STRUCTURAL HEART
2021, VOL. 5, NO. 2, 186–191
https://doi.org/10.1080/24748706.2021.1872818

ORIGINAL RESEARCH

Large Bore Vascular Access Closure Device Strategies

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ABSTRACT

Background: The optimal strategy for large bore vascular closure following TAVR is a matter of contention as major bleeding and vascular complications remain a challenge. We compared three strategies for post-TAVR vascular closure in terms of safety and efficacy: a dual ProGlide-based strategy, a hybrid strategy of ProGlide and Angio-Seal, and a MANTA strategy.

Methods: Patients were enrolled in one of the three strategies: two ProGlides, a single ProGlide with an 8 F Angio-Seal, or a single 18 F MANTA.

Results: In total, 172 patients were enrolled in this study: 86 in the MANTA group, 40 in the ProGlide/Angio-Seal group, 46 in the dual ProGlide group. Hemostasis was achieved in 95% of patients. MANTA was associated with vessel occlusion in 2% of cases. The dual ProGlide group required an extra device to achieve hemostasis in 35% of cases.

Conclusion: The three strategies of MANTA, dual ProGlides, or ProGlide/Angio-Seal are all effective, but there are important differences between them which mandate careful consideration by operators.

Abbreviations: TAVR: Transcatheter Aortic Valve Replacement; VCD: Vascular Closure Device; CT: Computed Tomography; DSA: Digital Subtraction Angiography

ARTICLE HISTORY Received 22 August 2020; Revised 30 November 2020; Accepted 23 December 2020

KEYWORDS Vascular closure device; ProGlide; Angio-Seal; MANTA; TAVR

Introduction

The optimal strategy for femoral artery closure following large bore access during structural heart intervention remains an area of clinical uncertainty with a number of percutaneous vascular closure devices (VCDs) available. Successful vascular closure is tied to patient prognosis following Transcatheter Aortic Valve Replacement (TAVR) and bleeding is a well-known predictor of adverse clinical outcomes.[1] Despite this, even in contemporary randomized trials, major bleeding still occurs at a rate of 5–15%.[1,2] In broad terms, VCDs can be divided into those that are suture based and those that are collagen-plug based. The prevailing strategy at present is based on the preclosure method using the ProGlide (Abbott Vascular, Santa Clara, CA, USA) vascular closure device, sometimes used in combination with Angio-Seal (Terumo, Somerset, NJ, USA). MANTA (Essential Medical Inc., Exton, PA, USA) is a newer device that has been shown to be safe and efficacious in the initial clinical experience.[3] Despite the evolution of percutaneous and transcatheter structural heart interventions and the reduction in the size of their associated equipment, vascular complications remain a challenge when employing any of the above VCDs: these may manifest as either bleeding complications related to complete or partial failure of the VCD strategy, or ischemic complications due to partial or complete occlusion of the access site artery. Such adverse events inevitably are associated with increased length of stay, blood transfusions, open surgical repairs, and ultimately an increased risk of short- and long-term mortality.[4]

A recent meta-analysis demonstrated the pooled rate of independently adjudicated major vascular complications after transfemoral TAVR was 7.7%.[5] In most contemporary trials, major bleeding in transfemoral TAVR has been reported at 8–11% using VCDs including ProGlide.[6] With respect to MANTA, in particular, bleeding rates in TAVR patients have been reported at 2–10%[7,8] and vascular complication rates are in the order of 2–8%[9,10] though there is a dearth of literature given the relative novelty of this VCD.

The aim of the present study was to enroll consecutive patients undergoing transfemoral TAVR into a non-randomized cohort in order to compare three distinct VCD strategies in terms of safety and efficacy: a ProGlide-based strategy, a hybrid strategy of ProGlide and Angio-Seal, and a MANTA strategy.

