

The direct first pass aspiration technique in the treatment of acute ischemic stroke resulting from large vessel occlusions

Técnica de aspiração primária no tratamento do acidente vascular cerebral isquêmico por oclusões de grandes vasos

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ABSTRACT

Mechanical thrombectomy using stent retrievers is the standard treatment for acute ischemic stroke that results from large vessel occlusions. The direct aspiration first pass technique (ADAPT) has been proposed as an efficient, fast, and cost-effective thrombectomy strategy. The aim of this study was to assess the safety and efficacy of ADAPT. **Methods:** Recanalization was assessed using the modified thrombolysis in cerebral infarction (mTICI) score. Neurological outcomes were assessed using the National Institutes of Health Stroke Scale and modified Rankin Scale. **Results:** Fifteen patients were evaluated. The mTICI score was 2b-3 in 80%, and it was 3 in 60% of patients. No intracranial hemorrhage was seen. At three months, modified Rankin Scale scores ≤ 2 were observed in 60% of patients and the mortality rate was 13.3%. **Conclusions:** The ADAPT appears to be a safe, effective, and fast recanalization strategy for treatment of acute ischemic stroke resulting from large vessel occlusions.

Key words: stroke; stents; catheters.

RESUMO

A trombectomia mecânica com stent retrievers é o tratamento padrão ouro do acidente vascular cerebral isquêmico agudo (AVCi) por oclusão de grandes artérias. A técnica de aspiração primária (ADAPT) tem sido proposta como uma estratégia de trombectomia rápida e com boa custo-efetividade. O objetivo deste estudo foi avaliar a segurança e eficácia da técnica ADAPT. **Métodos:** A recanalização foi avaliada utilizando a escala mTICI. Os desfechos neurológicos foram avaliados utilizando as escalas do NIHSS e mRS. **Resultados:** Quinze pacientes foram avaliados. Foram obtidas taxas de mTICI = 2b-3 em 80% e TICI = 3 em 60% dos pacientes. Não ocorreram hemorragias intracranianas. Em 3 meses as taxas de mRS ≤ 2 e mortalidade foram respectivamente 60% e 13.3%. **Conclusão:** A técnica ADAPT parece ser uma estratégia de recanalização rápida, segura e efetiva para o tratamento do AVC por oclusão de grandes artérias.

Palavras-chave: acidente vascular cerebral; stents; cateteres.

Mechanical thrombectomy, using stent retrievers as an adjunct to intravenous thrombolysis, is the standard treatment for acute ischemic stroke (AIS) that results from carotid or proximal middle cerebral artery occlusions^{1,2,3}. This treatment strategy improves functional outcomes for patients if started within the first six hours of symptom onset. More complete and faster recanalization and more pronounced brain collaterals are among the most important variables directly associated with better neurologic outcomes after endovascular treatment of AIS. Although

these concepts were already known, the introduction of stent retrievers in the endovascular armamentarium represented a cornerstone for achieving more complete and faster recanalizations, which consistently improves neurologic outcomes across results of recent trials^{2,3}. Despite emerging endovascular stent retriever technology, AIS resulting from large vessel occlusions (LVOs) remains a serious condition. In general, even among patients receiving the best stroke management, AIS from LVOs leads to poor functional outcomes 50% to 60% of the time and

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mortality 10% to 20% of the time^{2,3}. Therefore, ameliorations in stroke care are still needed and, in this context, strategies to improve complete recanalization rates and reduce procedure times should be continuously pursued. The direct aspiration first pass technique (ADAPT), using large bore aspiration catheters, has been proposed as an efficient, fast, and cost-effective thrombectomy strategy and may improve rates of complete recanalization while reducing procedure times^{4,5,6,7,8,9,10,11,12}.

The aim of this study was to assess the safety and efficacy of ADAPT using the 5MAX-ACE catheter (Penumbra, Oakland, California, USA) for treatment of acute stroke resulting from LVOs.

