

Thrombectomy for Anterior Circulation Stroke with a Hybrid Cell Design Stent Retriever: A Multicenter Registry

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Objective: Thrombectomy is the standard recanalization treatment for acute ischemic stroke (AIS) due to large vessel occlusions (LVO). However, thrombectomy was validated using a few brands of devices. New types of thrombectomy devices have been developed, and assessing their safety and efficacy is essential. This study aimed to evaluate the safety and efficacy of thrombectomy with the Aperio Hybrid stent retriever (Acandis, Pforzheim, Germany) in the treatment of patients with AIS due to anterior circulation LVO.

Methods: This was a multicenter registry of thrombectomy in the treatment of stroke due to anterior circulation LVO. Between January 2022 and January 2024, a total of 128 patients were included.

Results: The mean procedure time was 62 minutes. The rates of the main outcomes were recanalization (extended treatment in cerebral ischemia 2b-3) 102/128 (79.7%), symptomatic intracranial hemorrhage 9/128 (7.0%), good clinical outcome (modified Rankin Scale = 0–2) 67/128 (52.3%), and mortality 24/128 (18.7%) at 3 months.

Conclusion: This study showed that, in a multicenter real-life scenario, the Aperio hybrid stent retriever was safe and effective for thrombectomy of anterior circulation strokes. The outcomes of this study were similar to those of previous large thrombectomy studies.

Keywords acute ischemic stroke, large vessel occlusion, mechanical thrombectomy, stent retrievers

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Introduction

During the last decade, thrombectomy has proven to be the standard recanalization treatment for acute ischemic stroke (AIS) due to large vessel occlusions (LVO).^{1–15)} Initially indicated for AIS due to anterior circulation LVO, the benefits of thrombectomy have been expanded to a broad range of patients with AIS, including those presenting with posterior circulation occlusions, at late time windows, or even presenting with large baseline brain ischemic lesions.^{16,17)}

In the first randomized studies on thrombectomy, only a few brands of devices were tested and validated. This initiated a race in the development of thrombectomy devices, resulting in new models with novel designs. ^{18–25} While the expansion of device brands is very welcome for increasing patient accessibility to this treatment, the assessment of the safety and efficacy of new devices is essential.

This study aimed to evaluate the safety and efficacy of thrombectomy with the Aperio Hybrid stent retriever (Acandis, Pforzheim, Germany) for treating patients with AIS due to anterior circulation LVO.

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Materials and Methods

We analyzed data from a prospective registry of patients presenting with AIS due to LVO of the anterior circulation who were treated with thrombectomy in 5 Brazilian centers between January 2022 and January 2024. In all, 132 patients were treated with the Aperio Hybrid (Acandis) stent. Four patients were excluded because they presented with posterior circulation occlusions, while 128 patients with occlusion of the anterior circulation were included. All data were collected during daily clinical care practice. This study was approved by the ethics institutional review board of the Hospital Nove de Julho de São Paulo (number CAAE 68819323.9.0000.5455). The review board waived the need to obtain written informed consent from participants.

Patient evaluation

Upon admission, a brain computed tomography (CT) scan and a computed angio-tomography (CTA) were performed to assess the brain parenchyma using the Alberta Stroke Program Early CT Score (ASPECTS) and to identify the location of the artery occlusion. All images obtained were analyzed by the neuroradiologists and neurologists. All patients included were examined by certified vascular neurologists. Reperfusion and recanalization treatments, like intravenous thrombolysis and thrombectomy, were indicated according to the international acute stroke guidelines.¹⁵⁾

Clinical data collected in this study include age, gender, chronic kidney disease, hyperlipidemia, history of arterial hypertension, diabetes, tobacco smoking, coronary disease, atrial fibrillation, National Institutes of Health Stroke Scale (NIHSS) score, modified Rankin Scale (mRS; range: 0 [no symptoms] to 6 [death]), ASPECTS, site of arterial occlusion, collaterals (defined as grades 0, 1, 2, 3),²⁶⁾ number of patients admitted with an unknown time window, time from symptoms onset to admission, time from admission to arterial puncture, puncture performed 6 hours after symptom onset, intravenous thrombolysis with recombinant tissue plasminogen activator (rtPA), and procedure time (from arterial puncture until maximum revascularization of the occluded vascular territory). Recanalization was defined as an extended treatment in cerebral infarction (eTICI) score of 2b, 2c, or 3. The modified first-pass effect was defined as an eTICI 2b or 3 after the first pass of the Aperio device.

