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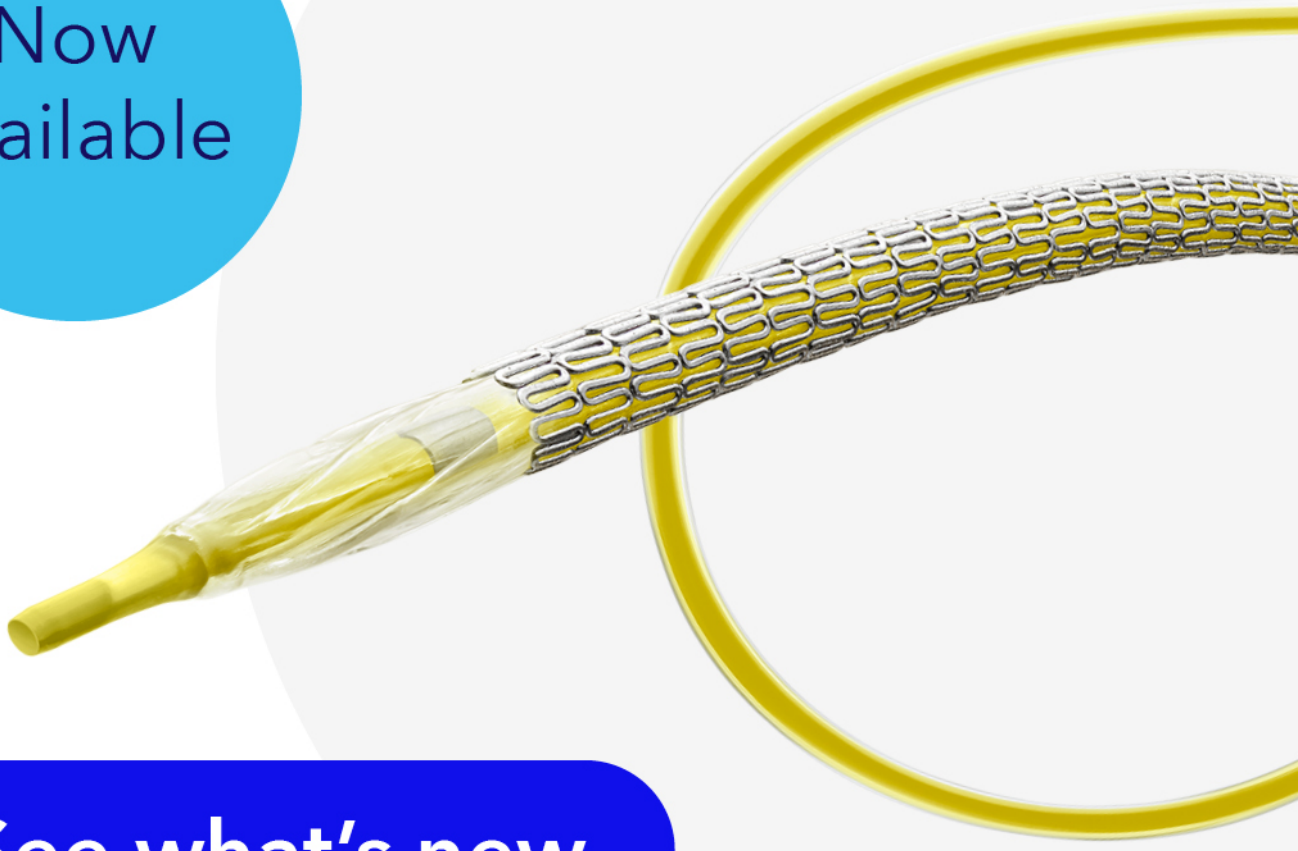

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ORIGINAL ARTICLE - CLINICAL SCIENCE

WILEY

Outcomes with plug-based versus suture-based vascular closure device after transfemoral transcatheter aortic valve replacement: A systematic review and meta-analysis

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Abstract

Background: Studies comparing plug-based (i.e., MANTA) with suture-based (i.e., ProStar XL and ProGlide) vascular closure devices (VCDs) for large-bore access closure after transcatheter aortic valve replacement (TAVR) have yielded mixed results.

Aims: To examine the comparative safety and efficacy of both types of VCDs among TAVR recipients.

Methods: An electronic database search was performed through March 2022 for studies comparing access-site related vascular complications with plug-based versus suture-based VCDs for large-bore access site closure after transfemoral (TF) TAVR.

Results: Ten studies (2 randomized controlled trials [RCTs] and 8 observational studies) with 3113 patients (MANTA = 1358, ProGlide/ProStar XL = 1755) were included. There was no difference between plug-based and suture-based VCD in the incidence of access-site major vascular complications (3.1% vs. 3.3%, odds ratio [OR]: 0.89; 95% confidence interval [CI]: 0.52–1.53). The incidence of VCD failure was lower in plug-based VCD (5.2% vs. 7.1%, OR: 0.64; 95% CI: 0.44–0.91). There was a trend toward a higher incidence of unplanned vascular intervention in plug-based VCD (8.2% vs. 5.9%, OR: 1.35; 95% CI: 0.97–1.89). Length of stay was shorter with MANTA. Subgroup analyses suggested significant interaction based on study designs such that there was higher incidence of access-site vascular complications and bleeding events with plug-based versus suture-based VCD among RCTs.

Conclusion: In patients undergoing TF-TAVR, large-bore access site closure with plug-based VCD was associated with a similar safety profile as suture-based VCD. However, subgroup analysis showed that plug-based VCD was associated with higher incidence of vascular and bleeding complications in RCTs.

