Original research

REcanalization of Distal Cerebral Vessels In Acute Stroke Using ApeRio (REVISAR)

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ABSTRACT

Background Although recently presented randomized trials have failed to prove an overall benefit of mechanical thrombectomy (MT) for patients with medium vessel occlusions (MeVOs), questions remain unanswered, particularly regarding the technology and the role of dedicated small devices. This prospective multicenter, core lab reviewed registry study investigates the efficacy and safety of the APERIO Hybrid used as a first-line device for the treatment of MeVO patients.

Methods Data from all MeVO patients who underwent MT with the APERIO or APERIO Hybrid[17] as a first-line technique were prospectively included. The primary endpoint was the successful recanalization (Thrombolysis In Cerebral Infarction (TICI) 2b/3) after up to three passes with the APERIO without the use of a rescue technique and without any symptomatic intracranial hemorrhage (ICH).

Results 134 patients were enrolled from 10 stroke centers. The primary endpoint was reached in 97 patients (81.5%, 95% CI 74.5% to 88.5%). In patients who failed the primary endpoint, TICI 2b/3 was reached with 4 to 6 APERIO passes in 4 patients (3.3%) and with other techniques in 18 patients (15%). Overall recanalization success was 95.8%. TICI 2b/3 with APERIO Hybrid was achieved after the first pass in 76 patients (63.9%), in 23 (19.3%) after 2 passes, and in 1 patient (0.8%) after 3 passes. Modified Rankin Scale (mRS) 0–2 at 90 days was reached by 79.0% of the patients. Symptomatic ICH occurred in no patients, asymptomatic ICH in 16 (13.5%), and subarachnoid hemorrhage in 15 patients (12.6%).

Conclusion APERIO and APERIO Hybrid[17] have been proven to be both safe and effective first-line devices for MT in MeVO stroke at different centers and with high rates of successful recanalization.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Mechanical thrombectomy (MT) has changed the prognosis of stroke patients with LVO; however, the initial results of the first randomized studies did not show any overall benefit of MT for medium vessel occlusion (MeVO) patients. One of several unanswered questions in this context is whether special devices adapted to the smaller vessel diameter and more distal anatomy may have any technical advantage.

WHAT THIS STUDY ADDS

⇒ This multicentric, prospective, monitored and core lab controlled study proves that MT with APERIO and APERIO Hybrid[17] are safe and effective in MeVO stroke patients.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ For well-selected patients, APERIO stent retrievers could contribute to improving the outcome of MeVO patients.

BACKGROUND

Mechanical thrombectomy (MT) has proven to be an effective treatment to improve the prognosis of severely affected patients with an acute ischemic stroke (AIS) due to a large vessel occlusion (LVO).[1] It has become the gold standard for treating this group of patients. However, 25–50% of all acute ischemic strokes are caused by medium vessel occlusions (MeVOs), where MeVO refers to occlusions of the M2 and M3 segments of the middle cerebral artery (MCA), the A2 and A3 segments of the anterior cerebral artery (ACA), and the P2 and P3 segments of the posterior cerebral artery (PCA).[2 3] The natural course of patients with an MeVO is better due to the smaller infarct area to be expected. However, even with intravenous (IV) lysis, more than 50% of these patients do not achieve complete recanalization,[3] and one out of four MeVO patients will not achieve functional independence at 90 days.[4] Given the outstanding therapeutic success of MT in patients with LVO, it seems only logical to also treat MeVO patients with MT, as this has been practiced by many neurointerventionalists for more than a decade.[5–8]

There have been several randomized trials aimed at investigating the superiority of MT for MeVOs; two of these studies (Escape MeVo and DISTAL) have recently been published,[9 10] and another one (DISCOUNT[11]) has been presented. All three of them failed to prove a benefit of MT in MeVO patients. The results of further randomized controlled trials (RCTs) are awaited.[12 13] However, these surprising results leave a lot of questions unanswered for many in the stroke community, including patient selection, the best technique, and the role of special devices adapted to the smaller vessel diameter and more distal anatomy.[14 15]

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APERIO Hybrid[17] (Acandis, Pforzheim, Germany) is a recently introduced fully radiopaque stent retriever with a hybrid cell design consisting of smaller closed cells to enhance vessel wall apposition and larger cells for clot capturing and incorporation. Initial studies have indicated a reasonable safety and efficacy profile of this device.[16–19]

This prospective, fully monitored and multicenter registry study investigates the efficacy, safety, and technical and clinical outcomes of using APERIO Hybrid, a low-profile stent retriever device, used as a first-line device for the treatment of patients with acute ischemic infarcts caused by MeVOs.

