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Article *in* Journal of Neurointerventional Surgery · February 2014

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ORIGINAL RESEARCH

ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy

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Received 16 January 2014
Revised 4 February 2014
Accepted 5 February 2014
Published Online First 25 February 2014

ABSTRACT

Background The development of new revascularization devices has improved recanalization rates and time, but not clinical outcomes. We report a prospectively collected clinical experience with a new technique utilizing a direct aspiration first pass technique with large bore aspiration catheter as the primary method for vessel recanalization.

Methods 98 prospectively identified acute ischemic stroke patients with 100 occluded large cerebral vessels at six institutions were included in the study. The ADAPT technique was utilized in all patients. Procedural and clinical data were captured for analysis.

Results The aspiration component of the ADAPT technique alone was successful in achieving Thrombolysis in Cerebral Infarction (TICI) 2b or 3 revascularization in 78% of cases. The additional use of stent retrievers improved the TICI 2b/3 revascularization rate to 95%. The average time from groin puncture to at least TICI 2b recanalization was 37 min. A 5MAX demonstrated similar success to a 5MAX ACE in achieving TICI 2b/3 revascularization alone (75% vs 82%, p=0.43). Patients presented with an admitting median National Institutes of Health Stroke Scale (NIHSS) score of 17.0 (12.0–21.0) and improved to a median NIHSS score at discharge of 7.3 (1.0–11.0). Ninety day functional outcomes were 40% (modified Rankin Scale (mRS) 0–2) and 20% (mRS 6). There were two procedural complications and no symptomatic intracerebral hemorrhages.

Discussion The ADAPT technique is a fast, safe, simple, and effective method that has facilitated our approach to acute ischemic stroke thrombectomy by utilizing the latest generation of large bore aspiration catheters to achieve previously unparalleled angiographic outcomes.

INTRODUCTION

Early and efficient revascularization of large vessel occlusions has been shown to correlate with improved outcomes in selected patients with acute ischemic stroke.[1–3] Aspiration thrombectomy using the Penumbra system, while an effective technique for achieving revascularization, has yielded only modest clinical results.[4–6] Stent retrievers have also been shown to be effective for vessel recanalization, with similar clinical outcomes.[2 3]

Recent advances in catheter technology have included very large, easily trackable, aspiration thrombectomy catheters that can now more easily and reliably navigate the cerebrovasculature. A novel technique using this newest generation of large bore aspiration catheters as a first approach for thrombectomy has recently been reported.[7] The purpose of this study was to follow-up the initial experience with a prospective report of all stroke cases that had undergone a direct aspiration first pass technique (ADAPT) with a large bore aspiration catheter as the primary method for vessel recanalization.

METHODS

Under an institutional review board approved protocol, prospectively identified patient data were collected on all stroke patients undergoing the ADAPT technique at the Medical University of South Carolina, Swedish Medical Center, Vanderbilt University, Stonybrook University, Erlanger Medical Center, and University of Buffalo. Patients were selected for intervention as per the investigator protocol at each site. Usual practice was advanced imaging with CT/CT angiography and CT perfusion for patient selection. Patients included in this study were identified to have a large vessel cerebral vessel occlusion with viable ischemic penumbra and less than one-third ischemic vascular territory.

The ADAPT technique has been described previously.[7] Briefly, a large guide catheter (Neuron 088; Penumbra, Oakland, California, USA) was advanced as far distally into the cervical or proximal petrous internal carotid artery (ICA) as possible. The largest caliber aspiration catheter that the vessel would accommodate was selected for each case, usually a 5MAX (Penumbra) or 5MAX ACE (Penumbra), for distal ICA, proximal middle cerebral artery, and basilar occlusions. This catheter was advanced to the level of the thrombus, usually coaxially over a 016 microwire (Fathom; Boston Scientific Corp, Fremont, California, USA) and Velocity microcatheter (Penumbra). Other obturating catheters, such as 3MAX or smaller microcatheters, can also be used in conjunction with any compatible microwire. With the large bore aspiration catheter at the face of the thrombus, aspiration was applied with either a 20 or 60 mL syringe or Penumbra aspiration pump. Absence of flow within the aspiration system confirmed engagement with the thrombus. At this point, the catheter was gently advanced for 1–2 mm to ensure solid engagement with the thrombus. Aspiration was left for approximately 20 s, and if no flow through the system was found then the catheter

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To cite: Turk AS, Frei D, Fiorella D, *et al*. *J NeuroIntervent Surg* 2014;**6**:260–264.

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was slowly withdrawn. If aspiration failed, then the large aspiration catheter was reinserted up to the level of the thrombus and repeat aspiration attempted. At the operator's discretion, additional devices (such as stent retrievers) were used if aspiration alone failed.

Patient demographic, angiographic, and clinical data were collected. The degree of vessel occlusion before and after treatment was defined by the modified Thrombolysis in Cerebral Infarction (TICI) classification and adjudicated by the operator. Successful revascularization was defined as a TICI score ≥2b post-treatment. Procedure time was defined as the time from groin access to at least TICI 2b revascularization. Symptomatic intracerebral hemorrhage (sICH) was defined as presence of hemorrhage after treatment, with worsening of clinical examination by ≥4 points on the National Institutes of Health Stroke Scale (NIHSS). The 90 day functional outcomes were determined by the modified Rankin Scale (mRS), and were obtained from the available clinic records. A good functional outcome was defined as an mRS score of ≤2 at 90 days. Mortality was defined as death occurring within 90 days of initial presentation. The 5MAX ACE became clinically available during the present study. Outcomes for 5MAX and 5MAX ACE were compared.

Data were tracked at each site. De-identified data were submitted to the sponsoring institution (Medical University of South Carolina) which performed the primary analysis. Statistical analyses were performed using SAS V.9.3 (SAS Institute, Cary, North Carolina, USA). Differences between groups were tested using Student's t test for continuous measures and a χ^2 test for categorical measures. Differences between groups were tested using Fisher's exact test for categorical measures with expected cell sizes <5. All tests were two sided and assessed at a significance level of 0.05.

RESULTS

Patient demographics and procedural data

Ninety-eight patients with 100 occlusions were treated at the six institutions, including 46 women, with an average age of 66 years (median 69, SD=15.7). The average time from when the patient was last seen normal to groin puncture was 8.5 h (mean 507 min; median 241.5 min, SD=506 min). The overall successful revascularization rate (TICI 2b-3) was 95%. The average time to TICI 2b or 3 revascularization was 36.6 min (SD=26.4 min). The aspiration component of the ADAPT technique alone was successful in achieving successful revascularization of the occluded vessel 78% of the time. When the aspiration component of ADAPT was successful as a standalone technique, the average time from femoral access to final revascularization was 31.6 min (SD=23.3 min). In those cases where an adjunctive device was required, revascularization times were significantly (p<0.0001) prolonged (average 56.8 min (SD=29.1 min)).

Ten of 100 (10%) cases had downstream emboli within the initially affected territory, all of which were subsequently removed with either subsequent aspiration at the occlusion site or utilization of a stent retriever. There were no instances of embolization to a new territory (ENT). Two (2%) device related complications were encountered. One case was related to vessel dissection trying to advance the 5MAX catheter through an occlusion that after aspiration thrombectomy revealed an underlying intracranial stenosis, which was successfully stented. One complication was related to advancing a 5MAC ACE from the distal ICA into the mid M1 middle cerebral artery without using an obturating microwire or microcatheter, and resulted in significant vessel dissection, which was unable to be opened.

Table 1 Comparison of the 5MAX and 5MAX ACE final outcomes

	5MAX	5MAX ACE	p Value
No of cases	44	44	
Mean time to revascularization (min)	37.7	35.6	0.71
TICI 2b (%)	54.6	36.4	0.09
TICI 3 (%)	40.9	61.4	0.06
mRS 0–2 (%)	34	50	0.19

TICI 3 revascularization was achieved more frequently with 5MAX ACE than with 5MAX (61.4% vs 40.9%; p=0.055).
mRS, modified Rankin Scale; TICI, Thrombolysis in Cerebral Infarction.

The primary ADAPT revascularization catheter was 5MAX in 44 cases, 5MAX ACE in 44 cases, 4MAX (Penumbra) in six cases, 3MAX (Penumbra) in four cases, Navien 058 (EV3 Covidien) in one case, and Neuron 088 MAX (Penumbra) in one case. TICI 2b or 3 revascularization with aspiration alone was achieved in 75% of cases in which a 5MAX was the primary catheter versus 82% (p=0.44) when a 5MAX ACE was used (table 1).

