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ORIGINAL ARTICLE
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Large-bore arterial access closure after transcatheter aortic valve replacement: a systematic review and network meta-analysis

Claudio Montalto [1,2], Andrea Raffaele Munafò[1,†], Luca Arzuffi[1,†], Francesco Soriano[2], Antonio Mangieri[3], Stefano Nava[2], Giovanni Luigi De Maria[4], Francesco Burzotta[5], Fabrizio D'Ascenzo[6,7], Antonio Colombo[3], Azeem Latib[8], Jacopo Andrea Oreglia[2], Adrian P. Banning[4], Italo Porto[9,*], and Gabriele Crimi[9]

[1]Department of Molecular Medicine, University of Pavia, 27100 Pavia, Italy; [2]De Gasperis Cardio Center, Interventional Cardiology Unit, Niguarda Hospital, 20172 Milan, Italy; [3]IRCCS, Humanitas Research Hospital, 20089 Rozzano, Italy; [4]Oxford Heart Centre, NIHR Biomedical Research Centre, Oxford University Hospitals, Oxford OX3 9DU, UK; [5]Institute of Cardiology, Fondazione Policlinico Universitario A. Gemelli IRCCS, Università Cattolica del Sacro Cuore, 00168 Rome, Italy; [6]Division of Cardiology, Cardiovascular and Thoracic Department, Città della Salute e della Scienza, 10126 Turin, Italy; [7]Cardiology, Department of Medical Sciences, University of Turin, 10126 Turin, Italy; [8]Montefiore Medical Center, New York 10467, USA; and [9]Division of Cardiovascular Medicine, Policlinico San Martino, University of Genova, 16132 Genova, Italy

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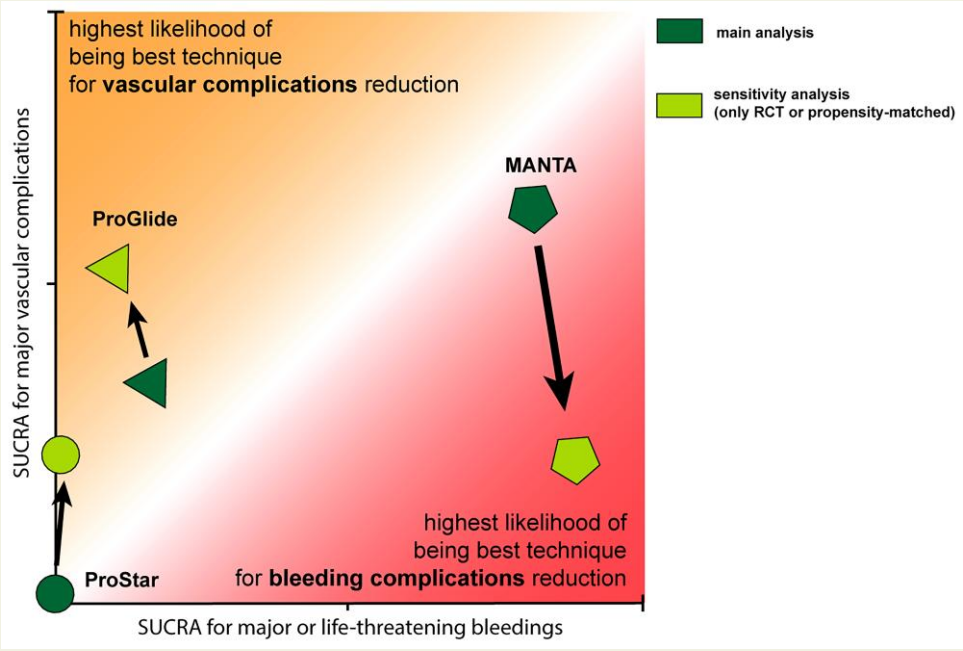
Aims As the indications to transcatheter aortic valve replacement (TAVR) expand to patients at increasingly lower risk, procedure-related vascular and bleeding complications events must be minimized. We aimed to evaluate the impact of different large-bore arterial access closure devices on clinical outcomes after TAVR.

