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Research Article

CLINICAL EVALUATION OF AN IN-OFFICE APPLICATION OF TWO COMMERCIALLY AVAILABLE DENTIFRICES ON DENTINE HYPERSENSITIVITY IN CHRONIC PERIODONTITIS PATIENTS

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ABSTRACT

Aim: To evaluate the clinical effectiveness of an in-office application of desensitizing paste containing 8% arginine calcium carbonate and 5% potassium nitrate paste on dentine hypersensitivity in chronic Periodontitis patients.

Materials and methods: A randomized double blind clinical trial was done in 60 chronic Periodontitis patients presenting hypersensitivity. All the patients were subjected to scaling and randomly assigned into two groups for in-office application of either 8% arginine calcium carbonate desensitizing paste (Group 1- 30 patients) or 5% potassium nitrate desensitizing paste (Group 2- 30 patients). Air blast hypersensitivity was assessed by Schiff scale at baseline, immediately post scaling and post application of desensitizing paste, 2 and 4 weeks. Clinical parameters including: full mouth plaque score (FMPS), sulcus bleeding index (SBI), clinical attachment level (CAL) and probing pocket depth (PD) were assessed at baseline and 4 weeks. The study was approved by institutional ethical committee. Data were analysed by using commercially available statistical software SPSS ($P<0.05$).

Results: Group 1 patients showed highly significant reduction in hypersensitivity from baseline to 4 weeks when compared to Group 2 patients.

Conclusion: The single in-office application of the 8% arginine calcium carbonate desensitizing paste (Colgate sensitive pro-relief®)after scaling provided significant reduction in dentine hypersensitivity when compared to 5% potassium nitrate desensitizing paste (Sensodent-k®) which sustained over a 4 week period.

Keywords: Dentin hypersensitivity, Arginine-calcium carbonate, Potassium nitrate, clinical trial, desensitizing paste, Periodontitis.

INTRODUCTION:

Dentin hypersensitivity is frequently reported dental condition that is characterized by brief, sharp pain that cannot be described to any other form of dental defect or pathology. It is a common problem which affects about 8-57 % of the adult population and mostly associated with gingival recession, periodontal disease, non-carious cervical lesions and congenitally missing cement-enamel junction. It occurs mainly due to the exposed dentin in response to thermal, tactile, osmotic and chemical stimuli.[1] These external stimulus cause displacement of the fluid in dentinal tubules, which activates the nerve endings at the pulp/ dentin interface, resulting in sharp and sudden pain.

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There are two discrete approaches to treat dentinal hypersensitivity. The first approach is by interrupting the neural response to pain stimuli and second approach is by blockage of the exposed dentinal tubules, thereby preventing the external stimuli from triggering the displacement of dentinal fluid which further preventing the onset of pain[2,3].

Various desensitizing agents have been used to treat hypersensitivity including: silver nitrate, fluoride, formaldehyde, strontium chloride and potassium nitrate[4,5,6]. Incorporation of these desensitizing agents into dentifrices which are typically used on daily basis world-wide.

Dentifrices containing potassium ions have been shown by several clinical studies as effective desensitizing agents in reducing dentinal hypersensitivity. Potassium ions are thought to act by the blockage of action potential generated in intradental nerves[7,8].

A new breakthrough technology based upon 8% arginine and calcium carbonate has been introduced as an in-office professional desensitizing paste and as a daily- use fluoride-containing dentifrice, in the treatment of dentin hypersensitivity[2,9,10]. Laboratory research has demonstrated that the technology provides rapid and complete occlusion of the exposed and open dentinal tubules and the occlusion that was achieved is seen to be resistant to acid challenge[11,12]. Clinical studies conducted on arginine-calcium in-office desensitizing paste have shown that a single professional application provides immediate relief when applied after a professional dental cleaning that lasts for a minimum of 28 days[13]. It also provided immediate relief when applied prior to a professional dental cleaning[14].

Therefore, the aim of this randomized double blind clinical study was to compare and evaluate the in-office application of commercially available dentifrices containing 8% arginine-calcium carbonate and 5% potassium nitrate on dentinal hypersensitivity in chronic Periodontitis patients.

MATERIALS AND METHODS:

A randomized double blind clinical study was designed and conducted by Department of Periodontics, Lenora Institute Of Dental Sciences, Rajahmundry, Andhrapradesh, India. A sample of 60 chronic Periodontitis patients was enrolled from October 2015 to January 2016. The study was approved by Ethical committee, Lenora Institute of Dental Sciences, Rajahmundry, Andhra Pradesh. Informed consent was taken from all the participants before commencing of the study following inclusion and exclusion criteria.

