Cardiovascular Revascularization Medicine xxx (xxxx) xxx–xxx

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

journal homepage: www.sciencedirect.com/journal/cardiovascular-revascularization-medicine

Percutaneous pulmonary thrombectomy with aspiration catheters in patients with high-risk pulmonary embolism and absolute contraindication to systemic thrombolysis

Daniel Tébar [a,*], Alfonso Jurado-Román [a], Santiago Jiménez-Valero [a], Guillermo Galeote [a], Ariana Gonzálvez [a], Borja Rivero [a], Andoni García [b], Jose Manuel Añón Elizalde [b], Alicia Lorenzo [c], Carmen Fernández Capitán [c], Rosario Torres [d], Clara Soto [e], Sergio Alcolea [e], Sandra Rosillo [f], Juan Caro Codón [f], Emilio Arbas [f], Fernando Tejera [g], Ignacio Plaza [h], Lisardo Boscá [i,j,k,l], Raúl Moreno [a,i]

[a] Interventional Cardiology Unit, Cardiology Department, La Paz University Hospital, Madrid, Spain
[b] Intensive Care Unit, La Paz University Hospital, Madrid, Spain
[c] Thromboembolic Disease Unit, Internal Medicine. La Paz University Hospital, Madrid, Spain
[d] Emergency Department, La Paz University Hospital, Madrid, Spain
[e] Pulmonary Hypertension Unit, La Paz University Hospital, Madrid, Spain
[f] Cardiac Intensive Care Unit, Cardiology Department, La Paz University Hospital, Madrid, Spain
[g] Intensive Care Unit, Infanta Cristina University Hospital, Madrid, Spain
[h] Cardiology Department, Infanta Sofia University Hospital, Madrid, Spain
[i] Hospital La Paz Research Foundation (IdiPAZ), Madrid, Spain
[j] Network Center for Cardiovascular Diseases Research (CIBERcv), Spain
[k] Sols-Morreale Biomedical Research Institute (CSIC-UAM), Spain
[l] Autonomous University of Madrid, Madrid, Spain

ARTICLE INFO

Keywords:
High-risk pulmonary embolism
Percutaneous pulmonary thrombectomy
Sistemic thrombolysis contraindications
Thromboaspiration
Aspiration thrombectomy
High-risk bleeding
Cardiac shock
ECMO

ABSTRACT

Background: High-risk Pulmonary Embolism (PE) mortality remains very high. Systemic thrombolysis is effective but carries significant complications and contraindications related to the hemorrhagic risk. Percutaneous thrombectomy using aspiration catheters may be an alternative in patients with a high bleeding risk.

Objective: This study aimed to evaluate the results of catheter-directed thrombectomy using aspiration dedicated catheters in patients with high-risk PE and absolute contraindication to systemic thrombolysis, with specific focus on procedural success, safety, and in-hospital outcomes.

Methods: A prospective study enrolled all consecutive patients diagnosed with high-risk pulmonary embolism and absolute contraindication to systemic thrombolysis, who underwent percutaneous pulmonary thrombectomy using dedicated aspiration catheters. The study documented the effectiveness and complications of the procedure, as well as patient outcomes at discharge and during the follow-up period.

Results: Thirteen patients underwent percutaneous pulmonary thrombectomy using aspiration dedicated catheters. The procedure was successful for all patients, resulting in hemodynamic and respiratory improvement within the first 24 h. No deaths attributable to cardiovascular or respiratory causes occurred during admission or follow-up. Furthermore, no serious adverse events or complications were reported during the procedure or hospitalization.

Conclusions: Percutaneous pulmonary thrombectomy with dedicated aspiration catheters in patients with high-risk pulmonary embolism and contraindications to systemic thrombolysis was associated with excellent clinical results and low rate of complications.

1. Introduction

Pulmonary Embolism (PE), is the third most common acute cardiovascular syndrome, exceeded only by acute myocardial infarction and acute stroke [1,2]. In patients diagnosed with high-risk PE, in-hospital mortality ranges from 30 % to even higher rates [3,4].

The overall mortality of PE has decreased in recent years, attributed to earlier diagnosis, treatment standardization, the introduction of Pulmonary

* Corresponding author at: La Paz University Hospital, Paseo de la Castellana, 261 28046 Madrid, Spain.
E-mail address: daniel.tebar.m@gmail.com (D. Tébar).

http://dx.doi.org/10.1016/j.carrev.2024.06.020
Received 26 January 2024; Received in revised form 25 May 2024; Accepted 26 June 2024
Available online xxxx

Embolism Response Teams (PERT), and multidisciplinary patient management. However, this reduction in mortality has not been reflected in the prognosis of high-risk patients [5]. This discrepancy can be explained by the rapid onset of the disease, the morbidity of the patients presenting it, and the underutilization of thrombolytic therapies, even in patients with indications according to clinical guidelines [6,7].

