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Original Research

A Comparison of Efficacy, Safety and Cost Between MANTA™ and Proglide Vascular Closure Devices Following Transfemoral Transcatheter Aortic Valve Implantation

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ABSTRACT

Aims

Access site vascular complications remain a recognised complication following transcatheter aortic valve implantation (TAVI). Suture-based vascular closure devices (VCDs) such as ProGlide® (Abbott Vascular Inc., Santa Clara, CA, USA) are widely used in order to achieve rapid haemostasis. The MANTA™ (Essential Medical Inc., Malvern, PA, USA) is a collagen plug-based VCD which can be used as an alternative to traditional suture-based devices, but is significantly more expensive per-unit. We compare the efficacy, safety and total cost associated with the use of the MANTA™ and ProGlide® VCDs.

Methods

This retrospective study included all consecutive patients who underwent transfemoral (TF) TAVI between November 2017-June 2018. The primary endpoints were primary access site-related VARC-2 vascular complications, VARC-2 bleeding and the overall per-patient cost incorporating treatment for complications or use of additional VCDs.

Results

A total of 136 patients were included in this study; 86 in the ProGlide® group and 50 in the MANTA™ group. Baseline characteristics of the two groups were well-matched. Three patients in the ProGlide® group required surgical repair compared to none in the MANTA™ group. However, no significant differences were observed with respect to overall primary access site-related VARC-2 vascular complications (10.5% *vs.* 10%; p=0.93) or VARC-2 bleeding (9.3% *vs.* 4.0%; p=0.25). There was no significant difference in the mean cost per patient when taking into consideration the use of additional VCDs and treatments for vascular complications (£568.79 *vs.* £599.95; p=0.90).

Conclusion

The use of the MANTA™ VCD following TF TAVI is cost-neutral compared to ProGlide® VCDs, whilst being associated with no increase in VARC-2 vascular or bleeding complications.

Keywords

Transcatheter valve interventions; Vascular complications; Vascular closure devices (VCD).

INTRODUCTION

Improvements in device technology and increasing procedural familiarity have allowed for an expansion in the use of transcatheter aortic valve intervention (TAVI). It is advocated by the European Society of Cardiology (ESC) as a viable alternative to surgical aortic valve replacement (SAVR) for selected patients at intermediate surgical risk.[1] Furthermore, recent trials have shown promising results with the use of transfemoral (TF)-TAVI in low surgical risk cohorts.[2,3] The ever-broadening indications for TAVI necessitate a clearer understanding of the risks and complications associated with the procedure. Access site vascular complications remain relatively frequent following TF-TAVI, with a reported incidence of between 4% and 19%.[4] Notably, these complications are associated with significant morbidity as well as increased mortality.[5] Suture-based vascular closure devices (VCD) such as ProGlide® (Abbott Vascular Inc., Santa Clara, CA, USA) are widely used in order to achieve rapid haemostasis following TF-TAVI,

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and have been demonstrated to reduce the rate of vascular complications.[4] However, failure to achieve adequate haemostasis following their use occurs in 4-9% of cases, and can require vascular surgical intervention.[6]

The MANTA™ (Essential Medical Inc., Malvern, PA, USA) is a relatively novel, collagen plug-based VCD which can be used as an alternative to traditional suture-based devices. Previous studies have demonstrated encouraging results, with vascular complication rates equivalent-to or lower-than ProGlide following TF-TAVI7-9. It has also been shown to reduce the need for additional VCDs in order to achieve haemostasis.[7] However, one of the barriers to widespread use of the MANTA™ device is its expense relative to suture-based VCDs; the cost of a MANTA™ device is approximately 5-times the cost of a single ProGlide. This study aims to compare not only the efficacy and safety of ProGlide® and MANTA™ VCDs following TF-TAVI, but also the total cost associated with the use of both devices, when taking into consideration the requirement for additional VCDs and/or treatment of complications.

