

Tool to Assess Risk of Bias in Case Control Studies

Contributed by the CLARITY Group at McMaster University

1. Can we be confident in the assessment of exposure?

Definitely yes
(low risk of bias)

Probably yes

Probably no

Definitely no
(high risk of bias)

Examples of low risk of bias:

- Evidence of exposure comes from previously created records and data abstractors are unaware of the study hypothesis

Examples of higher risk of bias:

- Evidence of exposure is acquired by patient interview, but interviewers are blinded to patient status
- Memory of exposure unlikely to be influenced by occurrence of outcome

Examples of high risk of bias:

- Evidence of exposure is acquired by patient interview, data collectors are not blinded to patient status or the study hypothesis
- Memory of exposure is likely to be influenced by the occurrence of the outcome

2. Can we be confident that cases had developed the outcome of interest and controls had not?

Definitely yes
(low risk of bias)

Probably yes

Probably no

Definitely no
(high risk of bias)

Examples of low risk of bias:

- Cases and controls undergo valid and reliable diagnostic procedures
- Surveillance for the outcome of interest clearly unrelated to the exposure of interest

Examples of higher risk of bias:

- The outcome of interest is acquired by subjective methods (e.g. patient interview)
- Reasonable steps are taken to independently validate results (e.g. independent validation by >1 person)
- Surveillance for the outcome of interest possibly related to the exposure of interest

Examples of high risk of bias:

- No description
- Cases are established with diagnostic procedures associated with high rates of false positive results
- Controls are established with diagnostic procedures associated with high rates of false negative results
- Surveillance for the outcome of interest clearly relate to the exposure of interest

3. Were the cases (those who were exposed and developed the outcome of interest) properly selected?

Definitely yes
(low risk of bias)

Probably yes

Probably no

Definitely no
(high risk of bias)

Examples of low risk of bias:

- All eligible cases are enrolled in a defined catchment area over a defined period of time during which diagnostic procedures would be unlikely to have changed
- Random sample of those cases

Examples of higher risk of bias:

- All eligible cases in a defined catchment area over a defined period of time during which diagnostic procedures would be likely to have changed
- Random sample of those cases

Examples of high risk of bias:

- Not reported

4. Were the controls (those who were exposed and did not develop the outcome of interest) properly selected?

Definitely yes
(low risk of bias)

Probably yes

Probably no

Definitely no
(high risk of bias)

Examples of low risk of bias:

- Controls clearly selected from the same underlying population as the cases and equally at risk of exposure to the putative causal factor

Examples of higher risk of bias:

- Differences in sampling frame of cases and controls that may be related to the exposure of interest

Examples of high risk of bias:

- Difference in sampling frame of cases and controls clearly related to the exposure of interest

5. Were cases and controls matched according to important prognostic variables or was statistical adjustment carried out for those variables?

Definitely yes
(low risk of bias)

Probably yes

Probably no

Definitely no
(high risk of bias)

Examples of low risk of bias:

- Comprehensive matching or adjustment for all plausible prognostic variables

Examples of higher risk of bias:

- Matching or adjustment for most plausible prognostic variables

Examples of high risk of bias:

- Matching or adjustment for a minority of plausible prognostic variables
- No matching or adjustment of plausible prognostic variables
- Statements of no differences between groups
- Statements that differences were not statistically significant are not sufficient for establishing comparability