Published in final edited form as:
Stroke. 2014 July ; 45(7): 1999–2003. doi:10.1161/STROKEAHA.114.005304.

The Capillary Index Score in the IMS I, II Trials

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Abstract

Background and Purpose—The Capillary Index Score (CIS) is a simple angiography-based scale for assessing viable tissue in the ischemic territory. We retrospectively applied it to Interventional Management of Stroke (IMS) trials I and II to evaluate the predictive value for good outcomes.

Methods—CIS was calculated from pre-treatment diagnostic cerebral angiograms (DCA) blinded to outcome. IMS I and II DCA images were reviewed and CIS calculated for treated subjects with ICA or M1 occlusion and a DCA of sufficient quality. CIS scoring (0-3) was dichotomized into favorable (*f CIS = 2 or 3)* and poor *(p CIS = 0 or 1).* Modified thrombolysis in cerebral infarction (mTICI) score 2b or 3 was considered good revascularization. CIS and mTICI scores were compared to good outcome, defined as modified Rankin Scale (mRS) score ≤ 2 at 90 days.

Results—28 of 161 subjects met the inclusion criteria. 13 (46%) had *f* CIS. Good clinical outcome was significantly different between the two CIS groups (62% for *f* CIS vs. 7% for *p* CIS, p value = 0.004). Good reperfusion correlated to good outcome (p value = 0.04). No significant differences in time to intravenous or intra-arterial treatment were identified between *f* CIS and *p* CIS groups (p > 0.25).

Conclusions—A *f* CIS was found in approximately 50% of subjects, and was a virtual prerequisite for good outcome in this study subgroup of IMS I and II. We call this the 50% barrier.

Keywords

ischemic stroke; revascularization; outcome; Capillary index score; 50% barrier

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Conflict of Interest/Disclosures Dr. Broderick has received compensation for research activities from Genentech, materials and supplies from EKOS, Codman and Concentric, and support for travel from Boehringer Ingelheim. Dr. Gebel serves as an expert witness related to stroke treatment. Dr. Tomsick served as an interventional primary investigator on the National Institutes of Health National Institute of Neurological Disorders and Stroke grant U01NS052220. No other authors have any conflicts of interest related to this study.

Introduction

The Capillary Index Score (CIS) has been proposed as a metric to identify acute ischemic stroke patients who have sufficient collateral blood flow for good functional outcomes following good revascularization. The CIS is a simple 4-point scale ranging from 0 (no angiographic capillary blush) to 3 (the whole ischemic area exhibits capillary blush) developed from the Borgess Medical Center-Acute Ischemic Stroke (BMC-AIS) Registry of patients treated with endovascular revascularization.[1] Capillary blush serves as a marker of residual viable tissue, with absence implying irreversible ischemia. Favorable CIS (*f* CIS) was found to be a prerequisite for a good clinical outcome, defined as a modified Rankin Scale (mRS) score of 2 or lower at 90 days.[1] In the original registry, a *f* CIS was identified in 42% of subjects, suggesting a limitation to potential clinical benefit, or a ceiling effect, of intra-arterial treatment for acute ischemic stroke (IAT-AIS). Since the BMC-AIC Registry population was similar to the general Caucasian population, these results may be generalizable, indicating that timely revascularization cannot produce a good functional outcome for approximately 50% of patients presenting with AIS (the 50% barrier).[1] To further evaluate the predictive value of the CIS in patient inclusion/exclusion for IAT-AIS, and to test the proposed 50% barrier, we retrospectively evaluated the CIS from two multi-center, international clinical trials, the Interventional Management of Stroke (IMS) I and II trials.[2,3]

Materials and Methods

The IMS I and II trials were multicenter, single-arm, pilot studies characterizing outcomes following intravenous treatment (IVT) combined with IAT following ischemic stroke. The studies included subjects aged 18 through 80 years with initiation of IVT tissue plasminogen activator (tPA) within 3 hours of onset of stroke symptoms and an NIH Stroke Scale Score (NIHSS) of at least 10 points at the onset of IVT.[2,3] Access to de-identified databases was provided by the publication committees of the IMS I and II series. Due to evaluation of previously collected data without subject identifiers, the current analysis was exempt from IRB review, although all subjects had provided informed consent for participation in each trial and subsequent analyses.

