

RISKS & BENEFITS of TNK (suggested language)

- TNK is considered standard-of-care for patients with functionally disabling stroke symptoms or ≤ 4.5 hours duration without listed contraindications
- Written informed consent is **NOT** required. Rather, it is suggested that there be a brief discussion of risks and benefits emphasizing the institutional recommendation to administer the drug
- Document your TNK discussion
- Visual aids and shared decision-making can help streamline the discussion
- Use this to discuss with patient/family:

“TNK is a robustly studied medication for the treatment of stroke. The FDA has approved it for use in heart attacks, however many medical societies and institutions around the world support its off-label use up to 4.5 hours of symptom onset. On the whole, more patients are helped than harmed from this medication and it is our recommendation that your loved one receive this medication as fast as possible. The major risk of getting TNK is bleeding, which can occur anywhere in the body and can be significant enough to cause symptoms in 5-8% of patients. This may be severe enough to require transfusion of blood products. TNK can also cause an allergic reaction in 1-5% of patients, which rarely can be severe. If you would like more information, I would be happy to show you a visual aid which summarizes the data on the use of TNK in stroke.”

0-3 HOUR Window

- Use this to discuss with patient/family:
- This shows the 3-month outcomes of 100 patients treated within 3 hours of stroke onset:
 - Patients treated with thrombolytics are between 1.5 and 2x as likely to return to normal or near normal function at 3 months
 - 1 in 7 patients who receive thrombolytics have an improvement in outcome due to the drug
 - The effects of the drug are time-dependent. If the drug can be given within 1.5 hours of onset, the chance of improvement increases to 1 in 3
 - 1 in 18 patients who received thrombolytics had significant bleeding due to the drug
 - The risk of dying from the stroke is similar regardless of the treatment
 - Thrombolytics increases the chances of functional independence, but with a 10-fold increase in risk of bleeding

Thrombolysis Risk vs Benefit

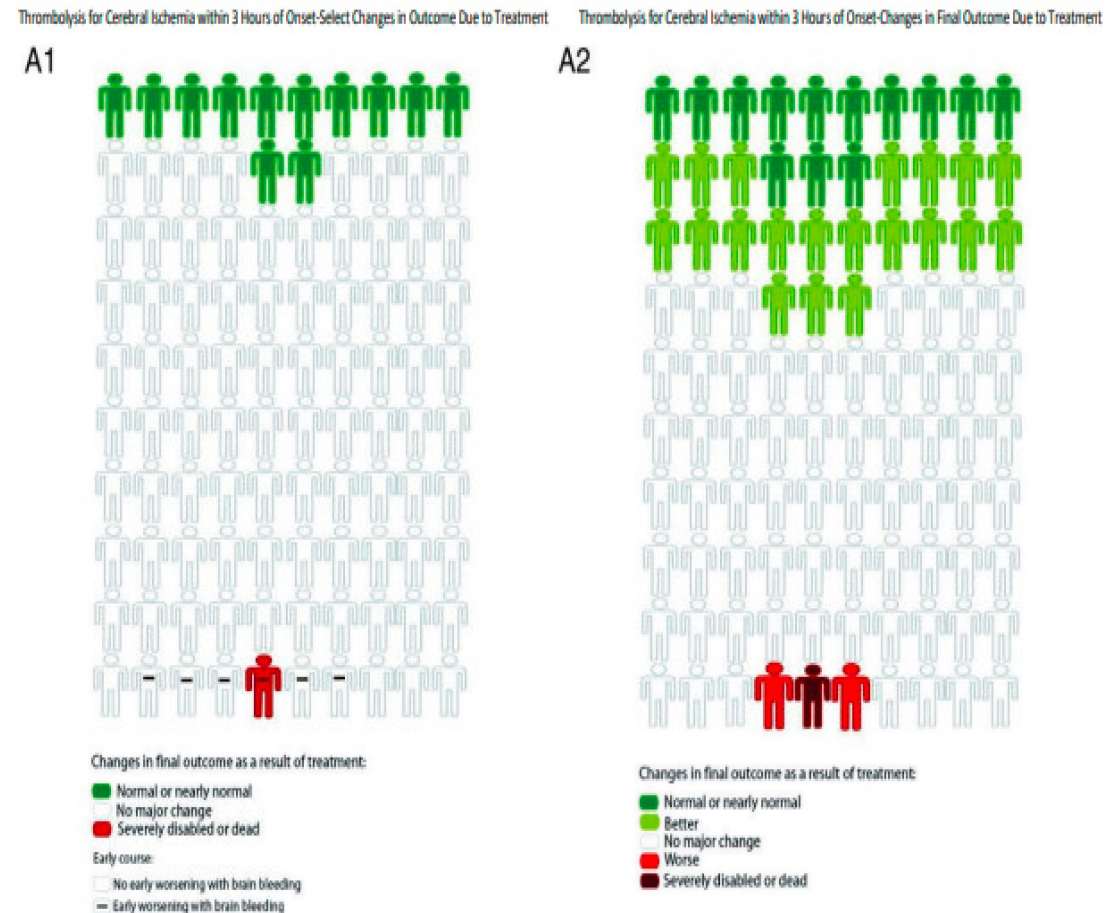


Figure I. Decision matrix figures illustrating the benefits and risks of intravenous thrombolytic in the <3-hour window based on data from the 2 NINDS-TPA trials. A1, Depicting only extreme changes in final outcome, appropriate for physicians who desire a tool that uses only dichotomized outcome observations, not results from joint outcome table analysis. A2, Depicting both extreme and moderate changes in final outcome, but not changes in short-term outcome. (Gadhia et al 2010).

3-4.5 HOUR WINDOW

- **Use this to discuss with patient/family:**
- **In the 3-4.5 hour window:**
 - TNK has been shown to be beneficial up to 4.5 hours from symptom onset
 - Though ideally administered within 3 hours from onset, many international medical societies, including the American Stroke Association, have endorsed its use in select patients
 - In one study, 52% of those given thrombolytics returned to normal or near normal at 3 months, compared 45% given placebo. This was statistically significant
 - **1 in 14** patients who received thrombolytics had an improvement in outcome because of the drug
 - **1 in 22** patients who received thrombolytics had significant bleeding due to the drug
 - The risk of dying from the stroke is similar regardless of the treatment
 - Thrombolytics increases the chances of functional independence, but with a 10-fold increase in risk of bleeding