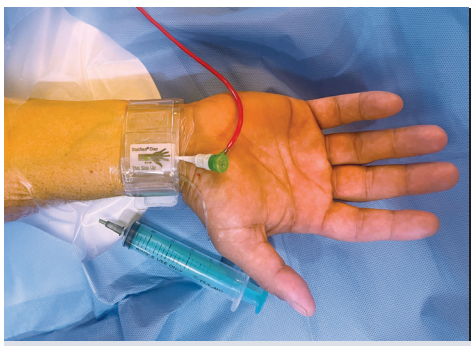
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CLINICAL UPDATE

Independent Investigations of the StatSeal Hemostatic Patch to Aid Same-Day Discharge on Two Continents

CLD talks with:

ARCH Trial Senior Investigator Professor R. H. Stables, MA (Cantab) DM Oxon BM BCh (Oxon) FRCP (London);

STAT2 Trial Principal Investigators Jordan G. Safirstein, MD, and Arnold H. Seto, MD, MPA.

Part I: ARCH Trial Senior Investigator Professor R. H. Stables, MA (Cantab) DM Oxon BM BCh (Oxon) FRCP (London), Liverpool, United Kingdom, describes his experience with same-day discharge and the ARCH trial[1], presented at the 2022 EuroPCR conference. Trial results allowed Liverpool Heart and Chest Hospital to implement a post procedure 2.5-hour minimum observation time for radial access same-day discharge patients.

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In This Issue

Effective Followership: What It is and Why It's Important

Morton J. Kern, MD

In any organization, including the cardiac cath lab, there is a life cycle of success, failure, and optimal/suboptimal performance that waxes and wanes over time. The causes of this cycle are multifactorial. The lab you work in today is not the same as the one you worked in 5 or 10 years ago (and may be better or worse). It is likely the same people are not working in the same place. The composition of the team is continuously evolving, always made up of different personalities. Moreover, changes beyond our control can impact operations, the institution as a whole, and the quality of the leadership.

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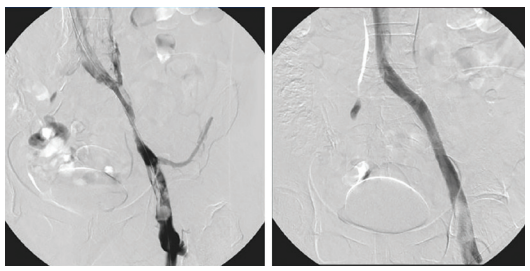
ACUTE VENOUS INTERVENTION

The Use of the Aspirex™ Thrombectomy System for Iliofemoral Deep Vein Thrombosis

CLD talks with Michael Lichtenberg, MD, FESC.

How are you treating iliofemoral deep vein thrombosis?

Our practice for acute iliofemoral deep vein thrombosis (DVT) is to perform mechanical thrombectomy. We are not performing thrombolysis therapy any longer and the reason is simple: we want to be efficient and we want to treat safely. Mechanical thrombectomy is much safer than local thrombolysis and has replaced the use of thrombolysis for many years now.



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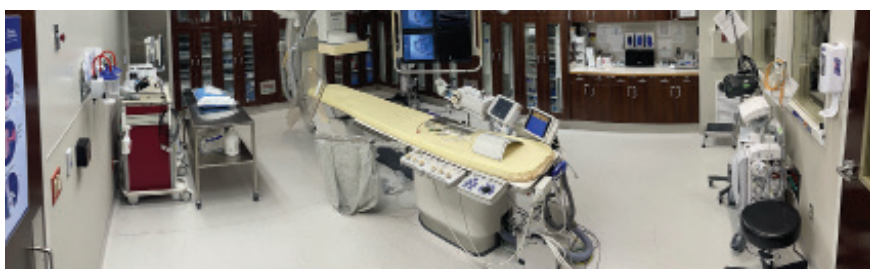
OUT-OF-HOSPITAL CARE

A Hybrid Office-Based Lab (OBL)/Ambulatory Surgical Center (ASC) on the Cutting Edge: HeartPlace

CLD talks with Timothy Dao, MD, FACC, and Rikesh Patel, MD, FACC about their practice and the best-in-class technology they utilize to provide high-quality cardiac care.



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The Use of the Aspirex™ Thrombectomy System for Iliofemoral Deep Vein Thrombosis

CLD talks with Michael Lichtenberg, MD, FESC.

How are you treating iliofemoral deep vein thrombosis?

Our practice for acute iliofemoral deep vein thrombosis (DVT) is to perform mechanical thrombectomy. We are not performing thrombolysis therapy as first-line therapy any longer and the reason is simple: we want to be efficient and we want to treat with less risk to the patient whenever possible. In my opinion, mechanical thrombectomy has a lower risk profile than local thrombolysis and has replaced the use of thrombolysis in my practice.