Inclusion criteria**:**

- Patients age from 18-70 years.
- Patients without medical conditions that would contraindicate periodontal treatment.
- Patients with moderate to severe Periodontitis.
- Patients with satisfactory dental restorations, patients with pre-existing dentin hypersensitivity in at least two teeth or using agents to treat hypersensitivity in the past 6 months.

Exclusion criteria:

- Patients with gross oral pathology, chronic disease, periodontal treatment within last 12 months, hypersensitive teeth with mobility greater than one, teeth with extensive or defective restorations, suspected pulpitis or cracked enamel.
- Patients with removable appliances such as removable partial dentures or orthodontic retainers.
- Patients taking anticonvulsants, anti-histamines, anti-depressants, sedatives, tranquilizers, anti-inflammatory drugs or daily analgesics within one month prior to enrolment to the study and pregnant or lactating women.
- Patients who were participating in any other clinical study or who had participated in a desensitizing tooth paste study or who used desensitizing toothpaste within the last 3 months or had a dental prophylaxis within 2-weeks prior to date of screening visit.
- Patients with unbalanced diet.
- Patients with history of allergy to the test products or allergies to oral care products or their ingredients.
- Patients with cervical abrasions.

For each patient who qualified for participation in the study, all hypersensitive teeth that satisfied the air blast hypersensitivity enrolment criteria were identified for evaluation throughout the study. Qualifying patients were randomly assigned to one of the two study treatments groups:

Group 1: Patients were treated with desensitizing paste containing 8% arginine-calcium carbonate (Colgate sensitive pro-relief®).

Group 2: Patients were treated with desensitizing paste containing 5% potassium nitrate (sensodent-k®).

Baseline periodontal examination was performed for all teeth which include: full mouth plaque score (FMPS), sulcus bleeding index (SBI), clinical attachment level (CAL) and probing pocket depth (PD). Baseline hypersensitivity evaluation was performed for all teeth by using the Schiff Cold Air Sensitivity scale, which was scored from 0 to 3.

0 = Patients does not respond to air stimulus.

1 = Patients responds to air stimulus but does not request discontinuation of stimulus.

2 = Patients responds to air stimulus and requests discontinuation or moves from stimulus.

3= Patients responds to air stimulus, considers stimulus to be painful, and requests discontinuation of the stimulus.

Periodontal treatment including scaling was performed using ultrasonic scaler and hand instruments. Then, all teeth were evaluated for hypersensitivity using Schiff scale (immediate post-scaling evaluation). After, each patient was randomly assigned to the in-office application of either Colgate sensitive pro-relief® (Group 1) or Sensodent-k® (Group 2) desensitizing tooth paste. Then, each patient received two consecutive 3-s applications of the assigned in-office paste at all hypersensitive teeth that satisfied the hypersensitivity enrolment criteria. Immediately after application, each patient was subjected to hypersensitivity evaluation (post-application of desensitizing paste evaluation). Thereafter, each patient was subjected to follow-up hypersensitivity evaluations at 2 and 4weeks. Periodontal parameters were evaluated at 4 weeks.

STATISTICAL ANALYSIS

Analyses were performed by using commercially available statistical software (SPSS). Inter group comparison of hypersensitivity and periodontal parameters were performed by using independent t-test. Intra group comparison of hypersensitivity and periodontal parameters were performed by using paired t test. $P<0.05$ was considered statistically significant.

RESULTS

The present study was conducted with a sample of 60 chronic periodontitis patients having hypersensitivity. 30 patients in each group (Group 1-Colgate sensitive pro-relief®, Group 2-Sensodent-k®) evaluated for reduction in number of hypersensitive teeth by in-office application of desensitizing paste.

When comparison of number of hypersensitive teeth with different time periods between Group 1 and Group 2 done: statistically significant reduction of hypersensitivity after application of desensitizing paste, 2 and 4 weeks but this reduction was more for Group 1 patients as showed in Table 1.

Comparison of number of hypersensitive teeth between baseline with different time periods in Group 1 and Group 2 done: there is a statistically significant reduction of hypersensitivity after application of desensitizing paste, 2 and 4 weeks in both the Groups as showed in Table 2 & 3.

When comparison of all periodontal parameters including: full mouth plaque score (FMPS), sulcus bleeding index (SBI), clinical attachment level (CAL) and probing pocket depth (PD) between Group 1 an Group 2 done: no statistical significant reduction from baseline to 4 weeks expect in sulcus bleeding index (SBI) as showed in Table 4.

Comparison of all periodontal parameters including: full mouth plaque score (FMPS), sulcus bleeding index (SBI), clinical attachment level (CAL) and probing pocket depth (PD) from baseline to 4 weeks in Group 1 and Group 2 done: statistically significant reduction was observed which showed in Table 5&6.