KEYWORDS

MANTA, ProGlide, ProStar, vascular closure device

Abbreviations: LOS, length of stay; SMD, standardized mean difference; TAVR, transcatheter aortic valve replacement; VARC-2, valve academic research consortium-2; VCD, vascular closure device.

1 | INTRODUCTION

Transcatheter aortic valve replacement (TAVR) is increasingly adopted as a treatment option for patients with severe aortic stenosis irrespective of surgical risk.[1–4] TAVR volumes have been increasing in recent years, and have surpassed the volumes of surgical aortic valve replacements.[5] The majority of TAVR procedures (~95%) in the United States are performed via transfemoral (TF) access, which has been associated with reduced bleeding risk, length of stay (LOS), and better rates of discharge to home compared with other access sites.[5] Despite advances in valve design, sheath technology, and vascular closure devices (VCDs), vascular complications are still present, even in low-risk patients.[6–8] Vascular complications contribute significantly to both short and long-term clinical outcomes, including hospital LOS, readmission, and all-cause mortality.[9,10]

Suture-based ProGlide and ProStar VCD (Abbott Vascular) are widely used in clinical practice for TAVR.[8] For large-bore access closure, 2 ProGlides are inserted before the procedure (preclosure). At the end of the procedure, the sutures are tightened with a safety wire in place in case additional VCDs are needed. On the other hand, the MANTA VCD (Teleflex) is a plug-based VCD that is specifically designed for large-bore access closure. It is available in two sizes: 14 (for 10–14 F arterial punctures) and 18 F for 15–22 F arterial punctures. Earlier studies have shown that MANTA device is safe and effective in achieving hemostasis with low complications rates.[11,12]

Studies comparing plug-based (i.e., MANTA) with suture-based (i.e., ProStar and ProGlide) VCDs for large-bore access closure after TAVR have yielded mixed results.[13–15] Our study aims to review and pool contemporary data regarding the safety and efficacy of plug-based versus suture-based VCDs in TAVR recipients.

2 | MATERIALS AND METHODS

2.1 | Data sources and search strategy

A computerized search of MEDLINE, COCHRANE, and EMBASE databases was performed through March 2022, using the terms "MANTA," "ProGlide," "ProStar," "vascular closure device," and "TAVR" separately and in combination to identify any study that evaluated the outcomes with plug-based versus suture-based VCD for large-bore access closure after TAVR. We did not apply language restrictions to our database search. A parallel search was also done for abstracts presented at the major scientific sessions (American College of Cardiology, European Society of Cardiology, the American Heart Association, and Society for Cardiovascular Angiography and Interventions meetings) using similar terms between March 2020 and 2022. Further screening of the bibliographies of the retrieved studies and ClinicalTrials.gov was performed to identify any relevant studies not retrieved through the primary search. The current meta-analysis was conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[16] (Supporting Information: Table 1) and was registered at PROSPERO (CRD42022327152). This study was exempted from institutional review board since this is a study-level meta-analysis.

2.2 | Selection criteria

Any study that compared main access-site vascular complications with plug-based versus suture-based VCDs for large-bore access site closure after TF TAVR was included. Studies which did not report main access site vascular complications were excluded.[17]

2.3 | Data extraction

Two independent investigators (R. S. and A.D.) extracted the study design, baseline characteristics, intervention strategies, and clinical outcomes. Discrepancies among investigators were resolved by consensus.

2.4 | Outcomes

The primary outcome of the study was major access-site vascular complications, as defined per valve academic research consortium-2 consensus document (VARC-2).[18] The secondary outcomes included major access-site vascular complications as defined per each study, minor vascular complications, life-threatening/major bleeding, minor bleeding, blood transfusion, VCD failure, additional unplanned access-site intervention (i.e., surgery or endovascular intervention), and all-cause mortality. Additionally, we reported the incidence of individual components of access-site complications (i.e., dissection, pseudoaneurysm, vessel occlusion, arteriovenous fistula, lower extremity ischemia, and hematoma). Definitions of outcomes, inclusion, and exclusion criteria as per each study are shown in Supporting Information: Table 2. In each study, we used the data at the longest reported follow-up.

2.5 | Assessment of the quality of the included studies

The quality of the randomized controlled trials (RCT) was evaluated using the Cochrane risk assessment tool of bias; including the following criteria: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias.[19] Accordingly, studies were classified into low risk, unclear risk, or high risk of bias.

The quality of the observational studies was assessed using Newcastle–Ottawa scale for assessing the quality of nonrandomized

studies in meta-analyses in which a study is judged on three broad perspectives: the selection of the study groups; the comparability of the groups; and the ascertainment of outcome of interest for cohort studies. Accordingly, the quality of the studies was classified as very good, good, satisfactory, or unsatisfactory corresponding to a score of 9–10, 7–8, 5–6, or 0–4 points, respectively.[20]

2.6 | Statistical analysis

The analysis was performed using intention-to-treat model. Data were pooled primarily using a random-effects model. Summary estimates for categorical variables were reported as odds ratios (OR), and for continuous variables were reported as standardized mean difference (SMD). Statistical heterogeneity across the included studies was ascertained using I^2 statistics; such that I^2 statistic values <25%, 25%–50%, and >50% corresponded to low, moderate, and high degree of heterogeneity, respectively.[21] Subgroup analyses were performed for all the outcomes to compare RCTs versus observational studies. Sensitivity analyses for the primary outcome were conducted after excluding studies in which ProStar XL VCD was used in the control group as it has been shown that, compared to ProGlide, Prostar is associated with a higher rate of vascular complications.[8,22] *p* Values were considered significant for subgroup interaction if <0.10,[23] while for all other analyses were considered statistically significant if <0.05. *p* Values and 95% confidence intervals (CI) presented in this report have not been adjusted for multiplicity, and therefore inferences drawn from these statistics may not be reproducible. Statistical analyses were conducted using RevMan 5.0 software (Cochrane Collaboration).

