Early Outcomes After Percutaneous Closure of Access Site in Transfemoral Transcatheter Valve Implantation Using the Novel Vascular Closure Device Collagen Plug-Based MANTA

Livia Gheorghe, MD[a,b,1,*], Jorn Brouwer, MD[a,1], Harold Mathijssen, MD[a], Vincent J Nijenhuis, MD[a], Benno JWM Rensing, MD, PhD[a], Martin J Swaans, MD, PhD[c], Dean RPP Chan Pin Yin, MD[a], Robin H. Heijmen, MD, PhD[d], Tom De Kroon, MD, PhD[d], Uday Sonker, MD, PhD[d], Jan AS Van der Heyden, MD, PhD[a], and Jurrien M Ten Berg, MD, PhD[a]

A new collagen-based MANTA vascular closure device (VCD) was developed for closing large-bore arteriotomies after transfemoral transcatheter aortic valve implantation (TAVI).

We evaluated safety and feasibility at 30-day follow-up in terms of vascular and bleeding complications and mortality of the collagen-based MANTA VCD compared with the suture-based Prostar XL VCD in a cohort of 366 patients who underwent transfemoral TAVI between January 2015 and April 2018. The MANTA VCD was used in 168 patients and the Prostar XL VCD in 198 patients, with successful closure of 98.8% and 98.5%, respectively. VARC-2 defined as major vascular and bleeding complications was similar in both groups (MANTA vs Prostar XL): 0.6% versus 1.0% (p = 0.661) and 0.6% versus 1.5% (p = 0.102). Minor vascular and bleeding complications, were significantly more frequent (10.7 vs 18.8 %, p = 0.003 and 13.7 vs 19.7%, p = 0.080, respectively) in the Prostar XL cohort. Thirty-day all-cause mortality was 2.7%, without significant difference between the groups (p = 0.278). The MANTA device is a safe and feasible option for vascular access closure in patients undergoing transfemoral TAVI. **(Am J Cardiol 2019;124:1265−1271)**

Transcatheter aortic valve implantation (TAVI) has become the standard of care in high-risk patients with severe symptomatic aortic stenosis.[1] Recent studies have shown promising results in low and intermediate risk patients.[2−4] In the actual context of an expanding ageing population, the number of TAVI is expected to grow four- to 10-fold over the next decade.[5] Although, the rate of vascular access complications has also decreased,[6−10] it still remains one of the pitfalls of TAVI. Prostar XL and Proglide (Abbott Vascular Inc., Santa Clara, California) devices are extensively used as vascular closure device (VCD) in TAVI procedure. The MANTA (Essential Medical inc., Malvern, Pennsylvenia) is a new collagen plug-based VCD, designed for closure of a large caliber arteriotomy, with favorable initial experience.[11,12] This study describes our experience using the MANTA VCD for percutaneous access closure during transfemoral TAVI, compared with our previous experience with the Prostar XL.

Methods

The study population encompassed 366 consecutive patients with severe symptomatic aortic stenosis who underwent transfemoral TAVI (TF-TAVI) between January 2015 and April 2018. The Heart Team evaluated patients as candidates for TAVI, according to the current guidelines. Multidetector computed tomography (MDCT) was performed in order to determine valve size and arterial access and it was analyzed using dedicated software (3Mensio, Pie Medical System).

All procedures were performed using transfemoral approach, under general or local anesthesia. The arterial access was obtained using fluoroscopic or ultrasound guidance. Direct aortic valve implantation was the preferred strategy with postdilatation, if needed. Final routine rotational angiography, to evaluate hemostasis achievement at the access site was performed only in the MANTA cohort. The angiography was performed from RAO 30° to LAO 30° using 20 ml contrast.

Aspirin was started before the TAVI procedure. Since 2015, all willing patients were included in POPULAR TAVI (NCT02247128) study and when randomized to additional clopidogrel, loading dose was started the day before or in the morning of the procedure. Novel oral anticoagulants were discontinued at least 24 hours before the procedure and

[a]Interventional Cardiology Unit, Sint Antonius Ziekenhuis, Nieuwegein, The Netherlands; [b]Interventional Cardiology Unit, Puerta del Mar Hospital, Cadiz, Spain; [c]Cardiac Imaging Unit, Sint Antonius Ziekenhuis, Nieuwegein, The Netherlands; and [d]Cardiothoracic Surgery Unit, Sint Antonius Ziekenhuis, Nieuwegein, The Netherlands. Manuscript received February 24, 2019; revised manuscript received and accepted July 2, 2019.

Funding: The authors did not receive any funding for this article.

[1]Both authors contributed equally to this work.

See page 1270 for disclosure information.

*Corresponding author: Tel: (+31) 652743031.

E-mail addresses: livia_gheorghe_ro@yahoo.es; gheorghelivia@yahoo.com (L. Gheorghe).

