



2013 OTA Basic Science Focus Forum  
International Research Symposium

### Selecting the Right Study Design- Balancing Science and Resources

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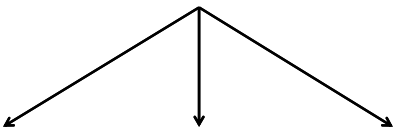
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### What is Evidence-Based Medicine?

- The **conscientious** use of current **best evidence** from clinical care research in making **health care decisions**



Clinical Expertise + **Hierarchy of Evidence** + Patient Values

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### Hierarchy based on minimizing “Bias”

- Randomize Patients
- “Conceal” randomization
- Blind/Independent Assessors
- Objective (important) outcomes
- Completeness of F/U [and Timing]
- [Balance expertise in treatment arms]

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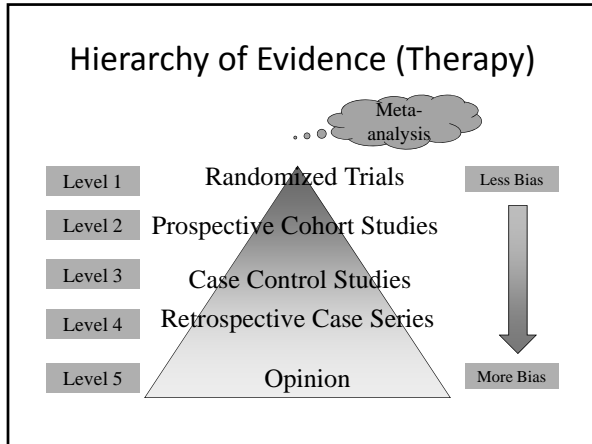
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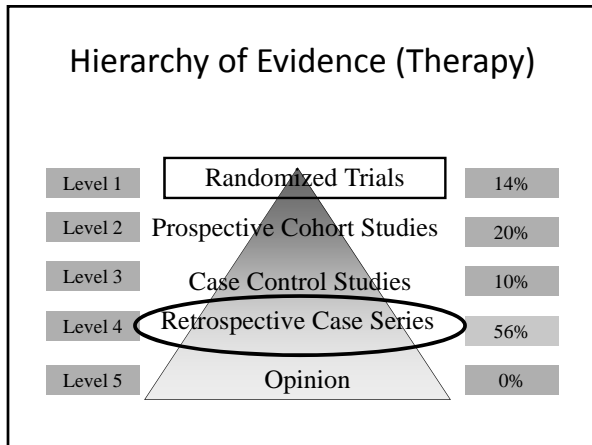
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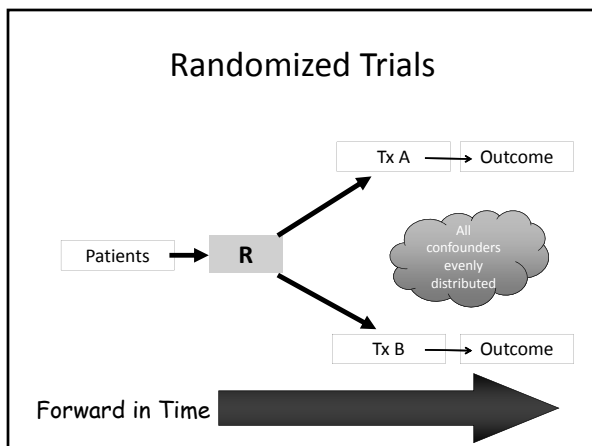
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## Why not always do and RCT?

- Ethical Issues
  - “Is it ethical to randomize patients”
- Outcomes are too rare?
  - “We’ll never be able to recruit so many patients”
- Surgeon “buy in”
  - Differential expertise
- The Primary Question
  - Prognosis
- Cost
  - We’ll never raise enough money to pull this off




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## Not all RCT's are equal!

### RANDOMIZED COMPARISON OF REDUCTION AND FIXATION, BIPOLAR HEMIARTHROPLASTY, AND TOTAL HIP ARTHROPLASTY

TREATMENT OF DISPLACED INTRACAPSULAR  
HIP FRACTURES IN HEALTHY OLDER PATIENTS

By JJ Reuben, PhD, Richard A. Cahley, DDM, M. Steven, MD, TS, Scott, MD,  
and JF Knaflitz, PhD, on behalf of the Scottish Orthopaedic Trials Network

**Background:** Orthopaedic surgeons vary in their management of displaced intracapsular fractures of the hip in healthy older patients. The aim of this investigation was to determine the functional, clinical, and resource consequences of three different types of surgical treatment.

