Catheter-based therapies may offer a less invasive alternative to conventional surgery for a wide array of cardiovascular diseases. These percutaneous interventions often require large-bore catheters, and vascular access management may be challenging. Suture-based closure devices can be used for arteriotomy closure. Transcatheter aortic valve replacement (TAVR) involves such large-bore arteriotomy closure. Despite smaller device profiles and growing experience with TAVR, the reported incidence of vascular complications still varies between 1% and 13% (1–3). Up to two-thirds of major vascular complications after TAVR are due to failed arteriotomy closure (4).

The percutaneous MANTA vascular closure device (VCD) (Essential Medical Inc., Malvern, Pennsylvania) is a novel collagen-based technology dedicated to the closure of large bore arteriotomies. The MANTA VCD contains an 8-F puncture location dilator, a dedicated sheath, a closure unit, and a delivery system. The closure unit consists of a resorbable polymer (poly-lactic-co-glycolic acid) intra-arterial toggle, an extravascular hemostatic bovine collagen pad, a connecting nonresorbable polyester suture, and a stainless steel suture lock, illustrated in Figure 1. This closure unit is attached to the delivery system that contains a carrier/release tube and a device handle with a tension gauge. Both the puncture location dilator and the MANTA sheath have centimeter markers on the respective surfaces. MANTA comes in 14-F and 18-F sizes for closing punctures of 10 to 14 F and 15 to 22 F, respectively. Use of the MANTA VCD precludes a pre-closure technique. After common femoral artery access is obtained with a 6-F sheath, this sheath is exchanged for the 8-F puncture location dilator to determine the distance of the subcutaneous track from skin level to the endoluminal arterial space. The planned cardiovascular intervention is then executed by upscaling the access sheath. Thereafter the procedural sheath is exchanged for the dedicated MANTA sheath to receive the MANTA closure unit. The MANTA sheath-closure unit assembly is withdrawn up to the predetermined deployment level. The toggle is released and the assembly is withdrawn from the patient. Pulling force can be monitored by the color code of the tension gauge. The blue tamper tube emerges and is advanced along the suture line to secure the stainless steel lock onto the vessel and further compact the collagen pad. The suture is cut above the tamper and at skin level. It takes 6 months for the MANTA components to resorb so that only the polymer suture and stainless steel suture lock remain at the access site.

In our initial MANTA experience in 10 consecutive patients undergoing TAVR (n = 8), balloon aortic valvuloplasty (n = 1), and high-risk percutaneous intervention with a 14-F circulatory support device (n = 1), sheath sizes varied from 14 to 22 F. MANTA access closure was successful in all patients. Hemostasis was obtained within 22 ± 20 s after starting MANTA deployment. A patent artery was angiographically confirmed in all cases. There were
neither significant bleeding events nor vascular complications at the access site closed by MANTA.

Our initial experience supports further study to determine if use of the MANTA VCD could reduce access-site complications with large-bore cardiovascular interventions. The CE-mark study (NCT02521948) to evaluate the safety and performance of the MANTA VCD has completed enrollment, and results will be presented in 2016.

Lennart van Gils, MD
Peter P.T. De Jaegere, MD, PhD
Gary Roubin, MD, PhD
*Nicolas. M. Van Mieghem, MD, PhD
*Department of Interventional Cardiology
Thoraxcenter, Erasmus MC
Room Bd 171
’s Gravendijkwal 230
Rotterdam 3015 CE
the Netherlands
E-mail: n.vanmieghem@erasusmc.nl
http://dx.doi.org/10.1016/j.jcin.2016.03.010

Please note: Dr. Van Mieghem has received research grants from Boston Scientific, Medtronic, and Edwards Lifesciences. Prof. Dr. De Jaegere is a proctor for Boston Scientific. Dr. Roubin is chief medical officer of Essentia Medical Inc., with equity interest. Dr. van Gils has reported that he has no relationships relevant to the contents of this paper to disclose.

REFERENCES

Fully Percutaneous Technique for Transaxillary Implantation of the Impella CP

In recent years, mechanical circulatory support devices have undergone tremendous design improvements, and they are now used frequently as bridges to recovery, as destination therapy, or for transplantation (1). Unfortunately, when placed via the femoral approach, such devices still require persistent bed rest, which limits rehabilitation. The Impella CP (Abiomed, Danvers, Massachusetts) facilitates blood flow from the left ventricle to the ascending aorta using an axial pump and can augment cardiac output by as much as 3.5 l/min. For placement via the upper extremity vessels, the standard technique involves surgical cut-down and end-to-side graft anastomosis for the 14-F delivery sheath and thus requires coordination of an anesthesiologist, a surgeon, and a hybrid operating room with fluoroscopic capabilities. In contrast, a fully percutaneous upper extremity approach in a standard catheterization laboratory bypasses these strategic challenges and facilitates earlier patient rehabilitation.

In this technical communication, we provide a description of a direct percutaneous technique for transaxillary insertion of an Impella CP.

Conscious sedation, topical anesthesia, and therapeutic anticoagulation with heparin are used. A 7-F femoral arterial sheath and a 6-F left radial arterial sheath are placed. A 5-F JR4 guide catheter is advanced through the femoral sheath into the left subclavian artery (SCA). Angiography ensures adequate luminal capacity and lack of atheroma in the left subclavian/axillary system. Ultrasound may also be used to determine vessel size. Generally, a diameter cutoff of $\geq$6.0 mm ensures adequate distal perfusion. Once deemed appropriate, a 0.018-inch wire is delivered to the descending aorta via the left radial sheath and captured in the left SCA by a 25/18 Ensnare advanced through the femoral sheath (Online Figure 1A). The 0.018-inch wire is thus externalized to form a radial-femoral rail. After our first 4 successful cases, we refined this step by placing a 6-F sheath in the femoral artery only and positioned a 0.018-inch wire into the left brachial artery without externalization.

With the externalized wire as a fluoroscopic landmark and SonoSite visualization (SonoSite, Bothell, Washington), left axillary access is obtained using standard micropuncture technique at a shallow angulation just medial to the shoulder (Online Figure 1B). Next, an 8- to 12-mm, 0.035-inch lumen peripheral balloon is positioned in the proximal left SCA over the 0.018-inch wire for endovascular hemostasis at 2 atm during sheath exchanges. The balloon is sized 0 to 1 mm larger than the diameter of the SCA to avoid artery dissection when inflated.

The axillary artery is then “pre-lassoed” with a Perclose ProGlide suture-mediated closure device (Abbott Vascular, Redwood City, California). Stepwise dilation of the axillary arteriotomy is performed. Between dilator exchanges, the peripheral balloon provides temporary hemostasis (Online Figure 1C).