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Guidelines for toothpaste selection - A cross-sectional study on sample toothpastes available in India.

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Abstract

Background: The chemical composition of toothpaste varies from one brand to another and even among several presentations of the same brand. Some of the constituent chemicals used include having been proved to be hazardous to human health, if above a certain limit. Continuous exposure to these components leads to high-risk health problems. Therefore, this study was undertaken to quantify five harmful ingredients present in different brands of dental pastes available in the Indian market and also to sensitize the safety of these pastes to consumers.

Methods: Study design: A cross-sectional study. Thirteen different brands of commercial toothpaste samples were randomly collected from the open market in India. They were analyzed for five ingredients *viz.*, sodium lauryl sulfate (SLS), sodium hydroxide, sodium bicarbonate, titanium dioxide, and sorbitol by using titration methods or by Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP OES).

Results: Among the fifteen-sample toothpaste, the quantity of the selected ingredients was obtained as follows.

1. The SLS content in toothpastes varies from 0.8% to 1.51%
2. Sodium hydroxide varies between 0.35 to 2.5 ppm.
3. The amount of sodium bicarbonate (baking soda) has shown remarkable variation among the sample products and is between 22.1 and 84.5ppm.
4. The Sorbitol content varies from 14.78% to 19.42% by wt among different products
5. The quantity of titanium dioxide has shown slight variation among the products and is between 0.32 and 0.92%.

Conclusion: The quantitative estimation of the toothpaste composition will help the Indian dental practitioners to suggest the toothpaste as per the individual needs with scientific evidence.

Clinical Relevance: Inactive ingredients of the toothpastes are non-toxic, but they can cause adverse effects like mouth ulcers. The selection of toothpaste should be based on individual's requirement and the toothpastes components.

Keywords: abrasive agent, foaming agent, sweetening agent, toothpaste, whitening agent

Introduction

Tooth brushing with the right toothpaste is daily essential for maintaining good oral hygiene and good general health. The public awareness about toothpaste is all about its cleansing action, protection against dental caries, and assuring a fresh mouth and brisk breath. There are varieties of toothpaste available in the market with different ingredients, new formulas, and forms like gel, paste, cream, or powder foam. Some key factors that determine the buying decision of the people are the cost, brand, appealing design of the pack, pleasant taste and smell, discounts, and the advertisement of the product highlighting the interesting facts and unique features. But when these people suffer from dental or oral diseases and visit their dentist, invariably ask "what toothpaste do you recommend to the doctor?"

The dental practitioners should seriously handle this question based on the needs of individual patients as with evidence-based facts.

The composition of toothpaste varies from one brand to another and even among several presentations of the same brand. A typical chemical composition (1,2) of toothpaste includes abrasive 10-40%, humectant 20-70%, water 5-30%, binder 1-2%, detergent 1-3%, flavoring agent 1-2%, preservative 0.05-0.5%, therapeutic agent 0.1-0.5%, coloring agents <1%, and sweetening agents 2%. Though there are no absolute toxic ingredients in any kind of toothpaste, the problem arises only when one or a few ingredients are present in excess in any toothpaste or when a person having a specific complaint is using toothpaste that is not favourable to solve the problem or capable of aggravating the problem. This demands an investigatory approach of the Dental professionals to play a guiding role in toothpaste selection. We have undertaken this study intending to quantify five common ingredients (Sodium Lauryl Sulfate, sodium bicarbonate, Sodium Hydroxide, Sorbitol, and Titanium dioxide) present in different brands of dental pastes available in the Indian market and also to sensitize the safety of these pastes as per the specific complaints and needs of patients.

Sodium lauryl sulfate: (SLS) ($C_{12}H_{25}SO_4Na$) is an anionic surfactant that lowers the surface tension of a liquid, allowing for the easier spreading of a droplet on the surface. This property of SLS allows it as a foaming and cleaning agent in most toothpaste. (3)

Sodium bicarbonate: (NaHCO3) or baking soda is used in dentifrices because of its abrasive property that leads to staining removal by dissolving the mucus and loosening the debris. Dental abrasion is the effect of

abrasive agents in the toothpaste; hence measuring the abrasive level of the dentifrices is beneficial from the clinical point of view as the value is never explored on the label. (4)

Sodium hydroxide: (NaOH) is otherwise known as caustic soda and is added to toothpaste at a dilute level to adjust the pH to around 6.5 by neutralizing the acid. This is an inactive ingredient in some pastes but if included the manufacturers insert a warning label to show the need for medical help "if swallowed accidentally". (5)

Sorbitol: (polyol) is used in toothpaste for its sweetening, humectant, and texturing properties. It keeps approximately 60% sweetness and one-third of the calories of the sucrose and possesses non-cariogenic, however not anti-cariogenic properties. Sorbitol is accepted as the safest sugar substitute by the World Health Organisation Expert Committee on Food Additives. (6)

