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# EKOS® Therapy Restores Quality of Life in Patients With Postthrombotic Syndrome

**BY MARK J. GARCIA, MD, FSIR, FACR**

For decades, physicians have advised their patients with chronic deep vein thrombosis (DVT) that they must simply live with the leg pain, edema, ulceration, and the often-devastating disability of postthrombotic syndrome (PTS). Aside from conservative management with anticoagulation and compression, there was little else to offer patients with PTS.

The recent ACCESS PTS study, sponsored by BTG International, has challenged that mindset. We can now offer millions of patients with PTS the chance to restore their quality of life (QOL) with endovascular treatment. Our multicenter, prospective, single-arm study—the first infrainguinal chronic DVT intervention trial—demonstrated that chronic DVT and PTS can be safely and effectively treated by recanalizing occluded veins with Acoustic Pulse Thrombolysis™ therapy (BTG International) with balloon dilatation.[1] The 73 participants (77 limbs) had ultrasound-confirmed femoral DVT for a minimum of 6 months, had failed 3 months of conservative therapy, and continued to have PTS sequelae with a Villalta score of ≥ 8. All patients received enoxaparin (1 mg/kg twice daily) for 48 hours before endovascular recanalization and up to 90 days after EKOS® treatment (BTG International). Patients underwent balloon dilatation of the occlusive DVT segments, followed by EKOS® therapy for a minimum of 12 hours. The mean duration of EKOS® therapy was 23 hours with a total tissue plasminogen activator (tPA) dose of 18.5 mg.

The study met its primary efficacy endpoint of a minimum of 50% of patients having at least a 4-point improvement in Villalta score at 30 days ($P = .003$). The total mean Villalta score improved by 6.1 points (35.5%) from baseline, and there was a 3.9-point improvement (27.6%) from baseline in mean venous clinical severity scores (VCSS) ($P \leq .0001$ for each). Patients' VEINES-QOL score also improved 21% from baseline at 30 days ($P \leq .0001$). One major bleed (epistaxis with severe complications) and one pulmonary embolism occurred within 30 days after treatment, which met the study's safety endpoint. In addition, the outcomes of the endovascular intervention at 180 days continue to look promising, and the study will continue to follow patients for 1 year.

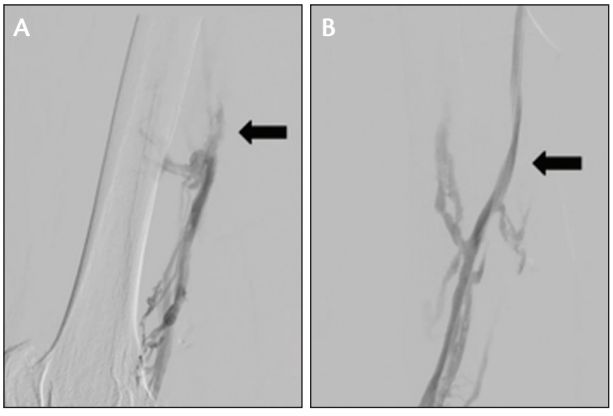


**Figure 1. A 75-year-old woman presented with DVT of her right leg since February 2010 (> 5 years). Her baseline Villalta score was 15, which improved to 7 at 30-day follow-up. Pretreatment occlusion of the femoral vein (A). After percutaneous transluminal angioplasty and EKOS® treatment, the femoral vein was recanalized (B).**

## SIGNIFICANT SYMPTOM RELIEF

The endovascular approach used to treat PTS patients in ACCESS PTS, consisting of EKOS® therapy with balloon dilatation and adjunct therapy (if needed), significantly improved the patients' symptoms. However, the procedure takes time, patience, and perseverance to work through chronic occlusions and, in some ways, can be more challenging than an arterial chronic total occlusion case. Case examples of patients with DVT treated with EKOS® therapy are shown in Figures 1 and 2. We've found the following strategies to be helpful in achieving excellent outcomes.

A day or two before the procedure, we start patients on the anticoagulant enoxaparin (twice-daily dosing) to help prevent an acute thrombosis from occurring.

The success of the procedure depends on the operator establishing direct in-line flow from the patient's ankle to the heart. To best accomplish this, access into the vessel must be below the lowest level of disease, which I believe helps minimize rethrombosis. This most commonly entails accessing the posterior or anterior tibial veins at the ankle for the initial full-leg venogram and subsequent treatment techniques.

