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Safety and Efficacy of the ADAPT Technique as First-Line Treatment in Patients with Acute Ischemic Strokes Treated with Mechanical Thrombectomy: ADAPT Learning Curve & Increased Efficacy with Evolving Aspiration Catheter Technology

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ABSTRACT

Purpose:

To report the safety and efficacy of A Direct Aspiration first-Pass Thrombectomy (ADAPT) technique as first-line treatment for anterior circulation emergent large vessel occlusions (ELVO), assess the presence of an ADAPT learning curve and its efficacy with evolving aspiration catheter technology.

Methods:

We retrospectively reviewed 100 consecutive patients with anterior circulation ELVOs treated with the ADAPT technique as first-line therapy at our institution. Baseline characteristics, procedural variables, and modified Rankin Scale (mRS) at 90 days were recorded.

Results:

Eighty-four patients were treated with ADAPT only and 16 patients required Solumbra rescue. Overall successful reperfusion rate was 90%, with 38.7-minute mean groin puncture to reperfusion time, 5% embolization to new territory rate, and 3% symptomatic intracranial hemorrhage rate. The successful reperfusion rate using ADAPT only was 78%. A good clinical outcome, 90-day mRS 0-2, was achieved in 46% of patients. Compared to the first 20 cases, in the subsequent 80 cases the successful reperfusion rate with ADAPT only was significantly higher (50% vs 85%, p=0.002), and the Solumbra rescue rate was significantly lower (45% vs 8.8%, p<0.001). Successful reperfusion with ADAPT only was 64% with ACE60, 88% with ACE64, and 100% with ACE68 (p=0.003). The Solumbra rescue rate was 29% with ACE60, 3% with ACE64 and 0 with ACE68 (p=0.001).

Conclusion:

The ADAPT technique is a safe and effective first-line treatment for patients with anterior circulation ELVOs. Increased operator experience with the ADAPT technique and use of larger ACE aspiration catheters may lead to its improved efficacy.

INTRODUCTION

After landmark randomized controlled trials showed that patients with acute ischemic strokes due to anterior circulation emergent large vessel occlusions (ELVO) had better clinical outcomes when best medical management was followed by mechanical thrombectomy [1-6], this strategy is now the standard of care in this patient population [7].

Although there is debate in the neurointerventional community regarding what is the safest and most effective technique for performing mechanical thrombectomy [8-15], direct aspiration at the face of the thrombus using A Direct Aspiration first-Pass Thrombectomy (ADAPT) technique with a large-bore aspiration catheter such as the ACE 60, ACE 64 or ACE 68 catheters (Penumbra, Alameda, CA) has gained increased acceptance as first-line treatment [16-25]. Further, stent-retrievers can be used as rescue devices when ADAPT only fails to achieve successful reperfusion (Solumbra technique) [16-30].

The purpose of this study is to report rates of successful reperfusion and clinical outcomes in a consecutive cohort of patients with anterior circulation ELVOs who underwent mechanical thrombectomy using the ADAPT technique as first-line treatment, to examine the presence of a learning curve to the ADAPT technique, and to assess its efficacy with evolving aspiration catheter technology.

METHODS

Our study was approved by our hospital's institutional review board and conducted in compliance with the Health Insurance Portability and Accountability Act. We analyzed our prospectively-maintained institutional neurointerventional database to examine the radiological and clinical outcomes in patients with anterior-circulation ELVOs who were treated with mechanical thrombectomy using the ADAPT technique as first-line treatment between July 12th, 2013 and September 15th, 2016.

Medical Record Review

We recorded baseline patient and radiological characteristics, procedural variables, periprocedural complications and clinical outcomes at 90 days in a consecutive cohort of patients with ELVOs treated with mechanical thrombectomy using the ADAPT technique as first-line treatment at our institution during the study period. The patient cohort was divided into 2 groups: (1) patients who underwent mechanical thrombectomy using the ADAPT technique only (ADAPT-only group), and (2) patients who underwent mechanical thrombectomy using the ADAPT technique first but required stent-retriever rescue (Solumbra-rescue group).