Materials and methods

Patient population, study design and inclusion criteria

Barts Heart Center is a major quaternary referral center that performs over 400 TAVRs per year. We performed an observational cohort study between March 2019 and November 2019 to

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Supplemental data for this article can be accessed on the publisher's website.

determine the safety and efficacy of the three main VCD strategies that have been described and are routinely performed in our center. Consecutive patients were enrolled and the only patients excluded were those that required conversion to a sternotomy or who died intra-procedure. Other patients with adverse characteristics for femoral access were not excluded from the study; however, they may have undergone alternative access TAVI during the study period. Ethics approval and sponsorship were obtained from Queen Mary University London. All subjects provided written, informed consent.

Procedural details

The strategies were defined by the operators originally planned strategy for closure, irrespective of additional devices that may have been subsequently used: two ProGlides deployed with preclosure, a single ProGlide deployed with preclosure combined with an 8 F Angio-Seal after removal of the TAVR delivery sheath, or a single 18 F MANTA device. A more detailed description of device deployment techniques has been described elsewhere.[8,11] Heparin reversal with protamine was standard before VCD use. The choice of strategy was left to the operator's preference and operators were able to use all available clinical information to inform their selection of closure device including femoral artery size and calcification based on pre-procedural computed tomography (CT) and intraprocedural ultrasound. A total of 10 different operators were involved in our study, divided into four teams: two of the teams were led by operators who were proctored in the usage of the MANTA device and these two teams used the MANTA device as a default strategy, except in cases where it was deemed anatomically unsuitable (mean vessel diameter <7.5 mm and severe calcification) in which case one of the other two strategies was used, at the operator's discretion. TAVR procedures and access sites were planned after the evaluation of CT scans. Vessel calcification was assessed for all patients on CT and all femoral artery punctures were performed under ultrasound guidance. Digital Subtraction Angiography (DSA) was performed on all patients after VCD deployment to assess efficacy, demonstrate vessel patency and grade vessel stenosis.

Endpoints

The primary outcomes of this study were the need for further vascular intervention, major bleeding, and major vascular complications according to the VARC-2 definition criteria.[12] Secondary outcomes included the use of additional VCDs, VARC-2 minor vascular complications, femoral/iliac arteries stenosis or dissection, and access site infection. Time to hemostasis was defined by the amount of time manual pressure was required from the final deployment of the VCD to hemostasis at the access site.

Statistical analysis

Baseline patient characteristics and outcomes are reported as mean ± standard deviation (SD), median (interquartile range) or number and percentage (%) where appropriate. All statistical analyses were performed using SPSS statistics software (v 20.0, IBM, Chicago, IL, USA) and all figures were made using GraphPad Prism v8 (GraphPad Software, La Jolla, CA, USA). Categorical data were analyzed using Fisher's exact test or chi-square testing with data presented as numbers or percentages as appropriate. Multivariate regression models were developed to assess the association between type of vascular closure device and procedural complications. A p value <0.05 was considered statistically significant.

Results

Study population

Between March 2019 and November 2019, 172 patients were enrolled in this study. Of these, 86 were in the MANTA group, 40 in the ProGlide/Angio-Seal group, and 46 in the dual ProGlide group. Baseline characteristics are summarized in Table 1.

Procedural outcomes

Hemostasis using VCDs was achieved in 95% of patients. There were no infections associated with the use of any of the VCDs. The relevant procedural outcomes for our cohort are summarized in Table 2 and further procedural characteristics are available in Supplementary Table 1.

Major vascular complications

VARC-2 major vascular complications occurred in 12% of the MANTA group, 13% of the ProGlide/Angio-Seal group, and 2% of the dual ProGlide group (p = 1). One patient in the study required unplanned open surgical repair following a failed MANTA VCD. Covered stents were deployed in 3% of the Angio-Seal/ProGlide group versus no cases in the other two groups. Peripheral angioplasty was required in 3% of cases of the MANTA group (for severe vessel stenosis or occlusion) and no cases in the other two groups (see Supplementary Table 2). VARC 2 major bleeding occurred in 5% of the MANTA group while there was no major bleeding in the other two groups (p = 0.081) (see Table 2). A logistic regression model was also used to determine the effect of key predictors of each complication including the type of device and other clinical factors which suggested that MANTA (Odds Ratio [OR] 2.255, p = 0.176) and vessel calcification more than mild (OR 2.706, p = 0.058) were the strongest predictors of vascular complications (see **Supplementary Table 3)**.