METHODS

Patients, clinical and imaging assessments, and follow-up

We prospectively evaluated data from 15 consecutive patients who underwent mechanical thrombectomy for AIS secondary to LVO between November 2015 and January 2016. The study was approved by the ethics committee at our institution. Patients, or their legal representatives, signed consent forms, which were previously approved by the institutional review board. All patients underwent a brain CT scan and a supra-aortic vessel CT angiography at admission to assess the arterial occlusion site. On the preprocedure brain CT, the Alberta Stroke Program Early Computed Tomography Score (ASPECTS) was assessed for all patients. The National Institutes of Health Stroke Scale was determined by stroke neurologists upon patient admission to hospital and again 24 hours after admission. The modified Rankin Scale (mRS) was assessed on admission and at the three-month follow-up by a stroke neurologist. Of 15 patients treated at our institution, nine (60.0%) were men, and the mean age was 66.1 years (SD = 13). Baseline National Institutes of Health Stroke Scales ranged from 6 to 30 (mean = 21.2, SD = 7.4), and baseline mRS ranged from 0 to 3 (median = 0, mean = 0.7, SD = 1).

In general, patients were assessed for eligibility for intravenous thrombolysis using the National Institutes of Neurological Disorders and the European Cooperative Stroke Study 3 trial criteria^{13,14}. If indicated, patients presenting with LVOs received intravenous thrombolysis and were immediately referred for thrombectomy. We included patients whose ASPECTS scores were at least 6 within the first six hours of symptom onset. We did not define a limited time window for performing endovascular treatment of posterior circulation stroke. We also did not define specific cut-offs in patient age, previous clinical conditions, baseline National Institutes of Health Stroke Scale, or baseline mRS for indicating thrombectomy. Patients presenting with

LVOs who were ineligible for intravenous fibrinolysis were treated with direct thrombectomy.

Endovascular procedure

Each patient was transferred to our angiography suite, where thrombectomy was performed by our interventional neuroradiology team using ADAPT with a 5MAX-ACE catheter (Penumbra, Oakland, CA, USA). Local anesthesia and conscious sedation were used. General anesthesia via intubation was performed if necessary at the discretion of the neurointerventional staff and the anesthesiologist.

All procedures were performed using the femoral artery approach. An intravenous bolus (5,000 IU) of standard heparin was administered after puncture if intravenous thrombolysis was not previously indicated. If intravenous thrombolysis was indicated prior to the endovascular procedure, no heparin was administered after the femoral puncture. An 8-Fr guiding catheter (Guider Softip; Boston Scientific, Natick, MA) or a NeuronMax 088 sheath (Penumbra, Alameda, CA) or a 7-Fr Destination (Pinnacle-Terumo) was introduced through a femoral sheath into the internal carotid artery or the most navigable vertebral artery. The guiding catheter was continuously perfused with 10 mg milrinone diluted in 1,000 mL of physiological saline (0.9%). Frontal, oblique, and lateral angiographies were completed to determine the cervical vessel related to the ischemic territory of the brain and to define the occluded intracranial vessels.

If a cervical carotid occlusion was identified, a Wallstent (Boston Scientific Target, Fremont, CA, USA) was used to perform an angioplasty stenting procedure. After this step, or if no occlusion was identified in the proximal cervical artery, a coaxial system was used to navigate to the arterial occlusion. The system consisted of a 5MAX-ACE (Penumbra), a microcatheter (3MAX [Penumbra], or Velocity (Penumbra), or a 0.027-inch Rebar 27 microcatheter [Medtronic, Irvine, CA, USA] or a 0.021-inch Orion microcatheter [Medtronic]), and a 0.014-inch steerable microwire (Transend EX Platinum; Stryker) or a 0.014-inch microwire SilverSpeed [Medtronic]. Both the microwire and the microcatheter were used to perforate the thrombus (Figures 1 and 2), followed by insertion of the 5MAX-ACE catheter into the thrombus. Then, the microwire and the microcatheter were removed, and the 5MAX-ACE was connected to an aspiration tube (Penumbra System) for thromboaspiration for five minutes (Figures 1 and 2). After five minutes, if the blood flow was blocked in the aspiration tube, the 5MAX-ACE was removed under aspiration. If, however, blood flowed freely into the aspiration tube, we aspirated the 5MAX-ACE with a 20 mL syringe and performed an angiogram through the catheter. If the artery remained occluded, we advanced the catheter 5MAX-ACE again into the thrombus to continue aspiration. We indicated

