

Clinical study to assess the safety of the seven variant components of Botanic toothpaste - A randomized controlled trial study

¹Dr. Swapna D. V, Department of conservative dentistry and endodontics, Dayananda Sagar college of dental sciences, Bangalore, India

²Dr. Veena Pai, Department of conservative dentistry and endodontics, Dayananda Sagar college of dental sciences, Bangalore, India

³Dr. Mohd. Sibghatullah Khatib *, Department of conservative dentistry and endodontics, Dr Syamala Reddy Dental College Hospital and Research Centre, Bangalore, India

⁴Dr. Ashok H K, Department of conservative dentistry and endodontics, Dayananda Sagar college of dental sciences, Bangalore, India

⁵Dr. Karthika Krishna kumar, Department of conservative dentistry and endodontics, Dayananda Sagar college of dental sciences, Bangalore, India

⁶Swetha A C, Himalaya drugs company Research Associate, Bangalore, India

⁷Dr. Roopa. R . Nadig, Department of conservative dentistry and endodontics, Dayananda Sagar college of dental sciences, Bangalore, India

Corresponding Author: Dr. Mohd. Sibghatullah Khatib, Department of conservative dentistry and endodontics, Dr Syamala Reddy Dental College Hospital and Research Centre, Bangalore, India

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Abstract

Introduction: From decades dentifrices are used to maintain oral hygiene. Widespread and regular use of the dentifrices serves as the most effective tool for prevention and control of oral diseases. The therapeutic impact of dentifrices is to scale dental cavity incidence, gingivitis, or tooth sensitivity.

Aim: The aim of the present study was to evaluate the safety of botanic toothpastes with its seven various ingredients.

Material and Methods: A randomized clinical trial was performed on 80 subjects who were allocated to the 4 study groups of 20 each, employing random sampling using lottery method. The present study employed was a triple blinding procedure. After obtaining the consent, the

subjects were instructed tooth brushing with botanic toothpaste and its seven variants.

Results: The test results demonstrated that Brand B showed significant burning sensation and irritation as compared to others brands and none of the brands showed any sensitivity or gum pain.

Conclusion: The herbal kinds of toothpaste can be an alternative to conventional kinds of toothpaste but inclusion of the thymol and ethanol should be taken into consideration in order to prevent the adverse reaction

Keywords: Dentifrices, Herbal toothpaste, Oral health, Saliva

Introduction

Optimal oral health requires proper oral hygiene measures which consist of mechanical methods, chemical methods

or a combination of both. Today, mechanical oral hygiene (tooth brushing) together with dentifrices is that the most reliable and safe means that of preventing and dominant plaque formation at the individual level.¹

Dentifrices are the routinely administered oral hygiene aid for cosmetic as well as therapeutic purpose.² among dentifrices, toothpaste is that the commonest and accessible means that of preventive oral health care tool. Available data from the scientific literature shows that when used regularly, modern toothpaste can help prevent dental caries and limit the regrowth of dental plaque and gingivitis.^{2,3}

However, modern allopathic kinds of toothpaste contain some ingredients that can be harmful in large doses and can lead to allergic reactions in a few individuals.⁴ Herbal dentifrices normally are formulated from naturally derived components.⁵

Till date, there is lack of sufficient peer-reviewed literature on the efficacious and quality of herbal ingredients used in herbal-based toothpaste. Most of the available literature focuses mainly on the antimicrobial properties of herbal toothpaste. Very few or none of them have tried to evaluate the effects and side effect of herbal toothpaste on the oral cavity. In this present study safety of botanic tubes of toothpaste with its seven various ingredients were evaluated.

Materials and methods

The present study was a triple blind, interventional randomized clinical trial conducted at Bangalore. The ethical clearance for the study was obtained from the Institutional ethical review board and informed consent was obtained from all the participants prior to the study.

Materials and equipments used were herbal toothpastes with its seven variants, sterile plastic containers, insulated containers and toothbrush.

Inclusion Criteria

Healthy volunteer between 20 to 50 years of age at the time of the study with Healthy gingival and oral soft tissue and the absence of dental caries, restoration

Exclusion Criteria

Subjects suffering from systemic diseases, currently using antibiotics, subjects undergoing orthodontic treatment, subjects using oral hygiene aids other than toothbrush & toothpaste, subjects having adverse habits like smoking, alcohol consumption & Allergic to any ingredient of the toothpaste were excluded from the study.