To enhance the treatment of these patients, dedicated percutaneous mechanical aspiration catheters designed for PE treatment have been developed and incorporated into clinical practice in recent years. These devices, similar to other catheters used in percutaneous interventions, have been adapted, increasing their size (currently up to 24 French (Fr)) and improving navigability, thus achieving the rapid extraction of large amounts of thrombus from the pulmonary arteries. The primary advantage of aspiration catheters over other devices used in PE is their ability to remove the thrombus and improve the patient's clinical condition without the need for any fibrinolytic therapy, which has led to excellent results with a low rate of major bleeding complications in the studies published to date [8–11].

There is evidence of the efficacy and safety of dedicated aspiration catheters in high-risk PE. However, the outcomes of these types of catheters in patients with high-risk PE and absolute contraindications for systemic thrombolysis have not been studied [8].

In this article, we present the results obtained in the treatment of high-risk PE in patients with absolute contraindications for systemic thrombolysis using aspiration catheters in a highly experienced center supported by a PERT team.

2. Methods

2.1. Study design

We conducted a prospective single-center registry at a high-volume hospital with a PERT team, including consecutive patients diagnosed with acute high-risk pulmonary embolism and absolute contraindication to systemic thrombolysis treatment from April 1, 2022, to August 31, 2023 ($n = 13$), on whom we performed the percutaneous mechanical aspiration thrombectomy procedure using a dedicated catheter.

All patients diagnosed with high-risk PE and contraindication to systemic thrombolysis, in whom the PERT team decided on interventional treatment, were included. The only exclusion criterion was out-of-hospital cardiac arrest.

2.2. Protocol: organization, diagnosis, treatment, hospitalization, and outpatient follow-up

All patients undergoing percutaneous thrombectomy followed the protocols established by the PERT team and were presented and discussed by team members.

The diagnosis was made using Computed Tomography Pulmonary Angiogram (CTPA) when possible. High-risk stratification was carried out following European guidelines [12].

Due to the absolute contraindications to systemic thrombolysis, none of the patients received systemic thrombolytic therapy before the percutaneous aspiration thrombectomy.

After the procedure, all patients were admitted to the Intensive Care Unit (ICU) or the Acute Cardiologic Care unit (ACCU), where laboratory tests were conducted within the next 24 h, including lactate, hemoglobin, coagulation profile, renal function, and cardiac biomarkers (high-sensitivity Troponin I, N-terminal pro-brain natriuretic peptided (NT-proBNP)). Following initial monitoring and care in the ICU or the ACCU, patients were transferred to a hospital ward under the Venous thromboembolic Diseases Unit. Before discharge, all patients underwent a follow-up transthoracic echocardiogram.

Upon discharge, all patients were scheduled for follow-up appointments with healthcare providers from the Venous thromboembolic Diseases Unit, during which their clinical status and functional class were evaluated. Hypercoagulability studies and follow-up assessments, including transthoracic echocardiography and pulmonary artery CT angiography, were conducted six months after hospital discharge.

3. Results

3.1. Inclusion and baseline characteristics

Between April 1, 2022, and October 1, 2023, 22 patients were admitted with high-risk PE. Of these, 13 (59 %) had an absolute contraindication to systemic thrombolysis and were included in the study. The mean age was 57.77 ± 18.76 years. 53.8 % were male, and 53.8 % were hospitalized at the time of diagnosis (Table 1).

The presence of at least one predictor of PE was present in 84.61 % of the patients: 53.8 % had undergone recent surgery or had a condition associated with immobility, 15.4 % were in the third trimester of pregnancy and 38.5 % had active cancer. None had a personal history of Venous thromboembolic (VTE) or any known coagulopathy.

The diagnosis of PE occurred within the first 48 h of symptom onset in 92.31 % of the patients. Syncope was the most frequent initial sign (69.2 %), and 38.5 % of those patients experienced potentially traumatic brain injury (TBI) without any evidence of intracranial bleeding.

In three patients (23.08 %), PE presented as an in-hospital cardiac arrest (IHCA). Of these three patients, one underwent thrombectomy during cardiac arrest, with restoration of spontaneous circulation after aspiration thrombectomy, and in two patients, blood flow was restored before thrombectomy by implanting a peripheral veno-arterial extracorporeal membrane oxygenation (VA-ECMO) device in the interventional cardiology lab, followed by immediately aspiration thrombectomy.

Excluding patients who presented with IHCA, the mean baseline systolic blood pressure (SBP) at diagnosis was 78.5 ± 11.8 mmHg. 84.6 % required vasopressors (norepinephrine) before the procedure (mean 1.66 μg/kg/min, median 1 μg/kg/min). The mean heart rate at diagnosis was 121.5 ± 18.4 bpm, and the initial baseline saturation was

Table 1
Baseline characteristics. VTE: venous thromboembolism; TBI: traumatic brain injury; ECMO: extracorporeal membrane oxygenation.

