

Levels of Evidence and Your Therapeutic Study: What's the Difference With Cohorts, Controls, and Cases?

Therapeutic studies are the heart of arthroscopic literature. And a great many of the therapeutic studies found in *Arthroscopy* fit into four categories: randomized controlled trials, cohort studies, case-control studies, and case series studies. But sometimes differentiating one category of study from another is not so simple. *Arthroscopy* is here to help.

The randomized controlled trial is perhaps the easiest category to recognize and the hardest to carry out. This type of study allows researchers to minimize bias by randomly assigning patients to treatment groups.

For a randomized controlled trial that shows a significant difference between treatment groups or achieves narrow confidence intervals, Level of Evidence = I.

For a randomized controlled trial with less than 80% follow-up, Level of Evidence = II.

The cohort study begins with two groups of subjects who lack a disease or an outcome. Researchers then collect multiple data points while looking for the development of disease or outcome in one of the groups. Frequently, this type of study involves lots of patients who are studied for a long time. However, there is no randomization.

A cohort study can be prospective (researchers formulate their hypothesis before data collection). **For a prospective cohort study, Level of Evidence = II.**

Or a cohort study can be retrospective (researchers formulate their hypothesis after data collection). **For a retrospective cohort study, Level of Evidence = III.**

Caution: "prospective" data collection does NOT ensure that your study is prospective. If you design the study or formulate the question(s) to be answered after the data are collected, then the study is still retrospective.

Second caution: the word "cohort" is often used, informally, to mean a collection or group—usually of

patients—as when we say, "Our study cohort." But the term **cohort study** is much more specific, involving groups of subjects that researchers study over time, looking for the development of a disease or an outcome.

The case-control study also involves two groups: cases (subjects with a disease or an outcome) who are compared with controls (subjects without the disease or outcome). Researchers choose all cases and controls from the same population. Controls are then matched to cases, allowing researchers to analyze past risk or exposure for the cases. There is no randomization and, as with a case series, datum is usually collected only once for each subject. **For a case-control study, Level of Evidence = III.**

The case series study, which is usually retrospective, involves one group of patients (its cases). Follow-up is rare and there are no controls. Likelihood of bias is high because researchers' selection of cases is often linked to the outcome(s) of interest. **For a case series study, Level of Evidence = IV.**

Being a Level IV study does not diminish the value of your research. Sometimes it is not ethical to have a control group when those patients would receive inferior treatment. That is why, in rapidly changing areas of arthroscopy, most therapeutic studies are Level IV, case series.

Arthroscopy has begun asking all authors to supply a Level of Evidence rating for each original article that involves the study of humans. But if your original article is in vitro or basic science, then *Arthroscopy* asks you to describe briefly the Clinical Relevance of your study.

When you write the structured abstract for your original article, place the Level of Evidence or Clinical Relevance between your Conclusions and Key Words.

GARY G. POEHLING, M.D.
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