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Original Article

Reduction of Dentine Hypersensitivity after Non-Surgical Periodontal Therapy Comparing 5% Calcium Sodium Phosphosilicate and 8% Arginine Dentifrices: A Single Centre Randomized Controlled Trial

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ABSTRACT

Objective: To evaluate the effectiveness of 8% arginine and 5% Calcium Sodium Phosphosilicate (CSPS) as desensitizing agents to provide relief against Dentine Hypersensitivity (DH).

Study Design: Randomized controlled study (ClinicalTrials.gov ID: NCT06273930).

Place and Duration of Study: Department of Periodontology, Armed Forces Institute of Dentistry, Rawalpindi, Pakistan, from Feb to Aug 2024.

Methodology: The study included eighty-seven subjects with chronic periodontitis and were allocated into three groups (Group-A: control, Group-B: CSPS and Group-C: arginine) in a ratio of 1:1:1. Participants were provided with dental care instructions to brush twice daily using only the dentifrice containing toothpaste. Each subject's score was recorded by averaging the three Schiff and VAS score values. The data was recorded at baseline, immediate in-office application, 1-, 2- and 4-week time, and Kruskal-Wallis and Mann-Whitney-U tests were applied.

Results: The Schiff and VAS score analysis indicated that a significant difference was observed among patients using dentifrice with 8.0% arginine, and 5.0% CSPS compared to control (p<0.001). Both groups B and C had mean DH reduction observed at in-office application and the following weeks. With 83.7% in CSPS, 78.9% in Group-C, and 63.9% in Group-A, week 4 produced the largest percentage mean DH reduction in Schiff score. Less than 50.0% of patients with DH were observed in groups B and C with CSPS after the first week.

Conclusion: Efficacy of Calcium Sodium Phosphosilicate (CSPS) and arginine as desensitizing agents was explored and its effects in reducing Dentine Hypersensitivity (DH) in patients with periodontitis was confirmed.

Keywords: Dentifrice, Dentin Hypersensitivity, Desensitizing Agents, Periodontitis, Randomized Controlled Trial.

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INTRODUCTION

Dentine hypersensitivity (DH) also known as dentinal hypersensitivity commonly occurs among patients in the age range of 20-50 years, causing the patient to experience both emotional and physical problems.[1] Patients of DH feel a sharp pain when exposed dentin part of the tooth experiences a stimulus of thermal, chemical or osmotic nature. This pain disappears shortly after removal of stimulus. Etiology of DH has been associated with conditions enamel corrosion, attrition and abrasion. Exposure of dentin due to gingival recession or periodontal tissue loss, aggressive brushing and soft tissue dehiscence are also leading causes to development of DH.[2]

Dentifrice is most commonly used and it can be coupled with in-office therapy. The main mode of action of the substances in the dentifrice that help relieve hypersensitivity problems is to obstruct dentinal tubules or impair nerve transmission.[3] The at-home desensitization relief is provided by toothpastes that contain sodium fluoride, sodium monofluorphosphate, dibasic sodium citrate, potassium and strontium salts and stannous fluoride.[4] Other promising desensitizing agents that can treat DH effectively include arginine and bioactive glass (Calcium sodium phosphosilicate or CSPS).[5]

There are several clinical trial studies that focus on the use of arginine and CSPS dentifrice to provide treatment for hypersensitive teeth.[6-9] Reports of 8% arginine as a desensitizer suggest it to be more effective than other desensitizers such as herbal and potassium salt-containing toothpaste by a definitive margin.[9] Studies suggesting CSPS dentifrice used in concentration range of 2.5%-15% also suggested that the concentration of 5% CSPS was highly effective in reducing DH at all time points.[10] The objective of this

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study was to assess the comparative efficacy of 5% CSPS and 8% arginine containing dentifrice in patients who were treated with non-surgical periodontal therapy.

METHODOLOGY

This double-blinded randomized controlled trial (RCT) was conducted in the Department of Periodontology in Armed Forces Institute of Dentistry (AFID), Rawalpindi, Pakistan, for which approval was obtained from the Institutional Review Board of the AFID (via letter no. 918/Trg dated 13 May 2020), from Feb to Aug 2024. This clinical trial was registered on www.clinical trial.gov (ClinicalTrials.gov ID: NCT06273930). Written consent was taken from all the participants during the enrollment for the study.

Inclusion Criteria: Patients of either gender aged between 30 to 65 years, who had no underlying health condition otherwise, diagnosed with generalized chronic periodontitis and who complained of at least three DH teeth were included.

