EuroIntervention
2024;20:e344-e353
published online e-edition March 2024
DOI: 10.4244/EIJ-D-23-00750

ORIGINAL RESEARCH

A study of bailout plug-based closure after failed suture-based closure in patients undergoing transfemoral TAVI

Oliver Dumpies[1], MD; Ahmed Abdelhafez[1], MD; Johannes Rotta detto Loria[1], MD; Ines Richter[1], MD; Hans-Josef Feistritzer[1], MD; Nicolas Majunke[1], MD; Steffen Desch[1], MD; Thilo Noack[2], MD; Holger Thiele[1], MD; Mohamed Abdel-Wahab[1]*, MD

**Corresponding author: Department of Structural Heart Disease/Cardiology, Heart Center Leipzig at University of Leipzig, Strümpellstraße 39, 04289, Leipzig, Germany. E-mail: mohamed.abdel-wahab@medizin.uni-leipzig.de*

The authors' affiliations can be found at the end of this article.

This paper also includes supplementary data published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-23-00750

ABSTRACT

BACKGROUND: Percutaneous suture-based arterial access site closure (ProGlide) is commonly applied in patients undergoing transfemoral transcatheter aortic valve implantation (TAVI). However, the failure of a suture-based vascular closure device (VCD) may require additional treatment.

AIMS: We aimed to evaluate the efficacy and safety of bailout access site closure using a large-bore plug-based device (MANTA) in patients with failed suture-based closure during transfemoral TAVI.

METHODS: Patients undergoing a bailout attempt with the MANTA VCD were identified from a prospectively enrolling, institutional registry. Efficacy was defined as haemostasis at the access site without the need for alternative treatment other than manual compression or endovascular ballooning. Safety was defined as freedom from vascular dissection, stenosis and occlusion requiring intervention.

RESULTS: Of 2,505 patients, 66 underwent a bailout attempt with MANTA as a result of ProGlide failure, which occurred before the large-bore sheath insertion in 16.7% of patients and after the sheath removal in 83.3% of patients. Bailout MANTA was deemed effective in 75.8% of patients (50/66), and the technique was considered safe in 86.4% (57/66) of patients. Failure of bailout MANTA occurred because of its superficial application, resulting in persistent bleeding in 18.2% of patients (12/66), and because of its deep application, resulting in stenosis or occlusion in 6.1% of patients (4/66). Operator experience with the technique (odds ratio [OR] 12.29, 95% confidence interval [CI]: 1.99-75.99; p=0.007) and prior use of three ProGlides (OR 0.02, 95% CI: <0.01-0.39; p=0.010) were the only independent predictors of the efficacy endpoint.

CONCLUSIONS: Bailout MANTA after ProGlide failure was effective and safe, but operator experience seems to be crucial. Further technological refinements to facilitate accurate placement appear necessary.

KEYWORDS: bailout; MANTA; TAVI; vascular closure

SUBMITTED ON 02/09/2023 - REVISION RECEIVED ON 11/11/2023 - ACCEPTED ON 21/11/2023

Vascular closure is a critical element of any transfemoral transcatheter aortic valve implantation (TAVI), and the percutaneous suture-based closure technique using the Perclose ProGlide device (Abbott) is the most widely applied in clinical practice[1,2]. However, despite a decade of experience, suture-based vascular closure device (VCD) failure occurs in 5.4% to 8.0% of procedures and is associated with prolonged hospitalisation[3,4]. In case of VCD failure, the interventionalist has few options for vascular access site closure. As a first step, additional suture-based VCDs can be applied. Supportive options may include prolonged manual compression and endovascular ballooning. Stenting is commonly required to avoid surgical repair if haemostasis cannot be achieved with the previously mentioned interventions.

The MANTA (Teleflex) VCD is a new-generation device specifically designed for large-bore vascular closure, relying on a plug-based rather than a suture-based mechanism. In the randomised MASH trial, no differences were observed between the MANTA and the suture-based ProGlide VCD in terms of vascular complications or bleeding events[5]. However, in the larger randomised CHOICE-CLOSURE trial, access site-related vascular complications occurred more frequently with the MANTA VCD[6].

Anecdotally, the MANTA device has been used as a bailout VCD if vascular closure could not be achieved with suture-based VCDs[5,6], which could reduce the need for unplanned endovascular or surgical interventions. However, the safety and success rates of this technique have not been systematically analysed. Therefore, we sought to investigate the efficacy and safety of the bailout MANTA technique after suture-based VCD failure in a large, consecutive, well-defined cohort of patients undergoing transfemoral TAVI.

Editorial, see page e333

Impact on daily practice

There are limited options for suture-based vascular closure device (VCD) failure after transfemoral TAVI. Anecdotally, the plug-based MANTA VCD has been suggested as a bailout device. Bailout MANTA after suture-based VCD failure was effective and safe in this study, but operator experience seems to be crucial with the current-generation device.

Methods

PATIENT POPULATION

All patients undergoing bailout arterial access site closure with MANTA during transfemoral TAVI between the introduction of the device in September 2019 and November 2022 were identified from the institutional database of the Heart Center Leipzig at the University of Leipzig. Patient demographics, clinical and procedural data were prospectively collected as part of a dedicated institutional registry (ClinicalTrials.gov: NCT05015452) approved by the local ethics committee. All patients provided written informed consent. A reference cohort of patients with elective vascular closure with MANTA from the randomised CHOICE-CLOSURE trial was also included[6].

PROCEDURAL DETAILS

All TAVI procedures and access site selection were planned with contrast-enhanced multislice computed tomography. Vascular access site calcification was classified as none, mild, moderate, or severe, according to the previously published MASH classification[5]. The decision to perform TAVI and access site selection were made by a multidisciplinary Heart Team.

Pre-existing antiplatelet therapy was not changed before TAVI. Direct oral anticoagulants were discontinued 24-36 hours before the procedure, depending on renal function. Vitamin K antagonists were maintained, aiming for an international normalised ratio (INR) between 2.0 and 2.5 on the day of the procedure.

Puncture of the main access site was performed using the previously described roadmapping technique[8] or with ultrasound guidance. The choice of puncture technique was made by the operator. Patients received intravenous unfractionated heparin during the procedure, and the target activated clotting time (ACT) was set at 250-300 seconds. At the end of the TAVI procedure, a reduced dose of protamine (500 IU/1000 IU heparin) was regularly administered to reduce the ACT to less than 250 seconds, followed by application of the VCD. The use of the full dose of protamine (1000 IU/1000 IU of heparin) was left to the operator's discretion.

A peripheral angiogram was subsequently performed to assess vascular closure, bleeding, and vascular complications.

DEVICE CHARACTERISTICS

The ProGlide VCD was the only suture-based VCD used at the Heart Center Leipzig during the study period. Above 8 French (Fr), the use of two ProGlide VCDs is recommended, but several studies have shown that one ProGlide VCD can also be sufficient for safe vascular closure[9,10]. The device is based on a suture-mediated closure principle. A detailed description regarding the application of the ProGlide VCD has already been provided elsewhere[11]. A crucial aspect of the device is the fact that wire access is maintained even after the sheath is removed and the sutures are tightened. Therefore, the ProGlide VCD offers the possibility of subsequently applying a different VCD if necessary.

The plug-based MANTA VCD consists of three parts: a luminal resorbable polymer toggle, an extraluminal collagen plug attached to a non-resorbable polyester suture, and a stainless-steel lock. The system is available in two sizes: 14 Fr and 18 Fr. Both sizes were used in this study. In an elective MANTA VCD setting, an 8 Fr depth locator is used to determine the implantation depth prior to the insertion of

Abbreviations

ACT	activated clotting time
Fr	French
IQR	interquartile range
OR	odds ratio
TAVI	transcatheter aortic valve implantation
VCD	vascular closure device

the large sheath. Further technical details of the device and its application have been described elsewhere[12]. Once the MANTA VCD is deployed, there is no guidewire left in the vessel and no more VCDs can be applied.

MANTA BAILOUT TECHNIQUE

Suture-based VCD failure can either occur as an upstream event prior to the insertion of the large-bore sheath, or as a downstream event after sheath removal. The preimplant depth measurement of a MANTA VCD in a downstream bailout situation can be more challenging than in an elective procedure due to two factors. First, the vascular puncture site after large-bore sheath removal is significantly larger than before its insertion, which leads to permanent bleeding next to the 8 Fr MANTA implantation depth locator. Consequently, measurement of the puncture depth could be inaccurate. Second, the groin tissue may significantly swell during the procedure, further impacting measurement accuracy.