Pre-treatment diagnostic cerebral angiograms (DCA) from the 161 subjects enrolled in these series were evaluated to identify subjects meeting the inclusion criteria: a) intracranial internal carotid artery (ICA) or middle cerebral artery trunk (M1) occlusion, b) all potential collaterals to the ischemic area injected, c) delayed images available including the venous phase, and d) no significant motion artifacts. These criteria allowed for clear visualization of the capillary blush. Thirty-one subjects met these criteria, of which 28 received IAT and comprise the analysis population.

The ischemic area was defined as the area lacking antegrade flow with blood supplied in a retrograde fashion through the pial collaterals. The CIS was calculated from anterior-posterior (AP) images after dividing the ischemic area into three equal segments (Fig 1). One point was awarded for each segment of identifiable capillary blush. A CIS equal to 0

(no staining) implies no viable tissue in the ischemic area, while a score of 3 implies that essentially all tissue may be salvageable. The AP images allow distinction between the left and right hemispheres. Based on prior findings, CIS scoring was dichotomized into favorable (*f* CIS = 2 or 3) and poor (*p* CIS = 0 or 1) scores.[1] Three reviewers blinded to all other information simultaneously measured the CIS and came to unanimous consensus on the final score. Since the CIS scale is relatively simple and differences between scores imply the presence or absence of capillary blush within one-third of the ischemic area, consensus was easily achieved.

Demographic information including age and sex, and outcome measures were collected from the IMS I and II de-identified databases. Parameters related to pre-IAT treatment included site of occlusion, time from stroke to onset of IV tPA administration, time to onset of IAT, and baseline NIHSS score. Post-treatment parameters included the modified thrombolysis in cerebral infarction (mTICI) score, cerebral infarction volume from follow-up CT-Scan (Cheshire software, Hayden Image Processing Group, Boulder, CO)[4], and 90-day mRS score. For dichotomization of the primary clinical outcome, a 90-day mRS score of 0-2 was considered a good outcome.[3] Other dichotomized parameters included mTICI score (poor = 0, 1, or 2a; good = 2b or 3), and occlusion site (ICA vs. MCA).

Statistical analysis focused on identifying parameters correlated with the mRS score and the CIS. The dichotomized data on CIS and mTICI score were compared to dichotomized clinical outcomes based on the 90-day mRS scale ≤ 2 using the Fisher's exact test. Stepwise multivariable linear regression analyses were used to relate infarction volume, time to IVT, time to IAT, NIHSS score, CIS, and mTICI score to mRS score. Only parameters that significantly ($p < 0.05$) contributed to the regression were retained for subsequent analysis. Relationships between CIS and other parameters were also evaluated. Proportions of males and females and good and bad mTICI scores were compared between the *f* CIS and *p* CIS groups with a Fisher's exact test or with a χ^2 analysis if the sample size was suitable. T-tests were used to compare ages, mRS scores, NIHSS scores, infarction volumes, IV times and IA times between subjects in the *f* CIS and *p* CIS groups. Analyses were conducted using a variety of statistical analyses programs (IBM SPSS Statistics version 20, Minitab version 16, and Microsoft Excel).

Results

Infarction volume and mRS were the parameters most strongly associated with CIS. No significant differences in age, baseline NIHSS, time to IVT or IAT were identified between the *f* CIS and *p* CIS groups ($p > 0.25$) (Table 1). Proportions related to mTICI score, occlusion site, and sex also did not vary significantly between the *f* and *p* CIS groups ($p > 0.25$) (Table 2). Mean infarction volume was 60,000 ± 47,000 mm^3 for the *f* CIS group compared to 121,000 ± 72,000 mm^3 for the *p* CIS group ($p = 0.02$). Mean mRS score was 2.8 ± 2.4 for the *f* CIS group compared to 4.6 ± 1.1 for the *p* CIS group ($p = 0.01$).

