

The logo for LINIC features the letters 'L', 'I', 'N', and 'C' in a white, sans-serif font, arranged horizontally. The letters are overlaid on a dark blue background with abstract, brush-stroke-like shapes in shades of blue, red, and orange. The 'L' and 'I' are on the left, 'N' is in the center, and 'C' is on the right.

L I N I C

PULMONARY EMBOLISM MANAGEMENT:

*PERCUTANEOUS MECHANICAL
THROMBECTOMY FOR
ACUTE PE*

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Disclosure

- Speaker name:
- JUAN J CIAMPI DOPAZO
- I have the following potential conflicts of interest to report:
 - Consulting for PENUMBRA
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
- I do not have any potential conflict of interest

Indigo Aspiration System

- Intended for the removal of fresh, soft emboli and thrombi from vessels
- Indicated for pulmonary emboli
- Indigo System Components:
 - ENGINE pump
 - Indigo Aspiration Catheter
 - Indigo Separator
 - Aspiration Tubing
 - ENGINE Canister



**One Touch for
Maximum
Aspiration**
Powerful, Deep
Vacuum

**Live Feedback
During
Procedure**
Integrated Clot
Catcher

-29 inHg^a

Easy Setup
Sleek, Simple
Design



Clinical data review

CLINICAL STUDY



CrossMark

Aspiration Thrombectomy for Treatment of Acute Massive and Submassive Pulmonary Embolism: Initial Single-Center Prospective Experience

Juan José Ciampi-Dopazo, MD, Juan María Romeu-Prieto, MD, Marcelino Sánchez-Casado, MD, PhD, Beatriz Romerosa, MD, Alfonso Canabal, MD, PhD, María Luisa Rodríguez-Blanco, MD, and Carlos Lanciego, MD, PhD

ABSTRACT

Purpose: To evaluate the feasibility of aspiration thrombectomy in patients with acute massive or submassive pulmonary embolism (PE).

Materials and Methods: This prospective study analyzed patient demographic data, procedural details, and outcomes in 18 consecutive patients (8 men and 10 women; mean age, 60.1 y; range, 36–80 y), 10 with acute submassive PE and 8 with massive PE, treated with an Indigo Continuous Aspiration Mechanical Thrombectomy Catheter between January 2016 and February 2017. Three patients underwent concomitant systemic fibrinolytic treatment with 100 mg tissue plasminogen activator. Technical success was defined as successful placement of devices and initiation of aspiration thrombectomy. Clinical success was defined as stabilization of hemodynamic parameters; improvement in pulmonary hypertension, right heart strain, or both; and survival to hospital discharge. Complications were also analyzed.

Results: The procedure was considered a technical success in 17 patients (94.4%) and a clinical success in 15 (83.3%). Echocardiography showed significant improvements in right ventricle size ($46.36 \text{ mm} \pm 2.2$ before treatment vs $41.79 \text{ mm} \pm 7.4$ after; $P = .041$), tricuspid annular plane systolic excursion (16 ± 3 before treatment vs 18.57 ± 3.9 after; $P = .011$), and systolic wave (10 ± 2.1 before treatment vs 13.1 ± 3.8 after; $P = .020$). Two patients died of massive PE, and 1 died of submassive PE. Two patients who received systemic fibrinolytic agents experienced intracranial bleeding, and abdominal bleeding developed in 1.

Conclusions: Aspiration thrombectomy is a feasible option for the treatment of acute massive or submassive PE in patients with hemodynamic compromise or right ventricular dysfunction.