Mechanical Thrombectomy Exclusion Criteria

Institutional exclusion criteria for mechanical thrombectomy were: (1) mild stroke symptoms, defined as an admission National Institutes of Health Stroke Scale (NIHSS) <5 without aphasia, (2) presence of a large completed territorial infarction by non-contrast CT (NCCT), defined as an Alberta Stroke Program Early CT Score (ASPECTS) <5, or (3) any intracranial hemorrhage. There was no strict time from last known well (LKW) cut-off for exclusion, as long as the NCCT ASPECTS was ≥5. CT angiography was generally performed in older patients to document an ELVO but was not required in younger patients with high admission NIHSS and LKW ≤6 hours.

Mechanical Thrombectomy Technique

The mechanical thrombectomy procedure was performed in a biplane neuroangiography suite (Axiom Artis, Siemens, Munich, Germany) by 1 of 3 neurointerventional radiologists with 5 to 15 years of experience in neurointervention. The procedure was performed under monitored minimal to moderate conscious sedation with intravenous fentanyl administered by a sedation nurse. In patients requiring intubation prior to mechanical thrombectomy for airway protection, the procedure was performed under a propofol infusion administered by a sedation nurse.

a. ADAPT Technique

The ADAPT technique was performed using a short 8F sheath through which a long sheath was positioned in the distal cervical vasculature (NeuronMax 088, Penumbra) using either an H1 or Simmons Select catheter (Penumbra). Then, a coaxial assembly comprising (1) a large-bore aspiration catheter (ACE 60, 64 or 68, Penumbra) and (2) a 0.025" microcatheter (Velocity, Penumbra) or 3 Max catheter (Penumbra) with an 0.016" microwire (double-angled Headliner, Terumo Medical, Somerset, NJ) was introduced through the sheath. The Velocity microcatheter or 3 Max catheter was then navigated past the site of occlusion over the microwire, over which the large-bore aspiration catheter was advanced to the face of the thrombus. The Velocity microcatheter or 3 Max catheter and the microwire were then removed, the aspiration tubing was connected directly to the hub of the large-bore aspiration catheter, and the Penumbra aspiration pump was turned on. After 30 to 90 seconds, the aspiration catheter was gently advanced into the thrombus and then slowly withdrawn under continuous aspiration until free blood flow was seen in the aspiration tubing. Then, the aspiration tubing was disconnected from the hub of the large bore aspiration catheter and the catheter was manually aspirated with a syringe to remove any residual thrombus fragments. If free blood flow was not seen in the aspiration tubing during aspiration catheter withdrawal, then the catheter was slowly removed from the patient under continuous aspiration from the Penumbra pump and the NeuronMax 088 was manually aspirated with a syringe to remove any residual thrombus fragments. This process was repeated until successful reperfusion (TICI 2b/3) was achieved. However, if 3-4 ADAPT passes failed to achieve incremental reperfusion, then Solumbra rescue was employed.

b. Solumbra Rescue Technique

As with the ADAPT technique, a Velocity microcatheter and reperfusion catheter were positioned distal to and at the site of occlusion, respectively. Then, a stent-retriever (either 4mm x 40cm or 6mm x 30mm Solitaire FR device, Medtronic Neurovascular, Irvine, CA) was advanced through the

microcatheter and deployed across the thrombus. The microcatheter was removed completely from the patient. After 3 minutes, the aspiration catheter was connected to continuous aspiration from the Penumbra pump, and tension was applied on the stent-retriever delivery wire to pull it into the aspiration catheter while simultaneously advancing the aspiration catheter up to the face of thrombus. If the thrombus was lodged between the stent-retriever and the tip of the aspiration catheter, then the system was carefully removed as a unit under continuous aspiration while also manually aspirating through the long sheath positioned in the cervical vasculature. This process was repeated until successful reperfusion (TICI 2b/3) was achieved or the procedure was terminated.