MATERIALS AND METHODS

This was a retrospective, cohort study undertaken at Leeds Teaching Hospitals NHS Trust (LTHT), a tertiary referral centre for cardiology and cardiac surgery in the United Kingdom. It was designed and reported using the STROBE guidelines.[8]

Participants

All consecutive patients who underwent TAVI between November 2017 and June 2018 were screened for inclusion in the study. The timeframe was selected since it incorporated the first 50 MANTA™ VCD cases at our institute. The inclusion criteria were TF-TA™VI with ProGlide or MANTA™ VCDs. Patients who underwent non-TF-TAVI or required planned femoral surgical cut-down were excluded.

Procedures

The decision to treat patients with TF TAVI was made on a case-by-case basis by the Heart Team following analysis of computerised tomography (CT) scans to ensure adequate vascular access. All procedures were carried out under conscious sedation or general anaesthesia (GA). Vascular access was gained under either fluoroscopic or ultrasound guidance. Unfractionated heparin (UFH) was used in all procedures, with a target activated clotting time (ACT) of >250 seconds. Patients were pre-loaded with 300 mg Aspirin prior to TAVI and maintained on 75 mg once daily thereafter.

For patients in the ProGlide group, 2 ProGlide VCDs were deployed at the beginning of the procedure into the common femoral artery (pre-closure) at the 2 o'clock and 10 o'clock positions. If a third ProGlide VCD was needed, this was deployed at the 12 o'clock position. Additional ProGlide VCDs were deployed at the end of the procedure if required for satisfactory haemostasis (post-closure). The MANTA™ VCD comes in two sizes (14-F and 18-F) and can close arteriotomies of upto 22-F. It comprises a resorbable polymer intra-arterial toggle connected to an extra-arterial hemostatic bovine collagen pad by a non-resorbable polyester suture, and secured with a stainless-steel suture lock. Deployment depth was ascertained at the beginning of the procedure by use of a graduated 8-F puncture dilator. Following completion of the TAVI, the procedural sheath was exchanged for the MANTA™-sheath and the closure unit inserted and withdrawn up to the predetermined deployment level. The toggle was released, assembly component withdrawn, and collagen pad secured onto the outer arterial wall by the stainless-steel lock.

In all cases, haemostasis was assessed *via* use of digital subtraction angiography (DSA). In the ProGlide group, protamine was administered at the discretion of the operator if DSA demonstrated contrast extravasation. For the MANTA™ group, protamine administration was required for all patients.

Variable and Data Sources

The institutional TAVI database was used to identify all patients who underwent TF-TAVI. Once patients had been identified, all clinical and outcome data was retrieved from electronic patient records. Data included patient demographics (age, sex), comorbidities, procedural information (date of TAVI, VCDs used, complications), and outcomes (post-procedure complications, blood transfusions, length of hospital stay, mortality). The cost of devices was obtained from the local procurement team, whilst estimated costs of additional treatments were obtained from our institute's patient-level information and costing systems (PLICS).

Endpoints

The primary endpoints were:

- Primary access site-related Valve Academic Research Consortium (VARC)-2 vascular complications.
- Primary access site-related VARC-2 bleeding complications.
- Overall per-patient cost associated with the use of VCDs, incorporating treatments for complications or use of additional VCDs.

The secondary endpoints were:

- Requirement for primary access site endovascular intervention (excluding balloon angioplasty)
    - Requirement for primary access site surgery
    - Length of hospital stay post-TAVI
    - All-cause 30-day mortality

Statistical Analysis

Statistical analysis was undertaken using Microsoft Excel for Mac (version 15.4). Continuous variables are presented as mean +/- standard deviation and were compared using 2-tailed student's *t*-test. Categorical variables are presented as counts and percentages and were compared using the chi-squared test. *p*-values of less than 0.05 were deemed to be of statistical significance.

Ethics

Institutional approval was sought from the Research and Development Department, on the basis of this study constituting a service evaluation, and therefore not requiring patient consent.

