



Catheter-directed aspiration thrombectomy with the indigo system for intermediate- and high-risk pulmonary embolism in older patients: preliminary findings from a single-center experience

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PURPOSE

Percutaneous mechanical thrombectomy (PMT) is a promising treatment for pulmonary embolism (PE), especially in older patients at high bleeding risk. This study assessed its safety and efficacy in patients with acute PE aged over 75 years.

METHODS

Using data from the prospective, multicenter China Pulmonary Thromboembolism Registry Study (NCT02943343), this study included all consecutive patients aged > 75 years with confirmed PE who underwent catheter-directed aspiration thrombectomy using the Indigo Aspiration System at the Affiliated Hospital of Jiangnan University between April 2020 and November 2024. The efficacy of PMT included improvements in hemodynamics, vital signs, dyspnea, and cardiac function. The safety endpoints were the incidence of major adverse events and major bleeding.

RESULTS

Of the 673 patients screened, 202 received PMT, and the data of 60 patients were analyzed. After the procedure, heart rate significantly decreased by an average of 4.40 bpm (5.1%, $P = 0.007$) and mean pulmonary arterial pressure significantly improved by 3.40 mmHg (13.3%, $P < 0.001$). At 48 hours post-procedure, N-terminal pro-brain natriuretic peptide (NT-proBNP) levels significantly decreased from 2,102.3 (556.5, 3,772.0) to 898.6 (561.1, 1,670.6) pg/mL ($P < 0.001$) and Modified Medical Research Council dyspnea scores improved from 2.52 ± 1.24 pre-procedure to 1.22 ± 1.03 ($P < 0.001$). Subgroup analysis revealed that patients with a low clot burden also had significant improvements in heart rate, NT-proBNP, and dyspnea score after surgery. No major bleeding occurred within 3 months.

CONCLUSION

PMT is safe and effective for older patients with acute PE. Potential advantages include immediate hemodynamic improvements, significant symptom alleviation, and recovery of right ventricular function, accompanied by minimal adverse events.

CLINICAL SIGNIFICANCE

Percutaneous mechanical thrombectomy is safe and effective in elderly patients with acute pulmonary embolism, including those at high bleeding risk, providing rapid hemodynamic and functional improvement with low major adverse events. Even patients with low clot burden derive clinical benefit.

KEYWORDS

Percutaneous mechanical thrombectomy, pulmonary embolism, older population, right heart function, safety



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Acute pulmonary embolism (PE) remains a leading cause of in-hospital mortality and is the third most common cause of cardiovascular-related death.^{1,2} Conventional treatments for acute PE include anticoagulation and reperfusion treatment, such as systemic thrombolysis, catheter-directed thrombolysis (CDT), percutaneous mechanical thrombectomy (PMT), and surgical embolectomy. For patients with PE at risk of clinical deterioration, systemic thrombolysis and CDT rapidly improve pulmonary perfusion and right ventricular (RV) function, thereby reducing the risk of recurrence and mortality.^{3,4} However, these treatments carry a substantial risk of major bleeding and intracranial hemorrhage. Additionally, thrombolytic therapy is not always effective, underscoring the necessity for alternative treatments.

PMT has shown promise across diverse PE populations. This treatment comprises several techniques, including thrombus fragmentation, rheolytic thrombectomy, rotational thrombectomy, and aspiration thrombectomy, which differ in their mechanisms of thrombus removal. Among these, aspiration thrombectomy removes thrombus through catheter-based suction and can be performed with or without adjunctive thrombolytic therapy. Observational studies have reported positive outcomes for aspiration thrombectomy in the treatment of patients with acute PE.⁵⁻⁸ The primary results of a randomized controlled trial indicated that PMT had lower rates of clinical deterioration and/or bailout and post-procedural intensive care unit (ICU) utilization compared with CDT without increasing the risk of bleeding and mortality.⁹ For patients with intermediate- or high-risk PE, growing evidence demonstrates that PMT combined with anticoagulation is safe and leads to a reduction in the RV-to-left ventricular (LV) ratio and vital sign normalization.¹⁰⁻¹² This intervention could provide rapid improvements in systemic hemodynamics and RV function in select patients. Moreover, as a valid alternative for patients with high bleeding risk, PMT could reduce the burden of mortality related to major bleeding. Nev-

ertheless, research is required to optimize the use of this treatment and define which patients would benefit the most.

