

The distribution of the modified Rankin scale scores change according to eligibility criteria in acute ischemic stroke trials: A consideration for sample size calculations when using ordinal regression analysis.

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Abstract

Background: Distribution shifts of the modified Rankin scale (mRs) is used as outcome measure in acute ischemic stroke (AIS) randomized controlled trials (RCT). Distribution across strata of mRs is relevant for sample size calculations and may be affected by eligibility criteria.

Aim: We aimed to assess the distribution of mRs scores across its different strata in AIS according to usual eligibility criteria.

Methods: We computed follow-up mRs strata distribution between an unselected cohort and samples with (a) time from symptom onset < 6 h (b) National Institutes of Health Stroke Scale (NIHSS) scores > 3 and < 25, and (c) both criteria combined. We compared distributions with the Mann-Whitney *U* Test and calculated sample sizes for each distribution.

Results: We included 5849 AIS patients. The unselected sample had a non-normal distribution with a median of 2. All selection criteria yielded significantly different distributions of mRs ($p = 0.04$, 0.02 and 0.02 respectively). This resulted in a significant variation in the calculated sample size when applying different selection criteria, with smaller numbers when RCT selection criteria are used (3616 versus 1553).

Conclusions: The use of usual RCT eligibility criteria result in significant differences in mRs distribution and smaller sample sizes compared to unselected AIS samples.