In general, thrombectomy was indicated for patients admitted with an NIHSS score ≥ 6 , ASPECTS ≥ 6 ,

occlusions of large arteries of the anterior circulation isolated or in association (tandem), which was defined as occlusion of the internal carotid artery (ICA), M1 segment of the middle cerebral artery (MCA), proximal M2 segment of the MCA, and <6 hours since the onset of symptoms. Patients that presented within 6 hours and 24 hours of symptom onset, or cases that presented at an unknown time of symptom onset, were treated by thrombectomy if they had ASPECTS ≥6 or if they had favorable results after evaluation of perfusion by CT, when available, following the DAWN or the DEFUSE trials criteria. 6,7) There were no exclusion criteria for the indication of mechanical thrombectomy based on the patient's age, previous clinical conditions, or specific mRS score. Symptomatic intracranial hemorrhage (sICH) was defined based on the criteria of the European Cooperative Acute Stroke Study II (ECASS II); that is, when parenchymal hemorrhage in the infarcted region resulted in a ≥4-point increase in the NIHSS scale in the period of 48 hours. CT scans of the brain were performed up to 48 hours after treatment.

Clinical assessments were performed at admission, during hospitalization, and at the 3-month follow-up. Patients who were not present for their 3-month follow-up were contacted by phone call. A good clinical outcome was defined as functional independence for daily life (mRS \leq 2).

Endpoints of the study

The primary efficacy endpoints were rates of recanalization eTICI 2b or 3 >75% and an mRS 0–2 at 3 months >35%. The primary safety endpoint was a rate of sICH <8%. Those cutoffs were extrapolated from the larger prospective studies on thrombectomy for stroke, considering the lower values for recanalization and mRS and the higher values for sICH.^{1–17)}

The secondary endpoints were to compare efficacy and safety of thrombectomy with the stent retriever with large trials and registries on thrombectomy for AIS due to LVO,^{1–17)} and to compare single stent retriever with combined technique regarding rates of recanalization (eTICI 2b-3, eTICI 2c-3), distal embolization to other territories after thrombectomy, sICH, mRS and mortality at 3 months.

Endovascular procedure

All thrombectomies were performed under the care of the anesthesiology team. The use of conscious sedation or general anesthesia was defined on a case-by-case basis. The target mean blood pressure values were ≥100 mmHg if there was no rtPA infusion and <180 × 105 mmHg if

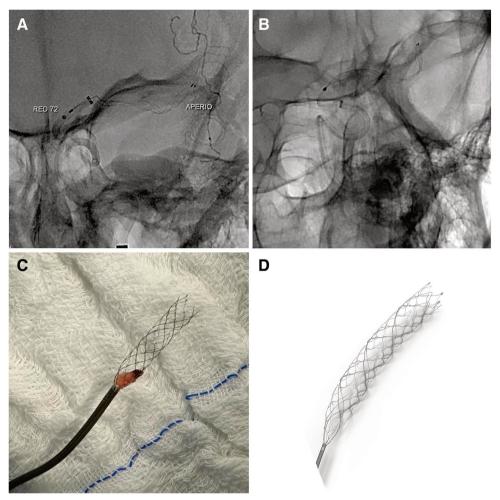


Fig. 1 X-ray images of the Aperio Hybrid device (Acandis, Pforzheim, Germany) and an aspiration catheter (RED 72; Penumbra, Alameda, CA, USA) during thrombectomy of an M1 occlusion (**A**) and a carotid tip occlusion (**B**). A photo (**C**) shows a thrombus captured by the Aperio Hybrid and the RED catheter. A magnified photo of the Aperio Hybrid and its unique design (**D**)

rtPA was used. Arterial accesses, devices, and thrombectomy techniques were defined by the interventionist neuroradiology team. Arterial accesses were obtained with 8 or 9F femoral sheaths. The access catheters used were conventional guides 7 or 8F, long sheaths Destination 6F (Terumo-Microvention, Tokyo, Japan), NeuronMax 088 (Penumbra, Alameda, CA, USA), balloon guide catheter (BGC) Cello 8 or 9F (Medtronic, Irvine, CA, USA), or Flowgate 8F (Stryker, Kalamazoo, MI, USA). The catheters were continuously perfused with a 10 mg solution of Milrinone diluted in 1000 mL of saline 0.9%. The thrombectomy devices used were the Aperio Hybrid, and ACE or RED aspiration systems (Penumbra), Catalyst 6F (Stryker), or SOFIA (Terumo-Microvention). As the Aperio Hybrid was made available on our local market, the participating center started to use the Aperio stent as a first-line device. There were no specific technical criteria

for using the Aperio Hybrid compared to other brands of stents. The new generation Aperio Hybrid has potential advantages over other brands, such as its full-length visibility, long sizes of up to 50 mm in length, and its hybrid cell design, composed of small closed cells and large open cells, which could potentially improve thrombus integration and extraction. The details of the Aperio Hybrid device are shown in **Fig. 1**.

