

A Clinical Trial to Evaluate Adverse Reactions to Herbal Dentifrices among Dental Students: A Preliminary Study

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Abstract

Background: Herbal products, including dentifrices, appear to have become an attractive alternative for some consumers and their use has gained appreciable acceptance all over the world. This could be partly due to the perception that herbal toothpastes like other herbal products are “natural”, devoid of chemicals and therefore superior to regular toothpastes. The disturbing remarks that adverse drug reactions do occur from the use of herbal toothpaste stated the need for post marketing surveillance of two herbal dentifrices and prompted this study. **Objective:** To evaluate the safety and possible adverse effects of two herbal dentifrices. **Materials and Methods:** 100 Dental students (45 males, 55 females) attending the first and second years (corresponding to age group 18-19 years) at Inderprastha Dental College and Hospital, Sahibabad - Ghaziabad, India; made up the study population. Oral signs and symptoms (adverse effects) to be seen included erythema, edema, pain, irritation and burning sensation. Data analysis was done using the SPSS (version 16.0). P values ≤ 0.05 was considered statistically significant. **Results:** A total of 98 students, 44 (45%) males and 54 (55%) females, who were allotted two experimental groups (Gel and Toothpaste), completed the 2 weeks clinical trial. The age range of participants was 18-19 years. There was no statistically significant association between the use of herbal toothpastes and adverse reactions (p value > 0.05). **Conclusion:** The use of the two herbal dentifrices in this study resulted in only negligible adverse effects (1 in 98; i.e. 1.02% population) and hence may be considered safe in consumers.

Keywords: Herbal dentifrices; Adverse reactions; Safety; Erythema; Burning sensation; Pain; Irritation; Dental students.

Introduction

The uses of herbal remedies have assumed a global dimension. They are used in the treatment of various ailments in both developed as well as developing countries. This alternative form of therapy appears to be the latest fad, as a number of herbal products are readily available to consumers. Teas, soaps, facial products, as well as mouth washes and dentifrices are a few of these products.[1] More than 60% of the Chinese use herbal therapy and a significant part of the rural population

in the Indian subcontinent rely on indigenous medical systems that use herbs, ash and heavy metals.[2]

A number of articles have been written on the efficacy or otherwise of herbal dentifrices. Some reports indicate that the lack of a consensus among dental professionals on the subject matter has made it difficult for dentists to provide information on the product safety and efficacy.[3] A dearth of scientific studies on natural and herbal products in peer reviewed dental literature has also been cited as posing a conundrum for health care professionals in dealing with these products. In addition, few research efforts have been directed toward addressing the potency or quality of herbal ingredients used in these dental products.[3] Reports have also indicated that since only a limited number of in vivo studies on herbal dentifrices have been published, it has not been determined whether they are superior, equivalent or substandard to conventional dentifrices in reducing

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(Received on 20.02.2013, Accepted on 05.03.2013)

plaque.[4-6] Allergy to oral hygiene ingredients is rare, probably due to the rinsing after use. Approximately 30 allergens have been identified in toothpastes and these are present in most. Flavorings in toothpastes give the 'fresh clean taste' and cover the bitter taste of pyrophosphates in tartar-control toothpastes. And these are the commonest ingredients that cause contact allergy. Toothpaste is classified as drugs because drugs should contain an ingredient to achieve the effect the consumer desires. Dentifrices (toothpastes) have been used since antiquity but recently, formulations which deliver active compounds aimed at preventing and/or treating oral diseases have been developed.

Toothpaste may be classed as either a cosmetic or a medicine depending on the claims that are made and the level of certain constituents. The primary function of toothpaste is to clean the teeth; which is considered to be a cosmetic benefit. The use of words such as 'protects', 'cleans', 'freshens breath', 'fights bacteria which may cause gum problems', 'whitens' or 'fights tartar' are considered to be cosmetic claims. A medicine is considered to be any substance used wholly or mainly for the purpose of treating or preventing disease. Claims such as 'reduces hypersensitivity', 'reduces gingivitis', 'reduces gingival bleeding' or 'controls periodontitis', "prevents/treats dental caries" are medicinal claims.[7]

Possible adverse effects of dentifrices

Toothpaste ingredients may be ingested, particularly by children or people with learning disability, and may contribute to damage to hard tissues (abrasion, staining) and occasionally soft-tissues. Soft tissue reactions may arise, most often to essential oils, flavorings, cinnamonaldehyde, benzoates, or carvone, and manifest as direct irritants or allergic reactions in the mouth, lips as contact cheilitis.[8] Essential oils, such as peppermint, cinnamon, cloves and spearmint and antimicrobial agents can cause cheilitis or circumoral dermatitis.[9] Tartar-control pyrophosphate dentifrices occasionally cause

erythema, scaling and fissuring of the perioral area, sometimes with cheilitis, gingivitis[10] and other reactions. Herbal toothpastes occasionally produce similar reactions.[11]

Aim of the study

To evaluate the safety and possible adverse reactions of two herbal toothpastes among dental students.