0002-9149/
https://doi.org/10.1016/j.amjcard.2019.07.030

vitamin K antagonist anticoagulation was continued, maintaining INR between 2 and 2.5. Intraprocedural unfractionated heparin was used, titrated to a target ACT of 250 to 300 seconds. Heparin reversal with protamine was routinely performed after the valve implantation and before vascular access closure.

Two closure devices were used at the TAVI-access site: Prostar XL (Abbott Vascular, Abbott Park, Illinois) and MANTA (Essential Medical inc., Malvern, Pennsylvenia). The mechanism and design of both closure devices have been previously described.[10,11,13] Three interventional cardiologists and 3 cardiac surgeons performed TAVI procedures during the study period. All practitioners were proctored during the first 3 cases for the use of MANTA. In summary, the Prostar XL device uses a "preclosure" technique where sutures are deployed before introduction of the large arterial sheath. After sheath removal the sutures are fastened individually with a sliding knot using a knot pusher in order to ensure approximation of the knot to the surface of the arterial wall. The MANTA VCD uses the same principals as Angioseal device (Abbott Vascular Inc., Santa Clara, California). It has 3 components, which actively seal the big arteriotomy. The bioabsorbable copolymer anchor is placed against the inside of the vessel wall and it is attached to the collagen pad (placed on top of the arteriotomy in the tissue tract) through a nonresorbable polyester suture and a stainless steel suture lock.[13] The MANTA VCD comes in 14 and 18 French sizes for closing punctures of 10 to 14 French (OD profile 14-18 French) and of 15 to 22 French (OD profile 18-24.5 French), respectively.

As part of the TAVI work-up, peripheral access evaluation was accomplished with MDCT by measuring the minimal lumen diameter using a centreline technique. Fluoroscopic and MDCT calcification of the iliofemoral arteries was graded as none, mild (some calcification), moderate (the course of the artery can be seen without injection of contrast dye), or severe (heavily calcified iliofemoral arteries).[14] The tortuosity of the iliofemoral system was defined as mild: 30° to 60°, moderate: 60° to 90° and severe >90°.[15]

The published outer sheath diameter was used to calculate the sheath-to-femoral artery ratio (SFAR).[15] A SFAR of <1.05 was considered as favorable. For detailed evaluation of hemostasis with the MANTA device, routine rotational angiography of the access site was performed 5 minutes after device implantation. The presence of the leakage at the access site after MANTA closure was graded as following: no leakage, small leakage (small contrast extravasation without external bleeding), moderate leakage (continuous extravasation with moderate external bleeding), and severe leakage (continuous extravasation with important external bleeding).

The primary outcome was acute closure success and occurrence of any access site related vascular injury, as well as major and life threatening/disabling bleeding complication according to the most recent Valve Academic Research Consortium definition.[16] Secondary outcomes included all vascular and bleeding complications as well as all-cause mortality at 30-day follow-up.

Descriptive statistics were used to summarize the demographic data. Categorical variables were presented as frequencies and percentages, and continuous variables as mean ± standard deviation (SD). Baseline data were checked for normal distribution using the Kolmogorov-Smirnov method. A 2-tailed unpaired Student *t* Test for comparison of continuous data between groups and a paired Student *t* Test for intragroup comparison were used. Ordinal variables were compared with the Mann-Whitney *U* test and Wilcoxon signed-rank. A chi-square test was used for investigating the relation between 2 categorical variables. A 2-tailed p value ≤0.05 was considered to indicate statistical significance. Commercially available software was used for analyses (SPSS 22.0, SPSS Inc., Chicago, Illinois). Ethical approval was sought and granted by the local institutional board.

Results

Between January 2015 and April 2018, 366 patients underwent transfemoral TAVI. The Prostar XL device was used in 198 patients, until April 2017. From then on, the MANTA device (168 patients) was used as VCD. In 18 cases, the MANTA device was used during the Prostar XL period (proctored cases). The baseline characteristics of both groups were similar except for STS score, which was significantly lower in the more contemporary MANTA group (Table 1). Almost half of the patients were chronically anticoagulated, whereas a combination of anticoagulation and antiplatelet therapy was more prevalent in the Prostar XL group (19 % vs 37.5 %, p <0.001).

A favorable SFAR was present in more than 95% of the patients without significant difference between both groups (p =0.382; Table 2).