Older patients with PE represent a large and unique population worldwide. The older population faces greater risks due to comorbidities, frailty, and polypharmacy, which complicate treatment decisions.¹³ Advanced age is associated with a 40% increase in bleeding risk for every 10-year increment.^{14,15} Despite their high prevalence, older patients are seldom included in clinical trials due to age-related exclusion criteria, leading to a paucity of evidence on their treatment. PMT may offer particular benefits to older patients with PE, especially those with multiple comorbidities and a high bleeding risk. However, data on the safety and efficacy of PMT in such patients are less described. Studies have associated the Supplier details for all equipment and software should be provided after each item in parentheses. This includes the name of the supplier and their location (city and country). For US suppliers, the two-letter state abbreviation is also included (e.g., the supplier details for SPSS software are usually "IBM, Armonk, NY, USA"). with a significant reduction in the RV/LV ratio and a low rate of major adverse events in patients with submassive PE.^{7,8} However, data regarding its use in older patients remain limited. This study aimed to evaluate the safety and efficacy of PMT using the Indigo Aspiration System in older patients with PE and to further investigate its effectiveness in a subgroup with a low clot burden.

Methods

Study design

We performed a single-center analysis using data from the prospective, multicenter China Pulmonary Thromboembolism Registry Study (CURES; NCT02943343).¹⁶ For CURES, consecutive adult patients with a confirmed diagnosis of PE were recruited. We identified all consecutive patients from the CURES database who were enrolled at the Affiliated Hospital of Jiangnan University between April 2020 and November 2024. This constituted a subgroup of 60 patients over the age of 75 years who had received PMT and had complete baseline and postoperative data. For this study, the institutional review board approved the retrospective review of electronic records (approval number: WSHIRB-K-2022004, date: November 28, 2022). Written informed consent was obtained from all participants.

Study procedure

The procedure was mostly performed via common femoral venous access under local anesthesia. An Indigo catheter (Penumbra, Alameda, CA, USA) was advanced over a 0.035-inch guide wire and deployed proximal to the thrombus in the lobar artery of the right or left pulmonary artery. Once engaged, the clot was extracted via vacuum or manual aspiration. The catheter was then removed, cleared of the aspirated thrombus, and reinserted if necessary. The procedure was repeated as needed based on the thrombus amount and improvement in distal flow on repeat angiography. Two sizes of Indigo catheter (8F and 10F) were available—a single or a combination can be selected based on the vessel diameter and thrombus location during the procedure. Appropriately sized introducer sheaths were used according to the selected aspiration catheter. An invasive hemodynamic assessment was performed before the procedure and 5 minutes after the removal of the aspiration catheter. Conscious sedation was used selectively when clinically indicated. All procedures were performed by physicians with ≥ 5 years of interventional procedural experience. Low-molecular-weight heparin in a weight-adjusted dose was continued for 24–48 hours depending on the patient's clinical status, and the anticoagulation drug administered to each patient at discharge was selected at the investigator's discretion.

Definitions and outcomes

The RV/LV ratio was measured using multiplanar reformatted reconstructions from computed tomography (CT) angiographic images to assess the short axis of each ventricle.¹⁷ Clot burden was quantified through CT angiography using the Qanadli score.¹⁸ For subgroup analyses, patients were stratified into low ($< 25\%$) and high ($\geq 25\%$) clot-burden groups using the median Qanadli score as the cutoff. Procedural time was defined as the interval between vascular access and final catheter removal at the completion of thrombectomy. The simplified Pulmonary Embolism Severity Index (sPESI) score was calculated based on risk factors such as age > 80 years, a history of cancer or cardiopulmonary disease, heart rate ≥ 110 beats/min, systolic blood pressure < 100 mmHg, and oxygen saturation $< 90\%$.¹⁹ Bleeding risk was assessed using the IMPROVE score.²⁰ Dyspnea was evaluated using the Modified Medical Research Council (mMRC) dyspnea scale.²¹ Acute kidney injury (AKI) was defined as a serum creatinine increase of ≥ 26.4 mmol/L

Main points

- Percutaneous mechanical thrombectomy is safe and effective in acute pulmonary embolism patients over 75 years old.
- No major bleeding occurred post-procedure in this high-risk fragile cohort.
- Patients with low clot burden also experienced significant clinical benefits.

or $\geq 50\%$ from baseline within 48 hours of surgery.²² Major adverse events were defined as any device-related death, major bleeding, treatment-related clinical deterioration, treatment-related pulmonary vascular injury, or treatment-related cardiac injury occurring within 48 hours of treatment.⁵ Major bleeding events met the criteria of life-threatening or disabling bleeding or major bleeding according to the Valve Academic Research Consortium-2 guidelines.²³ Cardiac and pulmonary vascular injuries were defined as injuries requiring intervention. Clinical deterioration included unplanned mechanical ventilation, arterial hypotension (> 1 hour or requiring vasopressors), cardiopulmonary resuscitation, persistent deteriorating oxygenation, or emergency surgical embolectomy.

