

Practical implications of assessing the risk of bias in a Cochrane review with alternative tools

Background

In 2008, Cochrane released the Cochrane risk-of-bias (RoB) tool. A revised version for randomized trials (RoB 2) that seeks to address different concerns is being tested since 2019

Objectives

To compare the performance of RoB vs RoB 2 tools when applied to the same Cochrane review, analyzing differences in the assessment results in both individual domains and overall risk of bias.

Methods

An ongoing Cochrane review entitled 'Blood pressure targets for hypertension in people with chronic renal disease' (protocol published in 2019: CD008564) was included in the RoB 2 tool pilot

The risk of bias of the review was assessed using RoB and RoB 2 tools

Any discrepancy on randomization, deviations-from-intended-interventions/blinding, missing/incomplete outcome data, reported result and overall bias, was noted and interpreted

The 'Outcome Measurement' domain was only estimated with the RoB 2 tool

Results

Six randomized trials (AASK, ACCORD, HOT, MDRD, SPRINT, SPS3) were included in the review

RESULTS OF THE RISK OF BIAS ASSESSMENT WITH RoB vs RoB 2:

ASSESSMENT WITH RoB:

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
AASK 2002	+	+	-	+	+	+	?
ACCORD BP 2010	+	+	-	+	+	+	?
HOT 1998	+	+	-	+	+	+	?
MDRD 1994	+	+	-	?	+	+	?
SPRINT 2015	+	+	-	+	+	+	-
SPS3 2013	+	+	-	+	+	+	?

Following RoB, all the included studies were judged as having an overall high risk of bias, mainly due to lack of blinding of participants and personnel (performance bias)

ASSESSMENT WITH RoB 2:

	Risk of Bias					
	A	B	C	D	E	F
AASK 2002	+	?	+	?	+	?
ACCORD BP 2010	+	?	+	+	+	?
HOT 1998	+	?	+	+	+	?
MDRD 1994	+	?	+	-	+	-
SPRINT 2015	+	?	+	+	+	?
SPS3 2013	+	?	+	+	+	?

Risk of bias legend

- (A) Bias arising from the randomization process
- (B) Bias due to deviations from intended interventions
- (C) Bias due to missing outcome data
- (D) Bias in measurement of the outcome
- (E) Bias in selection of the reported result
- (F) Overall bias

Following RoB 2, only one study (MDRD 1994) was judged as having an overall high risk of bias

Conclusions

RoB 2 led to a downplayed overall risk of bias compared to the RoB tool, mainly due to the fact that less emphasis is placed on blinding in the RoB 2 tool.

Further research is needed on the practical implications of moving to another risk-of-bias tool, which is closely linked to how the certainty of evidence will be graded in the future.