Computer-assisted vacuum aspiration thrombectomy in acute pulmonary embolism – a multicenter real-world registry

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Background: Data on interventional treatment of intermediate-high (IHR) and high-risk (HR) pulmonary embolism (PE) are still limited.
The novel Lightning 12 system (Penumbra, Alameda, California, US) utilizes continuously powered engine pump generating a negative suction pressure of 29 inHg, a 12F CAT12 catheter, with a relatively large 0.131'' lumen and angled tip for an additional circumferential sweep, and the lighting control unit with a pressure/flow sensor system and high-frequency valves aimed to efficiently regulate aspiration and prevent excessive blood loss. This report aims to evaluate outcomes of the Lightning 12 aspiration system, including immediate changes in hemodynamics, acute safety, and effectiveness, and longer-term clinical outcomes during 90-day follow-up.

Methods: This multicenter, prospective registry enrolled IHR and HR PE patients treated with CDMT using the Lightning 12 System. The primary safety endpoints included in-hospital all-cause mortality, procedure-related major bleeding, clinical deterioration, or bailout to another strategy. The primary efficacy outcomes were the reduction of PA pressures and change in the right-to-left ventricular (RV/LV) ratio 48 hours after the CDMT. Multivariate regression analyzed characteristics associated with RV/LV improvement.

