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Efficacy, Safety and Complications of Manta Vascular Closure Device in VA-ECMO Decannulation: A Systematic Review and Meta-Analysis

Joana Nunes Carvalho

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TÍTULO DISSERTAÇÃO/MONOGRAFIA (riscar o que não interessa)

Efficacy, Safety and Complications of Manta Vascular Closure Device in VA-ECMO Decannulation: A Systematic Review and Meta-Analysis

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Eu, Joana Nunes Vidal de Carvalho, abaixo assinado, nº mecanográfico 201907514, estudante do 6º ano do Ciclo de Estudos Integrado em Medicina, na Faculdade de Medicina da Universidade do Porto, declaro que:

☒ Não procedi à utilização de ferramentas de *chatbox* generativo baseadas em *large language models* para nenhuma das tarefas no contexto do meu trabalho de Dissertação ou Monografia

☐ Procedi à utilização de ferramentas de *chatbox* generativo baseadas em *large language models* no contexto do meu trabalho de Dissertação ou Monografia, encontrando-se todas as interacções (*prompts* e respostas) transcritas em anexo bem como a indicação das aplicações utilizadas.

Neste sentido, confirmo que a eventual utilização de ferramentas de *chatbox* generativo baseadas em *large language models* no contexto do meu trabalho de Dissertação ou Monografia foi exclusivamente descrita na sequência de *prompts* e respostas transcritos em anexo e nas aplicações indicadas.

Faculdade de Medicina da Universidade do Porto, 26/01/2025

Assinatura conforme cartão de identificação:

Joana Carvalho

Agradecimentos

Aos meus pais, o meu maior apoio. Obrigada por me darem a oportunidade de seguir este caminho e por fazerem de mim a pessoa que sou hoje.

Ao meu irmão, por estar ao meu lado desde sempre e para sempre.

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Efficacy, Safety and Complications of Manta Vascular Closure Device in VA-ECMO Decannulation: A Systematic Review and Meta-Analysis

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ABSTRACT

BACKGROUND

VenoArterial (VA)-ExtraCorporeal Membrane Oxygenation (ECMO) decannulation was traditionally performed surgically, often resulting in high rates of periprocedural complications such as surgical site infections, bleeding, and elevated patient mobilization costs. The advent of percutaneous techniques, particularly the MANTA® vascular closure device (MVCD), has significantly reduced these risks by enabling faster and safer decannulation. This study aimed to systematically review the success rates and complications associated with the use of percutaneous closure devices for VA-ECMO decannulation.

OBJECTIVE

Therefore, this systematic review with meta-analysis aims to evaluate the success rates and complications associated with the use of MVCD device for VA-ECMO decannulation.

MATERIALS AND METHODS

A systematic search was conducted across Pubmed, Web of Science, and Cochrane databases to identify studies evaluating postoperative outcomes in patients undergoing VA-ECMO decannulation using the MANTA® vascular closure device. The MANTA® efficacy, incidence of emergent open repair, arterial thrombosis, acute limb ischemia, pseudoaneurysms, and major bleeding were pooled by fixed-effects meta-analysis, with sources of heterogeneity being explored by meta-regression. Assessment of studies' quality was performed using the National Heart, Lung, and Blood Institute (NHLBI) Study Quality Assessment Tool for observational cohorts and case-series studies.

RESULTS

Six observational studies with 132 patients were included in the final analysis. Overall efficacy of MVCD in VA-ECMO decannulation was 95.8% (95% CI 92.4–99.1%). In 132 patients, the incidence of emergency open repair after MVCD failure was 3.7% (95% CI 0.6-6.8%), the incidence of arterial thrombosis was 5.2% (95% CI 1.5-8.9%), the incidence of pseudoaneurysms was 3.4% (95% CI 0.4-6.5%), the incidence of acute limb ischemia was 4.7% (95% CI 1.1-8.2%), and the incidence of major arterial bleeding was 3.5% (95% CI 2.0-6.6%).

CONCLUSION

This systematic review and meta-analysis highlights the safety and efficacy of the MANTA® vascular closure device in achieving hemostasis following VA-ECMO decannulation, demonstrating an acceptable success rate and a low incidence of major complications. Further studies with larger cohorts are necessary to validate these findings and to address the limitations of this preliminary experience.

1. INTRODUCTION

The increasing adoption of ExtraCorporeal Membrane Oxygenation (ECMO) as a cardiopulmonary support system has been driven by its relatively straightforward implementation, the growing presence of mobile ECMO teams, and the widening scope of clinical indications for its use. [1] In fact, data from the Extracorporeal Life Support Organization (ELSO) Registry reported 16,803 ECMO cases in 2022, highlighting its expanding role in patient care. [2]

VA-ECMO can be established using either a central or peripheral configuration. Typically, peripheral VA-ECMO is initiated by placing cannulas in the common femoral vein (CFV) for blood drainage and the common femoral artery (CFA) for the return of oxygenated blood. [3] Hemostasis for venous access sites can often be achieved through hemostatic sutures or extended manual compression, but repairing large arteriotomy wounds typically requires more complex interventions. While surgical decannulation was the standard practice initially, it often comes with significant risks, including high costs associated with patient mobilization and a considerable rate of complications, such as bleeding, ischemia, compartment syndrome, amputations and infections in a relevant proportion.[4] However, advancements in medical technology have made it possible to both implant and decannulate peripheral VA-ECMO using fully percutaneous techniques, eliminating the need for open surgery. [5, 6] A study by Haddad et al. reported infection rates as high as 45%.[7] In response, percutaneous techniques using suture-mediated closure devices have been increasingly adopted to minimize these complications. [6]

Devices like the MANTA® Vascular Closure Device (MVCD) (Teleflex, Wayne, PA, USA) enable clinicians to quickly achieve hemostasis while preserving vessel integrity following the removal of large-bore arterial cannulas used in peripheral VA-ECMO. The MANTA® VCD is the first vascular closure device designed explicitly for

large-bore arteriotomy closure, featuring a poly(lactic-co-glycolic acid) intra-arterial toggle and an extravascular bovine collagen plug. [8]

There is considerable evidence supporting the safety and effectiveness of the MVCD in procedures such as percutaneous endovascular aortic repair (EVAR), and transcatheter aortic valve implantation (TAVI).[9, 10] Additionally, recent studies have demonstrated its successful use in managing vascular access following the removal of devices like the Impella left ventricular support (Abiomed, Danvers, MA, USA), which involves arterial sheaths of 8–10 F.[11] However, its application in ECMO procedures still needs to be widely examined.

This study aimed to systematically review the safety and effectiveness of the MVCD for percutaneous VA-ECMO decannulation.

2. METHODS

This systematic review was conducted following the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement and the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) tool. [12, 13] The quality of evidence was assessed using the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) framework. [14] Ethical approval from an institutional review board was not required due to the nature of the study. The review protocol has been registered on PROSPERO (reference: CRD42024520215).

The PICO framework for the study can be outlined as follows: Population (P): Patients undergoing percutaneous Veno-Arterial Extracorporeal Membrane Oxygenation (VA-ECMO) decannulation. Intervention (I): Use of the MVCD for vascular access site closure after VA-ECMO. Comparison (C): The MVCD will be evaluated without a direct

comparison due to the lack of head-to-head comparisons. Outcome (O): The safety and effectiveness of using the MVCD for percutaneous VA-ECMO decannulation.

2.1 Search strategy

A systematic search was conducted in three databases—PubMed, Web of Science, and Cochrane—on March 30, 2024. The query and keywords, provided in Supplemental Table I, included terms such as “ECMO” OR “Extracorporeal membrane oxygenation” OR “Extracorporeal Circulation” and "MANTA" OR “Percutaneous Closure” OR "vascular closure devices". (Supplemental Table I)

Additionally, the references of the included primary studies and relevant available systematic reviews were screened to search for any further articles of possible interest.

