

ORIGINAL RESEARCH

Primary manual aspiration thrombectomy (MAT) for acute ischemic stroke: safety, feasibility and outcomes in 112 consecutive patients

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ABSTRACT

Aim To describe procedural aspects and clinical outcomes in a consecutive series of patients in whom manual aspiration thrombectomy (MAT) was performed as the first treatment modality with other techniques used only in case MAT did not yield recanalization.

Methods A retrospective review of a prospectively acquired acute stroke intervention database was performed. Primary MAT was carried out with a preference for the largest catheter considered to be trackable into the target occlusive lesion. The catheter was wedged into the thrombus followed by manual aspiration with a 20 ml syringe.

Results 112 consecutive patients were evaluated. The median age was 66 years and the median NIH Stroke Scale score was 17. Occlusion locations included the M1 (62%), M2 (8%), internal carotid artery terminus (19%) and the vertebrobasilar artery (11%). Patients with anterior occlusions had tandem extracranial/intracranial occlusive lesions in 18.7%. Median time from symptom onset to groin puncture was 267 min, and from groin puncture to recanalization was 70 min. Successful recanalization (defined as Thrombolysis in Cerebral Infarction (TICI) 2b/3) with primary MAT was 59% with a median of two passes. 41% of patients required the use of adjunctive therapy yielding an overall recanalization rate of TICI 2b/3 (86%) and TICI 3 (30.6%). Parenchymal hematoma of any type (PH1/PH2) was seen in 9.8% of patients, with symptomatic hemorrhage in 6%. Favorable outcomes (90-day modified Rankin Scale ≤ 2) were 46%. Mortality at 3 months was 31%. Primary MAT was associated with faster procedural times (mean 63 vs 97 min, $p < 0.0001$) but not with higher rates of favorable outcomes.

Conclusions Primary MAT is an alternative endovascular recanalization technique with reasonable first pass efficacy that will likely improve with technology and experience.

INTRODUCTION

For intracranial large vessel occlusive disease, recanalization within the fastest possible time frame predicts improved outcomes.¹ Intravenous tissue plasminogen activator (tPA), the only FDA-approved treatment for acute stroke, is associated with low recanalization rates for large vessel occlusions.² Alternative methods of opening blocked vessels include intra-arterial tPA and an assortment of mechanical devices. Randomized trials in the field of interventional cardiology have

shown that manual catheter aspiration is clinically equivalent to other mechanical thrombectomy devices, shortens procedure times, reduces complication rates and is cost-saving.^{3–4} Several reports in the literature have used similar techniques in acute ischemic stroke (AIS) interventions, described variously as manual aspiration thrombectomy (MAT), the ADAPT technique, forced suction thrombectomy or thromboaspiration.^{5–8} We have previously described our aspiration technique in 191 patients with acute stroke.⁶ The use of the Merci retriever (Concentric Medical, Mountain View, California, USA) in 89% of patients, primarily to facilitate advancing the aspiration catheter through the tortuous intracranial vasculature, obscured the potential utility or benefit of aspiration alone. Encouraged by improvements to this technique and the advent of new aspiration catheters, we decided to perform primary MAT in all acute stroke interventions when enrollment in clinical trials did not mandate a different treatment. The purpose of this study is to describe the technique, safety and efficacy of attempting to apply primary MAT upfront for removing intracranial thrombi in a single-center consecutive case series.

METHODS

Patient selection

We performed a retrospective analysis of a prospectively acquired database of all patients treated with endovascular therapy for stroke from September 2012 to June 2013 at our institution. Patients receiving intra-arterial stroke treatment at the University of Pittsburgh Medical Center are included in an Institutional Review Board approved prospective database after written informed consent is obtained by the patient or proxies. All patient information was de-identified and analyzed in compliance with Health Insurance Portability and Accountability Act regulations.