**Methods:** The study was a multicenter, randomized, controlled trial. Reduction and fixation was compared with bipolar hemiarthroplasty with cement and total hip arthroplasty with cement. Pre-specified comparisons related to outcomes that patients are most likely to care about: mortality, secondary surgery, and quality of life. Functional outcomes were measured with a hip disability questionnaire and the EuroQol quality of life scale. Clinical outcomes included mortality and complications. The direct health service costs were compared. Participants were followed up for two years.

**Results:** Six hundred and seven patients were randomized to be treated with one of the three operations, and almost one were randomized to be treated with either fixation or bipolar hemiarthroplasty. There were no differences in the mortality rates among the treatment groups. The rate of secondary surgery was highest in the fixation group (28%, compared with 2% in the group treated with bipolar hemiarthroplasty and 1% in the group treated with total hip arthroplasty). The fixation group had the worst hip disability questionnaire and EuroQol scores at four and twelve months. The total hip arthroplasty group had significantly better functional outcomes at four and twelve months than the other two groups. Although fixation was initially the least costly procedure, this short-term advantage was eroded by significantly higher costs for subsequent hospitalization admissions.

**Conclusions:** Arthroplasty is more clinically effective and cost-effective than reduction and fixation in healthy older patients with a displaced intracapsular fracture of the hip. The long-term results of total hip replacement may be best for those of bipolar hemiarthroplasty.

**Level of Evidence:** Therapeutic Level II. See Instructions to Authors for a complete description of levels of evidence.



< 80%  
follow-up  
I → II

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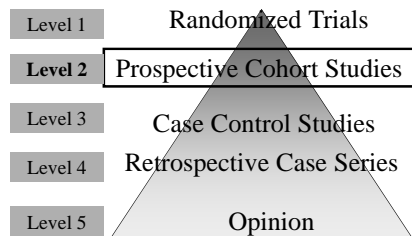
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## Hierarchy of Evidence (Therapy)




