



Available online at  
**ScienceDirect**  
www.sciencedirect.com

Elsevier Masson France  
**EM|consulte**  
www.em-consulte.com



Original article

# Variability of stroke patients meeting endovascular stroke trial criteria in a non-clinical trial setting

Jennifer E. Fugate<sup>a,\*</sup>, Waleed Brinjikji<sup>b</sup>, Harry Cloft<sup>b</sup>, David F. Kallmes<sup>b</sup>,  
Alejandro A. Rabinstein<sup>a</sup>

<sup>a</sup> Department of neurology, Mayo Clinic, 200, First St. SW, 55905 Rochester, Minnesota, USA  
<sup>b</sup> Department of neuroradiology, Mayo Clinic, Rochester, Minnesota, USA

## ARTICLE INFO

Article history:  
Available online xxx

Keywords:  
Stroke  
Endovascular procedures  
Cerebral infarction  
Randomized clinical trial

## ABSTRACT

**Background.** – Five randomized trials proving the efficacy and safety of mechanical embolectomy for ischemic stroke within 8 hours used differing radiological methods to select patients. We aimed to evaluate the proportion of patients in clinical practice that would meet radiological criteria for inclusion in these trials.

**Methods.** – Retrospective study of ischemic stroke patients at a large academic medical center who were considered for endovascular stroke therapy based on confirmed intracranial large vessel occlusion from April 2010–November 2014. All patients underwent computed tomography (CT) perfusion and CT angiogram.

**Results.** – Of 119 patients, median age was 69 years (IQR 57–79) and median NIHSS 18 (IQR 14–21). Most patients had ASPECTS  $\geq 6$  ( $n = 105, 88.2\%$ ). All 119 patients met radiological criteria for MR CLEAN while 105 (88.2%) met criteria for SWIFT-PRIME, 96 (80.7%) for REVASCAT, 80/116 (69.0%) for EXTEND-IA, and 74 (62.2%) for ESCAPE. About half ( $n = 58, 48.7\%$ ) were treated with IV rtPA and 66 (56%) underwent endovascular therapy. Any intracranial hemorrhage was more common in patients undergoing endovascular therapy than in those who were not (36% vs. 17%,  $P = 0.034$ ). The frequency of symptomatic intracranial hemorrhage (ICH) did not significantly differ between these groups (6% vs. 4%,  $P = 0.691$ ).

**Conclusions.** – The proportion of patients with acute stroke and large vessel occlusion presenting within 8 hours that would meet radiological criteria for endovascular stroke trials varies considerably (62–100%) in a cohort outside of clinical trials from an academic comprehensive stroke center. Thus, the radiological criteria used for candidate selection in daily practice will greatly influence the proportion of patients treated with endovascular therapy.

© 2017 Elsevier Masson SAS. All rights reserved.

## Introduction

After the publication of five positive randomized trials in 2015, endovascular therapy for acute ischemic stroke, previously criticized for a lack of proven efficacy, can now be considered standard of care for well-selected stroke patients [1–5]. These trials that proved the efficacy and safety of endovascular stroke therapy enrolled patients with excellent premorbid function who had severe strokes and presented early after symptom onset. However, they used differing radiological methods to select these patients (Table 1). While almost all of the studies mandated an Alberta stroke program early CT score (Aspects)  $\geq 6$  on

non-contrast computed tomography (CT) to be included, one study excluded patients with poor collateral circulation as assessed by CT-angiogram (CTA) [2], and another used CT perfusion to exclude patients with large regions of core infarct or an inadequate penumbra: core ratio [5].

These trials have shown that endovascular stroke therapy can be one of the most potent therapeutic interventions available in medicine, with a number-needed-to-treat of approximately 4 in order to prevent one additional patient from a disabling or fatal stroke [3]. The optimal radiological method of selecting patients for acute endovascular stroke treatment, however, remains unknown. The generalizability of these trials to non-clinical trial settings is also unclear. In the present study, we aimed to evaluate the proportion of patients evaluated in a non-clinical trial setting that would have met radiological criteria for inclusion in these trials.

\* Corresponding author.  
E-mail address: fugate.jennifer@mayo.edu (J.E. Fugate).

**Table 1**  
Radiological inclusion criteria for endovascular stroke trials.

	Non-contrast CT Criteria	Vessel and/or perfusion criteria
Mr Clean	No criteria	Proximal artery occlusion in anterior circulation
Escape	Aspects $\geq 6$	Proximal artery occlusion in anterior circulation CTA <sup>a</sup> – moderate-to-good collaterals ( $\geq 50\%$ filling of MCA pial arterial circulation)
Extend-IA	Hypodensity $< 1/3$ MCA territory	Proximal artery occlusion in anterior circulation CTP – Mismatch ratio $> 1.2$ Absolute mismatch volume $> 10$ mL Infarct core volume $< 70$ mL
Swift Prime	Aspects $\geq 6$	Proximal artery occlusion in anterior circulation
Revascat	Aspects $\geq 7$	Proximal artery occlusion in anterior circulation

Aspects: Alberta stroke program early CT score; CT: computed tomography; CTA: CT angiogram; MCA: middle cerebral artery; CTP: CT perfusion.

