The Next Generation of PE Care:
A Prospective Study of the AVENTUS Thrombectomy System with Autologous Blood Reinfusion

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CASE WESTERN RESERVE UNIVERSITY School of Medicine

PIVOTAL STUDY DESIGN

PRIMARY OBJECTIVE

- Evaluate the safety and efficacy of the AVENTUS Thrombectomy System for aspiration thrombectomy in subjects with acute pulmonary embolism

STUDY DESIGN

- Prospective, multi-center, single-arm, pivotal study
- Subjects were followed at 48 hours and 30 days

PRIMARY ENDPOINTS

Efficacy

- Change in RV/LV ratio in subjects from baseline to 48 hours post-procedure

Safety

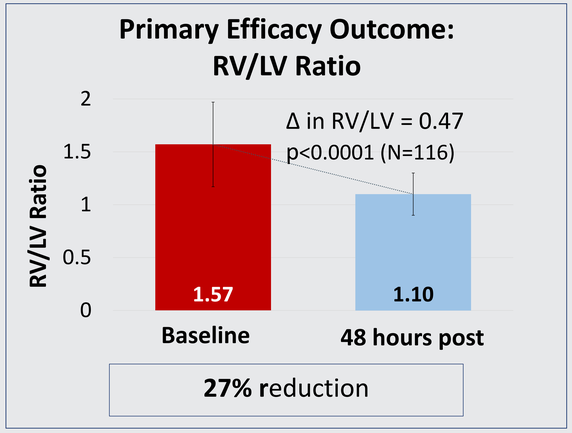
- Composite rate of ITT subjects having device related MAEs within 48 hours post-procedure, including:
  - Death
  - Major bleed
  - Clinical deterioration
  - Pulmonary vascular injury
  - Cardiac injury

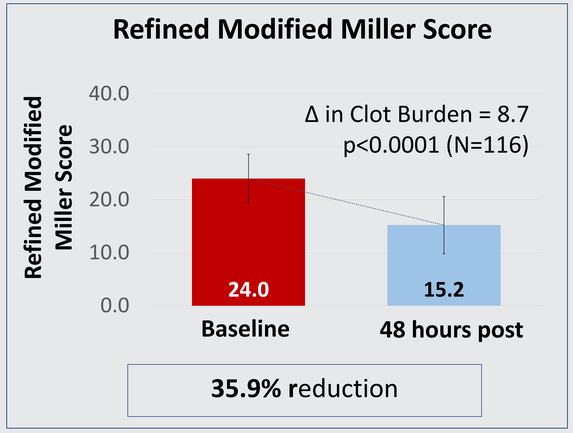
ENROLLMENT SUMMARY

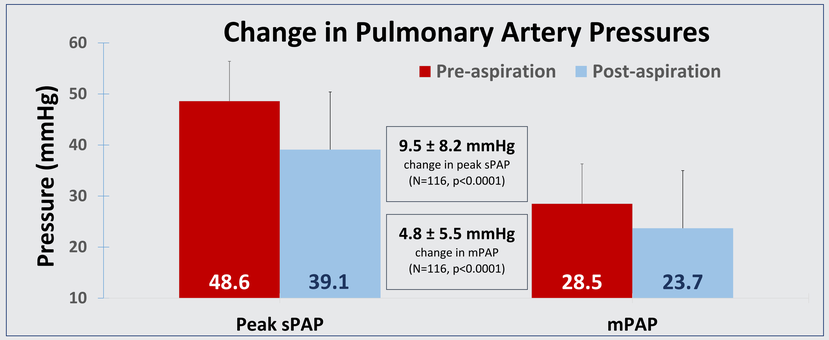
- 120 ITT, 10 roll-ins
- 22 sites
- 49 unique users
  - 71.4% IC
  - 22.4% IR
  - 6.1% VS

SUBJECT CHARACTERISTICS	ITT
Age, y	58.8±12.3 (120)
Sex, % Male	55.8 (67/120)
BMI, kg/m^2	35.6 ± 7.4 (115)
Prior PE	8.3% (10/120)
Prior history of DVT	10.0% (12/120)
Concomitant DVT	84.3% (86/102)
Pulmonary hypertension	66.1% (76/115)
Hypertension	54.2% (65/120)
Any cancer	9.2% (11/120)
Elevated troponins or BNP	87.4% (104/119)
Elevated troponins	75.8% (91/120)
Elevated BNP	87.4% (104/119)
Bilateral clot distribution	99.2% (119/120)

RESULTS







Primary safety outcome:
48 hours post device-related MAE

0% (0/120), p<0.0001*

*versus pre-specified Performance Goal

30-day composite device-related MAE and SAE

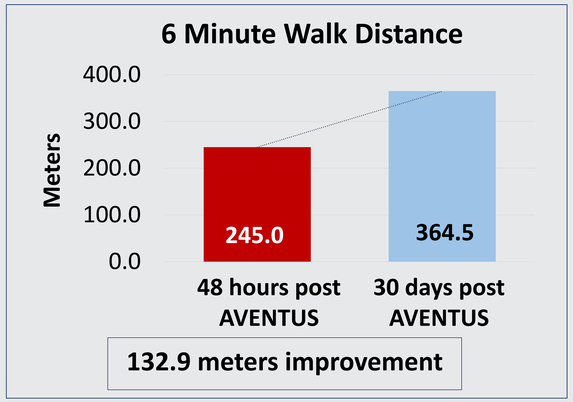
0% (0/120)

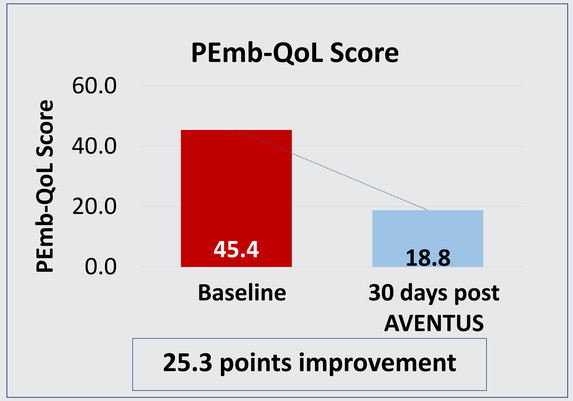
Catheter dwell time

39.5 minutes

Total hospital LOS

2.6 days





CONCLUSIONS

- The AVENTUS pivotal trial met its primary endpoints for efficacy and safety outcomes
- Clot was efficiently removed and blood was returned with no blood transfusions through 48 hours and short length of stay
- Functional status and subject-reported quality of life findings signaled directional improvement post-thrombectomy

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ABBREVIATIONS

RV/LV:right ventricle-to-left ventricle
MAE: major adverse event
ITT: intention-to-treat
IC: interventional cardiology
IR: interventional radiology
VS: vascular surgery
sPAP: systolic pulmonary artery pressure
mPAP: mean pulmonary artery pressure
SAE: serious adverse event
PEmb-QoL: Pulmonary Embolism Quality of Life

REFERENCES

AVENTUS Trial Investigators. Novel aspiration thrombectomy and blood reinfusion system for acute intermediate-risk pulmonary embolism: AVENTUS trial results. *J Soc Cardiovasc Angiogr Interv*. 2025 Jul;4(7):103661. doi:10.1016/j.jscai.2025.103661.