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Effectiveness of Potassium Oxalate mouthrinse in treating dentinal hypersensitivity

Maddula Y.S.L.N.V Amruthavalli[1], Nalamati Shiva Keerthi[1,*], Gummadi Anusha[2], Gorle Santhi[3], Nimmala Sriram Naidu[4], Sreekar Katru[5]

[1]Postgraduate Student, Department of Periodontics, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh, India.
[2]Professor, Department of Periodontics, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh, India.
[3]Reader, Department of Periodontics, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh, India.
[4]Assistant Professor, Department of Periodontics, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh, India.
[5]Assistant Professor, Department of Oral Medicine and Radiology, Vishnu Dental College, Bhimavaram, Andhra Pradesh, India.

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*Correspondence

Nalamati Shiva Keerthi
Postgraduate Resident,
Department of Periodontics
Lenora Institute of Dental Sciences,
Rajahmundry, Andhra Pradesh, India.
E-mail: *nskshivakeerthi@gmail.com*
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Abstract

Background: Dentinal hypersensitivity is a prevalent oral condition characterised by a short, sharp pain in response to chemical, thermal, tactile, or osmotic stimuli. It can be treated with in-office application of potassium oxalate (KO). This study assesses KO mouthrinse for home use.
Aim: To assess the efficacy of Vantej® mouthrinse, containing potassium oxalate (KO), in reducing dentinal hypersensitivity when used in combination with regular brushing for three months.
Materials and methods: In this double-blind, parallel group-controlled study, participants with dentinal hypersensitivity were randomly assigned to Group 1, which used the KO mouthrinse, and Group 2, which used a placebo. The participants used their assigned mouthrinses for three months. The success of each participant was measured using the mean cold air stimulus response (VAS) and Schiff sensitivity score.
Results: A significant decrease (p=0.00) in hypersensitivity in patients treated with potassium oxalate mouthrinse was observed.
Conclusion: Mouthrinse containing 1.4% potassium oxalate consistently demonstrated effectiveness in reducing dentinal hypersensitivity after three months of use.
Keywords: Cold air stimulus, Dentinal hypersensitivity, Oral rinse, Potassium Oxalate, Visual Analog Scale.

1. Introduction

Dentinal hypersensitivity (DH) manifests as brief, intense pain triggered by chemical, temperature, touch, or osmotic factors [1-3]. It results from the exposure of open dentinal tubules, often linked to conditions like gum recession and enamel erosion or abrasion. It is postulated that external factors, such as temperature changes or osmotic imbalances, lead to fluid movement within these tubules [3]. This fluid flow may activate nerve receptors within the pulpal region of the dentine, giving rise to the sensation of pain [3].

Occlusion-based treatments for dentine sensitivity aim to seal exposed dentine tubules using various methods, such as restorative materials, laser procedures, and precipitating solutions [4]. Within precipitating solutions, soluble oxalates have a rich history of use and are widely accepted by dental professionals [5]. Oxalates were first introduced as agents for addressing dentine sensitivity during the late 1970s to mid-1980s, primarily based on evidence from *in vitro* studies [6]. Oxalate salts, in particular, have been extensively investigated.

Laboratory experiments have shown that solutions containing 30% (di) Potassium Oxalate, or 3% monopotassium-monohydrogen oxalate led to significant reductions in tubule permeability in dentine [3]. Scanning electron microscopy, utilizing professional in-clinic formulations of 3% aqueous monopotassium oxalate, has revealed substantial precipitation on the dentine surface and within the tubules following a single application. With multiple treatments, the degree of surface occlusion progressively increases [7-8].

Mouthrinses offer an alternative method for delivering potassium ions to the dentin-pulpal junction. While they have not been as extensively studied as toothpaste, the effectiveness of mouthrinses containing potassium salts (such as 2% potassium citrate and 2.4% or 3% potassium nitrate) in alleviating dentin hypersensitivity (DH) has been evaluated in randomized controlled trials [9].

Laboratory experiments also indicate that oxalate crystals are more effectively deposited when potassium oxalate is delivered from an acidic solution rather than a neutral pH solution. Additionally, greater deposition occurs in the presence of fluoride [10].

The mechanism of action of a potassium oxalate mouthrinse involves the formation of insoluble calcium oxalate crystals. When the mouth is rinsed with a 1.4% potassium oxalate

solution, the soluble oxalate ions react with calcium ions in the dentinal fluid, creating these crystals within the dentinal tubules. Due to their relative insolubility in acidic environments, the calcium oxalate crystals help maintain tubule occlusion even under acidic conditions, providing quick relief from the pain associated with dentin hypersensitivity [11].

