MANTA®

Vascular Closure Device
Summary of Selected Clinical Studies

Teleflex

2017

Percutaneous Plug-Based Arteriotomy Closure Device for Large-Bore Access, A Multicenter Prospective Study†

Journal: *JACC: Cardiovascular Interventions.* 2017 Mar 27;10(6):613-619

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This prospective, non-blinded, single arm, multicenter (n=3) study was conducted to evaluate the safety and effectiveness of the MANTA® Large Bore Vascular Closure Device (VCD) for the purposes of obtaining CE Mark. Fifty patients were enrolled in elective procedures that included high-risk percutaneous coronary intervention (PCI), balloon aortic valvuloplasty (BAV), or transcatheter aortic valve replacement (TAVR) using procedure sheaths with Inner Diameters (IDs) of 12 - 19 French (Fr.). Operators (n=9) were first-time users of the MANTA® VCD and training included a detailed device description and deployments on a dry plastic model. CT angiography was recommended for each patient prior to the procedure, and an ultrasound was completed prior to the procedure, pre-discharge, and at 30 and 60-day follow-up time points. In addition, a post closure angiogram was performed in all patients. Critical exclusion criteria for the study included:

- femoral puncture outside the common femoral artery
- target artery size insufficient for required MANTA® VCD
- complicated femoral access (including excessive hematoma, arteriovenous fistula, and posterior wall puncture)
- renal insufficiency (serum creatinine >2.5mg/dl)
- inability to ambulate at baseline

The primary performance endpoint was hemostasis success, defined as hemostasis at the puncture site within 10 minutes of MANTA® VCD sheath removal without need for manual or mechanical compression and without later re-bleeding. The primary safety endpoints were the occurrence of any access site-related vascular injury, as well as major and life-threatening or disabling bleeding complications according to the most recent Valve Academic Research Consortium (VARC-2) definitions.

The secondary performance endpoint was time to hemostasis (TTH), defined as the time elapsed from removal of the MANTA® VCD sheath from the target artery to the first observed and confirmed arterial hemostasis.

The table below summarizes the effectiveness and safety results from Table 3 of the article.

MANTA® VCD Effectiveness and Safety (n=50)	
Hemostasis success %	
Overall	94
14F	100
18F	91.2
Time to hemostasis (mm:ss)	00:24 (00:02 - 37:10)
Safety* [N (%)]	
All-cause death (not related to the MANTA® VCD)	4 (8%)
VARC Bleeding	
Life-threatening/disabling	0
Major	1 (2%)
VARC Vascular Complications	
Major (treatment with stent, surgery to repair misplaced valve)	1 (2%)
Minor	0

* Defined according to the Valve Academic Research Consortium (VARC).

Hemostasis success criterion was achieved in 94% of patients. The mean TTH was two minutes, 23 seconds, and the median TTH was 24 seconds. According to an ad-hoc analysis using VARC-2 definitions, one patient (2%) experienced a major vascular and major bleeding complication with prolonged femoral bleeding that was successfully treated with a covered stent and eventual surgical repair because of persistent oozing. In addition, this patient needed emergency surgery to repair a misplaced TAVR valve. There were no late vascular complications due to the MANTA® VCD. Outcomes not captured in VARC-2 include, one prolonged balloon inflation to control bleeding, one balloon inflation to treat a pseudoaneurysm, and five patients with subcutaneous hematomas with no medical intervention. Final angiograms post procedure showed patent vessels in all subjects; however, three patients showed angiographic evidence of extravasation (two were treated with balloon inflation and one was treated surgically for valve complication noted above). Ankle brachial indices (ABI) remained stable through the follow-up time points.

The authors concluded that this initial study of the MANTA® VCD "demonstrated rapid and reliable hemostasis with low complication rates", and stated larger studies are needed. ■

† Disclosure(s): This study was sponsored by Teleflex Incorporated or its affiliates. Nicolas van Mieghem, MD is a paid consultant of and receives payments from Teleflex Incorporated or its affiliates in connection with the MANTA® VCD.

2018

MANTA Versus ProGlide Vascular Closure Devices in Transfemoral Transcatheter Aortic Valve Implantation

Journal: *International Journal of Cardiology.* 2018; 263: 29-31

Authors: Fausto Biancari, Hannu Romppanen, Mikko Savontaus, Antti Siljander, Timo Mäkikallio, Olli-Pekka Piira, Jarkko Piuhola, Viivi Vilkki, Antti Ylitalo, Tuija Vasankari, Juhani K.E. Airaksinen, Matti Niemelä

This retrospective, multicenter (n=3) study was conducted to evaluate the efficacy and safety of the novel MANTA® VCD versus the ProGlide™ VCD.

The data of 222 consecutive patients who underwent transfemoral TAVI using MANTA® or ProGlide™ VCDs were analyzed. The MANTA® VCD was used in 107 patients in which the outcomes were compared to 115 ProGlide™ patients. VCDs were deployed by seven senior cardiologists with extensive experience in TAVR procedures. All cardiologists deployed their first five to ten MANTA® VCDs under the guidance of a Teleflex technical advisor.

Primary outcome measures included: invasive treatment of bleeding, life-threatening/disabling bleeding per VARC-2 definitions, and major vascular complications per VARC-2 definitions. Additional (secondary) outcome measures included, among others: hospital/30-day mortality, stroke, VARC-2 VCD failure, VARC-2 major bleeding, surgical treatment for bleeding, transfusion, post-op hemoglobin decrease, and additional use of VCDs. Cost of devices was also included; however, postoperative outcomes were not factored into the calculation.