2.2 Selection Criteria

Studies that evaluated outcomes associated with the MVCD for decannulating percutaneously placed femoro-femoral VA-ECMO were included. There were no restrictions on publication date or language. Studies were excluded if the VA-ECMO cannulation was performed via open surgical cutdown or if alternative sites (e.g., internal jugular vein or axillary artery) were used. Studies that did not specify the MVCD as the primary closure device, as well as individual case reports, were also excluded. Inclusion criteria targeted original cohort or experimental studies in adults (18+ years).

2.3 Study selection and data extraction

After removing duplicates, two authors (JNC and JRN) independently conducted the study selection process, with any disagreements resolved by a third author (MMV). Initially, studies were screened based on titles and abstracts, with the remaining proceeding to full-text assessment. Attempts were made to contact authors to obtain full-

text articles that were not publicly accessible. Two authors (JNC and JRN) performed data extraction from the included studies using a custom-built .xls form. Data extraction included details on study and patient characteristics, technical specifics, and key outcome measures related to VA-ECMO decannulation using the MVCD.

2.4 Assessment of study quality

Concerning qualitative assessment, the National Heart, Lung, and Blood Institute (NHLBI) Study Quality Assessment Tool was used to assess the risk of bias, adequate reporting, and quality of statistical analysis of observational cohort and case-series studies. [15] This evaluation was carried out independently by two authors (JNC and JRN). In cases of disagreement, a consensus was reached through discussion, with the assistance of a third author (MMV).

2.5 Outcome measures

This study primarily evaluated technical success rates and complication incidences associated with decannulation using the MVCD in VA-ECMO patients. Key outcomes included rates of open repair following MVCD failure, acute limb ischemia, arterial thrombosis, pseudoaneurysm, hematoma, major bleeding, arterial dissection, arteriovenous fistula, wound infection, and procedure-related mortality.

Technical success was defined as achieving successful hemostasis following VA-ECMO decannulation with the MVCD, without unplanned surgical or endovascular interventions. Bleeding complications were classified according to the Bleeding Academic Research Consortium (BARC) guidelines[16]. Patients with BARC types 1 or 2 bleeding were classified as having minor bleeding, while those with BARC types 3, 4, or 5 were considered to have major bleeding.

2.6 Quantitative synthesis

A random-effects meta-analysis was conducted using the restricted maximum likelihood method on log-transformed proportions to calculate participants' pooled incidence of effective and safe percutaneous closure. The pooled estimates and their 95% confidence intervals (95% CI) were back-transformed to their original scale for easier interpretation. Heterogeneity was evaluated through the Q-Cochran p-value and the I^2 statistic, with a p-value <0.10 and $I^2 \geq 50\%$ indicating substantial heterogeneity. Covariates assessed included publication year, participants' mean age, percentage of male participants, percentage of patients with arterial atherosclerotic risk factors, and percentage of patients using antiplatelet and anticoagulant medications.

All statistical analyses were performed using Open Meta® (MetaMorph, Inc).

3. RESULTS

3.1 Search Results

Following the database search and removal of duplicates, a total of 175 studies were screened. After reviewing the titles and abstracts, 158 studies were excluded. Seventeen studies were deemed eligible for full-text evaluation (Figure 1). The primary reasons for exclusion during the full-text assessment included: incomplete data (n=7) and different exposure (n=1). Six published articles met the inclusion and exclusion criteria and were incorporated into this study (Table I).

3.2 Description of Studies

This review includes three observational case series [17-19], and three cohort studies [20-22]. All studies were published recently from 2020 onward. Overall, one of those studies was prospective[17] and five were retrospective [18-22]. The included publications were conducted across five countries within three continents: one from North America[19], four from Europe[17, 18, 20, 21], and one from Asia[22]. In total, 132 patients were evaluated across the studies, with sample sizes ranging from 10 to 38 patients per study. The average age of participants was 57.85 years, and 78.79% (n=104) were male (Table I).

Key characteristics from each study, along with the primary clinical features and comorbidities of the patients, were analyzed (Tables I and II). Procedure-related variables, including VA-ECMO indications, cannula sizes, and decannulation techniques, were also examined (Table III). Additionally, data on short-term outcomes and adverse events associated with cannula removal were compiled, covering surgical open repair, acute limb ischemia, arterial thrombosis, pseudoaneurysm, hematoma, major bleeding, arterial dissection, arteriovenous fistula, wound infection, and procedure-related mortality (Table IV).

3.3 Studies quality

Figures 2.1–3.2 outline the risk of bias in the included studies. Figure 2.1 details individual assessments for each observational cohort, while Figure 3.1 summarizes key areas of bias across cohorts.

In the case series, the domain with the highest risk of bias was the definition of outcomes (question D6). This reflects inconsistencies or a lack of clarity in how outcomes were specified or measured across the studies.

For cohort studies, the primary sources of bias were related to the determination of sample size adequacy (question D5), the definition of outcomes (question D11), and

the consideration of confounding factors in the analysis (question D14). These issues highlight limitations in study design, including insufficient statistical power, vague or incomplete outcome definitions, and inadequate adjustment for potential biases in the analyses.

There were no prohibitive concerns that would compromise the reliability or applicability of the results.

3.4 Decannulation techniques

All included studies had reported their technique for decannulation of the arterial cannula. VA– ECMO decannulation was performed either in the operating room[18, 19], in the catheterisation laboratory[18] or at bedside[21, 22].

The sizes of the arterial cannulas used for VA–ECMO ranged from 15 F to 21 F. Of the 132 patients, only one had the depth locator[19] used during decannulation, as emergent VA-ECMO cannulations generally did not allow for its use at the time of cannula placement. In 4 studies, the distance between the skin and the artery was determined by ultrasound examination prior to VA–ECMO decannulation[18, 20-22] while one study relied on measurements derived from computed tomography scan[19]. In one other study, the distance between the skin and the artery was not determined and was assumed to be five centimeters.[17] In preparation for MVCD placement during ECMO decannulation, wire access to the arterial cannula was achieved using several techniques. Most studies described clamping and separating the cannula from the ECMO circuit, followed by guidewire insertion under sterile conditions.[17, 18, 22] Another method introduced a stiff guidewire (Amplatz Extra Stiff) with an introducer dilator, confirmed via imaging (echocardiography or fluoroscopy) in the descending aorta.[20] Additionally, a

J-tip guidewire was used, with some protocols employing a hemostasis valve Y connector to facilitate controlled insertion for MANTA® VCD deployment.[19, 21]

The size of the venous cannulas used for VA– ECMO ranged from 21 F to 29 F. Following decannulation of the venous access site during ECMO weaning, various techniques were used to achieve hemostasis. Some studies reported applying compression with elastic bandages[17] or using a figure-of-eight skin suture followed by manual pressure for 10 minutes.[18] Other techniques included placing a Prolene purse-string suture around the cannula insertion site[19], or a deep Z-shaped suture with a sandbag applied for four hours to control bleeding.[20] Additional approaches involved continued manual compression for at least five minutes with a pressure bandage applied for 12 hours[21], or using a C-clamp for 30 minutes on both arterial and venous wounds.[22] No studies mentioned the use of a VCD for the decannulation of a venous cannula.

The size of the distal perfusion catheter used for VA–ECMO ranged from 6 F to 8 F. Following ECMO decannulation, several methods were used to remove and close the distal perfusion catheter access site. Techniques included the use of other closure devices in the superficial femoral artery (SFA)[18-20, 22], while some approaches relied on manual compression[17, 18, 21] or surgical cutdown[18] based on surgeon's discretion[18].

