The Clinical Application Value of RAPID Software for Endovascular Treatment Decision of Acute Isolated M2 Occlusion

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Abstract

Objective: The aim of this study is to analyze the impact of RAPID software on the efficacy and safety of Endovascular Therapy (EVT) for patients with acute isolated M2 occlusion.

Methods: The patients with acute isolated M2 occlusion received endovascular treatment in our hospital, between January 2020 and April 2021 were retrospectively analyzed. Baseline characteristics and imaging parameters of CTP-RAPID were collected for analysis. The primary outcomes included favorable functional outcomes (modified Rankin Scale ≤ 3) at 90 days, and mortality within 90 days and symptomatic intracerebral hemorrhage were analyzed.

Results: Among the 62 patients enrolled in this study, 48 (40.0%) achieved a good functional outcome (modified Rankin Scale score ≤ 3 at 90 days). In the univariate analysis, Alberta Stroke Program Early CT Score, perfusion deficit volume in time to maximum (Tmax) >6s, and mismatch volume were associated with functional outcomes (all $p<0.05$). In the multivariate analysis, infarct core (CBF<30%) remained independent outcome predictors ($p<0.05$).

Conclusion: RAPID software based on CTP represent a promising tool for patients with acute isolated M2 occlusion to make decision and predict prognosis for endovascular treatment.

Keywords: Computed tomography perfusion; RAPID software; Acute artery occlusion; Endovascular treatment

Introduction

The recanalization of occluded vessels in early stage of acute ischemic stroke is related to the improvement of clinical prognosis and the reduction of mortality [1-3]. However, the only FDA-approved treatment for AIS was intravenous injection of tissue Plasminogen Activator (tPA) [4]. Because tPA is associated with a low recanalization rate of large vessel occlusion, intravascular Endovascular Therapy (EVT) and various mechanical devices, such as retriever stent or aspiration catheter have been developed, leading to better recanalization of large vessels [5-7].

Recently, direct aspiration thrombectomy with aspiration catheters for AIS therapy has been identified with ideal outcomes [8-10]. However, there are many patients who fail to recanalize after EVT. In addition, the risks and benefits of EVT in the treatment of distal intracranial artery occlusion (M2 segment of MCA) remain to be discussed [11-13]. Theoretically, the small size of ischemic core and ischemic penumbra of distal intracranial artery occlusion can reduce the beneficial effect of EVT on M2 occlusion. In addition, the thin wall and narrow lumen of distal artery may also lead a high risk of EVT complications [14-16].

Therefore, preoperative evaluation is important to improve their prognosis. RAPID software (iSchemaView Inc., Menlo Park, CA) performs automatic image postprocessing of images obtained from a computed tomography perfusion imaging system [17]. However, there have been lack of relevant studies on whether Rapid can be used to evaluate the effective recanalization of EVT treatment, increase the good prognosis rate and reduce mortality in patients with acute M2 occlusion. Hence, this study aimed to explore the clinical application value of RAPID software in EVT of patients with acute M2 occlusion using Penumbra reperfusion catheter in a single-center analysis.

Methods

Patients

The subjects of this study were selected from the patients according to the registration of endovascular treatment of acute stroke center from January 2020 and April 2021 in our Hospital. The criteria for inclusion in the study were as follows: (1) age ≥ 18 years. (2) The patient had AIS, and the M2 segment occlusion was confirmed by angiography. (3) National Institute of Health Stroke Scale (NIHSS) score ≥ 6 at the time of arrival. (4) The time from symptoms to admission was <8 h. (5) EVT was performed using the FAST technique with the Penumbra reperfusion catheter technique. EVT was performed by the technique of semi dark zone reperfusion catheter. Exclusion criteria included evidence of intracranial hemorrhage or severe cerebral infarction in the affected M2 area. Demographic data and clot location were recorded. The design and protocol of retrospective analysis was approved by the local institutional Committee.

Data collection

Demographic and clinical data of the patients were collected, including (1) demographic data (age and gender), (2) risk factors (hypertension, diabetes, atrial fibrillation, smoking and alcohol consumption history), (3) pre-onset medication history (antiplatelet aggregation drugs, anticoagulant drugs), (4) clinical data (systolic and diastolic blood pressure, preoperative National Institutes of Health Stroke Scale [NIHSS] score, whether intravenous thrombolysis was administered, onset to puncture time, groin puncture to recanalization time, the results of the RAPID software, core volume of infarct [VCBF<30%], the volume of hypoperfusion of time to maximum >6s [Vtmax >6s] and the details of the operation), and (5) laboratory tests (leucocyte, platelet, fibrinogen, triglyceride, high-density.

Evaluation

All patients with symptoms of an acute stroke underwent a CT scan and cerebral CT-angiography/CT-perfusion exam to analyze the lesion vessel and ischemic penumbra. This CT scan was repeated promptly after the intervention and again approximately 24 h after symptom onset to exclude a symptomatic intracranial hemorrhage.

