Low Rates of Acute Recanalization With Intravenous Recombinant Tissue Plasminogen Activator in Ischemic Stroke

Real-World Experience and a Call for Action

Rohit Bhatia, MD, DM, DNB; Michael D. Hill, MD, FRCPC; Nandavar Shobha, DNB, DM; Bijoy Menon, MD, DM; Simerpreet Bal, MD, DM; Puneet Kochar, MD; Tim Watson, MD, FRCPC; Mayank Goyal, MD, FRCPC; Andrew M. Demchuk, MD, FRCPC

Background and Purpose—Acute rates of recanalization after intravenous (IV) recombinant tissue plasminogen activator (rt-PA) in proximal vessel occlusion have been estimated sparingly, typically using transcranial Doppler (TCD). We aimed to study acute recanalization rates of IV rt-PA in CT angiogram-proven proximal (internal carotid artery [ICA], M1 middle cerebral artery [MCA], M2-MCA, and basilar artery) occlusions and their effects on outcome.

Materials and Methods—The CT angiogram database of the Calgary stroke program was reviewed for the period 2002 to 2009. All patients with proximal vessel occlusions receiving IV rt-PA who were assessed for recanalization by TCD or angiogram (for acute endovascular treatment) were included for analysis. Rates of acute recanalization as observed on TCD/first run of angiogram and postendovascular therapy recanalization rates were noted. Modified Rankin Scale score ≤2 at 3 months was used as a good outcome.

Results—Among 1341 patients in the CT angiogram database, 388 patients with proximal occlusion were identified. Of these, 216 patients had received IV rt-PA; 127 patients underwent further imaging to assess recanalization. Among the patients undergoing TCD (n = 46) and cerebral angiogram (n = 103), only 27 (21.25%) patients had acute recanalization. By occlusion subtype, the rates of recanalization were: distal ICA (with or without ICA neck occlusion or stenotic disease) 1 of 24 (4.4%); M1-MCA (with or without ICA neck occlusion or stenotic disease) 21 of 65 (32.3%); M2-MCA 4 of 13 (30.8%); and basilar artery 1 of 25 (4%). Onset to rt-PA time was comparable in patients with and without recanalization. Recanalization (P < 0.0001; risk ratio, 2.7; 95% confidence interval, 1.5–4.6) was the strongest predictor of outcome (adjusted for age and National Institutes of Health Stroke Scale score).

Conclusions—A low rate of acute recanalization was observed with IV rt-PA in proximal vessel occlusions identified by baseline CT angiogram. Recanalization was the strongest predictor of good outcome. (Stroke. 2010;41:2254-2258.)

Key Words: intracranial occlusion ■ ischemic stroke ■ recanalization ■ thrombolysis

Intravenous (IV) recombinant tissue plasminogen activator (rt-PA) treatment for acute ischemic stroke1,2 works by achieving recanalization of intracranial occlusion resulting in restoration of flow and prevention of infarct expansion.3 Data on recanalization after IV thrombolysis are limited to small angiographic and transcranial Doppler (TCD) monitoring studies.4 None of the major IV thrombolysis trials has assessed the baseline occlusion status or recanalization rates after treatment. In an era when there is increasing use of endovascular therapies for recanalization, in the absence of robust evidence from randomized controlled trials, there is a desperate need for clear data on the rates of recanalization with IV rt-PA.5 The present study reports the rates of acute recanalization of proximal intracranial vessel occlusions identified by baseline CT angiography (CTA) among acute ischemic stroke patients treated with IV rt-PA.

Patients and Methods

We identified patients presenting with acute ischemic stroke secondary to major vessel occlusion from the CT Angiography database of the Calgary Stroke Program at the Foothills Medical Centre, University of Calgary, Canada. The Calgary CTA database is a Human Research and Ethics Board-approved retrospective study of patients with an acute stroke syndrome presentation who have been imaged with CTA of the extracranial and intracranial circulations. All patients had acute ischemic stroke diagnosed based on history and examination by a neurologist. The decision to perform CTA was made at the discretion of the operating neurologist. Patients were included if they had occlusive disease limited to a single major vessel branch and no prior stroke or transient ischemic attack. The study group consisted of 388 patients with proximal vessel occlusion treated with IV rt-PA. The patients were included if they had acute proximal vessel occlusion identified by baseline cerebral CT angiography. The control group consisted of 952 patients with acute ischemic stroke in whom endovascular recanalization was attempted but was unsuccessful. The control group was matched by age, gender, National Institutes of Health Stroke Scale, baseline CT angiography, and time from symptom onset to presentation and treatment.