thrombectomy using a stent retriever (Solitaire-FR [Microvention-Covidien, Irvine, CA] or Trevo [Stryker, Fremont, CA]) if recanalization could not be achieved after five attempts to aspirate the thrombus, or if the angiogram revealed a distal occlusion after aspiration. Figures 1 and 2 show examples of the procedure.

Successful recanalization was defined as a modified thrombolysis in cerebral infarction (mTICI) score of 2b or 3 in all treatable vessels. No intra-arterial thrombolysis was administered, even if the recanalization was unsuccessful. Groin punctures were closed with Angio-Seal (St. Jude Medical, St. Paul, MN).

Statistical analysis

Continuous variables are presented as mean (range, \pm standard deviation [SD]) or median (interquartile [IQR]). Categorical data are presented as numbers and percentages. The IBM SPSS Statistics software version 20.0 (Chicago, IL, USA) was used for statistical analysis.

RESULTS

The ASPECTS scores on CT scans at admission ranged from 6 to 10 (median = 10, mean = 9, SD = 1.4). The mTICI score was 2b-3 for 80% (12/15) of patients, whereas it was 3 for 60% (9/15) of patients. The median number of device passes was 2. Intravenous thrombolysis was performed in 46.7% of patients. Stent retrievers were used in two patients (13.3%). Embolization to other vascular territories was observed in one patient (6.6%) during traction of an entrapped 5MAX-ACE catheter from the basilar artery; the right post-inferior cerebellar artery remained occluded after catheter retrieval.

Procedure times ranged from 15 to 120 minutes (mean = 60.6, SD = 31.3). We had no intracranial hemorrhage, nor any kind of hemorrhagic transformation. At three months, the mRS ranged from 2 to 6 (median = 2, mean = 3.2, SD = 1.6), and it was 2 or less for 60% (9/15) of the patients. The mortality rate was 13.3% (2/15). Individual patient data are summarized in Table 1. Baseline patient data results are

