Vascular Complications in Patients Undergoing Femoral Cannulation for Extracorporeal Membrane Oxygenation Support

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Background. **Extracorporeal membrane oxygenation (ECMO) is a well-established treatment for severe cardiopulmonary failure. Patients undergoing ECMO support through femoral vessels are prone to vascular complications. The aim of this study was to evaluate such complications to outline basic technical principles for their prevention.**

Methods. **From January 2005 to December 2009, 174 patients underwent ECMO support through cannulation of the femoral vessels. The primary outcome was any vascular complication. Secondary outcomes were 30-day mortality and 1-year survival. A logistic regression analysis including ECMO duration, peripheral arterial disease, ECMO access (percutaneous versus open), and diabetes mellitus identified predictors for vascular complications.**

Results. **The venoarterial mode was used in 143 patients (82%), and venovenous in 31 patients (18%). Of the 17 (10%) observed vascular complications, 15 (88%) occurred in patients with venoarterial access, whereas 2 (12%) occurred after venovenous access ($p = 0.50$) Two patients who had extremity ischemia required limb amputation. Thirty-day mortality and 1-year survival rates were 63% and 26%, respectively. Peripheral arterial disease was the only strong predictor of vascular complications (odds ratio, 6.95; 95% confidence interval, 1.89 to 25.59; $p = 0.003$). Vascular complications were not associated with early or late mortality.**

Conclusions. **The incidence of vascular complications in venovenous cannulation was low, whereas in arterial cannulation, it is still considerable. Peripheral arterial disease remains a risk factor, and early involvement of vascular surgeons for open vascular exposure or alternative vascular access sites can be recommended. Vascular complications after ECMO support are not associated with higher mortality rates.**

(Ann Thorac Surg 2011;92:626–31)

Extracorporeal membrane oxygenation (ECMO) is a well-established treatment for temporary circulatory support after cardiopulmonary failure [1–3]. Approximately 1% of patients undergoing cardiac surgery requires postoperative ECMO support for refractory cardiopulmonary dysfunction [1–6]. Recently, the interest in ECMO devices was renewed owing to their decisive role in patients with respiratory failure caused by pandemic H1N1 2009 influenza virus [7–9]. Olsson and colleagues [10] demonstrated the feasibility of using ECMO support in nonintubated patients with cardiopulmonary failure as a bridging strategy to lung transplantation. However, ECMO support is still associated with several organ complications such as infections, renal failure, sepsis, bleeding tendency, and neurologic events [3, 10–13].

An important topic remains the rate of vascular complications (VCs) related to vessels cannulation. Ischemic complications using different approaches for femoral cannulation varied between 10% and 70% [14–17]. Most studies only use one type of femoral cannulation (either percutaneously or by vessel exposure). Furthermore, the use of an antegrade catheter to augment extremity perfusion is not always part of the standard therapy concept [15–17]. Thus, the mechanism of VCs and the relevance of adjuvant techniques for their prevention remain controversial.

Here, we report a large series of patients undergoing ECMO support in a single center specialized in vascular surgery and thoracic organ support. The aim of this study was to specifically evaluate the early and intermediate-term VCs and the associated risk factors. In addition, we provide recommendations regarding the safe placement of ECMO devices and the management of VCs.

Patients and Methods

A retrospective review of our prospectively obtained database for ECMO devices implanted between January 2005 and December 2009 indicated 242 patients requiring

Accepted for publication Feb 8, 2011.

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Published by Elsevier Inc

0003-4975/$36.00
doi:10.1016/j.athoracsur.2011.02.018

temporary ECMO support. Excluding patients younger than 16 years and patients dying within 12 hours after ECMO implantation, we included 174 patients (72%) undergoing ECMO support through femoral cannulation. Patients with central or subclavian artery cannulation were excluded as well. The Institutional Ethics Committee approved our study protocol (no: 942-2011). Patients' demographics, comorbidities, and indications for ECMO support are illustrated in Table 1.

Cardiogenic shock was defined as cardiac index less than 2.2 $L \cdot min^{-1} \cdot m^{-2}$, systolic blood pressure of less than 90 mm Hg or lactate value of 4.0 mmol/L or more under positive inotropic drugs, or intraaortic balloon pump support [13]. Venovenous ECMO was applied in cases of acute respiratory distress syndrome not responsive to conventional treatments. In these cases, severe hypoxia or hypercapnia hampered a protective ventilation strategy (tidal volume less than 6 mL/kg of predicted body weight and plateau pressure <30 cmH_2O), and were, therefore, indications for starting extracorporeal circulation.