The primary parameters associated with a good outcome were a *f* CIS and successful reperfusion. *f* CIS was identified in 13 of the 28 subjects. A mRS of 2 or lower was achieved in 8 (62%) of those subjects (Table 2). Only 1 of the 15 subjects (7%) with a *p* CIS had a

good outcome, but nevertheless with a relatively large infarction volume (100,000 mm^3). Ten subjects achieved mTICI 2b/3 reperfusion, with 6 reaching a mRS of 0-2, while 3 of 18 subjects with a poor mTICI score had a good clinical outcome, all with CIS = 2 (*f* CIS). The 3 with a good outcome were from a total of 8 subjects with *f* CIS and poor reperfusion (38%) (Table 3). All five subjects who presented with *f* CIS and achieved good reperfusion had a good outcome (100%). The rates of good clinical outcome were significantly related to *f* CIS ($p = 0.004$) and good mTICI score ($p = 0.04$). Rates of good outcome were not significantly related to occlusion site or sex ($p > 0.2$). Regression analyses did not find significant relationships between outcome and time to IVT or IAT ($p > 0.5$, $r^2 < 0.02$ for regressions). Stepwise multivariable linear regression indicated only CIS and mTICI score were significantly correlated with mRS score ($p < 0.03$). The adjusted r^2 from multivariable linear regression indicated the CIS and mTICI score combined to account for 41% of the total variation in the mRS over the study population. The standardized beta coefficients were nearly identical for the CIS and mTICI score (-0.54 for CIS and −0.53 for mTICI score), with a variance inflation factor of 1.04, indicating that the influence on mRS score is similar for the two parameters with minimal interdependence.

Discussion

The current analysis identified the CIS and mTICI score as the primary parameters contributing to good clinical outcomes in this cohort of the IMS I and II trials. No significant relationship was established between mTICI score and CIS, indicating these parameters contribute independently to likelihood of a good outcome. A previous study based on the BMCAIS Registry also identified CIS and reperfusion as parameters influencing good outcomes.[1] Neither study showed a significant relationship between time from ictus and CIS, suggesting that early treatment cannot overcome irreversible ischemia for some patients. The current analysis showed no significant association between good clinical outcome and time to IV tPA treatment or IAT, but significant associations were found between clinical outcome and CIS and mTICI scores. The current results, along with those from the BMC-AIS Registry, support the value of the CIS for identifying salvageable tissue. The rates of good clinical outcome for the *f* CIS and *p* CIS groups were 62% and 7%, respectively, for the current study, compared to 55% and 0%, respectively, for the BMC-AIS Registry. The single exception to a direct relationship of *p* CIS to mRS > 2 had a large infarction on follow-up CT (100,000 mm^3). The overall rate of good outcomes for this cohort of patients was 32%, compared to 31% of all patients from the IMS I and II databases with T or M1 occlusions.[5]

A *f* CIS seems to identify viable tissue, but does not appear to guarantee recovery without successful intervention. All five subjects with a *f* CIS and successful reperfusion had a good outcome (100%), compared to three of eight (38%) subjects with a *f* CIS but unsatisfactory reperfusion. Only one of the five subjects with a *p* CIS and successful reperfusion (mTICI 2b) had a good outcome. While the data does not exclude good outcomes for some patients with *f* CIS without treatment, revascularization still appears to provide the best chance for a good outcome in these patients.

Futile recanalization related to treating subjects with poor collaterals (*p* CIS) beyond approximately one hour after onset of symptoms is a concept that overrides any other conventional understanding of optimal treatment based on patient-specific characteristics or comorbidities. This finding is consistent with a primate model showing complete reperfusion within 1-2 hours from onset of occlusion salvaged only about 50% of ischemic brain.[6] While this concept needs verification from a larger prospective clinical trial, if proven, it will lead to substantial changes in the IAT-AIS paradigm. Reperfusion in subjects with *p* CIS can also be harmful since reperfusing non-viable tissue could increase the hemorrhagic transformation and vasogenic edema with harmful effects on the residual normal cerebral tissue.

The *f* CIS and the 50% barrier

The current results and those of the previous evaluation of the CIS[1] imply that a *f* CIS is a virtual prerequisite for a good clinical outcome. Agreement between the BMC-AIS Registry[1] and IMS I and II trials concerning the percentage of *f* CIS (42% and 46%, respectively), despite differences in methods and time to treatment, strengthen the hypothesis that approximately half of patients do not have sufficiently robust collaterals to sustain ischemia until reperfusion (the 50% barrier). Poor collaterals may account for a success rate of only approximately 60% for patients without large vessel occlusion (LVO) on DCA following IV tPA in IMS I and II ([Thomas A. Tomsick], unpublished data, 2013) and IMS III.[7] Treating all who exhibit LVO at DCA is unlikely to provide a significantly higher percentage of good outcomes, further pointing to a ceiling effect for good outcomes in patients with IAT-AIS.

