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ORIGINAL RESEARCH

The Preventive Effect of Distal Perfusion Catheters on Vascular Complications in Patients Undergoing Venous Artery Extracorporeal Membrane Oxygenation

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Objective: To investigate the preventive effect of distal perfusion catheters (DPCs) on vascular complications in patients undergoing venous artery extracorporeal membrane oxygenation (VA-ECMO).

Methods: Patients who underwent VA-ECMO through a femoral approach in our hospital were included in this study, and they were divided into two groups according to their use of DPC. Clinical indicators were compared between the two groups, including the ECMO running time, intensive care unit (ICU) time, length of hospital stay, ECMO auxiliary results, the incidence of limb ischemia and vascular complications.

Results: In total, 250 patients were included in this study, including the DPC group (age: 48 [32–62] years old, 58.4% male, n = 125) and the non-DPC group (age: 51 [36–63] years old, 65.6% male, n = 125). The DPC group was less likely to have limb complications than the non-DPC group (6.4% vs 17.6%, $P = 0.006$), mainly resulting from distal ischemia (4.0% vs 15.2%, $P = 0.003$) and necrosis (1.6% vs 9.6%, $P = 0.006$). The ECMO duration had a median of 92.3 (75.7–109) h in the DPC group and 71.2 (59.4–82.8) h in the DPC group, with a difference close to the statistical threshold ($P = 0.054$). There was no significant difference in ICU time or length of hospital stay between the two groups. The multivariate analysis showed that the DPC implantation was negatively associated with limb complications (odds ratio: 0.265, 95% confidence interval: 0.107–0.657, $P = 0.004$) after adjustment for confounding factors.

Conclusion: Distal perfusion catheter placement might be associated with a decreased risk of vascular complications and limb ischemia in patients undergoing femoral VA-ECMO cannulation. Further randomised studies are still needed to verify its benefit on clinical outcomes.

Keywords: distal perfusion catheter, extracorporeal membrane oxygenation, femoral cannulation, osteofascial compartment syndrome, distal ischemia

Introduction

One of the mechanical circulatory support devices used in patients with refractory heart failure is extracorporeal membrane oxygenation (ECMO).[1] Extracorporeal technology has improved recently, increasing the use of ECMO and broadening its potential applications. Arterial inflow is often obtained in refractory cardiogenic shock by direct cannulation of the aorta, axillary artery or femoral artery. Lower limb ischemia is prevalent with femoral artery

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cannulation in 10–70% of adult ECMO vascular complications when a distal perfusion catheter (DPC) is not placed.[2] With reported rates ranging from 4% to 15% after implantation of a DPC, limb ischemia is still a problem for patients receiving peripheral venous artery ECMO (VA-ECMO) because a retrograde arterial cannula may lead to significant artery occlusion.[3]

In patients receiving peripheral VA-ECMO, a number of preventative measures have been suggested to decrease the likelihood of limb ischemia, including cannula size and site selection, cannulation technique, and the implantation of a DPC. If the distal arterial flow to the leg is insufficient, the Extracorporeal Life Support Organisation guidelines advise placing a DPC in the distal superficial femoral artery to provide antegrade blood flow to the lower limbs. In fact, DPCs are often used in several ECMO facilities.[4] Those patients with a higher risk of developing limb ischemia (eg female patients, younger patients and patients taking high doses of vasopressors) may benefit most from the prophylactic use of a DPC. A recent meta-analysis also demonstrated the link between the use of DPCs and a decreased risk of limb ischemia.[5] However, there is a lack of evidence and sufficient guidelines to support DPC use as a first-line treatment. The indications and timing of DPC placement still depend on the clinical evaluation and decision-making processes of clinicians.

For this reason, this study aims to investigate the incidence of vascular complications and limb ischemia in patients undergoing VA-ECMO cannulation through a femoral approach and to evaluate the effect of a DPC in preventing the occurrence of vascular complications during the initial ECMO cannulation.