ECMO Circuit

The miniature-circuit ECMO is composed of a centrifugal pump (Levitronix Centrimag; Pharos, Waltham, MA) or Rotaflow centrifugal pump (MAQUET Cardiovascular, Fairfield, NJ) and a membrane oxygenator (Novalung, Hechingen, Germany; or Quadrox i Adult; MAQUET Cardiovascular). The system consists of a replaceable polycarbonate pump with a maximum flow of approximately 9.9 L/min at 5,500 revolutions per minute. The pump is connected to the membrane oxygenator with a short heparin-coated tubing system. The membrane oxygenator was originally designed as low resistance for pulsatile blood flow without the use of a blood pump and has a surface area of 1.3 m^2 with a maximum gas flow of 15 L/min. The priming volume is 175 mL, and by the use of a blood pump, the maximum device flow can be enhanced to 5.5 L/min. The pressure gradient across the membranes is 11 mm Hg at 2.5 L/min device flow.

Table 1. Patient Demographics, Comorbidities, and Indications for Extracorporeal Membrane Oxygenation (ECMO) Support

Demographics	Number of Patients (n = 174)
Male	111 (64%)
Mean age, years (range)	46 (17–83)
Comorbidities	
Arterial hypertension	77 (44%)
Renal insufficiency, acute or chronic	53 (30%)
Coronary artery disease	47 (27%)
Chronic obstructive pulmonary disease	25 (14%)
Diabetes mellitus	29 (17%)
Peripheral arterial disease	15 (9%)
ECMO indications, cardiopulmonary failure due to	
Low cardiac output syndrome, after cardiac surgery	60 (35%)
Cardiomyopathy	20 (12%)
H1N1 influenza virus infection	19 (11%)
Other reasons[a]	≤10%

[a] Including α_1-antitrypsin deficiency syndrome, acne inversa, bronchiectasis, bronchiolitis obliterans syndrome, chemotherapy, cystic fibrosis, hepatopulmonary syndrome, immunologic reaction, liver transplantation, lung fibrosis, lung transplant rejection, myocarditis, pulmonary hypertension, pulmonary embolism, resuscitation due to cardiogenic shock, and third-degree burn.

ECMO = extracorporeal membrane oxygenation.

Implantation Technique

Cannulation was performed after heparin administration (5,000 IU intravenous bolus). The contralateral or ipsilateral femoral vessels were percutaneously cannulated by the Seldinger technique. Cannula size (15F or 17F) was individually selected according to the body surface to achieve an effective blood flow. In cases of open access, cannulation sutures were placed after preparation of the femoral artery. Thereafter, an arterial cannula was inserted using the Seldinger technique. After connection of the ECMO device, the cannulation sutures were tied, and the skin was closed. In all cases but 1, a 6F single-lumen sheath (AVANTI + Sheath Introducer; Cordis, Bridgewater, NJ) was inserted along the arterial cannula in the distal direction into the femoral artery for lower limb perfusion. The femoral vein was always cannulated percutaneously. Vein cannula size was between 20F and 24F. The miniature ECMO circuit was completely deaired and connected to the cannulas. Pump run was started in the venoarterial mode in the following configuration: venous line, centrifugal pump, membrane ventilator, and arterial line. Continuous intravenous heparin infusion was administered for anticoagulation with an activated clotting time target of 160 seconds to 180 seconds.

Explantation Technique

In cases of percutaneous cannulation, explantation of the ECMO was performed in a standardized bedside fashion procedure. After 5 to 10 minutes of manual compression, a femoral compression system (FemoStop II Plus; Radi Medical Systems, Uppsala, Sweden) applied a mechanical pressure over the vessel puncture to induce hemostasis. The pressure of the pneumatic dome of the device was controlled by a reusable pump with manometer and remained for at least 10 hours. Puncture position and ankle pulses were evaluated every 60 minutes. For open access, the patient was routinely transported in the operating theater. The operative field was reopened, and cannulation sutures were revaluated. If insufficiency was assumed, the sutures were replaced, and after removal of the cannula, were tied. In cases of atherosclerotic arterial wall, vessel stenosis, or distal pulselessness, a reconstructive procedure was performed.

Study Design

The primary outcome of this study was any VC during the early or midterm period. Secondary outcomes were 30-day mortality and 1-year survival. A logistic regres-

sion analysis model including patients' comorbidities, implantation technique, and ECMO duration was designed to identify predictive factors associated with VCs and poor outcome. Other organ complications were not reported in this study, and were described extensively elsewhere [13].

