



# Single-center experience using the 3MAX or 4MAX reperfusion catheter for the treatment of acute ischemic stroke with distal arterial occlusions in patients not eligible for intravenous fibrinolysis

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## Abstract

**Background** In acute stroke, distal cerebrovascular occlusions can be linked to severe clinical symptoms, and treatment by mechanical thrombectomy may have an important clinical impact. When intravenous fibrinolytic therapy is firmly contraindicated, it remains the only treatment option.

**Methods** A total of 42 patients with isolated distal arterial occlusions and absolute contraindication for intravenous fibrinolytic therapy were retrospectively included. Mechanical thrombectomy was performed using Penumbra 4MAX or 3MAX aspiration catheters. When aspiration alone did not result in successful revascularization, a stent retriever was added.

**Results** Direct thromboaspiration was the first treatment option in all patients. 16.7% of cases required the additional use of a stent retriever. A TICI score  $\geq 2b$  reperfusion at the end of the procedure was obtained in 76.2% and a Rankin Score of 2 or less at 90 days in 45.7%. Two hemorrhagic complications were observed.

**Conclusions** Direct thromboaspiration appears a safe technique in acute isolated distal arterial occlusions. In a cohort of patients with absolute contraindication for intravenous fibrinolytic therapy, a significant percentage achieved good revascularization.

**Keywords** Acute stroke · Distal occlusions · Mechanical thrombectomy

## Introduction

In 2015, five randomized trials investigated the efficacy of modern endovascular therapies for stroke [1–5]. They provided strong evidence to support the use of mechanical thrombectomy when initiated within 6 h from stroke onset, prompting worldwide changes in the guidelines for management of acute stroke due to large-vessel occlusion.

These trials used a variety of treatment approaches, including the mandatory use of intravenous thrombolysis before the initiation of endovascular therapy.

Consequently, American Heart Association (AHA)/ American Stroke Association (ASA) published its Scientific Rationale for the Inclusion and Exclusion Criteria for Intravenous Alteplase in Acute Ischemic Stroke [6]. Even if some of the original exclusion criteria have proven to be unnecessarily restrictive in clinical practice, absolute contraindications remain.

The occlusion of smaller arteries, such as the M2 or M3 segments of the middle cerebral artery (MCA), A2 segments of the anterior cerebral artery (ACA) or the posterior cerebral artery (PCA), sometimes causes ischemic strokes with pronounced clinical impact on the patient [7].

The updated AHA 2018 Stroke Guidelines [8] specifically talk about distal occlusions. Notably it is stated that the use of mechanical thrombectomy with stent retrievers may be reasonable for carefully selected patients with acute stroke in whom treatment can be initiated within 6 h of symptom

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onset and who have causative occlusion of the MCA segment 2 (M2) or MCA segment 3 (M3).

Some studies have highlighted the efficacy of a direct thromboaspiration first-pass technique (ADAPT), successfully used to improve clinical outcome in large-vessel occlusions [9–12], to achieve revascularization and functional independence for patients with acute ischemic stroke secondary to M2 and M3 occlusions using ADAPT [13–15].

The purpose of this study is to assess the safety and efficacy of the Penumbra system including the 3MAX and 4MAX reperfusion catheters as frontline ADAPT therapy for acute isolated distal arterial occlusions in a cohort of patients with absolute contraindications for intravenous fibrinolytic therapy.

## Methods

From June 2014 to June 2017, 282 mechanical thrombectomies for acute ischemic stroke were performed in our institution.

This single-center observational and retrospective study collected data of all consecutive patients with acute distal cerebrovascular occlusions due to MCA (from M2), PCA (from distal P1) and ACA (from A2) undergoing ADAPT as the first treatment option for absolute contraindication to intravenous fibrinolytic therapy.

Before treatment, informed consent was obtained from the patient if conscious or a legal representative.

