EARLY STROKE TREATMENT ASSOCIATED WITH BETTER OUTCOME: THE NINDS rt-PA STROKE STUDY

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Background: The National Institute of Neurological Disorders and Stroke (NINDS) rt-PA Stroke Study showed a similar percentage of intracranial hemorrhage and good outcome in patients 3 months after stroke treatment given 0 to 90 minutes and 91 to 180 minutes after stroke onset. At 24 hours after stroke onset more patients treated 0 to 90 compared to 91 to 180 minutes after stroke onset had improved by four or more points on the NIH Stroke Scale (NIHSS). The authors performed further analyses to characterize the relationship of onset-to-treatment time (OTT) to outcome at 3 months, early improvement at 24 hours, and intracranial hemorrhage within 36 hours. **Methods:** Univariate analyses identified potentially confounding variables associated with OTT that could mask an OTT-treatment interaction. Tests for OTT-treatment interactions adjusting for potential masking confounders were performed. An OTT-treatment interaction was considered significant if $p \leq 0.10$, implying that treatment effectiveness was related to OTT. **Results:** For 24-hour improvement, there were no masking confounders identified and there was an OTT-treatment interaction ($p = 0.08$). For 3-month favorable outcome, the NIHSS met criteria for a masking confounder. After adjusting for NIHSS as a covariate, an OTT-treatment interaction was detected ($p = 0.09$): the adjusted OR (95% CI) for a favorable 3-month outcome associated with recombinant tissue-type plasminogen activator (rt-PA) was 2.11 (1.33 to 3.35) in the 0 to 90 minute stratum and 1.69 (1.09 to 2.62) in the 91 to 180 minute stratum. In the group treated with rt-PA, after adjusting for baseline NIHSS, an effect of OTT on the occurrence of intracranial hemorrhage was not detected. **Conclusions:** If the NINDS rt-PA Stroke Trial treatment protocol is followed, this analysis suggests that patients treated 0 to 90 minutes from stroke onset with rt-PA have an increased odds of improvement at 24 hours and favorable 3-month outcome compared to patients treated later than 90 minutes. No effect of OTT on intracranial hemorrhage was detected within the group treated with rt-PA, possibly due to low power.

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Comment from Kevin Barrett, MD, MSc: This analysis of The National Institute of Neurological Disorders and Stroke (NINDS) rt-PA Stroke Study established the clinical relationship between time to treatment and stroke outcome. The manuscript includes an often-cited figure that clearly demonstrates the improved odds of a favorable 3-month outcome with earlier rt-PA treatment.

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Early stroke treatment associated with better outcome: the ninds rt-pa stroke study

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