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EDITORIAL

On MANTA vascular closure devices following veno arterial extracorporeal membrane oxygenation: Effectiveness and complications

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Abstract

MANTA vascular closure device is an alternative vascular access closure device that is predominantly designed for large bore arteriotomy procedures. Its implementation to reduce morbidity and mortality following percutaneous procedures including peripheral veno-arterial (VA)-extracorporeal membrane oxygenation (ECMO) in critically ill patients with various severe clinical conditions such as refractory cardiogenic shock remains to be under scientific discussion. The use of the MANTA vascular closure device leads to a sufficient reduction in a number of post-decannulation complications such as bleeding, vascular complications, inflammatory reactions and major amputation. Furthermore, the technical success of percutaneous decannulation of VA-ECMO with the MANTA vascular closure device appears to be safe and effective. It has been reported that MANTA vascular closure device exerted a strict similarity with other vascular surgical systems in safe profile regardless of the indication for its utilization. Overall, the immobilized patients achieved a favorable recovery outcome with MANTA including safe decannulation and low risk of vascular complications. The authors suggest the use of pulse wave distal Doppler technology for early detection of these clinically relevant complications. In conclusion, MANTA vascular closure device seems to be safe and effective technical approach to provide low-risk vascular assess for a long time for severe sick individuals.

Key Words: Veno-arterial extracorporeal membrane oxygenation; Decannulation; Vascular complications; MANTA vascular closure device

Core Tip: Contemporary hybrid strategy of hemostasis through the use of vascular closure devices has demonstrated great benefits over standard rescue techniques (open surgery or vascular compression at the site of vascular intervention) in reducing vascular-related complications and improving patient satisfaction. Percutaneous decannulation with the MANTA Vascular Closure Device is an effective and safe procedure to provide low-risk vascular assess for a long time for individuals requiring veno-arterial-extracorporeal membrane oxygenation, while specific approach based on other variants of vascular closure devices or open surgery should be tailored to the actual patient's clinical characteristics and prognosis.

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INTRODUCTION

Interventional procedures, including diagnostic invasive manipulations and transcatheter interventions, have become an important part of the conventional approach to many cardiovascular diseases[1]. The increasing trend of invasive interventions from year to year shows that both conventionally preferred way and alternative vascular accesses may be accompanied by a unacceptably high variability of vascular-related complications, such as bleeding, abrupt vessel closure, perforation, thrombus, infections, ranging from 4.0% in trans-radial percutaneous coronary intervention (PCI) to 33.3% in peripheral extracorporeal membrane oxygenation (ECMO)[2,3]. Under certain circumstances bleeding, thrombus and infections are considered to be most often peri-procedural complications, which be time-consuming and requires intensive therapy leading to an increase in prolonged bed rest upon completion and consequently the economic burden [4]. In this context, effective and safe hemostasis techniques are essential for the improvement of patient outcomes and the reduction of the burden of major procedure-related complications[5,6]. Along with it, minor vascular complications including small hematoma and slightly persistent pain at vascular access site are frequently associated with a certain discomfort and consequently may intervene in patient' satisfaction of the procedure[7].

Indeed, vascular access closure is essential for large bore arteriotomy procedures, such as trans-catheter aortic valve replacement, veno-arterial ECMO (VA-ECMO), PCI to ensure effective pre-procedural hemostasis and safety during decannulation[8]. Finally, effective vascular access closure has not only been shown to provide sufficient benefits in terms of patient satisfaction and hemostasis of the vascular access site after interventional procedures, but also contributes to cost savings for patients and hospitals[9].

CONVENTIONAL METHODS OF VASCULAR ACCESS CLOSURE

The gold standard of vascular access closure at the puncture site is manual compression[10]. The effective compression ensures hemostasis in certain extend, while it may be associated with minor pain and discomfort among patient. The undoubted advantage of this approach is its absolute availability and extremely low cost. Depending on the procedure, there are several types of vascular access closure that can be used as an alternative to manual compression with an acceptable level of efficacy and safety. The main characteristics of the approaches are showed in Table 1.

Currently, vascular closure devises can be divided into three categories depending on their mechanism of action: Suture devices (Perclose and Prostar), vessel plugs (Mynx, AngioSeal, ExoSeal, and FemoSeal) and metal/stainless vascular clips (StarClose). Suture devices and vascular clips were designed to ensure full hemostasis through direct closure of the arterial wall defect. Vascular plugs effectively achieve closure by extravascular filling of the defect with several absorbable xenobiotic or biological materials, for instance polyethylene glycol, bovine-derived collagen and polyglycolic acid. Notably, MynxGrip does not require stitches, clamps, or metal implants and dissolves within about 4 weeks after femoral access interventions[11]. AngioSeal contains a bovine-derived absorbable collagen plug to ensure sufficient hemostasis of trans-femoral access for normal/near normal-weight and -height patients[12].

