PACU LITERATURE REVIEW

REFERENCE

Wang Y, Li S, Pan Y, et al. Tenecteplase versus alteplase in acute ischaemic cerebrovascular events (TRACE-2): a phase 3, multicentre, open-label, randomised controlled, non-inferiority trial. *Lancet*. 2023;401(10377):645-654.

PMID: 36774935

SUMMARY

Tenecteplase was non-inferior to alteplase in patients with ischemic stroke who were eligible for IV thrombolytic administration but ineligible for endovascular thrombectomy. There were no significant safety differences between the two agents.

BACKGROUND

- IV alteplase has been recommended as a standard therapy for eligible patients with acute ischemic stroke. Tenecteplase has a simpler dosing and administration strategy, which makes it an attractive alternative agent to alteplase. Previous data suggests tenecteplase is non-inferior to alteplase with a similar safety profile.

STUDY OBJECTIVE

- To determine if tenecteplase is non-inferior to alteplase in Chinese patients with acute ischemic stroke who are eligible for IV thrombolytic therapy but are ineligible for thrombectomy.

STUDY DESIGN

- Phase 3, multicenter, prospective, open-label, blinded-endpoint, randomized controlled, non-inferiority trial across 53 centers in China.

STUDY INTERVENTION & COMPARISON

- **IV tenecteplase (0.25mg/kg) vs IV alteplase (0.9mg/kg)**

RESULTS

- **Primary Efficacy Outcome**
  - Proportion of patients with an mRS score of 0-1 at 90 days (62% v 58%, RR 1.07, CI 0.98-1.16)
- **Primary Safety Outcome**
  - Rate of symptomatic hemorrhage at 36hr (2% v 2%, p=0.72)
- **Key Secondary Outcomes**
  - Proportion of patients with favorable functional outcome at 3 months (73% v 72%, p=0.74)
  - Proportion of patients with significant neurologic improvement at 7 days or discharge (68% v 66%, p=0.73)
  - Any intracranial hemorrhage within 90 days (6% v 7%, p=0.5)
  - Parenchymal hematoma 2 within 36hr (1% v <1%, p=0.053)

ADDITIONAL READINGS

- Huang X, Cheripelli BK, Lloyd SM, et al. Alteplase versus tenecteplase for thrombolysis after ischaemic stroke (ATTEST): a phase 2, randomised, open-label, blinded endpoint study. *Lancet Neurol*. 2015;14(4):368-376.
- Campbell BCV, Mitchell PJ, Churilov L, et al. Effect of intravenous tenecteplase dose on cerebral reperfusion before thrombectomy in patients with large vessel occlusion ischemic stroke: the extend-ia tnk part 2 randomized clinical trial. *JAMA*. 2020;323(13):1257-1265.
- Logallo N, Novotny V, Assmus J, et al. Tenecteplase versus alteplase for management of acute ischaemic stroke (NOR-TEST): a phase 3, randomised, open-label, blinded endpoint trial. *Lancet Neurol*. 2017;16(10):781-788.
- Menon BK, Buck BH, Singh N, et al. Intravenous tenecteplase compared with alteplase for acute ischaemic stroke in Canada (AcT): a pragmatic, multicentre, open-label, registry-linked, randomised, controlled, non-inferiority trial. *Lancet*. 2022;400(10347):161-169.