We have gradually introduced a few modifications to the MANTA VCD measurement and application technique in order to address these difficulties. First, measurement of the implantation depth is performed under slight compression of the surrounding tissue. Bleeding through the access site can thereby be reduced and accurate measurements obtained. Second, two centimetres are added to the measured puncture depth (instead of one centimetre in elective procedures). Finally, the success of the bailout MANTA procedure must be verified by angiography. In this study, operators defined as having "MANTA bailout experience" were those who had performed 10 or more bailout procedures.

VASCULAR CLOSURE AND VCD FAILURE STRATEGIES

During the study period, the bailout MANTA technique was implemented into the hospital's internal workflow for vascular closure and complication management after TAVI **(Figure 1)**. Preclosure was most commonly performed with one ProGlide, which could be followed by one to two additional ProGlides if VCD application was not successful or haemostasis was inadequate. If the suture-based VCD achieved a significant but incomplete reduction in bleeding from the access site, a final small plug-based VCD (Angio-Seal; Terumo) was used for completion of haemostasis. In this context, the Angio-Seal was not used as a bailout device but as part of the planned closure strategy[13,14]. If the ProGlide VCD could not be inserted prior to the procedure or if there was no significant haemostasis with ProGlide after the procedure, a bailout MANTA was considered. The decision for bailout MANTA was left to the operator's discretion. A second arterial access was routinely obtained to allow supportive crossover interventions in case of vascular complications or VCD failure. These included endovascular balloon inflation at the access site in case of bleeding or to treat stenosis or dissection. In addition, endovascular balloon inflation was sometimes accompanied by an injection of fibrin to treat access site bleeding[15]. However, implantation of a stent or vascular surgery could not always be avoided.

STUDY ENDPOINTS

The primary objective of this study was to assess both the efficacy and safety of the bailout MANTA technique. Efficacy was defined as achieving haemostasis without the need for

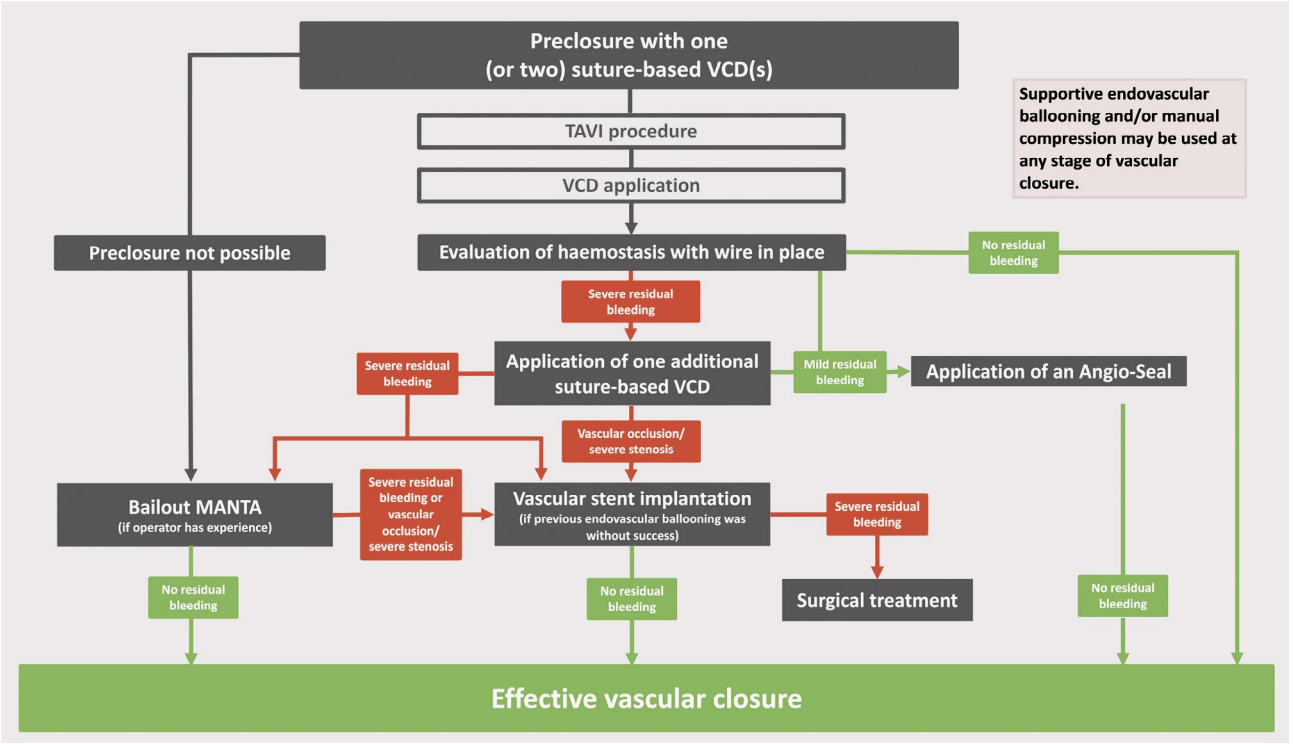


Figure 1. *Vascular closure and bailout strategies after transfemoral transcatheter aortic valve implantation. TAVI: transcatheter aortic valve implantation; VCD: vascular closure device*

alternative interventions, except manual compression or endovascular ballooning. If the efficacy endpoint was not met, the MANTA bailout procedure was deemed to have failed. Safety was defined as freedom from vascular dissection, stenosis or occlusion requiring interventional or surgical treatment. These endpoints were assessed in both the study population and the reference elective MANTA cohort of the CHOICE-CLOSURE trial. In order to examine the presence or absence of a learning curve, efficacy and safety endpoints were assessed for each tertile of patient enrolment. In addition, potential predictors of the efficacy endpoint were analysed.

STATISTICAL ANALYSIS

Continuous data are presented as mean (±standard deviation) or median (interquartile range [IQR]), as appropriate, and categorical data as number and proportion (%). Data distribution was tested for normality using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Differences between groups were tested with the Student's t-test or Mann-Whitney U test (continuous data) and Chi-square test or Fisher's exact test (categorical variables). Univariable and multivariable logistic regression analysis was performed to analyse potential predictors of the efficacy endpoint. Known risk factors and possible influencing variables for VCD failure were included in the univariable analysis. All variables with a p-value<0.05 were used for the multivariable analysis. A two-sided p-value of <0.05 was considered statistically significant. Statistical analysis was performed using SPSS Version 26.0 statistical software (IBM).

Results

BASELINE AND PROCEDURAL CHARACTERISTICS

Between September 2019 and November 2022, a total of 3,267 patients were treated with transfemoral TAVI. Of these, 2,505 patients received the suture-based ProGlide VCD as a primary vascular closure strategy. ProGlide VCD failure was observed in 4.3% (107/2,505) of these patients, of whom 61.7% (66/107) underwent a bailout MANTA attempt. The treatment of patients with suture-based VCD failure without a bailout MANTA attempt is detailed in **Supplementary Table 1**.

Most of the bailout MANTA patients were elderly (mean age 81.1±5.9 years) and had a low to intermediate Society of Thoracic Surgeons score (3.5 [2.3-6.4]) **(Table 1)**. The mean body mass index (BMI) was 29.4±5.5 kg/m², peripheral vascular disease was present in 7.3% of patients, and the mean diameter of the common femoral artery access site was 7.6±1.6 mm **(Supplementary Table 2)**. Overall, more than half of the patients had moderate (33.3%) or severe (31.8%) calcification of the iliofemoral access vessels. Furthermore, anterior calcification of the access site was prevalent in almost half of the study patients (45.5%).

Procedural details are provided in **Supplementary Table 3**. A total of 24.2% of access site punctures were performed under ultrasound guidance (all others by angiographic roadmap guidance).

Suture-based VCD failure occurred upstream (before large-bore sheath introduction) in 16.7% of patients and downstream (after sheath removal) in 83.3% of patients. Bailout MANTA was used after the failure of one ProGlide VCD in 30.3%, after the failure of two ProGlides in 60.6%, and following the failure of three ProGlides in 9.1% of patients. The 18 Fr MANTA VCD was used in the majority of bailout cases (74.2%).

Table 1. Baseline clinical characteristics.