Methods

Study Design and Population

This study was a retrospective, single-centre and case-control study. The institutional review committee approved the protocol at our institution on August 3, 2021 (Ethical Approval Number: 2021-E-03-001). The requirement of informed consent was waived due to the retrospective design.

We retrospectively screened consecutive patients for their eligibility using the hospital's electronic medical records. Patients (≥18 years old) were eligible if they underwent VA-ECMO cannulation through a femoral approach when admitted to the hospital between June 2016 and October 2018. The exclusion criteria were as follows: 1) congenital malformations of the femoral artery and 2) incomplete clinical data. All patients were divided into two groups (the DPC group and the non-DPC group) according to whether a DPC was used during VA-ECMO cannulation. The placement of the DPC was based on the clinician's discretion and evaluation. An early DPC installation was likely associated with multiple cardiovascular risk factors, a history of peripheral vascular disease and significant femoral artery calcification. Demographics and clinical characteristics were obtained from the electronic medical records, including comorbidities, indications, cannulation technical characteristics and clinical outcomes.

Outcomes

The primary outcome was the incidence of limb ischemic events and any other vascular complications. The secondary outcomes were the running time of the ECMO, the intensive care unit (ICU) time, the length of hospital stay and the auxiliary results of the ECMO. Vascular complications were defined as osteofascial compartment syndrome, amputation, limb ischemia requiring arterial thrombectomy/thrombectomy, vascular rupture, repair of pseudoaneurysm and peripheral cannulation due to excessive bleeding.[6] Any routine arterial repair performed during arterial decannulation was not considered a vascular complication. In-hospital clinical outcomes and survival discharge after 90 days were recorded.

Cannulation

Percutaneous or open arterial and venous catheterisation was used to conduct femoral arteriovenous catheterisation. The ECMO's indication and installation location often determined whether open or percutaneous technology was used. For instance, at our facility, percutaneous cannulation was more often utilised in patients with cardiogenic shock without cardiac arrest whereas open cannulation was more frequently used for extracorporeal cardiopulmonary resuscitation.

The Seldinger technique was used to conduct percutaneous cannulation using an ultrasound-guided puncture of the common femoral artery. The incision and cannulation were performed at the bedside by dissecting the common femoral artery via a 0.5-cm oblique skin incision at the lower margin of the inguinal ligament. The proximal and distal blood arteries were released during the procedure, and the cannula was fastened using purse-string sutures. The distal perfusion tube (typically No. 8–10) was attached to the arterial line of the VA-ECMO, and the other end was connected to the distal perfusion line in the artery. The ipsilateral or contralateral common femoral vein was used for femoral vein cannulation in a similar way. Purse-string sutures and an elastic bandage were used to ensure each cannulation was in place. A bolus of 2000–6000 U of heparin was administered for systemic anticoagulation prior to cannulation. A surgeon at the centre who specialises in cardiopulmonary bypass conducted every cannulation. Additionally, procedures involving incision or percutaneous delivery of the DPC were used. Using this technique, the lower limb shunt was performed by attaching the DPC tube to the lateral opening of the femoral artery cannulation. The ipsilateral superficial femoral artery was immediately intubated using a 5 or 6 F arterial sheath, depending on the patient's body shape.

Clinical Monitoring

Although the use of ECMO improves circulating blood flow, continuing overall hypoperfusion might potentially trigger early DPC implantation. For individuals who did not satisfy these clinical criteria in this trial, DPC implantation was not done during the first cannulation. After the first VA-ECMO cannulation, bilateral peripheral vascular exams were conducted every hour to identify indications of tissue ischemia, particularly in the limbs on the same side as the cannulation. The assessment included the relative temperature and colour of the bilateral limbs (eg the presence of paleness or plaques), sensorimotor examinations of the patient in an awake state (including evidence of peripheral pain in the lower limbs), and popliteal, dorsalis pedis, and posterior tibial palpation, or ultrasound Doppler detection of pulse signals. Any alterations discovered upon abnormal exams were verified by the ECMO team physician, and any action taken was at the discretion of the ECMO physician. Possible interventions included thrombectomy, conversion to axillary artery cannulation or replacement with a bigger DPC to correct distal limb ischemia.

