

Clinical trial demonstrates benefits of intravascular ultrasound vs. current diagnostics

February 29 2016, by Steve Klink

Royal Philips (NYSE: PHG; AEX: PHIA) today announced that Paul J. Gagne, MD, chief of vascular surgery at Norwalk Hospital in Norwalk, CT, has presented clinical trial data that demonstrates the benefits of its intravascular ultrasound (IVUS) technology compared to conventional contrast-enhanced X-ray imaging of the veins (also known as multiplanar X-ray venography) in the diagnosis of iliofemoral venous obstruction i.e. narrowed or blocked leg veins.

Philips Volcano, a Philips business, is a world leader in catheter-based imaging and measurements such as IVUS. In image-guided treatments of the [blood vessels](#), there is an increasing trend to use IVUS catheters that are capable of producing ultrasound images of the interior of blood vessels. There is a growing body of clinical evidence that the use of this technology in conjunction with interventional X-ray helps improve procedural outcomes.

"These results of the VIDIO study clearly show that IVUS is better at detecting lesions than multiplanar X-ray venography, the prior imaging gold standard," said Dr. Gagne, global Principal Investigator of the study. "IVUS is now my preferred imaging modality of choice for identifying this treatable condition and the VIDIO study shows how well these patients can do with the appropriate treatment."

"We are pleased to be advancing the science of deep venous diagnosis

and intervention," said Neil Hattangadi, MD, Business Leader of Peripheral Vascular at Philips Image Guided Therapy. "The VIDIO study shows the critical role that our IVUS technology can play in identifying venous obstruction and guiding therapy, and the contribution it can make to Philips' goal of delivering personalized care."

In the 100-patient prospective multicenter Venogram Versus Intravascular Ultrasound for Diagnosing Iliofemoral Vein Obstruction (VIDIO) study, 29% of patients were assessed to be free of lesions based on their X-ray venogram results but had lesions detected by Philips Volcano's phased-array IVUS technology. The results of the study, in which IVUS in total detected 88% more lesions than multiplanar X-ray venography (as assessed by Investigators at the point-of-care), were announced at the American Venous Forum 28th Annual Meeting.

Iliac/common femoral vein obstruction (ICFVO) is a significant cause of chronic venous insufficiency (CVI) – a condition that is estimated to affect between 10% and 35% of adults in the U.S. resulting in approximately 4.6 million lost workdays. Iliofemoral vein obstruction, which can eventually lead to swelling, chronic pain, and ulceration, can be treated via angioplasty and stenting with profound benefits to the patient's quality of life. However, many patients exhibiting symptoms may not be diagnosed with venography. There is, therefore, a real need for better ways to diagnose the condition.

VIDIO Study

The VIDIO study was designed to prospectively compare the diagnostic performance of conventional multiplanar venography vs IVUS for diagnosing and treating Iliac/common femoral vein obstruction; and to characterize patient response to iliofemoral vein intervention in terms of clinical improvement and quality of life over 6 months of follow up.

Between July 2014 and July 2015, the study enrolled 100 patients with advanced venous insufficiency (CEAP score 4, 5, and 6) at 11 U.S. and three European centers. Each patient had a multiplanar venogram performed, with an initial lesion characterization and treatment strategy recorded by the interventionalist based on the venogram. An assessment with Philips Volcano phased-array IVUS was then performed, with a second lesion characterization and treatment strategy recorded by the interventionalist. Stenting treatment was subsequently performed at the discretion of the interventionalist. All patients were followed for 6 months after the index procedure.

Across the full 100 patients enrolled, according to Investigator readings at the time of the index procedure, IVUS detected 88% more lesions than multiplanar venography (124 vs 66) (P

Phased-array IVUS imaging, which provides a 360-degree view of a blood vessel's internal wall structure, is a key component in Philips' arsenal of tools to help interventionalists decide, guide and confirm the right therapy for each patient in real-time during minimally-invasive procedures. Together with technologies spanning mobile ultrasound, interventional X-ray and more, Philips has a complete and increasingly integrated procedural solution for venous interventions.

Provided by Philips

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