Journal of Cardiology Cases 19 (2019) 81–84

Contents lists available at ScienceDirect

Journal of Cardiology Cases

journal homepage: www.elsevier.com/locate/jccase

Case Report

Use of the MANTA device to rescue failed pre-closure following transfemoral transcatheter aortic valve implantation

Noman Ali (PhD)*, Daniel J. Blackman (MD), Michael Cunnington (MD), Christopher J. Malkin (MD)

Department of Cardiology, Leeds General Infirmary, Leeds, UK

ARTICLE INFO

Article history:
Received 13 August 2018
Received in revised form 21 October 2018
Accepted 12 December 2018

Keywords:
Transcatheter aortic valve implantation
Vascular complications
Vascular closure device

ABSTRACT

Access site vascular complications remain relatively frequent following trans-femoral (TF) transcatheter aortic valve implantation (TAVI), and are associated with significant morbidity as well as increased mortality. Suture-based vascular closure devices (VCD) are widely used and have been demonstrated to reduce the rate of vascular complications. However, failure to achieve adequate hemostasis following their use occurs in some cases, and may necessitate surgical escalation.

We report a case of a patient with complex ileo-femoral anatomy in whom the novel plug-based MANTA VCD was successfully used to achieve hemostasis post-TF TAVI following failed closure with ProGlides®. A 79-year-old male underwent valve-in-valve TF TAVI for the treatment of severe degenerative disease of a Mitroflow prosthesis. Pre-procedural imaging demonstrated tortuous and calcific ileo-femoral arteries and torrential bleeding occurred following sheath removal and deployment of the pre-sited ProGlides®. Consideration was given to surgical intervention but the decision was taken to attempt rescue closure using a 14F MANTA VCD. Hemostasis was successfully achieved and the patient recovered well.

Early data assessing the efficacy of the MANTA VCD have been promising and this relatively novel technology appears to be a viable alternative to established VCDs.

<**Learning objective:** Access site vascular complications remain relatively frequent following trans-femoral (TF) transcatheter aortic valve implantation (TAVI), and are associated with significant morbidity and mortality. The MANTA vascular closure device (VCD) appears to be a promising alternative to established VCDs. Early data from clinical trials suggests that the MANTA may be non-inferior to currently used suture-based VCDs. Furthermore, experience from our case demonstrates its utility as a rescue device for emergency hemostasis when more traditional measures have failed.>

Introduction

Access site vascular complications remain relatively frequent following trans-femoral (TF) transcatheter aortic valve implantation (TAVI), with a reported incidence of between 4% and 30% [1]. Notably, these complications are associated with significant morbidity as well as increased mortality [1]. Suture-based vascular closure devices (VCD) such as Prostar® and ProGlide® (Abbott Vascular Inc., Santa Clara, CA, USA) are widely used in order to achieve rapid hemostasis following TF TAVI, and have been demonstrated to reduce the rate of vascular complications [1]. However, failure to achieve adequate hemostasis following their use occurs in 4–9% of cases, and may necessitate surgical escalation [2]. We report a case of a patient with complex ileo-femoral anatomy in whom the novel plug-based MANTA VCD (Essential Medical Inc., Malvern, PA, USA) was successfully used to achieve hemostasis post TF TAVI following failed closure with ProGlides®, avoiding the need for surgery.

Case report

A 79-year-old male who had previously undergone coronary artery bypass grafting (CABG) and aortic valve replacement (AVR) with a 21 mm Mitroflow (Sorin Group, Arvada, CO, USA) presented with symptoms of congestive cardiac failure and exertional angina.

* Corresponding author at: Department of Cardiology, Leeds General Infirmary, Great George Street, Leeds, LS1 3EX, UK.
E-mail address: nomanali456@doctors.org.uk (N. Ali).

https://doi.org/10.1016/j.jccase.2018.12.001
1878-5409/

Coronary angiography demonstrated patent surgical grafts and aortography confirmed the presence of severe aortic regurgitation. Echocardiography showed degeneration of the Mitroflow prosthesis with stenosis (peak pressure gradient [PPG] 87 mmHg and aortic valve area [AVA] 0.58 cm^2) and severe valvular regurgitation. Due to a number of other comorbidities, such as chronic obstructive pulmonary disease and limited mobility secondary to lower limb osteoarthritis, repeat surgical intervention was deemed to be prohibitively high risk (EuroSCORE II 11.5%) and the patient was referred for valve-in-valve TAVI.