Variable	N=66
Age, years	81.1±5.9
Female sex	28 (42.6)
Body mass index, kg/m²	29.4±5.5
Logistic EuroSCORE I	12.1 (6.5-18.0)
Society of Thoracic Surgeons score, %	3.5 (2.3-6.4)
New York Heart Association Functional Class	
Class I	5 (7.6)
Class II	11 (16.7)
Class III	44 (66.7)
Class IV	6 (9.1)
Diabetes mellitus	37 (56.1)
Coronary artery disease	39 (59.1)
Previous myocardial infarction	6 (9.1)
Previous CABG	3 (4.5)
Previous PCI	12 (18.2)
Previous valve surgery	7 (10.6)
Cerebral vascular disease	15 (22.7)
Previous stroke	11 (16.7)
Peripheral vascular disease	5 (7.6)
Previous peripheral intervention	2 (3.0)
Atrial fibrillation	29 (43.9)
Chronic dialysis	2 (3.0)
Severe chronic renal failure*	12 (18.2)
Baseline creatinine level, µmol/l	108.0 (85.0-136.0)
Baseline haemoglobin level, mmol/l	7.5±1.1
Baseline INR	1.1 (1.0-1.2)
Baseline platelet count, 10⁹/l	204 (161-265)
Baseline NT-proBNP level, ng/l	2,369 (910-5,776)
Antiplatelets/anticoagulation	
None	11 (16.7)
Single antiplatelet therapy	26 (39.4)
Dual antiplatelet therapy	0 (0)
Oral anticoagulation	25 (37.9)
Oral anticoagulation and antiplatelet therapy	4 (6.1)

Values are expressed as mean±SD or median (interquartile range) or n/N (%). *defined as a glomerular filtration rate <30 ml/min/1.73 m²
CABG: coronary artery bypass grafting; EuroSCORE: European System for Cardiac Operative Risk Evaluation; INR: international normalised ratio; N: number; NT-proBNP: N-terminal pro-brain natriuretic peptide; PCI: percutaneous coronary intervention; SD: standard deviation

EFFICACY AND SAFETY OF BAILOUT MANTA

In 54 (81.8%) patients, haemostasis was achieved with the MANTA bailout technique **(Table 2)**. Among this group,

Table 2. Main study outcomes.

Variable	N=66
Efficacy of bailout MANTA	**50 (75.8)**
Haemostasis after bailout MANTA	54 (81.8)
Haemostasis without additional support	43 (65.2)
Haemostasis after additional manual compression	4 (6.1)
Haemostasis after additional endovascular ballooning	7 (10.6)
No haemostasis after bailout MANTA	12 (18.2)
Need for stent implantation for haemostasis	9 (13.6)
Pseudoaneurysm with need for thrombin injection	3 (4.5)
Safety of bailout MANTA	**57 (86.4)**
Complete vascular occlusion	2 (3.0)
Vascular stenosis	7 (10.6)
Vascular stenosis with need for intervention	6 (9.1)
Vascular dissection	2 (3.0)
Vascular dissection with need for intervention	1 (1.5)
Treatment of vascular occlusion, stenosis or dissection after bailout MANTA	
Only endovascular ballooning	5 (7.6)
Stent implantation	3 (4.5)
Surgical repair	1 (1.5)

Values are expressed as n (%).

seven patients required additional endovascular ballooning and four patients required prolonged manual compression to achieve complete haemostasis. After haemostasis, four patients needed vascular surgery or stenting due to vascular complications (vascular stenosis or occlusion). Thus, the efficacy endpoint was met in 50 patients (75.8%) **(Central illustration)**. The number of successful MANTA bailouts increased numerically after the first tertile of patient recruitment. However, there was no statistically significant learning curve on the institutional level throughout the temporal tertiles of patient enrolment **(Figure 2)**.

Haemostasis could not be achieved with the bailout MANTA technique in 12 patients (19.7%). Stent implantation was required in 9 of these patients, and 3 patients were treated with injection of thrombin during endovascular ballooning.

The safety endpoint was met in 57 patients (86.4%) **(Table 2)**. The most frequent vascular complication was vascular stenosis (n=6), which was treated with endovascular ballooning and/or stenting in all patients. Two patients had complete vascular occlusions after bailout MANTA application, which required stenting in one case and surgery in the other. One patient had a vascular dissection that was managed by endovascular ballooning.

Overall, 12 patients (19.7%) needed vascular stenting despite bailout MANTA due to persistent bleeding (n=9) or vascular stenosis or occlusion (n=3).

EFFICACY AND SAFETY OF BAILOUT VERSUS ELECTIVE MANTA PROCEDURES

A total of 258 patients were enrolled in the MANTA cohort of the CHOICE-CLOSURE trial at three centres in Germany, between June 2020 and June 2021. The baseline characteristics of elective (CHOICE-CLOSURE) and bailout MANTA patients were largely comparable. However, patients with a bailout MANTA procedure were more likely to have diabetes mellitus (56.1% vs 38.0%; p=0.012), a history of cerebrovascular disease (22.7% vs 10.1%; p=0.011) or severe renal insufficiency (18.2% vs 9.7%; p=0.025) **(Supplementary Table 4)**. In addition, severe vascular calcification of the access site was more common in the bailout MANTA group (31.8% vs 12.7%; p≤0.001) **(Supplementary Table 5)**. Only the 18 Fr MANTA VCD was used in the CHOICE-CLOSURE trial, while the 14 Fr VCD was used in 25.8% of patients in the bailout population **(Supplementary Table 6)**.

The efficacy endpoint was achieved in 93.4% (241/258) and the safety endpoint in 94.6% (244/258) of elective MANTA patients. In comparison, the rates of both efficacy (75.8% vs 93.4%; p≤0.001) and safety (86.4% vs 94.6%; p=0.040) were significantly lower in the bailout MANTA population.

PREDICTORS OF EFFICACY

Most baseline characteristics were largely comparable between patients with and without an effective bailout MANTA application **(Supplementary Table 7)**. However, differences were observed in terms of vascular characteristics. Patients with a successful bailout procedure had calcification of the access site that was more severe, numerically, **(Supplementary Table 8)**, and anterior calcification was present significantly more often (56.0% vs 12.5%; p=0.003). Procedural characteristics were predominantly similar **(Table 3)**. All patients received either a reduced dose or a full dose of protamine at the end of the procedure, with no difference in the efficacy endpoint between the two groups. Operators with more experience in applying the bailout MANTA technique were more likely to achieve effective haemostasis. In addition, patients with an effective bailout MANTA were less likely to have had a previously attempted vascular closure with more than two suture-based VCDs (4.0% vs 25.0%; p=0.027).

In multivariable analysis, operator experience (adjusted odds ratio [OR] 12.29, 95% confidence interval [CI]: 1.99-75.99; p=0.007) was the only independent predictor of an effective bailout MANTA procedure **(Table 4)**. Conversely, the prior application of three ProGlide VCDs was associated with a reduced efficacy of the bailout MANTA technique (OR 0.02, 95% CI: <0.01-0.39; p=0.010).

BAILOUT MANTA FAILURE MODES

Patients with bailout failure more commonly had failed haemostasis (12/16) than vascular occlusion requiring stent implantation or surgical repair (4/16). A typical failure mechanism was observed in each of these groups. If bleeding persisted, the MANTA VCD had been implanted too superficially **(Figure 3)**. In patients with severe vascular stenosis or occlusion, the MANTA VCD had been applied too deeply into the vessel and had led to stenosis due to displaced vascular calcification or a suboptimal toggle position **(Central illustration)**.