RESULTS

A total of 136 patients were included in this study; 86 in the ProGlide group and 50 in the MANTA™ group. All patients were followed up for 30-days. Baseline characteristics of the two groups were well matched with no significant differences in age, male gender, body mass index (BMI), smoking history, prior myocardial infarction (MI) or percutaneous coronary intervention (PCI), presence of diabetes mellitus, pulmonary disease, peripheral vascular disease, NYHA ≥3 symptoms, pre-procedural haemoglobin, creatinine, anticoagulation or procedural urgency. The only significant difference noted was a higher preponderance in the ProGlide group for history of prior stroke or transient ischaemic attack (Table 1).

No significant differences were noted with respect to the diameter or the extent of calcification of the common femoral artery (CFA) at the site of puncture based on pre-TAVI CT analysis. The mean CFA diameters were 8.1 mm in the ProGlide group and 8.4 mm in the MANTA™ group (p=0.23). The level of CFA calcification was categorised into none, mild, moderate or severe and there were no proportional differences noted between the two groups (Table 2).

Vascular access was predominantly gained under fluoroscopic guidance in both groups (90.7% *vs.* 88.0%; p=0.62) and there were no significant differences in the sheath sizes used (Table 2). In the ProGlide group, a mean of 2.3 ProGlide VCDs (2.1 pre-closure and 0.2 post-closure) and 0.3 Angioseal VCDs were used per patient. In the MANTA™ group, a 1 MANTA™ VCD was used for each patient and no additional VCDs were required (Table 2).

Primary Endpoints

No significant differences were observed between the ProGlide and MANTA™ groups with respect to primary access site-related VARC-2 vascular complications (10.5% *vs.* 10%; p=0.93. See Table 3 and Figure 1a). However, whilst all of the vascular complications in the MANTA™ group were classified as minor, 3 (3.5%) in the ProGlide group were classified as major since they required unplanned surgical intervention and blood transfusion. Similarly, no significant differences were observed with respect to primary access site-related VARC-2 bleeding (9.3% *vs.* 4.0%; p=0.25. See Table 3 and Figure 1b). Once again, all of the bleeding in the MANTA™ group was classified as minor, whilst 3 (3.5%) in the ProGlide group were classified as major since they required unplanned surgical intervention and blood transfusion.

No significant difference was observed between the two groups with respect to mean cost per-patient (p=0.90 see Figures 1, 2). When taking into account the use of additional Angioseal VCDs (25 in total), administration of protamine (26), and the

Table 1. *Baseline Characteristics of the Study Population*

Baseline Characteristics	ProGlide n=86	MANTA n=50	*p* value
Age, years	79.1+/-8.0	81.5+/-6.8	0.07
Male gender (%)	49 (57.0)	28 (56.0)	0.91
BMI, kg/m^2	28.2+/-4.6	28.5+/-6.0	0.82
Diabetes mellitus (%)	26 (30.2)	12 (24.0)	0.43
Smoking history (%)	50 (58.1)	20 (40.0)	0.06
Pulmonary disease (%)	19 (22.1)	8 (16.0)	0.39
Pulmonary disease (%)	19 (22.1)	8 (16.0)	0.39
Peripheral vascular disease (%)	4 (4.7)	1 (2.0)	0.43
Prior CVA (%)	12 (14.0)	1 (2.0)	0.02
Prior MI (%)	11 (12.8)	3 (6)	0.21
Prior PCI (%)	16 (18.6)	4 (8.0)	0.09
NYHA ≥3 (%)	56 (65.1)	31 (62.0)	0.72
Pre-procedure creatinine, µmol/L	107.1+/-69.0	96.1+/-37.9	0.25
Pre-procedure Hb, g/L	121.8+/-16.1	122.4+/-16.0	0.83
Pre-procedure oral anticoagulation (%)	27 (31.4)	15 (30)	0.87
DOAC (%)	24 (27.9)	13 (26)	0.81
Warfarin (%)	3 (3.5)	2 (4)	0.88
Urgent or emergency TAVI (%)	8 (9.3)	6 (12.0)	0.59

BMI: body mass index; CVA: cerebrovascular attack; MI: myocardial infarction; PCI: percutaneous coronary intervention; NYHA: New York Heart Association; DOAC: direct oral anticoagulant; TAVI: transcatheter aortic valve implantation.

