ActaScientiarum
http://periodicos.uem.br/ojs/acta
ISSNon-line:1807-8648
Doi:10.4025/actascihealthsci.v47i1.72204

Presence and concentration of fluoride in dentifrices in the Brazilian market

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ABSTRACT. The use of fluoride dentifrices has contributed to a worldwide reduction in the incidence of dental caries. This study evaluated the dentifrices available on the Brazilian market regarding their fluoride content, concentration and registration status with the Brazilian National Health Surveillance Agency (Anvisa). Dentifrices were obtained from the Internet, pharmacies, and supermarkets. Anvisa registrations were verified through a search of the agency´s official website. All adult and children's dentifrices available in the Brazilian market were included in the search. Relevant information, such as product name, brand, presence, and fluoride concentration, was gathered from manufacturers' websites, sales websites, and product packaging (including leaflets). This data was systematically recorded for analysis. The data obtained were analyzed statistically using the chi-square test. Two hundred sixty dentifrices were identified in the Brazilian market during the research period from 2020 to 2023. Of these, 71.9% contained fluoride, 25.8% did not, and 2.3% did not provide any information regarding the presence or absence of fluoride. Among the fluoride dentifrices, 69.5% had at least 1000 ppm, the concentration recommended by the World Health Organization for an anti-caries effect. Additionally, 6.4% had lower fluoride concentrations, and 24.1% provided no information about fluoride concentration. Overall, 74.2% of the dentifrices were registered with Anvisa, while 25.8% did not present any registration. According to the fluoride concentrations provided by the manufacturers, only half of the dentifrices available on the Brazilian market contain at least 1000 ppm, the recommended concentration for effective caries prevention. The percentage of dentifrices that did not disclose fluoride concentration was significantly higher among those not registered with Anvisa. The large number of dentifrices that do not meet the recommended minimum fluoride concentrations undermines preventive measures for oral health promotion. It may increase the population's vulnerability to developing dental caries.

Keywords: dentifrices; toothpaste; fluoride; dental caries.

Received on May 27, 2025.
Accepted on October 08, 2025.

Introduction

Originally, dentifrices were developed to clean teeth only, but the addition of fluoride promoted an anti-caries effect, expanding the function of these products and their importance in public health. World Health Organization recommends a fluoride concentration in dentifrices of between 1000 and 1500 ppm for efficacy and its use as soon as the first tooth erupts (O'Mullane et al., 2016; Pitts et al., 2021; Unterbrink et al., 2024).

The dentifrice is the easiest way to enable frequent fluoride contact with the tooth for caries disease control (O'Mullane et al., 2016). The relevance of fluoride in prevention is well established, as it is the gold standard in remineralization compared to other active components (Amaechi & van Loveren, 2013; Elgamily et al., 2019; World Health Organization [WHO], 2023). The WHO has advocated its application since 1960 and considers its access a basic health right (O'Mullane et al., 2016; WHO, 2022). In the 1980s, most dentifrices available in developed countries were fluoridated, and the growing market for oral hygiene products has contributed to health promotion (Marinho et a., 2003).

Dental caries has already been identified as the most prevalent dental disease, affecting billions of people (Global Burden of Disease 2017 Disease and Injury Incidence and Prevalence Collaborators, 2018). Although increased treatment was observed (Qin et al., 2022), it was costly and unsuitable for the vulnerable population. (Benzian et al., 2022). Initial caries lesions, such as white spots can be treated by improving

hygiene, modifying eating habits, and applying fluoride (Weyant et al., 2013; Pitts et al., 2017); however, without treatment, it can progress, forming cavities, causing pain, tooth loss, and eventually systemic implications, affecting people's life quality (Pitts et al., 2017; Walsh et al., 2019). Therefore, it is important to invest in prevention strategies, especially in guiding the daily and home use of fluoride dentifrices (Marinho et al., 2003; Pitts et al., 2017).

Most of the population is unaware of the need for a minimum fluoride concentration of 1000 ppm in dentifrices to have anti-caries action. In Brazil, there's no law regulating this effective concentration, and new oral hygiene products are increasingly appearing on the market. The objective of this study was to evaluate the dentifrices available in the Brazilian market in terms of the presence and concentration of fluoride advertised by the manufacturers and their registration with the Brazilian National Health Surveillance Agency (Anvisa). The study aimed to determine whether the population has access to fluoride dentifrices with the appropriate concentration and whether the oral hygiene market contributes to the prevention of dental caries.

Materials and methods

Research methods

Dentifrices available in the Brazilian market were identified through online searches, pharmacies, and supermarket surveys, from 2020 to 2023.

An online search was conducted using various search engines, e-commerce platforms, supermarkets, and pharmacies in Brazil. This study began during the COVID-19 pandemic, which posed risks of contamination, and the following terms were used in the search strategy: "dentifrices", "toothpaste", "oral hygiene", "fluoride", and product brands.

In-person research was conducted in pharmacies and supermarkets located in the state of Rio de Janeiro, covering major national chains in the cities of Rio de Janeiro, Niterói, Petrópolis, Itaboraí, and Cabo Frio.

Product registrations with Anvisa were verified through individual searches on the agency's website for each dentifrice found.

Data collection

Both adult and children's dentifrices found were included in the study.

Relevant information for each dentifrice was recorded, such as product name, brand, the presence and concentration of fluoride. This data was collected from manufacturer's websites, sales platforms, and product packaging (leaflets).

Data analysis

The data obtained were submitted for statistical analysis using the chi-square test, which was performed using R 4.0.5 software (https://cran.r-project.org).

