

Single-Centre Experience with Patients Selection for Mechanical Thrombectomy Based on Automated Computed Tomography Perfusion Analysis—A Comparison with Computed TomographyCT Perfusion Thrombectomy Trials

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Background: In randomized clinical trials, mechanical thrombectomy (MT) was proved to be a highly effective treatment of acute ischemic stroke which improved clinical outcomes. Some of the trials used automated computed tomography perfusion (CTP) analysis for selection of participants. We present a single-center experience with CTP selection and comparison with CTP trials. *Methods:* Data of consecutive MT patients (from January 2016 to December 2017) were retrospectively reviewed. All patients with multiphase CT angiography confirmed the presence of anterior circulation large vessel occlusion/s in the intracranial internal carotid artery and/or middle cerebral artery (M1 or M2) and with admission brain CTP analyzed by RAPID software were included into the analysis. *Results:* Sixty-two patients fulfilled the inclusion criteria (mean age was 70.1 ± 13.6 years, females 48.5%). At baseline, National Institutes of Health Stroke Scale score was 16 (IQR = 13-20), Alberta Stroke Program Early CT Score (ASPECTS) was 8 (IQR = 7-9), CTP core volume was 20 mL (IQR = 2-36), and CTP penumbra volume was 145.5 mL (IQR = 107-184). Time from stroke onset to imaging was 1 hour 32 minutes, time from stroke onset to reperfusion was 3 hours 50 minutes, and median time from CT to reperfusion was 1 hour 56 minutes. Modified thrombolysis in cerebral infarction 2b/3 was achieved in 42 patients (67.7%). Twenty-three patients (37%) had modified Rankin scale 0-2 at 90 days. *Conclusions:* Our analysis of CTP-selected patients for MT supports clinical applicability of automated CTP analysis into everyday clinical practice.

Key Words: Mechanical thrombectomy—CT perfusion—RAPID—single-centre experience

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Level of Evidence: Level 4, Case series.

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Introduction

Recent randomized clinical trials (RCTs) demonstrated that mechanical thrombectomy (MT) with second-generation neurothrombectomy devices represents a highly effective and safe treatment for patients with acute ischemic stroke due to a large cerebral artery occlusion in the anterior cerebral circulation when performed within 6 hours after symptoms onset.¹⁻⁶

Following trials with an extended time window for the treatment, DAWN (DWI or CT perfusion [CTP] Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention with Trevo) and DEFUSE 3 (Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke), showed the clinical benefit on 90 days functional outcome for thrombectomy patients who had last been known to be well between 6 and 24 hours prior to presenting stroke symptoms and who had the evidence of salvageable tissue on perfusion imaging.^{7,8}

Since the neuroimaging protocol at our comprehensive stroke center from 2016 includes noncontrast computed tomography (CT), multiphase CT angiography (mCTA), and CTP evaluated automatically by RAPID software as used in all above mentioned perfusion trials, we decided to analyze real-world data and present our single-center experience and comparisons with above mentioned RCTs.

The main aim of our study was to compare short-term and long-term clinical outcomes in patients who were selected to undergo MT based on automated CTP analysis.

Methods

Patient Selection

Data of consecutive MT patients from January 2016 to December 2017 were retrospectively reviewed. All patients with mCTA confirmed presence of the anterior circulation large vessel occlusion in the intracranial internal carotid artery and/or middle cerebral artery (M1 or M2) and with admission imaging including mCTA and CTP were included into the analysis.

Ethics approval was obtained from the local Institutional Review Boards (the Boards waived the need for patient consent).

Imaging Protocol

Patients suspected of experiencing acute ischemic stroke and presenting no history of either renal failure or contrast allergy routinely undergo a noncontrast CT, mCTA from the aortic arch to vertex (Calgary Stroke Program protocol), and CTP.

Noncontrast CT was acquired on a multidetector scanner (120 kV, 328 mAs [419 mAs/slice], Brilliance iCT 256; Philips Healthcare, Cleveland, OH) with a section thickness of .9 mm and an image reconstruction of 3 mm.

