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Interventional treatment of bleeding complications due to percutaneous cannulation for peripheral extracorporeal membrane oxygenation

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KEYWORDS
Interventional radiology;
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Abstract
Purpose: This study aimed to evaluate the safety and effectiveness of interventional techniques as a treatment for bleeding complications secondary to percutaneous cannulation for peripheral extracorporeal membrane oxygenation (PECMO).
Materials and methods: Out of 1264 patients who underwent PECMO at our hospital between January 2009 and September 2018, we reviewed the clinical characteristics and outcomes of eight patients (4 men, 4 women; mean age, 54.9 years [range, 31—77 years]) who underwent percutaneous interventional treatment for bleeding complications secondary to percutaneous cannulation for PECMO.
Results: Both hemodynamic instability and coagulopathy were present in 7 patients who had direct injury during PECMO insertion and absent in one patient with pseudoaneurysm at the PECMO removal site. Percutaneous ultrasound-guided thrombin injection was performed in three patients with pseudoaneurysm of the common or superficial femoral artery, and adjunctive embolization was combined with microcoils or *n*-butyl 2-cyanoacrylate in two of them.

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Stent graft was inserted in four patients with contrast extravasation ($n = 3$) from external iliac artery ($n = 1$) or common femoral or iliac veins ($n = 2$) ruptures or the fistula between the superficial femoral artery and vein ($n = 1$). *N*-butyl 2-cyanoacrylate and coil embolization was performed for pseudoaneurysm from the internal pudendal artery branch in the remaining one patient. Technical success was achieved in all eight patients. There were no procedure-related complications. There was no rebleeding during the follow-up.

Conclusion: Interventional treatment is a safe, technically feasible and therapeutically effective modality for treating bleeding complications secondary to a percutaneous cannulation for PECMO.

Extracorporeal membrane oxygenation (ECMO) is a well-established life-saving therapy for acute or acute-on-chronic cardiac and/or respiratory failure [1,2]. There are two basic types of ECMO; venoarterial type, which provides support for the heart and lungs, and venovenous type, which provides support for the lungs only [3]. In adults and larger children, the femoral artery and vein are commonly cannulated using the Seldinger technique for vascular infusion because of their location and ease of access. This technique is known as peripheral ECMO (PECMO) [4]. Active bleeding secondary to puncture is a cannulation-related complication of PECMO [5]. Most patients can be treated with a pressure bandage, although significant blood loss requires surgical revision [2,6]. With improvements in endovascular technique, treatment options for patients with local bleeding from a puncture have evolved from solely surgical explorations to less invasive methods.

There have been few reports to date concerning the cannulation-related complications of PECMO [1,5,7,8]. In these studies, risk factors associated with vascular complications and technical considerations for percutaneous cannulation were analyzed for prevention purposes. Studies reporting interventional treatment for puncture-related active bleeding from PECMO have also been limited.

The purpose of this study was to evaluate the safety and effectiveness of interventional techniques as a treatment for bleeding complications secondary to percutaneous cannulation for PECMO.

Materials and methods

Patients

Our institutional review board approved this study's use of clinical data, and informed consent was waived due to the retrospective nature of the study design. This study used data from our electronic medical records database. Between January 2009 and September 2018, 1264 patients underwent PECMO in our hospital. When there was a sign of persistent or recurrent bleeding after PECMO insertion, conservative treatment such as compression was performed. For patients with bleeding refractory to conservative treatment or causing hemodynamic instability, interventional or surgical treatment was considered. Among these patients, eight consecutive patients (8/1264, 0.6%) who underwent interventional treatment for bleeding complications secondary to percutaneous cannulation for PECMO were included. There were 4 men and 4 women with a mean age of 54.9 years (range, 31—77 years).

The diagnosis of bleeding complications was made using computed tomography (CT) and/or digital subtraction angiography (DSA). The unenhanced and enhanced abdominopelvic CT examinations with a slice thickness of 5 mm were performed with a Somatom® Plus 4, Sensation 16, or Somatom® Definition scanner (Siemens Healthineers). Intravenous contrast material (120—150 mL iopromide [Ultravist® 370 or Ultravist® 300, Bayer Healthcare]) was administered at a rate of 2—3 mL/s. Portal venous phase images were obtained 70—80 s after the start of the intravenous injection. Image interpretation, DSA and interventional treatment were performed by five interventional radiologists with 15—19 years of clinical experience.