Pre-procedural imaging was undertaken with computed tomography (CT) scanning and demonstrated suitable anatomy at the valvular level but significant calcification and tortuosity in the ileo-femoral arteries (Fig. 1). In addition, both vessels were noted to have aneurysmal segments, with maximal diameters of 39.9 mm and 22.3 mm in the right and left ileo-femoral arteries, respectively. Whilst this anatomy presented a challenge for TF TAVI, prior grafting of the left internal mammary artery (LIMA) to the left anterior descending (LAD) artery increased the risk of subclavian TAVI. As such, the femoral route was selected, with delivery of the TAVI prosthesis via the left femoral artery (LFA).

Prior to the procedure the patient was administered a loading dose of 300 mg aspirin and bolus doses of teicoplanin and gentamycin. Vascular access to the LFA was obtained via use of an ultrasound guided micropuncture technique, and two ProGlides® were sited for pre-closure. The right femoral artery (RFA) and vein (RFV) were punctured under Sonosite (Fujifilm, Tokyo, Japan) guidance. Once access had been successfully obtained, 8000 units of intravenous heparin were given and an initial activated clotting time (ACT) was measured at 198 s. A 23 mm Evolut R™ valve (Medtronic, MN, USA) was successfully implanted with a good hemodynamic result; the invasive transvalvular gradient reduced from 40 mmHg to 30 mmHg, aortic regurgitation reduced from severe to mild, and left ventricular end diastolic pressure (LVEDP) reduced from 30 mmHg to 24 mmHg. However, difficulties arose when the vascular sheath was removed from the LFA, with torrential bleeding following deployment of the pre-sited ProGlides®. Despite use of a third ProGlide, heavy bleeding persisted. Urgent surgical support was requested, and a 14F Cook sheath was partially reinserted into the LFA to control bleeding. An exchange length Terumo wire from the right femoral artery was snared and exteriorized through the LFA, allowing a Glidecath® (Terumo, Somerset, NJ, USA) to be placed into the left external iliac artery (EIA). The exchange length Terumo wire was then placed into the left superficial femoral artery (SFA) and subsequently exchanged for a stiff wire to allow for adequate balloon support. Deployment of a covered stent was deemed inappropriate since its location would have been at the flexion point of the common femoral artery (CFA), leading to a long-term risk of fracture and thrombosis. Consideration was given to surgical intervention but the decision was taken to attempt rescue hemostasis using a 14F MANTA VCD, with provision for surgery if this failed. An ACT was checked at this point, and measured at 196 s. The MANTA VCD was deployed and following 10 min of manual compression as well as balloon tamponade, hemostasis was successfully achieved. Subsequent femoral angiography demonstrated no dissection or thrombus, with good flow in the CFA and SFA. The patient suffered significant blood loss with a hemoglobin drop from 128 g/L to 77 g/L, necessitating a blood transfusion. Nevertheless, he made a good recovery and was

