

Improving our knowledge about a new plug-based vascular closure device



Didier Tchétché*, MD

Groupe CardioVasculaire Interventionnel, Clinique Pasteur, Toulouse, France

The year 2019 has ushered in new insights concerning transcatheter aortic valve implantation (TAVI). We learnt that this treatment could be equal or even superior to surgery in low-risk patients in terms of mortality, stroke, rehospitalisation and bleeding^{1,2}. This reflects the improvement observed since the first-in-man case in 2002. We have witnessed a constant evolution in the devices utilised with better profiles, repositionability, more stable deployment, sealing features and a wider range of treatable annuli³. Various aspects of the procedure have also evolved during the last decade including (non-exhaustively) the use of cerebral protection devices, radial artery as the accessory access site and pacing through the left ventricle wire⁴.

TAVI-related complications have improved over time thanks to refinements in technology and the growing experience of operators. One of the aspects of the procedure that has remained immutable is vascular closure devices (VCD) for the main arterial access. Prostar[®] and ProGlide[®] (Abbott Vascular, Santa Clara, CA, USA) have been extensively used, despite their inherent

limitations, because there was no alternative. Efforts have been made to understand which of them was the most efficient, without clear conclusions⁵. In the PRAGMATIC initiative, vascular complications were mainly driven by the failure of these closure devices⁶. We all agreed that improvements were needed in this regard. The MANTA[™] vascular closure device (Essential Medical Inc., [now Teleflex], Morrisville, NC, USA) was recently introduced and has rapidly gained interest in a number of European centres. It consists of a bioresorbable toggle and a large collagen plug⁷. Low rates of vascular complications and bleeding were reported with this novel VCD⁸. Propensity-matched analyses demonstrated lower major vascular complication rates with MANTA as compared to ProGlide in patients undergoing TAVI^{9,10}. MANTA seems to be an improvement compared with the historical VCD utilised so far. Apart from its efficiency in preventing major vascular complications, what may strike one is its ease of use, with a reasonably short learning curve and reproducible haemostatic and angiographic results.

*Corresponding author: Groupe CardioVasculaire Interventionnel, Clinique Pasteur, 45 Avenue de Lombez, BP 27617, 31076 Toulouse, France. E-mail: d.tchetche@clinique-pasteur.com

However, as no device is perfect, we need to improve our understanding about its real performance in large-scale daily practice, its scope of application, limitations and potential complications. Personally, I would use the MANTA as a bail-out tool for torrential bleeding post failure of preclosure with suture-based devices. Ali and colleagues recently reported a similar case¹¹. Echographic guidance could be of tremendous help in such rescue situations, in order to confirm the position of the toggle within the common femoral artery before deployment of the collagen plug (**Figure 1**).

In this issue of EuroIntervention, two reports answer important questions we may have concerning this novel VCD. Kroon et al¹² demonstrate for the first time the successful use of MANTA for a fully percutaneous right axillary TAVI.

Article, see page 76

The transaxillary approach has been explored since the early days of TAVI because of its similarity, in terms of outcomes and recovery, with transfemoral procedures. This access route has even become the first alternative to transfemoral TAVI, as compared to apical or direct aortic techniques¹³. Right axillary TAVI being technically more challenging than left access, partly because of the vascular tortuosity which has to be overcome, securing the arteriotomy closure is of paramount importance for a fully percutaneous approach. This report from Kroon et al is reassuring in this regard. A stepwise approach has to be applied but the potential superiority of MANTA for haemostasis over the previously available VCD could be an asset for the right axillary technique.

As no VCD is 100% efficient, besides this exciting expansion of the indication for MANTA, Wong et al¹⁴ describe a potential complication that may occur and the way to use it as a bail-out tool.

Article, see page 74

The team discusses the potential reason for the occurrence of this event and its prevention. It reminds us that this closure device can lead to potential complications inherent to plug-based platforms. Given the dreadful impact of vascular complications and bleeding on survival, understanding the optimal use of MANTA and the prevention/rapid treatment of related vascular complications provides important information for the medical community. Both teams should be congratulated for their contributions that clearly improve our knowledge about the MANTA VCD. Have a good read!

Conflict of interest statement

The author has no conflicts of interest to declare.

References

1. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, Bajwa T, Heiser JC, Merhi W, Kleiman NS, Askew J, Sorajja P, Rovin J, Chetcuti SJ, Adams DH, Teirstein PS, Zorn GL 3rd, Forrest JK, Tchétché D, Resar J, Walton A, Piazza N, Ramlawi B, Robinson N, Petrossian G, Gleason TG, Oh JK, Boulware MJ, Qiao H, Mugglin AS, Reardon MJ; Evolut Low Risk Trial Investigators. Transcatheter Aortic-Valve Replacement with