3.5 Main findings and meta-analysis

In 132 patients, the meta-analytical technical success rate of MVCD in VA-ECMO decannulation was 95.8% [95% CI 92.4 - 99.1%, Standard error (SE) 1.7%, $p<0.001$] I^2 =8% (Fixed effects). In all results of leave-one-out sensitivity, the overall estimate remained stable across all iterations. VCD failure was defined as failure of MANTA® to achieve hemostasis at the arteriotomy site, requiring alternative treatment to manual compression. The eight patients with MANTA® device failure were managed primarily

through surgical cutdown[18, 21], except for one bleeding case, in which hemostasis was achieved with endovascular ballooning.[20] The incidence of reported emergency open repair following the failure of the MVCD device was 3.7% [95% CI 0.6-6.8%, Standard error (SE) 1.6%, p=0.020] I2=42.7% (fixed effects) (Table IV).[17-22]

The rate of patients experiencing arterial thrombosis was 5.2% [95% CI 1.5-8.9%, Standard error (SE) 1.9%, p=0.006] I2=0%. Among the 9 cases of thrombosis[17-19, 21], seven were detected during the procedure, one was identified a week after decannulation[18], and another was discovered pre-decannulation between the arterial cannula and the distal perfusion catheter.[19] Only two cases required surgical cutdown, involving MANTA® plug removal, catheter thrombectomy, and patch reconstruction of the CFA.[18, 21] The remaining cases were managed with suction embolectomy[19] or conservative treatment.[17, 21]

The incidence of patients with pseudoaneurysm after decannulation was 3.4% [95% CI 0.4-6.5%, Standard error (SE) 1.5%, p=0.026] I2=16% (fixed effects) (Table IV). [17-22] Three pseudoaneurysms were managed conservatively[17, 19], while four received percutaneous thrombin injections.[17, 19, 21] The remaining pseudoaneurysm was located at the CFA, with one case requiring CFA patch repair.[18]

The incidence of acute limb ischemia after VA-ECMO decannulation was 4.7% [95% CI 1.1 - 8.2%, Standard error (SE) 1.8%, p=0.010] I2=0% (fixed effects) (Table IV). [17-22] Three intravascular MANTA® deployment requiring MANTA® removal with additional catheter thrombectomy or CFA patch reconstruction [17], one requiring suction embolectomy [19]. The remaining cases managed with unspecified vascular surgery or managed conservatively with anticoagulation [21].

The observed rate of major arterial bleeding was 3.5% [95% CI 3.0-6.6%, Standard error (SE) 1.6%, p=0.033] I2=22.4%.[17, 18, 20-22] All cases were managed conservatively, except for one treated with endovascular ballooning[20], and another requiring surgical cutdown.[18]

In 94 patients, no study reported any case of wound infection. Out of 61 patients, there was a single report of an arterial dissection.[22] Across 65 patients, the occurrence of hematoma varied from 2.94% to 10.0%.[18-20] Among 44 patients, no study reported any case of arterio-venous fistula. Concerning other short-term outcomes in patients that underwent percutaneous VA-ECMO decannulation, available data was sparse but further withdrawn and displayed in Table IV.

4. DISCUSSION

This systematic review and meta-analysis investigates the use of the MVCD in VA-ECMO decannulation, offering important insights into its effectiveness for managing large-bore vascular access. It presents evidence indicating that this method is associated with a high technical success rate and a low incidence of complications related to decannulation.

Several studies have examined the MVCD's safety and effectiveness in closing large-bore arteriotomies. For instance, the SAFE MANTA clinical trial reported a technical success rate of 97.7% in patients undergoing percutaneous TAVI and T/EVAR, highlighting MANTA®'s strong performance and reliability in these procedures.[9] While MANTA® has shown promising outcomes in large-bore arterial access closure, managing access sites after VA-ECMO presents additional challenges. These arise from

the extended support duration and the ECMO-associated coagulopathy that can complicate hemostasis.[23] Despite these challenges, a technical success rate of 95.8% was detected in this systematic review, consistent with previous findings.

Due to its minimally invasive nature, VA-ECMO decannulation with the MVCD has demonstrated a favorable composite outcome regarding vascular complications and wound infections compared to surgical decannulation.[9] This approach avoids the need for transport to the operating room and general anesthesia, as well as a groin incision—an area prone to infection, poor healing, and lymphatic leakage.[24] Supporting this, the study by Rahman et al. reported that decannulation with the MVCD resulted in significantly lower rates of hematomas, seromas, and surgical site infections requiring intervention compared to surgical decannulation.[20]

In addition to the MVCD, the suture-based ProGlide VCD (Abbott, Chicago, IL, USA) is another option for percutaneous decannulation in VA-ECMO patients.[6] Although suture-based closure devices have been used for this purpose, they have yet to become widely adopted due to their requirement for pre-closure before cannulation, which may delay ECMO initiation in rapidly deteriorating patients. Additionally, the exposed sutures between insertion and decannulation could increase the risk of wound infection. [25] The systematic review included two studies comparing the MANTA® and ProGlide VCDs for VA-ECMO decannulation. Both reported higher success rates and fewer complications with the MVCD group.[21, 22] Despite these findings, the choice of device is only sometimes straightforward. Several clinical factors guide the decision for the best decannulation approach. For example, if infection is present or suspected, the ProGlide system may be preferred over the MANTA® due to the infection risk associated with the MANTA®'s collagen plug. Similarly, if there is a likelihood of needing to re-establish

vascular access on the same side, ProGlide might be advantageous since MANTA®'s components take about six months to reabsorb.[8] In selected scenarios, particularly in patients with a narrower native common femoral artery, the elevation of the toggle on the MANTA® VCD can result in artery occlusion. In these instances, the ProGlide VCD may be a better option, as it requires a minimum vessel size of 5 mm, smaller than the 6 mm requirement for the MANTA® device.[11]

In this review, the depth locator was used in only one patient, due to the emergency nature of VA-ECMO cannulations.[19] CT scans[19] and ultrasounds[17, 18, 20-22], depending on the preference of the authors, were used before decannulation to verify depth measurements, maximizing accuracy.

In the study by Dalén et al. Duplex scan after decannulation was used solely to confirm distal perfusion, without visualizing the MANTA® device position.[18] This approach may miss suboptimal device positioning, potentially explaining three cases of intravascular MANTA® placement that resulted in two thromboses and one pseudoaneurysm requiring surgical intervention. Intravascular positioning can occur if the toggle encounters arterial calcification or a branch, pushing the collagen plug inward. Ultrasound guidance can mitigate this risk by allowing precise release of the toggle near the arterial wall.[11, 26] To prevent these complications, the deployment of the MANTA® device should be performed under simultaneous ultrasound guidance, a technique recently described in several studies with MANTA® in transcatheter aortic valve implantation (TAVI)[27], and in VA-ECMO decannulation.[28]

Prolonged ECMO cannulation in the femoral artery can lead to fibrotic arteriotomy edges, complicating effective closure. The MANTA® device, typically effective for arteriotomies with flexible edges after shorter procedures, may struggle with

fibrotic openings. Dalén et al. described a case where an 11.5-day ECMO duration resulted in rigid, fibrotic edges, causing the MANTA® device to inadequately seal the vessel completely.[18]

It is worth nothing that the use of anticoagulation in patients undergoing VA-ECMO is common and is done to diminish circuit-associated thrombotic risks;[29] additionally, VA-ECMO is known to provoke an acquired von Willebrand disease.[30] However, this practice may potentially lead to increased rates of hemorrhagic complications. Only two studies reported stopping anticoagulation before VA-ECMO decannulation (1h and 4h before).[20, 21]

In most studies, limb ischemia was evaluated through Doppler ultrasound, having just one report[17] of use of Near-infrared spectroscopy (NIRS) for monitoring limb perfusion, an important tool in VA-ECMO decannulation.[31] No data about the selection of limb side was reported either.

