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ORIGINAL ARTICLE

COMPARATIVE EVALUATION OF THE EFFICACY OF NOVAMIN AND PRO-ARGIN IN REDUCING DENTINAL HYPERSENSITIVITY: A DOUBLE BLIND RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT:

Background:

Dentin hypersensitivity is the most prevalent condition among several factors which cause the patients discomfort and make them visit dental office frequently. Novamin and proargin are the newer technologies which are proposed to have a better sensitivity reduction efficacy. The main objective of this study was to compare the efficacy of commercially available desensitizing toothpastes containing Novamin and Pro-Argin in reducing dentin hypersensitivity. **Materials and methods:** This is a double blind trial in which simple randomization by using coin toss method was done.A total of 50 patients with a chief complaint of sensitivity of at least one tooth due to gingival recession were included in the study. Examination was carried out using tactile stimulation, air-blast stimulation and cold water stimulation at baseline. Each patient was then provided one of the test dentifrices and were instructed to massage gently with the dentifrice for 5 mins and then brush the teeth in the usual manner with a soft bristled toothbrush for 2 min, twice daily. Patients were recalled at 2 weeks, 4 weeks and 6 weeks and examinations were carried out. **Statistical analysis used:** Repeated measure analysis of variance, unpaired t test, post hoc analysis

Results: On comparing the efficacy of product A and B using all the 3 measurements, product A (VANTEJTM) showed greater reduction of sensitivity than product B (COLGATE SENSITIVE PRORELIEFTM), but statistically significant differences were observed only with cold water stimulation test.

Conclusion: Desensitizing toothpaste containing Novamin showed better reduction of sensitivity when compared to dentifrice containing Proargin technology.

Key Words: Dentin hypersensitivity, Gingival recession, Management

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INTRODUCTION:

The control or elimination of pain which may arise due to several factors is of important concern to the dentist, amongst which dentin hypersensitivity is the most prevalent condition.

Dentin hypersensitivity is the most prevalent disorder,mostly affecting canines and first premolars,followed by incisors and 2nd premolars,and finally, molars. The buccal surface of the teeth is most commonly affected.[1] It shows an increase in severity during 20 to 30 year olds and then rise again during the 50's.Females appear to suffer more than males presumably due to their overall health care and better oral hygiene awareness.[1]Although the prevalence of DH varies from 4 to 57 %, it is high in patients with periodontitis, reportedly between 60 and 98 %.[2]

Several factors have been reported as the causes for dentin hypersensitivity, amongst which gingival recession is closely associated with it. It is reported that teeth with gingival recession actually showed a higher level of DH than the teeth without gingival recession, the reason being attributed to overly enthusiastic oral hygiene measures.[2]

Other factors such as attrition from occlusal wear, abfractions, parafunctional habits, abrasive tooth brushing or erosion from acidic diet also resulted in dentin hypersensitivity.[3]The underlying cause for the resulting condition is the removal of protecting layer of enamel or cementum exposing the dentin surfaces.

In a majority of individuals, the pain attributed to dentinal hypersensitivity is episodic and is short in duration, although sharp in nature, which is annoying, but bearable.[4]However, in some individuals the pain is far more severe, lasts for hours or days and interferes with day-to-day activities and pleasures. There is no clearcut explanation for this but certain factors may be implicated like age, rate of exposure of dentin surface& environmental desensitizing mechanisms.

The primary prevention of dentinal exposure or hard tissue damage by prophylactic measures like avoidance of an erosive or abrasive diet is the best way to treat this phenomena.

Apart from the two varied therapeutic approaches like suppression of the nerve impulses by direct neurological interaction or mechanical blockage of the dentinal tubules, the latter forms the vital therapeutic approach in the treatment of dentinal hypersensitivity.[5]

Physical means like protein precipitation, plugging of dentin tubules, sealing or laser applications are the various mechanisms that are identified to modify the dentin surface or tubules apart from chemical and mechanical means.

Occlusion of the tubule openings on using newly introduced products containing arginine/calcium carbonate,bioactive glass have appeared to provide optimal pain relief amongst the various number of toothpastes in the market.

The Latest research on Pro-Argin™ Technology suggests that at physiological pH, arginine and calcium carbonate interact and bind to the negatively charged dentine surface to form a calcium rich layer on the dentin surface and in the dentin tubules to plug and seal them.[6]On the other hand, Pro-Argin™ Technology triggers occlusion of the dentin tubules that remains intact even after exposure to acids, preventing transmission of pain-producing stimuli.

