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Research Article

"Effect of Triclosan Containing Tooth Paste, Conventional Containing Fluoride Tooth Paste and Two Herbal Tooth Pastes on Plaque and Gingival Status of Rural Population of Barabanki District in Northern India"-Comparative Study

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Received: September 24, 2024; **Published:** October 15, 2024

Abstract

Objectives: The objectives of present study are 1) To evaluate the effect of Triclosan containing tooth paste, conventional fluoride tooth paste and two herbal tooth pastes individually on plaque and gingival status in the selected sample. 2) To compare the effect of Triclosan containing tooth paste, Conventional fluoride tooth paste and two herbal tooth pastes on plaque and gingival status in selected sample.

Methodology: A comparative study was conducted to evaluate the effect of Triclosan containing tooth paste, conventional fluoride tooth paste and two herbal tooth pastes on plaque and gingival status of 800 patients visiting in OPD of department of Periodontology of the Chandra Dental College and Hospital, Safedabad, Barabanki, U.P.as measured by Turesky's modification of Quigley Hein index for plaque status and Loe and Silness index for gingival health at base line and at the end of 3rd, 6th, 9th months. The data obtained was analyzed statistically by applying Chi square test, Paired "t" test, One way ANOVA and Newman Keuls test.

Results: All dentifrices used in this study showed statistical reduction in the plaque and gingival scores at the end of third month when compared to baseline with the p value of ≤ 0.05. At the end of third month the reduction in plaque scores between the individual groups was not statistically significant except between Triclosan containing dentifrice group and Neem containing dentifrice group with the p value of 0.00. At the end of third month there was no statistically significant difference between the individual groups in gingival scores.

Conclusion: As all dentifrices used in this study have shown significant effect on plaque and gingival status at the end of the study, it can be interpreted that all dentifrices do possess the antiplaque and antigingivitis effect. Triclosan containing dentifrice has shown better in reduction of plaque scores when compared to the Neem containing dentifrices.

Keywords: *Triclosan; Fluoride; Neem Multi Herbal; Plaque Status; Gingival Health; Dentifrice*

Introduction

Health and disease have been two prime factors which have had left a profound influence on humans and humanity throughout the history of human race. Oral micro biota represents a unique and complex ecosystem consisting of a plethora of microorganisms living together by establishing very complex interrelationships.

Dental plaque is a microbial biofilm which is invariably present on the hard and soft tissues of oral cavity and it contains a complex blend of various microorganisms. The prevention and control of dental caries and as well the periodontal disease is dependent on optimal plaque control [1].

The 1998 European workshop on mechanical plaque control emphasized the importance of regular oral hygiene practices. The past four decades of experimental research, clinical trials and demonstration projects in different geographical and social settings have confirmed that the effective removal of dental plaque is essential to dental and periodontal health throughout the life [2].

The role of plaque accumulated at the gingival margin in the initiation and progression of gingivitis and periodontitis has been well documented [3]. Tooth brushing is the most frequently used means of performing oral hygiene. In order to increase the antiplaque action during tooth brushing, it has been suggested that chemical control be utilized [4].

Among all chemical agents, chlorhexidine is the most widely used one. It has the properties such as high intrinsic efficacy against a wide range of organisms including subgingival bacteria, no systemic toxicity, unique substantivity and chemical stability. Unfortunately, it has adverse local side effects mainly discolouration of teeth, which contraindicates its long term use. Triclosan, a phenol derivative, non-ionic antimicrobial agent, has the potential to be a useful antiplaque agent, yet devoid of any such interference with the esthetics [5]. Thus, triclosan is being used in mouth washes and tooth pastes as an antimicrobial agent. Fluoride is another antimicrobial agent in addition to its anticariogenic effect, which has been incorporated in tooth pastes and mouth rinses since long time to prevent the plaque accumulation on the tooth surface. Comparative studies among these two have shown that the triclosan containing tooth paste is more efficient in plaque control and improvement of gingival health than conventional fluoride tooth paste [6-12].

