


tPA Use in ED Stroke Patients: What the Data Tells Us About Current Use

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Disclosures

- AstraZeneca, advisory board
- Genentech, speakers bureau
- ACEP Scientific Review Committee
- Executive Board, Foundation for Education and Research in Neurologic Emergencies

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NINDS Trial Results

Percentage with Favorable Outcome

	t-PA	Placebo
No. of patients: 312	157	145
Modified Rankin Scale	40%	28%
Glasgow Outcome Scale	43%	32%
NIHSS	34%	20%
Symptomatic ICH (within 36 hr)	6.4%	0.6%
Death (by 90 days)	17%	21%


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IV Thrombolysis

- 14% absolute increase for the best clinical outcomes as measured by an NIHSS of 0-1.
- **Benefit** = Need to treat 8 patients with t-PA in order to have one additional patient with this best outcome.
- 6% absolute increase in the number of symptomatic ICH.
- **Harm** = Will have one symptomatic ICH for every 16 patients treated with t-PA.
- 2 patients will have a minimal or no deficit for everyone patient with a symptomatic ICH


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Phase IV t-PA trials


Author	Eligible patients	Patients receiving tPA(%)	Mean time to Rx	Median NIHSS score	Favorable outcome	% ICH	% Symptomatic ICH	% Protocol deviation
NINDS		312		14	31-54%	10.9%	6.4%	
Chiu	1035	30(2.9%)	2'37"	14	63%	10%	6.6%	
Tanne		189	>2'	11-15		9%	5.8%	30%
Wang	900	57(6.3%)	2'28"	15	44-54%	9%	5%	9%
Buchan	1540	68(4.4%)		15	95%	31%	9%	16%
Albers		389	2'44"	13	35-43%	11.5%	3.3%	33%
Katzan	3948	70(1.8%)		12		22%	15.7%	50%
Chapman	2556	46(1.8%)	2'45"	14	30-48%	9%	2.2%	17%
Grotta	1688	268(16%)	2'17"	14	33%		4.5%	13%
Bravata		63		15		17%	6%	67%
Total	12,282	928(5.8%)	2'25"	10-15	33-95%	9.6%	5.2%	13-67%

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Re-analysis

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NINDS ICH Analysis

Risk Factors for ICH:

- Baseline NIHSS > 20
- Age > 70 years
- Ischemic changes present on initial CT
- Glucose > 300 mg/dl (16.7 mmol/L)

# of Risk Factors	# of patients treated with t-PA (n=310)	# Symptomatic ICHs (# of placebo patients with ICH)	Percentage (%)
0	114	2 (1)	1.8
1	144	7 (1)	4.9
> 1	52	11	21.2


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Re-analysis Conclusions

- The independent reanalysis of the NINDS t-PA clinical trial confirms the results from the initial *NEJM* publication
- Odds ratio in re-analysis is better, 2.1 than original, 1.7
- Support the use of t-PA in stroke patients within three hours of symptom onset
- Number needed to treat calculation based on this reanalysis confirms that approximately 8-10 patients need to be treated with t-PA in order to cause one extra patient to have the best clinical outcome.
- 2 patients will improve for every one that develops a symptomatic ICH


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ASA Guidelines 2007

- **New EMS Section**
 - Educate the public
 - EMS use of scales
 - “Closest institution that can provide emergency stroke care”
- **New Stroke Center Section**
 - Creation of Primary Stroke Center strongly recommended
 - Develop Comprehensive Stroke Centers
 - Bypass hospitals that do not have the resources to treat stroke


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ASA Guidelines 2007

- **ED Evaluation Section (Not Changed)**
 - Develop strict protocol
 - Use stroke scale
- **Imaging Section**
 - CT provides the information needed to treat
 - Dense artery sign assoc. with poor outcome
 - CTA and MR provide additional information
 - Insufficient data to say that other signs on CT should stop therapy
 - Do not delay treatment for other images


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ASA Guidelines 2007

- **Management Section**
 - Management of HTN is controversial
 - No good data to guide selection of BP meds, NTG paste??
 - If treat must maintain BP at 180/105 for 24 h
 - Glucose >140 mg/dl assoc. with poor outcome
- **TPA Section**
 - Caution should be exercised in treating pts with major deficits, NIHSS > 20
 - Aware of side effect of angioedema
 - Seizure is not a contraindication

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**FERNE / EMRA 2007 Acute Ischemic Stroke Patients :
tPA Use in EDStroke Patients: What the Data Tells Us About Current Use
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Documentation

- Onset time
- Level of deficit = NIHSS
- Risk factors for bleed
 - Coumadin
 - Surgery
 - Hypertension
 - Glucose

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Documentation

- Document well on patients we are considering for thrombolysis
- DO NOT document well on patients we are not considering for thrombolysis
- “This patient is or is NOT a candidate for thrombolysis because ...”

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Conclusions

- Data supports the use of IV t-PA when the NINDS protocol is strictly followed
- Develop a protocol that allows patients to have the greatest chance of receiving therapy as quickly as possible
- Sooner may be better, more work to be done on subgroups
- Document well on all patients, t-PA or not

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Questions?

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ferne_emra_2007_caseconf_bunney_tpause_100907_finalod
10/18/2007 10:49 AM

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