Number of patients treated in our experience

Period : **January 2016 and September 2019**

- Patients enrolled: 42
- Age ≥ 18 yrs presenting within 7 days of onset symptoms of acute massive and submassive pulmonary embolism (PE) who had computed tomography findings compatible with proximal PE.
 - **Massive PE** was defined as acute PE with sustained hypotension (systolic blood pressure < 90 mm Hg for ≥ 15 min or requiring inotropic support).
 - **Submassive PE** was defined as acute PE causing right ventricular dilatation and hypokinesia confirmed on echocardiography without hypotension.
- Radiologically, proximal PE was defined as a filling defect in **at least 1 main or lobar pulmonary artery on CT**

Risk stratification

American Heart Association (AHA)

AHA by type	Clinical presentation
Massive	Acute pulmonary embolism with sustained hypotension (less 90 mm/Hg systolic) <i>for 15 min or requiring inotropic support.</i>
Submassive	Systolic pressure more than 90 mm/Hg and either: <i>RV dysfunction by CT, ECG, or laboratory (BNP or ProBNP elevation).</i> <i>Myocardial infarction.</i>
Low risk	Absence of hypotension, RV dysfunction, Myocardial necrosis.

European Society of Cardiology (ESC)

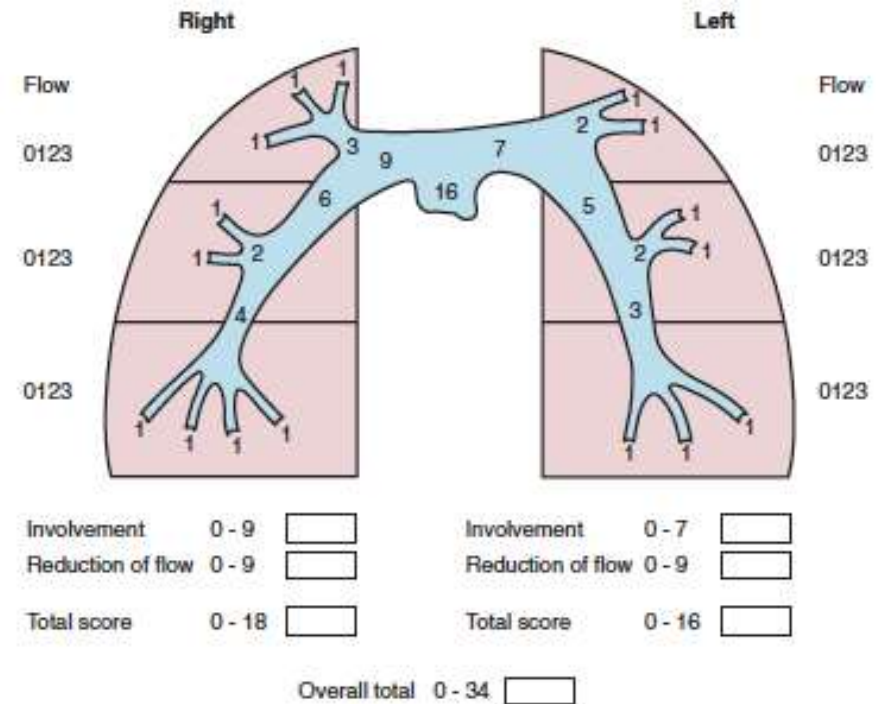
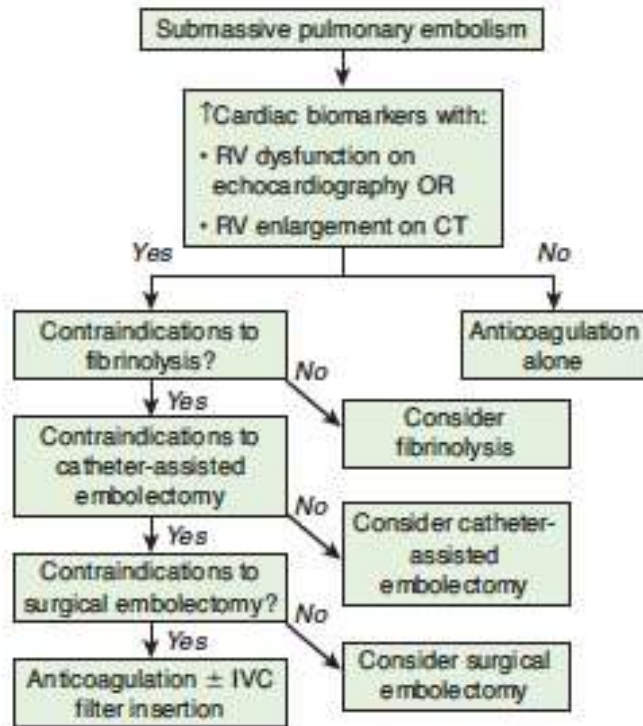
PESI- Severity index