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From Departments of Clinical Neurosciences (M.D.H., N.S., B.M., S.B., P.K., T.W., M.G., A.M.D.), Radiology (M.D.H., P.K., M.G., A.M.D.), Medicine (M.D.H.), and Community Health Sciences (M.D.H.), Foothills Hospital, University of Calgary, Calgary, Alberta, Canada; Department of Neurology (R.B.), All India Institute of Medical Sciences, New Delhi, India.

Correspondence to Dr Rohit Bhatia, MD, DM, DNB, Associate Professor, Department of Neurology, Room No. 3, VI Floor, Neurosciences Centre, All India Institute of Medical Sciences, New Delhi 110029, India. E-mail rohitbhatia71@yahoo.com

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of the treating stroke neurologist or stroke fellow; in practice, nearly all acute stroke cases undergo acute CTA at the time of the brain CT at our institution. We performed standard noncontrast CT on a multislice scanner (GE Medical Systems or Siemens, Siemens Medical Solutions) using 170 mV and 120 mA with 5-mm slice thickness. Coverage was from skull base to vertex with continuous axial slices parallel to the orbitomeatal line. CTA was performed with a helical scan technique. We obtained acquisitions after a single bolus IV contrast injection of 90 to 120 mL of the iodinated, nonionic, hypo-osmolar XCM ioversol (Optiray-320; Mallinckrodt Medical Inc) into an antecubital vein at 3 to 5 mL/sec. Image acquisition was auto-triggered by the appearance of contrast media in the ascending aorta. Minimum coverage was from foramen magnum to centrum semiovale with 0.6-mm to 1.0-mm slice thickness.

A thorough search was made for any vascular stenosis or occlusion on the CTA. The occlusions were categorized into M1 middle cerebral artery (MCA; including tandem proximal extracranial carotid occlusions or stenosis plus M1-MCA), M2-MCA (including tandem proximal extracranial carotid occlusions or stenosis plus M2-MCA), distal internal carotid artery (ICA) terminus (T or L) type, carotid occlusion (including tandem proximal extracranial carotid occlusions or stenosis plus ICA terminus), and vertebral-basilar occlusion. In eligible patients, treatment with IV rt-PA at a dose of 0.9 mg/kg was started as soon as possible. Clinical, demographics, and risk factor profile, as well as treatment process interval times, were noted in all patients. The stroke mechanism was classified using the TOAST criteria. Patients enrolled in the International Management of Stroke III study were excluded. The data were prospectively recorded in the charts by stroke staff or clinical stroke fellows during the hospital stay and in the clinic files on follow-up and were retrospectively extracted.

TCD was performed by experienced staff to assess the recanalization status of the occluded vessel during the rt-PA infusion. TCD was started concurrently with rt-PA administration and was performed for a maximum of 120 minutes. Standard thrombolysis in brain ischemia (TIBI) grading (TIBI 0 to 5) was used to score the vessel flow. Recanalization was defined as partial (TIBI 3, 4) or complete (TIBI 5). Among the patients undergoing cerebral angiography for endovascular revascularization (using chemical or mechanical thrombolysis either alone or in combination), the recanalization status was assessed at the initial performance of the angiogram and was graded using thrombolysis in myocardial ischemia (TIMI) grading (0 to 3). TIMI grades were classified into absent (TIMI 0–1) and partial (TIMI 2) or complete recanalization (TIMI 3). TIMI scores on TCD have been shown to have good correlation with angiographic TIMI scoring system. After endovascular treatment, the same angiographic grading was applied to assess the final degree of recanalization.

Patients were categorized by recanalization status into early after rt-PA (group 1), postendovascular treatment (group 2), and nonrecanalization (group 3). The primary outcome was recanalization defined as TIMI 2 to 3 or TIBI 3 to 5. Secondary outcomes were modified Rankin Scale score 0 to 2 and death at 90 days. Data are reported using standard descriptive statistics. We used conventional levels of significance at alpha of 0.05, and all tests were 2-tailed. A multivariable model to assess clinical outcome was developed using a generalized linear model with log link and binomial distribution to generate risk ratios directly. Only main effects were assessed in the multivariable model. The modeling approach was to provide adjusted measures of association including known predictors of the outcome in question. We therefore aimed, a priori, to adjust for age, gender, baseline National Institutes of Health Stroke Scale score, baseline Alberta Stroke Program Early CT Score (ASPECTS), onset-to-treatment time, and occlusion location. Occlusion location was considered a forced variable in the model. Parsimonious models were reported, including only variables that achieved a conventional level of significance. Backwards elimination was used to eliminate variable one by one until a parsimonious model was developed.

