Published in final edited form as:

J Neurointerv Surg. 2014 March ; 6(2): 83–86. doi:10.1136/neurintsurg-2013-010665.

2C or not 2C: defining an improved revascularization grading scale and the need for standardization of angiography outcomes in stroke trials

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INTRODUCTION

Although improvements in thrombectomy devices, stroke management and patient selection in clinical trials over the last two decades have occurred in concert with increasingly greater angiographic recanalization rates, clinical outcomes have remained largely unchanged.¹ For example, recently completed prospective trials using Stentriever technology have reported successful recanalization or reperfusion in upwards of 90% of enrolled patients, yet the percentage of patients with a good outcome at 90 days remains at only 35–55%.^{2–4} The association between adequate recanalization and good functional outcome has been well-documented in a number of studies.^{5–12} Furthermore, those making a dramatic recovery,

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Contributors

All authors contributed to the composition and/or critical review of the manuscript.

Competing interests

MG is a consultant for Covidien/ev3 and serves as a co-principal investigator for SWIFT-PRIME and ESCAPE trials. AST has research grants or consulting agreements with Stryker, Microvention, Penumbra and Codman. JM serves as a consultant for Lazarus Effect and Nfocus and has investor interests in Blockade Medical. DSL serves as a consultant for Stryker and Covidien. AMD has received honoraria from Covidien. All other authors have no disclosures to report.

Provenance and peer review

Not commissioned; internally peer reviewed.

defined as a decrease in the NIH Stroke Scale (NIHSS) score to ≤ 3 within 24 h, are more likely to have had early or more complete recanalization.¹³

However, the definition of ‘successful’ or adequate recanalization/reperfusion as an angiographic endpoint for treatment effect in such trials has become increasingly varied and confusing. The different grading scales and non-standardized definitions of successful thrombectomy reported in published stroke trials have made direct comparison of results difficult. In fact, some authors have called for increasing standardization of reporting among the stroke community using angiographic reperfusion to enhance generalizability.^{14,15} In this paper we review the current grading systems for recanalization/reperfusion, discuss the current controversies in grading systems and the need for standardization of recanalization and reperfusion in trial reporting. Finally, we offer a revised grading system that accounts for less than perfect but clearly excellent reperfusion within its scale.

CURRENT REVASCULARIZATION SCALES

There are a number of proposed scales for documenting the degree of revascularization after acute stroke intervention. These include the Thrombolysis In Myocardial Infarction scale (TIMI)¹⁶ recanalization, TIMI reperfusion, Thrombolysis In Cerebral Infarction scale (TICI),¹⁷ the modified TICI scale,¹⁸ the Mori reperfusion scale¹⁹ and the Qureshi score,²⁰ among others. These scales have been reviewed in detail recently by Zaidat and colleagues, with discussion of the advantages and disadvantages of each of them.¹⁴ From a practical standpoint, the utility of such grading systems is related to their ability to: create a common language for communication of results in the absence of illustrative pictures and diagrams; provide a means to compare across centers, studies, devices and operators; correlate the quality of revascularization with patient outcome or infarct size; and, probably most importantly, provide a guideline to the operators regarding when it would be appropriate to terminate the procedure even though perfect revascularization has not been achieved (ie, the old adage ‘better is the enemy of good’).

The two most commonly used scales for documenting the results of revascularization strategies in acute stroke treatment are the TIMI and TICI scales. These scales share similar traits and are shown for comparison in table 1. The utility of these two scales over other reported grading systems lies in their widespread popularity and ease of use, as well as their use in the majority of intra-arterial thrombectomy trials to date (table 2).

The TIMI score is a simple to use scale that focuses only on the site of occlusion and the rapidity of antegrade flow seen at that segment. However, this scale is limited by its inability to account for distal perfusion or the degree of collaterals present. The TICI score, in contrast, is more complicated but evaluates the degree of perfusion of the ischemic territory after recanalization. This system indirectly assesses the collateral flow by addressing the amount of total territory that has been reperfused, but it does not directly assess collateralization. Due to the inherent limitations in the assessment of perfusion of the distal territory, the TICI scale is much more complex and has been further divided into subcategories within partial perfusion. Both scales are limited by their inability to address the site of occlusion or the eloquence of the tissue within the ischemic territory.¹⁴

VARIABILITY IN TRIAL REPORTING

A close review of the best prospective intra-arterial thrombolysis or thrombectomy trials to date demonstrates the lack of standardization in reporting (table 2). Of 12 trials, nine used the TIMI grading system while the remaining three studies (including the unpublished Interventional Management of Stroke III study) used the TICI grading scale. Furthermore, only two-thirds used blinded core laboratory adjudication.

Further confusing the picture is the lack of association between recanalization and clinical outcomes in some studies. For instance, in the Penumbra Pivotal Stroke Study, TIMI grade 2 or 3 recanalization was seen in over 80% of patients but good outcome at 90 days occurred in only 25% of patients, in contrast to prior studies showing lower recanalization rates but better clinical outcomes.⁸ Others have argued that the original TICI scale itself is confusing, and there are specific situations where the TICI scale fails to adequately characterize angiographic results.²⁶²⁷ For instance, should a revascularized middle cerebral artery (MCA) territory, with slow filling of the MCA compared with the anterior cerebral artery territory yet a late arterial opacification of nearly all of the MCA region, be best represented by TICI 2A or 2B? Additionally, with the original TICI scale, how do you correctly categorize revascularization when it is more than two-thirds of the territory but not 'complete' filling?

There has been a lack of consensus on which scale should be used, and even the most recent studies on the subject (TREVO2 and SWIFT) used different scales. In addition, the definition of good or successful recanalization has varied across studies. Some studies have used 0 and 1 as poor recanalization and 2 and 3 as good recanalization, while other studies have used 2B and 3 as successful recanalization. There has been a difference in interpretation of final angiograms across many studies and many datasets, with participating centers generally reporting higher rates and quality of recanalization compared with core laboratory review.²

In general there is a lack of standardization with regard to: (1) what scale to use; (2) what constitutes successful or adequate revascularization within that scale; and (3) individual operator interpretation of the angiograms, given the significant inter-observer variability.

The next obvious questions are: (1) why do different studies use different grading parameters and (2) does the lack of uniformity in reporting matter?

There are probably several reasons for the discordant measurement and reporting of revascularization in stroke trials. First, trial designers may choose a scale that makes their data appear to have the greatest effect on revascularization, especially if the purpose of the study is to get USA Food and Drug Administration approval for a new device. For instance, devices that lead to excellent local recanalization but result in frequent distal emboli may appear better when evaluated by the TIMI scale than with the TICI scale. Second, there are probably inherent differences in operator or study designer preferences in measurement. Such preferences may be related to both prior training and experience in stroke trials as well as the fundamental goal of the proceduralist—to remove the clot and recanalize the vessel versus the re-establishment of cerebral perfusion. While this difference may seem merely an

issue of semantics, the goal of the proceduralist has important implications on the assessment of adequate treatment and for termination of the procedure once the goal has been obtained. Many interventionists favor recanalization over reperfusion as an endpoint because re-establishment of territorial perfusion is dependent on many other factors beyond the patency of the vessel that was occluded. For instance, factors that are distinct from the site of the thrombus and have little to do with the technical success of the thrombectomy procedure—such as the size of the ischemic territory and quality and robustness of collaterals—may significantly influence perfusion scoring. In an ideal world one would be able to determine whether the region of poor perfusion is salvageable or not and use that information to decide whether to continue with efforts to ‘improve’ the regional perfusion. However, given that the stroke community has not yet developed methodology to measure the size and location of the infarct during angiography, this remains a challenge.

To address the question whether uniform reporting is necessary, there is little argument that increased uniformity of scales across different studies is more desirable. Furthermore, improvement of our current scales to adequately quantify reperfusion may help to control for a number of important factors such as the presence or absence of collateralization. Standardization of revascularization measurement and reporting has few, if any, negative consequences. Uniform reporting of adequate recanalization/reperfusion will allow for direct comparison of angio-graphic success between trials and help to control for highly variable patient anatomy and collateralization when assessing technical thrombectomy success. Finally, standardization of reporting such that all trials use blinded core laboratory adjudication is necessary to control for interobserver variability and proceduralist bias. Currently, given that the two most common revascularization scales feature different criteria and evaluate different phenomena, we support the argument that journals should mandate reporting of both TIMI and TICI scores for stroke trials.