For the CTP protocol, 40 mL of contrast agent (Iomeron 300; Mallinckrodt Pharmaceuticals; Dublin, Ireland) was power injected at 5 mL/s followed by a saline chase of 50 mL at 5 mL/s. Sections of 8 cm thickness were acquired at 10 mm slice thickness. Scanning began after a delay of 5 seconds from contrast injection in every 1.8 seconds for 75 seconds.

Image Processing

Commercially available automatic software (RAPID, iSchemaView) was used to generate perfusion maps and calculate volumes of ischemic core (regional Cerebral Blood Flow (CBF) <30%), critically hypoperfused tissue— ischemic penumbra (time to the maximum of the residue function [T_{max}] > 6 seconds) and mismatch volume.

Image Analysis

Patient study images (admission CT, mCTA, digital subtraction angiography studies, and 24-hour control CT) were assessed independently of each other by consensus of 2 experienced readers (P.C. and O.V.) during different sessions. Early ischemic changes were assessed on CT using the ASPECT scoring system. The collateral status was scored on the mCTA as good, moderate, or poor as previously described. Good collaterals were defined as pial vessels with no delay or a delay of 1 phase on mCTA in filling in when compared with the asymptomatic hemisphere, and normal extent within the ischemic territory. Moderate collaterals were defined as pial vessels with a delay of 2 phases in filling in and normal to decreased extent, or as pial vessels with a 1-phase delay and a significantly reduced number of vessels, or the presence of regions with no vessels within the ischemic territory. Poor collaterals were defined as just a few or no vessels visible in any phase within the ischemic territory.⁹

Final infarction was assessed using the ASPECTS on a 24-hour control CT and the presence or absence of haemorrhagic transformation was noted (ECASS II classification). Angiographic studies from the endovascular procedure were assessed for reperfusion using the modified thrombolysis in cerebral infarction (TICI) score. The modified TICI score is a 5-point scale that ranges from 0 (no reperfusion) to 3 (complete reperfusion of the previously ischemic territory) including grade 2c (almost complete reperfusion).¹⁰

Clinical Assessment

Clinical assessments were performed at baseline and included the National Institutes of Health Stroke Scale (NIHSS) score and, at 90 days by the modified Rankin scale (mRS), both were determined by certified raters.

Outcomes

The primary efficacy outcome was the ordinal score on the mRS, range: 0 (no symptoms) to 6 (death) at day 90.

The score was assessed in person, or by telephone if an in-person visit was not feasible. The secondary efficacy outcome was functional independence (defined as a score on the mRS of 0-2) at day 90. The primary safety endpoints were death within 90 days and the occurrence of symptomatic intracranial hemorrhage, defined as parenchymal hematoma type 2 on a 24-hour control CT.

The technical efficacy of the endovascular procedure was defined as a modified TICI score of 2b (50%-90% reperfusion) to 3 (complete reperfusion).

The procedure-related outcomes were characterized by the time from symptom onset to admission imaging (CT), the time from symptom onset to reperfusion, and the time from CT to reperfusion.

Statistical Analysis

Standard descriptive statistics was applied in the analysis; absolute, and relative frequencies for categorical variables and mean supplemented with standard deviation or median supplemented by interquartile range (IQR) for continuous variables. The relation of clinical endpoint and its potential predictors was analyzed using logistic regression and described by odds ratios, their confidence intervals, and statistical significance; $P = .05$ was taken as a level of statistical significance in all analyses. Statistical analysis was computed using the SPSS 25.0.0.1 software (IBM Corporation, 2017).

Medians of core/penumbra in our cohort and in the RCTs were compared. Statistical significance of difference between our cohort and the RCTs was estimated by using a 2 sample t test with following assumptions: (1) normal distribution of log transformed data and (2) standard deviation estimated from the IQR.