The participating centers indicated, in most cases, a combination of Aperio and an aspiration catheter. A total of 8 passes were performed before the procedure was deemed a failure in recanalization. For cases with occlusion in the proximal segment of the carotid artery, angioplasty with X-Act (Abbott Vascular, Santa Clara, CA, USA) or Wallstent (Boston Scientific Target, Fremont, CA, USA) was performed. The procedure time was defined as the duration of arterial puncture until the maximum eTICI was obtained.

Table 1 Patient's baseline clinical and imaging data

	n = 128			
Male (n, %)	59 (46)			
Female (n, %)	69 (54)			
Age (mean, range, SD)	72.2 (28–100, SD ± 16.4)			
Hypertension (n, %)	87 (68)			
Chronic kidney disease (n, %)	11 (8.6)			
Hyperlipidemia (n, %) 42 (32.8)				
ronary disease (n, %) 23 (17.9)				
Atrial fibrillation/flutter (n, %) 45 (35.1)				
Diabetes (n, %) 34 (26.5)				
obacco (n, %) 11 (8.6)				
On-admission NIHSS (mean, range, IQR 25%-75%)	13 (2–35, 9.5–18)			
Pre-morbid mRS (median, range, IQR 25%-75%)	0 (0-4, 0-1)			
On-admission ASPECTS (median, range, IQR 25%-75%)	9 (3–10, 7–10)			
6–10 (n, %)	122 (95.3)			
3–5 (n, %)	6 (4.7)			
0–2 (n, %) 0 (0.0)				
llaterals grade 2 (0–3, IQ = 2)				
Vessel occluded				
Internal carotid artery (n, %)	18 (17)			
M1 (n, %)	83 (78.3)			
M2 (n, %)	5 (4.7)			
Carotid tandem (n, %)	13 (12.3)			
Unknown time window (n, %)	24 (29.6)			
Time from symptoms onset to admission (min, mean, range, SD)	276.3 (0–2160, 385)			
Time from admission to arterial puncture (min, mean, range, SD)	97 (30-600, SD ± 93.1)			
Puncture >6 hours from symptoms onset	21 (36.2)			
Intravenous rtPA (n, %)	40 (31.2)			

ASPECTS, Alberta Stroke Program Early Computed Tomography Score; IQR, interquartile range; mRS, modified Rankin Scale; NIHSS, National Institutes Health Stroke Score; rtPA, recombinant tissue plasminogen activator; SD, standard deviation

Statistical analysis

Categorical variables were presented in numbers and percentages. The mean and standard deviation (SD), interquartile range (IQR), or median were calculated for the numerical variables when appropriate. The Student's t-test, chi-square test (χ^2), and Fisher's exact test were used to compare groups when appropriate. The Stata program v.16.1 (StataCorp, College Station, TX, USA) was used for statistical analysis, and p values <0.05 were considered significant.

Results

The baseline data for the 128 patients included in this study are depicted in **Table 1** and treatment data are shown in **Table 2**. The mean age of patients was 72.2 years (28–100; SD \pm 16.4). A median on-admission NIHSS was 13 (2–35, IQR = 9.5–18). The median ASPECTS on admission was 9 (3–10, IQR = 7–10), and 95% of patients scored \geq 6. The median collateral grade was 2 (ranging from 0 to 3). One-third of the patients (n = 40; 31.2%) received

intravenous rtPA. Twenty-four (29%) patients presented with an unknown time of symptoms onset. The mean time from symptoms onset to hospital admission was 4.6 hours, the mean time from admission to puncture was 97 minutes, and the mean procedure time was 62 minutes.

General anesthesia was performed in 94.5% of the procedures. Most of the patients (77%) were treated by a combined technique (stent retriever and a large bore catheter), while 23% had only a stent retriever. The main recanalization rate (eTICI score ranging from 2b or 2c or 3) was obtained in 80% of patients. The modified effect (eTICI 2b-3) was obtained in 29.7% of patients. The rate of sICH was 7%. From treatment to the 3 months of follow-up, the mortality rate was 18.7%, and a favorable neurological outcome (mRS ≤2) was 52.3%.

