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Percutaneous angio-guided versus surgical veno-arterial ECLS implantation in patients with cardiogenic shock or cardiac arrest

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1 Abstract:

Background: Veno-arterial Extracorporeal Life Support (V-A ECLS) has gained increasing
place into the management of patients with refractory cardiogenic shock or cardiac arrest.
Both surgical and percutaneous approach can be used for cannulation, but percutaneous
approach has been associated with fewer complications. Angio-guided percutaneous
cannulation and decannulation may further decrease the rate of complication. We aimed to
compare outcome and complication rates in patients supported with V-A ECLS through
percutaneous angio-guided versus surgical approach.

9 Methods: We included all patients with emergent peripheral femoro-femoral V-A ECLS
10 implantation for refractory cardiogenic shock or cardiac arrest in our center from March 2018
11 to March 2021. Survival and major complications (major bleeding, limb ischemia and groin
12 infection) rates were compared between the percutaneous angio-guided and the surgical
13 groups.

14 Results: One hundred twenty patients received V-A ECLS, 59 through surgical approach and 15 61 through angio-guided percutaneous approach. Patients' baseline characteristics and severity scores were equally balanced between the 2 groups. Thirty-day mortality was not 16 significantly different between the 2 approaches. However, angio-guided percutaneous 17 18 cannulation was associated with fewer major vascular complications (42% vs. 11%, 19 p>0.0001) and a higher rate of V-A ECLS decannulation. In multivariate analysis, 20 percutaneous angio-guided implantation of V-A ECLS was independently associated with a 21 lower probability of major complications.

- 1 Conclusion: Compared to surgical approach, angio-guided percutaneous V-A ECLS
- 2 implantation is associated with fewer major vascular complications. Larger studies are needed
- 3 to confirm those results and address their impact on mortality.

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1 Introduction:

Veno-arterial Extracorporeal Life Support (V-A ECLS) has been described as an attractive 2 strategy for hemodynamic support in cardiogenic shock and refractory cardiac arrest $^{1-8}$. 3 Peripheral femoral cannulation is the primary line method for V-A ECLS cannulation and 4 5 surgical approach has been widely used for a long time. However, this invasive procedure 6 may be associated with severe vascular complications such as hemorrhage, limb ischemia and 7 infection^{9,10}. With the development of echographic guidance for vascular access and the 8 improvement of the techniques and devices, percutaneous approach for femoro-femoral V-A 9 ECLS is increasingly used and may be associated with a lower risk of vascular complications 11. 10

However, to date, even when percutaneous approach is used, V-A ECLS is usually implanted
in the operative room or at bedside, and very few studies focused on percutaneous approach
have used fluoroscopic guidance. Nevertheless, this latter helps to monitor wires and cannulas
progression in the vessels and might therefore increase the success rate and the safety of
implantation. Moreover, we recently reported that percutaneous removal using preclosing was
feasible and might further increase the safety of the procedure¹².

We therefore aimed to compare the outcomes of patients who received V-A ECLS usingpercutaneous angio-guided or surgical approach.

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1 <u>Methods:</u>

2 Study design and population

All consecutive adult patients admitted at Henri-Mondor University Hospital (Assistance
Publique des Hôpitaux de Paris, Créteil, France) and supported with peripheral V-A ECLS for
refractory cardiac arrest or refractory cardiogenic shock from January 2018 to March 2021
were included in a monocentric prospective observational registry. We excluded patients
supported by V-A ECLS following cardiac surgery.

8 Surgical approach was the only cannulation method performed before mid-2018. From mid-

9 2018, percutaneous approach was adopted and performed by the interventional cardiologists,

10 and both percutaneous and surgical cannulations were performed. The choice between

11 percutaneous and surgical approach depended on several factors including availability of the

12 operators and operative room, location of the patient and the choice of the intensivist in

13 charge of the patients.

All patients' data and outcome were analyzed. Study protocol was approved by Henri Mondor
University Hospital's ethics committee (registration code n°1778041).

16 Surgical cannulation procedure

All surgical V-A ECLS implantation were performed in the operative room or at bedside incase of extreme emergency by trained cardiac surgeons.