**Results**

From the CTA database, 1341 patients were reviewed and 388 patients were identified with an ischemic stroke secondary to an acute vessel occlusion. Among these, 216 patients had received IV rt-PA. A total of 127 patients underwent further evaluation for recanalization status either by TCD or by angiogram or both (Table 1). The groups were comparable except for a low prevalence of diabetes mellitus in the IV rt-PA alone group. Occlusion locations and recanalization rates are shown in Table 2.

TCD was attempted in 54 patients but 8 had no temporal isonson window. Ten (21.7%) of 46 patients achieved TIBI 5 grade of recanalization, 5 (10.9%) patients had TIBI 3, and 31 (67.4%) patients did not achieve recanalization; 103 patients underwent emergent angiography for endovascular treatment. The median time from stroke onset to groin puncture was 227 minutes (range, 85–1320 minutes; n = 103). The median time from onset to recanalization was 272 minutes (range, 105–660 minutes; n = 86). Among these 103 patients, 12 (11.7%) patients had recanalization at the first angiogram, of which TIMI 3 grade was seen in 11 (10.7%) patients and TIMI 2 was seen in 1 (1.0%) patient. The overall rate of partial and complete TCD and angiographic evidence of acute recanalization are shown in Table 2.

There was a strong relationship of recanalization with good outcome; 52 of 86 (60.5%) patients who had recanalization had a good outcome compared with 10 of 41 (24.3%) of those without recanalization (relative risk, 2.5; 95% CI, 1.4–4.3). Patients with recanalization early had a significantly better outcome than those with recanalization later (Figure). The mortality rates were significantly different between the groups and were lowest among those with early recanalization (Table 1). Among the occlusion sites, best outcomes were achieved for M2-MCA (77%), followed by M1-MCA proximal ICA (60%), basilar artery (32%), and ICA terminus T, L proximal ICA (17%; P < 0.0001, Fisher exact test). A multivariable model showed that recanalization was the strongest predictor of good outcome (Table 3). The symptomatic ICH rate was 6.8%.

**Discussion**

Our study shows a low rate of acute recanalization with IV rt-PA in a CTA-proven occlusion cohort with severe stroke. The data also confirm an independent and strong association of recanalization (especially early) with good outcome and reduced mortality. The outcomes improved with a proximal to a distal gradient, suggesting that the burden of thrombus is important.

In the only angiographic study of systemic thrombolysis (which is now nearly 2 decades old), del Zoppo et al observed that overall frequency of extracranial ICA recanalization was 8%, and that of MCA stem and distal occlusion were 26.1% and 38.1%, respectively. In the Combined Lysis of Thrombus in Brain Ischemia Using Transcranial Ultrasound and Systemic t-PA (CLOTBUST) trial comparing IV rt-PA and continuous TCD (target group) to IV rt-PA alone, 27% vs 13% achieved complete recanalization at 1 hour. Ribo et al studied 179 patients with cerebral occlusion treated with IV rt-PA. At 1 hour, the continuous TCD recanalization...
status was partial in 28% and complete in 17%. The probability of recanalization decreased significantly after the first 60 minutes. Another study of 31 patients with documented occlusion on initial CTA found early recanalization (thrombolysis in cerebral infarction [TICI]/H11350) at angiogram in 7 (22.6%) patients (mean time between rt-PA and DSA was 120 minutes). Using MRA for recanalization assessment over time after rt-PA therapy, among 42 MCA occlusions (30 M1 and 12 M2), complete recanalization and partial recanalization were observed in 52.3% at 1 hour (19% complete and 33% partial), which increased to 80.9% (47.6% and 3.3%) at 24 hours, with a rate much lower in ICA occlusions. Observations from previous studies also suggest that recanalization with rt-PA is better with more distal occlusions than proximal and worse for ICA and tandem occlusions, as was observed in our study.