Exclusion Criteria: Patients who had dentine hypersensitivity prior to getting periodontal treatment, and those having other reasons for which DH experience such as tooth fracture, dental caries, abrasive or crowded teeth, improper restoration or orthodontic treatment in the past three months were excluded.

Participants also did not have any history of using drugs that might hinder the protocol such as chronic use of analgesics, neural altering pharmaceuticals or therapeutic agents for hypersensitivity in the past few months. The participants also had no allergic reaction towards treatment products used in this study (8% arginine and calcium carbonate or 5% CSPS).

The sample size was determined using G*Power (version 3.1), taking into account the decrease in the scale of Schiff cold air sensitivity that occurred shortly after adding the dentifrice.[11] The dentifrice used in this study as test products were 1) control dentifrice, 2) dentifrice containing 5% CSPS, and 3) dentifrice containing 8% arginine and calcium carbonate.

Diagnosis of generalized chronic periodontitis (as per 1999 classification definition). The patients had a diagnosis with mild to serious DH (Schiff's scores of 2 to 3) or tactile test (Visual Analogue Scale (VAS) was >4) following non-surgical periodontal treatment. These patients had already undergone root canal treatment or scaling.

The patients were randomized into three groups: Control (Group-A), CSPS (Group-B), and Arginine (Group-C) with an equal distribution (1:1:1), as seen in Figure-1. After non-surgical periodontal therapy, Schiff and VAS scores were recorded for hypersensitive teeth. grams of dentifrice was applied for two 5-second intervals to exposed root surface area with rubber cups in slow speed air turbine. Sensitivity was reassessed immediately. For in-home dentifrice application, a tube containing dentifrice was provided to each patient which had an opaque wrapping on it enclosed in a sealed envelope. After this the evaluation of DH tooth of each patient was recorded at different times 1-, 2- and 4- weeks after in home-use of dentifrice during follow-ups. For obtaining Schiff score data, the examiner placed their fingers over the adjacent teeth to isolate the DH tooth and its exposed surface was then blasted with air at 60 psi (± 5 psi) by a dental syringe. This was done for one second at a perpendicular angle to the area of the tooth from a 10 mm distance and the response to this stimulus was then recorded. The Schiff scale ranged from 0 to 3, where "1" patient senses the air stimulus but does not ask for it to be stopped; "2" patient senses the stimulus and either distanced from it or asks for it to be stopped and "3" patient senses the stimulus, feels pain upon stimulus injection, and asks for it to be stopped. After 5 minutes of conducting the Schiff test, the tactile (VAS) test was performed. The participant was then asked to indicate the level of pain on a 10-cm line which had labelling of "zero pain" to "unbearable pain" as the examiner positioned the visitor in a mesio-distal manner over the exposed dentine.

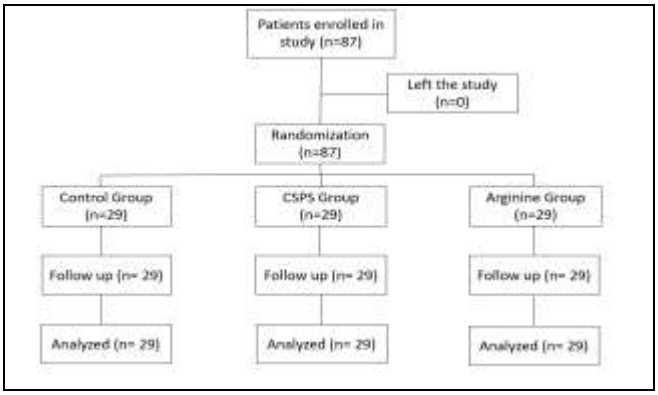

Figure-1: Consort flow diagram of RCT study

Before applying the dentifrice with a rubber cup at a slow speed, the dentist thoroughly cleaned the diagnosed DH teeth. For home-use the patients were instructed given a soft toothbrush and to use the

assigned tube of dentifrice only and avoid mouth wash while participating in this study trial. The instructions also included to brush carefully for precisely two minutes using 1-inch strip of the dentifrice and then rinsing it off one time with water. The dental assistant weighed the dentifrice tube upon each follow-up visit.

Microsoft Excel was used to record and present the patient's data which also included calculating the mean, median and standard deviation. The average score of three DH was evaluated for each patient. Statistical Package for the Social Sciences (SPSS) version 23 was used to perform the statistical tests on the recorded Schiff and VAS scores separately. Mean percent reduction (normalizing the test week scores to that of baseline score) and mean percent difference (percentage decrease at every time point in comparison to the control) were calculated. The normality of the data was evaluated by the Shapiro-Wilk test. The between group comparisons was done by Kruskal-Wallis test and pair-wise comparison was done by Mann-Whitney U test. Significance was evaluated at *p*-value of 0.05.

