

Bail-out treatment of pulmonary embolism using a large-bore aspiration mechanical thrombectomy device

Stefan Stadler¹, Kurt Debl¹, Markus Ritzka², Lars Siegfried Maier¹ and Samuel Sossalla^{1*}

¹Department of Internal Medicine II, University Hospital Regensburg, Franz-Josef-Strauss-Allee 11, Regensburg, 93055, Germany; and ²Department of General Surgery, Intensive Care Unit, University Hospital Regensburg, Regensburg, Germany

Abstract

We report on the first pulmonary embolism treatment via the large-bore aspiration mechanical thrombectomy device (Inari FlowTrieve[®]) outside the USA, in a resuscitated patient on veno-arterial extracorporeal membrane oxygenation (VA-ECMO) suffering from severe and acute right heart failure. In this particular high-risk patient population, where thrombolysis is mostly not applicable, this new technology could be a promising solution as the combination of large-bore thrombus aspiration and extraction successfully removes large emboli. In our case, right ventricular function improved rapidly after the procedure, ECMO could be weaned, and the patient was dismissed 2 weeks after. In summary, we provide a new therapeutic option for the often difficult treatment of pulmonary embolism in high-risk patients on VA-ECMO.

Keywords Pulmonary embolism; Large-bore aspiration mechanical thrombectomy device; FlowTrieve; Venous-arterial ECMO

Received: 11 May 2021; Revised: 1 July 2021; Accepted: 4 August 2021

*Correspondence to: Samuel Sossalla, Department of Internal Medicine II, University Hospital Regensburg, Franz-Josef-Strauss-Allee 11, 93055 Regensburg, Germany. Tel: +49-941-944-7211; Fax +49-941-944-7338. Email: samuel.sossalla@ukr.de

Introduction

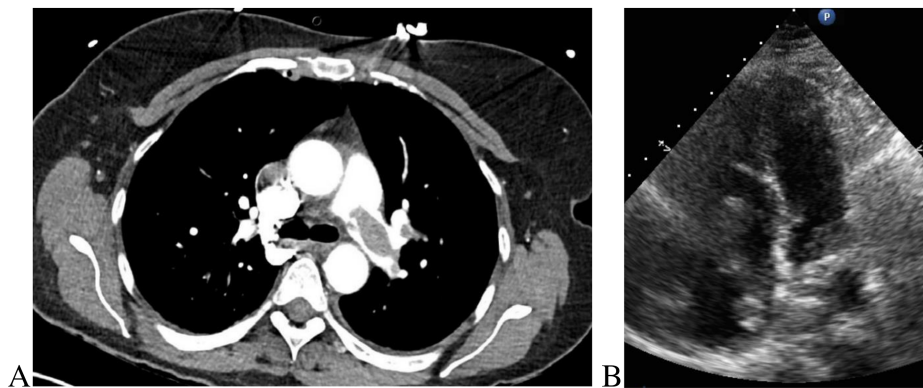
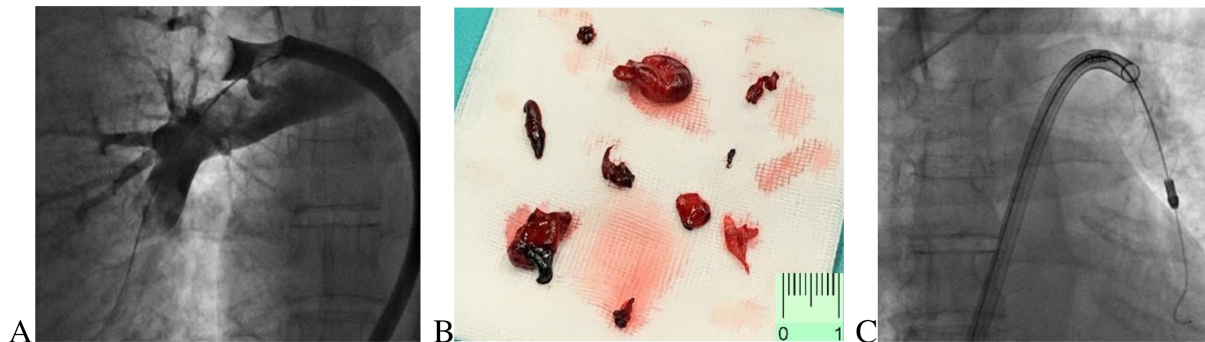
Pulmonary embolism is a common cause of acute right heart failure. Even with bridging extracorporeal membrane oxygenation (ECMO), haemodynamic stability can often not be regained. As it is known, there exists a number of contraindications against lysis therapy itself. Due to these two facts, it is necessary to invent new methods for the recanalization of the pulmonary arteries.