Statistical Analysis

SPSS software version 26 (IBM, Armonk, NY, USA) was used for all statistical analysis. Histograms and Q–Q plots were used to examine whether the data followed a normal distribution. The continuous data were expressed as mean ± standard deviation or median (interquartile range) and compared using the Student's *t*-test or Mann–Whitney *U*-test, as appropriate. The categorical data were expressed as counts (percentage) and compared using the chi-square or Fisher's exact test, as appropriate. A two-tailed *P* value of <0.05 was considered statistically significant. Multivariate logistic regression analysis was used to examine whether DPC implantation was an independent predictor of limb complications.

Results

Baseline Characteristics of the Included Population

In total, 250 patients who underwent VA-ECMO cannulation through a femoral approach were included, including 125 patients with DPC placement at the time of cannulation. Of all 250 patients, 187 (74.8%) received percutaneous cannulation and 69 (27.6%) underwent heart surgery. Patients had an average age of 48 (32–62) and 51 (36–63) years old in the DPC group and non-DPC group, respectively. The DPC group had 58.4% male patients and the non-DPC group had 65.6%. Compared with the non-DPC group, the DPC group had a significantly lower average body mass index (23 [21–26] vs 24 [22–27] kg/m^2, $P = 0.038$) and lower proportion of coronary artery disease (13.6% vs 30.4%, $P = 0.001$) but a higher proportion of heart surgery (37.6% vs 17.6%, $P < 0.001$). There was no significant difference in other features between the two groups. The baseline characteristics of the included population are shown in Table 1.

The proportion of patients with ECMO transfer between hospitals was comparable in the DPC and non-DPC groups (20.0% vs 17.6%, $P = 0.627$). Circulatory failure (68.0%) was the main indication for VA-ECMO, followed by circulatory plus respiratory failure (13.2%) and extracorporeal cardiopulmonary resuscitation (18.8%). Compared with the non-DPC group, patients in the DPC group were more likely to receive ECMO cannulation in the ICU (71.2% vs

Table 1 Comparison of Demographic and Clinical Characteristics

Variables	Overall (N=250)	DPC (N=125)	Non-DPC (N=125)	*P*-value
Age, years	50 (34, 62)	48 (32, 62)	51 (36, 63)	0.170
Male	155 (62.0)	73 (58.4)	82 (65.6)	0.241
BMI, kg/m^2	24 (21, 27)	23 (21, 26)	24 (22, 27)	0.038
Coronary heart disease	55 (22.0)	17 (13.6)	38 (30.4)	0.001
Fulminant myocarditis	36 (14.4)	19 (15.2)	17 (13.6)	0.719
Heart surgery	69 (27.6)	47 (37.6)	22 (17.6)	<0.001
TAVR	2 (0.8)	0 (0.0)	2 (1.6)	0.498
Heart transplant	3 (1.2)	2 (1.6)	1 (0.8)	1.000
Septic shock	23 (9.2)	15 (12.0)	8 (6.4)	0.126
After cesarean section	7 (2.8)	3 (2.4)	4 (3.2)	1.000
Trauma	12 (4.8)	5 (4.0)	7 (5.6)	0.554
Poisoning	6 (2.4)	5 (4.0)	1 (0.8)	0.213
Pulmonary embolism	11 (4.4)	4 (3.2)	7 (5.6)	0.355
COVID-19	1 (0.4)	0 (0.0)	1 (0.8)	1.000
Lung transplant	4 (1.6)	0 (0.0)	4 (3.2)	0.122
Cardiopulmonary transplantation	3 (1.2)	3 (2.4)	0 (0.0)	0.247
Transit ECMO	47 (18.8)	25 (20.0)	22 (17.6)	0.627

Note: Data are expressed as median (interquartile range) or n (%).
Abbreviations: DPC, distal perfusion catheter; BMI, body mass index; TAVR, transcatheter aortic valve replacement; COVID-19, coronavirus disease 2019; ECMO, extracorporeal membrane oxygenation.

