# Study Seeks Alternative For Femoral Artery Cath Lab Access

Arstasis announces that patient enrollment has begun in the RECITAL (A Patient Registry Evaluating Closure Following Access with the Arstasis One Access System) Study. The non-randomized, prospective, post-approval study is anticipated to enroll up to 500 patients in at least seven U.S. hospitals. The goal of the study is to observe the clinical safety and effectiveness of the Arstasis One Access System in patients undergoing diagnostic angiography procedures through the femoral artery.

The first patient was enrolled at La Paz Regional Medical Center in Parker, Arizona. "We've begun performing Arstaotomy procedures routinely in our cath lab because they make femoral artery access safer for our patients, easier for me and my staff, and less expensive for our hospital compared with closure devices or manual compression," said Dr. Frank Kresock, chief of interventional cardiology at La Paz Regional Medical Center, the physician who performed the procedure.

Since 1959, physicians have been using the Modified Seldinger Technique (or "Seldinger Technique" for short) to insert flexible catheters into the femoral artery of patients for the purpose of performing procedures in the patient's arterial-vascular system. The most prevalent such procedure, angiography, is thought to be performed more than half a million times per month worldwide.

At the end of every such case, each patient is left with a substantial hole in his/her femoral artery (upper inner thigh) which typically takes significant effort and cath lab resources to get to stop bleeding. With the Arstasis One Access System, however, physicians may create a shallow-angle needle pathway through the wall of the femoral artery. At the end of the procedure, when the sheath is withdrawn, the shallow-angle pathway collapses from the normal pressure of the patient's femoral artery blood flow from below and approximately 3-4 minutes of mild, non-occlusive finger-pressure from above, resulting in a quickly sealing access site.

"The Arstasis One femoral artery access system marks the beginning of a new approach to heart catheterization," commented Zoltan G. Turi, MD, the Director of the Vascular Center at Cooper University Hospital and Professor of Medicine at Robert Wood Johnson Medical School in Camden, New Jersey, and the national principal investigator of the RECITAL study. "We hope to show that patients who participate in this study benefit from femoral artery closure that has advantages over regular manual compression", Dr. Turi continued. "We are also interested in this technology because Arstasis facilitated closure, unlike vascular closure devices, does not result in any foreign materials being implanted."

The study will also assess patient satisfaction due to reduction of pain and discomfort as well as early mobility. In non-U.S. clinical trials the resulting closed

access site was typically so secure that a patient could get up from his/her bed and begin walking hours sooner than would be the case with a standard femoral arteriotomy, sometimes as soon as those patients receiving Vessel Closure Devices.

"This procedure over the Angioseal, in my opinion, was 100% better because of the recovery time, less swelling and bruising. This is much better, I'm glad I got the Arstaotomy," said Russell McKenzie, Dr. Kresock's 75-year old patient at La Paz Regional Medical Center who was the first to enroll in the RECITAL study.

Detailed information about the Arstasis One, and the Arstaotomy procedure, is available at www.arstasis.com [1]

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