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RESEARCH ARTICLE

EVALUATION OF SAFETY AND EFFICACY OF NOVEL HERBAL TOOTHPASTE-MOUTHWASH (HIORA K) COMBINATION IN REDUCING DENTIN HYPERSENSITIVITY - IN VIVO STUDY

¹Dr. Ranjini Ashwath, ¹Dr. Rashmi, K., ¹Dr. Vedavathi, B., ^{1,*}Dr. Sruthi Somasundaran,
¹Dr. Neeharika G., ¹Dr. Aswath and ⁶Dr. Roopa R Nadig

¹Department of Conservative Dentistry and Endodontics, Dayananda Sagar College of
Dental Sciences, Bangalore

⁶Project Manager, the Himalaya Drug Company, Bangalore.

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ABSTRACT

Background: Dentinal hypersensitivity is a leading problem and herbal based formulations have been in use recently for the same. **Objective:** This study was conducted to evaluate the safety and efficacy of novel herbal toothpaste-mouthwash (HioraK) combination with a Complete Care toothpaste-mouthwash (Hiora K) combination in reducing dentinal hypersensitivity in vivo. **Methods:** A total of 80 subjects (24 males and 56 females; aged 25–60 years) were randomly divided into two groups: Group A- Hiora K tooth paste and mouth wash (The Himalaya Drug Company Research and Development, Makali, Bangalore) and Group B – Complete Care tooth paste and mouthwash combination (Hi Ora K, The Himalaya Drug Company Research and Development, Makali, Bangalore). Sensitivity scores for tactile, air stimulus and cold water were recorded at baseline, 7, 14 and 28 days. **Results:** Group A was significantly better compared to the Group B at the end of 7days in reduction of dentinal hypersensitivity but statistically similar by the end of 28 days. **Conclusions:** The novel herbal dentifrice and mouthwash combination can be recommended for treatment of dentinal hypersensitivity.

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INTRODUCTION

As per the ongoing researches, currently it has been reported that 4-74% of the dentate population has been suffering from Dentine hypersensitivity which is often referred to as the "common cold of dentistry". It is characterized by short, sharp pain, arising from exposed dentin in response to stimuli typically, thermal, evaporative (air), tactile (rubbing), osmotic or chemical which cannot be ascribed to any other form of dental defect or pathology (Holland *et al.*, 1997). This mainly affects the middle aged population essentially involving the buccal aspect of cervical areas of the teeth. The most common cause for this is gingival recession due to improper brushing habits (Que *et al.*, 2013). Several theories have been proposed to divulge the pathophysiology of dentin hypersensitivity amongst which Brannstrom's hydrodynamic theory is the most widely accepted. It states that the enamel or cementum loss in cervical areas and the consequent opening of dentinal tubules

to the oral environment, under certain stimuli, allows the movement of dentinal fluid inside the tubules, indirectly stimulates the pulp nerves extremities, causing pain. These open dentinal tubules serve as channels for the ingress of bacterial elements in the oral cavity to the pulp, which may cause a localized inflammatory pulpal response (Brännström, 1964). So the treatment for such sensitive teeth should involve either blockade of the tubules or nerve desensitization or a combination of both. Of these potassium nitrate has been routinely used in the reduction of hypersensitivity. Potassium nitrate reduces dentine hypersensitivity by the depolarizing action of the K ion resulting in decreased dentinal sensory nerve activity (Peacock, 1995). Also, several herbal agents have gained popularity for the treatment of hypersensitivity. Of these, spinach and rhubarb stalks have found to be effective as topical desensitizing agents. The phytocomplexes of these agents forms calcium oxalate crystals that aid in occlusion of the dentinal tubules thereby reducing the hypersensitivity (Sauro *et al.*, 2006). A new novel herbal toothpaste has been introduced by Himalaya (Hiora – K) that has desensitizing properties. It mainly contains *Suryakshara*, *spinacea*, *triphal*, *trikatu*, *clove* and *cinnamon*.

