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"A Crossover Study Comparing the Efficacy of Toothpastes Containing Triclosan and Potassium Nitrate on Plaque, Gingivitis and Dental Hypersensitivity"

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ABSTRACT :-
Abstract: *The present randomized crossover study was to test the efficacy of Triclosan with Zinc Citrate containing toothpaste (TZ) and Potassium Nitrate toothpaste (PN) on anti-plaque, anti-gingivitis and desensitizing properties. The subjects were randomly assigned to either of the two groups (TZ and PN toothpaste groups).An analysis of Plaque Index(PI), Gingival Index (GI) and Visual Analogue Scales (VASs)indicating Dentinal Hypersensitivity levels were carried out at baseline and after 28 days followed by a wash out period. After which, the two groups were interchanged alternatively and assessment was done in the same fashion. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 20 (IBM, Chicago Inc., IL USA). Mann-Whitney U-test was applied with p<0.001 considered as significant.A substantial median change reduction in PI was observed to be 0.69 (TZ group) and 0.18 (PN group) in the Phase-I while 0.4 and 0.1 in the Phase-II period respectively. Similar superior reduction was assessed with TZ dentifrice for GI. But PN dentifrice reported higher median change reduction for hypersensitivity. Thus, it was found that the toothpaste containing 0.3% Triclosan was an effective antiplaque and anti-inflammatory agent while toothpaste containing 5% Potassium Nitrate was an effective desensitizing agent.*
Keywords: *dentifrice; dentinal hypersensitivity; gingivitis; plaque.*

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I. Introduction

An important etiological factor of gingivitis and periodontitis is dental plaque, control of whichdecreases the progression of periodontal disease(1).Supragingival plaque control is an important component of periodontal therapy, which controls gingivitis (2). Elimination of microbial dental plaque biofilm prevents gingivitis, periodontitis and dental cavities(3).

Various antimicrobial agents and chemicals have been added to dentifrices in order to produce a direct inhibitory effect on plaque formation therebyimproving gingival health(4,5,6,7).Triclosan (2,4,4',-trichloro-2'-hydroxydiphenylether) is a non-ionic antibacterial agent with broad spectrum activity against both gram-positive and gram-negative organisms (8). Effects on gingival inflammation have been primarily attributed to the antibacterial and anti-plaque effect of triclosan(9).

In an effort to improve the effectiveness of plaque removal and periodontal health, triclosan has been used in combination with zinc citrate (10,11,12) therefore the present study incorporated this combination and tested its utility.

Dentinal hypersensitivity is a common problem affecting between 8% and 57% of adult dentate population(13). It is associated with the exposure of dental root surfaces and is characterized by short, sharp pain in response to thermal, evaporative, tactile, chemical or osmotic stimuli, which cannot be ascribed to any other form of dental defect or pathology(14).

The American Dental Association Council on Dental Therapeutics has granted a Seal of Acceptance to dentifrices containing 5% potassium nitrate (Council on Dental Therapeutics 1986). This is the reason for which 5% potassium nitrate dentifrice has been incorporated in the present study, as a desensitizing agent. It is not surprising therefore that, new formulations, using new or recognized toothpaste additives need to be assessed as to whether their antiplaque potential is realized.

So, there is a definite need to evaluate the effectiveness of these commercially available dentifrices and the present controlled double blind cross-over experimental study was conducted for the purpose of comparing the effect of two toothpastes one containing0.3% Triclosan with Zinc Citrate (TZ) and another containing 5% Potassium Nitrate (PN)on plaque formation, gingival health and dentinal hypersensitivity in a 2 x 4 week experimental periods.

II. Materials and Methods

The present study was designed as a randomized double-blind, crossover controlled trial carried out in September 2022 for four months. Initially 60 patients with age range 20-59 years were enrolled in this study. They were admitted to the study after meeting the following eligibility criteria:

The subjects needed to have a minimum of 20 natural permanent teeth with no clinical attachment loss (CAL) greater than 5mm and no probing depth greater than 4 mm. In addition, the subjects had to have at least one tooth (either canines or premolars) with an exposed root surface from which a painful response could be elicited by both a dental explorer and air blast. Subjects were recruited from low socio-economic status who till date used only neem twigs for oral hygiene. Subjects were excluded from the study if they had any one of the following conditions: (1) a history of hypersensitivity to toothpaste, triclosan or chemicals used in the study products; (2) use of antibiotic, antimicrobial, analgesic medications, mouthwash or desensitizing toothpaste during the previous 2 months; (3) a history of periodontal therapy by surgical interventions; (4) a history of dentine hypersensitivity treatment; (5) orthodontic treatment with fixed appliances; (6) any removable device such as a removable partial denture or orthodontic retainer; (7) the presence of any fixed appliance, large or defective restorations, cracked enamel, or caries on the hypersensitive tooth.

