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A Double-Blind Clinical Trial for Dental Hypersensitivity Treatment using Dentifrice

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Abstract

A randomized double blind clinical trial performed for comparative efficacy among five different toothpastes for dental hypersensitivity. The trial was performed with 175 (one hundred seventy five) number of subjects in total divided into four groups of 35 each. The subjects were evaluated for instant relief (dab on study) after 60 sec of application and a long term relief from dental hypersensitivity after usage for 8 weeks. Test group 1 (Potassium nitrate, Alum, Herbal extract, essential oils) and test group 2 (Potassium nitrate, Hydroxyapatite, Alum, Herbal extract, essential oils) showed a statistically significant improvement in long term dental hypersensitivity relief and a better efficacy in instant relief when compared to commercially available toothpaste 3 and 4 (Control group 1 and 2). However, there were no significant results obtained against Control group 3.

Keywords: Dentin hypersensitivity; Toothpaste; Potassium nitrate; Hydroxyapatite; Sensitivity

Introduction

Exaggerated response to any stimuli which is generally not perceived in normal tooth is known as dentin hypersensitivity [1]. Scientifically it is defined as short, sharp pain arising from exposed dentin typically in response to chemical, thermal, tactile, or osmotic stimuli that cannot be explained by the presence of other forms of dental defect or pathology. Dentin under normal is covered by enamel or cement and is not directly exposed to the buccal environment [2]. However, due to gingival recession, periodontal treatment, improper brushing habits or a combination of more than one factor the enamel or cementum may be removed or denuded abrasion, erosion, attrition to root surface exposure causing dental hypersensitivity [3].

In many parts of the world, dentin hypersensitivity is a prevalent oral problem [4-6]. 70% of periodontal patients experience dentin hypersensitivity with potential high risk [7]. The condition can last for days, weeks or indefinitely unless treatment is provided. The impact of dental hypersensitivity ranging the minor inconvenience to the patient, limiting dietary choices, impeding effective oral hygiene, negatively affecting appearance, and significantly affecting individual's quality of life [8].

The management of dentin hypersensitivity generally encompasses treatment that addresses its etiological and predisposing factors. A correct diagnosis is based on history and examination. The signs and symptoms must be compatible with the clinical description of dentin hypersensitivity and must be differentiating and distinguishing from other conditions that can give rise to similar symptoms. Etiological and predisposing factors such as incorrect tooth brushing and corrosive dietary habits should be identified. Individualized oral hygiene instruction and dietary advice and analysis should also be provided. Treatment should aim to alleviate the pain and concern of the patient [9].

Everyday solution to the problem includes Over-The-Counter (OTC) toothpaste containing potassium nitrate, hydroxyapatite, bio-glass, arginine based toothpaste. But the most widely used and economical method is products based out of potassium nitrate. During pain sensation in dentin hypersensitivity, sodium potassium channel at the end of the nerve sends the signal, which is processed as pain at a particular site of tooth. So, one of the approach is to interrupt the neural response to pain stimuli by inserting potassium ions through the dentin tubules to the A-fibers of the nerves, thereby decreasing the excitability of these nerves[10].

Potassium from potassium nitrate provides excess potassium ions concentration outside the channel leading the signal blocking to brain. Hence the brushing with toothpaste containing potassium nitrate helps in management of pain from dental hypersensitivity. Certain essential oils like Clove which contains eugenol as major component, has an obtundent effect which numbs nerves and controls pain. The oil is also known to have antibacterial action against Streptococcus mutans which is involved in dental caries [11].

Cinnamon oil is another well-known essential oil and contains cinnamaldehyde as major constituent. It is very well known to possess anti-bacterial properties against gram negative and gram positive bacteria responsible for oral diseases like cavities, malodour etc. Metal salts like of zinc, aluminium etc are also widely used in maintaining oral hygiene. The metals salts are known to possess anti-bacterial action and acts by various mechanisms to inhibit the growth of bacteria and other disease causing germs. Aluminum has significantly proven to reduce the ability of streptococci to colonize on enamel surfaces and decreasing the colloidal stability of oral bacteria and thus has antimicrobial activity against cariogenic streptococci as well as the normal oral flora and periodontal pathogens [12].

