Definition of the Different Levels of Evidence (LoE)

**Articles on treatment**

<table>
<thead>
<tr>
<th>Level</th>
<th>Risk of bias</th>
<th>Study design</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| I     | Low risk     | Good quality RCT | • Random sequence generation  
  • Allocation concealment  
  • Intention-to-treat analysis  
  • Blind or independent assessment for important outcomes  
  • Counterinterventions applied equally  
  • F/U rate of 80%+  
  • Adequate sample size |
| II    | Moderately low risk | Moderate or poor quality RCT | • Violation of one of the criteria for good quality RCT  
  • Blind or independent assessment in a prospective study, or use of reliable dataa in a retrospective study  
  • Counterinterventions applied equally  
  • F/U rate of 80%+  
  • Adequate sample size  
  • Controlling for possible confoundingb |
| III   | Moderately high risk | Moderate or poor quality cohort | • Violation of any of the criteria for good quality cohort  
  • Any case-control design |
| IV    | High risk    | Case-control | • Any case series design |

**Articles on prognosis or risk**

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<th>Risk of bias</th>
<th>Study design</th>
<th>Criteria</th>
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</table>
| I     | Low risk     | Good quality cohort | • Prospective design  
  • Patients at similar point in the course of their disease or treatment  
  • F/U rate of ≥ 80%†  
  • Patients followed long enough for outcomes to occur  
  • Accounting for other prognostic factorsb |
| II    | Moderately low risk | Good quality cohort | • Prospective design, with violation of one of the other criteria for good quality cohort study  
  • Retrospective design, meeting all the rest of the criteria in level I  
  • A good case-control studyc  
  • A good cross-sectional studyd |
| III   | Moderately high risk | Poor quality cohort | • Prospective design with violation of 2 or more criteria for good quality cohort, or  
  • Retrospective design with violation of 1 or more criteria for good quality cohort  
  • A good case-control study  
  • A good cross-sectional study |
| IV    | High risk    | Poor quality-case control or cross-sectional Case series | • Other than a good case-control study  
  • Other than a good cross-sectional study  
  • Any case series design |

**Additional domains**: dose-response, strength of association, publication bias.

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<th>Criteria</th>
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| 1     | Good quality study  | • Broad spectrum of patients with the expected condition  
  • Adequate description of methods for replication  
  • Blinded performance of tests, measurements or interpretation  
  • Second test/interpretation performed independently of the first |
| 2     | Moderate quality    | • Violation of any one of the criteria for a good quality study |
| 3     | Poor quality study  | • Violation of any two of the criteria |
| 4     | Very poor quality study | • Violation of all three of the criteria |

**Definitions of the Different Levels of Evidence for Reliability Studies**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Strength of evidence</th>
<th>Conclusions and comments</th>
<th>Baseline</th>
<th>Downgrade</th>
<th>Upgrade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td>High</td>
<td>Summary of findings</td>
<td>High Level I/II studies</td>
<td>No Consistent, direct, and precise estimates</td>
<td>No</td>
</tr>
<tr>
<td>Outcome</td>
<td>Moderate</td>
<td>Summary of findings</td>
<td>Low Level III studies</td>
<td>No Consistent, direct, and precise estimates</td>
<td>Yes Large effect</td>
</tr>
<tr>
<td>Outcome</td>
<td>Low</td>
<td>Summary of findings</td>
<td>High Level I/II studies</td>
<td>Yes [2] Inconsistent indirect</td>
<td>No</td>
</tr>
</tbody>
</table>

a Required domains: risk of bias, consistency, directness, precision. Plausible confounding that would decrease observed effect is accounted for in our baseline risk of bias assessment through individual article evaluation. Additional domains: dose-response, strength of association, publication bias.

b Single study = “consistency unknown.”

Summary of the Different Levels of Evidence

- **I (High risk)**: Evidence from multiple RCTs of high quality, with no or minimal risk of bias.
- **II (Moderate low risk)**: Evidence from one RCT of high quality, or from multiple lower quality studies.
- **III (Moderate high risk)**: Evidence from high quality non-randomized studies.
- **IV (High risk)**: Evidence from lower quality studies, or from high quality studies with significant methodological limitations.

Definitions of the Different Levels of Evidence

- **LoE I** (Very low risk): Evidence from multiple RCTs of high quality, with no or minimal risk of bias.
- **LoE II** (Low risk): Evidence from one RCT of high quality, or from multiple lower quality studies.
- **LoE III** (Moderate risk): Evidence from high quality non-randomized studies.
- **LoE IV** (High risk): Evidence from lower quality studies, or from high quality studies with significant methodological limitations.

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