Reviewer's report

Title: The Hall Technique; a randomised control clinical trial of a novel method of managing carious primary molars in general dental practice: outcomes at two years.

Version: 3 Date: 15 July 2007

Reviewer: Paulo Nadanovsky

Reviewer's report:

General comment

1- This was a very interesting and highly relevant study. The tested intervention is simple and does appear to be comfortable for the patient and effective for the treatment of dental caries in primary teeth. The study adopted a pragmatic approach, which reflects more accurately the reality of clinicians and patients in every day real life circumstances, than most traditional clinical trials do.

Specific comments

Title

2- Instead of “randomised control clinical trial”, may be it is better “randomized controlled clinical trial”. Not only in the title, but also throughout the text, this term should be changed as suggested.

Introduction

3- The authors should avoid the discussion about “to fill or nor to fill” primary teeth. Their study did not deal with this question. They compared different restorative techniques, but did not assess the effectiveness of not restoring the teeth. They focused specifically on the performance of preformed metal crowns, comparing them to conventional restorative techniques.

The authors relied too heavily on the study by Pine et al. (2006), to conclude that it is in the best interest of the child to restore their decayed primary teeth than not to restore them. In the study by Pine et al 2006 (reference 12 in their manuscript), according to their regression model, restorations increased the chances of sepsis (odds ratio 1.15). It is noteworthy that the number of filled teeth in their sample was very small. Relatively few dentists filled primary teeth; possibly, their sample included preferentially less complex cavities and/or fillings placed by especially skilled dentists. Also, Pine et al. (2006) did not include in their regression model, the total caries experience (dmft). It appeared that dmft was an important predictor of sepsis. Pine et al. (2006) did not comment on either of these points. The social class, income and education of the parents were not considered in their analysis (deprivation score of residential area is a contextual variable; contextual socioeconomic variables have consistently shown
much lower associations with disease at the individual level than individual socioeconomic variables. Thus, the confounding effect of socioeconomic factors was poorly controlled in Pine et al). These factors are related to increased risks of most diseases and may increase the chances of sepsis, through poorer diets, lower tooth-brushing frequency with fluoridated toothpaste and other social related factors. For these and other reasons the group of children with untreated decay and the group with treated decay were not comparable, in Pine et al (2006). Also, the relatively few children with treated decay in Pine et al (2006) may not allow a wider generalization of the treatment effect. Therefore, Pine et al. (2006) study was not strong enough to allow the authors of the present manuscript to conclude that “The question should not be whether it is necessary to restore carious primary teeth, but instead how best to do so in the Primary Care environment so as to lead to a reduction in pain and dental sepsis.” Until now, there is not enough evidence supporting the view that the pain and psychological distress caused by restorative dental treatment are worthwhile costs to pay, on average, for children with one, a few or several decayed teeth, at every age.

A better justification for the present study is that, despite the fact that it is still not known whether it is better for the children to restore (or not to restore) their decayed primary teeth (references 4, 6, 12), many dental practitioners do restore them. In this case, it is important to assess the effectiveness of different techniques available to dentists, when they decide to restore a primary tooth.

Materials and methods

4- First paragraph is unaligned and in bold. Correct this.

5- The authors referred to a paper (reference 17), which is incomplete in the reference list (lacks the title of the journal, year of publication, volume and pages). Due to this error, I did not manage to have access to that paper. Thus, it was not possible to evaluate crucial aspects of the methods applied in the study.

“Further details of the study methodology, including entry criteria, randomisation, recruitment of patients, recruitment and training of dentists, and data relating to the placement of the restorations have been reported (reference 17).”

6- There is a sentence (“List of figures”), which is out of place (second line above “Power calculation”).

7- The study population needs to be better defined. Who are the participant children and dentists? Regularly attending patients or any patient with eligible teeth? Etc. This information should be given in the paper.

8- When more than two eligible teeth were present, how were the teeth selected? And what about the remaining teeth, how were they treated? Were both selected teeth treated at the same appointment? If not, what was the time interval between the appointments? This information should be given in the paper.

9- The Hall Technique PMC should be explained in more detail. In the title it is
claimed that this is a novel technique. But it appears that this is the usual stainless steel crown, popular in pediatric dentistry at least since the 1980s. May be the innovation is to use it without removing carious tissue and no tooth preparation, but this has to be explained in the methods section. So, it is not clear what is new about the technique and being new or not, the intervention procedure should be clearly explained in the methodology. For example, it should be explained how it is possible to fit a crown without any prior tooth preparation, and not to create a premature occlusal contact point with the antagonistic tooth, which could make the child feel uncomfortable due to the presence of a high restoration.

10- There was no explanation of how the data were analyzed. For example, what statistical tests would be applied to reject the null hypotheses? Include sub-section about data analysis in the methods.

Results

11- The reporting of major failures, of episodes of pain and of minor failures; as this was a split mouth design, it is appropriate to use statistical tests for paired data, in order to reject the null hypotheses.

Figures

12- All figures were identified as Figure 1. Correct this.

General

Comment 1.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Comments 3, 5, 7, 8, 9, 10, 11.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Comments 2, 4, 6, 12.

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Discretionary Revisions (which the author can choose to ignore)

None.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.