METHODS

Study design

REcanalization of Distal Cerebral Vessels In Acute Stroke Using ApeRio (REVISAR) is a prospective, one-armed, open-label, multicenter, national post-market clinical follow-up study. The aim of the study was to evaluate the safety and efficacy of the APERIO and APERIO Hybrid[17] thrombectomy device in distal artery occlusions in the anterior and posterior circulation (post-bifurcation MCA, ACA, PCA), requiring the use of an APERIO and/or APERIO Hybrid[17] device according to the instructions for use (IFU) for medical devices. Primary efficacy endpoint was a successful arterial recanalization of the occluded target vessel (measured by a modified Thrombolysis In Cerebral Infarction (mTICI) score of 2b or 3) following the use of the APERIO and APERIO Hybrid[17] thrombectomy device without any symptomatic intracranial hemorrhage (sICH) and without any rescue therapy within the first three passes. The secondary efficacy endpoint was a favorable clinical outcome, defined as a score of 0–2 according to the modified Rankin Scale (mRS).[20] For the primary safety endpoint, the rate of periprocedural ICHs associated with a worsening of the National Institutes of Health Stroke Scale (NIHSS) by ≥4 points within 48 hours, the rates of device and procedural (serious) adverse events, and the mortality rate were analyzed.

All data were monitored and reviewed independently by a central core lab (Eppdata, Hamburg, Germany).

Inclusion criteria

All patients with an acute occlusion of the post-bifurcation MCA, ACA, and PCA who underwent endovascular thrombectomy with the APERIO or APERIO Hybrid[17] thrombectomy device as a first-line technique according to IFU were prospectively collected and consecutively included. Informed consent from all participants or their legal representatives was waived either before or after the intervention.

Device

The APERIO and the further refined Hybrid thrombectomy device (Acandis, Pforzheim, Germany) is a recently introduced fully radiopaque stent retriever with a hybrid cell design consisting of small closed cells to enhance vessel wall apposition and larger cells for clot capturing and incorporation.

The novel APERIO Hybrid[17] thrombectomy device (figure 1) represents a further refinement of the existing APERIO with a low-profile structure, making it compatible with 0.017 inch microcatheters. The APERIO Hybrid[17] is approved for vessel diameters of 1.0 to 4.0 mm, compared with 1.5 to 5.5 mm with the conventional APERIO and APERIO Hybrid (figure 1). These technical advances may facilitate the endovascular treatment of medium or distal vessel occlusions that are difficult to approach with conventional stent retrievers.

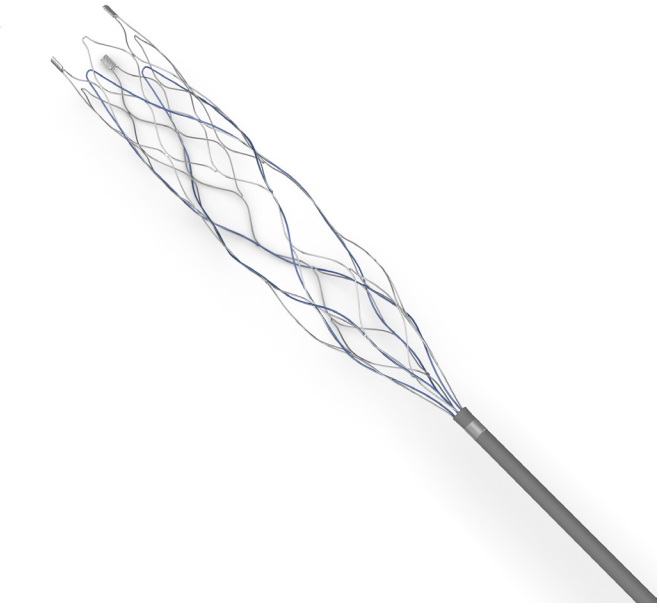

Figure 1 APERIO Hybrid[17] thrombectomy device.

