Evidence-Based Medicine in Clinical Nutrition

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CLINICAL EPIDEMIOLOGY
EVIDENCE-BASED MEDICINE
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The process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients

EVIDENCE-BASED MEDICINE

“A PARADIGM SHIFT IN MEDICAL PRACTICE …”

THE OLD PARADIGM

1. PATHOPHYSIOLOGIC UNDERSTANDING
2. COMMON SENSE
3. EXPERIENCE
4. EXPERT’S OPINION
THE NEW PARADIGM

1. MEDICAL EVIDENCE
2. PATHOPHYSIOLOGIC UNDERSTANDING
3. COMMON SENSE
4. EXPERIENCE
5. EXPERT’S OPINION
Where can we find information?

• Personal experience

• Reasoning and intuition

• Colleagues (speakers, teachers, professors)

• Published evidence
  - the only way to reduce ineffective, dangerous or costly interventions
EVIDENCE - BASED MEDICINE

INTEGRATION OF

1. Best research evidence
2. Clinical expertise
3. Patient values

IN MAKING CLINICAL DECISIONS
Critical Appraisal

A method of assessing and interpreting the evidence by systematically considering its validity, results and relevance
Are the results of the study valid?

- Were the experimental and control groups similar at the start of the study?

1. Were patients randomized?

2. Was randomnization concealed?

3. Were patients analyzed in the groups to which they were randomized?

4. Were patients in the experimental and control groups similar with respect to known prognostic factors?
Were patients randomized?

• Random allocation instead of conscious decisions by clinicians and patients (as what is seen in observational studies)

• Adverse outcomes influenced by many prognostic factors of which the experimental treatment is but one of them

• Known and unknown prognostic factors are equalized

• Observational studies can match known but not the unknown prognostic factors
Was randomization concealed?

• If allocation not blinded, may systematically assign patients with a different prognosis to one group

• Methods of concealment:
  - allocation code in sealed opaque envelopes
  - remote randomization
  - preparation of blinded medication in a pharmacy
Were patients analyzed in the groups to which they were randomized?

- Include non-compliant patients in the analysis (non-compliant patients fare worse compared to compliant ones)
- Concept of “intention to treat” analysis
- Analyze the outcomes according to where patients were randomized rather than to what treatment was actually administered
Were the groups similar with respect to known prognostic factors?

- Test of similarity of demographic factors, baseline nutrition, severity of illness, and other prognostic factors
- May be a test of “success” of randomization
- If difference exists, adjustment is done. And when unadjusted and adjusted give similar results then validity is maintained
- Stratified analysis can be done and see if the results will differ
Are the results of the study valid?

- Were the experimental and control groups similar after the study started?
  1. Were patients aware of group allocation?
  2. Were clinicians aware of group allocation?
  3. Were outcome assessors aware of group allocation?
  4. Was follow-up complete?
Were patients aware of group allocation?

- Concept of the “placebo” effect
- Provide placebo drugs or preparations with the same color, taste and consistency with active medication
- Difficult or impossible in some cases (e.g. enteral or parenteral nutritional modifications)
- Placebo controlled trials are most important in assessing nutritional or food supplements
- Comparison may be to placebo or standard management
Were clinicians aware of group allocation?

• Differences in patient care can cause imbalance of prognostic factors after the start of the study

• Balance the effect of co-interventions, additional interventions may be administered more to one group

• When a specific form of nutritional therapy is instituted, other modalities may unknowingly be utilized
Were outcome assessors aware of group allocation?

- May result in closer follow-up of one group
- Can be done even if patients and clinicians cannot be blinded
- May come into play even if the measuring instrument is deemed objective (e.g. digital weighing scale)
- Judgment of outcome assessors affected especially of marginal results
- The more judgment is involved in determining an outcome, the more important is blinding
Was follow-up complete?

- Patients lost to follow-up have different prognosis from those who are retained.

- Excessive if we assume the “worse case” scenario and the result or conclusion change.
  a) All patients lost in the treatment group did badly.
  b) All patients lost in the control group did well.
What are the results?

1. How large was the treatment effect?

2. How precise was the estimate of the treatment effect?
How large was the treatment effect?

• Risk without therapy (control) = X
• Risk with therapy (experimental) = Y
• ARR = X – Y
• RR = Y / X
• RRR = X−Y / X or 1−RR
How precise was the estimate of the treatment effect?

• Best estimate of treatment effect is that observed (point estimate) in the trial, but the true treatment effect will never be known

• Search for the interval estimate (confidence intervals)
How precise was the estimate of the treatment effect?

Study A  
(n=1000)

Study B  
n=100

The bigger the sample size, the narrower the confidence interval
How can I apply the results to patient care?

1. Were the study patients similar to the patient in my practice?

2. Were all clinically important outcomes considered?

3. Are the likely treatment benefits worth the potential harms and costs?
Were the study patients similar to the patient in my practice?

• Consider inclusion and exclusion criteria of the study

• If not, are there compelling reasons why it should not work?

• Issue of class effects especially of nutritional formulas

• Care must be exercised in applying results of a sub-group analysis
Were all clinically important outcomes considered?

- Measure outcome that is important to the patient e.g. all-cause mortality, cause-specific mortality rates, hospitalization stay.
- In clinical nutrition trials, frequently forced to measure “surrogate” markers – e.g. body weight, serum biochemical markers.
- Consider also adverse events.
“A drug should not be given because it ought to work but because it does...”

Opie L, 1991
Are the likely treatment benefits worth the potential harms and costs?

• **NNT = 1 / ARR**

• The number of patients treated over a certain period to prevent one adverse outcome or to produce one beneficial outcome

• Many pharma companies use RRR to show benefits but many times have low ARRs (and high NNTs)
Are the likely treatment benefits worth the potential harms and costs?

- Consider the costs involved
- Consider trade offs with serious adverse events (NNTh)
Why Bother with EBM?

• Easy to learn but hard to apply
• The benefits will only be realized if the principles of EBM are utilized in everyday practice
Thank You