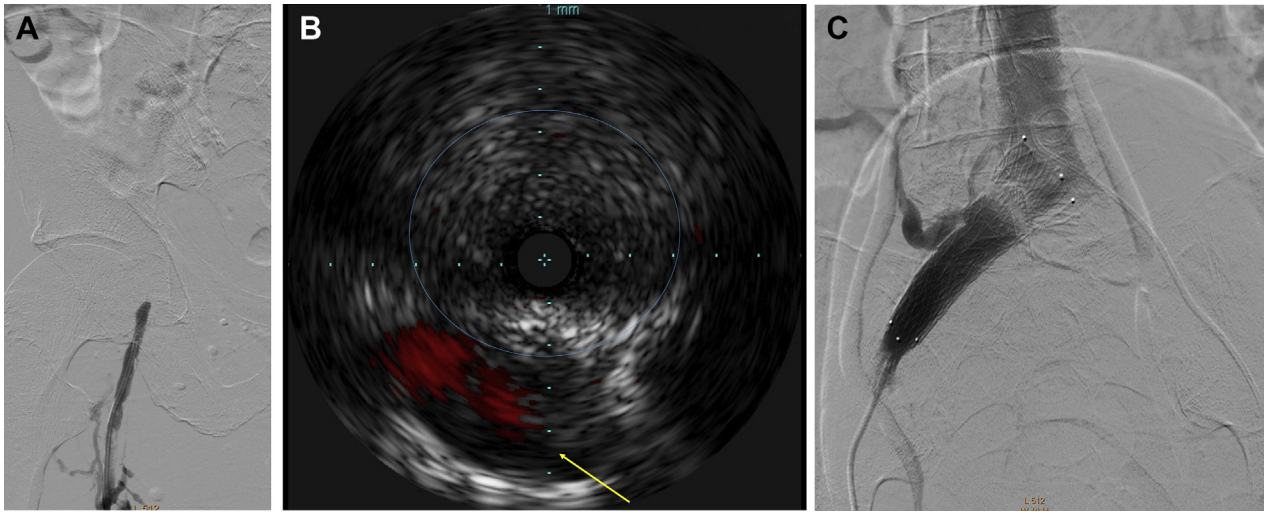
(A) Device with sheath. **(B)** Catheter. **(C)** Thrombus cored off the vessel wall.

FIGURE 2 **Case 1: Before and After Iliac Vein Venography**



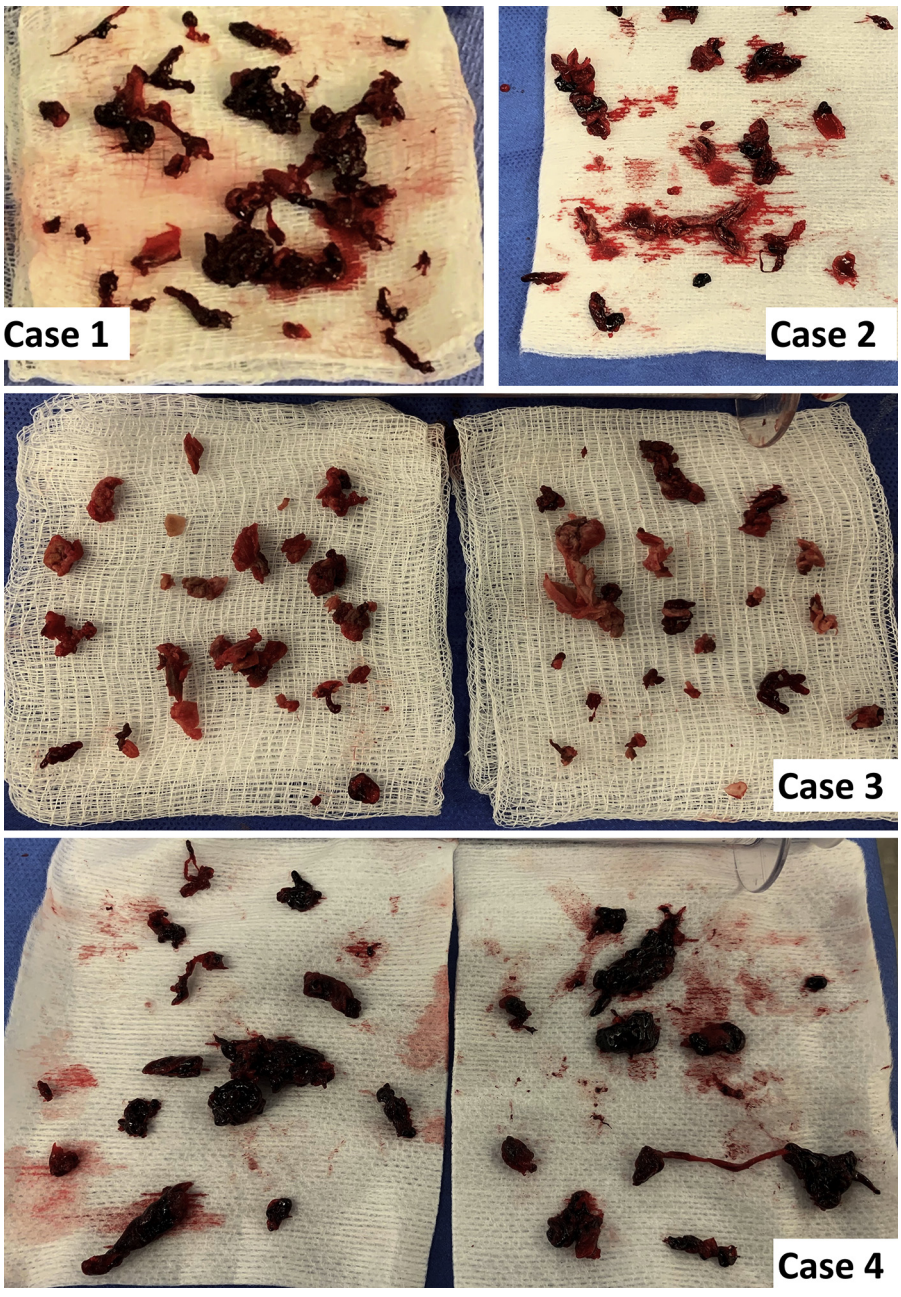
(A) Before and **(B)** after ClotTriever thrombectomy, showing restored flow in an initially completely occluded left common iliac vein.