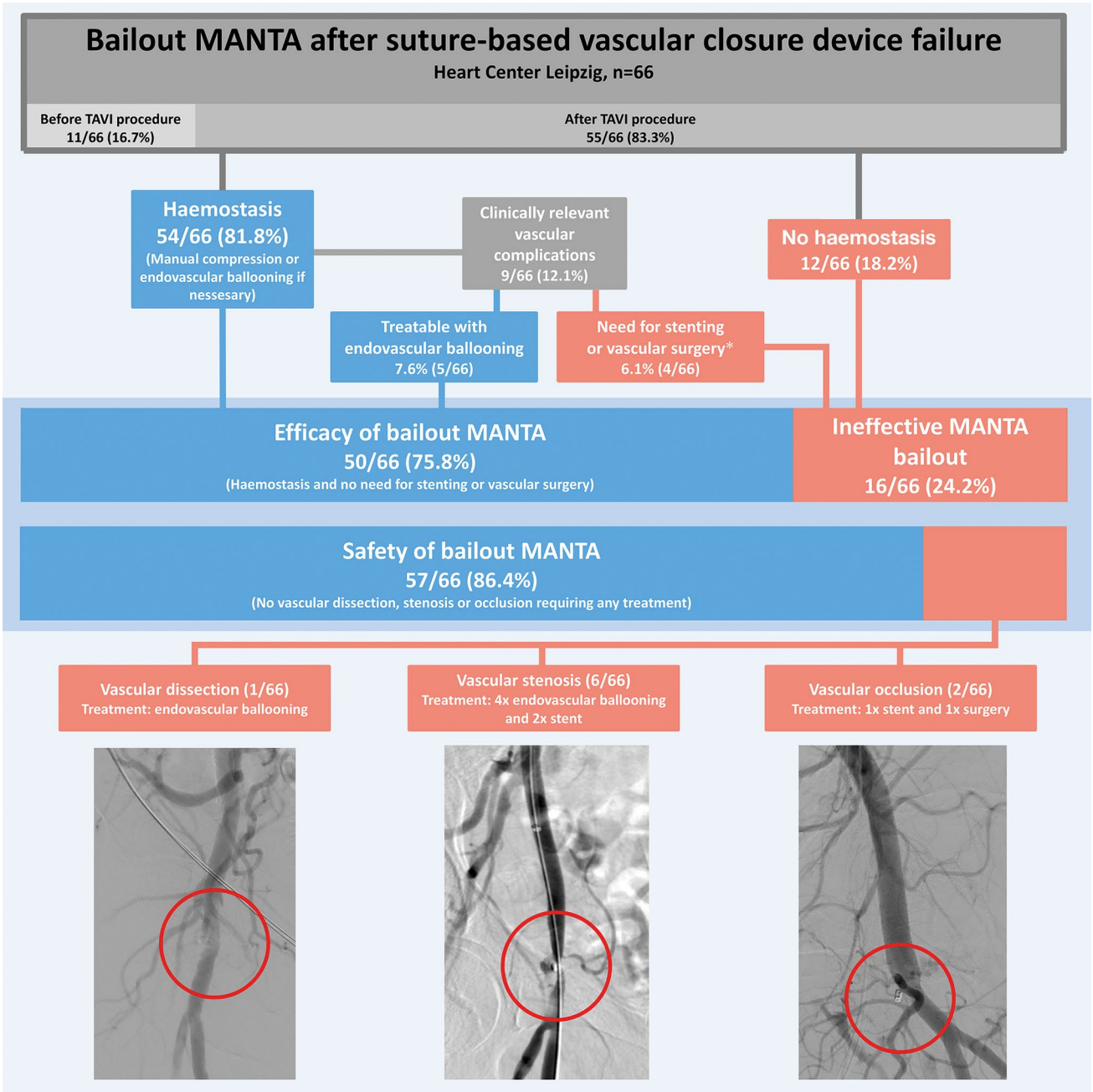
Discussion

To the best of our knowledge, this is the first systematic study analysing the bailout MANTA technique following the failure of suture-based vascular closure in patients undergoing transfemoral TAVI. The main findings of the study are as follows: 1) bailout MANTA is safe and effective in a large proportion of patients with upstream or downstream suture-based VCD failure; and 2) operator experience appears to be a crucial aspect with the current-generation device.

The baseline characteristics of this study cohort reflect a population with difficult vascular access. Known risk factors for VCD failure, such as moderate or severe vascular calcification or tortuosity, were predominant[16]. In addition, nearly half of the patients had anterior wall calcification, and

EuroIntervention — Central Illustration

Efficacy and safety of bailout MANTA.



Oliver Dumpies *et al.* • *EuroIntervention* 2024;20:e344-e353 • DOI: 10.4244/EIJ-D-23-00750

**Treatment: stenting – 3 patients, surgical vascular repair – 1 patient. TAVI: transcatheter aortic valve implantation*

patients were commonly overweight[17]. Overall, the results of this study suggest bailout MANTA as an additional step in the escalation algorithm in case of suture-based VCD failure. If two suture-based VCDs do not significantly reduce bleeding, bailout MANTA can be applied as the next step. Supportive manual compression and/or endovascular ballooning should subsequently be applied if necessary.

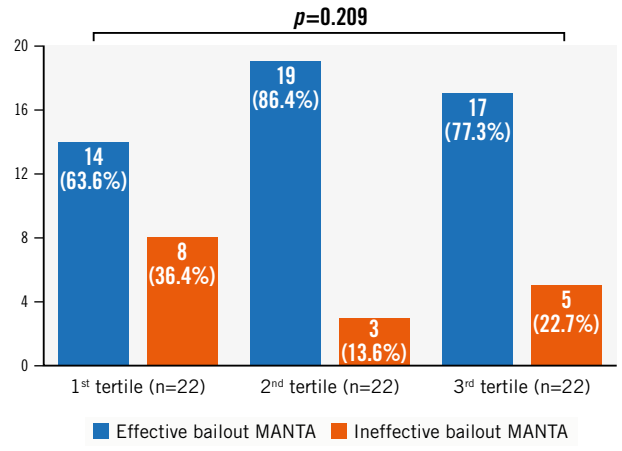


Figure 2. *Efficacy of bailout MANTA according to tertiles of patient enrolment.*

We could not demonstrate a significant learning curve with the bailout technique at the institutional level in this study. This can be attributed both to the overall limited number of cases and to the relatively large number of interventionalists with individual learning curves during the study period. However, individual operator experience was an essential factor in the success of the bailout attempt. Since previously published data on elective MANTA application have not indicated a relevant learning curve[18], it appears that tackling the previously mentioned challenges of depth measurement and correct application of the plug during a bailout situation requires experience. Therefore, it is not surprising that both efficacy and safety were achieved less frequently with bailout MANTA compared to the elective MANTA cohort of the CHOICE-CLOSURE trial. As already described, the downstream measurement of implantation depth is more challenging with bailout MANTA, and the technique is more demanding.

Therefore, optimisation of depth measurement could further improve the efficacy of the MANTA bailout technique and, in particular, reduce the proportion of inadvertent superficial implantations, which can potentially be reduced if depth measurement becomes as accurate as in the elective setting. A first step could be the implementation of the previously mentioned adapted technique. The MANTA depth measurement should be adjusted by measuring the implantation depth under slight compression of the surrounding tissue and adding two centimetres instead of one centimetre to the measured puncture depth. Second, a larger depth locator of 14 Fr could

Table 3. Procedural details stratified by the effectiveness of bailout MANTA.

Variable	Effective bailout MANTA N=50 (75.8)	Ineffective bailout MANTA N=16 (24.2)	*p*-value
Main access site, right	44/50 (88.0)	15/16 (93.8)	1.000
Mean sheath size, Fr	14 (14-16)	14 (14-16)	0.189
Sheath-to-femoral artery ratio	0.74 (0.66-0.88)	0.75 (0.66-0.87)	0.838
Ultrasound-guided puncture	15/50 (30.0)	1/16 (6.25)	0.091
Number of ProGlides used		0.017	
One	14/50 (24.0)	6/16 (37.5)	0.166
Two	34/50 (54.0)	6/16 (37.5)	0.060
Three	2/50 (4.0)	4/16 (25.0)	0.027
Heparin dose, IU	10,000 (10,000-13,000)	10,500 (9,500-13,500)	0.912
ACT at closure, sec	147 (136-171)	151 (137-159)	0.883
Use of protamine		0.221	
None	0/49 (0)	0/16 (0)	
Less than full dose	22/49 (44.9)	10/16 (62.5)	
Full dose	27/49 (55.1)	6/16 (37.5)	
Fluoroscopy time, min	16.3±8.1	32.7±25.8	0.001
Contrast dye amount, ml	94.8±32.7	159.2±70.5	0.001
MANTA size		0.205	
14 Fr	15/50 (30.0)	2/16 (12.5)	
18 Fr	35/50 (70.0)	14/16 (87.5)	
Experienced operator (≥10 bailout procedures)	44/50 (88.0)	9/16 (56.3)	0.005

Values are expressed as mean±SD, median (interquartile range) or n/N (%). ACT: activated clotting time; Fr: French; SD: standard deviation

Table 4. Univariable and multivariable analysis of efficacy of bailout MANTA.