What are some of the challenges around treating iliofemoral DVT?

One of the most significant challenges involves the age of the clot. When a patient shows up in our emergency department with an acute DVT, it does not automatically mean you are dealing with acute clot. Patients may have symptoms for a few days or patients may misinterpret their symptoms that have already been present for one or two weeks. It means we are dealing with a very inhomogeneous clot situation, going from fresh, partially organized thrombus to wall-adhering thrombus. Another challenge is the extension from where the clot is located. Usually it is a descending DVT, which we treat, but if it involves the popliteal vein or even the tibial vein, it becomes very challenging to remove all the thrombus.

What are the issues you have seen with the use of past devices?

I remember well the first devices from 20 years ago. I started with pharmacomechanical therapy for acute DVT treatment. It was mechanical therapy supported by local thrombolysis therapy. With these devices, we still, especially with the first- or even with the second-generation systems, need thrombolysis to be efficient, to get the clot out of veins. Unfortunately, we saw complications with the use of these pharmacomechanical devices, including bleeding, hemolysis, and renal failure. Sometimes we were forced to put the patient in the intensive care unit in order to monitor their bleeding complication or renal insufficiency. As a result, I believe we must chart a path away from the use of additional thrombolysis, even with reduced doses, to pure mechanical thrombectomy. Pharmacomechanical therapy has been an interim step. We have moved from catheter-directed thrombolysis therapy to mechanical thrombectomy. The focus for DVT treatment will probably only be on mechanical thrombectomy in the future.

What has been your experience with the Aspirex™ Thrombectomy System?

We have used the Aspirex™ Thrombectomy System (BD) for close to 10 years now. I was involved in the development of the Aspirex™ Thrombectomy System from the beginning and I appreciate having this system at our facility for acute DVT treatment. The training, preparation and use of the Aspirex™ Thrombectomy System is simple. It involves a catheter that you attach to a motor unit via a magnetic clutch allowing for ease of use.

Can you describe the mechanism of action?

The mechanism of action is mechanical thrombectomy by using the Archimedes principle, which has been proven to be very efficient. The Archimedes screw provides aspiration, maceration, and transportation of material throughout the full length of the catheter.

Are there particular cases where you favor this device?

Besides acute iliofemoral DVT treatment, in Europe we have the possibility of also treating other acute DVT areas, like subclavian veins. We use the Aspirex™ Thrombectomy System for Paget-Schroetter syndrome. No thrombolysis is needed; you simply aspirate the thrombus with the rotational method of action. It makes treatment easier in these locations. Typical patients are young to middle-aged, mobile, and active, where we are able to avoid post-thrombotic syndrome. From the outpatient department, patients are immediately referred into the cath lab, treated with mechanical thrombectomy, and sent home the next day or two days later.

What happens to the thrombus with use of the Aspirex™ Thrombectomy System and how is that beneficial for the treatment of iliofemoral DVT?

The thrombus is destroyed by the rotational thrombectomy mechanism of action. The Aspirex™ Thrombectomy System has a high suction rate, so the thrombus is sucked into the catheter as the catheter passes through the thrombus. This makes it very efficient, but of course it also means that a couple of passes with the system are needed to achieve maximum thrombus removal, including wall-adhering material. It is not so easy to get wall-adhering material detached and using a steerable sheath will help you push the catheter against the vessel wall.

How do you determine the number of passes with the Aspirex™ Thrombectomy System?

In a perfect world, you are done when you get 100% of the thrombus out, but this is not realistic nor possible. My approach is to get all the fresh, removable thrombus out of the veins. Of course, you may need to stent anyway, because of the underlying reason, like May-Thurner syndrome or other compression areas. The technology of mechanical thrombectomy plus lesion-based stenting, I think, goes hand in hand. You remove the fresh thrombus with Aspirex™ Thrombectomy System and leave in the nonremovable organized material that you then need to stent. With this approach, you first declot the removable thrombus with mechanical thrombectomy and can end the case by stenting only the underlying reason, which is typically May-Thurner syndrome or a compression area.

Is there a way to visualize thrombus when you are working in the vessel?

