Evaluating non-randomised intervention studies

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Authors' objectives

In the absence of randomised controlled trials (RCTs), healthcare practitioners and policy-makers rely on non-randomised studies to provide evidence of the effectiveness of healthcare interventions. However, there is controversy over the validity of non-randomised evidence, related to the existence and magnitude of selection bias. This study aims to consider methods and related evidence for evaluating bias in non-randomised intervention studies.

Authors' conclusions

Results of non-randomised studies sometimes, but not always, differ from results of randomised studies of the same intervention. Non-randomised studies may still give seriously misleading results when treated and control groups appear similar in key prognostic factors. Standard methods of case-mix adjustment do not guarantee removal of bias. Residual confounding may be high even when good prognostic data are available, and in some situations adjusted results may appear more biased than unadjusted results.

Although many quality assessment tools exist and have been used for appraising non-randomised studies, most omit key quality domains. Six tools were considered potentially suitable for use in systematic reviews, but each requires revision to cover all relevant quality domains.

Healthcare policies based upon non-randomised studies or systematic reviews of non-randomised studies may need re-evaluation if the uncertainty in the true evidence base was not fully appreciated when policies were made.

The inability of case-mix adjustment methods to compensate for selection bias and our inability to identify non-randomised studies which are free of selection bias indicate that non-randomised studies should only be undertaken when RCTs are infeasible or unethical.

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