In the MANTA® and ProGlide™ VCD cohorts, VARC-2 major vascular complications (9.3% vs. 12.2%), VARC-2 life threatening/disabling bleeding (9.3% vs. 6.1%) and the need for invasive treatment of bleeding (4.7% vs. 7.0%) from the index access site were similar. Additional VCDs were more frequently needed in the ProGlide™ cohort (1.9% vs. 58.3%). In addition, study results show VCD failure occurred less frequently in the MANTA® VCD cohort (3.7% vs. 7.8); however the difference did not reach statistical significance.

The cost analysis of these VCDs showed that the MANTA® VCD was significantly more expensive than the ProGlide™ device. Due to the lack of data on MANTA® VCD implanting, ambulation, and discharge times, cost-benefit analysis was not able to be conducted nor a reliable indication at the time of this study.

The table below summarizes the primary and secondary outcome measures from Table 2 of the article.

Outcomes	ProGlide™ [N (%)] (n=115)	MANTA® [N (%)] (n=107)
30-day Mortality	2 (1.7)	0 (0.0)
VCD Failure	8 (7.8)	4 (3.7)
VARC-2 Life-threatening Bleeding	7 (6.1)	10 (9.3)
VARC-2 Major Bleeding	19 (16.5)	17 (15.9)
Bleeding Requiring Invasive Treatment	8 (7.0)	5 (4.7)
Transfusion	10 (8.8)	14 (13.1)
Additional Use of VCD*	67 (58.3)	2 (1.9)
VARC-2 Major Complications	14 (12.2)	10 (9.3)
VARC-2 Minor Complications	3 (2.6)	4 (3.7)

* Note, for the Perclose ProGlide™ closures, 52 cases needed an additional AngioSeal® for closure and 19 cases needed an additional Perclose ProGlide™

The authors state the risk of VARC-2 bleeding and major vascular complications was similar between the study cohorts and preliminary results showed that the "novel MANTA® VCD is associated with a somewhat lower rate of VCD failure and a significantly lower rate of additional use of VCDs as compared to the ProGlide™ VCD". The authors conclude, "due to the limited size of this comparator analysis and the possible impact of an initial learning curve with the MANTA® VCD, further studies of larger size are needed to prove efficiency and safety of the MANTA® VCD". ■

2018

Impact of Percutaneous Femoral Arteriotomy Closure Using the MANTA™ Device on Vascular and Bleeding Complications After Transcatheter Aortic Valve Replacement

Journal: *Catheter Cardiovascular Interv.* 2018 Nov 1;92(5):954-961

Authors: Rodney De Palma, MBBS, Magnus Settergren, MD PhD, Andreas Ruck, MD PhD, Rikard Linder, MD PhD, Nawzad Saleh, MD PhD

This was a single center, prospective, observational study comparing results achieved using the MANTA® VCD and ProStar™ XL. Data from 346 consecutive transfemoral TAVR patients treated from January 2016 through September 2017 were analyzed. The first 257 cases were closed with Prostar™ XL devices, and the last 89 were treated with the MANTA® VCD. The primary outcome assessed was closure success and TTH, defined as the time elapsed after deployment of the MANTA® VCD until no visible bleeding. Additional secondary endpoints included mortality at 30 days, as well as vascular and bleeding complications as defined according to the VARC-2 criteria (NOTE: events were NOT independently adjudicated). Vascular access was obtained with or without ultrasound fluoroscopic guidance. Three operators using the Prostar™ XL had experience of >100 cases each and four operators used the MANTA® VCD after being proctored for three cases each.

The mean TTH reported for the MANTA® VCD was 42 seconds. One instance of an unplanned endovascular procedure to correct a femoral artery occlusion and clinical lower limb ischemia was reported. The composite of all-cause mortality and major complications related to the main access site in isolation was similar between the MANTA® VCD and Prostar™ XL groups, 1.1% vs 1.9% (p=0.61). Major bleeding occurred less frequently with the MANTA® VCD group, 1.1% vs. 7.78% (p=.02) and length of stay was shorter in the MANTA® VCD group compared to the ProStar™ XL group (2.5 days ± 3.8 vs 3.5 days ± 3.3, p=.041).

The authors state that even with the operators experience in the use of ProStar™ XL, fewer major bleeding complications occurred with the MANTA® VCD; however, when looking at overall composite frequency of complications, they point out that there was no statistical difference. The authors also state “compared to percutaneous suture-based devices, the novel MANTA® VCD has a shorter learning curve with no risk of post-deployment stenosis, which can be seen with suture-based devices and is concerning as TAVR extends to low risk patients”. Finally, the authors conclude, “a further advantage of this fully percutaneous closure device compared to open surgical closure and suture-based devices is the reducedmorbidity and enhanced speed of mobilization reflected in part by the lower length of stay observed”. The authors believe this data should prompt larger studies to evaluate the efficacy and safety of the MANTA® VCD. ■

The table below summarizes the clinical outcomes from Table 2 of the article.

