New Trends in Clinical Periodontal Research

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Abstract

Clinical research in required in each and every field so as to unveil the newer inventions which come in our way with the improvement of knowledge. Various articles are published to provide the knowledge world-wide regarding the updates in dentistry. Evidences are required so that they can bridge the theoretical knowledge to clinical practice. This aricle simplifies the issues related to designing, conducting and interpreting the study designs. This understanding will help the researcher to translate any scientific phenomena into clinical practice.

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Introduction

Very large numbers of papers are brought out each year that report all facets of periodontology, with their prime aim being to ameliorate the clinical management of periodontitis, a hugely widespread and abominable inflammatory disease that can have a substantial impact on quality of life. Yet, at the end of each research paper, the decisions are contained in competent terms, often with requirements for more research to be undertaken which is logical given the intricacies and the costs of leading research, predominantly clinical research. So far, progress is made nevertheless. We have made enormous developments in our understanding of the pathogenesis of this complex disease and the best means to treat it over the last 40–50 years.[1]

Possession of pace with the research developments as they are published can be a daunting task for experienced periodontal researchers and can feel all but impossible for those of our colleagues who are principally engaged in clinical periodontal practice.

How to Conduct Clinical Research

Pihlstrom et al. present this question in the setting of the reputation of evidence-based clinical practice – after all, we all require to know which treatments are the most effective for dealing specific clinical conditions .[2] The authors contend that randomized controlled trials are needed in periodontal research as they deliver the supreme level of reasonable suggestion concerning the effectiveness of particular treatments.

An enormous sum of thorough planning to confirm that they can answer the research queries that has been postured. In their paper, the authors take the reader progressively through all the phases of directing a clinical trial including protocol development, asking the correct research question, and deliberate statistical significance, clinical implication and influence. They designate the diverse types of clinical trials, such as efficacy studies, effectiveness studies, superiority studies and non inferiority studies. In detail explanation of the significant subjects of research governance related to directing a clinical trial, together with trial management and oversight, and the position of the Data Safety and Monitoring Board is given. Many periodontal researchers will discover this to be a precious guide of how to complete all types of clinical studies (not just randomized controlled trials). The facets relating to inclusion/exclusion criteria, informed consent, randomization, data collection, data management and data verification are considered by the authors. The issue of reporting clinical studies is also defined in detail, including clear supervision on authorship, which should demonstrate to be very beneficial for resolving the problems that are sometimes confronted when making conclusions about who within a research team merits being registered as an author. This commanding and existing paper is a unique resource for all who are involved in clinical periodontal research.

Williams et al. endure this debate of the role of randomized controlled trials in modern periodontal research.[3] They admit that randomized controlled trials are considered virtuous for science and for rendering knowledge, but what about the patients who contribute in them? Is there an advantage for these individuals? Those of us who are associated in clinical research are well alert of the burdens that can originate when registering patients to a clinical trial. As their clinician, we know the consequences that we are probable to attain by providing their treatment as part of routine clinical care, and we adjust the treatment to the precise requirements of the distinct patient. But, if we enroll the patient into a clinical trial, will the similar value and amount of care be provided? Periodontal clinical trials usually have very apparent treatment procedures stated in the study protocol, which may occasionally differ from what we might accept in routine clinical practice.[4] The study protocols characteristically treat all patients in the trial in precisely the same way, so that the only variable is the interfering of interest. The quality of the data resulting from clinical trials rest on on the experience, knowledge and skills of the clinical examiner(s) who are assessing the patients.

Therefore, training and standardization of clinical examiners is an essential constituent of clinical periodontal research, yet is often disregarded, or addressed in a very casual manner, in many research publications. An additional problem is that many of the scoring systems we use (such as plaque and gingival indices) are rather subjective, with much room for explanation of the scoring criteria by the clinician.

According to US National Institutes of Health[5], Clinical research is termed as research with human subjects that includes:

(i) Patient-oriented research,

(ii) Eepidemiologic and behavioral studies, and

(iii) Outcomes research and health services research.