Table 2. *Vascular Access Related Procedural Data*

Vascular Access Related Procedural Data	ProGlide n=86	MANTA n=50	*p* value
Common femoral artery diameter (mm)	8.11+/-1.39	8.40+/-1.34	0.23
No common femoral artery calcification (%)	24 (27.9)	15 (30.0)	0.79
Mild common femoral artery calcification (%)	41 (48.2)	24 (48.0)	0.97
Moderate common femoral artery calcification (%)	16 (18.8)	9 (18.0)	0.93
Severe common femoral artery calcification (%)	5 (5.9)	2 (4.0)	0.64
Ultrasound guided puncture (%)	8 (9.3)	6 (12.0)	0.62
14F sheath (%)	22 (25.6)	8 (16.0)	0.19
16F sheath (%)	40 (46.5)	29 (58.0)	0.20
18F sheath (%)	24 (27.9)	13 (26.0)	0.81
Peak activated clotting time (sec)	252.5+/-39.5	244.3+/-38.6	0.25
ProGlides used for pre-closure (mean per patient)	179 (2.1)	0 (0)	-
ProGlides used for post closure (mean per patient)	18 (0.21)	0 (0)	-
Total number of ProGlides used (mean per patient)	197 (2.3)	0 (0)	-
MANTA used (mean per patient)	0 (0)	50 (1)	-
Angioseals used (mean per patient)	25 (0.3)	0 (0)	-

Table 3. *Procedural Outcome Data*

Procedural Outcomes	ProGlide n=86	MANTA n=50	*p* value
Contrast extravasation on initial angiogram (%)	35 (40.7)	23 (46.0)	0.55
Requirement for balloon tamponade (%)	20 (23.3)	3 (6.0)	0.01
VARC-2 VCD failure (%)	3 (3.5)	0 (0)	-
Primary access site-related VARC-2 vascular complications (%)	9 (10.5)	5 (10.0)	0.93
Minor (%)	6 (7.0)	5 (10.0)	0.53
Major (%)	3 (3.5)	0 (0)	-
Non-primary access site related VARC-2 vascular complications (%)	4 (4.7)	2 (4)	0.86
Minor (%)	3 (3.5)	2 (4)	0.88
Major (%)	1 (1.2)	0 (0)	-
Primary access site-related VARC-2 bleeding (%)	8 (9.3)	2 (4.0)	0.25
Minor (%)	5 (5.8)	2 (4.0)	0.64
Major or life-threatening (%)	3 (3.5)	0 (0)	-
All VARC-2 bleeding (%)	12 (14.0)	2 (4)	0.66
Minor (%)	3 (3.5)	2 (4)	0.88
Major or life-threatening (%)	9 (9.3)	0 (0)	-
Requirement for primary access site endovascular intervention (%)	0 (0)	0 (0)	-
Requirement for primary access site vascular surgery (%)	3 (3.5)	0 (0)	-
Red blood cell transfusion (%)	7 (8.1)	0 (0)	-
Hb drop, g/L	18.4+/-9.1	16.0+/-10.8	0.19
Length of hospital stay post-procedure, days	3.2+/-3.5	2.6+/-2.6	0.27
30-day mortality (%)	0 (0)	0 (0)	-

VARC:Valve Academic Research Consortium;VCD: vascular closure device

Table 4. *Cost of VCDs and Supplementary Interventions for ProGlide Group*

VCDs and Supplementary Interventions for ProGlide Group (n=86)	Total Number	Cost per Unit (£)	Total Cost (£)
ProGlide	197	115.00	22655.00
Angioseal	25	101.00	2500.00
Protamine	26	49.55	1288.30
Red blood cell transfusion	7	128.99	902.93
Surgical repair	3	7190.00	21570.00
Combined cost			48916.23
Mean cost per patient			568.79

Table 5. *Cost of VCDs and Supplementary Interventions for MANTA Group*

VCDs and Supplementary Interventions for MANTA group (n=50)	Total Number	Cost per Unit (£)	Total Cost (£)
MANTA	50	550.00	27500.00
Angioseal	0	101.00	0
Protamine	50	49.55	2477.50
Red blood cell transfusion	0	128.99	0
Surgical repair	0	7190.00	0
Combined cost			29977.50
Mean cost per patient			599.55

requirement for red blood cell transfusions[7] and surgical repair,[3] the mean cost per patient in the ProGlide group was £568.79 (see Table 4, Figure 2). In the MANTA™ group, when accounting for the cost of the VCD and administration of protamine in all cases, the mean cost per patient was £599.55 (Table 5, Figure 2).

