JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 10, NO. 6, 2017

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jcin.2016.12.277

PERIPHERAL VASCULAR

Percutaneous Plug-Based Arteriotomy Closure Device for Large-Bore Access

A Multicenter Prospective Study

Nicolas M. Van Mieghem, MD, PhD,[a] Azeem Latib, MD,[b,c] Jan van der Heyden, MD, PhD,[d] Lennart van Gils, MD,[a] Joost Daemen, MD, PhD,[a] Todd Sorzano,[e] Jurgen Ligthart, RT,[a] Karin Witberg, CCRN,[a] Thom de Kroon, MD,[d] Nathaniel Maor,[e] Antonio Mangieri, MD,[b] Matteo Montorfano, MD,[b] Peter P. de Jaegere, MD, PhD,[a] Antonio Colombo, MD,[b,c] Gary Roubin, MD, PhD[e,f]

ABSTRACT

OBJECTIVES The authors sought to study the safety and efficacy of the MANTA Vascular Closure Device (VCD), a novel collagen-based technology dedicated to closure of large-bore arteriotomies.

BACKGROUND Novel transfemoral therapeutic interventions requiring large-bore catheters have become valid minimally invasive options but have inherent access management challenges. To date, no dedicated vascular closure devices exist for large arteriotomies.

METHODS A prospective, single-arm clinical investigation enrolling patients who underwent elective percutaneous interventions with large-bore catheters and planned percutaneous arteriotomy closure in 3 European institutions.

RESULTS A total of 50 patients with a mean age of 79.5 ± 8.3 years underwent high-risk percutaneous coronary intervention, balloon aortic valvuloplasty, or transcatheter aortic valve replacement with large-bore catheters sized 12-F to 19-F. MANTA closure was performed by 9 different operators. The 14-F MANTA VCD was deployed in one-third of the overall cohort (16 of 50, 32%), and the 18-F MANTA VCD in the remainder. The MANTA VCD was deployed successfully in all patients. The mean time to hemostasis was 2 min, 23 s. One patient had a major vascular and major bleeding complication with prolonged femoral bleeding that was successfully treated with a covered stent and eventual surgical repair. There were no other access site-related complications.

CONCLUSIONS This first multicenter experience demonstrates rapid and reliable hemostasis and low complication rates with the use of the plug-based MANTA VCD for large-bore arteriotomy closure. (J Am Coll Cardiol Intv 2017;10:613–9)

From the [a]Department of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, the Netherlands; [b]Department of Interventional Cardiology, San Raffaele Scientific Institute, Milan, Italy; [c]Department of Interventional Cardiology, EMO-GVM Centro Cuore, Milan, Italy; [d]Department of Cardiology and Cardiac Surgery, St. Antonius Ziekenhuis, Nieuwegein, the Netherlands; [e]Essential Medical, Inc, Malvem, Pennsylvania; and the [f]Cardiovascular Associates, Birmingham, Alabama. Dr. Van Mieghem has received research grants from Boston Scientific, Medtronic, Abbot Vascular, Claret Medical, and Edwards Lifesciences. Dr. Latib is a consultant for Medtronic and Direct Flow Medical. Dr. de Jaegere is a proctor for Boston Scientific. Dr. Roubin is the chief medical officer and holds equity interest in Essential Medical; and receives royalties from Cook Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Drs. Van Mieghem and Latib are joint first authors.

Manuscript received November 7, 2016; revised manuscript received December 22, 2016, accepted December 29, 2016.

ABBREVIATIONS AND ACRONYMS

CE = Conformité Européenne

CT = computed tomography

OD = outer diameter

RBC = packed red blood cells

TAVR = transcatheter aortic valve replacement

TTH = time to hemostasis

VARC = Valve Academic Research Consortium

VCD = vascular closure device

The advent of endovascular aneurysm repair, transcatheter aortic valve replacement (TAVR), and mechanical circulatory support has offered new, minimally invasive therapeutic options that are rapidly becoming standard of care. These percutaneous transfemoral interventions require large-bore catheters and have created challenges for femoral arterial access management. Current approaches include surgical cut-down with arterial puncture under direct vision, and suture-based "pre-closure." Surgical cut-down is associated with longer procedural time, increased patient discomfort, deeper anesthesia, risk of wound complications including infection, and slower ambulation. The pre-closure technique overcomes many of the disadvantages of surgical cut-down but can be technically demanding, time consuming, and associated with a significant failure rate. Recent randomized TAVR trials have reported major vascular complications in 6% to 8% (1,2). Furthermore, a study on the 2 suture-based closure techniques for management of TAVR access reported a 20% vascular complication rate despite being used by experienced operators (3). Currently, the majority of access site complications result from failed arteriotomy closure (4).