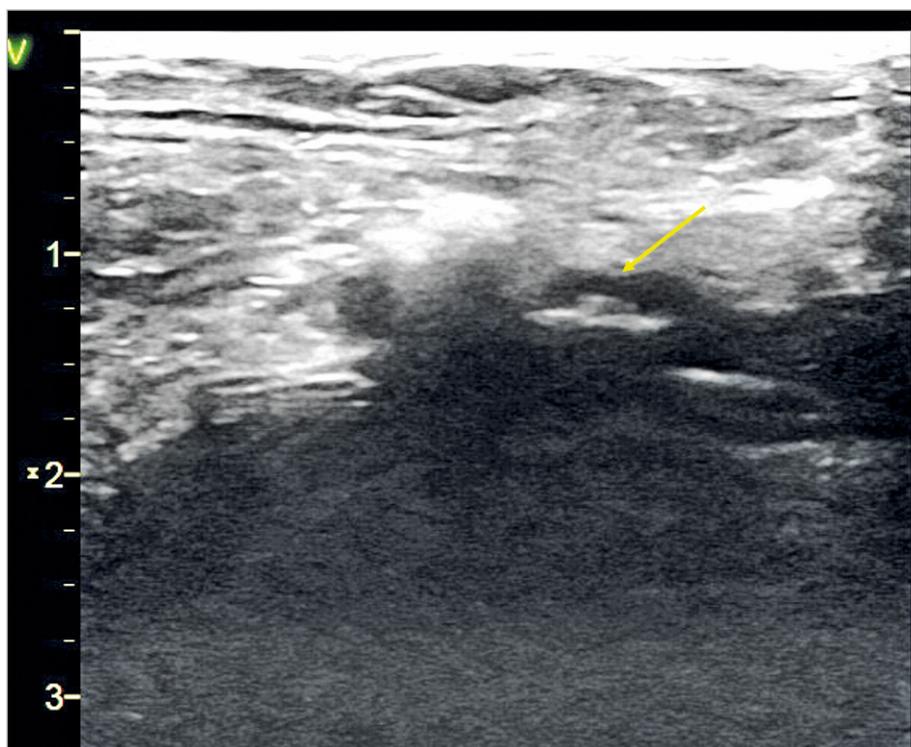


Figure 1. Echographic identification of the location of the MANTA toggle within the arterial lumen (yellow arrow) before deployment of the collagen plug.

a Self-Expanding Valve in Low-Risk Patients. *N Engl J Med*. 2019 Mar 17. [Epub ahead of print].

2. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, Kapadia SR, Malaisrie SC, Cohen DJ, Pibarot P, Leipsic J, Hahn RT, Blanke P, Williams MR, McCabe JM, Brown DL, Babaliaros V, Goldman S, Szeto WY, Genereux P, Pershad A, Pocock SJ, Alu MC, Webb JG, Smith CR; PARTNER 3 Investigators. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N Engl J Med*. 2019 Mar 17. [Epub ahead of print].

3. Tchetché D, Van Mieghem NM. New-generation TAVI devices: description and specifications. *EuroIntervention*. 2014;10 Suppl U:U90-100.

4. Tchetché D, de Biase C, Brochado B, Mastrokostopoulos A. How to Make the TAVI Pathway More Efficient. *Interv Cardiol*. 2019;14:31-3.

5. Barbash IM, Barbanti M, Webb J, Molina-Martin De Nicolas J, Abramowitz Y, Latib A, Nguyen C, Deuschl F, Segev A, Sideris K, Buccheri S, Simonato M, Rosa FD, Tamburino C, Jilaihawi H, Miyazaki T, Himbert D, Schofer N, Guetta V, Bleiziffer S, Tchetché D, Immè S, Makkar RR, Vahanian A, Treede H, Lange R, Colombo A, Dvir D. Comparison of vascular closure devices for access site closure after transfemoral aortic valve implantation. *Eur Heart J*. 2015;36:3370-9.

6. Van Mieghem NM, Tchetché D, Chieffo A, Dumonteil N, Messika-Zeitoun D, van der Boon RM, Vahdat O, Buchanan GL, Marcheix B, Himbert D, Serruys PW, Fajadet J, Colombo A, Carrié D, Vahanian A, de Jaegere PP. Incidence, predictors, and implications of access site complications with transfemoral transcatheter aortic valve implantation. *Am J Cardiol*. 2012;110:1361-7.

7. van Gils L, Daemen J, Walters G, Sorzano T, Grintz T, Nardone S, Lenzen M, De Jaegere PP, Roubin G, Van Mieghem NM. MANTA, a novel plug-based vascular closure device

for large bore arteriotomies: technical report. *EuroIntervention*. 2016;12:896-900.

8. Van Mieghem NM, Latib A, van der Heyden J, van Gils L, Daemen J, Sorzano T, Ligthart J, Witberg K, de Kroon T, Maor N, Mangieri A, Montorfano M, de Jaegere PP, Colombo A, Roubin G. Percutaneous Plug-Based Arteriotomy Closure Device for Large-Bore Access: A Multicenter Prospective Study. *JACC Cardiovasc Interv*. 2017;10:613-9.

9. Biancari F, Romppanen H, Savontaus M, Siljander A, Makikallio T, Piira OP, Piuholta J, Vilkki V, Ylitalo A, Vasankari T, Airaksinen JKE, Niemelä M. MANTA versus ProGlide vascular closure devices in transfemoral transcatheter aortic valve implantation. *Int J Cardiol*. 2018;263:29-31.

10. Moriyama N, Lindström L, Laine M. Propensity-matched comparison of vascular closure devices after transcatheter aortic valve replacement using MANTA versus ProGlide. *EuroIntervention*. 2019;14:e1558-65.

11. Ali N, Blackman DJ, Cunningham M, Malkin CJ. Use of the MANTA device to rescue failed pre-closure following transfemoral transcatheter aortic valve implantation. *J Cardiol Cases*. 2018; 19:81-4.

12. Kroon HG, De Jaegere PP, Van Mieghem NM. Plug-based closure in completely percutaneous right-sided transaxillary transcatheter aortic valve implantation. *EuroIntervention*. 2019;15: 76-77.

13. Dahle TG, Kaneko T, McCabe JM. Outcomes Following Subclavian and Axillary Artery Access for Transcatheter Aortic Valve Replacement: Society of the Thoracic Surgeons/American College of Cardiology TVT Registry Report. *JACC Cardiovasc Interv*. 2019;12:662-9.

14. Wong YH, De Backer O, Søndergaard L, Bieliauskas G. Percutaneous management of an embolised MANTA large bore arteriotomy closure device. *EuroIntervention*. 2019;15:74-5.