# Lightning 12 — an intelligent computer-assisted vacuum aspiration thrombectomy system in the treatment of pulmonary embolism: An initial experience

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## INTRODUCTION

Contemporary catheter-directed mechanical thrombectomy (CDMT) plays an emerging role in the treatment of intermediate-high (IHR) and high-risk (HR) pulmonary embolism (PE) [1]. CDMT is aimed at removing as much as possible of the embolic material from the pulmonary arteries, improving blood flow, and reducing the pulmonary resistance and the right ventricle (RV) strain, which results in quick reversal of the development of the spiral shock in life-threatening PE [1, 2]. According to the current guidelines, CDMT should be considered in HR PE with contraindications to systemic thrombolysis (ST) or its failure, or in IHR PE, in the case of hemodynamic deterioration, but also in cases where hemodynamic improvement has not been achieved after several hours of anticoagulation [1–3].

Recently, a new Lightning 12, intelligent computer-assisted vacuum aspiration system (Penumbra, Alameda, CA, US) has been introduced, which is thought to regulate aspiration more efficiently and reduce blood loss in comparison to the previous generation device (Indigo CAT8) [4–6]. This study aims to evaluate the outcomes of the Lightning 12 aspiration system.

## METHODS

In this prospective single-arm study, we included all consecutive patients aged >18 years, who were undergoing CDMT with the Lightning 12 system due to IHR or HR PE (June 2022–November 2023). The details concerning the risk stratification, patients' selection, and organization of our institutional PE response team were published previously [7]. Three of 8 patients (37.5%) categorized as high-risk PE had previously received systemic thrombolysis with no clinical improvement.

Demographic, clinical, laboratory, and imaging studies (echocardiography and computed tomography angiography) data obtained during hospitalization and 30-day follow-up were analyzed. The primary endpoints included device or PE-related death within 48 hours after CDMT, procedure-related major bleeding (BARC type 3a or higher), or other procedure-related major adverse events [8]. The Bioethics Committee approved the study (approval number 879/19). All the patients accepted the treatment and provided informed consent to participate in the study.

### *Statistical analysis*

The continuous variables were presented as arithmetic means and standard deviations (SD) for normal distributions or medians and quartiles (Q1–Q3) for skewed distributions. Categorical values were reported as counts and percentages. The normality distribution was assessed with the Shapiro–Wilk test. Continuous variables were compared using paired t-tests or Wilcoxon signed-rank tests as appropriate A two-tailed alpha of 0.05 was considered statistically significant. Statistical analysis was conducted using STATISTICA 13.7 software (TIBCO Software, Palo Alto, CA, US).

## RESULTS AND DISCUSSION

The study included 29 patients, 11 women (37.9%) and 18 men (62.1%) at a mean age of 60 (16) years. Eight patients (27.6%) were categorized as HR PE and 21 (72.4%) as IHR PE. In IHR PE patients, the median PESI score was 113 (105–124) points. PE risk factors included:

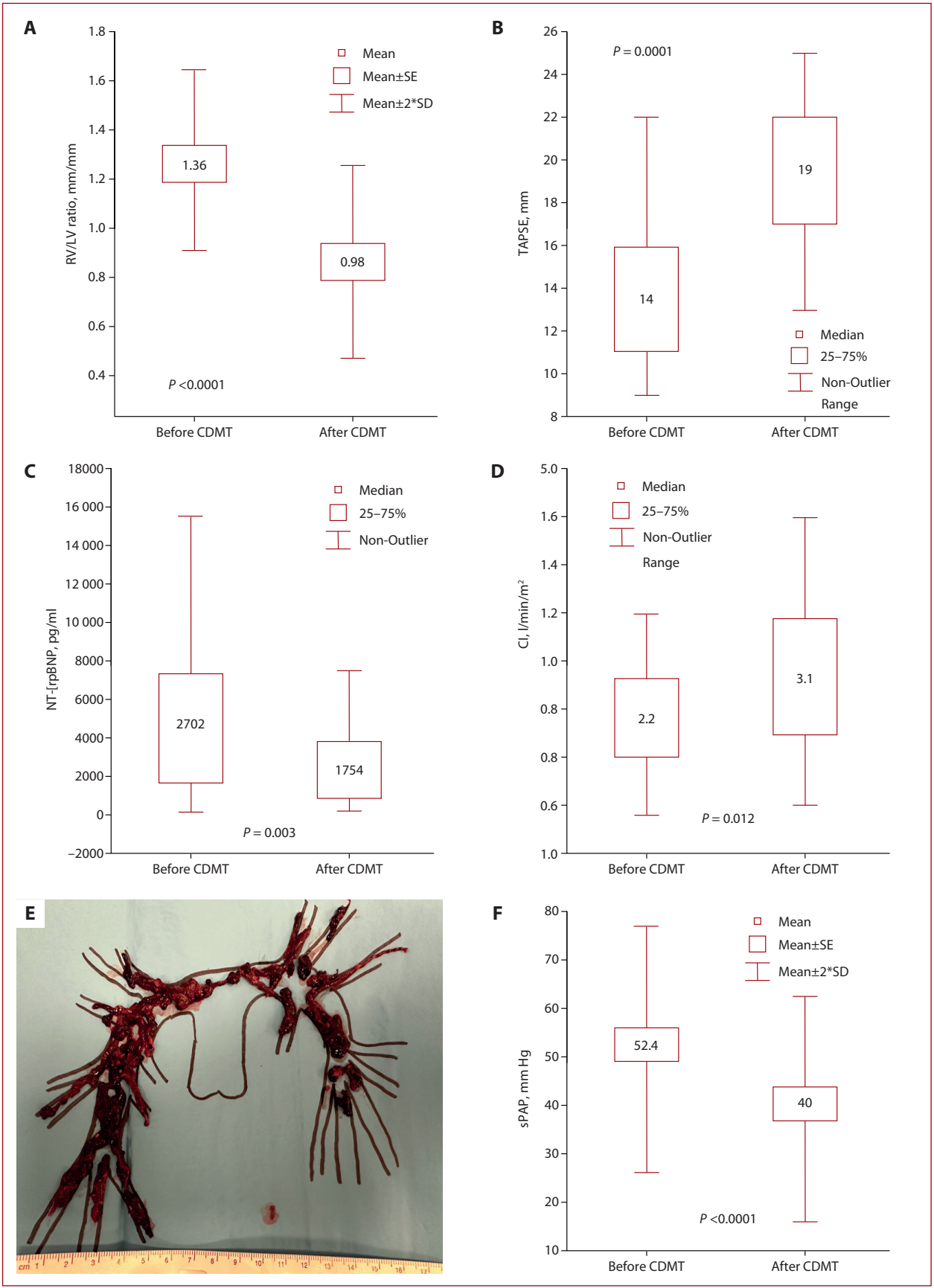


**Figure 1.** Key effectiveness outcomes of catheter-directed mechanical thrombectomy. Graphs on panels A, B, C, D, and F show parameter changes before and after the procedure. Panel E shows the image of the removed clots
*Data are presented as mean (SD) — RV/LV, sPAP (normal distribution) or median (IQR) — TAPSE, NT-proBNP, CI (skewed distribution)

Abbreviations: CI, cardiac index; IQR, interquartile range; NT-proBNP, N-terminal pro-B-type natriuretic peptide; RV/LV, right ventricular-to-left ventricular ratio; sPAP, systolic pulmonary arterial pressure; SD, standard deviation; TAPSE, tricuspid annular plane excursion

3 instances of (10.3%) major surgery within the last 14 days, 4 instances of (13.8%) neoplasm, 2 instances of (6.9%) thrombophilia, and 2 instances of (6.9%) immobilization. The median time from diagnosis to CDMT was 1 (1–3) days. The detailed characteristics of the study group are presented in Supplementary material, *Table S1* and *Table S2* (including characteristics of all patients treated by our PE-response team during the study period).

The procedure was performed *via* the femoral vein in 27 (93.1%) patients and *via* the right internal jugular vein in 2 cases (6.9%).

We observed significant hemodynamic and clinical improvement after the procedure (see Figure 1 and Supplementary material, *Table S3*). The heart and respiratory rates significantly decreased, and arterial pO2 increased notably. Mean (SD) systolic pulmonary artery pressure (PAP) decreased from 52.4 (13.6) mm Hg to 40.0 (12) mm Hg, ($P$ <0.0001), and mean PAP dropped from 30.5 (6.9) mm Hg to 22.9 (5.7) mm Hg, ($P$ <0.0001). Notably, the median (Q1–Q3) cardiac index increased from 2.2 (2.0–2.9) l/min/m$^2$ to 3.1 (2.4–3.8) l/min/m$^2$, ($P$ = 0.01). The mean (SD) RV-to-left ventricular (LV) ratio decreased from 1.36 (0.17) to 0.98 (0.16), ($P$ <0.0001), and median (IQR) tricuspid annular plane systolic motion (TAPSE) increased from 14 (11–16) mm to 19 (17–22) mm ($P$ <0.0001). N-terminal pro B-type natriuretic peptide, troponin I, and lactate levels also significantly reduced quickly after the procedure (Supplementary material, *Table S3*). It should be mentioned, however, that in 2 patients with the highest clot burden and blood loss over 500 ml, we decided to optimize the effect of CDMT with supplemental bilateral low-dose local fibrinolysis with a cumulative alteplase dose of 20 mg delivered over 8 hours per both lungs (bolus of 2 mg + 8 mg infusion per lung).

We observed no major bleeding requiring a blood transfusion. The mean procedure-related blood loss was 337 (128.7) ml. Although the hemoglobin level was significantly lower after the procedure, this had no clinical sequelae. We observed only one hemorrhagic transformation after ischemic stroke (and absolute contraindications to ST). There was one death during the procedure due to disseminated intravascular coagulation in a patient with persistent obstructive shock and failed ST. We observed no deaths during the 30-day follow-up. No other major adverse events, including cardiac tamponade, pulmonary artery injury, sustained ventricular arrhythmias, or cardiac arrest, were noted (Supplementary material, *Table S4*).

The results of our study, despite a relatively small number of patients, suggest that CDMT with the Lightning 12 system is well tolerated and effective in critically ill patients.

Auditory and visual feedback from the control unit makes the aspiration thrombectomy process easier. Moreover, the 12F catheter's flexibility improves maneuvers within tortuous vessels and enlarged right heart ventricles. A larger diameter, improved catheter design, and an intelligent control unit allow for more complete removal of thrombi from both pulmonary arteries without increasing periprocedural blood loss compared to the previous generation of the device (Indigo CAT8 device) [5, 9–11]. Using larger-bore catheters and sheaths seems feasible and effective. In conclusion, the results of our study suggest that the use of computer-assisted vacuum thrombectomy with the Lightning 12 device appears to be a reasonable option in the treatment of intermediate- and high-risk PE patients due to the fast reduction of right ventricular strain and improvement in clinical and functional outcomes. At the same time, the treatment is safe and effectively reduces blood loss despite using larger-bore catheters.

## Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

## Article information

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