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Peer Review Report for "Clinical and Radiographic Success Rate of Pulp Treated Primary Molars Restored with Stainless Steel Crown (SSC) Versus Glass Ionomer-SSC: A Double-Blind Randomized Clinical Trial"

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Review Timeline:

Submit Date:	19 Aug 2019
Revised Date:	26 Nov 2019
Accepted Date:	28 Nov 2019

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (0) 23 Sep 2019

Dear AE,
Comments for the authors:
Background
1. The first paragraph needs references
2. Please refer also to the papers investigating the failure rate of pulpotomies as well as the SSC's failure rate.
Methods
1. Sultan's prefabricated formocresol contains: Formaldehyde 48.5%, Cresol 48.5%, and should be diluted to Buckley's formula.
In addition, this product is excluded from FDA approved products, because of safety and effectiveness concerns
2. Six months of follow up is not necessarily indicate the success of a newly examined method. It is advocated to report the results after at least one year. In the case of drop out in longer follow ups, the authors may analysis the demographics of those who missed the follow up, and declare the findings in results.

Results

1. The success rate of groups was not significantly different. There are two concerns here, first the number of cases in one table row was low, hence it seems that a second power analysis needs to evaluate the real power of the study. Second, no significant difference was reported, so why regression model was used for a non-significant impact calculation. Thanks.

REFEREE: Reviewer | **Revision** (0) 6 Oct 2019

Dear AE,

The authors' attempt for evaluation of Clinical and Radiographic Success Rate of Pulp Treated Primary Molars Restored with Stainless Steel Crown (SSC) versus Glass Ionomer - SSC is valuable. The manuscript is generally well-written and the study design is very good. Here are the points which need to be clarified or revised for possible publication:

1. There are some grammatical and typo mistakes throughout your manuscript. please correct them.

Abstract:

2. 47 children finally finished the examination and were analyzed. Please correct that in the method's section.

3. Bring the p-value of the first result.

Background:

4. Please bring the exact references for each sentence in the background section.

5. Please explain more about GI, it's advantages and disadvantages and the more complete reason of selecting it for your study in this section.

Methods:

6. Had all the children a periapical radiography for exact evaluation for need for pulpotomy? How you confirm the lack of radiographic sign before your treatment?

7. Please bring some pictures from stages of each treatment. At least from 2 types of buildup.

8. It's better to bring some example picture from your patients especially for the radiographic criteria of failure.

9. When the reevaluation was done? Only for the radiographies? How the clinical examinations were confirmed?

Results:

10. Finally, 47 children were finished the study process. Add this to your results

Tables and Figures:

11. The figures are not enough.

Best regards

REFEREE: Associate Editor | **Revision** (0) 8 Oct 2019

Dear EIC,

This manuscript was reviewed by our reviewers. The reviewers have raised concerns regarding the manuscript, and therefore, the paper is not acceptable for publication in this format. However since the reviewers do find some merit in the paper, I would be willing to reconsider if the authors wish to undertake major revisions and re-submit, addressing the

referees' concerns.
Thanks.

REFEREE: EIC | **Revision** (0) 8 Oct 2019

Dear Authors,
Thank you for submitting your manuscript to Iran J Pediatr. Your manuscript has now been reviewed by two reviewers and an Associate Editor. I now have the reports of the Referees, which suggest that your manuscript might be suitable for publication following a number of revisions. I attach some reviewer comments and invite you to submit a revised version of your manuscript addressing the points made.
Thanks.

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Dear editor

Thanks for considering my manuscript entitled "**Clinical and Radiographic Success Rate of Pulp Treated Primary Molars Restored with Stainless Steel Crown (SSC) versus Glass Ionomer -SSC: A Double-blind Randomized Clinical Trial**" as "minor revision required". The response to reviewers are as below:

Best regards

Reviewer 1:

Background

1. The first paragraph needs references. References were added.

2. Please refer also to the papers investigating the failure rate of pulpotomies as well as the SSC's failure rate. It was added in background part.