Baseline patient characteristics	
Age (years)	57.77 (18.76)
Sex	
Female (%)	7 (53.84 %)
PE predictors	11 (84.61 %)
Recent surgery/inmobilization (%)	7 (53.84 %)
Active cancer (%)	5 (38.46)
Past VTE (%)	0 (0 %)
Coagulopathy (%)	0 (0 %)
Systemic thrombolysis contraindication	100 %
TBI (%)	5 (38.46 %)
Recent surgery (%)	7 (53.84 %)
Other (%)	1 (7.69 %)
Times (hours)	
Symptoms to diagnosis (h)	10.46
Diagnosis to Thrombectomy (h)	14.85
Vital sign (at diagnosis)	
Cardiac arrest (%)	3 (23.08 %)
Mean systolic blood pressure (mmHg)	78.5 (11.84)
Mean heart rate (bpm)	121.5 (18.45)
Required vasopresors (%)	11 (84.61 %)
Mean noradrenaline doses (μg/kg/min)	1,66 (2.38)
ECMO (%)	2 (15.38 %)
Basal O2 saturation (%)	86.3
Baseline laboratory results	
Hb (g/dL)	12.81
Platelets (x 10^3/μL)	266.69
Creatinine (mg/dL)	0.86
Peak Lactate (mmol/L)	6,75
Peak High-sensivity Troponin I (ng/L)	12,924.38
Peak NT-proBNP (pg/mL)	4753.00

86.3 %, with all patients requiring supplemental oxygen therapy or mechanical ventilation.

The mean initial lactate level was 6.7 mmol/L (median 5.2 mmol/L). The mean peak value of high-sensitivity troponin I was 12,924.4 ng/L (median 3520 ng/L), and the mean peak value of NT-proBNP was 4753 pg/mL.

During the diagnosis, all patients were found to have thrombi in both the left and right pulmonary arteries. Additionally, all patients showed severe right ventricular dysfunction and dilation on echocardiography conducted prior to the procedure. The invasively measured pulmonary artery systolic pressure (PASP) during the procedure was 56.7 mmHg.

The mean time from diagnosis to thrombectomy procedure was 14.85 h.

3.2. Procedure

The procedural characteristics are detailed in Table 2.

All patients underwent the procedure in the interventional cardiology laboratory. In patients who did not experience IHCA, the procedure was performed under conscious sedation.

In all patients, the access site was the femoral vein, typically on the right side (84.61 %), guided by vascular ultrasound.

Unfractionated heparin (100 U/kg) was used for anticoagulation during the procedure, regardless of the type of anticoagulation previously administered.

Three different types of aspiration dedicated catheters were used. In the majority of cases (76.92 %), the Triever 24 catheter (FlowTriever System, Inari Medical, Irvine, CA, USA) was used without the need for nitinol disks. In 2 instances (15.38 %), the procedure was performed with the Penumbra system (Penumbra Inc., Alameda, CA, USA) 8F catheter, and in one case (7.69 %), with the Penumbra 12F catheter.

All procedures were successful, achieving thrombus extraction associated with hemodynamic and respiratory improvement without experiencing severe complications in the first 24 h (Table 3).

No patient required local or systemic thrombolysis, surgery, or circulatory support during or after the procedure. One patient (7.69 %) had mild self-limited hemoptysis in the procedure room, which did not interfere with the normal course of the procedure. No other complications occurred during the procedure, including hemodynamic instability requiring circulatory support, worsening respiratory status, vascular complications, cardiac complications, or arrhythmias.

3.3. ICU and hospitalization

The overall survival rate was 92.31 %. There were no deaths due to cardiovascular, respiratory causes, or complications of the procedure. The cause of death of the one patient who did not survive (7.69 %) was brain death secondary to cerebral hypoxia during the initial cardiac arrest.

All patients exhibited improved hemodynamics and respiratory status 24 h post-procedure. Within this group, 76.92 % did not require vasopressors at this time. In the remaining 23.08 %, vasopressor doses had been reduced by over 75 % compared to pre-procedure levels, with all patients requiring less than 0.2 μg/kg/min in all cases. The average lactate level 24 h after the procedure was 1.38 mmol/L (median 1 mmol/L), with an 80 % decrease compared to before the intervention (6,75 mmol/L).

Respiratory improvement occurred in 100 % of cases. 92.31 % of patients had a PaO2/FiO2 ratio greater than 300 at 24 h after the procedure.

During hospitalization, no major complications related to access were detected. No patient had intracranial bleeding, access-related bleeding or other organ bleeding.

Hemoglobin (Hb) measurements 24 h after the procedure showed an average reduction of 2.04 ± 0.77 g/dL compared to admission laboratory values (Hb 12.81 g/dL at admission and Hb 10.77 g/dL at 24 h, a 15.93 % reduction). This value remained stable during the rest of the hospitalization (Hb at discharge 10.93 g/dL), and no active bleeding source was found in any case. Four patients (30.77 %) received at least one unit of packed red blood cells during hospitalization (with an average of 2 units per patient). Three of these patients (75 %) had presented with IHCA, and in two out of the four (50 %), the transfusion was carried out following the hospital's protocol for VA-ECMO implantation. Regarding renal function, there was an improvement in the average creatinine levels at 72 h (Cr 0.58 mg/dL) compared to admission levels (0.86 mg/dL), with a 32.56 % reduction. Two patients who initially presented with IHCA (15.38 %) required continuous extrarenal depuration therapy, with normalization of renal function at discharge. All patients were discharged with renal function within normal ranges (average Cr 0.69 mg/dL).

