

ORIGINAL ARTICLE

Three risk of bias tools lead to opposite conclusions in observational research synthesis

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Abstract

Objectives: The aim of this study was to assess the agreement and compare the performance of three different instruments in assessing risk of bias (RoB) of comparative cohort studies included in a health psychology meta-analysis.

Study Design and Setting: Three tools were applied to 28 primary studies included in the selected meta-analysis: the Newcastle-Ottawa Scale, quality of cohort studies (Q-Coh), and risk of bias in nonrandomized studies of interventions (ROBINS-I).

Results: Interrater agreement varied greatly from tool to tool. For overall RoB, 75% of the studies were rated as low RoB with the Newcastle-Ottawa Scale, 11% of the studies with Q-Coh, and no study was found to be at low RoB using ROBINS-I. No influence of quality ratings on the meta-analysis results was found for any of the tools.

Conclusion: Assessing RoB using the three tools may lead to opposite conclusions, especially at low and high levels of RoB. Domain-based tools (Q-Coh and ROBINS-I) provide a more comprehensive framework for identifying potential sources of bias, which is essential to improving the quality of future research. Both further guidance on the application of RoB tools and improvements in the reporting of primary studies are necessary. © 2018 Elsevier Inc. All rights reserved.

Keywords: Risk of bias; Methodological quality; Systematic review; Meta-analysis; Domain of bias; Quality tool

1. Introduction

Assessing the methodological quality or risk of bias (RoB) of primary studies is an essential component of any systematic review or meta-analysis [1,2] and should play a relevant role in interpreting the results of the review [3]. Moreover, the inclusion of poor-quality studies in a review may lead to invalid conclusions [3,4]. In fact, the results of such quality assessments often exert an important influence on some decisions made in the review process, such as whether to exclude studies not meeting certain quality standards, to perform sensitivity analyses, to

determine the strength of evidence, or to guide recommendations for future research and clinical practice [5,6].

Compared to clinical trials, the quality assessment of observational studies is often more demanding due to the variety of designs comprised and their increased susceptibility to bias [5,7,8]. These difficulties are probably the reason why in some areas such as health psychology, only about half of all reviews that include cohort and case-control studies assessed the RoB of the primary studies [9]. Although a wide range of tools suitable for observational studies have been reviewed by several authors [10–12], there is no consensus on which is the best procedure or tool to assess RoB in observational designs, despite observational studies are usually included in systematic reviews including those of Cochrane [13]. Moreover, most of these tools were poorly developed, and their developers often failed to follow standard methodological procedures or to test their tools' validity and reliability [10,14]. Thus, RoB assessments of a single study using different tools may lead to different conclusions [4,15,16], both in randomized controlled trials [1,14,17] and in observational studies [7,8,18].

Conflict of interest: None.

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What is New?

Key findings

- Assessing risk of bias (RoB) using the three tools may lead to opposite conclusions, especially at low and high levels of RoB, where most of the studies were rated as low RoB with the Newcastle-Ottawa Scale (NOS), contrary to risk of bias in nonrandomized studies of interventions (ROBINS-I) with which most of the studies were rated as high RoB, while quality of cohort studies (Q-Coh) showed greater variability. Therefore, both the NOS and ROBINS-I showed low capability in grading RoB in observational studies.
- Correlation between Q-Coh and ROBINS-I was good for most of the domains of bias, while correlations between these two tools and the NOS showed poorer agreement. Raters' assessments of the usability of the tools also reveal the similarities between Q-Coh and ROBINS-I.
- The results of subgroup and meta-regression analyses showed no clear association between RoB and combined effect sizes when a meta-analysis is performed.

What this adds to what was known?

- Although this study has found that Q-Coh and ROBINS-I are comprehensive and valid tools compared to the NOS, their reliability needs to be improved.
- This study provides empirical evidence that the NOS assessment of RoB is overly positive.
- To our knowledge, this is the first time that the properties of ROBINS-I have been tested. When applying ROBINS-I, the use of a target trial makes it difficult to discriminate levels of RoB between observational studies and hinders the understanding of some items.

What is the implication and what should change now?

- To improve the reliability of the tools, two conditions must be met: (1) the development of detailed guidance and training in the application of RoB assessment tools and (2) improvements in the reporting of primary studies.
- In the context of systematic reviews and meta-analysis, RoB assessments make it possible to identify weaknesses in research designs and should guide the improvement of the quality of future studies, which is especially relevant to synthesize the results of nonexperimental research.

Meanwhile, the use of scales that provide a single summary score is strongly discouraged [4,15,19] because it involves the weighting of component items, although some of them may be not related to RoB [3,11]. The alternative seems to perform an RoB assessment based on domains [20–23], which is increasingly applied and apparently provides a more structured framework within which to make qualitative decisions on the overall quality of studies and to detect potential sources of bias [16].

The general purpose of this study was to assess the agreement and compare the performance of three different instruments in assessing the RoB of comparative cohort studies included in a meta-analysis related to health psychology. The selected tools were as follows: (1) NOS [24], the most frequently used scale to assess the quality of cohort and case–control studies [9], which provides a summary score; (2) quality of cohort studies (Q-Coh) [21], a specific domain-based tool to assess the RoB of cohort studies with good psychometric properties; and (3) risk of bias in nonrandomized studies of interventions (ROBINS-I) [22], a new domain-based tool proposed by Cochrane, which is intended to assess RoB in nonrandomized studies of interventions but is also applicable to a wide variety of observational designs [25]. To be more precise, the specific objectives are as follows:

- To estimate, for each tool, the degree of interrater agreement when examining items, domains of RoB, and overall quality rating.
- To estimate the level of agreement between tools for specific biases, domains of RoB, and overall quality rating.
- To appraise the qualitative aspects of the tools related to their usability: the average time spent, clarity of instructions and items, coverage, and validity.
- To determine the effect of quality ratings on the results of a meta-analysis.

2. Methods

2.1. Risk of bias assessment tools

The NOS [24] was developed to assess the quality of observational studies included in systematic reviews. This tool exists in separate versions for cohort and case–control designs, although only the scale for cohort studies was applied here. Studies are assessed using eight items broken down into three dimensions: selection (four items), comparability (one item), and exposure for case–control studies or outcome for cohort studies (three items). A study can be awarded a maximum of nine stars. Although the tool's developers have said that the validity and reliability of the tool have been established, no further specific information has been published. Nevertheless,

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