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RESEARCH ARTICLE

EFFECT OF DENTIFRICE CONTAINING SALT ON SALIVARY SODIUM AND CHLORIDE IONS IN PREHYPERTENSIVE PATIENTS

***Dr. Aruna Nautiyal, Dr. Vikas Kumar and Dr. Sheela Kumar Gujjari**

Department no 9, JSS Dental College and hospital, Mysore-15, India

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ABSTRACT

Objective: Clinical studies on dentifrices formulated with different ingredients typically examine the effects of their use on clinical parameters .However the systemic absorption & its implications on health usually go unexplored. Hence this present randomised controlled double blinded cross-over design clinical study compared the changes in sodium and chloride ions & blood pressure brought about by using a dentifrice containing salt in Pre hypertensive patients.

Material and Methods: A total of 30 adults completed a 2 -week wash-out phase prior to providing baseline saliva samples. Subjects were then randomly assigned a test/control dentifrice to be brushed with twice daily for the next 28 days. On the 29th day, they arrived at the dental college prior to oral hygiene and provided saliva samples similar to that collected at baseline. An additional 2-week washout –out phase was assigned to subjects prior to completing the study with the alternate control dentifrice. Blood pressure was measured at baseline and 4 week periods.

Results: Saliva sample analysis in ion selective electrode auto-analyser indicated statistically significant increase($p<0.05$) in salivary sodium ions post 4 week usage of salt containing dentifrice as compared to no significant increase in both sodium and chloride ions post usage of control dentifrice. However chloride ions and the blood pressure in both groups showed no significant change from baseline in both groups.

Conclusions: There is a significant increase in salivary sodium ions post 4-week usage of a dentifrice containing salt.

INTRODUCTION

With the increasing stress levels and hectic life style of Indian population, the lifestyle diseases such as diabetes, cardio-vascular disorders are on a rise, causing a great threat to Indian masses. According to the World Health Statistics 2012 report, high BP is now becoming the biggest reason for adult deaths. Moreover nearly one-fourth of the Indian adult population has been found to be suffering from high BP (Gupta *et al*., 2004). Known as silent killer, high BP raises the chances of stroke and heart diseases. Hypertension is defined as blood pressure greater than 140/90 on two or more blood pressure readings taken at each of two or more visits after initial screening. Prehypertension is defined as systolic if the systolic blood pressure is between 120 and 139mm Hg, and /or diastolic if the diastolic blood pressure is between 80-89mm Hg in adults (Joint National Committee, 7). Many systematic reviews and meta-analyses have been conducted to assess the efficacy of salt reduction on hypertension. It has been shown that an advice on dietary salt restriction was effective in lowering blood pressure and has been found to have a significantly positive benefit (He *et al*., 2002).

**Corresponding author: Dr. Aruna Nautiyal*
Department no 9, JSS Dental College and hospital, Mysore-15, India

WHO recommends the daily intake of salt not to exceed 5g and Institute of Medicine (USA) recommends the salt intake to be 1500 milligrams (Salt and Hypertension, 2007). Against these recommendations, an average Indian consumes 9-10 grams of salt each day mainly through processed and home cooked food. Salt, apart from being an inseparable part of most consumables, has started exerting its presence also in most of oral hygiene products which are being marketed for their tooth whitening properties. The introduction of such a dentifrice raises a question in our minds about the implications of using such toothpaste on a regular basis over a long time especially in people who are otherwise on a strict salt restricted diet. Although the actual concentration of active salt absorption might be too minute to be considered, yet to our knowledge this area has remained untouched until now. Hence an attempt is being made to evaluate the changes in salivary sodium and chloride ions post usage of a commercially available dentifrice containing salt in pre -hypertensives.

Study Subjects

This was a double blinded randomised controlled study with a crossover design. The study took place from September 2013-February 2014. The study protocol was reviewed and approved by the ethical committee of JSS University, Mysore, India, in

accordance with the Helsinki Declaration of 1975, as revised in 2000.Before enrolment, a written informed consent was obtained from the patients. A total of 30 chronic periodontitis patients diagnosed with Pre hypertension were included in this study. Subjects (age range 30-60yrs) willingly interested to take part in the present study were screened by an examiner if they met the inclusion requirements desired for the study.

