Evidenced-Based Medicine: Where Does it Fit in Foot and Ankle Surgery?

MODULE: Choosing the Appropriate Statistical Analysis Tool
Evidence-Based Medicine

✓ The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of the individual patient

✓ It means integrating individual clinical expertise with the best available external clinical evidence from systematic research

Dr. David Sackett, 1996
Evidence-Based Medicine

Clinical Expertise

Patient Care

Patient Values

Best Evidence

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Fundamental Principles

 ✓ Evidence is never enough
 ✓ Hierarchy within EBM
Steps In EBM Process

✓ Clinical Problem
✓ Question
✓ Resource
✓ Evaluation
✓ Patient
Asking the Question

Foreground Question

Background Question

Novice ↔ Expert

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Hierarchy of EBM:

- Meta-Analysis
- Systematic Review
- Randomized Controlled Trial
- Cohort Studies
- Case Control Studies
- Case Series/Case Reports
- Animal Research/Laboratory Studies
"P.I.C.O."

- Patient + Problem
- Intervention
- Comparison
- Outcome
Levels of Evidence

✓ January 2003
  • Journal of Bone and Joint Surgery American

✓ February 2005
  • American Academy of Orthopaedic Surgeons
I, II, III, IV, V based on design

Types

- Therapeutic
- Prognostic
- Economic
- Decision Analysis
✓ **Randomized Control Trial**
  - Level I or II

✓ **Cohort**
  - Level II or III

✓ **Case Control**
  - Level III

✓ **Case Series**
  - Level IV

✓ **Expert Opinions**
  - Level V
Levels of Evidence in Orthopaedic Journals

- Journal of Bone and Joint Surgery Am + Br
- Journal of Orthopaedic Trauma
- Journal of Shoulder and Elbow Surgery
- American Journal of Sports Medicine
- Journal of Prosthetics and Orthotics
- Foot and Ankle International
- Journal of Hand Surgery
- Journal of Arthroplasty

JBJS 87A(12), 2005
Levels of Evidence

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- Level I
- Level II
- Level III
- Level IV

- Am J Sports Med
- FAI
- J Arthroplasty
- JBJS Am
- JBJS Br
- J Hand Surg
- JOT
- JPO
- J Shoulder/Elbow

JBJS 87A(12), 2005
Evaluation of the Foot and Ankle Literature

✓ Journal Foot and Ankle Surgery
✓ Foot and Ankle International
Evaluation of the Literature

✓ Jan/Feb 2005 – Nov/Dec 2010

• 593 Articles
• 19 Level I
Evaluation of the Literature

✓ January 2005 – November 2010

• 1201 Articles

• 18 Level I

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“Target your reading to particular issues related to the patient”
Against

✓ “Old Hat”
✓ Cook Book Medicine
✓ Population Studies
✓ Lack of Gold Standard
✓ Access Difficulty

For

✓ Strong Evidence
✓ One Part
✓ Patient Decision
✓ Evidence Pyramid
✓ Trained Professionals

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There are 3 steps in deciding which appropriate statistical tool should be used to evaluate for significance for a given data set.

Follow the pathway that leads you down the appropriate pathway by following the “pathway slide” numbers at the top left of the slide.

Each pathway slide will be followed by a slide that provides definitions.
What Type of Data Is It?

- Continuous or Discrete
  - Go To Pathway Slide #2

- Categorical – Nominal
  - Go To Pathway Slide #6

- Categorical – Ordinal
  - Go To Pathway Slide #7
DEFINITIONS: What type of data is it?

- **Continuous:** when the values/observations belonging to it can take on any value within a finite or infinite interval
  - Example: height; weight; temperature; time

- **Discrete:** when the values/observations are distinct and separate (they can be counted)
  - Example: number of patients; blood group
DEFINITIONS: What type of data is it?

✓ **Categorical:** when the values/observations belonging to it can be sorted according to category
  - Example: male/female

✓ **Nominal:** when the values/observations belonging to it can be assigned a code in the form of a number, where the numbers are simply labels
  - Example: male coded as 1, female coded as 2

✓ **Ordinal:** when the values/observations belonging to it can be ranked (put in order)
  - Example: 0-10 pain scale (0=no pain; 10=worst possible pain)
STEP #2: Continuous or Discrete

How Many Groups?

