

J Clin Periodontol 2008; 35: 773–774 doi: 10.1111/j.1600-051X.2008.01300.x

Journal of Clinical Periodontology

Guest Editorial

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Key words: clinical trials; periodontitis; study design

Accepted for publication 23 June 2008

the research community? Hughes FJ. Assessing the effects of bias on the magnitude of outcomes in clinical studies: lessons for the research community? J Clin Periodontol 2008; 35: 773–774.

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The drive for a sound evidence-based approach to clinical practice has been a prominent feature of the medical and dental specialties over the past 10 years. Within the clinical practice of periodontology the desire for an evidencebased approach reflects the belief that our discipline has a mature outlook and a wish to implement best practice based on the scientific literature. However despite the recognition of the value of a good scientific evidence base for our discipline, it is easy and may be tempting to overlook reports addressing methodologic issues in clinical trials and dismiss them to the niche market of professional statisticians and clinical academic researchers.

doi: 10.1111/j.1600-051X.2008.01300.x.

In the paper published in this issue, Fenwick and colleagues ask what at first glance might look to be a very "dry" question indeed: does the introduction of bias in a clinical study influence the magnitude of the clinical outcome? (Fenwick et al. 2008). Furthermore, it looks even more unpromising given the qualifying statement " – a pilot study." However an examination of this article will show that it is asking a fundamentally important question for all who seek to base their clinical practice on solid clinical evidence.

The randomized controlled trial (RCT) is considered to be the "gold standard" for clinical testing of the efficacy of treatments, because of its ability to avoid bias in a study through,

for example, patient selection, treatment allocation or measurement. Reports in the medical literature have described previously that where randomization procedures to allocate patients to test or control groups are inadequate, the potential bias introduced to the study can result in considerable increases in the size of the positive outcome of a study (Schulz et al. 1995, Berger 2005). In addition the failure to "blind" adequately an examiner from the patient group can also increase treatment outcome. Here Fenwick and colleagues ask the same question of studies of periodontal treatments. That is, does the introduction of bias through inadequate study design result in a measured increased effect of the treatment see in trials of periodontal treatments? Put simply, the question is whether some of the reported benefits of periodontal treatments may simply be the result of bias in the studies rather than a real effect. The reductionist question can be brought down to asking: how reliable is much of the clinical trials literature in periodontal treatment?

In order to address this question, the investigators identified all papers reporting RCTs that used probing depth or clinical attachment level (PD or CAL) as an outcome measure that had been cited in Cochrane systematic reviews. The objective then was to investigate if those papers with a higher probability of bias on the basis of judged inadequate allocation concealment or examiner masking had a higher treatment effect on PD or CAL than those studies with a low risk of bias. There are some technical methodological issues that could be raised with this methodology, which are discussed in the paper. Firstly, pooling all these studies using PD or CAL as outcome measures results in a very diverse group of studies investigating a whole range of treatments and processes in periodontology and implantology. This might in itself risk introducing some bias to the data. For example (as a purely hypothetical illustration) it is possible that the quality of study design has improved over the years, and equally periodontal treatments might have improved over the years, resulting in the likelihood of finding improved treatment outcomes in well-designed studies. Secondly this study might have excluded most of the studies most prone to bias because of their initial search strategy. However, notwithstanding these reservations the methodology is reasonable and a sound, pragmatic approach to addressing the question.

Unfortunately, despite the importance of the question, and the reasonableness of the approach used here, ultimately the authors are unable to answer definitively their initial question. From the 36 studies eventually included in the study there was no difference found between outcomes in those studies with high or low risks of bias. However this finding is not able to exclude the possibility that there is an effect, but only that there is insufficient data to reach a firm conclusion. Clearly if we think this is an important question, the finding here is disappointing. The authors further calculate that up to 265 RCTs might be needed to give sufficient power to answer the question definitively. This raises the very practical issue of whether such a definitive study is even feasible in the field; perhaps we will have to continue to speculate about the role of bias in periodontal treatment RCTs?

The absence of direct evidence of the influence of inadequate study design on treatment outcomes does not exclude the likelihood that this is an important issue in periodontal research. Secondly, within this study nearly all of the papers that were assessed as not showing adequate allocation concealment were judged to be "not clear", rather than demonstrably "inadequate." That is, it was not possible to tell from the description of the methodology in the paper.

So what conclusions are we to draw from this study and the issues surrounding it? Firstly, the clinician seeking to implement best practice based on the evidence base needs to be able to look at the literature critically, and should be

conversant with the principles of good study design. For clinical researchers the importance of proper careful study design, and full reporting of methodology is clearly emphasized here. For journal reviewers and editors there is a huge responsibility to ensure that studies are both adequately designed to avoid sources of bias, and particularly are adequately reported to enable evaluation of the work. Considerable progress has been made in recent years in considering these issues. There are plenty of guidelines and expertise on study design and publication such as the CONSORT guidelines, and many journals, this one included, now require completion of CONSORT checklists as part of the review process (Altman et al. 2001, Moher et al. 2001). Ultimately addressing the importance of study design will continue to enhance the evidence base for the practice of periodontology.

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