Subgroup analyses in randomised controlled trials: quantifying the risks of false-positives and false-negatives


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Citation

Authors' objectives
Objectives: - To quantify the extent to which subgroup analyses may be misleading. - To compare the relative merits and weaknesses of the two most common approaches to subgroup analysis: separate (subgroup-specific) analyses of treatment effect and formal statistical tests of interaction. - To establish what factors affect the performance of the two approaches. - To provide estimates of the increase in sample size required to detect differential subgroup effects. - To provide recommendations on the analysis and interpretation of subgroup analyses.

Authors' conclusions
While it is generally recognised that subgroup analyses can produce spurious results, the extent of the problem is almost certainly under-estimated. This is particularly true when subgroup-specific analyses are used. In addition, the increase in sample size required to identify differential subgroup effects may be substantial and the commonly used rule of four may not always be sufficient, especially when interactions are relatively subtle, as is often the case.

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