For each patient, we considered age, sex, risk factors, baseline mRS, NIHSS and ASPECT score (or early signs of ischemia in vascular territory of A2 or P1–P2), time from symptoms onset to groin puncture, time from groin puncture to revascularization, type of endovascular procedure (ADAPT alone vs stent retriever) and device used, TICI score at the end of the procedure, kind of anesthesia, ASPECT score at 24 h or signs of ischemia in vascular territory of A2 or P1, complications, NIHSS at 24 h and 30 days, Rankin Score (mRS) at 90-days follow-up.

All patients underwent unenhanced CT to exclude hemorrhage and CT angiography to detect cerebrovascular occlusions. In case of uncertain onset of the symptoms (i.e., wake-up stroke), patients were considered eligible for treatment when salvageable brain parenchyma was depicted by perfusion CT mismatch. All patients were evaluated by a stroke-dedicated neurologist.

Two blinded neuroradiologists with 8 and 23 years of experience in interventional neurovascular procedures (DGR and SB) reviewed all imaging data and assessed ASPECT score from the baseline CT scan and the TICI scores after intervention. They also reviewed the imaging data for complications of emboli to new territory, vessel dissection, vasospasm, vessel perforation and ICH.

Symptomatic ICH was defined by any evidence of a bleed from head CT at 24 h after the procedure and an increase of  $\geq 4$  points on the NIHSS score.

## Technical approach

Endovascular approach was performed using a large guide catheter, advanced into the internal carotid artery as distally as possible to reach the cervical or proximal petrous segment of the internal carotid artery or V1 tract of vertebral artery (in posterior cerebral artery occlusions).

Then, based on the location of the clot, a 4MAX (Penumbra, Alameda, California, USA) aspiration catheter (for M2 division and P1) or a coaxial system with a large bore catheter (ACE 0.60 or ACE 0.64) and a 3MAX (Penumbra, Alameda, California, USA) aspiration catheter for distal clot (for M2 branches and A2) were used.

The catheter was advanced in front of the thrombus, over a 0.014 in. microwire. Then, aspiration was applied through a high-vacuum aspiration pump (PMX220). As soon as the absence of flow was noted within the aspiration system, the catheter was slowly advanced to ensure solid engagement with the thrombus. Aspiration was left for approximately 60–90 s (Fig. 1). When aspiration alone did not result in successful revascularization, a stent retriever was added. The number of attempts was guided by TICI score after aspiration.

Technical success was defined as recanalization of the target vessel according to TICI score  $\geq 2b$ .

## Statistical analysis

Continuous parameters were compared using the Student's *t* test for normally distributed data or the Mann–Whitney *U* test for not normally or ordinally distributed data. A *p* value of 0.05% or lower was considered to be statistically significant.