Predictors	Univariable			Multivariable		
	OR	95% CI	*p*-value	adjusted OR	95% CI	*p*-value
Age	0.92	0.83-1.02	0.123	-	-	-
Sex, female	0.34	0.11-1.10	0.068	-	-	-
Body mass index	0.98	0.89-1.09	0.745	-	-	-
Diabetes	0.72	0.23-2.24	0.575	-	-	-
Peripheral arterial disease	0.77	0.08-7.40	0.818	-	-	-
Baseline platelet count, 10^9/l	1.00	1.99-1.00	0.359	-	-	-
Oral anticoagulation	0.85	0.28-2.63	0.780	-	-	-
Antiplatelet therapy	1.31	0.41-4.16	0.648	-	-	-
Severe vascular calcification at access site	10.00	1.22-81.81	0.032	3.54	0.13-100.34	0.458
Anterior vascular classification at access site	8.91	1.83-43.40	0.007	10.71	0.58-198.38	0.111
Prior use of three ProGlides	0.13	0.02-0.77	0.024	0.02	<0.01-0.39	0.010
Common femoral artery diameter	0.98	0.69-1.39	0.887	-	-	-
Mean sheath size, French	0.75	0.47-1.20	0.225	-	-	-
Sheath-to-femoral artery ratio	1.21	0.07-20.54	0.897	-	-	-
14 French MANTA	3.00	0.61-14.68	0.178	-	-	-
Ultrasound-guided puncture	6.43	0.78-53.17	0.084	-	-	-
Experienced operator (≥10 bailout procedures)	5.70	1.55-21.04	0.009	12.29	1.99-75.99	0.007

CI: confidence interval; OR: odds ratio

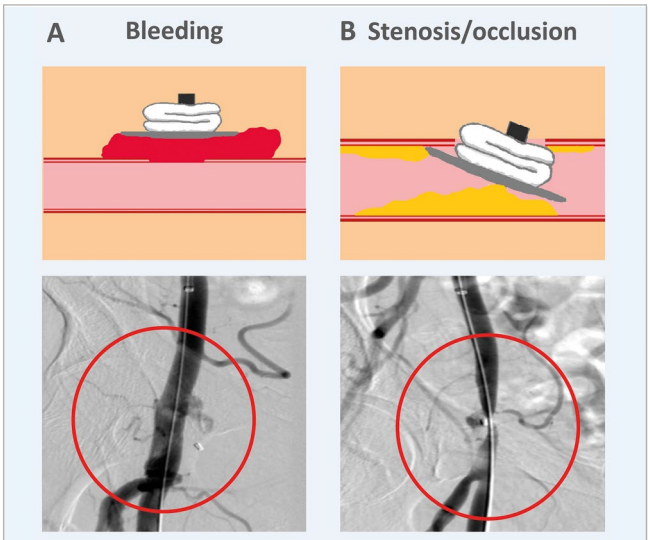


Figure 3. *Failure modes of bailout MANTA. A) Inadvertent superficial application of the MANTA device resulting in persistent bleeding. B) Deep, partially intravascular, application resulting in stenosis or occlusion.*

allow more accurate measurements without manual compression by completely sealing the puncture site. Such a device has recently been launched but was not available during the study period. A further possibility could be the use of ultrasound to guide accurate application in the target vessel, which has been demonstrated by Moriyama et al in the elective setting[19].

Finally, inflating a balloon during deployment may be useful as it would stop bleeding and may facilitate MANTA depth measurement as well as implantation. However, we do not have experience with the routine use of endovascular ballooning during bailout MANTA, and further studies are needed to determine if such an approach may further enhance efficacy.

Prior use of three ProGlides was a further predictor associated with a less frequent occurrence of the efficacy endpoint. While we cannot provide a definite explanation for this association, it can be assumed that the need for three suture-based VCDs indicates an extreme form of VCD failure, making a bailout MANTA application more difficult because of severe bleeding. It is also possible that effective haemostasis in such cases may no longer be possible with MANTA due to repeated vascular manipulation and the potential expansion of arterial injury. This observation may suggest that bailout MANTA should be considered at an early stage of suture-based VCD failure. However, this study only includes 6 cases of bailout MANTA after the failure of three ProGlides, which significantly limits the observed statistical association.

Interestingly, vascular complications associated with the MANTA bailout attempt seem to be treatable in the majority of patients with endovascular ballooning. However, stent implantation is still a possible option if the MANTA bailout attempt fails.

Whether the bailout MANTA technique is superior to direct stenting remains unknown. Overall, stent implantation after VCD failure seems to be associated with a low complication rate during follow-up[20]. Nevertheless, several aspects support a primary bailout MANTA attempt. First, the application of a MANTA VCD is faster and easier than stenting the vascular

access site. Second, in recent years, the TAVI population has become increasingly younger, and considerations of a future valve-in-valve procedure are of increasing importance[21]. In this context, stented iliofemoral vessels may be a significant limitation for subsequent procedures. Finally, a successful bailout MANTA can avoid more aggressive antithrombotic therapy due to stent implantation.

The randomised CHOICE-CLOSURE and MASH trials found no advantage of a systematic use of the MANTA VCD compared with the ProGlide VCD after TAVI[5,6], and MANTA was even associated with a higher rate of access site-related vascular complications in the CHOICE-CLOSURE trial[6]. Nevertheless, its efficacy as a bailout device appears to justify its presence among the toolbox of devices needed for contemporary percutaneous interventions requiring large-bore arterial access.

Limitations

This study has some important limitations. First, this is a non-randomised study and the choice of the bailout technique was made by the interventionalist. Thus, selection bias cannot be excluded. Second, because of the heterogeneous patient population and the small number of included patients, a direct comparison between the bailout MANTA technique and covered stent implantation was not performed. Third, the results may not be generalisable due to the monocentric study design and the high volume and experience of the study centre. Finally, the indication for using MANTA as a bailout device was not standardised. Therefore, it remains unclear whether the use of different additional closure devices would have been sufficient for haemostasis in some of the included cases.

Conclusions

Bailout application of the large-bore plug-based MANTA device was effective and safe in the majority of patients with suture-based VCD failure during transfemoral TAVI. Operator experience seems to be a crucial aspect with the current-generation device, which was not designed for bailout application. Further technological refinements to facilitate accurate placement in a bailout setting appear to be necessary.

Authors' affiliations

1. Department of Structural Heart Disease/Cardiology, Heart Center Leipzig at University of Leipzig, Leipzig, Germany; 2. Department of Structural Heart Disease/Cardiac Surgery, Heart Center Leipzig at University of Leipzig, Leipzig, Germany

Acknowledgements

We would like to thank all CHOICE-CLOSURE investigators for their support and contribution of patient-level data. Furthermore, we thank Mrs Salome Hecht for her significant contribution to data collection.

Funding

There was no external funding source for this study.

Conflict of interest statement

M. Abdel-Wahab reports that his hospital receives speaker honoraria and/or consultancy fees on his behalf from Boston Scientific, Abbott, and Medtronic. The other authors have no conflicts of interest to declare.

References

1. 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;59:113-8.

2. 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. True percutaneous approach for transfemoral aortic valve implantation using the Prostar XL device: impact of learning curve on vascular complications. *JACC Cardiovasc Interv.* 2012;5:207-14.

3. Nara Y, Watanabe Y, Kozuma K, Kataoka A, Nakashima M, Hioki H, Kawashima H, Nagura F, Shirai S, Tada N, Araki M, Naganuma T, Yamanaka F, Yamamoto M, Hayashida K. Incidence, Predictors, and Mid-Term Outcomes of Percutaneous Closure Failure After Transfemoral Aortic Valve Implantation Using an Expandable Sheath (from the Optimized Transcatheter Valvular Intervention [OCEAN-TAVI] Registry). *Am J Cardiol.* 2017;119:611-7.

4. Batchelor W, Patel K, Hurt J, Totten J, Burroughs P, Smith G, Cuervo M, Davis L, Damluji AA, Epps K, Sherwood M, Barnett S, Geloo N, Yazdani S, Sarin E, Ryan L, Noel T. Incidence, Prognosis and Predictors of Major Vascular Complications and Percutaneous Closure Device Failure Following Contemporary Percutaneous Transfemoral Transcatheter Aortic Valve Replacement. *Cardiovasc Revasc Med.* 2020;21:1065-73.