The study was initially planned with the APERIO, but after the introduction of APERIO Hybrid (CE mark, March 2019) and the APERIO Hybrid[17] (CE mark, March 2020), these two devices were predominantly used.

Exclusion criteria

Patients under 18 years of age, patients with a pre-stroke mRS ≥3, and any patients with contraindications according to the IFU, were excluded.

Statistics

All statistical analyses were performed using the statistical software SAS 9.4. The analyses were based on the per-protocol set excluding all patients with premature study discontinuation due to protocol deviations or lost to follow-up.

Continuous variables were summarized using descriptive statistics, including number of patients with non-missing data, arithmetic mean, standard deviation (SD), median, lower and upper quartile, minimum, and maximum. Categorical variables were summarized by the number of patients and percentages. In addition, for the efficacy and safety endpoints (response rates), the 95% confidence intervals (95% CI) were calculated.

RESULTS

Baseline data and results are summarized in table 1.

In total, 134 patients were enrolled from 10 German stroke centers. Fifteen patients (11%) were not included in the final evaluation: 10 were lost to follow-up, three were screening failures, one patient's follow-up was outside of the 90-day period, and one patient was not treated with the APERIO but with another stent retriever as the first line technique and therefore was excluded from the analysis. Data from the remaining 119 patients (89%) were evaluated. Sixty patients (50.4%) were female. Mean (SD) age was 71.7 (13.1) years, 39 patients (32.8%) were older than 80 years, and eight were younger than 50 years (6.7%).

ASPECT score

Pre-interventional ASPECTS (Alberta Stroke Program Early CT Score[21]) was missing in six patients (5.0%). ASPECTS was 10 in

Table 1 Summary of the baseline characteristics

Number of patients	119
Women, n (%)	60 (50.4%)
Age (years), mean±SD	71.7±13.1
Patients younger than 50 years	8 (6.7%)
Patients older than 80 years	39 (32.8%)
NIHSS at admission, median (IQR)	8.98 (7–13)
NIHSS at discharge, median (IQR)	2.59 (1–25)
ASPECT score	
6	3 (2.5%)
7	9 (7.6%)
8	17 (14.3%)
9	24 (20.2%)
10	60 (50.4%)
Missing	6 (5.0%)
Premedication	
ASA	27 (22.7%)
P2Y12 inhibitor	1 (1.2%)
Anticoagulants	26 (21.8%)
Intravenous thrombolysis, n (%)	61 (51%)
Primary combined approach (SR and aspiration), n (%)	99 (83.2%)
Other techniques after failed recanalization with APERIO ('rescue techniques')	18 (15.0%)
ADAPT	3 (10.7%)
Other stent retrievers	9 (32.1%)
PTA and intracranial stenting	3 (10.7%)
ADAPT, PTA and intracranial stenting	1 (3.5%)
Another stent retriever and ADAPT	2 (7.1%)
Occlusion location	
M2, n (%)	74 (62.2%)
M3, n (%)	20 (16.8%)
A2, n (%)	3 (2.5%)
A3, n (%)	4 (3.4%)
P1, n (%)	2 (1.7%)
P2, n (%)	13 (10.9%)
P3, n (%)	1 (0.8%)
SCA, n (%)	2 (1.%)
Intravenous thrombolysis, n (%)	61 (51%)
Technical success	
TICI 2b/3 after up to 3 passes with the APERIO, n (%)	97 (81.5%)
First pass recanalization, n (%)	76 (63.9%)
Final TICI 2b/3 with all techniques	114 (95.8%)
Outcomes	
NIHSS at discharge, median (IQR)	2.59 (1–25)
NIHSS improvement	102 (85.7%)
mRS 0–2 (90 days)	94 (79%)
Safety	
Emboli to new territory, n (%)	2 (1.7%)
Any intracranial hemorrhage (on post-interventional imaging)	
HI 1, n (%)	12 (10.1%)
HI 2, n (%)	1 (0.8%)
PH I	3 (2.5%)
Subarachnoid hemorrhage	15 (12.6%)
Worsening of ≥4 NIHSS points most likely related to hemorrhagic transformation, n (%)	0 (0%)
In-hospital mortality, n (%)	5 (4.2%)

ADAPT, a direct aspiration first pass technique; ASA, acetylsalicylic acid (aspirin); ASPECT, Alberta Stroke Program Early CT; HI, hemorrhagic infarction; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; PH, parenchymal hemorrhage; PTA, percutaneous transluminal angioplasty; SCA, superior cerebellar artery; SR, stent retriever; TICI, Thrombolysis In Cerebral Infarction.