For the surgical approach, femoral vessels were exposed with a limited transversal incision in
the groin. Purse string sutures were made before cannulation in the femoral artery and vein.
Access to the common femoral artery, to the femoral vein and to the superficial femoral artery
(anterograde access for distal perfusion line insertion) were obtained using the Seldinger's

technique¹³. Then, after preparation with adequate dilatators, femoral vessels were cannulated.
 The venous cannula was advanced under echocardiographic guidance to confirm its
 progression and positioning. After cannulation, the skin was surgically sutured.

4 Decannulation procedures were performed in the operative room by cardiac surgeons. At the 5 time of decannulation, the operative field was reopened. Then, the arterial cannula was 6 removed and the purse string sutures were tied and, after clamping the femoral artery, the 7 arteriotomy was sutured. The distal reperfusion cannula was then retrieved from the distal 8 superficial femoral artery and the purse string suture was tied.

9 Angio-guided percutaneous cannulation procedure

For the percutaneous approach, V-A ECLS was implanted in the cardiac catheterization 10 11 laboratory under fluoroscopic guidance by senior interventional cardiologists trained to echoguided vascular puncture, preclosing and large bore vascular access as previously described¹². 12 The common femoral artery and femoral vein were punctured under ultrasound guidance 13 14 using the Seldinger's technique. The position of the wires was verified using angiography. Preclosing using two Perclose ProGlides[®] (Abbott[®], Chicago, Illinois, USA) was performed 15 16 as often as possible before cannulation in both the femoral artery and the femoral vein, as previously described ¹⁴. Then, after preparation with adequate dilatators, femoral vessels were 17 cannulated over a stiff wire (Amplatz Super Stiff[®], Boston Scientific[®], Marlborough, 18 Massachusetts, USA) under fluoroscopic guidance. 19

V-A ECLS decannulation was performed percutaneously in the catheterization room except
for exceptional cases (no preclosing performed or removal by the cardiac surgeon at the time
of LVAD implantation or heart transplant). All percutaneous decannulation were performed
using the "the crossover balloon occlusion technique" as previously described¹⁵. Briefly, the
contralateral femoral artery was punctured to obtain a crossover access. A balloon was

advanced in the external iliac artery and inflated, to allow a non-traumatic occlusion of the
 vessel. The arterial cannula was removed and the knots were tied. The balloon was then
 deflated and an angiography of the femoral artery was performed to ensure the proper closing
 of the artery and the absence of complications.

For both approaches, a 23 cm length 17–19 Fr arterial cannula (Maquet[®] Rastatt, Germany) 5 6 (17 or 19 Fr depending on the patient's morphology) and a 55 cm 23 Fr venous cannula (Maquet[®], Rastatt, Germany) were used. The venous cannula was advanced to the right 7 atrium. An additional anterograde perfusion line (6 Fr sheath, Terumo[®], Shibuya, Tokyo, 8 9 Japan) was systematically inserted into the superficial femoral artery "y" connected to the arterial cannula to reduce the risk of leg ischemia¹⁶. This anterograde perfusion line was 10 11 inserted visually for the surgical approach and under ultrasound guidance (usually before the insertion of the arterial cannula) for percutaneous approach. 12

13 Outcomes

Outcomes included access-related complications (defined as major bleeding, lower limb ischemia and groin infection), 30-day survival and 30-day decannulation rate. Major bleeding was defined as peri-procedural bleeding at the sites of cannulation or the sites of puncture with a drop in hemoglobin level of at least 3.0 g/dL and/or requiring transfusion (3 units of packed red blood cells) ¹⁷. Limb ischemia was suspected clinically, and confirmed when it required a percutaneous or surgical intervention, or a change of cannulation site.

Groin infections were clinically suspected in the presence of local (inflammation, purulent
drainage) and general signs of sepsis with positive bacteriological sample.

Access related complications occurring at the time of cannulation, during V-A ECLS supportand after decannulation were recorded.

1 Statistical analyses

Continuous variables were expressed as median and interquartile range, and categorical variables as number and percentages, as appropriate. Continuous variables were compared using student t-test if normally distributed and Mann Whitney test if otherwise. Data's distribution was assessed with the Shapiro-Wilk test. Welch correction was used in case of non-homogeneous variance. Categorical variables were compared using chi-square test when appropriate and Fisher's exact test otherwise.