Neurological function evaluation

In order to quantify neurological function, NIHSS scores were obtained at admission and discharge, and modified Rankin scores were recorded at admission and after 90 days. A good neurological function was defined as mRS scores of 0-2. For the analysis of interventional treatment, the following parameters of each patient were recorded: time from symptom onset to inguinal puncture, occlusion site, time from symptom onset to successful revascularization defined as final Thrombolysis in Cerebral Infarction (TICI) score 2b or 3 within the affected territory, recanalization time defined as time from groin puncture to final angiogram after successful revascularization.

Endovascular procedure

The Penumbra reperfusion catheter (3Max; Penumbra, Alameda, California, USA) coaxially with a 0.014-inch microguidewire (Synchro-14; Stryker, Kalamazoo, Michigan, USA) and a 0.021-inch microcatheter (Prowler Select Plus; Cordis, Miami, Florida, USA) were advanced to the proximal end of the occlusion and wedged to the clot under manual aspiration using a 50 mL syringe. After the balloon of the BGC was inflated, the Penumbra reperfusion catheter was withdrawn while continuing to maintain manual aspiration.

After positioning the aspiration catheter with the catheter tip in the proximal part of the clot, microguidewire and/or microcatheter were removed and the hemostatic valve at the DAC was disconnected to verify that there was no back flow of blood through the catheter. Then, aspiration was performed by using a 60 mL syringe (VacLok, Vacuum Pressure Syringe, Merit Medical Systems, Utah, USA) for at least 1 min to 2 min. Next, the DAC was slowly removed under continuous aspiration. The DAC was slowly and gently withdrawn to the cavernous ICA or completely removed in case of a blocked catheter due to clot material. If sufficient recanalization (≥ TICI 2b) was not achieved with ADAPT as a front-line therapy after not more than 3 failed aspiration attempts, an additional stent retriever was deployed by using the DAC approach and the so called Solumbra technique was conducted at the discretion of the operator. The Solumbra technique combines a stent retriever distal to the clot with an aspiration catheter at the proximal aspect of the clot. The stent retriever is pulled directly into the aspiration catheter while maintaining aspiration and both are removed together.

Statistical analysis

A median test was used to compare continuous variables. Continuous variables are reported as mean ± standard deviation and categorical variables are reported as n (%). Results were considered statistically significant with P-values <0.05. Statistical analyses were performed using SPSS 20.0 (SPSS Inc., Chicago, IL, USA) and SAS 9.2 (SAS Institute, Cary, NC, USA).

Results

Baseline characteristics

A total of 61 patients with acute isolated M2 occlusion who met the criteria were included in this experiment. Among them, 22 (40.0%) had a good functional outcome after 90 days. 8 (23.6%) patients died. 6 patients (18.2%) had Intracerebral Hemorrhage (ICH). 44 (80.0%) patients achieved mTICI ≥ 2 b after EVT. In the univariate analysis (Table 1), Tmax >4s (p=0.004), Tmax >6s (p=0.005), and mismatch volume (p=0.005) were associated with clinical outcomes. The parameters with a high correlation (Tmax >4s and Tmax >6s) were both included in the multivariate analysis (VIF=4.091 and 4.066, respectively; online supplemental Table 1), which may not affect the final results. There was no statistically significant difference (P>0.05) between the groups for risk factors for stroke (hypertension, diabetes, atrial fibrillation, etc.).
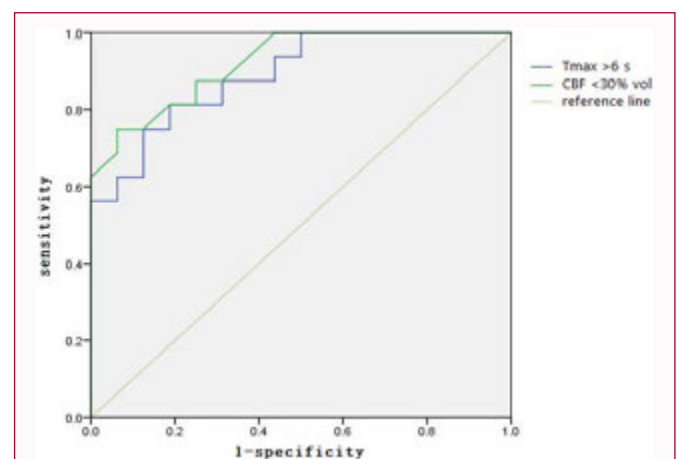

Figure 1: ROC analyses the AUC.

Table 1: Patient characteristics.