3 | RESULTS

3.1 | Included studies

The study selection process appears in Figure 1. Ten studies (2 RCTs and 8 observational studies) with a total of 3113 patients (MANTA = 1358, ProGlide/ProStar XL = 1755) were included. Eight studies compared MANTA with ProGlide, and 2 studies compared MANTA with ProStar XL.[24,25] Three studies used propensity-score matching [14,26,27] and 1 study was published only as an abstract.[26] The weighted mean age was 80.4 years and included patients were predominantly men. Use of ultrasound for obtaining arterial access was not universal and only 4 studies utilized ultrasound in all the patients,[14,15,24,27] while in the remaining studies, a mixture of angiographic, fluoroscopic, and/or ultrasound guidance was utilized. Self-expandable valves were the most commonly used valves and heparin reversal with protamine was performed in most of the studies. Study characteristics appear in Table 1, while patients' and procedural characteristics appear in Tables 2 and 3. The quality of included studies is outlined in Supporting Information: Tables 3–4. The study by Sa Mendes et al.[26] was published only as an abstract, so the quality of the study could not be fully ascertained. All studies, except 1,[31] were deemed to be of good quality/low risk of bias. All studies were open-label.

3.2 | Primary outcome

Access-site major vascular complication defined as per VARC-2 criteria was reported in 8 studies. On meta-analysis, there was no significant difference between plug-based and suture-based VCD in the incidence of the primary outcome (3.1% vs. 3.3%, OR: 0.89; 95% CI: 0.52–1.53,

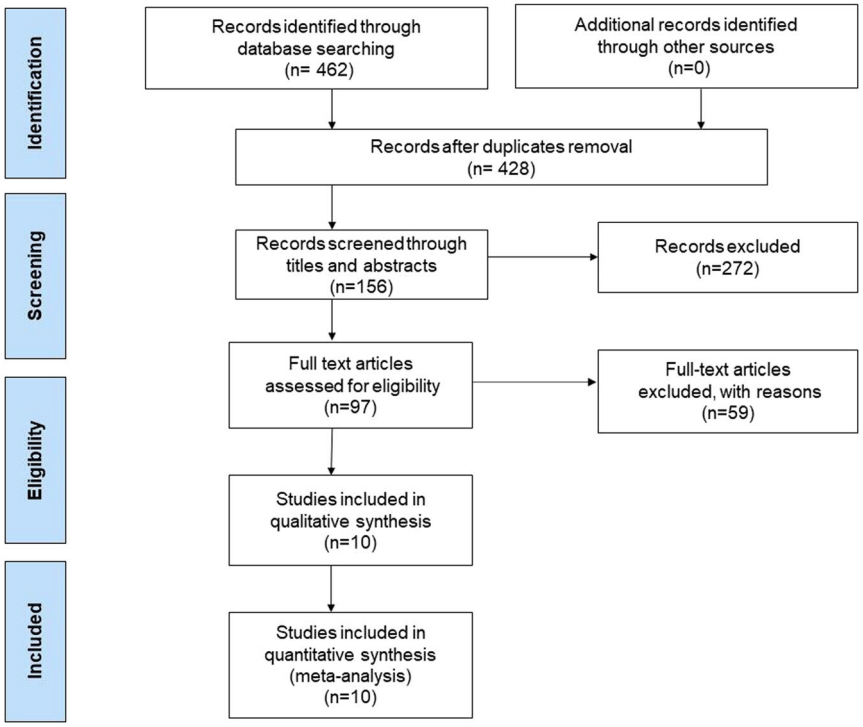


FIGURE 1 Flow diagram of the study selection process. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Characteristics of the included studies.

Study	Year	Design	MANTA VCD (*n*)	Suture-based VCD (*n*)	Type of suture-based VCD	Follow up period (days)	Periprocedural antithrombotic regimen	Protamine use	Method of obtaining vascular access
CHOICE-CLOSURE[13]	2022	Multicenter RCT	258	258	ProGlide	30	DOAC stopped 24 h before procedure. VKA were continued aiming at INR 2–2.5. Patients received intravenous unfractionated heparin during the procedure, with a target ACT of 250–300 s.	Reduced dose of protamine (500 IU/1000 IU of heparin) was regularly administered to reduce the ACT to <250 s	Angiography or ultrasound guidance
MASH[15]	2021	Two-center RCT	102	104	ProGlide	30	DOACs were stopped before the procedure.	Protamine was used at the operator's discretion with a target ACT < 200 s.	Ultrasound guidance
Medranda et al.[14]	2021	Single center observational (propensity matched)	124	124	ProGlide	In-hospital	NR	Protamine was utilized in cases to minimize bleeding when necessary.	Ultrasound guidance
Dumpies et al.[28]	2021	Single center observational	195	383	ProGlide	30	DOACs were stopped 24–36 h before the procedure. VKA were continued, aiming at an INR 2–2.5. Intravenous unfractionated heparin during the procedure with a target ACT of 250–300 s.	A reduced dose of protamine was regularly administered at the end of the procedure.	Angiography guidance (road-mapping)
Sa Mendes et al.[26]	2020	Single center observational (propensity matched)	129	129	ProGlide	NR	NR	NR	NR
Gheorghe et al.[25]	2019	Single center observational cohort	168	198[a]	Prostar XL	30	DOACs were stopped 24 h before the procedure. VKA were continued aiming at INR 2–2.5. Intravenous unfractionated heparin during the procedure with a target ACT of 250–300 s.	Heparin reversal with protamine was routinely performed after the valve implantation and before vascular access closure.	Fluoroscopy or ultrasound guidance
Biancari et al.[29]	2018	Multicenter observational	107	115	ProGlide	30	NR	NR	Fluoroscopy or ultrasound guidance
De Palma et al.[24]	2018	Single center observational	89	257[a]	Prostar XL	30	Intraprocedural unfractionated heparin was used in all and titrated to a target ACT of 250–300 s.	Protamine was at the discretion of the operator.	Ultrasound ± fluoroscopy guidance