Certain herbes like neem, meswak, babhul, manjistha, and vajjradanti are extensively used in the form of tooth pastes or as chewing sticks in India and perhaps in Indian subcontinent including Arabian peninsula and parts of Africa. A few herbal dentifrices are very popular in India and used by a significant segment of population (Smyle, Vicco Vajjradanti). As studies related to these herbal dentifrices are lacking and as clinicians, we confront piquant situation when patients seek our opinion about such herbal dentifrices. Research in this area to generate the necessary evidence is required. Thus, an attempt is made here to compare the effectiveness of Triclosan containing dentifrice (Colgate strong teeth), Conventional fluoride dentifrice (Colgate-Cibaca), Neem containing dentifrice (Smyle) and Multi herbal dentifrice (Vicco vajjradanti) by conducting a randomized controlled trial among patients visiting in patients visiting in OPD of Department of Periodontology of the Chandra Dental College and Hospital, Safedabad, Barabanki, U.P.

Aim of the Study

To evaluate the effect of Triclosan containing dentifrice, Conventional fluoride dentifrice and two herbal dentifrices on plaque and gingival status of patients visiting in OPD of department of Periodontology of the Chandra Dental College and Hospital, Safedabad, Barabanki, U.P.

Objectives of the Study

- To evaluate the effect of Triclosan containing dentifrice, Conventional fluoride dentifrice and two herbal dentifrices individually on plaque and gingival status in the selected sample.
- To compare the effect of Triclosan containing dentifrice, Conventional fluoride dentifrice and two herbal dentifrices individually on plaque and gingival status in the selected sample.

Materials and Methods

The present study is an experimental study, it was conducted to evaluate the effect of Triclosan containing tooth paste, conventional fluoride tooth paste and two herbal tooth pastes on plaque and gingival status of patients visiting in OPD of department of Periodontology of the Chandra Dental College and Hospital, Safedabad, Barabanki, U.P. as measured by Turesky's modification of Quigley Hein index for plaque status and Loe and Silness index for gingival health at base line and at the end of 3rd, 6rd, 9th months. Ethical approval was obtained from the Institutional Review before the study conducted.

The clinical examination of every subject was comprehensively carried out by chief investigator himself. Prior to conducting the study, the investigator was calibrated at the Department of Periodontology, Chandra Dental College and Hospital, Safedabad, Barabanki, U.P under the guidance of the Professor in order to limit the examiner variability. The calibration session for minimizing the inter examiner variability [Phase I calibration] was done first followed by the calibration for minimizing the intra examiner variability [Phase II calibration].

Phase I calibration

The investigator and the professor after having detailed discussion of the methods involved in the study and the indices selected for utilization in the study underwent a calibration session. The aim of this session was to train the investigator to make consistent judgments in par with the professor.

Ten selected subjects were examined by both the investigator and the professor in turns, and the findings were recorded separately in different formats. The kappa co-efficient values for inter examiner variability with respect to Turesky's modification of the Quigley and Hein plaque Index and Loe and Silness gingival Index were 0.89 and 0.97 respectively. These values reflect a high degree of conformity in observational judgments between the investigator and the professor.

Phase II calibration

The examiner was calibrated with respect to making consistent judgments on same individuals when examined at different intervals. On a given day the investigator was assigned to examine and record the findings in the prepared formats on specific number of subjects. 20% of the subjects were randomly selected for repeated examination by the investigator on the same day. The kappa co-efficient values for Turesky's modification of the Quigley and Hein plaque Index and using Loe and Silness gingival Index were 0.90 and 0.94 respectively, showing a high level of conformity in observational judgments.

Random assignment into groups was done by a separate person by coding method and the examiner was blinded about the group allocation and the tooth paste used by the patients.

Group I - Neem and clove containing tooth paste (Smyle). Group II - Triclosan containing tooth paste (Colgate strong teeth). Group III - Fluoride containing tooth paste (Cibaca - Colgate). Group IV - Multiherbal tooth paste (Vicco).

