

Informed Consent – tPA for Sudden Ischemic Stroke

Note: EmEx informed consent tools facilitate emergency physicians and nurses in their duty to inform patients (and family members) about procedures or treatments. This material is generally written at a more sophisticated level than most stand-alone patient education materials. It is appropriate for this document to be printed, given to the patient/family to review, further explained by an emergency physician or nurse and any remaining questions answered.

Disclaimer: EmEx does not direct patient care or take part in medical decisions. Hospitals are expected to modify ED Toolkit items to meet local and federal regulations and standards of care.

Definitions

There are two main types of stroke, those associated with rupture of the blood vessels (hemorrhagic stroke) and those associated with the blockage of blood vessels (ischemic stroke).

In a sudden ischemic stroke, blood flow to a part of the brain is interrupted because of abrupt blockage of a blood vessel. The blockage is usually due to a blood clot and starves the brain of needed oxygen and nutrients. This can result in loss of function in the affected area of the brain. The center of the starved area may die quickly over minutes, and the surrounding area may die slowly over hours.

Common signs and symptoms of stroke include abrupt onset of one-sided weakness/numbness, and difficulty with vision, speaking, thinking or coordination. The National Institute of Health Stroke Scale (NIHSS) is a standardized way to measure the severity of a stroke on a 0-42 point scale (normal to worst).

tPA stands for tissue Plasminogen Activator, a strong “clot dissolving” medicine that can sometimes dissolve the clot that is blocking the blood vessel and causing the ischemic stroke. If it does so the blocked blood vessel reopens, allowing the previously starved brain to receive blood flow again with oxygen and nutrients. If the clot is dissolved soon enough, some or all of the threatened injury to the brain may be avoided. This may decrease the amount of disability that results from the ischemic stroke.

Stroke mimic is a term used for medical problems that can present in a manner similar to stroke and not the result of a blocked blood vessel. Causes include aftereffects of seizures and migraine headaches, among others. Stroke mimics may be initially misinterpreted as a stroke.^{i,ii}



Potential Benefit of tPA

The potential benefits are all related to an increased chance of having a good outcome, namely little or no disability remaining after recovery from the stroke (i.e. minimal brain tissue loss). If stroke patients meet all the specific criteria, their chance of having a good outcome increases from about 6 out of 18 stroke patients (33%) without tPA to 8 out of 18 stroke (44%) with tPA.ⁱⁱⁱ Thus, even though the chances of a good outcome are improved in about 2 out of 18 (11%), over half of the stroke patients who are given tPA will still have disability from their stroke. So, it is important to realize that a good outcome is not guaranteed.

Potential Risk of tPA

There are serious risks associated with tPA administration.

The major risk of tPA therapy in stroke patients is bleeding into the injured area of the brain, causing a worsening of condition or even death. The chance of such bleeding is less than 0.6% in patients not treated with tPA versus 6.4% in patients treated with tPA. The NINDS study suggested that bleeding into the brain as a complication of tPA occurred in about 1 out of 18 patients (specifically, 5.8%). And, when this occurred, there was a 45 percent fatality rate. In other words, tPA increases about 10 times the chance of bleeding that can significantly worsen a patient's condition.

Several studies suggested treatment with “clot-dissolving” medications increases the number of patients who die following a stroke.^{iv, v, vi, vii, viii, ix}

Complications are more likely when tPA is used in patients over 70 years old, those with more severe stroke (NIHSS over 15), or those with glucose over 300 mg/dl. Moreover, using tPA more liberally than is recommended in the NINDS protocol resulted in an even higher rate of intracranial hemorrhage.^{x, xi, xii, xiii}

About 20% of patients will die within 30 days of their strokes, regardless of whether or not they receive TPA.



Visual Depiction of Benefit and Risk with tPA

The following diagram is a visual depiction of the benefit and risk associated with giving tPA for sudden ischemic stroke when all NINDS criteria met.

