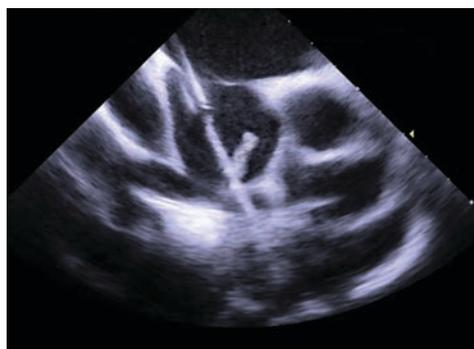


# Cath Lab Digest

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

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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.

*continued on page 16*

## In This Issue

### My Top Tips for a New Fellow Starting in the Cath Lab

Morton J. Kern, MD

page 6

### COAPT at 5 Years: MitraClip Benefits Persist

Gregg W. Stone, MD

page 26

### Ultrasound-Guided Thrombin Injection for Treating Iatrogenic Femoral Artery Pseudoaneurysm

Muhammad Anjum, MBBS, FCPS (Cardiology), FCPS (IVC), et al

page 28

## 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.



*continued on page 14*

## 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  $<0.9$ .<sup>1</sup>



*continued on page 20*

Continued from cover

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

Joyce Froetschel

PVD is a chronic condition that gradually develops over years and may not be diagnosed until it reaches the advanced stage of critical limb ischemia (CLI), characterized by chronic ischemic rest pain, ulceration, or gangrene. Contributing factors include smoking, diabetes, hypertension, dyslipidemia, chronic kidney disease, hypercoagulable states, and hyperhomocysteinemia. The mortality rate for patients with CLI is 20% within 6 months and 50% at 5 years.<sup>2</sup> Other risks include amputation and cardiac events.

Once a patient presents with CLI, options of care are limited to amputation, peripheral vascular intervention (PVI), or a combination of both. Bypass may also be a consideration, dependent on the extent of blockage in the distal arteries, but often, once a patient presents with CLI, the disease state has progressed beyond the point of bypass being an option. Although there are risk factors with each treatment option, amputation carries a higher level

experience phantom limb pain, muscle contractures, fatigue, psychological issues with confidence and self-esteem, and have an increased fall risk due to changes in their center of gravity.

Early diagnosis and treatment of PVD must improve so that fewer patients experience progression to the level of CLI. Well-known contributing risk factors for vascular disease include smoking, diabetes mellitus, hypertension, and hypercholesterolemia, all of which are manageable and easily diagnosed. Diabetic patients are five times more likely to present with CLI that requires amputation than non-diabetic patients.<sup>4</sup> Smoking contributes significantly to PVD as it initiates inflammatory processes and platelet activation leading to atherosclerosis.

It is safe to say that any patient who presents with the aforementioned conditions should be considered high risk for PVD and automatically screened. This process most often can be initiated at the level of

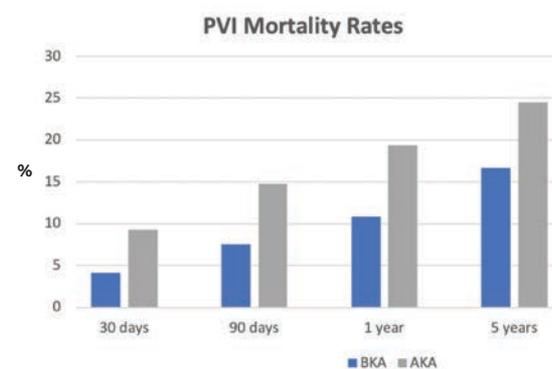
the primary care provider, or a podiatrist if the patient is being seen for neuropathy and diabetic screening of foot ulcers. These physicians can be the first line of communication for these patients, so it is imperative that these physicians make the connection between the contributing factors and risk of PVD. Additionally, there should be a team approach involving professional relationships between these first-line providers and the

vascular physicians (vascular surgeons, interventional cardiologists, and interventional radiologists) as a referral base. Since there is a strong connection between PVD and cardiovascular disease, a consult with a cardiologist, if the patient does not already have one, is always a consideration.