Statistical analysis

Data are presented either as numbers (%), mean $\pm$ standard deviation, or median (interquartile range). Continuous variables were assessed for normality using the Shapiro–Wilk test. Differences between groups were assessed using the independent samples t-test for normally distributed continuous variables or the Wilcoxon rank-sum test for non-normally distributed variables, whereas categorical variables were compared using the chi-square or Fisher exact tests. Changes between matched pairs were compared using the Wilcoxon signed-rank test or the McNemar test. All statistical analyses were performed using GraphPad Prism version 5 (GraphPad Software) and SPSS Statistics 17.0

(IBM SPSS Statistics, IBM Corporation). Results with $P < 0.05$ were considered statistically significant.

Results

Baseline demographics and procedural characteristics

A total of 673 inpatients were confirmed with acute PE. Among them, 60 patients aged > 75 years who underwent PMT were included in this study. The flowchart for selecting the study population is shown in Figure 1. The baseline characteristics of these patients are summarized in Table 1. The mean age was 79.7 ± 7.2 years, with the oldest being 91 years, and 46.7% were women. Almost all patients (96.7%) had comorbidities. More than a quarter of the patients (26.7%) required mechanical ventilation, and 8.3% needed vasoactive drugs. Nearly 15% of patients had undergone recent surgery, and 19 patients (31.7%) had a contraindication to thrombolytics, including 8.3% with absolute contraindications. Most patients (91.7%) had an sPESI score ≥ 1 , and 25% were classified as having high-risk PE. The majority of patients (76.7%) presented with bilateral PE, and 3 patients (5%) had a saddle PE.

Procedural characteristics are detailed in Supplementary Table 1. The 8F Indigo catheter was the most frequently used device, being employed in 56 patients (93.3%), whereas the 10F catheter was used in 4 patients (6.7%). The mean procedural time was 73.1 ± 30.8 minutes, with a mean fluoroscopy dura-

tion of 24.1 ± 13.4 minutes. Thrombus aspiration was the most frequently used procedure (95%), with a combination of aspiration and fragmentation used in 5% of cases. The median estimated blood loss was 100 (30, 160) mL. During the procedure, 2 patients (3.3%) received CDT as an adjunctive treatment. A vena cava filter was implanted in 16 patients (26.7%). The average stay in the ICU was 2 days.

Efficacy of percutaneous mechanical thrombectomy in older patients

A summary of acute changes in hemodynamics and vitals is shown in Figure 2 and Supplementary Table 2. Heart rate significantly decreased post-procedure by an average of 4.40 bpm (5.1%, $P = 0.007$), from 85.48 ± 16.20 bpm pre-procedure to 81.08 ± 9.51 bpm post-procedure. Mean pulmonary arterial pressure (mPAP) significantly improved by an average of 3.40 mmHg (13.3%, $P < 0.001$), from 25.48 ± 8.26 to 22.08 ± 6.06 mmHg. Moreover, N-terminal pro-brain natriuretic peptide (NT-proBNP) levels significantly decreased from 2,102.3 (556.5, 3,772.0) to 898.6 (561.1, 1,670.6) pg/mL ($P < 0.001$). Dyspnea scores, assessed using the mMRC scale, significantly decreased from 2.52 ± 1.24 pre-procedure to 1.22 ± 1.03 at 48 hours post-procedure ($P < 0.001$). Post-procedural changes in respiratory rate, shock index, and high-sensitivity cardiac troponin I were not significant (Supplementary Table 2). An example case using an Indigo aspiration catheter is illustrated in Figure 3.