***Corresponding author: Dr. Sruthi Somasundaran,**
Department of Conservative Dentistry and Endodontics, Dayananda
Sagar College of Dental Sciences, Bangalore.

A Himalaya Hiora K product mouth wash is also available for sensitive teeth. It contains *suryakshara*, *Lavanga* and extracts of *holy basil*, *cloves*, *mace* and *peppermint*. An in vitro study done by Jewel Darsan *et al* evaluated the tubule occluding ability of the above mentioned desensitizing herbal products viz. Hiora K toothpaste and Hiora K mouthwash using SEM analysis at various time interval. It concluded that all the groups excluding control showed complete occlusion of dentinal tubule on the 45th and 60th day. On the remaining days better results were shown by the tooth paste group followed by combination group and least occlusion was seen in mouth wash alone group (Jewel Darsan *et al.*, 2017). There has been evidence in literature which shows that these formulations have therapeutic effects to relieve dentinal hypersensitivity. But, the studies which compare the effectiveness of a combination of toothpaste and a mouthwash are rare. Hence the present study was undertaken to evaluate the safety and efficacy of novel herbal toothpaste-mouthwash (HioraK) combination with a Complete Care toothpaste-mouthwash (Hiora K) combination in reducing dentinal hypersensitivity in vivo.

MATERIALS AND METHODS

The Study was a two arm, double blind, adaptive randomized, control study to evaluate efficacy of HiOra K tooth paste and mouthwash with complete care toothpaste and HiOra K mouthwash conducted at Department of Conservative Dentistry and Endodontics, Dayanandasagar College of Dental Sciences, Bengaluru. The study design (Table no. :1) was done considering availability of subjects, investigation paste (IP), evaluation criteria of sensitivity and to eliminate bias (both selection and treatment bias).The study protocol had been approved by the institute's committee on human research. This was a Phase IV clinical study and was performed in accordance with the current version of the declaration of Helsinki (52nd WMA General Assembly, Edinburgh, Scotland October 2000). The trial was conducted in agreement with the International Conference on Harmonisation (ICH) guidelines on Good Clinical Practise (GCP).All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology. potential risks, anticipated benefits) and the investigator explained these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patient was then allowed time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. All the subjects were issued with HiOra K mouthwash which has desensitising properties. For one group both HiOra K Toothpaste and mouthwash was issued and for another group complete care toothpaste along with HiOra K desensitising mouthwash was issued.Each Gram of Hiora K Toothpaste contains 2.5mg Cinnamomumzeylanicum, 2.5mg Syzygiumaromaticum, 10mg Spinaciaoleracea,6.0mg Triphala,4.0 mg Trikatu,30.0 mg Suryakshara,10.0 mg Yashadabhasma. Each Gram of HiOra K Mouthwash contains Suryakshara50.0, Jatiphala 0.50,Mishreya 0.50, Tulasi0.30, Lavanga 1.00, Nilgiri1.00, Cinnamomum 1.00, Peppermint sattva 2.00. Subject of either gender with good health and presenting with dentine sensitivity, willing to give a written informed consent and follow the schedule were included in the study.

Patients with active skin infection, sensitivity due to caries or restoration, currently using desensitizing toothpaste or mouthwash, pregnant and lactating women were excluded from the trial. To obtain 1:1 ratio sample size between each group adaptive simple randomization was followed. A random list of numbers was generated using software and assigned to each group. At the time of enrolment subjects were assigned a number in random. All the IP tubes were numbered using pre-randomized sequence. After screening subjects were allowed to pick any IP from the list. This ensured blinding to both Investigator and subject. Toothpaste was blinded and mouthwash was open label during the study. A total of 89 individuals were assessed for eligibility and based on inclusion and exclusion criteria, randomized into two groups, each containing 40 individuals who finally completed the study excluding the dropouts in each group. The Subjects participating in the study were aged 25–60 years. The mean age was not statistically different among groups and ranged from 41.4 years for Group 1 and 40.4 years for Group 2. Prior to start the study subjects underwent a proper oral examination and oral prophylaxis if required. Subjects were instructed to brush their teeth twice daily using the issued toothpaste and use 15 ml of mouthwash immediately after brushing their teeth.