Echocardiography before discharge (Table 4) showed a normal-sized and functioning right ventricle in 58.33 % of patients. In pathological echocardiograms, right ventricular dilation (41.66 %) was more frequent than right ventricular dysfunction (25 %), and it was often mild to moderate in both cases. In all cases, echocardiography showed improvement compared

Table 2
Procedural characteristics. F: Frenchs.

Procedural characteristics	
Device used	
Flowtriever system (%)	76.92
Penumbra 8F (%)	15.38
Penumbra 12F (%)	7.69
Characteristics of the procedure	
Success (%)	100
Mortality (%)	0
Major complications (%)	0
Duration (min)	76.54
Contrast (mL)	135.60
Radiation dose (mGy)	661.54
Blood aspirated (mL)	337.65

Table 3
Complications encountered during the procedure and the hospitalization.

Complications	
Procedural complications	
Access related complications (%)	0
Bleeding complications (%)	0
Hemodynamic worsening (%)	0
Respiratory worsening (%)	0
Cardiac arrest (%)	0
In-Hospital complications	
All-cause mortality (%)	7,69
Cardiovascular/respiratory mortality (%)	0
Hemodynamic worsening (%)	0
Respiratory worsening (%)	0
Access related complications (%)	0
Major bleeding (%)	0
Minor bleeding (%)	23.08
Acute renal failure (%)	0

Table 4
Patient characteristics at discharge. PSAP: pulmonary systolic arterial pressure; ICU: intensive care unit.

Patient characteristics at discharge	
Echocardiography	
Normal right ventricle (%)	58.33
Dilated right ventricle (%)	41.6
Dysfunctional right ventricle (%)	25
Respiratory worsening (%)	0
PSAP (mmHg)	31
Clinical	
Need for supplemental oxygen therapy (%)	0
Median length of ICU (days)	2
Median lenght of hospitalization (days)	10
Laboratory	0
Average Creatinine (mg/dL)	0.69
Average hemoglobin (g/dL)	10.93
Average lactate levels (mmol/L)	0.8

to the one performed before the procedure. The estimated pulmonary artery systolic pressure (PASP) by echocardiography at discharge was 31 mmHg.

Low molecular weight heparin was used for in-hospital anticoagulation in 92.31 % of cases. Direct-acting anticoagulants (Rivaroxaban) were used in only one patient (7.69 %) who had been taking it prior to admission. There was no need to discontinue anticoagulation in any patient during hospitalization.

The median length of stay in the ICU was 2 days (1–34), with two patients (15.38 %) who initially presented with IHCA requiring a stay longer than 7 days. After ICU admission, patients were transferred to a general hospital ward without the need for intermediate care unit admission.

The median length of hospital stay (including ICU and general ward) was 10 days (2–90). One patient required an extended hospital stay (90 days), some of which took place in a functional rehabilitation center.

All patients were discharged home without the need for supplemental oxygen therapy and with therapeutic doses of anticoagulation.

3.4. Follow-up

A mean follow-up of 12 months per patient has been conducted. The 30-day survival rate from discharge was 100 %, and no patient required readmission for a new PE or its complications.

Out of the 12 patients who survived after discharge, 11 patients (91.67 %) are still alive. The only death occurred 4 months after hospital discharge due to stage IV lung carcinoma in a palliative care situation.

No patient has experienced readmission for a new PE or any other cardiovascular cause during the entire follow-up. Eight patients have undergone a follow-up pulmonary artery AngioCT without evidence of residual thrombus. The same eight patients underwent a follow-up echocardiogram. Among those with a normal echocardiogram at discharge, there were no observed changes. However, in patients with a pathological echocardiogram at discharge, ventricular dilation and function improved by at least one grade, accompanied by an approximate 20 % improvement in estimated PASP (from 31 mmHg at discharge to 25 mmHg during follow-up). No patient shows signs of developing chronic thromboembolic pulmonary hypertension.

4. Discussion

This is the first registry focused on patients with high-risk PE and contraindications for systemic thrombolysis who underwent percutaneous pulmonary thrombectomy using a dedicated aspiration catheter.

Over the past few decades, there has been significant improvement in the prognosis of patients with PE. However, this improvement has not been consistent across all risk groups. Most studies and registries estimate the in-hospital mortality of high-risk PE to be around 30 % or even higher [4], a figure that has changed little in the last decades since the introduction of systemic thrombolysis treatment [5]. Several factors may explain this lack of improvement.

Firstly, the lethality of the disease: High-risk PE often causes an obstructive shock that typically occurs suddenly, leading to death before receiving hospital care. When it occurs in the hospital, delayed diagnosis can result in death before initiating the recommended therapeutic measures.

Secondly, the patient comorbidities: High-risk PE frequently occurs in patients with significant comorbidities. Recent major surgery, severe trauma, active cancer, prolonged hospitalization, and other critical conditions are directly associated with high-risk PE. It is common for patient mortality to result not directly from PE but from associated morbidity.