Study Design

The 80 subjects were randomly divided into four groups of 20 each based on CONSORT 2010 Flow Diagram, employing random sampling using lottery method. The present study employed was a triple blinding procedure. The investigator, subjects and statistician were unaware of the toothpaste allocation. Each tube was printed variant code and volunteer randomization number. Subjects were instructed to brush twice daily using the toothpaste for a week. The same 80 subjects were given a wash out period of seven days before enrolling them for next four groups of 20 each. After 7th day of washout period, second sequence were assigned for the same patients with different variant of toothpaste for next 7 days.

Treatment of Subjects

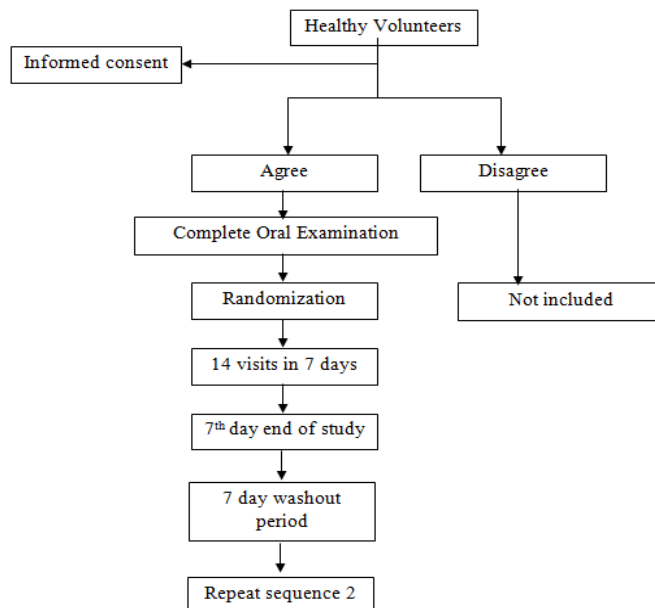
In the event of any adverse effect investigators address with routine treatment procedures. Topical analgesics gel prescribed for mouth wash.

The monitoring visits follows-

- Site selection and protocol feasibility visit
- Site initiation visit
- 1st study monitoring visit on Day 2
- 2nd study monitoring visit on Day 10
- 3rd study monitoring visit on Day 21
- 4th study monitoring visit on Day 28
- Study closeout visit after discussing with the investigator

- In case of any adverse effect which may require monitor visit

At every visit investigator perform complete oral examination for any adverse effect.



Results

Ingredient Name	A	B	C	D	E	F	G
Xylitol	25	25	25	25	25	25	25
Calcium carbonate	25	25	25	25	25	8	25
Purified water	22.07	22.07	18.56	18.56	22.07	15.87	22.24
Glycerine	14.55	14.55	18.05	18.05	14.55	26	14.55
Foaming agents	6	6	6	6	6	6	6
Silica	2.5	2.5	2.5	2.5	2.5	-	2.5
Sweetner	1.5	1.5	1.5	1.5	1.5	1.25	1.5
Xanthan gum	1	1	1	1	1	0.3	1
Sodium bicarbonate	0.5	0.5	0.5	0.5	0.5	-	0.5
Sodium Chloride	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Zinc citrate	0.2	0.2	0.2	0.2	0.2	-	0.2
Herbal actives	0.03	0.03	0.03	0.03	0.03	0.03	0.03
Menthol	-	0.4	-	0.4	-	0.4	0.35
Thymol	-	0.1	-	0.1	-	0.1	0.08
Flavour	-	0.95	-	0.95	0.95	0.95	0.85
Whitening enzymes	-	-	0.01	0.01		-	-
Hydrated silica	-	-	-	-	-	15	-
Carrageenan	-	-	-	-	-	0.4	-
Potassium sorbate	-	-	-	-	-	0.5	-

Table 1: Composition of the toothpaste with seven variant

*Values are in weight percentage

Table 2: Comparison of mean VAS scores for different variables between different brands of tooth paste using Kruskal Wallis test

