

Percutaneous decannulation of extracorporeal membrane oxygenation using a plug-based closure device

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Abstract

Background: There is limited experience of using the MANTA plug-based vascular closure device for percutaneous arterial closure of the femoral artery after venoarterial extracorporeal membrane oxygenation.

Objectives: To study femoral artery complications and need for subsequent vascular interventions after percutaneous decannulation of venoarterial extracorporeal membrane oxygenation (VA ECMO) using the MANTA plug-based vascular closure device.

Methods: We studied 34 consecutive patients who underwent percutaneous decannulation of VA ECMO using the MANTA device. Primary outcomes were conversion to surgical cutdown of the groin at decannulation (immediate) or later. Secondary outcomes were type of vascular complication necessitating conversion to surgical cutdown of the groin.

Results: Six (17.7%) patients had to undergo immediate ($n = 3$) or late ($n = 3$) conversion to surgical cutdown of the groin. Of these, three were owing to occlusion of the common femoral artery resulting in insufficient distal perfusion and three owing to bleeding or pseudoaneurysm. The mechanism of failure was complete intravascular deployment of the MANTA device in three patients, incomplete MANTA sealing of the arteriotomy in one patient, MANTA-unrelated thrombotic occlusion in one patient, and unknown in one patient. Surgical cut-down was typically performed with concomitant catheter thrombectomy with or without patch reconstruction of the artery.

Conclusion: Percutaneous decannulation of VA ECMO using the MANTA VCD was feasible but a substantial number of patients needed to be converted to unplanned surgical repair, owing to either closure site-located stenosis/occlusion or bleeding. If suboptimal MANTA positioning is suspected, a low threshold for conversion to surgical cutdown of the groin is recommended.

KEYWORDS

MANTA, vascular closure device, venoarterial extracorporeal membrane oxygenation

Abbreviations: CFA, common femoral artery; VA ECMO, venoarterial extracorporeal membrane oxygenation; VCD, vascular closure device.

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1 | INTRODUCTION

Venoarterial extracorporeal membrane oxygenation (VA ECMO) is most commonly initiated with cannulation of the common femoral artery and vein. Access is today usually and preferably achieved percutaneously using the Seldinger technique, with aid of ultrasound guidance and micropuncture needles, but can also be performed with surgical cutdown and arterial puncture under direct vision in less urgent situations.¹ Traditionally, VA ECMO decannulation of cannulas placed percutaneously has been performed with surgical cutdown and purse-string closure, however, cutdown in the groin is associated with a substantial risk for groin seroma/lymphatic leakage, infection, and impaired wound healing.^{2,3} The large size of arterial ECMO cannulas (usually 17–21 Fr in adults) creates challenges for percutaneous arterial access management. Percutaneous arterial decannulation using suture-based vascular closure devices (VCD) has been reported but has not achieved widespread use since these devices need pre-closing of the arteriotomy before cannulation,⁴ which might prolong ECMO initiation and increase the risk for wound infection. A novel plug-based arterial closure device (MANTA; Teleflex/Essential Medical) has been used in transcatheter aortic valve implantation, endovascular surgery and minimally invasive cardiac surgery, with low risk of adverse vascular events.^{5,6} However, arterial access and decannulation in VA ECMO is more complex compared with periprocedural support, owing to need for emergent cannulation, prolonged duration of support and ECMO-associated coagulopathy.⁷ The use of the MANTA device has been described in a few case series for the use of percutaneous arterial closure of the femoral artery after VA ECMO.^{8–10} The aim of this study was to summarize our initial experience of percutaneous decannulation of VA ECMO using the MANTA plug-based VCD, with specific focus on femoral artery complications and need for subsequent vascular interventions.

2 | METHODS

This single-center study included all patients undergoing percutaneous decannulation of femoral VA ECMO using the MANTA plug-based VCD between January 2018 and October 2021 at the Karolinska University Hospital, Stockholm, Sweden. Patients supported with intraoperative VA ECMO only as prophylactical hemodynamic support during percutaneous cardiac interventions (valve, coronary, and electrophysiological) who were decannulated after completion of the procedure were excluded. Demographics, preprocedural, procedural, and postprocedural data with focus on femoral artery complications were retrospectively collected from medical charts. Decannulation of the venous cannula and distal perfusion catheter was not the aim of this study and data are only presented for orientation. The manufacturer of the MANTA device was not involved in the decision-making for VCD use or for any other process relevant to the use in the patients of this study. The study was approved by the

Regional Ethics Review Board in Stockholm, Sweden. Informed consent was waived.