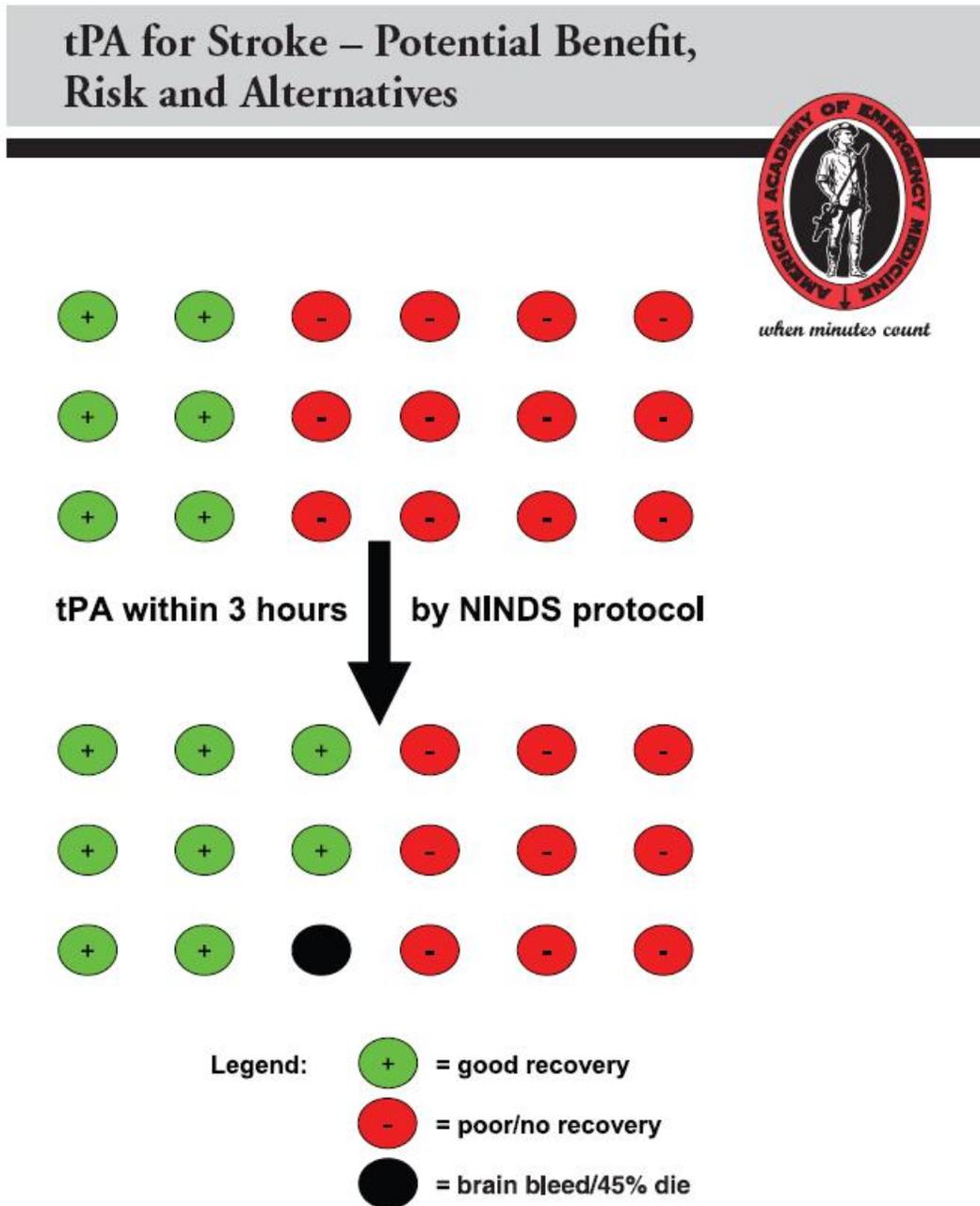


Diagram courtesy of AAEM – <http://www.aaem.org/education/tpaedtool-AAEM.pdf>



Balancing Benefits and Risks and Alternatives

It is important for physicians and patients (or family members) to weigh the possibility of benefit (improved function at 3 months) against the possibility of harm (severe bleeding or death). Symptoms alone are insufficient to definitively diagnose stroke and, in patients with a stroke mimic, use of tPA results in potential adverse effects without any possibility of benefit.

Alternative treatments with proven benefit for patients with stroke include aspirin and care in a specialized unit where staff members pay careful attention to a variety of basic aspects of care.^{xiv,xv} Several other experimental treatments, including invasive de-clotting procedures, may prove to be beneficial.

References

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