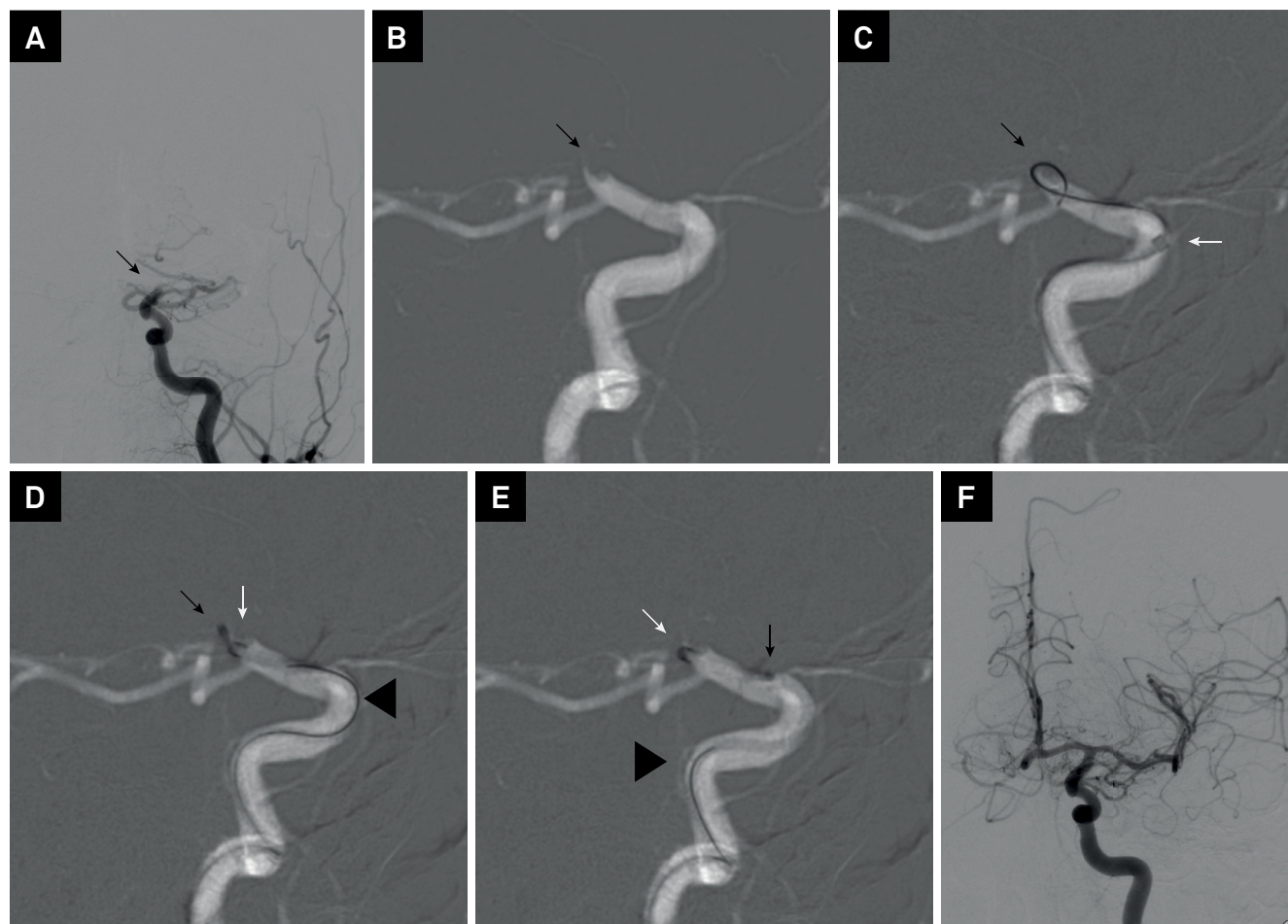


Figure 1. (A) Digital subtraction angiography (DSA), frontal view, shows an occlusion of the left internal carotid artery (LICA) (arrow); (B) road map of the LICA, lateral view, shows the occlusion at the distal carotid artery (arrow); (C) figure shows a micro-wire in the thrombus (black arrow) and the distal tip of the 5MAX-ACE catheter (white arrow); (D) a microcatheter is inserted into the thrombus (black arrow) and the distal tip of the 5MAX-ACE is engaged in the thrombus (white arrow) while micro-wire is removed (arrowhead); (E) both micro-wire (arrowhead) and microcatheter (black arrow) been removed while the 5MAX-ACE catheter remains into the thrombus ready for aspiration; (F) DSA frontal view, shows a complete recanalization of the LICA territory.