TABLE 1 (Continued)

Study	Year	Design	MANTA VCD (*n*)	Suture-based VCD (*n*)	Type of suture-based VCD	Follow up period (days)	Periprocedural antithrombotic regimen	Protamine use	Method of obtaining vascular access
Hoffman et al.[30]	2018	Single center observational	75	76	ProGlide	In-hospital	Anticoagulants were stopped 3 days before the procedure. All patients received intravenous heparin with a target ACT of 250–300 s.	Vascular closing with both VCDs was started after reversing the heparin effect with intravenous Protamine 50 mg.	Fluoroscopic ± ultrasound guidance
Moriyama et al.[27]	2018	Single center observational (propensity matched)	111	111	ProGlide	In-hospital	NR	Heparin reversal with protamine was mandatory before VCD use.	Ultrasound guidance

Abbreviations: ACT, activated clotting time; DOACs, direct oral anticoagulants; INR, international normalized ratio; NR, not reported; RCT, randomized controlled trial; VARC-2, valve academic research consortium-2; VCD, vascular closure device; VKA, vitamin K antagonists.

[a]ProStar XL.

$p = 0.67$) with low degree of heterogeneity ($I^2 = 17\%$) (Central Illustration 1, Panel A). Similar results were observed on sensitivity analysis excluding studies that used ProStar XL VCD in the control arm (3.8% vs. 4.4%, OR: 0.90; 95% CI: 0.48–1.69; $I^2 = 17\%$) and when analyzing the incidence of major vascular complications defined as per each study (OR: 0.95; 95% CI: 0.55–1.67; $I^2 = 35\%$) (Supporting Information: Figure 1). However, subgroup analyses suggested significant interaction based on study designs such that there was higher incidence of access-site major vascular complications with plug-based VCD versus suture-based VCD among RCTs (Central Illustration 1, Panel A and Supporting Information: Figure 1). Inspection of funnel plot suggested no evidence of publication bias (Supporting Information: Figure 2).

3.3 | Secondary outcomes

The incidence of VCD failure was lower in plug-based versus suture-based VCD (6.2% vs. 8.9%, OR: 0.60; 95% CI: 0.44–0.83, $p = 0.002$; $I^2 = 14\%$). There was a trend toward higher incidence of unplanned vascular intervention in plug-based versus suture-based VCD (8.2% vs. 5.9%, OR: 1.35; 95% CI: 0.97–1.89, $p = 0.07$; $I^2 = 3\%$) (Figure 2). There were no differences in the incidence of unplanned surgical or endovascular intervention between both groups (Supporting Information: Figure 1).

Both groups were associated with similar incidence of all-cause mortality (1.8% vs. 2.2%, OR: 1.01; 95% CI: 0.55–1.84; $I^2 = 0\%$), all bleeding events (10.2% vs. 13%, OR: 0.81; 95% CI: 0.50–1.32; $I^2 = 65\%$), life-threatening/major bleeding (5.8% vs. 7.5%, OR: 0.72; 95% CI: 0.35–1.47; $I^2 = 64\%$), minor bleeding (7.4% vs. 8.3%, OR: 0.86; 95% CI: 0.53–1.39; $I^2 = 50\%$), blood transfusion (6.5% vs. 7%, OR: 0.98; 95% CI: 0.50–1.93; $I^2 = 61\%$), minor vascular complications (9% vs. 9.2%, OR: 0.95; 95% CI: 0.63–1.44; $I^2 = 45\%$). Additionally, there were no differences in the incidence of acute dissection (1.9% vs. 2.5%, OR: 1; 95% CI: 0.53–1.91; $I^2 = 0\%$), vascular occlusion (1.1% vs. 0.6%, OR: 1.55 95% CI: 0.35–6.85; $I^2 = 0\%$), pseudoaneurysm (3.4% vs. 1.5%, OR: 1.96; 95% CI: 0.70–5.51; $I^2 = 47\%$), arteriovenous fistula (0.3% vs. 0.7%, OR: 0.61; 95% CI: 0.14–2.58; $I^2 = 0\%$), lower extremity ischemia (0.7% vs. 0%, OR: 2.68; 95% CI: 0.43–16.6; $I^2 = 0\%$), and access-site hematoma (7.7% vs. 7.5%, OR: 0.76; 95% CI: 0.33–1.75; $I^2 = 77\%$) between both VCDs. The LOS was shorter with MANTA VCD (SMD: −0.14; 95% CI: −0.26 to −0.02, $p = 0.02$; $I^2 = 53\%$) (Figures 2 and 3; Supporting Information: Figures 3,4).

Subgroup analyses showed significant interaction based on study designs. There was higher incidence of all bleeding events, major bleeding events, and minor vascular complications, with plug-based VCD versus suture-based VCD among RCTs (Figures 2 and 3).

4 | DISCUSSION

In this meta-analysis of 10 studies including 3113 patients, we evaluated the outcomes with plug-based (i.e., MANTA) versus suture-based (i.e., ProGlide and ProStar XL) VCDs in large-bore access site closure after

TABLE 2 Baseline characteristics of the included patients.

