Some issues in applied statistics in clinical restorative dental research

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Chapter 9

Summary
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Introduction

In this thesis three themes are discussed which may cause difficulties in clinical restorative dental research: observer variation, survival data from a split-mouth design and cost-effectiveness analysis. The aim is to compare different ways to handle these issues and to make suggestions for clinical restorative dental research.

Observer variation

The first theme is observer variation. Observer variation is an important problem for the reliability of clinical assessments. There are different ways to describe observer (dis)agreement. In Chapter 2 these methods are compared for the case in which marginal adaptation of composite restorations are assessed by two dentists. Marginal adaptation is a generally accepted characteristic of restoration quality. It is concluded that a kappa coefficient with confidence interval combined with a McNemar's test is sufficiently informative. Log-linear modelling does not add much in this particular situation. Although sometimes reported in the literature, percentage agreement is not very informative and is to be avoided. It is expected that these results also hold for other quality characteristics with a skewed frequency distribution, such as marginal disoloring.

In Chapter 3 the additional value of log-linear models is shown for the case where observer agreement depends on material. Log-linear modelling enables to look at observer variation and material performance at the same time. It is shown that the material that can be best assessed is not necessarily the best performing material.

Survival data from split-mouth designs

The second theme involves survival data obtained in a split-mouth design. In a split-mouth design multiple restorations are made in the same patient. Often, a possible patient effect is ignored in the data-analysis: the multiple units within a patient are regarded independent observations. There is yet no ready to use statistical method which can handle survival data from a split-mouth design. In Chapter 4 the Kaplan-Meier estimator which does not take the multiple units within patients into account, is compared with two methods which answer a slightly different question but do allow for a patient effect: logistic regression with a random component and a slightly adapted Friedman statistic. From these analyses it is concluded that the restorations within one patient can not be regarded independent. For now, logistic regression with a random
component is a suitable alternative for extremely complicated new techniques if it makes sense to limit the research question to survival of a certain period. In Chapter 5 logistic regression with a random component is applied to compare different treatment modalities for class II amalgam restorations. The treatment modalities have little effect on the risk on replacement within 15 years although clinical factors such as dentist, type of restoration (MO/DO or MOD) and -less evident- type of tooth (molar or premolar) do.

**Cost-effectiveness analysis in dentistry**

The third theme is cost-effectiveness analysis. Taking the increasing difficulties with resource allocation into perspective, economic evaluations can yield very useful information. In the field of dentistry few economic evaluations are published and their quality is often rather poor.

To increase the quality of economic evaluation guidelines were suggested in the scientific journal BMJ. These guidelines are described and critically appraised and illustrated with an example in Chapter 6. There seems little attention for ethical and methodological/statistical problems. Hence some changes are suggested.

In Chapter 7 relative cost-effectiveness is investigated of composite resins and amalgam for the replacement of old class II amalgam restorations. Five years after placement, all composite as well as all amalgam restorations are still in situ. The amalgam restorations have perhaps a slightly worse marginal adaptation but the composite resins need probably more often repair. A composite resin restoration takes about twice as much time to make as a similar amalgam restoration. So, rerestorating old amalgam restorations with composite resins instead of amalgam is equally effective but about twice as expensive.

**General discussion**

In Chapter 8, the general discussion, the significance and limitations of our studies are described. For each theme, recent developments are discussed, conclusions drawn and suggestions made. In addition, three general developments are described which will influence clinical research with respect to methodology, statistics as well as research questions. These developments necessitate more efficient handling of improved quality data. This is only feasible if dentist-researchers and statisticians cooperate more intense. The clinical researcher should be better aware of the quality gain by involving a methodologist-statistician early in the process. The methodologist-statistician should refrain from indulging in mathematics and keep the practical demands from the dentist-researcher in mind.