The Perclose Proglide is a well-studied suture-mediated closure device that is preferably used for the closure of the puncture site of the femoral artery[13]. Compared to the Perclose ProGlide system, the Prostar offers better results (up to 95% success rate) for obesity and vascular calcification and appears to require less experience to be installed offers a variety of options for percutaneous femoral artery access site repair 8.5-24F[14]. FemoSeal ensures almost 100% technical success for femoral artery access and associates with low rate (less 7%) peri-procedural vascular complications[15]. StarClose is predominantly recommended to cardiac catheterization/PCI and has demonstrated a very similar success rate in vessel closure when compared to the Angio Seal system[16]. Vascade appears to be feasible and safe for patients after catheter ablation for paroxysmal or persistent AF as well as for right and left cardiac catheterization[17]. Exoseal is a vascular occlusion device consisting of a plug applicator and a bioabsorbable polyglycolic acid plug that is specially designed for antegrade peripheral endovascular interventions with an extremely high technical success (up to 98.8%)[18]. Celt ACD vascular closure device is available to ensure about 100% technical success for diagnostic interventions and therapeutic retrograde and antegrade peripheral arterial procedures[19]. The MANTA is a new, easy to use, collagen plug based vascular occluding device specifically designed to close large bore arteriotomies[20].

Table 1 Basic characteristics of the suture-based, clip-based or collagen-based vascular access closure devices

Vascular access closure devices	Manufacturing	Definition of categories	Vascular access	Interventions	Resorption ability	Recommended sheath size (Fr)	Ref.
MynxGrip	Cordis	Plug-based	Femoral artery/femoral vein	PCI, CAG, left atrial appendage closure	Fully resorbable device containing bioabsorbable polyethylene glycol plug	5, 6, 7	[11]
AngioSeal	St Jude Medical	Plug-based	Femoral artery	BAV, PCI, CAG, TAVR	Bovine-derived bioabsorbable collagen plug	6, 8	[12]
Perclose ProGlide	Abbott	Suture-based	Femoral artery	BAV, PCI, TAVR, cardiac catheterization	None	5-8	[13]
Prostar	Abbott	Suture-based	Femoral artery	BAV, endovascular aneurysm repair	None	8.5-10	[14]
FemoSeal	St Jude Medical	Suture-based	Femoral artery	PCI, CAG, lower limb revascularization	Bioabsorbable polymer discs	6-8	[15]
StarClose	Abbott	Metal clip-based device	Femoral artery, brachial artery	PCI, CAG, cardiac catheterization	None	5, 6	[16]
Vascade	Cardiva Medical	Plug-based	Femoral artery, femoral vein	Right and left cardiac catheterization, left atrial appendage closure	Bioabsorbable polymer	5-12	[17]
ExoSeal	Cordis	Plug-based	Femoral artery, brachial artery	Cardiac catheterization, CAG	Bio-absorbent polyglycolic acid plug	5, 6, 7	[18]
Celt ACD	Vasorum	Stainless-steel clip based device	Femoral artery	Cardiac catheterization, CAG	None	5, 6, 7	[19]
MANTA	Teleflex	Biomechanical vascular plug-based closure device	Femoral artery	TAVR, VA ECMO	Collagen plug-based vascular closure device	12-25	[20]

BAV: Balloon aortic valvuloplasty; CAG: Coronary angiography; ECMO: Extracorporeal membrane oxygenation; PCI: Percutaneous coronary intervention; TAVR: Trans-catheter aortic valve replacement.

Meanwhile, there is no consensus on the benefits of vascular closure devices, including the potential reduction in procedure time, the length of hospital stay, or the time it takes for patients to become ambulatory. Indeed, a limited amount of data was obtained when the vascular closure devices were compared with each other. Most data suggest that vascular closure devise of different types are superior to manual compression in their ability to reduce the incidence of serious local adverse events as well as minor vascular complications such as bleeding with hematoma and pain at the puncture site. Only the Vaso Seal device has been shown to increase the risk of any vascular complication associated with diagnostic cardiac catheterization compared to manual compression control[21]. When TAVR was performed with closure of a large bore access site with a plug-based vessel closure device such as MANTA, the safety profile was similar to Pro Glide/Pro Star X, but the length of stay with MANTA was significantly shorter than with Pro Glide/Pro Star X [22]. Although in this meta-analysis a trend toward a higher incidence of unplanned vascular intervention in plug-based vessel closure device was found, there was no remarkable difference between plug-based and suture-based vessel closure devices in major access site complications[22].

Meta-analysis of 52 studies (19192 participants) of Robertson *et al*[23] revealed that both metal clip-based and suture-based vascular closure devices were associated with reduced time to hemostasis in comparison with extrinsic compression, whereas collagen-based devices did not. The authors found no difference in the incidence of vascular injury or mortality when vascular closure devices were compared with extrinsic compression[23]. On the other hand, the main advantage of these percutaneous vascular closure devices is the ability to perform these procedures at the bedside, given the criticality of the patient and the challenges of transferring a sick patient to the operating theatre. The weakness of the vascular closure devices are their relatively high-price compared to manual compression devices. However, open surgery remains the definitive method of hemostasis, especially suitable for patients in critical condition, hospitalized patients including intensive care unit patients.