PESI parameters :

- Age
- Sex
- Systolic blood pressure
- Pulse rate
- Respiratory rate
- Chronic heart disease
- Chronic pulmonary disease

Mortality risk	PESI class III-V	Shock or Hypotension	RV dysfunction by imaging	Elevated Biomarkers (Example BNP)
High	Yes	Yes	Yes	Yes
Intermediate - High	Yes	No	Yes	No
Intermediate - Low	Yes	No	Yes	No
Low	No	No	Not evaluated	No

Miller Score – During thrombectomy



Demographic data

VARIABLE	CATEGORY	COUNTING	PERCENTAGE
Sex	Men	19/42	45.23 %
Age		Mean 61.2 (29-81 y)	
Obesity	Yes	9/42	21.42 %
Immobilization	Yes	15/42	35.71 %
Previous PE	Yes	2/42	4.76 %
Submassive PE	Yes	26/42	61.90 %

- Original research article, **JVIR 2018**.
- Scientific presentation. Lisbon, **CIRSE 2018**.
- Scientific presentation at Spanish Society of Interventional Radiology Congress, **SERVEI 2019**.
- Scientific presentation at Spanish Critical Medicine Society Annual Congress, **SEMICYUC 2020**.

Demographic data

VARIABLE	CATEGORY	COUNTING	PERCENTAGE
Symptomatic days previous thrombectomy	1 - 2 days	27/42	64.28 %
Dyspnea	-----	35/42	83.33%
Right and left pulmonary artery afectation	-----	40/42	95.23%
NT- proBNP	-----	Mean 6785.6 Range 78-35000 pg/ml	-----

Clinical and echocardiographic findings

VARIABLE	Pre-Thrombect	Post-Thrombect	P value
Right ventricle diameter (mm)	46.34 ± 4.71 mm	42.13 ± 6.37 mm	0,020
TAPSE	15.29 ± 3.63 mm	18.49 ± 3.98 mm	0,002
S'wave	9.45 ± 1.93 cm/s	11.9 ± 3.26 cm/s	0,007
PASP	50.63 ± 13.80 mmHg	48.81 ± 19.14 mmHg	0,256
PaO ₂ /FiO ₂	186.87 ± 127.9	287.58 ± 97.348	0,001

PaO₂/FiO₂ = ratio of arterial oxygen partial pressure to fraction of inspired oxygen; PASP = pulmonary artery systolic pressure; TAPSE = tricuspid annular plane systolic excursion.
*Significant difference between time points at $P < .05$.
†Significant difference between time points at $P < .01$

Use of tPA

VARIABLE	CATEGORY	COUNTING	PERCENTAGE
Local tPA (inside thrombus)	Less than 10 mg.	5/42	11.9 %
Systemic tPA (IV)	100 mg.	6/42	14.28 %