All subjects were given verbal and written information in their local language, concerning the study and after entering the study, signed a written consent form regarding all information received. Institutional review board approved the research protocol of the study. All procedures in this experiment were performed according to the ethical principles established by the Declaration of Helsinki.

The present study had a controlled double blind cross-over experimental design. It consisted of 2 x 4 week experimental periods, separated by a ten days wash–out period. This time period was deemed sufficient to balance the carry-over effect from the preceding treatment calculated according to similar study(15).

The subjects were randomly assigned to either of the two groups (TZ and PN toothpaste groups). The random allocation sequence was generated by one of the authors, who used a random-number table. The random allocation sequence was concealed from the main investigator until the dentifrices were assigned to the participants. The investigator and study subjects were unaware of the contents of each tube. The concerned author revealed the contents of each tube only after the experimental period was over. The blinding was kept intact throughout the study period.

Volunteers in one group received a toothpaste tube containing0.3% Triclosan with Zinc Citrate (TZ toothpaste) while subjects in another group received a toothpaste tube containing 5% Potassium Nitrate (PN toothpaste). No prophylaxis was undertaken prior to commencement of the study, and no attempt was made to modify the volunteer's oral hygiene habits.

All patients were instructed in the use of the oral hygiene items. They were asked to brush their teeth thrice daily using the Modified Bass technique for approximately 2 min.

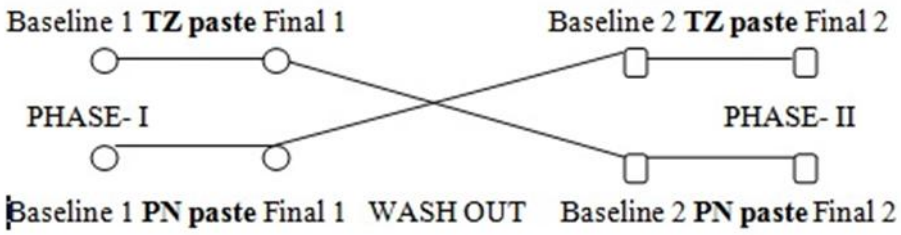
The baseline plaque index (PI)(16), gingival index (GI)(17) and visual analogue scales (VASs)(18) indicating dentinal hypersensitivity levels responding to tactile and air stimuli were assessed for phase one scoring, on all teeth at the buccal, mesial, distal and lingual aspects, with the exception of third molars. The participants were stained for plaque using an erythrosine disclosing solution and cotton swabs. The amount of plaque was scored using the Turesky(16) modification of the Quigley, Hein (19)Plaque Index(PI), gingival inflammation was recorded using the Gingival Index (GI)(17) and Dentinal hypersensitivity(18) to tactile stimulus was determined using a dental explorer (EXD 11-12 Hu–Friedy) drawn across the cervical area of each tooth at an approximatedconstant force. Approximately 10 min after the tactile stimulation, the hypersensitivity response to air blast wasevaluated using a 1 s application of air from a standard dental unit syringe of 40–65 psi at a temperature of 17–21^{0}C. The air blast was directed perpendicularly to the exposed dentin at a distance of 1–3mm after isolating the test tooth. The subjects were asked to record their perceived sensitivity during the application of stimuli on a 10 cm VAS,anchored at each end by the phrases''No Pain'' and ''Unbearable Pain''. All measurements were conducted by the main investigator who was previously calibrated. For calibration, two

measurements were performed with one-hour interval. Intra-examiner calibration was performed in 5 patients until an 80% agreement was obtained.

After 28 days, the subjects returned for another appointment, in which the participants were re-examined for PI, GI and VASs for dentinal hypersensitivity to tactile and air stimuli by the same investigator and the scores were titled as the final score for phase one. Only the tooth showing the highest VAS at the baseline was selected for the VAS reassessments. To check for compliance, the participants were asked to return their assigned tubes, so that the investigator could verify the amount of dentifrice that was used.

This was followed by a wash-out period of 10 days during which the subjects returned to their regular oral hygiene practice using neem twig. The two toothpaste groups were interchanged alternatively at the beginning of second study phase and the scorings were done at same time intervals. The scores were titled as baseline and final scores of phase second as described in FIGURE 1.