Methods and results We searched for papers that reported outcomes according to the type of vascular closure device/technique used after TAVR and performed a Bayesian network meta-analysis (NMA). Fifteen studies involving 9259 patients who underwent access site closure using PROSTAR™ XL percutaneous vascular surgical system (Abbott Vascular, Santa Clara, CA, USA), Perclose ProGlide™ suture-mediated closure system (Abbott), or MANTA™ vascular closure device (Teleflex, Morrisville, NC, USA) were included. NMA showed MANTA to have the highest likelihood of reducing a primary composite endpoint of intra-hospital death, major vascular complications, and major or life-threatening bleedings [surface under the cumulative ranking curve analysis (SUCRA) 94.8%], but this was mitigated when only randomized clinical trials and propensity-matched cohorts were included (SUCRA 56.1%). The ProGlide showed the highest likelihood to reduce major or life-threatening bleedings, especially with increasing procedural complexity, and the MANTA device to reduce major and minor vascular complications. The ProStar XL device performed poorly in all explored endpoints.

Conclusion Available evidence summarized through a NMA shows that ProGlide and MANTA devices appear to be both valid vascular closure devices globally and to be the best options to minimize vascular complications and reduce bleeding in patients undergoing TAVR, respectively.

* Corresponding author. Tel: +39-010-5553441, Email: italo.porto@unige.it
† A.R.M. and L.A. contributed equally to this manuscript.

Graphical Abstract



Keywords Transcatheter aortic valve replacement • TAVR • Vascular closure devices • ProGlide • MANTA

Introduction

Transcatheter aortic valve replacement (TAVR) has become standard of care for patients with symptomatic severe aortic stenosis at high surgical risk[1] and a viable option for those at lower risk.[2,3] With the wide adoption of a minimally invasive, fully percutaneous approach, the transfemoral access route has become predominant (95.3% in 2019 in the USA-based Society of Thoracic Surgeons [STS] American College of Cardiology [ACC] registry).[4] A percutaneous large-bore arterial access (LBAA), however, is inherently associated with an increased risk for vascular complications and bleeding.[5] In early TAVR experiences, haemostasis after LBAA was obtained by direct-suture closure as part of a surgical cut-down technique, but, as TAVR has moved away from surgical suites, the use of vascular closure devices (VCDs) has progressively become standard approach.

In clinical practice, despite a trend towards smaller TAVR delivery systems, the ever-increasing operator experience and the wide use of VCDs, bleedings related to major vascular complications remain relatively common, even in a low-risk setting,[2,3] exerting a negative impact on mortality.[6] Considering that major vascular complications are often linked to VCDs failure,[7,8] in the present systematic review and network meta-analysis (NMA), we aimed at collecting and summarizing the available evidence on the performance of VCDs regarding clinical outcomes.

Methods

This article has been reported in accordance with the Preferred Reporting Items for System Reviews and Meta-Analysis (PRISMA-NMA). The study protocol is available in Supplementary material online, *Methods 1* and was registered in PROSPERO (ID: 178406).

Data sources and searches

A systematic search of MEDLINE, EMBASE, Google Scholar, and the Cochrane Central Register of Controlled Trials from database inception through March 2021 (see Supplementary material online, *Methods 2*). The reference lists of included studies were searched for additional studies. Systematic reviews were identified and screened for additional trials (*Figure 1*).

After removal of duplicates, the title and abstracts of the search results were screened for relevance by a single author (A.M. or L.A.). The full text of the remaining results was independently assessed in duplicates by two authors (A.M. or L.A.) for inclusion, based on predetermined criteria. Any disagreement was decided upon by a senior author (G.C.). The final list of included studies was decided upon discussion between authors with full agreement required prior to inclusion.

Study selection

Papers were considered eligible if they: (i) compared different techniques/devices for LBAA closure; (ii) reported at least the endpoint of major vascular complications; and (iii) were published in English language. Proper ethical approval has been obtained in the context of each of the included studies.

Data extraction and quality assessment

Data were extracted using a dedicated electronic database, independently and in duplicate, by two authors (A.M. and L.A.). The data extracted from each paper included baseline participant characteristics, inclusion