Minor vascular complications

VARC 2 minor vascular complications occurred least frequently in the Angio-Seal/ProGlide group compared with the MANTA and dual ProGlide groups (3% vs 6% vs 9%, p = 0.577). Overall bleeding rates were not significantly different between the groups (13% in the MANTA group, 5% in the ProGlide/Angio-Seal group, and 9% in the dual ProGlide group, p = 0.448).

Table 1. Baseline characteristics.

Variable		MANTA (n = 86)	ProGlide and Angio-Seal (n = 40)	Dual ProGlide (n = 46)	P value
Age (years)		80 (77–86)	84 (82–87)	86 (78–87)	0.835
Body mass index (kg/m^2)		27.5 (25.2–30.6)	26.1 (23.1–30.5)	26.2 (22.2–31.8)	0.395
eGFR (ml/min)		56.2 ± 19.3	55.8 ± 16.7	62.4 ± 19.4	0.503
Diabetes mellitus		16 (19%)	9 (23%)	7 (15%)	0.688
Previous myocardial infarction		10 (12%)	3 (8%)	5 (11%)	0.852
Liver disease		1 (1%)	1 (3%)	2 (4%)	0.452
Hypertension		70 (82%)	34 (86%)	32 (69%)	0.238
Vessel calcification	None	22 (26%)	13 (33%)	13 (28%)	0.195
	Mild	53 (62%)	19 (48%)	19 (41%)	
	Moderate	6 (7%)	6 (15%)	6 (13%)	
	Severe	4 (5%)	2 (5%)	6 (13%)	
Mean vessel diameter (mm)		8 (7–9) [§]	7.5 (7.0–8.0)	7 (7–8)	0.001

Notes. Data is represented as median (interquartile range), mean ± standard deviation or number (percentage). eGFR = Estimated Glomerular Filtration Rate. DM = Diabetes Mellitus. Vessel Calcification is based on the degree of calcium at the chosen access site artery on CT scan prior to index procedure.
[§]pairwise comparison between MANTA and dual ProGlide group was statistically significant.

Table 2. Procedural complications.

Variable	MANTA (n = 86)	ProGlide and Angio-Seal (n = 40)	Dual ProGlide (n = 46)	P value
Additional device	1 (2%)	2 (5%)	30 (35%)	<0.005
Puncture site occlusion	2 (2%)	0 (0%)	0 (0%)	<0.005
Hematoma present	12 (14%)	8 (20%)	2 (4%)	0.086
Minor vascular access complication	5 (6%)	1 (3%)	4 (9%)	0.577
Major vascular access complication	10 (12%)	5 (13%)	1 (2%)	0.531
Any bleeding	11 (13%)	2 (5%)	4 (9%)	0.448
VARC 2 major bleeding	4 (5%)	0 (0%)	0 (0%)	0.081
Cost per patient (£)	435.58 ± 57.75 [§]	432.00 ± 8.15 [⌘]	532.83 ± 110.88	<0.005

Notes. Procedural complications are shown as median (interquartile range), mean ± standard deviation and number (percentage) as appropriate.
[§]difference between MANTA and dual ProGlide group is statistically significant.
[⌘]difference between ProGlide and Angio-Seal and dual ProGlide group is statistically significant.

Efficacy

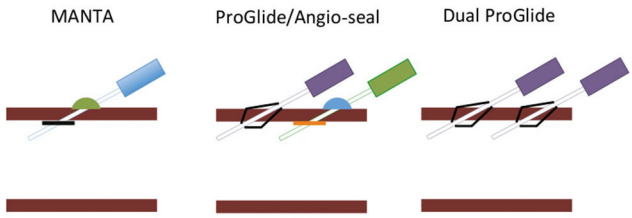
Median time to hemostasis was 2 minutes in the MANTA group, 3.5 minutes in the ProGlide/Angio-Seal group, and 2 minutes in the dual ProGlide group ($p = 0.321$).

