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EDITORIAL

Parachuting in the evidence-based dentistry minefield

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In December 2013, the scientific community celebrated 10 years since the publication of the cornerstone article by Smith and Pell,[1] titled "Parachute use to prevent death and major trauma related to gravitational challenge: a systematic review of randomized controlled trials". The paper concludes that "the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomized controlled trials". Furthermore, the authors suggested that society may benefit "if the most radical protagonists of evidence-based medicine organized and participated in a double-blind, randomized, placebo-controlled, crossover trial of the parachute". In other words, the authors suggest an experimental design in which two groups will be equipped with parachutes prior to jumping out of a plane. The control group will have a "placebo" parachute; ie, a parachute package that is not designed to open. Subjects will be randomized into the groups, so they will not know which parachute is placebo or active.

Although the article was published lightheartedly, the authors demonstrated a very serious point: there are interventions whose efficacy cannot be proved through a randomized controlled trial (RCT) design. Ethical or other practical limitations preclude a non-equivocal result that, according to the "most radical protagonists of evidence-based medicine", can be obtained only through an RCT.

If we accept the axiom that RCTs are the best design to evaluate the impact of an intervention or treatment, the next challenge is Rossi's "Stainless Steel Law of Evaluation".[2] This empirical law states that "the better designed the impact assessment…, the more likely is the resulting estimate of net impact to be zero"; ie, more rigorous designs are more likely to show no effects.

The medical and dental professions are driven by the search of best-available evidence to provide the best possible outcomes in tandem with patient's preferences. It is widely accepted that the best way to synthesize and interpret the evidence is by analyzing it through a systematic review methodology. As it became evident that this methodology is used without consistency, tools such as "assessment of multiple systematic reviews" (AMSTAR) were developed. Addressing the consistency challenge, in 1993 the Cochrane Collaboration was founded with the task to "prepare, maintain and disseminate systematic, up-to-date reviews of RCTs of health care, and, when RCTs are not available, reviews of the most reliable evidence from other resources".[3]

Although the Cochrane approach made sense and provided hope for a reliable reference source that will help clinicians and other decision makers to gain easy access to conclusions based on best-available evidence, it turned out that Cochrane reviews include mainly RCTs. In 2010, 16.7% of the Cochrane reviews published in the Oral Health section were "empty reviews" with no studies included; these reviews stopped short of including the best-available evidence once the determination was made that no RCTs were available. These empty reviews, together with a vast amount of Cochrane reviews that cannot reach conclusions because not enough "high-quality evidence" exists to allow bias elimination, contributed to what appears to be a generalized disappointment among some clin-

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icians and policymakers.[4] If we consider the Cochrane Collaboration as an experiment designed to confirm or refute Rossi's Stainless Steel Law of Evaluation, it seems that the results tend to confirm it; the more rigorous the review process, the less evidence there will be included to suggest that the intervention is effective.[5]

In response to this situation that leaves the clinician perplexed and helpless, the American Dental Association (ADA) created the Center for Evidence-Based Dentistry (http://ebd.ada.org/), which provides systematic reviews and clinical recommendations that are not limited to including only RCTs, but analyze results provided also by lower-level experimental designs. Clinical recommendations are presented together with the strength of the evidence that generated the recommendation, therefore allowing clinicians to evaluate how to incorporate a certain procedure in their practice.

Evidence-based dentistry (EBD) will continue to be the basic concept guiding dental education and practice in the foreseeable future. We have to embrace and apply EBD on a daily basis in the classroom and the clinic, but we also have to approach and apply it in a responsible way that ultimately will benefit our patients. We cannot continue to ignore evidence generated by thousands of researchers around the globe based only on the fact that the research design is not an RCT. We, as a profession, have to continue and encourage our peers who dedicate their careers to EBD to provide us with tools that are realistic and beneficial.

As for me, even though I am not a fan of extreme sports such as sky-diving and therefore do not consider myself a specialist in the field, I do not need an RCT to be convinced that parachute use prevents death and major trauma related to gravitational challenge.

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