Results

From January 2016 to December 2017, a total number of 62 patients fulfilled the inclusion criteria (mean age was 70.1 ± 13.6 years, females 48.5%). Patients' characteristics are shown in Table 1. At baseline, the median NIHSS score was 16 (IQR = 13-20). The baseline median ASPECTS was 8 (IQR = 7-9). The median infarct volume was 20 mL (IQR = 2-36), median penumbra volume was 145.5 mL (IQR = 107-184). Comparison of our cohort with the CTP-thrombectomy trials is summarized in Table 2.

The median time from the stroke onset to imaging was 1 hour 32 minutes, median time from the stroke onset to reperfusion was 3 hours 50 minutes, and the median time from the CT to reperfusion was 1 hour 56 minutes (Table 3). The modified TICI 2b/3 was achieved in 42 patients (67.7 %). Twenty-three patients (37%) had mRS 0-2 at 90 days.

Table 4 summarizes results of univariate logistic regression.

Univariate models were constructed for each potential predictor and their effects were evaluated separately. In all models, the outcome measure was a 90-day mRS score of 0-2.

Discussion

In our analysis we evaluated real-world thrombectomy data from a high volume centre in the Czech Republic and compared the data with RCTs which used an automated CTP analysis (RAPID software) for patient selection.

From a demographic standpoint, our and above mentioned CTP-trials' cohorts were balanced in age, sex, admission NIHSS score, and comorbidities. From an imaging standpoint, our and CTP-trials' cohorts were balanced in admission ASPECTS and clot localization in the anterior cerebral circulation. Patients in our cohort had larger admission ischemic cores (median 20 mL) and penumbra (145 mL) in comparison to the CTP trials, which selected their participants according to perfusion mismatch (SWIFT PRIME, EXTEND IA, DEFUSE 3) or clinical/imaging mismatch (DAWN). The difference in the size of core was statistically significant in comparison to DAWN ($P = .001$) and DEFUSE study ($P = .019$). However, this estimated results needed to be taken with some cautious as the data was tested assuming the normal distribution within the particular patient cohorts. It was discussed previously that strict patient selection criteria might have potentially increased the rate of patients who had a good clinical outcome but, on the other hand, reduced treatment effect.¹¹ Our analysis showed that a significant predictor for good clinical outcome was the successful reperfusion (TICI 2b/3). There was no association of either good or poor clinical outcome with the volume of the ischemic core on admission CTP in our cohort. A possible explanation might be that all patients met the recommended perfusion criteria for ischemic core (defined as <50 mL in the SWIFT-PRIME trial) or less than 70 mL in the EXTEND-IA trial, respectively). These findings indicate that volume of the core is just 1 parameter and that clinical outcome is dependent on other variables such as the localization of core (eg, ischemic injury/damage to the motor corticospinal tract), the volume of salvagable penumbra and its localization in hypoperfused territory as well as the level and time of successful reperfusion.

Previous trials have demonstrated that workflow speed is strongly associated with better functional outcomes, thus the reduction of procedural times must be targeted in clinical practice.¹²⁻¹⁴ The majority of patients included into our analysis were treated within the 6-hour time window from the symptom onset, which reflects efficient acute stroke care management at the regional level.¹⁵ On the other hand, there is still a place for improvement at our centre, especially in door-to-groin and groin-to-reperfusion times.¹⁶

In terms of clinical outcome, defined as mRS 0-2 after 3 months, this single-centre experience showed comparable rates of good outcome with the SWIFT-PRIME trial (mRS 0-1 18% versus 20%; mRS 0-2 37% versus 35%). The relative decrease in the number of patients with a good 3-month clinical outcome in comparison to other throm-

Table 1. Participants demographics, baseline imaging characteristics, procedural measures, and outcomes