Yes, infusion of the contrast/saline mix is a very helpful trick. Immediately before activating the Aspirex™ Thrombectomy System, you begin this continuous infusion through the sheath landing it at the distal end of the lesion. This allows you to visualize the thrombus

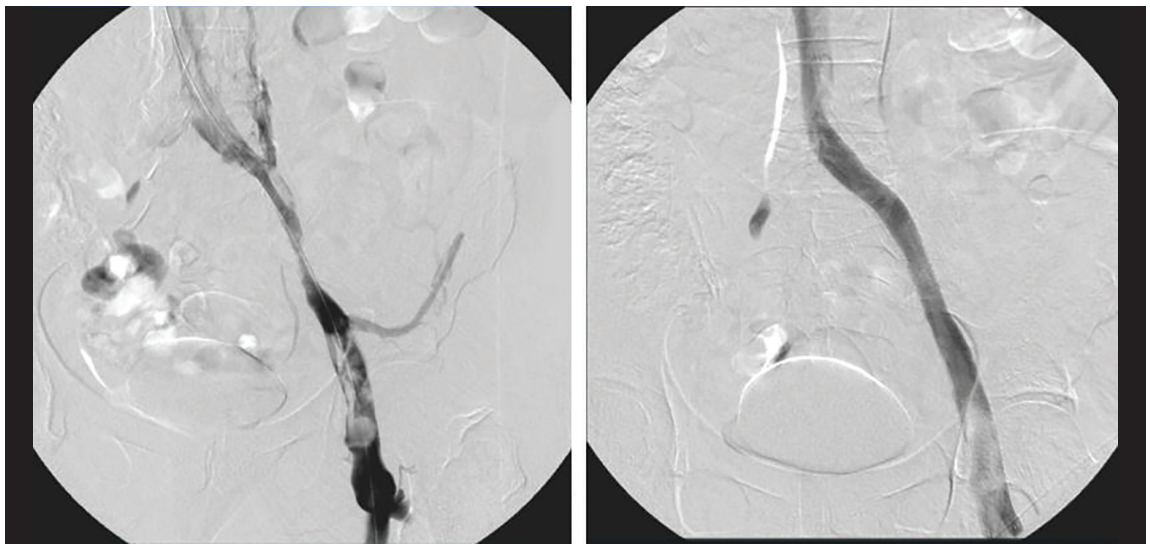

Figure. (Left panel) Subacute iliofemoral deep vein thrombosis in a 44-year-old female. (Right) Final result after mechanical thrombectomy (10 French Aspirex™ Catheter [BD]) and 14 mm x 160 mm Venovo™ Venous Stent System (BD) implantation.

burden and see everything you are removing. Whenever you pass through the contrast-filled thrombus with the Aspirex™ Thrombectomy System, you can see what is going into the Aspirex™ Catheter and is being removed. Otherwise, you are doing a blind flight and don't see anything. Visualization in this way also allows you to work selectively on any remaining thrombus. I would always recommend the infusion of a contrast saline mix, as not only is it valuable for thrombus burden analysis, but also it allows you to see if there is a valve, such as in the femoral veins. When I see a healthy valve, I stop the Aspirex™ Thrombectomy System for those few millimeters or one centimeter, so the valve is not sucked into the catheter. This infusion provides additional safety in my practice.

Does the additional fluid volume help the occluded vein stay open and avoid collapse from suction by the thrombectomy device?

Yes and no. When you have a high thrombus burden, these veins are usually over-expanded anyway. Always start from distal and try to establish an inflow, and when you establish inflow from a distal position, then you get flow the moment you remove the thrombus. The additional fluid you can give via the sheath during the procedure, is not only to expand the vein, but is more or less to cool down the system. As you know, the system runs at 40,000 to 60,000 rpm. Additional fluid, which is given through the sheath during the procedure, provides a cooling aspect which helps to avoid any heat-related issues between the guidewire and the screw.

How do you ensure that the thrombectomy coverage occurs from wall to wall?

Treated veins have diameters from 6 to 18 millimeters. The Aspirex™ Thrombectomy System comes in three French sizes: 6, 8, and 10 French. You can use two different techniques in these circumstances. One technique is to use a steerable sheath. It allows me to push the Aspirex™ Catheter against the vessel wall in large veins. The other technique is to use the Toc-toc technique, which was established by Bruno Freitas from Brazil, using the guidewire. If you push on the guidewire a little, it can help push the Aspirex™ Catheter against the vessel wall. This technique definitely requires training, but it works well. Using one of these two techniques allows for the facilitation of thrombus extraction with the Aspirex™ Thrombectomy System by pushing the catheter against the vessel wall, which means the device can also work to remove partially organized wall-adhering material.

What about follow-up?

One piece of advice I have is that all these patients need close follow-up over the years to avoid complications after treatment. We offer every patient a follow-up schedule. If you just do the case and forget about it, the vein may reocclude at some point, due to various factors including anticoagulation issues and noncompliance. Patients need to be in a scheduled, very intensive, post-interventional program. Of course, it is not possible for patients referred from 300 kilometers away. It shows again that we are at the beginning of this story. These patients need to be included in special outpatient departments or other programs to obtain good follow-up. Otherwise, we will fail, as, of course, a lack of follow-up means that they could have a reocclusion or other complication.

What do you see for the future of iliofemoral DVT treatment?