Complications

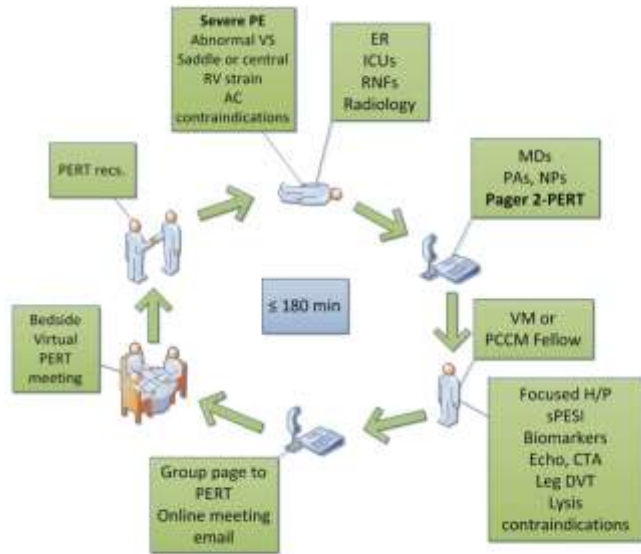
VARIABLE	CATEGORY	COUNTING	PERCENTAGE
Hemorrhage Complications *	Yes	6/42	14.28 %
Systemic Hypotension after thrombectomy @	Yes	11/42	26.19 %
Death #	Yes	8/42	19.04 %

*Intracranial bleeding 3 patients.

@ Systemic hypotension and respiratory compromise after thrombectomy is statistically associated with risk of death.

3 during thrombectomy procedure.

Fig. 1. PERT activation process



Initiation of a Multidisciplinary, Rapid Response Team to Massive and Submassive Pulmonary Embolism

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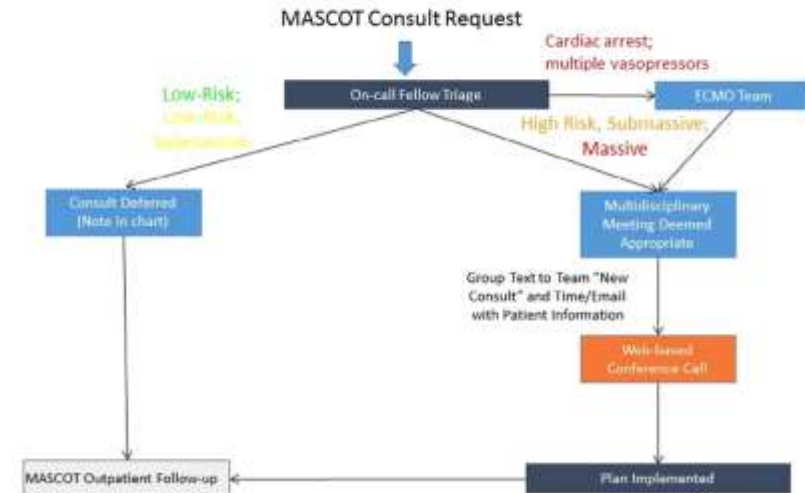
Pulmonary embolism (PE) can result in rapid clinical decompensation in many patients. With increasing patient complexity and advanced treatment options for PE, multidisciplinary, rapid response teams can optimize risk stratification and expedite management strategies. The Massive And Submassive Clot On-call Team (MASCOT) was created at our institution, which comprised specialists from cardiology, pulmonology, hematology, interventional radiology, and cardiac surgery. MASCOT offers rapid consultation 24 hours a day with a web-based conference call to review patient data and discuss management of patients with high-risk PE. We reviewed patient data collected from MASCOT's registry to analyze patient clinical characteristics and outcomes and describe the composition and operation of the team. Between August 2015 and September 2016, MASCOT evaluated 72 patients. Seventy of the 72 patients were admitted to our institution, accounting for 32% of all patients discharged with a primary diagnosis of PE. Average age was 62 ± 17 years with a female predominance (63%). Active malignancy (31%), recent surgery or trauma (21%), and recent hospitalization (24%) were common. PE clinical severity was massive in 16% and submassive in 83%. Patients were managed with anticoagulation alone in 65% (n = 46), systemic fibrinolysis in 11% (n = 8), catheter-directed therapy in 18% (n = 13), extracorporeal membrane oxygenation in 3% (n = 2), and an inferior vena cava filter was placed in 15% (n = 11). Thirteen percent (n = 9) experienced a major bleed with no intracranial hemorrhage. Survival to discharge was 89% (64% with massive PE and 93% with submassive PE). In conclusion, multidisciplinary, rapid response PE teams offer a unique coordinated approach to patient care. © 2017 Elsevier Inc. All rights reserved. (*Am J Cardiol* 2017;120:1393–1398)



