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Efficacy of Three Desensitizing Agents to Reduce Cervical Dentin Hypersensitivity: A Randomized Clinical Trial

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ABSTRACT

Introduction: Dentin hypersensitivity (DH) is a commonly encountered dental complaint, management of which is often challenging to dentists. It occurs when dentinal tubules are patent both at the pulpal and the oral surface. It is widely accepted that DH affects function and quality of life. Thus, it is necessary for dentists to manage it properly.

Objective: The objective of this study was to assess the efficacy of VivaSens and Propolis in comparison to Gluma in reducing cervical dentin hypersensitivity.

Methods: A randomized clinical trial, double-blinded, parallel-group study was conducted among forty five patients. They were randomly allocated into three different groups (n=15): Gluma (positive control), VivaSens and Propolis. Tactile and evaporative methods were used to assess pain using Numeric Pain Rating Scale (NPRS) in patients with cervical abrasion, with a complaint of dentin hypersensitivity. Pain score was recorded preoperatively, immediately after application, at one week and one month postoperatively. Data were analyzed using SPSS version 11.5 and Microsoft Excel version 2010. Mean NPRS scores were calculated.

Results: All three desensitizing agents significantly reduced DH scores from baseline to all subsequent follow-ups ($p<0.001$). Kruskal–Wallis test elicited no significant differences in the mean difference in DH scores among positive control and test groups for both stimuli at all-time intervals ($p < 0.05$).

Conclusions: Gluma, VivaSens and Propolis desensitizing agents were effective in relieving cervical DH. No statistically significant difference was found in relieving DH among the agents in all subsequent follow- ups.

Keywords: Cervical abrasion; dentin hypersensitivity; desensitizing agent; numeric pain rating scale.

INTRODUCTION

Dentin hypersensitivity (DH) is painful and least successfully resolved problems of the teeth.[1] It is characterized as a short and sharp pain arising from exposed dentin, which are patent both at the pulpal and the oral surface, in response to chemical, thermal, tactile or osmotic stimuli.[2, 3] When the external stimulus contacts exposed dentin, it causes displacement of the contents of the dentinal tubules causing mechanical stimulation of the intradental myelinated nerve fibers causing sharp and shooting pain.[4]

The prevalence of DH is reported to be 8-57%.[3] This heterogeneity can be due to different sample population, diagnostic criteria and whether the source data is based on clinical evaluation or questionnaires.[5] Its prevalence is predicted to be higher in future as individuals tend to retain their dentitions for a longer period of time.[6]

The most accepted hypothesis to explain the pain mechanism of DH is the hydrodynamic theory.[4]

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Thus the major modality of treatment is based on the occlusion of open tubules to block the hydrodynamic mechanism.

Gluma, VivaSens and Propolis are commonly used topical desensitizers which occlude open dentinal tubules. With limited literature comparing these three desensitizing agents, this study has been carefully designed to evaluate and compare these three agents.

METHODS

A randomized, double blind, clinical trial with parallel group study was conducted among patients visiting the Department of Conservative Dentistry and Endodontics, BP. Koirala Institute of Health Sciences, Dharan. The study was conducted between October 2017 to September 2018. Ethical approval was obtained from the Institutional Review Committee (Ref. No. 225 /074/075) and was registered as a clinical trial by the National Institute of Medical Statistics (India Council of Medical Research); the Clinical Trial Registry India identifier no. CTRI/2018/05/014258. The patients were explained about the purpose and design of the study and written informed consent was obtained from each patient prior to enrollment in the study. Sample size was calculated based on study done by Narmatha and Thakur.[7] A total of 12 patients in each group were considered adequate. Considering 20% dropout rate the final sample size was 45 in total, 15 in each group.

