

Advancing the Treatment of Chronic DVT With the New ClotTriever BOLD Catheter

Vascular Disease Management speaks with interventional radiologist Abdullah Shaikh, MD, about his use of the ClotTriever and ClotTriever BOLD catheters from Inari Medical when treating patients with deep vein thrombosis (DVT).

How are DVT patients identified, and what is your practice for treating them?

Patients come into our practice as inpatient consults, which are referred to us from various subspecialties. Discharged ER patients are referred to us and then seen and treated within 14 days of their ER visit. At that point, we are able to treat them confidently and more effectively with the ClotTriever System and the ClotTriever BOLD catheter. We do our best to have all acute and chronic patients seen in our Interventional Radiology clinic before their procedure. A certain percentage of our patients come in on their own after learning about their diagnosis. Our volume has been increasing steadily, mostly due to education and physician outreach. Referring physicians also get direct feedback from their treated patients, thus supporting the referral for the procedure.

When do you decide to intervene?

Simply put, any patient with a component of an iliac DVT will go straight to thrombectomy. For a patient with a femoral popliteal DVT and symptoms or burdensome physical signs, we discuss medical management vs thrombectomy. We also discuss expectations and data; we don't have a lot of data on whether patients with more distal clots benefit from treatment, but it may help relieve some acute symptoms and prevent long-term implications of leaving the clot behind. We have an honest discussion with patients to review available data, along with the risks and benefits of the therapy.

Intervening also depends on the clinical scenario, but we want to intervene as soon as possible. Data from the ClotTriever Outcomes Registry (CLOUT), which evaluates real-world patient outcomes after treatment of acute, subacute, and chronic proximal lower extremity DVT with the ClotTriever System, thus far supports treatment. We assess all the symptoms and signs using Villalta scores and venous clinical severity scores in all our patients. At the end of the day, we leave it up to the patient. If they want to have symptoms relieved as quickly as possible, we proceed.

What has your experience been with ClotTriever?

We were first introduced to the ClotTriever System at the end of October 2019. I remember working on a flow model before my first case—obviously, telling a patient that they're going to be my first case was an interesting experience. Each



Abdullah Shaikh, MD

Interventional Radiologist
Allegheny Health Network
Pittsburgh, Pennsylvania

case presents its own nuances, so preprocedural planning is an absolute must.

To date, I've completed more than 100 ClotTriever cases. In just over 2 years, our department has completed more than 250 cases using the ClotTriever System. Our volume continues to go up. Our patient outcomes have been favorable overall, with quick patient improvement within hours to days. It's very impressive to see how quickly these patients improve. Most of them feel normal again, with improved Villalta scores, which is what we really follow in these patients. These are results I've never seen before. I've used other devices in the past, but never had the same outcomes as I have with ClotTriever. Also, the time spent doing the actual procedure has been significantly reduced.

How often is a clot more chronic than would be suggested by symptom duration or clinical assessment at consultation?

It is almost always more chronic.

With the ClotTriever System we learned to assess these patients clinically. Previously, when a patient presented with a 3-day history of lower extremity swelling, pain, some cramps, and heaviness, it sounded like an acute DVT, and the ultrasound often supported that assessment. But when we went in and performed a venogram and looked with intravascular ultrasound, we noticed that the clot didn't always look acute. Once we extracted the clot and physically examined it, we saw that while acute clot is supposed to be fibrous and rich, nice bright red, and soft, what we were pulling out didn't look like that. What we were pulling out had a collagen component, an indication that the thrombus may be more chronic than symptom duration had suggested.

Having completed numerous cases, we now know that by about 3 weeks, 70% of all the thrombi removed have some

collagen component, which tells us the distinctive composition and structure of thrombus is rapidly changing within a short period of time. This has made us think that when patients present with symptoms that clinically seem to be acute, that is actually the moment when their body started to decompensate—clot had already begun to develop days before their initial symptoms and signs started to appear. Now I go in with the expectation that clot is rarely just acute; there's going to be some component of subacute to chronic.

Can you tell us about the new ClotTriever BOLD catheter from Inari?

I first used the BOLD catheter within a couple days of its limited market release, on November 1, 2021. There's a noticeable tactile difference from the original ClotTriever catheter. This is a result of the design change for BOLD. The coring element features ~30% greater radial force designed for improved wall apposition with an increase in atmospheres of pressure from 0.35 to 0.45 being exerted on the vein wall. The nice thing about this is that the coring element finds its way into the crevices and edges in the clot. This is what we describe as better engagement within the clot. There's a tactile feel that comes with having completed more chronic cases, which allows you to know when to pause and slow down and allow the coring element to work, and when to continue with your pullback.

