

Endovascular treatment for acute stroke

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New England Journal of Medicine, 2013

1. Why is this topic important?

Estimates are that there are 795,000 new strokes per year in the United States, and stroke is third leading cause of death. Currently, t-PA is the only stroke treatment given approval by the FDA; however endovascular revascularization or intervention by neuro-radiologists shows promise as an effective stroke treatment. This study looks at the efficacy of interventional radiology (IR) in improving the outcomes of stroke victims. EMS is a key player in providing stroke intervention; EMS providers need to stay abreast of treatment protocols.

2. What does this study attempt to show?

Two approaches to stroke therapy are compared in this study; intra-arterial t-PA in combination with clot retrieval or clot disruption through IR therapies, or IV t-PA treatment alone. This multi-hospital study attempted to determine if there would be any difference between the two groups in disability status after 90 days using the modified Rankin scale ([What's this?](#)). Only patients between 18 and 80 years of age, without intracranial hemorrhage were accepted, with 181 patients randomized to one of each treatment groups. Baseline characteristics were similar in both groups. IV t-PA was administered within 4.5 hours in the t-PA alone group, and interventional methods were performed within 6 hours in the IR group.

3. What are key findings?

The median time from stroke onset to the start of treatment was 3.75 hours for IR therapy and 2.75 hours for intravenous t-PA ($p < 0.001$). 30.4% of the IR group and 34.3% of the t-PA group were without disability at 90 days, respectively. The study found no significant differences between the treatment groups, ($p = 0.16$). This means that for this particular research, interventional radiology in combination with intra-arterial t-PA did not improve disability status at 90 days any more than IV t-PA alone. Also there was no significant difference in patient outcomes between the high volume and low volume stroke centers ($p = 0.32$).

4. How is patient care impacted?

The authors of this study theorized that for an eligible stroke patient, IV t-PA should not be delayed while the patient is evaluated and prepared for possible IR intervention. While other studies have demonstrated that time to treatment is crucial in stroke, time to intervention was not significant in this study possibly due to small sample size. From an EMS provider standpoint, nothing has changed. This research confirms that any patient who presents with stroke signs and symptoms should be transported to the closest primary or comprehensive stroke center. Primary and comprehensive stroke centers both have the ability to initiate the first line treatment of IV t-PA along with other therapies that have been shown to be clinically effective treatments for stroke.

Abstract <http://www.nejm.org/doi/full/10.1056/NEJMoa1213701>

Endovascular Therapy after Intravenous t-PA versus t-PA Alone for Stroke

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New England Journal of Medicine 2013**

1. Why is this topic important?

More effective treatments need to be researched for stroke treatment. Current treatments include t-PA, (the only FDA approved treatment from stroke), and neuro-intervention or invasive devices that perform clot busting or clot retrieval. There is considerable disability from stroke, and both treatments have shown to be less than 50% effective in preventing disability. It would be of great benefit if existing treatments could be improved and demonstrate definitive benefit to patients.

2. What does this study attempt to show?

This research attempted to determine if there was any significant difference in stroke outcomes in patients after t-PA administration. This sample of t-PA patients was then randomly assigned to one of two treatment groups; interventional radiology (IR) or the t-PA only group. Time to t-PA for all was no more than three hours after symptom onset. IR was performed no more than five hours after symptom onset. Patient outcome was measured by modified Rankin score after 90 days.

3. What are key findings?

This research study was terminated because of futility. This means that the numerical or statistical threshold for finding significant results between the groups had already been found and there was no point in continuing the study. Out of 656 patients, 40.8% of the interventional radiology group demonstrated less disability at 90 days compared to 38.7% of the t-PA alone group. Mortality was also similar between the two groups. The endovascular or IR group had an estimated increase in revascularization of 40 percentage points compared to the t-PA group. Time to revascularization remains a significant factor associated with patient outcomes in previous studies and possibly decreased time to intervention would have improved outcomes in this trial.

4. How is patient care impacted?

At this time, no significant clinical benefit to endovascular revascularization treatment has been demonstrated in research; therefore t-PA administration should continue to be the primary treatment for stroke patients. However, these studies do provide a valuable research platform to advance more research concentrating on new and improved antithrombotic therapies, and more effective IR devices. From an EMS perspective, only rapid transport to a primary or comprehensive stroke center will provide the best opportunity for improved patient outcomes.

Abstract <http://www.nejm.org/doi/full/10.1056/NEJMoa1214300>

Questions?

- If t-PA is the only FDA approved treatment for stroke, why is interventional radiology being used?

The FDA permits what is known as 501(k) clearance [what's this?](#) which allows certain medical devices to be used without FDA proof of efficacy?

- What is the NIH stroke scale [Stroke Scale](#)?

It is a numerical method of measuring the severity of a stroke. Special training is required to be able to perform this complicated assessment.