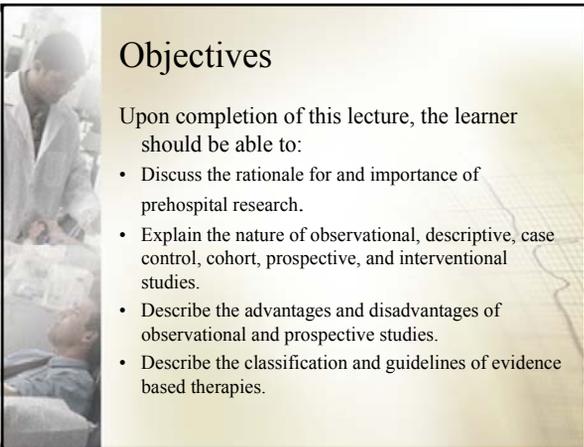


EMC 340 Introduction to Clinical Medicine

25 Introduction to Research

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Objectives

Upon completion of this lecture, the learner should be able to:

- Discuss the rationale for and importance of prehospital research.
- Explain the nature of observational, descriptive, case control, cohort, prospective, and interventional studies.
- Describe the advantages and disadvantages of observational and prospective studies.
- Describe the classification and guidelines of evidence based therapies.



Early EMS Development

- Best possible emergency care outside the hospital.
- Borrowed drugs, methods, and techniques.
- Originally developed from studies on stable patients, hospitalized patients, and animal models.
- Not developed from studies on unstable, acutely ill, or injured patients in the prehospital setting.



Evidence Based Medicine

- Pre hospital emergency medicine is expected to adopt the medical principle:
 - Try to be neither the first nor the last to adopt a new proven therapy
- *Evidence based* prehospital practice
 - The new basis for prehospital practice, with improvement in patient outcome.



Principles of Research

- A benefit if learning the principles of research is improving patient care.
- Other benefits for prehospital conditions include:
 - Habit of examining scientific basis for clinical practice.
 - Cost benefit analysis of new or old technology.
 - Evaluation of safety of certain practices (safety for paramedic as well as for patient)
 - Establishing an intellectual honesty associated with continuous evaluation.
 - Generation of new questions and further definition of scope of prehospital practice.



Controversy

- The use of MAST trousers
- Aeromedical transport
- Intubation by EMT-Basics
- Prehospital 12 lead EKGs
- Safety of “wide open” emergency transport (lights and siren)
- In the field clearance of C-spine



Types of Research

- Observational
 - e.g., number of county MVC's/intersection/year
- Interventional
 - e.g., do MAST trousers increase mortality in an urban setting? (K. Mattox, et al)



Observational Studies

- Descriptive
- Case control
- Does not attempt to influence outcome or discover the effects of a specific intervention.
- Predetermined criteria adhered in collecting data
- Data from already collected information
 - ACR; medical records
- Helps define the problem(s) and occasionally suggests a solution.



Example

- Epidemiologic
 - e.g., number of chest pain patients / grid / month
- Historical
- Ultimate outcome of chest pain patients transported by EMS.
- Safety studies
- Safety of prehospital Naloxone.



Interventional Studies

- **Not case control**
- Usually prospective
- Comparison of a noninterventional (or control) group with an interventional (experimental) group of patients
- Will experimental intervention influence disease process or change patient outcome?



Examples

- Does Prehospital 12 lead EKG transmission speed coronary reperfusion for patients with AMI ?
- Does application of MAST trousers increase mortality in an urban setting?
- Framingham Heart study (p. 604)



Retrospective Studies

- Previously collected data
- Advantages
 - Inexpensive (major)
 - Informed consent is easier
 - Quicker than prospective studies
 - Less difficulty with review boards
 - Easy to design and perform



Disadvantages

- Outcomes could have been influenced by many factors other than those under study. (major)
- Under identification of eligible patients
- Recall bias
- Very limited ability to establish cause and effect relationship



Prospective / Interventional

- More difficult
- More reliable
- Conclusions are stronger than simple observational studies
- Major advantage:
 - More closely predicts cause and effect relationship



Disadvantages

- Expensive
- Time-consuming
- Difficult
- Methodology
- Meticulous adherence to treatment criteria
- Consent
- Statistical analysis
- Characteristics of control group
- Calculation of sample size



Prospective Strengths

Strength of the study depends upon:

- Sample size
- Concurrent control group (**not** a control group from a previous study)



Prospective Studies

- Randomization
 - "Blinded" patient
 - "Blinded" practitioner
- Crossover
 - Where the control becomes the experimental group and the experimental group now becomes the control group



Prehospital Prospective

Problems in the prehospital setting include:

- Sample size - sometimes hard to accumulate large numbers
- Double "blinding" of patient and paramedic nearly impossible
- Crossover - impossible
- Informed consent - nearly impossible



Classes of Evidence

- Class I – always
- Class IIa – acceptable
- Class IIb – acceptable, but evidence is only fair to good.
- Class III – not acceptable, harmful
- Indeterminate – no recommendation, continuing research



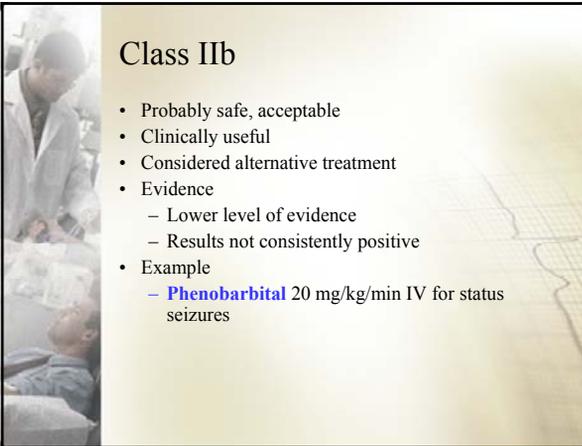
Class I

- Always acceptable, safe
- Definitely useful
- Proven effectiveness
- To be used in be appended to manner for the proper indication
- Evidence
 - One or more large prospective study (with rare exceptions)
 - Study results consistently positive and compelling
- Example
 - Lorazepam 2 mg / min IV for status seizures



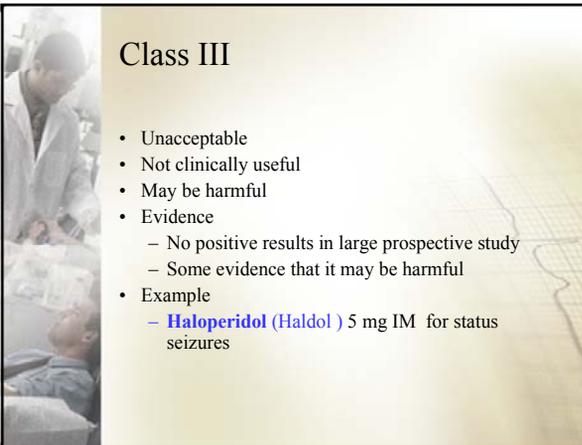
Class IIa

- Safe, acceptable
- Clinically useful
- Considered a treatment of choice
- Evidence
 - High levels of evidence
 - Consistently positive results
- Example
 - Phenytoin (Dilantin) 18 mg/min IV for status



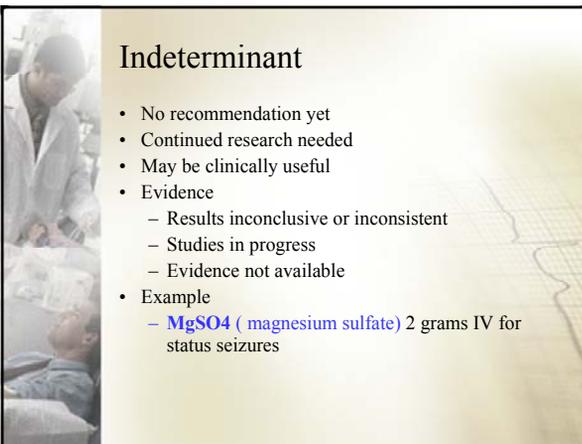
Class IIb

- Probably safe, acceptable
- Clinically useful
- Considered alternative treatment
- Evidence
 - Lower level of evidence
 - Results not consistently positive
- Example
 - **Phenobarbital** 20 mg/kg/min IV for status seizures



Class III

- Unacceptable
- Not clinically useful
- May be harmful
- Evidence
 - No positive results in large prospective study
 - Some evidence that it may be harmful
- Example
 - **Haloperidol (Haldol)** 5 mg IM for status seizures



Indeterminant

- No recommendation yet
- Continued research needed
- May be clinically useful
- Evidence
 - Results inconclusive or inconsistent
 - Studies in progress
 - Evidence not available
- Example
 - **MgSO₄ (magnesium sulfate)** 2 grams IV for status seizures



Summary

We have discussed:

- Some examples of the various types of studies.
- Class of evidence definitions and examples.
- Need for prospective trials of pre hospital therapies.
- Review questions.



Summary, continued

- Various kinds of pre hospital research design
- Some of the advantages and disadvantages of different research designs
- So-called "gold standard"
 - Prospective
 - Randomized
 - Double blind study



Summary, continued

Time has come for pre hospital research to:

- Become evidence-based.
- Determine cost-effectiveness of therapies.
- Determine safety of therapies.
- Determine medical soundness of therapies.