Materials and Methods

The present study was a clinical trial on 100 dental students (I and II year) in the age group 18-19 years; attending Inderprastha Dental College and Hospital, Sahibabad- Ghaziabad, India. The permission to conduct the trial was obtained from the institutional ethical committee and prior informed consent was taken from the participants. This study was conducted during January 16th to January 31st 2013. Study participants were recruited by convenient sampling. The students with orthodontic appliances or history of allergy to any medication were excluded from the study. All enrolled students underwent a thorough oral examination before entering the study. Then they were randomly put in two experimental groups (Group 1: Dabur Herbal Gel with Mint and Lemon and Group 2: Dabur Herbal Toothpaste with Basil). All subjects were advised to use their respective dentifrice with the toothbrushes provided to them (Colgate Zigzag toothbrush with soft bristles; Colgate-Palmolive India Ltd.) by their regular brushing method twice daily for 2 weeks. The participants were told to restrict themselves to the herbal toothpastes to be tested and resort to no other active treatment intervention during the study period. The dental students underwent thorough clinical examination on entry and 2 weeks and were questioned about the taste perceived with the use of their respective dentifrice. Participating dental students were allowed to voluntarily withdraw from the study, though efforts were made to

ascertain the reason for dropout. The criteria for evaluation were the signs and symptoms like erythema, edema, pain, irritation and burning sensation. All the adverse effects, either reported or observed by the patients, were recorded with information about severity, date of onset, duration and action taken regarding the study products. The statistical software SPSS (version 16.0) was used to analysis of the data and Microsoft excel have been used to generate graphs, tables, etc.

Presentation of toothpastes

Toothpastes used in this study were manufactured by Dabur India Limited, India.

1. Dabur Herbal Gel with Mint & Lemon: (Group 1)

Active ingredients: Natural Lemon Extract, Flavor containing Natural blend of Mint, Eucalyptus, Rosemary, Chamomile, sage, Myrrh & other natural oils.

Other Ingredients: Sorbitol , Silica, Treated water, Polyethylene glycol 1500, Sodium Lauryl Sulphate, Sodium carboxy methyl

cellulose, Sodium Saccharin, Trisodium orthophosphate, Sodium Fluoride, Citric acid, F D & C Blue # 1 , F D & C Yellow # 5 and preservative.

2. Dabur Herbal Toothpaste with Basil: (Group 2)

Active ingredients: Basil Oil (0.01%0, Herbal extract - 5% (obtained from: Bullet wood, Acacia Arabica, Lotur bark, Pelitory root, bark of Black berry), Chalk (Calcium Carbonate), Sodium lauryl sulphate, Blend of Peppermint, Spearmint, Coriander, Ginger, Eucalyptus & Lemon oil.

Other Ingredients: Sodium Silicate, Glycerin, Purified water, Gum Carrageenan, Sodium saccharin, Chlorophyllin, Sodium Mono-fluorophosphate, Tetra sodium pyrophosphate, preservative.

Results

100 Dental students (45 males, 55 females) attending the first and second years

Table 1: Demographic Data of patients on Entry

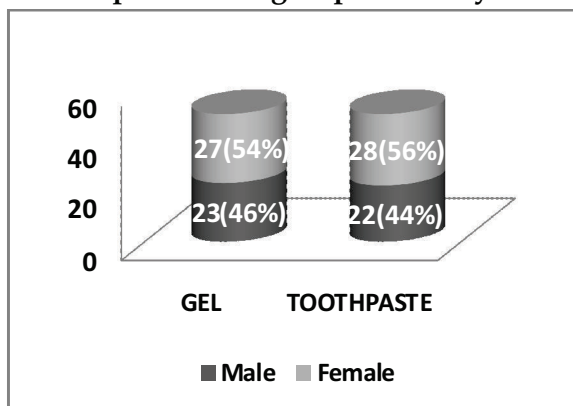
PARAMETER	GEL/ GROUP 1	TOOTHPASTE/ GROUP 2	Total
Age in years (mean± SD)	18.38 ± 0.490	18.35 ± 0.483	18.37 ± 0.485
Male [n (%)]	23 (46.0 %)	22 (44.0 %)	45 (45.0 %)
Female [n (%)]	27 (54.0 %)	28 (56.0 %)	55 (55.0 %)
Total [N (%)]	50 (100.0 %)	50 (100.0 %)	100 (100.0 %)

Table 2: Taste of two Dentifrices

TASTE	GEL/ GROUP 1 (N = 50)	TOOTHPASTE/ GROUP 2 (N = 48)	Total (N = 98)
GOOD [n (%)]	50 (100.0 %)	42 (87.5 %)	92 (93.9 %)
AVERAGE [n (%)]	0 (00.0 %)	06 (12.5 %)	06 (06.1 %)
POOR [n (%)]	0 (00.0 %)	00 (00.0 %)	00 (00.0 %)