MANTA VASCULAR CLOSURE DEVICE

MANTA vascular closure device (Teleflex, Morrisville, NC, United States) is a collagen plug-based device that provides an alternative approach to safety of invasive interventions[24]. In previous clinical studies and meta-analysis, the MANTA VCD was superior in reduction of length of stay and lower risk of device failure following large-bore arteriotomy procedures when compared with percutaneous vascular surgical system (Perclose ProGlide, Abbott) and suture-based closure system (Prostar XL, Abbott Vascular), whereas the differences in mortality, bleeding, or major and minor vascular complications, development of pseudo aneurysm, stenosis-dissection were not established between these approaches[25-27]. Therefore, in meta-analysis of 15 studies, involving 9259 patients who underwent trans-catheter aortic valve replacement, MANTA utilization was associated with better reducing a primary composite endpoint (intra-hospital death, major vascular complications, and major or life-threatening bleedings) than Prostar XL percutaneous vascular surgical system and Perclose Pro Glide closure system[27]. However, from 10% to 20% of critically ill patients had to be converted to unplanned surgical repair due to either closure site stenosis/occlusion or bleeding[28,29]. In this context, the impact of MANTA on morbidity, mortality and post-procedural complications remains to be uncertain.

VA ECMO AND MANTA DEVICE

VA-ECMO is a bridge-to recovery therapy, which is typically initiated with cannulation of the common femoral artery and vein and can stabilize patients with cardiogenic shock including post-cardiotomy cardiogenic shock, acutely decompensated heart failure with reduced ejection fraction, massive pulmonary thromboembolism, cardiac arrest, refractory ventricular tachycardia, as well as those with hemodynamic complications of various invasive interventions [30-34]. Contemporary practice favors percutaneous access, achieved using the Seldinger technique with ultrasound guidance and micropuncture needles. However, surgical cut-down and arterial puncture under direct vision may be employed in less urgent circumstances[35].

The study by Milioglou *et al*[36], published in this issue of the *World Journal of Cardiology*, was the first to evaluate the association between the risk of post-decannulation ischemic complications and the use of the MANTA device to assist of VA-ECMO. The authors established that manual compression of femoral artery after MANTA deployment ensured to achieve adequate hemostasis, low risk of ischemic complications in lower extremity and the lack of bleeding. Along with it, the authors suggested that the detection of calcification of the anterior femoral wall with Doppler technique is mindful to predict from the incidence of possible ischemic complications. Overall, MANTA device seems to be a simple, safe, and effective percutaneous technique for sufficient reduction of peri-procedural interventional complications.

Although the study by Milioglou *et al*[36] was retrospectively accomplished in a single center, it firstly provided important clinical evidence regarding combined outcomes, such as all-cause mortality, hemostasis, bleeding, limb ischemia, and site infection in extremely sick patients whose vessels have been cannulated for more than a week in real practice. Remarkably, MANTA device exerted a strict similarity with other vascular surgical systems, such as Perclose Pro Glide and Perclose Pro Glide, in safe profile regardless of the indication for its utilization (elective transcatheter aortic valve replacement and endovascular aneurysm repair). Overall, the immobilized patients achieved a favorable recovery outcome with MANTA vascular closure device including safe decannulation and low risk of vascular complications. These results open new possibilities for safe interventions in critically ill patients with long-term peripheral arterial catheterization. However, nearly half of the patients in the study had this procedure in the operating theatre. This fact needs to be fully discussed, because if the patient can be taken to the operating theatre-surgical repair with fewer complications would be preferable. Indeed, the safety and efficacy of the MANTA device requires to be determined high-powered study, because the benefit of the MANTA before suture-based (ProGlide and Prostar XL) devises or open surgery among moderate-to-severe risk in-patients has not been yet confirmed. In any case, we can partially agree with the authors of the study that the use of MANTA for these patients may be more practical than open surgery. Meanwhile, the SU-PER-ACCESS Study showed that surgical cut-down for transfemoral TAVR did not increase 30-day mortality and was remarkably associated with fewer minor vascular complications and bleeding compared with the percutaneous approach[37]. Recent meta-analysis of Doshi *et al*[25] has no shown convincing evidence regarding higher incidence of access-site vascular complications and as major life threatening bleeding events as minor vascular complications with plug-based *vs* suture-based vascular closure devices in patients undergoing transfemoral intervention, whereas previous meta-analysis had provided another conclusion[22]. Additionally, it is conceivable that these data are difficult to extrapolate to a population of immobilized high-risk or critical patients, for whom the primary safety conclusion of plug-based vascular closure devices may be different. However, further studies are needed to determine whether MANTA is the device of choice for high-risk and critically ill patients compared to open surgery and other large-bore access closure devices.

CONCLUSION

MANTA vascular closure device seems to be safe and effective technical approach to provide low-risk vascular assess for a long time for individuals at higher risk, while specific approach based on other variants of vascular closure devices or open surgery should be tailored to the actual patient's clinical characteristics and prognosis.

FOOTNOTES

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