Letters to the Editor

Stroke welcomes Letters to the Editor and will publish them, if suitable, as space permits. They should not exceed 750 words (including references) and may be subject to editing or abridgment. Please submit letters in duplicate, typed double-spaced. Include a fax number for the corresponding author and a completed copyright transfer agreement form (available online at http://stroke.ahajournals.org and http://submit-stroke.ahajournals.org).

Need to Clarify Thrombolysis In Myocardial Ischemia (TIMI) Scale Scoring Method in the Penumbra Pivotal Stroke Trial

To the Editor:

We congratulate the Penumbra Investigators on the successful completion of the Penumbra Pivotal Stroke Trial.1 The addition of the Penumbra System to the therapeutic armamentarium is an important advance in acute stroke care.

A major defect of the report is the investigators do not specify how they measured the primary trial outcome, angiographic revascularization. They state without further elaboration that the core laboratory used the Thrombolysis In Myocardial Ischemia (TIMI) scale to assess revascularization. However, the TIMI scale was developed for the myocardial circulation and cannot be applied in the more complex cervicocephalic arterial tree without the creation of additional operational rules. A recent review found no fewer than 7 different operationalized versions of the TIMI scale being used across different stroke trials.2 The Stroke Therapy Academic Industry Roundtable (STAIR) has for this reason recommended abandonment of the TIMI in future cerebral revascularization clinical trials and use of one or more of the more transparent and uniformly applicable scales that have been developed for the brain.3 For past studies that did use the TIMI, like the Penumbra Pivotal Trial, it is absolutely essential that the idiosyncratic rules used by the trial core laboratory to apply the TIMI to the brain circulation be specified in full, as was done in the reporting of the Mechanical Embolus Removal in Cerebral Ischemia (MERCI), Multi-MERCI, and Interventional Management of Stroke IMS 1 and 2 trials.4–6

It is difficult to determine whether the reported higher recanalization rate in the Penumbra Trial compared with the MERCI, Multi-MERCI, IMS 1, and IMS 2 trials is an artifact of different angiographic scoring methods or a genuine difference in device technical efficacy. The similar clinical outcomes of the Penumbral patients and the MERCI/Multi-MERCI patients suggest that, when scored with the same method, the actual revascularization rates likely were similar. To complete their trial report, the Penumbra trialists should provide a full specification of how they applied the TIMI scale to their cerebral angiograms. If the scoring method did indeed differ in the Penumbra trial from those used in the MERCI, Multi-MERCI, IMS 1, and IMS 2 trials, we would encourage all of these trial investigators to collaborate on having a single core laboratory reread all angiograms using a uniform method and reporting the results. This collaborative effort would allow genuine comparisons to be drawn that could inform clinical decision-making and provide a benchmark for future revascularization clinical trials.

Disclosures

J.L.S. is an employee of the University of California, which holds a patent on retriever devices for stroke; is a scientific consultant regarding trial design and conduct to Concentric Medical, Ev3, and Talecris (all modest); received devices for use in a National Institutes of Health (NIH) multicenter clinical trial from Concentric Medical (modest); is a site investigator in the NIH CLEAR-ER, IMS 2, and IMS 3 multicenter clinical trials and the Concentric Merci registry for which the University of California Regents received payments based on the clinical trial contracts for the number of subjects enrolled; and is funded by NIH National Institute of Neurological Diseases and Stroke (NINDS) Awards P50 NS044378 and U01 NS 44364. D.S.L. is an employee of the University of California, which holds a patent on retriever devices for stroke; is a scientific consultant regarding trial design and conduct to Concentric Medical (modest); is a site investigator in the NIH Combined Approach to Lysis Utilizing Eptifibatide and rt-PA in Acute Ischemic Stroke-Enhanced Regimen (CLEAR-ER), IMS 2, IMS 3, and MR and REcanalization of Stroke Clots Using Embolectomy (MR RESCUE) multicenter clinical trials and the Concentric Merci registry for which the University of California Regents received payments based on the clinical trial contracts for the number of subjects enrolled; and is funded by NIH NINDS Awards K23 NS054084, P50 NS044378, and U01 NS 44364. R.G.N. is a scientific consultant regarding trial design and conduct as well as research and development to Concentric Medical, ev 3 Neurovascular, CoAxia, and Rapid Medical (all modest); is a site investigator in the NIH IMS 3 and MR RESCUE multicenter clinical trials and the Concentric Merci registry for which Massachusetts General Hospital received payments based on the clinical trial contracts for the number of subjects enrolled. R.I. is an employee of the University of California, which holds a patent on retriever devices for stroke; is a scientific consultant regarding trial design and conduct to Ev3 and Talecris (all modest); received devices for use in an NIH multicenter clinical trial from Concentric Medical (modest); is a site investigator in the NIH CLEAR-ER, IMS 2, and IMS 3 multicenter clinical trials and the Concentric Merci registry for which the University of California Regents received payments based on the clinical trial contracts for the number of subjects enrolled; and is funded by NIH NINDS Award P50 NS044378.

Jeffrey L. Saver, MD
David S. Liebeskind, MD
Department of Neurology
David Geffen School of Medicine, and Stroke Center
Ronald Reagan Medical Center
University of California, Los Angeles
Los Angeles, Calif

Raul G. Nogueira, MD
Endovascular Neurosurgery/Interventional Neuroradiology Section
Department of Radiology, Massachusetts General Hospital
Harvard Medical School
Boston, Mass

Reza Jahan, MD
Stroke Center
Ronald Reagan Medical Center, and University of California, Los Angeles

(Stroke. 2010;41:e115-e116.)
© 2010 American Heart Association, Inc.
Stroke is available at http://stroke.ahajournals.org

DOI: 10.1161/STROKEAHA.109.566406

e115


Need to Clarify Thrombolysis In Myocardial Ischemia (TIMI) Scale Scoring Method in the Penumbra Pivotal Stroke Trial
Jeffrey L. Saver, David S. Liebeskind, Raul G. Nogueira and Reza Jahan

Stroke. 2010;41:e115-e116; originally published online December 24, 2009;
doi: 10.1161/STROKEAHA.109.566406
Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2009 American Heart Association, Inc. All rights reserved.
Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/41/2/e115