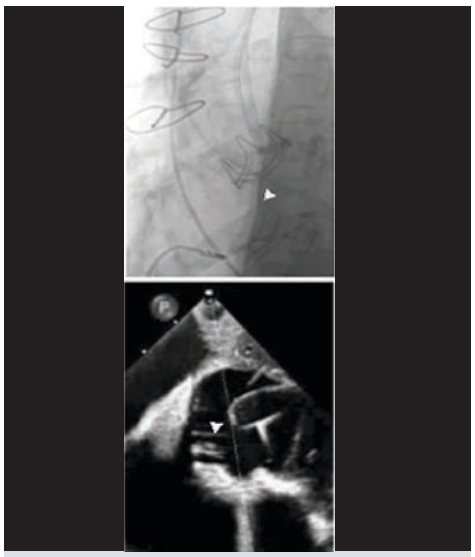
Cath Lab Digest

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



CUTTING EDGE

A Look at the Future of Structural Intervention: The Rise of the Imaging Specialists and Cardiac Electrosurgery

CLD talks with Stephen H. Little, MD.

Baptist Health's Echocardiography and Structural Heart Symposium took place September 27-28th, in Coral Gables, Florida. CLD shares a discussion focusing on one of Dr. Stephen Little's presentations, "Interventional Echocardiography: Bridging the Gap Between Sonographer, Structuralist, and Surgeon."

Dr. Little discusses the present and future of the structural echocardiographer on the heart team, as well as an evolving addition to the structural field, the application of percutaneous, image-guided electrosurgery.

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In This Issue

STRUCTURAL HEART & EP

A Growing Concern: Patients With CIED Leads and Tricuspid Regurgitation

CLD talks with Electrophysiologist Laurence M. Epstein, MD, and Cardiac Imaging Specialist Rebecca T. Hahn, MD.

Part I. Electrophysiologist Laurence M. Epstein, MD

How should we approach the treatment of patients with cardiac implantable electronic device (CIED) leads and tricuspid regurgitation (TR)?

Dr. Epstein: A heart team approach is mandatory, because these patients are very complicated and the leads may or may not be contributing to the TR. Heart failure physicians can help medically manage and optimize these patients. Imagers help us understand the anatomy and the relationship of the leads to the valve, and guide any interventional procedures.

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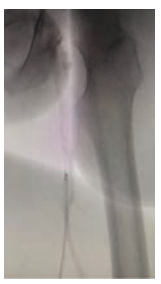
THROMBECTOMY

Use of the BD® Aspirex™ Mechanical Aspiration Thrombectomy System for the Treatment of DVT and Thrombosed AV Grafts and Fistulas

CLD talks with Jeffrey E. Silpe MD, MS-HPEd.



How are you treating deep vein thrombosis (DVT)?

Over the last year or so, my practice switched from only offering treatment to patients with iliofemoral DVT to patients with both iliofemoral DVT and femoropopliteal DVT, because I believe there is both a reduction of post-thrombotic syndrome and an improvement in subject well-being with thrombectomy compared with anticoagulation alone. The Aspirex™ Mechanical Aspiration Thrombectomy System (BD) is one of my top device choices for these cases because of its ease of use.

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Use of the BD® Aspirex™ Mechanical Aspiration Thrombectomy System for the Treatment of DVT and Thrombosed AV Grafts and Fistulas

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My practice switched from only offering treatment to patients with iliofemoral DVT to patients with both iliofemoral DVT and femoropopliteal DVT, because I believe there is both a reduction of post-thrombotic syndrome and an improvement in subject well-being with thrombectomy compared with anticoagulation alone.

It offers very powerful suction from a thrombectomy catheter, and does not take much coaching or guidance. It is as simple as putting the catheter into the clot, pressing a button, and slowly manipulating the catheter through the clot. I have been using the Aspirex™ Mechanical Aspiration Thrombectomy System for about two years. The catheter does a good job at moving and debulking all the acute clot in the iliofemoral and femoropopliteal segments. With the various sizes of the catheter (6F, 8F, and 10F), you can achieve thrombectomy in different vessel sizes.