Methods

Sultan's prefabricated formocresol contains: Formaldehyde 48.5%, Cresol 48.5%, and should be diluted to Buckley's formula. In addition, this product is excluded from *FDA approved products*, because of safety and effectiveness concerns. In my opinion, there is no need to add the composition of formocresol in the text, because it is not the main subject of our project.

Paragraph 2 of discussion has addressed the adverse effects of formocresole. Although these effects of formocresole is certain, but in many recent studies in primary teeth this solution has still been used as gold standard for comparison with new materials. The main reason of being gold standard is its excellent success and ease in use. The list of some new articles using formocresole are listed below:

1. Madurantakam P. Is calcium hydroxide more effective than formocresol or camphor phenol as intracanal disinfectants in acute pulpitis among deciduous teeth? Evid Based Dent. 2019 Sep;20(3):86-87.
2. Kahvand M, Mehran M, Haghgoo R, Faghihi T. Clinical and Radiographic Evaluation of Allium sativum Oil (Garlic Oil) in Comparison with Formocresol in Primary Molar Pulpotomy. J Int Soc Prev Community Dent. 2019 Jul 8;9(4):390-395.
3. Chakraborty A, Dey B, Jana S. A Nonconventional Approach to Formocresol Pulpotomy. Int J Clin Pediatr Dent. 2018 Nov-Dec;11(6):490-495.
4. Kola SR, Reddy NV, Sneha T, Reddy MA, Niharika P, Kumar PJ. A histopathological comparison of pulpal response to formocresol and sodium hypochlorite used as pulpotomy medicaments: In primary teeth - A clinical trial A histopathological comparison of pulpal response to formocresol and sodium hypochlorite used as pulpotomy medicaments: In primary teeth - A clinical trial. J Indian Soc Pedod Prev Dent. 2019 Apr-Jun;37(2):198-204.
5. Brignardello-Petersen R. There are probably no differences in the success rates of pulpotomies in primary teeth performed with formocresol or Biodentine. J Am Dent Assoc. 2019 Jul;150(7):e110. .
6. Olczak-Kowalczyk D, Samul M, Góra J, Gozdowski D, Turska-Szybka A. Ferric Sulfate and Formocresol pulpotomies in paediatric dental practice. A prospective-retrospective study. Eur J Paediatr Dent. 2019 Mar;20(1):27-32.
7. Ghoniem N, Vaidyanathan V, Zealand CM, Sushynski JM, Mettlach SM, Botero TM, Majewski RF, Boynton JR, Hu JC. Mineral Trioxide Aggregate and Diluted Formocresol Pulpotomy: Prospective and Retrospective Study Outcomes. J Mich Dent Assoc. 2018 Apr;100(4):40-65.

8. El Meligy OAES, Alamoudi NM, Allazzam SM, El-Housseiny AAM. BiodentineTM versus formocresol pulpotomy technique in primary molars: a 12-month randomized controlled clinical trial. BMC Oral Health. 2019 Jan 7;19(1):3.
9. Oliadarani FK, Haghgoo R, Mashhadiabbas F, Kahvand M. Histopathological Evaluation of Dental Pulp of Primary Teeth Pulpotomized with Formocresol with/without a Capping Agent: A Randomized Clinical Trial. J Int Soc Prev Community Dent. 2018 Sep-Oct;8(5):420-423.
10. Luengo-Fereira J, Ayala-Jiménez S, Carlos-Medrano LE, Toscano-García I, Anaya-Álvarez M. Clinical and Radiographic Evaluation of Formocresol and Chloramphenicol, Tetracycline and Zinc Oxide-Eugenol Antibiotic Paste in Primary Teeth Pulpotomies: 24 month follow up. J Clin Pediatr Dent. 2019;43(1):16-21.