Although some deaths have been reported[18, 19], none were attributed to VA-ECMO decannulation or the use of the MANTA® device. Therefore, no procedure-related deaths were observed, highlighting the strong safety profile of this technique.

This study encountered several limitations. The systematic review included a limited number of eligible articles, with small sample sizes without justification or power analysis, resulting in low precision and potentially compromising external validity. Notably, no randomized clinical trials were identified in the literature. The included studies lacked randomization, with treatment decisions likely influenced by surgeon's preference, experience, and patient selection, which may have impacted the reported success rates of the MVCD. Significant heterogeneity was observed across studies,

particularly regarding baseline patient characteristics, study designs, and methodologies, reflecting diverse indications for VA-ECMO cannulation. Furthermore, inconsistent or insufficient follow-up periods hindered the ability to accurately assess outcome rates at 6 months, especially for vascular complications. Additionally, the studies were susceptible to publication bias, which likely limited heterogeneity in the meta-analyses and may have underestimated the complication rates associated with VA-ECMO decannulation using the MVCD.

5. CONCLUSION

This review suggests that MVCD is an effective and reliable approach for achieving hemostasis following percutaneous VA-ECMO decannulation, with an acceptable success rate, and minimal major complications reported. It contributes to a growing body of evidence supporting the potential role of MVCD as a minimally invasive option for complex VA-ECMO decannulation procedures. Larger, multicenter studies with uniform follow-up are needed to confirm these findings, and precisely assess complication rates.

Conflicts of interest

The Authors declare that there is no conflict of interest.

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Author's contributions

Authorship was limited to those who have contributed significantly to the conception, design, execution, or interpretation of the reported study

References

1. Ramanathan K, Shekar K, Ling RR, et al. Extracorporeal membrane oxygenation for COVID-19: a systematic review and meta-analysis. *Crit Care* 2021; 25: 211. 20210614. DOI: 10.1186/s13054-021-03634-1.
2. Tonna JE, Boonstra PS, MacLaren G, et al. Extracorporeal Life Support Organization Registry International Report 2022: 100,000 Survivors. *Asaio j* 2024; 70: 131-143. 20240105. DOI: 10.1097/mat.0000000000002128.
3. Jayaraman AL, Cormican D, Shah P, et al. Cannulation strategies in adult veno-arterial and veno-venous extracorporeal membrane oxygenation: Techniques, limitations, and special considerations. *Ann Card Anaesth* 2017; 20: S11-s18. DOI: 10.4103/0971-9784.197791.
4. Cheng R, Hachamovitch R, Kittleson M, et al. Complications of extracorporeal membrane oxygenation for treatment of cardiogenic shock and cardiac arrest: a meta-analysis of 1,866 adult patients. *Ann Thorac Surg* 2014; 97: 610-616. 20131108. DOI: 10.1016/j.athoracsur.2013.09.008.
5. Danial P, Hajage D, Nguyen LS, et al. Percutaneous versus surgical femoro-femoral veno-arterial ECMO: a propensity score matched study. *Intensive Care Med* 2018; 44: 2153-2161. 20181114. DOI: 10.1007/s00134-018-5442-z.
6. Martins-Fernandes D, Rocha-Neves J, Ferreira AR, et al. Assessment of percutaneous closure for decannulation of veno-arterial extracorporeal membrane oxygenation: A retrospective study. *J Vasc Access* 2024: 11297298241300119. 20241124. DOI: 10.1177/11297298241300119.
7. Haddad P, Chasin C, Xu J, et al. Single-center surgical site infection rate after peripheral ECMO decannulation and surgical repair. *Ther Adv Infect Dis* 2022; 9: 20499361221132148. 20221020. DOI: 10.1177/20499361221132148.
8. van Gils L, De Jaegere PP, Roubin G, et al. The MANTA Vascular Closure Device: A Novel Device for Large-Bore Vessel Closure. *JACC Cardiovasc Interv* 2016; 9: 1195-1196. DOI: 10.1016/j.jcin.2016.03.010.
9. Krajcer Z, Wood DA, Strickman N, et al. Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Vascular Closure Device During Percutaneous EVAR and TEVAR Procedures. *J Endovasc Ther* 2020; 27: 414-420. 20200320. DOI: 10.1177/1526602820912224.
10. Kroon HG, Tonino PAL, Savontaus M, et al. Dedicated plug based closure for large bore access –The MARVEL prospective registry. *Catheterization and Cardiovascular Interventions* 2021; 97: 1270-1278. DOI: https://doi.org/10.1002/ccd.29439.
11. Moccetti F, Brinkert M, Seelos R, et al. Insights From a Multidisciplinary Introduction of the MANTA Vascular Closure Device. *JACC Cardiovasc Interv* 2019; 12: 1730-1736. DOI: 10.1016/j.jcin.2019.06.049.
12. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *International Journal of*

Surgery 2021; 88: 105906. 20210329. DOI: 10.1016/j.ijsu.2021.105906.
13. Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *Bmj* 2017; 358: j4008. 20170921. DOI: 10.1136/bmj.j4008.
14. Alonso-Coello P, Oxman AD, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. *BMJ* 2016; 353: i2089. 20160630. DOI: 10.1136/bmj.i2089.
15. National Heart L, and Blood Institute. Study Quality Assessment Tools, https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools (2013, accessed Oct 6 2024).

16. Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. *Circulation* 2011; 123: 2736-2747. DOI: 10.1161/circulationaha.110.009449.
17. Bemtgen X, Heidt T, Zotzmann V, et al. Venoarterial extracorporeal membrane oxygenation decannulation using the novel Manta vascular closure device. *European Heart Journal Acute Cardiovascular Care* 2020; 9: 342-347. DOI: 10.1177/2048872620918707.
18. Dalén M, Settergren M, Kastengren M, et al. Percutaneous decannulation of extracorporeal membrane oxygenation using a plug-based closure device. *Catheter Cardiovasc Interv* 2022; 99: 1945-1952. 20220123. DOI: 10.1002/ccd.30096.
19. Shah A, Ghoreishi M, Taylor BS, et al. Complete percutaneous decannulation from femoral venoarterial extracorporeal membrane oxygenation. *JTCVS Tech* 2021; 6: 75-81. 20201121. DOI: 10.1016/j.xjtc.2020.11.005.
20. Rahman T, Herajärvi J, Ahonen H, et al. Ultrasound-guided closure of the femoral artery during venoarterial decannulation using a large-bore closure device. *Scand J Surg* 2023; 112: 256-264. 20230710. DOI: 10.1177/14574969231181232.
21. Scherer C, Theiss H, Istrefi M, et al. Suture-based vs. pure plug-based vascular closure devices for VA-ECMO decannulation-A retrospective observational study. *Front Cardiovasc Med* 2023; 10: 1106114. 20230126. DOI: 10.3389/fcvm.2023.1106114.
22. Au SY, Chan KS, Fong KM, et al. Comparing the outcomes of bedside percutaneous VA-ECMO decannulation by ProGlide and Manta in a high-ECMO-volume center in Hong Kong. *Artif Organs* 2022; 46: 1382-1388. 20220219. DOI: 10.1111/aor.14198.
23. Fang ZA, Navaei AH, Hensch L, et al. Hemostatic Management of Extracorporeal Circuits Including Cardiopulmonary Bypass and Extracorporeal Membrane Oxygenation. *Semin Thromb Hemost* 2020; 46: 62-72. 20191213. DOI: 10.1055/s-0039-3400273.
24. Salna M, Takayama H, Garan AR, et al. Incidence and risk factors of groin lymphocele formation after venoarterial extracorporeal membrane oxygenation in cardiogenic shock patients. *J Vasc Surg* 2018; 67: 542-548. 20170816. DOI: 10.1016/j.jvs.2017.05.127.
25. Hwang JW, Yang JH, Sung K, et al. Percutaneous removal using Perclose ProGlide closure devices versus surgical removal for weaning after percutaneous cannulation for venoarterial extracorporeal membrane oxygenation. *J Vasc Surg* 2016; 63: 998-1003.e1001. 20160126. DOI: 10.1016/j.jvs.2015.10.067.
26. Díez-Delhoyo F, Elizaga J, Gutierrez-Ibañes E, et al. Toggle Malapposition and Femoral Subocclusion as a Potential Complication of Manta Closure Device During TAVR. *J Invasive Cardiol* 2019; 31: E300.
27. Moriyama N, Dahlbacka S, Vähäsilta T, et al. The Efficacy of the Ultrasound-Navigated MANTA Deployment Following Transfemoral Transcatheter Aortic Valve Replacement. *JACC Cardiovasc Interv* 2019; 12: 2564-2566. 20190927. DOI: 10.1016/j.jcin.2019.09.018.
28. Dahlbacka S, Vähäsilta T, Moriyama N, et al. Ultrasound-Navigated Manta Deployment After Removal of Extracorporeal Membrane Oxygenation Cannula. *Ann Thorac Surg* 2020; 110: e307-e309. 20200305. DOI: 10.1016/j.athoracsur.2020.01.064.
29. Aubron C, DePuydt J, Belon F, et al. Predictive factors of bleeding events in adults undergoing extracorporeal membrane oxygenation. *Ann Intensive Care* 2016; 6: 97. 20161006. DOI: 10.1186/s13613-016-0196-7.
30. Panholzer B, Bajorat T, Haneya A, et al. Acquired von Willebrand syndrome in ECMO patients: A 3-year cohort study. *Blood Cells Mol Dis* 2021; 87: 102526. 20201210. DOI: 10.1016/j.bcmd.2020.102526.
31. Lorusso R, Shekar K, MacLaren G, et al. ELSO Interim Guidelines for Venoarterial Extracorporeal Membrane Oxygenation in Adult Cardiac Patients. *Asaio j* 2021; 67: 827-844. DOI: 10.1097/mat.0000000000001510.

Legends

Figure 1 - PRISMA flow diagram illustrating the study identification and selection process.

Figure 2.1 - Risk of bias assessment for all cohort studies included in the systematic review, presented by individual article.

Figure 2.2 - Risk of bias assessment for all included cohort studies, presented by individual item.

Figure 3.1 - Risk of bias assessment for all case series studies included in the systematic review, organized by article.

Figure 3.2 - Risk of bias assessment for all included case series studies, presented by specific item.

Figure 4.1 - Forest plot illustrating the technical success rate of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

Figure 4.2 - Forest plot illustrating the incidence of emergency open repair cases following the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

Figure 4.3 - Forest plot showing the incidence of arterial thrombosis associated with the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

Figure 4.4 - Forest plot showing the incidence of pseudoaneurysms associated with the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

Figure 4.5 - Forest plot showing the incidence of acute limb ischemia associated with the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

Figure 4.6 - Forest plot showing the incidence of major bleeding associated with the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

Supplemental Table 1 - Search Strategy

Table I - Characteristics of the studies included in the systematic review

Table II - Summary clinical data of included patients

Table III - Procedure related variables

Table IV - Short-term outcomes and adverse events

Figure 1 - PRISMA flow diagram illustrating the study identification and selection process.

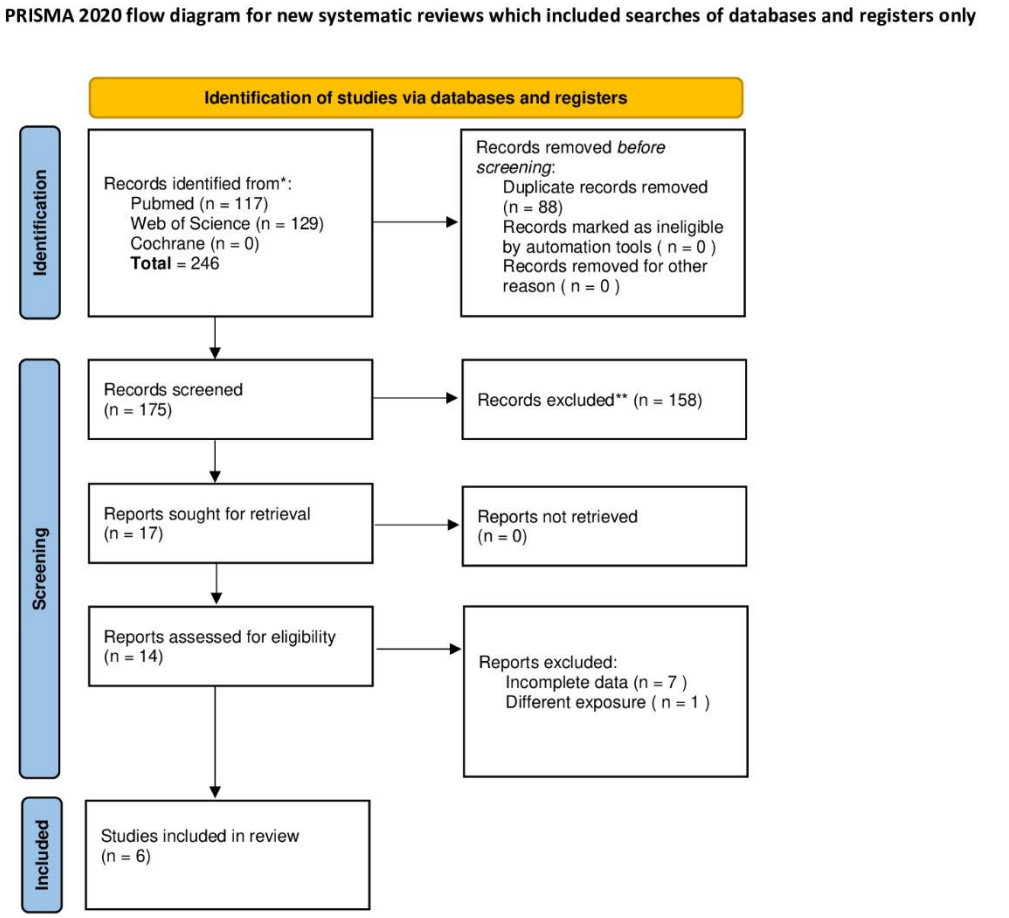


Figure 2.1 - Risk of bias assessment for all cohort studies included in the systematic review, presented by individual article.