Case report

We report on a 55-year-old woman who suffered a car accident with multiple fractures of the ribs, the sternum, and the right lower extremity as well as a haemothorax and a diaphragmatic rupture. After emergency operation with diaphragmatic reconstruction and positioning of a thoracic drainage, the patient was successfully weaned from ventilation the day after. Surgical reposition and plate osteosynthesis of a tibial head impression fracture was

successfully performed after 1 week. Two days later, the patient collapsed during physical therapy on the general ward and complained new onset dyspnoea. Computed tomography showed a massive bilateral pulmonary embolism (*Figure 1A*). Sonography revealed a thrombosis of the left popliteal vein. Repeated echocardiography showed an increasing dilatation of the right heart with a thrombus in the right atrium (*Figure 1B*). In spite of recent operations, lysis with 100 mg of alteplase was given, but the haemodynamic situation worsened and the patient was twice resuscitated before a veno-arterial ECMO (VA-ECMO; left femoral vein, right femoral artery, flow 3.8 L/min) was implanted. As signs of cardiogenic shock, the right heart was massively dilated and high doses of catecholamines were required.

Twenty hours after thrombolysis, we decided to use the large-bore aspiration mechanical thrombectomy device FlowTrieve[®] as a bail-out strategy although this device has not been used before outside USA so far.¹ A 26 French sheath was carefully inserted into the right femoral vein using fluoroscopy in order to avoid complications concerning the venous ECMO cannula. The 24 French catheter (Trieve24

Figure 1 (A) Computed tomography scan of the central pulmonary embolism. (B) Echocardiography of right heart thrombus.**Figure 2** Position of the large lumen catheter (Trieiver Aspiration Catheter®) in the right lung (A) and of the self-expanding nitinol mesh disks (FlowTrieiver Catheter®) in the left lung (B). Clots aspirated with the large-bore syringe (C).

Aspiration Catheter®) was carefully advanced after passing the right heart using a pigtail catheter to pulmonary artery over a stiff guide wire (*Figure 2A*). We managed to mobilize several clots from both sides under suction using the large-bore syringe. A total of 50–70 mL of blood were aspirated at each suction attempt. Due to the fact that the removed thrombus appeared as well subacute (*Figure 2B*), we additionally applied the self-expanding nitinol mesh disks (FlowTrieiver Catheter®), which is designed to engage, disrupt, and deliver clot to the aspiration catheter for extraction (*Figure 2C*).

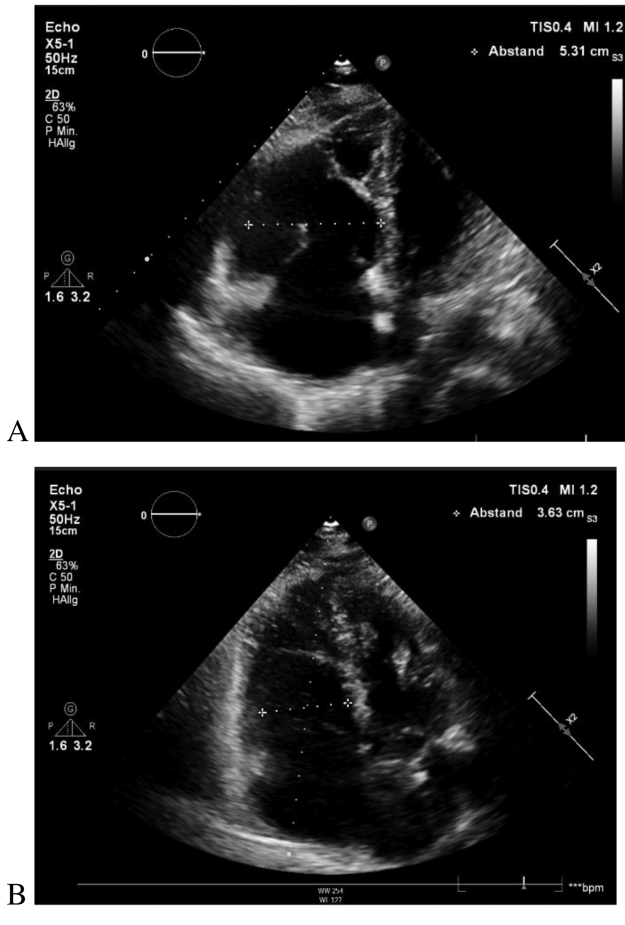
Echocardiography before and immediately after the intervention in the cath lab revealed considerable improvement of right ventricular function and dimension: the end-diastolic mid-diameter of the right ventricle markedly declined from 53 to 36 mm, and tricuspid annular plane systolic excursion increased from 10 to 13 mm (*Figure 3*). The flow of the VA-ECMO could be reduced from 3.8 to 2.7 L/min within the next 12 h. Finally, the device was explanted 60 h after the intervention using a Manta® system. Anticoagulation was performed with unfractionated heparin. Forty-two hours later, the patient developed a

heparin-induced thrombocytopenia so that the anticoagulation was changed into Argatroban (activated partial thromboplastin time was 60–70 s). The patient was successfully extubated 7 days after the Inari FlowTrieiver® tool had been used. The discharge from the hospital was 19 days following intervention. At that time, a normalized right ventricular function was measured.

