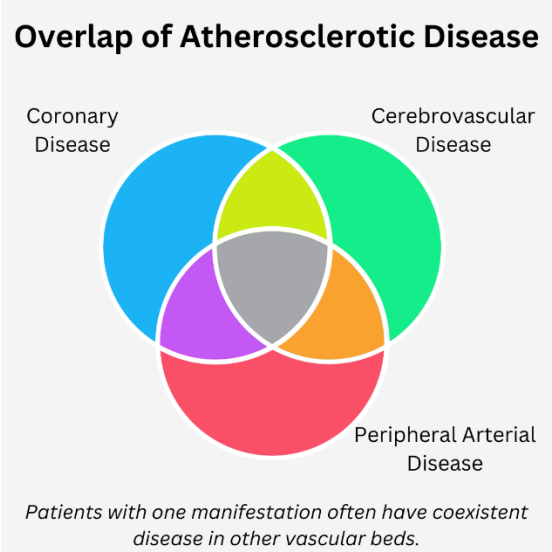
As seen in **Cath Lab Digest**

A Shift in Cardiovascular Care: Ambulatory Surgery Centers (ASCs), Peripheral Arterial Disease (PAD), and Peripheral Vascular Interventions (PVI)

By Michael Church & Amy Newell

It is not surprising that heart disease remains the leading cause of death in the United States and worldwide. However, recent years have expanded concerns around risk of mortality to include peripheral vascular disease. It is a common adage that if there is disease in one vessel or vascular bed, there is disease in another. Still, however, peripheral vascular disease often remains undiagnosed and untreated. The total number of patients in the U.S. diagnosed with peripheral arterial disease (PAD) is approximately 6.5 million[1], compared to 121.5 million with heart disease[2] in general. There is a significant amount of undiagnosed PAD, yet there remain challenges in meeting this need.



A Focus on Peripheral Arterial Disease

In July 2023, the *New York Times* published an article[3] about peripheral arterial disease and the adverse outcomes from selected physicians performing atherectomy procedures, which, in some instances, led to amputations or other complications for their patients. The article led to several responses, including one from the Society for Vascular Surgery[4], which further complicates a situation where increased resources and focus are needed to best meet patient needs.

The current PAD discourse is reminiscent of the interventional cardiology landscape roughly 15 years ago after allegations were raised related to the overutilization of stents for coronary procedures in the hospital setting. As a result, several hospitals and physicians were subjected to increased scrutiny over appropriate case selection and procedural outcomes. Since then, and with the inception of societal endorsement, recommendations specifically outlining appropriate use criteria have been endorsed and broadly accepted for interventional cardiology as the standard of care in hospitals of varying size, capability, and location.

In fact, interventional cardiology is so widely accepted as safe that it has migrated into the ambulatory care setting. While some states maintain regulations prohibiting this transition, others have adopted new regulations to specifically support this change in practice.[5] Interestingly, though, peripheral vascular intervention (PVI) procedures have rarely been regulated at a state level and have been offered within ambulatory care settings in ambulatory surgery center (ASC) and office-based lab environments for several years. Most regulations that affect the performance of PVI procedures are related to the availability of anesthesia and other support services, or may involve building codes for the facility itself.

Multiple specialties are involved in treating PAD, including interventional cardiology, vascular surgery, and interventional radiology. Providers from each of these specialties may possess the necessary skillset and training to diagnose and effectively treat the needs of this patient population. However, it is critically important for patient care that, regardless of which provider is involved, the following occurs:

- Appropriate case selection;
- Use of a multidisciplinary approach in the event a more advanced treatment plan is needed or required;
- Appropriate patient preparation and communication among the treatment team; and,
- Ongoing education and necessary patient follow-up with other physician specialties, such as nephrology, podiatry, and even plastic surgery, should it be required to ensure post-procedure compliance of care.

Additionally, it is highly recommended that the overarching vascular program incorporate formalized processes for quality oversight. The goal is to ensure every facet of the service maintains compliance with national societal

guidelines and recommendations, as well as federal and state regulations, while emphasizing patient safety and clinical outcomes.