Lastly, the use of thrombolytic treatment: Since the 1970s, numerous studies have demonstrated the effectiveness of systemic thrombolysis in treating high-risk PE compared to anticoagulation alone, [6,7] leading to its position as the treatment of choice for high-risk PE in European and American guidelines. However, the use of this therapy has significantly declined since the 1990s [6,7]. Two main reasons have driven this shift. On one hand, the adverse effects of systemic thrombolysis: Despite its high efficacy, systemic thrombolysis is associated with around 10 % major bleeding and 2–5 % intracranial or fatal hemorrhage [13,14]. On the other hand, the prevalence of contraindications for systemic thrombolysis in high-risk PE patients, estimated to be over 50 % in different studies, also played a significant role. These contraindications often stem from underlying conditions such as recent surgeries, advanced active cancers, recent severe illnesses, etc. [7]

This has led to most high-risk PE patients not receiving appropriate treatment, which, as confirmed in studies, increases mortality compared to optimal treatment [7]. In this context, we believe that dedicated aspiration catheters offer a safe alternative for these patients, as evidenced by studies published to date [8–11]. These devices allow high-risk PE patients to receive highly effective treatment, which they could not receive without the existence of these devices, as they cannot undergo fibrinolytic treatment. Moreover, the devices are associated with a low rate of hemorrhagic complications, allowing their safe use even in patients at higher risk of bleeding.

All patients included in our study were diagnosed with high-risk PE and had contraindications for fibrinolytic treatment. Percutaneous thrombectomy with a dedicated aspiration catheter was used as a low hemorrhagic risk alternative to systemic thrombolysis.

In general, our study population was at high risk, not only due to the severity of PE but also due to associated comorbidities. The patients had overall poor hemodynamic status, requiring vasopressors in most cases, and signs of hypoperfusion. Furthermore, most included patients had recent surgeries, active cancer, or prolonged cardiopulmonary resuscitation, all of which are potentially pro-hemorrhagic factors. However, the procedure was successful in all patients, resulting in immediate hemodynamic improvement and aiding their recovery from unstable hemodynamic situations or shock without the need for thrombolysis or circulatory support. Most patients did not require vasopressors 24 h post-procedure, and their analytical markers of hypoperfusion showed significant improvement. Importantly, noticeable respiratory enhancement was observed, with the majority of patients demonstrating low supplemental oxygen requirements within the first 24 h. Furthermore, the successful removal of the thromboembolism causing the PE led to sustained hemodynamic improvement throughout their hospital stay, with no worsening that necessitated a new intervention or alternative rescue procedure, and no recurrence of PE during the hospital stay or follow-up.

Mechanical thrombectomy after V-A ECMO implantation was performed in two patients who presented with refractory in-hospital cardiac arrest. V-A ECMO is a very useful tool in this type of patient, achieving instant restoration of flow, reducing the no-flow time associated with poorer neurological outcomes, and providing subsequent circulatory support. In patients with recent ECMO cannulation, systemic thrombolytic therapy is contraindicated due to the high risk of vascular complications, particularly related to the ECMO arterial cannula. In our center, the PERT team decided to perform thrombectomy in both cases, despite ROSC after ECMO implantation, for a primary reason: to remove the thrombi that caused obstructive shock and cardiac arrest, aiming to improve the hemodynamic situation and reduce the required ECMO support time, as complications associated with ECMO are known to increase exponentially the longer the support is needed. In patients supported with ECMO, some considerations must be taken during the procedure to avoid potential complications arising from the combined ECMO-aspiration catheter management [15], but these considerations are manageable by a trained team, and in our cases, no complications occurred.

Clinical improvement was also evident in echocardiography (Fig. 1, Fig. 2), demonstrating a significant enhancement in right ventricular dilation and function post-procedure. In more than half of the patients, right ventricular parameters normalized upon discharge, and these improvements persisted throughout the follow-up, correlating with pulmonary artery systolic pressure (PASP). Similarly, angiographic follow-up revealed the absence of thromboembolism in control AngioCT scans. These findings, along with the favorable clinical situation during the follow-up, support the conclusion that there is no evidence suggesting the presence of chronic thromboembolic pulmonary hypertension in the evaluated patients.

