Introduction: Evidence-based medicine: What is it and how should it be used?

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Definition

- EBM: The conscientious use of current best evidence from clinical care research in making healthcare decisions
  - Conscientious - requires clinical expertise
  - Current best evidence - implies hierarchy of evidence
  - Health care decisions - patient values

- EBM begins and ends with patients: Cycle

- Description of EBM: Hierarchy of Evidence

Importance of Evidence-Based Medicine

1. “Evidence-Based Medicine was honored as one of the top 15 Medical Discoveries in the past 166 years”

2. US Gov’t Earmarked $1.1 billion: U.S. Launches: Comparative, Effectiveness Research with economy stimulus program.

3. Most Journals Support EBM
   - Clinical Orthopaedics
   - Acta Orthopaedica
   - Journal of Orthopaedic Trauma
   - Canadian J. Surgery
   - AAOS
   - COA
   - OTA

Need for EBM

1. Provide patients with best available Treatment Options
2. Avoid Bias (systematic deviation from truth)
3. Avoid decision-making by:
   a. Industry Marketing
   b. Insurance Companies
   c. Other Interested 3rd parties

Evolution/History of EBM

Dr. David Sackett, OC, MD, FRSC, FRCP
2. Oxford Centre for Evidence-Based Medicine
3. Textbooks Clinical Epidemiology and Evidence-Based Medicine

James G. Wright, MD, MPH FRCS(C)
1. Introducing Levels of Evidence to the Journal
2. Grades of Recommendation
Mohit Bhandari  MD, PhD, FRCS(C)
Leader International Trauma Multicenter Randomized Conntrol Trials

Examples of Current Use of EBM (Personal Experience)

1. Evidence-Based Indications for Ankle Arthroscopy

2. AAOS Clinical Practice Guideline: Treatment of Achilles Tendon Rupture

Challenges with EBM in F&A

- Many conditions it is hard to generate good study numbers
- Disproportionate number of Level IV studies
- Multi-center clinical trials may be the answer
- Who pays??

Summary

The advent of EBM is significant advancement in patient care
EBM is widespread in Orthopedic Literature
EBM is here to Stay
If you are not practicing EBM you will be left behind............

Problems with EBM: The “Evidence Trap”

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Guidelines, Evidence Level and Grade of Recommendation are three different “tools” of the Evidence Based Medicine (EBM). EBM should be a solid and safe basis for decision making in medicine in general and of course also in foot and ankle surgery. However is a high level of evidence, i.e. outcomes research really better than a low level of evidence, i.e. experience. To answer this question a little more insight to the principal tools of EBM is needed:

Guidelines

For example in Germany, guidelines are an important basis for decision making and do have a high forensic importance, i.e. not following the guidelines can result in conviction in case of litigation.
Following the system of the Task Force of the Scientific Medical Societies (AWMF), guidelines were developed and classified into groups S1, S2 or S3. S3 is the group with the highest quality. The majority (76%) of all AWMF guidelines is S1 (lowest quality).

- **S1**: developed from an expert group with informal consensus
- **S2**: formal consensus or based on formal „evidence“ research
- **S3**: guideline with additional / all elements of a systematic development (Analysis of consistency, decision making, outcome, assessment of clinical relevance of scientific studies and recurrent approval

Evidence Level

Evidence levels are for example defined the Agency for Health Care Policy and Research (AHCPR). Interestingly, there are slight differences in the definition in different countries. One important issue is the subtle classification on more than just four different levels:

- **1++** High quality metaanalyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
- **1+** Well conducted metaanalyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1- Metaanalyses, systematic reviews or RCTs, or RCTs with a high risk of bias
2++ High quality systematic reviews of casecontrol or cohort studies or High quality casecontrol or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+ Well conducted casecontrol or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2- Casecontrol or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3 Nonanalytic studies, e.g. case reports, case series
4 Expert opinion

Consequently it’s not just level 1 or level 2 but 1 or 2 ++ or + or -. This differentiation is mostly not respected but is a more accurate basis for the classification of the evidence level.

Grade of recommendation
Based on the evidence level the grade of recommendation could be defined as follows:

A At least one metaanalysis, systematic review, or RCT rated as 1 ++ and directly applicable to the target population or A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1 + directly applicable to the target population and demonstrating overall consistency of results
B A body of evidence including studies rated as 2 ++ directly applicable to the target population and demonstrating overall consistency of results or Extrapolated evidence from studies rated as 1 ++ or 1 +
C A body of evidence including studies rated as 2 + directly applicable to the target population and demonstrating overall consistency of results or Extrapolated evidence from studies rated as 2 ++
D Evidence level 3 or 4 or Extrapolated evidence from studies rated as 2 +

The grade of recommendation is basis for all EBM guided decisions.

Is outcome research better than experience?
Experience alone could be a basis for a S1 guideline when informal consensus of an expert group is reached. However, experience alone is only level 4 evidence and could never reach a higher grade of recommendation the D. There is by definition always a conflict of interest. Therefore, experience alone is not more or less than one option that works but could never be proven to be better than any other option or even doing nothing or something wrong.

In contrast, outcome research could be a basis for a S3 guideline, evidence level 1 or 2 and grade of recommendation A, B or C. The most important issue is the controlled investigation that should be at best randomized, consecutive, blinded with validated outcome assessment. Consequently, outcome research is the only basis for high level of evidence and the only way to show that one method is better than another. Methodological weaknesses of level 1 and 2 studies could endanger the impact of those studies (Evidence trap). These weaknesses include conflict of interest of surgeons, investigators, patients, reviewers, missing randomization and different experience level of surgeons in different study branches and during the study.

In conclusion outcome research is the basis for high level of evidence and is always better than experience alone. Methodological weaknesses of level 1 and 2 studies (Evidence trap) should call the impact on our decisions into question.