Clinical Outcomes and Complications			
Complications related to TAVR	**MANTA® [N (%)] (n=89)**	**PROSTAR™ [N (%)] (n=257)**	**p Value**
All-cause mortality (30 days)	3 (3.4)	9 (3.5)	.965
Major bleeding	2 (2.3)	24 (9.3)	.030
Minor bleeding	12 (13.6)	19 (7.4)	.078
Major vascular	2 (2.3)	1 (0.4)	.478
Minor vascular	4 (4.6)	7 (2.7)	.379
Composite (death/major bleed/major vascular)	5 (5.6)	33 (12.8)	.061
Composite (death/major minor vascular/bleed, major minor bleed/stroke/TIA)	21 (23.6)	43 (16.7)	.148
Main access site complications in isolation			
All-cause mortality (30 days)	0	1 (0.4)	.055
Major bleeding	1 (1.1)	20 (7.78)	.023
Minor bleeding	10 (11.2)	14 (5.5)	.069
Major vascular	1 (1.1)	1 (0.4)	.454
Minor vascular	4 (4.5)	7 (2.7)	.403
Composite (death/major bleed/major vascular)	1 (1.1)	21 (1.9)	.614
Composite (death/major minor vascular/bleed, major minor bleed/stroke/TIA)	16 (18.0)	42 (10.5)	.065
Miscellaneous			
Length of stay in days	2.5 ± 3.8	3.5 ± 3.3	.041

2018

Access Site Complications After Transfemoral Aortic Valve Implantation – a Comparison of MANTA and ProGlide

Journal: *CVIR Endovascular.* 2018; 1:20

Authors: Pavel Hoffman, Ahmed Al-Ani, Thomas von Lueder, Jenny Hoffmann, Peter Majak, Ove Hagen, Helga Loose, Nils Einar KlØw, Anders Opdahl

This single-center, retrospective study compared 76 patients treated with ProGlide™ VCD and 75 patients with the MANTA® VCD following TAVI procedures. A learning period of the first 25 cases with each device was also analyzed.

The use of ProGlide™ and MANTA® VCDs was not randomized but performed consecutively using first ProGlide™ then MANTA® in patients scheduled for TAVI in a newly established TAVI center. There were four sub groups, for ProGlide™ and MANTA® VCDs; the first 25 of each were assigned as the "learning group" and the remaining 51/50 patients were classified as the "established group''.

The endpoints were 1: vascular complications including bleeding, occlusion, flow-limiting high-grade stenosis or dissection, pseudoaneurysm or other complications directly attributable to the puncture site or the VCD used or 2: non-planned vascular surgery and/or use of endovascular stent or stent-graft or other endovascular intervention at the puncture site. VARC-2 definitions were used for bleeding and vascular complications.

Overall, there were eight patients with complications (10.7%) in the MANTA® VCD cohort, with events consisting of one occlusion, six bleeding events, four pseudoaneurysms, and one flow-limiting stenosis or dissection. By comparison, two patients in the ProGlide™ cohort (2.7%) had major complications, with events consisting of one occlusion, two bleeding events, and one flow-limiting stenosis or dissection. In five of the eight reported access site related MANTA® VCD complications, the 14 Fr. MANTA® VCD was used to close the arteriotomy after a 16 Fr. procedure sheath was used. Per the MANTA® VCD Instructions for Use, the 14 Fr. MANTA® VCD can be used following the use of 10-14 Fr. devices or sheaths (max OD of 18 Fr.), and the 18 Fr. MANTA® VCD can be used following the use of 15-18 Fr. devices or sheaths (max OD of 25). The authors note, "this mis-match may have contributed to the higher rates of bleeding complications and pseudoaneurysms and one should use 18 Fr. MANTA® VCD for 16 Fr. puncture sites".

The tables below summarize vascular complications and interventions from Tables 5 and 7 of the article.

Major Vascular Closure Device / Puncture Site Complications in ProGlide™ and in Manta®

	ProGlide™ Learning (n=25)	MANTA® Learning (n=25)	ProGlide™ Established (N=51)	MANTA® Established (n=75)	Learning p Value/ Established p Value
All Complications, n (%)	1 (4.0)	2 (8.0)	1 (2.0)	6 (12.0)	0.551 / 0.047
Occlusion	1 (4.0)	0 (0.0)	0 (0.0)	1 (2.0)	-
Bleeding	1 (4.0)	1 (4.0)	1 (2.0)	5 (10.0)	-
Pseudoaneurysm	0 (0.0)	2 (8.0)	0 (0.0)	2 (4.0)	-
Flow limiting stenosis or dissection	1 (4.0)	0 (0.0)	0 (0.0)	1 (2.0)	-

Regarding vascular interventions, seven MANTA® VCD patients (9.3%) had complications requiring intervention: one periprocedural open vascular surgery, four periprocedural stents or stent-graft, two postprocedural stents or stent-graft, and one other vascular intervention. Two ProGlide™ patients (2.7%) had complications requiring intervention: one periprocedural open vascular surgery, and one periprocedural stent or stent-graft.

Vascular Interventions in patients with VCD complications in periprocedural and during hospital stay

	ProGlide™ Learning (n=25)	MANTA® Learning (n=25)	ProGlide™ Established (N=51)	MANTA® Established (n=75)	Learning p Value/ Established p Value
All Interventions, n (%)	1 (4.0)	1 (4.0)	1 (2.0)	6 (12.0)	1.000 / 0.047
Periprocedural – Open Vascular Surgery	1 (4.0)	0 (0.0)	0 (0.0)	1* (2.0)	-
Postprocedural – Open Vascular Surgery	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	-
Periprocedural – Stent/stent-graft	0 (0.0)	0 (0.0)	1 (2.0)	4* (8.0)	-
Postprocedural – Stent/stent-graft	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.0)	-
Other vascular intervention	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	-

* One patient had both a stent graft and open vascular surgery.