Angiography and interventional technique

Access to endovascular therapy was determined by the availability of accessible vessels remaining, as PECMO requires at least two large vessels. A 4-French catheter (Berenstein® Catheter; Cook) was introduced over a 0.035-inch guide wire (Radifocus®, Terumo) into the accessible vessel. A targeted arteriogram or venogram was obtained for suspected arterial or venous bleeding.

Therapeutic method was chosen considering angiographic findings and the interventional radiologist's clinical experience. Percutaneous ultrasound-guided thrombin injection (UGTI) combined with balloon inflation was performed when a pseudoaneurysm associated with or without arterial rupture was detected at the percutaneously accessible artery. The center of the pseudoaneurysmal sac was initially accessed with a 21-gauge Chiba needle (Cook). Correct placement of the needle tip was confirmed by ultrasound. Next, thrombin (King Pharmaceuticals Inc,) was slowly injected into the sac in 0.1 mL (100 IU) aliquots via a 1 cm^3 TB syringe until thrombosis was confirmed by the cessation of Doppler flow. Other embolic agents, such

as microcoils (Cook) and *n*-butyl 2-cyanoacrylate (NBCA, Histoacryl®, Braun), were used together if hemostasis was insufficient. Temporary balloon occlusion of the bleeding artery was performed to prevent embolic agent migration. In cases of active bleeding at percutaneously inaccessible artery, endovascular embolization was performed.

In cases of arterial or venous rupture or arteriovenous fistula (AVF) with hemodynamic instability, complete hemostasis required stent graft (VIABAHN®, W.L. Gore and Associates) insertion. Under fluoroscopy, a 4-French catheter and a 0.035-inch hydrophilic guide wire were inserted into the distal segments of the ruptured vessel through the available arterial or venous access. After replacement of the 0.035-inch hydrophilic guide wire with a 0.035-inch stiff guide wire (Terumo) a stent graft was transported through the ruptured section. After verifying the correct position, the stent graft was deployed across the ruptured vessels.

Definitions and study endpoints

Hemodynamic instability was defined as a pulse rate >100 beats/min and systolic blood pressure <90 mmHg. Coagulopathy was defined as an international normalized ratio of > 1.5, a platelet count of < 50,000/μL, or both.

Technical success was defined as immediate, complete angiographic occlusion of the target vessel contributing to the area of bleeding. Data were collected on demographics, indication for ECMO, comorbidities, vital signs, coagulopathy status, CT and angiographic findings, bleeding vessel status, therapeutic methods, technical success, bleeding control, complications, and follow-up.

Results

Clinical characteristics

The clinical characteristics of the eight patients are summarized in Table 1. Indications for PECMO were acute respiratory distress syndrome ($n = 3$), respiratory failure secondary to lung cancer or interstitial lung disease ($n = 3$), and septic or cardiogenic shock ($n = 2$).

Seven patients (7/8, 88%, Patient # 1—7) who had direct injury during PECMO insertion presented hemodynamic instability and coagulopathy at the time of angiography. Thus, they underwent packed red blood cell transfusion before angiography, and were transferred to the interventional radiology unit within 12 hours following PECMO insertion. All these seven patients were unsuitable for surgery due to vital instability and poor general condition. While, in one patient (Patient # 8), pseudoaneurysm at PECMO removal site, was found to increase in size, and interventional treatment was performed 24 days after PECMO removal.

CT examinations were obtained before interventional treatment in four patients for detailed evaluation of the bleeding focus, and revealed contrast extravasation from the right superficial (Patient # 1) (Fig. 1) and common femoral (Patient # 7) artery, contrast extravasation at the right pelvic cavity (Patient # 6), and pseudoaneurysm from the left superficial femoral artery (Patient # 8). For the remaining four patients, the diagnosis of active bleeding or fistula was established using digital subtraction angiography (DSA).

Angiographic details

The angiographic results for the study patients are shown in Table 1. Angiography was performed via the contralateral common femoral artery ($n = 3$) (Fig. 2), the right or left brachial artery ($n = 3$, Fig. 1), or right or left internal jugular vein ($n = 2$) (Fig. 3), depending on available vascular access.