A PADnet test (Biomedix), which measures ABI as first-line screening tool is crucial, especially for patients who are high risk but asymptomatic. PADnet testing for an ABI is inexpensive, simple to perform, and identifies arterial blockages and the quality of blood flow through the evaluation of pulse volumes and blood pressure. The equipment does not require much space and is easily portable,

## A team approach involving the patient and multidisciplinary providers is an absolute necessity, as treatment strategies involve cooperation across several specialties.

of risk given the possibility of complications from an invasive surgical procedure, deep sedation, and the trauma of losing a limb. For below-the-knee amputations (BKA), a 2023 analysis by Beeson et al reported mortality rates of 4.18% at 30 days, 7.50% at 90 days, 10.88% at 1 year, and 16.67% at 5 years.<sup>3</sup> Above-the-knee amputation (AKA) carries a higher risk of mortality, with rates at 9.27% at 30 days, 14.73% at 90 days, 19.40% at 1 year, and 24.49% at 5 years (Figure 1).<sup>3</sup> Lower limb amputation has a significant impact on quality of life, as it not only affects the patient's socioeconomic status and impairs mobility, but also has a systemic effect on the entire body. Patients can



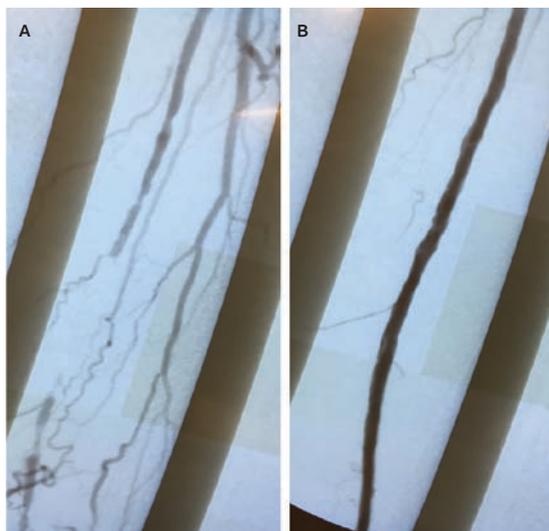
**Figure 1.** Mortality rates (%) for below-knee amputation (BKA) and above-knee amputation (AKA).<sup>3</sup>



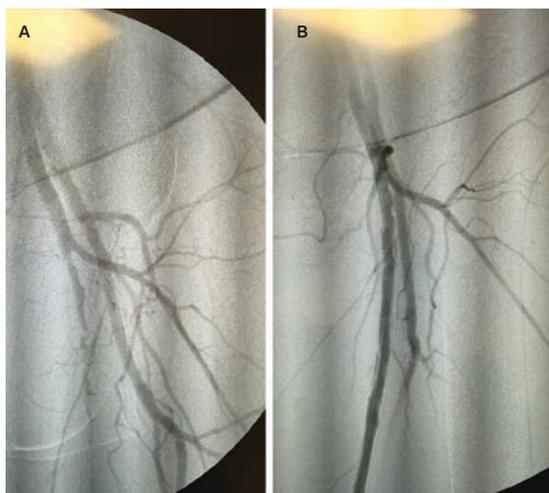
**Figure 2.** An example of bilateral gangrene.

making it ideal for community outreach programs. Often patients aren't screened for PVD until they exhibit symptoms, but symptoms aren't prevalent until the patient has advanced disease. The goal of screening should be to diagnose PVD before it reaches an advanced stage. Early identification through screening can lead to timely treatment with a wider range of treatment options, a reduction in complications, length of stay, readmissions, amputations, lowered overall costs coupled with increased patient volume, and most importantly, a higher quality of life for patients.

