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ORIGINAL ARTICLE

Retrospective Cohort Study

Percutaneous decannulation of extracorporeal membrane oxygenation using MANTA device: A real-world single-center experience

Ioannis Milioglou, Alice Qian, Pedro Rafael Vieira de Oliveira Salerno, Gabriel Tensol Rodrigues Pereira, Luis Augusto Palma Dallan, Kelsey E Gray, Michael Morrison, Yasir Abu-Omar, Mohammad Eldiasty, Cristian Baeza

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Abstract

BACKGROUND

The MANTA vascular closure device (VCD) represents a novel approach to achieving hemostasis after large-bore femoral access procedures. Numerous clinical studies have evaluated the efficacy of the MANTA device across a range of patient populations undergoing different procedures. However, there is still a paucity of data available concerning the use of MANTA devices in aiding the decannulation of venoarterial extracorporeal membrane oxygenation (VA-ECMO).

AIM

To present our single-center experience of utilizing the MANTA VCD in patients undergoing this procedure.

METHODS

This single-center study included all patients undergoing percutaneous decannulation of femoral VA-ECMO using the MANTA plug-based VCD between January 2021 and October 2023 at University Hospitals Cleveland Medical Center. Inclusion criteria were adult patients who required prolonged (> 24 hours) hemodynamic support with VA-ECMO. Outcomes included all-cause mortality, hemostasis, bleeding, limb ischemia, and site infection.

RESULTS

This is a retrospective cohort study of 19 patients with a mean age of 56.8 years. Twelve of them were males with a mean body mass index of 29. The most common extracorporeal membrane oxygenation indication was acute coronary syndrome complicated by cardiogenic shock at 36.8%. The mean length of intensive care unit stay for these patients was 18.8 ± 8.42 days. Seventeen out of 19 patients survived to discharge. The MANTA device was successfully deployed in 19 patients, with 10 procedures conducted at the bedside and 9 in an operating room setting. Complete hemostasis was achieved within 5 minutes of MANTA deployment in 17 out of 19 patients. In 2 patients manual compression after Manta deployment was required to achieve adequate hemostasis. Additionally, acute lower extremity ischemia was noted in two patients, necessitating endovascular interventions. No infections were reported at the site of MANTA deployment.

CONCLUSION

Overall, based on our experience and that of other centers, the MANTA VCD has proven to be a simple, safe, and effective percutaneous technique for facilitating in the OR, but most of all it opens the opportunity for bedside VA-ECMO decannulation. Post-decannulation ischemic complications are higher in this series of sick patients when compared with elective procedures like transcatheter aortic valve replacement and endovascular aneurysm repair. Additionally, operators should be mindful of the incidence of ischemic complications. Distal Doppler pulse signals should always be checked, to indicate bailout options when this occurs.

Key Words: Extracorporeal membrane oxygenation; MANTA; Decannulation; Hemostasis; Ischemia

Core Tip: The MANTA vascular closure device offers a novel approach to achieving hemostasis after large-bore femoral access procedures, particularly in complex interventions like transcatheter aortic valve replacement and endovascular aneurysm repair. This single-center study assessed the use of MANTA for percutaneous decannulation in 19 patients undergoing venoarterial extracorporeal membrane oxygenation. The device achieved rapid hemostasis in most cases, though some patients experienced late bleeding or ischemic complications. Despite these challenges, MANTA allowed for bedside decannulation, reducing the need for operating room resources. While promising, the study's small size and lack of a comparison group suggest that further research is needed to validate these findings.

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INTRODUCTION

The MANTA vascular closure device (VCD) represents a novel approach to achieving hemostasis after large-bore femoral access procedures. Its development addresses the need for effective closure devices in the era of complex percutaneous interventions, such as transcatheter aortic valve replacement (TAVR) and endovascular aneurysm repair (EVAR). The MANTA VCD is designed to achieve rapid and reliable closure of large arteriotomies, up to 24 French. Numerous clinical studies have evaluated the efficacy of the MANTA device across a range of patient populations undergoing different procedures[1,2].

However, there is still a paucity of data available concerning the use of MANTA devices in aiding the decannulation of venoarterial extracorporeal membrane oxygenation (VA-ECMO). This is particularly important because VA-ECMO standard cut-down decannulation is often troubled due to vascular injury, including significant, hard-to-control bleeding due to further vessel damage. There is also a significant risk of post-decannulation complications like groin hematomas, infection, lymphoceles, and others. In a recent study, major vascular complications were seen in 72/432 patients (16.7%) undergoing VA-ECMO decannulation with a conventional technique[3]. Therefore, considering the potential advantages of using the MANTA VCD and the limited data available regarding its application in VA-ECMO decannulation, our study aims to present our single-center experience of utilizing the MANTA VCD in patients undergoing this procedure.