Inclusion criteria

Patients willing to give informed consent and to attend the study.

- Patients diagnosed with pre hypertension (120-140mm Hg Systolic and\or 80-90 mm Hg diastolic)
- Age group 30-60 years both men and women.
- Not currently under any medication.
- Patients reported to have taken any medication in the past 3 months
- Patients with a minimum of 20 natural teeth.
- Mild-Moderate (1-4mm CAL) Chronic generalised (>30% sites involved) periodontitis patients.

Exclusion criteria

- Known allergy to any of the constituents of the toothpaste
- Patients with any systemic condition other than hypertension
- Patients on any prescribed medications 3 months prior to the study.
- Smokers
- Alcoholics
- Pregnant and lactating females

Study dentifrice: A commercially available dentifrice with sodium chloride as its active ingredient was the test dentifrice whereas the control dentifrice comprised of the same ingredients as the test dentifrice except the sodium chloride content. All the dentifrices were adequately overwrapped by a person not associated with the study to aid masking.

Clinical design: All of the enrolled subjects underwent a 14 days washout phase prior to the start of the study. Subjects were provided commercially available fluoride toothpaste and a soft bristle toothbrush to be used during the washout phase prior to baseline sampling. Patients were asked to brush twice daily and abstain from any other oral hygiene products and aids during the span of the study. On the 15th day the subjects were asked to refrain from oral hygiene methods and report to the dental college between 8-9 am to provide their baseline saliva samples. The saliva samples were collected by an examiner blinded to the study followed by recording of blood pressure of the patient . A computer generated randomisation was done and each subject was allotted either a test or a control dentifrice. Subjects were asked to brush twice daily with the dentifrice allotted to them for 28 days .On the 29th day, subjects were asked to report to the dental college between 8-9am prior to carrying out any oral hygiene and their saliva sample was collected and blood pressure recorded. This completed the phase of study with the first set of dentifrice. All the subjects again underwent a 14 days washout phase. Then the study subjects were crossed over i.e., those patients who had previously received test dentifrice received control dentifrice and viceversa. The same protocol concerning collection of saliva samples and blood pressure recordings were followed as mentioned previously. Common oral hygiene instructions were given to the patient during both washout periods. Patients were asked to not make any changes in their dietary intake.

Method of collecting saliva sample: Subjects were instructed not to eat or drink within 60 minutes prior to sample collection. Whole saliva was collected simply by drooling into a vial with forward tilted heads. The samples were then sent immediately for estimation of sodium and chloride ions with the use of ion selective electrode auto- analyzer.

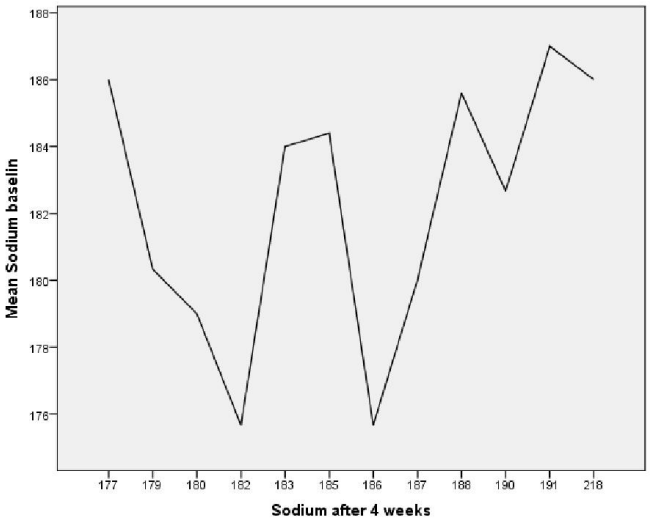
Method of blood pressure recording: Arterial blood pressure was measured by a mercury sphygmomanometer after 5 minutes of rest; the values recorded represented the average of three consecutive measurements taken over a 15 min period.