Table 2 ECMO Indications and Technical Characteristics

Variables	Overall (N=250)	DPC (N=125)	Non-DPC (N=125)	*P*-value
ECMO indication				0.345
Circulatory failure	170 (68.0)	89 (71.2)	81 (64.8)	
Circulatory + respiratory failure	33 (13.2)	17 (13.6)	16 (12.8)	
ECPR	47 (18.8)	19 (15.2)	28 (22.4)	
ECMO establishment location				0.004
Operating room	47 (18.8)	29 (23.2)	18 (14.4)	
ICU	175 (70.0)	89 (71.2)	86 (68.8)	
Emergency room	5 (2.0)	3 (2.4)	2 (1.6)	
Catheter room	22 (8.8)	4 (3.2)	18 (14.4)	
Others	1 (0.4)	0 (0.0)	0.8% (1.0)	
ECMO catheterization method				<0.001
Precatheterization	11 (4.4)	6 (4.8)	5 (4.0)	
Percutaneous puncture	187 (74.8)	79 (63.2)	108 (86.4)	
Incision	23 (9.2)	17 (13.6)	6 (4.8)	
Incision + puncture	29 (11.6)	23 (18.4)	6 (4.8)	
Conscious ECMO	26 (10.4)	4 (3.2)	22 (17.6)	<0.001

Note: Data were expressed as n (%).
Abbreviations: DPC, distal perfusion catheter; ECMO, extracorporeal membrane oxygenation; ECPR, extracorporeal cardiopulmonary resuscitation; ICU, intensive care unit.

68.8%) and operating room (23.2% vs 14.4%) with a significant difference (P = 0.004). In addition, there was a significant difference between the two groups in terms of catheterisation method and conscious ECMO (P < 0.001 for both, Table 2).

Limb Complications

The limb complications between the two groups are detailed in Table 3. Overall, the DPC group was less likely to have limb complications than the non-DPC group (6.4% vs 17.6%, P = 0.006), mainly resulting from distal ischemia (4.0% vs

Table 3 Limb Complications During ECMO

Variables	Overall (N=250)	DPC (N=125)	Non-DPC (N=125)	*P*-value
Limb complications	30 (12.0)	8 (6.4)	22 (17.6)	0.006
Distal ischemia	24 (9.6)	5 (4.0)	19 (15.2)	0.003
Necrosis	14 (5.6)	2 (1.6)	12 (9.6)	0.006
Osteofascial compartment syndrome	6 (2.4)	5 (4.0)	1 (0.8)	0.213
Amputation	1 (0.4)	0 (0.0)	1 (0.8)	1.000
Thrombus	5 (2.0)	3 (2.4)	2 (1.6)	1.000
Vessel rupture	2 (0.8)	1 (0.8)	1 (0.8)	1.000
Pseudoaneurysm	2 (0.8)	2 (1.6)	0 (0.0)	0.498

Note: Data were expressed as n (%).
Abbreviations: ECMO, extracorporeal membrane oxygenation; DPC, distal perfusion catheter.

Table 4 Multivariate Analysis of Limb Complications

Variables	OR	95% CI	*P*-value
DPC	0.265	0.107 to 0.657	0.004
BMI	0.957	0.856 to 1.070	0.443
Coronary artery disease	0.599	0.195 to 1.845	0.372
Heart surgery	1.517	0.647 to 3.560	0.338
ECMO establishment location	0.859	0.450 to 1.640	0.645

Abbreviations: BMI, body mass index; CI, confidence interval; DPC, distal perfusion catheter; ECMO, extracorporeal membrane oxygenation; OR, odds ratio.