Patient data	Good clinical outcomes (n=48)	Poor clinical outcomes (n=14)	P value
Age, years	67 (58-75)	69 (57-73)	>0.01
Gender, male	4 (81.3%)	22 (72.6%)	>0.01
NIHSS score	12 (6-18)	24 (12-32)	>0.01
Hypertension	18 (61.2%)	16 (60.7%)	>0.01
Atrial fibrillation	23 (28.4%)	19 (26.5%)	>0.01
Diabetes mellitus	13 (24.7%)	15 (22.8%)	>0.01
CTP RAPID data			
Tmax >4 s	184 (158, 258)	251 (209, 375)	<0.01
Tmax >6 s	116 (89, 173)	165 (121, 237)	<0.01
Tmax >8 s	72 (53, 113)	119 (81, 145)	<0.01
Tmax >10 s	42 (18, 83)	92 (46, 115)	<0.01
CBF <30% vol (mL)	5.00 (0, 21)	36 (16, 68)	<0.01

Table 2: Multivariate analysis of predictors for good clinical outcome.

Independent variables	OR (95% CI)	P value
Tmax >6 s	0.916 (0.872, 0.966)	<0.01
CBF <30% vol	0.972 (0.961, 0.986)	<0.01

Good clinical outcome defined as 90-day mRS score 0-3.

Prognostic value of imaging parameters

In multivariate binary logistic regression analyses adjusted for Tmax >4s (p=0.004) and Tmax >6s (p=0.005), we found that higher deficit volume of Tmax >6s (p=0.026, OR: 1.011 (95% CI 1.001 to 1.020)) was still independent predictors of good functional outcomes (Table 2). As shown in Figure 1, in ROC analyses the AUC of a higher deficit volume of Tmax >6s was 0.705 (95% CI 0.563 to 0.848). The cut-off values with the highest Youden index for the Tmax >6s deficit volume was 90 mL (accuracy 65.9%; sensitivity 68.2%; specificity 63.6%).

Discussion

MCA area infarction accounts for the largest proportion in AIS population. According to the specific location of MCA occlusion, the initial manifestation and clinical results may be various [18-20]. Patients with MCA M1 infarction showed severe neurological deficit and poor functional outcome. Therefore, the early recanalization of M1 occlusion is very important to obtain good functional results [21-23]. Isolated M2 infarcts showed relatively mild neurological symptoms compared with M1 infarcts. Therefore, the effect of invasive EVT on M2 occlusion is still controversial. However, the prognosis of AIS caused by M2 occlusion is not always good, leading to permanent disability. Hence, EVT is also an alternative therapy strategy for isolated M2 occlusion [24-26].

Currently, one case is processed in approximately 5 min to 7 min, depending in part on the hardware platform on which RAPID is implemented [27]. RAPID could easily be installed on a more powerful machine. RAPID currently identifies the ratio between the volume of the infarct core and the volume of the hypoperfused tissue, also known as the volumetric mismatch [28]. It has been demonstrated that RAPID is robust and accurate enough for a reliable identification of diffusion-perfusion-mismatch [29]. Evidence has shown the benefit of EVT for M2 segment occlusions compared with the best medical treatment [30]. However, the clinical application value of RAPID software for endovascular treatment decision of acute isolated M2 occlusion is very limited, and the optimal imaging parameters for M2 occlusion EVT remain elusive. In This study, we evaluated the prognostic efficacy for clinical outcomes of patients with M2 occlusion after EVT using RAPID.

According to the results of the Dawn study and the Defuse 3 study, which extended the time window of acute anterior circulation infarction to 6 h to 24 h, this study aimed to the utilize Rapid software to analyze CTP data and select patients with acute M2 occlusion suitable for EVT. We expected more patients could obtain benefit from EVT and have good prognostic efficacy. RAPID software can obtain cerebral perfusion phase information according to CTP, among which VCBF <30% and ischemic penumbra volume are the most important data. Tmax is a comprehensive and stable index, reflecting the degree of CBF decline, and related to vascular stenosis and collateral circulation, and CT machine parameters. Single factor analysis showed that Tmax >6s, Tmax >8s, Tmax >10s, and VCBF<30% were smaller in the good prognosis group than in the bad prognosis group. It indicated that the brain volume of the patients with good prognosis whose Tmax >6s affected the prognosis of the patients. However, multivariate logistic regression analysis showed that only VCBF<30% was independent prognostic factors. VCBF<30% determined the prognosis of patients with acute M2 occlusion after EVT.

This study had several potential limitations. Firstly, this was a prospective study, the effect of EVT on clinical results was determined in a nonrandomized pattern. Therefore, the study had some shortcoming of an observational design. Furthermore, the retrospective nonrandomized design of the study had undetected biases that may have influence the findings. Thirdly, this study was retrospectively analyzed based on single-center data, a relatively small number of patients were enrolled. Despite its limitations, our study still provides available data about M2 occlusion after EVT because of the promising clinical practice for patients.

In conclusion, the Tmax profile in RAPID may provide fast and objective parameters for M2 occlusion patient selection to receive EVT. VCBF<30% was independent prognostic factor of M2 occlusion after EVT.

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