Secondary Endpoints

None of the patients in either group required primary access site endovascular intervention (excluding balloon angioplasty). Two patients in the ProGlide group required endovascular intervention to the contralateral femoral artery (thrombin injection for psedoaneurysm and covered stent for injury to superficial femoral artery). As mentioned above, 3 patients in the ProGlide group required primary access site surgical repair due to common femoral artery injury in contrast to none in the MANTA™ group. There was no significant difference observed with respect to duration of hospital stay post-TAVI (3.2+/-3.5 *vs.* 2.6+/-2.6 days; p=0.27. See Table 3) and there was no 30-day mortality in either group.

Additional Endpoints

The overall rate of VARC-2 vascular complications across all patients was 14.7% (20/136), whilst the overall rate of VARC-2 bleeding was 10.3% (14/136). There was no significant difference between the two groups with respect to peak ACT. However, a significantly greater proportion of patients in the ProGlide group required balloon tamponade following DSA in order to achieve haemostasis (23.3% *vs.* 6.0%; p=0.01). Seven patients in the ProGlide group required post-procedure transfusion of red blood cells compared to none in the MANTA™ group. However, there was no significant difference in mean drop in haemoglobin post-procedure (18.4+/-9.1 *vs.* 16.0+/-10.8 g/L; p=0.19).

DISCUSSION

The MANTA™ VCD is an alternative to traditional suture-based VCDs such as ProGlide for achieving vascular closure and haemostasis following TF-TAVI. A multi-centre prospective study of the MANTA™ VCD demonstrated good efficacy and low complication rates,[9] and our group has described its use as a rescue for failed ProGlide pre-closure in a case which would otherwise have warranted surgical intervention.[10] Furthermore, a number of previously published retrospective studies have demonstrated encouraging results when comparing vascular and bleeding complications.[7,11,12] However, the significantly higher cost of the MANTA™

Figure 1. *A. Graph Comparing the Proportion of Patients with Primary Access Site-Related VARC-2 Vascular Complications in ProGlide and MANTA Groups. B. Graph Comparing the Proportion of Patients with Primary Access Site-Related VARC-2 b Feeding in ProGlide and MANTA Groups. C. Graph Comparing the Mean Per-Patient Cost of Achieving Haemostasis in ProGlide and MANTA Groups.*

