

EFFICACY OF A TOOTHPASTE CONTAINING 5% POTASSIUM NITRATE IN DESENSITIZING DENTIN HYPERSENSITIVITY

ANTON RAHARDJO^{1*}, AVINA ANIN NASIA², MELISSA ADIATMAN¹, DIAH AYU MAHARANI¹

¹Department of Preventive and Public Health Dentistry, Faculty of Dentistry, University of Indonesia, Indonesia. ²Cluster of Oral Epidemiology and Clinical Studies in Dentistry, Faculty of Dentistry, University of Indonesia. Email: antonrahardjo@gmail.com

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ABSTRACT

Objective: This clinical trial compared the pain reduction achieved by a 5% potassium nitrate (KNO₃) desensitizing toothpaste paste versus placebo on adult patients with tooth hypersensitivity.

Methods: Investigators identified adult patients with hypersensitive teeth (which are nonpathologic such as caries) after scaling. Each hypersensitive tooth was isolated and tested with a blast of compressed cold air delivered from a three-in-one syringe. The patient was then asked to indicate a sensitivity score using the visual analog scale (VAS) from 0 to 10. Patients received 30 seconds application of desensitizing toothpaste containing 5% potassium nitrate (KNO₃) (Group 1) and the others with placebo toothpaste (Group 2). The teeth were tested for the second time with compressed cold air, and the patients were asked to report the VAS again. A non-parametric test was used to analyze the results following a normality test of the VAS.

Results: The Primary sampling unit for analysis were tooth. A total of 78 teeth were analyzed (Group 1 = 32 teeth and Group 2 = 46 teeth). The mean age of the patients was 29.9, and 64% of the 33 subjects were female. The median pre-treatment VAS of Groups 1 and 2 was 6 and 5, whereas the post-treatment VAS was 0 and 4, respectively ($p < 0.001$). The median percentage reductions in sensitivity scores of Groups 1 and 2 were 60% and 20%, respectively ($p < 0.001$).

Conclusion: This clinical trial showed the use of the desensitizing toothpaste containing 5% potassium nitrate on hypersensitive teeth was significantly a more effective in immediate pain reduction than using placebo toothpaste.

Keywords: Toothpaste, 5% potassium nitrate, Dentine hypersensitivity.

INTRODUCTION

Dentinal hypersensitivity is an exaggerated response to a sensory stimulus that usually causes no response in a normal healthy tooth [1]. 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. Under normal conditions, dentin is covered by enamel or cement and is not directly exposed to the buccal environment [2]. However, the enamel or cementum which normally covers the dentine surface may be removed or denuded abrasion, erosion, attrition or root surface exposure caused by gingival recession, periodontal treatment, improper brushing habits, or a combination of more than one factor. These factors may expose the dentin tubules, resulting in dentin sensitivity [3].

Dentin hypersensitivity is a prevalent oral problem in many parts of the world [4-6]. Patients with periodontal disease are at particularly high risk, and studies have reported that as many as 70% of periodontal patients experience dentin hypersensitivity [7]. It was reported that 65% of Indonesians experienced dentin hypersensitivity, with 52% of them are females. The highest incidence was documented in the 25-40 years old age group [8]. The condition can last for days, weeks or indefinitely unless treatment is provided. The impact of dental hypersensitivity ranging from minor inconvenience to the patient, limiting dietary choices, impeding effective oral hygiene, negatively affecting appearance, and significantly affecting individual's quality of life [9].

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 distinguishable from other conditions that can give rise to similar symptoms. Treatment for secondary conditions that induce symptoms similar to hypersensitivity should also be provided [10]. 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 [11].

One of the approaches 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 [12]. Potassium nitrate (KNO₃) is used to provide potassium ions to decrease the excitability of the nerves that transmit pain sensations. Brushing with toothpaste containing potassium nitrate is a potential method of delivery [13]. The present study reported here was a clinical trial that aimed to compare the pain reduction achieved by desensitizing toothpaste containing 5% potassium nitrate versus the placebo to treat patients diagnosed with dentin hypersensitivity.

METHODS

The investigators recruited and assess adult subjects with hypersensitive teeth with exposed dentin the following scaling in the clinic. The recruited subjects were informed that they would receive a 30 seconds treatment with a desensitizing toothpaste. However, they did not know which desensitizing toothpaste was used (blinded test). They were told the purpose and procedure of the study, and their informed consent was sought, moreover ethical clearance was obtained. The hypersensitive tooth in each subject was selected for assessment. Each hypersensitive tooth was isolated and tested with a

blast of compressed cold air delivered from the three-in-one syringe [14]. The subject was then asked to give a self-perceived sensitivity score with the visual analog scale (VAS), from 0 to 10. The VAS of 0 (absence of pain) was considered to indicate no discomfort, and VAS of 10 was considered to indicate maximum pain causing great distress to the subject [15]. Subjects who reported a pre-treatment VAS <4 were excluded from the study.

Subjects who had, at least, one hypersensitive tooth with a VAS score of 4 or above were assigned to the two study groups in a sequential manner, i.e. the first patient to Group 1 and the second patient to Group 2, and so on. In Group 1, the subjects received a 30 seconds polish with a desensitizing toothpaste containing 5% potassium nitrate. The subjects in Group 2 received a placebo treatment. Each tooth was assessed for a second time with compressed cold air immediately after the toothpaste application, and the patients were again asked to report the VAS.

We estimated that the percentage reduction in VAS in the test and control groups would be 60% and 20%, respectively, with a common standard deviation of 30%. Using a power of 0.8 and alpha (Type 1 error rate) of 0.05, the minimum number of hypersensitive teeth needed for the study was calculated to be 50, with 25 teeth per group.

