

Addition of Steroids in Medicated Dentrifices marketed in Pakistan: a Possible Serious Health Hazard

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Abstract

Objective:

To determine whether some dentrifices contain steroids.

Material & Methods:

Samples of 20 brands claiming to have any medicinal benefit and readily available in the open market were submitted for testing for the presence of steroids to the Pakistan Council of Scientific and Industrial Research Laboratories, Karachi.

Results:

Eight samples tested positive on the first test and seven were positive after a second, confirmatory test.

Conclusion:

All these brands are freely available over the counter and their labels do not list steroid as an ingredient. Exposing consumers unknowingly to steroid may be regarded as a serious health hazard. Our state regulatory bodies and media need to play an active role in the prevention and monitoring of such possibly unethical marketing (JPMA 53:332;2003).

Introduction

Plaque is the major contributing factor to dental caries and periodontal disorders. As part of good oral hygiene measures, toothpastes play an important part in disease prevention. In addition to flavoring, toothpastes basically contain detergents and polishing agents. Additionally, toothpastes may contain additives for particular benefits, such as anticaries or antimicrobial effect or inhibition of the formation of tartar.¹ Active agents commonly incorporated in dentrifices include Chlorhexidine, Triclosan (Antimicrobial); Potassium Nitrate and Stannous Fluoride (Desensitizers); Sodium Fluoride, Sodium Monofluorophosphate, Acidulated phosphate Fluoride (Anti-cariogenic). According to the International Standards Organization these dentrifices are categorized as 'medicated' and defined as, "any dentfrice containing or claimed to contain ingredients having a beneficial, preventive or therapeutic action on oral tissues".²

Corticosteroids have limited use in the routine management of oral disease. At best, they are indicated in conditions not amenable to other measures and drugs. Steroids are known for their 'masking effects' and their abuse is documented in a previous study in the country.³ Their incorporation in some dentfrice brands was suspected from anecdotal reports of quick, symptomatic, relief from inflammatory diseases like gingivitis and periodontitis. Further, some toothpaste brands claim to 'cure' all diseases of teeth and gums without listing the active therapeutic ingredients on the label. Since toothpaste is

not included in the list of items under compulsory monitoring by the Pakistan Standard and Quality Control Authority⁴, manufacturers are not legally bound to follow Pakistan Standards Institution's specifications for toothpastes.⁵ We have not been able to find any reference in the international literature to the incorporation of steroids in over-the-counter dentifrices. In view of this possibility we decided to test some of these proprietary products for the presence of steroids.

Materials and Methods

One tube each of twenty locally marketed toothpaste brands, claiming therapeutic value in oral and dental problems, and thus falling into the category of medicated dentifrice, were purchased from a major store. These samples were tested for steroid at the Pakistan Council of Scientific and Industrial Research (PCSIR) Laboratories. The standard protocols of British Pharmacopoeia⁶ were followed in carrying out qualitative and quantitative tests for the presence of steroid. In order to avoid the possibility of batch contamination fresh samples of those brands that tested positive were purchased from another store in an entirely different area of the city after a gap of four months and submitted for re-testing. Samples that tested negative for steroid in the first test were excluded

Results

Eight out of twenty brand samples tested positive for the presence of steroid (cortisone). Both qualitative and quantitative tests were done on seven of the brands. (Quantitative test on one steroid-positive brand-sample was not done). In the second qualitative test of these eight samples, seven were found to contain steroid. (Table 1). The remaining twelve brands that were negative for steroid initially were not re-submitted for second analysis. (Table 2). The brands, purchasing date and date of reporting by the PCSIR are listed in the tables.

Discussion

According to the International Standards Organization (ISO) a medicated dentifrice is defined as, "any dentifrice containing or claimed to contain ingredients having a beneficial, preventive or therapeutic action on oral tissues".⁷ In the specifications for toothpaste standards by the Pakistan Standards Institution there is no reference regarding medicated dentifrices.⁵ Our review of the standards for toothpastes made by neighboring countries of India and Sri Lanka showed special mention of the same. Clause 2.2.4, regarding composition of toothpastes in the Sri Lankan standard states, "any other substance whose therapeutic or prophylactic functions have been clinically established may be used".⁸ Indian Standard for toothpaste, in its foreword, categorically states that medicated toothpastes (which are produced under drugs license) claiming therapeutic value to teeth and gums such as control of plaque and tartar are not covered.⁹ According to Medicines Control Agency of the United Kingdom, toothpaste is generally considered as a cosmetic, but if it is marketed with claims to treat or prevent "sensitive" teeth or contains an active ingredient known to have such an effect then it would fall within the definition of a medicinal product and be subject to medicines control.¹⁰ In Pakistan no specific standard or regulations exist under which production and marketing of medicated dentifrices can be regulated. Toothpastes do not come under the head of compulsory

items of Pakistan Standards and Quality Control Authority, the manufacturing of which could be monitored.¹¹ There are no medicated dentifrices produced in Pakistan under a drugs license granted by the Ministry of Health. It is left to the discretion of manufacturers to use any ingredient in any amount.