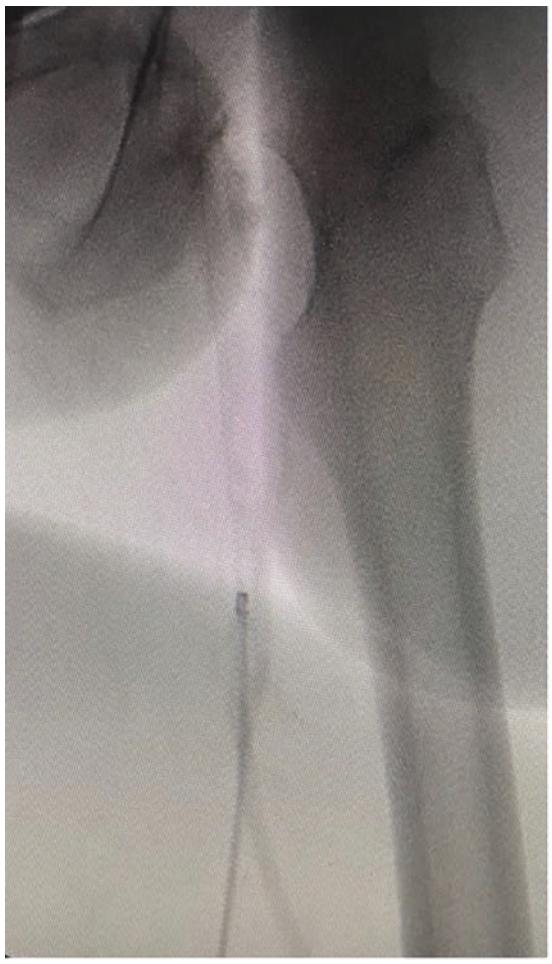

Figure. The Aspirex™ Mechanical Aspiration Thrombectomy System (Becton, Dickinson and Company [BD]) in action.

The Aspirex™ Mechanical Aspiration Thrombectomy System achieves quite an ideal debulking of acute clot. With any subacute or chronic clot, I will switch to maneuvers such as balloon angioplasty and/or stenting.

In the DVT space, one of the nice aspects of the Aspirex™ Mechanical Aspiration Thrombectomy System is that you can attach a pressurized bag mixed with contrast and heparinized saline, and infuse contrast as you are performing your thrombectomy. By virtue of its size, the catheter is close to being occlusive to a fistula or graft, so I don't use the contrast bag in the dialysis space. For DVT treatment, the contrast allows you to see what clot remains and direct your catheter towards those areas. I have found this ability to infuse contrast exceptionally valuable. I understand physicians are concerned about giving extra contrast in procedures, but in my experience, what makes the Aspirex™ Mechanical Aspiration Thrombectomy System unique is its strong aspiration, which can remove the contrast after it does its job in staining the residual clot. My goal is to stain the residual clot with contrast for better visibility under fluoroscopy. Use a longer sheath instead of a short sheath, keep your sheath tip close to the tip of the catheter, continuously infuse, and visualize any areas of clot that remain.

What about treating thrombosed arterial venous (AV) grafts and AV fistulas?

Both for AV grafts and AV fistulas, I have switched from using pharmaco-mechanical thrombectomy to solely mechanical thrombectomy. The Aspirex™ Mechanical Aspiration Thrombectomy System comes in an 8 French, 85 cm catheter, which facilitates treatment in dialysis access. I have seen good results in these patients, mostly related to the fact that the suction capacity of the Aspirex™ Mechanical Aspiration Thrombectomy System is so great. In order to achieve adequate debulking and clearance of the thrombosis, depending on the case, I pass the Aspirex™ Mechanical Aspiration Thrombectomy System only two or three times, whereas with previous catheters, sometimes I've had to pass a few more times in order to achieve adequate debulking of the clot. These procedures are performed mostly under local anesthesia and conscious sedation, so patients can be aware, and the more you are manipulating inside the graft or fistula, the more uncomfortable it may be for the patient.

I typically treat all of my dialysis access patients through a transradial approach. A lot of interventionalists will stick the graft or the fistula directly, and have to work in both an antegrade and retrograde direction in order to clear up the venous outflow tract, and then also remove the arterial plug. Transradial access allows you to achieve a one-direction thrombectomy. I move from the radial artery through the arterial plug and straight into the outflow, whether that be the graft or the outflow fistula. Treating in a single direction saves fluoro time and saves time with my hands underneath the fluoro machine.

What are challenges you see in treating patients with DVT and AV graft/fistula thrombosis?

Particularly in the DVT space, one of the things we struggle with is the presence of chronic disease in the iliofemoral segment. You have to rely on techniques such as balloon angioplasty and stenting if necessary, in order to really create the proper channel (improve luminal gain). Intravascular ultrasound (IVUS) helps to dictate when and if those adjunctive measures are needed.

The other issue with iliac veins in particular is their larger diameter. With both the Aspirex™ Mechanical Aspiration Thrombectomy System and many other thrombectomy catheters, especially suction thrombectomy catheters, you are looking at using anywhere between a two to three millimeter (mm) diameter catheter in a 10 mm or larger vein.