This study aimed to determine the sustained effectiveness of Vantej® oral rinse, which includes 1.4% dipotassium oxalate monohydrate (KOX) in occluding dentinal tubules, providing relief from DH, when used alongside regular brushing over an extended duration of three months.

2. Materials and methods

This is a double-blind, parallel group-controlled study conducted at Lenora Institute of Dental Sciences, Rajahmundry. The Institutional Ethical Committee approval (IEC No. 35/IEC/LIDS/2022) was obtained.

The sample size was determined using G*Power software. A total of 226 participants with dentinal hypersensitivity were randomly assigned to one of two mouthrinse groups - Vantej® mouthwash and Placebo - with 113 participants in each group. Informed consent was obtained from all study participants. The participants used their assigned mouthwashes for three months. The outline of this study design is presented in Figure 1.

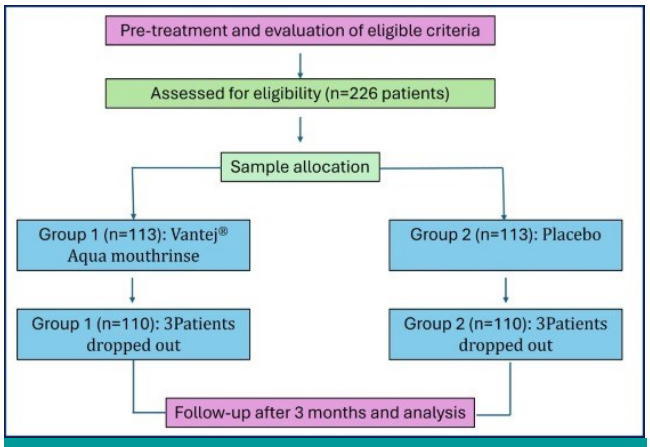

Figure 1. The outline of study design.

2.1 Inclusion criteria

Men and women patients of 18-years to 55-years in good general and oral health, with caries-free facial or buccal surfaces with cervical abrasion, erosion, or gingival recession were included. Two teeth eligible for the study were chosen in each quadrant, with two other teeth in between. Also, participants displayed no considerable oral soft-tissue conditions, maintained satisfactory oral hygiene, were free from severe marginal gingivitis or moderate to advanced periodontitis, and did not exhibit substantial supragingival calculus, were included. These determinations were made through clinical examinations conducted during each visit and at the investigator's discretion.

2.2 Exclusion criteria

The patients with kidney disease, celiac, chronic pancreatitis, other systemic conditions, chronic medical disease associated with episodes of daily pain, and long-term use of analgesics (more than 7 days) were excluded. Also, application of specific products or procedures prior to the screening process, use of desensitizing agents (8 weeks prior), utilization of teeth whitening or bleaching products (4 weeks), and involvement in a separate oral care study (30 days), were excluded. Patients with known allergenic to study products or the need to pre-medicate with antibiotics before dental procedures, pregnant or lactating women, and mobility exceeding grade 1 on a scale ranging from 0 to 3, were also excluded.

2.3 Interventions

Eligible participants commenced a 2-week pre-study run-in phase, during which they were directed to perform twice-daily tooth brushing. Following this period, we randomly allocated participants who still met the inclusion criteria into one of two treatment groups. They either received a 1.4% KOX mouthrinse or a placebo mouthrinse. Placebo mouthrinse resembled the test mouthrinse in formulation, excluding KO and other essential components needed to facilitate the availability and effectiveness of KO. Over the subsequent three months, participants continued brushing their teeth twice daily using the provided toothpaste. Patients rinsed with 10ml of their designated mouthwash for 60 seconds after 30 minutes following tooth brushing.

Throughout the study, participants who regularly used dental floss could continue to use floss. Participants underwent assessments at the screening, baseline, and three-month points to gauge their sensitivity to cold air, which was measured using a Visual Analog Scale (VAS). At baseline and three months, participants evaluated their subjective perception of pain or discomfort using VAS. Investigators assessed safety through oral examination and query of each participant at each visit for any new or continuing symptoms since the previous visit and through the tabulation of adverse events.

Participants initially performed their first toothbrushing and mouthrinsing sessions while being observed at the test centers. Each participant was provided with a standard toothbrush and toothpaste, the assigned mouthrinse in packaging that concealed its identity, dosage cups labelled for accuracy, and diaries for recording their adherence to the at-home oral care routine. The investigators regularly reviewed the diaries and assessed the weight of the mouthrinse containers during each visit to ensure compliance was maintained. The following Schiff scale given by Schiff *et al.* 1994 [12] was used to rate the degree of pain perceived by the patients on a single tooth.