Variable	Category/descriptive statistics	Study group (N = 62)
Age-y	Mean \pm standard deviation	70.1 \pm 13.6
Sex-no. (%)		
	Males	32 (51.6 %)
	Females	30 (48.4 %)
Baseline NIHSS score		
	Median	16.0
	Interquartile range	13.0-20.0
Baseline CT ASPECTS		
	Median	8.0
	Interquartile range	7.0-9.0
Clot localisation, no. (%)		
	M1	45 (72.6 %)
	M2	7 (11.3 %)
	Terminal internal carotid artery	10 (16.1 %)
Pial collaterals, no. (%)		
	Poor	7 (11.3 %)
	Medium	28 (45.2 %)
	Good	26 (41.9 %)
RAPID core (mL)		
	Median	20.0
	Interquartile range	2.0-36.0
RAPID penumbra, mL		
	Median	145.5
	Interquartile range	107.0-184.0
RAPID mismatch, mL		
	Median	118.5
	Interquartile range	84.0-153.0
IV Thrombolysis, no. (%)		43 (69.4 %)
Procedural measures, h:min		
	Median time from stroke onset to groin puncture* (IQR)	2:45 (2:15-4:38)
	Median time from CT onset to reperfusion [†] (IQR)	1:56 (1:36-2:38)
	Median time from stroke onset to reperfusion [‡] (IQR)	3:50 (3:00-5:27)
Thrombolysis in cerebral infarction, no. (%)		
	0-2a	20 (32.3 %)
	2b-3	42 (67.7 %)
Follow-up ASPECTS		
	Median	6.5
	Interquartile range	4.0-8.0
Haemorrhagic transformation, no. (%)		
	HI1 + HI2 + PH1	15 (24.2 %)
	PH2	2 (3.2 %)
Modified Rankin scale 3 mo, no. (%)		
	0-1	11 (17.7 %)
	0-2	23 (37.1 %)
Comorbidities, no. (%)		
Hypertension		49 (79.0 %)
	Hyperlipidemia	30 (48.4 %)
	Diabetes mellitus	16 (25.8 %)
	Atrial fibrillation	23 (37.1 %)
	Smoking (previous or current)	9 (14.5 %)
	Ischemic heart diseases	23 (37.1 %)
	Previous stroke	7 (11.3 %)

Abbreviations: CT, computed tomography; IQR, interquartile range; NIHSS, National Institutes of Health Stroke Scale.

*counted on smaller N = 51, due to some patients missing data.

[†]counted on smaller N = 50, due to some patients missing data.

[‡]counted on smaller N = 44, due to some patients missing data.

Table 2. Comparison of Brno thrombectomy data with randomized clinical trial using automated CTP analysis (RAPID)

Variable	Category	Brno (N = 62)	SWIFT PRIME (N = 98)	EXTEND IA (N = 35)	DAWN (N = 107)	DEFUSE (N = 92)
Age, y	Mean ± SD	70.1 13.6	65.0 ± 12.5	68.6 ± 12.3	69.4 ± 14.1	70.0 (59.0-79.0)
Sex, no. (%)	Male	32 (51.6 %)	54/98 (55 %)	17 (49 %)	51 (52 %)	46 (50 %)
NIHSS score	Median	16.0	17.0	17.0	17.0	16.0
	IQR	13.0-20.0	13.0-19.0	13.0-20.0	13.0-21.0	10.0-20.0
CT ASPECTS	Median	8.0	9.0	NA	NA	8.0
	IQR	7.0-9.0	7.0-10.0			7.0-9.0
Clot localisation, no. (%)	M1	45 (72.6 %)	62/93 (67 %)	20 (57 %)	83 (78 %)	60 (65 %)
	M2	7 (11.3 %)	13/93 (14 %)	4 (11 %)	2 (2 %)	
	ICA	10 (16.1 %)	17/93 (18 %)	11 (31 %)	22 (21 %)	32 (35 %)
Collaterals, no. (%)	Poor	7 (11.3 %)	NA	NA	NA	NA
	Medium	28 (45.2 %)				
	Good	26 (41.9 %)				
RAPID core, mL	Median	20.0	Target perfusion mismatch 83/98 (85%)*	12.0	7.6	9.4
	IQR	2.0-36.0		4.0-32.0	2.0-18.0	2.3-25.6
Core volume Brno versus other groups, <i>P</i> value [†]		-	-	.218	.001	.019
RAPID penumbra, mL	Median	145.5		106.0		114.7
	IQR	107.0-184.0		76.0-137.0		79.3-146.3
Penumbra volume Brno versus other groups, <i>P</i> value [†]		-	-	<.001	-	.001
RAPID mismatch	Median	118.5				
	IQR	84.0-153.0				
IV Thrombolysis-no. (%)		43 (69.4 %)	31/98 (32 %)	100%	5 (5 %)	10 (11 %)
TICI 2b/3		42 (67.7 %)	73/83 (88 %)	25/29 (86 %)	90 (84 %)	69/91 (76 %)
Control imaging	Median	6.5	Follow-up ASPECTS NA	NA	24h-infarct volume 8.0 cc	24h-infarct volume 35.0 cc
Extent of infarction	IQR	4.0-8.0			.0-48.0	18.0-82.0
Hemorrhagic transformation-no. (%)	PH2	2 (3.2 %)	PH2 1 (1 %)	PH2 0 (0 %)	SICH 6(6 %)	PH2 8 (9 %)