Table 5 Hospitalization and Clinical Outcomes

Variables	Overall (N=250)	DPC (N=125)	Non-DPC (N=125)	*P*-value
ECMO running time, hours	81.8 (71.7, 92)	92.3 (75.7, 109)	71.2 (59.4, 82.8)	0.054
ICU time, days	11 (9.5, 12.5)	10.5 (8.3, 12.6)	11.5 (9.5, 13.6)	0.201
Hospitalization time, days	22.4 (19.4, 25.5)	21.2 (17, 25.6)	23.6 (19.3, 27.9)	0.391

Note: Data are expressed as median (interquartile range) or n (%).
Abbreviations: ECMO, extracorporeal membrane oxygenation; DPC, distal perfusion catheter; ICU, intensive care unit.

15.2%, $P = 0.003$) and necrosis (1.6% vs 9.6%, $P = 0.006$). There was an upward tendency of osteofascial compartment syndrome in the DPC group, but the statistical value did not reach the threshold (4.0% vs 0.8%, $P = 0.213$). Multivariate analysis showed that DPC implantation was negatively associated with limb complications (odds ratio: 0.265, 95% confidence interval: 0.107–0.657, $P = 0.004$) after adjustment for confounding factors (Table 4).

Hospitalisation

The median duration of the ECMO operation was 92.3 (75.7–109) h in the DPC group and 71.2 (59.4–82.8) h in the non-DPC group, with a difference close to the statistical threshold ($P = 0.054$). There were no statistically significant differences in ICU time or length of hospital stay between the two groups (Table 5).

Clinical Outcomes

For the ECMO-assisted outcomes, death during the assisted period, death after weaning, successful weaning (survival at 24 h after weaning), and survival discharge in the overall population were 17.6%, 32.4%, 12.4%, and 37.6%, respectively.

Discussion

The present study explored the effect of DPC placement in preventing the occurrence of vascular complications in patients undergoing femoral VA-ECMO cannulation. The main findings can be summarised as follows: 1) vascular complications were commonly seen in patients receiving VA-ECMO cannulation, mainly limb ischemia and necrosis; 2) DPC placement was associated with a lower incidence of limb ischemia and overall vascular complications; and 3) the use of DPCs did not change the ICU or hospitalisation time and led to a downward tendency of ECMO duration. To the best of the authors' knowledge, this is the first study of the Chinese population to suggest that DPC placement might be related to a decrease of vascular limitations in the ipsilateral limbs, providing potential clinical benefit for patients undergoing VA-ECMO cannulation through a femoral approach.

Although the use of a DPC is a widespread strategy for the prevention and treatment of limb ischemia, the number of patients with limb ischemia and its aftereffects is rising as more adult patients are obtaining femoral VA-ECMO cannulation. The incidence of vascular problems in femoral VA-ECMO has been estimated to be between 10% and 70%.[7] According to Aziz et al, out of 101 patients, 18 (17.8%) suffered vascular problems, and almost all of them needed surgical intervention.[3] Recently, it was reported that 35 out of 100 patients with femoral artery cannulation had vascular complications, 7 of whom required fasciotomy or amputation due to compartment syndrome.[7,8] Only Foley et al[7] claimed that DPC did not increase the incidence of problems, even though many of these investigations remarked on the incidence of complications and the use of DPC. The majority of patients in this research suffered limb problems but did not get DPC intervention. There was no effective DPC intervention (the DPC placement failed) for one of two reasons: the administration of high dosages of vasoconstrictor medications or the family halting therapy because the patient's condition was too bad for a transfer.