All patients presenting with AIS symptoms underwent a baseline head CT scan. In general, as a first step, patients with anterior circulation stroke were selected for intra-arterial therapy if CT showed an Alberta Stroke Program Early CT score of >6 or less than one-third hypodensity of the middle cerebral artery (MCA) territory. Most patients underwent additional imaging studies (CT angiography/CT perfusion) or MRI/MR angiography and were considered for interventional therapy based on assessment of mismatch between



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the extent of infarcted brain relative to the extent of threatened but viable brain. In patients undergoing CT/CT perfusion, the ratio of low cerebral blood volume (threshold for infarct tissue $\leq 2.0 \text{ mL} \times 100 \text{ mL}$) to elevated mean transit time maps and/or to the severity of clinical deficit (NIH Stroke Scale (NIHSS)) was factored into the treatment decision. The minimum amount of mismatch necessary for treatment selection varied according to patient-specific considerations and stroke neurologist/interventionalist-specific practice patterns. In general, patients with a core volume less than one-third of the MCA territory in the presence of M1 occlusion and corresponding clinical deficit (NIHSS score $>6-8$) or severe perfusion deficit (time to peak $>6 \text{ s}$) involving two-thirds or more of the MCA territory were considered potential treatment candidates. Computer-generated volumetric analysis was not available and manual calculation of volumes is too lengthy a process to be useful for consideration in acute stroke intervention. Volumes were therefore estimated based on visual mismatch. Time from stroke onset was not considered a limiting factor. All patients who underwent intra-arterial treatment had a baseline modified Rankin Scale (mRS) score of ≤ 1 .

Treatment algorithm

After obtaining informed consent, patients underwent catheter-based angiography. Conscious sedation was used in preference to general anesthesia. A micropuncture kit was used to advance a 6 F sheath into the common femoral artery. Heparin was not routinely used. Once the occlusion was verified, V-18 control wires were used to exchange the diagnostic catheter for either a 6 F Cook shuttle sheath (Shuttle-SL; Cook Medical, Bloomington, Indiana, USA) or a Neuron MAX 088 (Penumbra, Alameda, California, USA). These base catheters were advanced as distal as possible into the target vessel over their co-packaged tapered dilators. Balloon guide catheters were never used. In the internal carotid artery (ICA), the Cook shuttle sheath was typically advanced to the skull base while the Neuron MAX was often advanced up into the cavernous segment. In the posterior circulation the same base catheters were advanced into the distal V2 segment. If there was a tandem lesion in the extracranial carotid, a stent was typically placed followed by advancement of the base catheter through the stent. These patients were initially managed with intravenous heparin and aspirin followed by loading with 300 mg clopidogrel if no hemorrhagic transformation was visualized after 24 h. Under roadmap guidance, a triaxial system consisting of an aspiration catheter, a microcatheter and guidewire were advanced as distal as possible. We initially used a Merci 18L microcatheter (Concentric Medical, Mountain View, California, USA) and a Synchro 0.014 inch wire (Stryker Neurovascular, Fremont, California, USA), but changed to using a larger Excelsior XT-27 (Stryker Neurovascular) or Marksman (Covidien, Irvine, California, USA) microcatheter with a Fathom 0.016 inch wire (Stryker Neurovascular). When choosing an aspiration catheter, we favored the largest available distal internal diameter in order to maximize the aspiration force. The guidewire and microcatheter were advanced past the clot and into the distal M2 or P2 segment, which provided the necessary support to track the aspiration catheter. Microcatheter injections distal to the thrombus were not part of a standard protocol as this practice was left to the discretion of the operator. If the catheter could not be advanced into the thrombus, it was considered a failed attempt and was counted as an attempted pass. The most common reason for this to occur was the inability to track past the ophthalmic artery, either due to the ledge effect or excessive friction from tortuosity. Typically, a

second smaller aspiration catheter was then used such as the 4MAX (Penumbra) or 044 DAC (Stryker Neurovascular). Every attempt was made to wedge the aspiration catheter as distal as possible into the clot. Subsequently, the microcatheter and wire were removed and a 20 ml syringe was attached directly to the hub of the aspiration catheter. Continuous manual aspiration was performed as the catheter was slowly withdrawn through the base catheter. Once the aspiration catheter was removed, the base catheter was also aspirated twice with a 20 ml syringe directly from the hub after removing the hemostatic valve. The choice of aspiration catheter and number of attempts was left up to the primary operator. If residual thrombus was seen in the M2 or P1 segment, a smaller aspiration catheter was used and counted as a successive pass. Typically, if no angiographic improvement was noted or if no thrombus was retrieved through the syringe after two passes, an adjunctive device was used. These devices included the Merci retriever, Solitaire or Trevo; t-PA was not routinely used.

