Guidelines for Reporting Pre-clinical In Vitro Studies on Dental Materials

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In vitro pre-clinical research is an important aspect of the development of new dental materials and techniques, because it can provide essential information for further testing of therapeutic approaches in clinical trials. These pre-clinical experiments should therefore be reported with the same rigor as studies involving humans. The objectives of this paper were twofold: (a) to search and assess existing guidelines for reporting in vitro studies in dentistry, and (b) to present a methodology for reporting these studies, based on the CONSORT checklist for reporting randomized clinical trials. After a comprehensive search in PubMed database, no guidelines for reporting in vitro studies in dentistry were found. The proposed methodology is presented and the rationale for the choice of fourteen guidelines for producing the different sections of such papers is described in detail. The assessment of a sample of in vitro studies using the proposed guidelines showed that the standards of reporting should be improved. Good standards of reporting of studies are necessary for improvement of efficiency in dental research. The guidelines presented are the first standards for reporting in vitro studies in dentistry. As with the original CONSORT document, the modified checklist is evolving. It should, therefore, be further tested by researchers and the results of these assessments should be used for further improvement of this tool.

Keywords: In vitro, Quality of reporting, Dental materials, Guidelines, Pre Clinical, CONSORT checklist.

INTRODUCTION

In vitro research for assessing potential new materials or techniques to be further tested in vivo, i.e., on animals and humans, is an important aspect of dentistry. One advantage of in vitro research is that it enables researchers to perform single-variable experiments under controlled conditions.[1] Although in vitro research cannot reproduce a dynamic environment, for example the stomatognathic system, pre-clinical experiments can provide important information about the properties and characteristics of a new material or technique. This information is of fundamental importance when testing efficacy in more robust studies, for example randomized clinical trials. It is, therefore, necessary to conduct in vitro research of the highest possible standard. Biased information from pre-clinical experiments is likely to lead to biased clinical studies.

In restorative dentistry many studies test the biocompatibility and/or toxicity[2] and efficacy of dental materials, for example composites, using extracted animal or human teeth.[3-6] Because systematic reviews of dental in vitro studies are becoming frequent,[7-10] maximization of the output from such research is essential. Moreover, good standards in reporting are

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required to provide interested people—readers, researchers, and editors—with detailed information indicating whether the research was appropriate and which aspects might need more scrutiny.[11] Some efforts were made in the last years to improve the quality of reporting of scientific literature. For example, the Consolidated Standards of Reporting Trials (CONSORT) checklist was developed to assist authors in writing reports of randomized controlled trials.[12] Although the CONSORT checklist was not originally designed for designing, conducting, and analyzing trials, its use may indirectly affect their design and conduct.[12]

The objectives of the present work were twofold: (a) to critically assess the literature on guidelines on the report of in vitro research in dentistry. The focus was on guidelines for reporting in vitro studies, instead of performing some specific experiment; and (b) to describe a checklist developed for reporting pre-clinical (in vitro) studies of dental materials, using modified items described in the CONSORT checklist. A sample of in vitro studies was tested with this new methodology and the results are presented. The idea is to improve conducting and reporting of pre-clinical testing of dental materials with potential for use in clinical treatment as to possibly minimize bias and optimize efficacy for subsequent RCTs.

MATERIAL AND METHODS

Search of Guidelines for Reporting In Vitro Studies

On 10 August 2012 a comprehensive search of the literature was performed in the PubMed database using the following key-words: *in vitro, in-vitro, preclinical, pre-clinical, reporting, CONSORT, recommendations, guidelines, dentistry, dental implants, and teeth.* The key-words words were combined using boolean operators *AND/OR.* The search was focussed only on guidelines for reporting any form of in vitro studies performed in teeth and dental implants. Guidelines relating to other forms of preclinical research (for example, experiments in animals) were not selected, because there are already specific guidelines for those studies.[13-15]

Description of New Checklist

The checklist proposed below contains 14 items enabling assessment of the standard of reporting in the different sections of a paper. See Table 1:

Checklist Items

Abstract. *Item 1. Structured summary of trial design, methods, results, and conclusions*

Explanation: the abstract should contain enough information to enable good understanding of the rationale for the approach. Because many readers do not have free access to the full text of articles to assess the validity of results,[16-18] they may rely on reading the abstract to make conclusions. Use of structured abstracts for reporting studies is recommended, because they enable easier access to the information reported.[19]

Introduction. *Item 2a. Scientific background and explanation of rationale*

Explanation: authors should provide direct and clear information about the background of the material or technique to be tested in the proposed experiment. In in vitro dental studies, similar previously published studies on the topic in question should be reported in detail to enable good comprehension by readers of the potential efficacy and limitations of the current experiment. The rationale for the new project should be explained in detail to avoid duplication of studies and consequent waste of resources.

Item 2b. Specific objectives and/or hypotheses

Explanation: the objective(s) of the study, with a defined hypothesis, should be reported in the introduction. The hypothesis is based on a well-developed research question (for example, use of the PICOT [population, intervention, comparison, outcomes, and time] format) and it should guide the objectives of the research.[20] Hypotheses are more specific than objectives and can be tested statistically to help meet the objectives of the project.[21]

Methods. *Item 3. The intervention for each group, including how and when it was administered, with sufficient detail to enable replication*

Explanation: to enable replication of the results by other interested researchers, authors should report the approach used in the experiment. Replication is regarded as one of the cornerstones of inference from experimental studies.[22,23]

Specific information on the type of intervention performed in the control and test groups should be described in detail. For example, when testing the effect of different adhesive systems on the surface of extracted human teeth, information on how the test specimens were prepared, etching time, procedures used to apply the adhesive, polymerization time, etc., should be provided.

Item 4. Completely defined, pre-specified primary and secondary measures of outcome, including how and when they were assessed

Explanation: it is important to precisely state the primary (and secondary) outcome(s) of the proposed experiment to enable comparison with results from similar studies. The validity of a study might be questionable if it does not enable comparison, and this can be a problem when the whole body of evidence is assessed in systematic reviews with meta-analysis, for example.[24]

Item 5. How sample size was determined

Explanation: in the planning of a randomized clinical trial, determination of the correct sample of patients enabling detection of true differences between therapies