FIGURE 1:-A randomized double-blind two arm cross-over experimental design



TZ- Triclosan with Zinc Citrate containing toothpaste group
PN- Potassium Nitrate containing toothpaste group

Statistical Analysis:Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 20 (IBM, Chicago Inc., IL USA). The protocol-defined primary outcome variable shows the reduction of PI, GI and Dentinal Hypersensitivity from baseline. At the 4 week visits, a median change from the baseline for PI, GI and Dentinal Hypersensitivity for both TZ and PN toothpaste groups were calculated, before and after crossover. The distribution of the variables was not normal, so group medians were compared using the Mann-Whitney U test. A median value was calculated for each of the study phases and an overall median of the differences from baseline was calculated, before and after crossover. Mann-Whitney U-test was applied to compare data between the TZand PN toothpastegroups. Any differences with $p<0.001$ was considered significant.

III. Results

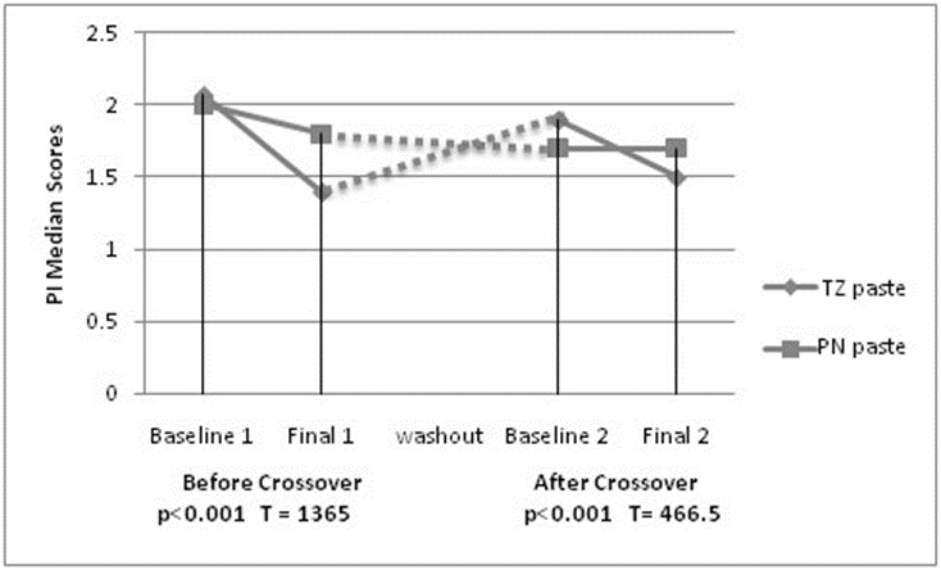
TABLE 1represents the highest median plaque index score change among TZ dentifrice group with 0.69, before crossover whereas the least differential change score between baseline and 28 days was reported with 0.1 for PN dentifrice group, after crossover. The difference between the TZ and PN toothpaste was statistically significant for pre and post crossover design. Maximum reduction of median gingival index score of 0.94, in the TZ group between baseline and 28 days, before crossover whereas least differential median gingival index score reduction of 0 was reported after crossover in the PN group. Thus, there was a significant reduction between the gingival index scores of TZ and PN group before and after crossover. Markeddifferences in VASs indicating dentinal hypersensitivity levels after crossover, which was reported to be 0.8 and 3.1 respectively, among the TZ and PNdentifrice groups.

Table 1: PI, GI and VAS median scores before and after crossover phases among Triclosan with Zinc Citrate and Potassium Nitrate groups

PI Score	**Before Crossover**					**After Crossover**				
Group	Baseline	Final	Change	T	P	Baseline	Final	Change	T	P
Triclosan with Zinc Citrate	2.07	1.4	0.69	1365	*	1.9	1.5	0.4	466.5	*
Potassium Nitrate	2	1.8	0.18			1.7	1.7	0.1		
GI Score	**Before Crossover**					**After Crossover**				
Group	Baseline	Final	Change	T	P	Baseline	Final	Change	T	P
Triclosan with Zinc Citrate	2.01	1.08	0.94	1365	*	1.9	1.5	0.5	465	*
Potassium Nitrate	1.91	1.82	0.1			1.45	1.45	0		
VASs Score	**Before Crossover**					**After Crossover**				
Group	Baseline	Final	Change	T	P	Baseline	Final	Change	T	P
Triclosan with Zinc Citrate	11.7	10.9	1.5	1260	*	10.9	10.5	0.8	484	*
PotassiumNitrate	11.3	8.5	2.4			11.7	8.5	3.1		