Alum or Spartika is also a well-known ingredient in ancient Ayurveda text to possess properties like astringent, anti-plaque, anti-gingivitis, antimicrobial, antiseptic, anti-calculus, decreasing dentinal hypersensitivity, prevention of halitosis, reduction of enamel dissolution, and symbiotic activity with fluoride. Anacyclus pyrethrum also known as toothache tree is another wonder plant reported in many ancient and traditions across the globe. It has been reported in Iranian and Indian ancient medicinal system for dental care. A particularly root of the plant have found to be sialagogue and has been reported in prevention and treatment tooth pain and other oral diseases. It is also found useful as a remedy for paralysis of the tongue and throat muscles, and in neuralgic problems of the teeth. These herbs alone or in combination like clove oil, cinnamon oil, Alum, extracts of roots of

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Anacyclus pyrethrum etc. has also been reported in Ayurveda literatures to give symptomatic relief [13].

Apart from individual herbs, certain traditional compositions are well known to provide symptomatic relief from dental hypersensitivity. One such classical composition mention in one of the ancient Ayurveda sculpture is irimedadi oil. The composition mentions odd 20 herbs prepared in a systemic manner to produce sesame oil based oil. The classical formula is known to provide relief from toothache, dental caries, bleeding gums and malodor [14].

Methodology

A 8 weeks, double blind, five-arm, parallel group, randomized clinical study involving subjects with at least two hypersensitive teeth. After baseline assessments, subjects (n=175) were randomly assigned to one of five study groups [15, 16].

Inclusion criteria

- The subject between the ages of 18-60 years exhibit dental hypersensitivity to at least two teeth.
- Patients with at least two sensitive teeth assessed by tactile test having Visual Analogue Scale (VAS).

Exclusion criteria

- Dental pathology which caused due to dentinal hypersensitivity
- Orthodontic appliances or restorations that may interfere with evaluation.
- Dentures interfering evaluation.
- Periodontal surgery within the previous 6 months
- Ongoing treatment with antibiotics and/or anti-inflammatory drugs or tooth hypersensitivity or anticonvulsants, antihistamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs, or daily analgesics.
- Pregnancy or lactation
- Any treatment taken for dental sensitivity other than the dentifrice product (toothpaste).

Statistical software

SPSS 19.0 will be used to analyze the data and Microsoft excels for graphs, tables, etc.

Clinical examination

Dental and complete mouth examination was done at base line, 60 seconds, 2 weeks, 4 weeks and 8 weeks. At each visit a minimum of two and up to four hypersensitive teeth were assessed using the most common and validated stimuli tests and summary of the test points are summarized in Table 1.

Tactile test: A sharp dental explorer (EXD 11-12, Hu-Friedy, and Chicago, IL, USA) passed across the facial area of the tooth, perpendicular to its long axis, at an approximated constant force. The test will be repeated three times before a score is recorded.

VAS scale: Visual Analog Scale (VAS) is a psychometric response scale. The degree of hypersensitivity was reported according to VAS. Score was given on a 10 cm sensitivity VAS, which had ratings from:

- 0 to 1 no pain,
- 2-3 for mild pain,
- 4-6 for moderate,
- 7-10 for severe pain.

Subjects with baseline values 4-6 on VAS was accepted into the present study.

Air blast test : A blast of air directed onto the affected area of the tooth for 1 s from a distance of 10 mm, while the adjacent teeth isolated using cotton rolls, using a standard dental unit syringe of 40–65 psi at a temperature of 17–21.1°C [17,18].

The schiff cold air sensitivity scale: For evaluating the air blast hypersensitivity, the tooth to be examined was isolated from the adjacent teeth by placing the examiner's fingers over the adjacent teeth. Air to be delivered from a standard dental unit air syringe at 60 psi (± 5 psi) and 70°F (± 3°F), directed at the exposed buccal surface of the hypersensitive tooth for one sec from a distance of approximately one cm.