Additional devices were needed more frequently in the dual ProGlide group compared with the ProGlide/Angio-Seal and MANTA groups (35% vs 5% vs 2%, $p < 0.005$). The additional devices in the dual ProGlide group were Angio-Seal (30%), ProGlide (2%), MANTA (2%); in the ProGlide/Angio-Seal group they were ProGlide (2.5%), MANTA (2.5%); in the MANTA group, there was ProGlide only (2%).

Discussion

This is to our knowledge, the first study comparing, in a real-world setting, the safety and efficacy of three distinct strategies (MANTA, dual ProGlides, or ProGlide/Angio-Seal) for large bore femoral access closure following TAVR. Our trial is also notable for the use of routine peripheral angiography in the identification of anatomical complications including vessel stenosis, ischemia, and bleeding. We demonstrated three important differences between the strategies (Figure 1). Firstly, the dual ProGlide strategy was associated with a low complication rate but also frequently required additional devices. Secondly, the MANTA device whilst effective was associated with the most complications, including vessel occlusion requiring additional intervention and surgical bail-out. Finally, the ProGlide/Angio-Seal strategy was effective and demonstrated an acceptable safety profile.

MANTA is a relatively new vascular access closure device that employs a collagen plug and anchor to seal the access point. Several studies have assessed its safety and efficacy—a majority of which had comparable findings to our study. The SAFE-MANTA trial[13] is the largest prospective, multicenter study of this device. In this single-arm study with a total of 263 patients, the primary endpoint of time to hemostasis (65±158 seconds) and the secondary endpoint of technical success (97.7%) were both comparable to our study. The rate of VARC-2 major complications within 30 days was 4.2% and minor complications 3.4%, which is also comparable although slightly lower than our study. Similarly, another recent trial using MANTA demonstrated major and minor complications occurred at a rate of 7% and 4%, respectively, with complete hemostasis within 5 minutes occurring in 87% of patients.[14] Biancari et al. reported in a retrospective study of 222 patients undergoing TAVR at three Finnish hospitals; a major vascular complication rate and life-threatening bleeding rate were 9.3% in 107 patients who underwent vascular closure with MANTA.[7] In a propensity matched study of VCDs, Moriyama et al. showed that major vascular complications were similar between MANTA and ProGlide groups (7% vs. 8%, $p = 0.79$).[9] Interestingly, some studies have shown lower rates of complications: de Palma et al. showed in



Additional devices	2%	5%	35%
Time to haemostasis	2 minutes	3.5 minutes	2 minutes
Puncture site occlusion	2%	0%	0%
VARC-2 major bleeding	5%	0%	0%

Figure 1. Vascular closure devices are broadly divided into suture based (such as ProGlide) and plug based (such as Angio-Seal and MANTA) strategies. The table compares three strategies from this study (Dual ProGlides, Hybrid Angio-Seal and ProGlide, and MANTA) with respect to our findings of the main differences between groups. There was a non-significant trend toward longer time to hemostasis with the hybrid strategy, while the dual ProGlide strategy carried a significant association with the need for additional devices. The MANTA strategy resulted in a significantly higher occurrence of VARC-2 bleeding and of abrupt vessel closure at the puncture site.

a consecutive cohort of 346 patients undergoing transfemoral TAVR, MANTA was successful in all with a mean time to hemostasis of 42 ± 115.5 seconds. In comparison to suture-based closure with Prostar XL within the same center, the composite of all-cause mortality and major complications related to the main access site was similar between both groups (1.1% vs 1.9%, $p = 0.61$). Major bleeding occurred less frequently with MANTA (1.1% vs 7.8%, $p = 0.02$).[8] A smaller multicenter prospective study also showed relatively low major vascular (2%) and major bleeding (2%) rates in 50 patients who received MANTA device; the mean time to hemostasis was 2 min, 23 s. One patient had a major vascular and major bleeding complication.[10]

Recently, plausible mechanistic explanations for MANTA device failure have been described and it has been suggested that the risk of vessel occlusion due to the nature of the size of the device's toggle may necessitate avoiding its use in smaller iliofemoral arteries.[14] Our data support the notion that distinct patterns of MANTA device failure are observed in a real-world setting including common femoral artery occlusion, perivascular bleeding, and pseudoaneurysm formation. We have previously demonstrated the use of sonographic guidance when utilizing MANTA to prevent the most significant device failures, which is supported by recently published data.[15,16] Sonographic guidance was not used in this early experience. Clearly, an operator learning curve may account for complications with MANTA in our study; however, the ease of deployment is one of the major upsides to this device and the mechanistic risk of vessel closure due to femoral artery occlusion remains regardless of operator experience due to the nature and size of the plug-based device.

