

<u>Information on the Treatment of Acute Ischemic Stroke</u> <u>with Tissue Plasiminogen Activator (TPA)</u>

What is a stroke?

A stroke is a sudden loss of brain function and injury to part of the brain resulting from a problem with the blood vessels supplying the brain. There are two main types of stroke, those associated with rupture of the blood vessels (hemorrhagic strokes) and those associated with the blockage of blood vessels (ischemic strokes).

What happens in an acute ischemic stroke?

In an acute ischemic stroke, the blood flow to a part of the brain is interrupted because of sudden blockage of a blood vessel. The blockage is usually due to a blood clot and starves the brain of needed oxygen and nutrients. The center of the starved area may die quickly, and the surrounding area may die slowly over hours.

What is tissue plasminogen activator or TPA?

TPA is a medication that can dissolve blood clots.

How can TPA help someone with an acute ischemic stroke?

TPA 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 brain may be rescued from the threatened injury. Rescuing brain that was starved may decrease the amount of disability that results from the ischemic stroke.

Do all stroke patients get this treatment?

No. Specific criteria are used to identify those patients most likely to benefit and to avoid serious side effects. If a stroke patient does not fulfill all of those criteria, the risks of therapy are probably higher than the possible benefit.

What are the potential benefits?

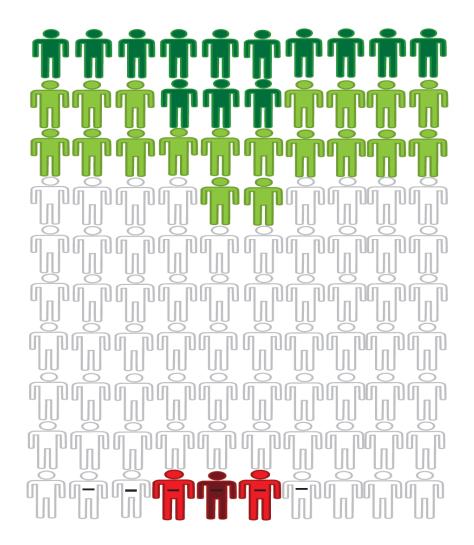
The potential benefits are all related to an increased chance of having a good outcome, namely little or no disability remaining after recovery from the stroke. In the study done that led to the approval of TPA, 39% of patients treated with this medication had no or minimal disability compared to 26% of those not receiving the medication. Another way to explain the possible benefit of TPA is to say that treatment doubles the odds of being normal or nearly normal. The attached picture (see page 3) is a visual way of depicting the effect of TPA for a hypothetical group of 100 patients in which an estimated 32 patients benefit and 3 are harmed.

Even though the chances of a good outcome are improved with TPA, over half of the stroke patients who are given TPA will still have disability from their stroke. A good outcome is not guaranteed.

What are the potential risks?

The major risk of TPA therapy in stroke patients is that they will bleed into the brain, causing a worsening of their condition and even death. The chance of this type of serious bleeding is, on average, less than 1% in stroke patients not treated with TPA versus 6% in those who get TPA. Other less common side effects of TPA include bleeding into other parts of the body and allergic reactions.

TPA for Cerebral Ischemia within 3 Hours of Onset-Changes in Outcome Due to Treatment



Changes in final outcome as a result of treatment:

- Normal or nearly normal

 Better

 No major change

 Worse

 Severely disabled or dead

 13 patients for every 100 patients treated
 32 patients for every 100 patients treated
 3 patients for every 100 patients treated
 1 patient for every 100 patients treated
 1 patient for every 100 patients treated
- No early worsening with brain bleeding
 Early worsening with brain bleeding

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