

THE JOURNAL OF

HAND SURGERY

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Book

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Chapter in edited book

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LEVELS OF EVIDENCE FOR PRIMARY RESEARCH QUESTION

Types of Clinical Studies				
	Therapeutic Studies— Investigating the Results of Treatment	Prognostic Studies— Investigating the Effect of a Patient Characteristic on the Outcome of Disease	Diagnostic Studies— Investigating a Diagnostic Test	Economic and Decision Analyses—Developing an Economic or Decision Model
Level I	High-quality randomized controlled trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic review ² of Level-I randomized controlled trials (studies were homogenous)	High-quality prospective study ⁴ (all patients were enrolled at the same point in their disease with $\geq 80\%$ follow-up of enrolled patients) Systematic review ² of Level-I studies	Testing of previously developed diagnostic criteria in series of consecutive patients (with universally applied reference “gold” standard) Systematic review ² of Level-I studies	Sensible costs and alternatives; values obtained from many studies; multiway sensitivity analyses Systematic review ² of Level-I studies
Level II	Lesser-quality randomized controlled trial (eg, <80% follow-up, no blinding, or improper randomization) Prospective ⁴ comparative study ⁵ Systematic review ² of Level-II studies or Level-I studies with inconsistent results	Retrospective ⁶ study Untreated controls from a randomized controlled trial Lesser-quality prospective study (eg, patients enrolled at different points in their disease or <80% follow-up) Systematic review ² of Level-II studies	Development of diagnostic criteria on basis of consecutive patients (with universally applied reference “gold” standard) Systematic review ² of Level-II studies	Sensible costs and alternatives; values obtained from limited studies; multiway sensitivity analyses Systematic review ² of Level-II studies
Level III	Case-control study ⁷ Retrospective ⁶ comparative study ⁵ Systematic review ² of Level-III studies	Case-control study ⁷	Study of nonconsecutive patients (without consistently applied reference “gold” standard) Systematic review ² of Level-III studies	Analyses based on limited alternatives and costs; poor estimates Systematic review ² of Level-III studies
Level IV	Case series ⁸	Case series	Case-control study Poor reference standard	No sensitivity analyses
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

1. A complete assessment of the quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (eg, with cemented hip arthroplasty) compared with patients treated another way (eg, with cementless hip arthroplasty) at the same institution.
6. Study was started after the first patient enrolled.
7. Patients identified for the study on the basis of their outcome (eg, failed total hip arthroplasty), called “cases,” are compared with those who did not have the outcome (eg, had a successful total hip arthroplasty), called “controls.”
8. Patients treated one way with no comparison group of patients treated another way.

This chart was adapted from material published by the Centre for Evidence-Based Medicine, Oxford, UK. For more information, please see www.cebm.net.

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