60 patients (50.4%), 9 in 24 patients (20.2%), 8 in 17 patients (14.3%), 7 in nine patients (7.6%), and 6 in three patients (2.5%).

Vessel occlusion

Detailed location of the thrombus is shown in table 1.

Mean (SD) diameter of the occluded artery was 1.9 (0.5) mm (minimum 0.95 mm, maximum 3.0 mm) at the proximal location and 1.5 (0.4) mm (minimum 0.7 mm, maximum 3.0 mm) at the distal target zone of the stent retriever.

Devices

Table 2 provides an overview of the devices and sizes that were used.

In relation to the proximal diameter of the target vessel, the device diameter was in range in 86 patients (72.3%), oversized in 24 patients (20.2%), and undersized in nine patients (7.6%). In relation to the distal vessel diameter, the device was in range in 66 patients (55.5%), oversized in 48 patients (40.3%), and undersized in four patients (3.4%).

Technique

First line technique was a combination of direct aspiration and APERIO stent retrievers in 99 patients (83.2%). All other cases were performed using the stent retriever only technique without distal aspiration.

The mTICI before the procedure was 0 in 114 patients (95.8%), 1 in two (1.7%), and 2a in three (2.5%).

The primary endpoint (technical success defined as successful arterial recanalization of the occluded target vessel measured by an mTICI score of 2b or 3 following the use of the APERIO and APERIO Hybrid[17] thrombectomy device without any sICH and rescue therapy within three passes) was reached in 97 patients (81.5%, 95% CI 74.5% to 88.5%). First pass recanalization success with APERIO/APERIO Hybrid was reached in 76 patients (63.9%). Recanalization was successful in 23 patients (19.3%) after two passes and in one patient (0.8%) after three passes with APERIO/APERIO Hybrid.

Table 2 Sizes and devices that were used

Device size (mm)	APERIO Hybrid[17]	APERIO Hybrid	APERIO
2.5×16	15 (12.6%)	–	–
2.5×18	1 (0.8%)	–	–
2.5×28	36 (30.3%)	–	–
3.5×28	30 (25.2%)	–	2 (1.7%)
4.5×30	21 (17.6%)	1 (0.8%)	–
4.5×50	–	13 (10.9%)	–