Table 1
Baseline characteristics

Variable	MANTA (n = 168)	Prostar XL (n = 198)	p Value
Clinical variables			
Age (years)	80.7 ± 6.7	81.7 ± 6.1	0.114
Male gender	94 (56%)	94 (48%)	0.106
BMI (kg/m^2)	26.2 ± 4.1	26.6 ± 4.2	0.359
Peripheral vascular disease	18 (11%)	25 (13%)	0.571
Diabetes mellitus	36 (22%)	46 (23%)	0.690
Systemic arterial hypertension	120 (71%)	133 (67%)	0.380
Atrial fibrillation	55 (33%)	83(42%)	0.071
Previous stroke/transient ischemic attack	31 (19%)	26 (13%)	0.162
Previous myocardial infarction	26 (16%)	38 (19%)	0.351
STS score	3.58 ±3.0	4.278 ±2.7	0.020
Echocardiographic variables			
LVEF <30%	18 (10%)	31 (10%)	0.883
Mean aortic gradient (mmHg)	39.5 ±15.5	39.5±14.6	0.989
Antiplatelet/anticoagulation therapy			
Anticoagulation-antiplatelet therapy	32 (19%)	74 (37%)	<0.001
Anticoagulation monotherapy	40 (24%)	22 (11%)	0.001
Dual-antiplatelet therapy	52 (31%)	77 (39%)	0.113
Single-antiplatelet therapy	44 (26%)	25 (13%)	0.001

Data are presented as mean ± SD (p values for 2-sided Student's *t* Test).
BMI = body mass index; LVEF = left ventricular ejection fraction.

Table 2
Femoral characteristics of the access site

Variable	MANTA (n = 168)	Prostar XL (n = 198)	p Value
Mean common femoral diameter (mm)	8.4 ± 1.3	8.2 ± 1.1	0.222
Moderate-severe femoral calcification	18 (10.8%)	35 (18.6%)	0.021
Moderate-severe femoral tortuosity	24 (14.5%)	36 (19.1%)	0.240
Sheath-to femoral artery ratio <1.05	162 (96.4%)	189 (95.2%)	0.382
Sheath size (French)			0.004
14	64 (31.0%)	67 (33.3%)	
16	48(28.6%)	25 (12.7%)	
18	45(26.7%)	20 (10.3%)	
20	5(3.0%)	26 (13.3%)	
22	6(3.6%)	60 (30.4%)	

Data are presented as mean ± SD (p values for 2-sided Student's *t* Test).

Table 4
Clinical outcome and access site related complications

Variable	MANTA (n = 168)	Prostar XL (n = 198)	p Value
Major bleeding	1 (0.6%)	2 (1.0%)	0.661
Minor bleeding	23 (13.7%)	39 (19.7%)	0.080
Major vascular complications	1 (0.6%)	3 (1.5%)	0.109
Occlusion	0	1	
Femoral dissection	0	1	
Closure failure	1	1	
Minor vascular complications	18 (10.7%)	36 (18.2%)	0.003
Hematoma	12	28	
Occlusion	0	1	
Femoral dissection	0	2	
Closure failure	1	2	
Pseudoaneurysm	4	3	
Hospitalization length	5.26 ±3.3	6.25±3.4	0.006
30-day all-cause mortality	6 (3%)	4 (2.0%)	0.278

Data are presented as mean ± SD (p values for 2-sided Student's *t* Test).

The used sheath size (Table 2) and the implanted valve (Table 3) were heterogeneous between the 2 groups.

The incidences of vascular and bleeding complications are shown in Table 4. Overall, the occurrence of major vascular and bleeding complications was similar in both groups (0.6% vs 1%, p = 0.661 and 0.6% vs 1.5%, p = 0.102, respectively). Minor vascular complications occurred significantly more in Prostar XL group (10.7 vs 18.8 %, p = 0.003).

The mortality rate was similar (3.6% vs 2% p = 0.278) in both groups and none of the deaths were related to the access site complication. The hospitalization length was shorter in the MANTA cohort (5.26 ± 3.34 vs 6.25 ± 3.43 days, p = 0.006).

Both sizes of the MANTA device were used, with a significantly higher percentage of minor vascular complications when using the smaller MANTA size (16.4% vs 6.3%, p = 0.035; Figure 1). Routine rotational angiography was performed in the MANTA group. The results are presented in Figure 2.

Table 3
Procedural characteristics

Variable	MANTA (n = 168)	Prostar XL (n = 198)	p Value
Type of valve			
Evolut R (Pro)	117(67%)	89 (45%)	<0.001
Lotus	6 (4%)	86(43%)	<0.001
Sapien 3	27(16%)	19(10%)	0.063
Portico	6 (4%)	1 (1%)	0.017
Direct flow	0	3(2%)	0.109
Symetis-Acurate Neo	11(7%)	0	<0.001
Procedural data			
Predilatation	39 (23%)	24 (12%)	0.005
Postdilatation	46(27%)	35 (18%)	0.026
Estimated GFR pre-TAVR (ml/min)	59.7± 21.7	60.7 ± 23.6	0.676
Estimated GFR post-TAVR (ml/min)	63.7 ± 23.6	65.6 ± 26.7	0.491
Hb pre-TAVR (mmol/L)	8.0 ± 0.7	7.9 ± 0.9	0.566
Hb post-TAVR (mmol/L)	7.0 ± 1.0	6.8 ± 0.9	0.030
Right femoral access	138 (82%)	176 (89%)	0.127
Contrast (ml)	97.8 ± 49	80.1 ± 43	<0.001

Data are presented as mean ± SD (p values for 2-sided Student's *t* Test).
GFR = glomerular filtration rate; Hb = haemoglobin; TAVR = transcatheter aortic valve replacement.