3 | OUTCOMES

Primary outcomes were conversion to surgical cutdown of the groin at decannulation (immediate) or later. Secondary outcomes were the type of vascular complication necessitating conversion to surgical cutdown of the groin.

4 | VASCULAR CLOSURE TECHNIQUE

Femoral decannulation was performed using the MANTA VCD in either the catheterization laboratory or the operating room by three interventionists and three surgeons, all with large experience MANTA procedures in non-ECMO cases. Skin to artery depth was measured using ultrasound. Computed tomography to measure the skin to artery depth of the arterial cannula was not routinely performed. Since all 34 VA ECMO cannulations were performed emergently, the depth locator was not used during cannulation. Generally, to prevent clotting in the ECMO circuit when reducing blood flow during weaning, additional heparin was administered to maintain activated clotting time > 400 s. The MANTA arterial closure procedure is illustrated in Figure 1. The use of the device has been previously described.^{3,11} The device is composed of a delivery handle containing the closure unit, which consists of an absorbable collagen pad and an absorbable polymer toggle that are connected by a suture. Hemostasis is achieved primarily by the mechanical means of the sandwiching of the anterior arterial wall between the intravascular toggle and the extravascular collagen pad. An extravascular stainless-steel lock secures and marks the location of the absorbable closure unit. The arterial cannula was clamped and separated from the ECMO circuit. An arterial cannula introducer and stiff wire (Amplatz Extra Stiff; Cook Medical) was inserted into the arterial cannula, or the cannula was directly punctured with a needle through which the stiff wire was inserted. The correct positioning of the stiff wire was verified in the descending aorta using transesophageal echocardiography or fluoroscopy. The arterial cannula was exchanged for the MANTA sheath, and the closure unit was inserted and withdrawn to the appropriate deployment level (skin to artery depth measured by ultrasound + 1.5 cm). The toggle was released, the assembly component was withdrawn, and the collagen pad was secured onto the anterior arterial wall by the stainless-steel lock. After hemostasis was achieved, the suture was cut at skin level. The distal perfusion catheter access was handled based on the surgeon's discretion with an Angio-Seal device (St. Jude Medical), manual compression, or surgical cutdown. The femoral venous cannula was withdrawn, a figure-of-eight skin suture tied down, and manual pressure was applied for 10 min. Adequate distal perfusion and device positioning was assessed through ultrasound and/or fluoroscopy.