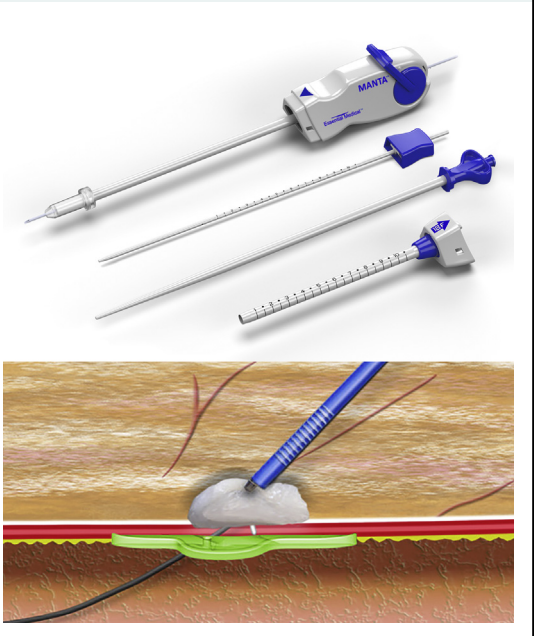
The percutaneous MANTA Vascular Closure Device (VCD) (Essential Medical Inc., Malvern, Pennsylvania) is a novel collagen-based technology dedicated to closure of large-bore arteriotomies (5). The MANTA VCD underwent prospective multicenter evaluation for Conformité Européenne (CE) mark approval in the first detailed report of outcomes achieved with a dedicated large-bore vascular closure device.

METHODS

This prospective, multicenter, nonblinded, single-arm clinical investigation enrolled 50 patients in 3 European institutions. Eligible patients underwent elective percutaneous interventions with large-bore catheters sizes 12-F to 19-F (sheath outer diameter [OD] profile of 16-F to 24.5-F) and planned percutaneous arteriotomy closure. All patients were discussed in a multidisciplinary heart team including interventional cardiologists and cardiac/vascular surgeons. Key exclusion criteria were: 1) arterial puncture outside of the common femoral artery; 2) common femoral artery size inappropriate for the selected sheath size; 3) complicated femoral access, including excessive hematoma surrounding the puncture site, arteriovenous fistula, and posterior wall puncture; 4) renal insufficiency defined by a serum creatinine >2.5 mg/dl; and 5) inability to ambulate at baseline. Patients provided written informed consent before enrollment. Operators were first-time users of the MANTA VCD, and their training included a detailed device description and bench-top training on a dry plastic model. The study design was approved by each institutional review board and was conducted in accordance with the Declaration of Helsinki, Good Clinical Practice principles, and the International Organization for Standardization of medical devices for human subjects (ISO 14155:2011). The study was registered as NCT02521948 (Clinical Study to Evaluate the Safety and Performance of MANTA Vascular Closure Device).

DEVICE DESCRIPTION. A detailed description of the MANTA VCD and its mode of operations has been previously described in detail (5). In brief, the MANTA VCD consists of an implantable closure unit and a delivery system. The delivery system comprises a device handle, a carrier/release tube, a custom introducer and device sheath, and an 8-F puncture location dilator (Figure 1). The location dilator and device sheath have centimeter markers. The closure unit consists of an intra-arterial bioresorbable polymer (poly-lactic-co-glycolic acid) toggle, an

FIGURE 1 MANTA Vascular Closure Device



(Upper panel: from top to bottom) MANTA device with closure unit, 8-F puncture locator, introducer, and sheath. **(Lower panel)** Schematic representation of arteriotomy closure with MANTA toggle and plug.