FIGURE 3 **Case 3: Before and After Iliac Vein Venography**



(A) Prethrombectomy venogram, showing complete occlusion of common iliac, external iliac, and femoral veins. **(B)** Intravascular ultrasound, showing femoral vein **(blue oval)** filled with dense thrombus. Artery running alongside vein **(yellow arrow)** confirms true lumen access. **(C)** Postprocedural venogram, showing restoration of blood flow.

FIGURE 4 Extracted Thrombus



Variety of acute and organized thrombus extracted from each case.

iliac vein with the use of 6-10-mm balloon catheters to establish flow revealed extensive acute-on-chronic thrombotic burden. We decided to perform PMT with ClotTriever, followed by the placement of a 20 mm × 60 mm Venovo venous stent (BARD Peripheral Vascular, Tempe, Arizona) in the right common iliac vein to restore complete patency (**Figure 3**, Videos 3 and 4). The procedure was performed without any complications.

The patient was discharged the following day on 15 mg oral rivaroxaban twice daily with complete resolution of symptoms.

CASE 4

A 51-year-old woman on oral contraceptive and with a history of hypopituitarism and lupus anticoagulant positivity presented complaining of increasing pain over several weeks and swelling of her right LE. DUS showed acute occluding DVT of the right iliofemoral veins. Venography performed from right popliteal vein access confirmed complete occlusion of the iliac and femoral veins with extensive collaterals. Based on the large thrombus burden, we decided to perform PMT with ClotTriever. The patient tolerated the procedure well and was discharged home the following day on 10 mg oral apixaban twice daily with dramatic reduction in swelling and pain at 4-week follow-up.

DISCUSSION

This case series describes our initial experience with the ClotTriever system in DVT treatment. We were able to successfully treat 4 patients with varying DVT presentations, including extensive occlusive DVT, phlegmasia cerulea dolens, chronic thrombosis, and thrombolysis-resistant disease. All patients tolerated the procedure well and were discharged the following day, without ICU stay after thrombectomy, on direct oral anticoagulants per our protocol.