0 - Subject does not respond to air stimulus
1 - The subject responds to air stimulus but does not express a desire to stop the stimulus.
2 - The subject responds to air stimulus and either asks for it to be stopped or physically moves away from the stimulus.
3 - Subject responds to air stimulus, deeming it painful, and asks for the stimulus to be halted.

2.4 Assessments and outcomes

Dental clinical examiners, who were trained in the data collection methods used in the study, performed the clinical assessments throughout the study at each site. Throughout the study, a single examiner consistently assessed every

participant. The examiners conducted the assessments in the order presented here.

2.4.1 Visual Analog Scale (VAS) [13]: The Visual Analog Scale (VAS) consists of a horizontal line, with one end labelled "no pain or discomfort" at 0 mm and the other end labelled "intense pain or discomfort" at 100 mm. Participants were instructed to mark the line at the position that best corresponded to their own perception of the pain or discomfort intensity they felt. In the case of the global subjective VAS, participants marked the line to indicate their perception of the dentinal hypersensitivity-related pain or discomfort experienced during their daily activities over the preceding two weeks.

2.4.2 Oral Examination: During oral examinations, the examiners observed the oral soft and hard tissues to assess the tolerance of the study products. They documented any adverse events, including clinically significant signs or symptoms that emerged or worsened following the initial screening.

2.5 Statistical analysis

All the clinical parameters were subjected to the following statistical analysis using IBM® SPSS® software version 25.0. Inter and intra group comparison between the groups with respect to sensitivity scores and VAS. Inter group comparisons were done by independent sample t-test and intra group comparisons were done by paired t-test. The p value less than or equal to 0.05 was considered as statistically significant.

3. Results

Table 1 shows the demographic details of the study participants. Out of total 110 participants of group, 57 were males and 53 were females, and out of 110 participants of placebo group, 48 were males and 62 were females. The mean age of Vantej® group is 40.1 years and the mean age of placebo group is 41.8 years.

Table 2 presents the mean VAS score and Schiff score at baseline and after 3 months in Vantej® group. Mean VAS and Schiff score of Vantej® group at baseline was higher than mean VAS and Schiff score after 3 months which is statistically significant (p=0.000).

Table 3 depicts the mean VAS score and Schiff score at baseline and after 3 months in placebo group. Mean VAS and Schiff score of placebo group at baseline was slightly higher than mean VAS and Schiff score after 3months which was statistically significant (p=0.00).

Table 4 depicts the inter group comparison of mean VAS score of Vantej® group and placebo group at baseline and at after 3 months. At baseline mean VAS score of Vantej® group is slightly higher than mean VAS score of placebo group which is not statistically significant (p=0.854) and at after 3 months the mean VAS score of Vantej® group was lower than mean VAS score of placebo group which was statistically significant (p=0.000).

Table 5 shows the inter group comparison of mean Schiff score of Vantej® group and placebo group at baseline and at after 3 months. At baseline mean Schiff score of Vantej® group is higher than mean Schiff score of placebo group which was statistically significant (p=0.034) and at after 3 months the mean Schiff score of Vantej® group is lower than mean Schiff score of placebo group which was statistically significant (p=0.000).

Table 1. Demographic details of the study participants.

Parameters		Vantej® aqua	Placebo
Mean Age		40.1	41.8
Sex	Male (%)	57 (51.8)	48 (43.6)
	Female (%)	53 (48.1)	62 (56.3)

Table 2. Intra-group comparison of VAS and Schiff in Vantej® aqua group (Paired t-test).

Groups		N	Mean	Standard deviation	Standard error	p-value
VAS	Baseline	110	5.70	1.48	0.14	0.000*
	After 3 months	110	4.21	1.19	0.11	
Schiff	Baseline	110	2.91	0.73	0.69	0.000*
	After 3 months	110	2.15	0.71	0.68	

*Statistically significant.

Table 3. Intra-group comparison of VAS and Schiff Sensitivity Index in placebo group (Paired t-test).

Group		N	Mean	Standard deviation	Standard error	p-value
VAS	Baseline	110	5.66	1.45	0.138	0.000*
	After 3 months	110	5.21	1.41	0.134	
Schiff	Baseline	110	2.69	0.84	0.080	0.045*
	After 3 months	110	2.65	0.85	0.081	

*Statistically significant.