Moreover, the results of patients treated with a stent retriever alone (29 cases) were compared with the outcomes of patients treated using a combined technique (99 cases). Patients treated with the Aperio Hybrid (Acandis) alone and those treated with a combined technique did

Table 2 Thrombectomy data

Table 2 Thrombotomy data			
	n = 128		
Procedure time (min, mean, range, SD)	62 (17–240, SD ± 43.4)		
Thrombectomy technique			
Stent retrieval (n, %)	29 (22.7)		
Combined stent retriever and aspiration (n, %)	99 (77.3)		
Carotid angioplasty stenting (n, %)	9 (7.9)		
Intracranial angioplasty stenting (n, %)	8 (6.2)		
Balloon guiding-catheter (n, %)	73 (57)		
Recanalization (eTICI) (n, %)			
eTICI = 0 or 1	10 (7.8)		
eTICI = 2a	16 (12.5)		
eTICI = 2b	34 (26.5)		
eTICI = 2c	12 (9.4)		
eTICI = 3	56 (43.7)		
eTICI = 2b-3	102 (79.7)		
eTICI = 2c-3	68 (53.1)		
Modified first-pass effect (eTICI 2b-3) (n, %)	38 (29.7)		
Number of passes (median, range, IQR)	2 (1–10, 1–3)		
Distal emboli to other territories (n, %)	17 (13.3)		
Symptomatic intracranial hemorrhage (n, %)	9 (7)		
Subarachnoid hemorrhage (n, %)	11 (8.6)		
NIHSS at 24 hours (median, range, IQR)	8 (0–35, 4–5)		
mRS at 3 months (median, range, IQR)	2 (0-6, 1-4)		
mRS = 0-1 (n, %)	45 (35.1)		
mRS = 0-2 (n, %)	67 (52.3)		
mRS = 0-3 (n, %)	77 (60.1)		
mRS = 4-5 (n, %)	23 (17.9)		
Mortality (n, %)	24 (18.7)		

eTICI, extended treatment in cerebral infarction scale; IQR, interquartile range; mRS, modified Rankin Scale; NIHSS, National Institutes Health Stroke Score; SD, standard deviation

not statistically differ from each other in terms of eTICI 2c or 3 (58.6% vs. 51.5%, p=0.53), eTICI 2b, 2c, or 3 (82.7% vs. 78.7%, p=0.79), distal embolization to other territories (6.8% vs. 13%, p=0.51), sICH (6.8% vs. 7.1%, p=1.00), mRS 0–2 (68.9% vs. 50.5%, p=0.10), and mortality (13.8% vs. 19%, p=0.59).

Discussion

Over the past 10 years, thrombectomy became the standard treatment for stroke due to LVO. The efficacy of thrombectomy has consistently surpassed that of the best medical management in terms of good neurologic outcomes across trials. When reviewing trial results, thrombectomy typically yielded rates of good neurologic outcome (mRS 0-2) >35%, whereas patients receiving the best medical management usually had rates of mRS 0-2 <25%. Thus, thrombectomy has resulted in absolute differences of mRS 0-2 of at least greater than 10% compared to the medical treatment, which is reflected in

numbers needed to treat from 8 to 3. Moreover, thrombectomy achieved recanalization rates >75% and sICH < 8%. Therefore, the primary endpoints of the present study were specified based on the results of the efficacy and safety of thrombectomy (**Table 3**).

Randomized trials assessing thrombectomy included only a few brands and types of devices, like the Solitaire (Medtronic), Trevo (Stryker), and Penumbra aspiration catheters (Penumbra). Although other types and brands of thrombectomy devices have been developed and approved by regulatory agencies, phase 4 studies assessing the outcomes of real-world patients treated in a daily care practice are essential. Real-world registries provide data on daily clinical care routines that reflect much more of the reality of care than the randomized controlled trials.

In this study, primary outcomes of 80% of recanalization, 52% of mRS 0-2, and 7% of sICH achieved the pre-specified values and were similar to those of previous trials (**Table 3**). Moreover, when analyzing only the Aperio stent retriever (Acandis) in the literature, 669 patients with AIS were treated

Table 3 The outcomes of the largest trials and registries on thrombectomy for acute ischemic stroke due to anterior circulation large vessel occlusion