5. van Wiechen MP, Tchétché D, Ooms JF, Hokken TW, Kroon H, Ziviello F, Ghattas A, Siddiqui S, Laperche C, Spitzer E, Daemen J, de Jaegere PP, Dumonteil N, Van Mieghem NM. Suture- or Plug-Based Large-Bore Arteriotomy Closure: A Pilot Randomized Controlled Trial. *JACC Cardiovasc Interv.* 2021;14:149-57.

6. Abdel-Wahab M, Hartung P, Dumpies O, Obradovic D, Wilde J, Majunke N, Boekstegers P, Müller R, Seyfarth M, Vorpahl M, Kiefer P, Noack T, Leontyev S, Sandri M, Rotta Detto Loria J, Kitamura M, Borger MA, Funkat AK, Hohenstein S, Desch S, Holzhey D, Thiele H; CHOICE-CLOSURE Investigators. Comparison of a Pure Plug-Based Versus a Primary Suture-Based Vascular Closure Device Strategy for Transfemoral Transcatheter Aortic Valve Replacement: The CHOICE-CLOSURE Randomized Clinical Trial. *Circulation.* 2022;145:170-83.

7. 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;4:851-8.

8. El-Mawardy M, Schwarz B, Landt M, Sulimov D, Kebernik J, Allali A, Becker B, Toelg R, Richardt G, Abdel-Wahab M. Impact of femoral artery puncture using digital subtraction angiography and road mapping on vascular and bleeding complications after transfemoral transcatheter aortic valve implantation. *EuroIntervention.* 2017;12:1667-73.

9. Bazarbashi N, Ahuja K, Gad MM, Sammour YM, Kaur M, Karrthik A, Saad AM, Khubber S, Dhaliwal K, Mick SL, Navia JL, Puri R, Reed GW, Krishnaswamy A, Kapadia SR. The utilization of single versus double Perclose devices for transfemoral aortic valve replacement access site closure: Insights from Cleveland Clinic Aortic Valve Center. *Catheter Cardiovasc Interv.* 2020;96:442-7.

10. Kodama A, Yamamoto M, Shimura T, Kagase A, Koyama Y, Tada N, Takagi K, Araki M, Yamanaka F, Shirai S, Watanabe Y, Hayashida K. Comparative data of single versus double proglide vascular preclose technique after percutaneous transfemoral transcatheter aortic valve implantation from the optimized catheter valvular intervention (OCEAN-TAVI) japanese multicenter registry. *Catheter Cardiovasc Interv.* 2017;90:E55-62.

11. 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 1: basic anatomy, imaging, sheaths, wires, and access routes. *JACC Cardiovasc Interv.* 2013;6:643-53.

12. van Gils L, Daemen J, Walters G, Sorzano T, Grintz T, Nardone S, Lenzen M, De Jaegere PP, Roubin G, Van Mieghem NM. MANTA, a novel

plug-based vascular closure device for large bore arteriotomies: technical report. *EuroIntervention*. 2016;12:896-900.

13. Gmeiner JMD, Linnemann M, Steffen J, Scherer C, Orban M, Theiss H, Mehilli J, Sadoni S, Peterß S, Joskowiak D, Hagl C, Tsilimparis N, Curta A, Maurus S, Doldi PM, Löw K, Haum M, Roden D, Hausleiter J, Massberg S, Rizas K, Deseive S, Braun D. Dual ProGlide versus ProGlide and FemoSeal for vascular access haemostasis after transcatheter aortic valve implantation. *EuroIntervention*. 2022;18:812-9.

14. Ko TY, Kao HL, Liu YJ, Yeh CF, Huang CC, Chen YH, Hung CS, Chan CY, Lin LC, Chen YS, Lin MS. Intentional combination of ProGlide and AngioSeal for femoral access haemostasis in transcatheter aortic valve replacement. *Int J Cardiol*. 2019;293:76-9.

15. Lindner JU, Markuske M, Szczanowicz L, Jobs A, Abdel-Wahab M, Desch S, Thiele H, Sulimov DS. Balloon-assisted injection of fibrin sealant for the treatment of postintervention access-site bleeding complications. *Catheter Cardiovasc Interv*. 2022;99:1327-34.

16. Langouet Q, Martinez R, Saint-Etienne C, Behlaj Soulami R, Harmouche M, Aupart M, Le Breton H, Verhoye JP, Bourguignon T. Incidence, predictors, impact, and treatment of vascular complications after transcatheter aortic valve implantation in a modern prospective cohort under real conditions. *J Vasc Surg*. 2020;72:2120-9.e2.

17. Chen IM, Lee TH, Chen PL, Shih CC, Chang HH. Factors in ProGlide® Vascular Closure Failure in Sheath Arteriotomies Greater than 16 French. *Eur J Vasc Endovasc Surg*. 2019;58:615-22.

18. Kastengren M, Settergren M, Rück A, Feldt K, Saleh N, Linder R, Verouhis D, Meduri CU, Bager J, Dalén M. Percutaneous plug-based vascular closure device in 1000 consecutive transfemoral transcatheter aortic valve implantations. *Int J Cardiol*. 2022;359:7-13.

19. Moriyama N, Dahlbacka S, Vähäsilta T, Vainikka T, Aho P, Viikilä J, Lammintausta O, Laine M. The Efficacy of the Ultrasound-Navigated MANTA Deployment Following Transfemoral Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv*. 2019;12:2564-6.

20. Drouelle E, De Poli F, Couppie P, Uhry S, Heyer H, Morel O, Ohlmann P, Hess S, Kibler M, Leddet P. Suivi clinique après implantation d'un stent couvert dans l'artère fémorale commune au décours immédiat d'une complication vasculaire per-TAVI [Common femoral artery bailout stenting with covered stent graft due to TAVR vascular complication: Clinical long term follow-up]. *Ann Cardiol Angeiol* (Paris). 2019;68:316-24.

21. Tarantini G, Nai Fovino L. Lifetime Strategy of Patients With Aortic Stenosis: The First Cut Is the Deepest. *JACC Cardiovasc Interv*. 2021;14:1727-30.

Supplementary data

Supplementary Table 1. Management and outcome of patients with ProGlide failure that were not treated with bailout MANTA (n=41).

Supplementary Table 2. Echocardiographic and multidetector computed tomography characteristics of the study population (n=66).

Supplementary Table 3. Procedural details.

Supplementary Table 4. Baseline clinical characteristics of bailout MANTA and elective MANTA procedures.

Supplementary Table 5. Echocardiographic and multidetector computed tomography characteristics of bailout MANTA and elective MANTA procedures.

Supplementary Table 6. Procedural details of bailout MANTA and elective MANTA procedures.

Supplementary Table 7. Baseline clinical characteristics stratified by the effectiveness of bailout MANTA.

Supplementary Table 8. Echocardiographic and multidetector computed tomography characteristics stratified by the effectiveness of bailout MANTA.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-23-00750

Supplementary data

Supplementary Table 1. Management and outcome of patients with ProGlide failure that were not treated with bailout MANTA (n=41).

Variable	
Treatment resulting in hemostasis	
Manual compression	6 (12.2%)
Additional ProGlide VCD	23 (56.1%)
Endovascular ballooning	2 (4.9%)
Stent implantation	9 (22.0%)
Fibrin injection	1 (2.4%)
Vascular complications	
Vascular occlusion	1 (2.4%)
Vascular stenosis	2 (4.9%)
Vascular dissection	2 (4.9%)
Pseudoaneurysm	3 (7.3%)
Values are numbers (%). VCD = Vascular closure device.	

Supplementary Table 2. Echocardiographic and multidetector computed tomography characteristics of the study population (n=66).

