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Grading the evidence: Levels of evidence and grades of recommendation

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Summary Evidence-based medicine is using the best available evidence in order to make accurate and knowledgeable treatment decisions. It is not the automatic gainsay of ''low quality'' evidence and acceptance of randomized controlled trials (RCT's). To be able to make a sound recommendation for a therapy based on the best available evidence, it is necessary to follow steps in acquiring literature, appraising it for study design and quality, and to assess its results, as well as look at the net benefits and net harms.
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Introduction

The practice of evidence-based medicine requires a practitioner to integrate clinical knowledge and judgement with the best available evidence.[22] Determining what constitutes the best evidence requires an ability to identify, critique and categorize literature, placing it into a so-called hierarchy of evidence or, rank-order, with randomized controlled trials (RCT's) and meta-analyses of RCT's at the top and uncontrolled studies or opinion at the bottom.[8,9,22] This is a necessary first step as the ability to infer a recommendation or establish a grade of recommendation for a treatment or intervention is directly related to the quality of evidence that is available for review. These steps then provide the basis for the development of clinical practice guidelines, to not replace clinical decision making but augment it.[8,22]

There have been a number of systems developed to try to categorize studies into their respective levels of evidence.[3] Examples of these include those from the Oxford Centre for Evidence-Based Medicine (OCEBM), the Scottish Intercollegiate Guidelines Network (SIGN) and the American College of Chest Physicians (ACCP) to name a few.[15,16,20] Using the OCEBM system as a representative system, studies range from the highest quality, level 1 evidence (randomized trials or systematic reviews/meta-analyses of high quality RCT's) to the lowest quality, level 5 (expert opinion). This system then allows literature to be graded. These grades are then used to determine a strength of recommendation ranging from grade A, that is, evidence from level 1 studies, to grade D, evidence from level 5 or other very poor inconsistent or inconclusive studies.[20]

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These scales are in widespread use but have been associated with some drawbacks. They have been developed mostly from consensus expert opinions and have not been validated to any extent.[27] Also, different systems or hierarchies may categorize studies into different levels of evidence.[1,27] For instance if one uses the SIGN system to categorize the study by Keating et al. *A Randomized Controlled Trial of Reamed* versus *Unreamed nails in Open Tibial Fractures*, it would be considered level ''1-'' evidence.[18] If this same study is classified according to the OCEBM system, it could be considered as class ''2b'' evidence. This then affects the ability to infer a grade of recommendation when incorporating this with other studies of a similar nature. Would this study be included as argument for Grade A evidence (a randomized trial) or Grade B evidence? How does this affect treatment decisions regarding the use of reamed or unreamed nails in open tibial shaft fractures? Since more than two different systems are in use there may be even greater confusion in the correct placement of a study within the hierarchy of evidence. Thirdly, the use of different systems does not allow for effective communication between users or governing bodies attempting to establish quality practice guidelines.[2,27] One last confounder in assigning a study into a particular level within the hierarch is a potential lack of agreement even using the same grading system.[3] Indeed, agreement between system users using a modified OCEBM system for grading evidence was 69% in non-epidemiologically trained reviewers.[4] The agreement between users however did increase significantly in those who were trained in epidemiology.[4]

Recently the GRADE working group, a group interested in ''addressing shortcomings such as these in systems for grading evidence and recommendations'' has looked at the different systems of guidelines.[3] In rating the systems there was no clear agreement between raters that these systems would successfully or reproducibly categorize a study into a specific level of evidence.[3] Secondly, they found that some systems were better at grading levels of evidence than at determining a grade of recommendation and vice versa.[3] Also, there were discrepancies in determining which systems were clear and simple for use by guideline developers. To this end they have devised a new rating system that attempts to address deficiencies seen within the other systems.[2] Through initial pilot study work, this system has been refined and improved for grading the quality of evidence (Table 1). This is done to infer a graded recommendation for practice. In this paper we will address the process by which a recommendation can be made regarding an orthopaedic intervention using the GRADE working group criteria for assigning evidence.

Table 1 Criteria for assigning grade of evidence[2]

Type of evidence
Randomised trial = high quality
Quasi-randomized = moderate quality
Observational study = low quality
Any other evidence = very low quality
Decrease grade(s) if
Serious (−1) or very serious (−2) limitation to study quality
Important inconsistency (−1)
Some (−1) or major (−2) uncertainty about directness
Imprecise or sparse data (−1)
High probability of reporting bias (−1)
Increase grade if
Strong evidence of association—significant relative risk of >2 (<0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1)
Very strong evidence of association—significant relative risk of >5 (<0.2) based on direct evidence with no major threats to validity (+2)
Evidence of a dose response gradient (+1)
All plausible confounders would have reduced the effect (+1)

Levels of evidence

Study design

To place a study into the hierarchy of evidence, a necessary first step is to determine the type of study being assessed in terms of study design. Generally the type of study that is rated as the highest level of evidence is the randomized controlled trial.[9] This trial helps to decrease bias and thus is considered the ''least likely to be wrong'' in its conclusion or, put another way, to more accurately estimate the truth.[21] It does so by controlling for any known variables within study populations, but more importantly, controls for any unknown variables that can bring bias into the study.[14,21] At the other end of the spectrum is the case series. While this type of study design may have a significant role in hypothesis generation, describing a rare entity or technique or describing post-operative complications after an intervention, it does little to govern treatment decision within a population.[9] Some of the major strengths and weaknesses of each study design are shown (Table 2).

Between these two types of study designs are the case-control design and the cohort design. Case-

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