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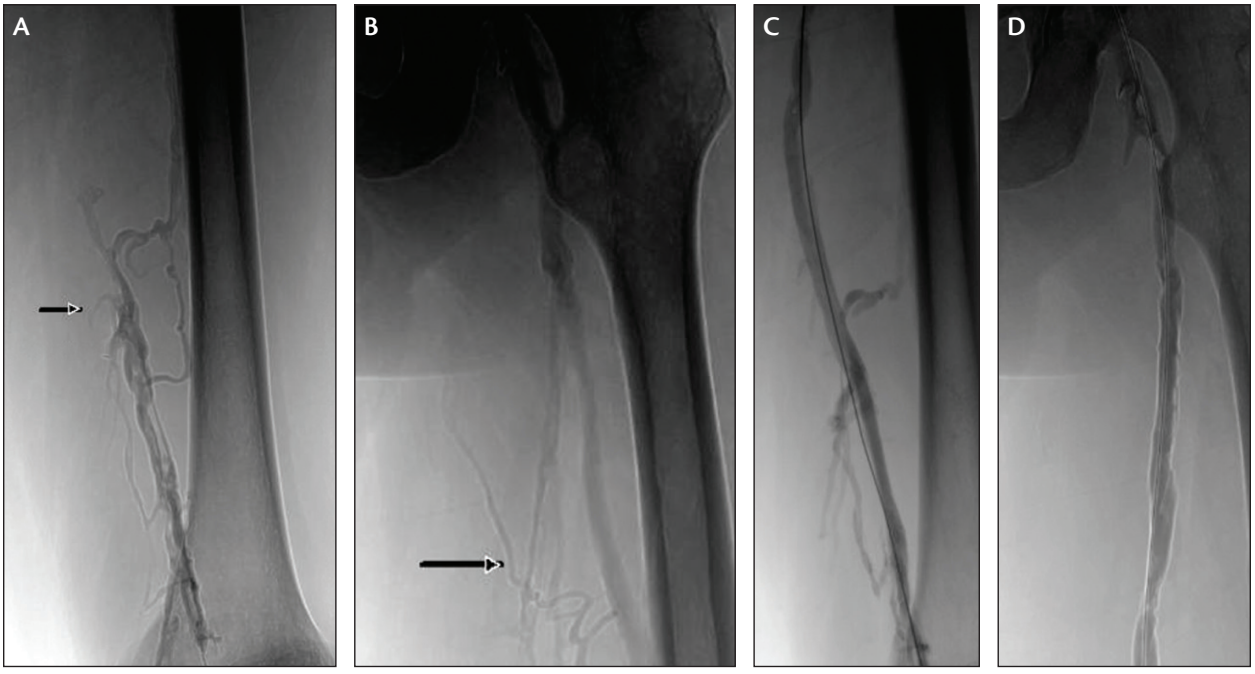


**Figure 2. A 67-year-old man with a history of multiple episodes of DVT in 2006, 2007, and 2013. An inferior vena cava filter was placed in 2007 after DVT while on anticoagulation; he was diagnosed with prothrombin 20210 mutation and placed on lifelong warfarin. In November 2013, he developed DVT in both lower extremities and a large bilateral pulmonary embolism after discontinuing warfarin earlier in the month. The patient underwent DVT lysis of the inferior vena cava and both lower extremities, but there was no change in the extensive right lower extremity chronic DVT. In July 2014, he presented for evaluation of severe right lower extremity PTS and was enrolled in the ACCESS PTS trial. At baseline, the patient was CEAP 4b, with a Villalta score of 20 and a VCSS of 15. The initial pretreatment venogram showed chronic scarring and venous change of the popliteal artery with femoral vein occlusion (A, B). Posttreatment venograms showed recanalization with direct in-line flow from the popliteal artery through femoral veins (C, D). At 1 month posttreatment, the patient was CEAP 4b with a Villalta score of 4 and VCSS of 4. At 3-months posttreatment, the patient had improved to CEAP 2 with a Villalta score of 2 and VCSS of 5, and at 6 months, he was CEAP 2 with a Villalta score of 3 and VCSS of 5.**

To cross the occlusion, I start by using the NaviCross device (Terumo Interventional Systems) and a stiff straight Glidewire (Terumo Interventional Systems), and if needed, I'll use the TriForce device (Cook Medical). When the venous occlusions are successfully crossed, a space is created with serial balloon venoplasty to the expected size of the "normal" vessel at that level. For example, I typically dilate the femoral vein up to 10 mm and the popliteal to 6 to 7 mm. It is important not to undersize these vessels during final balloon dilatation and to dilate in a slow and prolonged fashion to "stretch" the diseased vessel and help prevent recoil.

The early ACCESS PTS study results demonstrate that the ultrasound effect of EKOS® therapy is very effective. I believe that ultrasound helps soften the scarred vein walls and allows for better dilatation and remodeling, which may improve the vein wall compliance and function in the long run.

Our patients continue on enoxaparin for 1 month after the procedure, and then they transition to an oral anticoagulant, typically for a minimum of 1 year. Every patient I treat is also educated on the ABCs of self-care: activity, blood thinners, and compression.

## CONCLUSION

Acoustic Pulse Thrombolysis™ with balloon dilatation should be considered in the appropriate setting for any patient with chronic DVT and PTS who does not have a contraindication to lytic therapy and who has failed conservative treatment. The results of the ACCESS PTS trial offer hope to patients with PTS. ■

1. Garcia MJ, Sterling K, Jaff M, et al. ACCESS PTS study: ACCElerated thrombolySiS for post-thrombotic syndrome using the Acoustic Pulse Thrombolysis EkoSonic® endovascular system—initial results of a multi-center study [abstract]. Vasc Med. 2017;22:260-261.

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