<sup>a</sup> Preferably multi-phase CTA. Perfusion imaging was performed in 67% of patients in Mr Clean and 81% in Swift-Prime.

## Methods

We conducted a retrospective study of consecutive acute ischemic stroke patients who were considered for endovascular stroke therapy based on confirmed intracranial large artery occlusion at an academic comprehensive stroke center from April 2010–November 2014. The protocol for acute endovascular stroke therapy at our center during this time period defined potential candidates as:

- patients with substantial neurological deficits (National institute health stroke scale [NIHSS] score  $\geq 8$ );
- presenting within 8 hours of symptom onset;
- having potential for functional recovery (i.e. excluding those aged 85 years or greater, or patients with advanced comorbid medical illness).

It specified the exclusion of patients with:

- mild, non disabling stroke symptoms;
- large region of already-established brain infarction;
- life expectancy  $< 1$  year;
- pre-morbid modified Rankin scale score  $> 3$ .

All patients underwent CTA and CT perfusion (CTP). Patients with posterior circulation strokes were excluded and patients without proximal large vessel intracranial artery occlusions were excluded.

The following variables were abstracted from the comprehensive electronic medical record: basic patient demographics and comorbidities, NIHSS score on presentation, location of arterial occlusion (M1 or M2 segment of middle cerebral artery [MCA], terminal intracranial carotid artery [tICA], treatment with intravenous [IV] recombinant tissue plasminogen activator [r-tPA], whether patients underwent endovascular treatment, degree of angiographic reperfusion, post-treatment intracranial hemorrhage [ICH], and symptomatic ICH [sICH]). Successful angiographic reperfusion was defined as a score of 2b or 3 on the modified thrombolysis in cerebral infarction (mTICI) scale. sICH was defined as the presence of ICH on brain imaging with an associated clinical decline consisting of an increase in NIHSS by  $\geq 4$  points [6]. The ASPECTS score, collateralization by CTA, and CTP scans were retrospectively

reviewed by four readers: three neurointerventional radiologists and one vascular neurologist. Each reader graded half of the patient cohort independently and they were blinded to all clinical information, including whether the patient underwent any stroke treatment. Discrepancies were resolved by a neurointensivist who had independently reviewed all imaging without knowledge of the four readers' interpretations.

All readers successfully took the online Aspects training course prior to recording Aspects scores [7]. The CTA and CTP scans were visually assessed in a qualitative manner. Collaterals were dichotomized similarly to the methods used in the Escape trial [2]. "Moderate-to-good" collateral circulation was defined as contrast opacification of  $\geq 50\%$  of the MCA pial arterial circulation. CTP was used to estimate regions of salvageable brain tissue (penumbra) and regions of already-established infarction (core) similar to that used in the EXTEND-IA trial [5]. If the following criteria were met, the core size was considered "acceptable" for consideration of endovascular therapy:

- mismatch between penumbra and core ratio with penumbra at least 20% larger than core;
- absolute mismatch volume between penumbra and core of  $> 10$  mL;
- infarct core volume  $< 70$  mL.

Whether patients would have met the main radiological inclusion criteria for each of the five recently published endovascular stroke therapy trials was recorded (Table 1) [1–5]. This study was approved by our institutional review board.

## Statistical analyses

Categorical variables are presented as counts and frequencies. Continuous variables are described with means or medians as appropriate, given the distribution of data.

Univariate comparisons between dichotomous subgroups were carried out with  $\chi^2$  test or two-sided Fisher's Exact test. For comparisons of continuous variables, we used  $t$  tests or the Mann-Whitney  $U$  test. Probability ( $P$ ) values  $< 0.05$  were considered statistically significant. We used JMP 9.0, a SAS-based statistical package, to analyze the data. This study was approved by our Institutional Review Board.

## Results

A total of 119 patients with confirmed proximal intracranial artery occlusion in the anterior circulation were included. The median age was 69 years (IQR 57–79). Half ( $n=60$ , 50.4%) were men. Strokes were severe, with a median presenting NIHSS of 18 (IQR 14–21) and affected the left hemisphere in 64 patients (53.8%). Almost all patients ( $n=113$ , 95%) were functionally independent prior to the stroke. Table 2 shows the remainder of the baseline clinical characteristics.

A great majority of patients had little evidence of ischemia on the initial noncontrast head CT as 106 patients (89.0%) had Aspects  $\geq 6$  and 79 (66.4%) had Aspects  $\geq 8$ . CTA was available for all 119 patients. The most common location of arterial occlusion was the M1 segment of the MCA ( $n=81$ , 68.1%) followed by the M2 segment ( $n=21$ , 17.6%) and the tICA ( $n=17$ , 14.3%). A concomitant cervical ICA occlusion was present in just over one-fifth of patients ( $n=25$ , 21.9%). Moderate-good collateralization on CTA was present in 78 patients (65.5%). CTP scans were available for interpretation for 116 patients (97.5%). Three CTPs were of insufficient quality and thus were excluded. An acceptable infarct core size on CTP was present in 80/116 patients (69.0%).

Download English Version:

<https://daneshyari.com/en/article/8823632>

Download Persian Version:

<https://daneshyari.com/article/8823632>

[Daneshyari.com](https://daneshyari.com)