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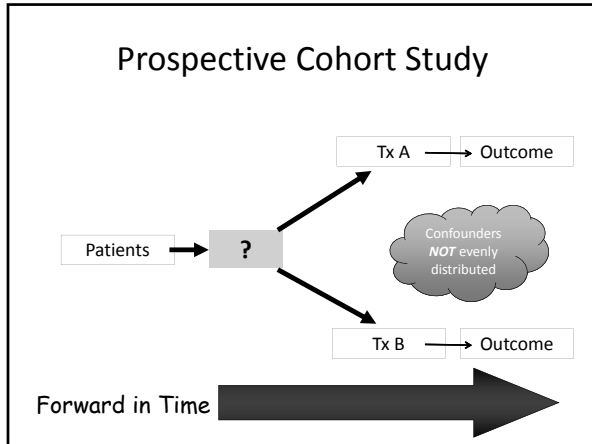
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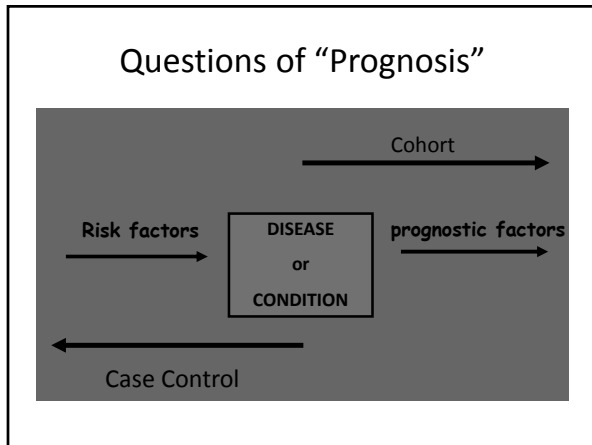
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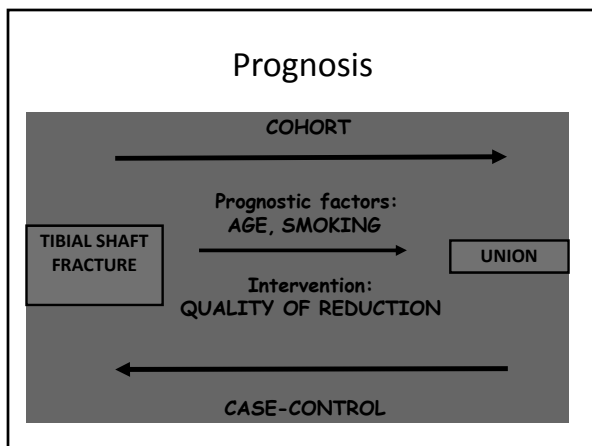
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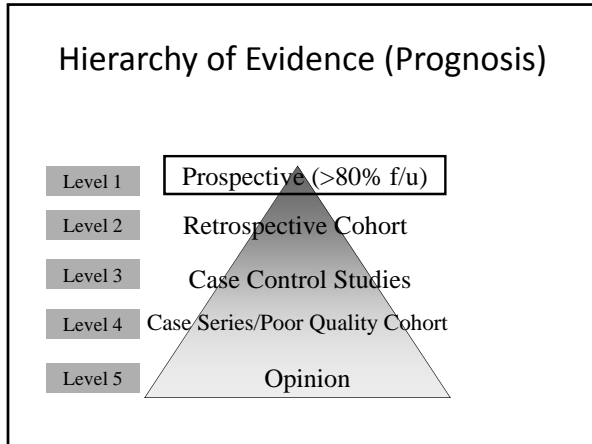
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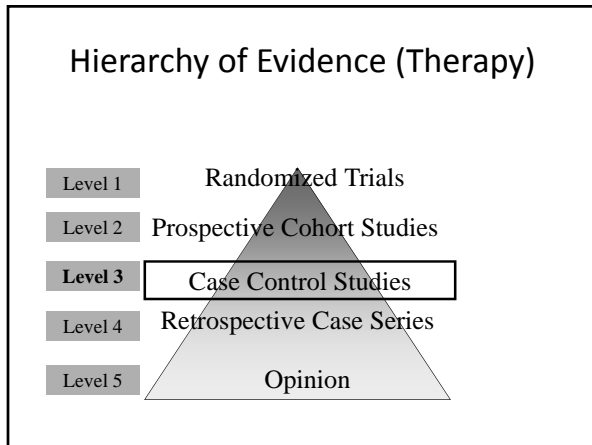
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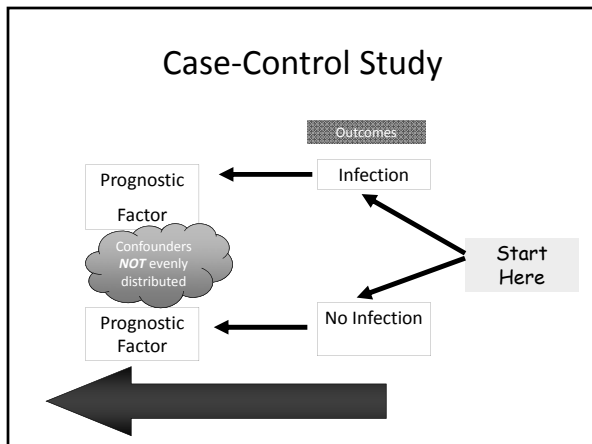
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### When are Case-Control Studies Used?

- Rare outcomes
- Outcomes that take a long time to develop
- Answer prognostic questions (factors associated with the development of a disease)

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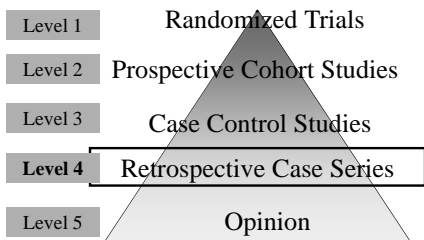
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### Hierarchy of Evidence



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### Case Series

- Strengths
  - Description of general characteristics and distribution of a disease
  - Description of complications or results associated with a procedure
  - Can provide information on rare diseases or entities
  - May be hypothesis generating
  - Short duration

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### Levels of Evidence

- JBJS-Am
- Clinical Orthopaedics
- Acta Orthopaedica
- Journal of Orthopaedic Trauma
- Canadian Journal of Surgery
- AAOS
- COA
- OTA

**It's Everywhere!**

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### Remember

- The “Hierarchy of Evidence” provides a guide to selecting clinical research design
- Studies that limit bias to the greatest extent are higher levels of evidence
- Balance pragmatism and bias reduction

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