The authors concluded that the ProGlide™ device is associated with "significantly lower rates of vascular complications compared to the MANTA® VCD". They also note that their results conflict with previous reports and that further multicenter randomized testing is suggested. ■

2019

Insights From a Multidisciplinary Introduction of the MANTA Vascular Closure Device

Journal: *Journal of the American College of Cardiology: Cardiovascular Interventions.* 2019; Vol. 12, No. 17.

Authors: Federico Moccetti, MD, Miriam Brinkert, MD, Robert Seelos, MD, Stefan Ockert, MD, Matthias Bossard, MD, Florim Cuculi, MD, Richard Kobza, MD, Stefan Toggweiler, MD.

This single center, prospective study reports a systematic review of the first 100 consecutive cardiovascular procedures with the MANTA® VCD and also provides details on specific failure modes encountered during MANTA® VCD deployments. Of 100 patients, 75 underwent TAVR, 21 underwent endovascular aortic replacement (EVAR), and 4 underwent Impella® left ventricular support. Twenty two patients had bi-lateral large-bore access, and therefore a total of 122 MANTA® VCDs were used in 122 access sites. Hemostasis following deployment of the MANTA® VCD was recorded, and complications were assessed according to VARC-2 definitions.

Immediate hemostasis was achieved in 70 patients, and hemostasis within 10 minutes was achieved in 97 patients. Protamine was not administered to any of the patients. Seven patients (7%) experienced major complications and four (4%) patients experienced minor complications associated with the MANTA® VCD. In total, two patients experienced femoral artery occlusion, five patients experienced ongoing bleeding, and four patients experienced pseudoaneurysms. Additionally, two major complications and one minor complication occurred that were unrelated to the MANTA® VCD.

The article found that complications occurred significantly more often in patients with peripheral vascular disease and in patients with minimal femoral artery diameter less than six millimeters (mm). The article also detailed three distinct failure modes of the device: “(1) Elevation of the toggle due to calcification of the artery leading to mechanical and/or thrombotic occlusion of the artery; (2) Incomplete apposition of the [collagen] plug with substantial risk for bleeding, including retroperitoneal bleeding; and (3) Incomplete apposition of the plug with pseudoaneurysm formation that may be at risk for delayed rupture”. Figures are provided in the paper showing examples of these failure modes.

The authors concluded that “immediate hemostasis was achieved in the majority of patients when using the MANTA® VCD, but the complication rate was not negligible”. Additionally, they reiterated that the failure modes of 'elevation of the toggle' and 'incomplete apposition of the plug' along with their associated complications occurred significantly more often in patients with minimal femoral artery diameters less than six mm.

Comment(s): The article uses pictures to illustrate technique and complications discussed. Per the instructions for use, the 18 Fr. MANTA® VCD should be used in vessel size ≥6. ■

The table below summarizes 30-day outcomes from Table 2 of the article.

Outcomes				
	All (n=100)	**No Failure (n=89)**	**MANTA® VCD Failure (n=11)**	**p Value**
Time to Hemostasis (min)*	0 (0-28)	0 (0-13)	10 (0-900)	0.007
Vascular Complications (VARC-2)				<0.001
None	86 (86)	86 (96)	0 (0)	-
Minor	5 (5)	1 (1)	4 (36)	-
Major	9 (9)	2 (2)	7 (63)	-
Bleeding Complications (VARC-2)				<0.001
None	85 (85)	83 (93)	2 (18)	
Minor	7 (7)	4 (5)	3 (27)	
Major	3 (3)	0 (0)	3 (27)	
Life-threatening	4 (4)	1 (1)	3 (27)	
Any Packed RBC Transfusion	4 (4)	1 (1)	3 (27)	0.002
Surgical Revision	7 (7)	0 (0)	7 (63)	<0.001
Hospital Stay (days)	4 (2–7)	3 (2–6)	10 (2–13)	0.60
30-day Mortality	1 (1)	1 (1)	0 (0)	0.24

Values are median (interquartile range) or n (%); RBC - red blood cell.

* Immediate hemostasis was achieved in 70 patients, within 1 minute in 79 patients, within 5 minutes in 87 patients, and within 10 minutes in all but 3 patients.

2019

Propensity-matched Comparison of Vascular Closure Devices after Transcatheter Aortic Valve Replacement Using MANTA Versus ProGlide.

Journal: *EuroIntervention,* 2019 Feb 8. 14 (15).

Authors: Noriaki Moriyama, MD, Linda Lindstrom, Mika Laine, MD, PhD.

This single-center, retrospective study is the first study to provide a propensity-matched analysis to compare outcomes following the use of the ProGlide™ and MANTA® VCD's. Additionally, a learning curve analysis was conducted where patients were divided into tertiles based on the procedure date. One hundred sixty three consecutive patients from January 2016 through April 2017 were treated with ProGlide™, while 162 consecutive patients from April 2017 through March 2018 were treated with the MANTA® VCD. Propensity score matching resulted in 111 matched pairs. The main outcomes of bleeding and vascular complications were reported according to VARC-2 definitions.

The table below summarizes a selection of the vascular complication and bleeding rates as reported in Table 3 and 4 of the article.