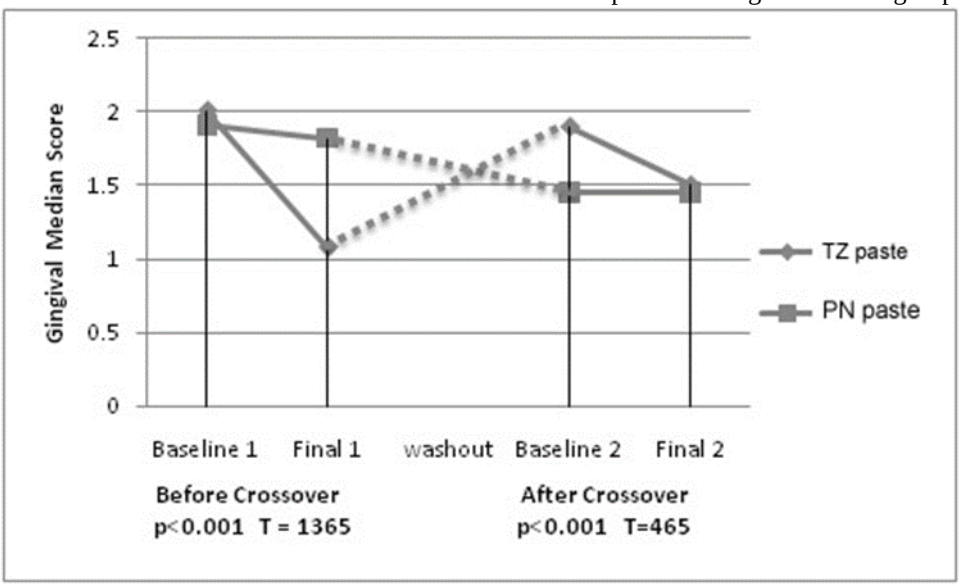
*:<0.001

FIGURE 2:-PI median scores before and after crossover phases among TZ and PN groups



(TZ- Triclosan with Zinc Citrate and PN- Potassium Nitrate) containing toothpaste group

FIGURE 3:-GI median scores before and after crossover phases among TZ and PN groups



(TZ- Triclosan with Zinc Citrate and PN- Potassium Nitrate) containing toothpaste group

IV. Discussion

In the present trial, we examined dentifrices containing 0.3% Triclosan with Zinc Citrate (TZ toothpaste) and 5% Potassium Nitrate (PN toothpaste) to evaluate its effects on periodontal health and dentinal hypersensitivity by a randomized double-blind two arm, crossover study design.

There are several factors in toothbrushing studies that might obscure the beneficial activity of the antiplaque and antigingivitis chemical products. One is the so-called Hawthorne effect (20). The repeated encounters with dental health personnel, repeated oral examinations, and the free supply of dentifrice and toothbrush in the present study might have motivated the subjects to improve their oral hygiene irrespective of the toothpaste type they received. In this study, toothbrushing was selected for oral hygiene care based on the fact that it is the actual method used to apply dentifrice.

In this study, there was significant difference in the PI, GI and Dentinal Hypersensitivity scores among the two comparison groups at various stages of the study design.

A number of studies using tooth brushing method found that the effects of triclosan in dentifrice on gingival inflammation and plaque formation was not clearly evident (20,21). This is not in accordance with the present study, as the present study showed that triclosan with zinc citrate containing dentifrice (TZ) had significant effect on plaque formation and gingivitis.

The present study revealed a median change plaque reduction of 0.69 and 0.4 along with median GI reduction of 0.94 and 0.5 for TZ paste respectively in before and after crossover design. Such scores proves Triclosan as a decent anti-inflammatory agent which is supported by (22,23), who tested the agent for its anti-inflammatory property.

For Dentinal Hypersensitivity, significant median change reduction in VAS score from 2.4 to 3.1 is reported in the PN toothpaste group when compared to median change reduction of 1.5 to 0.8 in TZ toothpaste group, before and after crossover.

Several clinical studies have demonstrated that the dentifrice containing potassium nitrate provides effective desensitization (24,25,26). The mechanism by which potassium nitrate reduces dentinal hypersensitivity may involve the depolarizing action of the K1 ion resulting in the decrease of dentinal sensory nerve (27,28).

The present study has evaluated the efficacy of two toothpastes, one containing (0.3% triclosan) and another containing (5% potassium nitrate) on plaque formation, gingival health and dentinal hypersensitivity. It was found that the toothpaste containing 0.3% Triclosan was an effective antiplaque and anti-inflammatory agent while toothpaste containing 5% Potassium Nitrate was an effective desensitizing agent. More studies are needed to further determine the potential interaction between triclosan and potassium nitrate in the dentifrice.

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