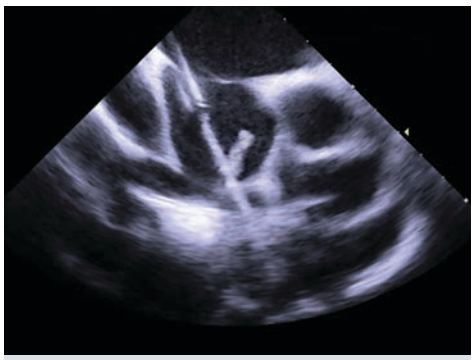
Cath Lab Digest

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



CASE REPORT

A Flame That Can Ignite Disaster: A Rare Hyperacute Thrombus Formation During Percutaneous Closure of an Atrial Septal Defect

Juan Guzmán-Olea, MD; Juan Francisco Rodríguez-Alvarado, MD; Raúl Cruz-Palomera, MD; Gonzalo Tolosa-Dzul, MD; Gabriel Guzmán-Olea, MD; Jorge Guillermo Arenas-Fonseca, MD; Daniel Iván Pérez Vásquez, MD; Héctor Hugo Escutia Cuevas, MD; Carlos Javier González Álvarez, MD

The percutaneous closure of atrial septal defects (ASD) has become a feasible and safe alternative to conventional surgical closure. Percutaneous ASD closure has established its procedural safety through operator experience and improved device structure and deliverability. The evolution of ASD closure device usage in the last 4 decades incorporates developments minimizing a wide range of serious side effects that have been reported over the years.

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In This Issue

LOWER-EXTREMITY INTERVENTION

The Arnsberg Registry: Thrombus Removal With the Aspirex Mechanical Aspiration Thrombectomy System

CLD talks with Michael K. W. Lichtenberg, MD.

Can you tell us about the Arnsberg Registry?

The intention of the Arnsberg Registry is to analyze the efficacy and safety of a mechanical thrombectomy device, the Aspirex Mechanical Aspiration Thrombectomy System (BD), in daily routine practice in patients with acute and subacute iliofemoral deep vein thrombosis (DVT) via a retrospective analysis. The Arnsberg registry is an overall construct of many registries, prospective and retrospective.

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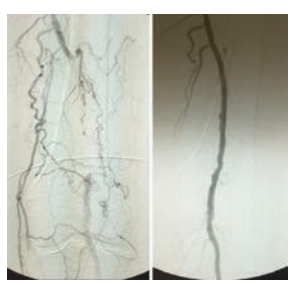
PVD AWARENESS

Improving Early Diagnosis and Treatment of Peripheral Vascular Disease: Enhancing Patient Outcomes and Quality of Life

Joyce Froetschel

Approximately 200 million people worldwide suffer from peripheral vascular disease (PVD), and yet it is one of the most underdiagnosed and undertreated conditions in healthcare today. Although coronary and cerebral vascular disease are concomitant conditions with PVD, the PVD population's morbidity and mortality rates are greater, with a 60% excess risk of all-cause mortality and a 96% increase in cardiovascular deaths where the ankle brachial index (ABI) is <0.9.[1]



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The Arnsberg Registry: Thrombus Removal With the Aspirex Mechanical Aspiration Thrombectomy System

CLD talks with Michael K. W. Lichtenberg, MD.

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We further define substudies, such as the Aspirex study,[1] to analyze the efficacy and safety of different devices and technology. We saw great success in patients with the use of the Aspirex device for acute and subacute DVT treatment. Included in this study were patients with native iliofemoral DVT, but we also included patients with already stented iliac veins, which reoccluded for whatever reason. These patients were then treated with the Aspirex mechanical thrombectomy device, which comes in different sizes. The 8 and 10 French systems are typically utilized for deep venous interventions, and in this trial, we mostly used the 10 French Aspirex device. The analysis of the 56 patients included in this study demonstrated success in terms of technical outcome, defined as any residual thrombus after usage of the Aspirex device. In more than 90% of the cases, there was greater than 90% clot removal, so the demonstrated efficacy was high. The study demonstrated that the Aspirex device is a good option for treatment of acute, subacute, native, and in-stent thrombosis patients. In terms of safety events, there was nothing to report: no bleeding complications, access complications, hematoma, or other device-related complications, so the Aspirex device was proven to be safe. Patients were followed out to 6 months and 6-month patency rates were close to 90% in the included patients, demonstrating that mechanical thrombectomy is efficacious for patients with acute or subacute DVT, and for the prevention of post-thrombotic syndrome (PTS) symptoms. We will soon have available the 12-month full cohort analysis that is evaluating PTS and expect these data will also support the long-term efficacy of the Aspirex device.