## Results

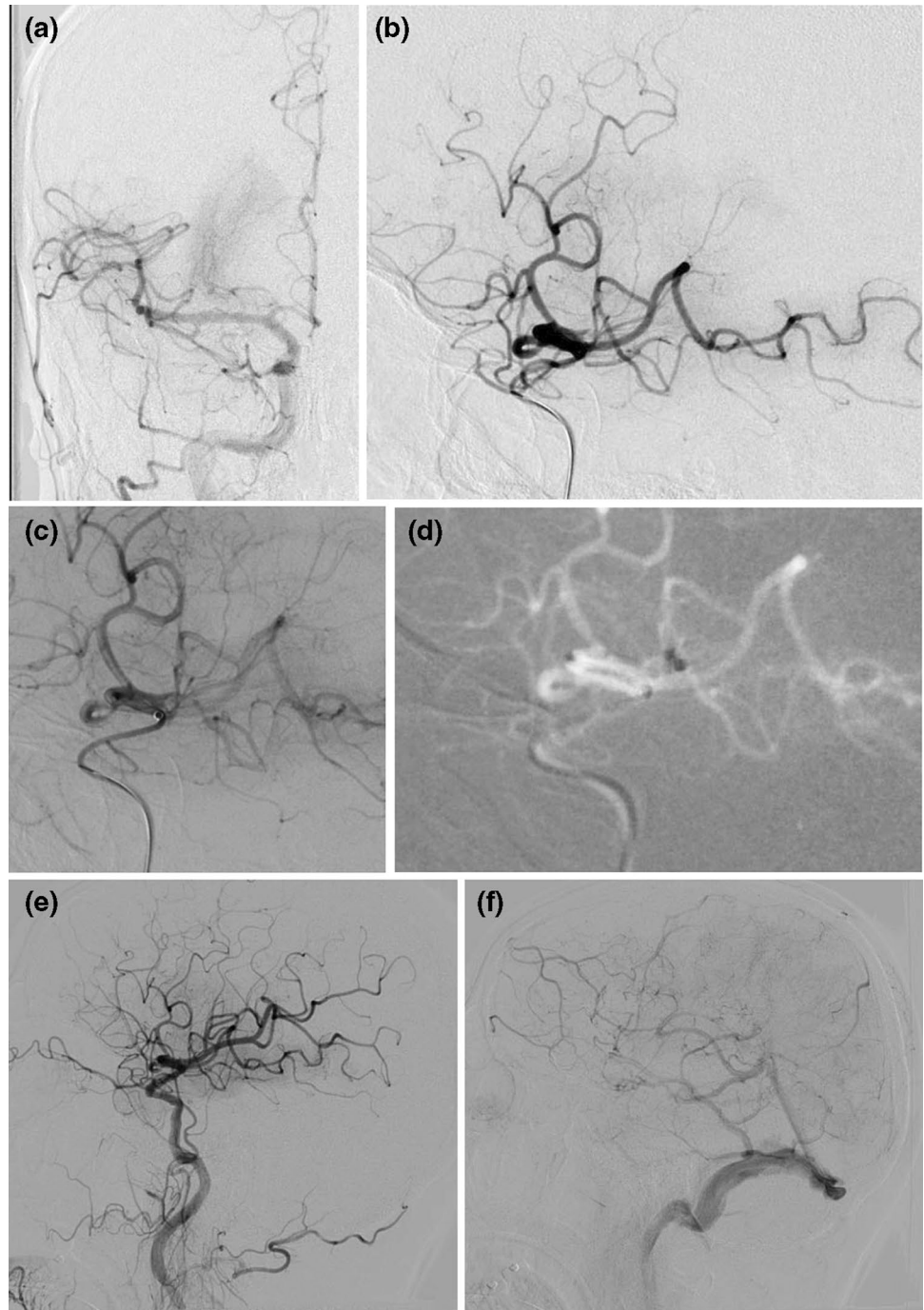
We retrospectively included 42 consecutive patients with acute ischemic stroke from distal arterial occlusions and absolute contraindication to fibrinolytic therapy for the following reasons: current use of anticoagulant with INR  $> 1.7$  or PT  $> 15$  s ( $n = 13$ ), platelet count  $< 100\,000/\text{mm}^3$  [1], after 4.5 h time window ( $n = 28$ ).

Patients with wake-up stroke were 11/42.

All patients were treated in our hospital with thromboaspiration as first intention using the Penumbra reperfusion catheter.

Target vessel occlusions were: M2 ( $n = 46$ ), P1 ( $n = 4$ ), A2 ( $n = 2$ ).

**Fig. 1** Male patient, 72 y.o with right M2 parietal branch occlusion (**a, b**), ACE 64 reperfusion catheter was advanced over a 3MAX aspiration catheter into the right MCA to the site of occlusion and left at the face of the thrombus (**c, d**), aspiration was applied resulting in successful revascularization 4 h after symptom onset (**e, f**)



57.1% were female ( $n=24$ ). Mean age was 75.2 years (SD 11.9, range 35–93.8), and 38.1% were older than 80 years old ( $n=16$ ).

Median baseline mRS was 0–2 in 88.10% ( $n=37$ ).

Median baseline NIHSS was 18 (range 2–27), and median baseline ASPECT score was 10 (range 0–27) and  $\geq 6$  in 97.6% ( $n=41$ ).

Characteristics of the study population are shown in Table 1.

Mean time from symptoms onset to groin puncture was 259 min (SD 69.5) in 31 patients with clear onset of symptoms.