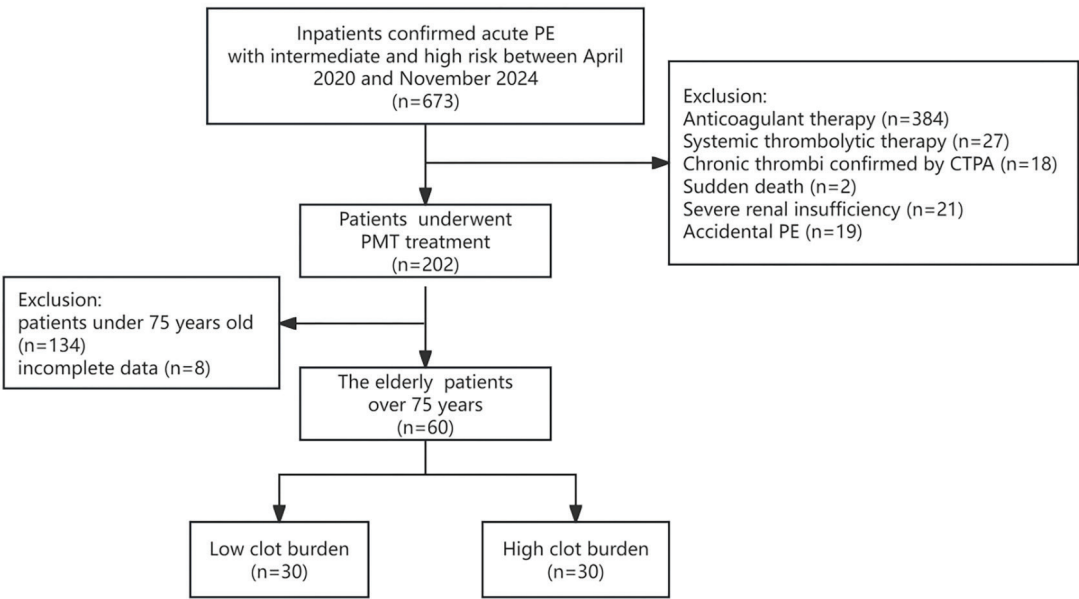


Figure 1. Flowchart of study population selection. PE, pulmonary embolism; PMT, percutaneous mechanical thrombectomy; CTPA, computed tomography pulmonary angiography.

Characteristic	Baseline
Age, years	79.67 ± 7.23
Women	28 (46.7)
BMI, kg/m²	22.92 ± 3.95
Symptoms duration, days	6.35 ± 4.89
Comorbidities	
Coronary artery disease	11 (18.3)
Diabetes mellitus	7 (11.7)
Chronic pulmonary disease ^a	19 (31.7)
Prior PE	5 (8.3)
Chronic kidney disease	2 (3.3)
COVID-19	3 (5)
Active cancer	8 (13.3)
Cerebrovascular accident	4 (6.7)
Recent surgery^b	8 (13.3)
Concomitant DVT	24 (40)
Mechanical ventilation	16 (26.7)
Invasive	4 (25)
Non-invasive	12 (75)
Vasopressor use	5 (8.3)
Systemic thrombolysis before procedure	1 (1.7)
Lytics contraindication	19 (31.7)
Absolute	5 (8.3)
Relative ^c	14 (23.3)
sPESI ≥ 1	55 (91.7)
PE severity	
High risk	15 (25)
Positive biomarkers^d	41 (68)
PE location	
Saddle	3 (5)
Unilateral	11 (18.3)
Bilateral	46 (76.7)
Clot burden scores^e	29.46 ± 20.23
Complicated with pulmonary infarction	17 (28.3)

a, chronic pulmonary disease includes chronic obstructive pulmonary disease, interstitial lung disease, and pulmonary tuberculosis. b, recent surgery is defined as a surgical history within the past 3 months. c, fourteen patients with relative thrombolysis contraindications had other contraindications in addition to being aged > 75 years. d, positive biomarkers included elevated N-terminal pro-brain natriuretic peptide (≥ 1,800 pg/mL) and/or cardiac troponins (≥ 0.04 ng/mL). e, Qanadli score on computed tomography angiography was utilized to evaluate clot burden. BMI, body mass index; PE, pulmonary embolism; COVID-19, coronavirus disease 2019; DVT, deep vein thrombosis; sPESI, simplified Pulmonary Embolism Severity Index.

An age- and sex-matched anticoagulation cohort was identified from the institutional registry for exploratory comparative analyses. The baseline characteristics of the anticoagulation group are presented in Supplementary Table 3. Compared with anticoagulation alone, PMT was associated with a significantly greater reduction in heart rate and a more favorable mMRC dyspnea score distribution at 48 hours after treatment, whereas the respiratory rate was comparable

between the two groups (Supplementary Figure 1).

Safety of older patients with pulmonary embolism during and after percutaneous mechanical thrombectomy

The safety assessment is presented in Table 2. One patient experienced clinical deterioration, categorized as a major adverse event, necessitating emergent intubation and resulting in death within 48 hours

post-procedure. One patient exhibited agitation during the procedure, required increased sedation, and developed paroxysmal atrial fibrillation necessitating pharmacological cardioversion. Minor vascular injuries were observed in three patients due to multiple catheter passes, but these did not require intervention. No incidences of major bleeding or treatment-related cardiac injury were observed. AKI developed in three patients (5%) within 48 hours post-procedure. Creatinine and hemoglobin levels remained stable pre- and post-operation (Supplementary Table 2).

The overall mortality rate at 1 month was 8.3% (five patients), with four deaths (6.7%) unrelated to the procedure or PE. Among these, two fatalities resulted from the progression of pre-existing comorbidities (interstitial lung disease and ischemic stroke), and two were attributed to COVID-19-related complications. Additionally, one patient with advanced lung cancer succumbed to cerebral infarction 53 days after discharge. During the 3-month follow-up, PE recurrence was observed in one patient. Among the five patients with absolute contraindications to thrombolysis, three were classified as high risk, and two developed AKI postoperatively. Among these, three were classified as high risk, and two developed AKI postoperatively. No major bleeding or deaths occurred within 3 months. In the anticoagulation group, three patients died within 3 months, and one patient discontinued anticoagulation due to gastrointestinal bleeding. Recurrent PE occurred in one patient (Supplementary Table 3). No statistically significant differences were observed between the PMT and anticoagulation groups in the 3-month outcomes.