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How do the Aspirex study results compare to other types of treatment for DVT?

We always have to set a newer therapy in direct comparison to other established therapy, and the Aspirex study compared mechanical thrombectomy with a much older therapy, thrombolysis therapy. First, we found that efficacy, in terms of effective thrombus removal, is much better with mechanical thrombectomy than with thrombolysis. Second, thrombolysis takes hours, sometimes days, to achieve a good result in terms of thrombus removal. If prolonged thrombolysis is necessary, repeat angiography is required to prove a good outcome. Third, the use of thrombolysis means that these patients have a catheter in the groin or in the popliteal area, and therefore need to stay on the intensive care unit (ICU) so that bleeding complications are not missed, which means a high amount of resource utilization is required for thrombolysis. This a clear disadvantage of thrombolysis compared to mechanical thrombectomy. Finally, thrombolysis is always associated with a higher rate of bleeding complications in comparison with mechanical thrombectomy. We did not have any significant major bleeding complications with the Aspirex mechanical thrombectomy device. The arguments for modern mechanical thrombectomy are clear. Today, we might only use thrombolysis in certain bailout situations, but its use occurs very rarely, because we can easily achieve success with the use of different mechanical thrombectomy techniques. Patients only need one treatment with mechanical thrombectomy and can be sent home even the next day. Mobilization is much faster. There are normally no bleeding complications and no ICU stay. We have seen good outcomes in the pulmonary embolism complication rate as well, which is extremely low with mechanical thrombectomy and with other devices, and this complication has been reported with thrombolysis. There are many arguments for the use of mechanical thrombectomy in DVT patients.

Mechanical thrombectomy is not just used for iliofemoral DVT, but can be used for a range of conditions.

Correct. We use also use it for subclavian vein thrombosis, for example, including patients with venous inflow disease and outflow disease, and patients who are on dialysis and have thrombosis of their subclavian vein. The 8 French Aspirex device is a good candidate for this treatment indication and we have had good success with its use in these patients.

What other benefits have you found with the Aspirex mechanical thrombectomy device?

It is easy, fast, and safe. The Aspirex device offers short intervention times, a short hospital stay for patients, and low complication rates. In terms of economic analysis, which would be also a very interesting sub-analysis, we believe it would show a positive impact, as the patient can be sent home quickly. They don't need to stay in the ICU and don't require repeat angiographies.

You had mentioned the use of different techniques with mechanical thrombectomy. Can you elaborate further?

We have been able to enhance the efficacy of mechanical thrombectomy with the Aspirex device by combining it with other technologies. We use steerable sheaths to increase attachment to eccentric thrombosis within the iliac veins. Using steerable sheaths, we can guide the Aspirex catheter against the wall to work on attached material.

The Aspirex has a negative pressure and sucks out thrombus using an Archimedes screw. It is not working actively on the attached material to detach it, but instead uses the negative pressure. Per definition, it may not be as effective as other devices that can actively work on wall-adherent thrombus. Therefore, it is important to evaluate the age of the thrombus in order to find out which technology has the best indication for the situation. It is an important aspect we as interventionists have to evaluate and discuss when a patient presents. Are we treating fresh thrombus? Are we dealing more with very organized material? Based on the age of the thrombus, we can then decide on the most appropriate technology for use. We use duplex ultrasound, but we also perform magnetic resonance venography (MRV) and in a very few patients we perform computed tomography venography (CTV). Based on this noninvasive technology, we can judge the age of the thrombus definitively. Perhaps with a short duration of symptoms there is fresh thrombus, and use of the Aspirex device is appropriate. If the symptoms are long and ongoing, and the MRV or

CTV is showing organized material, then we may decide to use a different technology to remove wall-adherent material.

