CLINICAL STUDY

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

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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 mm ± 2.2 before treatment vs 41.79 mm ± 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.

ABBREVIATIONS

PaO_2/FiO_2 = ratio of arterial oxygen partial pressure to fraction of inspired oxygen, PE = pulmonary embolism, TAPSE = tricuspid annular plane systolic excursion, TPA = tissue plasminogen activator

Acute pulmonary embolism (PE) is the third most common cause of cardiovascular death after myocardial infarction and stroke and is considered the leading cause of preventable death in hospitalized patients (1). Treatment with systemic thrombolysis is effective and decreases mortality, but it is associated with a greater risk of hemorrhagic complications, including a 2%–5% risk of hemorrhagic stroke (2).

Right ventricular dysfunction and hemodynamic instability are strong predictors of poor prognosis in patients with acute PE (2,3). A definitive treatment for right ventricular dysfunction secondary to acute PE has yet to be defined, and

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the use of thrombolytic agents in patients with right ventricular dysfunction but without systemic hypotension remains controversial (3). In these patients, effective early treatment can prevent further deterioration of right ventricular function that can lead to cardiogenic shock (4).

Catheter-directed thrombolysis with directed low-dose thrombolytic infusion has proven efficacious in alleviating right heart strain and pulmonary hypertension in trial populations (5,6). In recent years, growing interest has focused on diverse endovascular strategies for thrombus removal. One promising strategy in patients with massive/submassive PE is the use of continuous aspiration mechanical thrombectomy catheters. The present study aimed to evaluate the feasibility of this approach.

MATERIALS AND METHODS

The institutional review board approved this prospective study. Between January 2016 and February 2017, all consecutive patients aged ≥ 18 years presenting within 7 days of onset of symptoms of acute massive or submassive PE who had computed tomography (CT) findings compatible with proximal PE were eligible for first-line treatment with aspiration thrombectomy. The study included 18 patients (age range, 36–80 y; 8 [44.4%] men), 6 of whom (33.3%) were obese (body mass index > 31 kg/m^2) and 1 of whom (5.5%) had had a previous PE. PE was submassive in 10 patients (55.6%) and massive in 8 (44.4%). The right main pulmonary artery was affected in 17 patients (94.4%), and the left main pulmonary artery was affected in 13 (72%).

Table 1 summarizes patients' personal histories, baseline characteristics, and outcomes. Radiologically, proximal PE was defined as a filling defect in at least 1 main or lobar pulmonary artery on CT. Clinically, acute massive PE was defined as acute PE with sustained hypotension (systolic blood pressure < 90 mm Hg for ≥ 15 min or requiring inotropic support), and submassive PE was defined as acute PE causing right ventricular dilation and hypokinesia confirmed on echocardiography without hypotension (7). Patients with tumor thrombi in the pulmonary arteries were excluded.

Table 1. Personal History, Baseline Characteristics, and Outcome

Variable	Value
Personal history	
Hypertension	10 (55.6)
Dyslipidemia	7 (38.9)
Diabetes mellitus	4 (22.2)
Obesity	6 (33.3)
Smoking	3 (16.7)
Contraceptives	1 (5.6)
Immobilization	4 (22.2)
Prior PE	1 (5.6)
Baseline characteristics	
Male sex	8 (44.4)
Age (y)	
Median	60.1
Interquartile range	36–80
Duration of PE signs/symptoms before thrombectomy	
Median	2
Interquartile range	1–5
Outcome	
Hemorrhagic complications	3 (16.7)
Hospital stay (d)	
Median	10
Interquartile range	14–22
Follow-up (d)	
Median	38
Interquartile range	25–66
Death	3 (16.7)

Note–Values in parentheses are percentages.
PE = pulmonary embolism.

Treatment Procedure and Devices

Common femoral venous access was obtained by placing a 10-cm, 5-F vascular sheath (Terumo, Tokyo, Japan). The main pulmonary artery was catheterized by using a 5-F angled pigtail diagnostic catheter (Cordis, Miami Lakes, Florida), and an initial pulmonary angiogram was obtained with contrast media injected at < 8 mL/s (Fig 1) to demonstrate filling defects. A 115-cm, 8-F continuous aspiration mechanical thrombectomy catheter (Indigo CAT8 XTORQ; Penumbra, Alameda, California) was advanced through a 65-cm, 8-F sheath (Destination; Terumo) to perform mechanical thrombectomy. A direct-aspiration first-pass technique was performed with the aim to attach a large thrombus to the catheter tip by suction and subsequently pull it through the sheath. If the first-pass technique was unsuccessful, a separator wire was repeatedly passed through the thrombus to break it up and allow it to be suctioned through the catheter (8,9). Occasionally, a 100-cm C2 catheter (Terumo) was used with a 0.035-inch stiff hydrophilic guide wire to facilitate access to the lobar arteries; the C2 catheter was then replaced with the 115-cm Indigo CAT8 XTORQ catheter. The procedure was terminated when the interventional radiologist considered that the thrombus had been reduced as far as possible (Fig 1).

At the beginning of the study, 3 patients received concomitant systemic fibrinolytic treatment with 100 mg tissue plasminogen activator (TPA) before thrombectomy. During all thrombolytic infusions, full therapeutic anticoagulation was suspended. Only heparin (300 U/h) was continued. After completion of mechanical thrombectomy, all patients resumed therapeutic parenteral anticoagulation as a "bridge" to oral vitamin K antagonist anticoagulant therapy or low molecular weight heparin except when contraindicated. To prevent further thromboembolic episodes, vena cava filters were also deployed based on patients' individual risk: 3 patients were candidates for vena