Clinical Outcomes and Vascular Complications	ProGlide™ (n=111)	MANTA® (n=111)	p Value
Any vascular complication	23 (21%)	16 (14%)	0.21
Major	9 (8%)	8 (7%)	0.79
Minor	14 (13%)	7 (6%)	0.10
Any bleeding complication	37 (33%)	21 (18%)	0.01
Life-threatening or disabling	6 (5%)	5 (4%)	0.75
Major	21 (20%)	11 (10%)	0.05
Minor	11 (10%)	5 (4%)	0.11
Composite endpoint 1 (all-cause mortality, life-threatening or disabling bleeding, major bleeding, and major vascular complications)	30 (27%)	16 (14%)	0.02
Composite endpoint 2 (all-cause mortality, life-threatening or disabling bleeding, major and minor bleeding, major and minor vascular complications, and percutaneous closure device failure)	41 (37%)	21 (19%)	<0.01
Access-site or access-related vascular injury	20 (17%)	9 (8%)	0.04

The authors summarize that "VARC-2 vascular complications occurred less often in the MANTA® VCD group compared to ProGlide™ (14% vs. 21%) but the difference did not reach significance (p=0.21)." VARC-2 bleedings occurred significantly less in the MANTA® VCD group (18% vs. 33%, p=0.01) and composite endpoints 1 and 2 were significantly different in both groups (composite endpoint 1, ProGlide™ vs. MANTA®: 27% vs. 14%, p=0.02, and composite endpoint 2: 37% vs.19%, p<0.01). Additionally, access-site or access-related vascular injury was significant (p=0.04), 17% in the ProGlide™ group and 8% in the MANTA® VCD group. Finally, red blood cell transfusions occurred in 14% of ProGlide™ patients and 4% of MANTA® VCD patients; and length of stay after TAVR for ProGlide™ patients was 5.8±4.8 days, while for MANTA® VCD patients, it was 3.3±7.9 days.

As for the learning curve analysis, no significant differences in outcomes were observed across the three tertiles.

The authors concluded "the rate of VARC-2 vascular complications were comparable between the MANTA® VCD and ProGlide™ groups; however, the MANTA® VCD was associated with a lower rate of access-site or access-related vascular injury and VARC-2 bleeding complications." There were several limitations to this study therefore the authors suggest larger, randomized trials are needed to solidify their findings. ■

2019

Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Percutaneous Vascular Closure Device†

Journal: *Circulation: Cardiovascular Interventions.* July 2019. VOL. 12, NO. 7

Authors: David A Wood, Zvonimir Krajcer, Janarthanan Sathananthan, Neil Strickman, Chris Metzger, William Fearon, Mark Aziz, Lowell F Satler, Ron Waksman, Marvin Eng, Samir Kapadia, Adam Greenbaum, Molly Szerlip, David Heimansohn, Andrew Sampson, Paul Coady, Roberto Rodriguez, Amar Krishnaswamy, Jason T Lee, Itsik Ben-Dor, Sina Moainie, Susheel Kodali, Adnan K Chhatriwalla, Pradeep Yadav, Brian O'Neill, Mark Kozak, John M Bacharach, Ted Feldman, Mayra Guerrero, Aravinda Nanjundappa, Robert Bersin, Ming Zhang, Srinivasa Potluri, Colin Barker, Nelson Bernardo, Alan Lumsden, Andrew Barleben, John Campbell, David J Cohen, Michael Dake, David Brown, Nathaniel Maor, Samuel Nardone, Sandra Lauck, William W O'Neill, John G Webb

This paper summarises the outcomes of the U.S. IDE study of the MANTA® VCD. This was a prospective, multicenter, single-arm study evaluating the safety and effectiveness of the MANTA® VCD. A total of 341 patients were enrolled across 20 centers in North America. Of the 341 patients enrolled, 78 were roll-in patients and 263 patients consisted of the primary analysis cohort (PAC). TAVR procedures were completed in 210 patients (79.8%), and PEVAR/TEVAR procedures were completed in 53 patients (20.2%). Fourty-two operators deployed the MANTA® VCD, all physician operators were initial users and each had at least one roll-in case. The 18 Fr. MANTA® VCD was utilized in 221 cases (84%) and the 14 Fr. MANTA® VCD was used in 42 cases (16%). All adverse events determined by the investigator to be related to the MANTA® VCD, as well as all events that occurred in the ipsilateral MANTA® VCD access site were adjudicated by a clinical events committee to determine if the event met the criteria for IDE defined major and minor complications and VARC-2 major complications.[1a,b] Additionally, all ultrasound studies (required within 48 hours of the index procedure and at 30-day follow-up) were reviewed by an ultrasound core lab.

Average TTH in the PAC was 65±157 seconds, with a median TTH of 24 seconds. Hemostasis was achieved in less than one minute in 227 of 263 patients (86%), and less than 10 minutes in 255 of 263 patients (97%). Technical success, defined as puncture closure obtained without the use of unplanned endovascular or surgical intervention, was achieved in 97.7% of patients in the PAC. A single MANTA® VCD was deployed in 262 of 263 patients (99.6%).