Study	Intervention	Age mean (SD)	Female %	BMI mean (SD)	HTN %	DM %	CAD %	PAD %	CVA %	LVEF mean (SD)	EuroSCORE II mean (SD)	STS score mean (SD)	Iliofemoral moderate/severe calcification %	Iliofemoral moderate/severe tortuosity %
CHOICE-CLOSURE[13]	Plug VCD	80.7 (5.7)	44.6	28.5 (5.1)	NR	38	54.7	7	13.6	54.2 (12.5)	4.5 (4.8)	4 (3)	55.6[a]	60.3[a]
	Suture VCD	80.4 (6.5)	44.6	28.6 (5.3)	NR	39.9	45.7	8.1	12	54.6 (13.1)	4.6 (4.3)	4.1 (2.8)	56.3[a]	59.6[a]
MASH[15]	Plug VC	81 (75–85)[b]	48	26 (24–29)[b]	74	24	NR	6	21	NR	2.6 (1.9–3.6)[b]	2.7 (1.8–4.3)[b]	38	NR
	Suture VCD	82 (74–84)[b]	44	26 (23–29)[b]	68	22	NR	3	15	NR	2.4 (1.6–4.3)[b]	2.8 (1.6–3.9)[b]	43	NR
Medranda et al.[14]	Plug VCD	77.5 (8.7)	36.3	NR	87.9	41.1	NR	10.5	4.8	55 (12.6)	NR	3.4 (2.9)	36.3	29.5
	Suture VCD	76.9 (9.4)	25.8	NR	83.1	35.5	NR	12.1	5.6	51.9 (15.4)	NR	3.5 (2.6)	44.5	50.4
Dumpies et al.[28]	Plug VCD	80.9 (6.3)	44.6	29.2 (6.1)	89.2	42.6	58.5	10.8	13.8	54.7 (12.4)	21.2 (17.8)[c]	5.1 (3.4)	22.1[d]	66.7
	Suture VCD	80.1 (6.1)	52.2	28.8 (11.8)	90.3	42.6	59.8	9.4	10.7	54.6 (13.5)	16.4 (12.1)[c]	4.4 (3.4)	19.8[d]	64.2
Sa Mendes et al.[26]	Plug VCD	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Suture VCD	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Gheorghe et al.[25]	Plug VCD	80.7 (6.7)	44	26.2 (4.1)	71	22	NR	11	19	NR	NR	3.6 (3)	10.8	14.5
	Suture VCD	81.7 (6.1)	52	26.6 (4.2)	67	23	NR	13	13	NR	NR	4.3 (2.7)	18.6	19.1
Biancari et al.[29]	Plug VCD	79.8 (6)	61.7	27.3 (4.8)	NR	25.2	56.1	9.3	6.5	NR	4.4 (3.7)	NR	NR	NR
	Suture VCD	80.7 (6.8)	54.8	28 (5)	NR	26.1	53	9.6	12.2	NR	4.4 (3.2)	NR	NR	NR
De Palma et al.[24]	Plug VCD	81.1 (6.7)	44.9	26.8 (5.1)	67.4	21.4	NR	9	15.7	NR	4.8 (3.8)	NR	NR	NR
	Suture VCD	80.7 (7.2)	42.7	26.1 (5.1)	76.3	23.7	NR	19.8	7	NR	7.2 (7.9)	NR	NR	NR
Hoffman et al.[30]	Plug VCD	81.2 (6.5)	44	25.7 (4.3)	72	20	NR	NR	NR	52 (11.2)	NR	2.8 (1)	42.7	NR
	Suture VCD	80.8 (8.3)	60.5	25.6 (4.7)	69.7	18.4	NR	NR	NR	54.2 (6.5)	NR	2.9 (1)	63.2	NR
Moriyama et al.[27]	Plug VCD	79.5 (7.1)	57	26.7 (4.8)	86	27	NR	18	14	57 (10.7)	4.4 (3.3)	4.3 (3.2)	NR	NR
	Suture VCD	79.8 (7.2)	59	27.6 (5.5)	91	24	NR	16	18	56 (12.3)	4.6 (3.9)	4.3 (2.9)	NR	NR

Abbreviations: BMI, body mass index; CAD, coronary artery disease; CVA, cerebrovascular accident; DM, diabetes mellitus; HTN, hypertension; NR, not reported; PAD, peripheral arterial disease; SD, standard deviation; STS, Society of Thoracic Surgeons; VCD, vascular closure devices.

[a]Average right- and left-sided vessels.

[b]Median (interquartile range).

[c]Logistic EuroSCORE.

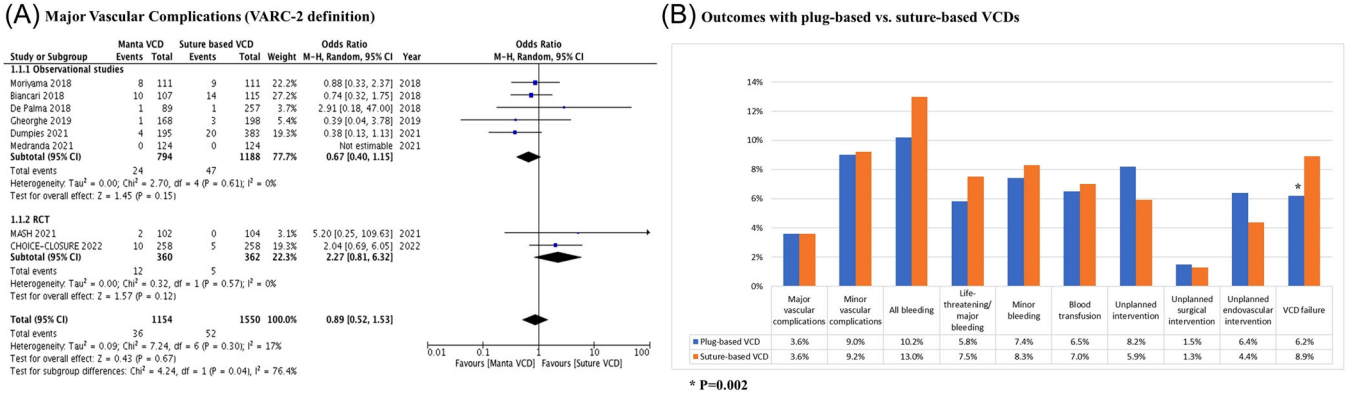
[d]Severe calcification.