Statistical Analysis

All analyses and graphs were performed with MedCalc 9.4.2.0 for Windows (Mariankerke, Belgium). Categorical variables and frequencies were presented as percentages and continuous variables as mean (range) or median (interquartile range) according to their distribution. Distribution of continuous variables was tested with Kolmogorov-Smirnov test. Ordinal data with two categories were compared with Fisher's exact test. Survival rates were calculated using the Kaplan-Meier method with 95% confidence interval, and patients are censored at their last known date of follow-up. The logistic regression analysis identified predictors of VCs through the enter method. A p value of 0.05 or less was considered statistically significant for individual tests.

Results

The venoarterial ECMO mode was used in 143 patients (82%). Femoral arterial access was established by percutaneous cannulation in 136 (95%) and by open vessel exposure in 7 (5%). A percutaneous venovenous mode was used in 31 patients (18%).

Primary Outcomes

VASCULAR COMPLICATIONS. At least one VC was observed in 17 patients (10%), of whom 15 patients underwent a venoarterial mode procedure (88%) and 2 patients (12%), a venovenous mode ($p = 0.50$). Clinical manifestations in the venoarterial cohort were acute embolism/thrombosis (n = 6), dissection of the common femoral artery (n = 2), postoperative false aneurysm (n = 2), groin hematoma (n = 1), perforation of the femoral artery (n = 1), and compartment syndrome (n = 6). As result of limb ischemia, we had to perform two major amputations (one above and one below the knee). Both patients had no wound infections, but subsequently died of sepsis-related multiple organ failure. One patient with a perforation of the femoral artery had a wound infection, which was successfully treated by systemic antibiotics and vacuum-assisted device (infoV.A.C. Therapy Unit; KCI Concepts, San Antonio, TX). Comparably, in patients undergoing venovenous support, an accidental puncture of the femoral artery led to groin hematoma (after heparin administration) requiring open surgery (n = 2).

All patients with acute arterial embolism/thrombosis underwent balloon catheter thrombectomy, and 2 patients received additional arterial reconstruction using bovine pericardium (VascuGuard; Synovis, St. Paul, MN). In 3 patients with acute embolism, a prophylactic dermatofasciotomy was done. Interestingly, in 3 patients, the initial clinical manifestation was compartment syndrome caused by an ischemia-reperfusion problem. Noteworthy is that for 1 of these patients, no distal perfusion had been used. Dissection of the common femoral artery was incidentally diagnosed in 1 patient during the surgical removal of the cannula. In this case, a Dacron (Uni-Graft K DV, B. Braun Melsungen AG, Melsungen, Germany) interposition graft was used as the treatment option. In another patient, postmortem examination revealed femoral artery dissection, without any preoperative signs of limb ischemia. One false aneurysm as well as all groin hematomas (due to the dislocation of the distal perfusion catheter [n = 1] and accidental artery puncture by venovenous mode [n = 2]) were treated with open surgery. One small false aneurysm (<2 cm) was successfully treated using a femoral compression system. In 1 patient, an iatrogenic laceration of the femoral artery occurred. Immediate vascular repair with a Dacron interposition graft was successfully performed. Finally, in 1 patient with compartment syndrome a biopsy of the vastus lateralis muscle showed extended necrosis; therefore, an amputation above the knee was performed. Similarly, in 1 patient with acute embolism, an amputation below the knee could not be avoided after rhabdomyolysis.

PREDICTORS OF VASCULAR COMPLICATIONS. Logistic regression analysis revealed peripheral arterial disease as the only prognostic factor for vascular events (odds ratio 6.95, 95% confidence interval: 1.89 to 25.59, $p = 0.003$). Duration of ECMO support and the type of cannulation were not associated with VCs (Table 2).

Secondary Outcomes

Thirty-day mortality after the initiation of ECMO support was 61% (110 of 180 patients). The majority of patients died of multiple organ failure. Median duration of ECMO support was 6 days (range, 1 to 11 days). Neither the duration of ECMO support nor the implantation technique (percutaneous versus open) showed a significant association with 30-day mortality. Median follow-up time was 18 days (range, 1 to 61 days). One-year survival rates were 26% (95% confidence interval, 19.05% to 32.95%; Fig 1).