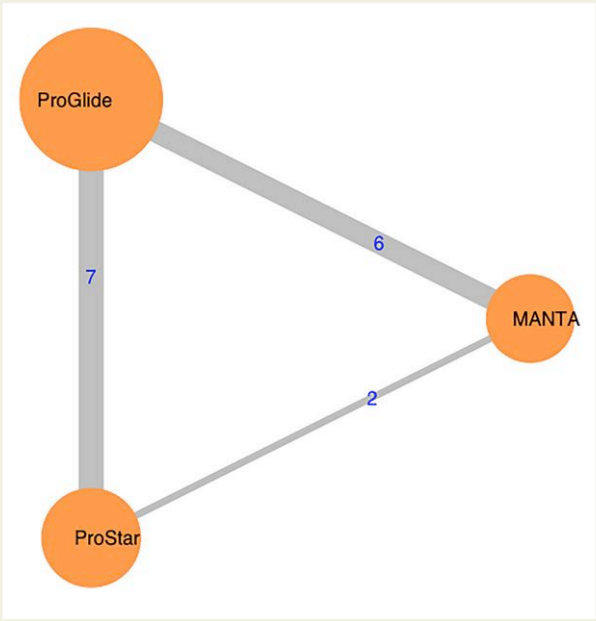


Figure 1 Network plot for primary endpoint. The nodes represent large-bore arterial access closure techniques to be compared, and the edges represent the observed direct comparisons in the included trials. The size of the nodes is proportional to the number of patients assigned to each drug and the thickness of edges is proportional to the sample size of each direct comparison. In blue, the number of studies for each direct comparison.

criteria, technique for large bore vessel closure, follow-up duration, and end-point data.

Risk of bias assessment was conducted by two authors in duplicate (A.M. and L.A.). For randomized clinical trials (RCTs), version 2 of the Cochrane risk-of-bias tool for randomized trials (ROB2) was used, assessing five domains of bias for each outcome: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Assessment of risk of bias in non-randomized studies was instead performed using the Risk of Bias In Non-randomized Studies of Interventions-I tool. We used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to assess confidence in estimates of effect (quality of evidence) associated with specific comparisons. The Egger's test was used to identify asymmetry of funnel plots for publication bias.

Data synthesis and analysis

The primary outcome was a composite of intra-hospital death, major vascular complications, and major or life-threatening bleedings. Secondary endpoints were the cumulative of major or life-threatening bleedings, of major vascular complications, of minor vascular complications, and of intra-hospital death alone. Definitions of endpoints in individual studies are in *Table 1*; all but one reported vascular outcomes according to the Valve Academic Research Consortium (VARC) definition.[9] Definition of major bleeding events was heterogeneous among randomized clinical trials (RCTs) included (*Table 1*) but was considered acceptable for the purpose of this analysis.[10]

A Bayesian hierarchical NMA (*Figure 1*) was performed using the *BUGSnet* package on R (version 3.6.1).

Random effect models were selected for each outcome. Analysis was performed using the Markov-chain Monte Carlo methods, based on 100 000 iterations with a burn-in of 10 000. Convergence was assessed with the Gelman-Rubin convergence diagnostic test (see Supplementary material online, *Figure S1*). We used a random seed and vague priors. Results are presented as risk ratio (RR) with 95% credible intervals (CrIn). Transitivity (similarity between sets of trials with respect to important effect modifiers) was assessed by constructing summary to qualitatively assess baseline clinical similarities of trial populations (see Supplementary material online, *Table S1*). The probability that each treatment class ranked in each position (from best to worst) was estimated and presented in ranking plots.

Network consistency was analyzed by analysis of traceplots, leverage plots, and posterior mean deviance comparison plots (see Supplementary material online, *Figure S2*). Between trial heterogeneity was assessed with using the I^2 statistics.

Results are presented as OR with 95% confidence intervals. Two-tailed *P* values of.05 were used for statistical significance.

Two sets of sensitivity analysis were performed. First, we included RCTs or propensity matched studies and transcatheter VCDs only. Second, as the clinical risk of patients undergoing TAVR has changed over the last decade, we included only cohorts enrolled after 2015 (earliest patient treated with MANTA in our analysis) to homogenize the risk as best as possible. Additional statistical methods are in Supplementary material online, *Methods 3*, PRISMA checklist in Supplementary material online, *Methods 4*. Finally, a meta-regression with STS mortality risk score was performed on all endpoints analyzed.

Results

Study search and network characteristics

Our systematic research identified 15 articles,[11,12,21–25,13–20] of which two were RCTs[22,23] and four were propensity-matched populations.[11,19,21,26] (see Supplementary material online, *Figure S3*) In total, 9259 patients were included in the NMA. Of them, 3622 (39.1%) with PROSTAR™ XL percutaneous vascular surgical system (Abbott Vascular, Inc, Santa Clara, CA, USA), 4483 (48.4%) with Perclose ProGlide™ suture-mediated closure system (Abbott) and the remaining 1154 (12.5%) with MANTA™ VCD (Teleflex, Morrisville, NC, USA). Further details on studies included and techniques employed are in *Table 1*. For direct comparison, seven studies compared ProStar XL to ProGlide, whereas six and two MANTA vs. ProGlide and vs. ProStar XL, respectively. The baseline characteristics and preprocedural vascular assessment were deemed sufficiently similar based on sex, age, diabetes mellitus and clinical presentation to permit network comparison (see Supplementary material online, *Tables S1 and S2*).

