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Opinion Paper

Meta-analysis of ProGlide versus MANTA vascular closure devices for large-bore access site management



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ABSTRACT

Introduction: The comparative effectiveness of ProGlide® compared with MANTA® vascular closure devices (VCDs) in large-bore access site management is not entirely certain, and has only been evaluated in underpowered studies. This meta-analysis aimed to evaluate the outcomes of ProGlide® compared with MANTA® VCDs.

Methods: PubMed, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL) were searched systematically for relevant articles from the inception of the database until August 27, 2021. The outcomes of interest were all bleeding events, major bleeding, major and minor vascular complications, pseudoaneurysm, stenosis or dissection, and VCD failure. Risk ratios were used as point estimates of endpoints. All statistical analyses were carried out using R version 4.0.3.

Results: Four observational studies and 1 pilot randomized controlled trial (RCT) were included in the final analysis. There was no significant difference between the ProGlide® and MANTA® groups in the risk of all bleeding events, major/life-threatening bleeding, major vascular complications, minor vascular complications, pseudoaneurysms, and/or stenosis or dissection of the entry site vessel. However, the incidence of VCD failure was higher in the ProGlide® group compared with the MANTA® group (RR 1.94; 95% CI 1.31–2.84; $I^2 = 0\%$).

Conclusion: In conclusion, both VCDs (ProGlide® and MANTA®) have comparable outcomes with regard to risk of bleeding, vascular complications, pseudoaneurysms, and/or stenosis or dissection of entry vessel. ProGlide® was however associated with higher device failure.

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1. Introduction

The use of transcatheter-based approaches has increased over the past decade for interventions such as transcatheter aortic valve replacement (TAVR) for aortic stenosis and other valve repairs, mechanical circulatory support devices, and endovascular aneurysm repair.¹ Transcatheter technology requires large-bore access for interventions, which, in turn, is associated with vascular complications, despite the progressive decrease in sheath diameter.^{2,3}

Puncture site complications have a significant impact on procedural outcomes, and hence, efficient percutaneous closure of large-bore access site is of critical importance.³ Vascular closure devices (VCDs) help in minimizing these complications, and also minimize the need for general anesthesia and longer hospital stay that are associated with a surgical cutdown approach.⁴ ProGlide® (Abbott Vascular, Abbott Park, Illinois) is a percutaneous pre-suture mediated VCD, while MANTA® (Teleflex Inc., Wayne, Pennsylvania) is a collagen plug-based newer approach for large-bore arteriotomy closure.⁵

The comparative effectiveness of ProGlide® compared with MANTA® VCDs is not entirely certain, and has only been evaluated in underpowered studies. This meta-analysis aimed to evaluate the outcomes of ProGlide® compared with MANTA® VCDs.

2. Methods

The present systematic review and meta-analysis was conducted in accordance with the Cochrane Collaboration guidelines and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.^{6,7}

2.1. Study search

Electronic databases including PubMed, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL) were searched systematically using the key terms “ProGlide,” “MANTA,” and “vascular closure device” to identify relevant articles from the inception of the respective databases until August 27, 2021. No language restrictions were applied. A detailed search strategy is provided in [Supplementary Table 1](#). A manual review of bibliographies of the included articles was conducted for further identification of potentially eligible studies.

2.2. Study selection and inclusion criteria

The articles retrieved from the initial search were exported to EndNote (Clarivate Analytics, Thomson Reuters Corporation, Philadelphia, Pennsylvania) to check for duplicates. A title and abstract-based screening of the non-duplicate articles and later, a full-text review of the eligible articles was conducted independently and in tandem by two investigators (A.K. and G.M.), based on a priori inclusion and exclusion criteria.

The predefined inclusion criteria were: (1) observational studies or randomized clinical trials (RCTs) comparing the safety and/or efficacy of ProGlide® with MANTA® VCDs in patients undergoing transcatheter procedures, (2) studies with an adult population (age >18) and sample size >100 patients, and (3) conference papers with adequate data on the outcomes of interest. Single-arm studies, letters, review articles, and/or commentaries were excluded.