Log-Rank test was used for univariate survival analysis. A Cox proportional hazard regression 8 9 model was performed to identify independent multivariable factors predictive of survival. Variables included in the model were based on their clinical relevance (regardless of their p-10 11 values), with others variables when their p-values was inferior or equal to 0.15 on univariate 12 analysis. The variables included were age, body mass index, chronic heart failure, Sequential 13 Organ Failure Assessment (SOFA) score at cannulation, LVEF, preclosing, cardiac arrest and refractory cardiac arrest. The proportional hazards assumption was tested by Schoenfeld 14 15 residuals and inspection of hazard ratio (HR) plots.

Finally, risk factors for total complications including major bleeding, vascular complications, groin infection and limb ischemia were assessed within the whole cohort using univariate and multivariate logistic regression model. Variables were included in the multivariate logistic model when their p-values was inferior or equal to 0.15 on univariate analysis. Odds-ratios and their 95% confidence interval were calculated.

21 Differences were considered significant if two-sided p < 0.5.

Statistical analysis was performed using R software, version 3.6.0 (R Project for StatisticalComputing).

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1 <u>Results:</u>

2 **Population**

3 Between January 2018 and March 2021, 120 patients were supported with V-A ECLS for 4 refractory cardiogenic shock or cardiac arrest. Among those 120 patients, 59 underwent 5 surgical cannulation and 61 underwent angio-guided percutaneous cannulation (Flowchart in 6 Figure 1). The use of percutaneous cannulation increased over time while the use of surgical 7 cannulation decreased (P=0.001, Figure 2). The baseline characteristics of the whole 8 population and of the surgical and percutaneous groups are presented in Table 1. The median 9 age of the population was 57 [47-66] years old and 72% of the patients were male (Table 1). 10 Patients in the percutaneous group were older (60 [51-67], vs. 53 [41-64], P=0.007) with lower LVEF (15 [11-20] vs 26 [15-45], P<0.0001) and a higher rate of diabetes mellitus (34%) 11 12 vs. 15%, P=0.015). They also presented more frequently with STEMI, while patients in the 13 surgical groups had more frequently a previous history of chronic heart failure. There was a 14 higher prevalence of long-term anticoagulation in the surgical group. No significant 15 difference in the rate of cardiac arrest and refractory cardiac arrest was observed, and the SOFA scores at admission and before cannulation were similar. 16

1 V-A ECLS duration and outcome

2 Both arterial and venous cannula were successfully inserted in all patients except for one 3 patient in the surgical group. Distal perfusion line was inserted in 96% of patients in the surgical group and 98% in the percutaneous group. Preclosing was performed in 75% of the 4 5 patients with percutaneous approach with an increase over time. Indeed, in the early months, 6 patients with refractory cardiac arrest did not undergo pre-closing, before becoming 7 systematic. Consequently, all of the last 39 patients implanted underwent pre-closing. 8 Overall, 45 (37%) of the 120 patients were weaned from V-A ECLS. This proportion was 9 higher in the angio-guided percutaneous group as compared to the surgical group (46% vs. 10 29%, p=0.05). In the percutaneous group, V-A ECLS decannulation was performed 11 percutaneously in the catheterization room in 22/28 patients. The reason for surgical 12 decannulation after percutaneous cannulation was absence of pre-closing in 4 and 13 decannulation during cardiac surgery (LVAD or heart transplant) in 2. Although decannulation rate was higher in the percutaneous group, 30-day survival was not 14 15 different between the 2 groups, even after adjustment for confounding variables, with 30-day 16 survival rates of 26% and 17% in the percutaneous and surgical groups respectively (Figure 17 3).