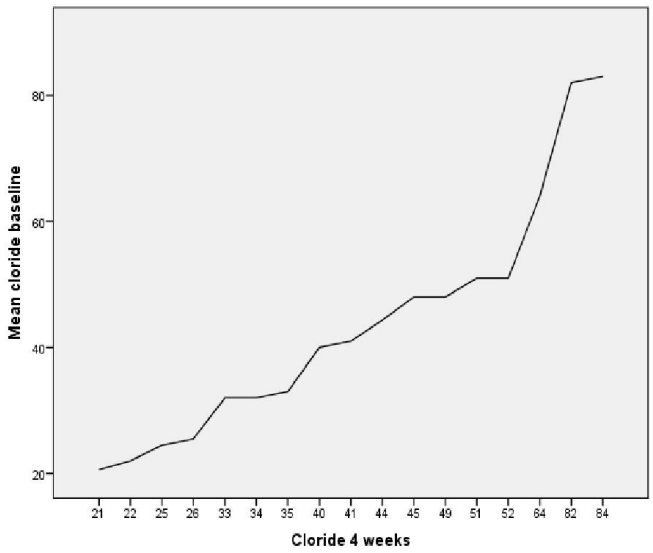
Statistical Analysis: All statistical analysis was performed using a software programme (SPSS 16.0). Changes in salivary sodium & chloride ions and Blood pressure from baseline to 4 weeks were analyzed using Paired t test. Significance was set as $P<0.001$.

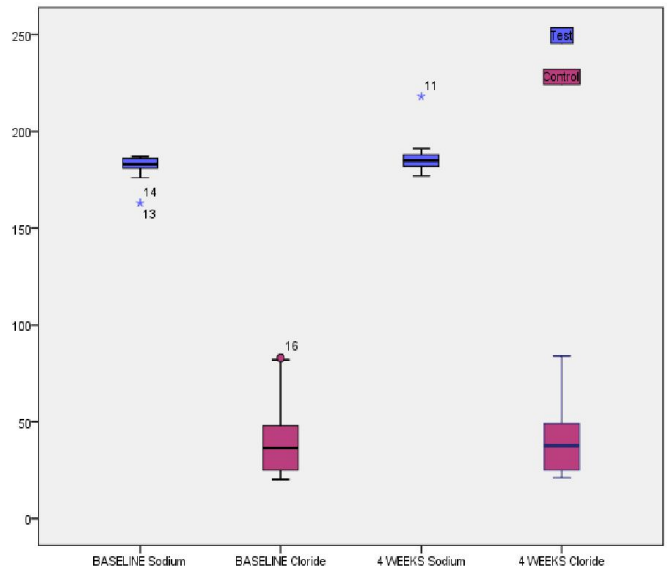
RESULTS

All 30 Patients attended the Baseline and follow-up appointments. At four week follow up interval, the mean changes in salivary sodium ions were statistically significant from the baseline values (P<0.001). When comparing the mean values of salivary chloride ions post four week usage of test dentifrice, there was no statistically significant difference observed from the baseline values. (table). also there was no statistically significant change in the blood pressure recording pre and post usage of test dentifrice. Also post usage of control dentifrice there was no statistically significant change observed both in sodium & chloride ions and on blood pressure as well. There were no reports of any adverse effects of using the dentifrice.