2.3. Data extraction

Three investigators (M.S., G.M., and S.D.) independently extracted the following data from the included articles using a standardized study form: the first author's name, year of publication, country of the study cohort, study design, number of cases in each treatment group, mean age, male percentage, co-morbidities (diabetes mellitus, hypertension, previous stroke), and prior surgery. The outcomes of interest were all bleeding events, major bleeding, major and minor vascular complications, pseudoaneurysm, stenosis or dissection, and VCD failure. Any disagreements with respect to the study selection or data extraction were resolved by discussion and consultation with other authors until a mutual consensus was reached.

2.4. Statistical analysis and quality assessment

In this study, we utilized the Mantel-Haenszel method with a Paule-Mandel estimator of Tau² with Hartung-Knapp-Sidik-Jonkman adjustment to estimate risk ratio (RR) with a 95% confidence interval (CI). Higgins' I² statistics were used to assess heterogeneity across the studies; I² values 25%–50%, 50%–75%, and >75% were considered low, moderate, and high degree of heterogeneity, respectively. The statistical significance was set at a p-value <0.05. All statistical analyses were carried out using R version 4.0.3. The risk of bias of the included studies was evaluated using Newcastle–Ottawa scale (NOS) tool for observational studies and Cochrane Risk of Bias (RoB)-2 tool for RCTs.⁸ Publication bias could not be explored due to the limited number (<10) of included articles.

3. Results

3.1. Literature search and baseline characteristics

The database search initially identified a total of 315 records. After checking for duplicates, 182 articles were screened on the basis of title and abstract; subsequently, 30 full-text articles were assessed for eligibility. A total of 5 articles were included in the final quantitative analysis.^{3,9–12} (Fig. 1) A total of 1059 participants were included, of which MANTA® device was utilized in 524 participants, whilst the ProGlide® VCD was used in 535 patients. Of the included studies, 4 were observational studies^{3,9–11} and 1 was a pilot RCT.¹² The demographic details of the included studies are summarized in [Table 1](#). The Newcastle–Ottawa Scale for quality assessment of observational studies ranked 2 studies as high quality and 2 studies were ranked as moderate quality ([Supplementary Table 2](#)). The one RCT was identified as “low risk” of bias based on ROB-2 tool.

3.2. Results of meta-analysis

Our study demonstrated that there was no significant difference between the ProGlide® group and the MANTA® group in the risk of all bleeding events (RR: 1.17; 95% CI 0.63–2.16; I² = 41%), major/life-threatening bleeding (RR: 1.11; 95% CI 0.42–2.93; I² = 48%), major vascular complications (RR: 0.82; 95% CI 0.20–3.30; I² = 36%), minor vascular complications (RR: 0.98; 95% CI 0.14–6.80; I² = 50%), pseudoaneurysms (RR: 1.91; 95% CI 0.00–5659.60; I² = 0%), stenosis or dissection of the entry site vessel (RR: 0.78; 95% CI 0.39–1.59; I² = 0%). However, the incidence of VCD failure was found to be higher in the ProGlide® group compared with MANTA® group (RR 1.94; 95% CI 1.31–2.84; I² = 0%) ([Fig. 2](#)).

4. Discussion

The incidence of vascular complications post interventions requiring large-bore access has reduced significantly with the advent of new-generation devices, smaller sheath diameter, operator comfort with newer techniques, appropriate patient selection, improved delivery techniques, increased utilization of pre-procedure imaging, and VCDs.¹³

VCDs have emerged as an effective alternative to traditional mechanical compression in patients undergoing percutaneous interventions requiring large-bore access. The advantages of these devices are reduction in the time of hemostasis, early patient mobilization, minimizing patient discomfort associated with prolonged bed rest, improved patient satisfaction, and decreased length of hospital stay.¹⁴ Although VCDs have demonstrated promising benefits, they are also associated with significant