The comparison of early and late mortality rates between patients with and without VCs showed no statis-

Table 2. Logistic Regression Analysis for Predictors of Vascular Complications in Patients Undergoing Extracorporeal Membrane Oxygenation (ECMO) Support Through Cannulation of Femoral Vessels

Variables	Odds Ratio	95% CI	p Value
Diabetes mellitus[a]	1.83	0.49 to 6.92	0.36
Implantation technique[b]	1.54	0.15 to 16.35	0.72
Length of ECMO support, days	0.92	0.80 to 1.05	0.21
Peripheral arterial disease[c]	6.95	1.88 to 25.59	0.003

[a] Type I, type II, or due to corticosteroids. [b] Percutaneous versus open. [c] Peripheral arterial disease was defined according to Norgren et al [18].

CI = confidence interval.

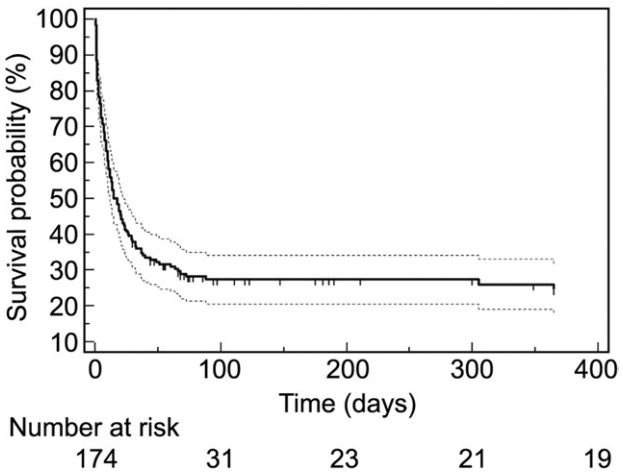

Fig 1. Kaplan-Meier life table analysis presenting 1-year survival rates (including 95% confidence intervals) of patients undergoing extracorporeal membrane oxygenation support for cardiopulmonary failure.

tically significant difference. The early (≤30 days) mortality rates were 65% (11 of 17 patients) for patients with VCs in comparison with 61% (99 of 163 patients) for VC-free patients ($p = 0.95$). The overall (1-year) mortality was 77% (13 of 17 patients) and 69% (113 of 163), respectively ($p = 0.73$).

Comment

Early VCs were observed in 10% of our patients, without any additional midterm vascular events among patients successfully weaned from ECMO. The majority of VCs was observed in the venoarterial mode and was severe. Six compartment syndromes—three as initial clinical manifestation—and two limb amputations were observed. In patients with venovenous mode, only accidental groin hematomas appeared.

The utmost challenge for the prevention of such complications is the rapid clinical diagnosis of embolism or cannula-dependent vessel occlusion, which remains difficult in this patient cohort. Additionally, unnecessary transport, for example, to a diagnostic contrast-enhanced computed tomography scan can be life-threatening [19]. The following factors complicate the early diagnosis of an acute embolism: (1) detection of peripheral pulses—the diameter of the cannula (15F to 17F) almost occludes the femoral vessel to a great extend, and the lower limb perfusion is only ensured by the use of 5F to 7F single-lumen catheters through the ECMO system; in contrast, a small-size cannula cannot achieve an effective blood flow [13]; (2) the patient's sedation; (3) a high level of catecholamines causing peripheral vasoconstriction [20]; and (4) the frequent presence of generalized edema [21].

The importance of the distal perfusion catheter is underlined by our results, as in the only patient without selective perfusion of the limb, an acute compartment syndrome developed rapidly. Foley and colleagues [17] observed no limb ischemia in 10 patients, in whom the superficial femoral artery was prophylactically cannulated and perfused in the antegrade direction. Several authors prefer a selective application of antegrade perfusion and propose different techniques. Hendrickson and coworkers [22] addressed an antegrade cannulation of the femoral artery with 8F to 14F pediatric arterial cannulas in cases of an open arterial access. Haft and associates [23] described a technique used in patients weighing more than 30 kg where the posterior tibial artery is ligated and a retrograde catheter is used to reperfuse the distal extremity. A similar procedure has been reported for an elderly patient with peripheral arterial disease using the dorsalis pedis artery [24]. Another method to perfuse the distal leg is cannulation through a vascular graft, which is anastomosed to the femoral artery [4]. Although this technique requires open vessel exposure, it has been reported as easier in selected patients with a damaged artery and a limb with severe ischemia-reperfusion injury. Our policy is the percutaneous puncture of the femoral artery with the distal perfusion catheter as a first step (when pulsatility is still present) followed by placement of the ECMO cannula afterward. In case of difficulties during the puncture and to minimize additional trauma to the patient, an ultrasound-guided approach is recommended. Noteworthy is the recommendation by Huang and associates [15], using a pressure criterion for the placement of a distal perfusion catheter to prevent limb ischemia in 9 patients. The pressure in the superficial femoral artery was measured through a 23G needle. If the mean pressure was below 50 mm Hg, a perfusion catheter was inserted [15].

