Tackling Stroke One Module At A Time

Critical Conversations: Determining IV-tPA Eligibility & Obtaining Consent for Treatment

Anne W. Alexandrov
PhD, CCRN, NVRN-BC, ANVP-BC, FAAN
Professor & Program Director, NET SMART
Health Outcomes Institute, Fountain Hills, Arizona
Professor, University of Tennessee Health Science Center, Memphis
& Chief NP, UT Memphis Mobile Stroke Unit

The "Golden Half-Hour"

T= -10 min Suspected stroke patient hospital pre-notification. Stroke team Notified

0 min Patient arrives. Met at triage by stroke and ED team

≤ 10 min Triage, direct-to-CT, rapid (basic) stroke assessment, IVB

≤ 25 min CT scan completed & interpreted

≤ 30 min t-PA given if patient is eligible

The U.S. *SHOULD BE* the leading provider of IV tPA for acute ischemic stroke

- First country to approve intravenous alteplase for treatment of acute ischemic stroke
- Currently, more than 2000 certified Stroke Centers in operation
  - NINDS 1997 recommended purpose of Stroke Centers: To administer IV tPA
- *HOWEVER*:
  - tPA treatment rates are significantly lower in the U.S. compared to foreign countries that have had approval for a shorter period of time
  - Informal networking with interdisciplinary colleagues on the topic of IV tPA treatment often reveals varied interpretations of what constitutes an acceptable IV tPA treatment candidate

New FDA Label Indications (Physician Labeling Rule Compliant)

- Alteplase is indicated for the treatment of acute ischemic stroke
- Exclude intracranial hemorrhage as the primary cause of stroke signs and symptoms prior to treatment
- Initiate treatment as soon as possible, but within 3 hours after symptom onset

New FDA Label Contraindications (Physician Labeling Rule Compliant)

- Current intracranial hemorrhage
- Subarachnoid hemorrhage
- Active internal bleeding
- Recent (within 3 months) intracranial or intraspinal surgery, or serious head trauma
- Presence of intracranial conditions that may increase the risk of bleeding
- Bleeding diathesis
- Current severe uncontrolled hypertension
- What's different:
  - Seizure is not an exclusion
  - NIHSS > 22 is not a warning
  - Rapidly improving or low NIHSS patients are no longer considered warnings

What is a Symptomatic Intracerebral Hemorrhage (sICH) post-IV tPA?

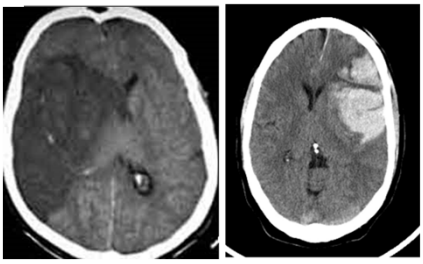
- IV alteplase trials used different definitions for sICH:
  - NINDS rtPA Stroke Study – any blood on the noncontrast CT and any clinical deterioration
    - Endpoint = 6.4% sICH
  - SITS MOST and ECASS 3 – parenchymal hematoma type 2 in combination with 4 or more point worsening on the NIHSS
    - The hemorrhage is solely responsible for the clinical worsening, NOT infarct evolution

This constitutes how sICH is defined today!

- Contemporary sICH rates are commonly < 3%

sICH Definitions: What's the Difference…

Infarction Causing NIHSS Worsening | **sICH Causing NIHSS Worsening**



What is Informed Consent

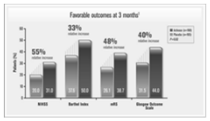
- *"Permission granted in the knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with full knowledge of the possible risks and benefits."*
- Consent is an act of reason
  - For consent to be valid, the person giving consent must be of sufficient mental capacity, must not be coerced or provided with fraudulent information, and must be in possession of all essential information (risks, benefits, alternatives)

Elements of Informed Consent

- **Informed consent** is based on the principles of autonomy and privacy; this is central to morally valid decision making in health care and research
- Seven criteria constitute provision of informed consent:
  1. Competence to understand and to decide
  2. Voluntary decision making
  3. Truthful, factual disclosure of material information
  4. Recommendation of a plan
  5. Comprehension of terms 3 and 4 above
  6. Decision in favor of a plan; and,
  7. Authorization of the plan
- A person gives informed consent only if all of these criteria are met; if all of the criteria are met except that the person rejects the plan, that person makes an informed refusal

What Information Should Be Disclosed in the Informed Consent Process?

- Large clinical trial outcomes:
  - NINDS rt-PA Study results used to support FDA drug approval in 1996



At least 30% greater likelihood of minimal or no disability with Alteplase compared with placebo

Alteplase was associated with a global odds ratio for a favorable outcome of 1.7 (95% CI: 1.2-2.6)

  - Effectiveness trial results of treatment within the 3 hour window
  - ECASS 3 Study results for treatment between 3-4.5 hours
  - Limitations in relation to the subject and whether he/she mirrors study inclusions
- Current site results and experience

Verbal vs. Written Informed Consent

- Non-emergency treatments generally require written informed consent
- Emergency treatments (i.e. acute stroke):
  - Provision of standard of care treatments proven to reduce disability and/or death may be provided without written consent
- 3-hour FDA-label vs. 4.5-hour evidence-based guideline recommendation for IV-tPA
  - What constitutes standard of care at your organization, in your community, in your region, nationally?

How do we obtain informed consent in our patients?

- Key message:
  - IV-tPA is the only medication proven to reduce neurologic disability from acute ischemic stroke AT NO INCREASED RISK OF DEATH.