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RESEARCH ARTICLE

COMPARATIVE EVALUATION OF EFFICACY OF DENTIFRICE CONTAINING NANO-HYDROXYAPATITE AND 5% POTASSIUM NITRATE ON DENTINAL HYPERSENSITIVITY: RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Dentin hypersensitivity (DH) is a common oral health problem affecting one or more teeth of many individuals. Recently, considerable attention is being given to the research concerning the use of mineral components of inorganic portion of the tooth structure - calcium and phosphate in dentistry. Nano-HAP containing dentifrices are newer products which are available in market for DH. **Objective:** To compare and evaluate the effect of nano-HAP dentifrice with 5% Potassium nitrate containing dentifrice, which has been widely used in reducing DH. **Methods:** The study was a single centre, randomized double blind, parallel group design with a duration of 4 weeks. About 46 patients were selected, randomly divided into two groups and provided with one of the either dentifrices:

- Nano-HAP containing - Aclaim™, Group Pharmaceuticals, Bangalore, India.
- 5% Potassium Nitrate containing - RA Thermoseal™, ICPA Health Products Ltd., Mumbai, India.

They were evaluated clinically using three different stimuli, i.e., tactile, air blast, and cold water test. Patient's response to various stimuli were recorded using Visual Analog Scale (VAS) at baseline and after 4 weeks. Inter-group comparison and Intra-group comparison at baseline and after 4 weeks were evaluated using Mann-Whitney Test and Wilcoxon matched-pairs signed-ranks test for non-normally distributed variables. **Results:** Both groups showed reduction in sensitivity scores at 4 weeks of usage of respective dentifrices, difference between groups was statistically non-significant. **Conclusions:** Because nano-HAP containing dentifrice showed greater reduction in sensitivity compared to potassium nitrate containing dentifrice, it may provide a new direction for treatment of DH.

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INTRODUCTION

Dentin hypersensitivity (DH) is a common oral health problem affecting one or more teeth of many adult individuals all over the globe. DH is defined as "a short, sharp pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic or chemical and which cannot be ascribed to any other form of dental defect or pathology (disease)" (Canadian Advisory Board on Dentin Hypersensitivity, 2003). Hypersensitivity may present, on one specific tooth, on several teeth or in one area of the oral cavity. Canines and premolars are the most commonly affected teeth. Buccal aspect of the cervical area of these teeth is the commonly affected site (Addy, 1987). Two processes are required for DH to occur: dentin has to be exposed (lesion localisation) and dentin tubules have to be open to external stimuli and patent at the pulp (lesion initiation) (Addy, 2002; Dababneh et al., 1999). Gingival recession is important route through which dentin becomes exposed. Once recession occurs, the cementum covering dentinal surface gets easily removed thereby exposing the underlying dentin (Addy, 2002; Cummins, 2009). The second route through which dentin can become exposed is enamel loss. Enamel loss occurs as a part of tooth wear from attrition, abrasion or erosion (Dowell, 1983; Osborne-Smith *et al*., 1999). Attrition is the loss of tooth substance caused by tooth-to-tooth contact. Abrasion is the progressive loss of hard tooth substance caused by mechanical actions other than mastication or tooth-to tooth contacts such as the over-vigorous use of a tooth brush, or the consumption of abrasive and fibrous diets. Erosion is the progressive loss of hard dental tissues by chemical processes or acids not produced by cariogenic bacteria as in case of GERD or extrinsic acids derived from dietary and medication sources (Litonjua *et al*., 2003).

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Numerous theories have been cited to explain the mechanism involved in dentinal hypersensitivity. The currently accepted hypothesis is the hydrodynamic theory. Brännström, working on Gysi's hypothesis that dentine hypersensitivity may be caused by movement of the dentinal tubule contents, suggested this theory (Gysi, 1990) A thermal, tactile, chemical, osmotic or evaporative stimulus leads to the movement of the fluid contained within dentinal tubules, which in turn stimulates pulpal nerve fibres and results in a short, sharp pain characteristic of DH, as detailed in the 'hydrodynamic theory' of DH (Brännström, 1963).