Table 4. Inter group comparison of VAS at baseline and after 3 months (Independent sample t-test).

Group		N	Mean	Standard deviation	Standard error	p-value
Baseline	Vantej® aqua	110	5.70	1.48	0.41	0.854
	Placebo	110	5.66	1.45	0.13	
After 3 months	Vantej® aqua	110	4.21	1.19	0.11	0.000*
	Placebo	110	5.21	1.41	0.13	

*Statistically significant.

4. Discussion

Dentinal hypersensitivity presents a widespread issue; however, demonstrating clinically significant enhancements resulting from the utilization of a product to mitigate and manage it poses a challenge [2]. In this study, the mean VAS score of the Vantej® group at baseline (Table 2) was higher than the mean VAS score after 3 months which is statistically significant (p=0.000). The mean Schiff score of the Vantej® group at baseline was higher than the mean VAS score after 3 months which is statistically significant (p=0.000). Hodosh initially proposed the utilization of potassium nitrate to alleviate dentin sensitivity. He administered a topical application of 35% potassium salts on teeth and recommended the incorporation of 5% (495 mm) into desensitizing toothpaste formulations [14].

Orchardson and Gillam conducted a comprehensive review of the supporting evidence for the effectiveness of potassium nitrate as a dentin desensitizer and concluded that the potassium ions released from toothpaste containing

potassium nitrate likely could permeate through open dentinal tubules, reaching the pulp and partially diminishing the activity of intradental nerves [15]. Various mechanisms operate within dentin to eliminate potassium ions from dentinal tubules. Additionally, pulpal capillaries situated near intradental nerves play a role in absorbing excess potassium ions and transporting them away from the pulp [4]. A human *in vivo* study demonstrated the impact of 500 mm potassium chloride on intradental nerve activity [1]. Notably, the oxalate content in the desensitizing mouthrinse used in this study is relatively low, with approximately 140 mg of oxalate present in 10 mL of mouthrinse. When these soluble oxalates are ingested, they undergo conversion to insoluble calcium oxalate due to the calcium content in saliva and gastric fluid. Calcium oxalate, being poorly absorbed, is primarily excreted through urine and faeces. Bonner *et al.* fed children 100 g of spinach or 700 mg of oxalic acid per day in the diet for 25 days without any untoward effects [1].

However, the use of a placebo-controlled, randomized design should be able to avoid this effect that would only take place in the placebo group. Table 4 presents the inter-group comparison of the mean VAS scores for the Vantej® and placebo groups at baseline and after 3 months. Initially, the Vantej® group had a slightly higher mean VAS score compared to the placebo group, but this difference was not statistically significant (p=0.854). However, after 3 months, the Vantej® group showed a significantly lower mean VAS score than the placebo group (p=0.000*). On the other hand, the improvement in DH symptoms could also be explained by the 'placebo effect' itself, by which an innocuous therapy induces improvement in the patient's complaint. This effect would be explained by the patient's self-conditioning because he knows he is taking part in a trial and expects to experience an improvement derived from the treatment he has been administered [5].

New research indicates that incorporating an oxalate rinse alongside twice-daily brushing using a fluoride dentifrice can effectively alleviate dentin hypersensitivity (DH) [1]. *In vitro* studies proposing that this relief is attributed to enhancements in oxalate crystal deposition both on the dentin surface and within tubules prompted the development of three distinct formulations of a KOX oral rinse [3].

Potassium Oxalate mouthrinse demonstrated a clinically significant decrease in dentinal hypersensitivity compared to a placebo mouthrinse, as measured by the participants' individual success at the 3-month mark using the mean cold air stimulus VAS score and Schiff sensitivity averaged across study teeth. This outcome complements findings from prior *in vitro* and *in vivo* studies highlighting the efficacy of KO in addressing dentinal hypersensitivity [2]. Regrettably, the current evidence on desensitizing mouthwashes is limited, hindering our ability to conduct thorough comparisons among various active principles for treating hypersensitivity symptoms [5].

The future of dentinal hypersensitivity treatment is promising, with ongoing research and technological advancements paving the way for more effective, personalized, and preventive solutions. Future research can significantly enhance the effectiveness, safety, and patient acceptance of mouthrinses, leading to better oral health outcomes.

6. Conclusion

The findings of this study revealed that incorporating Vantej® mouthrinse into a twice-daily routine alongside tooth brushing resulted in a statistically significant and clinically relevant reduction and management of dentinal hypersensitivity compared to the outcomes observed with a placebo mouthrinse.

Conflicts of interest: Authors declared no conflicts of interest.
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