Risk of bias and publication bias

Risk of bias assessment is shown is Supplementary material online, *Figure S4*; no concern for serious-critical risk of bias was present. Quality of evidence according to GRADE assessment is in Supplementary material online, *Table S3*. Funnel plots and Egger's test results are in Supplementary material online, *Figure S5*, and no significant bias was observed.

Primary outcome

In total, the primary composite endpoint of intra-hospital death, major vascular complications, and major or life-threatening bleedings occurred in 1557 (16.8% patients): 809 (22.3%) of those treated

Table 1 Study characteristics

References	Study type	Follow-up (days)	PSM analysis	N	VC definition	Bleeding definition	Arm 1	Arm 2	Notes
Barbash *et al.*[11]	Obs retrospective	30	Yes	944	VARC-2	VARC-2	Prostar XL (472)	ProGlide (472)	
Barbanti *et al.*[12]	Obs retrospective	—		278	VARC-2	VARC-2	Prostar XL (153)	ProGlide (125)	
Dimitriadis *et al.*[13]	Obs retrospective	30		398	VARC-2	VARC-2	Prostar XL (215)	ProGlide (183)	
Seeger *et al.*[14]	Obs prospective	30		585	VARC-2	BARC	Prostar XL (237)	ProGlide (348)	
Mehilli *et al.*[15]	Obs prospective	30		1022	VARC-2	VARC-2	Prostar XL (516)	ProGlide (506)	
Biancari *et al.*[16]	Obs retrospective	30		222	VARC-2	VARC-2	ProGlide (115)	MANTA (107)	
De *et al.*[17]	Obs retrospective	30		346	VARC-2	VARC-2	ProStar XL (257)	MANTA (89)	
Power *et al.*[18]	Post hoc analysis RCT	30		746	VARC-2	BARC	Prostar XL (352)	ProGlide (394)	
Moryiama *et al.*[19]	Obs retrospective	—	Yes	325	VARC-2	VARC-2	ProGlide (111)	MANTA (111)	
Gheorghe *et al.*[20]	Obs retrospective	30		366	VARC-2	VARC-2	Prostar XL (198)	MANTA (168)	
Berti *et al.*[21]	Obs prospective	365	Yes	2583	VARC-2	VARC-2	ProStar XL (1222)	ProGlide (1361)	
van Wiechen *et al.*[22]	RCT	30		206	VARC-2	VARC-2	ProGlide (104)	MANTA (102)	
Dumpies *et al.*[25]	Obs retrospective	30		578	VARC-2	VARC-2	ProGlide (383)	MANTA (195)	1 ProGlide used in 82%; MANTA 18F only
Medranda *et al.*[24]	Obs retrospective	—	Yes	247	VARC-2	BARC	ProGlide (123)	MANTA (124)	
Abdel-Wahab *et al.*[23]	RCT	30		516	VARC-2	VARC-2	ProGlide (258)	MANTA (258)	2 ProGlide used; MANTA 18F only

Unless specified in *Notes*, there were no clear details about the use of 1 vs. 2 ProGlide or about the use of MANTA 14F vs 18F.
Obs, observational; NR, not related; PSM, propensity score matching; VC, vascular complication; VCD, vascular closure device; —, not available.

with ProStar XL, 636 (14.2%) of those treated with ProGlide, and 112 (9.7%) of those treated with MANTA. Both the MANTA (RR: 0.29; 95% CrIn: 0.11–0.60) and ProGlide (RR: 0.49; 95% CrIn: 0.25–0.85) devices showed a statistically significant superiority over the ProStar XL device, but no statistically significant superiority was present between difference these two devices. Of note, our Bayesian surface under the cumulative ranking curve analysis (SUCRA) analysis highlighted that MANTA and ProGlide had the highest and second highest likelihood of reducing the primary composite endpoint (SUCRA of being best or second best: 99% for both ProGlide and MANTA; *Figure 2A*), whereas the ProStar XL performed poorly when compared to other treatments and was the most likely worst treatment (98.9%) (***Table 2***).