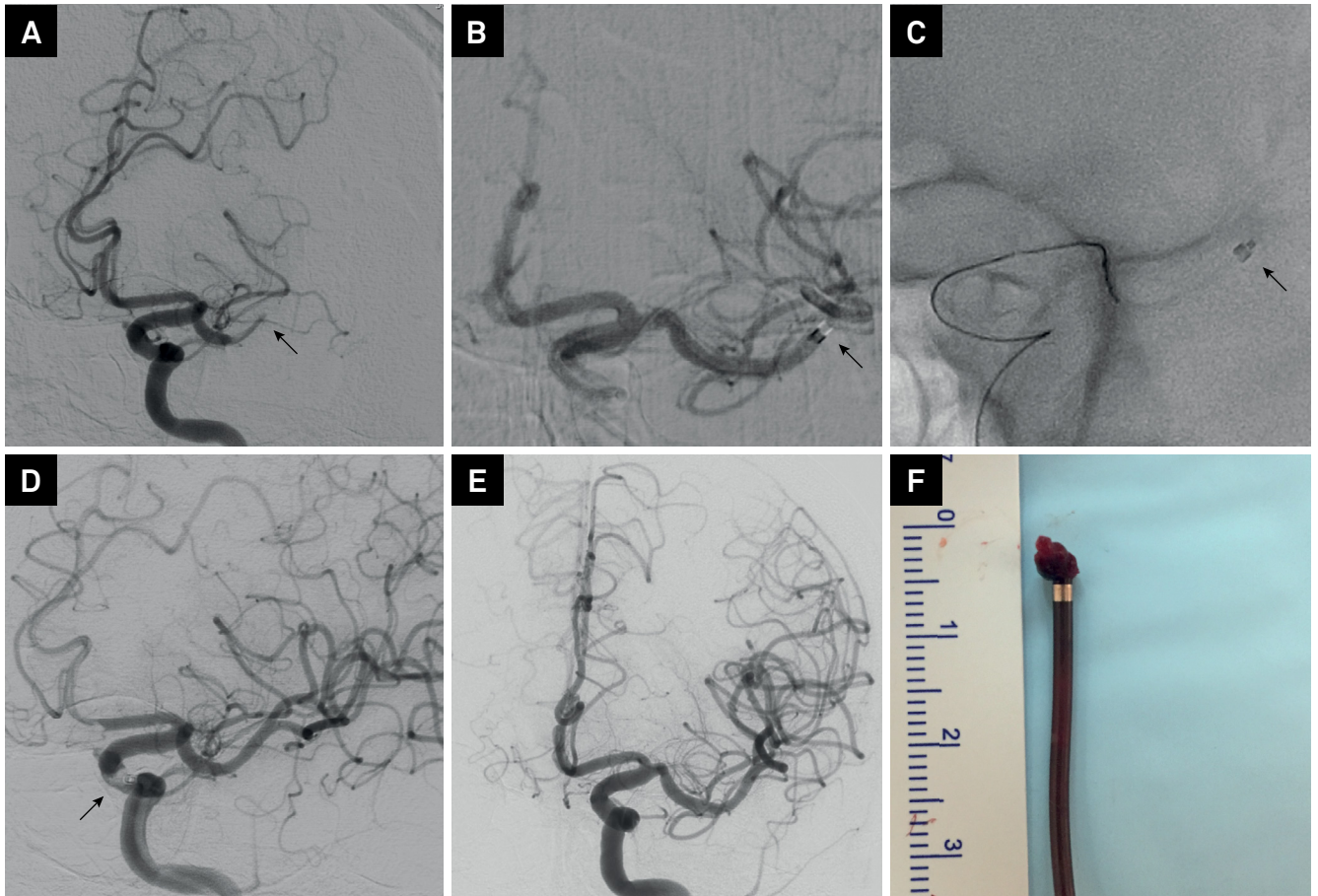


Figure 2. (A) Digital subtraction angiography (DSA) of LICA, oblique view, shows an occlusion of the distal M1 segment of the left middle cerebral artery (MCA) (arrow); (B) distal tip of the 5MAX-ACE is engaged in the thrombus (arrow); (C) distal tip of the 5MAX-ACE and a micro-catheter engaged in the thrombus (arrow); (D) DSA of LICA, oblique view, shows the exact moment of thrombus is removed from circulation entrapped in the 5MAX-ACE catheter (arrow); (E) DSA frontal view, shows a complete recanalization of the LICA territory; (F) picture of thrombus entrapped in the 5MAX-ACE catheter.

aggregated and summarized in Tables 2 and 3. Table 4 summarizes all studies published on thrombus aspiration using large bore catheters for treatment of acute stroke.