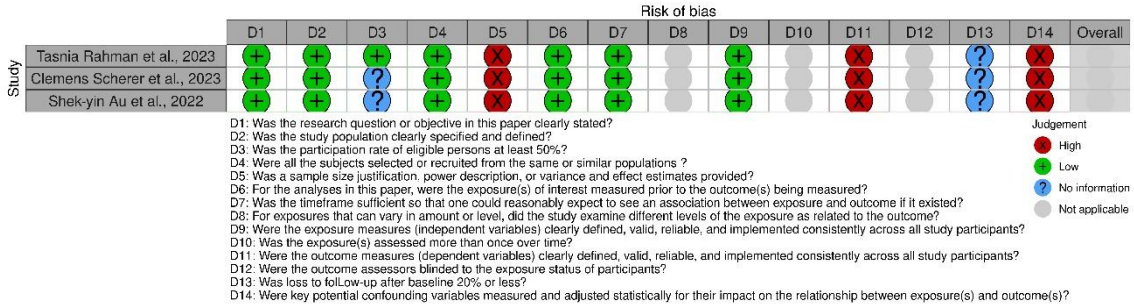
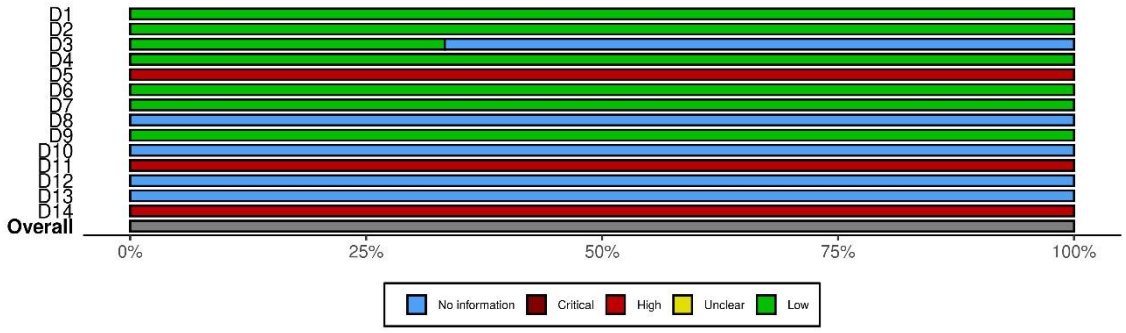


Figure 2.2 - Risk of bias assessment for all included cohort studies, presented by individual item.



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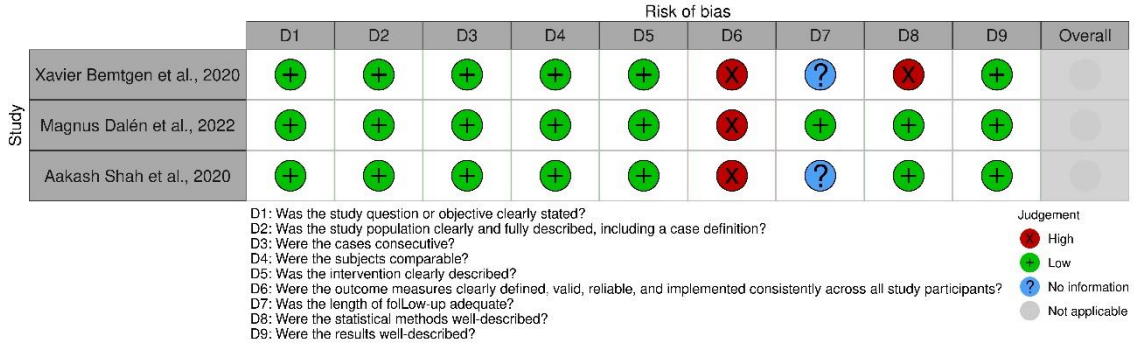
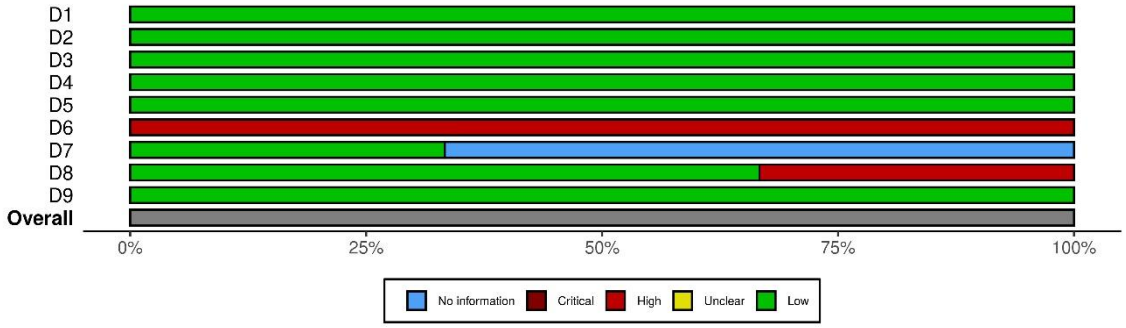


Figure 3.2 - Risk of bias assessment for all included case series studies, presented by specific item.



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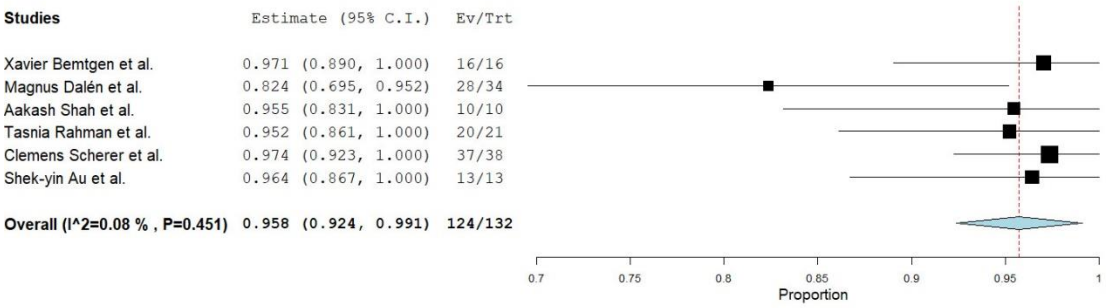


Figure 4.2 - Forest plot illustrating the incidence of emergency open repair cases following the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

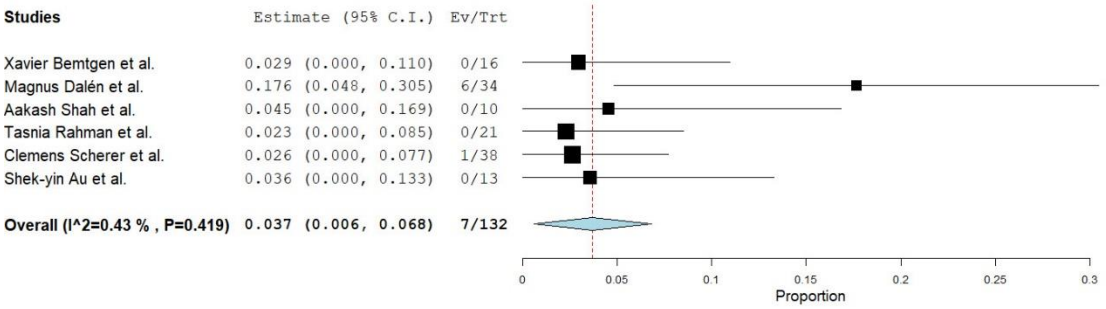


Figure 4.3 - Forest plot showing the incidence of arterial thrombosis associated with the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.

