Angiographic Thrombus Burden Reduction With a Novel Thrombectomy Device for the Treatment of Acute Pulmonary Embolism Substudy Results From the Pilot ENGULF Trial

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Background

The ENGULF pilot study evaluated the novel Hēlo PE Thrombectomy System. The catheter includes a flexible and collapsible funnel with an internal agitator for the treatment of acute pulmonary embolization (PE). Angiography may offer a reliable measure of efficacy for thrombus aspiration following thrombectomy for PE. We report the angiographic core laboratory methods and results.

Methods

The Hēlo PE catheter was evaluated prospectively, in a single-arm safety and feasibility study at 8 centers. Patients presenting with an acute (<14 days) intermediate-risk PE and proximal PE confirmed by CT and RV/LV ratio >0.9 were enrolled and underwent a pre- and 48-hour post-procedural CT scans. **An angiographic substudy** of 12 patients underwent angiographic evaluation pre- and post-thrombectomy assessment of thrombus area reduction.

Primary clinical efficacy was the difference in the pre-to-post procedural RV/LV ratios.

Primary and secondary safety included all-cause mortality, major life-threatening bleeding, device-related serious AEs, pulmonary or cardiac injury, and clinical decompensation at 48 hours and 30 days post-procedure.

Angiographic methods: Angiographic thrombus was defined as discrete intraluminal filling defects with defined borders ± contrast staining. Thrombus area was measured at baseline and after thrombectomy using manual planimetry (Medis, QAngio XA version 7.3). **Validation of thrombus area** was performed based on 10 repeated measures >1 month apart with an accuracy (mean difference) = 0.5 mm^2, precision (SD of mean difference) = 0.9, and intraclass correlation = 1.

Results

25 patients were included.

Procedure and embolectomy success was 100%

RV/LV ratio Baseline: 1.53±0.27
Post-procedure: 1.15±0.18
Reduction: 23.2%±12.8%.

Angiographic Outcomes

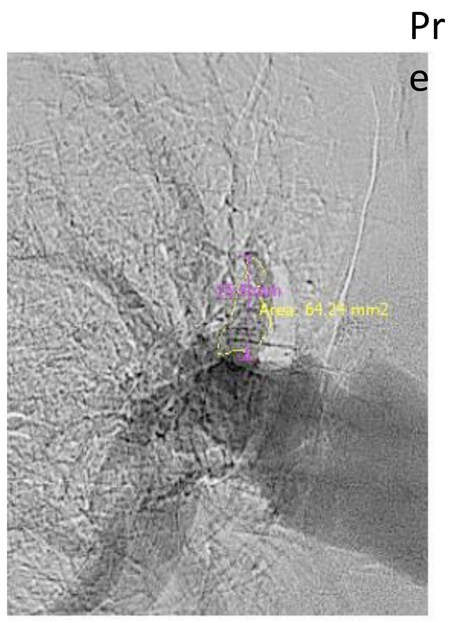
Thrombus area reduction 83.8%±22.4%

Thrombus length reduction: 76%±31%

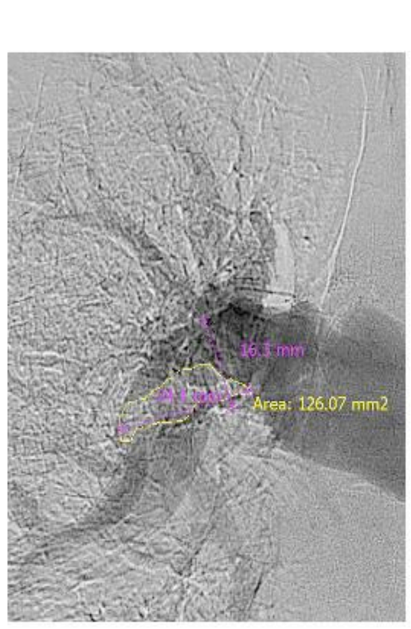
Clinical Outcomes	
Primary Safety End Points	
Device-related death within 48 hours	0.0% (0/25)
Major bleeding within 48 hours	0.0% (0/25)
Device-related serious adverse events within 48 hours	8.0% (2/25)
Pulmonary vascular injury	0.0% (0/25)
Cardiac injury	0.0% (0/25)
Secondary Safety End Points	
Clinical deterioration within 48 hours	0.0% (0/25)
All-cause mortality within 30 days	0.0% (0/25)
Device-related serious adverse events within 30 days	8.0% (2/25)
PE recurrence within 30 days	0.0% (0/25)

Conclusions

The novel Hēlo PE Thrombectomy System was safe and effective in treating acute PE and provides a notable reduction in angiographic thrombus area.



Thrombus location: Right truncus anterior
Thrombus length: 15.4 mm
Thrombus area: 64.24 mm^2
Prox RVD: 9.5 mm
Flow: Reduced



Thrombus location: Right main PA
Thrombus length: 24.1 mm
Thrombus area: 126.07 mm^2
Prox RVD: 16.3 mm
Flow: Normal

Reduction of thrombus: 100%
Thrombus area: 0.0 mm^2
Flow: Normal
Dissection: No
Vessel spasm: No
Perforation: No

Disclosures

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