TABLE 3 Procedure characteristics.

Study	Intervention	SFAR	Sheath size (mean ± SD, Fr)	Self-expandable valve %	Balloon/mechanical expandable valve %	Fluoroscopy time (mean ± SD, min)	Contrast volume (mean ± SD, mL)
CHOICE-CLOSURE[13]	Plug VCD	NR	15.1 (1.7)	60.5	39.5	15.9 (9)	106.6 (49.6)
	Suture VCD	NR	15.1 (1.7)	62.8	37.2	15.4 (8.2)	105.5 (44.4)
MASH[15]	Plug VC	0.75 (0.66–0.82)[a]	16 (14–16)[a]	62.7	36.3	NR	NR
	Suture VCD	0.74 (0.64–0.87)[a]	16 (14–16)[a]	52.9	47.1	NR	NR
Medranda et al.[14]	Plug VCD	0.73 (0.15)	NR	NR	44.4	21.7 (11.6)	116.7 (55.1)
	Suture VCD	0.73 (0.13)	NR	NR	45.2	18.3 (13)	105.1 (38.1)
Dumpies et al.[28]	Plug VCD	0.69 (0.23)	15.5 (1.9)	56.4	43.6	21 (13.4)	120.5 (55.1)
	Suture VCD	0.68 (0.20)	14.7 (1.1)	66.1	33.9	16.2 (12.6)	117.9 (51.7)
Sa Mendes et al.[26]	Plug VCD	NR	NR	NR	NR	NR	NR
	Suture VCD	NR	NR	NR	NR	NR	NR
Gheorghe et al.[25]	Plug VCD	96.4% <1.05	16 (2.1)	79.8	19.6	NR	97.8 (49)
	Suture VCD	95.2% <1.05	17.9 (3.4)	45.5	50	NR	80.1 (43)
Biancari et al.[29]	Plug VCD	NR	15.7 (1.9)	44.9	55.1	NR	NR
	Suture VCD	NR	15.2 (1.6)	72.2	27.8	NR	NR
De Palma et al.[24]	Plug VCD	0.93 (0.2)	NR	96.6	3.4	NR	64.8 (25.6)
	Suture VCD	NR	NR	83.7	16.3	NR	62.6 (31.8)
Hoffman et al.[30]	Plug VCD	NR	15.4 (1.7) for 25 patients 15.5 (1) for 50 patients	100	0	7.9 (14) for 25 patients 18.9 (5.6) for 50 patients	162.4 (52.4) for 25 patients 145.9 (52.1) for 50 patients
	Suture VCD	NR	15.1 (1.8) for 25 patients 15.3 (1.7) for 51 patients	100	0	29.5 (5.4) for 25 patients 24.1 (6.1) for 51 patients	171.8 (71.2) for 25 patients 147 (41.4) for 51 patients
Moriyama et al.[27]	Plug VCD	NR	16.6 (1.6)	52.3	47.7	NR	NR
	Suture VCD	NR	16.7 (2.3)	22.5	77.5	NR	NR

Abbreviations: NR, not reported; SD, standard deviation; SFAR, sheath to femoral artery diameter ratio; VCD, vascular closure device.

[a]Median (interquartile range).



CENTRAL ILLUSTRATION 1 (A) Forest plot for major vascular complications with plug-based versus suture-based VCDs after TAVR as defined per VARC-2 consensus. (B) Summary of outcomes with plug-based versus suture-based VCDs after TAVR. No corrections for multiple testing were applied. TAVR, transcatheter aortic valve replacement; VARC-2, valve academic research consortium-2; VCDs, vascular closure device.

