Early Outcomes of AlphaVac F18-85 vs. FlowTriever T24 for Pulmonary Embolus Thrombectomy: A Single-User, Single-Center Retrospective Device Comparison

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Purpose

The purpose of this study is to compare the procedural efficiency and hemodynamic outcomes of the AlphaVac F18[85] mechanical thrombectomy device in its first 42 uses to the most recent 42 cases performed with the Inari FlowTriever device. All procedures were performed by a single operator at a single center with over 400 prior pulmonary embolus (PE) thrombectomy cases of experience using the Inari FlowTriever device. This retrospective study aims to evaluate whether AlphaVac offers advantages in procedural time and hemodynamic effect, particularly during the operator's early learning curve with the device.

Background

This study was conducted at a high-volume center for PE thrombectomy, where the Inari FlowTriever has been the primary device used since 2018. This study compares the first 42 AlphaVac F18[85] cases performed by a single experienced operator to the most recent 42 Inari FlowTriever cases by the same operator. The goal is to determine whether the AlphaVac device could match or exceed outcomes; even during the operator's initial learning curve relative to a device with years of established clinical use.

Methods

A retrospective analysis was conducted on 116 patients who underwent mechanical thrombectomy for PE. This included the first 48 consecutive AlphaVac cases performed between September 26, 2024, and April 29, 2025. Six patients were excluded from this cohort: four due to the combined use of AlphaVac and Inari in a single procedure, and two due to incomplete pulmonary artery (PA) pressure data. The final AlphaVac cohort included 42 patients. PE severity for the AlphaVac cohort: 2 massive, 40 sub-massive.

For comparison, 68 consecutive patients who underwent PE thrombectomy with the Inari FlowTriever device between June 11, 2024, and May 10, 2025, were screened. From this group, 26 patients were excluded due to confounding procedural factors such as concurrent central line placement, lower extremity deep vein thrombectomy, and lower extremity venous stent placement which would have impacted the accuracy of fluoroscopy time. Additional exclusions included patients with incomplete pulmonary artery pressure data and those with internal jugular vein procedural access, to ensure consistent procedural technique. This resulted in a matched cohort of 42 Inari FlowTriever cases performed by the same single operator. PE severity for the Inari cohort: 3 massive, 39 sub-massive.

Fluoroscopy time and pre/post procedural PA systolic, diastolic, and mean arterial pressure (MAP) changes were compared between the device groups. Statistical analysis included independent t-tests and two-tailed Mann-Whitney U tests. All-cause mortality within 30 days of the procedure was recorded and evaluated descriptively.

Results

Fluoroscopy time was shorter in the AlphaVac group (18.0 ± 6.7 minutes; median 15.6) compared to Inari (19.6 ± 7.2 minutes; median 19.6). This difference was not statistically significant (t-test p = 0.31; Mann-Whitney p = 0.18).

PA systolic pressure reduction was greater in the AlphaVac group (14.1 ± 9.6 mmHg; median 15) compared to Inari (10.6 ± 10.7 mmHg; median 10), though the difference did not reach statistical significance (t-test p = 0.12; Mann-Whitney p = 0.18).

PA diastolic pressure reduction showed minimal differences between groups (AlphaVac: 1.6 ± 5.6 mmHg, median 1.5; Inari: 2.6 ± 4.9 mmHg, median 2), with no statistically significant difference (t-test p = 0.42; Mann-Whitney p = 0.33).

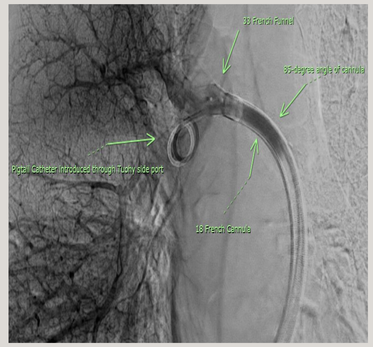
MAP reduction was slightly greater in the AlphaVac group (7.1 ± 7.0 mmHg; median 8) compared to Inari (5.4 ± 5.5 mmHg; median 5.5), but the difference was not statistically significant (t-test p = 0.27; Mann-Whitney p = 0.42).

Thirty-day all-cause mortality was observed in 1/42 AlphaVac patients (2.4%) and 6/42 Inari patients (14.3%). None of these deaths were attributed to procedural complications. The AlphaVac mortality involved a patient with metastatic lymphoma and HIV transitioned to comfort care. The Inari mortalities included patients with terminal cancer, mesenteric ischemia, pulmonary fibrosis, and sequelae from massive PE with pre-procedure cardiac arrests.

Demographics		
	Alpha	Inari
Age (Average)	62.1	63.1
Gender		
Male	50%	62%
Female	50%	38%
PE Severity		
Massive	2	3
Submassive	40	39
Fluoroscopy Time Comparison		
	Alpha	Inari
Average+/-STD	18.0+/-6.7	19.6+/-7.2
Median	15.6	19.6
T test	p=0.3	
Mann-whitney 2 tailed	p=0.2	
PA Systolic Difference		
	Alpha	Inari
Average+/-STD	14.1+/-9.6	10.6+/-10.7
Median	15.0	10.0
T test	p=0.1	
Mann-whitney 2 tailed	p=0.2	
PA Diastolic Difference		
	Alpha	Inari
Average+/-STD	1.6+/-5.6	2.6+/-4.9
Median	1.5	2
T test	p=0.4	
Mann-whitney 2 tailed	p=0.3	
MAP Difference		
	Alpha	Inari
Average+/-STD	7.1+/-7.0	5.5+/-5.5
Median	8	4
T test	p=0.4	
Mann-whitney 2 tailed	p=0.6	
30 Day All-Cause Mortality		
	Alpha	Inari
Total	1	6
Percent	2.4%	14.3%

AlphaVac F18-85 System (AVS) Description:

- 18 French cannula with 85-degree distal cannula angle
- 33 French atraumatic funnel cannula tip.
- 105 cm catheter length
- 22 Fr introducer sheath with locking valve
- Over-the-wire or wireless maneuvering of device once positioned within the pulmonary arteries.
- Operator-controlled aspiration initiation and aspiration volume through handle trigger and 10 mL or 30 mL handle toggle button.
- Built-in 9 Fr Tuohy-Borst side-arm adapter for introduction of catheters through the device.
- Drain bag attached to the handle for aspirated contents.
- Blood-return device is currently not available through AngioDynamics.



Conclusion

Despite representing the operator's first 42 consecutive AlphaVac cases, outcomes were comparable to those achieved with Inari after extensive prior experience. No statistically significant differences were observed between groups across any measured parameter; however, AlphaVac demonstrated directional trends toward improved PA systolic pressure reduction, MAP improvement, and reduced fluoroscopy time. Notably, 30-day all-cause mortality was lower in the AlphaVac group (2.4%) compared to Inari (14.3%), though none of the deaths in either group were attributed to procedural complications. These findings suggest that AlphaVac is not associated with increased risk and may offer a safe and effective alternative to FlowTriever, even during the early phase of device adoption. With continued experience, AlphaVac may offer procedural efficiency benefits due to its steerable cannula design and safe, wire-free advancement and maneuverability, allowing direct clot engagement compared to Inari's passive aspiration approach. These findings suggest early performance of AlphaVac is non-inferior and may offer unique advantages worth further exploration in prospective trials.

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