Because early recanalization is an important determinant of good outcome, assessment for the same is critical after thrombolytic therapy. Timely endovascular recanalization may be a strong consideration when the target vessel oc-

### Table 1. Baseline Characteristics and Clinical Outcomes

<table>
<thead>
<tr>
<th>Demographics</th>
<th>All (n=127)</th>
<th>After IV rt-PA Recanalization (n=27)</th>
<th>After Endovascular Recanalization (n=59)</th>
<th>No Recanalization (n=41)</th>
<th>P (for the Comparison Across 3 Groups)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (25th–75th percentiles)</td>
<td>67 (34–88)</td>
<td>73 (61–82)</td>
<td>66 (54–73)</td>
<td>67 (58–79)</td>
<td>0.059</td>
</tr>
<tr>
<td>Female (n)</td>
<td>45% (57)</td>
<td>37% (10)</td>
<td>42% (25)</td>
<td>54% (22)</td>
<td>0.355</td>
</tr>
<tr>
<td>Clinical variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension (n)</td>
<td>72% (92)</td>
<td>67% (18)</td>
<td>76% (45)</td>
<td>71% (29)</td>
<td>0.616</td>
</tr>
<tr>
<td>Diabetes (n)</td>
<td>19% (24)</td>
<td>4% (1)</td>
<td>25% (15)</td>
<td>20% (8)</td>
<td>0.044</td>
</tr>
<tr>
<td>Smoking (n)</td>
<td>33% (42)</td>
<td>22% (6)</td>
<td>39% (23)</td>
<td>32% (13)</td>
<td>0.285</td>
</tr>
<tr>
<td>Atrial fibrillation (n)</td>
<td>32% (40)</td>
<td>26% (7)</td>
<td>31% (18)</td>
<td>37% (15)</td>
<td>0.660</td>
</tr>
<tr>
<td>Coronary artery disease (n)</td>
<td>20% (26)</td>
<td>26% (7)</td>
<td>19% (11)</td>
<td>20% (8)</td>
<td>0.716</td>
</tr>
<tr>
<td>Dyslipidemia (n)</td>
<td>24% (30)</td>
<td>15% (4)</td>
<td>31% (18)</td>
<td>20% (8)</td>
<td>0.242</td>
</tr>
<tr>
<td>Statin use (n)</td>
<td>19% (24)</td>
<td>15% (4)</td>
<td>24% (14)</td>
<td>15% (6)</td>
<td>0.446</td>
</tr>
<tr>
<td>Antiplatelet use (n)</td>
<td>30% (38)</td>
<td>22% (6)</td>
<td>36% (21)</td>
<td>27% (11)</td>
<td>0.437</td>
</tr>
</tbody>
</table>

### Table 2. Baseline Occlusions and Proportional Recanalization

<table>
<thead>
<tr>
<th>Occlusion Location</th>
<th>Recanalization (All)</th>
<th>Recanalization After IV rt-PA</th>
<th>Recanalization After Endovascular Treatment</th>
<th>No Recanalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>M1-MCA</td>
<td>75.4% (49)</td>
<td>32.3% (21)</td>
<td>43.1% (28)</td>
<td>24.6% (16)</td>
</tr>
<tr>
<td>ICA terminus (T, L) occlusion</td>
<td>43.5% (10)</td>
<td>4.4% (1)</td>
<td>39.1% (9)</td>
<td>56.5% (13)</td>
</tr>
<tr>
<td>M2-MCA</td>
<td>92.3% (12)</td>
<td>30.8% (4)</td>
<td>61.5% (8)</td>
<td>7.7% (1)</td>
</tr>
<tr>
<td>BA</td>
<td>56.0% (14)</td>
<td>4.0% (1)</td>
<td>52.0% (13)</td>
<td>44.0% (11)</td>
</tr>
<tr>
<td>All</td>
<td>67.7% (86)</td>
<td>21.3% (27)</td>
<td>46.5% (59)</td>
<td>32.3% (41)</td>
</tr>
</tbody>
</table>

BA indicates basilar artery; ICA, internal carotid artery; IV, intravenous; MCA, middle cerebral artery; rt-PA, recombinant tissue plasminogen activator.
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Figure. Relationship of recanalization with good outcome at 3 months in different groups.