Titanium dioxide: (TiO_2) is an opacifying agent used as a whitener in toothpaste, because of its brilliance and refractive index but the percentage of TiO_2 is never mentioned in the products. The International Agency for Research on Cancer (IARC) has declared the as carcinogenic potential of titanium dioxide. (7)

Material and Methods

We randomly collected fifteen commercial toothpaste samples that come with 6 different brands (6 of Colgate-Palmolive Company, 6 of Hindustan Unilever Limited, 1 of Vicco Group, 1 of The Himalaya Drug Company, and 1 of Dabur India Limited) from the open market of Chennai city, India. All the samples were conventional toothpaste except for samples Dauber red, Himalaya, and Vicco, described as Herbal toothpaste by manufacturers. A cross-sectional analysis was carried out for the quantification of five inactive ingredients *viz.*, Sodium lauryl sulfate, sodium hydroxide, sodium bicarbonate, titanium dioxide, and sorbitol in the sample toothpaste by using titration methods or by Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP OES). To mask the identity during the lab procedure, the fifteen sample toothpastes selected were transformed into sterile 0.2 ml microcentrifuge tubes represented as P1, P2, and P15 (Table 1).

Experimental procedure

All reagents were of analytical grade and were used without further purification. Deionized water was used throughout the experiment.

Chemical Composition Analysis

Qualitative Identification**:** The presence of 5 chosen ingredients in all thirteen-sample toothpaste was confirmed by checking the product pack label.

Quantitative Estimation**:** The sample toothpaste was subjected to the quantification of five ingredients by using the techniques. The technique used for the analysis of each ingredient is tabulated (Table 1).

Determination of sodium lauryl sulfate (8)

1.5 g of each sample paste was dissolved and diluted to 1000 ml with water. 10 ml of the diluted solution was added with 25ml of Methylene blue solution (0.003% w/v), 15 ml of methylene chloride solution, and 20 ml of water. The resultant solution was titrated with 0.004 M benzethonium chloride and shaken vigorously until the separated layers attained blue colour. 1 ml of 0.004 M benzethonium chloride was equivalent to 1.154 mg of sodium alkyl sulfates, calculated as C12H25NaO4S.

Determination of total alkalinity of Sodium Bi Carbonate ($NaHCO_3$)

A sample of each paste weighing 3 g was mixed with 100 ml of water in a titration flask and titrated with 1N hydrochloric acid using methyl red as an indicator. The total volume of hydrochloric acid consumed was

calculated. Each mL of 1 N hydrochloric acid was equivalent to 84.01 mg of $NaHCO_3$. (9)

Determination of Sodium Hydroxide (NaOH)

Each sample was weighed accurately for 1.5 g and dissolved individually in 40 ml of carbon dioxide-free water and titrated against 1N Sulphuric acid using Phenolphthalein as an indicator. The total volume of acid used for the titration was noted and the quantity of NaOH was calculated, taking 1ml of 1 N sulfuric acid is equivalent to 40.00 mg of NaOH.

Determination of Sorbitol

About 0.4g of each sample was weighed accurately and diluted to 100 ml with water in a volumetric flask. 10 ml of the diluted solution was pipetted into a stoppered Erlenmeyer flask, and 20 ml of 2.14 %W/V solution of sodium periodate and 2 ml of 10 % W/V sulphuric acid were added. The flask was heated in a water bath for 15 minutes and cooled slowly. To the contents, 3 g of sodium bicarbonate and 25 ml of 0.2 N sodium arsenite were mixed thoroughly and then 5 ml of 20% W/V potassium iodide was added and allowed to stand for 15 minutes. This preparation was titrated with 0.1N iodine until the solution changed to yellow colour. The blank titration was performed, and the calculations were done taking 1 ml. of 0.1 N iodine equivalents to 0.001822 gm of C6H14O6.

Determination of Titanium Oxide (TiO_2)

Each sample was weighed accurately at about 1.0 g and transferred into pre-cleaned and weighed Silica Crucible. The crucible containing TiO_2 was kept in the Muffle Furnace at 550°C for 2 h. It was then taken out and cooled. 15 ml of 1:1 Conc HCl and Conc HNO3 was added and digested on a hot plate until the residues dissolved completely. It was then cooled, filtered, and made up to 100 ml in a Standard flask. The above sample was analyzed through Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP OES).