Efficacy measurements assessed

To determine sensitivity level three tests were conducted on all visits. A gap of 3 minutes given between each test. Each visit different personal from investigator team performed the VAS pain scale: (FIG 1). Subjects were instructed to mark the point in the scale for which they can relate the pain intensity.

Tactile method: (FIG 2A)

Mechanical stimulation using a hand-held probe or explorer and apply mild force required to elicit a painful response.

Evaporative stimuli/Air blast stimulation: (FIG 2B)

A blast of air from a dental three-way syringe placed perpendicularly to the tooth at a distance of 3cms and the pain stimulus recorded.

Thermal stimulation/ Water jet stimulation: (FIG 2C) A jet of water from a dental three-way syringe placed perpendicularly to the tooth at a distance of 3cms and the pain stimulus recorded. Tooth with the highest value in the pain scale was selected for all future visit analysis. During screening investigator performed sensitivity test for the teeth which subjects complains of sensitivity. To reduce error due to brushing procedures only anterior and premolars labial surface was considered for sensitivity test. Investigator was allowed to continue treatment of all remaining teeth during trial except the tooth selected. Every visit Investigator performed complete oral examination and noted any abnormality or adverse events. Subjects were instructed to inform investigator if they experience any untoward events during the course of study.

Statistical Methods

Analysis was performed using Graphpad Prism 6 software Version 6.07 for Windows, Graph Pad Prism 6 Software, San Diego, California, USA. Results were analysed statistically by Friedman test followed by Dunn's multiple comparisons test for clinical efficacy parameters within the group analysis and

statistical analysis was performed for Plaque index and gingival index parameters using Repeated measures' ANOVA followed by Tukey's multiple comparisons test. Statistical analysis was performed for QOL Questioner calculated in percentage on Standard scale. The values are expressed as mean±SD.

RESULTS

HiOra K toothpaste and mouthwash combination reduced sensitivity by 37.47% in the first week whereas Complete care toothpaste and HiOra K mouthwash reduced sensitivity by 31.72%.

Table 1. Discussion of study design

Informed consent	✓			
Inclusion /Exclusion criteria	✓			
Demographic data	✓			
Present complaints	✓	✓	✓	✓
General Oral Examination	✓	✓	✓	✓
Clinical assessment and Pain scale	✓	✓	✓	✓
Randomization	✓			
Adverse effect assessment		✓	✓	✓
Study toothpaste and Mouthwash	Dispensed			Returned