Trial (year)	Main thrombectomy device	Recanalization (TICI = 2b/3) n (%)	mRS 0-2 at 3 months n (%)	sICH n (%)	Mortality at 3 months n (%)
MR-CLEAN (2014)	Solitaire Trevo	115/196 (58.7)	76 (32.6)	14 (6.0)	49 (21.0)
ESCAPE (2015)	Solitaire Trevo Penumbra	113/156 (72.4)	87 (52.7)	6 (3.6)	17/164 (10.4)
SWIFT-PRIME (2015)	Solitaire	73/83 (88.0)	59 (60.2)	0 (0)	9 (9.2)
EXTEND-IA (2015)	Solitaire	25/29 (86.2)	25 (71.4)	0 (0)	3 (8.6)
REVASCATE (2015)	Solitaire	67 (65.0)	45 (43.7)	2 (1.9)	19 (18.4)
DAWN trial (2017)	Trevo	90 (84.1)	52 (48.6)	6 (5.6)	20 (18.7)
DEFUSE 3 trial (2017)	Solitaire Trevo	69 (75.0)	41 (44.5)	6 (6.5)	13 (14.1)
SONIIA registry (2015)	N/A	327 (79.7)	204 (49.7)	10 (2.4)	59 (14.4)
TRACK registry (2017)	Trevo	505 (80.3)	277 (47.9)	44 (7.1)	106 (19.8)
STRATIS registry (2017)	Solitaire	724/824 (87.9)	512/906 (56.5)	12/841 (1.4)	142 (14.4)
German registry (2019)	N/A	1857/2236 (83)	732/1997 (36.7)	349/2637 (13.2)	570/1997 (28.5)
RESILIENT (2020)	Solitaire Penumbra	91/111 (82.0)	39/111 (35.1)	8/111 (7.2)	27/111 (24.3)
Present study (2024)	Aperio Hybrid	102/128 (79.7)	67/128 (52.3)	9/128 (7)	24/128 (18.7)

Aperio Hybrid, Acandis, Pforzheim, Germany; mRS, modified Rankin Scale; Penumbra, Penumbra, Alameda, CA, USA; slCH, symptomatic intracranial hemorrhage; Solitaire, Medtronic, Irvine, CA, USA; TICI, treatment in cerebral infarction scale; Trevo, Stryker, Kalamazoo, MI, USA

Table 4 The results of the studies on thrombectomy for acute ischemic stroke using the Aperio stent retriever

Study (year)	Recanalization (TICI = 2b-3) n (%)	mRS 0–2 at 3 months n (%)	sICH n (%)	Mortality at 3 months n (%)
Kallenberg et al. (2016) ²⁰⁾	85/119 (71)	_	12/119 (10)	-
Kaschner et al. (2019) ²¹⁾	70/82 (85.3)	28/82 (41.2)	6/82 (7.3)	15/82 (18.3)
Kaschner et al. (2020) ²²⁾	46/48 (95.8)	11/30 (36.7)	3/48 (6.3)	10/46 (21.7)
Weiss et al. (2022) ²³⁾	51/51 (100)	18/44 (40.9)	0 (0)	9/44 (20.4)
Goertz et al. (2022) ²⁴⁾	63/71 (88.7)	29/42 (69)	2 (2.8)	12/69 (17.4)
Vogt et al. (2022) ²⁵⁾	231/298 (75.7)	-	14/298 (4.7)	49/298 (16.4)
Present study (2024)	102/128 (79.7)	67/128 (52.3)	9/128 (7)	24/128 (18.7)

Aperio, Acandis, Pforzheim, Germany; mRS, modified Rankin Scale; sICH, symptomatic intracranial hemorrhage; TICI, treatment in cerebral infarction scale

with the Aperio stent. The overall results were recanalization ranging from 71% to 100%, mRS 0–2 from 37% to 69%, and sICH from 0% to 10% (**Table 4**). The present study results were also in accordance with the Aperio results.

Regarding thrombectomy techniques, 3 main strategies have been described in the literature: thrombectomy using a stent retriever, a large-bore aspiration catheter, or a combination of both. In the present study, the equivalence of the results between the stent retriever and the combined devices was consistent with 2 previous randomized trials, which failed to demonstrate the superiority of one technique over another.^{27,28)}

The main limitations of the present study were the small sample, the lack of a control group, and the absence of independent data monitoring and analysis.

Conclusion

This study showed that, in a multicenter real-life scenario, the Aperio hybrid stent retriever (Acandis) was safe and effective for thrombectomy of anterior circulation strokes. The outcomes of this study were similar to those of previous large thrombectomy studies.

Declarations

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used ChatGPT to correct English grammar. After using this tool, the author reviewed and edited the content as needed and takes full responsibility for the content of the publication.

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Data availability

Unpublished or unprocessed data, protocols, or images are available upon request from the corresponding author.

Disclosure statement

The authors declare that they have no conflicts of interest.

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