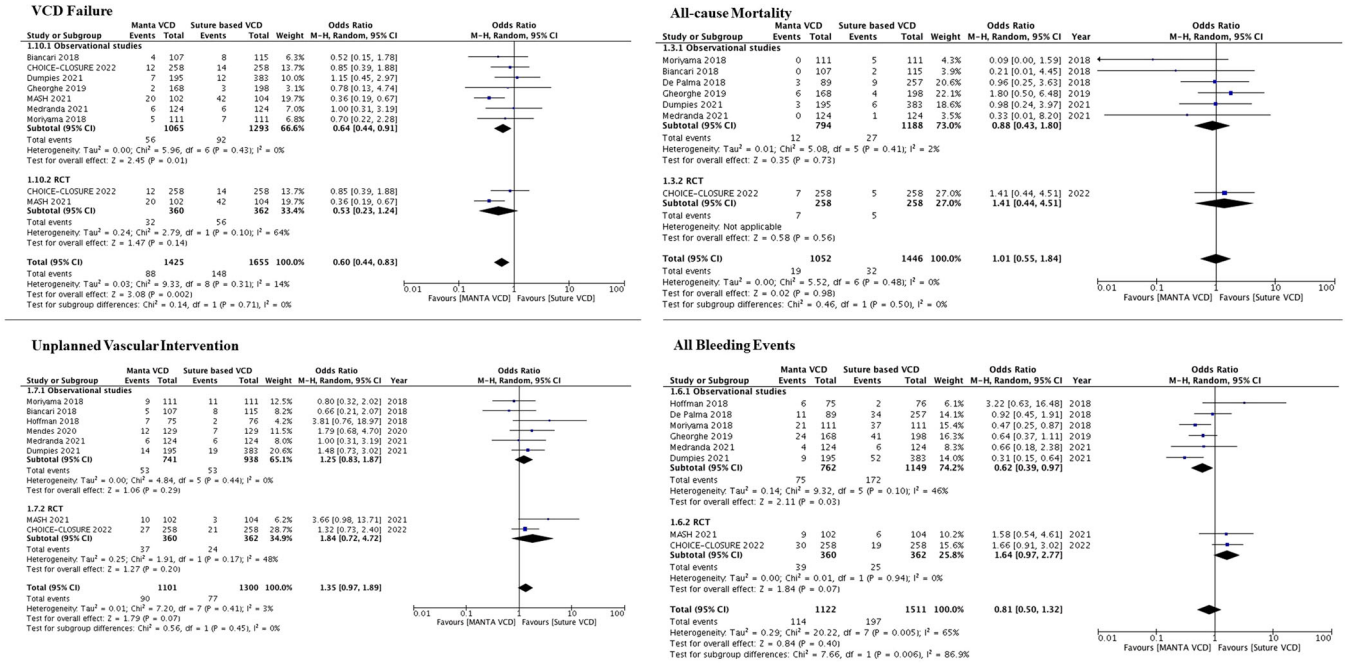


FIGURE 2 Forest plots for VCD failure, unplanned vascular intevention, all-cause mortality, and all bleedinge events with plug-based versus suture-based VCDs after TAVR. No corrections for multiple testing were applied. TAVR, transcatheter aortic valve replacement; VCDs, vascular closure device.

TAVR. The main findings were (1) there was no difference between both VCDs in the incidence of access-site major vascular complications; (2) MANTA VCD was associated with a lower incidence of VCD failure and shorter LOS but with a trend toward higher incidence of unplanned vascular intervention; (3) both VCDs were associated with similar rates of minor vascular complications, bleeding, blood transfusion, and individual components of access-site complications; (4) subgroup analyses suggested an interaction based on study designs (i.e., RCT vs. observational) for certain outcomes, including major/minor vascular complications, and bleeding events, such that there were worse outcomes with MANTA versus suture-based VCDs among RCTs.

Major vascular complications after TF TAVR are common and range from 15% in high-risk cohorts[31] to 2.8%–6% in low- and intermediate-risk patients.[3,32] Vascular complications are associated with worse clinical outcomes, need for blood transfusion, increased mortality, and longer LOS.[7,33] The incidence of vascular complications after TAVR decreased over time[34,35] which can be explained by better procedural experience, patient selection, and the use of newer devices with smaller delivery sheaths.[36,37] In the MARVEL (MAnta Registry for Vascular Large-borE Closure) registry,[38] the incidence of major vascular complications among 500 patients receiving MANTA VCD was 4%, while in the RISPEVA (Registro Italiano GISE

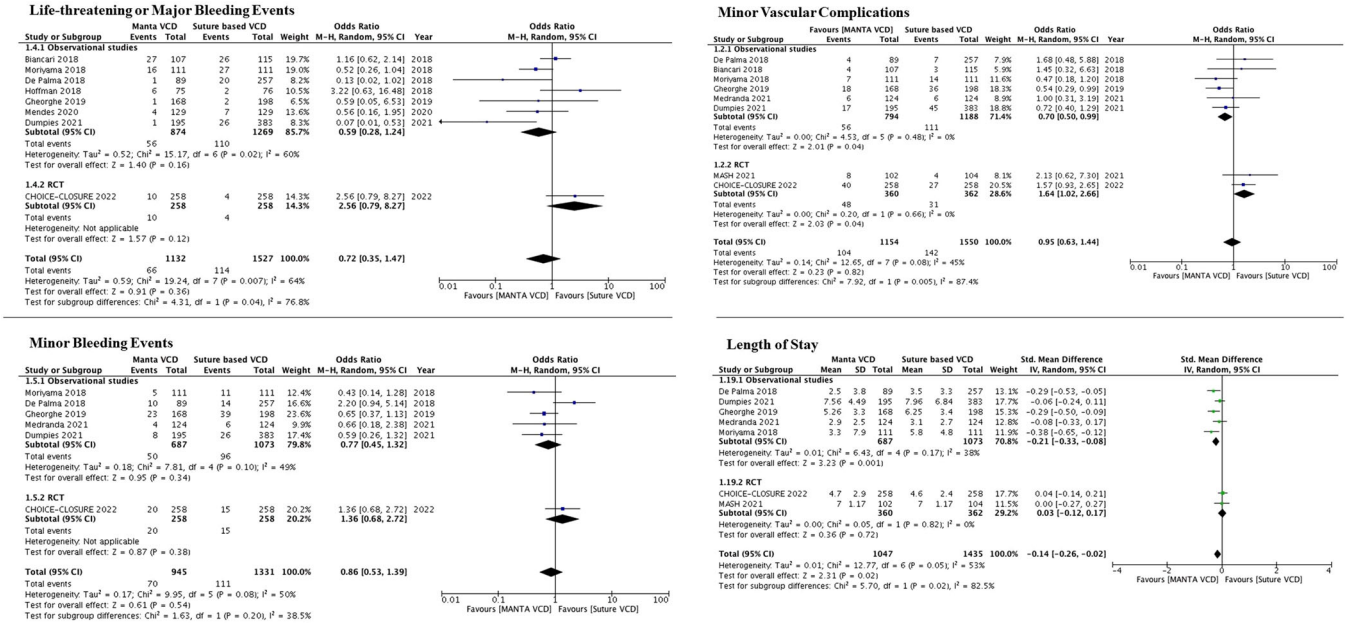


FIGURE 3 Forest plots for life-threatening/major bleeding events, minor bleeding events, minor vascular complications, and length of stay with plug-based versus suture-based VCDs after TAVR. No corrections for multiple testing were applied. TAVR, transcatheter aortic valve replacement; VCDs, vascular closure device.