Image Analysis

Two experienced neurointerventionalists reviewed the (1) pre-treatment NCCTs to determine the baseline ASPECTS, (2) treatment angiograms to determine thrombus location and post-thrombectomy Thrombolysis In Cerebral Infarction (TICI) score, (3) follow-up NCCTs to determine the presence and type of intracranial hemorrhage, and (4) pre-treatment CT angiograms, treatment angiograms and/or post-treatment MR angiograms to determine the degree of cervical vascular tortuosity in the common and internal carotid arteries (CCA, ICA) proximal to the ELVO using the methodology described by Faggioli *et al.* [31]. Severe vascular tortuosity proximal to the ELVO was defined as ≥360 degrees in the combined common and internal carotid artery tortuosity score. Differences in image interpretation were resolved by consensus.

In cases where intracranial hemorrhage was present in the post-treatment NCCT, consensus with a vascular neurologist independent of the procedure was reached to determine if the hemorrhage was symptomatic according to the SITS-MOST criteria [32].

Clinical Outcomes

A modified Rankin Scale (mRS) at 30 and 90 days post-thrombectomy was obtained during routine clinical follow-up visits performed by 1 of 2 nurse practitioners independent of the procedure and certified in the modified Rankin Scale. If the patient was unable to return to clinic for a follow-up visit, an mRS was obtained using a validated phone interview questionnaire [33]. A good clinical outcome was defined as functional independence, mRS 0-2, at the time of the 90-day follow-up.

Statistical Analysis

Statistical analysis was performed utilizing the MedCalc 11.1 software package (MedCalc Software, Mariakerke, Belgium). Student's t-test was used to analyze continuous variables. Fisher's exact or Chi-square tests were used to analyze categorical variables. A p-value ≤ 0.05 was considered statistically-significant.

RESULTS

From July 12th, 2013 until September 15th, 2016, 135 patients with acute ischemic strokes due to an ELVO underwent mechanical thrombectomy at our institution. Eight of these patients had a posterior-circulation ELVO (5.9%), 5 patients were enrolled in a mechanical thrombectomy randomized controlled trial (3.7%), 4 patients were enrolled in an investigational thrombectomy device clinical trial (3%), and 18 patients were treated with the Solumbra technique as first-line treatment (13.3%).

Hence, 100 patients with anterior-circulation ELVOs were treated with mechanical thrombectomy using the ADAPT technique as first-line treatment during the study period at our institution, comprising this study's cohort. Among these patients, 86 were treated with ADAPT only and 16 were treated with ADAPT first followed by Solumbra rescue. The aspiration catheter utilized for the ADAPT technique was an ACE 60 in 45 cases, ACE 64 in 34 cases, ACE 68 in 16 cases, NeuronMax in 3 cases (all cervical internal carotid artery thrombi), and 3 Max in 2 cases (both M3 thrombi).

Table 1 summarizes the baseline clinical and radiological patient characteristics. There were no significant differences in baseline clinical and radiological characteristics between patients in the ADAPT-only and Solumbra-rescue groups.

Table 2 summarizes the procedural variables. Overall, successful reperfusion using the ADAPT technique as first-line treatment was achieved in 90 patients, including 78 patients in whom it was achieved with ADAPT only. The mean times from groin puncture to reperfusion with ADAPT only and Solumbra techniques were 30.5 and 81.8 minutes, respectively. The mean number of passes in which ADAPT only achieved successful reperfusion was 2.4 (median 2, range 1-9). The mean number of ADAPT passes prior to switching to Solumbra rescue was 2.8 (median 3, range 1-6). The mean number of passes with the Solumbra technique after failed ADAPT was 2.5 (median 2, range 1-9) overall and 2.7 (median 2, range 1-9) for cases in which reperfusion was successful. Of note, among the 78 cases in which successful reperfusion was achieved with ADAPT only, this was achieved after 1-2 passes in 50 cases (64%) and after ≥3 passes in 28 cases (36%).

Table 3 summarizes the clinical outcomes. The symptomatic intracranial hemorrhage (SICH) rate in our cohort was 3% (2 subarachnoid, 1 intra-parenchymal). Mean lengths of stay in the neurological intensive care unit and hospital were 3.1 and 6.8 days, respectively. Twenty-five patients were discharged home and 42 to an acute rehabilitation facility. Overall, 46 patients had a good clinical outcome at 90-days (mRS 0-2), while 90-day mortality was 21%. There were no significant differences in clinical outcomes between patients in the ADAPT-only and Solumbra-rescue groups.

