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Comparative Evaluation of Effect of a Herbal Versus A Non-Herbal Dentifrice on Dentinal Hypersensitivity: A Randomized, Controlled Clinical Trial

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Abstract
Background: *Dentinal hypersensitivity(DH) is a common problem and there is a growing interest in herbal based formulations for the treatment of oral diseases.*
Aim: *To assess and compare the effect of a commercially available herbal dentifrice versus a non-herbal dentifrice on dentinal hypersensitivity.*
Method: *A total of 57 sites showing DH were divided into two groups:*
Group 1 (28 sites) - Herbal dentifrice group (Hi Ora® K, The Himalaya Drug Company Research and Development, Makali, Bangalore, India)
Group 2 (29 sites)- Non-herbal dentifrice group (Sensodent- K, Indoco Remedies Limited, Mumbai)Respective dentifrices were dispensed to the subjects depending on the designated groups.*
The sensitivity scores were recorded at baseline and after 4 weeks:

- *Visual Analog Scale for air (VAS A),*
- *Visual Analog Scale for cold water (thermal) (VAS T),*
- *Verbal Rating Scale for air (VRS A),*
- *Verbal Rating Scale for cold water (thermal) (VRS T),*
- *Scratchometer test and*
- *Schiff's scale*

Results: *Intragroup comparisons showed statistically significant changes from baseline to 4 weeks for both the groups(p=0.000). On Intergroup comparison, group 2 (non herbal group) showed statistically more significant change in mean VAS A (0.037) and mean VRS T (0.019). Other variables showed no statistically significant difference.*
Conclusion: *The herbal (5% suryakshara + spinacea oleracea) and non-herbal (5% potassium nitrate) dentifrice showed significant difference in the reduction of DH from baseline to 4 weeks, however non herbal dentifrice showed better results.*
Key Words: *Dentinal Hypersensitivity, herbal, non-herbal, dentifrice.*
There are no conflict of interests in the present study.

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I. Introduction

Dentinal hypersensitivity (DH) is a common painful condition of the teeth in adult patients and is manifested in a manner that is physically and psychologically uncomfortable for them.[1] It is defined as a characteristic pain that arises from exposed dentine, typically in response to various stimuli, such as thermal, evaporative, tactile, osmotic, or chemical, which cannot be attributed to any other form of dental defect or pathology.[2] The prevalence ofDH varies from 4% to 57%, and mostly occurs in patients who are between 30 and 40 years of age.[3,4] (1) Any tooth or tooth surface can be affected but dentine hypersensitivity has a predilection for the buccal cervical regions of canines and premolars.[5]

The etiology of DH is multifactorial and results from dentine exposure and opening of dentinal tubules[4]by enamel loss by abrasion, erosion, or loss of cementum due to brushing or periodontal treatment,[6] or more commonly, by the association of two or more of these factors.[7,8]

Various models have been proposed to explain DH;

- Direct stimulation theory,
- Odontoblastic transducer mechanism,
- Gate control theory,
- Hydrodynamic theory,

The **hydrodynamic theory** is considered to be the**most plausible**.[9,10]

According to the **hydrodynamic theory** (Braennstroem and Astroem), the enamel or cementum loss in cervical areas opens upthe dentinal tubules to the oral environment. Due to any form of stimulus, there is movement of dentinal fluid inside the tubules which stimules the extremities of the pulp nerves, causing pain.[11]It was also found that open dentinal tubules serve as pathways for the diffusive transport of bacterial elements from the oral cavity to the pulp, which may cause a localized inflammatory pulpal response.[12] Microscopic examination reveals that patent dentinal tubules are more numerous and wider in hypersensitive dentine than in non-sensitive dentine.[13]

Therefore, the ideal treatment of DH, should be able to reduce fluid flow within dentinal tubules, block pulpal nerve response, or both.[14]Treatments can be applied by a dental professional in the dental office or self-administered by the patient at home.[15]Desensitizing dentifrices are the most commonly used over the counter products which can be used by the patients at home.

The American Dental Association Council on DentalTherapeutics has granted a seal of acceptance todentifrices containing 5% potassium nitrate.[16,17] The use of **potassium nitrate** as an effective desensitizing agent dates backs to the testimonial report of Hodosh in 1974. [18]Recently there has been growing interest in herbal based or health care products, **Herbal dentifrices** containing rhubarb stalks and spinach leaves have been shown effective in treatment of DH. Rhubark stalks and spinach leaves form calcium oxalate crystal by reacting with dentinal calcium which creates microcrstal deposition on dentine and inside dentinal tubules, thus reduce the tubular diameters by forming crystals.

