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A comparative clinical evaluation of Herbal and synthetic dentifrices in dentinal hyper-sensitivity

Research Article

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Abstract

Dentin hypersensitivity defined as a short, sharp pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic, or chemical and which cannot be ascribed to any other form of dental defect or pathology. Teeth are sensitized to cold/breeze, hot, dry and sour eatables and have pain and shaky feeling, the condition is called '*Dantaharsha'*. Toothpastes are the most widely used dentifrices for delivering over-the-counter desensitizing agents. Aim to evaluate the effect of Herbal dentifrices in Dentinal hypersensitivity. Objective to prepare palatable formulation of Herbal Dentifrices. Materials and Methods: In this open-labelled, randomized, controlled study, 60 patients were enrolled and randomized into trial and control groups. Those in the trial group received Herbal dentifrices, control group participants received Synthetic dentifrice apply twice a day for 3 wks. Dentifrice was prepared under all hygienic conditions and safety precautions in GMP certified pharmacy. Effect in Dentinal hypersensitivity was assessed by scored using VAS on air stimulus, cold-water stimulus and Air Blast Stimulation. Appropriate statistical tests applied to the data to obtain results. Results: Improvement was seen in both group though synthetic dentifrice showed better results than the herbal one, the trial drug exhibited a promising output in the study. Statistically Group B shows better results in the median Hypersensitivity score on VAS and Air blast stimulation compared to Group A. Conclusion: In present study, improvement was seen in both the groups. Synthetic dentifrice showed better results than the herbal one.

Key Words: *Dentinal Hypersensitivity, Dentifrices, Dantaharsh.*

Introduction

Dentin hypersensitivity could be defined as a short, sharp pain arising from exposed dentin in response to stimuli typically thermal, evaporative, tactile, osmotic, or chemical and which cannot be ascribed to any other form of dental defect or pathology.(1) A modification of this definition was suggested by the Canadian Advisory Board on dentin hypersensitivity(2) in 2003 which suggested that the 'disease' should be substituted for 'pathology'.

The difficulty found in treating dentinal hypersensitivity is expressed by the enormous number of techniques and therapeutic alternatives to relieve it. Several methods and materials such as varnishes, liners, restorative materials, dentinal adhesives (3) dentifrices and mouthwashes are used to reduce dentinal sensitivity (4). There are many dentinal hypersensitivity studies, nevertheless most dental professionals are confused about the diagnosis, aetiology and mechanism of dentin hypersensitivity. Practitioners also report that they lack the confidence to manage the condition effectively (5) and this frequently leads to clinical failure.

In Ayurveda Dentinal Hypersensitivity can be compared with *Dantaharsha*. When teeth are sensitized to cold/breeze, hot, dry and sour eatables and have pain and shaky feeling, the condition is called '*Dantaharsha'*(6)

Toothpaste is a dentifrice used to clean, maintain and improve the health of teeth(7,8).

Herbal medicines have been used widely throughout human history and according to World Health Organization (WHO), about 80% of the human population used herbal medicine for primary healthcare(9). Some of them are potent antimicrobial, Anti-diabetic, antiviral, anticancer and antifungal. Oral cavity infections are the most common types of infections (9).

Plant based toothpastes have received great attention in reducing gingival inflammation (10).

The aim of the study was to evaluate the effect of Herbal dentifrices in Dentinal hypersensitivity. The objective of this study was to prepare palatable formulation of Herbal Dentifrices to maintain oral health and prevent oral pathologies.

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Materials and Methods

Study site

This two-arm, open-labelled, randomized, prospective-controlled clinical trial was conducted at D.Y.Patil Ayurvedic Hospital,Nerul.

Ethical considerations

Ethical approval was obtained from the Institutional Ethics Committee of the trial site Informed consent was obtained from all the participants before including them in the present study.

Inclusion criteria

Patients age between 18– 40 years who had dentinal hypersensitivity with no dental caries, the loss of dentin should be less than 2 mm deep. Patients with adequate oral hygiene and only those who were willing to participate in the study.

Exclusion criteria

Patients with a history of any systemic illnesses and/or psychological diseases, and previous hospitalization. Teeth which had dental caries, cracks or fractures in the cervical areas of the teeth. Teeth with any extensive or unsatisfactory restorations, prostheses or orthodontic appliances which involved the cervical areas. Patients with a history of drug addictions and use of analgesic and/or anti-inflammatory drugs and patients who failed to give their consents.

Sample size

A dropout rate of 20% was considered for fixing the sample size of 60 patients. Enrolment, allocation, follow-up, and analysis scenario of the study are presented in the CONSORT flow diagram (Figure 1).