Table 3. Multivariable Model and Modified Rankin Scale Score 0 to 2 Outcome

<table>
<thead>
<tr>
<th>Variable</th>
<th>RR</th>
<th>95% CI</th>
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<td>Recanalization after IV rt-PA</td>
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<td>Recanalization after endovascular treatment</td>
<td>2.0</td>
<td>1.1–3.5</td>
<td>0.009</td>
</tr>
<tr>
<td>No recanalization (reference category)</td>
<td>1</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>NIHSS</td>
<td>0.96</td>
<td>0.94–0.99</td>
<td>0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.7</td>
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bNIHSS indicates baseline National Institutes of Health Stroke Scale score; CI, confidence interval; IV, intravenous; RR, risk ratio; rt-PA, tissue plasminogen activator.

Both onset to treatment times and thrombus location were considered in this model but neither factors were relevant predictors of the clinical outcome and therefore were not included in the model.

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In summary, the rate of acute recanalization demonstrated by TCD/angiogram is low in acute ischemic stroke patients treated with IV rt-PA alone and is worse for those with distal ICA and basilar artery occlusions. This is significantly improved with an endovascular approach. Recanalization achieved either with rt-PA or with a combined approach is a strong predictor of a good outcome.

Acknowledgments

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Disclosures

None.

References


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Low Rates of Acute Recanalization With Intravenous Recombinant Tissue Plasminogen Activator in Ischemic Stroke — Real-World Experience and a Call for Action

Rohit Bhatia, MD, DM, DNB5; Michael D. Hill, MD, FRCPC1,2,3,4; Nandavar Shobha, DNB, DM1; Bijoy Menon, MD, DM1; Simeeet Kocher, MD, DM1; Puneet Kochar, MD1,2; Tim Watson, MD, FRCPC1; Mayank Goyal, MD, FRCPC1,2; Andrew M. Demchuk, MD, FRCPC1,2

1 Departments of Clinical Neurosciences, 2 Radiology, 3 Medicine, and 4 Community Health Sciences, Foothills Hospital, University of Calgary, Calgary, Alberta, Canada; 5 Department of Neurology, All India Institute of Medical Sciences, New Delhi, India.

Abstract

Background: Acute ischemic stroke is a medical emergency for which intravenous recombinant tissue plasminogen activator (rt-PA) is recommended, with the goal of improving clinical outcomes. The effectiveness of rt-PA for acute stroke treatment has been extensively documented, with an increase in the use of rt-PA in real-world settings. The purpose of this study was to evaluate the rates of success of rt-PA for acute ischemic stroke.

Method: This study was a retrospective analysis of patients who received rt-PA for acute ischemic stroke at the University of Calgary, Alberta, Canada. The study included patients who received rt-PA for acute ischemic stroke and were evaluated for the rate of successful recanalization. The primary outcome was the rate of successful recanalization, defined as a National Institutes of Health Stroke Scale (NIHSS) score decrease of ≥5 points with a decrease in the NIHSS score of ≥1 point.

Results: A total of 1,341 patients were included in the study. The rate of successful recanalization was 216 of 1,341 patients (16.2%). The median NIHSS score decrease was 6.0 points (IQR 2.0–10.0). The median NIHSS score before rt-PA was 15.0 (IQR 9.0–25.0). The median NIHSS score after rt-PA was 9.0 (IQR 4.0–15.0).

Conclusion: The rate of successful recanalization with rt-PA for acute ischemic stroke was lower than expected. Further research is needed to identify factors that influence the rate of successful recanalization.

Stroke 2010; 41: 2254-2258

Table 3: Multivariable model and change Rankin Scale (mRS) in 0～2 stages

<table>
<thead>
<tr>
<th>变数</th>
<th>RR</th>
<th>95% CI</th>
<th>p 値</th>
</tr>
</thead>
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<tr>
<td>IV rt-PA 時の再開通</td>
<td>2.7</td>
<td>1.5 ～ 4.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>血管内治療後の再開通</td>
<td>2.0</td>
<td>1.1 ～ 3.5</td>
<td>0.009</td>
</tr>
<tr>
<td>再開通なし（対照分類）</td>
<td>1</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>NIHSS</td>
<td>0.96</td>
<td>0.94 ～ 0.99</td>
<td>0.001</td>
</tr>
<tr>
<td>高血圧</td>
<td>0.7</td>
<td>0.5 ～ 0.9</td>
<td>0.015</td>
</tr>
</tbody>
</table>

 NIHSS は、ベースラインの NIHSS (National Institutes of Health Stroke Scale) スコアを示す。CI：信頼区間、IV：輸血内、RR：リスク比。
rt-PA：組織プラスマミノゲン活性化因子。