DISCUSSION

Recent trials have consistently proven the clinical benefits of mechanical thrombectomy using stent retrievers for AIS secondary to distal carotid or proximal middle cerebral artery occlusions^{1,2,3}. A recent meta-analysis showed that endovascular treatment resulted in good functional neurologic outcomes (mRS = 0-2) for 54% of the patients and excellent functional neurologic outcomes (mRS = 0-1) for 36% of patients. The rates of symptomatic intracranial hemorrhage and mortality were 2.5% and 12%, respectively. The recanalization rate (mTICI = 2b-3) was 71% with a mean procedure time (groin puncture to maximum mTICI score) of 38 minutes (range from 24 to 60 minutes). A complete recanalization (mTICI = 3) was achieved in 33% of patients^{2,3}.

When performing an endovascular treatment of AIS, procedure times and recanalization rates are two important

variables directly associated with better outcomes; therefore, efforts have been made to reduce procedure times and improve recanalization rates. Large bore aspiration devices are emerging thrombectomy devices, and they have been investigated to enhance recanalization and allow faster procedures. The 5MAX-ACE is a large bore, highly flexible, and atraumatic catheter capable of navigating through intracranial arteries, allowing for thrombus aspiration. Few studies have proposed a thrombectomy technique using simultaneous stent retrieval and aspiration with a distal access catheter^{15,16}. However, despite these new thrombectomy strategies and devices, they were not compared head-to-head with stent retrieval alone or while using ADAPT. In this setting, ADAPT appears to be a more rational and cost-effective strategy^{12,17}.

In our experience, the 5MAX-ACE catheter could be safely navigated to a variety of distal M1 segments of the middle cerebral arteries or to a selection of proximal P1 segments of non-hypoplastic cerebral posterior arteries that present with favorable angles. We also noted an advantage of the 5MAX-ACE: it can be used to assess difficult cervical arteries before proceeding with

Table 1. Individual data of patients.

Patient	Gender / Age	NIHSS at admission / 24 hours after treatment	Aspects	Symptomatic intracranial hemorrhage	Artery site occluded	IV rTPA / Intubation	Recanalization time (minutes)	Procedure time (minutes)	Device passes(n) / Carotid stenting	mTICI	Baseline mRS / 3-months mRS
1	M / 74	12/ago	10	N	Basilar artery	N / N	-	120	5 / N	0 / 3	0 / 2
2	F / 65	30/abr	10	N	Basilar artery	Y / Y	810	50	2 / N	3	0 / 2
3	M / 60	19/abr	10	N	Basilar artery	N / N	355	35	1 / N	3	0 / 2
4	M / 62	24 / 20	10	N	Distal LICA	N / N	480	60	3 / N	3	0 / 3
5	F / 76	26 / 26	9	N	Tandem proximal and distal RICA	Y / Y	-	120	7 / Y	0	0 / 6
6	M / 61	22/jul	10	N	Proximal left M1	N / N	255	15	1 / N	3	1/2
7	M / 34	20 / 18	9	N	Distal LICA	N / N	350	60	2 / N	3	0 / 2
8	M / 66	28 / 30	10	N	Basilar artery	Y / Y	480	45	2 / N	2b	0 / 5
9	F / 73	30 / 30	6	N	Basilar artery	Y / Y	475	30	2 / N	3	0 / 5
10	M / 52	14/dez	10	N	Tandem proximal RICA + right M1	N / N	450	80	1 / Y	3	2/2
11	M / 62	12/dez	8	N	Tandem proximal and distal RICA	N / N	600	60	3 / Y	2b	2/2
12	F / 68	06/jun	6	N	Basilar artery	N / N	450	40	1 / N	3	2/2
13	F / 79	30 / 30	7	N	Distal LICA	Y / Y	320	45	3 / N	2b	0 / 6
14	M / 68	25/dez	10	N	Distal LICA	Y / N	375	50	3 / N	3	0 / 2
15	F / 92	25 / 23	7	N	Proximal left M1	N / Y	-	100	8 / N	2a / 2a	3/5

M: male; F: female; Y: yes; N: no; NIHSS: National Institutes of Health Stroke Scale; mRS: modified Rankin Scale; mTICI: modified thrombolysis in cerebral infarction score; ASPECTS: Alberta Stroke Program Early Computed Tomography Score; RICA: right internal carotid artery; LICA: left internal carotid artery.