Thus, the strategies to treat DH either aim to block the pulpal nerve response or occlude dentine tubules to prevent fluid movement. The first approach is the use of a dentifrice that desensitizes the nerves, disrupting the effect of stimuli on the nerve transmission and the pain response in the dentinal tubules. Potassium salts, such as potassium nitrate generally used as the active agents in desensitizing dentifrices is believed to work by penetrating the length of the dentin tubule and depolarizing the nerve, interrupting the neural response to pain stimuli (Markowitz & Kim, 1992; Ajcharanukul *et al*., 2007) Agents employed in the latter approach include stannous, strontium or oxalate salts; arginine; silicas and bioactive glasses, all of which act by forming precipitates over the dentine surface and within the tubules, thereby reducing dentinal fluid movement and nerve activation in response to external stimuli (Bamise & Esan, 2011; Ling & Giam, 1996).

Recently, considerable attention is being given to the research concerning the use of mineral components of the inorganic portion of the tooth structure - calcium and phosphate in dentistry (Earl *et al*., 2006; Kim *et al*., 2009) It has inspired the preparation of hydroxyapatite (HAP) for occlusion of dentinal tubules (Shetty *et al*., 2010). Nano-HAP containing dentifrices are the newer products which are available in the market for DH. So, the aim of the study was to compare and evaluate the effect of nano-HAP dentifrice with another dentifrice containing 5% Potassium nitrate, which has been widely used in reducing DH.

MATERIALS AND METHODS

The study was a single centre, randomized double blind, parallel group design with a duration of 4 weeks. Prior to the start of the study, ethical clearance was obtained from the Institutional Ethics Committee, Government Dental College and Hospital, Aurangabad. The study was conducted in agreement with the principles of the Declaration of Helsinki (World Medical Association Declaration of Helsinki, 2008). Prior to commencement of the study, written informed consent was obtained from all participants. Patients with self-reported hypersensitivity of teeth to hot or cold stimuli, visiting the out-patient department of Government Dental College and Hospital, Aurangabad during the period of August-November 2018, were recruited for the study with the following inclusion and exclusion criteria.

Inclusion criteria: Patients with a history of hypersensitivity to hot or cold stimuli, having at least 20 permanent teeth in their mouth and willing to participate in the study were included in the study.

Exclusion criteria: Patients with active cervical caries, chipped teeth or defective restorations; who have undergone periodontal surgery in the preceding 6 months; having orthodontic appliances, dentures or bridgework that would interfere with evaluation of hypersensitivity were excluded from the study. Also, patients who underwent any dental treatment for hypersensitivity of teeth in last 6 months; having history of use of medications that could interfere with the perception of pain including chronic use of anti-inflammatory, analgesic, anticonvulsant, sedative or other psychotropic drugs and pregnant or lactating females were not included.

About 46 subjects (26 females and 20 males) between the age of 20 and 58 years fulfilled the inclusion and exclusion criteria. The study was explained to the subjects and signed informed consent was obtained from them. After thorough clinical examination at the baseline, the subjects received oral prophylaxis, oral hygiene instructions and dietary counselling. They were then randomly divided into two groups of 23 subjects each. Each group was provided with one of the either dentifrices:

- Nano-HAP containing - Aclaim™, Group Pharmaceuticals, Bangalore, India.
- 5% Potassium Nitrate containing - RA Thermoseal™, ICPA Health Products Ltd., Mumbai, India.

The subjects were advised to use the respective toothpaste with soft bristle toothbrush twice a day for brushing teeth. They were also refrained from using any other dentifrice or mouthrinse during the study.

Sensitivity assessment: To assess tooth sensitivity, tactile stimuli (dental explorer), air/evaporative stimuli (blast from dental syringe) followed by thermal stimuli (cold water) were used. The stimuli were applied in the same order with 10 min interval between them. Following application of each stimuli, responses of the subjects to these stimuli were recorded using a Visual Analog Scale (VAS) at baseline and after 4 weeks. VAS is a 10 cm scale, with the score of 0 being a no-pain response and a score of 10 being extreme pain or discomfort.

For the tactile test, a sharp dental explorer was passed across the buccal surface of the tooth, perpendicular to its long axis. For the airblast/evaporative test, a blast of air was directed onto the affected area of the tooth for 1 second from a distance of 10 mm using a standard dental unit syringe at a pressure of 40–65psi. For the thermal test, 0.3 ml cold water obtained from freshly melted ice was applied immediately to the buccal cervical region of tooth using a disposable dental syringe. The tests were repeated three times before a mean score was recorded. The adjacent teeth were isolated with cotton rolls before applying the stimuli. The subjects were recalled after 4 weeks for the assessment of tooth sensitivity.