MATERIALS AND METHODS

This single-center study included all patients undergoing percutaneous decannulation of femoral VA-ECMO using the MANTA plug-based VCD between January 2021 and October 2023 at University Hospitals Cleveland Medical Center in

Cleveland, Ohio, United States. Inclusion criteria were adult patients who required prolonged (> 24 hours) hemodynamic support with VA-ECMO. Demographics, preprocedural, procedural, and postprocedural data with a focus on femoral artery complications were retrospectively collected from medical charts using RedCap software. All statistical analyses were performed on R platform. IRB approval was obtained for the conduction of this study.

Decannulation and vessel closure technique: Once the ECMO circuit was disconnected, the arterial cannula was clamped and cut leaving about 5 centimeters length distal to the clamp. Using 3 medium size tegaderms at the distal end of the cannula, a water-sealed membrane was created. The clamp was removed and then an 18 G needle was used to perforate the tegaderm membrane to push the guide wire inside the artery. To avoid complications and follow the device instructions for use, a pre-deployment depth measurement is necessary to ensure the plate is inside the vessel but not too deep into the vessel lumen so other complications are avoided. For obvious reasons, in this situation, this cannot be achieved so we used a standard 8 centimeters depth. This was decided based on our own experience using Manta on elective cases. None of those cases were above 8 centimeters in depth. Once the wire was secured inside the artery, the cannula was removed holding manual compression while the Manta sheath was pushed over the wire. Subsequently, the insert piece was removed from the sheath and the closure unit was inserted. The toggle was then released, the assembly component was withdrawn, and the collagen pad was secured onto the anterior arterial wall using the stainless-steel lock.

RESULTS

This is a retrospective cohort study of 19 patients in which the MANTA device was utilized during decannulation from VA-ECMO. The mean age of these patients was 56.8 years (± 13.6), 12 were male (63.2%) and the body mass index was 29.0 (± 5.43). Baseline characteristics and pre-decannulation labs are shown in Table 1. The most common ECMO indication was acute coronary syndrome complicated by cardiogenic shock at 36.8%, followed by cardiac arrest and decompensated heart failure with reduced ejection fraction complicated by cardiogenic shock, each at 21.1%. The mean length of intensive care unit (ICU) stay for these patients was 18.8 (± 8.42) days. The 18 Fr MANTA device was used for most of the patients, especially given the larger size of the arterial cannulas as shown in Table 1. All patients received distal perfusion catheters at initial VA-ECMO cannulation. Seventeen out of 19 patients survived to discharge. The MANTA device was successfully deployed in 19 patients, with 10 procedures conducted at the bedside and 9 in an operating room setting. Complete hemostasis was achieved within 5 minutes of MANTA deployment in 17 out of 19 patients (Table 2). In 2 patients, manual compression after Manta deployment was required to achieve adequate hemostasis. We had 2 patients with late bleeding after 24 hours post-decannulation and before discharge; both were managed conservatively. There were no significant post-deployment bleeding events observed until discharge. Additionally, acute lower extremity ischemia was noted in two patients, necessitating endovascular interventions. No infections were reported at the site of MANTA deployment.

DISCUSSION

This is a single-center, retrospective review of the results using a MANTA VCD closure device for trans-femoral VA-ECMO decannulation. The initial findings are consistent with other retrospective studies and meta-analyses regarding its use in VA-ECMO decannulation. Most of the current data on MANTA's use in VA-ECMO decannulation come from observational studies, as the major randomized controlled trials (RCTs) reporting outcomes on MANTA's safety and efficacy are focused on transcatheter aortic valve intervention (TAVI) and EVAR procedures[4]. These results cannot be extrapolated to our results since this is an entirely different patient population, situation, and scenario. The patients are sicker and the groins are considered as “hostiles” since the vessels have been cannulated for more than a week. Regarding hemostasis, the MANTA device has demonstrated a similarly safe profile regardless of the indication for its use (TAVI *vs* VA-ECMO). VA-ECMO decannulation with MANTA has resulted in a higher incidence of ischemic complications, necessitating endovascular limb salvage procedures which is consistent with the literature, however, these complications can be easily related to the previous vessel damage than the actual use of the closure device[5]. Our results show that when a patient is ready to be decannulated, they have been in the ICU sedated and connected to mechanical ventilation for a week or more. On top of that, they are usually fluid-overloaded with some degree of edema and hematoma around the cannulation area. This scenario makes a standard cut-down decannulation extremely difficult, it requires patient transportation and mobilization which always represent a major risk. It also requires an operating room setting. Essentially, this is a group of extremely sick patients; many of them were cannulated in very suboptimal conditions due to acute decompensation or definitely in the middle of cardiopulmonary ressuscitation maneuvers. It is crucial to note that all ischemic complications are usually associated with this kind of very challenging cannulation situation. Using the MANTA closure device for a bedside procedure becomes very useful when it comes to mobilizing these patients and requires a very limited resource like an operating room. Additionally, Manta device deployment requires an accurate depth measurement which was not possible to be performed in this series. We do not think this played a role in our results, but it is a factor to be considered. In theory, prolonged VA-ECMO cannula stays in critically ill ICU patients can also make the arteriotomy edges less elastic and more prone to complications[6]. While studies have compared other VCDs (*e.g.*, Proglide) with MANTA for VA-ECMO decannulation without significant differences in complication rates and hemostasis success, operators must consider the potential future need for re-accessing the same vessel since suture-based VCDs demonstrate a better profile in this regard, as the MANTA plug requires approximately 6 months to be fully reabsorbed[7].