Two elementary categories of clinical research are: observational and interventional. Observational studies are characteristically conducted early in the life cycle of the investigation, while interventional studies originate later when precise research questions are better demarcated. Each assist to improve knowledge and each has some strong point and shortcomings. Observational studies eyewitness and quantify disease amongst groups of individuals. No interfering is presented and the investigator does not perform any measures that disturb the condition being calculated.[6] If observations are made by seeing forward and collecting new data, the study is considered prospective; if previous data (such as found in dental records) are considered, the study is retrospective; if new data are gathered at the current time only, the study is cross-sectional.

Types of Clinical Research

1) Observational Research:

A) Case Studies/Case Series

B) Cross-Sectional Studies

C) Case-Control Studies

D) Prospective Cohort Studies

2) Interventional Research:

Clinical Trials

a) Phase 1-Early safety studies

b) Phase 2- Preliminary efficacy and safety

c) Phase 3-Definitive efficacy and safety

d) Phase 4-Postmarketing surveillance

Observational study designs include case reports, case–control studies and cohort studies.

Case Reports

Case reports denominate clinical features and treatment conclusions about individual patients or groups of patients. These direct the weakest evidence for clinical decision making; however, they may deliver a basis or background for producing a testable hypothesis.[7] While reporting a rare form of pneumonia (caused by Pneumocystis carinii) which was prevalent among young adult male homosexuals in 1981, the examiners were able to identify and characterize AIDS is an example of case reports.[8]

Case–Control Studies

In a case–control study, individuals with a definite disease (cases) are equated with others deprived of the disease (controls) for introduction to various risk factors that may have been connected with the disease or

condition. Controls must be cautiously coordinated to the cases for numerous demographic or other identified risk factors for the disease being calculated. One can evaluate the probabilities of developing the disease in the presence of numerous introduction factor(s) by equating cases and controls.[9] For example: Offenbacher et al. conducted a study in which the comparison was made between 2 groups of women : first group consists of 93 women who gave birth to preterm or low-birthweight babies while the second group consists of 21 women who had full-term, normal-birthweight babies. According to their report they concluded that periodontal disease (exposure) acted as a statistically significant risk factor for preterm, low birthweight (odds ratio = 7.5; 95% confidence interval = 1.95–28.8).[10]

Cross-Sectional Studies

Often, a group of individuals share mutual features that permit the prevalence of a disease or condition to be expected. Prevalence is defined as the sum of individuals with an explicit disease at a particular time. In this design, measurements are made in a population to evaluate the prevalence of a condition or various factors connected with health or disease. For example: Solis et al. conducted a study in which they found no relationship between anxiety or depression and the presence of periodontitis.[11]

Prospective Cohort Studies

Prospective cohort studies, also called longitudinal cohort studies, make available stronger observational indication for etiology and outcome in comparison with cross-sectional or retrospective observational studies. A cohort is a group of individuals is considered as a cohort, and prospective cohort studies are frequently used for estimation of the incidence of a disease. An example is of Beck et al. who surveyed 1,147 men and found that periodontal bone loss was connected with the cumulative incidence of coronary heart disease and stroke.[12]

Interventional Research

Contrary to observational studies, interventional research includes doing something to participants or their environment, such as giving treatment for a disease in the form of a procedure, drug or other agent that is being verified for safety and effectiveness. Extents of the treatment consequence are then measured to regulate how the intervention impacts participant health or behavior.

Clinical Trials

A clinical trial is demarcated as a forthcoming study equating the consequence and worth of intervention(s) against a control in human beings.[13] Clinical trials are intended to answer definite questions about biomedical or behavioral interferences, including new drugs, treatments or devices, or new methods of using known drugs, treatments or devices. They are used to regulate whether biomedical or behavioral interventions are safe, efficient and effective.[14]

Phase I Clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to assess safety (e.g., to ascertain a safe dosage range, and to detect side effects).

Phase II Clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III Studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV Studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.[14]

Randomized Controlled Trials

Randomized controlled trials are perceived by many people as the standard by which all clinical research is pronounced. Randomized controlled trials are every now and then declared to as randomized clinical trials, even though this terminology is not as much of accurate since not all randomized controlled trials are restricted to the clinical setting. An appropriately implemented randomized controlled trial delivers the firmest indication for the effectiveness of preventive and therapeutic measures. It is ingenious to be the most consistent form of scientific evidence because it can minimalize preconceptions that may compromise the rightfulness of medical research. Randomization can be stated as a means of attributing participants to study groups in a way that the known and unknown factors are balanced in order to minimize bias.[13] Randomization of participants for a trial is very different from random sampling. When the population selected is a truly a random sample only then the results can be generalized to that population.[15] Dentistry has come in a new period of evidence-based practice. Clinicians, patients and society are asking for prevention and the distribution of treatment that has been recognized to be effective in relation to substantial health outcomes. Huge, multicenter randomized controlled trials are the "gold standard" of evidence-based practice and there is a strong requirement for more of these trials in oral health research. Randomized controlled trials are academically simple but operationally very complex, challenging and expensive.