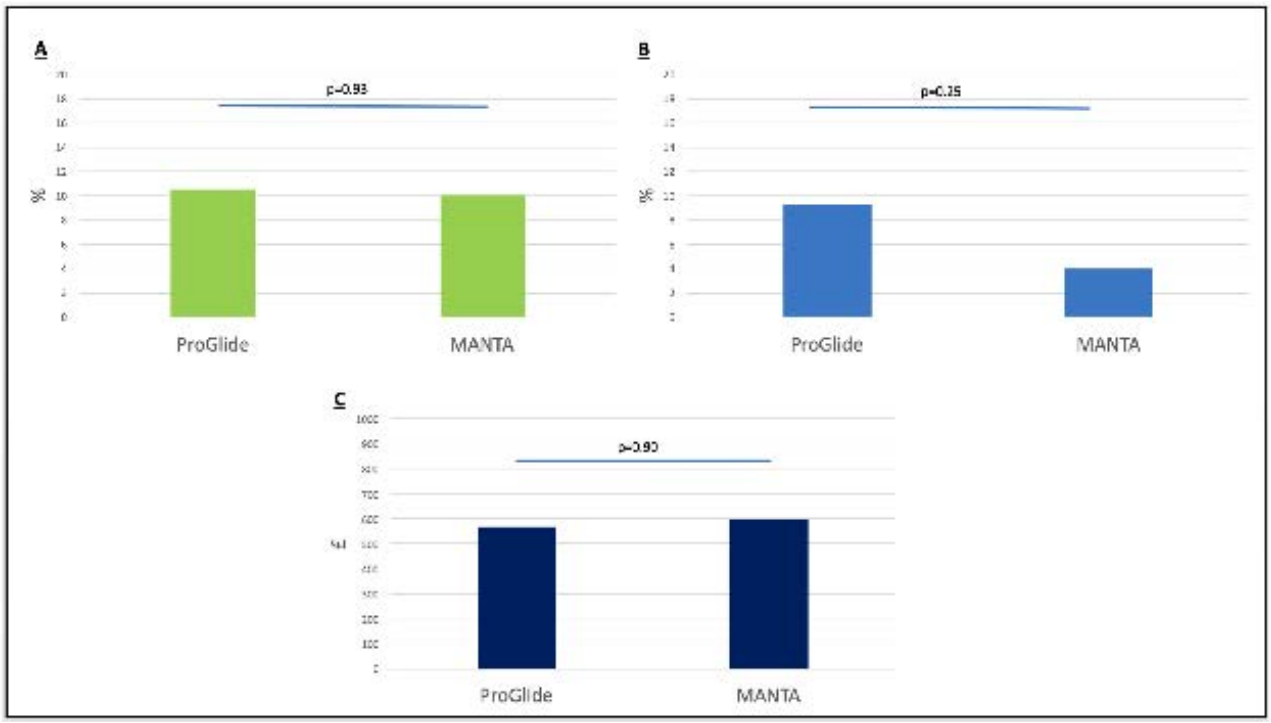
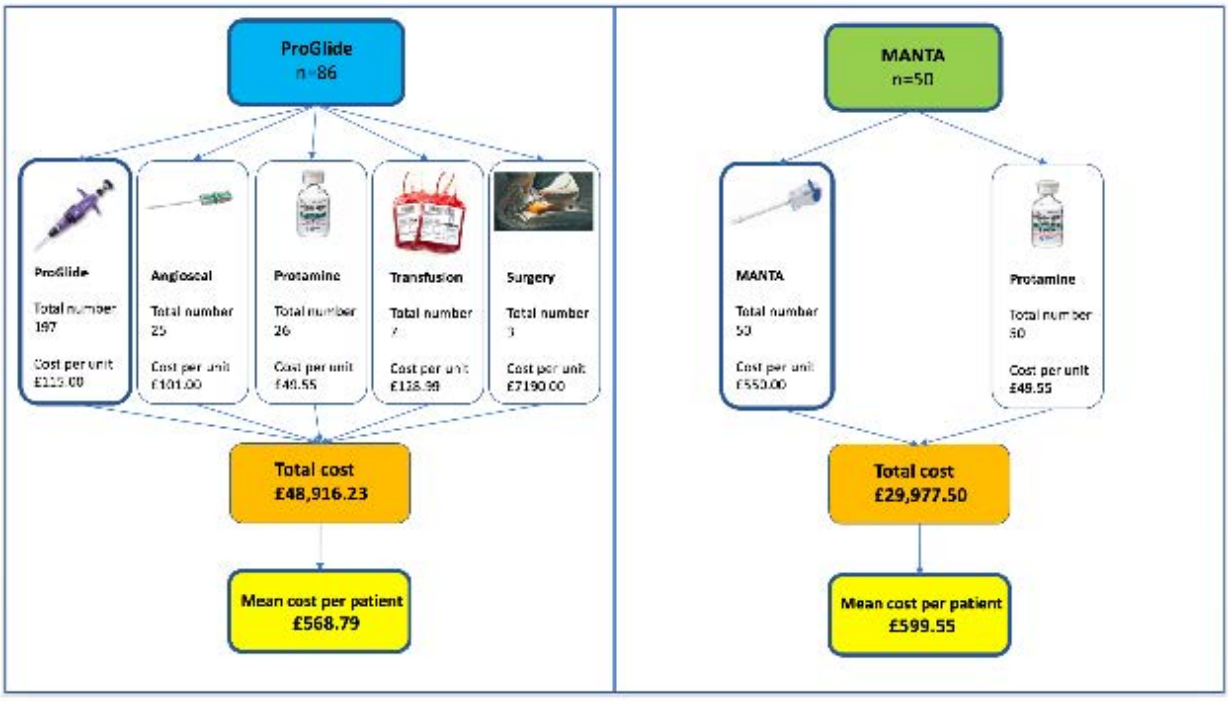