1 Group
- 1 Group With Paired Data (before/after)
- Greater Than 2 Groups

2 Groups With Different Individuals

ANOVA
STEP #3: Continuous or Discrete: 1 Group

- Normally Distributed?
  - YES: t-Test
  - NO: Wilcoxin Test
DEFINITIONS

✔ Normally Distributed: *a frequency distribution defined by a particular mathematical function; a normal random variable*
  - Example: height at a given age, gender, race

✔ t-Test: *a statistical inference used to determine the probability of something occurring by chance*
**DEFINITIONS**

- **Wilcoxin Test**: compares two paired groups and calculates the difference between the set of pairs and provides information about the magnitude of the differences

- **ANOVA (Analysis of Variance)**: a statistical inference to test differences between 3 or more groups or repeated times for a single group
STEP #3: Continuous: 1 Group with paired data (before/after)

Pathway Slide # 4

- Normally Distributed?
  - YES
    - Paired t -Test
  - NO
    - What is the Sample Size Per Group?
      - $n \geq 10$
        - Paired t -Test
      - $n < 10$
        - Wilcoxon Signed Rank Test
**DEFINITIONS**

- **Paired t-Test:** used to determine whether there is a significant difference between the average values of the same measurement made under two different conditions.

- **Wilcoxon Signed Rank Test:** designed to test a hypothesis about the median of a population distribution; e.g. before and after data (does not require the assumption that the population is normally distributed).
**Step #3: Continuous: 2 Groups with different individuals**

- **Normally Distributed?**
  - **YES**
    - Look at Standard Deviation (t-test)
      - Same Standard Deviation
        - t-Test for Independent Samples
      - Different Standard Deviation
        - Welch’s t-Test
  - **NO**
    - What is the Size of Smaller Group?
      - n ≥ 10
        - Go to “Yes”
      - n < 10
        - Mann-Whitney U-Test
DEFINITIONS

✓ Standard Deviations: *measure of the spread or dispersion of the data*

✓ T-Test for Independent Samples: *used to compare two small sets of quantitative data when samples are collected independently of one another*

✓ Welch’s Test (similar to the t-test): *tests two samples with unequal variances*
Mann-Whitney U-Test: compares two unpaired groups; looks at relative ranks of subjects in the two groups

F-Test: compares standard deviations
**STEP #2: Categorical - Nominal**

**How Many Groups?**

- **1 Group**
  - One Sample Binomial Test

- **1 Group With Paired Data (before/after)**
  - McNemar Test

- **2 Groups With Different Individuals**
  - Chi-Square Test; Use Fischer’s Test if expected value(s) < 5
DEFINITIONS

- **One Sample Binomial Test:** When there are two possible outcomes
- **McNemar Test:** Tests the difference between paired proportions; same subjects before and after measurements
- **Chi-Square Test:** Comparison of two attributes in a sample of data/population to determine if there is any relationship between them
- **Fischer’s Exact Test:** Used to determine if there are nonrandom associations between two categorical variables; used when expected frequencies are small
**STEP #2: Categorical - Ordinal**

**PATHWAY**

Slide #7

- **How Many Groups?**
  - 2 Groups With Different Individuals
  - > 2 Groups With Different Individuals
  - 1 Group With Paired Data (before/after)
  - 1 Group With > 2 Data Point

- **What is the Sample Size per Group?**
  - n ≤ 10
    - Mann-Whitney U-Test
  - n > 10
    - Z-Test
DEFINITIONS

✓ Mann-Whitney U-Test: compares two unpaired groups; looks at relative ranks of subjects in the two groups

✓ Z-Test: used to compare the mean of a sample with the population mean when the standard deviation is known

✓ ANOVA (Analysis of Variance): a statistical inference to test differences between 3 or more groups or repeated times for a single group
**DEFINITIONS**

- **Wilcoxon Signed Rank Test:** *designed to test a hypothesis about the median of a population distribution; e.g. before and after data (does not require the assumption that the population is normally distributed)*

- **Friedman Test:** *used to detect differences across multiple test attempts*
CONCLUSIONS

✓ After following this pathway you can be confident that you are using the appropriate statistical tool to establish significance of your data

✓ Utilize a computer statistical package to conduct the actual statistical analysis

✓ It is a good idea to get a statistician involved in the process
Where Does EBM Fit with Foot and Ankle Surgery??
**Where Does EBM Fit?**

- ACFAS
- Research
- EBM ONLY??
- Your Step

"The surgery went well - we were able to save the foot after all."

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