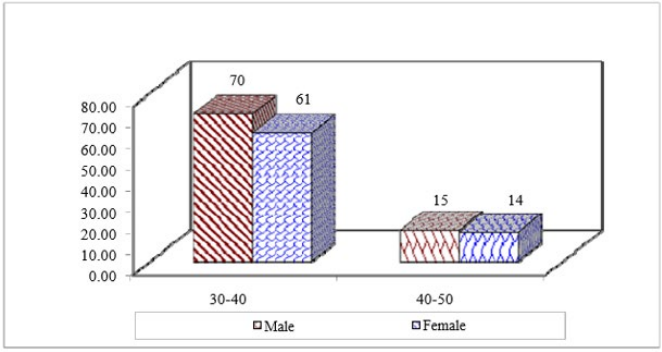
Details of clinical examination

After the patients used placebo dentifrice for week, the baseline clinical examination was done. The general information component of the survey proforma was filled first and each subject was examined by the investigator himself. A recording assistant who was trained to assist in the recording procedure helped the investigator in recording the findings as per the indices selected. The clinical examination was similarly repeated at the end of 3rd, 6th and 9th months.

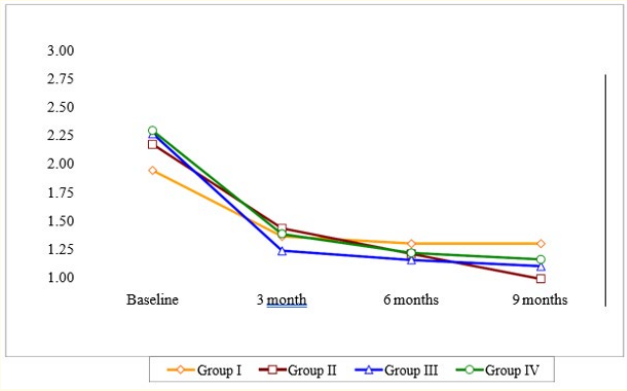
Statistical procedure

The obtained data was compiled systematically. A master table was prepared and the total data was subdivided and distributed meaningfully and presented as individual tables along with graphs. Statistical analysis was done using personal computer with SPSS (version 11) USA. Data comparison was done by applying specific statistical tests to find out the statistical significance of the comparisons. Statistical tests employed for the obtained data in this study were chi-square test, unpaired 't' test, one way ANOVA test, Newman-Keul test.

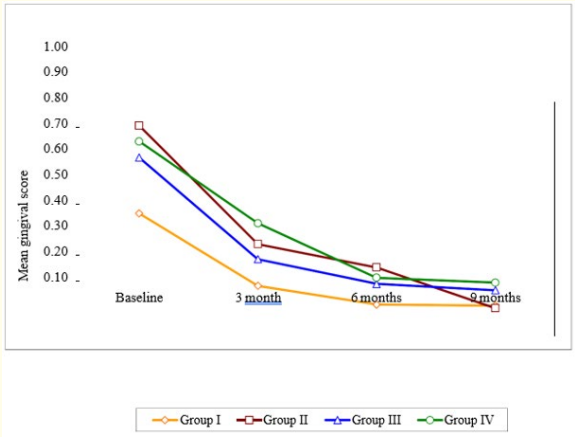
Observation and Results



Graph 1: *Distribution of study samples according to age and sex.*



Graph 2: *Comparison of mean dental plaque scores at baseline, 3 months, 6 months and 9 months between four dentifrices group.*



Graph 3: *Comparison of mean gingival scores at baseline, 3 months, 6 months and 9 months between four dentifrice groups.*

Discussion

Extensive research of last several decades has shown the crucial role played by dental plaque in the initiation and progression of dental caries and periodontal disease. The importance of periodic removal of dental plaque cannot be ignored or over emphasized. Tooth brushing is the most common mechanical method for plaque removal and control. A variety of chemical and herbal substances have been used traditionally or otherwise along with the tooth brush as dentifrices.

In India there are few herbal dentifrices which are marketed and claim to contain variety of herbal extracts e.g. Smyle (Neem) and Vicco vajjradanti (Multi herbal). The efficacy of these dentifrices in reducing dental plaque and their influence on gingival and periodontal health needs an exploration. As available literature in this domain was found to be devoid of any relevant studies, a randomized control trial was planned and conducted to compare these two dentifrices with the commonly used Fluoride containing dentifrice (Colgate-cibaca) and Triclosan containing dentifrice (Colgate strong teeth) as positive controls.

A thorough exploration of available literature revealed a very few studies in which different herbal dentifrices were compared with fluoride containing dentifrice and Triclosan dentifrice. The present study is not an exact duplication of any of those studies. Although an accurate comparison of the present study with other studies may not be possible, an attempt is made to compare selected results wherever possible maintaining the validity of comparisons to the possible extent.