Plan of study

Enrolled patients were randomly divided into two groups, namely trial and control groups. Clinical history, general physical examination and systemic examinations were carried out to rule out any illness.

Interventions

Trial group patients received Herbal dentifrices, control group participants received Synthetic dentifrices. Herbal and synthetic dentifrices given to apply twice a day for 3 wks. Follow up was taken after second week and third week. The duration of treatment was of 21 days.

Table No.1: Drug and Posology of the clinical Trial

	Trial Group	Control Group
Sample Size (n)	30	30
Intervention	Herbal dentifrices	Purchased Synthetic dentifrices
Dosage	Peanut size twice a day	Peanut size twice a day
Time of administration	Morning and Night	Morning and Night
Duration	21 Days	21 Days

Preparation of herbal dentifrices

Dentifrice was prepared under all hygienic conditions and safety precautions in GMP certified pharmacy. For preparation of toothpaste *Yashtimadhu* (Glycyrrhiza glabra), *Karanj* (bark) (*Millettia pinnata*), *Khadir* (*Senegalia catechu*), *Vijaysaar* (bark) (*Pterocarpus marsupium*), Propolis, and clove oil (*Sygizium aromaticum*). (11, 12, 13, 14, 15, 16, 17, 18) All the extracts are authentified and standardized. Dentifrices was prepared under all hygienic conditions and safety precautions in GMP certified pharmacy (11, 19). Prepared dentifrices is packed in a collapsible tube and at last, sealed with the help of a collapsible tube sealing machine (9)

Table No. 2: Ingredients of Herbal Toothpaste (20, 21)

Sr. No.	Ingredients	Quantity % W / W
1	Precipitate Cal. Carbonate	35.00
2	Sorbitol 70%	30.00
3	Purified Water	18.02
4	Glycerin	1.00
5	SLS Liquid 28%	5.00
6	PPT Silica M-FIL (P)	4.00
7	*Yashtimadhu* (*Glycyrrhiza glabra*), *Karanj* (bark) (*Millettia pinnata*), *Khadir* (*Senegalia catechu*), *Vijaysaar* (bark) (Pterocarpus marsupium), Propolis, and clove oil (Syzizium aromaticum), Propolis, (1:1:1:1 ratio)	4
8	Propolis ext	1
9	Clove oil	1
10	Xanthan gum	0.75
11	Sodium Saccharine	0.2
12	Methyl Paraben	0.020
13	Propyl Paraben	0.010
	TOTAL	**100.00**

Tools for assessment of efficacy parameters (24)

The Visual Analog Scale (VAS) - is an accepted method of pain measurement. Dental hypersensitivity will be scored using VAS on air stimulus and cold water stimulus. A VAS scale is a line of 10 cm in length. This line represents the limit of pain patient might experience from an external stimulus. No pain is represented at one end (Marked as 0) and the most severe pain at the other end of the line (Marked as 10). Subjects were asked to place a mark on the 10cm line, indicating the intensity of their current level of Dental hypersensitivity.

Air Blast Stimulation Schiff Cold Air Sensitivity Scale(24)

- 0 = Tooth/subject does not respond to air stimulus.
- 1 = Tooth/subject responds to air stimulus but does not request discontinuation of stimulus.
- 2 = Tooth/subject responds to air stimulus and requests discontinuation or moves from stimulus.
- 3 = Tooth/subject responds to air stimulus, considers stimulus to be painful, and requests discontinuation of stimulus.

Plan for Statistical Analysis

All baseline and demographic data were summarized descriptively. GraphPad in Stat Version 3.6 (www.graphpad.com) software was used for the statistical analysis of data. The primary and secondary outcomes were analysed by applying appropriate statistical tests.

Results

Demographic Details

All 60 patients were enrolled from D.Y.Patil Ayurvedic Hospital, Nerul, Navi Mumbai, Maharashtra, India. It was observed that most of the study participants belonged to middle and upper middle class only.