The primary safety endpoint, IDE protocol-defined major complications, occurred in 14 patients (5.3%). There were six patients with major bleeding (2.3%), covered stent in four (1.5%), balloon inflation in two (0.8%), and surgical repair in two (0.8%). IDE protocol-defined minor complications, a secondary safety endpoint, occurred in nine patients (3.4%), with eight (3.0%) patients experiencing pseudoaneurysms and one patient experiencing a transient nerve injury (0.4%). An additional secondary safety endpoint, VARC-2 major vascular complications, occurred

a. Major Complications defined as composite of: i) vascular injury requiring surgical repair/stent-graft; ii) bleeding requiring transfusion; iii) lower extremity ischemia requiring surgical repair/additional percutaneous intervention; iv) nerve injury (permanent or requiring surgical repair); and v) infection requiring IV antibiotics and/or extended hospitalization.

b. Minor complications defined as; pseudoaneurysm, arteriovenous fistula, access site hematoma ≥10 cm, access site–related bleeding after discharge, ipsilateral lower extremity arterial emboli or vein thrombosis, transient access site–related nerve injury, access site wound dehiscence, and localized access site infection.

The table below summarizes the safety and effectiveness results from the article.

Overall Outcomes in PAC (n=263)	
Device Effectiveness Outcomes	
Technical Success, n (%)	257 (97.7%)
Median TTH (seconds)	24
Clinical Safety Outcomes, [N (%)]	
IDE Defined Major Complications (primary)	14 (5.3%)
Major bleeding *	6 (2.3%)
Covered stent	4 (1.5%)
Balloon inflation	2 (0.8%)
Surgical Repair	2 (0.8%)
IDE Defined Minor Complications (secondary)	9 (3.4%)
Pseudoaneurysm	8 (3.0%)
Transient nerve injury	1 (0.4%)
VARC-2 Major Vascular Complications (secondary)	11 (4.2%)
Covered Stent	4 (1.5%)
Major bleeding	3 (1.1%)
Surgical repair	2 (0.8%)
Balloon inflation	2 (0.8%)

* Major bleeding was treated with manual pressure and transfusion. One major bleeding event resulted in RP bleed and death, another was vessel perforation not related to the MANTA® VCD.

in 11 patients (4.2%). This included a covered stent in four patients (1.5%), major bleeding in three patients (1.1%), surgical repair in two patients (0.8%), and balloon inflation in two patients (0.8%). The patients requiring treatment with covered stent, surgery, and balloon were the same between the IDE protocol-defined major complications and VARC-2 major complications. The difference between the two groups was in the major bleeding definition of the IDE protocol defined major complications, which was more stringent and required only one unit transfusion to trigger the complication, while VARC-2 major complications required two units. The authors note, "major bleeding has been reported consistently in the range of 3-15% in multiple prior multi center studies. By comparison, overall major bleeding in this prospective SAFE MANTA Study was 1.1% or 2.3%, depending on the use of VARC-2 or IDE definition."

The authors concluded, "in a selected population, this study demonstrated that the MANTA® VCD can safely and effectively close large bore arteriotomies". ■

† Disclosure(s): This study was sponsored by Teleflex Incorporated or its affiliates. Zvonimir Krajcer, MD and David Wood, MD are paid consultants of and receive payments from Teleflex Incorporated or its affiliates in connection with the MANTA® VCD.

2019

Late Pseudoaneurysm After Access Site Closure with MANTA in Transfemoral Valve Implantation

Journal: *EJVES Short Reports,* 42, 34–36

Authors: Pavel Hoffmann, Ahmed Al-Ani, Thomas von Lueder, Øyvind W. Skoe, Thien T. Tran, Anders Opdahl

This case study summarizes a 73-year-old male who had a history of aortocoronary surgery in 1992, hypertension, diabetes, and atrial fibrillation. The patient presented with increasing chest pain and dyspnea. An angiogram was performed, and it was determined that the patient required aortic valve replacement and underwent a TAVI procedure. Access was made under fluoroscopy distal to the left common femoral artery which measured 7.4 mm in diameter. A 16 Fr. Sentrant™ procedure sheath was used to place a Medtronic Evolut™ PRO 29 mm valve. Fifty milligrams (mg) of protamine was given prior to closure. A 14 Fr. MANTA® VCD was used for closure of the access site and a post closure angiogram showed no bleeding. Both the procedure and the access site closure were described as uneventful. The patient was readmitted to the hospital five weeks after the TAVI for pain in the left groin and symptoms of claudication. A CT showed a pseudo aneurysm at the access site and a dissection distal to the access site. Vascular surgery was performed successfully.

The author acknowledges that a 14 Fr. MANTA® VCD was used to close an access site when a 16 Fr. procedure sheath was used and recommends future closure with an 18 Fr. MANTA® VCD. The author recommends the following future directions:

- Post closure angiogram for percutaneous large bore vascular puncture sites be done in two orthogonal projections
- Use of CT and duplex ultrasound prior to discharge if there are any complications at the access site
- Follow-up duplex ultrasound of the access site one week post TAVR for any patient where a new closure device has been used
- Clinicians should be aware of possible pseudoaneurysms in patients presenting with discomfort from the arterial access site up to several weeks after closure with the MANTA® VCD. ■

2019

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

Journal: *American Journal of Cardiology.* 2019; 00: 1-7

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

This retrospective, single center study evaluated the safety and feasibility of the novel MANTA® VCD compared to the suture-based Prostar™ XL VCD in terms of vascular and bleeding complications as well as mortality, up to 30 days. The data of 366 consecutive patients who underwent transfemoral TAVR using a MANTA® or Prostar™ XL VCD were analyzed. The MANTA® VCD was used in 168 patients and the outcomes were compared to 198 ProStar™ XL patients. There were six operators who were proctored for three cases when first deploying the MANTA® VCD.

Primary outcome measures included: acute closure success and occurrence of any access site-related vascular injury, as well as major and life-threatening/disabling bleeding complications according to the most recent VARC-2 definition. Secondary outcomes included all vascular and bleeding complications as well as all-cause mortality at 30-day follow-up.