Endovascular treatment according to angiographic findings is schematized in Fig. 4. On angiography, arterial complications ($n = 6$, 6/8, 75%) manifested as pseudoaneurysm with or without contrast extravasation (Patients # 1, 6—8) (Fig. 1), contrast extravasation from the external iliac artery (Patient # 5) or superficial femoral arteriovenous fistula (Patient # 4) (Fig. 2), while venous complications were shown as contrast extravasation from common iliac or femoral vein (Patients # 2, 3) (Fig. 3).

UGTI for pseudoaneurysm, combined with balloon dilation state in the bleeding artery, was performed in three patients (Patients # 1, 7, 8) with 4000 or 5000 IU of thrombin. In two patients (Patients # 1, 7), microcoils were inserted percutaneously to prevent thrombin spillage into the pelvic cavity through the ruptured pseudoaneurysm, prior to UGTI for pseudoaneurysm (Patient # 1) (Fig. 1) or NBCA embolization was performed endovascularly to fill the remained pseudoaneurysmal sac following UGTI for pseudoaneurysm (Patient # 7).

Stent graft insertion was performed for contrast extravasation ($n = 3$) from arterial (Patient # 5) or venous (Patients # 2, 3) ruptures or the fistula between the superficial femoral artery and vein (Patient # 4) (Fig. 2) in four patients. In two patients with venous ruptures (Patients # 2, 3) (Fig. 3), stent graft insertion was decided instead of balloon tamponade because there was much contrast extravasation in the presence of coagulopathy.

NBCA and coil embolization was performed for pseudoaneurysm from the internal pudendal artery branch in one patient (Patient # 6).

Technical and clinical outcomes

Technical success was achieved in all eight study patients. There were no procedure-related complications in any of these patients. In seven patients with hemodynamic instability, vital signs stabilized after interventional treatment. There was no recurrent bleeding after the procedure.

In three patients (Patients # 1, 7, 8) who underwent UGTI for pseudoaneurysm from the common or superficial femoral artery, after interventional treatment, angiography indicated the disappearance of the pseudoaneurysm with patency of the adjacent artery. In one patient (Patient # 6) who underwent NBCA and coil embolization for pseudoaneurysm from the internal pudendal artery, pseudoaneurysm was well embolized without pelvic ischemic complications. In four patients (Patients # 2—5) who underwent stent graft insertion, after interventional treatment, angiography indicated good vascular patency through the stent grafts without contrast medium extravasation or fistula visualization.

Table 1 Clinical characteristics and outcomes for bleeding complications related to percutaneous cannulation for pECMO in eight patients.

No./Sex/Age (yr)	Indication	Vital instability/ Coagulopathy[a]	pRBC[b]	CT findings	Interval[c]	Angiography (access)	Treatment	TS	Bleeding control	Survival (death cause)
1/F/31	ARDS d/t necrotizing bronchiolitis	Yes/Yes	16 units	CE from Rt SFA, hematoma	3 hours	PSA/CE from Rt SFA (Lt brachial a.)	UGTI (BA), coils	Yes	Yes	14 days (ARDS)
2/F/56	Resp. failure d/t lung ca.	Yes/Yes	4 units	NA	2 hours	CE from Rt CFV (Lt IJV)	Stent graft (9 mm—5 cm)	Yes	Yes	19 days (DP)
3/F/49	Septic shock d/t infective endocarditis	Yes/Yes	16 units	NA	3 hours	CE from Lt CIV (Rt IJV)	Stent graft (12 mm—4 cm)	Yes	Yes	26 days (DP)
4/M/77	Resp. failure d/t lung ca.	Yes/Yes	3 units	NA	2 hours	Fistula between SFA-SFV (Rt CFA)	Stent graft (8 mm—2.5 cm)	Yes	Yes	172 days (DP)
5/M/59	Cardiogenic shock d/t myocarditis	Yes/Yes	3 units	NA	5 days	CE from Lt. EIA (Rt brachial a.)	Stent graft (8 mm—2.5 cm)	Yes	Yes	4 days (DIC)
6/F/41	ARDS d/t HLH	Yes/Yes	9 units	CE & hematoma in Rt pelvis	12 hours	PSA from Rt internal pudendal a. (Lt CFA)	NBCA (1:5) & coils	Yes	Yes	92 days (DP)
7/M/60	Resp. failure d/t ILD	Yes/Yes	14 units	CE from Rt CFA	9 hours	PSA/CE from Rt CFA (Lt brachial a.)	UGTI (BA), NBCA (1:3)	Yes	Yes	2 days (DIC)
8/M/66	ARDS d/t pancreatic ca. with bleeding	No/No	No	PSA from Lt SFA	24 days after ECMO removal	PSA from Lt SFA (Rt CFA)	UGTI (BA)	Yes	Yes	27 days (DP)