Once a patient is diagnosed with PVD, treatment options depend on the progression of the disease and may begin with medical therapies, including blood pressure control and statins, and smoking cessation. For advanced disease, options include surgical revascularization (bypass), peripheral vascular intervention, amputation, or a combination of these treatments. Treatment with 2 or more statins that includes aspirin and/or angiotensin-converting enzyme inhibitors/angiotensin receptor blockers (ACEi/ARB) is linked to a 65% reduced risk of mortality and a reduction in the risk of major adverse limb events.<sup>1</sup> Although dual antiplatelet therapy is recommended post peripheral vascular intervention for 1 month and followed up with a lifetime platelet aggregation inhibitor such as clopidogrel, the phase 3 VOYAGER PAD trial has provided evidence that it is beneficial to add rivaroxaban, due to its ability to reduce the occurrence of thrombotic events. Including



**Figure 3A-B.** (A) Femoral artery (left) with the profunda femoris filling in on the right. (B) Femoral artery post intervention. The profunda femoris is not visible due to placement of the catheter prior to injection.



**Figure 5A-B.** (A) Popliteal artery with extensive disease. (B) Post intervention.

rivaroxaban in combination with aspirin early on in the pharmacological treatment resulted in a 15% reduction in major adverse events such as major bleeding, cardiac event, stroke, amputation, and mortality.<sup>5,6</sup>

Shared decision-making should be foremost in the treatment plan, especially in the case of advanced disease and the existence of comorbidities. Palliative care is often a consideration when a patient has poor predicted outcomes for mortality and morbidity in early post-op stages. In these cases, combined peripheral vascular intervention and amputation are often considered to allow for limited revascularization through intervention allowing for amputation at a lower level; for example, amputation of the foot as opposed to a below-knee amputation. A team approach involving the patient and multidisciplinary providers is an absolute necessity, as treatment strategies involve cooperation across several specialties. Agreement on who is to provide the follow-up care should be incorporated into these decisions.

Additionally, a focus on community outreach and education is an integral component of program



**Figure 4A-B.** (A) Femoral artery with extensive disease. (B) Post intervention.



**Figure 6A-B.** (A) Femoral artery with extensive disease. (B) Post intervention with a contained subintimal tear.

success. Post procedure care should incorporate follow-up calls and have a strong emphasis on compliance with medical therapies, smoking cessation, and diabetes care. The vascular team should conduct regular meetings that include quality analysis and quality improvement (QA/QI), as well as peer review.

Although there are no formal regulations mandating involvement in a quality registry, having a robust process for measuring quality metrics is essential to properly evaluate the efficacy of any program. This can be done through an internal dashboard that will measure parameters that have been chosen by the program to meet certain goals such as discharge meds or referral to smoking cessation, or it may be implemented through a formal registry. Two registries that focus on PVD are the Society for Vascular Surgery's Vascular Quality Initiative (VQI) and the Outpatient Endovascular and Interventional Society National Registry (OEIS). VQI has two options: basic and comprehensive. The basic registry is designed for office-based labs (OBLs) and physician offices, while the comprehensive option is more appropriate

for larger programs. OEIS is focused on outcomes in outpatient interventional suites (OIS). The advantage of participating in a national registry is that a program can evaluate its data on a national level and therefore understand where it stands in comparison to other programs, identifying possible areas for improvement.

Once a program decides on its approach to quality metrics, it should subsequently implement a strong and effective quality improvement process. There is no point in measurement if there is no action behind the data. A program should identify areas of weakness or fall-outs and execute an improvement plan. Moreover, ongoing evaluation is crucial to track sustained improvement and pinpoint areas that require adjustments in the plan. Once the desired outcome has been reached, the process should begin again with another identified need for improvement. Industry standards are always changing with improvements in treatment strategies and technology. A quality program needs to constantly change in order to keep up with progress.

Even with a quality program, it is difficult to keep all of the components running smoothly. Keeping abreast of ever-changing technologies, communications across modalities, and compliance with standards are just some of the challenges facing the success of a PVD treatment program. Sometimes there are gaps in services needing to be addressed or processes needing to be tightened up. In these cases, there may be a benefit to a gap analysis, operations assessment, or accreditation from an outside, unbiased entity. Employing any of these services can assist programs in overcoming challenges and pave the way for them to excel as a community leader in PVD treatment and care. ■

References are available with the article online. Scan the QR code:



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