RESULTS

A total of 87 patients were divided into group of three with 29 patients each. The demographic data, as shown in Table-I, appeared as Asian patients with age ranging between 30-65. The mean age of patients was 48.48±8.5 years in Group-A, 45±9.8 years in Group-B and 43.69±8.7 years in Group-C. Higher percentage of females (51.7% and 55.2%) compared to males (48.3% and 44.8%) in both groups A and B respectively, while it was observed that males had a greater percentage (55.2%) than females (44.8%) in Group-C. The average number of follow-up visits were 4.41±0.6 weeks in Group-A, 4.31±0.66 weeks in Group-B and 4.21±0.91 weeks in Group-C. Both VAS and Schiff scores at baseline were comparable between the groups and no significant difference was observed.

Table-I: Demographic and Baseline score distribution across Groups (n=87)

Variables	Control (n=29)	CSPS (n=29)	Arginine (n=29)	*p*-value
Age (years)				
Median (IQR)	49.00 (1.20)	45.00 (17.00)	41.00 (12.00)	0.135*
Range	32.00-64.00	33.00-62.00	30.00-61.00	
Gender n (%)				
Male	14.00 (48.28)	13.00(44.83)	16.00 (55.17)	0.725**
Female	15.00 (51.72)	16.00(55.17)	13.00 (44.83)	
Number of visits				
Median (IQR)	4.00(1.00)	4.00 (1.00)	4.00 (1.00)	0.551*
Baseline VAS score				
Median (IQR)	5.00 (1.00)	4.66 (1.00)	4.33 (1.33)	0.112*
Baseline Schiff score				
Median (IQR)	2.66 (0.33)	2.33 (0.33)	2.66 (0.33)	0.446*

**Kruskal-Wallis test. **Chi-square test*

In our study, we determined the efficacy of CSPS and arginine dentifrice in reducing DH immediately after in-office application. The Schiff score distribution across the three groups indicated the percentage DH immediate reduction of 5.51% (p=0.090), 20.29% (p<0.001) and 14.07% (p<0.001) for groups A, B and C respectively. This indicated significant DH reduction for both CSPS and arginine and not in control group. Similarly, VAS score distribution indicated immediate DH reduction of 3.72% (p=0.335), 30.48% (p<0.001) and 30.57% (p<0.001) in groups A, B and C respectively. This also indicated significant reduction in VAS score in the treatment groups (Table-II).

Table-II: Within-group Comparison of VAS and Schiff score Distribution after In-Office Application of Dentifrice (n=87)

Variables		Study Groups		
		Group-A (n=29)	Group-B (n=29)	Group-C (n=29)
VAS Score Median (IQR)	Baseline	5 (1.00)	4.66 (1.00)	4.33 (1.33)
	Immediate	5 (0.66)	3 (1.33)	3 (1.33)
p-value		0.335	<0.001	<0.001
Schiff Score Median (IQR)	Baseline	2.66 (0.33)	2.33 (0.33)	2.66 (0.33)
	Immediate	2.66 (0.33)	2.00 (0.33)	2.33 (0.33)
p-value		0.090	<0.001	<0.001

We further examined the average VAS score at different time points. At week 1, close to 50% reduction was achieved in both Group-B (48.3%) and Group-C (43.1%) compared to (21.4%) Group-A. The percentage mean reduction in VAS score was nearly half in Group-B (68.79%) and Group-C (60.01%) compared to that in Group-A (33.64%) on week 2. The maximum percent mean VAS score reduction was observed at 4 weeks with 83.33% in CSPS, 73.44% in arginine and 45.82% in control group. The total percentage reduction in VAS and Schiff score is depicted in Table-III.

Table-III: VAS and Schiff Score Distribution at various Time Points (n=87)

Factors	Time Point	Group-A (n=29) Median (IQR)	Group-B (n=29) Median (IQR)	Group-C (n=29) Median (IQR)
Schiff Score	Baseline	2.67 (0.33)	2.33(0.33)	2.67 (0.33)
	Immediate	2.67 (0.33)	2.00 (0.33)	2.33 (0.33)
	Week 1	2.00 (0.33)	1.33 (0.66)	1.66 (0.66)
	Week 2	1.33 (0.66)	0.67 (0.33)	1 (0.66)
	Week 4	1 (0.66)	0.33 (0.33)	0.33 (0.33)
	Total Reduction (%)	63.50	83.10	78.4
VAS Score	Baseline	5 (1.00)	4.67 (1.00)	4.33 (1.33)
	Immediate	5.00(0.67)	3.00 (1.33)	3 (1.33)
	Week 1	4.00 (1.33)	2.67 (0.67)	2.67 (1.00)
	Week 2	3.33 (0.67)	1.33 (1.00)	1.67 (1.00)
	Week 4	2.67 (0.67)	0.67 (0.67)	1.00 (1.00)
	Total Reduction (%)	45.70	82.50	73.50