Secondary endpoints

The networks and diagnostics for secondary outcomes are in Supplementary material online, *Figure S6 and Table S4*. Major vascular

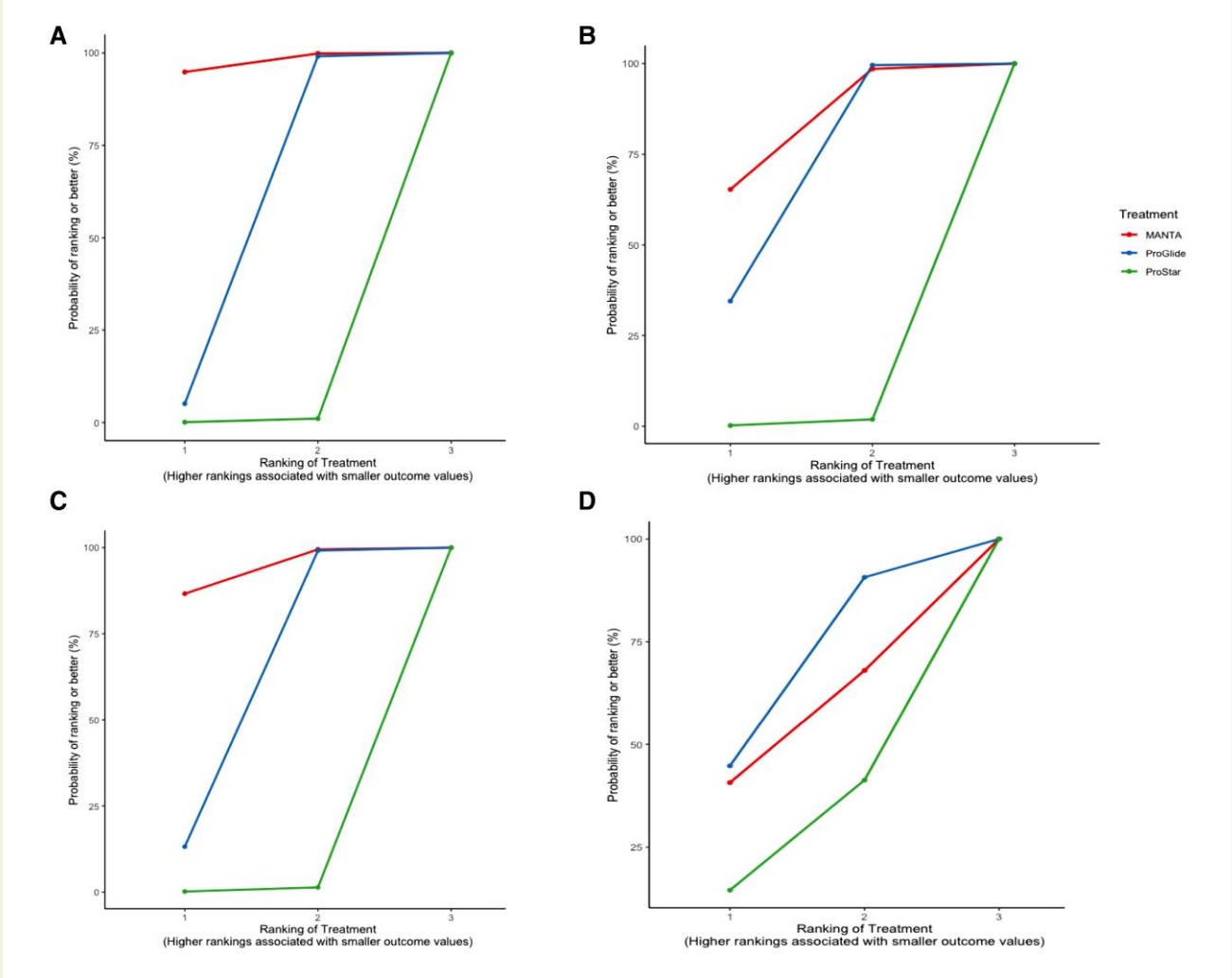


Figure 2 Ranking plots for primary endpoint (*A*), major vascular complications (*B*), major or life-threatening bleedings (*C*), and in-hospital death (*D*).

complications occurred in 520 (5.6%) patients (3.5%, 4.5%, and 7.9% of those treated with MANTA, ProGlide, and ProStar, respectively), and our SUCRA Bayesian analysis showed that neither ProGlide nor MANTA had a significantly higher likelihood of being the best treatment (RR: 1.15; 95% CI: 0.55–2.36) to reduce this endpoint (*Figure 2B*). Both devices showed a statistically significant superiority over the ProStar device (RR: 0.44; 95% CI: 0.24–0.87 and 0.30; 95% CI: 0.16–0.90, respectively) which was the most likely worst treatment in our Bayesian analysis (SUCRA 98.1%). A non-significant superiority of MANTA was observed also for minor vascular complications (SUCRA 79.3; RR vs ProGlide: 0.81, 95% CrIn: 0.51–1.32) (*Table 2*; see Supplementary material online, *Figure S7*). A granular illustration of individual vascular complications is reported in Supplementary material online, *Table S5*.