An iliofemoral DVT is usually of a mixed morphology, which is more challenging to treat. We can't really associate the state of the thrombus with the symptoms of the patient. A patient who has had only a short duration of symptoms does not necessarily only have fresh thrombus. There may be older, wall-adherent morphologies from the past few weeks — existing thrombosis which then was incorporated into the vessel wall. There may be collagen-like material which is extremely challenging to remove and because we can't remove this super-organized, collagen-rich material out of the vessel, stenting may be required.

You recently presented another Arnsberg Registry study, the Venovo Arnsberg study, at the LINC 2023 meeting. Can you tell us about it?

Our Venovo Arnsberg experience is an all-comers registry[2,3] that took place in addition to the IDE trial, the VERNACULAR trial, for the Venovo venous stent (BD). We sought to evaluate whether in addition to the very selective patient population in the VERNACULAR trial, Venovo use in an all-comers population would also demonstrate efficacy and safety. In terms of patency rate and reintervention rate, the registry data was on absolutely the same level as the rates shown in the VERNACULAR trial, even though the Venovo Arnsberg registry included a higher level of complexity, with more complex lesions, longer lesions, and longer stent lengths. The Venovo venous stent demonstrated high efficacy and safety, and is a good option for different kind of indications, including May-Thurner Syndrome and PTS, with patency rates greater than 90% at two years for both the MTS and PTS groups.

Are you planning for any future studies?

We are now planning for a more prospective study, to include other international centers, in order to collect more data for the Aspirex mechanical thrombectomy device. ■

References

1. Lichtenberg M, Stahlhoff WF, Özkapi A, et al Safety, procedural success and outcome of the Aspirex®S endovascular thrombectomy system in the treatment of iliofemoral deep vein thrombosis - data from the Arnsberg Aspirex registry. *Vasa*. 2019 Jul; 48(4): 341-346. doi:10.1024/0301-1526/a000779

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3. Lichtenberg MKW, Stahlhoff WF, Stahlhoff S, et al. Venovo venous stent for treatment of non-thrombotic or post-thrombotic iliac vein lesions - long-term efficacy and safety results from the Arnsberg venous registry. *Vasa*. 2021 Jan; 50(1): 52-58. doi:10.1024/0301-1526/a000893

More from Dr. Lichtenberg (CLD Dec 2022):

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

www.*hmpgloballearningnetwork.com/site/cathlab/original-contribution/use-aspirextm-thrombectomy-system-iliofemoral-deep-vein*

Or use: tinyurl.com/AspirexDVT

In the Literature: *CLD* Editor's Picks

Dual-Lumen Catheter and Floating-Wire Technique to Access Protruding Aorto-Ostial Stent

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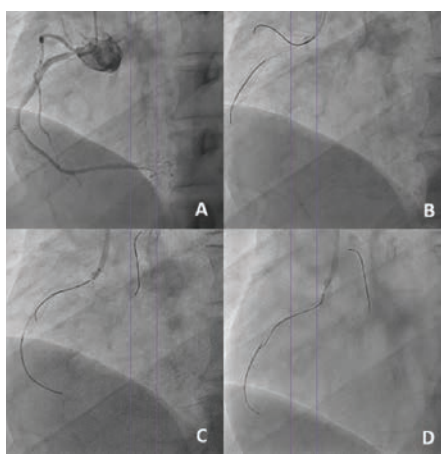
Percutaneous coronary intervention in the setting of previous aorto-ostial stenting can be difficult, especially if there is excessive stent protrusion. Various techniques have been described, including double-wire technique, double-guide snare technique, side-strut sequential ballooning technique, and guide-extension facilitated side-strut stenting.[1-5] These techniques can sometimes be complicated, and intervention through a side-strut may lead to excessive stent deformation or avulsion of the protruding segment. Our novel technique uses a dual-lumen catheter and floating wire to back the JR4 guide away from the protruding stent while maintaining stability for another guidewire to enter the central lumen.



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VDM Vascular Disease Management

Intravascular Imaging for Infrainguinal Peripheral Arterial Disease Intervention

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Many experts recognize that the success of peripheral endovascular treatment is heavily dependent on the data provided by the imaging modality used during the case. This manuscript reviews the applications and supporting data for the use of intravascular ultrasound and optical coherence tomography in infrainguinal endovascular intervention.

Vascular Disease Management July 2023 • vasculardiseasemanagement.com