

Evidence-Based Medicine Journal Club: How to Evaluate an Article on Therapy

Erin L. Giudice, MD

Peds EBM teaching slides credits-- materials developed with help from:

- User's Guide to EBM (reproduced with permission of JAMA): <http://www.cche.net/usersguides/main.asp>
- Dr. Susan Guralnick of Stony Brook (SUNY)
- EBM Pediatric Program Directors and Educators Workshop at University of Illinois at Chicago
- Epidemiology and Preventive Medicine Dept. at Univ. of MD (Masters Program)

Evidence-Based Medicine Journal Clubs

- Introduction (and ACQ's)
- How to evaluate an article on...
 - Treatment
 - Diagnosis
 - Prognosis
 - Harm/Etiology
 - Special topics (such as Meta-analysis)

EBM: Framing the Question

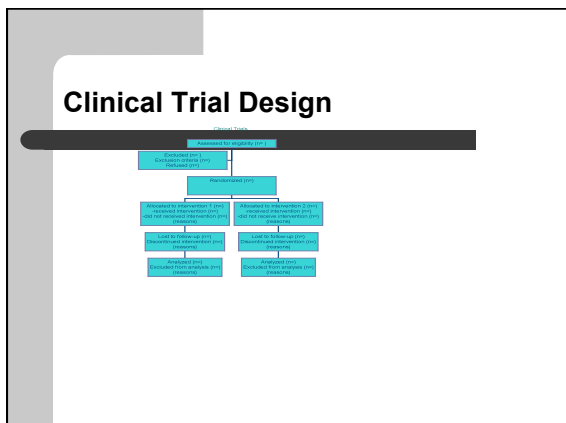
- Developing a well framed Answerable Clinical Question (ACQ) allows an efficient and effective search for evidence.
- 4 parts of an ACQ: PICO
 - P = Patient and Problem
 - I = Intervention
 - C = Comparison (to another intervention)
 - O = Outcomes of interest

How to Use an Article about Therapy

- Are the results likely to be valid?
 - Was the assignment of patients to treatment randomized?
 - What was the method of randomization?
 - Were patients and clinicians kept blind to treatment?

How to Use an Article about Therapy

- Are the results likely to be valid?
 - Were all the patients who entered the trial properly accounted for and attributed?
 - Follow-up sufficiently complete?
 - **"Intention to treat"**: the principle of attributing all patients to the group to which they were randomized



How to Use an Article about Therapy

- **Intention to Treat:** the principle of attributing all patients to the group to which they were randomized
- Preserves the value of randomization
- Prognostic factors that we do and don't know about will be, on average, equally distributed between the two groups, and the effect we see will be just that due to the treatment assigned

How to Use an Article about Therapy

Intention to Treat:
 Excluding non-compliant patients from the analysis leaves behind those who may be destined to have a better outcome, and destroys the unbiased comparison provided by randomization

In many randomized trials, non-compliant patients from both treatment and placebo groups have fared worse than compliant patients

Patients too sick to receive a tx shouldn't only count as control cases

How to Use an Article About Therapy

- **Are the results Clinically Significant?**

	Outcome present	Outcome absent	Totals
Drug	A	B	A+B
Placebo	C	D	C+D
Totals	A+C	B+D	A+B+C+D

Are the Results Clinically Significant?

	Outcome present	Outcome absent	Totals
Drug	A	B	A+B
Placebo	C	D	C+D
Totals	A+C	B+D	A+B+C+D

Control Event Rate = CER = c/c+d

Exper. Event Rate = EER = a/a+b

Absolute Risk Reduction ARR = CER-EER

Number Needed to Treat = NNT = 1/ARR

Are the Results Significant?

- Absolute Risk Reduction = Risk Difference
 - No difference = risk difference of 0
- Number Needed to Treat = number of patients who need to be treated to prevent one adverse outcome

Are the results significant?

Relative Risk (RR)

- Disease Prevalence in an exposed vs. non-exposed population
- The risk (or incidence) of the adverse effect in the exposed group divided by the risk of the adverse effect in the unexposed group
- Actual prevalence data needed for 2x2 chart
- Describes the disease prevalence in specific exposed vs. non-exposed populations
- Relative Risk > 1 means an increase in risk associated with the exposure

Are the results significant?

Odds Ratio (OR)

- Ratio of Odds
- The odds of a case patient being exposed divided by the odds of a control patient being exposed
- Proportion exposed in a diseased vs. non-diseased patient sample
- When the outcome of interest is rare in the population from which the sample was drawn (often the reason for using a case-control study), the OR closely approximates the RR

Are the results significant?

• Odds Ratio (OR)

- Describes the relative harm of an exposure independent of disease prevalence
 $OR = 1$ No effect
 $OR > 1$ + Harm
- If the disease prevalence is small, then $RR \approx OR$

Are the Results Significant?

	Adverse Outcome Present	Adverse Outcome Absent	Totals
Exposed	a	b	a+b
Unexposed	c	d	c+d
Total	a+c	b+d	a+b+c+d

- Relative Risk (RR) = $[a/(a+b)]/[c/(c+d)]$
- Odds Ratio (OR) = $(a/b)/(c/d) = ad/bc$

How to Use an Article about Therapy

- Are the results applicable to my patient?
 - Is our patient similar to those in the study?
 - Is treatment feasible in our setting?