Discussion

The present study proved that the rate of major vascular and bleeding complications after percutaneous closure of the access site in TAVI is low and similar in the MANTA and Prostar XL group. Moreover a significantly lower rate of minor vascular complications was observed in the MANTA group. In addition, there was no difference in the outcome at 30-day follow-up between the MANTA and Prostar XL VCD group.

A large proportion of TAVI cases worldwide are now performed using a "minimalistic" approach, in order to reduce the hospitalization length and possible derived complications. Although the rate of vascular complications and major bleeding has been decreased (4.5% and 3.9%, respectively),[17] it still remains an important cause of morbidity, mortality, and prolonged hospitalization. Percutaneous closure during TAVI is associated with superior outcome compared with classical surgical cut-down.[18–20]

Currently, the Prostar XL and Proglide are the most used VCDs. Several studies have compared both devices in TAVI settings, showing that the Proglide device has lower rates of vascular complications.[21–23] Nevertheless, Prostar XL is still used, with good outcomes in experienced hands. Recently, a novel VCD, collagen-based technology MANTA, has been developed for closing large bore arteriotomies. The first results demonstrated (n = 50) rapid hemostasis and a low complication rates.[11] Moreover, Palma et al[12] published the first observational study comparing the MANTA with Prostar XL device in a TAVI population, showing less vascular complications in MANTA group.

In our study, the rate of major vascular and bleeding complications was low (<2%). Nevertheless, more minor vascular complications were observed in the Prostar-XL group, especially in the group of patients where a bigger

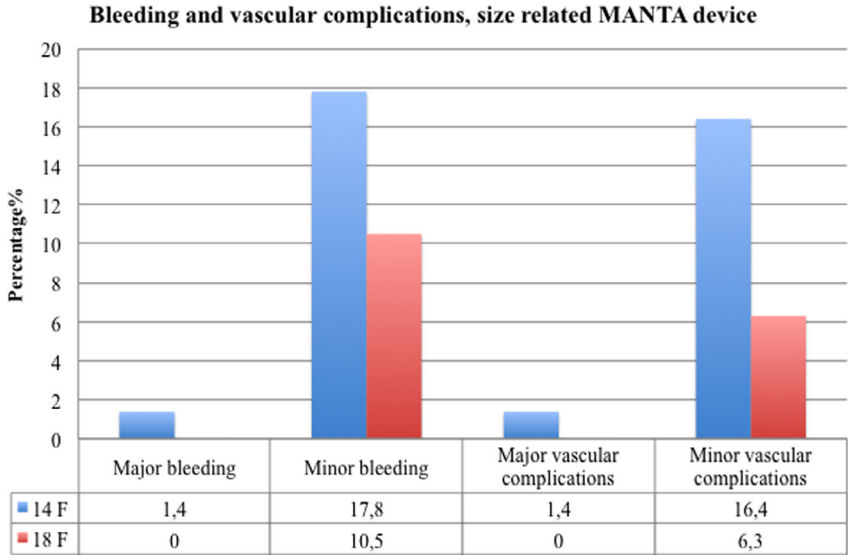

Figure 1. Bleeding and vascular complications MANTA device size related.