Purposive sampling method was used. Forty-five patients of age group 18 years or above with hypersensitive permanent tooth and cervical abrasion, which does not require any restorative regimen were allocated in the trial. Patient currently on desensitizing therapy, cracked tooth, defective restorations, deep dentinal caries, periodontal surgery within last six months or having systemic conditions predisposing to dentin hypersensitivity were excluded.

The randomization was done using computer generated random numbers. Randomization was concealed in opaque sealed envelope. Principal investigator was not involved in the randomization process. The subjects were randomly allocated into three intervention groups:

Group A received therapeutic application of Gluma desensitizer (Hareus kulzer, Armonk, NY, USA) (positive control)

Group B received therapeutic application of VivaSense (Ivoclar Vivadent AG, Schaan, Liechtenstein) (test group)

Group C received therapeutic application of Propolis extract (HERB PHARM Oregon,U.S.A.) (test group)

The most sensitive tooth as reported by patient was selected for further procedure. The baseline pain score using tactile and evaporative stimuli, was recorded on numeric pain rating scale (NPRS) ranged from 0 being no pain to 10 being the worst possible, unbearable, excruciating pain by a single calibrated assessor. The assessor was trained and calibrated to record the sensitivity of the participants. Intra-examiner reliability of assessor was examined in 10% of the total sample. The pain scores were recorded after evaporative and tactile stimuli. After two days, patients were recalled and the pain score were re-recorded. Using Kappa statistics, the result showed moderate agreement (0.52) in both tactile and evaporative stimuli.

For tactile stimuli, a probe was used under slight manual pressure in the mesiodistal direction of the hypersensitive area of the selected tooth. For evaporative stimuli, a one-second blast of air from a dental unit syringe applied 1-3 mm away from and perpendicular to the exposed buccal cervical areas of exposed dentin was used.[8] The adjacent teeth were protected by cotton rolls. Tactile stimulus was performed followed by evaporative as it is considered to be least distressing. The test stimuli were applied in the same order, throughout the trial, within minimum 5-minute interval between the stimuli.

Table 1: Materials used in the study and procedure of application.

Desensitizing agent	Procedure of application
Gluma Desensitizer (Hareus kulzer, Armonk, NY,USA)	A few drops of agent were applied with a applicator tip using a gentle but firm rubbing motion. After 30 seconds, the area was dried thoroughly until the fluid disappears and the surface was no longer shinny.
Vivasens (Ivoclar Vivadent AG, Schaan, Liechtenstein)	A few drops of agent were applied using a disposable brush provided. Area was air dried for 10 seconds.
Propolis extract (HERB PHARM Oregon, U.S.A.)	A few drops of agent were applied with a brush and left undisturbed at the site for five minutes.
Patients were instructed not to rinse or to take anything for half an hour so that the desensitizing agent would take sufficient time to act without getting washed away and to avoid using any other professionally or selfapplied desensitizing agent in the course of the investigation.	

The desensitizing agents used in this study were Gluma, VivaSens and Propolis extract. Bottle of three desensitizer were wrapped with white paper to conceal the allocation. All the agents were applied by a single operator who was not involved in the assessment. The application procedures of the desensitizing agents are summarized in Table 1.

Immediately after application of the agent, subjects' responses to evaporative and tactile stimuli were recorded in a NPRS by the assessor. Both the patient and assessor were blind throughout the study. The subjects were recalled after one week and one month from the time of application of the agents, and the subjects' responses was recorded. Patients were also requested to report in case of burning of adjacent gingival area or even ulceration. Patients were given operators' phone number to seek consultation in case of any adverse effect or symptom.

After completion of the study, data obtained were entered in Microsoft Excel Sheet version 2010 and analyzed using the Statistical Package for Social Sciences, version 11.5. The level of significance was set at less than 0.05. For descriptive statistics: mean, median, standard deviation and range were calculated. A Friedman test was used to investigate the effectiveness of each agent at different time intervals. Similarly, Kruskal Wallis test was used to evaluate the mean pain score differences among three groups.

RESULTS

A total of 45 patients were enrolled in the study, majority of them were female (62%). The mean (SD) age of all the participants was 41.78 (11.16). CONSORT flowchart of the study is depicted in Figure 1.

At baseline, mean pain score in tactile and evaporative stimuli among all the groups were comparable and the difference was not statistically significant (P>0.05) (Table 2).

All the three groups showed statistically significant reduction in DH pain scores from baseline to all subsequent follow- ups for both tactile and evaporative stimuli (P=0.001) (Table 3).

In intergroup comparison among test and control group, Kruskal Wallis test showed no statistically significant difference (P>0.05) in reduction of DH immediately after application, after one week and after one month in both tactile and evaporative stimuli (Table 4).

In tactile stimuli, Gluma and VivaSens showed more reduction of pain score immediately after application of agent. After one week and one month they reported gradual increase in pain score but when compared with the baseline the reduction was statistically significant, while Propolis showed more reduction of pain score after one month of

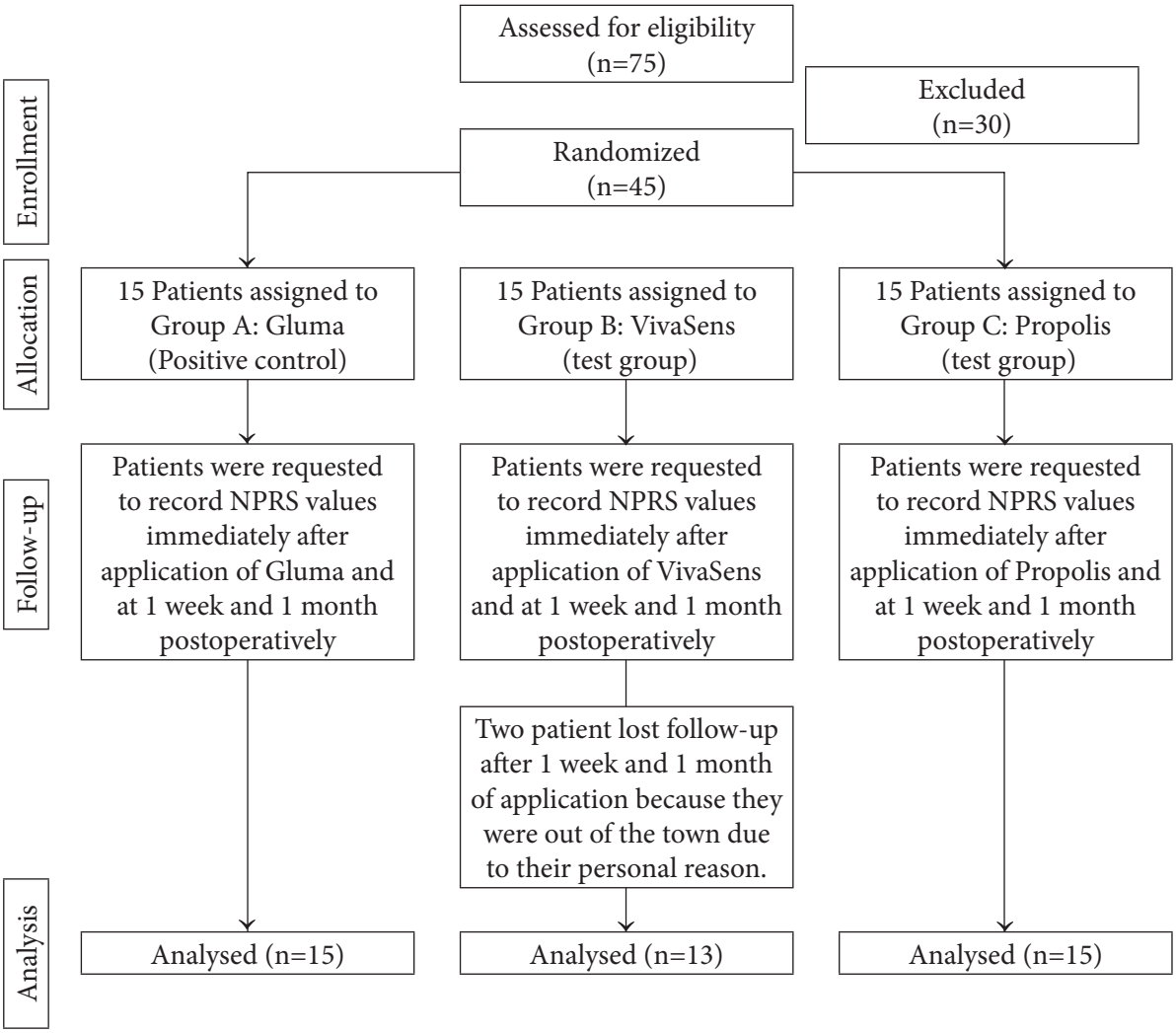

Figure 1: CONSORT flow chart for the patient participated in the study.

Table 2: Tactile and evaporative pain score at baseline.

Treatment Group		Baseline			
		Tactile	P[a] Value	Evaporative	P[a] Value
Gluma (n=15)	Mean±SD	4.20±2.04	0.87 (NS)	5.40±2.19	0 .60 (NS)
	Median	5.00		5.00	
	Minimum	2		2	
	Maximum	10		10	
VivaSens (n=15)	Mean±SD	4.60±2.35		4.46±2.40	
	Median	5.00		5.00	
	Minimum	2		1	
	Maximum	10		10	
Propolis (n=15)	Mean±SD	4.80± 2.36		4.60±1.84	
	Median	4.00		5.00	
	Minimum	2		2	
	Maximum	9		8	

a= Kruskal Wallis, NS= Not significant

Table 3: Mean rank of pain score of three desensitizing agent at different time intervals.

Treatment Group	Stimulus Applied	Mean Rank				P Value[a]
		Baseline	Immediate	1 week	1 month	
Gluma (n=15)	Tactile	3.83	1.77	2.10	2.30	0.001*
	Evaporative	3.93	1.97	2.37	1.73	0.001*
VivaSens (n=15)	Tactile	3.92	1.65	2.46	1.96	0.001*
	Evaporative	3.85	1.73	2.15	2.27	0.001*
Propolis (n=15)	Tactile	3.87	1.97	2.27	1.90	0.001*
	Evaporative	3.70	1.87	2.30	2.13	0.001*

a= Friedman Test *P<0.05

Table 4: Intergroup comparison for tactile and evaporative stimuli.

	Difference in score from baseline	Group	Number (N)	Mean±SD	Median	Mean Rank	P Value[a]
Tactile stimulus	Immediate	Gluma	15	3.73±2.28	3.00	25.13	0.54 (NS)
		VivaSens	15	3.67±2.35	3.00	23.73	
		Propolis	15	2.93±1.44	3.00	20.13	
	1 week	Gluma	15	3.47±1.92	3.00	25.27	0.34 (NS)
		VivaSens	13	3.38±2.69	2.00	22.12	
		Propolis	15	2.53±2.06	2.00	18.63	
	1 month	Gluma	15	3.13±2.69	3.00	22.43	0.94 (NS)
		VivaSens	13	3.15±2.99	3.00	21.04	
		Propolis	15	3.20±2.04	3.00	22.4	
Evaporative Stimulus	Immediate	Gluma	15	3.87±2.10	4.00	25.80	0.11 (NS)
		VivaSens	15	3.87±2.07	4.00	25.90	
		Propolis	15	2.47±1.60	3.00	17.30	
	1 week	Gluma	15	3.13±1.36	3.00	26.77	0.09 (NS)
		VivaSens	13	2.85±2.48	2.00	22.19	
		Propolis	15	2.07±1.94	2.00	17.07	
	1 month	Gluma	15	3.80±2.08	5.00	26.10	0.22 (NS)
		VivaSens	13	3.23±2.55	2.00	21.46	
		Propolis	15	2.47±2.64	2.00	18.37	

a= Kruskal Wallis, NS= Not Significant

Table 5: Intragroup comparison of Gluma, VivaSens and Propolis group.

	Stimulus		Difference of score between baseline and immediately	Difference of score between baseline and one week	Difference of score between baseline and one month	P Value[a]
Gluma	Tactile	Number(n)	15	15	15	0.27
		Mean±SD	3.73±2.282	3.47±1.922	3.13±2.696	(NS)
	Evaporative	Number(N)	15	15	15	0.76
		Mean±SD	3.87±2.100	3.13±1.356	3.80±2.077	(NS)
VivaSens	Tactile	Number(n)	15	13	13	0.30
		Mean±SD	3.67±2.35	3.38±2.694	3.15±2.996	(NS)
	Evaporative	Number(n)	15	13	13	0.03*
		Mean±SD	3.87±2.066	2.85±2.478	3.23±2.555	
Propolis	Tactile	Number(n)	15	15	15	0.57
		Mean±SD	2.93±1.44	2.53±2.07	3.20±2.04	(NS)
	Evaporative	Number(n)	15	15	15	0.49
		Mean±SD	2.47±1.60	2.07±1.94	2.47±2.64	(NS)

a= Friedman Test, * p<0.05, NS= Not Significant

application. In evaporative stimuli, Gluma, VivaSens and Propolis reported more reduction in their pain score immediately after application of agent and after one month in comparison to one week. However, the observed difference was not statistically significant (P>0.05) (Table 5).

DISCUSSION

DH is a relatively common problem in which the patient may feel discomfort while eating, drinking, brushing: affecting the quality of life of the individual.[9]

DH can occur at any age from early adolescent to the old age.[10] In the present study the mean age of patient having DH was 41.78 (±11.16) years with a range of 22-65 years. This finding was also supported by various studies.[7, 11] With the increase in the life expectancy, there is longer retention of teeth, more gingival recession, more exposure to periodontal treatment, more loss of enamel and cementum, more cervical abrasion, which can result in the exposure of dentinal tubules to external stimuli, resulting in DH. However, the occurrence of DH is less in older people due to the natural processes of aging: decline in neural sensations and dentin permeability as well as sclerosis of dentin and formation of tertiary dentin leading to the occlusion of dentinal tubules.[12]

On the basis of recommendation of Holland et al.[2], at least two hydrodynamic stimuli should be utilized for the assessment of DH. Thus, in our study tactile and air blast stimuli were used. Use of an explorer or a probe as mechanical stimuli and air blast from dental syringe as evaporative stimuli can be considered appropriate and relatively inexpensive methods in evaluating DH.[13] Tejaswi and Anand conducted a systematic review[14] observed that tactile test performs better than other diagnostic tests in evaluation of dentin hypersensitivity.

For the evaluation of pain, in our study, Numeric Pain Rating Scale (NPRS) was used. There are numerous scale and methods to assess pain perception. Many studies[15, 16] have used Visual Analogue Scale (VAS). Both VAS and NPRS agree well and are equally sensitive. NPRS is more practical and easier to understand for most people.[17]

The most commonly practiced mode of treatment of DH is to apply the topical desensitizing agents. As the topical agents applied by a dental professional in office, promote immediate relief ,[18] the present study has assessed three topical desensitizing agents: Gluma, VivaSens and Propolis, for professional use.

The result of the present study showed that all three desensitizing agents were effective in reducing DH in all subsequent follow-ups for both tactile and evaporative stimuli (P=0.001). Gluma was considered as a positive control. Several randomized clinical trials[19-21] have shown Gluma reduces DH significantly. In our study, reduction in pain score for tactile and evaporative stimuli for Gluma were 84% and 73% immediately after its application and 69% and 73% at one month respectively which was comparable with the randomized, double blind, split mouth study: 82% and 80% immediately after application and 73% and 75%, at one-month respectively.[20] Aranha et al. [1] reported that Gluma showed an immediate effect after application and reduction in pain level was observed throughout the six-month follow-up. However Olusile et al. [22] reported that gluma performed best at 24 hrs of treatment and statistically significant reduction at one week.

In a spectroscopic investigation[23], the mechanism action of Gluma was described as a two-step reaction: First, gluteraldehyde which is an effective cross-linking and fixative agent reacts with serum albumin to induce precipitation, there by occluding the dentinal tubule. Second, the reaction of glutaraldehyde with serum albumin induces the polymerization of hydroxyethyl methacrylate (HEMA). HEMA physically blocks dentinal tubule. These mechanisms were also supported by the study of Schupbach et al.[24] In their study, tubular occlusions was seen at a depth of 200 microns in dentin treated with Gluma examined under confocal laser scanning microscopy, scanning electron microscopy and transmission electron microscopy.

Current study found out that VivaSens also reduced pain score in all subsequent follow-ups for both tactile and evaporative stimuli (P=0.001) but lower than positive control. It reduces DH by occluding open dentinal tubules by two mechanisms: 1) by precipitating proteins and calcium ions out of the dentinal fluid and 2) by co-precipitating polyethylene glycol dimethacrylate (PEG-DMA).[25] Immediately after the application of VivaSens, hydroxypropyl cellulose film is formed that transiently seals the dentin tubule, which might be one of the reasons of its immediate action that was observed in our study.

In our study, in tactile stimulus, Gluma showed highest percentage reduction in pain score in all time intervals whereas, in evaporative stimuli, VivaSens showed highest reduction. Thus, it showed both desensitizing agents were comparable. Moreover, it also supported the significance of taking more than one hydrodynamic stimuli in the assessment of DH as suggested by Holland et al.[2]

Since the olden days, many biological application of Propolis were reported.[26] The use of Propolis in dentistry has been emphasized by several studies.[27,28] In this study, Propolis as a desensitizing agent showed significant reduction in DH in all subsequent follow-ups for both tactile and evaporative stimuli (P=0.001). Similar findings were reported by other studies. [27, 29] Immediate action of Propolis in reducing DM can be attributed due to its capacity of obliterating the dentin tubules which was observed under SEM in in-vitro study.[29] Histological analysis of rat dental pulp tissue capped with Propolis revealed partial bridge formation in Propolis flavonoid group at one month suggestive of formation of reparative dentin that could be one of the reason for its sustained desensitizing effect.[28]

All three agents effectively reduce DH by occluding the dentinal tubules as has been shown by numerous microscopic studies.[24, 25, 29] Their similar mechanism of action could play a role in explaining the statistical indifference in the results of this study, despite of differences in chemical composition and technique of application.

The ultimate goal in the treatment of DH is the immediate and permanent relief of pain. These three desensitizing agents have shown promising result in immediate and sustained reduction of DH for one month. Hence, any of these three desensitizing agents can be used in clinical practice as per their availability and cost effectiveness.

Limitation of the study: In our study, the evaluation period is shorter. Longer follow up studies on patient would allow determining whether desensitizing agents have a long term sustained effect in reducing DH. Subjective response of pain has been measured in this study. For the reason, there is no exact measurement of pain and psychological, emotional factors may affect patients' pain response, this could be the limitation of the present study.

CONCLUSIONS

Within the limitation of the study, all the desensitizing agents Gluma, VivaSens and Propolis were effective in relieving dentin hypersensitivity: immediately, after one week and after one month of their application.

Gluma was found to be the most effective agent followed by VivaSens and Propolis but the difference was not statistically significant.

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Conflict of interest: None

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