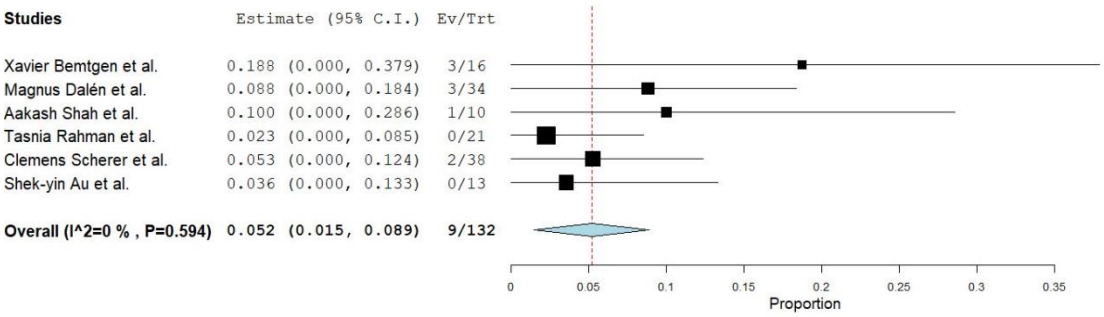
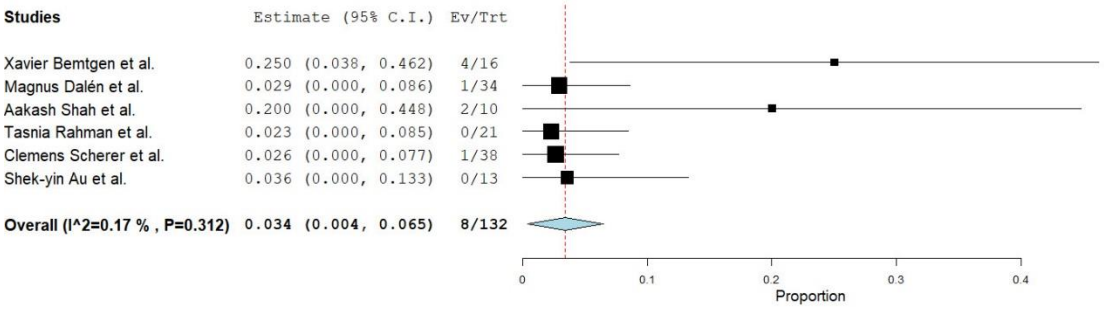


Figure 4.4 - Forest plot showing the incidence of pseudoaneurysms associated with the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.



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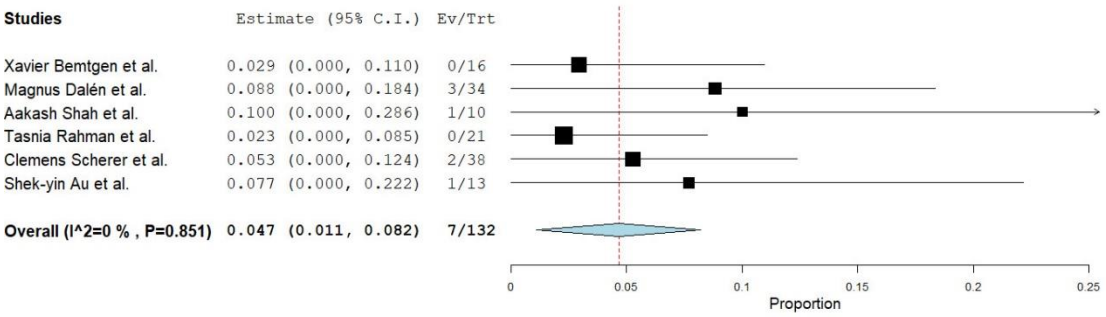
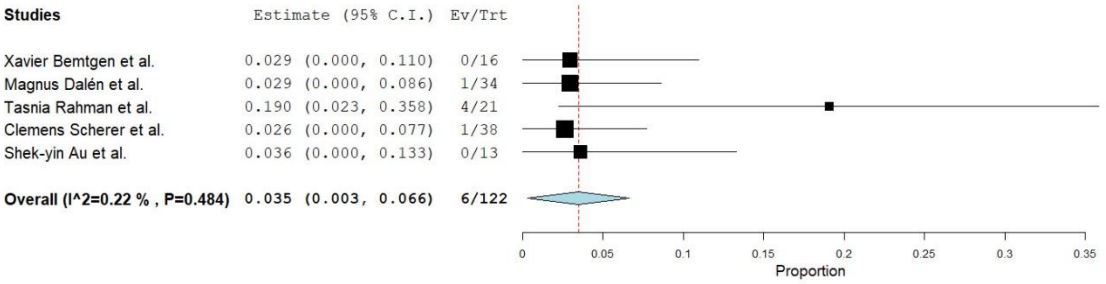


Figure 4.6 - Forest plot showing the incidence of major bleeding associated with the use of the MANTA vascular closure device in VA-ECMO decannulation across the included studies.



Supplemental Table I: Search Strategy

Databases	Query and keywords	Articles found
Pubmed	(“ECMO” OR “Extracorporeal membrane oxygenation” OR “Extracorporeal Circulation” OR “ECLS” OR “extracoporeal life-support” OR “venous-arterial” OR “extracorporeal cardiopulmonary resuscitation” OR “ECPR” OR “venoarterial” OR “Mechanical circulatory support”) AND ("Manta” OR “MANTA Closure” OR "vascular closure devices" OR ("vascular" AND "closure" AND "device") OR "vascular closure device" OR “Vascular closure” OR “Closure device” OR “Percutaneous closure” OR “artery closure” OR “Arterial Puncture closure”)	117
Web of Science	(“ECMO” OR “Extracorporeal membrane oxygenation” OR “Extracorporeal Circulation” OR “ECLS” OR “extracoporeal life-support” OR “venous-arterial” OR “extracorporeal cardiopulmonary resuscitation” OR “ECPR” OR “venoarterial” OR “Mechanical circulatory support”) AND ("Manta” OR “MANTA Closure” OR "vascular closure devices" OR ("vascular" AND "closure" AND "device") OR "vascular closure device" OR “Vascular closure” OR “Closure device” OR “Percutaneous closure” OR “artery closure” OR “Arterial Puncture closure”)	129
Cochrane	(“ECMO” OR “Extracorporeal membrane oxygenation” OR “Extracorporeal Circulation” OR “ECLS” OR “extracoporeal life-support” OR “venous-arterial” OR “extracorporeal cardiopulmonary resuscitation” OR “ECPR” OR “venoarterial” OR “Mechanical circulatory support”) AND	0

("Manta” OR “MANTA Closure” OR "vascular closure devices" OR ("vascular" AND "closure" AND "device") OR "vascular closure device" OR “Vascular closure” OR “Closure device” OR “Percutaneous closure” OR “artery closure” OR “Arterial Puncture closure”)

TABLES

Table I: Characteristics of the studies included in the systematic review

Author	Publication year	Journal	Study center	Study design	Study period	Quality of evidence (GRADE)	Number of patients
Xavier Bemtgen et al.[16]	2020	European Heart Journal	Heart Center Freiburg, Germany	Prospective Case Series	jan-june 2019	⨁⨁◯◯ Low	16
Magnus Dalén et al.[17]	2022	Catheterization and Cardiovascular Interventions	Karolinska University Hospital, Stockholm, Sweden	Retrospective Case Series	jan 2018 - oct 2021	⨁⨁◯◯ Low	34
Aakash Shah et al.[18]	2020	JTCVS Techniques	University of Maryland School of Medicine, Baltimore	Retrospective Case Series	jan - may 2020	⨁⨁◯◯ Low	10
Tasnia Rahman et al.[19]	2023	SAGE Journals	Helsinki University Hospital, Finland	Retrospective Cohort	oct 2012 - nov 2020	⨁⨁◯◯ Low	21
Clemens Scherer et al.[20]	2023	Frontiers in Cardiovascular Medicine	Ludwig-Maximilians-University Munich	Retrospective Cohort	jan 2010 - nov 2021	⨁⨁◯◯ Low	38

Shek-yin Au et al.[21]	2022	Artificial organs	Queen Elizabeth Hospital	Retrospective Cohort	nov 2018 - june 2021	 Low	13