Statistical Analysis: Data obtained from the study was entered in Microsoft Excel spreadsheet and analysed using SPSS software (version 18). For the tests, a two-tailed value of $p < 0.05$ was considered as statistically significant. The normality distribution of all scores was assessed using the Kolmogorov and Smirnov test. Inter-group comparison at baseline and after 4 weeks were evaluated using Mann-Whitney Test for non-normally distributed variables. Intra-group comparison at baseline and after 4 weeks were evaluated using Wilcoxon matched-pairs signed-ranks test for non-normally distributed variables.

RESULTS

The mean VAS scores of each of the three tests - tactile, airblast and cold water test at baseline and after 4 weeks by both the groups are reported in Table 1.

particular attention has been given to home use dentifrices containing various active compounds which act by either blocking the hydrodynamic mechanism or the neural response (Orsini, 2010). Desensitizing dentifrices have been used widely in the past because of their low cost and ease of use for the home application.

Table 1: Comparison of mean VAS scores at baseline and after treatment between groups

Tests		Aclaim™ (mean ±SD)	RA Thermoseal™ (mean ±SD)	p value	
Tactile	Baseline	6.47 ± 0.99	6.304 ± 0.92	0.5425	NS
	4 weeks	4.65 ± 0.93	4.60 ± 0.83	0.8245	NS
Air Blast	Baseline	6.69 ± 0.87	6.39 ± 0.78	0.2022	NS
	4 weeks	4.91 ± 0.73	4.65 ± 0.71	0.2333	NS
Cold Water	Baseline	7.26 ± 0.91	7.34 ± 1.07	0.8337	NS
	4 weeks	5.13 ± 0.75	5.21 ± 0.73	0.7223	NS

SD- Standard deviation, NS- Nonsignificant

Table 2. Comparison of mean VAS scores at baseline and after 4 weeks of treatment with nano-HAP containing - Aclaim™ dentifrice

Tests	Aclaim™ (mean ±SD)		Mean Difference	p value
	Baseline	4 weeks		
Tactile	6.47 ± 0.99	4.65 ± 0.93	1.826	< 0.0001
Air Blast	6.69 ± 0.87	4.91 ± 0.73	1.783	< 0.0001
Cold Water	7.26 ± 0.91	5.13 ± 0.75	2.13	< 0.0001

SD- Standard deviation

Table 3. Comparison of mean VAS scores at baseline and after 4 weeks of treatment with 5% Potassium Nitrate containing - RA Thermoseal™ dentifrice

Tests	RA Thermoseal™ (mean ±SD)		Mean Difference	p value
	Baseline	4 weeks		
Tactile	6.30 ± 0.92	4.60 ± 0.83	1.696	< 0.0001
Air Blast	6.39 ± 0.78	4.65 ± 0.71	1.739	< 0.0001
Cold Water	7.34 ± 1.07	5.21 ± 0.73	2.13	< 0.0001

SD- Standard deviation

There was no significant difference between groups at baseline for tactile, air blast and cold water tests. Although both the groups showed reduction in sensitivity scores at 4 weeks of usage of respective dentifrices, the difference between the groups was statistically non-significant.

Table 2 shows the comparison of mean VAS scores at baseline and after 4 weeks of treatment with nano-HAP containing - Aclaim™ dentifrice to each of the three tests - tactile, airblast and cold water test.

There was a reduction in sensitivity scores of all the three tests after 4 weeks of using nano-HAP containing - Aclaim™ dentifrice. The difference in mean VAS score at baseline and after 4 weeks for all the three tests with nano-HAP dentifrice was found to be statistically significant ($P < 0.001$).

Table 3 shows the comparison of mean VAS scores at baseline and after 4 weeks of treatment with 5% Potassium Nitrate containing - RA Thermoseal™ dentifrice to each of the three tests - tactile, airblast and cold water test. There was a reduction in sensitivity scores of all the three tests after 4 weeks of using 5% Potassium Nitrate containing - RA Thermoseal™ dentifrice. The difference in mean VAS score at baseline and after 4 weeks for all the three tests with 5% Potassium Nitrate dentifrice was found to be statistically significant ($P < 0.001$).