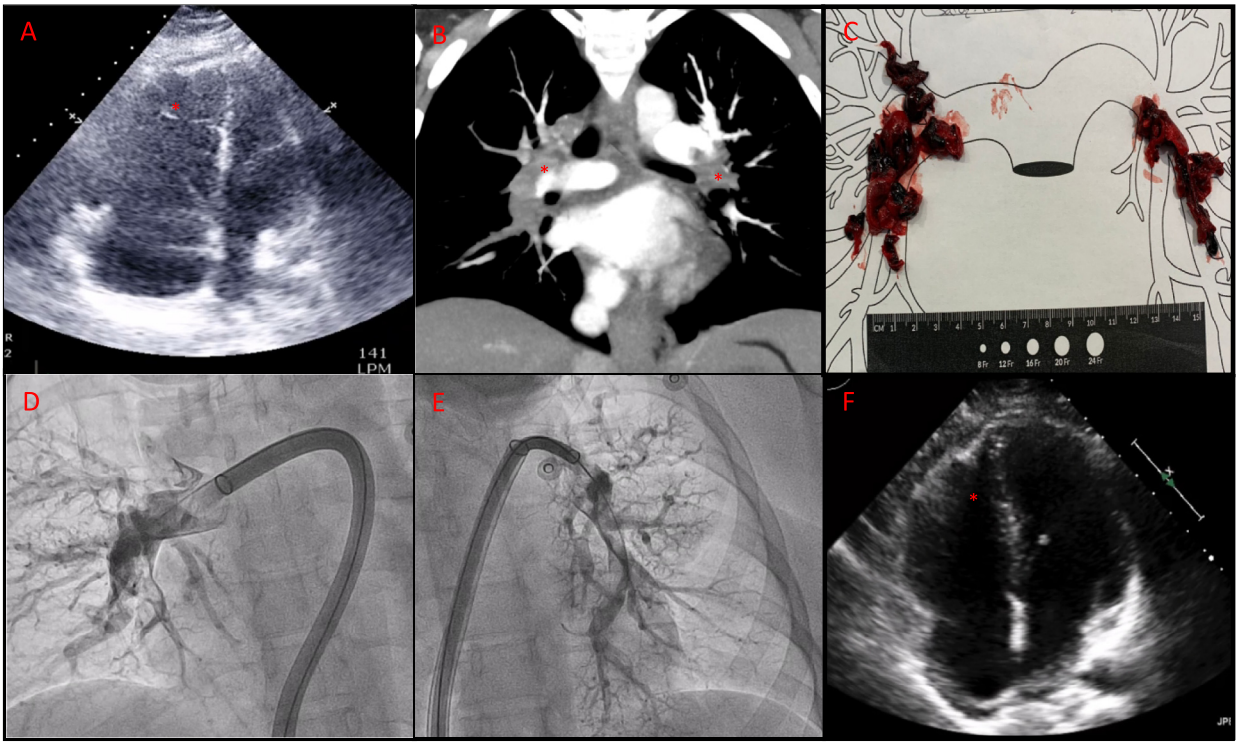

Fig. 1. A: Transthoracic echocardiogram (TTE) showing a severely dilated right ventricle (RV) with severe systolic dysfunction. B: Massive pulmonary embolism by computed tomography pulmonary angiogram. C: Large number of thrombi extracted from pulmonary arteries. D: Post-aspiration angiography of the right pulmonary artery with Triever-24F catheter. E: Post-aspiration angiography of the left pulmonary artery with Triever-24F catheter. F: TTE performed 24 h after the procedure showing normalization of the size and function of the RV.