While DVT treatment options have evolved, clinical evidence guiding advanced therapy use remains inconsistent. CAVENT (Catheter-Directed Venous Thrombolysis in Acute Iliofemoral Vein Thrombosis) and TORPEDO (Endovenous Therapy for Deep Venous Thrombosis), two randomized controlled trials of long-term outcomes of endovenous therapies, reported reduced PTS risk (2,3), which was not universally confirmed by the more recent ATTRACT (Acute Venous Thrombosis: Thrombus Removal With Adjunctive Catheter-Directed Thrombolysis) and CAVA (Catheter Versus Anticoagulation Alone for Acute Primary (Ilio)Femoral DVT) (5,6). Furthermore, CAVENT, ATTRACT, and CAVA showed more bleeding complications and prolonged hospital stays with CDT. In addition to bleeding risk concerns, limited thrombolysis efficacy in more chronic settings poses additional challenges, as observed in one of our cases. ClotTriever was able to remove large, organized thrombus rapidly and safely in all of our cases (**Figure 4**). We have previously used thrombectomy and CDT with an EkoSonic catheter to treat severe occlusive iliofemoral DVT, but ClotTriever has become a valuable stand-alone tool to treat a variety of DVT presentations at our center. Our positive experience matches another single-center case series, which showed excellent safety and effectiveness (7). Furthermore, interim data from the prospective ClotTriever Outcomes Registry (CLOUT) highlighted significant improvements in disease severity and quality of life in patients treated with ClotTriever, with no procedure- or device-related adverse events (8). Although ClotTriever effectively removes large clot and restores venous blood flow, the thrombotic milieu, especially in patients with known prothrombotic conditions, remains a concern after treatment. Appropriate anticoagulant regimen and follow-up is therefore crucial to ensure good long-term outcomes.

While available data are still evolving, current results point to the ability of ClotTriever to successfully treat a variety of DVT presentations and to its potential to minimize risks and help avoid ICU stays.

CONCLUSIONS

PMT with ClotTriever appears to be safe and effective, with minimal bleeding risk and short hospital stay. Our observations are in line with other encouraging experiences, but upcoming larger and longer-term data sets are needed to provide further assessment of the ClotTriever system in treating proximal DVT.

FUNDING SUPPORT AND AUTHOR DISCLOSURES

All authors have reported that they have no relationships relevant to the contents of this paper to disclose.

ADDRESS FOR CORRESPONDENCE: Dr. Adam B, Raskin, Division of Endovascular Cardiology, Department of Medicine, Mercy Heart Institute, 3301 Mercy Health Boulevard, Suite 125, Cincinnati, Ohio 45211, USA. E-mail: abraskin@gmail.com.

REFERENCES

1. Ten Cate-Hoek AJ, Amin EE, Bouman AC, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT). Lancet Haematol 2018;5:e25–33.

2. Enden T, Haig Y, Kløw NE, et al. Long-term outcome after additional catheter-directed thrombolysis versus standard treatment for acute iliofemoral deep vein thrombosis (the CAVENT study). Lancet 2012;379:31–8.

3. Sharifi M, Mehdipour M, Bay C, et al. Endovenous therapy for deep venous thrombosis: the TORPEDO trial. Catheter Cardiovasc Interv 2010;76:316–25.

4. Wang L, Zhang C, Mu S, et al. Safety of catheter-directed thrombolysis for the

treatment of acute lower extremity deep vein thrombosis: a systematic review and meta-analysis. Medicine (Baltimore) 2017;96:e7922.

5. Vedantham S, Goldhaber SZ, Julian JA, et al. ATTRACT Trial Investigators. Pharmacomechanical catheter-directed thrombolysis for deep-vein thrombosis. N Engl J Med 2017;377:2240–52.

6. Notten P, Ten Cate-Hoek AJ, Arnoldussen CWKP, et al. Ultrasound-accelerated catheter-directed thrombolysis versus anticoagulation for the prevention of post-thrombotic syndrome (CAVA): a single-blind, multicentre, randomised trial. Lancet Haematol 2020;7:e40–9.

7. Benarroch-Gampel J, Pujari A, Aizpuru M, et al. Technical success and short-term outcomes after treatment of lower extremity deep vein thrombosis with the ClotTriever system: a preliminary experience. J Vasc Surg Venous Lymphat Disord 2020;8:174–81.

8. Dexter D. Early outcomes from the ClotTriever registry (CLOUT). Presented at: VIVA 2019, Vascular Interventional Advances meeting. NV: Las Vegas, November 4–7, 2019.

KEY WORDS **catheter-directed thrombolysis (CDT), ClotTriever system, deep vein thrombosis (DVT), percutaneous mechanical thrombectomy, post-thrombotic syndrome**

APPENDIX **For supplemental videos, please see the online version of this paper.**