

Instructions for Authors (continued)

Levels of Evidence for Primary Research¹

Types of 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	<ul style="list-style-type: none"> • High-quality randomized controlled trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review² of Level-I randomized controlled trials (studies were homogeneous³) 	<ul style="list-style-type: none"> • High-quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) • Systematic review² of Level-I studies 	<ul style="list-style-type: none"> • Testing of previously developed diagnostic criteria in series of consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level-I studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from many studies; multi-way sensitivity analyses • Systematic review² of Level-I studies
Level II	<ul style="list-style-type: none"> • Lesser-quality randomized controlled trial (e.g., <80% follow-up, no blinding, or improper randomization) • Prospective⁴ comparative study⁵ • Systematic review² of Level-II studies or Level-I studies with inconsistent results 	<ul style="list-style-type: none"> • Retrospective⁶ study • Untreated controls from a randomized controlled trial • Lesser-quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review² of Level-II studies 	<ul style="list-style-type: none"> • Development of diagnostic criteria on basis of consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level-II studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from limited studies; multi-way sensitivity analyses • Systematic review² of Level-II studies
Level III	<ul style="list-style-type: none"> • Case-control study⁷ • Retrospective⁶ comparative study⁵ • Systematic review² of Level-III studies 	<ul style="list-style-type: none"> • Case-control study⁷ 	<ul style="list-style-type: none"> • Study of nonconsecutive patients (without consistently applied reference “gold” standard) • Systematic review² of Level-III studies 	<ul style="list-style-type: none"> • Analyses based on limited alternatives and costs; poor estimates • Systematic review² of Level-III studies
Level IV	Case series ⁸	Case series	<ul style="list-style-type: none"> • Case-control study • Poor reference standard 	<ul style="list-style-type: none"> • 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 (e.g., with cemented hip arthroplasty) compared with patients treated another way (e.g., 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 (e.g., failed total hip arthroplasty), called “cases,” are compared with those who did not have the outcome (e.g., had a successful total hip arthroplasty), called “controls.”
8. Patients treated one way with no comparison group of patients treated another way.

Reprinted with permission. Copyright © 2005 by The Journal of Bone and Joint Surgery, Incorporated.