With regards to the secondary endpoint of major or life-threatening bleedings that occurred in 1,028 subjects (5.7%, 11.1% and 16.4% of those treated with MANTA, ProGlide and ProStar, respectively), MANTA had the highest SUCRA (86.6% vs. 13.2%, for ProGlide), but did not reach statistical significance (RR: 0.74; 95% CI: 0.40–1.31). Moreover, evidence suggested that ProStar XL performed significantly worse that all other techniques (*Figure 2C*) with both MANTA and ProGlide being statistically superior to ProStar (RR: 0.39; 95% CrIn: 0.18–0.78 and RR: 0.53; 95% CrIn: 0.31–0.87, respectively) (***Table 2***).

Finally, 81 in-hospital deaths were observed (0.8%, 1.4% and 1.8% of those treated with MANTA, ProGlide and ProStar, respectively) with similar SUCRA for the ProGlide (44.8%) and MANTA (40.7%) devices, while ProStar scored the lowest probability for reduction of this endpoint (*Figure 2D*).

Sensitivity analysis and meta-regression

Our sensitivity analysis of 4122 patients comprised two RCT and 4 propensity matched-population cohorts. The MANTA device had a numerically higher SUCRA with regards to our primary endpoint, with a (56.1% vs. 30.7% for the ProGlide) and with regards to major bleedings (SUCRA 89.6%) and in-hospital death (SUCRA 77.7%; see Supplementary material online, *Figure S8*). On the other hand, the

Table 2 SUCRA tables for the main and sensitivity analysis

Rank	Main analysis			Rank	Sensitivity analysis 1 (RCT or PM)			Rank	Sensitivity analysis 2 (cohorts after 2015)		
	MANTA	ProGlide	ProStar XL		MANTA	ProGlide	ProStar XL		MANTA	ProGlide	ProStar XL
	Primary endpoint										
1	94.8	5.08	0.08	1	56.1	30.7	13.2	1	81.1	11.4	7.55
2	5.01	94.0	0.98	2	29.2	56.5	14.3	2	17.7	66.4	15.9
3	0.15	0.91	98.9	3	14.7	12.8	72.5	3	1.18	22.2	76.6
	Major vascular complications										
1	65.3	34.5	0.2	1	22.5	53.9	23.7	1	48.1	48.1	3.71
2	33.2	65.1	1.67	2	34.6	38.7	26.7	2	49.2	46.5	4.37
3	1.44	0.43	98.1	3	42.9	7.44	49.6	3	2.71	5.41	91.9
	Minor vascular complications										
1	79.3	15.6	5.09		63.1	10.8	26.1		52.5	17.4	30.1
2	14.4	68.5	17.1		23.2	50.4	26.4		39.2	39.9	20.9
3	6.29	15.9	77.8		13.7	38.7	47.6		8.24	42.7	49.0
	Major or life-threatening bleedings										
1	86.6	13.2	0.18	1	89.6	9.15	1.24	1	67.2	28.7	4.09
2	12.8	86.0	1.19	2	8.34	86.7	4.96	2	31.0	63.0	5.94
3	0.51	0.86	98.6	3	2.05	4.14	93.8	3	1.79	8.24	90.0
	In-hospital death										
1	40.7	44.8	14.5	1	77.7	5.95	16.4	1			
2	27.3	45.9	26.8	2	12.0	43.4	44.6	2			
3	32.0	9.32	58.7	3	10.3	50.7	39	3			

Network-meta analysis was not possible for in-hospital death for sensitivity analysis n.2 due to too few nodes.

ProGlide showed a higher SUCRA with regards to major vascular complications (53.9% vs. 22.5%; *Table 2*). This profile was confirmed also in our analysis including eight studies and 2703 patients treated after 2015, with the MANTA device having the best profile to reduce our primary endpoint (SUCRA 81.1%) and major or life-threatening bleedings (SUCRA 67.2%), while the ProGlide and MANTA had similar likelihood of major vascular complications reduction (both SUCRA 48.1%) (see Supplementary material online, *Figure S9*). Finally, the ProStar devices scored the lowest likelihood for all endpoints analyzed in both sensitivity analysis.