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19 V-A ECLS related complications

In the whole population, 36 major complications occurred in 32 patients (Table 2) with no
significant decrease over time (P=0.2). Three patients experienced multiples major
complications, all in the surgical group. The most frequent major complication of V-A ECLS
was major bleeding (n=22), followed by lower limb ischemia (n=7) and groin infection (n=7).
No amputation was required. Overall, the rate of major vascular complications (i.e. major
bleeding, limb ischemia and groin infection) was higher in the surgical group compared to the

angio-guided percutaneous group (29 complications in 25 patients vs. 7 complications in 7 1 patients, P<0.0001 for both the patient level and complication level analysis). Individual 2 3 analysis of the different sub-types of complications revealed a statistically significant 4.5 fold increase in the rate of major bleeding (31% vs. 7%, P=0.0007), but no significant increase in 4 5 the rate of groin infection (10% vs. 2%, P=0.059) and limb ischemia. The only infection that 6 occurred in the percutaneous group occurred after surgical removal of the cannulas following 7 heart transplant. 8 Last, we investigated the variables associated with the occurrence of vascular complications 9 using multivariable logistic regression. Only two variables were associated with vascular complications. Percutaneous cannulation was strongly associated with a lower risk of vascular 10

12 index (OR 1.11 (1.01-1.23) for every 1-unit increase in BMI; p=0.04) was associated with a

complications of V-A ECLS (OR 0.23 (0.08-0.70)); p=0.009) while increased body mass

- 13 higher risk (Table 3).
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2 **Discussion:**

In this study, we compared angio-guided percutaneous approach to surgical approach for V-A ECLS implantation in patients with cardiac arrest or refractory cardiogenic shock. No difference in 30-day mortality was observed between angio-guided percutaneous and surgical approaches for V-A ECLS cannulation. However, angio-guided percutaneous approach was associated with a significant reduction in vascular complications including major bleeding, limb ischemia and groin infection.

9 Surgical approach for cannulation and decannulation of V-A ECLS has been used for
10 long. It provides a fast access to the femoral vessels and allows cannulas insertion under
11 visual guidance¹⁸. However, it is associated with a non-negligible number of vascular
12 complications including major local bleeding (2-15%) limb ischemia (8-30%) and surgical
13 site infection (25-40%) ^{11,19-22}.

With the development of structural heart disease interventions and the improvement in 14 the techniques and devices, percutaneous approach for V-A ECLS implantation has been 15 described, with attractive results ^{11,23}. However, to date, in most of the studies that focused on 16 17 percutaneous approach, the cannulation of the femoral vessel was performed at bedside or in 18 the operative room, without fluoroscopic guidance. Moreover, retrieval of the cannula was 19 also performed bedside without systematic assessment of the results. In our study, all 20 percutaneous implantation were performed under fluoroscopic guidance in the catheterization 21 laboratory with punctures under echographic guidance. This approach was associated with a 22 significant reduction of vascular complication especially of major bleeding. Indeed, 23 echographic guidance increases the safety of the vascular access as previously described²⁴ 24 and, fluoroscopic guidance enables to monitor closely the progression of the wires and of the cannula. Regarding retrieval, we set up a systematic approach for cannula explantation. 25 26 During implantation, preclosing using two ProGlide (Abbott®, Chicago, Illinois, USA)

devices was performed as often as possible (75% of the patients, 39 of the last 39 patients). 1 Then, decannulation was performed under fluoroscopic guidance using a "TAVR-like 2 strategy" with a final angiography as previously described ^{12,15}. This strategy further increased 3 the safety of the percutaneous approach and decreased vascular complication. Indeed, very 4 few vascular events were observed in the percutaneous group (including events after 5 6 decannulation), unlike what had been observed in previous studies using manual or and/or device assisted compression for hemostasis^{11,25,26}. In those studies, the rate of major bleeding 7 8 was superior when percutaneous approach was used. It is likely that the discrepancy between these studies and our results is due to the use of preclosing and angiographic guidance for 9 10 percutaneous removal of the cannula in our study. Indeed, the closure using the ProGlide 11 devices associated to the performance of a final angiographic control enables, not only a safe and non-invasive closure of the artery, but also a reliable assessment of the proper closure. 12 13 Thus, we may assume that this strategy is superior to strategies using either manual 14 compression or post-closing although randomized studies are yet to be performed. It must 15 however be noted that, in our study, the rate of major bleeding observed in the surgical group 16 was high. Nevertheless, unlike in previous published studies, all implantations were performed in extreme emergency in patients with refractory cardiac arrest or cardiogenic 17 18 shock and no patients underwent semi-urgent or post-operative V-A ECLS. The critical 19 condition of our population is further demonstrated by the high 30-day mortality, and may 20 explain, at least partially, the rate of major bleeding observed in the surgical group. On the other hand, these data reinforce the interest of angio-guided percutaneous V-A ECLS in these 21 22 patients. Indeed, despite the very high-risk profile of this population, the number of major 23 bleeding and other vascular complication observed in the percutaneous group was 24 dramatically low. Additionally, the rates of limb ischemia after cannulation were also rather 25 low as compared to previous studies including both surgical and percutaneous approaches