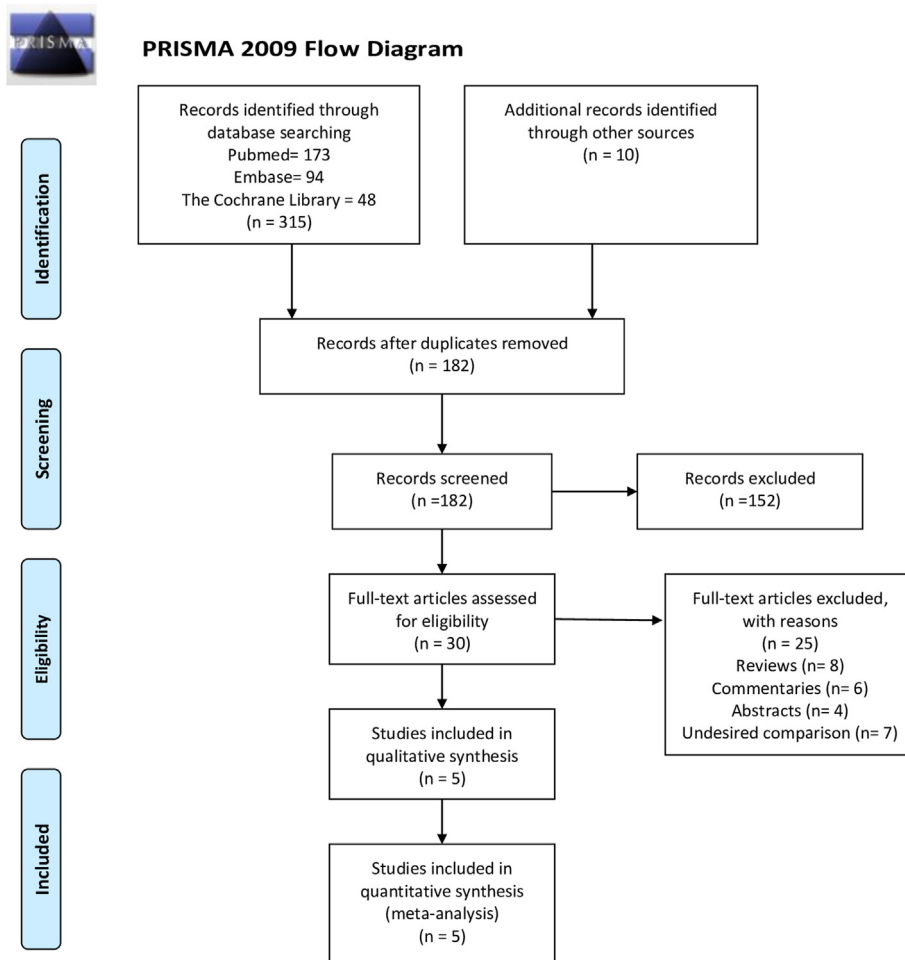


Fig. 1. PRISMA Flow Diagram: Schematic representation of systematic literature search.

Table 1
Baseline characteristics of included studies.

Study, year	Country	Study design	Number of patients		Age (mean, SD) in years		Male N (%)	EuroSCORE II (%)		Diabetes mellitus	Hypertension N (%)	Prior Stroke/TIA	Prior CABG	Prior PCI
			MANTA	ProGlide	MANTA	ProGlide		MANTA	ProGlide					
van Wiechen MP et al, 2021	France, Netherlands	Pilot Randomized Controlled Trial	102	104	81 (76–85)*	82 (74–84)*	111 (54)	2.6 (1.9–3.6)	2.4 (1.6–4.3)	47 (23)	146 (71)	36 (18)	16 (8)	69 (33)
Mendes GS et al, 2020	Portugal	Prospective propensity matched	129	129	–	–	108 (42)	–	–	–	–	–	–	–
Moriyama N et al, 2019	Finland	Retrospective, propensity matched	111	111	79.5 ± 7.1	79.8 ± 7.2	98 (44.1)	4.4 ± 3.3	4.6 ± 3.9	57 (25.7)	196 (88.3)	35 (15.8)	16 (7.2)	54 (24.3)
Biancari F et al, 2018	Finland	Retrospective	107	115	79.8 ± 6.0	80.7 ± 6.8	93 (41.9)	4.4 ± 3.7	4.4 ± 3.2	57 (25.7)	–	21 (9.5)	–	54 (24.3)
Hoffmann P et al, 2018	Norway	Retrospective	75	76	81.2 ± 6.5	80.8 ± 8.3	72 (47.7)	–	–	29 (19.2)	107 (70.9)	–	17 (11.3)	49 (32.5)