Variable	
Echocardiography	
Aortic valve area (cm²)	0.7 (0.6 – 0.9)
Mean gradient (mmHg)	41 (33– 51)
LV ejection fraction (%)	56 (50 – 60)
Severe aortic regurgitation	2/66 (3.0%)
Severe mitral regurgitation	2/66 (3.0%)
Severe tricuspid regurgitation	2/66 (3.0%)
Systolic pulmonary artery pressure (mmHg)	46 (35 – 67)
Multidetector computed tomography	
Diameter of iliofemoral arteries (access-site)	
Common iliac (mm)	9.2 ± 1.8
External iliac (mm)	7.6 ± 1.6
Common femoral (mm)	7.6 ± 1.6
Tortuosity of the iliofemoral arteries (access-site) *	
None	8/66 (12.1%)
Mild	22/66 (33.3%)
Moderate	26/66 (39.4%)
Severe	10/66 (15.2%)
Calcification of iliofemoral artery (access-site) †	
None	4/66 (6.1%)
Mild	19/66 (28.8%)
Moderate	22/66 (33.3%)
Severe	21/66 (31.8%)
Anterior vascular calcification of the access-site	30/66 (45.5%)
Height of the common femoral bifurcation (access-site) ‡	
Grade 1	33/65 (50.8%)
Grade 2	10/65 (15.4%)
Grade 3	18/65 (27.7%)
Grade 4	3/65 (4.6%)
Grade 5	1/65 (1.5%)
Grade 6	0/65 (0.0%)

Values are mean ± SD or median (interquartile range) or no/total no (%).
LV = left ventricle.
*Vessel tortuosity was graded on the following scale: grade 0, no tortuosity; grade 1, mild tortuosity (30°-60°); grade 2, moderate tortuosity (60° to 90°); and grade 3 severe tortuosity (≥90°).
† None: no calcification; (B) mild: ≤1 cm, ≤180º; (C) moderate: >1 cm, ≤180º; severe: >180º.
‡ Bifurcation height was graded as follows: grade 1, below the inferior border of the femoral head; grade 2, at the inferior border of the femoral head; grade 3, below the center of the femoral head but above the inferior border of the femoral head; grade 4, at the center of the femoral head; grade 5, above the center of the femoral head; grade 6, above or at the superior border of the femoral head.

Supplementary Table 3. Procedural details.

Variable	
Main access site (right)	59/66 (89.4%)
Mean sheath size (French)	14 (14 – 16)
Sheath-to-femoral artery ratio	0.74 (0.66 – 0.88)
Ultrasound guided puncture	16/66 (24.2%)
Valve type	
Evolut R	5/66 (7.6%)
Evolut PRO	17/66 (25.8%)
Evolut PRO+	6/66 (9.1%)
Sapien 3	16/66 (24.2%)
Sapien 3 ultra	10/66 (15.2%)
Acurate neo2	12/66 (18.2%)
Number of used ProGlides	
One	20/66 (30.3%)
Two	40/66 (60.6%)
Three	6/66 (9.1%)
Heparin dose (IU)	10000 (10000 – 13000)
ACT at closure (seconds)	148 (136 – 169)
Use of protamine	
None	0/65 (0%)
Less than full dose	32/65 (49.2%)
Full dose	33/65 (50.8%)
MANTA size	
14 French	17/66 (25.8%)
18 French	49/66 (74.2%)
Fluoroscopy time (min)	19.8 ± 15.2
Contrast dye amount (ml)	110.4 ± 52.0
Experienced operator (≥10 bailout procedures)	53/66 (80.3%)

Values are mean ± SD or median (interquartile range) or no/total no (%).
ACT = Activated clotting time.

Supplementary Table 4. Baseline clinical characteristics of bailout MANTA and elective MANTA procedures.

Variable	Bailout MANTA	Elective MANTA	p- value
	n=66	n=258	
Age (years)	81.1 ± 5.9	80.7 ± 5.7	0.792
Female sex	28/66 (42.6%)	115/258 (44.6%)	0.861
Body mass index (kg/m²)	29.4 ± 5.5	28.5 ± 5.1	0.209
Society of Thoracic Surgeons score (%)	3.5 (2.3 – 6.4)	3.2 (2.1 – 5.0)	0.215
Logistic EuroScore (%)	12.1 (6.5 – 18.0)	10.6 (7.0 – 16.6)	0.673
New York Heart Association class			0.455
Class I	5/66 (7.6%)	20/258 (7.8%)	
Class II	11/66 (16.7%)	67/258 (26.0%)	
Class III	44/66 (66.7%)	152/258 (58.9%)	
Class IV	6/66 (9.1%)	19/258 (7.4%)	
Diabetes mellitus	37/66 (56.1%)	98/258 (38.0%)	0.012
Coronary artery disease	39/66 (59.1%)	141/258 (54.7%)	0.794
Previous myocardial infarction	6/66 (9.1%)	35/258 (13.6%)	0.442
Cerebral vascular disease	15/66 (22.7%)	26/258 (10.1%)	0.011
Previous stroke	11/66 (16.7%)	35/258 (13.6%)	0.655
Peripheral vascular disease	5/66 (7.6%)	18/258 (7.0%)	0.921
Previous peripheral intervention	2/66 (3.0%)	4/258 (1.6%)	0.776
Atrial fibrillation	29/66 (43.9%)	88/258 (34.1%)	0.180
Severe chronic renal failure*	12/66 (18.2%)	25/258 (9.7%)	0.025
Baseline creatinine level (µmol/l)	108.0 (85.0 – 136.0)	94.8 (74.0 – 119)	0.013
Baseline hemoglobin level (mmol/l)	7.5 ± 1.1	7.7 ± 1.1	0.929
Baseline INR	1.1 (1.0 – 1.2)	1.0 (1.0 – 1.2)	0.201
Antiplatelets/anticoagulation			
None	11/66 (16.7%)	68/258 (26.4%)	0.140
Single antiplatelet therapy	26/66 (39.4%)	92/258 (35.6%)	0.675
Dual antiplatelet therapy	0/66 (0.0%)	15/258 (5.8%)	0.048
Oral anticoagulation	25/66 (37.9%)	68/258 (26.4%)	0.090
Oral anticoagulation and antiplatelet therapy	4/66 (6.1%)	15/258 (5.9%)	0.828

Values are mean ± SD or median (interquartile range) or no/total no (%).
CABG = coronary artery bypass grafting, PCI = percutaneous coronary intervention, INR = International Normalized Ratio, NT-pro BNP = N-terminal prohormone of brain natriuretic peptide.
* defined as a glomerular filtration rate <30 ml/min/1.73 m2

Supplementary Table 5. Echocardiographic and multidetector computed tomography characteristics of bailout MANTA and elective MANTA procedures.

Variable	Bailout MANTA	Elective MANTA	p- value
	n=66	n=258	
Echocardiography			
Aortic valve area (cm²)	0.7 (0.6 – 0.9)	0.7 (0.6 – 0.9)	0.521
Mean gradient (mmHg)	41 (33– 51)	41 (31 – 50)	0.712
LV ejection fraction (%)	56 (50 – 60)	57 (47 – 63)	0.525
Severe aortic regurgitation	2/66 (3.0%)	9/253 (3.6%)	0.870
Severe mitral regurgitation	2/66 (3.0%)	3/254 (1.2%)	0.359
Severe tricuspid regurgitation	2/66 (3.0%)	5/250 (2.0%)	0.663
Multidetector computed tomography			
Diameter of iliofemoral arteries (access-site)			
Common iliac (mm)	9.2 ± 1.8	9.7 ± 2.2	0.092
External iliac (mm)	7.6 ± 1.6	7.9 ± 1.4	0.161
Common femoral (mm)	7.6 ± 1.6	7.8 ± 1.6	0.300
Tortuosity of the iliofemoral arteries (access-site) *			0.131
None	8/66 (12.1%)	25/257 (9.7%)	
Mild	22/66 (33.3%)	86/257 (33.5%)	
Moderate	26/66 (39.4%)	74/257 (28.8%)	
Severe	10/66 (15.2%)	72/257 (28.0%)	
Calcification of iliofemoral artery (access-site) †			<0.001
None	4/66 (6.1%)	46/244 (18.9%)	
Mild	19/66 (28.8%)	84/244 (34.4%)	
Moderate	22/66 (33.3%)	83/244 (34.0%)	
Severe	21/66 (31.8%)	31/244 (12.7%)	
Anterior vascular calcification of the access-site	30/66 (45.5%)	83/244 (34.0%)	0.117
Height of the common femoral bifurcation (access-site) ‡			0.993
Grade 1	33/65 (50.8%)	123/245 (50.2%)	
Grade 2	10/65 (15.4%)	40/245 (16.3%)	
Grade 3	18/65 (27.7%)	63/245 (25.7%)	
Grade 4	3/65 (4.6%)	13/245 (5.3%)	
Grade 5	1/65 (1.5%)	5/245 (2.0%)	
Grade 6	0/65 (0.0%)	1/245 (0.4%)	

Values are mean ± SD or median (interquartile range) or no/total no (%).
LV = left ventricle.
*Vessel tortuosity was graded on the following scale: grade 0, no tortuosity; grade 1, mild tortuosity (30°-60°); grade 2, moderate tortuosity (60° to 90°); and grade 3 severe tortuosity (≥90°).
† None: no calcification; (B) mild: ≤1 cm, ≤180º; (C) moderate: >1 cm, ≤180º; severe: >180º.
‡ Bifurcation height was graded as follows: grade 1, below the inferior border of the femoral head; grade 2, at the inferior border of the femoral head; grade 3, below the center of the femoral head but above the inferior border of the femoral head; grade 4, at the center of the femoral head; grade 5, above the center of the femoral head; grade 6, above or at the superior border of the femoral head.