Discussion

We report on the first treatment of pulmonary embolism with acute right heart failure via the large-bore aspiration mechanical thrombectomy device (Inari FlowTrieiver®) outside the USA. It has to be pointed out that the patient of our case report was a complex one with implanted VA-ECMO and cardiopulmonary resuscitation. The use of the Inari FlowTrieiver® under these circumstances was safe, feasible, and very effective. Initial thrombolysis was not effective enough to restore the required pulmonary perfusion most likely due to the mixture of an acute and subacute event.

Figure 3 Echocardiography focusing on the right heart immediately before (A) and after (B) aspiration of the pulmonary embolisms.



Although in previous publications, even larger thrombi could be extracted by this particular device,² the patient benefitted most likely from thrombus aspiration as the need for catecholamines declined quickly, right ventricular function rapidly improved, and the VA-ECMO could be explanted shortly after.

Patients with haemodynamic instability due to a massive pulmonary embolism remain challenging for clinicians. On the one hand, thrombolytic agents are occasionally contraindicated due to their bleeding risk. On the other hand, they are often insufficient to restore haemodynamic stability. Surgical interventions for acute pulmonary embolism mainly have a poor prognosis.³ VA-ECMO can be a bridge to recovery for patients with massive pulmonary embolism, but vascular and bleeding problems are frequent, in particular if lysis was already administered or is necessary on top. However,

even the combination of VA-ECMO and thrombolytic agents may not be effective enough in severe cases of pulmonary embolism, as we have demonstrated in the aforementioned case.

By the combination of large-bore thrombus aspiration and extraction, the removal of large and potentially subacute emboli seems to be possible. The Inari FlowTrieve[®] might be a novel unique tool, which is helpful to have up one's sleeve in acute pulmonary embolism with haemodynamic instability. However, it is important to note that the large sheath and the catheter itself can potentially injure the femoral insertion site as well as the right ventricle and the pulmonary artery. In addition, the vascular access site has to be free of thrombosis, and large vascular sheaths should generally be avoided in the setting of severely impaired coagulation very early after thrombolysis.

It is well known that residual pulmonary vascular obstruction, as it often persists after ECMO in pulmonary embolism patients without thrombolysis, constitutes an independent predictor of mortality and chronic thromboembolic pulmonary hypertension (CTEPH). This unique large-bore device can remove thrombus at the whole piece due to a higher rate of aspirational blood flow compared with common small lumen devices. Additionally, the wider catheter can carry more blood volume at a lower resistance.

As discussed earlier, it might be presumed that there probably exists a positive effect against the development of CTEPH in this particular patient collective by using this new Inari FlowTrieve[®] tool. Therefore, it would be necessary and of particular interest to prospectively investigate whether this intervention is of prognostic benefit in patients with pulmonary embolism and particularly in those who are treated with ECMO. Moreover, it is of great necessity to further investigate the safety and efficacy of this new device in such particular patients.

Conflict of interest

None declared.

Funding

Open Access funding is enabled and organized by Projekt DEAL.

References

1. Tu T, Toma C, Tapson VF, Adams C, Jaber WA, Silver M, Khandhar S, Amin R, Weinberg M, Engelhardt T, Hunter M, Holmes D, Hoots G, Hamdalla H, Maholic RL, Lilly SM, Ouriel K, Rosenfield K. A prospective, single-arm, multicenter trial of catheter-directed mechanical thrombectomy for intermediate-risk acute pulmonary embolism: the FLARE study. *JACC Cardiovasc Interv* 2019;**12**: 859–869. <https://doi.org/10.1016/j.jcin.2018.12.022>
2. Toma C, Khandhar S, Zalewski AM, D'Auria SJ, Tu TM, Jaber WA. Percutaneous thrombectomy in patients with massive and very high-risk submassive acute pulmonary embolism. *Catheter Cardiovasc Interv* 2020; **96**: 1465–1470. <https://doi.org/10.1002/ccd.29246>
3. Fukuda I, Taniguchi S. Embolectomy for acute pulmonary thromboembolism: from Trendelenburg's procedure to the contemporary surgical approach. *Surg Today* 2011; **41**: 1–6. <https://doi.org/10.1007/s00595-010-4416-8>