A pulmonary embolism response team (PERT) approach: initial experience from the Cleveland Clinic

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Mechanical thrombectomy technique

- **PE symptoms/CT confirmation**
- **Massive - Submassive PE**
 - A filling defect in at least one main or lobar pulmonary artery
- *For massive*
 - ✓ Clinical signs : systolic BP less than 90 mmHg at least 15 minutes
 - ✓ Inotropic support.
- *For submassive*
 - ✓ RV dysfunction with hypokinesis on echocardiography.
- **Therapeutic anticoagulation regimen**
- **Thrombectomy with aspiration device and local fibrinolysis (low dose)**

Mechanical thrombectomy technique

1. Access through common femoral vein. Catheterize the main pulmonary artery by using a 5F angled pigtail diagnostic catheter.
2. Inject contrast media at < 8 cc/s to demonstrate filling defects.



ECG information: VD dilated/low ventricular ejection fraction/ventricle strain



Diagnostic pulmonary angiography

Mechanical thrombectomy technique

3. Place an 8F 115 cm Indigo Aspiration Catheter (CAT8XTORQ115) inside the thrombus through an 8F 65 cm Destination[®] introducer sheath (Terumo).



CAT8 Tip Shapes



Straight

Available in 85 cm



TORQ

Available in 85 cm



XTORQ

Available in 115 cm

Angle: 20–45°
Tip length: 1 cm

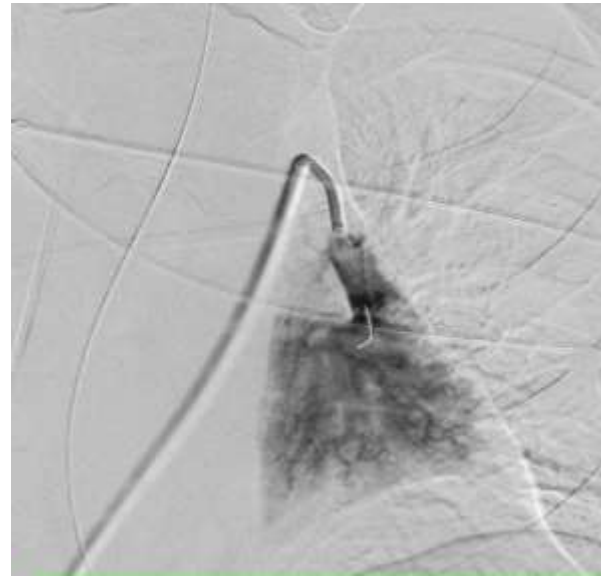
Angle: 20–45°
Tip length: 1.8 cm



8 F 65 cm Destination introducer sheath[®]

Mechanical thrombectomy technique

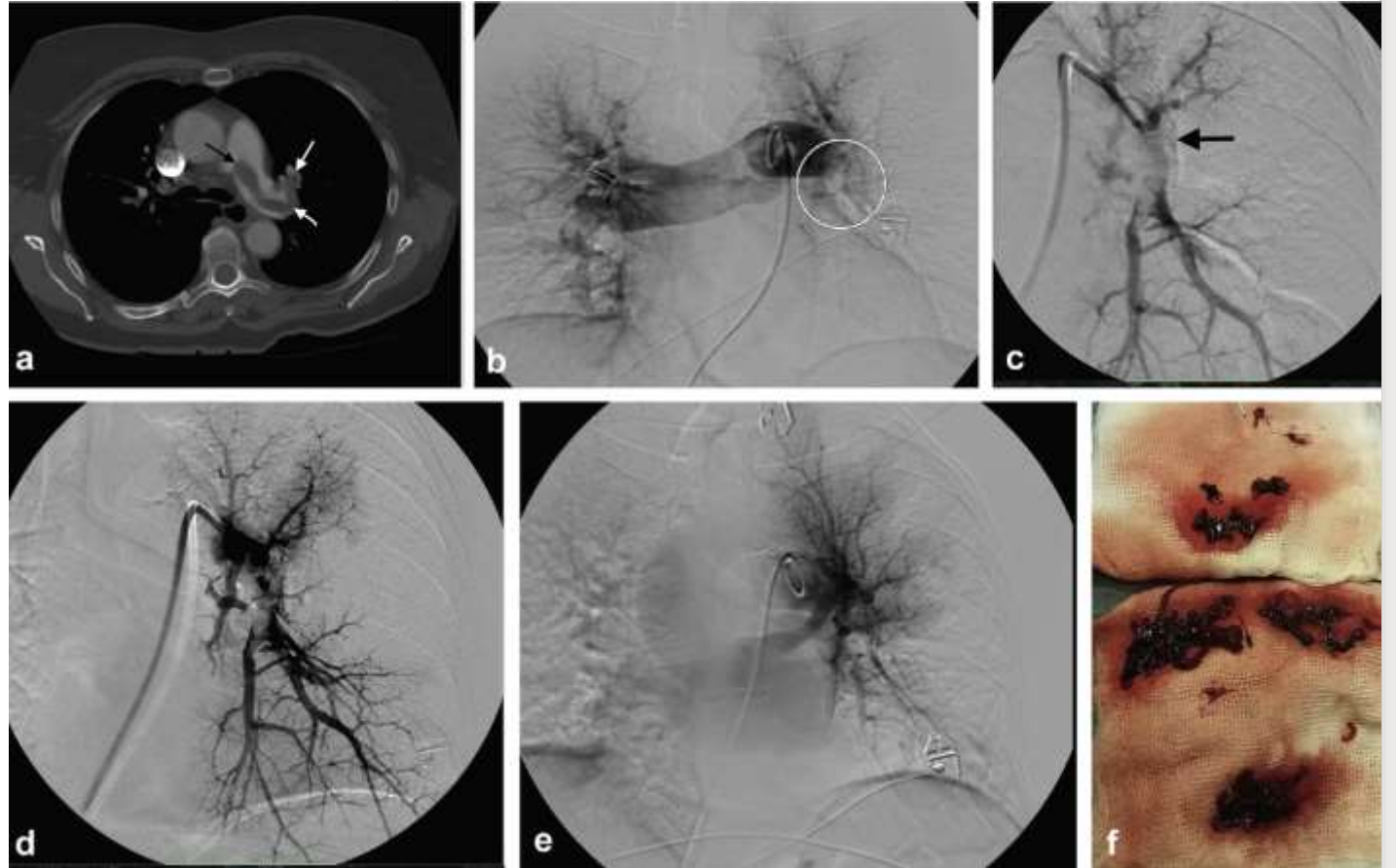
4. Perform direct aspiration first-pass technique with the aim to attach large thrombus burden at the tip of CAT8.
5. Utilize a Separator 8 to clean thrombus occluding tip of CAT8 allowing continuous aspiration.



6. Occasionally, a 100-cm C2 catheter can be used with a 0.035-inch stiff hydrophilic guide wire to facilitate access to the lobar arteries.

Mechanical thrombectomy technique

- Normally patients with massive and submassive PE included central PE thrombus demonstrated by CT (at least one lobar artery)
- Never segmental arteries





Goldhaber SZ (Chest 114:1237-1238, 1998) has suggested that catheter interventions should be considered in patients with acute PE with RV dysfunction, while systemic arterial pressure is preserved.

The NEW ENGLAND
JOURNAL of MEDICINE

ORIGINAL ARTICLE

Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism

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THANK YOU