Clinical assessment

Statistical analysis

Group B shows better results in the median Hypersensitivity score on VAS compared to Group A. (Table no.3)

Group B shows better results in the median Air blast stimulation score compared to Group A. (Table no.4)

Clinical Efficacy Assessment Parameters

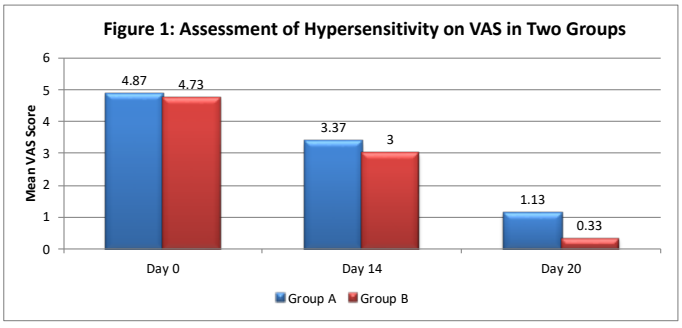
Table No. 3: Hypersensitivity on VAS

	Group A			Group B		
	Day 0	**Day 14**	**Day 20**	**Day 0**	**Day 14**	**Day 20**
Sample Size (n)	30	30	30	30	30	30
Mean ± SD	4.87 ± 1.14	3.37 ± o.93	1.13 ± 1.11	4.73 ± 1.11	3.00 ± 1.15	0.33 ± 0.76
Median (Range)	4 (2 – 6)	4 (2 – 4)	1.5 (0 – 4)	4 (2 – 6)	4 (0 – 4)	0 (0 – 2)
Test of Significance	Friedman test (Nonparametric Repeated Measures ANOVA)			Friedman test (Nonparametric Repeated Measures ANOVA)		
Sum of Ranks	86.000	61.500	32.500	88.000	61.500	30.500
Friedman statistic Fr	53.626			57.617		
P value	< 0.0001, extremely significant			< 0.0001, extremely significant		
Day 0 vs Day 14	< 0.0001, extremely significant			< 0.0001, extremely significant		
Day 0 vs Day 20	< 0.0001, extremely significant			< 0.0001, extremely significant		
Day 14 vs Day 20	< 0.0001, extremely significant			< 0.0001, extremely significant		
	Inter – Group Comparison Mann – Whitney Test					
Day 0	p = 0.6683, considered not significant					
Day 14	p = 0.2854, considered not significant					
Day 20	p = 0.0075, considered very significant					

In Group A, the median Hypersensitivity score on VAS on Day 0, Day 14 and Day 20 were 4 (2 – 6), 4 (2 – 4) and 1.5 (0 - 4) respectively. The difference in median hypersensitivity score on VAS among three visits was found to be statistically significant ($p < 0.0001$).

In Group B, the median Hypersensitivity score on VAS on Day 0, Day 14 and Day 20 were 4 (2 – 6), 4 (0 – 4) and 0 (0 – 2) respectively. The difference in median hypersensitivity score on VAS among three visits was found to be statistically significant ($p < 0.0001$).

In comparison between two groups, the statistically insignificant difference ($p = 0.6683$) in the median Hypersensitivity score on VAS on Day 0 shows that both the groups were derived from the same population. The difference in the median Hypersensitivity score on VAS on Day 14 was also statistically insignificant ($p = 0.2854$) although it was statistically significant on day 20 ($p = 0.0075$) which shows that **Group B shows better results in the median Hypersensitivity score on VAS compared to Group A.**



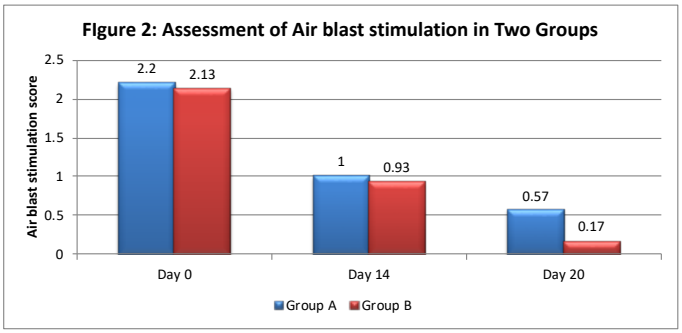


Table No. 4: Air blast stimulation

	Group A			Group B		
	Day 0	**Day 14**	**Day 20**	**Day 0**	**Day 14**	**Day 20**
Sample Size (n)	30	30	30	30	30	30
Mean ± SD	2.20 ± 0.76	1.00 ± 0.69	0.57 ± 0.63	2.13 ± 0.73	0.93 ± 0.64	0.17 ± 0.38
Median (Range)	2 (1 – 3)	1 (0 – 2)	0.5 (0 – 2)	2 (1 – 3)	1 (0 – 2)	0 (0 – 1)
Test of Significance	Friedman test (Nonparametric Repeated Measures ANOVA)			Friedman test (Nonparametric Repeated Measures ANOVA)		
Sum of Ranks	87.500	53.500	39.000	88.500	56.500	35.000
Friedman statistic Fr	51.113			54.187		
P value	< 0.0001, extremely significant			< 0.0001, extremely significant		
Day 0 vs Day 14	< 0.0001, extremely significant			< 0.0001, extremely significant		
Day 0 vs Day 20	< 0.0001, extremely significant			< 0.0001, extremely significant		
Day 14 vs Day 20	0.0002, extremely significant			< 0.0001, extremely significant		
	Inter – Group Comparison Mann – Whitney Test					
Day 0	0.7256, considered not significant					
Day 14	0.7356, considered not significant					
Day 20	0.0192, considered significant					