Mean Schiff score distribution at different time points was also observed. At week 1, there was a mean % DH reduction of 44.7% in Group-B 39.6% in Group-C and 23.4% in Group-A. More than half of DH was reduced at week 2 among patients in Group-B (68.2%) and Group-C (61.1%) compared to Group-C (48.5%). The highest percent mean DH reduction was observed at week 4 with 83.7% in Group-B, 78.9% in Group-C and 63.9% in Group-A.

Sciff score ≥2 was treated as DH and we therefore analyzed patients experiencing DH after application of dentifrice at different time points. There was a 20.7% reduction in percentage of patients with sensitivity after in-office application of dentifrice both in Group-B (CSPS) and Group-C (arginine). After week 1, less than 50% patients were recorded with DH in groups B and C. After week 4, where the total remaining patients with DH in control group were 24.1%, less than 7% remained sensitive in both groups B and C (Figure-2).

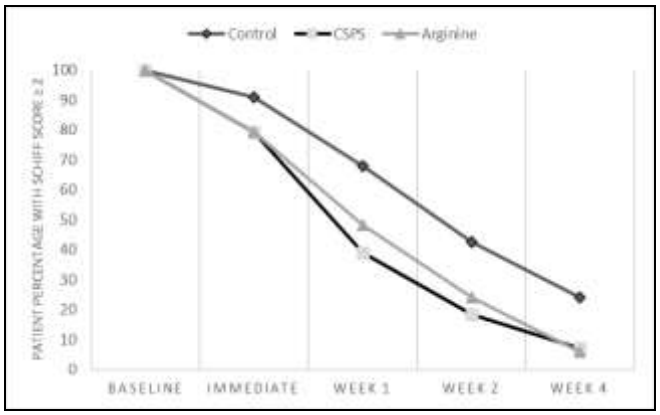

Figure-2: Percentage of Patients Presenting with Dentine Hypersensitivity (n=87)

DISCUSSION

This RCT focused on assessing the effectiveness in reduction of DH subsequent to non-surgical periodontal therapy. A total of 87 patients diagnosed with chronic periodontitis were randomly allocated in an equal ratio into three groups (29 patients each). The patient's Schiff score and VAS score were recorded following non-surgical periodontal treatment. The in-office application of dentifrice indicated significant decrease in DH evaluated by patient's Schiff and VAS score. The highest percent mean DH reduction observed through Schiff score was greater in Group-B compared to Group-C at all time points.

At week 4, significant decline in Schiff score is a more reliable method of detecting hypersensitivity compared to VAS score, because the cervical pain caused by air stimulus is more frequent and stronger. Previously conducted clinical trials suggested that CSPS arginine significantly reduced DH immediately after in-office application which is in accordance with our study as well.[12-15] Another study that used arginine and CSPS as desensitizers, similar to our study, had Schiff score reduction ≈ 50% after in-office immediate application while we found 20% and 14% reduction after in-office application.[14] This difference may be due to different patient population, sample size or sensitivity assessment timing.

All studies suggesting increased reduction of DH by arginine and CSPS implicate that the mode of action of CSPS is mediated by releasing phosphate and calcium ions that forms hydroxycarbonate apatite (HCA) while arginine combines with calcium to carbonate calcium-arginine-phosphate complex.[16-19] Both products form layers on exposed dentin tubules and reduce fluidity, thereby reducing sensitivity. The generalizability of this finding and its increased applicability in patients who suffer from DH after non-surgical periodontal therapy requires more clinical trial studies and bigger sample size.

LIMITATIONS OF STUDY

Our main limitations were a small sample size and our study being conducted at a single centre, both of which may limit the generalizability of our findings.

CONCLUSION

Efficacy of Calcium Sodium Phosphosilicate (CSPS) and arginine as desensitizing agents was explored and its effects in reducing Dentine Hypersensitivity (DH) in patients with periodontitis was confirmed.

Conflict of Interest: None.

Discolure:

Funding Source: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MJI & MSA: Data acquisition, data analysis, critical review, approval of the final version to be published.

YIA & AR: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

AA & RA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity

of any part of the work are appropriately investigated and resolved.

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