No significant relationships were established between *f* CIS and age, sex, occlusion site, time to IVT, or time to IAT, although these comparisons were limited by a small sample size. Based on the effect size noted for the current study, more than 150 patients would be needed to evaluate the relationship between CIS categorization and time to IVT with a power of 0.8. Similarly, no significant relationships with age or time to reperfusion were noted in the BMCAIS.[1] With recent reports identifying genes believed to be responsible for poor versus good pial collaterals in mice,[8] the presence of a similar gene in humans is plausible. A trial to search for such a gene is ongoing (Genetic Determinants of Collateral Status in Stroke/GENEDCSS trial).

Relationship between time and ischemia: linear versus logarithmic

The data from IMS I and II and BMC-AIS suggest no relationship between CIS and time from ictus. In other words, the CIS of a patient presenting within two hours of ictus is not necessarily more favorable than the CIS of a patient presenting at five hours. Time from ictus to DCA was similar for the *f* CIS and *p* CIS groups for both the BMC-AIS Registry and current data, and the percentage of subjects with *f* CIS was similar for the two studies despite the current study only including patients presenting within 3 hours of ictus, as opposed to 6 hours for the BMC-AIS Registry. These data suggest that the proportion of *f* CIS remains relatively stable up to 6 hours. Previous trials demonstrate a decrease in % mRS 0 to 2 between 3 and 6 hours. Subjects in IMS I and II and in a pre-IMS registry with IA therapy initiated within 3 hours demonstrated approximately 60% good outcomes.[7] Trial

subjects with angiograms but no treatable occlusion recovered similarly. Subjects with M1 or M2 occlusion in PROACT II achieved 40% mRS 0 to 2 with treatment initiated at mean 5.3 hours, and control subjects achieved 25% good outcomes.[8] Control subjects in MERCI recovered proportionately less well than treated subjects in PROACT II.[9] The approximately 20% decrease in proportion of good outcome over 2.3 hours from IMS I and II to PROACT II may be attributed to different treatment methods or individual subjects' ability to maintain collateral viability over time. This approximately 10% per hour difference is not applicable to each subject.[8] We hypothesize those with greater collaterals and higher CIS show less decrease in % mRS 0 to 2 with time than those with a lower CIS. Other authors have demonstrated a statistically significant decrease in the odds ratio of mRS 0 to 2 outcomes within the IMS studies with increasing time from ictus to reperfusion (up to 6 hours), also suggesting a linear relationship between good outcomes and time from ictus to reperfusion.[10,11]

The current data suggests the decrease in percentage of good outcomes and stable percentage of *f* CIS are not consistent with a linear relationship between time from ictus and proportion of patients with potentially good outcomes (Fig 2). We do know a time limit exists before brain tissue becomes irreversibly damaged for a specific patient, depending on residual cerebral blood flow (rCBF). To reconcile this observation, we propose that the linear relationship of time to outcome is a subset of the overall relationship when all AIS patients are taken into account. Analysis of IMS III data regarding odds ratios of good outcomes in CIS 0 to 1 versus CIS 2 to 3 versus time will be of interest in this regard.

When examining the entire population of AIS patients, the rCBF value of some will be so low that they experience irreversible ischemia within an hour to two of ictus (approximately 50% of all patients, the 50% barrier). These patients are seldom enrolled in studies due to evidence of ischemia on diagnostic imaging, or typically do poorly if they are enrolled. A second group of patients are hypothesized to present with intermediate rCBF and will demonstrate a gradual decrease in reversible ischemia with time. A third group of patients with a higher rCBF, but still below the 23 ml/100g/min[4] threshold established previously, will exhibit a more asymptotic, flat curve (Fig 2), with many typically excluded from studies or treatment due to the artificial time window. Combining these three groups, the relationship between time from ictus and reversible ischemia will resemble a more logarithmic function. This logarithmic, rather than linear, fit of time from ictus vs. reversible ischemia was actually alluded to by Jones et al.'s empirical data available on cerebral ischemia in primates. In their seminal paper,[4,12,13] rCBF was measured in the ischemic area of monkeys with the time until irreversible tissue damaged recorded. An infarction threshold was created separating data that represented normal and infarcted tissue. The data points seem to fit a logarithmic pattern, and we utilized a logarithmic best fit (Fig 3, $r^2 = 0.94$) to quantify the relationship between rCBF (ml/100g/min) and time from ictus to irreversible cerebral tissue damage (infarction) (hours) along the threshold as:

$$\mathbf{rCBF} = \mathbf{6.3} \ln(\mathbf{time}) + \mathbf{3.1}$$

This logarithmic model explains the interesting (and numerous) case reports of similar proportions of good clinical outcomes following treatment before and after 6 hours of ictus.[14-17]