(Continued)

Table 2 (Continued)

Variable	Category	Brno (N = 62)	SWIFT PRIME (N = 98)	EXTEND IA (N = 35)	DAWN (N = 107)	DEFUSE (N = 92)
mRS 3 mo, no. (%)	0-1	11 (18 %)	20 (20 %)	18 (52 %)	31%	26%
	0-2	23 (37 %)	36 (35 %)	25 (72 %)	48%	54%

Abbreviations: CTP, computed tomography perfusion; ICA, internal carotid artery; IQR, interquartile range; mRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale; SD, standard deviation; TICI, thrombolysis in cerebral infarction.

*The target mismatch profile was defined as the core infarct lesion measured 50 mL or less, the volume of tissue with a time to maximum delay of more than 10 s was 100 mL or less, and the mismatch volume was at least 15 mL and the mismatch ratio was more than 1.8.

†Statistical significance of difference between our cohort and the RCTs was estimated by using a 2 sample *t* test with following assumptions: (1) normal distribution of log transformed data and (2) standard deviation estimated from the IQR.

Table 3. Comparison of procedural times

	Brno (N = 62)	SWIFT PRIME (N = 98)	EXTEND IA (N = 35)	DAWN (N = 107)	DEFUSE (N = 92)
Time interval-h:min					
Symptom onset to groin puncture* (IQR)	2:45 (2:15-4:38)	3:44 (2:45-4:35)	3:30 (2:46-4:11)	NA	NA
CT to reperfusion* (IQR)	1:56 (1:36-2:38)	0:57 (0:40-1:20)	1:33 (1:11-2:18)	NA	0:59
Stroke onset to reperfusion* (IQR)	3:50 (3:00-5:27)	NA	4:08 (3:24-4:37)	NA	NA

Abbreviations: CT, computed tomography; IQR, interquartile range.

*The time interval expressed as the median.

