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TRIALS

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A new large-scale meta-epidemiological study on bias in randomized trials using routinely collected risk-of-bias assessments by cochrane reviewers: results from the robes study

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Introduction

Empirical evidence suggests that certain aspects of trial design may lead to biased intervention effect estimates. We examined the influence of risk-of-bias judgements from Cochrane reviews for sequence generation, allocation concealment, blinding and incomplete data on intervention effect estimates in a large collection of meta-analyses (MAs).

Methods

We selected MAs with dichotomous outcomes and > 4 included trials from intervention reviews with fully completed risk-of-bias tool, published in issue 4, 2011 of the Cochrane Library. We classified outcome measures as mortality, other objective or subjective, and estimated the effect of risk-of-bias domain judgements on average bias (ratios of odds ratios [ROR] with 95% credible intervals [Cr-I]) using Bayesian hierarchical models.

Results

Among 2815 trials in 256 meta-analyses, intervention effect estimates were on average exaggerated in trials with high or unclear risk-of-bias (versus low) for random sequence generation (ROR 0.91 [95% Cr-I 0.86, 0.98]), for allocation concealment (ROR 0.92 [95% Cr-I 0.86-0.98]) and for blinding (ROR 0.87 [95% Cr-I 0.80, 0.93]). Unlike our previous study, we did not observe consistently different bias or between-trial heterogeneity in bias in MAs with subjective outcomes compared to mortality. Results from analyses of the influences of incomplete data were inconclusive.

Limitations

Possible inconsistency in criteria for risk-of-bias judgments applied by individual reviewers is a likely limitation of routinely collected bias assessments.

Conclusions

Inadequate randomization or lack of blinding may lead to exaggeration of intervention effect estimates in trials, but it is unclear if this effect differs by outcome type.

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