The schiff cold air sensitivity scale to be used to assess subject response to this stimulus, as follows:

- 0=Subject did not respond to air stimulus;
- 1=Subject responded to air stimulus but did not request discontinuation of stimulus.
- 2=Subject responded to air stimulus and requested discontinuation or moved from stimulus.
- 3=Subject responded to air stimulus, considered stimulus to be painful, and requested discontinuation of the stimulus.

The above stimuli tests were applied in the above order, with a minimum 5 min. gap between the applications of different stimuli.

For instant relief measurement: The test products were massaged onto the tooth exhibiting dentin hypersensitivity only once with a gloved finger by the investigator for a minute (60 sec) after the initial baseline examination (Table 1).

Parameters		
Time points	**Air blast**	**Tactile test**
Visit 1/baseline	√	√
Visit 1/Day 0/Instant Relief (60 Sec)	√	X
Visit 2 (2 weeks)	√	√
Visit 3 (4 weeks)	√	√
Visit 4 – (8 weeks)	√	√

Table 1: Evaluation time points.

The oral tissue examination includes visual assessment of the soft and hard palate, gingival and buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, and the tonsillar and pharyngeal areas.

Materials

Commercially available soft-bristle toothbrushes were provided to the panellists for use during the study. Safety studies were also performed on all the above test and control products and no adverse effects were observed (Table 2).

Results

The patients were clinically analysed as per defined protocols for 60 sec dab study for instant relief and upon prolong usage (8 weeks twice a day) for long lasting relief from dental hypersensitivity. Upon completion of study, it was found that both the test group 1 and 2 were statistically significant to provide instant sensitivity relief than Control group 1.

Also, test group 1 and test group 2 were statistically significant in providing long lasting sensitivity relief than Control group 1 and control group 2 as summarized in Tables 2-4 respectively.

The percentage reduction in air blast test and tactile test for estimation of long-term sensitivity relief when compared to control group 1 and control group 2 are summarized in Tables 5 and 6 respectively. These percentage reductions are calculated as change from baseline values. However, test group 1 and 2 showed no statistical difference than control group 3 in instant and long-term sensitivity relief (Tables 3 and 4).

Groups	Details	Active ingredients
Test group 1 toothpaste	Dabur sensitive gel toothpaste	Potassium nitrate (Shora), Potash alum (Spartika), Herbal extracts (Pipali, Tomar, Maricha, Sunthi) and essential oils excipients (Gel Base): Q.S
Test group 2 toothpaste	Dabur sensitive gel advanced toothpaste	Potassium nitrate (shora) Hydroxyapatite Potash alum (spartika) Herbal extracts (pipali, tomar, maricha, sunthi) and essential oils Excipients (gel base): q.s
Control group 1-toothpaste	Commercial toothpaste-dental cream	Sodium monoflurophosphate in calcium carbonate base
Control group 2-gel	Commercial sensitivity toothpaste-freshmint	Sodium fluoride and potassium nitrate in gel base
Control group 3-gel toothpaste	Commercial sensitivity toothpaste-repair and protect	Sodium monofluorophosphate, novamin in gel base

Table 2: Product details of toothpastes.

	Instant relief		Total	"X" times instant Relief (as compared to ordinary fluoride toothpaste i.e. control group 1-toothpaste)
Group	Yes	No		
Control group 2-Gel	19	16	35	2.1X
n/%	54.30%	45.70%	100.00%	
Control group 3-Gel toothpaste	24	11	35	2.6X
n/%	68.60%	31.40%	100.00%	
Control group 1-toothpaste	9	26	35	X
n/%	25.70%	74.30%	100.00%	
Test group 1 toothpaste	27	8	35	3.0X
n/%	77.10%	22.90%	100.00%	
Test group 2 toothpaste	28	7	35	3.1X
n/%	80.00%	20.00%	100.00%	
Total	107	68	175	3.1X
N/%	61.10%	38.90%	100.00%	
Note: Pearson chi-square test=29.006, df=4, p–value<0.001 (very highly significant).				

Table 3: Instant relief day 1 brushing compared to ordinary Fluoride toothpaste.