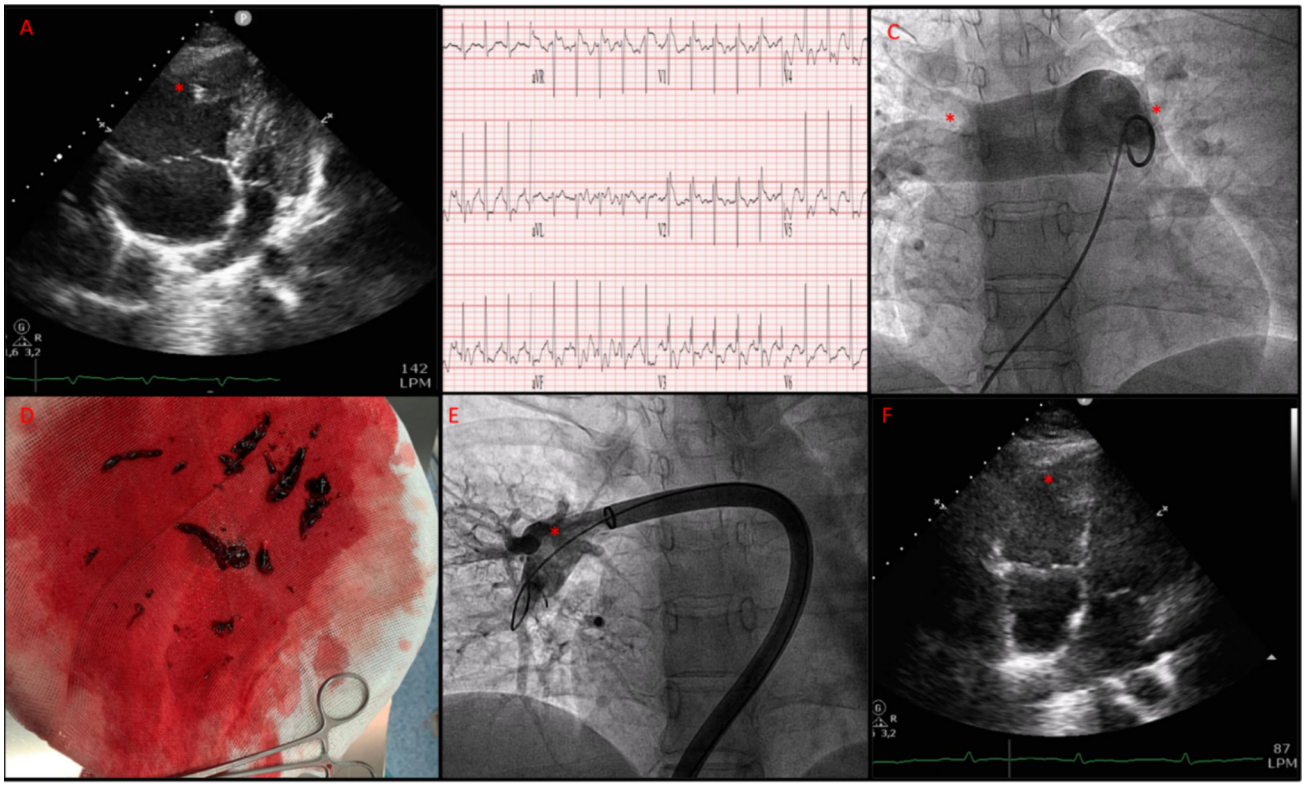

Fig. 2. A: Transthoracic echocardiogram (TTE) showing a severely dilated right ventricle (RV) with severe systolic dysfunction. B: ECG showing sinus tachycardia with signs of right ventricular overload. C: Bilateral pulmonary embolism diagnosed by angiography. D: Large number of fresh thrombi extracted during the procedure. E: Selective angiography of the right pulmonary artery after thrombectomy. Elimination of the proximal thrombus with adequate perfusion of the pulmonary artery. F: TTE performed 12 h after the procedure showing normalization of the size and function of the RV.

Our study further affirms the safety of these devices and the associated procedure. No serious complications related to the procedure or PE were observed. No instances of local, intracranial, or other solid organ bleeding complications were recorded. However, a significant decrease in hemoglobin levels was observed within 24 h after the procedure, although this did not pose a hemodynamic risk, and most patients did not require red blood cell transfusions.

Several factors may explain this decrease in hemoglobin levels. Firstly, there is the blood loss during the aspiration thrombectomy procedure, noting that the blood recovery device from the FlowTriever system (FlowSaver) had not yet been implemented in our country. Secondly, blood loss could be associated with the administration of therapeutic anticoagulation before, during, and after the procedure. A third contributing factor to this decrease was the multifactorial anemia associated with hospitalization for severe illnesses. This included volume overload, minor vascular procedures (such as peripheral and central venous lines, arterial lines), daily blood sample collection, and other contributing factors. It is common for patients admitted with PE to manifest multifactorial anemia during their hospital stay, even in the absence of thrombolysis or thrombectomy therapy.

The median length of stay in the ICU (2 days) was relatively short given the severity of these patients, a factor attributed to the effectiveness of the procedure, facilitating early recovery from shock. The difference between the median (2 days) and the mean (6.3 days) can be explained by two significantly prolonged admissions (more than 3 weeks) that occurred in two patients admitted due to a pulseless cardiac arrest, requiring advanced resuscitation and circulatory support.

The median hospital length of stay (10 days), although prolonged compared to other medical conditions, can be explained not only by the severity of the disease but also by the associated comorbidities of the patients. The mean length of stay (17.84 days) was increased by three prolonged admissions due to the patients' pre-existing comorbidities. The mean length of stay was significantly lower (8.6 days) in patients who were not admitted for another cause at the time of experiencing the PE.

5. Conclusions

In our study, percutaneous pulmonary thrombectomy with dedicated aspiration catheters in patients with high-risk pulmonary embolism and contraindications to systemic thrombolysis was associated with excellent clinical results and an extremely low rate of complications. Further studies are needed, but this therapy appears to be a promising alternative for these complex patients.

CRediT authorship contribution statement

Daniel Tébar: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Alfonso Jurado-Román:** Writing – review & editing, Writing – original draft, Conceptualization. **Santiago Jiménez-Valero:** Writing – review & editing, Writing – original draft, Data curation. **Guillermo Galeote:** Writing – original draft, Validation, Supervision, Data curation, Conceptualization. **Ariana Gonzálvez:** Validation, Supervision, Data curation, Conceptualization. **Borja Rivero:** Validation, Supervision, Data curation, Conceptualization. **Andoni García:** Writing – original draft, Visualization, Validation. **Jose Manuel Añón Elizalde:** Data curation, Conceptualization. **Alicia Lorenzo:** Formal analysis, Data curation. **Carmen Fernández Capitán:** Methodology, Investigation. **Rosario Torres:** Validation, Supervision. **Clara Soto:** Data curation, Conceptualization. **Sergio Alcolea:** Data curation, Conceptualization. **Sandra Rosillo:** Visualization, Validation, Resources. **Juan Caro Codón:** Visualization, Data curation, Conceptualization. **Emilio Arbas:** Validation, Methodology, Investigation. **Fernando Tejera:** Visualization, Validation, Supervision. **Ignacio Plaza:** Visualization, Validation. **Lisardo Boscá:** Visualization, Validation. **Raúl Moreno:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