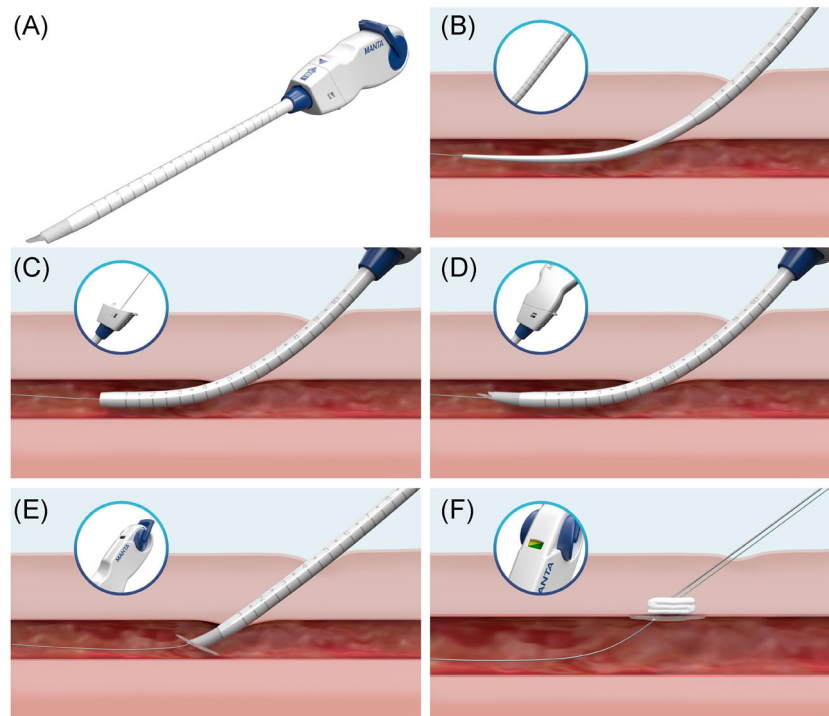


FIGURE 1 Schematic representation of arterial access closure with the MANTA vascular closure device (Teleflex/Essential Medical). (A) The MANTA closure device delivery handle. (B) A stiff guidewire is introduced in the femoral artery and the extracorporeal membrane oxygenation arterial cannula is exchanged for the MANTA sheath. (C) The introducer is withdrawn. (D) The closure unit is inserted. (E) The closure unit is withdrawn to the appropriate deployment level and the intravascular absorbable polymer toggle is released. (F) The absorbable collagen pad is secured onto the anterior arterial wall by a stainless-steel lock, sandwiching the arterial wall between the intravascular toggle and the extravascular collagen pad. After hemostasis, the suture is cut at skin level. Images courtesy of Teleflex/Essential Medical Inc. [Color figure can be viewed at wileyonlinelibrary.com]

5 | STATISTICAL ANALYSIS

Continuous variables are presented as mean \pm standard deviation or as median (interquartile range). Categorical variables are presented as numbers (percentages). Statistical analyses were conducted using SPSS Statistics for Windows, Version 28.0 (IBM Corp.).

6 | RESULTS

During the study period, 41 patients underwent percutaneous decannulation of VA ECMO using the MANTA VCD. Of these, seven (17.1%) patients were only supported with intraoperative VA ECMO during percutaneous interventions (valve/coronary/ventricular tachycardia ablation) and were excluded. Hence, 34 patients were included in the current analysis. Patient characteristics are presented in Table 1. The median ECMO duration was almost 7 days and the majority of ECMO runs was longer than 5 days (21/34; 61.8%). The arterial cannula size most commonly used was 19 Fr (21/34; 61.8%). At decannulation, the majority of patients were treated with antithrombotic medications in addition to heparin infusion (31/34; 91.2%). Three patients (8.8%) were decannulated without general anesthesia. The median follow-up was 53 days.

Outcomes are presented in Table 2 and description of patients converted to surgical cutdown either at decannulation or late after percutaneous decannulation of VA ECMO are presented in Table 3. In total, six (17.7%) patients had to undergo conversion to surgical cutdown of the groin at decannulation or later. Of these, three patients were converted to surgical cutdown at decannulation; two patients (number 14 and 28) because of insufficient distal perfusion and one patient (number 20) because of bleeding. Intraprocedural ultrasound confirmed CFA occlusion in the two patients with insufficient distal perfusion. In one of these patients, the mechanism was intravascular deployment of the MANTA device. The device was removed and catheter thrombectomy performed. In the other patient, the mechanism was thrombotic occlusion of the stagnant flow zone between the arterial cannula access site in CFA and the distal perfusion catheter access in the superficial femoral artery. This was treated with catheter thrombectomy and patch reconstruction of the CFA. In the patient where the procedure was converted to cutdown owing to bleeding, it was found that the MANTA did not completely seal the fibrotic CFA arteriotomy, after an ECMO duration of 11.5 days.

Of the three patients who underwent late conversion to surgical cutdown of the groin, one was because of insufficient distal perfusion with symptoms of intermittent leg ischemia, and CT confirmed CFA occlusion. This patient underwent vascular surgery 4 days after decannulation and the MANTA device was found to be located intravascularly.

TABLE 1 Patient characteristics at percutaneous decannulation of VA ECMO using a plug-based vascular closure device

Variables	Patients (n = 34)
Age (years)	60 ± 13
Male	27 (79.4)
BMI ≥ 30 (kg/m ²)	12 (35.3)
Left ventricular ejection fraction <30%	13 (38.2)
Indication for VA ECMO	
Acute myocardial infarction	13 (38.2)
Postcardiotomy	10 (29.4)
Cardiac arrest (ECPR)	5 (14.7)
Other	6 (17.7)
Hemoglobin (g/L)	92 ± 8
Platelet count (10 ⁹ /L)	154 ± 71
Antithrombin (kIU/L)	0.83 ± 0.16
ACT (seconds)	424 ± 134
Antithrombotics	
Heparin with ACT > 400 s	28 (82.4)
Aspirin	18 (52.1)
Clopidogrel or Ticagrelor	11 (32.3)
Argatroban	3 (8.8)
ECMO femoral access	
Arterial cannula, size Fr.	
17	6 (17.6)
19	21 (61.8)
21	7 (20.6)
Distal perfusion catheter	34 (100)
Distal perfusion catheter, size Fr.	
6	16 (47.1)
8	18 (52.9)
Venous cannula, size Fr.	
21	1 (2.9)
23	12 (35.3)
25	20 (58.8)
29	1 (2.9)
ECMO duration	
Days, median (range)	6.7 (0.6-18.6)
<5 days	13 (38.2)
5-10 days	12 (35.3)
>10 days	9 (26.5)
Femoral access closure technique	
Arterial cannula	
MANTA device 18 Fr.	34 (100)