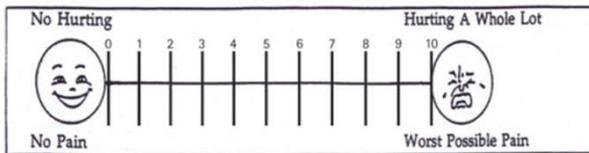


Figure 1. Visual Analog Pain Scale



A: Tactile method with probe



B: Evaporative stimuli with airspray



C. Thermal Stimuli With Ice Stick

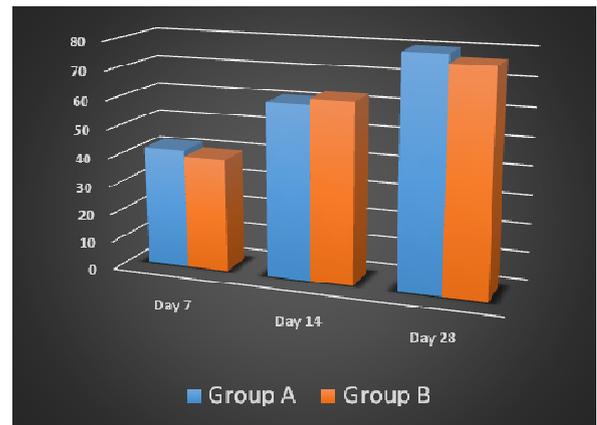


Fig. 3. Percentage Reduction In Total Sensitivity Between Groups

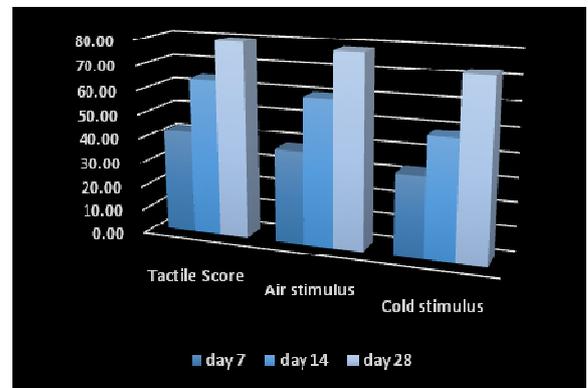


Fig. 4. Percentage reduction in sensitivity to all three test in hiora k toothpaste and mouthwash group (groupa)

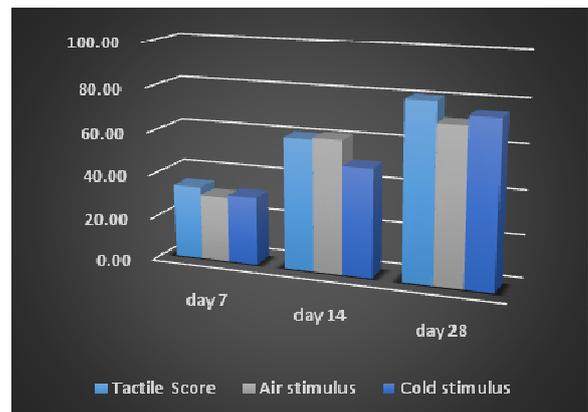


Fig. 5. Percentage reduction in sensitivity to all three test in complete care toothpaste and hiora k mouthwash group (group b)

The HiOra K toothpaste and mouthwash combination reduced sensitivity by 76.83% whereas Complete care toothpaste and HiOra K mouthwash reduced sensitivity by 78.72% at the end of 28 days. However, at the end of 14 and 28 days there was no significant difference between the groups. (Fig:3). For both the groups the maximum reduction insensitivity was seen for the tactile stimuli followed by air and then by cold stimuli (Fig: 4 & Fig: 5) Group A had shown a greater decrease in sensitivity for tactile and air stimuli compared to Group B.

DISCUSSION

Dentin hypersensitivity is one of the leading causes of dental problems in the dentate population. It is seen that the incidence is more in the middle aged group and most commonly affects cervical area of buccal surfaces of the lower anteriors & premolars.² Hence in this study the labial surfaces of anteriors and premolars were considered. Tactile stimulus was used first for sensitivity assessment followed by evaporative & water stimuli because the least severe stimulus should be applied first to prevent interpretation error. The interval of ≥ 5 minutes was allowed between the two stimuli to minimize interactions between stimuli (Pradeep, 2010). This study focused on the use of herbal products in the treatment of dentine hypersensitivity. The products included were HIORA K tooth paste and mouth wash used in combination and evaluating its efficacy against Complete Care toothpaste and Hiora-K mouthwash combination. Hiora K tooth paste contains *Suryakshara*, *Palakya*, *Lavanga*, *triphala*, *clove* and *cinnamon*. *Suryakshara* contains Potassium nitrate which inhibits pain in hypersensitive teeth through its desensitizing effect on dentinal nerves (Peacock, 1975; Wichgers, 1997).