ADAPT Learning Curve

Table 4 summarizes procedural variables between the first 20 and subsequent 80 ADAPT cases in our cohort. Compared to the first 20 ADAPT cases, in the subsequent 80 cases there was a significant increase in the rate of successful reperfusion with ADAPT only (50% vs 85%, p-value 0.002), a significant decrease in the rate of Solumbra rescue (45% vs 8.8%, p-value<0.001), and a trend toward

shorter mean groin puncture to reperfusion times (48.7 vs 36.2 minutes, p-value 0.09). The mean number of ADAPT passes prior to switching to Solumbra rescue in the first 20 ADAPT cases was 2.3, while in the subsequent 80 cases it was 3.3 (p-value 0.23). Further, 26 of the 28 cases (92.9%) in which successful reperfusion was achieved after ≥3 ADAPT passes were performed in the latter 80 ADAPT cases. Of note, 18 of the first 20 ADAPT cases were performed with ACE 60 (90%), while 27 of the subsequent 80 ADAPT cases were performed with ACE 60 (33.8%).

Among the 45 ADAPT cases performed with ACE 60, compared to the first 20 cases, in the subsequent 25 cases there was a significant decrease in the rate of Solumbra rescue (45% vs 16%, p-value 0.049), trends toward increased rates of successful reperfusion with ADAPT only (50% vs 76%, p-value 0.12) and successful reperfusion after 1 ADAPT pass (20% vs 40%, p-value 0.2), and shorter median groin puncture to reperfusion times (49.5 vs 29 minutes). The mean number of ADAPT passes prior to switching to Solumbra rescue in the first 20 ACE 60 cases was 2.3, while in the subsequent 25 cases it was 3.8 (p-value 0.14).

Efficacy of the ADAPT Technique with Evolving Aspiration Catheter Technology

Table 5 summarizes procedural variables with the ACE 60, 64 and 68 aspiration catheters in our cohort. There was a significant decrease in mean groin puncture to reperfusion times between ADAPT cases performed with ACE 60 and ACE 64/68 (48.8 vs 29.9 minutes, p-value 0.002). There was a significant difference in the rate of successful reperfusion with ADAPT only between cases performed with ACE 60 (64.4%), ACE 64 (88.2%) and ACE 68 (100%, p-value 0.003). There was a significant difference in the rate of Solumbra rescue between cases performed with ACE 60 (28.9%), ACE 64 (2.9%) and ACE 68 (0, p-value 0.001).

DISCUSSION

Our cohort's overall rates of (1) successful reperfusion, 90%, (2) SICH, 3%, (3) embolus to uninvolved territory, 5%, and (4) good clinical outcome at 90-days, 46%, are within the range of the landmark randomized controlled trials [1-6]. Angiographic and clinical results of the ASTER European randomized controlled trial showed that the ADAPT technique was equivalent in safety and efficacy to stent-retriever thrombectomy for patients with anterior circulation ELVOs [15]. Thus, the ADAPT technique is a safe and effective alternative to stent-retriever mechanical thrombectomy for this patient population and represents a valuable option for neurointerventionalists. Further, stent-retriever rescue can easily be utilized in the minority of cases when ADAPT fails to achieve successful reperfusion.

Successful reperfusion using ADAPT only was achieved in 78% of cases. Nevertheless, we achieved significantly higher rates of successful reperfusion with ADAPT only after our first 20 cases (50% vs 85%). Moreover, the median time from groin puncture to reperfusion decreased from 49.5 minutes in the first 20 cases to 25 minutes in the subsequent 80 cases. These findings suggest the presence of a learning curve associated with the ADAPT technique. Navigation of a large-bore reperfusion catheter into the intracranial vasculature and past the ophthalmic artery is similar but not identical to other neurointerventional maneuvers, and efficient execution requires practice. Time to reperfusion may also have been influenced by increased awareness that ≥3 ADAPT passes may be necessary in order to achieve successful reperfusion before resorting to the more expensive and time-consuming Solumbra technique. These results should be considered in discussions regarding increasing access to mechanical thrombectomy in areas where the financial cost associated with establishing a neurointerventional practice may be prohibitive, as operators must gain sufficient experience to achieve the levels of safety and effectiveness reported in randomized trials.