Results

Table 2 reveals the highest and the lowest quantity of the 5 selected inactive ingredients in the sample toothpaste. The amount of sodium lauryl sulfate was less in Vicco Vajradanti and Colgate charcoal whereas highest in Colgate max fresh. Sodium hydroxide is minimum in Colgate visible white and maximum in close-up diamond attraction. The quantity of sodium bicarbonate is minimum in Pepsodent clove salt and maximum in close-up 12-hour protection. Sorbitol level is minimal in Colgate visible white and maximum in Pepsodent clove salt. Colgate active salt lemon contains the maximum amount of titanium dioxide and Dauber red contains the same at a minimal level. By listing out the three kinds of toothpaste among the fifteen samples that contain the highest and lowest level of the selected ingredients (Table 3), Vicco Vajradanti contains less amount of sodium lauryl sulfate and sodium hydroxide, hence can be preferred for individuals complaining about recurrent oral ulcers and burning mouth syndrome. Dauber red contains sodium hydroxide, sodium bicarbonate, and titanium dioxide in the upper limits, and hence better to advise avoiding regular usage.

Discussion

Toothpaste is categorized under cosmetic products that are explained as "a substance or mixture to be applied on the teeth and the oral mucous membranes for cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors". (10) The manufacturers have been introducing several formulations of toothpaste and are consistently working to enhance the quality and satisfy the users' expectations. The active ingredients (5) of the toothpaste are almost similar and include anticaries agents, anti-plaque and anti-calculus agents, and anti-malodor agents. Added to these active

therapeutic components, other inactive substances like preservatives, abrasives, surfactants, colouring agents, whitening agents, vehicles, humectants, and sweeteners are used to make the product more agreeable. The inactive ingredients are common in many types of toothpaste and when someone reads the label, they can't recognize what most of that is or their benefits. This study explores the nature of the five common inactive ingredients of the fifteen-sample toothpaste and gives an overall impression for the dental practitioners to recommend the toothpaste based on their needs.

Foaming agent

Sodium lauryl sulfate consists mainly of sodium dodecyl sulfate, a white or pale-yellow powder or crystals with a distinctive odor and is a strong denaturing agent. It denaturalizes the mucin layer glycoproteins, leading to moderate-to-severe irritation of oral and gingival epithelial cells and causing mouth ulcerations in some individuals[8]. The association between the use of toothpaste containing SLS and an increased frequency of recurrent aphthous ulcers (RAU) and dry mouth is reported in the literature. (3) The use of toothpaste containing SLS should not be advised for individuals suffering from recurrent aphthous ulceration, xerostomia, burning mouth syndrome, and patients on tricyclic antidepressants, chemotherapy, and radiotherapy.

Abrasive agents

Sodium bicarbonate (baking soda) is low in terms of abrasiveness but holds the same stain and plaque removal capabilities compared with other abrasive agents with greater Relative Dentin Abrasivity index (RDA). Baking soda has also possessed antimicrobial properties (11) hence toothpaste having it as an ingredient is more effective in reducing plaque formation, gingival inflammation, and gingival bleeding. (12) Its low abrasiveness, antimicrobial property, and compatibility with sodium fluoride make it recommended to recommend sodium bicarbonate containing dentifrices as a routine dental paste for individuals with normal requirements (no hypersensitivity and not highly susceptible to caries lesion). Being the softest abrasive agent, (13) toothpaste containing NaOH can be recommended for individuals who are at the risk of developing abrasion and erosion and have undergone resin composite restorations.

pH adjusting agent

Sodium hydroxide (caustic soda) is used to neutralize the pH level of toothpaste. Using toothpaste containing sodium hydroxide more than required for brushing or using the increased quantity of paste for brushing is potentially dangerous and may lead to a chemical burn, ulceration, and pain. (14) Sound advice not to use by patients suffering from aphthous stomatitis, allergic stomatitis, burning mouth syndrome, chronic mucosal lesions (Lichen planus, Pemphigus, etc.,)

Humectants and sweeteners

Sorbitol is a non-fermentable nutritive sweetener and humectant (avoid hardening of toothpaste during storage). Sorbitol has anti-cariogenic properties, though not as significant as xylitol but is proven for its benefit in preventing periodontal infections. (15) It is prone to cause aggravate irritable bowel syndrome when ingested. It also acts as an osmotic laxative in larger doses and causes diarrhea. It's used in proportions of about 20 to 70% by weight of the toothpaste. Sorbitol-containing containing toothpaste should be avoided in case of unsupervised brushing in children to prevent accidental swallowing and can be recommended for adults suffering from chronic gingivitis and periodontitis. Also, the use of sorbitol-containing toothpaste is not advisable

for patients with sodium polystyrene sulfonate and Dichlorphenamide to avoid drug interactions. (16)

Colouring agent

In toothpaste, titanium dioxide is present as smaller particles measuring less than 100 nm (referred to as a nanoparticle) in size. These nanoparticles have a relatively large surface area and can be reactive and cause harmful effects. In addition, they can penetrate the gingiva and mucous membrane and act as a potential carcinogenic agent, and eventually may end up at different sites in the human body. No limit has been set for the amount of titanium dioxide that man can daily ingest. (17) So the use of TiO2-containing$_2$ containing toothpaste should be strictly avoided in patients having potentially malignant oral disorders.

