2013 OTA Basic Science Focus Forum
International Research Symposium

Selecting the Right Study Design- Balancing Science and Resources

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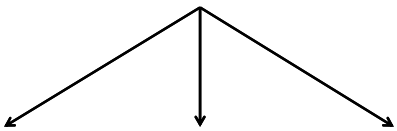
What is Evidence-Based Medicine?

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

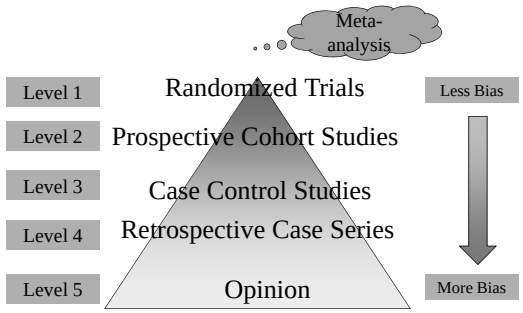


Clinical Expertise + **Hierarchy of Evidence** + Patient Values

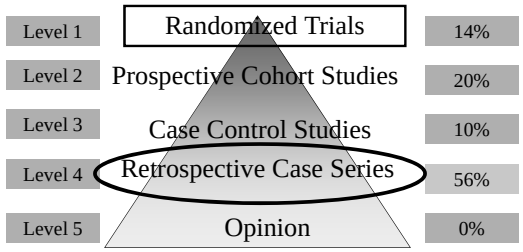
Hierarchy based on minimizing **"Bias"**

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

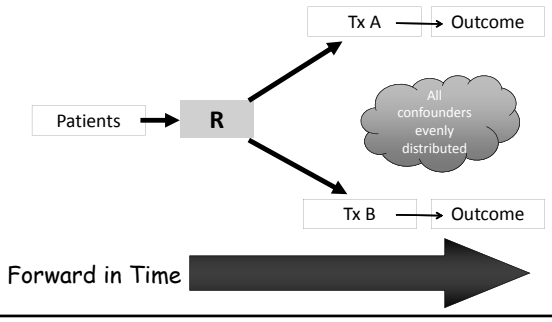
Hierarchy of Evidence (Therapy)



Hierarchy of Evidence (Therapy)



Randomized Trials



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 patien
- Surgeon "buy in"
  - Differential expertise
- The Primary Question
  - Prognosis
- Cost
  - We'll never raise enough money to pull this off

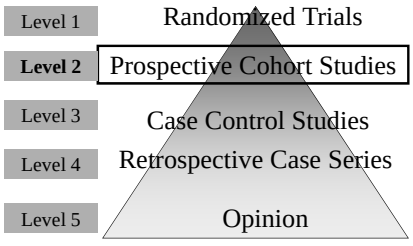
Not all RCT's are equal!

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

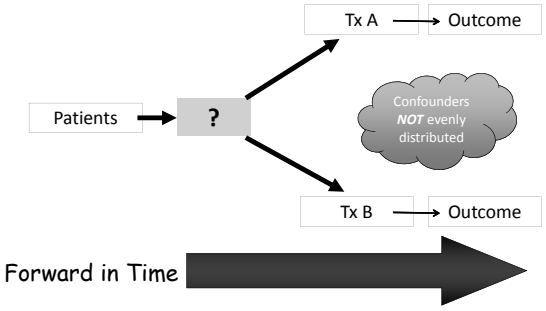
TREATMENT OF DISPLACED INTRACAPSULAR HIP FRACTURES IN HEALTHY OLDER PATIENTS

< 80% follow-up
I → II

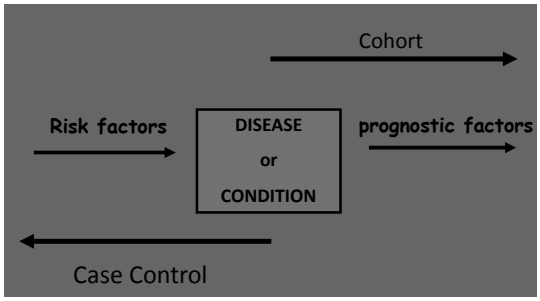
Hierarchy of Evidence (Therapy)



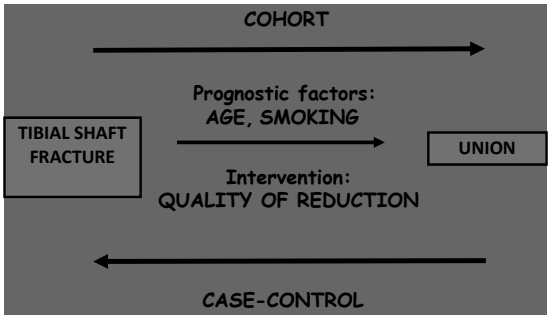
Prospective Cohort Study



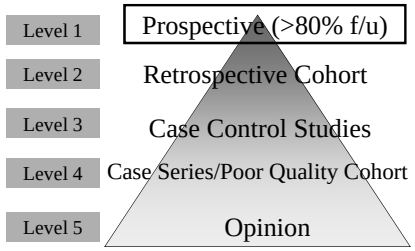
Questions of "Prognosis"



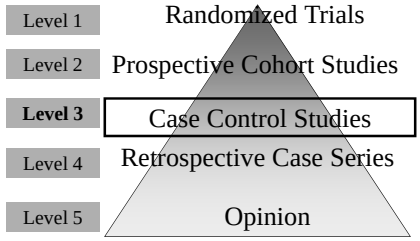
Prognosis



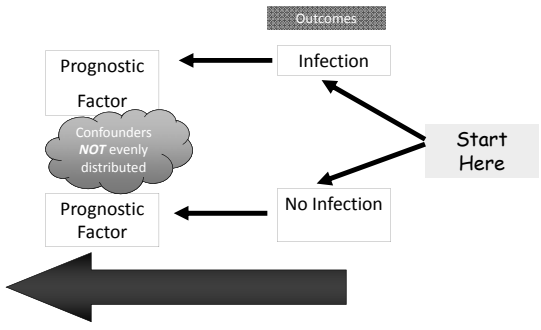
Hierarchy of Evidence (Prognosis)



Hierarchy of Evidence (Therapy)



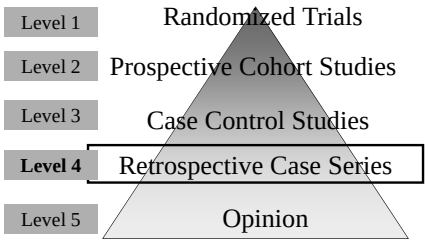
Case-Control Study



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)

Hierarchy of Evidence



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

Levels of Evidence

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

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