Visually, the ClotTriever BOLD has a distinctive feature in the purple marker band that extends to the distal end of the BOLD catheter (Figure 1). Also, it is a 12 French (F) catheter, whereas the standard ClotTriever catheter is 11 F. The BOLD catheter is compatible with both the 13 F and 16 F ClotTriever sheaths.

So overall, the ClotTriever BOLD's increased radial force results in advanced control and better thrombus engagement upon retraction. The increase in F size has better trackability over the wire, so it has more robust navigation through the clot. I'm finding that I'm doing fewer passes with the new BOLD than I was with the standard ClotTriever. I have used this in acute cases, and I've realized that it's 1 or 2 fewer passes than what I was typically doing. The chronic cases always require more passes than the acute cases, but I'm finding that those chronic cases are going more smoothly (Figure 2).

The BOLD catheter was designed to treat the full range of DVT with improved performance in chronic cases. The DVT cases in which we use the BOLD catheter have been typically with patients who've have had issues for months to years. So, we won't exclude anyone unless the vessel size is very small, below the 6-mm cutoff. These patients present with chronic thrombi that may appear on ultrasound with noncompressible veins or wall thickening. So given the tactile learning curve, you should consider doing some preemptive venoplasty to help

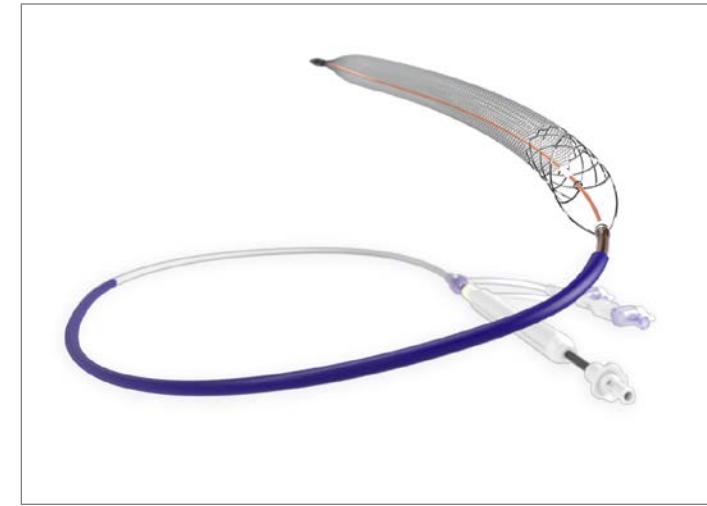


Figure 1. ClotTriever BOLD catheter.

create those edges so the coring element can find its way into those crevices and engage the thrombus more effectively. I'm finding that the BOLD is just overall better with the chronic patients.

When would you use BOLD instead of the standard ClotTriever?

For any chronic case—any patient who's had a thrombus burden for more than 6 weeks—I will go straight to the BOLD catheter. For patients with acute to subacute thrombus, I'd typically start with a standard ClotTriever catheter. But as I said earlier, the BOLD catheter requires fewer passes, and I wouldn't be surprised if in the next few weeks I just switch over completely to using the BOLD catheter for all my cases.

Do you have any additional comments about dealing with DVT?

When treating my non-post-thrombotic syndrome (PTS) patients, ClotTriever preserves or restores valve function. When I consider my care goals with respect to treating chronic thrombus, I recognize that a lot of damage has already been done from the disease process. When we talk to those chronic patients, we let them know that while we can't restore vessels to their original state, venous diseases can progress, and we want to work to prevent the dreaded ulcer complication. We tell patients with PTS that our goals are different for them than for those patients with an acute DVT. For PTS patients, our goal now is to halt the progression of PTS symptoms or slow them down as much as possible. We don't know how long that improvement will last. Venoplasty, in combination with the ClotTriever System, will allow us to expand the vein to restore flow. Treating a chronically diseased vein is like stretching an elastic band—you can stretch or expand it, but we're not sure how long before the elastic recoil will happen or what degree of recoil will occur.

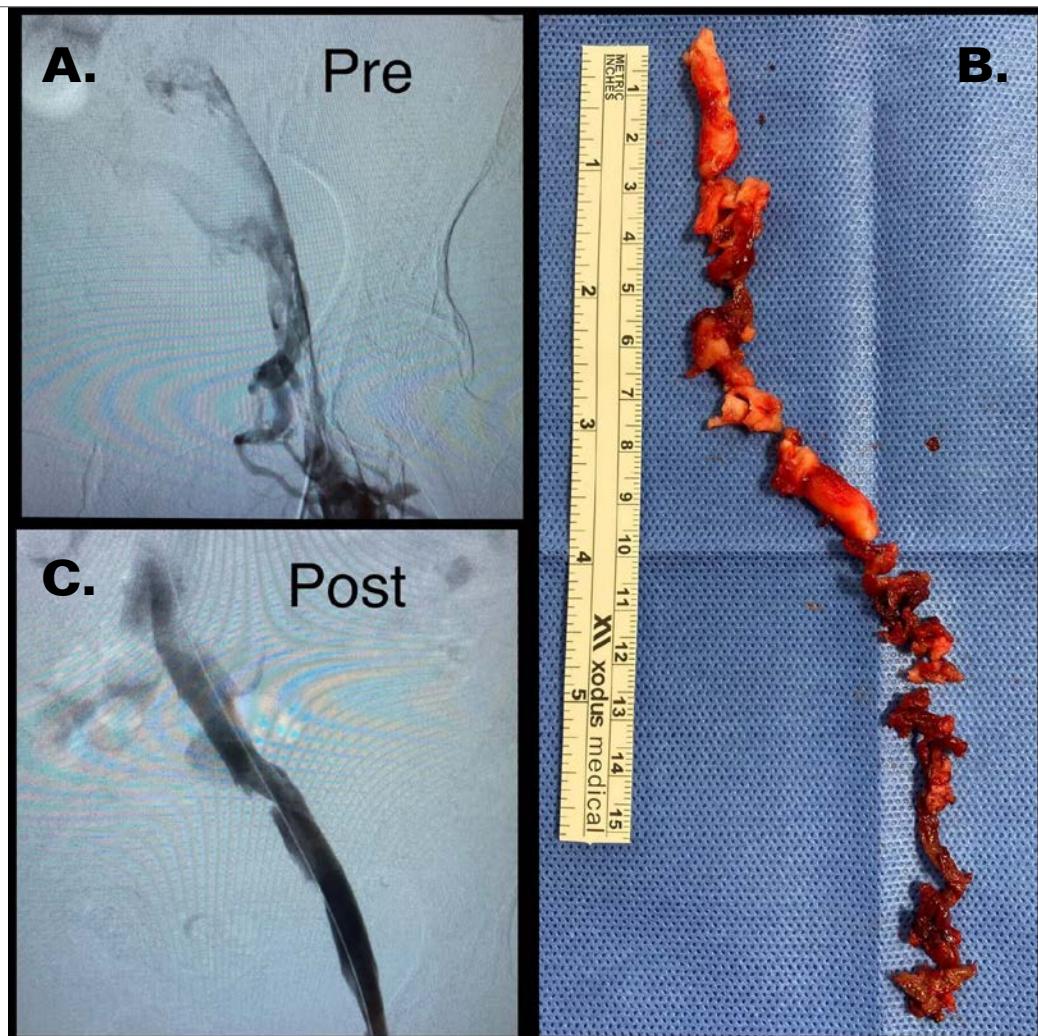


Figure 2. Venography of a 78-year-old woman with left lower extremity DVT (A); intravascular ultrasound confirmed that the thrombus extended from the left common femoral vein to the infrarenal inferior vena cava. Two passes with the ClotTriever BOLD removed the thrombus (B). Chronic thrombus came out in the first pass; more acute thrombus was seen in the second pass. This was a single-session procedure, and no thrombolytics were used. Venography shows the vein after the procedure (C).

It's important to set expectations with our patients. We have the capability to remove thrombus, and while the risk to do that is low, there is always a risk of rethrombosis—so our patients are followed regularly. We see them about 6 times over 2 years. Good history-taking skills are key. It's worth noting that although infrequent, some patients will tell us they did great for a period of time post procedure, then plateaued, and started regressing a little. That's when I know I need to bring them back, reassess, and possibly reintervene. We set those expectations with our patients so they know that although they may see us more frequently than they had anticipated, it is for a good reason—we want to prevent problems from happening in the future. Our patients are receptive and appreciate the continuity of care. ■

Indications For Use: The ClotTriever Thrombectomy System is indicated for: (1) the non-surgical removal of thrombi and emboli from blood vessels (2) Injection, infusion and/or aspiration of contrast media and other fluids into or from a blood vessel. The ClotTriever Thrombectomy System is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).

Refer to IFU for complete Indications For Use, contraindications, warnings and precautions.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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