Table 1 Baseline and per-procedural characteristics of patients undergoing venoarterial extracorporeal membrane oxygenation decannulation with MANTA vascular closure device

Items	Overall (*n* = 19)
Age (years)	
Mean (SD)	56.8 (13.6)
Median (Min, Max)	56.0 (31.0, 83.0)
Sex, *n* (%)	
Male	12 (63.2)
Female	7 (36.8)
BMI	
Mean (SD)	29.0 (5.43)
Median (Min, Max)	29.0 (19.1, 42.6)
Smoking, *n* (%)	
Never	11 (57.9)
Former	4 (21.1)
Active	4 (21.1)
HTN, *n* (%)	
Yes	11 (57.9)
No	8 (42.1)
Diabetes, *n* (%)	
Yes	8 (42.1)
No	11 (57.9)
CAD, *n* (%)	
Yes	15 (78.9)
No	4 (21.1)
Total duration of ECMO (days)	
Mean (SD)	6.79 (4.20)
Median (Min, Max)	5.00 (2.00, 20.0)
ECMO indication, *n* (%)	
ACS	7 (36.8)
Cardiac arrest	4 (21.1)
Cardiogenic shock	4 (21.1)
Postcardiotomy	2 (10.5)
TAVI	2 (10.5)
Length of ICU stay (days)	
Mean (SD)	18.8 (8.42)
Median (Min, Max)	19.0 (5.00, 43.0)
Arterial cannula size (Fr), *n* (%)	
17	9 (47.4)
18	1 (5.3)
19	8 (42.1)
21	1 (5.3)
Manta size (Fr), *n* (%)	

14	2 (10.5)
18	17 (89.5)
Hb prior to decanulation	
Mean (SD)	8.85 (1.12)
Median (Min, Max)	8.50 (7.50, 12.5)
Platelets prior to decanualtion	
Mean (SD)	106 (67.9)
Median (Min, Max)	90.0 (38.0, 336)
INR prior to decanulation	
Mean (SD)	1.23 (0.338)
Median (Min, Max)	1.20 (0.900, 2.50)

BMI: Body mass index; HTN: Hypertension; CAD: Coronary artery disease; ECMO: Extracorporeal membrane oxygenation; ACS: Acute coronary syndrome; ICU: Intensive care unit; Hb: Hemoglobin; INR: International normalized ratio.

Table 2 Outcomes of MANTA vascular closure device post venoarterial extracorporeal membrane oxygenation decannulation, *n* (%)

Items	Overall (*n* = 19)
Survival to discharge	
Yes	16 (84.2)
No	3 (15.8)
Additional closure method	
None	17 (89.5)
Manual pressure	2 (10.5)
Bleeding	
No	17 (89.5)
Yes	2 (10.5)
Bleeding based on BARC	
No Bleeding	17 (89.5)
Type 1	0 (0)
Type 2	1 (5.3)
Type 3	1 (5.3)
Type 4	0 (0)
Type 5	0 (0)
Limb Ischemia post MANTA	
No	17 (89.5)
Yes	2 (10.5)

BARC: Bleeding academic research consortium.

This study has certain limitations, including its reliance on our single-center experience and the small number of reported patients, as well as the lack of a comparison group. Although our data aligns with other retrospective studies, more robust conclusions could be drawn from larger RCTs. Notably, calcification of the anterior femoral wall, which can be an independent risk factor for post-deployment complications, was not recorded in our study.

CONCLUSION

Overall, based on our experience and that of other centers, the MANTA VCD has proven to be a simple, safe, and effective percutaneous technique for facilitating in the OR, but most of all it opens the opportunity for bedside VA-ECMO decannulation. Post-decannulation ischemic complications are higher in this series of sick patients when compared with elective procedures like TAVR and EVAR. The crucial deployment step is to make sure the plate is inside of the vessel which was accomplished in this subset of patients by using 8 cm depth as a standard. Additionally, operators should be mindful of the incidence of ischemic complications. Distal Doppler pulse signals should always be checked, to indicate bailout options when this occurs.

FOOTNOTES

Author contributions: Milioglou I, Qian A, Salerno PRVO and Pereira GTR gathered and analyzed data; Milioglou I and Qian A contributed to the writing of the manuscript; Palma Dallan LA, Gray KE, Morrison M helped with the supervision of data analysis and gathering; Abu-Omar Y, Eldiasty M and Baeza C were responsible for the overall supervision of all steps of this research project.

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