Test	Product	N	Mean	Std. Deviation	Std. Error
Tactile test score at baseline	Control group 2-Gel	35	5.7143	0.45835	0.07748
	Control group 3-Gel toothpaste	35	5.6857	0.47101	0.07961
	Control group 1 toothpaste	35	5.6286	0.49024	0.08287
	Test group 1 toothpaste	35	5.7143	0.45835	0.07748
	Test group 2 toothpaste	35	5.3143	0.58266	0.09849
	Total	175	5.6114	0.51180	0.03869
Tactile test score at 2 weeks	Control group 2-gel	35	5.2000	0.40584	0.06860
	Control group 3-gel toothpaste	35	5.1143	0.32280	0.05456
	Control group 1-toothpaste	35	5.4286	0.50210	0.08487
	Test group 1 toothpaste	35	4.9429	0.23550	0.03981
	Test group 2 toothpaste	35	4.8000	0.40584	0.06860
	Total	175	5.0971	0.43779	0.03309
Tactile test score at 4 weeks	Control group 2-gel	35	4.8857	1.27813	0.21604
	Control group 3-gel toothpaste	35	4.7143	1.25021	0.21132
	Control group 1 toothpaste	35	5.2857	0.45835	0.07748
	Test group 1 toothpaste	35	3.8571	0.97446	0.16471
	Test group 2 toothpaste	35	3.5714	0.55761	0.09425
	Total	175	4.4629	1.15348	0.08719
Tactile test score at 8 weeks	Control group 2-gel	35	4.6000	1.43895	0.24323
	Control group 3-gel toothpaste	35	4.4000	1.75231	0.29619
	Control group 1 toothpaste	35	4.9714	1.01419	0.17143
	Test group 1 toothpaste	35	3.2857	1.34101	0.22667
	Test group 2 toothpaste	35	2.7143	0.75035	0.12683
	Total	175	3.9943	1.54807	0.11702

Table 4: Tactile test for teeth hypersensitivity (long term sensitivity relief) at different time points.

One way anova test find out the tactile sensation among 5 groups at 4 different time intervals. It was found that Test Group 2 toothpaste and Test Group 1 toothpaste were showing highly significant reduction in tactile sensation at 8 weeks interval as compared to Control group 2-Gel, Control group 1-toothpaste. Test Group 2 toothpaste is showing higher reduction in tactile sensation as compared to Test Group 1 toothpaste (Table 5).

Test Group	CFB% 2 weeks	CFB% 4 weeks	CFB% 8 weeks	"X" times Percent reduction hypersensitivity ABT at 8 weeks (as compared to least efficacy, i.e. Control group 1-toothpaste)
Control group 1-toothpaste	1.81	9.08	14.50	---
Test Group 1 toothpaste	10.50	43.80	50.80	3.50X
Test Group 2 toothpaste	10.70	41.10	55.35	3.81X
Note: CFB : Change From Baseline, ABT: Air Blast Test				

Table 5A: CFB Percentage Reduction of ABT (long term sensitivity relief) scores compared to ordinary fluoride toothpaste (control group 1 toothpaste); at various time points.

Test Group	CFB% 2 weeks	CFB% 4 weeks	CFB% 8 weeks	"X" times Percent reduction hypersensitivity ABT at 8 weeks (as compared to Control group 2-gel)
Control group 2 gel	3.38	13.50	16.90	-----
Test Group 1 toothpaste	10.50	43.80	50.80	3.00X
Test group 2 toothpaste	10.70	41.10	55.35	3.15X
Note: CFB: Change From Baseline, ABT: Air Blast Test				

Table 5B: CFB Percentage Reduction of ABT (long term sensitivity relief) scores compared to marketed gel containing only potassium nitrate (control group 2 gel); at various time intervals.

Test group	CFB% 2 weeks	CFB% 4 weeks	CFB% 8 weeks	"X" times Percent reduction hypersensitivity TT at 8 weeks
Control group 1 toothpaste	3.60	6.09	11.60	-----
Test Group 1 toothpaste	13.40	32.50	42.50	3.66X
Test Group 2 toothpaste	9.67	32.80	48.90	4.21X
Note: CFB: Change From Baseline, TT: Tactile Test				

Table 6A: CFB Percentage Reduction of TT (long term sensitivity relief) compared to ordinary fluoride toothpaste (control group 1 toothpaste); at various time intervals.