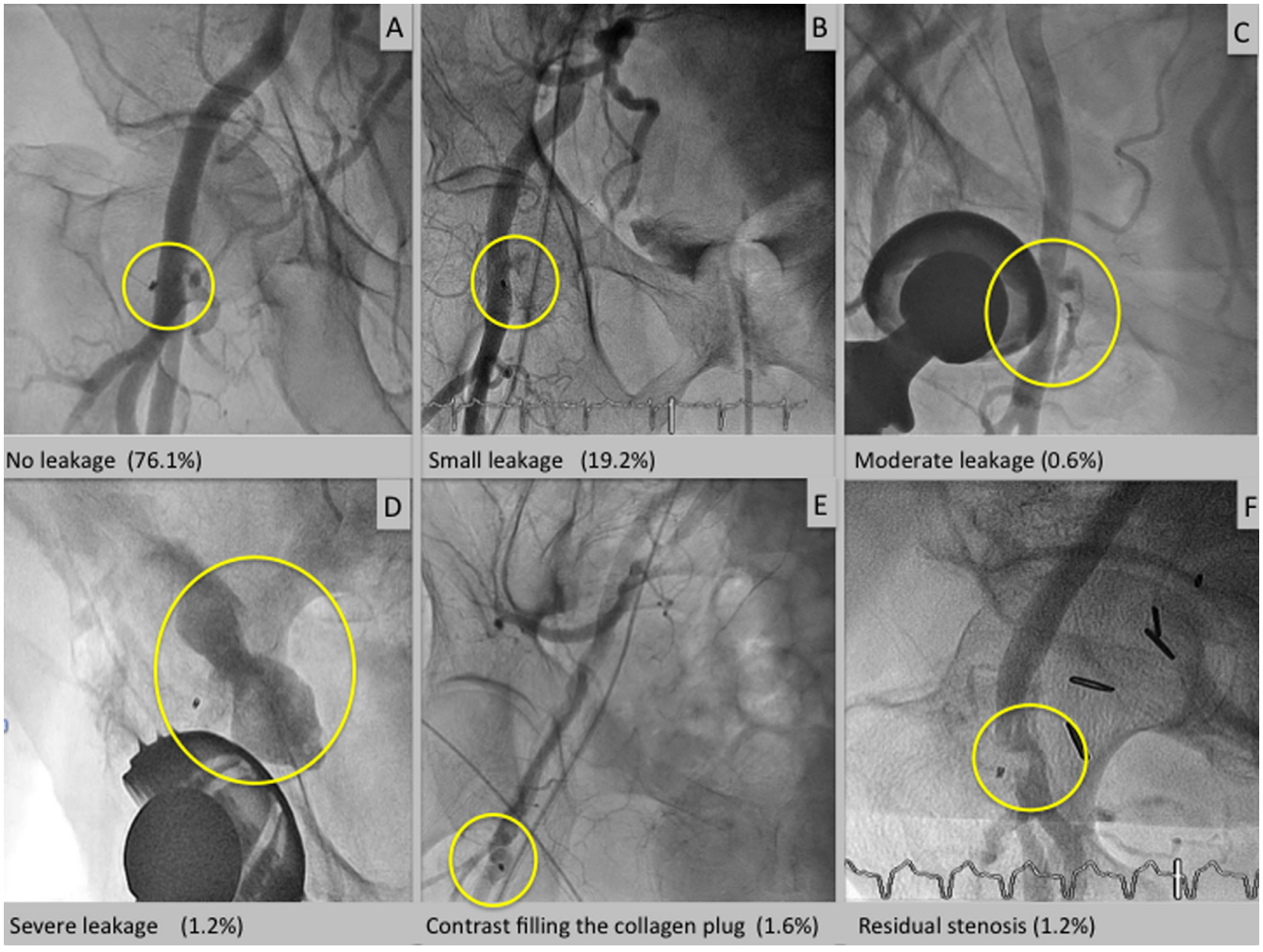

Figure 2. Angiographic findings after MANTA closure (yellow circle). (*A*) Complete access sealing; (*B*) Small leakage; (*C*) Moderate leakage; (*D*) Severe leakage; (*E*) Contrast filling the collagen plug without external or internal bleeding; (*F*) Impingement of the common femoral artery by the device.

sheath was required (>14 French sheath) (Supplementary Table 1). The groin hematoma was the most frequent vascular complication with a conservative management (compressive bandage) in all cases. Although the average sheath size was bigger in the Prostar XL group, the SFAR was favorable in both groups.

There was no difference regarding the rate of vascular closure failure (2 cases in MANTA group and 3 cases in Prostar XL group). These were related to severe ileofemoral calcification, especially on the anterior wall of the common femoral artery. In the MANTA group, both cases presented severe circumferential calcification at the access site. The puncture was performed under echo guidance and confirmed by angiography, aiming for a zone with less calcification. However, during vascular access closure, hemostasis was not achieved. In one case, a covered stent was needed to achieve the hemostasis. The suspicion that the device has been externalized from the lumen artery (bigger distance between the metallic steal lock and the artery) was confirmed by control MDCT (Figure 3). In the other case, vascular surgery with femoral endarterectomy and patch angioplasty was required, which revealed the presence of the collagen plug in the subcutaneous tissue.

Severely calcified vessels do not have the same elasticity as healthy arteries. Therefore, during dilatation with large-bore sheaths, it is difficult to predict the size and shape of artery opening and it may affect an adequate vascular closuring. However, in very calcified arteries, even with an adequate caliber, vascular access closure remains challenging for any percutaneous device.

Echo-guided puncture showed a reduction in vascular complications, allowing the safe deployment of closure devices, even in patients with peripheral artery disease.[24]

To our knowledge this is the first study describing the angiographical results after MANTA closure. Routine control rotational angiography after vascular closure with the MANTA device helped to better understand the sealing process and improved the decision making for postprocedural management. Small leakage, during angiography was the most frequent finding (32 patients, 19.6%). In the early experience, small leakage was seen in the control angiography but without external bleeding. Initially, it was interpreted as harmless and no further actions were taken. Nevertheless, those patients presented hours later with a minor bleeding at the access site, ultimately leading to an adjustment in our local policy. When this angiographic finding occurred, a preventive dedicated compression bandage was installed for 12 hours, which turned out to be very effective in preventing delayed bleeding.

