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**New proposal of silver diamine fluoride use in arresting approximal caries: study protocol for a randomized controlled trial**

**1. When was the work published ?**

The work was published in November 19th, 2014.

**2. What are the main points of the article?**

The main points of the article are to investigate the cost and prove the efficacy of silver diamine fluoride in arresting approximal caries comparing to the resin infiltration and flossing. A second hypothesis is also included in this article to evaluate patients parent discomfort and satisfaction. A previous study specified that resin infiltration is an accurate method or a way to seal and control caries lesions in proximal areas. It has been already approved that it works well but requires the use of a rubber and clamps. This can make a patient to deny this method due to the cost.

The experiment design is randomized, double blinded and contains a standard controlled study. During this experiment three parallel groups will be created. The first group will be using silver diamine fluoride. The second group will be using resin infiltration. The third group will be the control group using floss. But all patients of every group will be oriented and instructed to floss every surface that will be tested. Children and adolescents with at least one approximal initial caries lesion in primary molars, permanent premolars or molars will participate in this experiment. Patients with advanced caries lesions or negative behavior will not be able to participate. Patients will be randomly assigned to each group by using a statistical software. 94 individuals were assigned to each group.

Each group will contain a sample size of 168 surfaces per group. During this experiment follow up visits are required. Evaluation regarding biofilm assessments will be done during the first three months. During the sixth to twenty fourth months, biofilm assessments, caries detection by visual inspection and radiographic examination will be done. First of all, the outcome considered is caries lesion progressing to dentin. The second outcome is to measure patients discomfort and satisfaction. According to the article and the status trial, this experiment still in process to obtain accurate results.

**3.**  **Does the work meet the standards to be considered an appropriate/academic scholarly source?**

Yes, the work does meet the standards to be considered an appropriate scholarly source because it states the name of the authors and publishers. All sources are cited under references. The article is provided from MEDLINE, which is a great resource for medical research since it is authoritative and peer-reviewed.

**4. Are the qualifications of the author(s) appropriate for an academic article? Briefly describe the authors' qualifications.**

Yes, the qualifications of the authors are appropriate for an academic article. For example one of the authors of this article named Juliana Mattos-Silveira is a PhD, who attended to University of Sao Paulo from February 2012 – April 2016. She has written 4 articles and contributed in 8. All of them related to dentistry and dental hygiene epidemiology.

**5. Is the purpose clearly stated? Restate the purpose of the paper in your own words.**

Yes, the purpose is clearly stated in the article. It has two purposes. One of them is to assess the effectiveness and cost of silver diamine fluoride for initial caries lesions located in the mesial or distal surfaces of a tooth. The second purpose is to see and evaluate if patients feel comfortable and satisfied during the experiment.

**6. Is the experimental design clearly described? Describe the design in your own words.**

Yes, the experimental design is clearly described but not accurate. The experiment consists of a randomized, double-blinded and parallel design. Children and adolescents with at least one initial caries lesion in a distal or mesial surface was required. There are three groups: silver diamine fluoride, resin infiltration and flossing. The control group was flossing. When choosing the sample size, the characteristics of individuals were significantly different from children to adolescents and primary teeth are usually more prominent to caries progression than permanent teeth, various procedures were done to determine the sample size and ended up with 168 surfaces per group. Children, adolescents, parents and examiners were blinded and did not to which group they were going to be assigned. These individuals were randomly assigned to a group by using a power analysis known as MedCalc software. Each group had 94 individuals participating in every experiment. Same placebo therapy and same instructions to floss after the treatments were given to every group, but the interventions were different from the SDF and Resin Infiltration groups because different products and percentage of amount were used.

**7. Have the possible influences on the findings been identified and controls instituted? Describe and evaluate the use of controls and possible influences (spurious variables)**

No, because there are not accurate findings during this experiment and authors provided some bias and opinions in the discussion as fluoride water, aesthetic concerns and options that will be more efficacious to remove biofilm than flossing.

**8. Has the sample been appropriately selected (if applicable)? Describe the sample used in the study, and evaluate its appropriateness.**

I don’t think the sample size was appropriately selected because it was not chosen randomly and not everyone had an equal chance of being selected for the sample. The authors did not specify the characteristics of the sample either, which creates doubts to a reader. The sample used in this study was considered by two possible comparisons as flossing vs SDF/Infiltration and SDF vs Infiltration. Authors, also considered similar studies or treatments to get a sample size. Similar sample sizes were included for all groups. First, they assumed 258 surfaces as a sample size but ended up with 168 surfaces per group.

**9. Has the reliability and validity of the article been assessed? Evaluate and state the test/ diagnosis results.**

The reliability and validity could not been assessed because not results were found during the experiment. This study cannot be replicated because the variables are too broad and not specific.

**10. Is the experimental therapy compared appropriately to the control therapy? Describe and evaluate the use of the control group.**

The control group in this study stated that children will receive sterile water application as a placebo or standard treatment. This comes to be the inactive substance and the active will be only the instructions for daily flossing that were also stated in the other two groups: SDF and Resin infiltration. The control group only involved children but the whole experiment also included adolescents, so it is questionable why adolescents were not included in the control group. In the SDF group, the control therapy stated individuals will receive sterile water application, does this includes adolescents or children only?

**11. Is the investigation of sufficient duration? Evaluate and explain your reasoning.**

The investigation does not state the duration of the experiment in the methods section. It only states the time allowed when SDF and substances needed during Resin Infiltration are applied to the surface of a tooth. But there is a table in a picture where states the duration of the experiments with follow-up visits. The total duration is for 24 months that is only required for the Resin infiltration group but what about the other two groups?

**12. Have the research questions or hypothesis been answered? Restate the research questions and/or hypothesis in your own words, and describe if or how they are answered.**

This article does not consists of an hypothesis because a hypothesis includes a dependent and independent variable, so I prefer to call them purposes. One of the purposes is to assess the effectiveness and cost of silver diamine fluoride for initial caries lesions located in the mesial or distal surfaces of a tooth. The second purpose is to see and evaluate if patients feel comfortable and satisfied during the experiment. These purposes were not answered because there were no results. The article states that this experiment still ongoing.

**13. Do the interpretations and conclusion logically follow the experimental finding? Restate the conclusion and explain if or how they follow the experimental findings.**

No interpretations and conclusions were provided. All that the authors stated are statistical analysis that they will use or perform when they get the evaluated outcome. In the discussion section, they just provide information about flossing and propose a possible efficacious treatment for initial caries lesions on approximal surfaces.

**14. Do you agree or disagree with the article and findings? Explain why?**

I disagree with this article because it doesn't provide any accurate information. Also, I think there was no need to evaluate initial caries lesions using resin infiltration because they stated in this article that a previous study approved that resin infiltration worked well on approximal surfaces of a tooth for caries lesions.

**15. What would you change in the article? Why? Think outside of the box. What would you add or delete?**

In this article I would have only use the main topic Silver Diamine Fluoride and deleted resin infiltration. I would have created a hypothesis stating silver diamine fluoride arresting interproximal caries lesions in children. Children are more prominent to acid attack and get caries because of their thinner enamel, so in case SDF worked well means that it can work in adults too. I would have choosen children of a specific age, diets, medical conditions, etc. All these factors that at some point could affect the results.