DISCUSSION

Dentinal hypersensitivity is a relatively common problem experienced in clinical dental practice. A number of treatment modalities have been recommended over the years, and

The present randomized controlled trial investigated the efficacy of two dentifrices in reduction of DH. Of these dentifrices is a newly developed nano-HAP containing - Aclaim™ dentifrice, and an active control represented by 5% Potassium Nitrate containing - RA Thermoseal™ dentifrice. The results of the present study demonstrate reduction in sensitivity scores for both the treatment groups from baseline to 4 weeks for all the three tests of sensitivity. The reduction in sensitivity scores was greatest for cold water test, followed by airblast and tactile tests. Although the reduction in sensitivity scores for tactile and airblast tests after 4 weeks was greater for nano-HAP containing - Aclaim™ dentifrice as compared to 5% Potassium Nitrate containing - RA Thermoseal™ dentifrice, no statistical difference was found between the two dentifrices for all the three sensitivity tests.

Potassium nitrate is one of the many desensitizing agents that have been used and studied. According to Wichgers and Emert (Wichgers & Emert, 1997) and Kim, (Kim, 1986) the desensitizing effect of potassium nitrate is due to the increase in concentration of extracellular potassium around the nerve fibres which cause their depolarization and prevents repolarization. This results in inactivation of the action potential blocking the axonic action and thus the passage of nerve stimulus. It has been considered a superior desensitizer by Hodosh, (Hodosh, 1974) as it could cause rapid relief of symptoms.

HA is a major component of human bones and teeth (Driessens, 1982). Artificial HA is widely recognized as a safe biological material which has a crystal structure similar to natural bone minerals and human teeth (Li *et al*., 1994). Nano-HA dentifrice technology has been recently developed and

introduced in dentistry. In a study, 10% nano-hydroxyapatite solution was able to remineralise artificial carious lesions (Huang *et al*., 2009). The Scanning Electron Microscopy (SEM) images of nano-hydroxyapatite treated dentine surface has showed that the entire dentine surface was covered by precipitate layer deposit of nano-hydroxyapatite thereby plugging and forming a protective layer on the surface of dentine (Amaechi *et al*., 2015) Thus, this biofunctional material has both desensitizing and remineralizing potential for treatment of DH.

In vitro studies have also suggested that use of HAP containing dentifrices is better than fluoride dentifrices, as HAP induces a surface remineralization, forming a biomimetic apatite coating on enamel and dentin surface, which quickly occurs due to the chemical-physical characteristics of innovative nano-structured HAP particles, which closely resemble mineral enamel constituents (Roveri *et al*., 2009; Wang *et al*., 2009) Browning *et al* reported that nHAP-containing dentifrice was able to provide relief of bleaching related tooth sensitivity (Browning *et al*., 2012)

Conclusion

In conclusion, this study demonstrates that the two study groups using either a nano-HAP containing - Aclaim™ dentifrice or 5% Potassium Nitrate containing - RA Thermoseal™ dentifrice over a duration of 4 weeks experienced statistically significant reductions in DH compared to baseline, however no statistically significant difference was found between them for all the three sensitivity tests. Because nano-HAP containing dentifrice showed greater reduction in sensitivity compared to highly efficacious potassium nitrate containing dentifrice, it may provide a new direction for the treatment of DH.

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Keypoints

- nano-HAP containing – dentifrice showed statistically significant reductions in sensitivity scores compared to baseline.
- nano-HAP containing – dentifrice may provide a new direction for the treatment of dentin hypersensitivity.
- As the prevalence of dentin hypersensitivity is increasing in public, relatively cheaper treatment options like nano-HAP containing – dentifrice have important role to play in approving public oral health.

Glossary of Abbreviations

DH - Dentin hypersensitivity
GERD -Gastroesophageal reflux disease
HAP - hydroxyapatite
VAS - Visual Analog Scale
SPSS – Statistical Package For The Social Sciences
NS – Non-significant
SD – Standard deviation
HA – Hydroxyapatite
SEM - Scanning Electron Microscopy

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