RECANALIZATION, REPERFUSION OR BOTH?

Arteriographic demonstration of flow restoration or revascularization has two distinct components (recanalization and reperfusion) that are not measured simultaneously with any existing scale. All endo-vascular trials should therefore measure and report both components in a consistent fashion. Recanalization of the primary arterial occlusive lesion is best measured with the TIMI recanalization scale focused on the most proximal arterial occlusive lesion. Reperfusion past the occlusion into the distal arterial bed and terminal branches is best assessed with the TICI scale.²⁷ Both components should be evaluated in all endovascular studies.

OPTIMIZING REPERFUSION ASSESSMENT WITH A REVISED TICI SCALE INCLUDING 2C

There is a general consensus that the use of modern stroke devices, most notably the Stentriever, has improved the frequency and quality of recanalization.²⁴ However, due to the presence of the infarct core and the occurrence of distal emboli, particularly as documented with recent expanded Stentriever use,^{28,29} achieving TIMI or TICI 3 flow remains relatively infrequent. This is especially true when the post-procedure angiogram is

being evaluated by an experienced core laboratory. However, the frequency of near-perfect reperfusion has dramatically increased in recent years. Currently, the modified TICI score does not differentiate between perfusion of 51% of the ischemic territory and complete perfusion except for the presence of a small distal embolus (95% reperfusion). Patients with small distal emboli after complete recanalization and reperfusion are currently labeled as TICI 2B, yet very likely exhibit a clinical outcome closer to those with complete reperfusion (TICI 3). To address this issue in the past, Noser and colleagues generated a revised TICI scale including 2C, which they defined as ‘near complete perfusion without clearly visible thrombus but with delay in contrast run-off’.³⁰

To account for near-perfect results, we have started using the term TICI 2C for situations when the angiogram is nearly normal but one or two of the M4 branches demonstrate slow flow or a tiny distal embolus. Similar to Noser’s TICI scale, the 2C designation categorizes those patients who have abnormal angiographic findings but probably with minimal clinically significant implications. A revised TICI scale is shown in table 3. Why is this new designation of potential importance?

First and foremost, this designation very likely correlates much better with patient outcome (although this would be highly dependent on other factors including size of core, rate of infarct growth, efficiency of recanalization from the time of imaging and brain eloquence). The idea that a patient with one small distal cortical embolus is equivalent to a patient with 51% reperfusion through recanalization of a large anterior division (and therefore probably remains aphasic and hemiplegic) is a major limitation of the current methodology. It is highly likely that this is a significant (though not the sole) cause of the disassociation between angiographic and clinical outcomes. Furthermore, the scale can sometimes influence the procedure. If physicians feel TICI 2B is generally the definition of success and that TICI 3 is unlikely, they may be more likely to accept a 50–60% reperfusion and not attempt to reperfuse remaining critical ischemic tissue. By capturing those patients with near-perfect treatment results, this scale would also provide a better means of comparing new thrombectomy devices that achieve high recanalization rates. At our centers we are already using this designation locally as a means of communicating a near-perfect angiographic result. For instance, what we would previously refer to as ‘better than a TICI 2B, but not perfect’, we now refer to as a TICI 2C.

PRIMARY DEVICE REVASCULARIZATION ASSESSMENT

In the era of thrombectomy devices, some standardization of evaluation is needed to determine the magnitude of revascularization achieved by the primary thrombectomy device in question, especially when the endovascular procedure is often ‘contaminated’ by other subsequent ancillary treatments (second thrombectomy device, distal clot manipulation or intra-clot or regional thrombolytic administration). A primary device TICI and TIMI arterial occlusive lesion recanalization assessment should be performed once the primary thrombectomy device has been abandoned before ancillary therapies are initiated. This standard approach is now very feasible since primary thrombectomy is the first major endovascular procedure in most cases.