Hence, the current study was designed to compare the effect of a commercially available herbal dentifrice versus a non-herbal dentifrice on dentinal hypersensitivity.

II. Materials And Method

Study Design

This was a single-centre, longitudinal, single masked (subjects only), randomized parallel arm study design. A total of 100 individuals were assessed for eligibility.

Inclusion Criteria

1. History of DH caused by gingival recession, erosion, abrasion, post surgical or non surgical periodontal treatment,
2. Having 20 natural permanent teeth.

Exclusion Criteria

1. Teeth with caries, defective restorations or chipped teeth
2. Subjects with orthodontic appliances or bridge work
3. Subjects who had undertaken treatment with any product that could influence the DH of the patient in the 30 days prior to baseline
4. Subjects allergic to ingredients used in the study
5. Smokers or tobacco chewers (ADA Guidelines),
6. Subjects having any systemic disease or any disease requiring repeated or regular analgesia, anti-inflammatory drugs
7. Pregnant or lactating women & those using oral contraceptive pills. 2

III. Study Protocol

A total of 57 sites were included in the study. Informed written consent was obtained from all subjects. The subjects included were randomized using lottery randomization method and categorized into two groups,

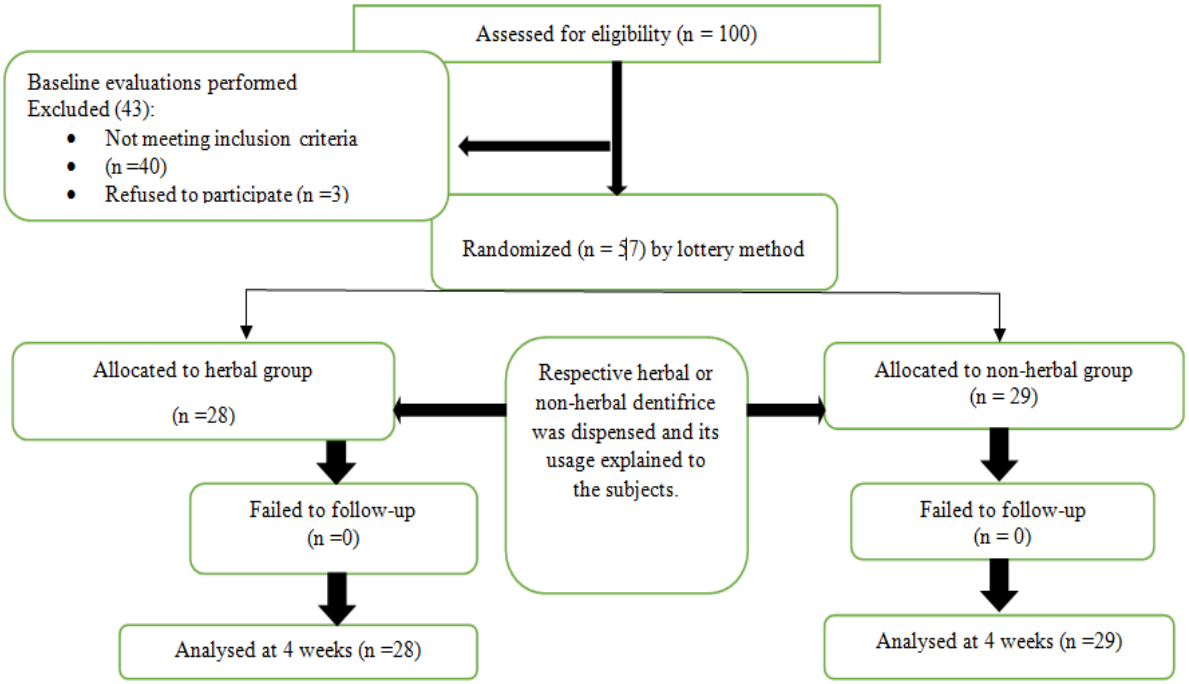
Group 1 (herbal group - HiOra® K; The Himalaya Drug Company Research and Development, Makali, Bangalore, India) containing **28 sites** and

Group 2 (non-herbal group - Sensodent*- K, Indoco Remedies Limited, Mumbai) consisting **29 sites**.
Each gram of **herbal dentifrice contained** 2.5 mg Cinnamomum zeylanicum, 2.5 mg Syzygium aromaticum, 10.0 mg Spinacia oleracea, 6.0 mg Triphala, 4.0 mg Trikatu and 30.0 mg Suryakshara (Potassium nitrate) and 10.0 mg Yashada bhasma (zinc oxide), sodium benzoate, calcium carbonate with sorbitol, glycerine and xanthan gum.