In order to detect minimal leakage at the access site, rotational angiography can be more revealing then static angiography, due to the fact that superposition can hide small leakage. Video 2 is an example of static angiography, which is showing in LAO 30°, apparently complete sealing

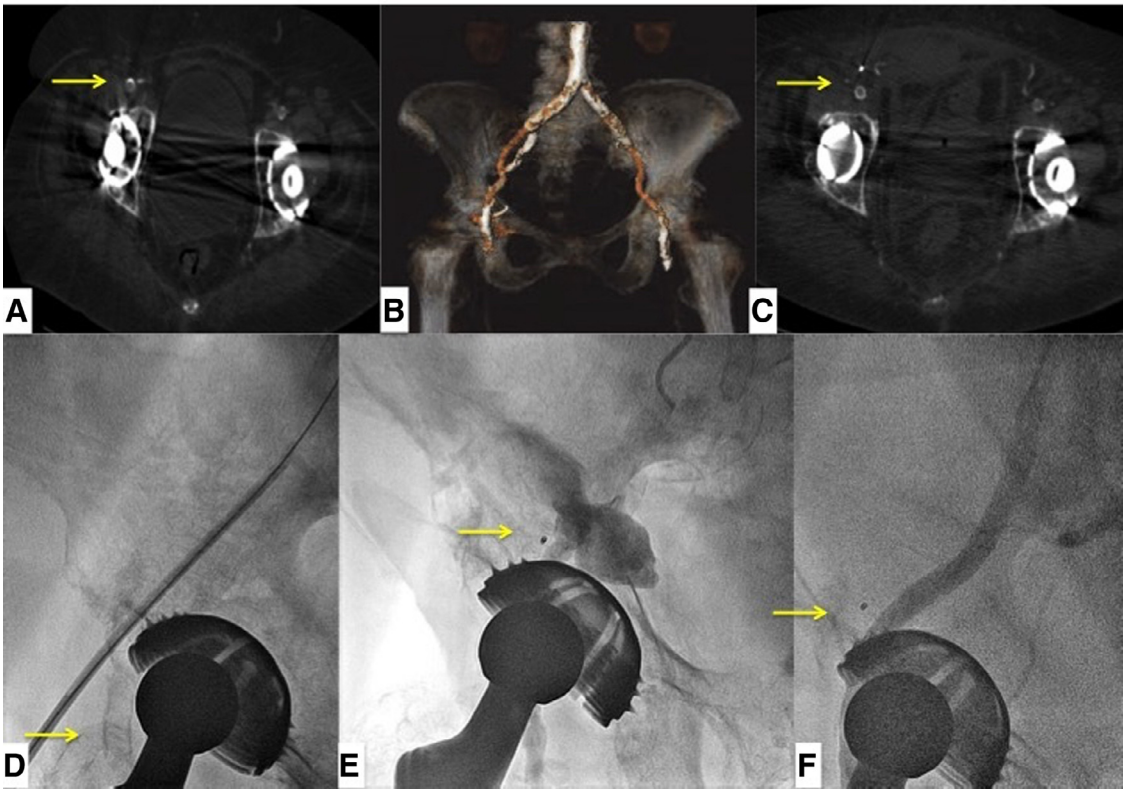

Figure 3. Failure of vascular access closure with MANTA VCD. (*A*) MDCT previous TAVI implantation showed severe calcification on the anterior wall of the common femoral artery; (*B*) Ileofemoral access reconstruction, both femoral arteries present severe calcifications, with a zone less calcified above the femoral head; (*C*) MDCT postprocedure showed the stainless steel lock at 10 mm distance from the femoral artery wall; (*D*) Severe calcification in fluoroscopy; (*E*) Presence of severe leakage after MANTA closure; (*F*) After covered stent implantation, no leakage is observed. Stainless steel lock at 10 mm distance from the femoral artery.

after MANTA deployment, and in RAO 30° presence of a small leakage. Beside leakage, 2 other findings were seen: impingement of the arterial lumen caused by the collagen plug in 2 cases and "contrast filling of the collagen plug" in 4 cases (Video 3). The latter was associated with the development of a pseudoaneurysm, requiring vascular surgery in 3 cases and thrombin injection in one case.

When comparing both sizes of MANTA VCD, there were more minor vascular complications using 14 French device (16.4 vs 6.3%, $p = 0.035$) (Figure 1). We could not find a clear explanation for this observation; there was no difference between the 2 groups regarding SFAR, anterior wall calcification or anticoagulant treatment.

There are still some questions that should be addressed such as device reabsorption, healing process, device influence on the femoral artery wall and reaccess after MANTA. In experimental settings the reabsorption is completed in about 8 to 10 months, but in the real world no data exists to this date. Finally, in case of device closure failure, although the wire is maintained in place it is not possible to use other device as Angioseal or Proglide do the fact that the wire is crossing through the toggle, which can't be accessed.