Clinical improvement of patients with low clot burden

To further investigate the impact of clot burden on the outcomes of PMT, patients were stratified into high (Qanadli score ≥ 25%) and low (Qanadli score < 25%) clot-burden groups based on the Qanadli scoring system. The baseline characteristics of both groups are presented in Supplementary Table 4. Preoperatively, patients with a high clot burden exhibited higher mPAP and mMRC scores than those with a low clot burden. No significant differences were observed in NT-proBNP levels or RV/LV ratios between the two groups.

Post-procedurally, significant improvements were noted in the high clot burden group, with reductions in heart rate (89.33 ± 14.27 vs. 82.53 ± 9.10 bpm; *P* = 0.022), mPAP

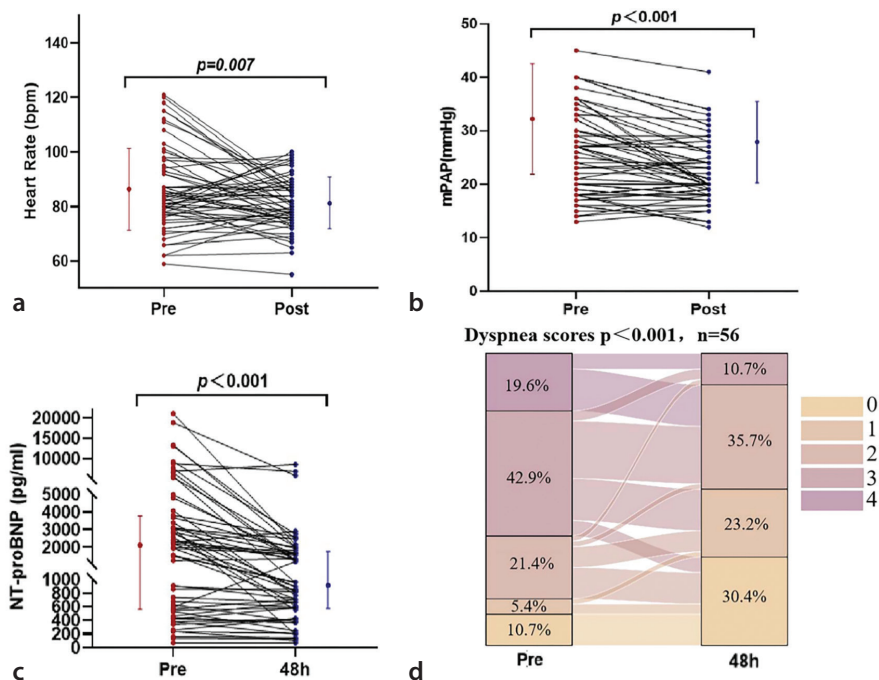


Figure 2. Short-term clinical improvement of older patients with pulmonary embolism following thrombectomy. After thrombectomy, heart rate (a) and mPAP (b) decreased immediately; NT-proBNP (c) and dyspnea score (d), based on the mMRC dyspnea scale, improved significantly 48 hours after thrombectomy. mPAP, mean pulmonary artery pressure; NT-proBNP, N-terminal pro-brain natriuretic peptide; mMRC, Modified Medical Research Council.

(30.17 ± 7.50 vs. 23.87 ± 6.61 mmHg; $P < 0.001$), NT-proBNP [$2,493.7$ (828.5, 4,052.6) vs. 927.20 (609.60, 1,633.18) pg/mL; $P < 0.001$], and mMRC dyspnea score (2.89 ± 1.10 vs. 1.35 ± 0.99 ; $P < 0.001$). An improvement in heart rate (83.13 ± 15.22 vs. 78.40 ± 8.81 bpm; $P = 0.039$), NT-proBNP [$1,078.9$ (411.4, 3,355.6) vs. 830.30 (405.10, 2,058.98) pg/mL; $P = 0.035$], and mMRC dyspnea score (2.21 ± 1.20 vs. 1.14 ± 1.04 , $P < 0.001$) were also observed in the group with a low clot burden (Figure 4). Patients with a low clot burden also benefited from PMT treatment in terms of right heart function and dyspnea score despite limited hemodynamic improvement.

Discussion

In the present study, we assessed the safety and efficacy of PMT in patients aged > 75 years with acute PE. Our data demonstrated significant improvements in heart rate, hemodynamics, NT-proBNP, and dyspnea scores following the procedure, with a low incidence of major adverse events (1.7%) and no major bleeding. This is the first study to demonstrate the safety and efficacy of PMT in older patients with PE, providing preliminary evidence supporting its application in this population.