The data were assessed for a normal distribution using the Shapiro-Wilk test for normality using the computer software SPSS Statistics. Parametric or nonparametric tests were used as appropriate. A Mann-Whitney U test was used to study the pre- and post-treatment VAS and the reduction in VAS of the treatment group as these data were not normally distributed. The medians and interquartile ranges are reported for all of the continuous variables to provide information on the distribution of the data. All of the statistical tests were two-tailed, and the significance level was set at 0.05. Reduction in hypersensitivity score was acquired by calculating the change of VAS score (VAS after - VAS before).

RESULTS

The measurements were done to 78 teeth as the primary unit analysis. Data were analyzed from 46 placebo group and 32 others as a test group. The mean age of the patients were 29.9, and 64% of the 33 subjects were female. No side affect nor adverse events occurred. Research results represented in Table 1 and Graph 1 showed the mean of sensitivity measurements results before and after toothpaste usage. Mann-Whitney statistical tests was employed to compare mean between toothpastes groups at baseline, after toothpaste application, and reduction between the two groups. Tested toothpaste showed a significant difference, decreasing the sensitivity of teeth compared to placebo.

The non-parametric Mann-Whitney, rather than a paired t-test, was used to study the pre- and post-treatment VAS and the reduction in VAS in the treatment group because the data did not follow a normal distribution. Moreover, Mann-Whitney was employed as the statistical test, due to its robust properties in calculating unequal sample size between conditions, inhomogeneity of variance between conditions and not normally distributed data.

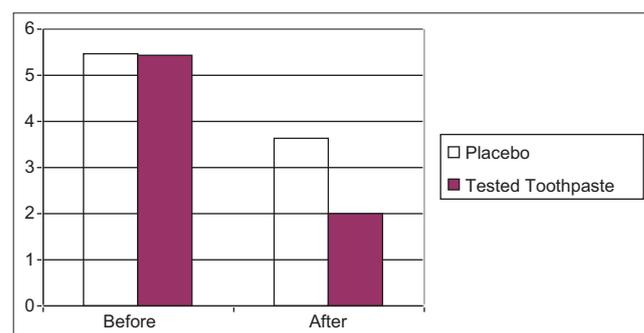
DISCUSSION

Dentin hypersensitivity is a prevalent oral problem that can last for days, weeks or indefinitely unless treatment is provided [1]. Incorrect tooth brushing method and gingival recession due to periodontal disease are some reasons for tooth hypersensitivity [3]. The clinical trial found a significant immediate pain reduction from tooth hypersensitivity after desensitizing toothpaste containing 5% potassium nitrate was applied for 30 seconds to tooth dentine. This 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 [16]. There was thus no conflict of interest or potential for abuse.

Table 1: Mean (SD), range and median of the pre- and post-treatment sensitivity score (VAS) and percentage reduction in the sensitivity score by treatment group

Hypersensitivity scores	Group 1 (n=32)	Group 2 (n=46)	p value
Pre-treatment hypersensitivity score			0.765
Mean (SD)	5.44 (1.24)	5.48 (1.65)	
Range	4-8	4-10	
Median	6	5	
Post-treatment hypersensitivity score			<0.001
Mean (SD)	1.19 (1.42)	3.63 (2.22)	
Range	0-4	0-10	
Median	0	4	
Reduction in hypersensitivity score			<0.001
Mean (SD)	42.5 (21.6)	18.5 (18.5)	
Range	0-70	0-60	
Median	60	20	

Group 1: 5% potassium nitrate paste, Group 2: Placebo paste, SD: Standard deviation, VAS: Visual analog scale



Graph 1: Sensitivity test (visual analog scale) measurements results before and after of toothpaste usage in mean

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 [16,17]. A commonly accepted theory of dentin hypersensitivity is the hydrodynamic theory, suggesting that hypersensitivity is caused by changes in the flow of fluid in the dentin tubules due to changes in temperature and air pressure. This, in turn, triggers pain receptors at the nerve endings located at the pulpal aspect to fire nerve impulses, thereby eliciting pain. The 5% potassium nitrate (KNO₃) desensitizing toothpaste is primarily for home use [2]. This treatment is effective. It was used in this study compared with placebo.

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 30 seconds of toothpaste application, the variations between subjects would be small and unlikely to affect the outcome measured. The placebo effect may have played a role [14]. Patients were informed that they were being treated with a desensitizing toothpaste, although they were not told what kind of toothpaste it was. The placebo effect is a pervasive phenomenon that is part of the response to active medical intervention. A systematic review of clinical trials concluded that the placebo effect can be significant in the treatment of pain and continuous subjective outcomes [18].

The toothpaste containing 5% potassium nitrate is considered to be the option for the treatment of tooth hypersensitivity. Potassium nitrate provides potassium ions to decrease the excitability of the nerves that transmit pain. Brushing with potassium nitrate containing toothpaste

is effective in pain relief due to dentin hypersensitivity [19]. Another method of reducing the pain from tooth hypersensitivity is to occlude the open tubules to block the hydrodynamic mechanism [20]. This study showed that the tested toothpaste is sufficient to relieve the pain caused by hypersensitivity. Moreover, the results of the study showed a substantial percentage reduction in dentin hypersensitivity after a single treatment with the toothpaste which contains 5% potassium nitrate.

CONCLUSION

In this clinical trial, the use of the desensitizing toothpaste containing 5% potassium nitrate on hypersensitive teeth was significantly more effective in immediate pain reduction than using placebo toothpaste.

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