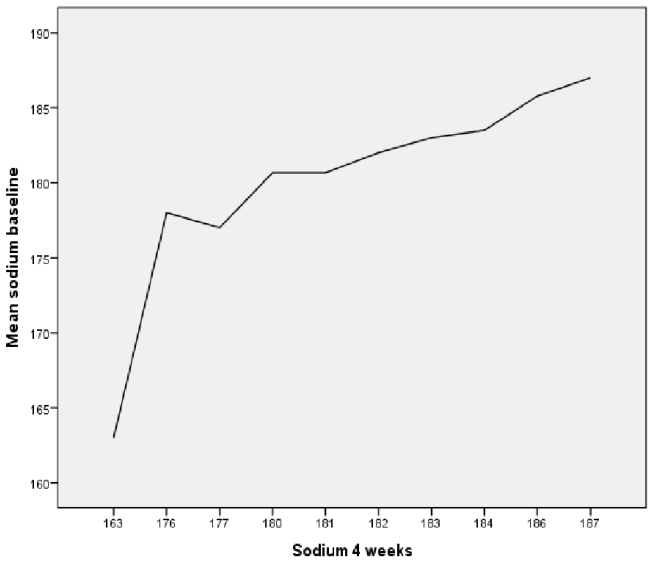
Test group

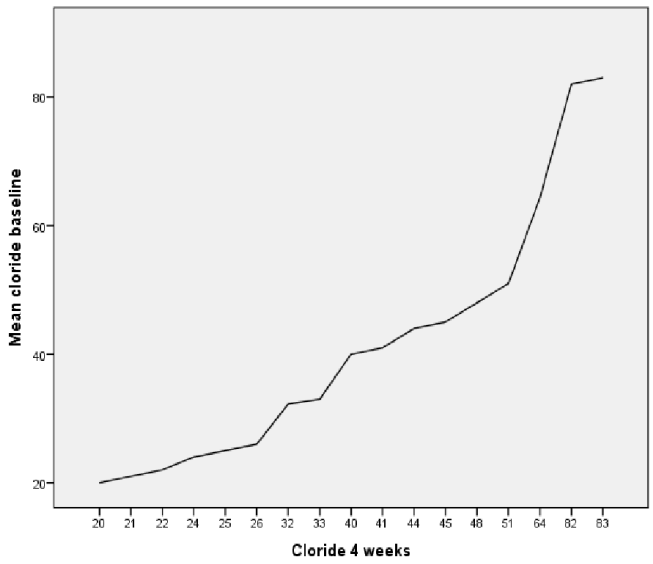






Control Group





DISCUSSION

The rising burden of Hypertension is evident from the fact that 35% of Indian population is hypertensive. The effect of dietary salt intake and its effect on hypertension has been vastly documented (Francesco *et al*., 2000; Jalal *et al*., 2001; Stanley Shaldon *et al*., 2002). Ina classic study, 14 normotensive patients were exposed to experimentally high sodium diets containing 1200–1600 mmol of sodium chloride and it was found that all the patients showed an increase in blood pressure just in 3 days (Luft *et al*., 1979). This study could not be carried out on a long term due to ethical concerns. Most studies show proportional relationship between blood pressure and sodium chloride intake. In another study it was stated that , a life style modification by restriction in dietary salt intake of sodium chloride to 6 gm of sodium chloride per day reduce blood pressure by 2-8 mm Hg. Studies have shown that the constituents of dentifrices do get absorbed into the saliva and reflect in its composition .Owing to lack of literature on the bioavailability of sodium chloride that gets absorbed from salt containing dentifrices, there exists a dilemma among dentists if or not to prescribe such dentifrices in people on salt restricted diet. Hence an opinion poll was conducted in the of city of Mysore, among physicians to find out how many hypertensive patients are advised concerning the use of dentifrice containing salt.

It was seen that 70% of the physicians prefer to refer the patient to the dentist than making a decision themselves. Hence a similar poll was conducted among dentists, and surprisingly it was seen that 80% of them were also not sure of the same. Since the findings of this study showed a significant rise in sodium ions post usage of a dentifrice containing salt, it becomes a matter of concern especially in people who are on a strict salt restricted diet. It is very important to be well aware about the masked sources that add up to salt burden. As there is hardly any research in. addressing this issue, we chose to explore this area to bring about clarity in making a decision to exercise caution in prescribing such a dentifrice in pre hypertensive patients. This study highlights the effects of having sodium chloride as an active ingredient of a dentifrice

and its effect on hypertensive patients. In this study post usage of a dentifrice containing salt, there was a statistically significant raise in salivary sodium ions. No controlled studies are present till date addressing this issue. So this study is a stepping stone towards further research in this direction. Limitations of the present study include smaller sample size and no previous studies on this subject. Patients diagnosed with pre hypertension were chosen as our study subjects since the treatment protocol for prehypertension is purely lifestyle modification without the use of any drugs that could possibly have interfered with the results of our study .Although proper care was taken to reinforce no change in diet during the study and to rule out differences in metabolism, each patient served their own control, still how much of the raise in salivary sodium ions can be directly attributed to the dentifrice still remains a question . Hence more research in this area is invited to bring about clarity in addressing this issue.

Conclusion

The results of this study show that post usage of a dentifrice containing salt, there is a significant increase in Salivary sodium ions however there are no significant changes in salivary chloride ions and blood pressure. Since this is the first study relating salivary sodium and chloride ions to usage of salt containing dentifrice, further long term studies with a larger sample size are required to authenticate this co-relation.

Acknowledgement

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