The dual ProGlide strategy with preclosure remains the prevailing method in the current TAVR era. However, VARC-2 vascular complication rates occur in 5% to 20% of patients, and operator experience is known to be a variable[17,18]; overall, the frequency of life-threatening or disabling bleeding even in large trials of intermediate-risk TAVR patients remains at 4–11%.[1,19] A recent retrospective, propensity score-matched trial comparing MANTA and ProGlide in patients who underwent TF-TAVR found that MANTA was associated with a lower rate of VARC-2 bleeding (10% vs 20%, $p = 0.05$) and access site or access related vascular injuries (8% vs 17%, $p = 0.04$) – of note, the only ischemic complication in the trial occurred in the MANTA group.[9] A subgroup analysis of the BRAVO-3 randomized control trial found that the rate of major vascular complications for the ProGlide strategy was 7% and major bleeding (BARC> 3b) was 8%.[6] Our study reflects similar rates of complications in the ProGlide group but the novelty of our data is in the reported use of extra devices which we found to occur in a substantial proportion of patients. Nonetheless, the requirement of an additional device that does not translate into an adverse clinical event for the patient is a substantially smaller penalty than a bleeding or ischemic event related to device failure. In this context, the numerically higher incidence of VARC-2 major bleeding, peripheral angioplasty, and surgical repair with the MANTA group in our study is of more concern in its clinical implications that the high rate of additional device requirement in the dual ProGlide group. Indeed, the use of a single ProGlide as a provisional strategy prior to consideration of the use of an additional device is increasingly recognized as a valid strategy.[20]

The ProGlide/Angio-Seal strategy has been described in the literature previously, but limited data have become available recently in the setting of large bore femoral access for TAVR specifically. Al-Ani et al. demonstrated safety and efficacy in this context, with successful hemostasis without major vascular or bleeding complications in 97.3% of patients.[21] Our data support the validity of this strategy as being comparable in safety and efficacy. It is likely that the differences in the use of covered stents in this study compared to our trial can be attributed to a combination of operator preference for management of vascular complications, in combination with the inherent requirement of withdrawal of the guidewire from the femoral artery during Angio-Seal deployment, resulting in a need for treatment via an "up and over" technique from the contralateral femoral artery. This contrasts with the adjunctive device use in the dual ProGlide group which resulted in substantial use of a device via the ipsilateral femoral artery as guidewire position is maintained. It was also notable in our study that peripheral angioplasty for severe stenosis or vessel occlusion was only

required in the MANTA group and this reflects the known ischemic risk with this device based on the mechanisms that have been described.

Our study is not without limitations. Firstly, it is a single-center study and is limited by a small sample size – some of the differences between groups, in particular, the trend toward more complications with MANTA may not have reached statistical significance due to a lack of power. Secondly, bias, especially from operator differences and unmeasured confounders cannot be eliminated as it is non-randomized and observational. Additionally, the operators involved had considerably more experience with the ProGlide and Angio-Seal VCDs than the MANTA VCD at the time of the study. It should also be noted the 18 F MANTA device was the only device used, and therefore no comment can be made on the 14 F MANTA device from this study. Finally, our logistic regression model which was used to assess the impact of MANTA and vessel calcification on vascular complications should be interpreted with caution as the number of events for each complication was low, thus limiting the number of variables included in the model.

Conclusion

Optimizing vascular closure strategies for large bore arterial access is a key step in improving clinical outcomes from transcatheter cardiac procedures. Our study demonstrates that there are important differences in outcomes and safety profiles between vascular closure strategies which mandate careful consideration by operators and individualization to case specifics when choosing between them.

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Funding

The authors have no funding to report.

Disclosure statement

The authors have no conflicts of interest to report.

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