Reviewer’s report

Title: Effects of Lactobacillus salivarius-containing tablets on caries risk factors: open-label clinical trial

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Reviewer: Takahiko Oho

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The purpose of this study was to evaluate the effects of Lactobacillus salivarius-containing tablets on caries risk factors. The authors analyzed saliva samples obtained from volunteers before and after taking 4 types of tablets. They found a reduction in the number of mutans streptococci, increases in salivary flow and buffering capacity in L. salivarius groups compared with the control group. In a short-term experiment using L. salivarius WB21-containing tablet, the tablet also decreased mutans streptococci level. They concluded that L. salivarius-containing tablets were effective to increase resistance to caries risk factors. This paper may be interesting, but the statistical methods and results are questionable. More discussions about interpretation of the results are necessary. Several concerns arise that should be addressed.

1. Fig. 1A
The authors directed 64 subjects to lick a tablet, and showed L. salivarius WB21-containing tablet reduced mutans streptococci level. Is it possible to decrease mutans streptococci level using just one tablet containing L. salivarius WB21. What is the mechanism? Does this organism have anti-microbial activity against mutans streptococci? It seems to be due to clearance effect of saliva, and the statistical method is not appropriate as described below.

2. Fig. 1B
Lactobacilli level increased in two groups, which used Lactobacillus-containing tablets. The authors ascribed it to the viable lactobacilli in the tablets. When did authors collect saliva sample after taking tablets? How long did viable lactobacilli derived from tablets exist in the oral cavity?

3. Fig. 1C
Salivary flow was increased by TI2711-containing tablet, but not with WB21-containing tablet. Why did only TI2711 increase salivary flow? Salivary flow is affected by several stimuli including taste, flavor, texture, etc. Each tablet contains different amount of ingredients. Do the ingredient rather than lactobacilli or Ovalgen DC have any effects on salivary flow?

4. Fig. 1E
Buffering capacity was increased by TI2711-containing tablet and Ovalgen DC-containing tablet. Why did those two tablets increase buffering capacity?
Buffering capacity is mainly based on bicarbonate concentration in saliva, and is proportional to salivary flow. Ovalgen DC-containing tablet decreased salivary flow in Fig. 1C, but increased buffering capacity. What is the mechanism of Ovalgen DC to increase buffering capacity?

5. Fig. 2
This figure seems to be boxplot, but the style is different from Figs. 1C-E.

6. In page 8, line 9
Mutans streptococci were detected in 75% of the subjects. How did authors determine the mutans streptococci level?

7. Statistical methods
In Figs. 1A and 1B, authors used Wilcoxon’s signed-rank test for statistical analysis. This method is usually used to compare data before and after intervention in one group. In this case, authors compared distribution of scores among four groups. So, other methods for multiple comparison should be used to compare 4 groups as a whole, then compare 2 groups individually. In Figs. 1C-E, authors may have compared differences obtained by calculating values before and after intervention. It is also necessary to perform multiple comparison using other methods.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
I declare that I have no competing interests.