COMPASS Trial

Aspiration Thrombectomy vs. Stent Retriever Thrombectomy as First-Line Approach

Turk AS, Siddiqui A, Fifi JT, et al. Aspiration thrombectomy versus stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS): a multicentre, randomised, open label, blinded outcome, non-inferiority trial. Lancet. 2019;393:998-1008.

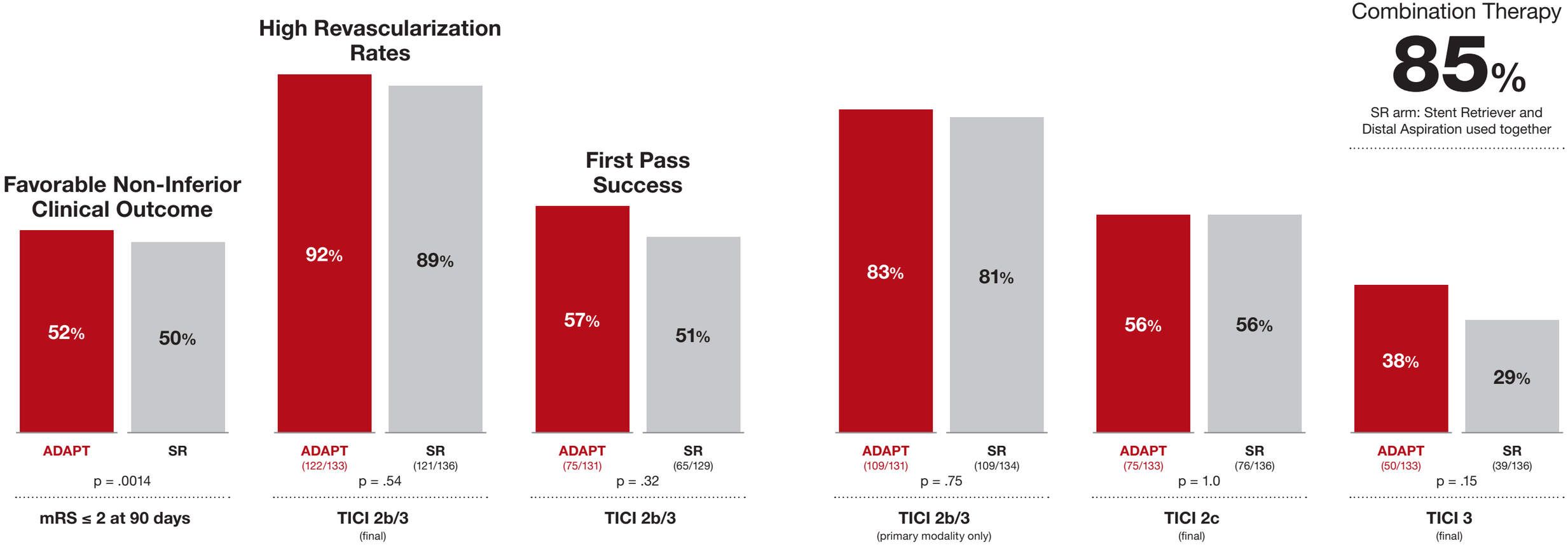
Note: COMPASS is an independent, physician-initiated study funded with a research grant by Penumbra, Inc. Penumbra did not play a role in the execution, data collection, data analysis, interpretation, or presentation of results of the COMPASS study.

Distal Aspiration Drives Success with ADAPT or Combination Therapy

Combination Therapy

85%

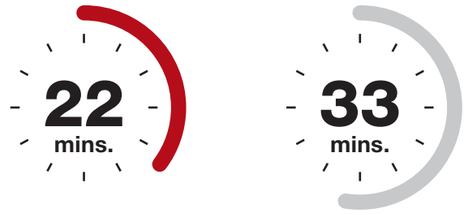
SR arm: Stent Retriever and Distal Aspiration used together



Safety

	ADAPT	SR	OR (95% CI)
Mortality at 90 days	22.0%	22.0%	1.02 (.57, 1.81)
sICH (all ICH with NIHSS ≥ 4 worsening)	6%	6%	1.01 (.37, 2.77)

Time to TICI ≥ 2b



p = .0194

Total Procedure Cost*

(median)

p < .0001

The opinions and clinical experiences presented herein are for informational purposes only. The results may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors.

