

Appendix :

Study Design Types & Levels of Evidence

Modified From:

J. Karlsson, R. G. Marx, N. Nakamura, and M. Bhandari, “A Practical Guide to Research: Design, Execution, and Publication,” *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, vol. 27, no. 4, pp. S1–S112, Apr. 2011.

A Study Designs Defined

Meta-analysis: A combination of all of the results in a systematic review using accepted statistical methodology.

Systematic review: On the basis of a specific clinical question, an extensive literature search is conducted identifying studies of sound methodology. These studies are then reviewed, assessed, and summarized according to the predetermined criteria related to the question at hand.

Randomized (clinical) control trial: A prospective, analytic, experimental study that uses data generated typically in the clinical environment. A group of similar individuals are divided into 2 or more groups (1 acting as a control and the other[s] receiving the treatment[s]) and the outcomes are compared at follow-up. Prospective, blind comparison to a gold standard: To show the efficacy of a test, patients with varying degrees of an illness undergo both the test being investigated and the “gold standard” test.

Cohort study: A large population with a specific exposure or treatment is followed over time. The outcomes of this group are compared with a similar but unaffected group. These studies are observational, and they are not as reliable because the 2 groups may differ for reasons aside from the exposure.

Case-control study: Patients who have a specific outcome or condition are compared with those who do not. This is a retrospective approach used to identify possible exposures. These are often less reliable than RCTs and cohort studies because their findings are often correlational rather than causative.

Case series/report: Reports on the treatment of an individual patient are reviewed. These have no statistical validity because they use no control group for comparison. Case reports do, however, have a role for novel and rare presentations, because no large populations exist in these cases.

B Study Level of Evidence Defined

Level I

Therapeutic studies

- RCTs with (a) significant difference or (b) no significant difference but narrow confidence intervals
- Systematic reviews of Level I RCTs (studies were homogeneous)

Prognostic studies

1. Prospective studies 2. Systematic review of Level I studies

Diagnostic studies

1. Testing of previously developed diagnostic criteria in series of consecutive patients (with universally applied reference “gold” standard)

2. Systematic review of Level I studies

Economic and decision analyses studies

1. Clinically sensible costs and alternatives; values obtained from many studies; multiway sensitivity analyses

2. Systematic review of Level I studies

Level II

Therapeutic studies

- Prospective cohort study
- Lesser-quality RCT (e.g., □80% follow-up, no blinding, or improper randomization)
- Systematic review of Level II studies or Level I studies with inconsistent results

Prognostic studies

1. Retrospective study

2. Untreated controls from an RCT

3. Systematic review of Level II studies

Diagnostic studies

1. Development of diagnostic criteria on basis of consecutive patients (with universally applied reference “gold” standard)

2. Systematic review of Level I and II studies

Economic and decision analyses studies

1. Clinically sensible costs and alternatives; values obtained from limited studies; multiway sensitivity analyses

2. Systematic review of Level II studies

Level III

Therapeutic studies

1. Case-control study

2. Retrospective cohort study

3. Systematic review of Level III studies

Diagnostic studies

- Study of nonconsecutive patients (without consistently applied reference “gold” standard)
- Systematic review of Level III studies

Economic and decision analyses studies

1 Analyses based on limited alternatives and costs; poor estimates

2 Systematic review of Level III studies

Level IV

Therapeutic studies

Case series (no, or historical, control group)

Prognostic studies

Case series

Diagnostic studies

1. Case-control study

2. Poor reference standard Economic and decision analyses studies

No sensitivity analyses

Level V

Therapeutic studies

Expert opinion

Prognostic studies

Expert opinion

Diagnostic studies

Expert opinion

Economic and decision analyses studies

Expert opinion