Table 1: Comparison of number of hypersensitive teeth with different evaluation time periods between Group 1 and Group 2.

No of hypersensitive teeth at					
Evaluation time	GROUP I	GROUP II	DIFFERENCE	t value	P value
	MEAN±SD	MEAN±SD	MEAN±SD		
Baseline	9.88±1.45	9.80±1.26	0.08±0.19	0.153	0.880 NS
Post scaling	10.94±1.48	11.40±1.18	0.46±0.30	-0.956	0.347 NS
Immediate Post application of paste	4.31±0.87	5.67±1.05	1.36±0.18	-3.922	<0.001 S
2weeks	4.75±0.77	6.53±1.19	1.78±0.42	-4.985	<0.001 S
4 weeks	5.31±0.87	7.33±1.23	2.02±0.36	-5.289	<0.001 S

Statistical analysis: Independent sample t test. Statistically significant if P<0.05.

Table 2: Comparison of number of hypersensitive teeth in Group 1 between baseline with different evaluation time periods.

No of hypersensitive teeth at					
Evaluation time	GROUP I: Baseline	GROUP I	DIFFERENCE	t value	P value
	MEAN±SD	MEAN±SD	MEAN±SD		
Post scaling	9.88±1.45	10.94±1.48	1.06±0.03	-4.977	<0.001 S
Immediate Post application of paste		4.31±0.87	5.57±0.58	27.336	<0.001 S
2-weeks		4.75±0.77	5.13±0.68	20.006	<0.001 S
4-weeks		5.31±0.87	4.57±0.58	18.933	<0.001 S

Statistical analysis: Paired t test. Statistically significant if P<0.05.

Table 3: Comparison of number of hypersensitive teeth in Group 2 between baseline with different evaluation time periods

No of hypersensitive teeth at					
Evaluation time	GROUP II: Baseline	GROUP II	DIFFERENCE	t value	P value
	MEAN±SD	MEAN±SD	MEAN±SD		
Post scaling	9.80±1.26	11.40±1.18	1.60±0.08	-8.411	<0.001 S
Immediate Post application of paste		5.67±1.05	4.13±0.21	21.539	<0.001 S
2-weeks		6.53±1.19	3.27±0.07	15.838	<0.001 S
4-weeks		7.33±1.23	2.47±0.03	8.488	<0.001 S

Statistical analysis: Paired t test. Statistically significant if P<0.05.

Table 4: Comparison of Periodontal parameters including: sulcus bleeding index, Plaque index, probing depth, clinical attachment level between Group I and Group II from baseline to 4 weeks.

Parameters	Evaluation time	GROUP I MEAN±SD	GROUP II MEAN±SD	DIFFERENCE MEAN±SD	t value	P value
Sulcus bleeding index	Baseline	2.75±0.45	2.53±0.52	0.22±0.07	1.251	0.221 NS
	4 weeks	0.13±0.34	0.73±0.59	0.60±0.25	-3.526	0.001 S
Plaque index	Baseline	2.31±0.48	2.60±0.51	0.29±0.03	-1.624	0.115 NS
	4 weeks	1.00±0.00	1.00±0.00	0.00±0.00	0.00	1.000 NS
Probing depth	Baseline	6.19±0.75	5.73±0.59	0.46±0.16	1.861	0.073 NS
	4 weeks	3.19±0.40	3.00±0.38	0.19±0.02	1.334	0.193 NS
Clinical attachment level	Baseline	6.63±0.62	6.13±0.64	0.50±0.02	2.174	0.038 S
	4 weeks	3.19±0.66	3.47±0.52	0.28±0.14	-1.312	0.200 NS

Statistical analysis: Independent sample t test. Statistically significant if P<0.05.

Table 5: Comparison of periodontal parameters including: sulcus bleeding index, Plaque index, probing depth, clinical attachment level in Group 1 from Baseline to 4 weeks.

GROUP I					
Parameters	Evaluation time	MEAN±SD	Difference MEAN±SD	t value	P value
Sulcus bleeding index	Baseline	2.75±0.45	2.62±0.11	21.00	<0.001 S
	4 weeks	0.13±0.34			
Plaque index	Baseline	2.31±0.48	1.31±0.48	10.967	<0.001 S
	4 weeks	1.00±0.00			
Probing depth	Baseline	6.19±0.75	3.00±0.35	16.432	<0.001 S
	4 weeks	3.19±0.40			
Clinical attachment level	Baseline	6.63±0.62	3.53±0.04	15.413	<0.001 S
	4 weeks	3.19±0.66			

Statistical analysis: Paired t test. Statistically significant if P<0.05.