Recanalization (Thrombolysis in Myocardial Infarction (TIMI) and Thrombolysis in Cerebral Infarction (TICI) scores) was recorded by the treating interventionalist and was deemed successful if post-procedure angiography revealed TICI $\geq 2b$ flow.^{9 10} The 90-day mRS score was determined at the patient's follow-up appointment. If patients were physically unable to attend these appointments, they or their next of kin were reached by mRS-certified stroke nurse practitioners or stroke fellows and outcomes were obtained over the telephone. Good outcomes were defined as mRS ≤ 2 . Embolization to a previously uninvolved or new territory (ENT) was defined as any new vessel occlusion or infarct in a previously unaffected territory.

Statistical analysis

Statistical analysis was performed using STATA IC V.10 software (StataCorp LP, College Station, Texas, USA). Descriptive statistics were performed. In univariate analysis, several variables of interest were correlated with a good functional outcome. For each endpoint, all covariates with $p < 0.2$ were then entered into a multivariate stepwise logistic regression model; significant association was considered for $p < 0.05$.

RESULTS

The study included 112 consecutive patients of median age 66 years and median NIHSS score 17. Occlusion locations were as follows: M1 (62%), M2 (8%), ICA terminus (19%), vertebro-basilar artery (11%). Tandem lesions were encountered in 18% of patients. Median times from symptom onset to groin puncture and from groin puncture to recanalization were 267 and 70 min, respectively. The range from symptom onset to groin puncture was 70–2058 min. Our series also included 12 wake-up strokes. Final recanalization rates were TICI 2b/3 (86%) and TICI 3 (30%). Primary MAT achieved successful recanalization with a single aspiration catheter in 46 of 112 patients (41%); another catheter was necessary in 20 patients. Thus, primary MAT was successful in 66 of 112 patients (59%) when using one or more aspiration catheters. Aspiration was carried out with the following catheter makes and sizes (in inches): Navien (Covidien) 0.072 and 0.058 (84% of cases), Penumbra (Penumbra) 0.054 and 0.041 (23% of cases) and DAC (Stryker) 0.070, 0.054 and 0.044 (4% of cases). Largest bore catheters (≥ 0.070 inch) were used in 27% of cases and medium size catheters (0.054–0.058 inch) in 73%. Neither catheter make nor size was associated with higher or faster recanalization rates. An adjunctive device was used in 46 of 112 patients (41%), consisting of a stent retriever in 32 (28.5%), a

Merci device in six (5.3%), intra-arterial tPA in three (2.6%) or a combination of multiple modalities in five (4.4%). Of the 21 tandem lesions, 11 underwent extracranial stent placement prior to addressing the intracranial occlusion.

Good outcomes occurred in 52 of the 112 patients (46%) and there were 35 deaths (31%). Four (3.5%) intracranial distal wire perforations led to cessation of the procedure. Three perforations resulted in symptomatic intracerebral hemorrhage and clinical deterioration. ENT was documented in four of 112 patients (3.5%), with two of 66 events in the primary MAT group and two of 46 events in the adjunctive device group. There were no intracranial dissections but there were four extracranial ICA dissections presumably related to placement of the shuttle sheath or Neuron MAX catheter into the distal ICA.

One type II dissection was treated with intravenous heparin and angioplasty, one type II dissection was stented and two type I dissections were treated with aspirin. No significant intracranial vasospasm was caused by the aspiration catheters. The baseline clinical variables, treatment modalities and predictors of good outcome are shown in table 1.