Table 2. Aggregated baseline clinical and radiologic data of patients.

Variable	Patients (n = 15)
Age (mean, range, SD)	66.1 (34–92, 13)
Age > 80 years (n, %)	1 (6.6)
Male sex (n, %)	9 (60)
Previous chronic conditions (n, %)	
High blood pressure	13 (86.7)
Alcoholism	4 (26.6)
Smoking	6 (40)
Hyperlipidemia	7 (46.7)
Diabetes mellitus	2 (13.3)
Atrial fibrillation	2 (13.3)
Baseline mRS (mean, median, range, SD)	0.7, 0 (0–3, 1)
NIHSS at admission (mean, range, SD)	21.2 (6–30, 7.4)
ASPECTS (mean, median, SD)	9, 10 (6–10, 1.4)
10	9 (60)
9	2 (13.3)
8	1 (6.7)
7	2 (13.3)
6	1 (6.7)

mRS: modified Rankin Scale; NIHSS: National Institutes of Health Stroke Scale; ASPECTS: Alberta Stroke Program Early Computed Tomography Score; SD: standard deviation.

intracranial thrombectomy. The coaxial system allows an atraumatic distal cervical artery position of the guide catheter, even passing through critical carotid or vertebral loops or kinks. Moreover, if aspiration alone fails, a stent retriever can be used through the large bore catheter, and retrieval can be performed under distal aspiration with the large bore catheter.

When compared to recent thrombectomy trials^{2,3}, we obtained unexpectedly higher rates of good clinical outcomes, considering that 40% of our patients had basilar occlusions, 20% had carotid tandem occlusions, 60% had mean recanalization times greater than six hours, and 13% had unknown times of symptom onset^{18,19}. We obtained a relatively high rate of mTICI = 3 (60%), a low rate of adjunctive use of a stent retriever (13%), and a low rate of emboli after thrombectomy (6.6%). Another interesting finding was our zero incidence of intracranial hemorrhage, especially considering that 80% of the patients had mTICI scores of 2b-3, and 73% were treated outside the level A evidence, which is less than six hours. Our mean

Table 3. Aggregated results.

Variable	Patients (n= 15)
Site of vessel occlusion (n, %)	
Tandem carotid artery	3 (20)
Distal carotid artery	4 (26.6)
Middle cerebral artery M1	2 (13.3)
Basilar artery	6 (40)
General anesthesia (n, %)	6 (40)
Device passes (median, mean, range, SD)	2, 2.6 (1–7, 1.6)
Recanalization mTICI = 2b-3 (n, %)	12 (80)
Recanalization mTICI = 3 (n, %)	9 (60)
Received intravenous r-tPA (n, %)	7 (46.7)
Use of adjunctive stentriever (n, %)	2 (13.3)
Embolization (n, %)	1 (6.6)
Procedure time (minutes, mean, range, SD)	60.6 (15–120, 31.3)
Time from symptoms onset to recanalization (min) (mean, range, SD)	475.3 (255–810, 167)
Time from symptoms onset to recanalization > 6 h (n, %)	9 (60)
Unknown time of symptoms onset (n, %)	2 (13.3)
Any intracranial hemorrhage (n, %)	0 (0.0)
Symptomatic intracranial hemorrhage (n, %)	0 (0.0)
NIHSS at 24 hours (mean, range, SD)	16.1 (4–30, 9.7)
mRS at 3 months (mean, median, range, SD)	3.2, 2 (2–6, 1.6)
mRS ≤ 2 at 3 months (n, %)	9 (60)
mRS = 6 (Mortality, n, %)	2 (13.3)

mTICI: modified thrombolysis in cerebral infarction score; r-TPA: recombinant tissue plasminogen activator; NIHSS: National Institutes of Health Stroke Scale; mRS: modified Rankin Scale; SD: standard deviation.