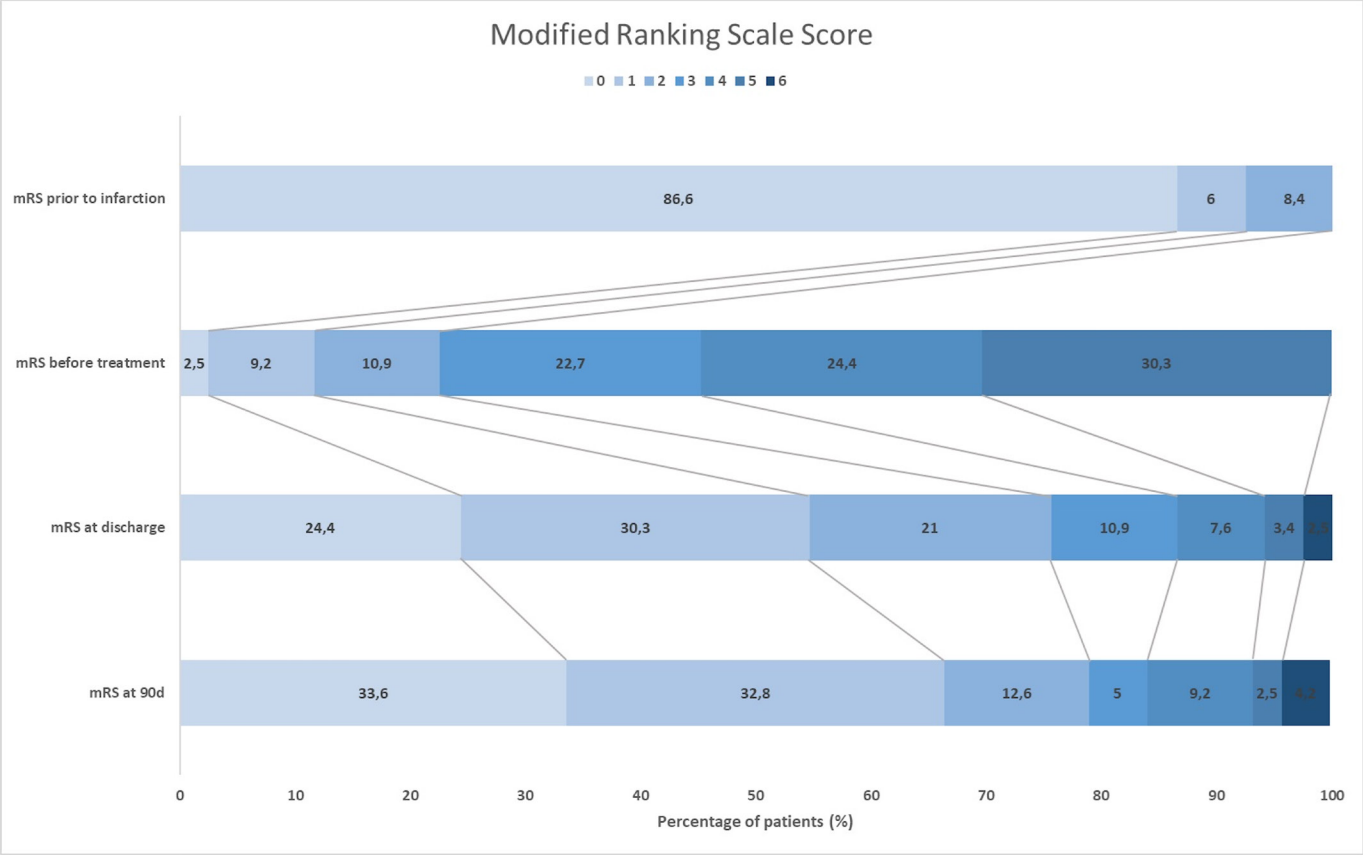

Figure 2 Modified Rankin Scale (mRS) scores before the ischemic event, before treatment, at discharge, and after 90 days.

In four (3.3%) patients who did not reach the primary endpoint, successful recanalization was achieved after four passes with the APERIO stent retriever in three (2.5%) patients and six passes in one (0.8%) patient. In 18 patients, other techniques were used: a direct aspiration first pass technique (ADAPT) in three (10.7%) patients, other stent retrievers in nine (32.1%), percutaneous transluminal angioplasty (PTA) and intracranial stenting in three (10.7%; all after the first pass with APERIO), ADAPT, PTA and intracranial stenting in one (3.5%), and the combination of another stent retriever and ADAPT in two (7.1%).

Balloon guide catheters were used in 24 of the cases (20.2%).

Overall, recanalization was successful in 114 patients (95.8%) with a mean number of 1.8 passes.

Clinical outcome

After the recanalization procedure, NIHSS improved in 102 (85.7%) patients, was unchanged in four (3.4%), and increased in five (4.2 %). NIHSS during the hospital stay was not available in eight patients (6.7%).

At 90 days follow-up, a good clinical outcome (mRS 0–2) was reached by 94 patients (79.0%, 95% CI 71.7% to 86.3%).[22] Figure 2 illustrates the mRS scores.

Safety

sICH within the first 48 hours and associated with clinical deterioration of at least 4 NIHSS points occurred in none of the patients (0%). In total, ICH during hospital stay occurred in 16 patients (13.5%). Any subarachnoid hemorrhage (SAH) occurred in 15 patients (12.6%); the majority of these were discrete and circumscribed subarachnoid blood deposits on the initial CT scan, and none of the cases were with intraventricular hemorrhage. Embolization into previously uninvolved regions or distal embolization occurred in two patients (1.7%).

There were no device and procedure-related serious adverse events; there were six (5.0%) procedure-related adverse events, and five patients died (4.2%).