The adjunctive role of toothpastes in the overall management of oral health care is well documented.¹²⁻¹⁴ Epidemiological studies, based on the tooth surface as a unit of reference, confirm a strong correlation between dental plaque and the initiation of dental caries and periodontal disease. Therefore, prevention of caries and periodontal disease must be based on plaque control. Dental plaque can be controlled mechanically and chemically. Dentists and dental hygienists can achieve both methods in the population through proper promotion of home self-care and by professional treatment. Chemical antimicrobial products are used for non-specific plaque control, as well as against specific microbes associated with the etiology of caries and periodontal disease.¹⁵ The plaque control product formulations have been extensively discussed in the literature.¹⁶⁻¹⁹ We were unable to find any reference in the international literature regarding the use of steroid compounds or preparations in products labeled as dentifrices and marketed over the counter.

According to ISO specifications all ingredients (on the label of toothpaste-brand) shall be mentioned according to the International Nomenclature of Cosmetic Ingredients (INCI) Dictionary or with descriptive names of ingredients: "identification of ingredient shall be consistent with the dictionary, which states how the declaration should be made and ingredient identified".²⁰ In none of the dentifrices that tested positive was steroid cited as an ingredient. Since this is a pharmacological agent the product would automatically come into a drug category requiring prior approval and licensing by the Health Ministry. This is both expensive and time consuming. Further, the manufacturers / agents would need to show documentary evidence from the international literature, or significant local clinical evidence, of the therapeutic benefits of that addition. Some of the brands did not list their ingredients at all.

The finding of illegal, and possibly hazardous, addition of corticosteroids in dentifrices raises a number of issues of public interest. First, the role of government regulatory and monitoring bodies needs to be re-defined particularly in terms of over-the-counter oral health products. Products like medicated toothpastes must be monitored to ensure their safety and verifiability of ingredients for use in dental diseases. The International Standard Organization's specifications can be followed in determining these regulations. Once this is done it must be monitored periodically and any manufacturer found to violate the regulations must be made to face strict punitive measures.

As earlier mentioned, steroids when administered unwarrantably and irrationally can obscure the true diagnosis of the inflammatory disease as seen in systemic disorders (e.g. Rheumatoid Arthritis). Steroids are neither specific nor curative: instead they provide palliation by virtue of their anti-inflammatory and immunosuppressive actions.²¹ The quick relief of symptoms of pain, swelling and bleeding gums, by the unknowing use of steroid containing dentifrices, entices people to re-use that brand whenever symptoms recur or exacerbate. This would also be a logical alternative to an expensive dental consultation. The vicious cycle continues till a 'ceiling effect' of the amount of steroid is reached. There are no studies done so far on the long-term local effects of steroids when applied topically on gingiva. However the effects on skin are well documented. With

prolonged use side effects will be encountered, in the form of local atrophy, or as a result of systemic absorption, for example hypothalamic-pituitary-adrenal suppression and Cushing's syndrome.²² Its topical use is also associated with perioral dermatitis.²³⁻²⁵ It is quite possible that since oral mucosa has far greater absorptive capacity than skin systemic side effects may result earlier and with lesser steroid quantities. Further studies will be needed to confirm this possible relationship.

The role of advertising agencies and the media in possible unethical promotion of products and the routine publication of unverifiable or spurious claims is brought into question by this study. Pakistan needs to have an equivalent of the Advertising Standards Authority, an international watchdog body, whose functions include the monitoring of ethical advertising. The claims of some of these products to cure most dental diseases are not only grossly misleading but also fraudulent. Such claims are commonly propagated to the detriment of unsuspecting, often uneducated and mostly poor, people. Instead of educating people about the real causes of dental problems the media can, inadvertently, become a major source of misinformation.

Conclusion

potentially serious health hazard exists by the unknowing use of steroid containing toothpastes by the public. Medicated dentifrices must only be manufactured and marketed under license and the Advertising Standards Authority needs to investigate questionable claims and ethically approve such proposals before they are completed and readied for release. On the part of the government and the health authorities there is an urgent need for appropriate legislation and implementation to make sure that such products do not reach the market

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