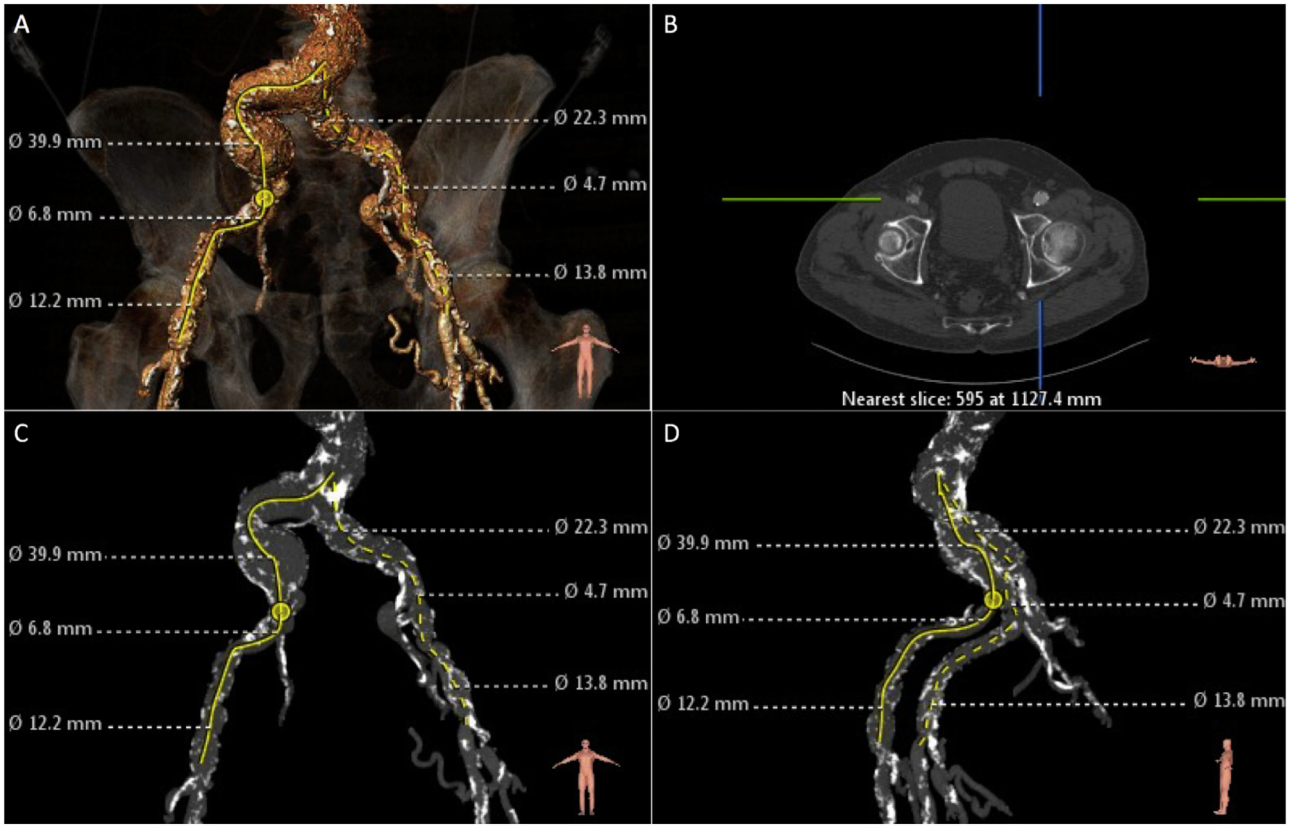

Fig. 1. Pre-transcatheter aortic valve implantation computed tomography (CT) images. (A) 3D reconstructed image demonstrating significant tortuosity and aneurysmal segments within the ileo-femoral vessels. (B) An axial cross-sectional image, used to determine the optimal site of access for the left femoral artery. (C and D) 3D reconstructed images demonstrating the extent of calcification within both ileo-femoral arteries.