In the early phases of ECMO, it has been clinically shown that the initial ischemia status of the lower extremities on the side of femoral artery cannulation naturally improves without DPC intervention.[9–11] Due to their condition not rapidly improving following an ECMO procedure, some patients can progressively acquire severe limb ischemia.[12–14] Therefore, it is crucial to assess whether DPC implantation is successful in treating or preventing limb ischemia in addition to its efficacy.[12,15–18] It seems that the DPC cannulation approach must be changed, and the DPC time must be adjusted. Therefore, the "risk" of distal limb ischemia in patients should be based on more than just the ECMO catheterisation technique, setup location or indication category. It should also be based on meticulous observation and monitoring of limb ischemia. It would also seem that the security of limb blood flow cannot be totally guaranteed by the effective pre-setting of a DPC.

Recent research has focused on the insertion of corrective DPCs in individuals who suffer from limb ischemia. Yeo et al[19] documented this rescue procedure; they noted that in a small subset of patients who had corrective DPC insertion, the frequency of whole limb ischemia reduced, but the rate of bleeding at the cannulation site rose. They also noted that 44 of 151 patients getting preventive DPC did not have any instances of limb ischemia, which was consistent with earlier data. In another study, 68 patients who had received DPC at the time of their first cannulation were examined. The major cause of the relatively high (42%) frequency of vascular problems was haemorrhage. Overall vascular problems (vascular rupture and pseudoaneurysm) were rare in this research and only occurred in the DPC group. The fundamental reason for this was that patients who have a percutaneous puncture are more likely to experience vascular problems than are people who undergo incision and catheterisation. These studies make it evident that further research is necessary before an agreement is reached on the value of early DPC implantation. More large sample data studies are required to develop better solutions since there are presently no standards for the use of preventative distal limb perfusion techniques.

Another strategy to avoid limb problems is early conversion to central cannulation. The use of intra-arterial pressure monitoring to determine intervention thresholds and the use of posterior tibial artery cannulation for retrograde distal limb perfusion have both been investigated in several studies.[20] Except for one study that suggested peripheral vascular disease and challenging decannulation procedures are risk factors for delayed problems, the occurrence and treatment of late vascular issues (including artery stenosis) have not yet been documented.[21] This study's findings are comparable with those of the aforementioned research in the lack of random or high-quality multi-institutional data (ie preventative

DPC placement is linked to a decreased frequency of vascular problems from femoral artery cannulation and limb ischemia).[22]

This study has several limitations. First, it is a retrospective, single-centre and case-control study rather than a randomised controlled study. Thus, the results may be vulnerable to potential selection bias. Additionally, this study does not evaluate the potential effect of DPC placement on mortality because of various factors, including early withdrawal of ECMO-assisted treatment due to expenses. Future large, multicentre randomised studies are warranted to provide insights into the efficacy and safety of DPC implantation. Second, there is currently no accurate predictive method to guide the clinical decision-making process of prophylaxis DPC placement. The patient's critical condition and the family's willingness to continue treatment will introduce certain interference factors to the placement of remedial DPC, as many patients require a surgical incision for DPC due to the failure of percutaneous DPC. Therefore, until a better procedure is developed, it is vital to depend on qualitative clinical judgment. The factors of hemodynamic fluctuations, information about changes in the use and measurement of vasoactive drugs, and information about cannulation technology, such as the size of the arterial cannulation and the distinctions between various types of arteriovenous cannulation, were not collected in the current study. This data will help future studies and provide insight into situations of inadequate limb perfusion caused by other factors.

Conclusion

In conclusion, the use of a DPC during femoral VA-ECMO cannulation may be associated with a lower incidence of ipsilateral limb vascular complications and limb ischemia. Additional multicentre studies are warranted to determine the impact of DPC placement on the prognosis of patients undergoing VA-ECMO.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of Chinese PLA General Hospital. The requirement of informed consent was waived due to the retrospective design. No identifiable participant information (such as patients' images, faces, or names) was disclosed in the study.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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