Paste	Sensitivity		Burning		Irritation		Gum Pain		Flavour	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Brand A	0.00	0.00	0.16	0.37	0.02	0.07	0.00	0.00	2.92	1.29
Brand B	0.00	0.00	1.50	2.12	0.05	0.14	0.01	0.03	2.77	2.21
Brand C	0.25	0.55	0.28	0.52	0.20	0.56	0.02	0.08	2.72	1.97
Brand D	0.05	0.09	0.44	0.69	0.09	0.34	0.01	0.06	2.24	1.38
Brand E	0.01	0.03	0.15	0.62	0.01	0.03	0.00	0.00	2.44	1.34
Brand F	0.05	0.17	0.63	0.89	0.18	0.42	0.02	0.07	2.60	1.38
Brand G	0.21	0.46	0.43	0.77	0.32	0.77	0.00	0.00	2.77	1.97
Brand H	0.13	0.57	0.31	0.58	0.09	0.20	0.00	0.00	2.14	1.49
P-Value	0.07		0.01*		0.56		0.51		0.77	

* - Statistically Significant

Table 3: Multiple comparison of mean Difference of VAS scores for Burning Sensation b/w different tooth paste using Mann Whitney U test

Brand	B Vs A	B Vs C	B Vs D	B Vs E	B Vs F	B Vs G	B Vs H
P-Value	0.01*	0.02*	0.26	0.001*	0.31	0.30	0.10

* - Statistically Significant

80 subjects completed the 28-days study period. There were no dropouts throughout the trial. They were examined and received a prophylaxis one or two weeks later.

The collected data were entered into Excel data sheet. The data were subjected to Kruskal Wallis test followed by Mann Whitney Post hoc Analysis was performed to compare the mean VAS scores for different study variables between different tooth brands.

At the baseline there were no significant difference among groups in terms of Sensitivity Burning sensation, Irritation, Gum Pain and Flavors The P value was statistically significant for Brand B while comparing the

mean scores of different variables (Sensitivity Burning sensation, Irritation, Gum Pain and Flavors) between different brands of tooth paste, the mean score of Brand B for burning sensation was 1.50 ± 2.12 . [Table 2].

Multiple comparisons of mean Difference of VAS scores for Burning Sensation b/w different tooth paste shows that $P < 0.05$ between Brand B V/s Brand A, Brand B V/s Brand C and Brand B V/s Brand E [Table 3].

Discussion

The seven variants in 8 different toothpaste were Menthol, Thymol, Glycerin, Whitening enzymes, Hydrated Silica, Carrageenan, Potassium sorbate incorporated in various proportion in every toothpaste.[Table- 1]

The present study was an in-vivo eight parallel groups and the randomized clinical trial that evaluated the comparative efficacy of eight different herbal kinds of toothpaste to determine the safety of botanic toothpaste. Available scientific literature shows that herbal toothpaste is as effective as conventional kinds of toothpaste.^{6,7} But there is a dearth of scientific literature showing comparative efficacy of one herbal toothpaste over the other. Hence, only herbal toothpaste has been selected for the present study to assess the efficacy.

In the present study, no clinically significant adverse reactions of the tested herbal toothpaste were reported or observed, during the entire study period except Brand B, which showed the significant amount of burning sensation ($P < 0.01$). There was no statistically significant difference between gender and age distribution among different study toothpaste brands and among different variables between different brands of toothpaste.

Brand B contain Xylitol, Calcium carbonate, Purified water, Glycerin, Foaming agents, Silica, Sweetener, Xanthan gum, Sodium bicarbonate, Sodium Chloride, Zinc citrate, Herbal actives, Menthol, Thymol, Flavour. Brand A, Brand C, Brand E also contain the same ingredient in various concentration except for Menthol, Thymol.

Thymol and Menthol are broad-spectrum antimicrobial agents, act by destructing bacterial cell wall and inhibition of the enzyme. Even with regular tooth brushing and flossing thymol and menthol can be recommended as an adjunct especially in patients with gingival inflammation because they have plaque control effects but it is not advisable to use these ingredients in pediatric toothpaste as a precautionary measurement and also should be avoided in patients suffering from dry mouth because they might exaggerate the condition.^{8,9}

The dryness of the mouth can lead to the burning sensation.¹⁰ This could be the possible reason for burning

sensation of the participant using Brand B toothpaste. Brand A, Brand C, Brand E doesn't contain thymol and ethanol and results of the present study showed that there was a significant difference in burning sensation between Brand A, Brand C, Brand E with Brand B.

Conclusion

With the limitations of the study, it can be concluded that among all the variants, toothpaste containing thymol and ethanol showed the burning sensation as compared to the toothpaste without them. It can be concluded that the herbal kinds of toothpaste can be an alternative to conventional kinds of toothpaste but inclusion of the thymol and ethanol should be taken into consideration in order to prevent the adverse reaction.

For understanding better effectiveness of the variant long term clinical study required along with the combination of the herbal mouthwash.

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