Table 6: Comparison of periodontal parameters including: sulcus bleeding index, Plaque index, probing depth, clinical attachment level in Group 2 from Baseline to 4 weeks.

GROUP 2					
Parameters	Evaluation time	MEAN±SD	Difference	t value	P value
Sulcus bleeding index	Baseline	2.53±0.52	1.80±0.07	16.84	<0.001 S
	4 weeks	0.73±0.59			
Plaque index	Baseline	2.60±0.51	1.60±0.51	12.22	<0.001 S
	4 weeks	1.00±0.00			
Probing depth	Baseline	5.73±0.59	2.73±0.21	23.13	<0.001 S
	4 weeks	3.00±0.38			
Clinical attachment level	Baseline	6.13±0.64	2.66±0.12	21.17	<0.001 S
	4 weeks	3.47±0.52			

Statistical analysis: Paired t test. Statistically significant if P<0.05.

DISCUSSION

The present study was designed to evaluate the clinical effects of in-office application of two commercially available desensitizing pastes containing 8% arginine calcium carbonate (Group 1- 30 patients) and 5% potassium nitrate (Group 2- 30 patients) after scaling. Periodontal measurement including: full mouth plaque score (FMPS), sulcus bleeding index (SBI), clinical attachment level (CAL) and probing pocket depth (PD) were recorded at baseline and 4 weeks. Hypersensitivity was evaluated at baseline, post-scaling, immediate post application of desensitizing paste, 2 and 4 weeks by using Schiff scale. Significant improvements in periodontal parameters were seen in both the groups.

Hypersensitivity has a negative effect on the patient's compliance especially during the initial post-scaling weeks. The in-office application of a desensitizing agent with immediate effect is used for the instant hypersensitivity relief. The use of a prophylaxis paste containing desensitizing agents immediately after scaling and root planing helps in decreasing the hypersensitivity thereby decreasing the patient's discomfort and helps in increasing the patient's compliance.

The present study explored the single in-office application of dentifrice containing 8% arginine – calcium carbonate after scaling provided significant immediate hypersensitivity reduction when compared to the dentifrice containing 5% potassium nitrate. The main components of this paste are arginine and amino acid which are positively charge at physiological ph. The amino acid which is naturally found in saliva carries a positive charge (at physiological pH) attracts the calcium carbonate to the negatively charged dentin surface. The calcium carbonate and arginine bind to the dentin surface leads to precipitation of calcium rich layer which seals the dentinal tubules. The blocking of fluid movement in the tubules reduces pain and discomfort. This paste has previously achieved significant hypersensitivity reduction when applied as single professional application prior to (**Hamlin et al. 2009**) or during tooth cleaning **(Schiff et al. 2009)**. It mimics the natural process of plugging and

sealing patent tubules **(Kleinberg 2002, Cummins 2009)**.

Our results demonstrated that the dentifrice containing 5% potassium nitrate provides effective desensitization from baseline to 4 weeks. These results were in accordance with studies by **Tarbet et al. 1980, 1982, Silverman 1985, Nagata et al. 1994, Silverman et al. 1996, Sowinski et al. 2001, Markowitz et al. 1991, Peacock & Orchardson 1995.** The mechanism by which potassium nitrate reduces dentine hypersensitivity may involve the depolarizing action of the K^+ ion resulting in the decrease of dentinal sensory nerve activity.

Hypersensitivity was assessed by air-blast rather than tactile stimulus in this study since air-blast stimulus causes cervical pain more frequently than the tactile one **(von Troil et al. 2002, Gillam et al. 2002, Rees et al. 2003, Patsouri et al. 2011)** which implies that it is a more sensitive method in detecting hypersensitivity.

Periodontal parameters including: full mouth plaque score (FMPS), sulcus bleeding index (SBI), clinical attachment level (CAL) and probing pocket depth (PD) in both the groups showed significant reduction from baseline to 4 weeks. In our study we are not explore any association between hypersensitivity scores and periodontal measurements and we include only scaling treatment.

Among the strengths of this study, limitations include: it is a 4-week observation period and has multiple evaluations, which made it possible to detect any relapse in hypersensitivity within the 4 weeks. The patients require further treatment for chronic periodontitis. Although the sample size is small: So Larger sample with multi-centre studies are required to confirm if the present findings to other population of patients with hypersensitivity.

CONCLUSION

In the light of our results, it was concluded that single in-office application of the 8% arginine-calcium carbonate desensitizing paste (Colgate sensitive pro-relief®) after scaling provide immediate reduction in dentin hypersensitivity compared to 5% potassium nitrate desensitizing paste (Sensodent-k®). This reduction of hypersensitivity was sustained over a 4 week period.

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