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.

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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 Essential Medical Inc., with equity interest. Dr. van Gils has reported that he has no relationships relevant to the contents of this paper to disclose.

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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 ≈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).
Confirmation of endovascular hemostasis is noted by loss of the pressure waveform transduced via the radial sheath or loss of plethysmographic signal measured on left index finger. Finally, the 14-F Impella CP delivery sheath is advanced into the mid-left SCA under fluoroscopy. Advancement of the delivery sheath around the proximal SCA flexure is avoided to prevent traumatic injury, so the sheath is left protruding out of the body during Impella delivery (Online Figure 2).

The peripheral balloon is withdrawn to the thoracic descending aorta (while maintaining 0.018-inch wire position in the axillary artery). The routine Impella placement technique is then used to deliver the Impella CP into the left ventricle (Figure 1). Next, the peripheral balloon is readvanced to the mid-SCA. The 14-F peel-away sheath is removed while the balloon is inflated next to the Impella CP drivetrain. The repositioning sheath is advanced into the arteriotomy, and the Perclose suture is tightened around the repositioning sheath to ensure hemostasis. With the balloon deflated, digital subtraction angiography is performed through the balloon wire lumen with the 0.018-inch wire in place by using a Tuohy-Borst valve attachment (Online Figure 3). Vascular patency and lack of extravasation are confirmed. The 0.018-inch wire and balloon are removed, and the repositioning sheath is sutured in place (Online Figure 4).

All patients are subsequently managed in the cardiac intensive care unit. Beyond initial femoral access bed rest, no prolonged bed rest restrictions are needed. Routine nursing checks of the left radial pulse are performed. Patients are advised not to raise the left arm above the shoulder and not to perform significant exertion with the left arm.

Device explantation requires consideration. After removal of indwelling devices, we have generally pursued suture-based closure methods for large-bore arteriotomies when manual pressure is a concern. We have not seen infection of device-mediated sutures, and the residual in-dwelling suture material is similar to that used in surgical closure. The challenge for percutaneous closure is regaining arterial wire access following Impella removal (the newest iteration of the Impella CP repositioning sheath now has a wire access port, which makes this process considerably easier, but it is not yet routinely available). Our strategy in the absence of a wire port on the repositioning sheath requires wiring through the Impella itself, which can be done using a J-tipped 0.035-inch wire. Proximal vessel balloon tamponade limits bleeding and thereby improves visualization of the Impella outflow ports for wiring. With wire access reestablished, vascular closure is performed per routine using suture-mediated systems.

Thus, to explant the device, a 6-F sheath is placed in the common femoral artery. A 5-F JR4 diagnostic catheter is then advanced into the left SCA, and angiography is performed. A 0.018-inch wire is advanced through the JR4 catheter into the distal brachial artery, and a similar 8- to 12-mm peripheral balloon is passed over the 0.018-inch wire into the mid-left SCA. The Impella CP is turned to P2 and withdrawn from the left ventricle into the ascending aorta. It is then switched to P0 (off) and pulled into the left SCA until the outflow port is partway externalized. During this time, the peripheral balloon is inflated (1 to 3 atm) to obstruct blood flow into the inflow port of the Impella (Online Figure 5A). Through the externalized outflow cannula, a 0.035-inch short J-wire is advanced out of the inflow port and into the left axillary/subclavian artery (Online Figure 5B). The Impella CP device and the repositioning sheath are then completely removed from the body. At this point, the vessel is closed using a Perclose or Prostar device (Abbott Vascular). The peripheral balloon is deflated, and the skin site is
inspected for superficial hemostasis. Angiography is repeated to demonstrate vessel patency and hemostasis. All balloons, wires, and catheters are removed in standard fashion. A single skin stitch is placed at the left axillary puncture site using 3-0 Vicryl (Ethicon, Somerville, New Jersey), and the area is covered with Steri-Strips (3M, Minneapolis, Minnesota) (Online Figure 5C).

In our preliminary experience with percutaneous access of the axillary artery, suture closure has been very successful as confirmed by completion angiography. One patient had mild residual contrast extravasation noted at the arteriotomy following explantation and was treated with 2 min of balloon tamponade to achieve hemostasis. In another case, regaining wire access to the vessel was unsuccessful, and a covered stent graft was used.

We have successfully implanted the Impella CP via the direct percutaneous transaxillary technique described in 8 patients (7 via the left and 1 via the right axillary artery). There were no unsuccessful attempts. The duration of support ranged from 1 to 22 days. In 4 patients, explantation was eventually indicated and achieved percutaneously without complications. For the other patients, 1 proceeded to heart transplantation (with Impella explant at that time), and 3 died prior to removal. (For patient descriptions, see Online Table 1).

No neurovascular complications were noted in the upper extremity in any of our cases. No access-related hematomas were noted. All patients who received Impella support for >1 day participated in physical therapy. For some, this included walking while pushing the impella console. We found device position to be quite stable, with little evidence of migration, even in patients who were maintained on the Impella for >2 weeks. Additionally, we did not see any evidence of early or late insult to the brachial plexus, which is consistent with national experience accessing the subclavian vein for central venous catheters (2).

We have described a technique for percutaneous implantation and explantation of the Impella CP device using a left or right transaxillary approach that is both safe and feasible, even in critically ill patients. This technique presents multiple clinical advantages over traditional femoral access, as highlighted here. To the best of our knowledge, ours is the first technical description illustrating a fully percutaneous transaxillary technique using the Impella CP device. Further work is needed in this domain with a larger patient population to demonstrate the safety profile and clinical advantages of our technique.

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Please note: Drs. Lombardi and McCabe have received honoraria from Abiomed. Abiomed did not fund, conceive, review, or in any way participate in the creation of this report. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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APPENDIX For supplemental figures and a table, please see the online version of this article.

Does Chronic Total Occlusion Percutaneous Coronary Intervention Improve Survival

A Never-Ending Debate

We read with great interest the article by Lee et al. (1), who found no long-term survival benefit of successful chronic total occlusion (CTO) percutaneous coronary intervention (PCI) in their well-performed single-center cohort study. Several observations need to be made.

The incidence of prior coronary artery bypass graft in their population was 2.8%, ejection fraction was mostly normal (only 3.8% of patients had values <40%), mean CTO length was <20 mm, and retrograde PCI was successful in only 8.5%. Although the Japanese-CTO (J-CTO) score was not calculated, these data indicate that the population treated by Lee et al. is quite selected. Additionally, because patient inclusion spanned 11 years (2003 to 2014), the techniques used in this study are not representative of contemporary CTO PCI based on the “hybrid algorithm.” For example, in the all-comer PROGRESS-CTO (Prospective Global Registry for the Study of Chronic Total Occlusion Intervention) registry (2), mean