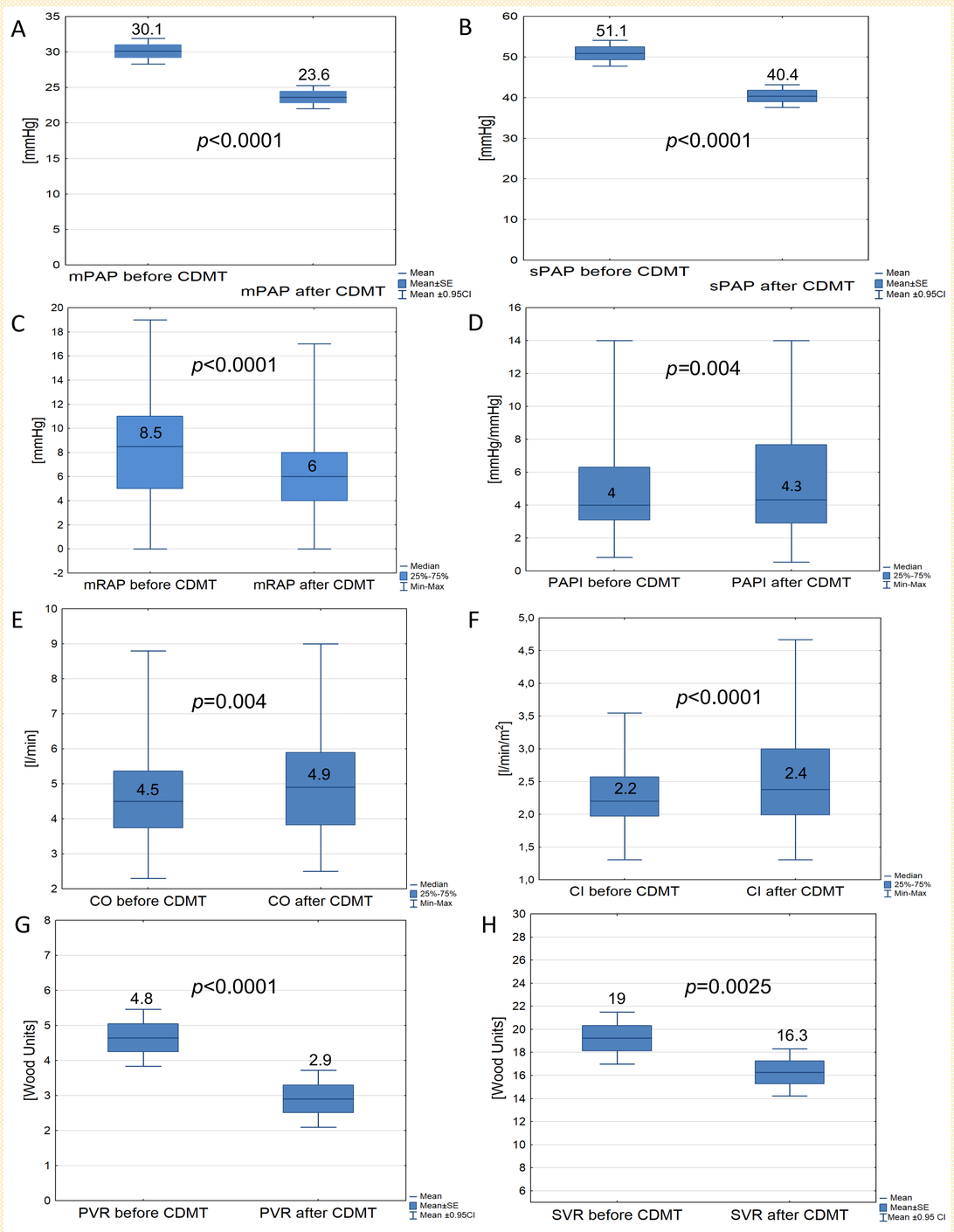
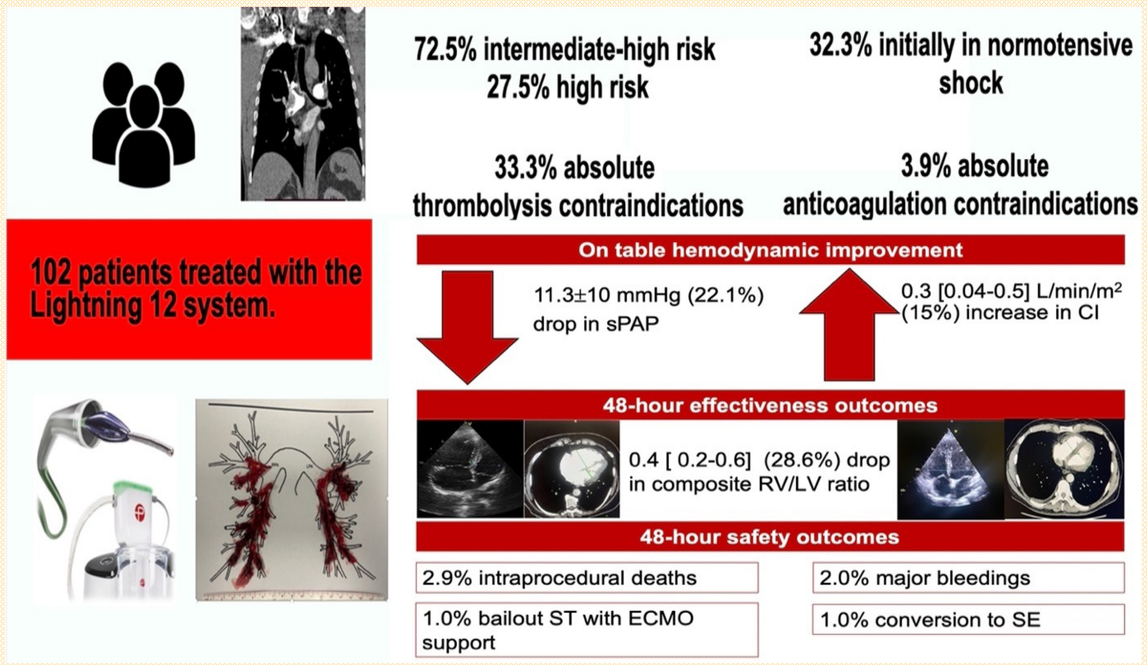


Figure 1. Key hemodynamic outcomes.
#Values are expressed as mean±SD, or median [IQR].
CDMT: catheter-directed mechanical thrombectomy; CI: cardiac index; CO: cardiac output; mPAP: mean pulmonary artery pressure; mRAP: mean right atrial pressure; PAPI: pulmonary artery pulsatility index; PVR: pulmonary vascular resistance; sPAP: systolic pulmonary artery pressure; SVR: systemic vascular resistance

