Editorial

# Value of randomized controlled trials

Marco FERRARI
MD, DMD, PhD, FADM, Professor, Chairperson, Dean
University of Siena, Siena, Italy
Stomatology Edu Journal
Editor-in-Chief

Dear readers,

In the globalization era technology is rapidly advancing in all the fields of dentistry and there is an urgent need to collect longitudinal clinical data to be shared in the world dental community. Hundreds of laboratory studies performed following different techniques are continuously published in international peer-reviewed journals (with Impact Factor) and they are useful to provide comparative data among several products within the same category. Such investigations can potentially predict to some extent the clinical performance of new materials and techniques. However, in vivo trials based on predictable and reproducible protocols should always precede the large-scale clinical use of recently introduced products. Clinical validation is indeed a cornerstone of 'Evidence-Based Dentistry'. Such requirement is understandably strict with new adhesive materials, but it should be even more cogent when dealing with implant surgery techniques. Based on the Helsinki Declaration on the ethical principles for medical research involving human subjects, a clinical research protocol should preliminarily receive the written approval of the pertinent Ethical Committee, and should clearly state the study's inclusion and exclusion criteria. Patients should be fully informed on the objectives of the research, as well as on the methods and possible related risks. The patients' written informed consent to the study should be obtained. All the researchers performing clinical studies should conform to this policy and the editorial boards of scientific journals should verify that all the requirements are met. However, by reading some of the internationally published literature, the impression can be gained that ethical issues are not always given the due attention by the authors and then also overlooked by the journals reviewers. It is not uncommon that published papers are found to miss relevant details on the ethical aspects of the clinical study, such as whether or not the protocol was approved by a pertinent Ethical Committee, what were the contents of the patient informed consent, who was the principal investigator. Such defective information can indeed limit the scientific value of the research. Moreover, some published clinical studies have been conducted in countries where the regulation on research in humans is more permissive than that of the Helsinki Declaration. Not to mention that false declarations, although disreputable, are always possible.

Those we agree that credibility is the highest quality of a researcher cannot escape the feeling that in some studies patients are used as experimental animals or even worse, if one considers that in some advanced countries animal research is actually strictly ruled.

Certainly, imposing a more ethical approach to clinical research will not be an easy task. Nevertheless, against this perspective, it would be advisable if peer-review journals could request, as a condition for publication of clinical studies, that the authors provide evidence of the Ethical Committee approval and if reviewers could verify with the authors a proper list of required ethical issues related to the study have been properly addressed. Although such a policy would predictably, initially affect the submission rate of clinical studies, however it would also limit the dissemination of research that does not have a solid, ethical foundation.

Sincerely yours,

M. Ferrari
Stomatology Edu Journal
Editor-in-Chief

https://doi.org/10.25241/stomaeduj.2021.8(1).edit2