Although it may not be feasible to completely parse the differences in efficacy related to experience and aspiration catheter diameter in our cohort, and we indeed evidenced increased efficacy of the ADAPT technique among early and latter ACE 60 cases in our cohort, our overall results suggest that

newer generation aspiration catheters are more effective. The distal internal diameters of the ACE 60, 64, and 68 are 1.8mm, 1.9mm, and 2mm, respectively. Since aspiration force is proportional to the square of the catheter diameter, the ACE 68 generates 25% more aspiration force than the ACE 60. Importantly, the increased force generated by the larger-bore aspiration catheters was not associated with increased complications in our cohort.

Our study's limitations are the modest sample size, retrospective design, and lack of external adjudication of angiographic findings and clinical outcomes.

CONCLUSION

The ADAPT technique is a safe and effective first-line treatment for patients with anterior circulation ELVOs. Increased operator experience with the ADAPT technique and use of larger ACE aspiration catheters may lead to shorter procedure times, higher rates of successful reperfusion with ADAPT only and decreased need for stent-retriever rescue.

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Table 1. Baseline Clinical and Radiological Patient Characteristics

	All patients, N=100	ADAPT only, N=84 (%)	Solumbra rescue, N=16 (%)	p-value*
Mean age, years	68	67.9	68.7	0.83
Sex				1
Female	50	42 (50)	8 (50)	
Male	50	42 (50)	8 (50)	
Atrial fibrillation	35	27 (32)	8 (50)	0.25
Diabetes mellitus	23	18 (21)	5 (31)	0.52
Hypertension	62	53 (63)	9 (56)	0.78
Mean NIHSS	18.2	18.2	18.1	0.94
IV-tPA administration	53	46 (55)	7 (44)	0.59
Mean baseline NCCT ASPECTS	9	9	9.1	0.62
CT angiography	73	64 (76)	9 (56)	0.13
Thrombus location				
ICA	34	26 (31)	8 (50)	0.16
MCA M1	47	42 (50)	5 (31)	0.19
MCA M2	16	13 (16)	3 (19)	1
MCA M3	3	3 (4)	0	1
Left side	52	44 (52)	8 (50)	1
Tandem ICA origin occlusion	20	18 (21)	2 (13)	0.52
Mean cervical tortuosity, degrees	251	245	284	0.37
Severe, ≥360°	30	23 (27)	7 (44)	0.24
Mean time LKW to puncture, min	258	258	261	0.94

*p-value for the difference between the ADAPT-only and Solumbra-rescue groups using either Student's t-test or Fisher's exact test. N: number of patients; NIHSS: National Institutes of Health Stroke Scale; IV-tPA: intravenous tissue plasminogen activator; NCCT: non-contrast computed tomography; ASPECTS: Alberta Stroke Program Early CT Score; CT: computed tomography; ICA: internal carotid artery; MCA: middle cerebral artery; LKW: last known well; min: minutes

Table 2. Procedural Variables

	All Patients, N=100	ADAPT only, N=84 (%)	Solumbra rescue, N=16 (%)	p-value*
Mean number of ADAPT passes	2.4	2.4	2.8	0.41
Mean number of total device passes	2.8	2.4	5.3‡	**<0.0001**
IA-tPA administration	2	2 (2)	0	1
Glycoprotein IIb/IIIa inhibitor administration	2	2 (2)	0	1
Successful reperfusion (TICI 2b-3)	90	78 (93)	12 (75)	**0.05**
Mean time puncture to reperfusion, min	38.7	30.5	81.8	**<0.0001**
Mean time LKW to reperfusion, min	297	288	343	0.21
Carotid stent deployment	8	7 (8)	1 (6)	1
Embolus to uninvolved territory	5	3 (4)	2 (13)	0.18
Cervical dissection	4	2 (2)	2 (13)	0.12
Vessel perforation	3	3 (4)	0	1
Carotid-Cavernous fistula	1	1 (1)	0	1

*p-value for the difference between the ADAPT-only and Solumbra-rescue groups using either Student's t-test or Fisher's exact test. ‡Includes total number of ADAPT and Solumbra passes. N: number of patients; IA-tPA: intra-arterial tissue plasminogen activator; TICI: thrombolysis in cerebral ischemia; min: minutes; LKW: last known well.