yr: year; ARDS: acute respiratory distress syndrome; d/t: due to; resp.: respiratory; ca.: cancer; HLH: hematophagocytic lymphohistiocytosis; ILD: interstitial lung disease; pRBC: packed red blood cells; CE: contrast extravasation; Rt: right; SFA: superficial femoral artery; NA: not available; CFA: common femoral artery; Lt: left; PSA: pseudoaneurysm; CFV: common femoral vein; IJV: internal jugular vein; SFV: superficial femoral vein; EIA: external iliac artery; UGTI: ultrasound-guided thrombin injection; BA: balloon assisted; NBCA: *n*-butyl cyanoacrylate (ratio with ethiodized oil); TS: technical success; DP: disease progression; DIC: disseminated intravascular coagulation.

[a] Vital instability and coagulopathy at the time of angiography.

[b] Packed RBC before angiography.

[c] Interval between bleeding onset and interventional treatment.

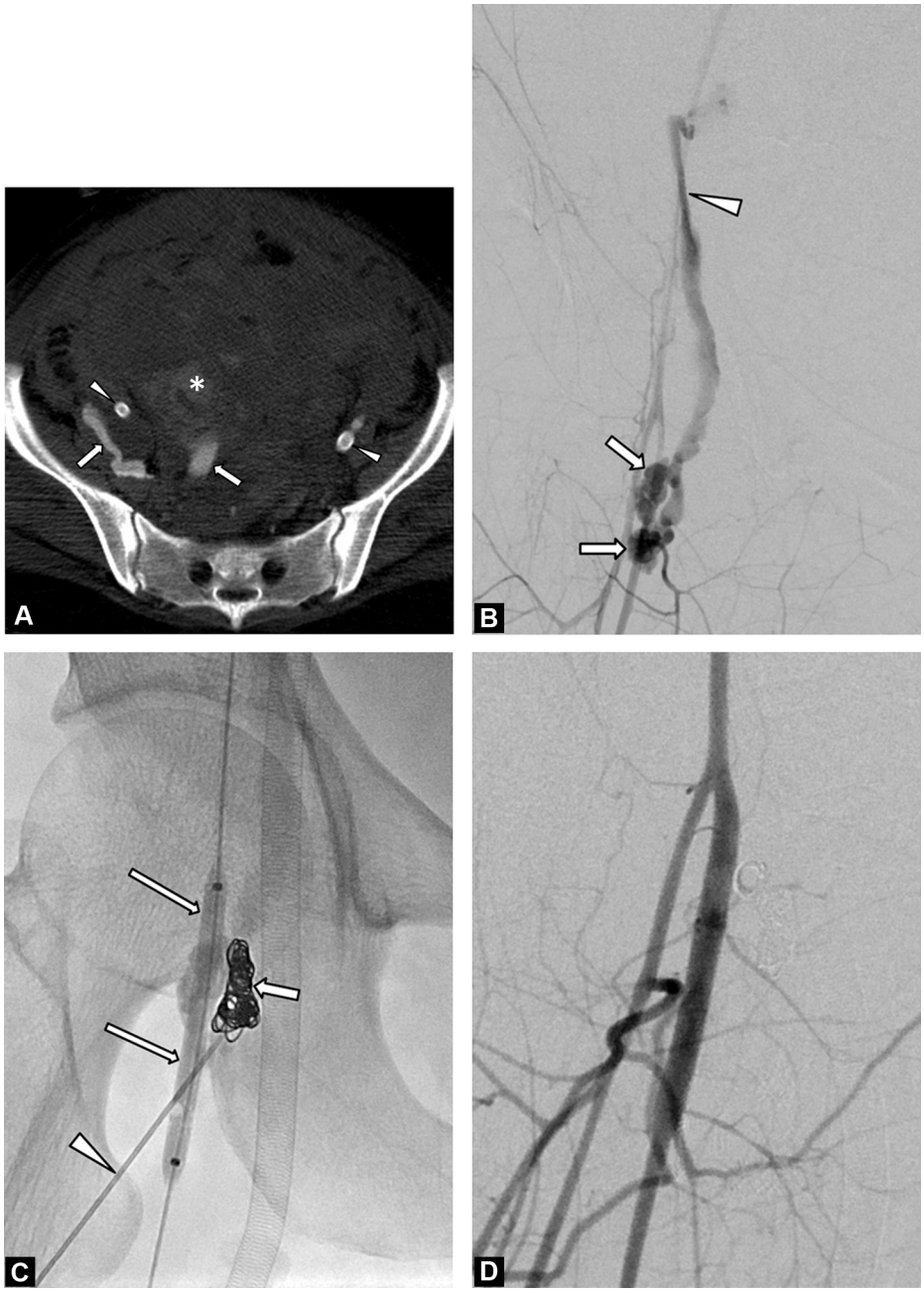

Figure 1. A 31-year-old woman with superficial femoral artery (SFA) rupture secondary to PECMO (Patient No. 1). A. A post-contrast CT scan before interventional treatment showing contrast extravasation (arrows) from the right SFA and a hematoma (asterisk) in the pelvic cavity. Bilateral cannulated femoral veins (arrowheads) are notable. B. Common femoral artery angiogram through the left brachial artery access showing active bleeding with pseudoaneurysm (arrows) from the right SFA. Active bleeding reflux into the pelvic cavity is evident (arrowhead). C. The pseudoaneurysm outflow was embolized with microcoils (arrow) and 4000 IU of thrombin was then injected into the pseudoaneurysm through the Chiba needle (arrowhead) with inflated balloon catheter assistance (long arrows). D. Post-thrombin injection angiogram showing no further bleeding into the pseudoaneurysm, and smooth blood flow through the SFA.

All patients died from ongoing acute respiratory distress syndrome ($n = 1$), disseminated intravascular coagulation ($n = 2$) or underlying disease progression ($n = 5$) 2 to 172 days (median, 22.5 days) after interventional treatment.

Discussion

Vascular complications such as bleeding, dissection, or occlusion, are the major cause of morbidity and mortality in patients with ECMO [9]. Particularly, bleeding is the most serious complication one among vascular ones, with an incidence ranging between 7 and 14% after ECMO, compounded by coagulopathy [2,6,9,10]. Although one study showed that PECMO presented significantly lower rate of bleeding requiring exploration compared to central ECMO (44% vs. 100%; $P = 0.01$), the rate was still considerably high [4]. Bleeding complications can be treated with surgery, but a majority of the patients requiring ECMO are unsuitable to surgery because of their poor general condition and