2. Six months of follow up is not necessarily indicate the success of a newly examined method. It is advocated to report the results after at least one year. In the case of drop out in longer follow ups, the authors may analysis the demographics of those who missed the follow up, and declare the findings in results.

Our study was designated for six month follow-up. Of course in the future, we will report long term outcomes. Some relevant posts regarding the duration of follow up has been stated in the last page of discussion part.

Though I think it is not necessary to report in the result part, demographics of those who missed the follow up are as below:

Totally, 3 girls and 5 boys dropped with the mean age of 64.36±8.52 months (sum of subjects who received one allocated treatment because of poor cooperation (2 subjects), who demonstrated pain during the procedure (2 subjects), who not showed clot formation (1 subject) and who not returned for follow-up (3 subjects).

Results

1.The success rate of groups was not significantly different. There are two concerns here, first the number of cases in one table row was low, hence it seems that a second power analysis needs to evaluate the real power of the study. Second, no significant difference was reported, so why regression model was used for a non-significant impact calculation. The sample size was determined based on reference number 16 using relevant formula, considering a power of 90% and type I error of 0.05. After seeing the referee's comment, I consulted with a statistician and it became clear that this analysis is sufficient and there is no need for additional analysis.

Regarding the sentence “Analysis indicated that P/SSC were nearly 2.5 times more likely to show failure (Odds Ratio=2.667, 95% Confidence Interval=0.754-9.437).” It is necessary to explain that I extract this from output of SPSS table of Fisher's Exact Test. No regression was performed. So to remove the existing ambiguity, I removed the sentence from result.

Reviewer 2:

Dear author,

Your attempt for evaluation of Clinical and Radiographic Success Rate of Pulp Treated Primary Molars Restored with Stainless Steel Crown (SSC) versus Glass Ionomer -SSC is valuable. The manuscript is generally well-written and the study design is very good.

Here are the points which need to be clarified or revised for possible publication:

1. There are some grammatical and typo mistakes throughout your manuscript. Please correct them. It was corrected.

Abstract:

2. 47 children finally finished the examination and were analyzed. Please correct that in the method's section. It was corrected in the abstract.

3. Bring the p-value of the first result. Since no clinical signs of failure were observed in both types of restorations and frequency of clinical failure was zero in both, there was no need for analysis and reporting of P.

Background:

4. Please bring the exact references for each sentence in the background section. It was corrected.

5. Please explain more about GI, its advantages and disadvantages and the more complete reason of selecting it for your study in this section. It was completed.

Methods:

6. Have all the children a periapical radiography for exact evaluation for need for pulpotomy? How you confirm the lack of radiographic sign before your treatment? Eligibility for pulpotomy were confirmed based on clinical and radiographic examinations (PA radiography). Due to word count limitation it was removed first. But, now it was added for more clarification.

7. Please bring some pictures from stages of each treatment. At least from 2 types of buildup. It was added.

8. it's better to bring some example picture from your patients especially for the radiographic criteria of failure. It was added.

9. When the reevaluation was done? Only for the radiographies? How the clinical examinations were confirmed? As stated in the method, 6 months follow-up was conducted. As stated in the method, both clinically and radiographically, teeth were evaluated. The condition of clinical evaluation were added.

Results:

10. Finally, 47 children were finished the study process. Add this to your results. It was added.

Tables and Figures:

11. The figures are not enough. Figures were added.

OPEN PEER REVIEW

Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Associate Editor | **Revision** (1) 28 Nov 2019

Dear EIC,
The authors have modified the manuscript accordingly and have provided specific answers in an accurate manner. I suggest that this version is suitable for publication in the Iran J Pediatr.
Thanks.

REFEREE: EIC | **Revision** (1) 28 Nov 2019

Dear Authors,
The second round of peer review of your manuscript has been completed, and I am pleased to inform you that your manuscript has now been accepted for publication in our journal.
Thanks.