Clinical outcomes

There were no incidences of postprocedure sICH. The presenting NIHSS was 17.2 (median 17.0; SD=6.4) on average and improved to an average of 7.3 (median 4.0; SD=7.5) at discharge (table 2).

mRS was available in 81 of 98 patients (83%) (table 3). Forty per cent of patients achieved an mRS score of 0–2 and 20% an mRS score of 6 at the 3 month follow-up. In the 78% of cases

Table 2 Baseline characteristics

Variable	
Mean age (years)	66.3
Gender	
Men (n (%))	46 (47)
Women (n (%))	52 (53)
NIHSS	
Pretreatment	17.2/17.0*
Post-treatment	7.3/4.0*
IV tPA	
Yes (n (%))	27 (28)
No (n (%))	70 (72)
Average time to groin puncture (h)	8.5
Average time to TICI 2b/3 recanalization (min)	37
Site of occlusion (n (%))	
Right M1	20 (20)
Right M2	11 (11)
Right ICA	3 (3)
Right ICA terminus	3 (3)
Left M1	23 (23)
Left M2	7 (7)
Left ICA	6 (6)
Left ICA terminus	11 (11)
Basilar	5 (5)
Right cervical ICA–MCA	8 (8)
Left cervical ICA–MCA	3 (3)

*Mean/median values.
ICA, internal carotid artery; IV tPA, intravenous tissue plasminogen activator; MCA, middle cerebral artery; NIHSS, National Institutes of Health Stroke Scale; TICI, Thrombolysis in Cerebral Infarction.

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Table 3 Demographics and outcomes of ADAPT FAST cases

Outcome parameter	
TICI pretreatment (n (%))	
0	96 (96)
1	1 (1)
2a	3 (3)
TICI post-treatment (n (%))	
0–2a	5 (5)
2b	44 (44)
3	51 (51)
NIHSS	
Pretreatment	17.2
Post-treatment	7.3
90 day mRS (n (%))	
0	10 (13)
1	16 (20)
2	5 (6)
3	12 (15)
4	11 (14)
5	8 (10)
6	15 (19)
Missing	23 (23)
sICH (n (%))	0 (0)

The90 day mRS outcomes calculated on percentage of patients that had a follow-up (n=79).
mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; sICH, symptomatic intracerebral hemorrhage; TICI, Thrombolysis in Cerebral Infarction.

where ADAPT alone was successful, 47% of patients achieved an mRS score of 0–2 and 14% resulted in an mRS score of 6. In the cases where ADAPT required a stent retriever or was unsuccessful, 18% achieved mRS 0–2 and 35% resulted in mRS 6.

DISCUSSION

Catheter aspiration thrombectomy has been reported previously, but as either a bailout after traditional techniques had failed or as a strategy by which to achieve revascularization of an occluded large extracranial artery.[8–12] ADAPT represents a novel revascularization strategy made possible by the availability of newer, flexible, atraumatic, large bore aspiration catheters. These catheters are easily navigated into the intracranial circulation and provide a large cross sectional area for the aspiration and engagement of the occluding thrombus. This technique is based on using aspiration alone as the primary mechanism of thrombectomy and, if initially unsuccessful, then incorporating adjunctive alternatives such as a stent retriever to achieve revascularization. The technique was successful alone in achieving TICI 2b/3 revascularization in 78% of cases or with adjunctive devices in 95% of cases. On average, revascularization was achieved within 37 min of groin puncture, and in 15 min or less from groin puncture in more than 20 cases. These efficient revascularization metrics were manifest clinically, with average discharge NIHSS improvement of 10 points and with favorable clinical functional outcomes (mRS 0–2 at 90 days) in 40% of cases.