This study has several limitations. First, evaluating the impact of a specific VCD for transfemoral TAVI using a retrospective study can lead to incorrect conclusions because of the influence of selection bias. The choice of VCD was not made according to specific criteria, Prostar XL was used until April 2017 and, since then, the MANTA device replaced it. The second limitation is the fact that in the Prostar XL group bigger sheaths were used, nevertheless the SFAR was similar in both cohorts. The learning curve for the Prostar XL is longer than for the MANTA, nevertheless our center has an extended experience with Prostar XL device, since the TAVI program started in 2007. The learning curve with MANTA indeed was shorter (only 3 cases). The third limitation is the diversity of antiplatelet and anticoagulation treatment, anticoagulation being used more often in the Prostar XL group, which could explain the presence of more minor vascular and bleeding complications. The fourth limitation is that the hospitalization length is longer than in other studies and it may not be related to the device efficiency. Finally, although the hemostasis time was not recorded, prolonged manual compression was needed only in those cases with moderate and severe leakage. In the rest of cases the hemostasis was immediately achieved.

Conclusions

The MANTA, collagen plug-based, VCD seems to be a safe and feasible option to obtain adequate hemostasis in patients undergoing a transfemoral TAVI procedure. Control rotational angiography was useful in decision-making in postprocedural management after MANTA implantation. The presence of small leakage should be conservatively treated using a dedicated compression bandage.

Disclosures

The authors have no conflicts of interest to disclose.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2019.07.030.

1. Bonow RO, Brown AS, Gillam LD, Kapadia SR, Kavinsky CJ, Lindman JR, Mack MJ, Thourani VH, Dehmer GJ, Bonow RO, Lindman BR, Beaver TM, Bradley SM, Carabello BA, Desai MY, George I, Green P, Holmes DR, Johnston D, Leipsic J, Mick SL, Passeri JJ, Piana RN, Reichek N, Ruiz CE, Taub CC, Thomas JD, Turi ZG, Doherty JU, Dehmer GJ, Bailey SR, Bhave NM, Brown AS, Daugherty SL, Dean LS, Desai MY, Duvernoy CS, Gillam LD, Hendel RC, Kramer CM, Lindsay BD, Manning WJ, Mehrotra P, Patel MR, Sachdeva R, Wann LS, Winchester DE, Allen JM. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 appropriate use criteria for the treatment of patients with severe aortic stenosis. *J Am Soc Echocardiogr* 2018;31:117–147.
2. Cahill TJ, Chen M, Hayashida K, Latib A, Modine T, Piazza N, Redwood S, Søndergaard L, Prendergast BD. Transcatheter aortic valve implantation: current status and future perspectives. *Eur Heart J* 2018;39:2625–2634.
3. 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, 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. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *New Engl J Med* 2019;380:1706–1715.
4. 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. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *New Engl J Med* 2019;380:1695–1705.
5. d'Arcy JL, Coffey S, Loudon MA, Kennedy A, Pearson-Stuttard J, Birks J, Frangou E, Farmer AJ, Mant D, Wilson J, Myerson SG, Prendergast BD. Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study. *Eur Heart J* 2016;37:3515–3522.
6. Ruiz CE. Optimizing Transcatheter Aortic Valve Sizing and Minimizing Vascular Complications. *J Am Coll Cardiol* 2012;59:128–129.
7. Toggweiler S, Gurvitch R, Leipsic J, Wood DA, Willson AB, Binder RK, Cheung A, Ye J, Webb JG. Percutaneous aortic valve replacement: vascular outcomes with a fully percutaneous procedure. *J Am Coll Cardiol* 2012;59:113–118.
8. Toggweiler S, Leipsic J, Binder RK, Freeman M, Barbanti M, Heijmen RH, Wood DA, Webb JG. Management of vascular access in transcatheter aortic valve replacement: part 2: vascular complications. *JACC Cardiovasc Interv* 2013;6:767–776.
9. Van Mieghem NM, Tchetche D, Chieffo A, Dumonteil N, Messika-Zeitoun D, van der Boon RMA, Vahdat O, Buchanan GL, Marcheix B, Himbert D, Serruys PW, Fajadet J, Colombo A, Carrié D, Vahanian A, de Jaegere PPT. Incidence, predictors, and implications of access site complications with transfemoral transcatheter aortic valve implantation. *Am J Cardiol* 2012;110:1361–1367.
10. Dimitriadis Z, Scholtz W, Börgermann J, Wiemer M, Piper C, Vlachojannis M, Gummert J, Horstkotte D, Ensminger S, Faber L, Scholtz S. Impact of closure devices on vascular complication and mortality rates in TAVI procedures. *Int J Cardiol* 2017;241:133–137.
11. 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;10:613–619.
12. De Palma R, Settergren M, Rück A, Linder R, Saleh N. Impact of percutaneous femoral arteriotomy closure using the MANTATM device on vascular and bleeding complications after transcatheter aortic valve replacement. *Catheter Cardiovasc Interv* 2018;92:954–961.