Present study was conducted in a natural setting including a total of 800 patients belonging to patients visiting in OPD of department of Periodontology of the Chandra Dental College and Hospital, Safedabad, Barabanki, U.P. The patients were randomly selected from the departmental OPD. The subjects were not individually allocated to different interventional groups and rather the patients were subjected to random allocation. The technique of randomization employed in the study can be well designated as "Block randomization". This method was employed in order to blind the subjects with respect to the different dentifrices used. As the commercial dentifrices tested were of different color, taste, flavor, texture and as they were supplied in the same container (collapsible tubes) as available over the counter, the only way to blind the subjects to the use of other dentifrices was by doing block randomization. Although this method may not ensure complete blinding of subjects with respect to different dentifrices used in the study. There was no other alternative method to overcome this problem, neither it was possible to homogenize the different dentifrices with regard to the variation in color, texture, taste, flavor, consistency and other product specific characteristics.

The study aimed to test the different dentifrices in real life situation without exercising too many controls on subject specific characteristics such as the brushing method, frequency of brushing, amount of dentifrice used and the brushing period. The study being a community trial has made an attempt to test the selected four dentifrices in natural conditions unlike clinical trial.

Graph no 1 show the gender wise distribution of subjects. The studies of Subraya Bhat., *et al*, Mullaly BH., *et al*. and J Moran., *et al*. used a sample size of 159, 70 and 15 respectively.

The difference in mean dental plaque scores of Group I (Smyle, Neem containing dentifrice) between baseline to three months, baseline to six months and baseline to 9months were found to be statistically significant with the p value of 0.00. The plaque score has slightly raised between sixth month to nine month, although the difference was statistically not significant. Similar findings were observed in the studies conducted by Subraya Bhat., *et al*. (comparison between Neem containing tooth paste and conventional fluoride tooth paste), Ozaki., *et al*, Mullaly., *et al*, J Moran., *et al*. (comparison between parodontax tooth paste and conventional fluoride tooth paste. The difference in mean gingival index scores of group 1 between baseline to three month, baseline to six months and baseline to nine months were found to be statistically significant with the p value of 0.00. Similar findings were observed in the studies conducted by Subraya Bhat., *et al*. (comparison between Neem containing tooth paste and conventional fluoride tooth paste), Ozaki., *et al*, Mullaly., *et al*, J. Moran., *et al*. (comparison between parodontax tooth paste and conventional fluoride tooth paste).

The difference in the mean dental plaque scores of group II (Triclosan containing dentifrice, Colgate strong teeth) between baseline to three month, baseline to six months, baseline to nine months, three month to six months, three month to nine months and six months to nine months were found to be statistically significant with the p value of 0.00. Similar results were obtained in other studies published in the literature such as Lindhe., *et al.* [7], Muller., *et al.* [11], Schacken., *et al.* [12], Ellwood., *et al.* [6], Rosling., *et al.* [8], Cullinan., *et al*. [9]. This may be attributed to the triclosan present in the dentifrice which is a potent anti plaque agent. The difference in mean gingival index scores of group II (Triclosan containing dentifrice, Colgate strong teeth) between baseline to three months, baseline to six months, baseline to nine months, three to nine months, six to nine months and between three to six months were found to be statistically significant with the p value ≤ 0.05. There are other studies in conformity with this result [7,8]. Moreover Triclosan acts on the cyclo-oxygenase and lipo-oxygenase pathways of inflammation and inhibits the inflammatory mediators.

The difference in mean dental plaque scores in Group III (Colgate - Cibaca, Fluoride containing dentifrice) between baseline to three months, baseline to 6months and baseline to 9months were found to be statistically significant with the p value of 0.00. Whereas the difference in mean dental plaque scores between three to six months, between three to nine months and between six to nine months were found to be statistically not significant with the p value of 0.35, 0.11, and 0.06 respectively. There are other studies in conformity with this result [8]. The difference in the mean gingival index scores between baseline to three month, baseline to six months, baseline to nine months, three months to six months, three months to nine months were found to be statistically significant at p value ≤ 0.05 respectively. There are other studies in conformity with this result.