Figure 2. *A Pictorial Comparison of the Mean Cost per Patient in ProGlide and MANTA Groups*



VCD has been a concern, and has limited its use in many centres. This single-centre, retrospective study explores in greater detail the cost comparison between ProGlide and MANTA™ VCDs, as well as providing additional data regarding vascular and bleeding complication rates.

This study of 136 patients shows a 14.7% overall rate of VARC-2 vascular complications. This is consistent with other studies[7,9,11,12] but highlights that vascular injury remains relatively frequent following TF TAVI. Our data demonstrate no significant differences between ProGlide and MANTA™ VCDs with respect to overall VARC-2 vascular (10.5% *vs.* 10.0%; p=0.93) or bleeding (9.3% *vs.* 4.0%; p=0.25) complications at the primary access site. These findings are consistent with that of a similarly designed study published by Biancari et al.[7] However, when analysing the complications in more detail it is notable that three of the patients in the ProGlide group went on to have open vascular surgical repair of the primary access site compared to none in the MANTA™ group. As such, when assessing major VARC-2 vascular or bleeding complications only, there was a notable discrepancy between the two groups. This potentially corroborates the findings of Moriyama et al,[12] where use of MANTA™ was associated with a lower rate of vascular and bleeding complications, especially for major bleeding.[13]

The most novel and significant finding from the present study is that of cost neutrality between ProGlide and MANTA™ groups. Whilst a single MANTA™ VCD is approximately 5 times more expensive than a single ProGlide VCD (£550.00 vs. £115.00), the gap is narrowed to the point of being non-statistically significant when taking into consideration the mean per-patient cost due to use of additional VCDs and treatments for complications (£599.55 *vs.* £568.79).

This study has a number of limitations which need to borne in mind when appraising the results. Chief among these is the fact that it was non-randomised, which means that we cannot rule out selection bias within the study population. The decision to use ProGlide or MANTA™ VCDs was made at the discretion of the operator following analysis of a CT scan showing the extent of disease of the ileo-femoral vasculature. Whilst the patient groups appear well-matched with respect to baseline (demographics and comorbidities) and procedural (method of vascular access, sheath size, peak ACT) characteristics, it is feasible that ProGlide may have been selected in cases with more complex peripheral vascular anatomy due to greater operator familiarity. Furthermore, the cases included in this study pre-date the widespread uptake of ultrasound guided vascular access in our institute. Ultrasound was used in only 10.3% of cases in this study, whereas its use is now near-universal. The use of ultrasound allows for real-time assessment of vessel wall health, including calcification, allowing the operator to select the optimal puncture site. This is particularly pertinent to the use of ProGlide VCDs, since calcification and atheromatous disease can prevent suture-based VCDs from drawing together the edges of an arteriotomy. In contrast, the MANTA™ VCD is less reliant on the quality of the artery. Taking all of the above into account, it could be argued that the conditions of the study were more advantageous towards the MANTA™ VCD. However, as a counterpoint, it should be noted that this study involved the first 50 cases of MANTA™ usage post-TAVI at our institute and therefore incorporated the operator learning curve that is inherent to the use of all novel devices.

CONCLUSION

This study demonstrates that use of the MANTA™ VCD following TF TAVI is associated with no increase in primary access site-related VARC-2 vascular or bleeding complications relative to ProGlide VCDs, whilst also being cost-neutral when overall per-patient expense is considered. Whilst further studies, including randomised controlled trials (RCTs), are warranted in order to explore this in more detail, current evidence suggests the MANTA™ VCD to be a clinically and economically viable alternative to traditional suture-based VCDs.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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