Two dissections of vessels other than the target vessels were documented (1.7%), and there were four cases with vasospasm (3.4%), all of them being without any clinical sequelae.

Two patients suffered another stroke in a different territory during the initial hospital stay and during the 90 days follow-up, respectively (3.4%).

Procedural data

Mean (SD) time from puncture to revascularization was 43.7 (30.2) min (minimum 6, maximum 200), mean (SD) time from stroke onset to puncture was 220.3 (139.3) min (minimum 62, maximum 887), and mean (SD) time from stroke onset to revascularization was 261.1 (139.8 min) (minimum 111, maximum 909).

Sixty-one patients (51%) were treated with IV lysis.

Figure 3 shows an illustrative case.

DISCUSSION

Our prospective study shows that MT for primary MeVOs can be performed effectively with the APERIO and APERIO Hybrid[17] device, both low-profile stent retrievers explicitly designed for this purpose.

Technical success

Reported recanalization success in MeVOs varies greatly between different series, ranging from 57–91%.[23–25] Three

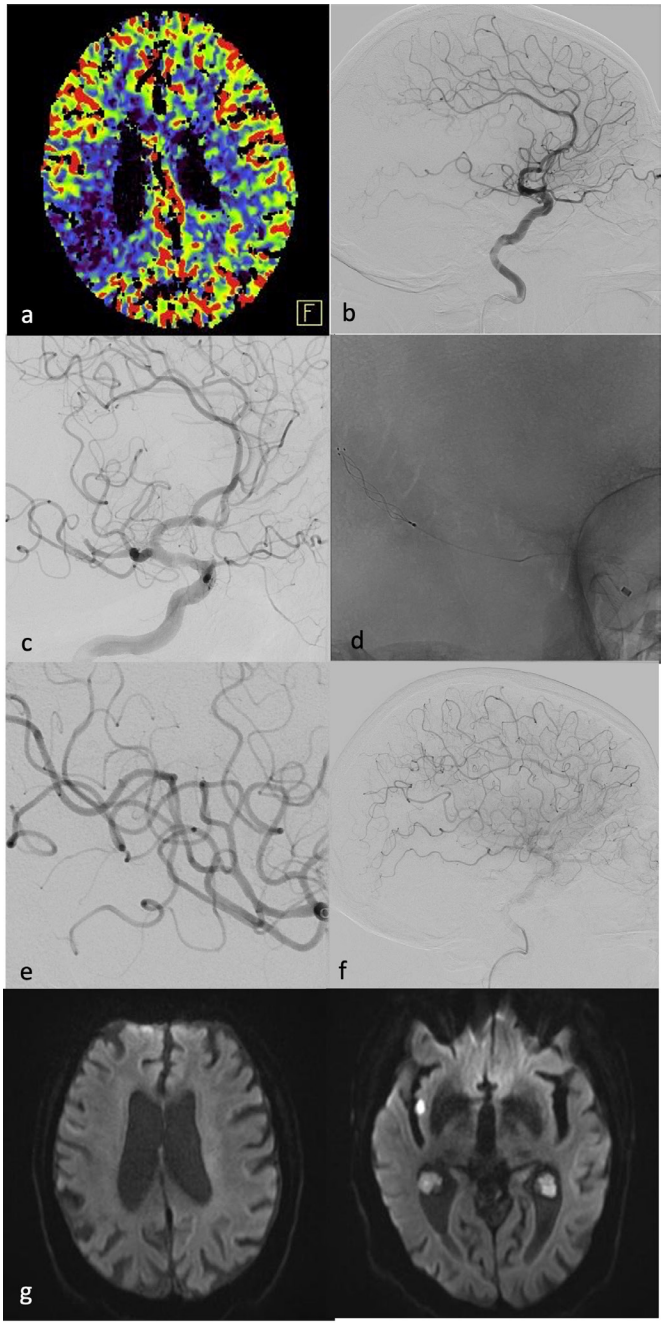

Figure 3 Illustrative case. (A) CT perfusion in a patient with right-sided middle cerebral artery M2 segment occlusion. Cerebral blood flow decrease indicating the infarct core with surrounding penumbra. (B, C) Lateral and oblique angiograms showing inferior trunk M2 occlusion. (D) Placement of an APERIO[17] 2.5–28 mm stent retriever. (E, F) Final angiograms confirming complete recanalization. (G) MRI DWI imaging on day 1 post-treatment showing dotted right insular cortical infarct. DWI, diffusion-weighted imaging.