Test group	CFB% 2 weeks	CFB% 4 weeks	CFB% 8 weeks	"X" times Percent reduction hypersensitivity TT at 8 weeks
Control group 2 gel	9%	17.40%	19.50%	-----
Test Group 1 toothpaste	13.40%	32.50%	42.50%	2.18X
Test group 2 toothpaste	9.67%	32.80%	48.90%	2.50X
Note: CFB: Change From Baseline, TT: Tactile Test				

Table 6B: CFB percentage Reduction of TT (long term sensitivity relief) scores compared to marketed gel containing only potassium nitrate (control group 2 gel); at various time intervals.

It was found that the percentage reduction in air blast test scores and tactile score were greater in test group 1 toothpaste and test group 2 toothpastes when compared to control group 1 toothpaste and control group 2 gel (Table 6).

Discussion

Dentin hypersensitivity is a common oral health problem that can last for days, weeks or indefinitely unless treatment is provided [19]. Some of the reasons for tooth hypersensitivity includes incorrect tooth brushing method and gingival recession [20]. The clinical trial found a significant immediate pain reduction and a long-lasting sensitivity relief from tooth hypersensitivity after desensitizing toothpaste containing herbs and potassium nitrate or combination of potassium nitrate with hydroxyapatite was applicator for 60 seconds to tooth dentine. The study was a practitioner-based clinical, and thus had the advantage of creating study patient accrual rates. It also broadened the pool of study patients in clinical trials, thus making study results more generalizable [21-25].

A blast of compressed cold air delivered from a three-in-one syringe to the tested teeth was used in the dental clinics to assess hypersensitivity. This is a common assessment method that has been used in several clinical studies [26,27]. The 5% Potassium Nitrate (KNO_3) desensitizing toothpaste is primarily for home use [2]. This treatment is effective. Subjects, as well as the investigators, were blinded to their study group assignment. The second evaluation of self-perceived sensitivity score was performed right after the 60 seconds of toothpaste application, the variations between subjects would be small and unlikely to affect the outcome measured.

Brushing with potassium nitrate containing toothpaste is effective in pain relief due to dentin hypersensitivity [28]. Additionally, the hydroxyapatite is believed to occlude open dentins and thus provides relief in dental hypersensitivity. The trial suggests the synergistic effect of potassium nitrate containing toothpaste with the herbs used in formulation of test group 1 toothpaste. Another method of reducing the pain from tooth hypersensitivity is to occlude the open tubules to block the hydrodynamic mechanism [29-31]. Test group 2 toothpastes suggest further synergy of herbs along with potassium nitrate and hydroxyapatite. Both the test products have shown statistically significant results when compared to control 1 toothpaste and control 2 gels when measured for long term sensitivity relief at 8 weeks. Superior efficacy when compared to Control 1 toothpaste that lacks sensitivity control agents. However, the superiority shown over Control 2 is of point of interest. Here the Test 1 and Test 2 formula containing an admixture of Herbs, Minerals and Essential Oils along with Potassium Nitrate is postulated to provide an edge over the regular Potassium Nitrate based gel product [32,33].

Conclusion

It can be concluded that test product 1 (Potassium Nitrate, Alum, Herbal Extracts, essential oil) and Test 2 (Potassium Nitrate, Hydroxyapatite, Alum, Herbal Extracts, essential oil) were found to be statistically significant in reducing the dentin hypersensitivity long-term when used for 8 weeks duration twice daily as compared to the two-control marketed products Control 1 and Control 2.

Test 1 (Potassium Nitrate, alum, herbal extracts, essential oil) and Test 2 (Potassium Nitrate, Hydroxyapatite, Alum, Herbal Extracts, essential oil) were effective for instant sensitivity dab on relief when compared to control 1 toothpaste.

There was no statistically significant comparison of Test 1(Potassium Nitrate, Alum, Herbal Extracts, essential oil) and Test 2 (Potassium Nitrate, Hydroxyapatite, Alum, Herbal Extracts, essential oil) when compared to control group 3.

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