13. van Gils L, De Jaegere PPT, Roubin G, Van Mieghem NM. The MANTA vascular closure device: a novel device for large-bore vessel closure. *JACC Cardiovasc Interv* 2016;9:1195–1196.
14. Barbanti M, Binder RK, Freeman M, Wood DA, Leipsic JA, Cheung A, Ye J, Tan J, Toggweiler S, Yang TH, Dvir D, Maryniak K, Lauck S, Webb JG. Impact of low-profile sheaths on vascular complications during transfemoral transcatheter aortic valve replacement. *EuroIntervention* 2013;9:929–935.
15. Hayashida K, Lefèvre T, Chevalier B, Hovasse T, Romano M, Garot P, Mylotte D, Uribe J, Farge A, Donzeau-Gouge P, Bouvier E, Cormier B, Morice MC. Transfemoral aortic valve implantation: new criteria to predict vascular complications. *JACC Cardiovasc Interv* 2011;4:851–858.
16. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Am Coll Cardiol* 2012;60:1438–1454.
17. Barbanti M, Buccheri S, Rodés-Cabau J, Gulino S, Généreux P, Pilato G, Dvir D, Picci A, Costa G, Tamburino C, Leon MB, Webb JG. Transcatheter aortic valve replacement with new-generation devices: a systematic review and meta-analysis. *Int J Cardiol* 2017;245:83–89.
18. Drafts BC, Choi CH, Sangal K, Cammarata MW, Applegate RJ, Gandhi SK, Kincaid EH, Kon N, Zhao DX. Comparison of outcomes with surgical cut-down versus percutaneous transfemoral transcatheter aortic valve replacement: TAVI transfemoral access comparisons between surgical cut-down and percutaneous approach. *Catheter Cardiovasc Interv* 2018;91:1354–1362.
19. Hernández-Enriquez M, Andrea R, Brugaletta S, Jiménez-Quevedo P, Hernández-García JM, Trillo R, Larman M, Fernández-Avilés F, Vázquez-González N, Iñiguez A, Zueco J, Ruiz-Salmerón R, del Valle R, Molina E, García del Blanco B, Berenguer A, Valdés M, Moreno R, Urbano-Carrillo C, Hernández-Antolín R, Gimeno F, Cequier Á, Cruz I, López-Mínguez JR, Aramendi JI, Sánchez Á, Goicolea J, Albarrán A, Díaz JF, Navarro F, Moreu J, Morist A, Fernández-Nofrerías E, Fernández-Vázquez F, Ten F, Mainar V, Mari B, Saenz A, Alfonso F, Diarte JA, Sancho M, Lezáun R, Arzamendi D, Sabaté M. Puncture versus surgical cutdown complications of transfemoral aortic valve implantation (from the Spanish TAVI Registry). *Am J Cardiol* 2016;118:578–584.
20. Ismail A, Mehmet C. Percutaneous access versus surgical cut down for TAVI: Where do we go from here? *Catheter Cardiovasc Interv* 2018;91:1363–1364.
21. Maniotis C, Andreou C, Karalis I, Koutouzi G, Agelaki M, Koutouzis M. A systematic review on the safety of Prostar XL versus ProGlide after TAVI and EVAR. *Cardiovasc Revasc Med* 2017;18:145–150.
22. Mehilli J, Jochheim D, Abdel-Wahab M, Rizas KD, Theiss H, Spenkuch N, Zadrozny M, Baquet M, El-Mawardy M, Sato T, Lange P, Kupatt C, Greif M, Hausleiter J, Bauer A, Schwarz F, Pichlmaier M, Hagl C, Richardt G, Massberg S. One-year outcomes with two suture-mediated closure devices to achieve access-site haemostasis following transfemoral transcatheter aortic valve implantation. *EuroIntervention* 2016;12:1298–1304.
23. Seeger J, Gonska B, Rodewald C, Rottbauer W, Wöhrle J. Impact of suture mediated femoral access site closure with the Prostar XL compared to the ProGlide system on outcome in transfemoral aortic valve implantation. *Int J Cardiol* 2016;223:564–567.
24. Seto AH, Abu-Fadel MS, Sparling JM, Zacharias SJ, Daly TS, Harrison AT, Suh WM, Vera JA, Aston CE, Winters RJ, Patel PM, Hennebry TA, Kern MJ. Real-time ultrasound guidance facilitates femoral arterial access and reduces vascular complications: FAUST (Femoral Arterial Access With Ultrasound Trial). *JACC Cardiovasc Interv* 2010;3:751–758.