Table 4. Relation of clinical result mRS 0-2 (endpoint) with predictors

Univariate logistic regression	N	endpoint	OR (95% CI)	P value
Age				
	<70	27	10 (16.1 %)	-
	70+	35	13 (21.0 %)	1.01 (.36-2.84)
Sex				
	Female	30	6 (9.7 %)	-
	Male	32	17 (27.4 %)	4.53 (1.46-14.07)
NIHSS score				
	Median and less	36	15 (24.2 %)	-
	More than median	26	8 (12.9 %)	.62 (.22-1.80)
CT ASPECTS				
	Median and less	38	14 (22.6 %)	-
	More than median	24	9 (14.5 %)	1.03 (.36-2.96)
Clot localisation				
	M1	45	17 (27.4 %)	-
	M2	7	4 (6.5 %)	2.43 (.46-12.81)
	ICA + tICA	10	2 (3.2 %)	5.33 (.62-45.99)
Collaterals				
	Good	26	11 (18.0 %)	-
	Medium	28	10 (16.4 %)	.23 (.02-2.17)
	Poor	7	1 (1.6 %)	.76 (.25-2.27)
RAPID core				
	20 mL and more	32	11 (17.7 %)	-
	10-20 mL	9	3 (4.8 %)	1.43 (.46-4.44)
	0-10 mL	21	9 (14.5 %)	.96 (.20-4.57)
IV Thrombolysis				
	No	18	7 (11.5 %)	-
	Yes	43	16 (26.2 %)	.93 (.30-2.89)
TICI				
	Other	21	3 (4.8 %)	-
	2b-3	42	20 (32.3 %)	5.71 (1.46-22.42)
HTN				
	No	13	5 (8.1 %)	-
	Yes	49	18 (29.0 %)	.93 (.26-3.27)
HLP				
	No	32	9 (14.5 %)	-
	Yes	30	14 (22.6 %)	2.24 (.78-6.41)
DM				
	No	19	19 (30.6 %)	-
	Yes	4	4 (6.5 %)	.47 (.13-1.70)
AFib				
	No	39	17 (27.4 %)	-
	Yes	23	6 (9.7 %)	.46 (.15-1.41)
Smoking				
	No	53	18 (29.0 %)	-
	Yes	9	5 (8.1 %)	2.43 (.58-10.18)
IHD				
	No	39	15 (24.2 %)	-
	Yes	23	8 (12.9 %)	.85 (.29-2.50)
Previous stroke				
	No	55	22 (35.5 %)	-
	Yes	7	1 (1.6 %)	.25 (.03-2.22)
Time from stroke onset to CT				
	Median and less	26	10 (18.9 %)	-
	More than median	27	11 (20.8 %)	1.10 (.37-3.31)
Time from stroke onset to reperfusion				
	6 h and less	37	18 (40.9 %)	-

(Continued)

Table 4 (Continued)

Univariate logistic regression		N	endpoint	OR (95% CI)	P value
Time from CT to groin puncture	More than 6 h	7	3 (6.8 %)	.96 (.30-3.22)	.97
	Median and less	29	13 (22.0 %)	-	-
	More than median	30	10 (16.9 %)	.62 (.21-1.77)	.37
Time from CT to reperfusion	Median and less	25	13 (26.0 %)	-	-
	More than median	25	9 (18.0 %)	.52 (.17-1.61)	.26

Abbreviations: AFib, Atrial Fibrillation; CI, confidence intervals; CT, computed tomography; DM, Diabetes Mellitus; HLP, Hyperlipoproteinemia; HTN, Hypertension; IHD, Ischemic Heart Disease; mRS, modified Rankin scale; NIHSS, National Institutes of Health Stroke Scale; OR, odds ratio; TICI, thrombolysis in cerebral infarction.

*TICI 2b-3 and also the male sex were statistically significant.

bectomy trials might be explained by lower rates of successful reperfusion and the nonrandomized design of our study (TICI 2b/3 67.7% versus 76%-88%). Additionally, the fact that patients in our cohort had larger cores may reflect in the lower rates of good clinical outcome. In a recent study by Rebello et al,¹⁷ it was demonstrated that patients with large cores (more than 50 mL) and large mismatch profiles may still benefit from endovascular treatment, and reach a favourable shift in the distribution of 90-day mRS score. However, the rate of good clinical outcome (mRS 0-2) was lower (25%) in comparison to the trials with relatively small cores.

Our study has several limitations. We are aware that our comparisons with the RCTs are merely qualitative, since our data are based on retrospective and single-center analysis with a relatively limited number of patients. The aim of this study was to evaluate the effect of using the multimodal imaging protocol for the selection of patients indicated to MT and the correlation with the final clinical outcome, so only patients with admission CTP imaging were included. As clinical evaluation of disability and outcome (NIHSS and mRS) was not completely blind, there may be a source of bias.

In conclusion, our analysis of CTP-selected patients for MT supports clinical applicability of automated CTP analysis into everyday clinical practice. Multimodal imaging protocols have a potential to better distinguish patients with a malignant CTP profile and thus prevent futile reperfusion as well as avoid excluding patients who may still benefit from the endovascular treatment regardless the time of onset or in patients with unknown time of onset.

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