Table 3. Clinical Outcomes

	All Patients, N=100	ADAPT only, N=84 (%)	Solumbra rescue, N=16 (%)	p-value*
Any post-thrombectomy ICH	27	23 (27)	4 (25)	1
Any post-thrombectomy SAH	7	5 (6)	2 (13)	0.59
Post-thrombectomy SICH	3	2 (2)	1 (6)	0.41
Intraparenchymal	1	1 (1)	0	1
Subarachnoid	2	1 (1)	1 (6)	0.3
Mean Neuro-ICU LOS, days	3.1	3	4	0.31
Mean Hospital LOS, days	6.8	6.7	7.4	0.57
Discharge disposition				
Home	25	23 (27)	2 (13)	0.35
Rehabilitation	42	36 (43)	6 (38)	0.79
SNF	18	15 (18)	3 (19)	1
Expired/Hospice	15	10 (12)	5 (31)	0.06
90-Day mRS				
0-2	46	41 (49)	5 (31)	0.28
3	17	15 (18)	2 (13)	0.73
4-5	16	13 (16)	3 (19)	1
6	21	15 (18)	6 (38)	0.1

*p-value for the difference between the ADAPT-only Solumbra-rescue groups using either Student's t-test or Fisher's exact test. N: number of patients; ICH: intracranial hemorrhage; SAH: subarachnoid hemorrhage; SICH: symptomatic intracranial hemorrhage according to SITS-MOST criteria; ICU: intensive care unit; LOS: length of stay; SNF: skilled nursing facility; mRS: modified Rankin Scale.

Table 4. ADAPT Learning Curve

	All 100 ADAPT Cases	First 20 ADAPT Cases (%)	Subsequent 80 ADAPT Cases (%)	p-value*
Mean time puncture to reperfusion, min	38.7	48.7	36.2	0.09
Median time puncture to reperfusion, min	26.5	49.5	25	n/a
Mean number of ADAPT passes	2.4	2.1	2.5	0.27
Successful reperfusion† with ADAPT only	78	10 (50)	68 (85)	**0.002**
Successful reperfusion† after 1 ADAPT pass	38	6 (30)	32 (40)	0.45
Solumbra rescue	16	9 (45)	7 (8.8)	**<0.001**
Mean number of ADAPT passes before Solumbra rescue	2.8	2.3	3.3	0.23

*p-value for the difference between the first 20 and subsequent 80 cases using either Student's t-test or Fisher's exact test. †Defined as thrombolysis in cerebral ischemia 2b, 2c or 3. Min: minutes, n/a: not applicable.

Table 5. Efficacy of the ADAPT Technique with Evolving Aspiration Catheter Technology

	ACE 60, N=45 (%)	ACE 64, N=34 (%)	ACE 68, N=16 (%)	p-value*
Mean time puncture to reperfusion, min	48.8	30.2	29.3	**0.002**
Median time puncture to reperfusion, min	33	25.5	21	n/a
Mean number of ADAPT passes	2.4	2.5	2.6	0.78
Successful reperfusion† with ADAPT only	29 (64)	30 (88)	16 (100)	**0.003**
Successful reperfusion† after 1 ADAPT pass	14 (31)	13 (38)	8 (50)	0.4
Solumbra rescue	13 (29)	1 (3)	0	**0.001**
Mean number of ADAPT passes before Solumbra rescue	2.8	3	n/a	0.89

*p-value for the difference between the ACE 60, ACE 64 and ACE 68 using Chi-Square test for categorical variables, or for the difference between ACE 60 and ACE 64/68 using Student's t-test for continuous variables. †Defined as thrombolysis in cerebral ischemia 2b, 2c or 3. Min: minutes, n/a: not applicable.