Computer-Aided Aspiration Thrombectomy for the Treatment of Pulmonary Embolism: Interim Analysis of the STRIKE-PE Study

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Purpose

The objective of the STRIKE-PE study is to evaluate real-world long-term functional outcomes, safety, and performance of computer-aided mechanical aspiration thrombectomy with the Indigo Aspiration System (Penumbra, Inc., Alameda, CA) for the treatment of pulmonary embolism (PE). The purpose of this abstract is to report results from an interim analysis of this study.

Methods – STRIKE-PE Study

Study design: Post-market, prospective, multicenter

Planned enrollment: 600 subjects, 55 global sites

Study device: Indigo Aspiration System

Follow-up schedule: 48 hours, discharge, 90 days, and 365 days

Key inclusion criteria:

- Clinical signs and symptoms consistent with acute PE with duration of 14 days or less
- RV/LV ratio ≥0.9 assessed by diagnostic computed tomographic angiography (CTA) or echocardiogram
- Frontline endovascular treatment with the Indigo Aspiration System per IFU

Primary performance endpoint: Change in RV/LV ratio (matched imaging pairs with CTA or echo) at 48 hours post-procedure

Primary safety endpoint: Composite of major adverse events (major bleeding and device-related death, clinical deterioration, pulmonary vascular injury, and cardiac injury) at 48 hours

Secondary endpoints:

- Quality of life and functional outcome at 90 days
- Incidence of device-related SAEs
- Any-cause mortality within 30 days
- Symptomatic PE recurrence within 30 days

Interim analysis:

- 60 patients enrolled in 17 sites
- Follow-up and monitoring are ongoing

Results

Baseline characteristics	Interim analysis (N=60)
Demographics	
Age, y	59.4 ± 15.7
Sex, female, % (n)	43.3% (26)
Medical history, % (n)	
Hypertension	53.3% (32)
Hyperlipidemia	35.0% (21)
Diabetes	33.3% (20)
Deep vein thrombosis	25.0% (15)
COVID-19, active or previous	20.0% (12)
PE classification, % (n)	
Submassive	95.0% (57)
Massive	5.0% (3)

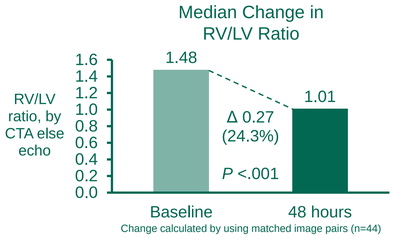
Periprocedural data, median [IQR] or % (n)	Interim analysis (N=60)
Symptom onset to admission time, h[a]	24 [8-104][b]
Symptom onset to puncture time, d	2.4 [1.1-4.7][c]
Thrombectomy time, min[d]	36 [21-50][c]
ICU length of stay after procedure, d[e]	1 [1-2][f]
No ICU stay required	34.5% (19)[g]
Hospital length of stay after procedure, d	4 [3-6][g]

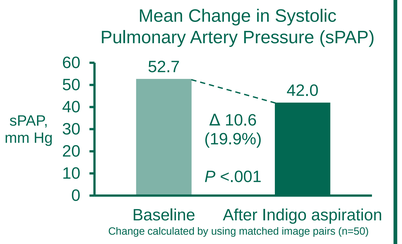
[a]Patients admitted before symptom onset were imputed to an admission time of 0. [b]N=59. [c]N=58. [d]First Indigo device insertion to last Indigo device removal. [e]Subjects indicated as not admitted to the ICU are excluded from the calculation. [f]N=36. [g]N=55.

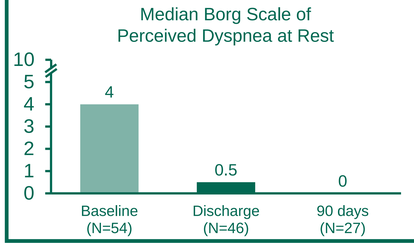
Outcomes, % (n)	Interim analysis (N=60)
Major adverse events within 48 h (composite)	1.7% (1)
Major bleeding[a]	1.7% (1)[b]
Device-related death[c]	0.0% (0)
Device-related clinical deterioration[a]	0.0% (0)
Device-related cardiac injury[a]	0.0% (0)
Device-related pulmonary vascular injury[a]	0.0% (0)
Device-related serious adverse events[c]	1.7% (1)
Any-cause mortality within 30 d[d]	0.0% (0)
Recurrent PE within 30 d[d]	0.0% (0)

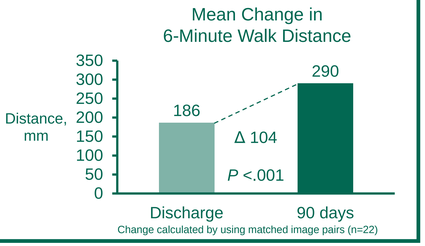
[a]Per independent medical reviewer. [b]Access site hematoma requiring transfusion. [c]Per independent medical reviewer else principal investigator. [d]Per principal investigator.

Results (continued)

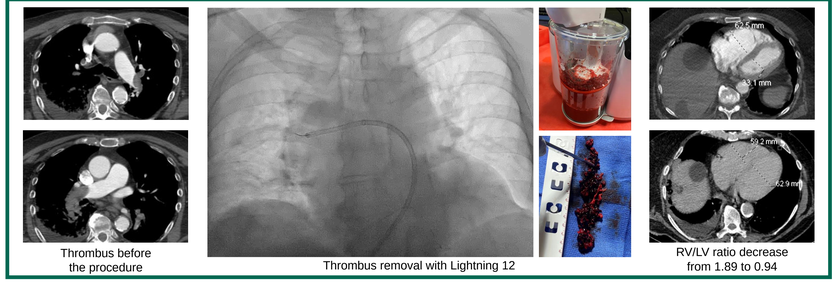








Case Presentation



Conclusions

The substantial reductions in RV/LV ratio and sPAP, short thrombectomy time, and improvements in functional outcome measures demonstrate that treating PE with Lightning 12 is safe and effective in a real-world population.