Finally, our meta-regression analysis showed that, for all endpoints analyzed, the performance of both ProGlide and MANTA decreased linearly with increasing STS scores, but the latter more rapidly than ProGlide (see Supplementary material online, *Figures S7 and S10*).

Discussion

Our pooled NMA of 9259 patients undergoing TAVR suggests that both MANTA and ProGlide are associated with a reduction of clinical endpoints compared to ProStar. While the totality of evidence available suggest MANTA to have the highest likelihood of minimizing major or life-threatening bleedings and major vascular complications, this is mitigated when only randomized clinical trials and propensity-matched populations are considered (*Graphical abstract*). In contrast, the ProStar XL device performed poorly when compared to other VCDs with regards to all of the examined endpoints and in all secondary analysis performed.

As the indications to TAVR expand to patients at increasingly lower risk,[2,3] minimization of procedure-related vascular and bleeding complications is mandatory.[27] Major vascular complications remain relatively common in modern TAVR registries, especially in high-intermediate risk subjects (5.9–11%)[28–31] but are worryingly observed also in subjects at low surgical risk (2% and 3.8% in the PARTNER 3 and Evolute Low Risk trials, respectively).[2,3] Surgical cut-down, the initial technique of choice for LBAA, allows for maximum vessel control and minimal vascular complications but implies a higher degree of invasiveness, longer procedural time, and higher risk of infections and acute kidney injury and has been progressively abandoned.[32] On the other hand, VCDs allow for a totally percutaneous TAVR with shorter procedural times. Nonetheless, VCD failures are not uncommon (1–8%),[11,22,33] are associated with major vascular complications and, in turn, with a higher risk of in-hospital and short-term death.[8] Major vascular complications after TAVR are associated with increased rates of in-hospital and short-term death,[5–7] reflecting the morbidity and mortality of a bleeding event and of vascular surgery performed in an emergency setting. Therefore, it is important to understand the difference between the available VCDs and to highlight any benefit to optimize the outcomes after TAVR.

Both the ProStar XL and the Perclose ProGlide are suture-based devices inserted over a wire; they are pre-implanted before the TAVR procedure and have shown to reduce procedural time, groin

complications and infections.[34] Recently, a new dedicated VCD, the MANTA (Essential Medical, Inc, Malvern, PA), has been introduced.[35] This is a second-generation collagen-based anchor which is deployed at the end of the procedure; it has shown promising results in terms of hemostasis achieved and low rates of vascular complications have been reported in observational registries.[24,35,36] It should be noted that there are technical reasons that discourage operators from using the MANTA device, including the lack of a percutaneous bailout strategy in case of device failure. Furthermore, in a recent RCTs, the MANTA VCD was associated with a higher rate of vascular complications compared to ProGlide, and therefore, its field of application is under question.[23]

Our analysis that summarizes the totality of evidence available in the literature suggests that the MANTA device might have a peculiar profile, having the highest likelihood of reducing our primary endpoint of relevant clinical events, major or life-threatening bleedings and major vascular complications, despite not being significantly superior to the ProGlide use (*Table 2*). Nonetheless, these beneficial results appear to be mitigated in our sensitivity analysis including only data from RCTs and propensity-matched cohorts in which no definite advantage of the MANTA or ProGlide devices emerges in terms of primary endpoint (SUCRA: 56.1% and 30.7%), and the ProGlide has the highest SUCRA for the reduction of major vascular complications (53.9% vs. 22.5%). In the studies included, intrahospital deaths were relatively infrequent, with MANTA and ProGlide having similar SUCRA for this endpoint (*Table 2*). In summary, this secondary analysis suggests that, while MANTA appears to offer an optimal profile for reduction of major or life-threatening bleedings (SUCRA 86.6% and 89.6% in our primary and sensitivity analysis, respectively), there is small or no advantage in terms of mortality and major vascular complications between the ProGlide and MANTA systems.

We also performed a sensitivity analysis limited to patient treated with TAVR after 2015, which scenario might better represent current clinical practice. Using this approach, MANTA was confirmed to have the highest SUCRA with regards to the composite clinical endpoint and major or life-threatening bleedings (SUCRA 81.1% and 67.2%, respectively), but both MANTA and ProGlide showed optimal results for the reduction of major vascular complications (SUCRA 41.7% and 44.4%, respectively). Furthermore, our meta-regression analysis suggests that with increasing STS score the ProGlide device performs better than the MANTA device. This is not unexpected, as increasing surgical risk and procedural complexity might warrant a back-up strategy in case of VCD failure, which is guaranteed only by the ProGlide system.