Supplementary Table 6. Procedural details of bailout MANTA and elective MANTA procedures.

Variable	Bailout MANTA	Elective MANTA	p- value
	n=66	n=258	
Main access site (right)	59/66 (89.4%)	228/258 (88.4%)	0.987
Mean sheath size (French)	14 (14 – 16)	14 (14 – 16)	0.248
Ultrasound guided puncture	16/66 (24.2%)	51/258 (19.8%)	0.528
Valve type			
Heparin dose (IU)	10000 (10000 – 13000)	10000 (10000 – 11000)	0.001
Use of protamine			<0.001
None	0/65 (0%)	4/256 (1.6%)	
Less than full dose	32/65 (49.2%)	202/256 (78.9%)	
Full dose	33/65 (50.8%)	50/256 (19.5%)	
MANTA size			<0.001
14 French	17/66 (25.8%)	0/258 (0%)	
18 French	49/66 (74.2%)	258/258 (100%)	
Fluoroscopy time (min)	19.8 ± 15.2	15.9 ± 9.0	0.008
Contrast dye amount (ml)	110.4 ± 52.0	106.6 ± 49.6	0.583

Values are mean ± SD or median (interquartile range) or no/total no (%).
ACT = Activated clotting time.

Supplementary Table 7. Baseline clinical characteristics stratified by the effectiveness of bailout MANTA.

Variable	Effective bailout MANTA	Ineffective bailout MANTA	p-value
	n= 50 (75.8%)	n= 16 (24.2%)	
Age (years)	80.4 ± 6.3	83.1 ± 4.2	0.119
Female sex	18/50 (36.0%)	10/16 (62.5%)	0.062
Body mass index (kg/m²)	29.3 ± 5.1	29.8 ± 6.8	0.749
Logistic EuroSCORE	12.1 (6.3 – 17.4)	14.1 (7.6 – 19.3)	0.394
Society of Thoracic Surgeons score	3.4 (2.3 – 6.4)	4.1 (3.2 – 10.5)	0.081
New York Heart Association class			0.264
Class I	4/50 (8.0%)	1/16 (6.3%)	
Class II	7/50 (14.0%)	4/16 (25.0%)	
Class III	36/50 (72.0%)	8/16 (50.0%)	
Class IV	3/50 (6.0%)	3/16 (18.8%)	
Diabetes mellitus	21/50 (41.0%)	8/16 (50.0%)	0.575
Coronary artery disease	31/50 (62.0%)	8/16 (50.0%)	0.395
Previous myocardial infarction	5/50 (10.0%)	1/16 (6.3%)	1.000
Previous CABG	3/50 (6.0%)	0/16 (0.0%)	0.571
Previous PCI	8/50 (16.0%)	4/16 (25.0%)	0.465
Previous valve surgery	6/50 (12.0%)	2/16 (12.5%)	1.000
Cerebral vascular disease	12/50 (24.0%)	3/16 (18.8%)	1.000
Previous stroke	9/50 (18.0%)	2/16 (12.5%)	1.000
Peripheral vascular disease	4/50 (8.0%)	1/16 (6.3%)	1.000
Previous peripheral intervention	1/50 (2.0%)	1/16 (6.3%)	0.429
Atrial fibrillation	23/50 (34.8%)	6/16 (37.5%)	0.551
Chronic dialysis	2/50 (4.0%)	0/16 (0.0%)	1.000
Severe chronic renal failure*	9/50 (18.0%)	3/16 (18.8%)	1.000
Baseline creatinine level (µmol/l)	108 (87 – 136)	123 (84 – 145)	0.761
Baseline hemoglobin level (mmol/l)	7.6 ± 1.1	7.2 ± 1.0	0.093
Baseline INR	1.1 (1.0 – 1.3)	1.1 (1.0 – 1.2)	0.737
Baseline Platelet count (10^9/l)	210 (157 – 255)	201 (179 – 311)	0.220
Baseline NT-pro BNP level (ng/l)	2582 (760 – 5811)	1958 (1203 – 6957)	0.697
Baseline antithrombotic therapy			
None	9/50 (18.0%)	2/16 (12.5%)	0.898
Single antiplatelet therapy	18/50 (36.0%)	8/16 (50.0%)	0.482
Dual antiplatelet therapy	0/50 (0.0%)	0/16 (0.0%)	--
Oral anticoagulation	19/50 (38.0%)	6/16 (37.5%)	0.795
Oral anticoagulation and antiplatelet therapy	4/50 (8.0%)	0/16 (0)	0.565

Values are mean ± SD, median (interquartile range) or no/total no (%).
CABG = coronary artery bypass grafting, PCI = percutaneous coronary intervention, INR = International Normalized Ratio, NT-pro BNP = N-terminal prohormone of brain natriuretic peptide, IQR = interquartile range.
* defined as a glomerular filtration rate <30 ml/min/1.73 m2

Supplementary Table 8. Echocardiographic and multidetector computed tomography characteristics stratified by the effectiveness of bailout MANTA.

Variable	Effective bailout MANTA	Ineffective bailout MANTA	p-value
	n= 50 (75.8%)	n= 16 (24.2%)	
Echocardiography			
Aortic valve area (cm²)	0.7 (0.6 – 0.9)	0.6 (0.5 – 0.8)	0.115
Mean gradient (mmHg)	43.0 (31 – 52)	37.0 (35 – 43)	0.669
LV ejection fraction (%)	57.0 (51– 60)	55.0 (50 – 65)	0.647
Multidetector computed tomography			
Diameter of iliofemoral arteries (access-site)			
Common iliac (mm)	9.2 ± 1.9	9.0 ± 1.7	0.674
External iliac (mm)	7.5 ± 1.7	7.7 ± 1.3	0.715
Common femoral (mm)	7.6 ± 1.7	7.5 ± 1.4	0.889
Tortuosity of the iliofemoral arteries (access-site)			0.722
None	5/50 (10.0%)	3/16 (18.3%)	
Mild	17/50 (34.0%)	5/16 (31.3%)	
Moderate	21/50 (41.0%)	5/16 (31.3%)	
Severe	7/50 (14.0%)	3/16 (18.3%)	
Calcification of iliofemoral artery (access-site)			0.056
None	5/50 (10.0%)	1/16 (6.3%)	
Mild	11/50 (22.0%)	7/16 (43.8%)	
Moderate	14/50 (28.0%)	7/16 (43.8%)	
Severe	20/50 (40.0%)	1/16 (6.3%)	
Anterior vascular calcification of the access-site no/total no. (%)	28/41 (56.0%)	2/14 (12.5%)	0.003
Height of the common femoral bifurcation (access-site)			0.045
Grade 1	28/49 (57.1%)	5/16 (31.3%)	
Grade 2	9/49 (18.4%)	1/16 (6.3%)	
Grade 3	10/49 (20.4%)	8/16 (50.0%)	
Grade 4	2/49 (4.1%)	1/16 (6.3%)	
Grade 5	0/49 (0.0%)	1/16 (6.3%)	
Grade 6	0/49 (0.0%)	0/16 (0.0%)	

Values are mean ± SD, median (interquartile range) or no/total no (%).
LV = left ventricle.
*Vessel tortuosity was graded on the following scale: grade 0, no tortuosity; grade 1, mild tortuosity (30°-60°); grade 2, moderate tortuosity (60° to 90°); and grade 3 severe tortuosity (≥90°).
† None: no calcification; (B) mild: ≤1 cm, ≤180º; (C) moderate: >1 cm, ≤180º; severe: >180º.
‡ Bifurcation height was graded as follows: grade 1, below the inferior border of the femoral head; grade 2, at the inferior border of the femoral head; grade 3, below the center of the femoral head but above the inferior border of the femoral head; grade 4, at the center of the femoral head; grade 5, above the center of the femoral head; grade 6, above or at the superior border of the femoral head.