Each gram of **non-herbal dentifrice** contained Potassium nitrate 5% w/w in flavoured base Tartrazine, Brilliant blue FCF.

The **study duration** was **4 weeks**, in which sensitivity scores weremeasured at **baseline** and after**4 weeks**. A flowchart of the study is provided in Figure 1.

Fig. 1 Consort flow chart.



Sensitivity assessment

1. Controlled air stimulus (evaporative stimulus):

To assess tooth sensitivity using a 10- cm Visual analogue scale(VAS A) score, and 10 -cm Verbal rating scale (VRS A) score. A score of zero was given for a pain-free response both visually (by the operator) and verbally (by the patient). A score of 10 was given for excruciating pain or discomfort. Controlled air pressure, from a standard dental syringe at 40 to 65 psi at ambient temperature, directed perpendicular and at a distance of 1 to 3 mm from the exposed dentine surface was used. The adjacent teeth were protected with gloved fingers to prevent false–positive results.[19]

2. Cold water stimulus:

The second stimulus for testing tooth sensitivity was done after a period of at least five minutes. 10 ml of ice cold water was applied to the exposed dentine surface, keeping the neighbouring teeth isolated during testing by using the operator's fingers and cotton rolls.[19] using similar VAS (VAS T) and VRS (VRS T) scores.

3. Schiff Air Sensitivity Scale (Sh)

0 – Tooth/subject does not respond to air stimulus
1 – Tooth/subject responds to air stimulus but does not request discontinuation of stimulus
2 – Tooth/subject responds to air stimulus and requests discontinuation or moves from stimulus
3 – Tooth/subject responds to air stimulus, considers stimulus to be painful, and
requests discontinuation of the stimulus

4. Scratchometer test

which was used for eliciting pain.Force from 0 – 80 grams was employed. Higher the force that was required to elicit pain, lesser the sensitivity score.(S)

After recording parameters at baseline, subjects were given the respective dentifrice&advised to use it with a soft bristle toothbrush twice aday. Subjects were also directed to refrain from usingany other dentifrice or mouthrinse during the trial butwere allowed to continue their normal oral hygiene practice during the trial period. (1)

IV. Statistical Analysis

Data obtained was compiled on a MS Office Excel Sheet (v 2010). Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 21.0, IBM).Intra group comparison of variables at baseline vs at 30 days in each group was done using Wilcoxon Signed Ranks Test (WSR). For all the statistical tests, $p<0.05$ was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study as 80%.Inter group comparison of various variables (between the 2 groups) was done using Mann Whitney U test (since data was not distributed normally, as determined by Komlogorov-Smirnov test, $p<0.05$).Also inter group comparison of differences between various variables from baseline to 30 days was done using Mann Whitney U test.

V. Results

In intragroup comparison, there was a statistically highly significant difference seen in the mean for all the variables from baseline to 4 weeks ($p<0.01$) for both the groups.(Table 1).

TABLE 1- INTRAGROUP COMPARISON – from baseline to 30 days for both the groups :

	GROUP 1		**GROUP 2**	
Parameters	Mean	p value	Mean	p value
VAS A B VAS A 30D	4.04±1.232 3.07±1.215	0.000**	4.07±1.361 2.52±1.326	0.000**
VAS T B VAS T 30D	4.25±1.506 3.11±1.524	0.000**	4.10±1.263 2.72±1.192	0.000**
S B S 30D	28.21±2.63 30.64±2.614	0.000**	26.83±2.592 29.45±2.667	0.000**
VRS A B VRS A 30D	4.11±1.499 3.04±1.319	0.000**	3.97±1.295 2.69±1.004	0.000**
VRS T B VRS T 30D	4.64±1.420 3.54±1.478	0.000**	4.07±1.252 2.83±.928	0.000**
SH B SH 30D	1.39±.497 1.07±.262	0.003**	1.34±.484 1.03±.421	0.003**

* * = Statistically highly significant difference ($p<0.01$)

In intergroup comparison at <u>baseline</u> there was a statistically non-significant difference seen in mean VAS A, VAS T, VRS A & SH between both groups ($p>0.05$), however there was a statistically significant difference seen in mean S & VRS T at baseline ($p<0.05$). (Table 2)

In intergroup comparisons at 4 weeks non-herbal (Group 2) (Sensodent*- K) showed highly statistically significant change in mean VAS A (0.037) and VRS T (0.019) but other variables showed no statistically significant difference. (Table 2).