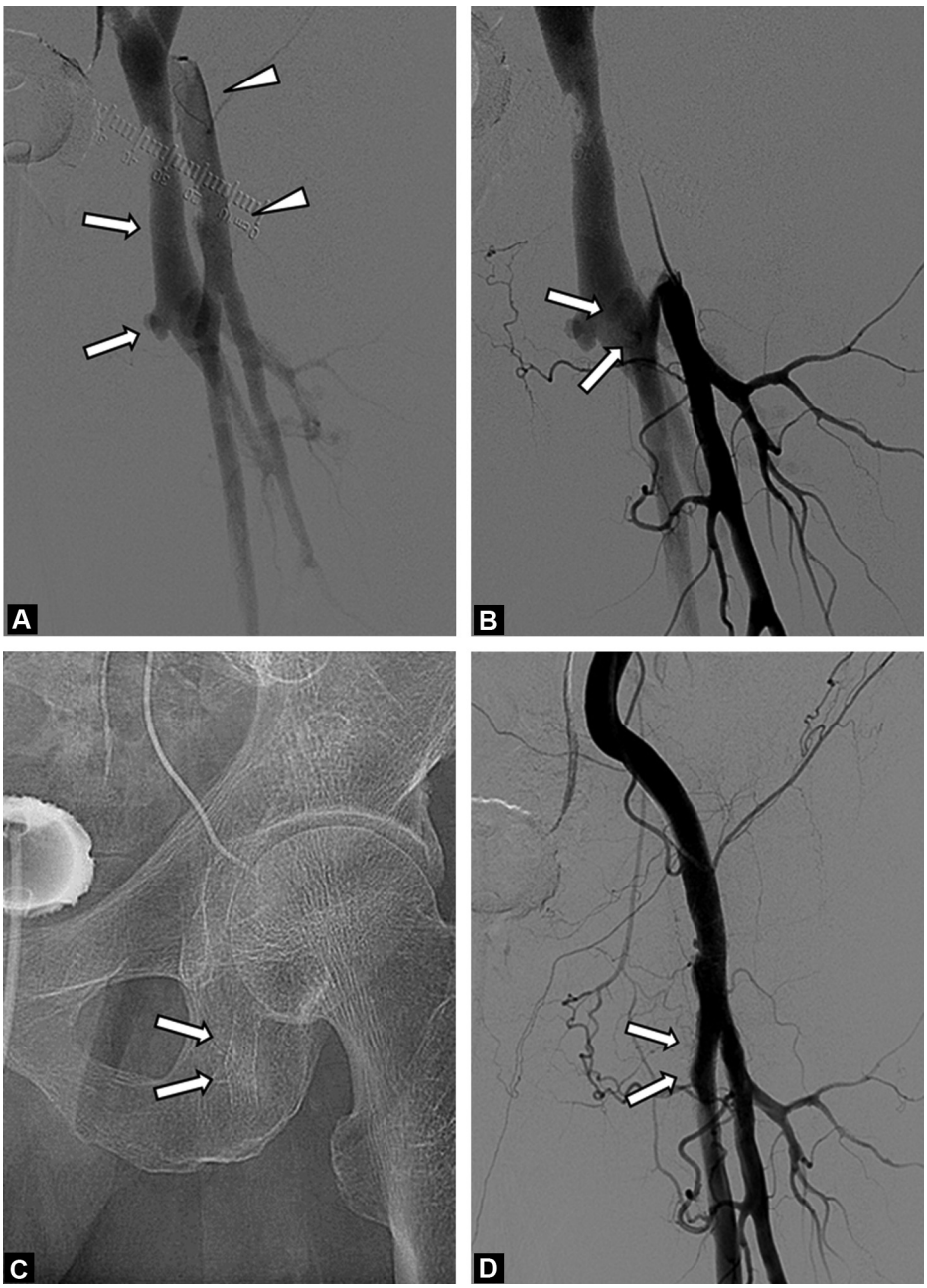

Figure 2. A 77-year-old man with left superficial femoral artery — superficial femoral vein fistula secondary to a percutaneous cannulation for PECMO (Patient No. 4). A. Left common femoral artery (arrowheads) angiogram shows early visualization of common femoral vein (arrows). B. Angiogram with the tip at the entrance of the fistula shows good fistula itself (arrows). C. A 8 mm × 2.5 cm fully covered stent graft (arrows) was inserted to cover the arteriovenous fistula site. D. After stent graft insertion, angiogram showed good contrast passage through the stent graft, and the fistula was sealed off successfully (arrows).

bleeding tendency. Recently, several endovascular techniques emerged as the treatment of bleeding complications after ECMO due to their less invasive nature. However, the safety and efficacy of these interventional treatments for bleeding complications after PECMO are not well-documented because of a paucity of data.

In the present study, immediate hemostasis was achieved in all eight patients, without any procedure-related complications or rebleeding, in spite of accompanying coagulopathy and hemodynamic instability. This indicates that interventional treatment is a safe, technically feasible and therapeutically effective modality for treating bleeding complications secondary to a percutaneous cannulation for PECMO. Preferential use of interventional treatment is supported by the results of the study by Scott et al. who reported that amount of operative blood loss was significantly lower when using interventional technique, without any differences in clinical outcomes compared to surgical therapy [11].

One important issue regarding angiography is the selection of access vessel, because accessible arteries are quite limited in PECMO because femoral arteries and veins are