EuroSCORE II: European System for Cardiac Operative Risk Evaluation II, TIA: transient ischemic attack, CABG: coronary artery bypass grafting, PCI: percutaneous coronary intervention.

complications, such as access-site infections, pseudoaneurysm, hematoma, limb ischemia, and requirement of vascular site repair.¹³ VCDs have been broadly classified as plug-based versus suture-based devices, primarily based on their method used for hemostasis. While plug-based VCDs like MANTA® and Angioseal work by formation of a plug at the site of access, suture-based VCDs like ProGlide® and Prostar XL work by suturing of the access site. While studies have reported ProGlide® to have superior efficacy

compared with Prostar XL, the evidence comparing ProGlide® with MANTA® is not adequate.^{4,15} Both the devices, MANTA® and ProGlide® have their plausible access-site risks of major and minor vascular complications.¹²

The present meta-analysis evaluated the outcomes of ProGlide® compared with MANTA® VCDs. The present meta-analysis demonstrated that there is no significant difference in bleeding outcomes between the two VCDs. The results of the present study

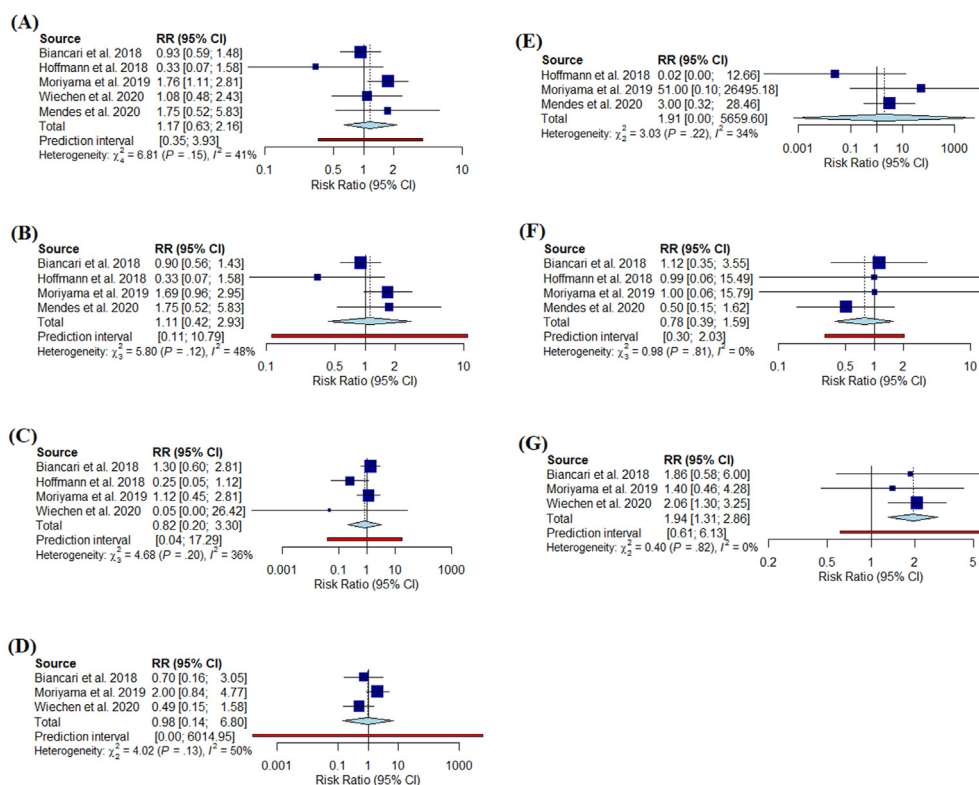


Fig. 2. Forest plot for outcomes comparing ProGlide® with MANTA®. PANEL A: All bleeding events; PANEL B: Major/life-threatening bleeding events; PANEL C: Major vascular complications; PANEL D: Minor vascular complications; PANEL E: Pseudoaneurysm; PANEL F: Stenosis or dissection of the entry site vessel; PANEL G: Vascular closure device failure.

are in congruence with other studies by van Wiechen et al., Mendes et al., and Biancari et al.^{9,10,12} Further, the only pilot randomized study, MASH-TAVI trial, included in our analysis reported no difference in clinically significant bleeding between the two VCDs.¹² These bleeding episodes occurred either during the procedure or during hospital admission, as there was no documentation of bleeding events post discharge.¹²