sull'impianto di Valvola Aortica Percutanea) registry,[39] the incidence among 2583 patients receiving ProGlide/ProStar XL VCD was 2.9%. In the current analysis, the overall incidence of major vascular complications was 3.2%, with no difference between MANTA versus suture-based VCDs. We also noted that, while the individual components of vascular complications were not universally reported in the included studies, there were no differences between both groups in the incidence of dissection, pseudoaneurysm, vessel occlusion, arteriovenous fistula, lower extremity ischemia, and hematoma, indicating that MANTA VCD is associated with similar safety profile as suture-based VCDs.

While most of the observational studies comparing MANTA versus suture-based VCD reported similar—or even superior—outcomes with MANTA,[14,27,28] recent RCT failed to replicate such results.[13] Our analyses revealed significant interaction based on study designs such that MANTA was associated with higher incidence of vascular and bleeding complications among RCTs. In CHOICE-CLOSURE (Randomized Comparison of Catheter-based Strategies for Interventional Access Site Closure during Transfemoral Transcatheter Aortic Valve Implantation) RCT,[13] the primary endpoint of access-site major or minor vascular complications was higher among MANTA VCD (19.4% vs. 12%; relative risk 1.6, 95% CI: 1.07–2.44, $p = 0.03$). Additionally, access-site hematoma and pseudoaneurysm were significantly higher among MANTA recipients. The reasons behind such discordance between observational and randomized studies are not entirely clear and may be related to differences in study population or protocol (e.g., routine use of postprocedural ultrasound in CHOICE-CLOSURE trial may have contributed to higher detection rate of access-site pseudoaneurysm).

In patients who received VCD after TAVR, major vascular complications were related to VCD failure in 64% of cases.[10] In our analysis, we found that MANTA was associated with a lower risk of VCD failure, mainly by the results of the MASH trial[15] which included the need for additional VCDs in the definition of VCD failure. In contrast, CHOICE-CLOSURE trial[13] allowed the use of additional VCDs as a part of routine clinical practice after at least 3 min of manual compression in those who received ProGlide XL VCD. Possible failure modes of MANTA VCD include failure of deployment, intraluminal or subcutaneous deployment, detachment of the collagen, arterial occlusion by the toggle, or incomplete apposition of the toggle.[15,40] ProGlide XL/ProStar mechanisms of failure include suture-related malfunction, failed deployment, or incomplete apposition of vessel walls.[41] One of the major differences between MANTA and ProGlide/ProStar XL is the presence of safety wire in suture-based VCD which allows the use of additional VCD in case of incomplete hemostasis, while in case of MANTA VCD failure, endovascular, or surgical interventions are usually needed.[42] This explains the trend toward more unplanned vascular interventions in MANTA VCD seen in the current analysis. Recently, ultrasound guidance allowed optimization of MANTA deployment and was found to be effective in reducing access-site bleeding and vascular complications.[43] Currently, the cost of MANTA is substantially higher than suture-based VCD, which might be the limiting factor in the widespread use of MANTA VCD.[44] Further studies examining the cost-effectiveness of various VCDs and analyzing whether shorter

LOS with MANTA VCD can mitigate its higher cost or not are warranted.

The current analysis comprises the totality of available data evaluating MANTA versus suture-based VCDs after TAVR. Our results indicate that both plug-based and suture-based VCD are viable options for large-bore access-site closure after TAVR with comparable safety and efficacy. However, our subgroup analyses suggested that plug-based VCDs performed worse in RCTs in comparison to observational studies. Further adequately powered RCTs are warranted to evaluate the short- and long-term outcomes after plug-based versus suture-based VCDs.

5 | LIMITATIONS

There are a few limitations to the current analysis. First, although most of the included studies were observational studies that are subject to selection bias and confounding, we performed several sensitivity and subgroup analyses to mitigate this bias. After careful assessment, we deemed that all the included studies were of good quality in general and, in particular, that all outcome comparisons were adequately controlled for indication bias. Only 1 study [30] was found to have a high risk of bias mainly because it did not control for baseline patients' characteristics and there was no follow-up. Second, some of the secondary endpoints had a considerable degree of heterogeneity. However, we adopted a random effect model to mitigate the heterogeneity. Importantly, the primary study outcome (i.e., major vascular complications) had low degree of heterogeneity. Third, certain factors that could potentially affect the outcomes were not systematically reported in the included studies (e.g., sheath to femoral artery diameter ratio). Fourth, the definition of VCD failure differed between studies. Finally, our analysis is limited to TAVR population. Whether this applies to other large-bore access site closure is unclear.

6 | CONCLUSION

In patients undergoing TF-TAVR, large-bore access site closure with plug-based VCD (i.e., MANTA) was associated with a similar safety profile as suture-based VCD (i.e., ProStar XL and ProGlide). Subgroup analyses based on study designs showed that MANTA was associated with higher incidence of vascular and bleeding complications among RCTs. Further adequately powered RCTs are warranted to evaluate the short- and long-term outcomes after plug-based versus suture-based VCDs.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of inerest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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