All the patients performed ADAPT as first interventional step. In 16.7% ( $n=7$ ), a stent retriever was used as second device.

A TICI score  $\geq 2b$  at the end of the procedure was observed in 76.2% (TICI=2b in 15.4% and TICI=3 in 61.8%) in 27 cases (64.3%) in the ADAPT-alone group and

**Table 1** Characteristics of the study population at baseline

Age range (mean)	35–93.8 (75.2)
Male/female ( <i>n</i> )	18/24
No risk factors, <i>n</i> (%)	2 (4.7)
Atrial fibrillation, <i>n</i> (%)	20 (47.6)
Coronary artery disease, <i>n</i> (%)	5 (11.9)
Heart failure, <i>n</i> (%)	6 (14.3)
Diabetes, <i>n</i> (%)	10 (23.8)
Hypertension, <i>n</i> (%)	30 (71.4)
Hypercholesterolemia, <i>n</i> (%)	15 (35.7)
Cancer, <i>n</i> (%)	2 (4.7)
Smoking habit, <i>n</i> (%)	6 (14.3)
Valvular heart disease, <i>n</i> (%)	3 (7.1)
TIA or stroke last 3 months, <i>n</i> (%)	2 (4.7)
NIHSS median (range)	18 (2–27)
Minutes from symptoms onset to groin puncture, mean (SD)	259 (69.5)

in 32 cases (76.2%) in the ADAPT plus stent retriever group, respectively.

Mean number of passages was 1.85 (SD 0.96).

Hemorrhagic complications were observed in two cases; in both cases, it was symptomatic (both in the ADAPT-alone group).

Complications of vessel perforations or dissections were not observed.

In 30 cases (71.4%), the procedure was performed under general anesthesia, in seven cases (16.7%) in conscious sedation and in five (11.9%) without any kind of anesthesia (only local anesthesia at groin site of puncture).

Median ASPECT score at 24 h was 7.5 (range 1–10), median NIHSS at 24 h was 11.5 (range 1–18) and median NIHSS at 30 days was 6.2 (range 1–8).

Rankin Score of 2 or less at 90 days resulted in 45.7% (*n* = 19).

Mean time from groin puncture to revascularization was 48.4 min (SD 30.1); in particular, in ADAPT-alone group, mean time was 42 min (SD 22.3) while in ADAPT plus stent retriever group was 83 min (SD 41.5) (*p* < 0.05).

## Discussion

Distal strokes are less frequent than large-vessel occlusions [16], but they can lead to severe disability in up to 50% of the cases [17]. For this reason, treatment by mechanical thrombectomy may have an important clinical impact.

Notably the recommendation for mechanical thrombectomy for M2/M3 occlusions does not change substantively from the 2015 AHA/American Stroke Association-focused update.

A post hoc analysis of the STAR, SWIFT and SWIFT-PRIME studies [16] showed that the use of a stent retriever in M2 occlusion had similar results compared with those with M1 occlusions in terms of successful reperfusion (85% vs. 82%).

Most recently, primary stent retriever and direct aspiration showed similar efficacy [17] and it was suggested that the 3MAX reperfusion system is safe and effective in achieving successful revascularization and functional independence for patients with acute ischemic stroke secondary to M2 and M3 occlusions using ADAPT, either as frontline monotherapy, or in combination with adjunctive devices [18].

Intravenous fibrinolysis represents the gold standard for acute distal occlusions [8].

In fact, the ischemic penumbra volume of distal occlusions tends to be smaller and can also lessen the benefit of endovascular thrombectomy.

However, when contraindicated (for the high risk of hemorrhagic complications or beyond the therapy time window), mechanical thrombectomy remains the only treatment option to reduce the risk that important eloquent areas could be affected despite limited vascular territory involvement.

In our study, a good technical endpoint was reached in 76.2% of the cases; in particular, in 64.3% after ADAPT only.

A good clinical endpoint was reached in 45.7% of the cases, most of which after ADAPT only.

In Table 2 (modified from Chen et al.), a comparison between our results and previous works is presented. [19].