[1] Wendelboe AM, Raskob GE. Global burden of thrombosis: epidemiologic aspects. Circ Res. 2016;118:1340–7.
[2] Keller Karsten, Hobohm Lukas, Ebner Matthias, Kresoja Karl-Patrik, Münzel Thomas, Konstantinides Stavros V, et al. Trends in thrombolytic treatment and outcomes of acute pulmonary embolism in Germany. Eur Heart J. 21 January 2020;41(4):522–9.
Guijarro R, Trujillo-Santos J, Bernal-Lopez MR, de Miguel-Díez J, Villalobos A, Salazar C, et al. Trend and seasonality in hospitalizations for pulmonary embolism: a time-series analysis. J Thromb Haemost. 21 January 2020;13(1):23–30.
[3] Konstantinides Stavros V, Meyer Guy, Becattini Cecilia, Bueno Héctor, Geersing Geert-Jan, Harjola Veli-Pekka, et al. ESC scientific document group, 2019 ESC guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS): the task force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC). Eur Heart J. 21 January 2020;41(4):543–603.
[4] Calé R, Ascenção R, Bulhosa C, Pereira H, Borges M, Costa J, et al. In-hospital mortality of high-risk pulmonary embolism: a nationwide population-based cohort study in Portugal from 2010 to 2018. Pulmonology. 2024 Feb 1;S2531-0437(23):00200–3. https://doi.org/10.1016/j.pulmoe.2023.11.002. [Epub ahead of print. PMID: 38307782].
[5] Silver Mitchell J, Giri Jay, Duffy Áine, Jaber Wissam A, Khandhar Sameer, Ouriel Kenneth, et al. Incidence of mortality and complications in high-risk pulmonary embolism: a systematic review and Meta-analysis. Journal of the Society for Cardiovascular Angiography & Interventions. 2023;2(1):100548. [ISSN 2772-9303].
[6] Stein PD, Matta F. Thrombolytic therapy in unstable patients with acute pulmonary embolism: saves lives but underused. Am J Med. 2012;125:465–70.
[7] Keller Karsten, Hobohm Lukas, Ebner Matthias, Kresoja Karl-Patrik, Münzel Thomas. Stavros V Konstantinides, Mareike Lankeit, trends in thrombolytic treatment and outcomes of acute pulmonary embolism in Germany. Eur Heart J. 21 January 2020;41(4):522–9.
[8] Silver MJ, Gibson CM, Giri J, Khandhar S, Jaber W, Toma C, et al. Outcomes in high-risk pulmonary embolism patients undergoing flowtriever mechanical thrombectomy or other contemporary therapies: results from the FLAME study. Circ Cardiovasc Interv. 2023 Oct;16(10):e013406. https://doi.org/10.1161/CIRCINTERVENTIONS.123.013406. Epub 2023 Oct 17. PMID: 37847768; PMCID: PMC10573120.
[9] Sista AK, Horowitz JM, Tapson VF, Rosenberg M, Elder MD, Schiro BJ, et al. Indigo aspiration system for treatment of pulmonary embolism: results of the EXTRACT-PE trial. JACC Cardiovasc Interv. 2021 Feb 8;14(3):319–29.
[10] Tu T, Toma C, Tapson VF, Adams C, Jaber WA, Silver M, et al. A prospective, single-arm, multicenter trial of catheter-directed mechanical Thrombectomy for intermediate-risk acute pulmonary embolism: the FLARE study. JACC Cardiovasc Interv. 2019 May 13;12(9):859–69.
[11] Toma C, Bunte MC, Cho KH, Jaber WA, Chambers J, Stegman B, et al. Percutaneous mechanical thrombectomy in a real-world pulmonary embolism population: interim results of the FLASH registry. Catheter Cardiovasc Interv. 2022 Mar;99(4):1345–55.
[12] Konstantinides SV, Meyer G, Becattini C, Bueno H, Geersing GJ, Harjola VP, et al. 2019 ESC guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS). Eur Heart J. 2020 Jan 21;41(4):543–603. https://doi.org/10.1093/eurheartj/ehz40531504429.
[13] Tibbutt DA, Davies JA, Anderson JA, Fletcher EW, Hamill J, Holt JM, et al. Comparison by controlled clinical trial of streptokinase and heparin in treatment of life-threatening pulmonay embolism. Br Med J. 1974 Mar 2;1(5904):343–7. https://doi.org/10.1136/bmj.1.5904.343. PMID: 4594580; PMCID: PMC1633603.
[14] Marti C, John G, Konstantinides S, Combescure C, Sanchez O, Lankeit M, et al. Systemic thrombolytic therapy for acute pulmonary embolism: a systematic review and meta-analysis. Eur Heart J. 2015 Mar 7;36(10):605–14. https://doi.org/10.1093/eurheartj/ehu218. Epub 2014 Jun 10. PMID: 24917641; PMCID: PMC4352209.
[15] Tébar-Márquez D, Juárez V, Arbas E, Rosillo S, Jurado-Román A, Moreno R. Aspectos prácticos de la trombectomía pulmonar mediante aspiración en pacientes soportados con ECMO. REC Interv Cardiol. In-press. doi: . 10.24875/RECIC.M24000455