PMT offers rapid hemodynamic benefits comparable to systemic or CDT. In our cohort, mPAP decreased by 3.4 mmHg immediately post-procedure, consistent with the FlowTrieve All-Comer Registry for Patient Safety and Hemodynamics (FLASH).⁶ Given that acute mortality in PE is primarily attributable to hemodynamic compromise resulting from RV failure, RV size and function have been established as reliable prognostic markers and indicators of therapeutic efficacy.^{3,24} The Evaluating the Safety and Efficacy of the Indigo Aspiration System in Acute Pulmonary Embolism (EXTRACT-PE) study, utilizing the Indigo Aspiration System, reported a 0.43 reduction in RV/LV ratios at 48 hours post-procedure.⁷ Comparable improvements have been reported with the FlowTrieve system, with RV/LV ratio reductions of 0.38 reported in the FlowTrieve Pulmonary Embolism Clinical Study and 0.36 in FLASH.^{5,6} Similarly, AngioJet rheolytic thrombectomy achieved a 0.41 reduction in the RV/LV ratio.²⁵ Our study further demonstrated a significant reduction in NT-proBNP levels, supporting the clinical benefit of PMT in older patients. These data indicate that PMT effectively improves RV function, regardless of device design or procedural technique. This observation was further supported by an exploratory comparison with a matched anticoagulation

Table 2. Safety and mortality outcomes

Safety outcomes	n, (%)
During the thrombectomy procedure	
Composite MAE	
Procedure-related death	0
Major bleeding	0
Treatment-related pulmonary artery injury ^a	0
Treatment-related cardiac injury	0
Treatment-related clinical deterioration	1 (1.7)
Paroxysmal atrial fibrillation	1 (1.7)
48 hours after procedure	
PE-related mortality	1 (1.7)
All-cause mortality	1 (1.7)
Major bleeding	0
Clinical deterioration	0
Acute kidney injury	3 (5)
Infection (pneumonia/sepsis)	0
1-month follow-up	
PE-related mortality	1 (1.7)
All-cause mortality	5 (8.3)
3 months follow-up	
PE-related mortality	1 (1.7)
All-cause mortality	6 (10)
PE recurrence	1 (1.7)
Bleeding event	0

a, three patients with minor vascular injury without any intervention were not considered to have treatment-related pulmonary artery injury. MAE, major adverse event; PE, pulmonary embolism.

