

Critical Analysis of a Randomized Controlled Trial

Balkrishna D Nimavat¹, Kapil G Zirpe², Sushma K Gurav³

ABSTRACT

In the era of evidence-based medicine, healthcare professionals are bombarded with plenty of trials and articles of which randomized control trial is considered as the epitome of all in terms of level of evidence. It is very crucial to learn the skill of balancing knowledge of randomized control trial and to avoid misinterpretation of trial result in clinical practice. There are various methods and steps to critically appraise the randomized control trial, but those are overly complex to interpret. There should be more simplified and pragmatic approach for analysis of randomized controlled trial. In this article, we like to summarize few of the practical points under 5 headings: "5 Rs" of critical analysis of randomized control trial" which encompass Right Question, Right Population, Right Study Design, Right Data, and Right Interpretation. This article gives us insight that analysis of randomized control trial should not only based on statistical findings or results but also on systematically reviewing its core question, relevant population selection, robustness of study design, and right interpretation of outcome.

Keywords: Critical analysis, Evidence based medicine, Randomised control trial.

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INTRODUCTION

"Statistics are like bikinis. What they reveal is suggestive, but what they conceal is vital." (Aaron Levenstein)

Being up-to-date with knowledge is pivotal in world of evidence-based medicine. Sometimes, it is also crucial in terms of medicolegal aspect and to improve best current practice. In view of this background, plenty of articles and trials are emerging out in various journals every day. Among all types of study design, randomized control trial (RCT) is considered as supreme in terms of strength of evidence. Appropriately planned and vigorously conducted RCT is the best study design to see the intervention-related outcome difference, but simultaneously poorly conducted biased RCTs will misguide the reader. It is ideal to read RCTs and optimize clinical practice, but it is critical to understand strong and weak points of those RCTs before being dogmatic about their result or conclusion. There are many methods to appraise the RCTs, but in this article, I tried to simplify the points under 5 headings with mnemonic "5Rs" that helps to understand things in better way (Flowchart 1).

STEPS FOR CRITICAL ANALYSIS OF RANDOMIZED CONTROL TRIALS

Formulate Right Question/Address Right Question

As Claude Lévi-Strauss said, "The scientist is not a person who gives the right answers. He is one who asks the right questions."

It is crucial to look for right question that possesses characteristic such as innovative, practice changing, knowledge amplifying, and above all having some biological plausibility.

*Is Randomised Control Trial Address New/Relevant Question?
Does Answer to this Question Lead to More Information that
Will Help to Improve Current Clinical Practice or Knowledge?*

Questions arises from any of topic are mostly of two types: background questions and foreground questions. RCTs are the experimental design that usually target foreground questions that are more specific to establish intervention/drug and their effect/outcome relationship. Foreground research question has four components to get relevant information like Population,

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Intervention, Control, and Outcome (PICO format). Whether study question and design are ethical and feasible for relevant population can be decided by FINER criterion.¹

Outcome are the variables that are monitored during study to observe presence/absence of impact of intervention on desired population. Outcome is also labeled as events or end points. Most common clinical end points are mortality, morbidity, and quality of life. It is decisive to choose right end point with their background knowledge and its relevance to formulated question (Fig. 1).²⁻⁴

So, it is evident that no single end point is perfect, but end points should be assessed in the context of clinical question, power, and randomization.

Is Cause and Effect Having Biological Plausibility?

Biological plausibility is one of the essential components to establish that correlation means causation. Just mere association or having significant p value without biological plausibility is like beating a dead horse (purely punitive). That means statistically significant data make least sense or should be interpreted with caution if they lack biological plausibility, and data that are unable to give statistical significance but have strong biological plausibility with vigorously conducted study should be evaluated again and discussed before rejection.⁵

To determine whether correlation is equivalent to causation, many criteria and methods are available. One of such criteria is Bradford Hill criteria. It is also important to understand that

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