The learning curve with the Aspirex™ Mechanical Aspiration Thrombectomy System requires understanding how to rely on wire bias to manipulate and deflect the tip of the catheter from wall to wall as you are performing the thrombectomy,

which allows you to realize the full debulking potential of the device, rather than remaining in the center line in the middle of the vein. After learning the wire bias technique, you can watch on venography as the tip of the catheter deflects from wall to wall and your thrombectomy success dramatically improves.

In the dialysis access space, one of the challenges is working in smaller veins. You can see vein spasm and your catheters can have difficulty tracking. On the plus side, I went from using lysis with tPA to not having to use it at all. We have mitigated some of the risks of the pharma side of the pharmaco-mechanical thrombectomy, but sometimes have to figure out how to maneuver and track the catheter better in these smaller veins and tighter stenoses than what you see in the DVT segments. I have found in my practice that the Aspirex™ Mechanical Aspiration Thrombectomy System does track well, however, when using proper technique.

You are no longer using tPA?

No, I don't use tPA at all for venous or dialysis access thrombectomy. The recent strategy for venous thrombectomy is definitely moving away from pharmaco-mechanical thrombectomy and more towards supporting straight percutaneous mechanical thrombectomy.

You mentioned using wire bias in DVT to access both sides of the vessel wall. Can you describe that technique?

Prior to starting with the Aspirex™ Mechanical Aspiration Thrombectomy System, using wire bias is something that I wasn't doing with any other device. The learning curve was about five or six cases before I was actually comfortable. You have to move the handle of the catheter and the wire, which comes out of the back of the handle, in opposite directions of each other, while you have someone on the front end manipulating and turning the front end of the catheter. This combination of movements will produce the deflection from wall to wall of the vein. It is a movement most operators aren't initially comfortable with, because people worry about bending the wire or causing problems with device malfunction by too much manipulation of the catheter. However, I have learned that it does take a strong back-and-forth motion with the catheter handle and the wire, and someone at the front directing that tip of the catheter against the walls.

Why do you use the Aspirex™ Mechanical Aspiration Thrombectomy System for acute clot over other devices?

I wouldn't necessarily say I use the Aspirex™ Mechanical Aspiration Thrombectomy System over other devices in every instance of acute clot, but it is a useful device to have in the toolbox. The reason I use the Aspirex™ Mechanical Aspiration Thrombectomy System frequently for acute clot is due to its ease of use and success rate in reducing or eliminating acute thrombus burden in an efficient manner. In my experience, it does not require an excessive number of passes, thereby reducing procedural time. Lastly, it allows direct visualization of the residual clots' location with instillation of contrast, making each pass more efficient.

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Are there similar concerns about endothelial injury in the venous and arterial space?

Yes and no. In the arterial space, obviously by causing endothelial injury, you are really worried about causing dissection, which can limit flow, cause flow-limiting stenosis, or it could also cause vessel thrombosis. In the venous space, I worry less about venous dissection, but it doesn't really cause any limitations to flow. It's a low-flow space to begin with, and the vessel diameter is much greater than the arteries. What you really worry about from venous endothelial injury is that you will leave a nidus for re-thrombosis. What we know is from basic science and Virchow's triad, which is that the procedure itself causes hypercoagulability and then endothelial injury. Many of these patients are hypercoagulable to begin with, which is why they are in this space in the first place. But endothelial injury is a contributor to the risk that someone will have a re-thrombosis or form new clot on the area that was just treated, which obviously negates the success of your treatment.

What is the timeframe where you worry most about re-occlusion or re-thrombosis?

I don't think it would occur immediately, but probably within the first couple of weeks to months after treatment. It may not cause an acute occlusive thrombosis, but it may cause stenosis of the vessel, which could lead to thrombosis down the road.

How do you know if you are facing fresh clot or more chronic, organized thrombus?

I strongly believe that almost all DVTs or dialysis access thromboses have mixed morphology clot. Not so much in the dialysis space, but in the DVT space, I will perform IVUS before and after thrombectomy in all of my cases. IVUS is a great tool at showing you what's acute, what's more subacute, or chronic, and you can have a good sense of where those areas are located, marking the areas on IVUS and your fluoroscopy. If a particular area is more acute, I probably don't have to spend as much time debulking in that area, because the catheter will achieve a good result in taking care of that clot regardless.

Because chronic clot is adhered to the wall of the vein, you will need to figure out whether or not you need to balloon angioplasty that segment. You measure the healthy vein above and below in order to know what size of balloon you will use. Then, after you balloon, IVUS again and see if you need to place a stent. Two-dimensional venography is not going to tell you this information. The vessel can look really nice on the venography, but basically what you are looking at is a flat pancake. IVUS will give you that three-dimensional idea of exactly what is happening and what you need to do to succeed.

Can you talk more about using transradial access?

For radiocephalic fistulas, brachiocephalic fistulas, brachiobasilic fistulas, and brachial-axillary grafts, using a radial access works wonders. There is plenty of literature showing that a transradial approach to intravascular intervention is safe and effective. Prior to the procedure, I do a modified Allen's test. I will put an O_2 sensor on the patient's finger and occlude the radial artery to make sure that the oxygen remains at an acceptable level. If it does, I proceed with the idea that the ulnar artery and palmar arch are patent and complete. Under ultrasound guidance, I access the radial artery using a micropuncture kit. I would probably shy away from using radial access when there is circumferential calcification of the radial artery, but we don't see that very often, or a very diminutive radial artery — one that feels good on pulse exam, but looks really, really small on ultrasound. But probably in about 97-98% of my cases, I am sticking the radial artery. I give 2.5 mg of verapamil and 2000 IU of heparin, and flush the catheter and the sheath with heparinized saline. I use a 6F Glidesheath Slender® Hydrophilic Coated Introducer Sheath (Terumo Interventional Systems), take my initial arteriogram, venogram, or fistulogram, then redirect the wire from the radial artery into the fistula. If it is radiocephalic, typically you don't need a catheter. If it's brachiocephalic,

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brachiobasilic, or an AV graft, it would be up the arm, but sometimes you do need a selective catheter to get in, especially if there is any peri-anastomotic stenosis. After I perform balloon angioplasty or thrombectomy, what I want to see is brisk flow from the artery into the fistula itself. I don't want to see any more filling of the artery proximal to the fistula. If the artery is filling proximal to the fistula, then there is still something there, either clot in the arterial plug, clot in the outflow vein or graft, or some stenosis that I haven't yet recognized. The nice part about radial access, as I previously mentioned, is with the ability to treat in one direction, you can access in flow such as in the artery distal to the anastomosis in an antegrade fashion, or beyond the clot in the vein and go retrograde, when treating in the AV circuit. The Aspirex™ Mechanical Aspiration Thrombectomy System has an atraumatic catheter design, so I start performing the thrombectomy just distal to the anastomosis. That way I know that I am starting where there is sufficient blood flow, which is necessary with this particular catheter. I slowly advance retrograde to the arterial plug and then use a slow, back-and-forth motion throughout the entire outflow in an antegrade fashion, which is the indicated catheter movement for the Aspirex™ Mechanical Aspiration Thrombectomy System. I then take another fistulogram and continue to perform fluoroscopic-directed catheter thrombectomy where needed.

Any advice for those operators interested in trying the Aspirex™ Mechanical Aspiration Thrombectomy System?

Definitely talk to someone who has used the Aspirex™ Mechanical Aspiration Thrombectomy System before, because it does come with a learning curve. Talking to someone who has used it, even only once before, is helpful. Take your time with the device and give it a chance. I was initially using the Rotarex™ Rotational Excisional Atherectomy System (BD) in the arterial side as our atherectomy/thrombectomy catheter. Switching from the Rotarex™ Rotational Excisional Atherectomy System to the Aspirex™ Mechanical Aspiration Thrombectomy System is a no-brainer because of its ease of use. The learning curve actually becomes much more minimal because you are already using a similar type of catheter and drive system, and now you are just applying it to venous thrombectomy. Nevertheless, there still is a learning curve, as there is with any other device. As you become more comfortable with the catheter, you will see that you are successful and will continue to improve to the point where you are confident in your ability to use the device in each of your cases. The Aspirex™ Mechanical Aspiration Thrombectomy System has become my first-line therapy for dialysis access maintenance and DVTs. Once you learn the system, it is something that you can take off the shelf and use very easily, without any company representative present, to achieve thrombectomy in both the DVT and dialysis access spaces. If you are struggling or having issues, there are resources available to help guide you. ■

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

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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. The 6F and 8F Aspirex™ Thrombectomy Catheters are indicated for the removal of acute emboli and thrombi from hemodialysis access grafts and native arteriovenous fistulas.

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. Do not use in sharply angled vessels with a <2 cm radius. Do not use in immature native AV fistula or recently-implanted AV graft. Caution should be used when dislodging the platelet plug at the arterial anastomosis to minimize the risk of arterial embolization. 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 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; Pseudoaneurysm; 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.