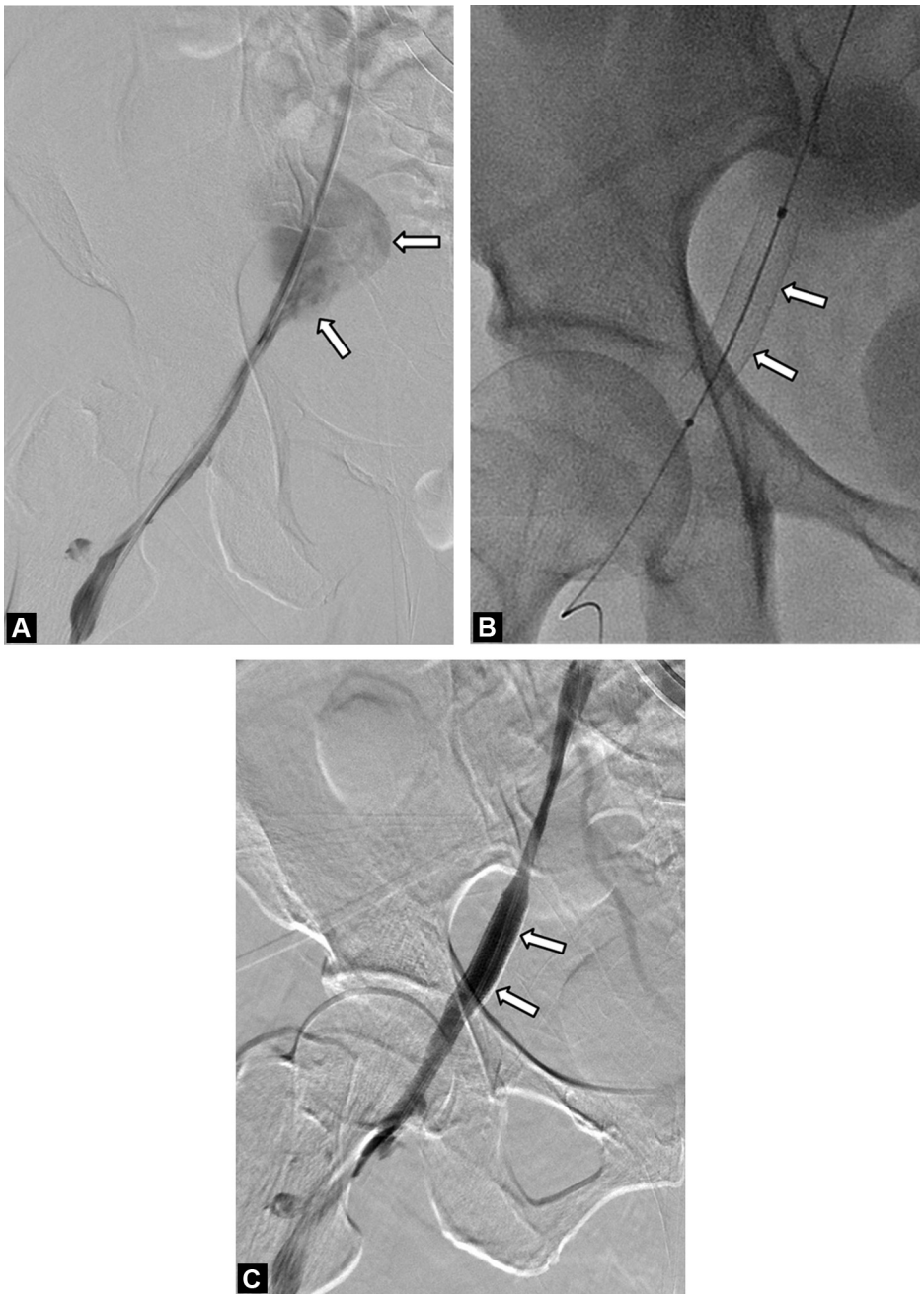

Figure 3. A 56-year-old woman with right femoral vein rupture secondary to a percutaneous cannulation for PECMO (Patient No. 2). A. Right femoral venogram through the left internal jugular vein access showing contrast extravasation (arrows) from the right common femoral vein. B. A 9 mm × 5 cm, fully covered stent graft (arrows) was inserted to cover the venous rupture site. C. Post-stent insertion venogram showing ood contrast passage through the stent graft (arrows) without contrast medium.

the preferred sites for ECMO access. In our study, the brachial artery ($n = 3$) and internal jugular vein ($n = 2$) were frequently used as an access route without any technical difficulty. Indeed, brachial arterial access is necessary for complex endovascular procedures, obligatory in as much as 40% out of 323 endovascular procedures, and can be achieved in most patients safely [12]. Chatziioannou et al. also reported a 99.5% success rate in catheterizing the right brachial arteries for 2250 lower extremity arteriograms [13]. Gordon et al. reported a 99.9% success rate for ultrasound-guided cannulation of the internal jugular vein in 868 procedures [14]. Therefore, brachial artery or internal jugular vein should be considered as an alternative access vessel for angiography firstly due to limited availability of femoral vessels.

