


**FERNE / EMRA 2007 Acute Ischemic Stroke Patients :  
tPA Use in EDStroke Patients: What the Data Tells Us About Current Use  
E. Bradshaw Bunney, MD, FACEP**


**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	1689	269(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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## **Documentation**

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

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## **Documentation**

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- 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**

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- 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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10/18/2007 10:50 AM

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