TABLE 1 (Continued)

Variables	Patients (n = 34)
Distal perfusion catheter	
Angio-Seal device	22 (64.7)
Manual compression	6 (17.7)
Surgical cutdown	6 (17.7)
Venous cannula	
Manual compression/skin suture	34 (100)
General anesthesia during decannulation	31 (91.2)

Note: Categorical variables are presented as n (%) and continuous variables as mean ± standard deviation.

Abbreviations: ACT, activated clotting time; BMI, body mass index; ECPR, extracorporeal cardiopulmonary resuscitation; VA ECMO, venoarterial extracorporeal membrane oxygenation.

TABLE 2 Outcomes after percutaneous decannulation of VA ECMO using a plug-based vascular closure device

Variables	Patients (n = 34)
Procedural outcome	
Conversion to surgical cutdown at decannulation	3 (8.8)
Owing to CFA occlusion	2 (5.9)
Owing to bleeding	1 (2.9)
Endovascular treatment	0 (0)
Postprocedural outcome	
Late surgical cutdown	3 (8.8)
Owing to CFA occlusion	1 (2.9)
Owing to CFA pseudoaneurysm	1 (2.9)
Owing to hematoma	1 (2.9)
Any surgical cutdown (at decannulation or later)	6 (17.7)
30-day mortality	11 (32.4)

Note: Variables are presented as n (%).

Abbreviations: CFA, common femoral artery; VCD, vascular closure device.

The MANTA was removed followed by catheter thrombectomy. The two other patients (number 16 and 17) underwent late conversion to surgical cutdown of the groin owing to bleeding-related complications. In one patient, pseudoaneurysm was suspected but during vascular surgery 11 days after decannulation, only subcutaneous hematoma without any arterial leak was noted. The other patient developed a pseudoaneurysm in the groin, which was initially treated conservatively. On Day 66, vascular surgery confirmed a pseudoaneurysm that was owing to intravascular MANTA which was removed, and the CFA was reconstructed using a patch. All 3 patients who underwent immediate conversion to surgical cutdown at decannulation died before hospital discharge owing to refractory multiorgan failure, unrelated to VA ECMO decannulation or use of the MANTA device. The three patients who underwent late

TABLE 3 Patients converted to surgical cutdown either at decannulation or late after percutaneous decannulation of VA ECMO using the MANTA vascular closure device

Patient number	VA ECMO duration, days	Arterial cannula size, Fr	CFA diameter, mm	CFA calcification	Conversion to surgical cutdown at decannulation	Late surgical cutdown	Reason for surgical cutdown	Mechanism	Cutdown procedure
10	9.0	19	9	None	No	4 days after decannulation	Insufficient distal perfusion, CT confirmed CFA occlusion	Intravascular MANTA	MANTA removed, catheter thrombectomy
14	13.1	19	8	Severe	Yes	No	Insufficient distal perfusion, ultrasound confirmed CFA stenosis	Arterial occlusion, CFA severely calcified	MANTA removed, catheter thrombectomy, patch reconstruction of CFA
16	5.1	21	10	None	No	11 days after decannulation	Hematoma	N/A	Evacuation of subcutaneous hematoma
17	1.6	21	11	Moderate	No	66 days after decannulation	Pseudoaneurysm	Intravascular MANTA	MANTA removed, patch reconstruction of CFA
20	11.5	19	10	None	Yes	No	Bleeding	MANTA did not seal the fibrotic CFA arteriotomy	MANTA removed, suturing of CFA
28	18.6	17	6	None	Yes	No	Insufficient distal perfusion, ultrasound confirmed CFA stenosis	Intravascular MANTA	MANTA removed, catheter thrombectomy, patch reconstruction of CFA

Abbreviations: CFA, common femoral artery; CT, computed tomography; VA ECMO, venoarterial extracorporeal membrane oxygenation.

conversion to surgical cutdown of the groin were alive without any residual symptoms or need for additional groin procedures at the end of follow-up.

7 | DISCUSSION

In this single-center initial experience, we found that percutaneous decannulation of VA ECMO using the MANTA VCD was feasible but that a substantial number of patients needed to be converted to unplanned surgical repair, owing to either closure site-located stenosis/occlusion or bleeding.