The main limitation of the current study was the low rate of inclusion from the IMS I and II databases for the current analysis (17%), which can primarily be attributed to a current emphasis on minimizing time to treatment leading to incomplete DCA. The authors believe that more importance should be placed on obtaining complete DCA images and quantifying the CIS as part of patient selection, since the additional few minutes will not adversely influence the outcome. While attempts (unsuccessful still) have been made to relate the CIS to measures from perfusion MRI[18], no other imaging modality currently provides a similar threshold for patient selection.

Summary

Although time is brain, our data suggests a logarithmic, rather than linear, relationship. During the traditional time window for IAT-AIS, around 50% of patients may have already sustained irreversible damage prior to treatment (the 50% barrier). Poor patient selection may explain why the recent IMS III trial and other studies failed to show efficacy of IAT-AIS. Using the CIS for patient selection in future trials should demonstrate the efficacy of IAT-AIS. A large, prospective, multicenter trial is needed.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The authors acknowledge the contribution of Danielle Filipkowski to preparation of the manuscript.

Sources of Funding IMS I and II were funded by the National Institute of Neurological Diseases and Stroke (NINDS #NS39160).

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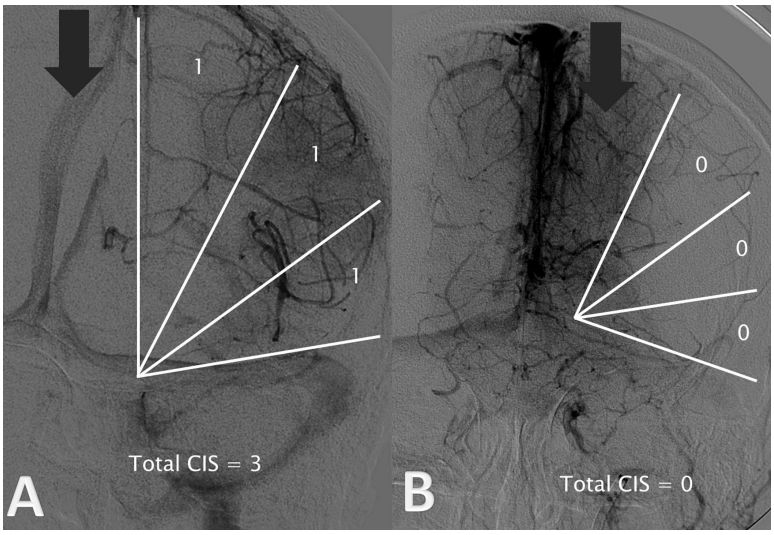

Figure 1.

Quantification of the CIS based on an AP cerebral angiogram. A. The site of ischemia was the middle cerebral artery (MCA). The arrow marks the anterior cerebral territory. CIS = 3 for this image. B. CIS = 0 for this image.

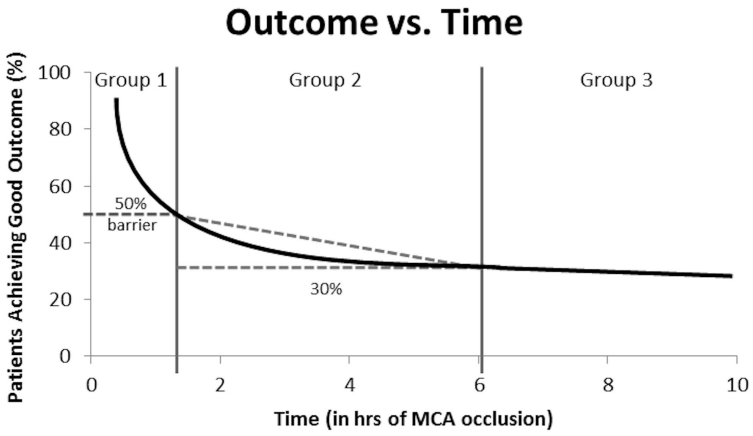

Figure 2.