Results: Our analysis included **102 patients**, 72.5% with IHR PE and 27.5% with HR PE. 33.3% had absolute contraindications to systemic thrombolysis (ST) and in 3.9% of patients, ST failed. There were 2.9% intraprocedural deaths (2.0% due to RV failure, and 1.0% due to massive interstitial bleeding), with no more deaths during follow-up. In 1.0% CDMT was converted to open surgery and in 1.0% bailout ST and extracorporeal oxygenation support. Major bleedings occurred in 2.0% within 48 hours post CDMT. Immediate hemodynamic improvements included a mean 11.3±10 mmHg (22.1%) drop in systolic PAP ($p < 0.0001$) and a median 0.33 (0.25-0.45), (25.2%) drop in RV/LV ratio ($p < 0.0001$ for paired values),



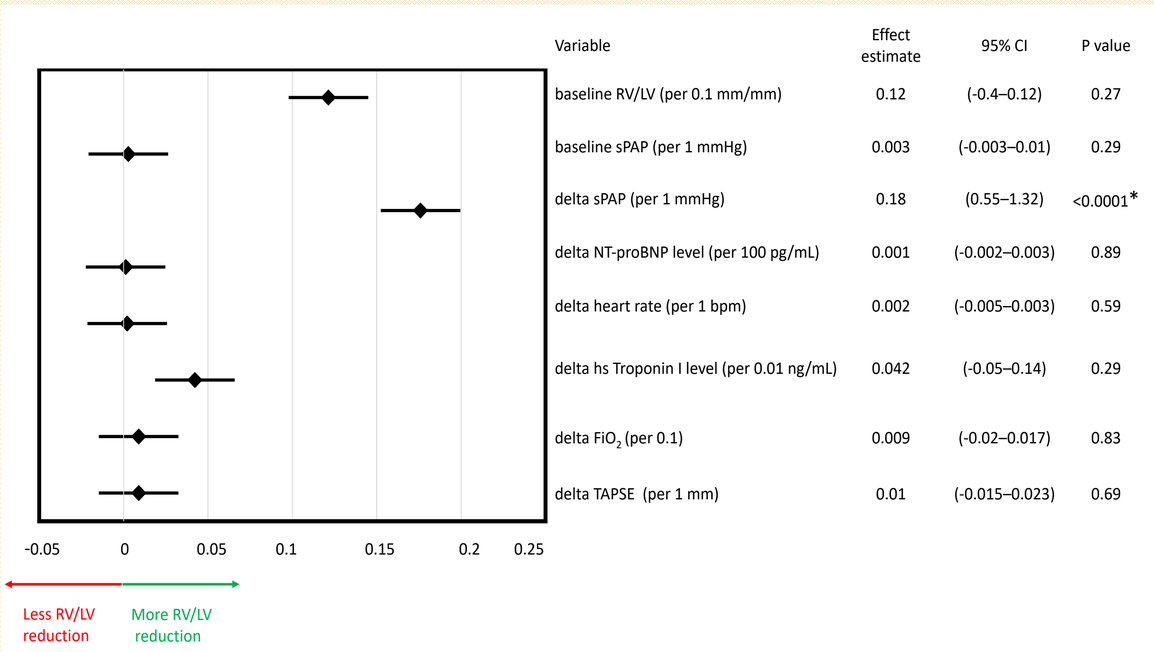


Figure 2. Multiple linear regression model of absolute reduction in RV/LV ratio.
Composite used CTPA or echo measurements, prioritizing CTPA if both were available
* statistically significant.
FiO_2: fraction of inspired oxygen; hs: high sensitive; NT-proBNP: N-terminal pro-brain natriuretic peptide; RV/LV right-to-left ventricle ratio; sPAP: systolic pulmonary artery pressure; TAPSE: tricuspid annular plane systolic excursion

Conclusions: Aspiration thrombectomy with the Lightning 12 system characterizes an acceptable safety profile, substantial improvements in hemodynamic outcomes, and low mortality for patients with IHR and HR PE.