Compared with the outcomes of stent retriever data, ADAPT yielded similar rates of good functional outcome (mRS 0–2), mortality, and device related complications (table 4).[2 3 13–16]

In the present series using ADAPT, fewer sICH were observed, and times to recanalization were, on average, probably shorter. It is likely that ADAPT produced higher rates of recanalization; however, this is difficult to establish with the documented methods of assessing successful recanalization used in the predicate stent retriever studies. With ADAPT, TICI 2b-3 revascularization was achieved with aspiration alone in 78% of cases compared with rates of TICI 2a-3 recanalization (ranging from 68% to 83%) for stent retrievers. A modified TICI score of 2a indicates a large area of non-perfused brain parenchyma and is increasingly not considered technically successful revascularization.[17] The final procedural TICI 2b/3 revascularization was 95% with ADAPT, which is higher than that achieved in the STAR study (85%) and in the NASA study (76%).[14 16]

The NASA registry recently reported an organized retrospective experience of 354 stroke cases from 24 centers.[14] The overall results were similar to those reported in the meta-analysis by Walcott *et al*.[13] A subgroup analysis from the NASA study was subsequently reported to determine if the use of a balloon guide catheter (BGC) improved outcomes.[18] The use of a BGC significantly improved TICI 3 revascularization rates to 54%, although overall TICI 2b/3 revascularization rates remained similar at 75%. This is similar to the TICI 3 rate of 51% but remains lower than the final 95% TICI 2b/3 revascularization we were able to achieve with ADAPT. Stent retriever

Table 4 Comparison of outcomes from current ADAPT FAST, SWIFT, TREVO, NASA, and stent retriever meta-analysis

	ADAPT FAST (n=100)	SWIFT trial (n=89)	TREVO trial (n=88)	STAR study (n=202)	NASA registry (n=354)	Solitaire data* (n=355)	Trevo data* (n=221)
TICI 2a/2b/3 (%)	N/A	83†	90	N/A	87.5	82	83
Device TICI 2b/3 (%)	78	75.9‡	68‡	79‡ 91§	72.5	NR	NR
Final TICI 2b/3 (%)	95	75.9‡	68‡	85	72.5	82	83
mRS 0–2 (%)	40	36	40	55	42	47	51
Mortality (%)	20	17	34	19	30.2	14	31
Time to final revascularization (min)	37	NR	NR	NR	50¶	NR	NR
Device related complications (%)	2	8.6	9	7.5	NR	6	5
Symptomatic ICH (%)	0	2	7	4	9.9	6	8

*Meta-analysis of real world published experience.
†Site reported rate of recanalization.
‡Core laboratory reported.
§Site investigator reported data.
¶Time to revascularize after guide catheter access.
ICH, intracerebral hemorrhage; mRS, modified Rankin Scale; N/A, not applicable; NR, not reported; TICI, Thrombolysis in Cerebral Infarction.

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procedures have been shown to be significantly faster with use of a BGC (average of 120 min), which is markedly longer than the average 38 min ADAPT case.[16] However, the times are difficult to compare as the BGC definition of procedure time was from groin access to groin closure whereas the ADAPT procedure time was groin access to at least TICI 2b revascularization. Finally, average discharge NIHSS score in those with BGC was 12 versus 17.5 when a BGC was not used, which is higher than our average discharge NIHSS score of 7.

One main advantage of ADAPT as a firstline approach is that it is versatile. The technique does not preclude the operator from incorporating other devices if aspiration alone is not working. Having the large bore aspiration catheter at the face of the clot facilitates the use of adjunctive devices, such as stent retrievers, as it provides a direct conduit to the thrombus. The technique of using stent retrievers in conjunction with local aspiration at the face of the clot has also been reported, with very high rates of technical success and good neurological outcomes. This approach was originally proposed to address the high incidence of ENT that has been reported with thrombectomy.[19] Kurre *et al*[19] reported in 175 occluded vessels a TICI 2b/3 revascularization rate of 91% and an improvement in ENT to 3.5% from 14% when distal aspiration was used with stent retrievers. Using combined local aspiration with stent retrieval,[20] Humphries *et al*[20] recently reported minimal ENT (<5%) with very high rates of revascularization (TICI 2b-3 of 88%) and low (5%) sICH rates. This approach is also being validated in the ongoing Penumbra three-dimensional separator trial.