I foresee that more patients will be referred, because awareness is rising. The data are positive for treatment via thrombus removal. I see this technique as one that will increase over the next few years. Our job now is to work on awareness. Not only should awareness be raised by physicians, but also by industry. With rising awareness, we could definitely recommend that more patients be sent to special venous centers, where they could be immediately analyzed to see if they would benefit from thrombectomy. It would be a very appreciable improvement. Not every patient is destined to have post-thrombotic syndrome after a couple of years, even if they do not undergo this therapy. We need to analyze other definitive risk factors that predict post-thrombotic syndrome. We need to establish randomized, controlled trials of mechanical thrombectomy versus conservative treatment with anticoagulation and compression.

Do you have any advice for someone who has not used the Aspirex™ Thrombectomy System before and is looking to get started?

Begin with easy cases. A patient with acute symptoms and fresh thrombus, such as an acute descending iliofemoral DVT, with a simple extension of the thrombus. We do a transpopliteal approach with a 10 French Aspirex™ Catheter. You should have theory training on the device first, which BD can provide. You will need to learn how to advance the system through the thrombus. You can utilize some tips and tricks to navigate the catheter up, but for an interventionist who has already done work in the venous space, it is not very complicated. I do think the greatest advantage of the Aspirex™ Thrombectomy System is its simplicity. You can just turn it on and aspirate the thrombus out. ■

This article is sponsored by Becton, Dickinson and Company (BD). Dr. Lichtenberg is a paid consultant of BD. See important Safety and Risk Information below.

Scan the QR code with your smartphone camera to be taken to the online article.

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Chief Medical Officer, Angiology Department, Vascular Centre Clinic, Arnsberg, Germany

Aspirex™ Thrombectomy System Safety and Risk Information:

Indications for Use: The Aspirex™ Thrombectomy System is indicated for the removal of acute emboli and thrombi from vessels of the peripheral venous system.

Contraindications: Not for use in the vessels of the cardiac, pulmonary, coronary and neurovasculature.

Warnings: The Aspirex™ Thrombectomy Catheters may only be used in conjunction with the Drive System and the provided Aspirex™ Guidewire of appropriate size. The Aspirex™ Thrombectomy Catheters are supplied sterile and are intended for single use only. Do not resterilize or reuse the device. Failure to ensure sufficient blood flow to the catheter head could result in drawing of the vessel wall into a side window(s). Failure to ensure sufficient blood flow through the catheter head could result in damage to the catheter due to overheating. Do not operate the Aspirex™ Thrombectomy Catheter near fractured areas of broken stents or stent grafts. Do not use the Aspirex™ Thrombectomy Catheter or Aspirex™ Guidewire if kinked or through a kinked or damaged introducer sheath. The safety and efficacy of this device has not been established in vessels with a radius of curvature < 2 cm. It is recommended to select the largest catheter diameter in order to reduce the potential for embolism. The catheter size should be selected based on the minimum vessel diameter. The risk of embolism increases with the difference in diameter between the native vessel and the minimum vessel diameter.

Precautions: The Aspirex™ Thrombectomy System should only be used under adequate visual monitoring with suitable radiographic techniques. The Aspirex™ Thrombectomy System does not contain any parts that can be maintained or serviced by the end-user. Do not repair or change the configuration of the product. The Aspirex™ Thrombectomy Catheters must not operate dry and must be primed and flushed using heparinized saline before and during use per the Directions for Use. The Aspirex™ Thrombectomy Catheters must not operate without an Aspirex™ Guidewire. Do not use the Aspirex™ Thrombectomy Catheter Set when product damage is evident, if packaging is damaged, or if the sterilization expiration date has passed. Ensure the Aspirex™ Thrombectomy Catheter is manipulated slowly with a back-and-forth motion as described in the Directions for Use. Insufficient blood flow through the catheter may result in intra-catheter clot formation, slow or absent therapeutic function, fracture of the helix and/or guidewire, and/or overheating of the catheter. The device is intended for use by physicians who have received appropriate training.

Potential Adverse Events: Potential adverse events include, but are not limited to: Acute occlusion; Air embolism; Allergic/anaphylactic reactions; Amputation; Arteriovenous fistula, pseudo-aneurysm; Atrial Fibrillation; Death; Detachment of catheter or guidewire; Device malfunction; Distal embolization; Emboli; Emergent surgery; Entrapment; Excessive blood loss; Hematoma, hemorrhage; Hypotension; Inability to completely remove thrombus; Intimal disruption; Ischemia; Kidney damage from contrast media; Myocardial infarction; Respiratory failure; Sepsis/Infection; Thrombophlebitis; Thromboembolic events; Vessel spasm, thrombosis, dissection or perforation, or valve damage.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.