Conclusion

- Our study results declare that no single sample of toothpaste is ideal.
- Though the estimated components are permitted by FDA (U.S. Food and Drug Administration) and IPC (Indian Pharmacopoeia Commission), these components should be avoided in individuals with potential health risks.

Study limitations and prospects

The present study analyzed only fifteen samples out of the hundreds of toothpaste brands in our country. Though the samples were selected randomly based on the popularity of the brands, selection based on a survey among the dental patients who are asking for toothpaste recommendations will be more appropriate.

Collaborative studies are needed on this topic to include more samples and quantitatively list out all ingredients. This will help the Indian dentists to recommend the most appropriate toothpaste with strong scientific evidence and justify our professional responsibilities.

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17. Safety CP. Health Effects Due to Titanium Nanoparticles in Food and Toothpaste Cannot be Excluded.

Legend Tables

Table 1: List of the fifteen toothpaste samples

Code for representation	**Commercial name of the toothpaste**
P1	Colgate visible white (Dazzling white)
P2	Colgate active salt
P3	Colgate total Charcoal (Deep clean)
P4	Colgate active salt lemon
P5	Colgate strong teeth
P6	Close-up – Diamond attraction
P7	Pepsodent clove salt
P8	Pepsodent G
P9	Pepsodent Whitening (cavity protection)
P10	Himalaya sparkling white
P11	Dabur red
P12	Close-up 12 hours protection
P13	Colgate Max Fresh
P14	Close-up Fresh breath
P15	Vicco Vajradanti

Table 2: The quantity of the selected five ingredients in the fifteen sample toothpastes

Sn.	Parameters	Unit	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
1	Sodium Lauryl Sulphate	%	1.21	1.11	0.89	0.94	1.01	1.11	0.98	1.32	1.24	0.99	1.04	1.26	1.51	1.22	0.87
2	Sodium Hydroxide	ppm	0.35	0.48	0.68	1.02	1.50	2.5	0.55	0.60	0.75	0.50	1.05	0.40	0.51	0.38	0.45
3	Sorbitol	%	14.78	17.32	18.35	19.11	18.14	16.45	19.42	17.74	18.64	18.32	16.66	16.74	15.01	17.45	19.05
4	Sodium Bicarbonate	ppm	45.1	65.7	32.5	44.5	31.3	22.8	22.1	28.6	65.6	62.5	76.8	84.5	25.1	85.2	47.5
5	Titanium dioxide	%	0.48	0.62	0.48	0.32	0.84	0.66	0.67	0.38	0.46	0.88	0.92	0.74	0.89	0.55	0.84

n.	Ingredients	Sample toothpastes with highest level of the ingredients	Sample toothpastes with lowest level of the ingredients
1	Sodium Lauryl Sulphate (SLS)	1.51% - Colgate Max Fresh 1.32% - Pepsodent G 1.21% - Colgate Visible White - Dazzling White	0.87% - Vicco Vajradanti 0.89% - Colgate Charcoal 0.94% - Colgate Active Salt-Lemon
2	Sodium Bi Carbonate ($NaHCO_3$)	84.5ppm – Close-up 12 hrs protection 76.8ppm – Dauber Red 65.7ppm – Colgate Active Salt	22.1ppm – Pepsodent Clove Salt 22.8ppm – Colgate Diamon Attraction 25.1ppm – Colgate Max Fresh
3	Sodium hydroxide (NaOH)	2.50 ppm – Close-up Diamond Attraction 1.50 ppm – Colgate Strong Teeth 1.05 ppm – Dauber Red	0.35ppm - Colgate Visible White – Dazzling white 0.40ppm - Close-up 12 hrs protection 0.45ppm- Vicco Vajradanti
4	Sorbitol	19.42% - Pepsodent Clove Salt 19.11% - Colgate Active Salt– Lemon 19.05% - Vicco Vajradanti	14.78% - Colgate Visible White – Dazzling White 15.00% - Colgate Max Fresh 16.45% - Close-up Diamond Attraction
5	Titanium Oxide (TiO_2)	0.92% - Dauber Red 0.89% - Colgate Max Fresh	0.32% - Colgate Active Salt- Lemon

		0.88% - Himalaya Sparkling White	0.38% - Pepsodent G 0.46% - Pepsodent (Cavity protection)

Table 3: The maximal and minimal quantities of the selected inactive ingredients in the three kinds of toothpaste among the samples