The difference in the mean plaque scores Group IV (Vicco vajjradanti, Multi herbal dentifrice) between baseline to three months, baseline to six months, baseline to nine months, three month to six months, three months to nine months were found to be statistically significant with the p value of ≤ 0.01. Whereas, the difference in the mean dental plaque scores between six months and nine months was statistically not significant at p value 0.21. Similar findings were observed in the studies conducted by Subraya Bhat., *et al*, Ozaki., *et al*, Mullaly., *et al*, J. Moran., *et al.* which compared herbal dentifrice with fluoride containing dentifrice.

This shows that the multi herbal dentifrice (Vicco Vajjradanti) does have significant anti plaque effect. The different herbal ingredients of Vicco vajjradanti (Manjistha, Babhul, Vajjradanti) may perhaps have antimicrobial effects. The difference in mean gingival index scores between baseline to three months, baseline to 6 months and baseline to 9 months were found to be statistically significant at p value 0.00.

At the end of nine months the variation in the plaque scores between the groups was statistically significant. Maximum reduction was observed in the triclosan group when compared to other groups (Graph 2). Although the overall variation in the plaque scores between the groups was found to be statistically significant at the end of nine months, in order to understand between which individual groups the variation was statistically significant pair wise comparison of four groups was done by employing Newman Keuls test procedure. The results which indicates a statistically significant difference between first group (Neem group) and second group (Triclosan group). It exemplifies that the Triclosan dentifrice was exceedingly better when compared to the neem dentifrice in reducing dental plaque. The other two dentifrices namely Vicco vajjradanti and Colgate - Cibaca, although reduced dental plaque they were moderately effective and their efficacy lies in between triclosan containing dentifrice (Colgate strong teeth) which was highly effective and Neem containing dentifrice (Smyle) which was least effective. These results are not in conformity with other study which has shown that there is no comparable plaque inhibiting effect of Triclosan containing dentifrice against fluoride and herbal containing dentifrice. This contradiction may be attributed to short duration of the study by Ozakie., *et al*.

Graph 3 presents results of one way ANOVA on gingival scores of four groups at three months, six months and nine months period. Only at the end of third month a statistically significant difference was observed in the gingival scores between the groups. Although all dentifrices used in the study were found to have reduced gingival scores considerably throughout the study, between group comparison of gingival scores remains statistically non significant at the end of nine months. It clearly implies that these dentifrices do have similar degree of effect on gingivitis.

The results of current study are in contrary to some study results [6-8,10-12]. Among these, most of the studies were conducted for six months period. In the present study nine months period may not be sufficient to produce the significant difference on gingival health.

There are few studies reported in the literature which do support the findings of our study which reveal statistically not a significant difference in gingival scores between different dentifrice groups at the end of the study. Further exploration is required in order to clarify certain issues which arise out of these contradictions. A systematic review with meta-analysis if conducted may provide solutions for many questions. As there are very few studies of similar kind with similar objectives as that of current study being reported on literature a meta-analysis at this stage may not be fruitful. More studies are required to contribute to the evidence base for a meta-analysis to be done.

The present experimental study has shown that at the end of nine months all the dentifrices have similar effect on plaque and gingival health but for Triclosan containing dentifrice, which has shown superior effect on plaque level when compared to Neem containing dentifrice. This indicates that all the selected dentifrices have anti plaque and antigingivitis properties, but there was no significant difference between the individual groups. This is one of the important limitations of this study along with lack of standardization of oral hygiene practice of the subjects and improper blinding.

In order to maintain the optimal oral health and reduce disease burden in the community, people can be motivated to use these dentifrices especially Triclosan containing dentifrice for their routine oral hygiene practice with proper brushing method.

Conclusions

From the results of the present study, it can be concluded that:

- All the selected four dentifrices tested in this study have shown significant antiplaque and anti gingivitis properties by the end of nine months.
- Triclosan containing dentifrice was found to be better antiplaque agent on comparison with Neem containing dentifrice.

- At the end of three month there was significant reduction of gingival scores in subjects belonging to Neem containing dentifrice group (Smyle) when compared to multi herbal dentifrice group (Vicco vajjradanti).
- At the end of nine months all the dentifrices have found to exhibit significant reduction in gingival scores when compared to baseline. None of the dentifrices were found to be superior to others in their anti gingival effect.

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Volume 23 Issue 11 November 2024