It still remains unclear which blood flow or pressure through the implanted sheath is optimal for adequate muscle nutrition of the limb. However, we measured the arterial volume flow at the end of our distal perfusion; under pump flow of 4 L/min, the arterial volume flow was 240 mL/min. Taking under consideration that in healthy persons, the arterial volume flow in the common femoral artery under normal circumstances (normal range of cardiac output, 4 to 8 L/min) ranged between 100.7 mL/min and 364.5 mL/min (mean flow 232.6 mL/min) [25, 26], the arterial volume flow of the distal perfusion seems to be enough for limb protection.

Peripheral arterial disease was the only significant predictor for VCs. Atherosclerotic vessels are vulnerable, and the placement of the ECMO cannula might initiate dislocation of local plaques [14]. Therefore, ankle-brachial index should basically be measured before ECMO implantation. In case of absent ankle pulses, the flow profile in the common femoral artery should be observed to exclude hemodynamically relevant stenosis of the iliac axis. Obviously, in urgent situations (for example, cardiac arrest) such an evaluation is impossible, and the risk of VCs cannot be minimized. Particularly in patients presenting with peripheral arterial disease, a vascular surgeon should preferably be involved at an early stage, and both cannulation and removal should be performed as open procedures with direct artery view. Vein cannulation can be performed percutaneously in the majority of cases.

Few studies deal extensively with the mechanisms and the prevention of ECMO-related VCs [14, 15, 17, 22, 24]. Foley and colleagues [17] describe limb ischemia rates of 21% for 33 patients who did not undergo prophylactic distal catheterization. Hendrickson and coworkers [22] reported 11.5% ischemic complications among 26 patients undergoing open cannulation. Zimpfer and colleagues [14] observed VC rates of 28% for 174 patients. The lower rates in the present study may be due to the application of distal perfusion catheter and early involvement of vascular surgeons in peripheral arterial disease patients.

Alternative cannulation sites such as central aortic cannulation (after median sternotomy in cardiac surgery) and axillary or subclavian artery cannulation should be considered in selected patients [27–29]. Moazami and associates [28] presented axillary artery cannulation as a safe method of arterial cannulation for cardiopulmonary bypass in patients with extensive peripheral arterial disease. We do not recommend this technique as a primary approach for ECMO cannulation, as several complications (brachial plexus injury, pericardial effusion, and axillary artery thrombosis) have been reported [27]. Subclavian artery cannulation carries the benefits of central cannulation while allowing closure of the chest and therefore reducing the risk of mediastinitis as a major complication of central cannulation [29].

Finally, at the time of this study, we did not follow any nursing protocol. As a result of the activity during the study, a protocol has been established and includes following points for the prevention of VCs during ECMO implantation: (1) clinical examination of feet and legs for temperature, color, capillarity, and compartment syndrome; additionally, continuous measurement of oxygen saturation of toe and comparison with the respective finger; (2) Doppler detection of peripheral pulses/arterial blood flow by an experienced physician every 6 hours; (3) measurement of myoglobin and creatine kinase every 8 hours; and (4) if items 1 to 3 reveals any problems, color Duplex ultrasonography is used, or in case of inconsistent results, contrast-enhanced computed tomography angiography. The same protocol is followed during the first 48 hours after ECMO explantation.

The limitations of this study are the retrospective design as well as the small number of patients undergoing open cannulation, which, further, does not allow a safe comparison with the respective percutaneous procedures. Furthermore, we did not include the absence of ankle pulses before implantation in our regression analysis; the urgent procedures did not permit an analytical documentation in every case, and the high levels of catecholamines at the time of ECMO implantation might produce bias.

In conclusion, cannulation of femoral vessels for the implantation of an ECMO device remains a safe method, but is still associated with considerable rates (10%) of vascular events. Antegrade femoral artery sheaths should be routinely used to augment the limb perfusion. Peripheral arterial disease is an independent predictor of VC, and assessment of ankle-brachial index before ECMO implantation is recommended. Early involvement of vascular surgeons for open vessel exposure or alternative access sites (subclavian artery) should be considered for selected patients.

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An advance program with a registration form, hotel reservation information, and details regarding spouse/guest activities will be mailed to STS members this fall. Nonmembers may contact the Society's secretary, David A. Fullerton, MD, to receive a copy of the advanced program; however, detailed meeting information will be available on the STS website at www.sts.org.

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