In summary, our NMA highlighted that, while the MANTA device offers a peculiar profile with a possible advantage in reducing clinically relevant events and major bleedings, the difference with other VCDs, albeit small with the ProGlide, might depends on several factors. Firstly, this device was specifically designed for LBAA closure (up to 25F) while the ProStar XL is used off-label up to 24F (it is licensed for closure of arteriotomy sites up to 10F) and the ProGlide was originally designed for post-closure of small-bore arteries (≤ 8F), and the pre-closure strategy using two devices is a relatively novel development. Secondly, MANTA involves a collagenic, fully resorbable anchor instead of the classic suture-based technology.[35] Thirdly, this device was designed to be easier to deploy and has a shallower learning curve than the ProGlide and ProStar XL, which might at least partly account for the lower occurrence of minor vascular complications with this device. Nonetheless, recent evidence suggest that the reported low rates of vascular complications are often not observed in the early roll-in phase of the device in real-world scenarios.[37] Therefore, operator's experience and centre volumes with individual VCDs should be factored in the decision-making process also for the MANTA device. Furthermore, the MANTA device is not available in many centres and that the overall experience of many skilled TAVR operators with this device is still quite limited. In contrast, the ProGlide device is the most frequently used VCD worldwide and with a large base of evidence supporting its role in TAVR. Moreover, a possible reporting bias in observational studies with MANTA should be taken into considerations since the observed, small possible advantage is mitigated when only RCTs, and propensity-matched cohorts are included: this highlights how this superiority might depend on observational studies, with possible selection bias toward recruitment of patients with an overall lower risk. On the contrary, the literature for the ProGlide dates to 2013, when TAVR was licensed only in the high-risk population and when only more recent studies where included, the possible advantage of MANTA was mitigated. This latter secondary analysis that included only a relatively lower number of patients from non-randomized studies; therefore, it should be interpreted with caution.

Finally, the evidence available for the MANTA device are less abundant (with only 12% of patients in our main analysis being treated with this device) which might limit the confidence of our estimates with regards to this device.

Limitations

Some limitations should be considered. Firstly, although this approach has been used before,[38] we recognize that the results of our NMA are weakened by the inclusion on non-randomized clinical trials with potential unmeasured bias. Nonetheless, our sensitivity analysis aimed at a smaller subset of studies with the lowest possible risk of bias according to study design, and its results were appropriately addressed and put into context in our *Discussion*. Of note, propensity-matched studies included in the sensitivity analysis had a low risk of bias in the vast majority of the domains explored by the ROBIN-I tool (see Supplementary material online, *Figure S5*). Moreover, we addressed and explored heterogeneity across studies (see Supplementary material online, *Figures S3* and *S6*) and other possible source of bias as far as possible (see Supplementary material online, *Table S2*). Secondly, formal statistical significance was not observed for some endpoints and CrINs were relatively wide; therefore, our results should be intended to tailor the best therapy on the individual patient and not as a surrogate of RCT evidence. We believe that our meta-analysis gives insights and inform on a clinically relevant research question given the evidence currently available in the literature. However, our results should be interpreted in the light of these limitations.

Conclusion

Available evidence suggests that the MANTA and the ProGlide device appears to have similar profile to reduce clinically relevant

endpoints after TAVR, with the former showing a possible advantage to minimize major or life-threatening bleedings and the latter to minimize vascular complications and particularly in patients at higher procedural risk. On the contrary, the ProStar XL was associated with worse performance compared to MANTA and ProGlide with regards to all endpoints analyzed.

Lead author biography

Dr Montalto graduated with summa cum laude at San Raffaele Vita-Salute University and teaching hospital (Milan) and completed his residency in Cardiology at the IRCCS Policlinico San Matteo and University of Pavia. During these years, he grew an interest for clinical research, in particular in the field of interventional cardiology and acute cardiovascular care. As part of this, he won the ESC ACCA Research Prize 2019. In 2021 he completed a fellowship in interventional cardiology at the Oxford University Hospital NHS Trust. Currently, he is an interventional cardiologist at the De Gasperis CardioCenter at Niguarda Hospital in Milan (Italy).

Data availability

All data relevant for this study are already published and available. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Supplementary material

Supplementary material is available at *European Heart Journal Open* online.

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Conflict of interest: None declared.

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