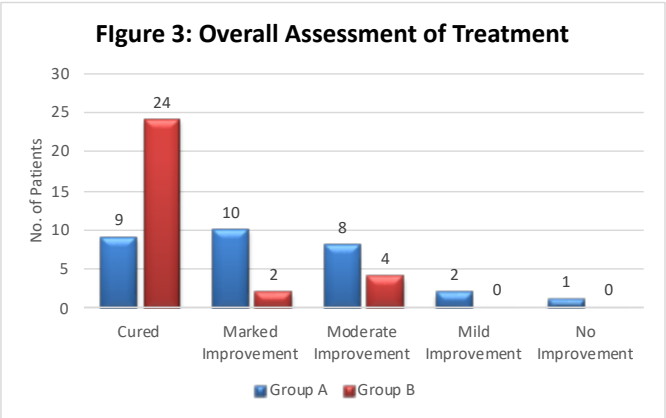
In Group A, the median **Air blast stimulation score** on Day 0, Day 14 and Day 20 were 2 (1 – 3), 1 (0 – 2) and 0.5 (0 - 2) respectively. The difference in median hypersensitivity score on VAS among three visits was found to be statistically significant ($p < 0.0001$).

In Group B, the median **Air blast stimulation score** on Day 0, Day 14 and Day 20 were 2 (1 – 3), 1 (0 – 2) and 0 (0 - 1) respectively. The difference in median hypersensitivity score on VAS among three visits was found to be statistically significant ($p < 0.0001$).

In comparison between two groups, the statistically insignificant difference ($p = 0.7256$) in the median **Air blast stimulation score** on Day 0 shows that both the groups were derived from the same population. The difference in the median **Air blast stimulation score** on Day 14 was also statistically insignificant ($p = 0.7356$) although it was statistically significant on day 20 ($p = 0.0192$) which shows that **Group B shows better results in the median Air blast stimulation score compared to Group A.**

Table No. 5: Overall Assessment of Treatment in Two Groups

Sr. No.	**Assessment**	**Group A**		**Group B**	
		No. of Patients	**Percentage**	**No. of Patients**	**Percentage**
1	**Cured (100%)**	9	30%	24	80%
2	**Marked Improvement (75 – 100%)**	10	33.33%	2	6.67%
3	**Moderate Improvement (50 – 74%)**	8	26.67%	4	13.33%
4	**Mild Improvement (25 – 49%)**	2	6.67%	0	0%
5	**No Improvement (< 25%)**	1	3.33%	0	0%
	Total	**30**	**100%**	**30**	**100%**



The percentage relief of all subjective and objective criteria were calculated separately and their average were calculated to get the overall assessment of treatment.

Discussion

Topical desensitizing agents may cause adverse reactions if swallowed accidentally. Moreover, they are not advisable for children below 12 years. Also, the available toothpastes in the market cost double the regular ones. Hence researchers are trying to explore safer, cheaper and still efficient option to treat Dentinal Hypersensitivity.

Treatments for dentinal Hypersensitivity are time-consuming and not available in rural area.

Toothpastes are the most widely used dentifrices for delivering over-the-counter desensitizing agents.

In today's era there has been a growing interest in natural products, and herbal based toothpastes (dentifrices). Hence it calls for an Ayurvedic dentifrice

for treating DH, which will have no adverse effect even if it's got ingested and will be cost effective as well.

Evaluation of reading paste was done(25)

The formulated Dentifrices is capable of the tooth and oral hygiene show antimicrobial activity against pathogens.

These herbal ingredients are abundantly available, easily accessible, economically feasible and culturally acceptable. They possess minimal side effects and hence can be recommended for long term use.[23]

The symptoms of *Dantaharsha* are similar to Dentinal Hypersensitivity to a great extent. Thus, the knowledge of *Dantaharsha* can be considered as a precedent to Dentinal Hypersensitivity of modern age. The cause of disease is similar for both. All the causes that aggravate Vata, well as the common causes of Mukha roga are similar to etiological factors of dentinal hypersensitivity.

Probable mode of action of *Dentifrices*

Herbal dentifrice contains extract of *Yashtimadhu* (Glycyrrhiza glabra), *Karanj* (bark) (Millettia pinnata), *Khadir* (Senegalia catechu), *Vijaysaar* (bark) (Pterocarpus marsupium), Propolis, and clove oil (Syzizium aromaticum)*Yashtimadhu* has *vranaropak* properties, that means it helps in healing of wounds and smoothens the surface. It is also *Vatashamak* which is necessary to treat *Dantaharsha* which is a predominantly *vataj* disease. It also shows anti-inflammatory properties & antinociceptive activity.

Karanj clove oil is also proven to be having antimicrobial [22] and anti-inflammatory properties It has also shown neuro protective and antinociceptive activity which helps blocking the painful stimulus coming from sensory nerve endings. *Khadira* is known for its use in oral diseases. It also can act as *vranaropak*. It also exhibits antinociceptive activity. *Vijaysara* has analgesic properties. Clove oil contains eugenol, and eugenyl acetate. These compounds inhibit the decalcification and/or may promote the remineralization and improve the surface roughness. Propolis had a positive effect in the control of dentinal hypersensitivity. It occludes the dentinal tubules and helps desensitize the nerve endings.

Thus collectively *Yashtimadhu, Karanj* (bark), *Khadir, Vijaysaar* (bark) contribute to pain relief through their analgesic and antinociceptive properties. Propolis(23) blocks the dentinal tubules leading to desensitization of dentin and Clove oil helps healing of dentin surface by decalcification. Herbs in the study drug augment the pain-relieving action of the clove oil and propolis in the dentifrice.

These herbs were used to treat dental issues in the form of *dant manjan(tooth powder) pratisaran (tongue cleaner), kawal or gandush(Gargling)* by Ayurvedic practitioners as well as common people as a part of folklore medicine. But using them in a form of herbal dentifrice toothpaste makes it more user friendly and more acceptable in the current era. The toothpaste preparation was done in a GMP certified pharmacy and the final product analysis and standardization was done.

Herbal Toothpaste is a very less explored form of medicine in Ayurvedic research domain. The standards and procedure of preparation of Herbal toothpaste not mentioned anywhere in ancient text. Hence, this study can be used as a benchmark for the future Pharmacological & clinical studies.

Synthetic dentifrices definitely gave better results which was used in group B but in synthetic dentifrices chemicals are used having side effects such as Oral discomfort, swollen tongue, oral pain and cannot use in children below 12 years, whereas in herbal dentifrices natural products are used so you can use it regularly for long time with no side effects and in all age groups.

Conclusion

The novel preparation of Herbal dentifrice (toothpaste) was user friendly, palatable, tasty, acceptable by patients, well preserved and free from microbes.

In present study, improvement was seen in dentinal hypersensitivity in both the groups. Synthetic dentifrice showed better results than the herbal one. Although the results in the trial group were not disappointing. Hence there is definitely scope for further research on this drug. More studies can be conducted with higher concentration of herbal extract or with addition of other drugs in it to make it equivalent to the synthetic dentifrice.

Conclusively this study can be considered as the first step on the path of contemporary research in the field of Ayurvedic dentistry.

Future Scope

The sustainability effect of herbal dentifrices can be studied on large scale.

Study can be further conducted by adopting advanced assessment criteria like SEM (Scanning Electron Microscope)

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Nil.

Conflicts of interest

There are no conflicts of interest.

Toothpaste Preparation-

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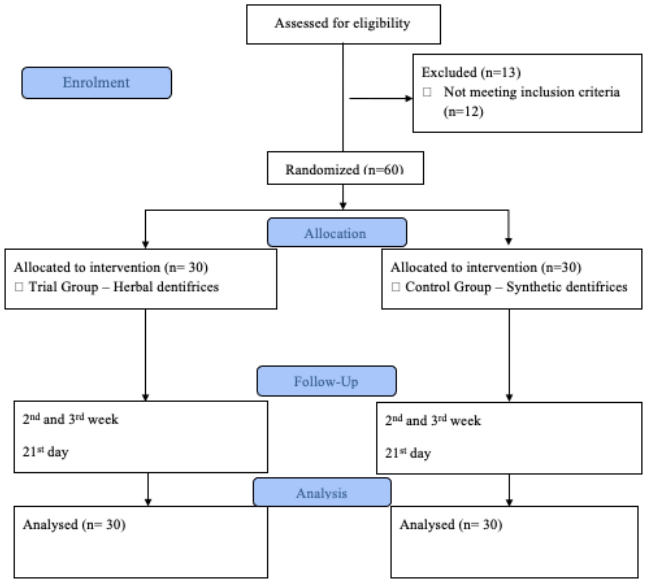
Figure 4: CONSORT Flow Diagram



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