

Correspondence: Comparative Efficacy of Oil Pulling and Chlorhexidine on Oral Malodor: A Randomized Controlled Trial

RYAN ARMSTRONG

Dear Sir,

Query - In the article, "Comparative Efficacy of Oil Pulling and Chlorhexidine on Oral Malodor: A Randomized Controlled Trial", DOI: 10.7860/JCDR/2014/9393.5112 [1]" the authors wish to test the hypothesis of whether an oral hygiene routine using sesame oil is significantly different than one using chlorhexidine. They fail to reject the null hypothesis and conclude: "Oil pulling with sesame oil is equally efficacious as chlorhexidine in reducing oral malodor and microbes causing it." Any scientist must understand that failing to reject the null hypothesis is not proving its truth. As a follow-up to this claim, authors then conclude in reference to sesame oil based oral hygiene: "It should be promoted as a preventive home care therapy." This is dangerous medical advice that simply does not follow from the content of the article.

Author's Reply - The results of this study showed no significant difference between oil and chlorhexidine group. So the hypothesis that the groups differ significantly was rejected. In research it is not always necessary that we should prove that a new agent is superior to the previously used one. It can be equally efficacious as well if not superior. Further, its recommendation can also take into consideration the cost, availability and mass public appeal of the product (secondary to efficacy). These were the results of this study in a particular set up and might not be same if someone else does or may be same. No research is error proof and authors have taken into consideration level of significance and power of study. Further authors have clearly cited the limitations of this study (discussion, last paragraph, page 21) in relation to relative younger age and females. The need for further studies has also been highlighted (conclusion, larger sample, time period, page number 21). So authors request readers to interpret it keeping in mind limitations and need for future studies. To the point raised that 'dangerous medical advice' authors would like to clarify that till the study was done and published in 2014, they could not find any scientific evidence or research citing it dangerous. Rather lot of studies had supported it (reference number 12, 13, 14, 15, 16, 19, 26 in the article) [1], Had it shown dangerous effects it would have never been taken into consideration as would have been breach in ethics. Human trials are done only after safety is ensured and other prelims are over. Authors have never recommended it as a replacement to mechanical oral hygiene aids. It was recommended in place of Chlorhexidine which is an adjunct to mechanical aids. Authors feel any product/ technique which can have a large public health application is locally available and culturally acceptable should always be taken up for research.

Reader response on author's reply- As noted in their response, the authors were somewhat forthcoming in pointing out most methodological flaws. In addition to the flaws mentioned, there are weaknesses in randomization (randomizing hostel groups rather than between hostels) and in the application of treatment. References are made to a disparity in rinse duration, but as far as I can tell specific duration of each treatment is not mentioned. Particularly when considering the improvements seen in the control group (possibly attributable to mechanical disruption), the rinse duration

is of critical importance. When considering the other limitations, even the authors are willing to recognize that "The results cannot be generalized to other age groups." Yet, the authors conclude "Oil pulling with sesame oil is equally efficacious as chlorhexidine in reducing oral malodor and microbes causing it. It should be promoted as a preventive home care therapy." This conclusion does not follow from the article and is scientifically inappropriate. The author's response to my initial criticism does not make a palatable defense; rather, it further illustrates the limitations that should be taken into consideration regarding their overreaching conclusion. In fact, in their response, they claim that they "[recommend oil pulling] in place of Chlorhexidine which is an adjunct to mechanical aids." This is not scientifically defensible within the context of the current literature. In regards to the "dangers", perhaps we speak in different terms. I don't mean to call oil pulling a dangerous practice. As far as I can tell, it is entirely safe and can possibly offer some benefits to oral health. Rather, I consider it dangerous to promote any medical practice as an alternative before the research is conclusive, as this study explicitly does. This approach could lead patients away from more well established medical care that they may require.

Author's reply- we would like to reply about randomization. The three hostels selected belonged to the Maharani Group of colleges. The students shared same baseline characters, had access to the same mess food and other relevant things as per self-administered questionnaire. The hostels were randomized to prevent bias which may arise from participants of different interventions interacting with each other. Though participants from different hostels could also interact with each other, but chance from being in the same hostel would have been more. All hosteliars who agreed to participate in the study were screened and those who fulfilled inclusion and exclusion criteria were selected for study. Further among those who qualified random sampling was done to select 20 participants of each group. The duration of rinses has not been mentioned as it was as per standard protocol and details were provided in references.

Queries by another reader- Table/Fig-2 and Table/Fig-3 both contain incorrect labels (* or **) that designate that results are significant when the listed p values clearly show that they are not. And an odd statement: "(give reasons)" is included in many parts of Table/Fig-1 and it looks like something the authors forgot to remove from the figure. Further, there is insufficient description of statistics – the authors seem to switch back and forth between non-parametric and parametric tests freely. To use non-parametric tests, the authors should have tested for normality, which there is no indication that they did. Also, they do not indicate which post-hoc test was used.

Authors reply- In table / figure 2 and table/ figure3, " * or ***" has been used as a symbol only to indicate that for the p value given in table (for eg Gingival Index (GI) 0.944, table/ fig 2) the level of significance taken is $p < 0.05$ and test which has been done for given parameter is Kruskal Wallis or ANOVA. It has been supported with a line in text part statistical analysis "the value of $p < 0.05$ was accepted as statistically significant. Readers should correlate text and tables. Usually * is used to indicate significant value along

with italics. However, it can also be used to provide explanation for a cited value or text. Sometimes to constraint text matter, full lines are avoided in tables/ figures. However, the authors feel that a sentence "*" the test done was Kruskal Wallis and p-value taken was $p < 0.05$ could have been written to reduce confusion among readers or the legend should have clearly spelled it out. Authors consider the mistake. The phrases (give reasons) should have been deleted. This chart is the blueprint based on the CONSORT flowchart (linked- consort-statement.org/consort-statement/flow-diagram), and author has just filled the numbers in that chart. But erroneously did not remove it from the flow chart when they had no reasons and no exclusion was done. Further, at times explanation cannot be provided due to the word limit constraints for publishing articles. Five parameters namely GI, PI, ORG1, ORG2 and ABC

were checked. It is understood that if para or non-parametric tests were used normality was tested and only then decision made. May be a sentence in text could have helped readers understand that normality was tested. Here Shapiro's test was used. The first 4 parameters did not have normal distribution so non parametric test like Kruskal Wallis and Wilcoxon test were used. While for 'ABC' parameter ANOVA and student t test was used. Bonferorni's test was used as Port hoc test. The constraint for number of tables limited authors to provide table for this.

REFERENCES

- [1] Sood P, Devi M A, Narang R, V S, Makkar DK. Comparative efficacy of oil pulling and chlorhexidine on oral malodor: a randomized controlled trial. J Clin Diagn Res. 2014 Nov;8(11):ZC18-21.

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