

Is there a Place for Case Reporting in a Randomized Controlled Trial Era?

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The case report is the written mirror of a striking duality: the low level of evidence supported by a single case and the scientific breakthrough of someone's judge when facing something new. The knowledge-box is well defined in every textbook or main article we may find. However, when confronted to the unknown or unexplained, this box can only support the jump to the unknown as it doesn't contain all the answers. Only the continuous restlessness of an unconfirmed clinician is able to achieve new answers and throw the first basis of a new development – the Case Report (CR).

This active observational state of mind is threatened by the huge global impact of Randomized Controlled Trials (RCTs). As opposed to the simplicity of a single report to highlight something new in the dark, the RCTs impose their selves as the rule in the field empowered by strong multidisciplinary organizations strongly supported by funding agencies. Statistically significant differences are now the golden treasure pursuit all over the world as they are the basis to our clinical practice. Basic scientists and clinicians are now rated according to their statistically significance achieves. Nowadays, RCTs have a game-changing effect in medical knowledge.

Is there a place for case reporting in a randomized controlled trial era? Undoubtedly yes!

The answer to this question relies on this well-known crude reality: there is no perfect trial. In fact, the inclusion and exclusion criteria while increasing the internal validity of the study limit its external validity. This represents the real focus of RCTs in efficacy – expected effect of a treatment in an ideal situation - rather than in effectiveness – expected effect of a treatment in actual practice. So, the RCTs conclusions cannot be simply transferred to our real patients as they may not fit the RCT trial patient. On the other hand, different RCTs designed to evaluate the same or quite similar research questions failed to achieve similar results (examples, CAVATAS trial [1] and CREST trial [2] for carotid stenting versus endarterectomy). Different study samples or statistical analyzes may justify these results but one cannot exclude the role played by inter-individual characteristics and specifications from everyone involved as possible co-explanatory factors. And it should not be forgotten that some questions can't be answered by a properly conducted RCT according to ethic or organizational limitations (examples: equipoise of the research question [3], unreasonable blinding). Nevertheless, RCTs are still the most significant studies to support Class A Evidence in medical knowledge. As the gold standard among experimental studies, RCTs remove potential bias in allocation of subjects, balance the known and unknown confounders between groups which

tend to produce comparable groups and are the best studies to estimate causal effects.

CR and RCTs should co-exist as a bi-directional duality. CRs should not be considered as examples that destroy the RCTs rules. Indeed, while RCTs need to state the common and known situation to define the standard of care, the CRs should alert for the individual and unknown situation that force to think outside of the box in a permanent reflexive clinical attitude.

References

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