IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 22, Issue 8 Ser.8 (August. 2023), PP 38-43
www.iosrjournals.org

Comparative Evaluation Of Efficacy Of Colgate Sensitive Pro Relief And Sensodyne Rapid Action In Relieving Dentine Hypersensitivity – A Two Month Clinical Study.

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Abstract
Objective: *Objective of study was to compare the clinical efficacy of the Pro-argin in Colgate Sensitive Pro-Relief Toothpaste to that of 8% strontium acetate in Sensodyne Rapid action Toothpaste in reducing dentin hypersensitivity immediately and after two weeks, 1 month, and 2 months of twice-daily brushing.*
Methods: *A randomised, controlled, double blind clinical trial was conducted with 70 participants clinically diagnosed with DH and equally randomized into two groups with parallel treatment assignment of Pro-Argin and 8% strontium acetate and tested for DH with air blast, mechanical, and water jet stimuli on SCHIFF cold air sensitivity scale (SCASS) and visual analogue scale (VAS) at interim efficacy intervals of one minute, two weeks, 1 month, and 2 months subsequently.*
Results*: All the seventy participants completed the trial. Both the treatment groups showed statistically significant improvement in DH with p < 0.001 relative to baseline at all time points. Pro-Argin showed a greater reduction in DH with mean scores of (1.343±0.67) (4.10 ± 1.70) (3.02 ± 2.16) compared to strontium acetate (1.56± 0.81) (4.64 ± 1.76) (3.77± 1.98) on SCASS and VAS for mechanical and water jet stimuli, one minute after application. There was no statistically significant treatment difference between the two (p = 0.477). Pro-Argin on VAS for mechanical stimuli and water jet stimuli showed greater reduction with mean scores of (2.12± 1.88)(2.26±1.97) compared to strontium acetate (3.04±2.05)(2.76±1.52) in 2 months.*
Conclusion: *Both Pro-argin in Colgate Sensitive Pro-relief and 8% strontium acetate in Sensodyne Rapid Action are effective for pain relief in DH with better treatment response of Proargin than strontium acetate.*
Keywords*::Dentine hypersensitivity, Strontium Acetate, Arginine*

Date of Submission: 18-08-2023 Date of Acceptance: 28-08-2023

I. Introduction

Dental hypersensitivity is short, sharp pain elicited by external stimuli which may be experienced after the root surface of an individual are exposed to the oral environment. These stimuli are most commonly of a thermal, osmotic, electrical, chemical, or dehydrating nature.[1] 47% of the general population with age range of 29-49years is affected by DH.[2] and it commonly involves the facial surfaces of Canines and premolars. The well-known, widely disseminated explanation for tooth DH is Brannstrom and Astrom's hydrodynamic theory[3] which states that when the patent dentinal tubules experience external stimulation, it causes movement of the intra-dentinal tubular fluid, stimulating the intratubular nerve endings, and generating discomfort. The number, size, and diameter of the patent dentinal tubules determine the level of sensitivity experienced by individuals.[4]

It remains a prevalent global disease with two different treatment modalities of home-care desensitisation with the over-the-counter (OTC) desensitisers such as potassium, fluorides, arginine, strontium, and bioactive glasses (BAG)[5] and in-office application of bioactive formulations such as glutaraldehyde, resin-based bonding agents and restorative materials, amorphous calcium phosphate based-tooth mousse, and lasers in the dental clinics.[6] Though all bioactive agents have a significant treatment effect in reducing DH, there is currently no consensus on the unequivocal efficacy of any product or bioactive agent used for managing the condition due to huge variations and heterogeneity in the conduct of clinical trials on DH.[7] Nowadays prime focus of treatment is based on the exploration of novel materials to remineralise the exposed tubular endings and mimic and restore the structure of the dentin.[8] Desensitisers containing pro- argin and strontium acetate has shown great promise for the treatment of dentin hypersensitivity. Strontium acetate can potentially obliterate dentinal tubules by replacing the calcium ions of hydroxyapatite crystal lattice structure with strontium ions along with its nerve depolarisation treat DH.[9] In comparison, the Pro-argin™ can make mechanical barrier of

calcium phosphate precipitates on exposed dentinal tubules up to 2 μm depth by the interaction of positively charged arginine, amino acids and type 1 collagen fibres.[10]

The objective of clinical study was to compare the clinical efficacy of the Pro-argin in Colgate Sensitive Pro-Relief Toothpaste to that of 8% strontium acetate in Sensodyne Rapid action Toothpaste in reducing dentin hypersensitivity immediately and after two weeks, 1 month, and 2 months of twice-daily brushing.

II. Materials and Methods

The study was a double-blind, parallel-group, stratified, and randomized clinical investigation conducted at Department of Dentistry, Government Medical College, Doda. The study was approved by the board of research ethical committee Government Medical College, Doda. Seventy patients (33 males, 37 females), with an age range of 19–51 years, with one or two teeth with DH due to erosions or abrasions with or without an associated gingival recession were enrolled in the study after the informed consent. Subjects with any of the following conditions were excluded from the study: gross oral pathology; chronic oral diseases; advanced periodontal disease; treatment for periodontal disease within one year; sensitive teeth with mild mobility (mobility index > 1), extensive or defective restorations, suspected pulpitis, caries, cracked enamel; or teeth used as abutments for removable partial dentures, current use of anticonvulsants, anti histamines, antidepressants, sedatives, tranquilizers, anti-inflammatory drugs, or daily analgesics; pregnant or lactating women; participation in a desensitizing dentifrice study or use of a desensitizing dentifrice within the last three months; currently participating in another clinical study.

III. Randomization and blinding

The participants were randomized equally by the principal investigator into two entitled treatment groups using computer-generated random sequence numbers, and treatments were allocated randomly using sequentially numbered, opaque, sealed, and stapled envelopes. The sealed envelope contained details of unique subject numbers assigned individually in ascending order, group titles, and treatment codes and was placed in the box. Participants were asked to pick up the envelope from the box. The two toothpastes used were: 1) Colgate Sensitive Pro-Relief containing 8.0% arginine, calcium carbonate, and 1450 ppm fluoride as MFP (Colgate-Palmolive Co. 2) Sensodyne Rapid Action containing 8% strontium acetate and 1040 ppm fluoride as NaF (Glaxo-SmithKline Co.) All tested dentifrices were supplied in their original packaging and wrapped with a white label with treatment codes to keep the principal investigator and participants blinded at the time of treatment assignment. The statistician was also kept blind. DH was recorded at baseline (pretreatment), immediately after treatment and at 2 weeks, 1 month and 2 months post-treatment.

IV. Evaluation of hypersensitivity

Soft tissues were isolated with cotton rolls, and adjacent teeth were isolated with cotton pellets and baseline scores were recorded to measure the intensity of pain due to DH on Schiff Cold Air Sensitivity Scale [SCASS] with scores ≥ 2[11] against air blast stimulus with a triple syringe of the dental unit and on a linear visual analog scale [VAS] of 10 cm length with scores ≥ 4 cm,[12] against mechanical stimulus with a dental probe and water jet stimulus with a triple syringe. During the first visit dentifrices were applied and massaged gently with the applicator on at least two sensitive teeth per subject at two different sites, including cementoenamel junction and exposed dentinal surface, by the doctor in the office. Dentifrices were removed carefully after one minute of undisturbed application and first post-treatment measure of SCASS and VAS scores was obtained immediately. All participants were instructed to dry the tooth surface with the cotton ball and apply a paste of about half-inch length on the dried surface for one minute, then brush the teeth twice daily after breakfast and before sleep. Participants were recalled at intervals of two weeks, 1 month and 2 months for assessment of sustained relief and were strictly advised to refrain from acidic food and drink intake at least four hours before follow up visit. Participants were asked to record the overall sensitivity of their day-to-day experience on provided VAS sheets reporting pain on brushing, taking hot or cold beverages, and rinsing with tap water for the 2 months of the study. SCASS and VAS were introduced on each visit as primary and secondary outcome measures, respectively.

V. Statistical analysis

Statistical Package for the Social Sciences software v.21.0.was used for statistical analysis. The primary analysis population could be described as 35 participants per treatment group in the six-week trial who responded to the air blast stimulus for the primary outcome measure of treatment response one minute after topical application and after two weeks, 1 month and 2 months subsequently, on SCASS with scores of ≥ 2. Paired sample T-test was used to compute mean scores to observe change relative to baseline at each time point. In addition, one-Way ANOVA with Post Hoc Tukey for pair-wise comparison was used to compare treatment

groups computing percent change from baseline with formula (post-application mean scores-baseline mean scores/baseline mean scores). The secondary analysis population could be described as 35 participants per treatment group in two month trial who responded to mechanical and water jet stimuli on VAS with scores of ≥ 4 as secondary outcome measures. Wilcoxon Signed-Rank Test was used to compute mean scores relative to baseline at each time point. Kruskal–Wallis test was used to compare treatment groups. *p* values of < 0.05 were considered as statistically significant.

VI. Results

All 70 subjects completed the 2 month clinical study randomised into the two treatment groups, with thirty five in each group TABLE 1.

Table 1 The participant's allocation and treatment assignments

Treatment groups	No. Of participants(N=70)	Group titles	Treatments	Active ingredients	Treatment Codes
1	35	A	Colgate® Sensitive Pro-Relief	Pro-Argin™ with 8.0% arginine and 1450 ppm fluorides as sodium monofluoro-phosphate in calcium carbonate base	1
2	35	B	Sensodyne Rapid Action	8% strontium acetate, 1040 ppm fluorides as sodium fluoride	2

Table 2 presents descriptive statistics of the primary analysis population as the primary statistical analysis was performed for 33 males and 37 females of age ranging from 19 to 51 years with a mean age of 35.1±7.9. There was statistically no significant difference in the baseline characteristics of gender, age, baseline mean scores of clinical parameters of SCASS, and VAS used for mechanical and water jet stimuli between the two treatment groups ($p > 0.05$).

Table 2 Baseline descriptive statistics of two treatment groups

Baseline characteristics	Group A	Group B	*p* value
Age (mean ± • SD)	34±7.5	35±7.3	0.619
Gender			
Male	12	13	
Female	23	22	
Baseline mean scores for SCASS	2.45 • ± 0.40	2.45 • ± 0.50	>.98
Baseline mean scores for VAS with mechanical stimulus	6.70 ± 1.02	6.70 ± 1.15	0.987
Baseline mean scores for VAS with water jet stimulus	6.70 ± 0.70	6.70 • ± 0.70	0.614

SD standard deviation, *SCASS* Schiff cold air sensitivity scale, *VAS* visual analogue scale
One way ANOVA; α Chi-square test; >Mann–Whitney test; *p* values were considered significant at 0.05.

Table 3 demonstrates the percent change in the mean scores of DH on SCASS relative to baseline within the group for each treatment arm. Post-application changes on SCASS were observed after one minute, two weeks, 1month, and 2 months, subsequently. There was a significant ($p < 0.001$) reduction of 43.7% with Proargin, 36.4% with 8% strontium acetate relative to baseline on SCASS after one-minute application on sensitive teeth and there was a significant ($p < 0.001$) reduction of 59.4% with Pro-argin™ and 52.1% with 8% strontium acetate, relative to baseline after subsequent 2 months of application observing sustained relief from DH on SCASS.

Table 3 The primary outcome measure of Immediate and sustained treatment response relative to baseline in DH using Schiff cold air sensitivity scale

Post-application efficacy intervals	Group A	Group B	*p* value
Immediate			< 0.001
Mean scores ± SD	1.33 • ± 0.67	1.56 • ± 0.71	
(*p* value)	< 0.001	< 0.001	

Percent change from baseline (%)	43.7	36.4	
2 weeks Mean scores ± SD (*p* value) Percent change from baseline (%)	 1.30 ± 0.56 < 0.001 46.7	 1.56 • ± 0.50 < 0.001 36.2	< 0.001
1 month Mean scores ± SD (*p* value) Percent change from baseline (%)	 1.09 • ± 0.62 < 0.001 55.4	 1.32 • ± 0.63 < 0.001 44.4	< 0.001
2 months Mean scores ± SD (*p* value) Percent change from baseline (%)	 0.97 • ± 0.68 < 0.001 59.4	 1.18 • ± 0.57 < 0.001 52.1	< 0.001

Table 4 demonstrates a comparison between two treatment groups observing better clinical efficacy in managing DH on SCASS. There was no significant difference between dentifrices containing Pro-argin™, and 8% strontium acetate ($p > 0.05$) on completion of 2 months clinical trial.

Table 4 Comparison of treatment response between two treatment groups on Schiff cold air sensitivity scale

Post-application efficacy intervals	Percentage difference between two treatment groups (%age)
Immediate p-value	7% 0.477
Week 2 p-value	10% 0.33
1 month p-value	10% 0.33
2 months p-value	7% 0.71

Table 5 presents the change in the mean scores of VAS against mechanical stimulus from baseline to subsequent efficacy interval within each treatment arm. Dentifrices containing Pro-argin™ showed a significant reduction in DH with mean scores of (4.10 ± 1.60) compared strontium acetate (4.64 ± 1.77) one minute after application. After 2 months, Proargin ™-based dentifrices showed greater clinical efficacy with mean scores (2.12 ±1.88) than 8% strontium acetate for mechanical stimulated DH.

Table 5 The secondary outcome measure of Immediate and sustained treatment response in DH on visual analogue scale using mechanical stimulus.

Post application efficacy intervals	Group A	Group B	p-value
Immediate Mean scores ± SD *p* value	 4.10±1.60 < 0.001	 4.64±1.76 < 0.001	0.002
2 weeks Mean scores ± • SD *p* value	 3.10±2.18 < 0.001	 3.61±2.32 < 0.001	0.002
1 month Mean scores • ± SD *p* value	 2.42±2.15 < 0.001	 3.12±2.29 < 0.001	0.001

2 months Mean scores ± SD *p* value	2.12±1.88 < 0.001	3.04±2.05 < 0.001	0.001

Table 6 presents the change in the mean scores on VAS against water jet stimulus from baseline to subsequent efficacy interval within each treatment arm. Dentifrices-containing Pro-argin™ showed a significant reduction in DH with mean scores of (3.02 ± 2.16) compared to strontium acetate (3.77 ± 1.98) one minute after application.

Table 6 The secondary outcome measure of Immediate and sustained treatment response in DH on visual analogue scale using water jet stimulus

Post application efficacy intervals	Group A	Group B	*p* value
Immediate Mean scores ± SD *p* value	3.02 ± 2.16 < 0.001	3.77 ± 1.98 < 0.001	< 0.001
2 weeks Mean scores ± SD *p* value	3.12 ± 2.07 < 0.001	3.59 ± 1.46 < 0.001	< 0.001
1 month Mean scores ± SD *p* value	2.71 ± 21.97 < 0.001	3.06 ± 1.71 < 0.001	< 0.001
2 months Mean scores ± SD *p* value	2.26 ± 1.97 < 0.001	2.76 ± 1.52 < 0.001	< 0.001

No adverse events like gingival inflammation, bad taste, allergies, fluoride incompatibility, and dental or tongue stains were observed during the two month clinical trial.

VII. Discussion

Desensitising toothpastes introduced into the market recently have been formulated specifically for their dentine tubule occluding abilities in order to reduce the pain of dentine hypersensitivity. These pastes are formulated to achieve the majority of Grossman's[13] ideal characteristics for treatment of the condition. One property of particular interest is their ability to alleviate pain instantaneously or within a brief period of time. Studies have shown that both strontium acetate and arginine based toothpaste have the capability to reduce pain due to DH by tubule occlusion.[14-18]

The objective of this study, was to compare the ability of a strontium based paste and an arginine based paste, to assuage the pain due to dentine hypersensitivity immediately after application of the paste and after home use for 2 months. Participants in this study were randomised into two treatment groups and each group with more than thirty subjects fulfilling the requirement of Holland's guidelines for conducting clinical trials for the management of DH[19] and according to these guidelines two diagnostic tools are sufficient for quantitative assessment of the clinical efficacy of desensitisers.

Both the treatment groups in the present study revealed a clinically significant symptomatic reduction in DH relative to the pre-treatment condition that was also statistically significant.

It was measured by change in SCASS scores of pains with Pro-argin™ and 8% strontium acetate after one minute of topical application on the sensitive teeth. Both the groups showed clinically and statistically significant ($p < 0.001$) relief in pain due to DH relative to baseline on immediate post-treatment observation, as shown in Table 3. Pro-argin treatment revealed an immediate clinical reduction of 43.7% on SCASS, 58% on VAS used for mechanical stimuli, and 44.7% on VAS used for water jet stimuli in DH demonstrated in Tables 3, 5, and 6. These findings were similar to a studies conducted by Schiff et al.[11] (reporting the instant relief from DH by 44.1% with Pro-argin™ on SCASS), Vu Pham and Anh Nguyen (reporting clinical improvement in DH by 38.9% on SCASS and 40.2% on VAS for mechanical stimulated DH immediately after application of Pro-argin™).[20]

8% strontium acetate showed clinical reduction of 36.4% on SCASS and 46% on VAS from baseline using mechanical and 43% on VAS used for water jet stimuli immediately after topical application on sensitive teeth as depicted in Tables 3, 5, and 6. The outcomes are in concordance with the previous studies conducted by Layer and Hughes,[21] Zang and Shaw,[22]and Mason et al.[14] reporting the immediate effect of 8% strontium acetate

in alleviating clinical symptoms of DH with clinically and statistically significant (< 0.001)measures relative to baseline.

The comparative evaluation was done for the clinical efficacy of Pro-argin™ and 8% strontium acetate, but no statistically significant ($p > 0.05$) difference was found between these two formulations in this study, yet Pro-Argin on VAS for mechanical stimuli and water jet stimuli showed greater reduction with mean scores of (2.12± 1.88)(2.26±1.97) compared to strontium acetate (3.04±2.05)(2.76±1.52) in 2 months as shown in Tables 4 and 5. However more robust trials with a large number of participants are recommended for further assessing the impact of DH on the oral health-related quality of life and the difference in the efficacy of treatments**.**

VIII. Conclusion

Based on the study results, we can conclude that both Pro-argin™ in Colgate Sensitive Pro-relief™ and 8% strontium acetate in Sensodyne Rapid Action™ are effective for pain relief in DH with better treatment response of Proargin ™ than strontium acetate.

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