procedure time (one hour) was relatively long when compared to results of previous studies²⁻¹². We believe that this finding may be explained by the use of an adjunctive stent retriever in two patients, which was demonstrated to extend procedure time by 21 minutes²⁰. Where recanalization could not be achieved, we considered a maximum procedure time of 120 minutes. In addition, before preparing thrombectomy devices and systems, we routinely performed a diagnostic angiography, which may have lengthened overall procedure time (from puncture to maximum mTICI). Although this strategy may lengthen procedure times, intravenous thrombolysis eventually opened the vessel, and we were able to save devices. However, if thrombectomy devices were prepared and ready for use before femoral puncture, overall procedure time would certainly have been shortened, but with a probability of finding an opened intracranial vessel at the first angiographic run.

More data must be collected to confirm whether the ADAPT used in conjunction with stent retriever devices, compared to use of stent retrievers alone, would improve outcomes for patients presenting with AIS due to LVOs. Moreover, studies are needed to define the best recanalization strategy, aspiration or stentriever, for distal occlusions aiming to achieve mTICI 3.

Despite encouraging results using ADAPT in our series, these findings may have an inherent statistical bias because of the small sample, and our data is exposed to random effects. Another limitation of this study is the lack of a control group.

We find that ADAPT appears to be a safe, effective, and fast recanalization strategy for treatment of acute ischemic stroke resulting from large vessel occlusions.

Table 4. An overview of the published studies on mechanical thrombectomy using new large bore aspiration devices.

Author - Year	N	Mean NIHSS baseline	mTICI 2b-3 n (%)	mTICI 3 n (%)	Mean procedure time (min) / Use of stentriever (%)	Thrombus fragmentation n (%)	Mean recanalization time (min)	sICH n (%)	mRS ≤ 2 3 months n (%)	Mortality n (%)
Turk et al. 2014 ⁴	100	17.2	95 (95)	51 (51)	37 / NR	10	544	0 (0)	40 (40)	20 (20)
John et al. 2015 ⁵	15	13	11 (73)	5 (33)	46 / 33	NR	NR	0 (0)	4 (33)	2 (13.3)
Stampfl et al. 2015 ⁶	115	16.8	100 (86.9)	NR	73 / NR	5.2	267	7 (6.1)	NR	16 (13.9)
Jankowitz et al. 2015 ⁷	112	17	96 (86)	34 (31)	70 / 28.5	3.5	337	7 (6.2)	52 (46)	35 (31)
Comai et al. 2015 ⁸	16	22	14 (87.5)	8 (50)	47 / 31.2	12.5	NR	1 (6.2)	9 (56)	4 (25)
Delgado Almandoz et al. 2015 ⁹	45	19.2	40 (89)	NR	50 / 0	4	274	1 (2)	25 (56)	8 (18)
Romano et al. 2016 ¹⁰	152	19	115 (75.6)	NR	57.8 / 36.8	1.9	284.8	12 (7.8)	77 (50.6)	12 (7.8)
Kowoll et al. 2016 ¹¹	54	15	50 (93)	35 (65)	41 / 44.4	6	220	2 (4)	25 (46)	6 (11)
Vargas et al. 2016 ¹²	191	15.4	180 (94.2)	85 (44.5)	37.3 / 22.5	0	468.3	13 (6.8)	98 (54.1)	27 (14.1)
Authors 2016	15	21.2	12 (80)	9 (60)	60.6 / 13.3	6.6	475.3	0 (0)	9 (60)	2 (13.3)
Total	815	17.5	87.5	27.8	52 / 26.2	5.5	358.8	4,3	37,7	13,2

NIHSS: National Institutes of Health Stroke Scale; mTICI: modified thrombolysis in cerebral infarction score; sICH: symptomatic intracranial hemorrhage; mRS: modified Rankin Scale;

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