POST-PROCEDURE ANGIOGRAPHIC REASSESSMENT

An additional point to consider when discussing the quality of revascularization obtained is the concept of delayed angio-graphic reassessment. As continued flowing blood is an excellent thrombolytic, it is possible that the quality of the flow may continue to improve after the procedure is over. On the other hand, the use of intraluminal devices introduces the possibility of intimal injury and platelet activation that can potentially lead to reocclusion after the procedure is concluded. As an example, acute thrombotic complications have been shown to occur in the 30 min following cerebral stenting.³¹ As the revascularization is subject to change following thrombectomy, it may be worthwhile evaluating the stability of the revascularization in a delayed fashion, such as 5–10 min after completion.

Standardization of delayed post-procedure angiography could potentially be another means of improving the accuracy of the revascularization that is reported.

CONCLUSIONS

The measurement and reporting of revascularization remains variable. To improve the generalizability of procedural results following thrombectomy, we advocate uniform reporting standards. Journals on stroke should mandate reporting both TIMI and TICI grading systems in published trials. In addition, we advocate a revised TICI scale that includes a 2C designation to describe those patients with near-complete reperfusion except for slow flow in one or two distal cortical vessels or the presence of minor distal emboli. This designation would assist in defining an endpoint for treatment success as well as improving comparisons between Stentriever technologies. Finally, we suggest delayed angiographic reassessment as a means of controlling for thrombolytic or thrombogenic phenomena that may occur immediately after completion of the procedure and may potentially influence the clinical outcome.

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Table 1

Comparison of Thrombolysis in Myocardial and Cerebral Infarction (TIMI and TICI) scales

Score	Thrombolysis In Myocardial Infarction (TIMI) scale	Modified Thrombolysis in Cerebral Infarction (TICI) scale
0	No recanalization	No perfusion or antegrade flow beyond site of occlusion
1	Minimal recanalization	Contrast passes the area of occlusion but fails to opacify the entire cerebral bed distal to the obstruction during angiographic run
2	Partial recanalization	Partial perfusion wherein the contrast passes the occlusion and opacifies the distal arterial bed but rate of entry or clearance from the bed is slower than non-involved territories 2A: Partial filling only (<50%) of territory visualized [*] 2B: Partial filling 50% of territory is visualized [†]
3	Complete recanalization	Complete reperfusion with normal filling

^{*} 2A is represented by partial filling, less than two-thirds of the ischemic territory, in the original TICI scale.

[†] 2B is represented by complete filling that is slower than normal in the original TICI scale.

Table 2

Revascularization grading in intra-arterial stroke intervention studies

Stroke study	Definition of successful revascularization
PROACT, 1998 ²¹	TIMI grade 2 or 3
PROACT II, 1999 ²²	TIMI grade 2 or 3
IMS I, 2004 ⁶	TIMI grade 2 or 3
MERCI, 2005 ²³	TIMI grade 2 or 3
IMS II, 2007 ⁷	TICI grade 2 (2A or 2B) and 3
Multi MERCI, 2008 ²⁴	TIMI grade 2 or 3
Penumbra Pivotal, 2009 ⁸	TIMI grade 2 or 3
RECANALISE, 2009 ⁹	TIMI grade 2 or 3
SARIS, 2009 ²⁵	TIMI grade 2 or 3
TREVO 2, 2012 ⁴	TICI grade 2 (2A or 2B) and 3
SWIFT, 2012 ²	TIMI grade 2 or 3
IMS III, unpublished ¹⁸	TICI grade 2 (2A or 2B) and 3

IMS, Interventional Management of Stroke; TICI, Thrombolysis In Cerebral Infarction scale; TIMI, Thrombolysis In Myocardial Infarction scale.

Table 3

Proposed revised Thrombolysis In Cerebral Infarction scale (TICI) scale including a 2C designation

Score	Revised TICI
0	No perfusion or anterograde flow beyond site of occlusion
1	Penetration but not perfusion. Contrast penetration exists past the initial obstruction but with minimal filling of the normal territory
2	Incomplete perfusion wherein the contrast passes the occlusion and opacifies the distal arterial bed but rate of entry or clearance from the bed is slower or incomplete when compared with non-involved territories
2A	Some perfusion with distal branch filling of <50% of territory visualized
2B	Substantial perfusion with distal branch filling of 50% of territory visualized
2C	Near-complete perfusion except for slow flow in a few distal cortical vessels or presence of small distal cortical emboli
3	Complete perfusion with normal filling of all distal branches