Table 3: Adverse reactions/ Safety evaluation of two Dentifrices

SIGNS & SYMPTOMS	GEL/ GROUP 1 (N = 50)	TOOTHPASTE/ GROUP 2 (N = 48)	Total (N = 98)
Erythema	0 (00.0 %)	0 (00.0 %)	0 (00.0 %)
Edema	0 (00.0 %)	0 (00.0 %)	0 (00.0 %)
Pain	0 (00.0 %)	0 (00.0 %)	0 (00.0 %)
Irritation	0 (00.0 %)	1 (02.1 %)	1 (01.05 %)
Burning sensation	0 (00.0 %)	1 (02.1 %)	1 (01.05 %)

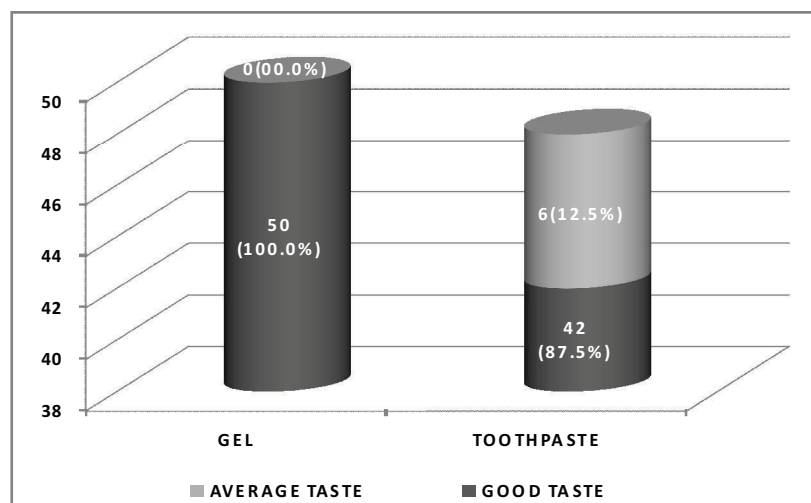
Graph 1: Gender distribution in 2 experimental groups on entry

(corresponding to age group 18-19 years) at Inderprastha Dental College and Hospital, Sahibabad- Ghaziabad, India; made up the study population (Graph 1). A total of 98 students, 44 (45%) males and 54 (55%) females, who were allotted two experimental groups (Gel and Toothpaste), completed the 2 weeks clinical trial. The students in Group 1 (Gel group) had a mean age of 18.38 ± 0.490 years; while Group 2 (Toothpaste group) had a mean age of 18.35 ± 0.483 years (Table 1). As per taste perception, majority (93.9%) liked the taste of two dentifrices; though 12.5% in Group 2 rated it at average taste (Graph 2, Table 2). The two dropouts from Group 2 gave "unpleasant taste" as the reason to withdraw from the trial. Only one student (out of total of 98) reported irritation and burning sensation

in Group 1; though in Group 2 none reported any adverse effects (Table 3). There was no statistically significant association between the use of herbal toothpastes and adverse reactions (p value > 0.05).

Discussion

There has been growing interest in natural products especially in dentistry. The herbs which have properties to influence on the oral hygiene have been of interest in people.[12] A typical toothpaste contains an abrasive, humectant, binder, detergent, flavor, preservative and therapeutic agent. The humectants, binders, flavors, preservatives and colorings are used routinely in the food and pharmaceutical industries and should pose minimal health risks when used in toothpaste. The flavors, colorings or preservatives may give rise to allergic reactions, but these are relatively rare. The detergent or essential oil flavors may produce localized mucosal irritation, but this is also rare. Toothpaste is a personal care product that is commonly used by consumers starting at a very young age. This is one exposure through which sensitivity to flavors can develop. Not only are consumers exposed to flavoring allergens through toothpaste, but also through chewing gum, ice cream, soft drinks, candies, and mouthwash.[13] These

Graph 2: Distribution of study population according to taste perception (Gel v/s Toothpaste)

common exposures heighten the chance of becoming allergic to common toothpaste flavors.

For the majority of people, herbal toothpastes, when used properly, are safe and help to maintain dental health.

Conclusion

Toothpaste contains many potential allergens that are commonly the cause of allergic contact cheilitis. Many toothpaste ingredients have the potential to cause either an irritant or allergic reaction, making it essential for healthcare providers to be well versed in toothpaste ingredients.

It can be difficult to determine the actual cause of the allergy, even if flavoring is suspected. Many healthcare providers may want to empirically recommend alternative flavored toothpaste, but even this can be challenging. The regular use of the herbal dentifrices identified in this study can result in adverse oral signs and symptoms affecting taste, nutrition, aesthetics and general oral physiology in some consumers. These findings would suggest that further long term clinical trials need to be conducted on herbal dentifrices available to consumers to identify the noxious agents causing these adverse reactions. The formulation and use of these dentifrices need to be standardized and regulated.

Acknowledgement

We acknowledge the support provided by the Dabur India Limited, India; during this study.

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