^{11,27–29}. This is probably related to the systematic insertion of a distal perfusion line, which has 1 been showed to decrease the risk of limb ischemia³⁰. Last, the number of infections was also 2 3 notably low, especially in the percutaneous group in which only one infection was observed, and it must be highlighted that this latter occurred after surgical decannulation of the V-A 4 5 ECLS. Thus, none of the patients with percutaneous removal of the V-A ECLS had a groin infection. This finding is not surprising since several studies had found a decrease in the 6 number of cannulation site infections with the use of the percutaneous approach, this latter 7 8 being far less invasive than open surgery 31,32 .

Last, this study confirms the safety and feasibility of angio-guided percutaneous V-A
ECLS implantation, with a very high rate of cannulation success and a low rate of
complication. These results may promote the development of V-A ECLS as an emergency
support in centers without onsite cardiac surgery, providing that dedicated teams (medical and
paramedical) are trained to the priming of the ECMO machine and to the management of
patients with ECLS, and that dedicated network are set up in case heart surgery is considered.

16 Limitations :

This study has several limitations. First, this is a monocentric observational study including a 17 small number of patients with all the potential bias inherent to such studies. Moreover, the 18 19 exact benefit of angiography as not been examined since no direct comparison with 20 ultrasound alone guided cannulation was performed. Therefore, further studies will be needed 21 to confirm our results. Secondly, complications were recorded up to 30 days, and some very 22 late events may have been missed. Another limitation is that V-A ECLS cannulation was performed by two different teams. Indeed, while in most of the previous studies both surgical 23 24 and percutaneous cannulation were usually performed by the same team (the surgeons), in our study, surgical V-A ECLS cannulation was performed by cardiac surgeons and angio-guided 25

1 percutaneous V-A ECLS cannulation was performed by the interventional cardiologists.

2 However, all operators were familiar with the technique and trained to V-A ECLS

3 cannulation.

4 Finally, the studied population was composed of instable patients with a high mortality rate

5 (even though consistent with other studies) and these results may not be applicable to semi-

6 urgent or post-operative patients with mild hemodynamic instability. Moreover, percutaneous

7 cannulation will not completely replace surgical cut down technique in special groups of

8 patients such as patients with anatomical vessels abnormalities.

2 <u>Conclusion :</u>

3 In this observational study, angio-guided percutaneous V-A ECLS is associated with fewer

4 major vascular complications compared to surgical approach. Larger studies are needed to

5 confirm those results and address their impact on mortality.

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7 <u>Disclosures:</u> none

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1 Figure 1: Flowchart of the study

Figure 2: Evolution of the use of percutaneous angio-guided and surgical approach for V-A
ECLS cannulation from 2018 to 2021.

- 4 **Figure 3:** Panel A Unadjusted Kaplan Meier survival curves for the percutaneous and
- 5 surgical approach. Panel B Adjusted Kaplan Meier survival curves for the percutaneous and
- 6 surgical approach; survival was adjusted on age, body mass index, chronic heart failure,
- 7 SOFA score at cannulation, LVEF, preclosing, cardiac arrest and refractory cardiac arrest
- 8

- **Table 1:** Baseline characteristics of the whole population and of the surgical and
- 2 percutaneous groups. V-A ECLS: Veno-arterial extracorporeal membrane oxygenation;

