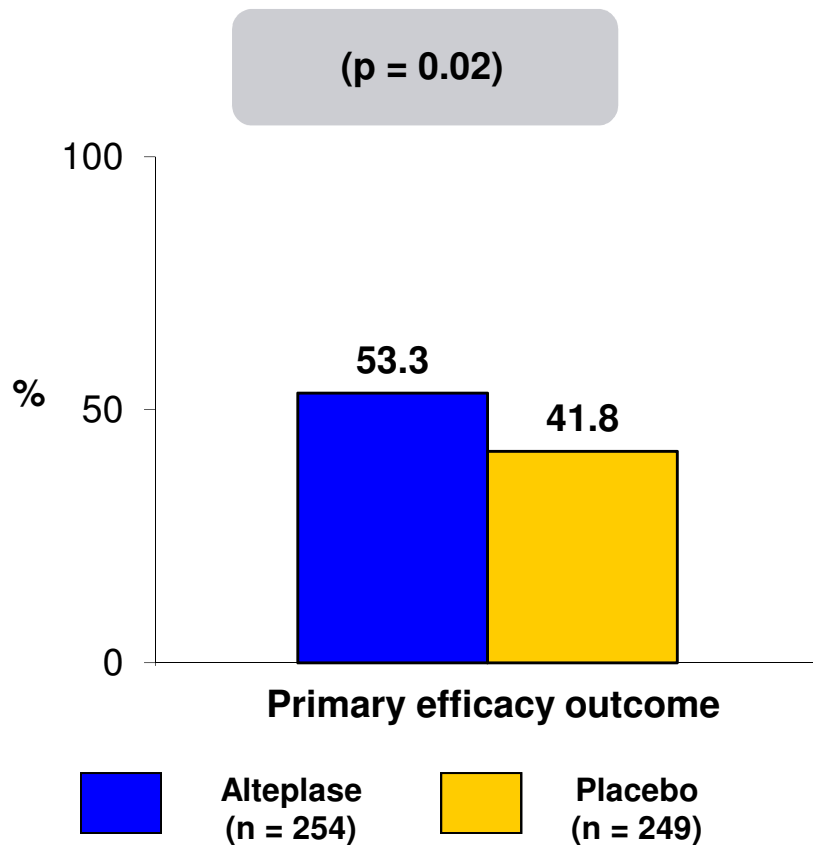


WAKE-UP

Trial design: Patients with unclear onset of stroke (last time known well >4.5 hours) and MRI evidence of DWI-FLAIR mismatch were randomized in a 1:1 fashion to either alteplase 0.9 mg/kg or placebo. Patients were followed for 90 days. Trial was terminated early.



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Results

- Primary efficacy outcome, favorable outcome at 90 days: alteplase vs. placebo: 53.3% vs. 41.8%, p = 0.02
- Primary safety outcome, death or dependency (at 90 days, alteplase vs. placebo): 13.5% vs. 18.3%, p = 0.17; death: 4.1% vs. 1.2%, p = 0.07
- Median score on mRS at 90 days: 1 vs. 2, p = 0.003; symptomatic ICH per NINDS: 8.0% vs. 4.9%, p = 0.13

Conclusions

- Among patients with unclear time of stroke onset but with evidence of DWI-FLAIR mismatch on MRI, functional outcome at 90 days was better among patients who received alteplase compared with placebo; however, both death and symptomatic ICH were numerically higher with this strategy
- Both findings have to be considered in the light of a prematurely halted trial

Thomalla G, et al. N Engl J Med 2018;May 16:[Epub]