larger meta-analyses with 835, 1080, and 630 patients reported successful recanalization (TICI 2b/3) in 86.8%, 81%, and 78% of the cases.[26–28]

In our study, TICI 2b/3 within three or fewer passes with the APERIO stent retrievers in question was 81.5%. When other techniques were used additionally, final TICI 2b or better was reached in 95.8%. These high numbers probably reflect the ongoing technical advances during the last years with increasing recanalization numbers that can also be seen in LVO studies.

Goertz *et al* recently published a retrospective series of 71 patients with acute ischemic stroke who were treated with the APERIO Hybrid stent retriever device; among these patients, 29 (41%) had an M2 occlusion.[19] In the subgroup of M2 occlusions, the final TICI 2b recanalization rate was 89.7%, which compares well to the results in our study. Previous MeVO studies that used dedicated smaller stent retriever devices report final TICI 2b or better recanalization in 84.4% with the Tigertriever 13 (Rapid Medical, Yokneam, Israel[7]), in 78% with the Catch Mini device (Balt, Montmorcy, France[29]), and in 89.7% with the Solitaire X.[30] In a retrospectively obtained multicentric series of 227 patients who were treated with the pReset Lite device (Phenox, Wallaby) for an MeVo, successful reperfusion of the target vessel (mTICI 2b/2c/3) was attained in 85% of proximal MeVO and 97% of distal medium vessel occlusion, with a median of 2 passes (IQR 1–3) overall.[15] Real-life data from the German Stroke Registry (GSR) showed that recanalization success was not different between M2 and M1 occlusions (1115 patients with M2 and 2689 patients with M1 occlusions, TICI 2b/3: 83.2% vs 87%).[14]

Clinical outcome

In our series, 79% of all patients achieved functional independence after 3 months. This is much higher than in most LVO series (46% in the Hermes registry[1]) and is most likely due to the more distal occlusion sites in our study. When compared with series published by Wang *et al* (58%) and the retrospective series from the GSR published by Herzberg *et al* (51%),[14 15] our rate of good clinical outcomes was even higher. However, it is important to note that the vast majority of patients in our study had a baseline mRS of 0 (103 patients), 16 patients had an mRS of 1 or 2, and there were no patients with a higher mRS, whereas in Wang's study, for example, 22% had a baseline mRS of 3 or 4.

In the GSR series published by Herzberg *et al*, mortality in patients with M2 occlusions was the same as in patients with M1 occlusions (11.1%). Overall, mortality was low in our series (4.2%) when compared to Wang's series (12%), as well as to the Hermes registry (15.3% in the interventional group, 18.9% in the control group). However, our data must be interpreted carefully as 15 patients were lost for follow-up and again, the overall baseline mRS was favorable in our series.

Safety

The smaller diameter and the more distal, potentially more difficult to access location, as well as the increased vessel wall stress, make MeVO thrombectomy more prone to complications compared with LVOs. sICH was the most consistently reported complication type in MeVO endovascular therapy in previous reports: in two studies, sICH rates ranged from 10–11%.[14 31] None of the patients in our study experienced symptomatic ICH, which is in line with the very low rate of sICH in Wang's study (1%) and significantly lower compared with the 4.4% reported for LVOs in the Hermes registry.[1]

It is important to mention that the APERIO devices were combined with an aspiration catheter in the majority of cases of our study (83.2%); in Wang's series, the pReset Lite device was combined with distal aspiration in almost all cases (96%).[15] Reduction of vessel traction using this combined technique may potentially decrease the vessel wall stress and be an explanation for the relatively low rate of severe hemorrhage. However, any SAH was noted in 15 patients (12.5%). Subarachnoid deposits are described to occur in up to 45% of patients immediately after MT. There is growing evidence that they are associated with an unfavorable clinical outcome.[22 32] To what extent these

subarachnoid blood deposits precisely play a role in the clinical course is the subject of several studies and will certainly receive more attention in the future as more and more distal occlusions are treated by thrombectomy.