ADAPT is technically straightforward, requiring only the navigation of a catheter to the face of the occlusion followed by the application of aspiration. The operator typically does not have to completely traverse the occlusion, and in most cases no additional devices have to be deployed or manipulated. Aspiration alone with the larger 5MAX ACE (0.060 inner diameter) catheter resulted, on average, in 82% TICI 2b/3 revascularization rates compared with the original 5MAX (0.054 inner diameter) catheter of 75%. This validates the intuitive concept of the improved aspiration performance of a larger bore catheter. In addition, clot extraction with ADAPT places little or no traction on the parent artery and regional penetrating arteries. As such, the potential for endothelial injury is likely to be far lower, possibly accounting for the absence of sICH in our current series.[21] The ability of ADAPT to engage the face of the thrombus and avoid superselective contrast injections into the ischemic region may also contribute to the lower hemorrhage rate.[22] Intracranial hemorrhage reportedly occurs in as many as 41% of stroke patients after thrombectomy with stent retrievers, of which approximately one-fifth lead to a symptomatic deterioration.[2 3 5 14 18]

ADAPT was, on average, faster than traditional methods of thrombectomy, particularly when the strategy worked as a standalone technique, as it did in the majority of cases. Moreover, thrombus which was difficult to extract with ADAPT, and was also typically challenging to clear with adjunctive devices, reflected in the marked prolongation of procedural times (57 vs 32 min) observed in those cases in which adjunctive devices were required.

ADAPT seemed to cause minimal clot disruption and fragmentation, often allowing the extraction of the occlusive embolus en bloc with a single pass. This may decrease the frequency and number of downstream emboli. In vitro tests have shown that stent retriever and traditional aspiration thrombectomy (performed with a separator) result in fragmentation of the embolus during extraction, creating downstream emboli and potentially emboli to previously uninvolved vascular territories.[23] When fragmentation of the embolus did occur with ADAPT (observed in 10% of cases in the present series), the emboli were usually large enough and proximal enough to allow extraction using aspiration alone with a smaller catheter, such as 3MAX in the M2 middle cerebral artery segment or a stent retriever.

Similar functional outcomes (mRS 0–2) of 40% were found with ADAPT as with other previously reported thrombectomy strategies,[2 3 5 14 18] despite a relatively long average time (8.5 h) from symptom onset to treatment in the present series. These rates of favorable neurological outcome are similar to those reported in previous studies using a modern perfusion guided imaging paradigm to select patients for intervention rather than time alone.[24] The variability in patient selection can affect clinical outcomes and is a limitation of this study. It is important to consider however, that the operator reported assessments in the current study are more prone to bias in comparison with independently assessed and monitored outcomes reported in some of the comparative thrombectomy device trials.

CONCLUSION

This multicenter series supports the hypothesis that, in comparison with modern thrombectomy techniques, ADAPT is a fast, simple, efficient, and safe strategy to achieve revascularization in patients with acute ischemic stroke secondary to a large vessel occlusion. In the minority of cases in which aspiration alone is unsuccessful in achieving complete revascularization, the platform is versatile, allowing the rapid incorporation of adjunctive devices (such as stent retrievers).

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Competing interests AST reports grants and non-financial support from Penumbra, grants from Microvention, grants and non-financial support from Stryker, non-financial support from Microvention, non-financial support from Covidien, non-financial support from Siemens, and grants and non-financial support from Boston Scientific, outside the submitted work. BB reports non-financial support from Stryker, non-financial support from Penumbra, non-financial support from Covidien, non-financial support from Silk Road, non-financial support from Reverse Medical, and non-financial support from Rapid Medical, outside the submitted work. AS reports non-financial support from Pulsar Vascular and grants from Simbionix, outside the submitted work. JM reports non-financial support from Lazarus Effect, non-financial support from Medina Medical, non-financial support from Pulsar Vascular, non-financial support from Reverse Medical, and non-financial support from Edge Therapeutics, outside the submitted work. RT reports grants and non-financial support from Penumbra, grants and non-financial support from Microvention, and grants and non-financial support from Stryker, outside the submitted work. IC reports grants and non-financial support from Penumbra, grants and non-financial support from Microvention, and non-financial support from Stryker, outside the submitted work.

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Ethics approval The study was approved by the institutional review board of the Medical University of South Carolina.

Provenance and peer review Not commissioned; externally peer reviewed.

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J NeuroIntervent Surg 2014 6: 260-264 originally published online February 25, 2014
doi: 10.1136/neurintsurg-2014-011125

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