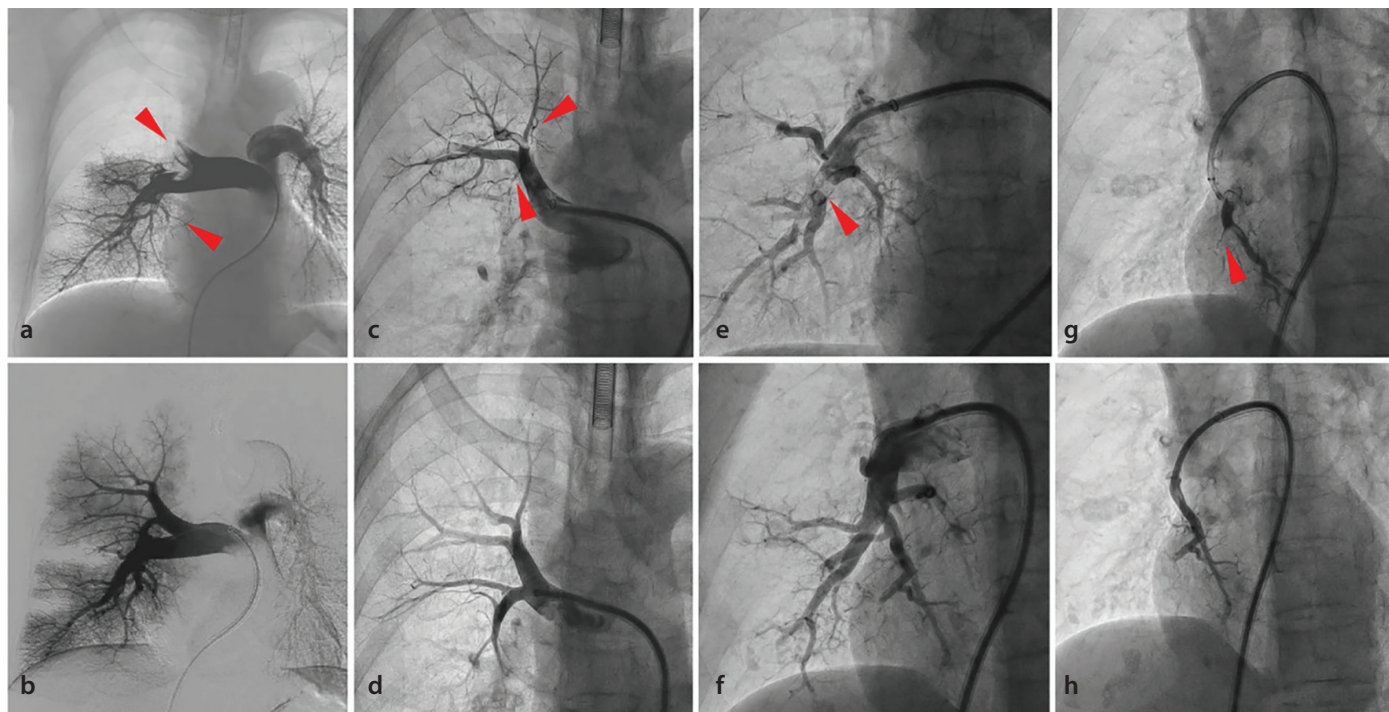


Figure 3. Example case of pulmonary angiography before and after removing thrombus through Indigo aspiration catheter. A 76-year-old man was admitted to the hospital due to massive hemoptysis. He was diagnosed with concurrent acute high-risk pulmonary embolism and massive hemoptysis. Sputum culture confirmed aspergillus infection. Bronchial artery embolization was performed twice within 6 months due to hemoptysis. (a) Baseline right pulmonary artery angiogram revealing filling defects with occluded superior and lower lobar branches (arrows). (b) Final angiogram showing restoration of flow to all previously occluded branches. Pre-treatment of selective pulmonary angiography revealed filling defects (arrows) in the right superior lobar branches (c), basilar artery trunk (e), and posterior basal segment (g) of the right lower lobe. (d,f,h) Angiogram showing the previous thrombotic obstruction resolved after thrombus removal.

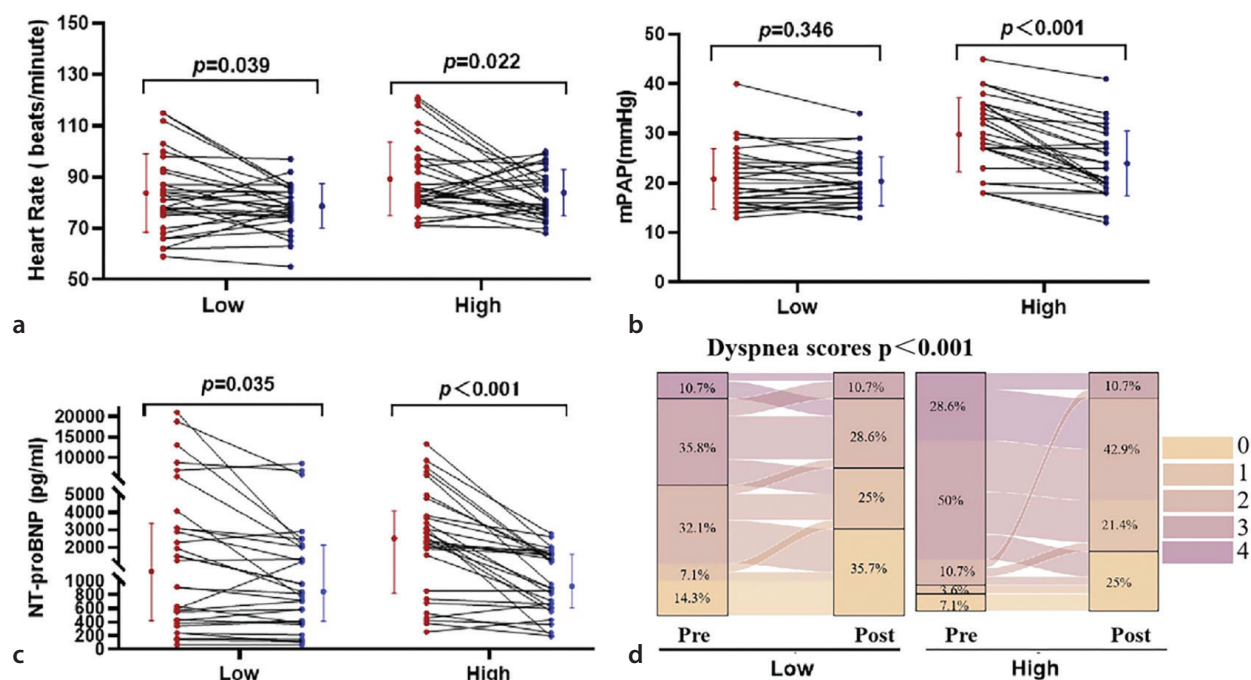


Figure 4. Clinical improvement after thrombectomy in older patients with pulmonary embolism with high and low clot burden. (a) Heart rate significantly reduced in both groups at 48 h after thrombectomy; (b) mPAP decreased immediately after the procedure in patients with high clot burden. Improvements were seen in NT-proBNP (c) and mMRC dyspnea score (d) in both groups at 48 h after thrombectomy. mPAP, mean pulmonary artery pressure; NT-proBNP, N-terminal pro-brain natriuretic peptide; mMRC, Modified Medical Research Council.

cohort, which suggested greater early clinical improvement following PMT.