3 LVEF: Left ventricle ejection fraction; SOFA: Sequential Organ Failure Assessment; STEMI:

4 ST-elevation myocardial infarction; PCI: Percutaneous coronary intervention.

	All (n=120)	Surgical approach (n = 59)	Percutaneous approach (n= 61)	P-value		
Age (years)	57 (47 - 66)	53 (41 - 64)	60 (51 - 67)	0.007		
BMI (kg/m²)	26 (23 - 29)	27 (23 - 31)	25 (23 - 28)	0.43		
Male	86 (72 %)	39 (66 %)	47 (77 %)	0.18		
Underlying medical conditions						
Diabetes mellitus	30 (25 %)	9 (15 %)	21 (34%)	0.015		
Tobbacco use	30 (25 %)	19 (32%)	11 (18%)	0.073		
Arterial hypertension	53 (44 %)	22 (37%)	31 (51%)	0.14		
Peripheral artery disease	7 (6 %)	4 (7 %)	3 (5 %)	0.71		
Long term anticoagulation before V-A ECLS	16 (13 %)	12 (20%)	4 (7%)	0.026		
Antiplatelet therapy before V- A ECLS	25 (21 %)	14 (24%)	11 (18%)	0.44		
<u>Admission</u>						
LVEF	20 (11 - 35)	26 (15-45)	15 (10-20)	<0.0001		
Cardiogenic shock	108 (90 %)	51 (86%)	57(93%)	0.20		
Cardiac arrest :	81 (68 %)	43 (73%)	38 (62%)	0.22		
- Ressuscitated cardiac arrest	43 (36 %)	22 (37 %)	21 (34 %)	0.85		
- Refractory cardiac arrest	38 (32 %)	21 (36 %)	17 (28 %)	0.43		
SOFA score at admission	10 (8 - 12)	10 (6-12)	10 (8-12)	0.97		
SOFA score at cannulation	11 (9 - 13)	12 (10-13)	11(9-13)	0.10		
Etiology :						
- STEMI	51 (42 %)	17 (29%)	34 (56%)	0.003		
- Chronic heart failure	24 (20 %)	17 (29 %)	7 (11 %)	0.018		
- Other	45 (38%)	25 (42%)	20 (33%)	0.34		
PCI	47 (39 %)	18 (31 %)	29 (48 %)	0.056		
Procedural characteristics						
Distal perfusion line	104 (97 %)	56 (96%)	60 (98%)	0.36		
Pre-closing	46 (38 %)	0(0%)	46 (75%)	<0.0001		

- **1 Table 2:** Thirty-day outcome of patients with surgical and percutaneous approach. V-A
- 2 ECLS: Veno-arterial extracorporeal membrane oxygenation; ICU: Intensive Care Unit. One
- 3 patient had three simultaneous complications, and two patients had two simultaneous
- 4 complications

	Surgical approach (n = 59)	Percutaneous approach (n= 61)	P-value
30-day survival n (%)	10 (17%)	16 (26 %)	0.22
Weaning from V-A ECLS n (%)	17 (29 %)	28 (46 %)	0.05
V-A ECLS duration (days)	2 (1 – 6)	4 (1 – 7)	0.30
ICU stay (days)	6 (2 - 14)	10 (1 - 22)	0.34
Major complications			
Patients with ≥ 1 complication n (%)	25 (42 %)	7 (11 %)	0.0001
Patients with multiple complications n (%)	3 (5%)*	0 (0%)	0.11
Major bleeding n (%)	18 (31 %)	4 (7 %)	0.0007
Lower limb ischemia n (%)	5 (8 %)	2 (3 %)	0.27
Groin infection n (%)	6 (10 %)	1 (2 %)	0.059

- **1 Table 3:** Univariate and multivariate analysis of factors associated with vascular
- 2 complications following implantation of V-A ECLS. V-A ECLS: Veno-arterial extracorporeal
- 3 membrane oxygenation; BMI: Body mass index.

Variables	Univariate		Multivariate	
	OR (95% CI)	P-value	OR (95% CI)	P-value
Age	1.01 (0.98-1.04)	0.58		
BMI (kg/m ²)	1.12 (1.01-1.23)	0.02	1.11 (1.01-1.23)	0.04
Diabetes Mellitus	1.25 (0.50-3.11)	0.63		
Long term anticoagulation	3.33 (1.13 – 9.82)	0.03	3.41 (0.90-13.00)	0.07
before V-A ECLS				
Chronic heart failure	1.90 (0.74-4.92)	0.18		
Peripheral artery disease	1.11 (0.20-6.01)	0.91		
Percutaneous approach	0.18 (0.07-0.45)	0.0003	0.23 (0.08-0.70)	0.009
Cardiac arrest	1.08 (0.45-2.58	0.86		
Days of V-A ECLS	1.02 (0.96-1.09)	0.48		

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Time (Days)