Table II: Summary clinical data of included patients

Author	**Xavier Bemtgen et al.[16]**	**Magnus Dalén et al.[17]**	**Aakash Shah et al.[18]**	**Tasnia Rahman et al.[19]**	**Clemens Scherer et al.[20]**	**Shek-yin Au et al.[21]**
Age (years)	64.7 (59–77.1)	60 ± 13	61.5 ± 7.7	46 ± 15	57.9 ± 12.0	57.0 [52– 65]
Male gender (%)	13 (81.2)	27 (79.4)	7 (70)	17 (80.9)	31 (81.5)	9 (69.2)
BMI (kg/m2)	25.5 (24.2-27.7)	N/A	35.0 ± 8.3	25.6 ± 5.9	27.9 ± 4.0	N/A
HT	N/A	N/A	8 (80)	0 (0)	N/A	N/A
DLD	N/A	N/A	8 (80)	N/A	N/A	N/A
DM	N/A	N/A	4 (40)	0 (0)	N/A	N/A
Smoking	N/A	N/A	3 (30)	2 (9.5)	N/A	N/A
CAD	N/A	N/A	6 (60)	4 (19.0)	N/A	N/A
CKD	N/A	N/A	2 (20)	2 (9.5)	N/A	N/A

AFib	N/A	N/A	N/A	1 (4.8)	N/A	N/A
Mean PlatBD	65	154	N/A	116	77	N/A
Anticoagulation therapy at cannula removal	yes	yes	N/A	No	No	N/A
Antiplatelet therapy – number of patients	13	29	N/A	N/A	34	N/A

Abbreviations: AFib – Atrial fibrillation; BMI– Body mass index; CAD – Coronary artery disease; CKD – Chronic kidney disease; DLD - dyslipidemia; DM – Diabetes mellitus; HT - Arterial hypertension; N/A – Unavailable data; PlatBD – Platelet number before decannulation

Table III: Procedure related variables

Author	Indication for VA-ECMO – Number of patients (%)	Time spent in ECMO (days)	Procedure setting	Assessment of skin to artery distance	Arterial cannula size (Fr)	DPC - Number of patients (%)	DPC size (Fr)	Decannulation of DPC	Venous cannula size (Fr)	Decannulation of venous cannula
Xavier Bemtgen et al.[16]	Cardiac arrest - 8 (50) Severe cardiogenic shock – 7 (43.8) Fulminant pulmonary embolism – 1 (6.2)	3.76 (2.9-6.1)	N/A	No. 5cm was assumed	15-17	10 (62.5)	8	Manual compression	23	Compression with elastic bandages
Magnus Dalén et al.[17]	Acute myocardial infarction – 13 (38.2) Postcardiotomy – 10 (29.4) Cardiac arrest – 5 (14.7) Other – 6 (17.6)	6.7 [0.6-18.6]	Catheterization laboratory or operating room	US	17 - 21	34 (100)	6 - 8	Angio-Seal VCD -22 Manual compression – 6 Surgical cutdown - 6	21-29	Haemostatic skin sutures and manual compression
Aakash Shah et al.[18]	Cardiogenic shock – 4 (40) Bridge to LVAD – 2 (20) Massive PE – 2 (20) Ca channel overdose – 1 (10) Procedural support – 1 (10)	7.4 (3.6-11.2)	Operating room	CT scan – 9 Depth locator - 1	17 - 21	10 (100)	6	Angio-Seal VCD – 6 MYNX VCD – 3 Manual compression - 1	N/A	Haemostatic skin sutures
Tasnia Rahman et al.[19]	Cardiomyopathy – 7 (33.3) Acute coronary syndrome – 6 (28.6) Drug toxicity – 2 (9.5) Myocarditis – 1 (4.8) Other – 5 (23.8)	7 ± 7	N/A	US	15-17	21 (100)	N/A	Angio-Seal VCD	N/A	Skin sutures and compression

Clemens Scherer et al.[20]	STEMI – 14 (36.8) Decompensated CMP – 12 (31.6) Primary arrhythmia – 4 (10.5) NSTEMI – 3 (7.9) Myocarditis – 2 (5.3) Valvular – 1 (2.6) Other – 2 (5.3)	4.7 [2.7-7.4]	At bedside	US	15-19	38 (100)	N/A	Manual compression	22.4	Manual compression
Shek-yin Au et al.[21]	Acute myocardial infarction – 7 (53.8) Shock post open heart operation – 4 (30.8) PE – 2 (15.4)	5.31 [3.77-6.64]	At bedside	US	15-19	13 (100)	7	ProGlide VCD	21-23	Haemostatic skin sutures and compression with femoral compression device

Abbreviations: DPC – Distal Perfusion Catheter; ECMO - extracorporeal membrane oxygenation; LVAD - left ventricular assist device; N/A – Unavailable data; NSTEMI - Non-ST-Elevation Myocardial Infarction; PE – Pulmonary embolism; STEMI - ST-Elevation Myocardial Infarction; VCD – Vascular closure device;

Table IV: Short-term outcomes and adverse events

Author	Xavier Bemtgen et al.[16]	Magnus Dalén et al.[17]	Aakash Shah et al.[18]	Tasnia Rahman et al.[19]	Clemens Scherer et al.[20]	Shek-yin Au et al.[21]
Open repair following Manta VCD failure (%)	0 (0)	6 (17.6)	0 (0)	0 (0)	1(2.6)	0 (0)
Acute limb ischemia (%)	0 (0)	3 (8.8)	1 (10)	0 (0)	2 (5.3)	1 (7.7)
Arterial thrombosis (%)	3 (18.8)	3 (8.8)	1 (10)	0 (0)	2 (5.3)	0 (0)
Pseudoaneurysm (%)	4 (25)	1 (2.9)	2	0 (0)	1 (2.6)	0 (0)
Hematoma (%)	N/A	1 (2.9)	1 (10)	2 (9.5)	N/A	N/A
Major bleeding (BARC>3) (%)	0 (0)	1 (2.9)	N/A	4 (19.0)	1 (2.6)	0 (0)
Arterial dissection (%)	N/A	N/A	0 (0)	N/A	0 (0)	1 (7.7)
Arteriovenous fistula (%)	N/A	N/A	0 (0)	0 (0)	N/A	0 (0)
Wound infection (%)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Procedure related death (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Abbreviations: BARC - Bleeding Academic Research Consortium; Manta VCD – Manta vascular closure device; N/A – Unavailable data;

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Page 1, lines 1-2.
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	Pages 4 and 5.
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pages 6 and 7, lines 1-9.
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 7, lines 10-11.
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 8, lines 12-18.
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 8, lines 4-5.
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplemental table 1.
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pages 8 and 9, line 1.
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 9, line 1-4.
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 9, lines 14-24.
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Table I, II and III
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Page 9, lines 14-24.
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Page 10, lines 3-11.
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Page 9, line 1-4.
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	No data synthesis was

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Section and Topic	Item #	Checklist item	Location where item is reported
			performed.
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	No data synthesis was performed.
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Page 10, lines 3-11.
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Nothing to report.
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Page 10, lines 7-12.
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 9, lines 14-24.
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Not possible.
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Figure 1.
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 10, lines 16-21.
Study characteristics	17	Cite each included study and present its characteristics.	Page 11, lines 1-7.
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Figures 2 and 3.
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Table IV and Figures 4.1 – 4.6.
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Figures 2 and 3.
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Page 13, lines 19-24 to page 15, lines 1-10.
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Page 13, lines 19-24 to page 15, lines 1-10.
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Page 13, lines 19-24 to

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
			page 15, lines 1-10.
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Nothing to report.
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Page 13, lines 19-24 to page 15, lines 1-10.
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Page 15, lines 13-23 to page 18, lines 1-16.
	23b	Discuss any limitations of the evidence included in the review.	Page 18, lines 17-23 to page 19, lines 1-7.
	23c	Discuss any limitations of the review processes used.	Page 18, lines 17-23 to page 19, lines 1-7.
	23d	Discuss implications of the results for practice, policy, and future research.	Page 19, lines 10-16.
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Page 7, lines 19-20.
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Fully available.
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Nothing to report.
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Page 20, lines 4-5.
Competing interests	26	Declare any competing interests of review authors.	Page 20, line 2.
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Supplemental Table I.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.

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