Major and minor vascular complications are often seen following VCD use. The short- and long-term clinical outcomes are affected by vascular complications, such as hematoma, seroma, and infection. These complications occur less frequently at low or intermediate surgical risks, however, they are not admissible as they have a negative impact on the lifestyle of patients. Major consequences of these vascular complications include renal failure, endovascular interventions and additional vascular surgeries, prolonged hospital stay, and increased mortality. The MASH-TAVI trial did not show any superiority with regard to vascular complications with either MANTA® or ProGlide®, which is comparable to our study results.¹² However, the ProGlide® complication rates were better than former trials (CONTROL and BRAVO-3), whilst the MANTA® complication rates were consistent with prior prospective and retrospective multicenter cohort studies.¹² The study by Hoffman et al. showed significantly lower rates of vascular complications with ProGlide® compared with MANTA®.³ The authors proposed that the higher rates of vascular complications, bleeding, and pseudoaneurysm in the MANTA® cohort could be attributed to discrepancy in the size of the MANTA® device used. A 14-Fr MANTA VCD was used for closure of access site after using a 16-Fr introducer in 5 out of 8 patients with access site-related complications.³

Our analysis reported higher failure rates among ProGlide® compared with MANTA®. This result is consistent with the MASH-TAVI trial, which showed statistically significant lower rates of

failure with MANTA® compared with ProGlide® (20% vs. 40%). These failure rates are still greater than a former study by Power et al. (6% failure rate).¹⁶ This notable difference could be due to varied endpoint definitions for VCD failure. The definition of VCD failure in the MASH-TAVI trial was consistent with stringent modified VCD failure definition that included prolonged manual compression and the need for additional closure devices. On the contrary, Power et al. did not include the use of prolonged manual compression or additional closure devices in their VCD failure definition. Similarly, Biancari et al. also found a lower rate of VCD failure in MANTA® although the difference was not significant.⁹

The most common cause of bleeding complication irrespective of the VCD used can be attributed to erroneous measurement of the vessel depth, which in turn leads to malpositioning and incomplete apposition of the device in the subcutaneous tissue.⁴ Failed preclosure, suture tear, incomplete apposition of arteriotomy wall segments, or approximation of sutures outside the vessel wall can lead to ProGlide® failure.¹⁷ The use of computed tomography to assess the exact anatomical location of the iliofemoral vessels and performing ultrasound-guided access techniques can aid in minimizing vascular-related bleeding complications.⁵ Additionally, the VCD failure complications like vascular occlusions or subcutaneous placement can be effectively managed by surgical techniques or utilization of covered stents, by timely identification and performing an angiographic confirmation of the device deployment. Device failures can also be caused by severely calcified vascular lesions, which may be harder to grasp by sutures. A puncture site that is free from wall calcification can lead to better results regardless of the device used.

5. Limitations

The present study has the following limitations. First, this study is a study-level meta-analysis and a patient level meta-analysis would be helpful in reaching a better level of conclusion. Patient level meta-analyses are better in addressing heterogeneity among included studies. Second, the present study was primarily composed of observational studies since there was lack of RCTs, which can provide a higher level of evidence. The present study did not account for operator experience and comfort level in using these devices, which can play a major role in their outcomes. The role of emergence of the procedure, which could impact complication rates has not been accounted for in the present analysis. Finally, other risk factors for bleeding, such as antiplatelet therapy, anticoagulation, and liver disease have not been accounted for in the present analysis.

6. Conclusions

In conclusion, both VCDs (ProGlide® and MANTA®) have comparable efficacy with regard to the risk of bleeding, vascular complications, pseudoaneurysms, and/or stenosis or dissection of entry vessel. ProGlide® was, however, associated with higher failure rates compared with MANTA®. Additional high-powered studies are required to document significant differences in bleeding events and vascular complications between the two groups.

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Authorship contribution

All authors participated in the research and preparation of the manuscript as per the International Committee of Medical Journal Editors (ICMJE).

Declaration of competing interest

Dr. Kalra is the Chief Executive Officer and Creative Director of makeadent.org.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ihj.2022.03.003>.

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