The table below summarizes a selection of clinical outcomes from Table 4 of the article.

Clinical Outcomes and Access Site Related Complications

	MANTA® (n=168)	Prostar™ XL (n=198)	p Value
Major bleeding, n (%)	1 (0.6)	2 (1.0)	0.661
Minor bleeding, n (%)	23 (13.7)	39 (19.7)	0.080
Major vascular complications, n (%)	1 (0.6)	3 (1.5)	0.109
Minor vascular complications, n (%)	18 (10.7)	36 (18.2)	0.003
Hospitalization stay	5.26+3.3	6.25+3.4	0.006
30-day all-cause mortality	6 (3%)	4 (2.0%)	0.278

Successful closure was achieved in both the MANTA® and Prostar™ XL VCD groups (98.8% vs. 98.5% respectively). VARC-2 defined major vascular and bleeding complications was similar in both groups, 0.6% versus 1.5% (p = .109) and 0.6% versus 1.0% (p = 0.661); however, minor vascular complications occurred more frequently in the Prostar™ XL group compared to the MANTA® VCD group (10.7 vs 18.2 %, p = 0.003). The authors further comment that more minor complications were seen with closure of the 14 Fr. MANTA® VCD. The all cause mortality was similar between groups, but the hospitalization length of stay was shorter in the MANTA® VCD group.

The authors comment in the article that in their early MANTA® VCD experience, small leakage was seen in the control angiography but with no external bleeding. It was later determined that those patients presented hours later with minor bleeding at the access site. The hospital adjusted their local policy by adding a preventative dedicated compression bandage for 12 hours which turned out to be effective in preventing delayed bleeding. In this study, small leakage was seen in 19.6% of patients. The authors state that routine control rotational angiography after MANTA® VCD closure helped to better understand the sealing process and improved the decision making for postprocedural management. It is important to note in this study, post closure angiography was not used in the Prostar™ XL group. The authors concluded that "the MANTA® VCD seems to be a safe and feasible option to obtain hemostasis in patients undergoing a transfemoral TAVI procedure". They suggest performing control rotational angiography in postprocedural management after MANTA® VCD implantation." ■

2020

Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Vascular Closure Device During Percutaneous EVAR and TEVAR Procedures

Journal: *Journal of Endovascular Therapy.* 2020

Authors: Zvonimir Krajcer, MD, David A. Wood, MD, Neil Strickman, MD[1], Nelson Bernardo, MD, Chris Metzger, MD, Mark Aziz, MD, J Michael Bacharach, MD MPH, Aravinda Nanjundappa, MD, John Campbell, MD, Jason T. Lee, MD, Michael D. Dake, MD, Alan Lumsden, MD, and Samuel Nardone, BS on behalf of the SAFE MANTA Study Investigators

The SAFE trial was a prospective, single arm, multicenter IDE trial conducted at 20 centers in the US and Canada. This publication looks at a subset of the primary analysis cohort (PAC) patients in the SAFE trial that underwent PEVAR (n=51) or TEVAR (n=2) as opposed to TAVR (n=210). The PEVAR/TEVAR patients represented 20.2% of the total SAFE patient population. The SAFE trial recommended that patients undergo ultrasound to guide access and mandated only one femoral access sites be closed with the MANTA® VCD. A CTA was required to be performed prior to the procedure to determine target artery diameter and level of calcification. An angiogram was required post closure to examine the closure site. In addition, an ankle brachial index (ABI) was required prior to and post closure, pre discharge, and at both the 30 and 60-day follow-up appointments. Additionally, a duplex ultrasound of the access site was required within 48 hours of MANTA® VCD deployment and again at the 30-day follow-up appointment. Primary effectiveness outcome was TTH measured from the time of withdraw of the MANTA® VCD sheath to confirmed hemostasis. The primary safety endpoint was IDE defined major complication and the secondary safety endpoints were IDE defined minor complications and VARC-2 major complications. An additional secondary endpoint was technical success measured as access closure with the MANTA® VCD without use of endovascular or surgical intervention. The primary and secondary endpoints were measured at the time of closure up to the 30-day follow-up appointment.

The table below summarizes the safety and effectiveness of the PEVAR/TEVAR group within the SAFE MANTA study.

	EVAR Patients [N (%)] (n=53)	**Overall SAFE-MANTA** [N (%)] (n=263)
Median Time to Hemostasis (minutes)	0.32	0.40
Major IDE Protocol Complications	1 (1.9)	14 (5.3)
Minor IDE Protocol Complications	3 (5.7)	9 (3.4)
VARC-2 Major Complications	1 (1.9)	11 (4.2)

The mean TTH was 35±91 seconds (.58 minutes) and the median TTH was 19 seconds (.32 minutes). There was one event defined by the protocol to be a major event and a VARC-2 major complication, this patient required a covered stent to repair an occluded CFA. There were three minor complications, all pseudoaneurysms, one was seen prior to discharge, one at the 30-day follow-up appointment, and one at the 60-day follow-up appointment. One was treated with compression and the other two required no treatment. Technical Success was seen in 52 of 53 patients (98%).

The authors concluded "the MANTA® VCD demonstrated a short time to hemostasis and low complication rates in PEVAR/TEVAR patients compared to published results reported for other percutaneous closure devices". Additionally, the safety and effectiveness data in the PEVAR/TEVAR patients were comparable to the outcomes of the overall SAFE MANTA PAC. The authors further comment, "the MANTA® VCD may be a possible solution to providing reliable closure with a single percutaneous device for PEVAR/TEVAR procedures as well as other large-bore catheter procedures." ■

† Disclosure(s): This study was sponsored by Teleflex Incorporated or its affiliates. Zvonimir Krajcer, MD and David Wood, MD are paid consultants of and receive payments from Teleflex Incorporated or its affiliates in connection with the MANTA® VCD.

NOTES

INDICATIONS FOR USE: The MANTA Vascular Closure Device is indicated for closure of femoral arterial access sites while reducing time to hemostasis following the use of 10-20F devices or sheaths (12-25F OD) in endovascular catheterization procedures.

CONTRAINDICATIONS: There are no known contraindications to the use of this device.

WARNINGS: 1) Do not use if the puncture site is proximal to the inguinal ligament or above the most inferior border of the epigastric artery (IEA), as this may result in retroperitoneal bleeding. 2) Do not use in patients with severe calcification of the access vessel and/or common femoral artery stenosis resulting in a vessel <5mm in diameter for the 14F MANTA or <6mm in diameter for the 18F MANTA, or >50% diameter femoral or iliac artery stenosis. 3) Do not use in patients with severe peripheral vascular disease, as evidenced by severe claudication when ambulating <100 feet, weak or absent pulses in the affected limb, or ABI <0.5 at rest. 4) Do not use if the temperature indicator dot on package has changed from light gray to dark gray or black. 5) Do not use if the package is damaged or any portion of the package has been previously opened. 6) Do not use if the items in the package appear damaged or defective in any way. 7) Do not REUSE or RESTERILIZE. The MANTA Device is single use only. The MANTA Device contains bioresorbable materials that cannot be reused or re-sterilized. Reuse or re-sterilization may cause degradation to the integrity of the device, leading to device failure which may result in patient injury, illness, or death. 8) Do not use the MANTA Device where bacterial contamination of the procedure sheath or surrounding tissues may have occurred, as this may result in infection. 9) Do not use if the MANTA delivery system becomes kinked. 11) Do not inflate a contralateral balloon in the femoral or iliac artery during MANTA Sheath exchange or the MANTA Closure procedure. 12) Do not use MANTA if there has been a femoral artery puncture in same vessel within the prior 30 days, recent femoral artery puncture in same groin that has not healed appropriately, and/or recent (<30 days) vascular closure device placement in same femoral artery. 13) Do not use if the puncture site is at or distal to the bifurcation of the superficial femoral and profunda femoris artery, as this may result in the (a) anchor catching on the bifurcation or being positioned incorrectly, and/or (b) collagen deposition into the vessel. 14) Do not use if there is difficult dilation from initial femoral artery access (e.g., damaging or kinking dilators) while step dilating up to the large-bore device. Difficult dilation of the puncture tract due to scar tissue may lead to swelling of surrounding tissue, thus compromising the accuracy of the puncture depth determined during the puncture location procedure. 15) Do not use if sheath insertion is in a vessel other than the femoral artery. 16) Do not use if there is marked tortuosity of the femoral or iliac artery. 17) Do not use if the patient has marked obesity or cachexia (BMI >40 kg/m2 or <20 kg/m2). 18) Do not use if the patient has post-procedure blood pressure >180 mm Hg that cannot be lowered prior to access site closure. 19) Do not use in patients who cannot be adequately anticoagulated for the procedure. 20) Do not use the MANTA Device in patients with known allergies to bovine products, collagen and/or collagen products, polyglycolic or polylactic acid polymers, stainless steel or nickel.

PRECAUTIONS: 1) The MANTA Device should only be used by a licensed physician or healthcare provider trained in the use of this device. 2) This device contains a small radiopaque stainless-steel lock that is implanted in the puncture tract. See MRI information in these instructions for use and patient implant card. 3) In the event that bleeding from the femoral access site persists after the use of the MANTA Device, the physician should assess the situation. Based on the physician assessment of the amount of bleeding, use manual or mechanical compression, application of balloon pressure from a secondary access site, placement of a covered stent, and/or surgical repair to obtain hemostasis.

POTENTIAL ADVERSE EVENTS: The following potential adverse events related to the deployment of Vascular Closure Devices have been identified: 1) Ischemia of the leg or stenosis of the femoral artery. 2) Local trauma to the femoral or iliac artery wall, such as dissection. 3) Retroperitoneal bleeding as a result of access above the inguinal ligament or the most inferior border of the epigastric artery (IEA). 4) Perforation of iliofemoral arteries, causing bleeding/hemorrhage. 5) Thrombosis formation or embolism. 6) Nerve damage or neuropathy. 7) Other access site complications leading to bleeding, hematoma, pseudoaneurysm, or arterio-venous fistula, possibly requiring blood transfusion, surgical repair, and/or endovascular intervention. Potential Adverse Events associated with any large bore intervention, including the use of the MANTA Vascular Closure Device, include but are not limited to: Arterial damage; Arterio-venous fistula; Bradycardia; Compartment syndrome; Death related to the procedure; Deep vein thrombosis; Ecchymosis; Edema; Infection at the puncture site which may require antibiotics or extended hospitalization; Inflammatory response; Late arterial bleeding; Oozing from the puncture site; Pressure in groin/access site region; Vessel laceration or trauma; Wound dehiscence.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.
Please see the instructions for use for complete product information.

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