At this point, it is important to note that although no patient deteriorated significantly due to ICH, the overall rate of all (both parenchymal and subarachnoid) hemorrhagic complications was high (>25% for any ICH and SAH). Should this be confirmed in the randomized studies on MeVOs, the increased risk for ICH has to be taken into account when selecting MeVO patients for endovascular treatment.

Strengths and limitations

The strength of this study is the prospective design with prospective collection of the data, continuous monitoring (100%), and data evaluation by a core lab. Limitations of our study include the non-randomized nature, with all inherent potential biases. Although all patients were consecutively and prospectively included, some patients with no legal representatives being available for the consenting process according to the ethic committee's requirements, might account for a missed cohort with a potentially worse clinical outcome prohibiting them from signing the consent form themselves. The majority of cases were M2 occlusion, thus the results may not be generalizable to all occlusion sites, which involve the M3 segments, the ACA or PCA, and the cerebellar arteries. Lastly, the combination of guide catheters and aspiration catheters together with the questioned stent retrievers was on the respective institutional standards.

Our manuscript was overtaken by the presentation of the first three randomized trials which failed to show superiority and even suggested potential harm of MT over standard treatment for stroke patients with distal and medium MCA (MeVO) occlusions.[9–11]

The most reasonable explanation for the widely unexpected results of these RCTs is that physicians chose intervention over randomization for potentially eligible and severely affected patients. This hypothesis is supported by the fact that the patients in ESCAPE MeVO and DISTALS were older than in the previous RCTs that proved the efficacy of MT in stroke[33] and had less severe symptoms, with 41% of the patients in DISTALS presenting with an NIHSS score of 5. This could mean that younger and severely affected patients were not randomized but were chosen directly for endovascular treatment.

RCTs are the gold standard in clinical research, and despite all criticism, we must not close our eyes to the evidence but adapt our clinical practice accordingly. However, the results of these studies implicate that physicians' beliefs may lead to a severe selection bias. On the other hand, findings from post hoc analyses of previous trials, observational cohorts, as well as registry data such as the REVISAR study presented here, all suggest a benefit from thrombectomy in stroke due to medium vessel and possibly also to distal vessel occlusion.[4 33 34] These data cannot be denied as well.

Certainly, we cannot exclude the possibility that there is also selection bias in post-market registry studies such as REVISAR, where patients or their relatives had to give their consent before or after the procedure in order to be included in the study. It cannot be completely dismissed that some severely affected patients were excluded from the study, as consent is generally difficult to obtain if relatives cannot be reached.

Most likely, the truth lies somewhere in the middle, and the true significance of endovascular treatment in patients with small diameter vessel occlusions is potentially less favorable than in registries (with the tendency to positive patient selection), but also better than in RCTs, when physicians believe in the efficacy of the method and rather tend to include patients with primarily poor prognosis and treat the promising candidates outside of randomization. It will only be possible to prove or disprove the actual role of endovascular treatment in both cases if all consecutive patients with medium and distal MCA occlusions are included—no matter the study design.

CONCLUSION

APERIO and APERIO Hybrid[17] have been proven to be both safe and effective first-line devices for MT in MeVO stroke at different centers and with high rates of successful recanalization. Especially against the background of the rather sobering results of the RCTs on MeVOs that have just been presented, our study results can contribute to the discussion regarding the optimal technique for selected patients with small vessel occlusions who can still benefit from MT.

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Competing interests FD reports scientific grants from Johnson&Johnson, consulting fees and speakers honoraria from Johnson&Johnson, Microvention, Acandis, Penumbra, Q'Apel, Medtronic, Tonbridge. HN reports consulting fees from Acandis, Balt, Johnson&Johnson, Rapid Medical. DB reports consulting for Balt, Stryker, Acandis, Phenox, Vesalio. CK reports consulting fees from Acandis, Balt and Microvention. TL reports consulting fees from Stryker and Phenox. AF reports speakers honoraria from Penumbra.

Patient consent for publication Not applicable.

Ethics approval Approval for this multicenter prospective study was granted by the local ethics committees (LMU, Munich, Germany 19–651). The data supporting our findings are available from the corresponding author upon reasonable request. The results of this study are reported in accordance with the Strengthening the Reporting of Observational Cohort Studies in Epidemiology guidelines. Participants gave informed consent to participate in the study before taking part.

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