DISCUSSION

To our knowledge, this report is the first consecutive case series describing the feasibility, safety and clinical results of primary manual aspiration for AIS. Previous reports including our own published experience have described this approach either as adjunctive therapy to other mechanical embolectomy modalities or in non-consecutive case series. Our preliminary results

Table 1 Baseline clinical variables, treatment modalities and univariate analysis for predictors of good outcome (mRS ≤ 2) at 90 days

Variable	N (%)	Median (IQR)	mRS ≤ 2 *		
			OR	p Value	95% CI
Age (years)		66 (29–93)	0.97	0.041	0.94 to 0.99
NIHSS score		17 (4–36)	0.78	0.000	0.70 to 0.88
Baseline ASPECT score		9 (4–10)	1.50	0.008	1.11 to 2.04
Time to procedure (h)*		4.45 (1.16–34.3)	0.99	0.113	0.99 to 1.00
Treatment time (min)†		70 (15–289)	0.99	0.047	0.980 to 0.99
Men	61 (54.4)		1.63	0.215	0.75 to 3.5
Left MCA	54 (54)		0.79	0.056	0.34 to 1.79
HTN	81 (72.3)		0.88	0.766	0.37 to 2.04
DM	22 (19.8)		0.43	0.124	0.153 to 1.252
Afib	40 (36)		0.88	0.77	0.39 to 1.88
Smoking	16 (17)		1.41	0.53	0.46 to 4.32
CAD	29 (26.8)		1	1	0.47 to 2.47
TICI $\geq 2b$	97 (86.6)		2.07	0.010	1.18 to 3.62
Intubation	13 (12.4)		0.45	0.2	0.13 to 1.59
Intravenous tPA	46 (41)		1.6	0.20	0.75 to 3.63
M1	70 (62)		1.2	0.53	0.57 to 2.89
M2	9 (8)		1.18	0.8	0.27 to 5.00
ICA terminus	21 (18.7)		0.81	0.69	0.29 to 2.23
Tandem	21 (18.7)		2.08	0.16	0.73 to 5.88
Any ICA	38 (33.9)				
Basilar	12 (10.7)				
Number of passes		2 (1–8)	0.88	0.35	0.68 to 1.14
Intra-arterial tPA	3 (2.6)				
Stent retriever	32 (28.5)				
Merci	6 (5.3)				
Intra-arterial tPA	3 (2.6)				
Multiple devices	5 (4.4)				
Hemorrhagic transformation	31 (27)				
Parenchymal hematoma	11 (9.8)				
Symptomatic bleed	7 (6.2)				
ENT	4 (3.5)				
mRS ≤ 2 at 90 days	52 (46.1)				
mRS 6	35 (31)				
Pure MAT	66 (59)		1.14	0.73	0.522 to 2.50
Aspiration catheter 0.4/0.5/0.6			0.75	0.45	0.36 to 1.55
Aspiration catheter brand	Navien (84) DAC (4) Penumbra (23)		1.2	0.46	0.73 to 1.97

*Time to procedure: from onset of symptoms or last seen normal to groin puncture.

†Treatment time: from puncture to recanalization.

ASPECT, Alberta Stroke Program Early CT score; CAD, coronary artery disease; DM, diabetes mellitus; ENT, embolization to a new territory; HTN, hypertension; IA, intra-arterial; ICA, internal carotid artery; MAT, manual aspiration thrombectomy; MCA, middle cerebral artery; mRS, modified Rankin Scale; NIHSS, NIH Stroke Scale; TICI, Thrombolysis in Cerebral Infarction.

indicate that this technique is feasible as a first step approach in a significant proportion of patients. Previous prospective multicenter studies investigating procedural outcomes with stent retrievers have reported TICI 2b/3 recanalization rates of 68.5% and 67.8% with Solitaire and Trevo, respectively, translating into favorable clinical outcome rates (mRS ≤ 2) of 36.3% and 40%, respectively.^{11 12} Our results compare favorably with those obtained with this latest generation of FDA-approved neurothrombectomy devices.

Successful revascularization following large vessel occlusion offers patients the best chance for recovery. The recently published Interventional Management of Stroke III trial demonstrated a high correlation between the degree of revascularization and patient outcomes after stroke: 12.7% of individuals with TICI scores of 0 had favorable neurologic outcomes while those with TICI scores of 1, 2a, 2b and 3 had rates of 27.6%, 34.3%, 47.9% and 71.4%, respectively.¹³ The importance of rapid revascularization in eliciting favorable outcomes was underscored by the findings that each 30 min delay in reperfusion was associated with a 10% reduction in the likelihood of a favorable outcome.¹⁴ Thus, the ideal treatment offers a high degree of recanalization in the minimal amount of time.