Park et al. [20] and Altenbernd et al. [14] achieved 84% and 100% of successful reperfusion using Penumbra 4MAX and Penumbra 3MAX reperfusion catheters, respectively.

Mokin et al. [17] performed a multicenter retrospective analysis of consecutive patients with acute MCA M2 segment occlusion who underwent thrombectomy with stent retrievers or primary aspiration thrombectomy. Authors found no differences in terms of efficacy between direct thromboaspiration and primary stent retriever thrombectomy. In 29% of cases in which direct thromboaspiration was performed, a stent retriever was subsequently used.

In our population, the percentage of use of a stent retriever is 16.7%. This lower result could be justified by operator's comparable technical expertise in a single-center study.

Kim et al. [18] achieved substantially the same clinical outcome in the treatment of M2 occlusions using stent retriever versus thromboaspiration, with slightly less complications in the last.

Notably aspiration catheters offer an alternative strategy for achieving thrombus removal by applying suction at the proximal portion of the occlusion and drawing it into the catheter lumen. Several Penumbra aspiration catheters have been developed for aspiration thrombectomy

**Table 2** A comparison between previous studies and the current study (table modified from Chen et al. [19])

	Population	Mean age (y.o)	Median NIHSS (baseline)	IV rt-PA, N (%)	Technique	TICI 2b-3%	mRS 0–2% at 90 days	sICH	Duration, median (min)
Flores et al.	65	66	16	35 (54%)	Stent retriever	71	51	9	–
Coutinho et al.	50	71	13	36 (72)	Stent retriever	68	60	2	29
Kim et al.	41	72	13	20 (49)	Stent retriever, FAST	78	80	2	–
Protto et al.	22	69.8	14	9 (41)	Stent retriever	77	50	–	–
Sarraj et al.	288	66	16	172 (60)	Stent retriever, aspiration	78	63	6	41
Park et al.	32	70.1	10.9	28 (88)	Aspiration	84	78	0	–
Mokin et al.	117	67	15	52 (44)	Stent retriever, ADAPT, others	85	56	–	–
Present study	42	75.2	18	0	ADAPT (stent retriever)	76.2	45.7	2	40

including 4MAX and 3MAX. Each of these catheters is compatible with the Penumbra continuous aspiration pump. The Penumbra reperfusion catheter has a highly navigable flexible tip, and it could help to overcome impedance with the use of a coaxial system (0.021 in. microcatheter and 0.014 in. microwire).

Some authors found that successful or unsuccessful reperfusion was associated with the location of the thrombus and the tortuosity between M1 and M2 [18].

In the present study, a good clinical endpoint was obtained in 45.7%. The smaller percentage of successful outcome was explained by the inclusion criteria (patients with absolute contraindication for intravenous fibrinolytic therapy) and clinical characteristics of our population (moderate to severe stroke with a mean NIHSS score of 18).

The duration of the endovascular treatment (time from groin puncture to reperfusion) was significantly lower in patients who underwent ADAPT alone because a stent retriever was used in case of failure of ADAPT. Nonetheless, switching to other techniques might provide better angiographic outcomes in cases with unsuccessful reperfusion after a few attempts with the ADAPT technique.

General anesthesia (used in 71.4% of cases), keeping the patient motionless, allows a safer procedure when dealing with a small intracranial vessel occlusion and permits the operator to concentrate on the procedure.

Procedural or anesthetic complications did not occur in the present study.

The risk profile for symptomatic bleeding was similar to that in recently reported controlled clinical trials [1–5].

Main limitations of this paper are the lack of randomization and the fact that it is a single-center, retrospective and observational study over a long period.

## Conclusions

In a cohort of patients with absolute contraindication for intravenous fibrinolytic therapy, a significant percentage achieved good revascularization.

Direct thromboaspiration appears a safe technique in acute isolated distal arterial occlusions. In case of failure, a stent retriever was used as adjunctive treatment.

## Compliance with ethical standards

**Conflict of interest** All authors declare that they have no conflict of interest.

**Ethical approval** This article does not contain any studies with animals performed by any of the authors.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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