Cardiology Shift to Ambulatory Settings of Care

Considering this recent change in paradigm, hospitals, health systems, and ASCs need to be very deliberate in their approach to the provision of cardiology services, particularly in the ambulatory setting. Providers must develop and integrate an ambulatory strategy into their overarching cardiovascular strategic plan, whether through joint ventures, acquisition, or other alignment structures with existing ASCs, or through investment into their own facility(ies), because this growing shift is imminent in all markets for cardiology. Providers can opt to collaborate or compete with a growing ambulatory healthcare market.

As an ASC or office-based lab initiates planning for introducing new services (eg, percutaneous coronary intervention [PCI], PVI, etc.), a sound plan must be enacted to ensure clinical quality. Although there is currently relatively little oversight related to specific ASC quality standards for cardiovascular services, the Society for Cardiovascular Angiography and Interventions (SCAI) included several recommendations as part of their 2023 Expert Consensus Statement on PCI Without On-Site Surgical Backup[6]; unfortunately, this most recent iteration of these important, updated societal recommendations have not yet been referenced in state regulatory language and guidelines. Instead, several state regulations refer to the previous recommendations from 2013 and 2014.

Without more formal requirements related to quality monitoring from regulatory agencies, the primary responsibility for addressing these issues falls to individual providers. This is where third-party accreditations, such as Corazon Accreditation, can provide significant value to providers to ensure best-practice program design, clinical processes, and protocols are incorporated within clinical programming. Accreditation provides assurances that the clinical program meets and exceeds the standards expected in acute care settings. Furthermore, proactive evaluations of program quality help the facility team to integrate continuous quality improvement into day-to-day operations. It cannot be overstated how critical quality oversight is, not only to the provider, but most importantly, to patient safety and clinical outcomes.

Additional Considerations

Considerations for cardiovascular services go well beyond PCI and PVI procedures, and the shift to an ambulatory setting. However, the procedures will likely have the broadest reach, based on the general profile of the facilities offering these services. At the same time, tertiary and quaternary providers must also consider how this shift will affect their programs. A proactive strategy is necessary to participate in and appropriately manage the shift toward an ambulatory environment. Part of such a strategy involves determining what will need to remain in the hospital setting. Program leaders must ask important questions about the hospital's preparedness to offer emerging higher acuity services, like transcatheter aortic valve replacement, hybrid cardiac and vascular surgeries, advanced heart failure, complex electrophysiology procedures, advanced neuroscience treatments, and other procedures as they become available.

The last several years have been turbulent and full of change, particularly within healthcare. However, as management consultant Peter Drucker has said, “The greatest danger in times of turbulence is not the turbulence – it is to act with yesterday’s logic.” Leaders must look to the future, find opportunities to support evolving organizations, and in doing so, better serve their communities.

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References

1. *Peripheral arterial disease (PAD). Heart disease. Centers for Disease Control and Prevention (CDC). https://www.cdc.gov/heartdisease/PAD.htm*
2. *Cardiovascular diseases affect nearly half of American adults, statistics show. American Heart Association News. January 31, 2019. https://www.heart.org/en/news/2019/01/31/cardiovascular-diseases-affect-nearly-half-of-american-adults-statistics-show*
3. *Thomas K, Silver-Greenberg J, Gebeloff R. They lost their legs. Doctors and health care giants profited. New York Times. July 15, 2023. https://www.nytimes.com/2023/07/15/health/atherectomy-peripheral-artery-disease.html*
4. *Mills JL. In response to The New York Times article on overuse of interventions. Society for Vascular Surgery. July 17, 2023. https://vascular.org/news-advocacy/articles-press-releases/svs-response-new-york-times-article-overuse-interventions#:~:text=The%20Society%20for%20Vascular%20Surgery,the%20delivery%20of%20vascular%20care*
5. *Abresch S. States take steps to allow cardiac procedures in ASCs. ASC Focus. December 2021. https://www.ascfocus.org/ascfocus/content/articles-content/articles/2021/digital-debut/states-take-steps-to-allow-cardiac-procedures-in-ascs#:~:text=The%20new%20CON%20Review%20Standards,CON%20to%20perform%20PCI%20procedures*
6. *Grines CL, Box LC, Mamas MA, et al. SCAI expert consensus statement on percutaneous coronary intervention without on-site surgical backup. JACC Cardiovasc Interv. 2023 Apr 10; 16(7): 847-860. doi: 10.1016/j.jcin.2022.12.016*