*Per analysis using aggregate supply chain data as primary source and list price as secondary source

Trial Background

Design

- Prospective, randomized, international, multi-center, blinded assessment concurrent controlled trial

Population

- Anterior circulation ELVO (ICA to MCA Bifurcation) within 6 hours of onset

Randomization

- 1:1 ADAPT vs. Stent Retriever Frontline (SRFL)

Assessment

- Blinded core lab adjudication of imaging
- Blinded mRS certified clinical assessment

Sites

- 15 centers in North America
  - 6 centers with ≥ 67% ADAPT cases
  - 6 centers with ≥ 67% SRFL cases
  - 3 centers with mixed technique
  - 270 patients enrolled

Baseline Characteristics

	ADAPT (134)	SRFL (136)
Age	71.8 ± 13.1	71.1 ± 12.9
Gender (female)	58%	50%
Baseline NIHSS (median)	17	17
Baseline ASPECTS Score (median)	8	8
Site of Occlusion		
MCA		
M1 Proximal	61% (82/134)	63% (85/136)
M1 Distal	14% (19/134)	11% (15/136)
M2 Proximal	8% (11/134)	8% (11/136)
M3	0 (0/134)	<1% (1/136)
ICA		
Supraclinoid ICA (ICA Terminus)	13% (18/134)	15% (21/136)
Petrocavernous	<1% (1/134)	<1% (1/136)
Other		
Mid-basilar	0 (0/134)	<1% (1/136)
Tandem Cervical-ICA	2% (3/134)	<1% (1/136)
Directly admitted to a comprehensive stroke center	56% (75/134)	57% (78/136)
IV tPA pre-procedure	69% (92/134)	71% (96/136)
General Anesthesia %	29% (39/134)	30% (41/136)

PENUMBRA SYSTEM™ – Indication for Use
Penumbra Reperfusion Catheters and Separators
As part of the PENUMBRA SYSTEM, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Penumbra 3D REVASCULARIZATION DEVICE™
As part of the PENUMBRA SYSTEM, the Penumbra 3D REVASCULARIZATION DEVICE is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Penumbra Aspiration Tubing
As part of the PENUMBRA SYSTEM, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.
Penumbra Aspiration Pump
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.
Contraindications
There are no known contraindications.
Warnings
• The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location. • Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor. • Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device. • Confirm vessel diameter, and select an appropriate size Penumbra Reperfusion Catheter. Do not use in arteries with diameters smaller or equal to the distal outer diameter of the Penumbra Reperfusion Catheters. Refer to the Reperfusion Catheter labeling for dimensional information. • Do not advance, retract or use any component of the PENUMBRA SYSTEM against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter, revascularization device, or SEPARATOR™ against resistance may result in damage to the device or vessel. • Do not use the PENUMBRA SYSTEM with a pump other than the Penumbra Aspiration Pump. • The Penumbra 3D REVASCULARIZATION DEVICE has not been evaluated in patients with angiographic evidence of pre-existing arterial injury.
Precautions
• The PENUMBRA SYSTEM should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke. • Use prior to the "Use By" date. • Use the PENUMBRA SYSTEM in conjunction with fluoroscopic visualization. • As in all fluoroscopy procedures, consider all necessary precautions to limit patient radiation exposure by using sufficient shielding, reducing fluoroscopy times and modifying radiation technical factors whenever possible. • Maintain a constant infusion of appropriate flush solution. • When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended. • The Penumbra SEPARATOR is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques. • Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.[1] Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice. • As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

1. Adams, et al., Guidelines for the Early Management of Adults with Ischemic Stroke: A Guideline from the AHA/ASA Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists, Stroke May 2007; 38:1655-1711.

Penumbra Pump MAX™– Indication for Use
The Penumbra Pump MAX is indicated as a vacuum source for the Penumbra Aspiration Systems.
Contraindications
There are no contraindications.
Warnings/Precautions
• The canister/tubing is intended for single use only. Do not reuse. Reuse may result in canister cracking or tubing blockages, which may result in the inability to aspirate. • Do not block bottom or back air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow. • To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. • Do not position the pump so that it is difficult to operate the power cord disconnection device. • Remove and service the pump if liquids or solids have been drawn into the vacuum pump. • Do not use in the presence of a flammable anaesthetic mixture with air or nitrous oxide. • Do not use in oxygen rich environment. • To prevent fire or shock hazard, use replacement fuses of equal size and rating. • To prevent fire or shock hazard, use a replacement power cord of equal rating. • Do not re-infuse blood or fluid from the canister back into patient. • Do not use petroleum base compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce the service life of the pump. Use only water-base solvents for cleaning. • Federal (USA) law restricts this device to sale by or on the order of a physician. • No modification of this equipment is allowed.

PENUMBRA SYSTEM – Intended Use
The PENUMBRA SYSTEM is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease using continuous aspiration.
Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media; acute occlusion; air embolism; arteriovenous fistula; death; device malfunction; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at access site; inability to completely remove thrombus; infection; intracranial hemorrhage; ischemia; kidney damage from contrast media; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation; radiation exposure that may lead to cataracts, skin reddening, burns, alopecia, or neoplasia from x-ray exposure.

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Penumbra Pump MAX – Intended Use
The Penumbra Pump MAX is intended as a vacuum source for the Penumbra Aspiration Systems.

Penumbra™

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