Surgical preparation of groin vessels is associated with a substantial risk for seroma/lymphatic leakage and infection.^{2,3} Percutaneous decannulation after femoral VA-ECMO has the potential to lower the risk for such complications. The use of the MANTA plug-based arterial closure device has been used in transcatheter aortic valve implantation, endovascular surgery, and minimally invasive cardiac surgery, with low risk of adverse vascular events.^{3,5} The most frequent complications when using the MANTA VCD have been persistent bleeding and arterial occlusion, which is managed either endovascularly or surgically.¹² In the setting of VA ECMO decannulation, the use of MANTA has only been reported in small case series.⁸⁻¹⁰ Although the use of MANTA for periprocedural closure of large-bore arterial accesses has shown good results, access site management after VA ECMO is more complex owing to prolonged duration of support and ECMO-associated coagulopathy.⁷

Indeed, the number of patients needed to be converted to surgical cutdown of the groin was 17.7% which is far more than has been reported for MANTA in the non-ECMO setting, with need for surgical repair in a very limited number of patients.^{3,5} In the current series, 3 of 6 patients who underwent unplanned surgical repair, the complete MANTA device was found to be located within the artery. This highlights the importance of confirming correct positioning of the MANTA device with ultrasound during the procedure. In the early part of our experience, we only used ultrasound to confirm adequate distal perfusion, and did not visualize the MANTA device. By doing so, one could fail to detect suboptimal positioned MANTA devices. This could potentially explain two cases in which the intravascular deployment of the MANTA device was not diagnosed until later vascular surgery (patient number 10: insufficient distal perfusion; patient number 17: pseudoaneurysm). If intravascular deployment of the MANTA device is suspected, percutaneous closure should be converted to surgical cutdown. Key technical points are summarized in Table 4.

Intravascular location of the MANTA device after femoral artery decannulation can principally be caused by two mechanisms. In the non-ECMO decannulation setting, this is often caused by the intravascular toggle getting stuck in a calcification in the posterior wall of the artery or an arterial branch, which leads to the extravascular collagen pad getting pushed into the artery. To decrease the risk of the intravascular toggle getting stuck in a calcification or arterial branch, it is recommended to release the toggle as close to the anterior arterial wall as possible. This is achieved by measuring the skin to artery depth with ultrasound or computed tomography. Another recently described appealing technique

TABLE 4 Key technical points in percutaneous decannulation of extracorporeal membrane oxygenation using the MANTA vascular closure device

Vascular closure technique

- Before percutaneous decannulation, ultrasound should be used to confirm adequate arterial cannulation site and exclude extensive thrombus formation in the zone between the arterial cannula and the distal perfusion catheter.
- A stiff wire can be introduced into the arterial cannula either with the use of an arterial cannula introducer, or by direct puncture of the arterial cannula.
- Correct positioning of the stiff wire is verified using transesophageal echocardiography or fluoroscopy.
- Skin to artery depth can be measured by ultrasound, alternatively deployment can be performed with ultrasound-guidance.
- The intravascular toggle should not be released excessively proximal in the artery since this increases the risk for the intravascular toggle getting stuck in a calcification in the posterior wall of the artery or an arterial branch.
- Adequate distal perfusion and device positioning should be assessed through ultrasound and/or fluoroscopy.
- The suture should not be cut at skin level before adequate device positioning has been confirmed, since an intravascularly located device might embolize.

Complications

- Inaccurate arterial puncture and cannulation for ECMO can lead to problems during decannulation. Incorrect too low puncture close or distal to the femoral bifurcation might lead to the MANTA toggle getting stuck at an arterial branch. Distal to the bifurcation, the superficial femoral artery lumen can be so small that even a correctly placed MANTA device could impede on distal blood flow. Decannulation using surgical cutdown should be considered.
- A too high puncture might result in the inguinal ligament hampering adequate sandwiching of the anterior arterial wall between the intravascular toggle and the extravascular collagen pad. Decannulation with surgical repair should be performed.
- Intravascular location of the device can be caused by two mechanisms. (1) The intravascular toggle getting stuck in a calcification or an arterial branch, which leads to the extravascular collagen pad getting pushed into the artery. Risk is decreased by releasing the toggle as close to the anterior arterial wall as possible, possibly using simultaneous ultrasound-guidance. (2) Fibrotization of the arteriotomy after a prolonged time of placement of a cannula in the artery, which is often the case in ECMO treatment.
- Acceptable distal perfusion and no bleeding can be seen even if the MANTA device is intravascularly deployed, therefore correct positioning of the MANTA device with ultrasound should be performed.
- In some instances, bleeding can diminish after manual compression, however, this can be caused by thrombus formation adjacent to an intravascular MANTA completely occluding the artery and should thereby be converted to surgical repair.
- In case of minor bleeding after decannulation, conversion to surgical cutdown should be strongly considered since a device not completely sealing the arteriotomy may confer a risk for pseudoaneurysm development.