Palakya (spinach) contains natural oxalate compounds, which help in forming phytocomplexes on the teeth. This occludes dentinal tubules and blocks the transmission of pain from the surface to the tooth's nerves. These oxalate compounds produce protective films and thus, helps to prevent tooth destruction (Sauro *et al.*, 2006). *Lavanga* (Clove) contains eugenol, having an obtundent effect which numbs nerves and controls pain. The *essential oil of clove* also has antibacterial action against bacterial species involved in dental caries like *Streptococcus mutans* (Gupta *et al.*, 2011). *Triphala* has also been found to be effective in preventing a significant increase in the caries (Tandon, 2010). Moreover, zinc oxide has also shown a significant effect on the inhibition of dentine demineralization and may be effective in the prevention of caries (Takatsuka, 2005). Hiora K mouth wash contains *Suryakshara* and extracts of *holy basil*, *cloves*, *mace* and *peppermint*. *Suryakshara* contains potassium nitrate which inhibits pain in hypersensitive teeth through its desensitizing effect on dentinal nerves. *Lavanga* (clove) has an anaesthetic effect due to eugenol which numbs nerves and controls pain. The *essential oil of clove* is also an antiseptic, which helps eliminate oral bacteria (Gupta, 2011; Cai, 1996). On the other hand, complete care tooth paste did not contain any desensitizers. This was used in combination with the Hiora K mouthwash to evaluate whether the mouthwash alone could prove effective in reducing hypersensitivity. In the first week, HiOra K toothpaste and mouthwash combination reduced sensitivity by 37.47% whereas Complete Care toothpaste and HiOra K mouthwash reduced sensitivity by 31.72%. Novel toothpaste and mouth wash combination gave quicker relief from sensitivity due to synergistic effect. The reduction in sensitivity is statistically similar by the end of 28 days.

This indicates that HiOra K mouthwash is very effective in reducing sensitivity in long term usage. The possible explanation for this could be that once the dentinal tubules are closed and there is a relief from sensitivity patients will not be able to give more specific scale. Cold stimulus causes contraction of the dentinal fluid within the dentinal tubules, resulting in a rapid outward flow of fluid within the patent tubule. Also, cold action activates interdentary nerve activity leading to sensitivity. Dehydrating the surface of the dentin with compressed air and dry-heat causes dentinal fluid movement and its evaporation without activation of the nerves (Brännström, 1964; Brännström, 1984; Brännström, 1979; Pashley, 1983). Rapid flow of fluid through the tubules and activation of the nerves is thought to be a cause of dentin sensitivity (Matthews, 1994). The slow outward movement of dentinal fluid is not sufficient to activate the mechanoreceptor nerves responsible for dentin insensitivity. Indeed, there is a positive correlation between rate of fluid flow in the tubules and discharge evoked in intradental nerves (Matthews, 1994; Matthews, ?; Vongsavan, 1994) with outward fluid movements producing a much stronger nerve response than inward movements (Matthews, 1994). Hence, air and tactile response to treatment was better than cold stimuli.

Pain associated with dentinal hypersensitivity is not easy to reckon and reproduce (Blong *et al.*, 1985). Tolerance to the same pain can be subjective and vary considerably according to individual factors such as psychological factors, personality and intellect (Kanapka, 1990). Another possible phenomenon which could occur is the Hawthorne effect which is a response to non-intervention procedures such as frequent examinations, improved oral hygiene or compliance with the treatment regimen. Patients frequently appear to improve merely from the effects of being placed on a trial (Dowell, 1983).

Conclusion

From the results of the in vivo study, it can be concluded that the novel herbal dentifrice and mouthwash combination can be recommended as quicker and lasting relief of dentine hypersensitivity. Further studies are required to evaluate the long term effectiveness of the treatment retention and changes in surface morphology after its prolonged use as well as comparison with other commercially available dentifrices to confirm the findings of this study.

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List of Abbreviations

- ANOVA = analysis of variance
- DH = dentine hypersensitivity
- IP = investigation paste
- SD = standard deviation
- VAS = visual analog scale

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