

Clinical Orthopaedics and Related Research[®]

Levels of Evidence for Primary Research Question^a

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

Types of Studies

Level	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
I	<ul style="list-style-type: none"> High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic review^b of Level I RCTs (and study results were homogenous^c) 	<ul style="list-style-type: none"> High quality prospective study^d (all patients were enrolled at the same point in their disease with $\geq 80\%$ of enrolled patients) Systematic review^b of Level I studies 	<ul style="list-style-type: none"> Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review^b of Level I studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review^b of Level I studies
II	<ul style="list-style-type: none"> Lesser quality RCT (eg, < 80% followup, no blinding, or improper randomization) Prospective^d comparative study^e Systematic review^b of Level II studies or Level I studies with inconsistent results 	<ul style="list-style-type: none"> Retrospective^f study Untreated controls from an RCT Lesser quality prospective study (eg, patients enrolled at different points in their disease or < 80% followup) Systematic review^b of Level II studies 	<ul style="list-style-type: none"> Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review^b of Level II studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review^b of Level II studies
III	<ul style="list-style-type: none"> Case control study^g Retrospective^f comparative study^e Systematic review^b of Level III studies 	<ul style="list-style-type: none"> Case control study^g 	<ul style="list-style-type: none"> Study of nonconsecutive patients; without consistently applied reference “gold” standard Systematic review^b of Level III studies 	<ul style="list-style-type: none"> Analyses based on limited alternatives and costs; and poor estimates Systematic review^b of Level III studies
IV	Case series ^h	Case series	<ul style="list-style-type: none"> Case-control study Poor reference standard 	<ul style="list-style-type: none"> Analyses with no sensitivity analyses
V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

^a A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

^b A combination of results from two or more prior studies.

^c Studies provided consistent results.

^d Study was started before the first patient enrolled.

^e Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.

^f The study was started after the first patient enrolled.

^g Patients identified for the study based on their outcome, called “cases” eg, failed total arthroplasty, are compared with patients who did not have outcome, called “controls” eg, successful total hip arthroplasty.

^h Patients treated one way with no comparison group of patients treated in another way.