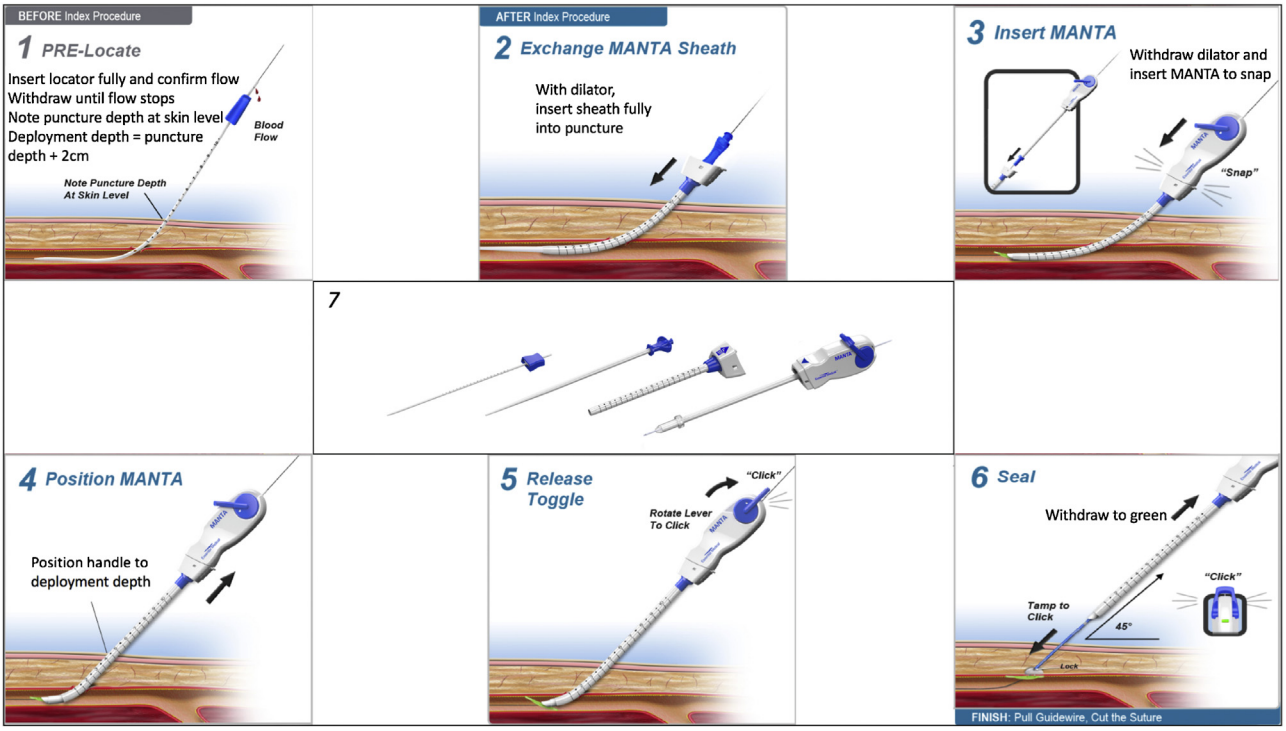

Fig. 2. The MANTA device.
(1–6) Schematic representation of the steps involved in the deployment of the MANTA. In the present case, steps 1 and 2 were omitted since the device was used as a rescue rather than electively. Images provided by Essential Medical Inc., Malvern, PA, USA.

discharged home. Subsequent follow up has demonstrated amelioration of anginal symptoms, significant improvement in exertional dyspnea, and no lasting complications with regard to lower limb vasculature.

Discussion

Use of suture-based VCDs following TF TAVI is well established and reduces the incidence of vascular complications [1]. Nevertheless, failure of these devices to achieve hemostasis can occur, and often requires prompt vascular surgical repair. We present a case in which the MANTA VCD was utilized in order to rescue failed hemostasis, and prevented the need for surgical intervention. The MANTA is a novel collagen-based VCD which comprises a resorbable polymer intra-arterial toggle connected to an extra-arterial hemostatic bovine collagen pad by a non-resorbable polyester suture, and secured with a stainless-steel suture lock (Fig. 2). It is currently commercially available in most European countries, and will become available in the USA, Canada, and Australia by the end of 2019.

In the present case, the MANTA VCD succeeded in achieving hemostasis where pre-sited Proglides had failed. Suture-based devices, such as the Proglide, work by capturing, drawing together, and tensioning the edges of the arteriotomy. If the artery is calcified or damaged then these sutures may partially or completely fail. In this case we suspect that due to calcification and atheromatous disease in the femoral artery, the Proglides were unable to draw together the edges of the arteriotomy and control bleeding. In comparison, the Manta VCD is less dependent on the quality of the artery.

The MANTA is available in 14F and 18F sizes, for closure of 10–14F and 15–18F arteriotomies, respectively [3]. This allows it to be used as a standalone post-closure device following TF TAVI, in contrast to other collagen-based VCDs such as Angio-Seal™ (Terumo). The MANTA is currently being used in a small number of European centers and initial experience is encouraging. A recently published retrospective study comparing MANTA and ProGlide VCDs following TF TAVI demonstrated Valve Academic Research Consortium (VARC-2) VCD failure to be less frequent in the MANTA cohort (3.7% vs. 7.8%, $p = 0.378$). Whilst this difference did not reach statistical significance, use of the MANTA was found to significantly reduce the need of additional VCDs for completion of hemostasis (58.3% vs. 1.9%, $p < 0.0001$) [4]. These early data suggest that the MANTA may be non-inferior to currently used suture-based VCDs. Furthermore, our center has performed a 50-case trial of MANTA as a standalone first-choice post-closure device and found it to be as effective and safe as a pre-close strategy.

Conclusion

The MANTA is a relatively novel technology and appears to be a promising alternative to established VCDs. Its success in achieving hemostasis and avoiding emergency surgery in the present case suggests that the MANTA may be a useful rescue device for TAVI operators. Further investigation is required to evaluate the place of MANTA in the toolbox of VCDs as a routine closure device.

Conflicts of interest

Dr Daniel Blackman and Dr Christopher Malkin are consultants and proctors for Boston Scientific and Medtronic.

Acknowledgments

None.

References

[1] Dimitriadis Z, Scholtz W, Börgermann J, Wiemer M, Piper C, Vlachojannis M, et al. Impact of closure devices on vascular complication and mortality rates in TAVI procedures. Int J Cardiol 2017;241:133–7.
[2] Toggweiler S, Leipsic J, Binder RK, Freeman M, Barbanti M, Heijmen RH, et al. Management of vascular access in transcatheter aortic valve replacement: part 2: vascular complications. JACC Cardiovasc Interventions 2013;6:767–76.
[3] van Gils L, Daemen J, Walters G, Sorzano T, Grintz T, Nardone S, et al. MANTA, a novel plug-based vascular closure device for large bore arteriotomies: technical report. EuroIntervention 2016;12:896–900.
[4] Biancari F, Romppanen H, Savontaus M, Siljander A, Mäkikallio T, Piira OP, et al. MANTA versus ProGlide vascular closure devices in transfemoral transcatheter aortic valve implantation. Int J Cardiol 2018;263:29–31.