UGTI is a well-known effective treatment of percutaneously accessible active bleeding. However, some technical considerations when using UGTI deserve to be emphasized. Firstly, when using thrombin as a main embolic agent, other embolic materials can be used adjunctively. In one of our study patients with a pseudoaneurysm from superficial femoral artery rupture, coil embolization was presciently

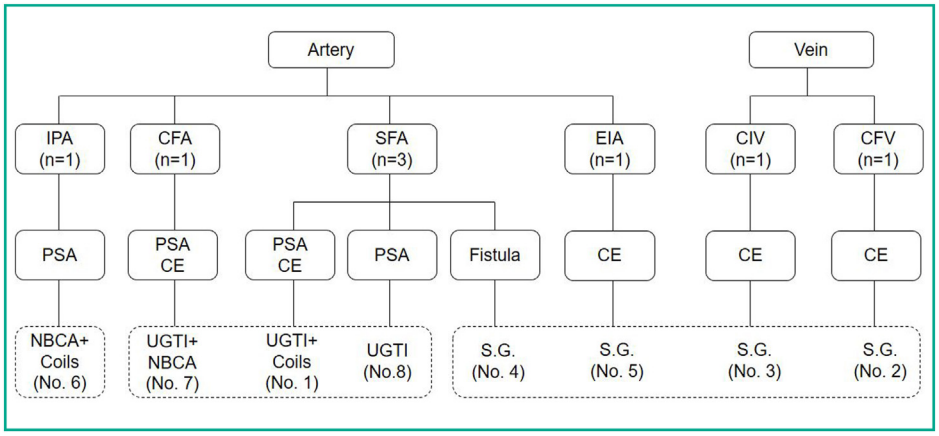

Figure 4. Schema of endovascular treatment according to angiographic findings.

performed to prevent the active bleeding reflux into the pelvic cavity before UGTI, resulting in successful hemostasis. Since the recurrence of pseudoaneurysm treated by UGTI was reported to be not uncommon (7%, 10/140), especially when an anticoagulant and an antiplatelet are used in combination [15], secure embolization of the pseudoaneurysm outflow tract accompanying UGTI would be expected to decrease the chance of recurrence. Secondly, to prevent spillage of thrombin into the bleeding artery, it has been suggested that the puncture needle tip should be at the periphery of the pseudoaneurysmal sac during thrombin injection [16]. In our experience, temporary balloon occlusion of the bleeding artery during thrombin injection may be safer than just observing the puncture needle tip site when preventing thrombin spillage.

The clinical significance of vein rupture depends on the severity of the tear and presence of coagulopathy. In our study, two patients presenting with venous rupture, which was identified by contrast extravasation on angiogram. All these patients were unsuitable to surgery because of hemodynamic instability and coagulopathy, or deep location of the rupture site. Among endovascular treatment techniques, stent insertion was selected and showed good results. The reason of high efficacy in stent insertion in venous rupture can be explained by complete exclusion of bleeding site. Thus, in venous rupture, stent insertion may be a safe option for venous bleeding:

Iatrogenic femoral AVFs have traditionally been managed by open surgical repair. As a result, many patients were left with large incisions, limited mobility, and high rates of wound infection (up to 15%) [17]. A new mode of therapy for treating AVF is stent graft insertion although percutaneous stent graft insertion for AVF has associated inherent risk such as long-term durability. In our study, there was one patient who underwent stent graft for the AVF and his stent graft was durable for six months until his death. Recent literature has revealed favorable midterm patency using stent graft for AVF. It was reported that the patency rates of stent grafting in the superficial femoral artery were 76% and 55% at one and four years for primary patency, respectively, with secondary patency approaching 80% at four years [18]. Furthermore, patency appears to increase with use in larger vessels and also larger stent graft diameters.

Our study has several limitations. First, we retrospectively analyzed the data from a small number of patients at a single center. Second, only referred patients to angiography were included in this study, which may have introduced a selection bias. Therefore, there is the need for larger scale prospective studies.

In conclusion, interventional treatment is a safe, technically feasible and therapeutically effective modality for treating active bleeding secondary to percutaneous cannulation for PECMO. Such procedures seem to be fast and less invasive for the high-risk patients unsuitable for surgery.

Disclosure of interest

The authors declare that they have no competing interest.

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