They necessitate teamwork among investigators, enrollment sites and data-coordinating centers. Furthermore, to authorize protection of human subjects and extensive acceptance of results, clinical trials must encounter rigorous regulatory, institutional, sponsor, funding agency and publication requirements. Though, if appropriately planned and implemented, controlled clinical trials and transformation of their outcomes into clinical practice will result in enhanced patient care and public health.

To conclude, clinicians need to repeatedly update on treatment choices, modalities and validation as new research emerges. By following a systematic method, evidence can be considered and applied to clinical practice. This approach is standardized and repeatable, and enables the practice of evidence-based dentistry. The submission of evidence is vital in modern dentistry, and this approach is the central part of the evolution in the direction of an evidence-driven practice.[2]

Conclusion

Evidence-based practice is of prime importance nowadays. In today□s time, society demands preventive and treatment options that have been proven to have significant outcome. RCTs act as "gold standard" in the field of clinical research. Properly designed and executed studies fulfill the basic purpose of opening new gates for advancement in terms oftechniques/procedures used in clinical practice.

References

1. Preshaw PM. Critical isssues in clinical periodontal research. Periodontology 20002012;59:7-13.
2. PihlstromBL,Curran A, Voelker HT, Kingman A Randomized controlled trials:what are they and who needs them? Periodontology 2000 2012;59:14-31.
3. Williams KB, Glaros A, Walker MP, Cobb CM. Randomizedclinical trials: is periodontal research good for patients?Periodontol 2000 2012: 59: 32–40.
4. Armitage GC. Effect of periodontal therapy on generalhealth – is there a missing component in the design ofthese clinical trials? J Clin Periodontol 2008: 35: 1011–1012.
5. NIH DHHS Office of Extramural Research. Glossary andacronym list.http://grants.nih.gov/grants/glossary.html.accessed October 2011].
6. Rosenbaum PR. Observational studies. New York: Springer-Verlag, 2002.1-17
7. OCEBM Levels of Evidence Working Group. The Oxford2011 levels of evidence. Oxford Centre for Evidence-BasedMedicine. http:http://www.cebm.net/index.aspx?o=5653[accessed October 2011].
8. Gottlieb MS, Schroff R, Schanker HM, Weisman JD, Fan PT,Wolf RA, Saxon A.Pneumocystis carinii pneumonia andmucosal candidiasis in previously healthy homosexualmen: evidence of a new acquired cellular immunodeficiency.NEngl J Med 1981: 305: 1425–31.
9. Rothman KJ. Epidemiology: an introduction. New York:Oxford, 2002.1-27.
10. Offenbacher S, Katz V, Fertik G, Collins J, Boyd D, MaynorG, McKaig R, Beck J. Periodontal infection as a possible riskfactor for preterm low birth weight. J Periodontol 1996: 67:1103–1113.
11. Solis AC, Lotufo RF, Pannuti CM, Brunheiro EC, MarquesAH, Lotufo-Neto F. Association of periodontal disease toanxiety and depression symptoms, and psychosocial stressfactors. J Clin Periodontol 2004: 31: 633–38.
12. Beck J, Garcia R, Heiss G, Vokonas PS, OffenbacherS. Periodontal disease and cardiovascular disease. J Periodontol1996: 67: 1123–37.
13. Friedman LM, Furberg CD, DeMets DL. The randomizationprocess. In: Fundamentals of clinical trials. New York:Springer-Verlag, 1998: 61–81.
14. U.S. National Institutes of Health. ClinTrials.gov. http://clinicaltrials.gov [accessed October 2011].
15. Jadad AR, Rennie D. The randomized controlled trial gets amiddle-aged checkup. JAMA 1998: 279: 319–20.