CDT remains an established reperfusion strategy for patients with intermediate- and high-risk PE. Previous studies have demonstrated significant improvements in RV dysfunction with low doses of thrombolytic agents.^{3,26} Nevertheless, bleeding risk remains a major consideration, particularly in older patients and those with contraindications to systemic thrombolysis. By contrast, PMT enables thrombus removal without thrombolytic exposure and may represent an attractive alternative in selected patients at high bleeding risk. These two approaches should be viewed as complementary treatment options, and the choice of therapy should be individualized based on patient characteristics and institutional expertise. Advanced age is associated with an increased bleeding risk, with major bleeding occurring in 2.5% of patients aged > 80 years, compared with 0.9% in younger patients.^{27,28} This risk is further compounded by comorbidities, polypharmacy, and drug interactions.²⁹ Although antiplatelet, anticoagulant, and fibrinolytic therapies effectively reduce the mortality and severity of thrombotic events, they also increase the bleeding risk, particularly in older patients. Even with reduced dosing, systemic thrombolysis does not fully mitigate these risks.^{30,31} For older populations, the key challenge is whether the benefits outweigh the bleeding risks. Given the advanced age of our cohort and the relatively high prevalence of contraindications to thrombolytic therapy, PMT was selected as a reperfusion option. The low incidence of major bleeding events is encouraging and suggests a favorable safety profile for PMT in older patients.

The Indigo Aspiration System has been utilized in various clinical trials for thrombectomy, with its smaller diameter allowing access to more distal clots. The catheter facilitates multiple passes through the thrombus for extensive clot removal. The EXTRACT-PE trial utilized the 8F Indigo aspiration catheter, whereas our study included Revised: 8F and 10F catheters to enhance clot removal efficiency. Despite larger catheters being potentially more challenging to handle and associated with a higher risk of complications, the incidence of device-related vascular injury was not higher than in the EXTRACT-PE trials.⁷ The potential blood loss and AKI are limitations of this technology.^{32,33} In our study, no significant differences in renal function or hemoglobin levels were observed before and after the procedure. Post-

operative AKI occurred in three patients, two of whom underwent concomitant bronchial artery embolization for concurrent massive hemoptysis. Overall, our findings suggested that PMT did not increase the risk of AKI in older patients.

Our analysis revealed that patients with a low clot burden also experienced significant improvements in heart rate, NT-proBNP, and dyspnea score, highlighting that clot burden alone may not fully identify patients who could benefit from PMT. Previous studies have demonstrated that clot burden is associated with risk stratification and clinical outcomes in PE.³⁴⁻³⁶ However, clot burden is not currently incorporated into guideline recommendations for selecting reperfusion therapies. Accordingly, PMT selection in our cohort was based on overall clinical assessment by the multidisciplinary team. This assessment included hemodynamic status, RV dysfunction, symptom severity, bleeding risk, and contraindications to thrombolytic therapy, rather than clot burden alone. Older patients typically have greater comorbidities and are more fragile, often presenting with RV dysfunction despite minor thrombus obstruction. This may explain the favorable clinical response observed in selected patients with a low clot burden.

This study has several limitations. First, although patients were enrolled through a prospective multicenter registry, the present study represents a retrospective analysis of a single-center cohort, which may limit the generalizability of the findings. As a non-randomized study, the causal relationships between PMT and the observed clinical improvements cannot be definitively established, and residual confounding may remain despite prospective data collection. Due to the small number of patients with larger devices, outcomes were not compared between catheter diameters. Second, treatment indications were heterogeneous, as the decision to perform PMT was made by the local Pulmonary Embolism Response Team. Additionally, the relatively short follow-up period limits evaluation of long-term outcomes, which include recurrent PE, chronic thromboembolic pulmonary hypertension, functional status, and mortality. Further prospective studies with an extended follow-up period are warranted to clarify the long-term benefits of PMT in older patients.

PMT is a safe and effective treatment for older patients with acute PE. Further studies are warranted to evaluate age-related differences in outcomes and to better define the role of

PMT across different patient populations.

Footnotes

Conflict of interest disclosure

The authors declared no conflicts of interest.

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Supplementary Tables: <https://d2v96fxpocvxx.cloudfront.net/e6921826-40a4-4ec2-8c4c-3b8dc63111d7/content-images/937e8e42-7d35-4299-bd39-05ca1a54683e.pdf>

Supplementary Figure: <https://d2v96fxpocvxx.cloudfront.net/e6921826-40a4-4ec2-8c4c-3b8dc63111d7/content-images/bb6bf5fd-4a0f-4c22-bde3-e9ec62fe7c.pdf>

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