to decrease this risk is deployment of the MANTA device under simultaneous ultrasound-guidance,^{13,14} however, this technique was not applied in the current series.

The placement of an ECMO cannula in the femoral artery for a prolonged time might lead to fibrotization of the arteriotomy. This is the second cause why the extravascular collagen pad might be pushed into the artery during ECMO decannulation. The MANTA device is designed for closure of an arteriotomy with adaptable edges, which is the normal case when MANTA is being used after short transfemoral procedures. In the current series, we had one case of bleeding after percutaneous decannulation that upon surgical repair was confirmed to be caused by rigid edges of a fibrotic opening in the artery, which the MANTA device was not able to seal completely (patient number 20, ECMO duration 11.5 days). In case of minor bleeding after ECMO decannulation using MANTA, conversion to surgical cutdown should be strongly considered since a MANTA device not completely sealing the arteriotomy may confer a significant risk for development of pseudoaneurysm. Alternatively, bleeding after decannulation can also be caused by intravascular MANTA deployment. In some instances, the bleeding can diminish after manual compression, however, this can be caused by thrombus formation adjacent to the intravascular MANTA completely occluding the artery and should thereby be converted to surgical repair. Hence, prolonged ECMO duration might be related to increased risk for MANTA failure (mediated by creation of a fibrotic arteriotomy), but the number of patients in this series is too small to draw definitive conclusions.

Before deciding whether to decannulate using percutaneous closure of the femoral artery, it is advisable to examine the occurrence of thrombus in the stagnant flow zone between the arterial ECMO cannula and the distal perfusion catheter. This zone is prone to thrombus formation if a small artery is cannulated with a large cannula. If thrombus formation is detected by ultrasound in the stagnant flow zone, decannulation using surgical cutdown of the groin with concomitant catheter thrombectomy should be performed. By doing so, one unplanned conversion to surgical repair might have been avoided (patient number 14, severe calcification of an 8 mm CFA).

Inaccurate arterial puncture and cannulation for ECMO can lead to problems during decannulation. The MANTA toggle getting stuck at an arterial branch can be owing to incorrect puncture close or distal to the femoral bifurcation. Distal to the bifurcation, the superficial femoral artery lumen can be so small that even a correctly placed MANTA device could impede on distal blood flow. A too high puncture, adjacent to the inguinal ligament, should also be carefully avoided since the ligament could hamper adequate sandwiching of the anterior arterial wall between the intravascular toggle and the extravascular collagen pad. Before deciding whether to decannulate percutaneously, the adequate location of the arterial cannulation site should be confirmed by ultrasound or in selected cases by computed tomography. If interference with the inguinal ligament is suspected, decannulation with surgical repair should be performed. If arterial puncture is below the femoral bifurcation, decannulation using surgical cutdown should be considered, since there is a high risk for the toggle getting stuck in the profound femoral artery branch.

8 | LIMITATIONS

Although this is the largest report today of percutaneous decannulation of femoral VA ECMO using the MANTA VCD, the analysis is limited by the small number of patients included. Larger cohort of patients will be needed to identify patients in whom conventional surgical cutdown should be primarily used. Furthermore, the interventionists and surgeons performing the procedures in this study had large experience with use of the MANTA device, which may limit generalizability of our findings.

9 | CONCLUSIONS

Percutaneous femoral decannulation of VA ECMO using the MANTA VCD was feasible but a substantial number of patients needed to be converted to unplanned surgical repair, owing to either closure site-located stenosis/occlusion or bleeding. When deciding whether to decannulate VA ECMO percutaneously, we advocate careful planning with ultrasound, confirming adequate arterial cannulation site and excluding extensive thrombus formation in the zone between the arterial cannula and the distal perfusion catheter. After MANTA closure of the artery, ultrasound should be used to confirm adequate positioning of the device, and if suboptimal positioning is suspected low threshold for conversion to surgical cutdown of the groin is recommended.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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