Evaluating the Risk of Bias of a Study

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Abstract

Objective: This first article of a series of 4 is aimed at guiding dental practitioners on how to evaluate the internal validity (risk of bias,) of randomized controlled trials (RCT). All RCT's contain different areas and potential sources of bias. Understanding risk of bias (ROB) will allow dental practitioners to improve the quality of dental treatments.
Methods: The following areas of bias were elucidated: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and "other bias". The reader determines the ROB level by evaluating the areas or potential source of bias in the first phase. Normally, ROB levels are classified as low, high and unclear ROB.
Results: This article reported the concepts and methods of evaluation of ROB in several areas of an RCT. An RCT with low ROB in all evaluated areas gives the dental practitioners more certainty and confidence that a specific clinical procedure is in fact effective and relevant to the patient.
Conclusions: The information provided here may guide dental practitioners in the evaluation of ROB in an RCT. The correct evaluation of ROB may improve the quality of dental treatments.

Keywords: Risk of bias, Internal validity, Randomized controlled trial.

A CLINICIAN'S GUIDE FOR IMPROVING CLINICAL DECISION MAKING

Clinical decision making process is a multifaceted approach that requires the understanding of several variables to adequately address dental treatment needs. Concepts such as level of scientific evidence, cost-effectiveness of treatments, benefits and harms of treatments, and patient's opinion form the basis for clinical decision-making[1,2] (Figure 1). Thus, it is important that dental practitioners are able to adequately evaluate and understand this information.

This series of papers aims to discuss these concepts to inform dental practitioners how to improve their decision making skills to provide the best available therapy for a given clinical situation. The idea is to provide a practical guidance on how to interpret limitations/strengths of evidence and how to apply this knowledge to daily clinical practice, mainly when the evidence is of low quality.

The first article will be on the evaluation of the internal validity (risk of bias) of randomized controlled trials (RCT) that are considered to generate the highest level of evidence for clinical interventions.[3] The other articles of this series will discuss how dental practitioners could incorporate domains other than scientific evidence into their own decision-making process.

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Figure 1. Concepts that should be observed when deciding the best therapy for patients.

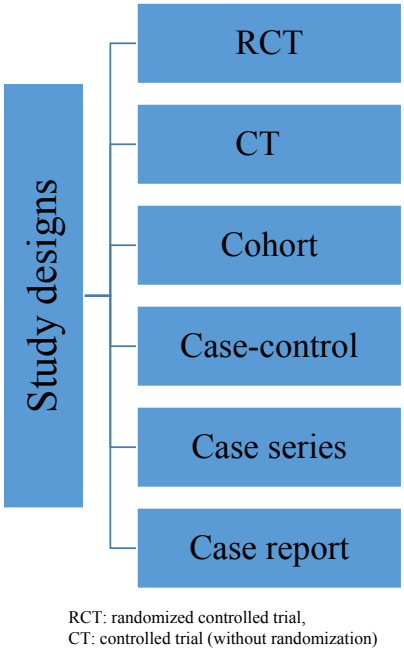

Figure 2. Hierarchy of evidence for clinical studies on interventions.

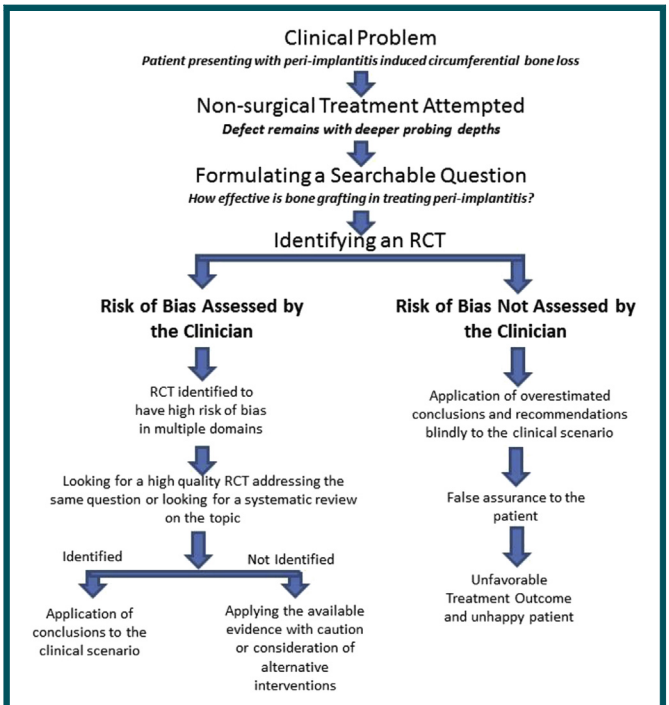

Figure 3. Treatment of peri-implantitis bone loss with bone graft. Not evaluating the ROB can lead to unfavorable outcomes (Figure 4). Algorithm source: Professor Satheesh Elangovan. University of Iowa Department of Periodontics.

The Randomized Trial and the Hierarchy of Evidence

Studies on clinical interventions have different designs, from a case report (when only the data from one patient treated is evaluated) to an RCT (when several patients are randomly treated with different therapeutic approaches). Among clinical studies on interventions, the RCT occupy the highest echelon in the evidence hierarchy (Figure 2). An RCT study design provides investigators the ability to evaluate the safety and/or efficacy of a given intervention in subjects (patients) who are assigned randomly to control and test groups, thereby strongly minimizing the chance of several types of bias to interfere with accurate estimates of the treatment effect.

Not all RCTs are designed, executed and/or reported with the highest required standards. A poorly designed and executed RCT with methodological limitations may be far less impactful and clinically meaningful than a well-designed non-randomized clinical study. Thus, only taking the study design into account for determining the quality or strength of evidence may be misleading. It is therefore essential that dental practitioners have enough knowledge to evaluate whether an RCT is or not methodologically sound.

In this first of 4 articles of this series a useful tool developed by the Cochrane Collaboration to evaluate risk of bias (ROB) is presented to the dental practitioner. It may be expected that the information provided in this article will guide dental practitioners in the appraisal of RCTs.

Bias Domains

An RCT is designed and planned to contain different areas (or potential sources of bias in the RCT) with each area sensitive to different types of bias. One interesting approach to help evaluate these areas is known as *domain-based appraisal.*[4,5] The areas are the following: