Original Article

Comparison of Desensitizing Efficacy of an Iranian Dentifrice and a Commercially Available Dentifrice: A Randomized Double-Blinded Controlled Clinical Trial

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Abstract

Objective: The aim of this randomized controlled clinical trial was to investigate the effect of a new Iranian toothpaste and a commercially available toothpaste containing desensitizing agent (5% potassium nitrate) on dentine hypersensitivity in a 24-week study.

Materials and Methods: Fifty healthy volunteers, who had at least two sensitive root surfaces, completed the study period. The participants were randomly given one of the two toothpastes; Iranian (antihypersensitive Pooneh) or commercially available (fresh mint Sensodyne) toothpaste. Visual analogue scales (VASs) indicating the intensity of tooth hypersensitivity responding to tactile, airblast and cold-water stimuli were examined at baseline and weeks 2, 4, 12 and 24.

Results: Overall, VAS scores for tactile, airblast, and cold-water tests significantly reduced compared with the baseline in both groups (all P values <0.001). However, there was no significant difference between the two groups regarding the measured parameters.

Conclusion: This study demonstrated that the Iranian dentifrice (antihypersensitive Pooneh) was as effective as the commercially available one (fresh mint Sensodyne) in reducing tooth hypersensitivity.

Key Words: Clinical Trial; Potassium Nitrate; Dentin Hypersensitivity; Toothpaste

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INTRODUCTION

Dentinal hypersensitivity is a relatively common complaint in adults. It is one of the most painful and the least successfully resolved problems of the teeth [1]. There are several predisposing factors related to dentin hypersensitivity. Removal of enamel, as a consequence of attrition, abrasion, and erosion, or denudation of root surface from overlying cementum as a result of periodontal attachment

loss are considered as common causes of dentin hypersensitivity [2]. Pain caused by dentin hypersensitivity can be explained by the widely accepted "hydrodynamic" theory [3]. Generally, the management of dentin hypersensitivity is based on either nerve depolarization or dentinal tubule occlusion [4]. Potassium ion tends to concentrate in the dentinal tubule and depolarize the nerve terminals. This process results in reduction of tooth sensitivity [5]. Utilizing antihypersensitive toothpaste is an economical and easy method for management of hypersensitivity. Previous studies demonstrated that potassium-based dentifrices reduce tooth hypersensitivity [6-8].

Sensodyne dentifrice containing 5.0% potassium nitrate and sodium monofluorophosphate in a silica base (fresh mint Sensodyne, GlaxoSmithKline, London, UK) has been approved for its good antihypersensitivity properties [9-10]. An antihypersensitive dentifrice available in the Iranian market (Pooneh®, Goltash corporation, Isfahan, Iran) containing 5.0% potassium nitrate and sodium monofluorophosphate in a silica base has a much lower price than Sensodyne®.

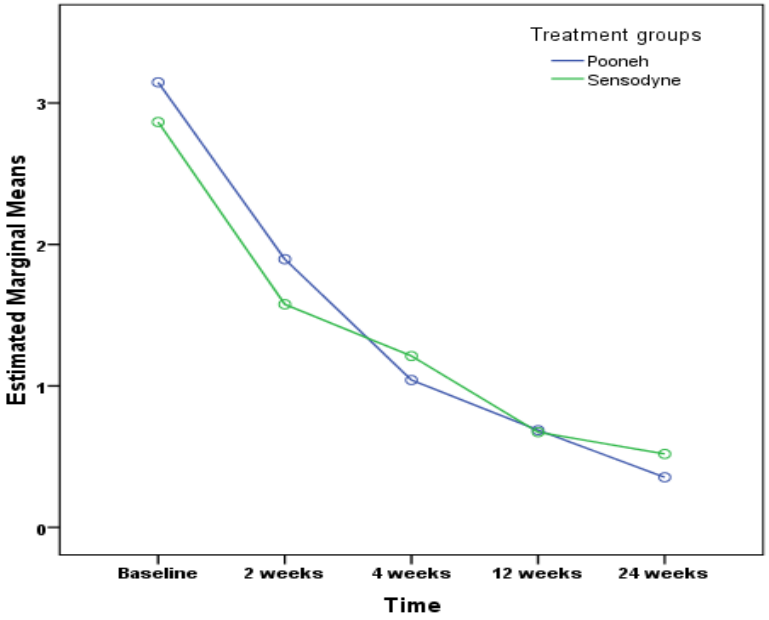
However, to the best of our knowledge, no study has yet investigated the efficacy of Pooneh® versus Sensodyne® toothpaste. The aim of this study was to compare the desensitizing efficacy of these two toothpastes over a period of 6 months.

MATHERIALS AND METHODS

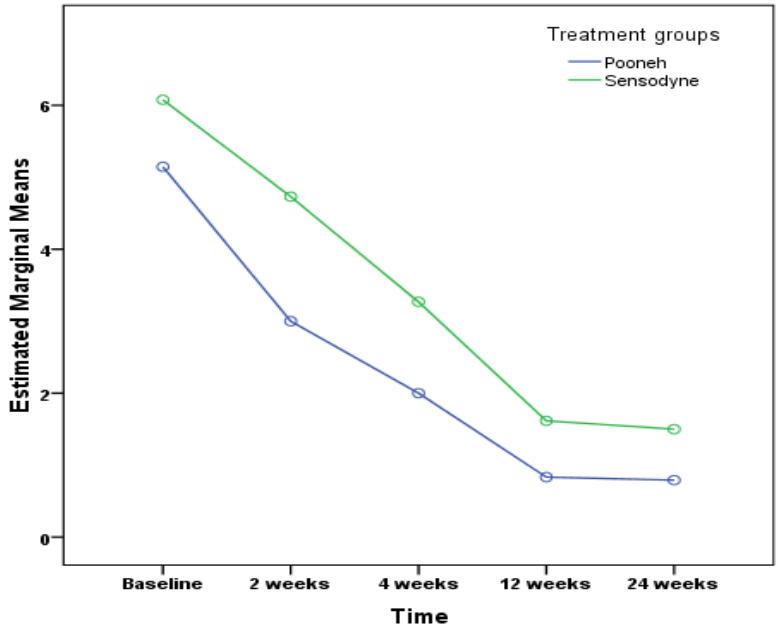
This study was a double-blind, randomized parallel-arm controlled clinical trial (IRCT ID: IRCT138903291150N3) carried out from October 2010 to September 2012. The study protocol was approved by the Research Ethics Board of Tehran University of Medical Sciences (No: 89-02-70-10751). The subjects were selected from the patients referred to the Department of Periodontics, Tehran University of Medical Sciences. After explaining the study protocol, all patients signed the informed consent form.

Patients with good physical health who had at least two exposed root surfaces with a minimum tactile sensitivity score of one were included. All included teeth had to be vital. Patients with the following criteria were excluded: poor oral hygiene, active periodontal disease, under antihypersensitive therapy, under orthodontic therapy, congenital disease of dentin or enamel, affected by relevant systemic disease, alcohol or smoking habits, drug abuse, allergic to toothpaste contents, undertaking anti-inflammatory medications or antihistamines, and pregnant or lactating women. Patients who underwent periodontal surgery within the previous 6 months or teeth with caries, cracks, large restorations or crown and bridge works that would interfere with the evaluation were excluded as well [11]. All patients underwent tooth cleaning and polishing before the study; they were instructed to brush their teeth with a soft toothbrush and use non-traumatizing brushing technique. Patients were advised to brush their teeth for one minute twice daily and not to use any other desensitizing agent or dentifrice during the study period. To monitor the patients' compliance, they were asked to return their toothbrushes and toothpastes in each appointment. The experimental group received Iranian antihypersensitive dentifrice containing 5.0% potassium nitrate and sodium monofluorophosphate in a silica base (antihypersensitive Pooneh®). The control group received a commercially available dentifrice containing 5.0% potassium nitrate and sodium monofluorophosphate in a silica base (fresh mint Sensodyne dentifrice).

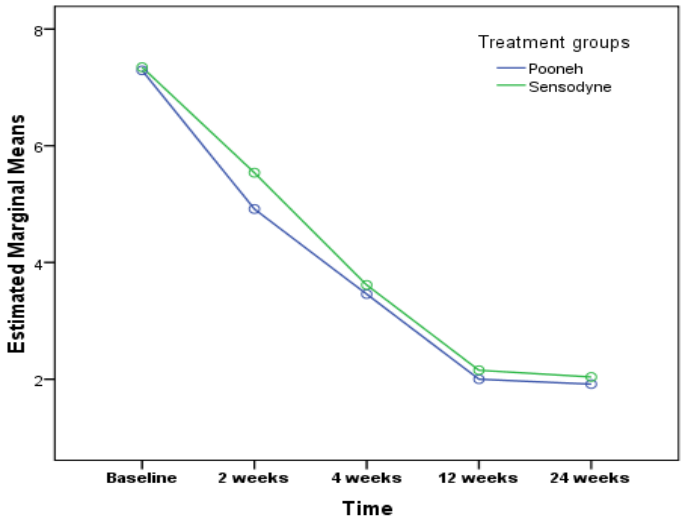
Investigators and patients were blinded to the toothpaste content. The toothpastes were dispensed in tubes labeled A and B, the contents of which were defined to the investigators only after completion of the statistical analyses. By block randomization, patients were balanced equally with regard to their mean baseline air and tactile sensitivity scores.



Tactile test



Airblast test



Cold-water test

Fig1. Estimated marginal means of pain sensation with ice test in the treatment groups

The participants were examined for dentine hypersensitivity to tactile, air, and cold-water stimuli using visual analogue scales (VASs). A single masked examiner carried out all the measurements at all-time points (N.M). Before performing clinical examinations, the neighboring teeth were isolated using cotton rolls. Sensitivity was measured using a 10-cm VAS score (0= no pain; 10= unbearable pain). A minimum five-minute period was between the examinations.

The parameters were measured, as follows:
1- Tactile test: This test was carried out using a sharp dental explorer (EXD 11-12, Hu-Friedy, Chicago, IL, USA). The explorer was passed across the exposed region of the root surface, perpendicular to the long axis of the tooth, at an approximated constant force [11].
2- Airblast test: compressed air directed from a dental unit syringe (40-65 psi at a temperature of 17-21°C) was applied onto the affected area of the tooth for 1 second from a distance of 1 cm [11].
3- Cold water test: 10 µl of ice cold water was applied to the exposed dentine surface [12].
All parameters were measured at baseline, and 2, 4, 12, and 24 weeks after treatment.

The sample size calculation determined that 25 patients per group would be required to detect 30% difference in tactile VAS scores between test and control groups [13] using a two-tailed significance level of 5% with a 80% statistical power.

Statistical Analysis

Analysis of all clinical parameters was patient-based. The median value of VAS scores of all involved teeth was measured in each patient [14]. Change in tactile sensitivity test was defined as the primary outcome variable and changes in other parameters were considered as the secondary outcome variable. The distribution of data was analyzed by Kolmogorov-Smirnov test. Inter-group and intra-group comparisons of clinical parameters were analyzed using repeated measure ANOVA adjusting for baseline values. The level of statistical significance was set at 0.05 for all comparisons.

RESULTS

Fifty-seven patients entered the study. Three patients failed to follow-up and four patients in the test group discontinued the therapy due to occurrence of aphthous stomatitis.

Finally, 50 patients (33 women and 17 men) attended for all examinations. The VAS scores for tactile, airblast, and cold-water tests were normally distributed (Z score = 1.13, 0.89, and 0.92, respectively, all P values > 0.05).

Age and gender distribution and the mean VAS scores for tactile, airblast, and cold-water tests in treatment groups throughout the study period are shown in Table 1.

The comparisons of mean VAS scores for tactile, airblast, and cold-water tests between the two groups at all time periods are provided in Table 2. There was no statistically significant difference between the two groups with regard to the measured parameters at baseline, and 2, 4, 12, and 24 weeks post-treatment (all P values>0.05 in within-subject effects column). The comparison of mean changes of VAS scores for tactile, airblast, and cold-water tests between the two groups from baseline to 24 weeks post-treatment are provided in Table 2.

No statistically significant difference was observed between the treatment groups regarding the changes of mean VAS scores for sensitivity tests in the study period (all P values>0.05 in between-subject effects column). A repeated measure ANOVA with Greenhouse-Geisser correction determined that mean values of all parameters showed a statistically significant difference between time points (all P values <0.001). Post hoc tests using the Bonferroni correction revealed that all treatment groups elicited a statistically significant reduction in VAS scores for sensitivity tests from the baseline to the end of the study (pair wise comparisons column in Table 2 and Fig 1).

DISCUSSION

This was the first randomized controlled clinical study that compared the desensitizing efficacy of an Iranian toothpaste (Pooneh®) and a commercially available toothpaste

Table 1. Gender and Mean (±Standard Deviation) Values of Age, Sensitivity Scores to Tactile, Airblast, and Cold-Water Tests in the Treatment Groups

	Pooneh	**Sensodyne**
Age (year)	41.11 ± 10.14	42.90 ± 13.96
Male/Female	9/18	8/15
Tactile Test (cm)		
Baseline	3.15 ± 1.87	2.86 ± 1.97
2 weeks	1.89 ± 1.32	1.58 ± 1.32
4 weeks	1.04 ± 0.99	1.21 ± 1.21
12 weeks	0.69 ± 0.63	0.67 ± 0.79
24 weeks	0.35 ± 0.59	0.52 ± 0.61
Airblast Test (cm)		
Baseline	5.14 ± 2.23	6.13 ± 3.28
2 weeks	3.00 ± 2.56	4.73 ± 3.35
4 weeks	2.00 ± 2.11	3.26 ± 2.48
12 weeks	0.83 ± 1.19	1.61 ± 1.54
24 weeks	0.79 ± 1.16	1.50 ± 1.49
Cold Water Test (cm)		
Baseline	7.29 ± 2.22	7.34 ± 2.56
2 weeks	4.92 ± 2.35	5.54 ± 3.02
4 weeks	3.46 ± 2.37	3.62± 2.50
12 weeks	2.00± 1.49	2.15 ± 1.82
24 weeks	1.92± 1.43	2.04 ± 1.56

(Sensodyne®). The results of this 6-month study showed that the Iranian toothpaste was comparable with the commercially available toothpaste in reducing hypersensitivity symptoms. Consistent with other formerly reported clinical trials, we found that both test and control toothpaste types containing 5% potassium nitrate with a silica base could effectively reduce tooth hypersensitivity [6, 10, 17-19]. A Cochrane meta-analysis reported that the effect of potassium nitrate toothpaste on airblast, tactile and thermal sensitivity was statistically significant.

In addition, it was suggested that more well-designed and well-conducted randomized controlled trials are needed to confirm the results of the meta-analysis [8].

The desensitizing effect of potassium nitrate may be associated with an increase in the concentration of extracellular potassium around the nerve fibers, which affects their depolarization, avoids repolarization and blocks the axonic action. This blocks the passage of nerve stimulus and results in inactivation of its action potential [15-16].

Interestingly, at the third month, the VAS sensitivity score in response to airblast and cold-water stimuli reached the lowest level in both groups and did not change until the last examination at 6 months. However, the VAS scores in response to tactile stimulus decreased from the baseline to 6 months (Fig 1). One important finding in patients treated with Pooneh® dentifrice was the occurrence of intraoral aphthous in four patients within 4 weeks of the initiation of therapy. Therefore, these patients discontinued the desensitizing therapy with this dentifrice.

Previous studies documented that sodium lauryl sulfate, a foaming agent (detergent) used in this product, could reduce the natural resistance of the oral mucosa and subsequently increase the incidence of minor aphthous ulceration [17-21].

Noteworthily, while fresh mint Sensodyne® toothpaste contains a small amount of sodium lauryl sulfate [22], aphthous lesions were not observed in any patient of this group. Within the limitations of this study, it may be concluded that the Iranian and commercially available dentifrices could equally reduce tooth sensitivity. However, minor aphthous ulcer was observed in few patients treated with Iranian toothpaste.

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Table 2. Comparison of Mean Sensitivity Scores to Tactile, Airblast, and Cold-Water Tests in the Two Treatment Groups During the Study Period

	Within-Subject Effects *P value*	**Between-Subject Effects *P value***	**Pair Wise Comparisons *P value***
Tactile Test	0.73	0.81	<0.001
Airblast Test	0.27	0.08	<0.001
Cold-Water Test	0.67	0.69	<0.001

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