Theoretical relationship between good outcomes and time. The 50% barrier is caused by a decline in rCBF so steep that early treatment cannot reverse tissue damage. Group 1: rarely enrolled in studies due to early signs of irreversible ischemia. Group 2: patient population in most IAT-AIS trials. Group 3: patients excluded from most studies due to artificial time window.

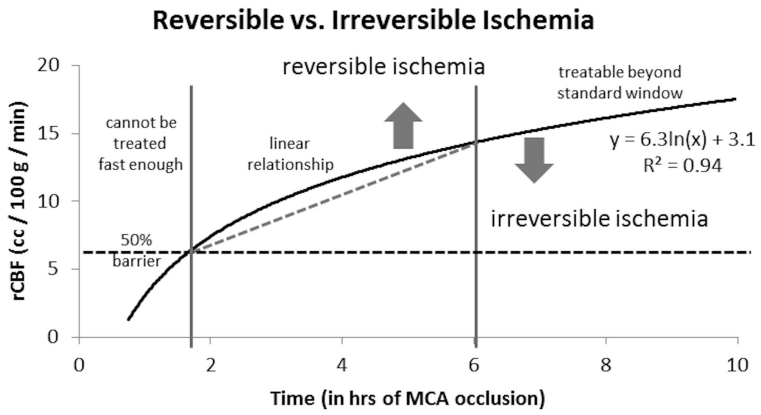

Figure 3.

Logarithmic time curve: the infarction threshold distinguishing between reversible and irreversible ischemia as a function of rCBF and time from ictus. The vertical lines are an approximation and have not yet been validated.

Table 1

Comparisons between f CIS and p CIS groups for continuous data

	f CIS*	*p* CIS†	p-value
Age (years)	61 ± 13	63 ± 13	0.66
NIHSS‡ score	19 ± 4	20 ± 3	0.32
Time to IVT§ (minutes)	120 ± 36	133 ± 22	0.26
Time to IAT// (minutes)	218 ± 41	218 ± 40	0.98
Infarction volume (cm^3)	60 ± 47	121 ± 72	**0.02** #
mRS ** **score**	2.8 ± 2.4	4.6 ± 1.1	**0.01**

* *f* CIS: favorable CIS (2 or 3),

† *p* CIS: poor CIS (0 or 1)

‡ NIHSS: NIH stroke scale,

§ IVT: intravenous treatment

// IAT: intra-arterial treatment,

Bold *p*-value indicates a significant difference

** mRS: modified Rankin Scale

Table 2

Proportions of subjects with good outcomes (mRS score ≤ 2) and a favorable CIS for dichotomized parameters along with the level of significance from comparisons

		good mRS/total	p-value	f CIS/total	p-value
CIS	(*p*) 0 or 1	1/15 (7%)	**0.004** //		
	(*f*) 2 or 3	8/13 (62%)			
mTICI* score	0, 1, or 2a	3/18 (17%)	**0.04**	8/18 (44%)	1
	2b or 3†	6/10 (60%)		5/10 (50%)	
Occlusion site	ICA‡	2/12 (17%)	0.22	4/12 (33%)	0.28
	MCA§	7/16 (44%)		9/16 (56%)	
Sex	Male	6/15 (40%)	0.43	7/15 (47%)	0.98
	Female	3/13 (23%)		6/13 (46%)	

*mTICI: modified thrombolysis in cerebral infarction;

†2b or 3 considered good revascularization

‡ICA: internal carotid artery,

§MCA: middle cerebral artery

//Bold p-value indicates a significant difference

Table 3

Proportions of subjects with good outcomes (mRS score ≤ 2) for combinations of dichotomized CIS and mTICI scores.

	good mRS/total	
mTICI[‡] score	***p* CIS (0 or 1)**	***f* CIS (2 or 3)**
0, 1, or 2a	0/10 (0%)	3/8 (37.5%)
2b or 3	1/5 (20%)	5/5 (100%)

[*] mTICI: modified thrombolysis in cerebral infarction;

[†] 2b or 3 considered good revascularization