In the case of Novamin products, calcium sodium phosphosilicate is the active ingredient which plays a role in the reduction of hypersensitivity. This component reacts when exposed to aqueous media and provides calcium and phosphate ions that form a hydroxy-carbonate apatite (HCA) with time. This layer results in the physical occlusion of dentinal tubules which relieves hypersensitivity.[7]

Since Pro-Argin formula and Novamin crystals are newer technologies, few studies have been done to compare their reduction efficacy clinically.

Hence, this study aimed to compare the efficacy of commercially available desensitizing toothpastes containing Novamin and Pro-Argin in reducing dentin hypersensitivity.

SUBJECT AND METHODS:

The study was single centered, double blind (investigator and patient) randomized controlled clinical design. Sample size was calculated based on previous studies with 95% confidence levels, α value of 0.05 and 80% power and the final sample size was found to be 25 in each in group.

The study protocol was approved by the Ethical Research Committee, Vishnu dental college, Bhimavaram, India.

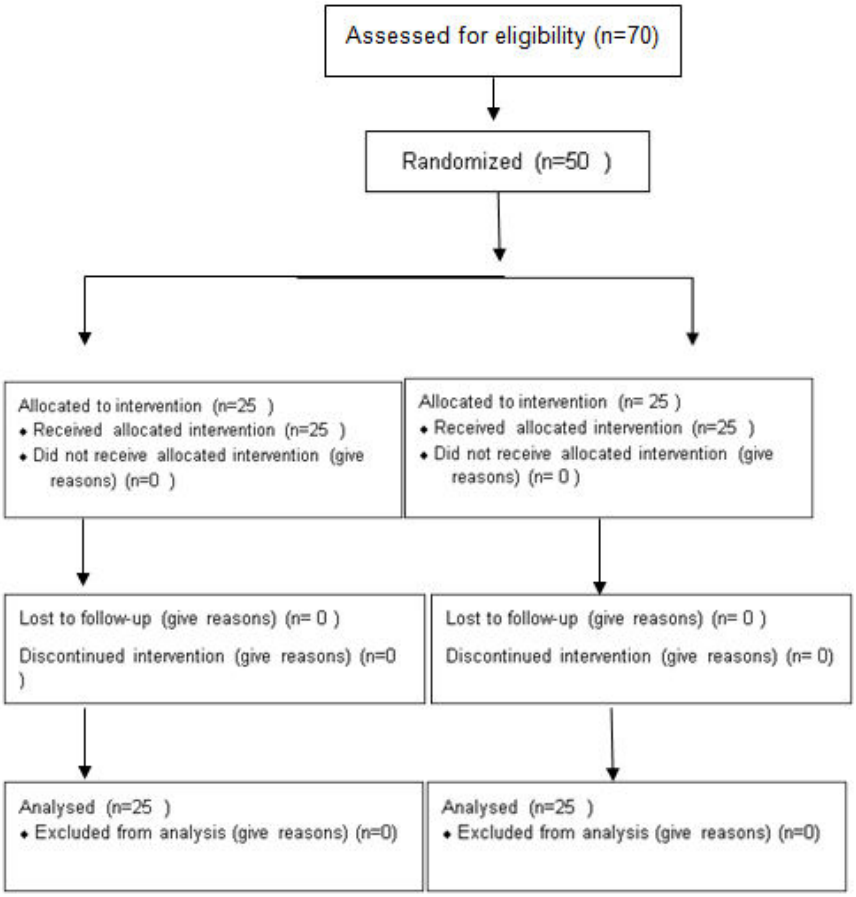
After ethical approval, 70 subjects who visited the Department of Periodontics & Implantology were recruited for the study. After assessing the patients for eligibility, 20 patients were excluded. A total of 50 patients were then randomized by coin flip method into 2 treatment groups A and B, each containing 25 patients.

A special questionnaire, which included questions like age, sex, chief complaint, cause, whether pain experienced on having either cold or hot food stuffs or sweets, duration of pain, tooth/teeth involved, prior treatments received (if any) on the tooth/teeth of interestwere recorded in a proforma by the investigator. Selected subjects were then randomly assigned to one of the treatment groups A or B and informed consents were obtained.

The Inclusion criteria for the present study included subjects between the ages of 20-65 years who were systemically healthy and had at least 20 natural permanent teeth in the oral cavity with a history of hypersensitivity to hot, cold or sour stimuli primarily because of gingival recession.

The exclusion criteria were patients who had a history of hypersensitivity due to attrition/ abfraction, abscess, periapical periodontitis, pericoronitis, bleaching sensitivity, post-operative sensitivity,current use of anti‑depressants, sedatives or analgesics,women who have been pregnant or lactating,history of allergy to any of the test product, patients who had any kind of priortreatment for dentinal hypersensitivity on a particular tooth, extensive or defective restorations/suspected pulpitis andcracked enamel with the tooth of interest.

Randomization according to CONSORT guidelines:



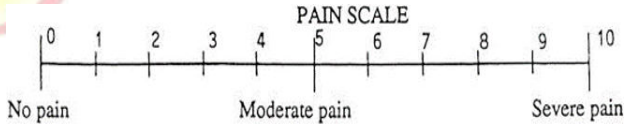
SENSITIVITY MEASUREMENT:

Prior to baseline examination, the teeth of interest were isolated. Baseline examination was carried out using tactile stimulation, air-blast stimulation and cold water stimulation.

Tactile stimulation was done by marking along the tooth surface from mesial to distal direction. Air blast stimulation was done first by using controlled air pressure, from a standard dental syringe directed perpendicularly and at a distance of 1 to 3 mm from the exposed dentin surface.

This was followed by scoring of tooth sensitivity using 2 ml of ice cold water applied to the exposed dentin surface. Care was taken in protecting the adjacent teeth using gauze to avoid any bias.

A period of at least 5 minutes was allowed between these stimuli on each tooth. Sensitivity was measured using a 10-cm VAS score, with the score of zero being a pain-free response and ascore of 10 being excruciating pain or discomfort. The scores were recorded 3 times and the average final score was recorded.



Each patient was then provided one of the test dentifrices. The patients were instructed to apply a pea size amount of dentifrice on the area of complaint and massage gently for 5 mins and then brush the teeth in the usual manner with a soft bristled toothbrush for 2 min, twice daily. Patients were instructed not to eat or drink anything within half an hour of brushing with the dentifrices.

Patients were recalled at 2 weeks, 4 weeks and 6 weeks for the measurement of tooth sensitivity.

STATISTICAL ANALYSIS:

Comparison between the two treatment groups were performed by unpaired t test. Comparisons between different time periods i.e., from baseline to 2 weeks,

4 weeks, 6 weeks were performed using repeated measure analysis of variance. Post hoc analysis using tukey test was done to compare the sensitivity reduction efficacy of both groups during different time periods. All analytical tests employed a level of significance of 0.001.

RESULTS:

A total of 50 subjects completed the entire study from baseline to 6 weeks, with a gender distribution of 30 females and 20 males. There was no report of any side effects on usage of either of the dentifrices. In the present study, statistically significant reduction of VAS scores were observed from baseline to 6 weeks.

On comparing the efficacy of product A and B using all the 3 measurements, product A showed greater reduction of sensitivity than product B, but statistically significant differences were observed only with cold water stimulation test.

On comparing sensitivity reduction efficacy using tactile stimulation test between group A and group B, statistically significant differences were observed from baseline to 6 weeks. (Table 1).

On comparing sensitivity reduction efficacy using air blast stimulation test between group A and group B, sensitivity gradually reduced but statistically significant differences were observed at 2 weeks and 6 weeks (table 1).

On comparing sensitivity reduction efficacy using cold water stimulation test between group A and group B, statistically significant differences were observed from baseline to 6 weeks. (Table 1).

Comparison of sensitivity reduction between two groups at different time periods on using various stimulations was done by using unpaired t test. (Table 2). Post hoc analysis by tukey was used to compare the reduction in sensitivity within the different time periods i.e., from baseline to 2, 4, 6weeks; from 2 weeks to 4, 6weeks; from 4 weeks to 6 weeks. (Table 3).

Table 1: Repeated measure analysis of variance

Type of stimulation	Groups	Time	Mean	Std. dev	F value	P value
Tactile stimulation	Vantej	Baseline	.6280	.69253	7.839	0.001*
		2 weeks	.4480	.55160		
		4 weeks	.3840	.50223		
		6 weeks	.0840	.22301		
	Colgate sensitive pro relief	Baseline	1.1600	.99708	3.714	0.012*
		2 weeks	1.0240	.98034		
		4 weeks	.9880	.81819		
		6 weeks	.8080	.79368		
Air blast stimulation	Vantej	Baseline	1.5680	1.14591	18.121	0.000*
		2 weeks	1.0040	.58272		
		4 weeks	.7720	.53814		
		6 weeks	.4560	.45376		
	Colgate sensitive prorelief	Baseline	2.1680	2.04343	12.732	0.000*
		2 weeks	1.6800	1.61219		
		4 weeks	1.3840	1.59861		
		6 weeks	1.3760	1.51473		
Cold water stimulation	Vantej	Baseline	1.9680	1.59340	18.676	0.000*
		2 weeks	1.2880	.68576		
		4 weeks	.9880	.53176		
		6 weeks	.5080	.49406		
	Colgate sensitive prorelief	Baseline	2.2760	1.63740	5.987	0.004*
		2 weeks	2.0840	1.86406		
		4 weeks	1.7480	1.62484		
		6 weeks	1.6120	1.51913		

Table 2: Unpaired t test

	Groups	N	Mean	Std. Deviation	T value	P value
tactile after 2 weeks	vantej	25	.1800	.25331	.549	.586
	colgate	25	.1360	.31075	.549	.586
tactile after 4 weeks	vantej	25	.2440	.43213	.594	.555
	colgate	25	.1720	.42477	.594	.555
tactile after 6 weeks	vantej	25	.5440	.55308	1.244	.219
	colgate	25	.3520	.53784	1.244	.219
ab after 2 weeks	vantej	25	.5640	.84601	.377	.708
	colgate	25	.4880	.54721	.377	.708
ab after 4 weeks	vantej	25	.7960	.93161	.053	.958
	colgate	25	.7840	.64851	.053	.958
ab after 6 weeks	vantej	25	1.1120	.97866	1.198	.237
	colgate	25	.7920	.90872	1.198	.237
cw after 2 weeks	vantej	25	.6800	1.32476	1.172	.247
	colgate	25	.1920	1.60648	1.172	.247
cw after 4 weeks	vantej	25	.9800	1.32130	1.023	.311
	colgate	25	.5280	1.77024	1.023	.312
cw after 6 weeks	vantej	25	1.4600	1.40149	2.084	.043
	colgate	25	.6640	1.29739	2.084	.043

Table 3: Posthoc analysis

Group A	Tactile stimulation	Airblast stimulation	Coldwater stimulation	Group B	Tactile stimulation	Airblast stimulation	Coldwater stimulation
Baseline – 2weeks	0.01	0.017	0.102	Baseline – 2weeks	0.2	0.001	1.00
Baseline-4 weeks	0.05	0.002	0.007	Baseline-4 weeks	0.32	0.000	0.89
Baseline -6 weeks	0.00	0.000	0.000	Baseline -6 weeks	0.01	0.001	0.10
2 weeks-4 weeks	1.00	0.164	0.001	2 weeks-4 weeks	1.00	0.001	0.02
2 weeks – 6weeks	0.001	0.000	0.000	2 weeks – 6 weeks	0.01	0.07	0.02
4 weeks-6 weeks	0.003	0.000	0.000	4 weeks-6 weeks	0.04	1.00	1.000

DISCUSSION:

Painful symptoms arising from exposed dentin are a common finding in adult population & have been reported to effect as many as 1 in 7 patients attending the dental operatory.[8]Although dentinal hypersensitivity is not considered a lethal problem it can lead to both physical and psychological problems for the patient thereby having a negative effect on the quality of a person's life.

Dentin hypersensitivity is characterized by "short painful responses to stimuli-typically thermal, evaporative, tactile, osmotic, or chemical—which cannot be ascribed to any other form of dental defect or pathology.[9]The two processes need to occur for a tooth to become sensitive are the lesion localization wherein the dentin has to become exposed and lesion initiation wherein the dentin tubule system has to become opened and be patent to the pulp.

The exposure of the dentine may be a result of one of the following processes:

(1) Anatomical characteristics in the region of cementum– enamel junction (CEJ),

(2) Removal of the enamel covering the crown of the tooth, and
(3)Denudation of the root surface due to loss of cementum and overlying periodontal tissues. This denudation can be due to gingival recession increasing with age, chronic periodontal disease.[10]
Currently, the two treatment approaches for managing dentinal hypersensitivity, are the occlusion of the dentinal tubules, thereby blocking the hydrodynamic mechanism, and blockage of the neural transmission to the pulp.
Although, both approaches are effective at reducing or eliminating the hypersensitivity, the duration of relief is highly variable. Hence, the need for materials which reduce dentin hypersensitivity by chemically reacting with the tooth surface has led to the development of newer technologies such as those employing novamin and proargin technologies.
Novamin is found in many over-the-counter dental products as the main ingredient which is designed to give immediate and long-lasting relief from tooth sensitivity.[11]Novamin® is technically described as calcium sodium phosphosilicate, which reacts when exposed to the body fluids, and deposits hydroxycarbonate apatite, a mineral that is chemically similar to the mineral in enamel and dentin.[11]
On the other hand, Arginine provides naturally protective oral health benefits.At physiological pH, arginine and calcium carbonate interact and bind to the negatively charged dentin surface to form a calcium rich layer on the dentin surface and in the dentin tubules to plug and seal them.
Since, tooth hypersensitivity is a subjective symptom that is difficult to quantify, the use of VAS scale in this study was justified, as it is an accepted method of pain measurement. In this study, cold water, tactile and air blast stimuli were used for assessing sensitivity, because patients often experience this symptom during cold water intake, while tooth brushing and on exposure to cold air.[12]
The present study compared the sensitivity reduction efficacy of novamin (calcium sodium phosphosilicate) and proargin containing dentifrices, wherein there was a remarkable pattern towards reduction of DH from baseline to 6 weeks independently with both the treatment groups. The novamin group showed greater reduction of sensitivity from baseline to 6 weeks. This is in accordance with two previous studies.[13, 14]
A double blind study was conductedin 30 volunteers comparing 5% NovaMin or 5% potassium nitrate, and a non-desensitizing dentifrice. Clinical evaluation for dentin hypersensitivity was done using tactile, air blast, and cold water methods. The results suggest that the dentifrice containing 5% NovaMin occludes dentin tubules, and provides rapid and significantly more relief from dentin hypersensitivity in four weeks compared to a dentifrice containing 5% potassium nitrate or a non-desensitizing dentifrice.[13]
A similar randomized, double-blind pilot study was conducted in 66 subjects comparing 2.5% NovaMin, 7.5% NovaMin, or placebo. Measurement was done using tactile and thermal air tests. Comparison of the mean change from baseline among the three treatment groupsindicated a meaningful reduction in sensitivity scores in the 7.5% group that was significant compared to reductions observed in the placebo control group at all time points. [14]
A study comparing novamin containing tooth-powder, novamin containing toothpaste and a control toothpaste showed better reduction of sensitivity with novamin containing toothpowder and toothpaste than desensitizing toothpaste containing potassium nitrate and fluoride.[12]
The efficacy of calcium sodiumphosphosilicate in hypersensitivity was evaluated in a similar study conducted in 110 subjects in which calcium sodium phosphosilicatewas compared to potassium nitrate and to a placebo. Measurements were done using air stimulus and cold water stimulus. All three groups showed reduction in sensitivity scores at 2 weeks and 6 weeks for air stimulus and cold water. The calcium sodium phosphosilicate group, however, was found to be significantly better in reducing the visual analog scale score compared to the potassium nitrate group and the placebo group. [15]
In this study, Proargin group also showed a statistically significant reduction of VAS scores from baseline to 6 weekswhich is in accordance with a similar study.[16]
When comparing both groups, Novamin showed statistically significant difference with tactile, air blast and cold water stimulation at 6 weeks which is in agreement with a pilot study.[16]The pilot study was a single centered design in which 80 subjects were compared using two commercially available desensitizers containing Novamin and proargin.The evaluation was done using air blast technique which

concluded that desensitizing paste containing 5% NovaMin crystals provided a statistically significant reduction at 15 days interval when compared with the one containing Pro-Arginine.

CONCLUSION:

Within the limitations of the present study, both the treatment groups showed reduction of sensitivity from baseline to 6 weeks. But, while comparing both the groups, Novamin group showed statistically significant differences on cold water stimulation. Hence, it can be concluded that novaminhas a better efficacy in reducing sensitivity when compared to proargin.

Although one study comparing Novamin and proargin in the treatment of dentinal hypersensitivity does exist in the literature, further long term studies with large sample size are needed to validate the outcomes of these products as an efficacious desensitizing agents.

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