

2017 Canadian Stroke Congress Abstract

BC.01 Risk Of Selection Bias And Misrepresentation Of Stroke Populations With Dichotomous Analyses Of The Modified Rankin Scale In Stroke Trials

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Introduction: Acute stroke trials using dichotomous analysis of the modified Rankin Scale (mRS) – 0-1/2-5 or 0-2/3-5 – as their primary outcome measure are incentivized to exclude patients with pre-morbid mRS of >1 or >2 as they cannot meet the trial definition of a “favourable” outcome. We assessed the proportion of patients in the general stroke population that would be excluded by such techniques.

Methods: In 3-month survivors of ischaemic stroke (Oxford Vascular Study; 2002-2014), we examined the proportion of patients that had pre-morbid mRS of >1 and >2, both overall and in the following groups: age>85 versus <85, and different quintiles of socio-economic deprivation. Significance was assessed using chi-squared tests

Results: Among 1,422 survivors, 244(17.1%) had pre-morbid mRS > 2 and 434(30.5%) had mRS > 1. 92/247(37.3%) of patients >85 had a pre-morbid mRS > 2 versus 152/1,175(12.9%) of those <85, the proportion grew to 150/247(60.7%) of patients >85 versus 284/ 1,175(24.2%) of those <85 (90/365[24.7%] versus 68/593[11.5%]) or pre-morbid mRS > 1 (151/365[41.4%] versus 133/593[22.4%]). P < 0.001 for all comparisons.

Conclusion: Dichotomous approaches risk excluding a significant proportion of the stroke population from acute stroke trials, with a particularly high risk of misrepresenting older patients and lower socio-economic strata. Since trial-based exclusion criteria are often applied in clinical practice, these patients also risk poorer access to acute stroke therapies. Ordinal analysis can allow acute stroke care to become more equitable.