TABLE – 2 - INTERGROUP AT BASELINE AT 4 WEEKS

PARAMETERS	GROUPS	Mean	p value	Mean	p value
VAS A	1 2	4.04± 1.232 4.07± 1.361	0.830#	3.07±1.215 2.52±1.326	**0.037***
VAS T	1 2	4.25± 1.506 4.10±1.263	0.744#	3.11±1.524 2.72±1.192	0.424#
S	1 2	28.21±2.630 26.83±2.592	**0.033***	30.64±2.614 29.45±2.667	0.086#
VRS A	1 2	4.11±1.499 3.97±1.295	0.800#	3.04±1.319 2.69±1.004	0.230#
VRS T	1 2	4.64±1.420 4.07±1.252	**0.048***	3.54±1.478 2.83±.928	**0.019***
SH	1 2	1.39±.497 1.34±.484	0.710#	1.07±.262 1.03±0421	0.716#

* = Statistically significant difference ($p<0.05$)

= statistically non-significant difference ($p>0.05$)

VI. Discussion

The current study compared commercially-available herbal dentifrices with 5% potassium nitrate containing dentifrices. The results demonstrated that there was a significant reduction in symptoms of DH for both the Herbal group (group 1) (HiOra® K) and Non-herbal (group 2) (Sensodent*- K) from baseline to 4 weeks for all measures of sensitivity.

In the present study, DH decreased in the herbal group (group 1) from baseline to 4 weeks.

The components responsible for reducing DH in herbal group were Suryakshara (potassium nitrate) and Spinacia oleracea.

Past studies have found that soluble oxalates and oxalic acid are present in phytocomplexes in Spinacia oleracea (spinach leaves) and they form calcium oxalate crystals by reacting with dentinal calcium.[20] Reduction of the diameter of dentinal tubules reduce fluid flow and could induce clinically-acceptable reduction in pain.[21,22].The fluid volume moving across the dentine is proportional to the diameter and number of tubules.[19] In neutral and alkaline environments, calcium and oxalate could bind together forming different shaped crystals of calcium oxalate.[23]

Sauro et al. conducted a study [20] and concluded that treatment with oxalate-containing phytocomplexes induce microcrystal deposition on dentine and inside dentinal tubules, and thus reduce the tubular diameters by forming crystals or crystal-like structures. Therefore, Spinacia oleracea, and suryakshara (potassium nitrate) present in the herbal group, might have a synergistic effect in reducing DH by their dentinal tubule-obliterating properties. According to a study by, **Kumari M**, et al. in 2013 the herbal dentifrice (HiOra – K) can be recommended for treatment of dentinal hypersensitivity.[24]The current study is in accordance with the above studies.

Past studies have found that pastes containing 5% potassium nitrate significantly decrease DH when compared with baseline or negative controls.14–16,22 [25] The increase in the concentration of extracellular potassium around the nerve fibres causes their depolarization, avoids repolarization and blocks the axonic action and passage of nerve stimulus, thus inactivating the action potential.[26,27]

The decrease in the 5% potassium nitrate group (group 2 non herbal) in the current study is in accordance with the previous studies by **Schiff** et al in 2000 and **Sowinski** et al in 2001 . It has been found that potassium nitrate blocks passage of nerve stimulus but does not diminish dentin hydraulic conductivity or promote the obstruction of dentinal tubules by the deposition of crystals.[26]

In the present study, non-herbal (Group 2) (Sensodent*- K) showed highly statistically significant change in mean Visual Analog Scale using Air stimulus (0.037) and Verbal Rating Scale using Thermal Stimulus (0.019) but other variables showed no statistically significant difference. [22] The present study is not in accordance with a previous study ofKumari M et al in 2016 whoconcluded that the herbal dentifrice (Hi Ora – K) showed comparable results to the non-herbal dentifrice and can be recommended for the treatment of DH.

V. Conclusion

- Both the herbal (5% Suryakshara + Spinacea oleracea) and non-herbal (5% Potassium nitrate) dentifrice showed significant difference in the reduction of DH from baseline to 4 weeks.
- However, non-herbal dentifrice showed statistically better results for Visual Analog Scale using Air Stimulus and Verbal Rating Scale using Thermal Stimulus.
- Hence, according to this study we can conclude that **Non herbal dentifrice showed better results** for reduction in dentinal hypersensitivity from baseline to 4 weeks.

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