The MAT technique was first described in the cardiac literature and has been shown to be an effective adjunctive treatment for revascularization of coronary arteries.^{15 16} There is a paucity of data pertaining to the application of MAT in the intracranial circulation. Early case reports, primarily in the posterior circulation, posited MAT as a promising technique owing to the reduced time for recanalization, low hemorrhagic risk and possible prevention of distal clot migration.^{5 8 17} More recent publications have confirmed high recanalization rates and improved outcomes in larger series of patients undergoing MAT in the setting of large vessel intracranial occlusions. In their report involving 22 consecutive patients, Kang *et al* were able to achieve TICI 2b/3 recanalization in 81.9% of patients and favorable outcomes (90-day mRS ≤ 2) in 45.5%.⁷ In a multi-institutional carefully selected series of 37 patients, Turk *et al* demonstrated successful recanalization with aspiration alone in 75% of patients.¹⁸ In the largest series published to date, Jankowitz *et al* studied the outcomes of 191 patients at a single institution.⁶ Although successful recanalization (TICI 2b/3 scores) was achieved in 71% of patients with a favorable outcome (90-day mRS ≤ 2) rate of 54%, MAT was preceded by clot manipulation with the Merci device in the majority of cases. Although primarily used as an anchoring tool to help advance the aspiration catheter through the carotid siphon, the Merci device may have facilitated aspiration by disrupting the clot or by pulling it into the catheter tip.

This prospective registry was designed to overcome this concern. Every attempt was made to rely on pure MAT for recanalization with the largest catheter deemed appropriate, even in cases that were considered unlikely to succeed based on tortuous anatomy or small vessels. The goal was to provide a realistic assessment of aspiration as a stand-alone thrombectomy technique. It should not be surprising that this paradigm was initially successful in only 41% of patients, with another 18% requiring multiple catheters, or that the median treatment time was 70 min. The latter is longer than that described in recent reports of manual aspiration in acute stroke.¹⁸ This finding may be explained by the fact that this is a truly consecutive case series of primary aspiration in which an attempt was made to use MAT as first-line treatment in all patients, even in cases where aspiration catheter access was perceived as difficult based on review of the angiographic runs or on other considerations.

We are not aware of another case series describing a similar approach in the literature, and therefore feel that a comparison of procedural times in our study compared with those described in other studies is not meaningful. Furthermore, with regard to other recent non-aspiration case series, our median time to revascularization of 70 min is comparable to the 77 min recently published in the North American Solitaire Stent Retriever Acute Stroke registry that included a similar patient population.¹⁹

Two other points should be noted. First, since aspiration catheters are significantly less expensive than other devices that are commonly used in mechanical thrombectomy, the use of pure MAT as a first-line modality for clot removal has the potential for significant cost reduction, even with the use of multiple catheters. Second, improved technology will facilitate this technique. The evolution of more supportive wires and microcatheters, along with advances in aspiration catheter technology, will facilitate tracking of large-bore aspiration catheters into the MCA. Improved operator experience will also play a significant part.

The limitations of our study include its lack of a prospective design. In addition, lack of core laboratory adjudication of procedural results sheds some concern about the validity of a comparison between the outcomes reported in this study and those obtained through core laboratory adjudicated trials. The analysis across manufacturers of aspiration catheters is limited by the overwhelming predominance of a single brand and a limited number of patients. Nonetheless, our study adds to the growing body of literature supporting the use of MAT as part of a multimodality recanalization strategy.

CONCLUSIONS

In our experience, employing primary MAT as the first-line technique to perform intracranial thrombectomy is associated with reasonable recanalization rates, good clinical outcomes, equivalent safety profiles and a lower cost compared with other mechanical revascularization devices currently on the market in the USA. Further prospective randomized trials of well-matched populations should provide ultimate evidence of benefit with this intra-arterial approach compared with standard medical therapy or other commonly used intra-arterial mechanical thrombectomy devices.

Contributors All authors contributed to the work presented through study design, manuscript composition and critical review.

Competing interests None.

Ethics approval Ethical approval was obtained from the Institutional Review Board at the University of Pittsburgh Medical Center (IRB# PRO08120394).

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