Results

This study identified a total of 260 dentifrices on the market in Brazil.

Among these, 187 (71.9%) contained fluoride, 67 (25.8%) did not, and 6 (2.3%) did not provide information regarding the presence of fluoride. As for the fluoride concentration, 130 (50%) had more than 1000 ppm, necessary for the anticaries effect, of which 129 (49.6%) were between 1000 and 1500 ppm, as recommended by the WHO, and 1 (0.4%) with 5000 ppm; 12 (4.6%) had less than 1000 ppm; and 45 (17.3%) did not indicate the amount.

Anvisa was contacted with a request for records of dentifrices in Brazil and informed that there is no list of dentifrices regulated by the agency. Individual searches on the Anvisa website revealed that of the 260 products reviewed, 193 (74.2%) were registered, while 67 (25.8%) were unregistered.

According to Table 1, 82.9% of the dentifrices registered with Anvisa contained fluoride, and 40.3% of the unregistered dentifrices were fluoridated ($p < 0.001$). The percentages of dentifrices that did not report the presence of fluoride were similar between registered and unregistered products.

Table 2 compares the characteristics of 187 fluoridated dentifrices with and without registration. The percentage of products that did not report the fluoride concentration was significantly higher among the

unregistered products ($p < 0.001$). However, among registered products, 26 (16.2%) did not provide this information. Furthermore, 58 (31%) of the fluoridated dentifrices either fell outside the recommended fluoride range (1000 to 1500 ppm) or did not report their fluoride concentration.

Table 1. Distribution of fluoride presence according to registration with Anvisa.

Presence of fluoride	Anvisa registration		
	No	Yes	Total
Yes	27/67 (40.3%)	160/193 (82.9%)	187/260 (71.9%)
No	39/67 (58.2%)	28/193 (14.5%)	67/260 (25.8%)
Not reported	1/67 (1.5%)	5/193 (2.6%)	6/260 (2.3%)

p-value for chi-square test for association < 0.001.

Table 2. Distribution of recommended fluoride concentration according to Anvisa registration.

Fluoride concentration	Anvisa registration		
	No	Yes	Total
Above recommended	0/27 (0.0%)	1/160 (0.6%)	1/187 (0.5%)
Within the recommended range	7/27 (25.9%)	122/160 (76.2%)	129/187 (69.0%)
Less than recommended	1/27 (3.7%)	11/160 (6.9%)	12/187 (6.4%)
Not reported	19/27 (70.4%)	26/160 (16.2%)	45/187 (24.1%)

p-value for chi-square test for association < 0.001.

Figure 1 displays a histogram of the presence and concentration of fluoride in the dentifrices found in the survey and highlights the high number of products that either did not contain fluoride or did not report its concentration. It also shows the predominance of the 1450 ppm concentration in fluoride dentifrices.

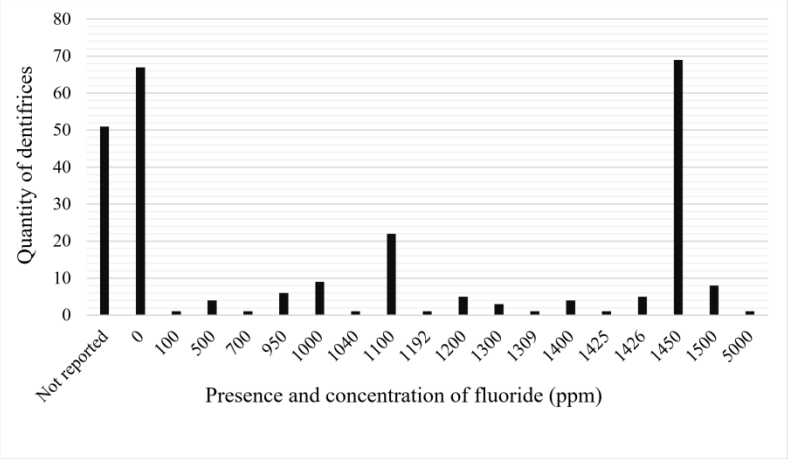

Figure 1. Histogram of the presence and concentration of fluoride (ppm) in dentifrices.

Discussion

Dental caries is a chronic, non-communicable, multifactorial, biofilm-sugar-dependent disease (Pitts et al., 2021; Meyer et al., 2024; Unterbrink et al., 2024). Repeated sugar consumption triggers an acid challenge, resulting in a drop in the pH of the biofilm fluid and demineralization of enamel and dentin (Weyant et al., 2013; Pitts et al., 2017).

The COVID-19 pandemic and associated social isolation have significantly impacted people's health (Barros et al., 2020). During this period, oral health problems were associated with mental health disorders (Tiwari et al., 2021), and a marked increase in depression and anxiety was observed in adults (Barros et al., 2020), as well as in children and adolescents (Oliveira et al., 2022). This period also saw a deterioration in dietary habits, with increased consumption of sugary foods and alcohol, neglect of oral hygiene, and fear of seeking dental care due to the risk of contamination (Wdowiak-Szymanik et al., 2022).

The incidence of caries in permanent teeth reached more than 3 billion cases before the pandemic. The post-COVID-19 period unleashed an even more alarming situation, perpetuating caries as a public health issue (Qin et al., 2022). Caries have a relevant impact on quality of life, highlighting the greater susceptibility of the population in disadvantaged socioeconomic conditions (Lamster, 2021; Benzian et al., 2022).

Studies indicated that access to dental care and restoration of caries lesions have increased. However, the incidence of caries continues to grow. Individual treatment of the disease demands more resources than a population-based prevention approach, which would direct health investments in a more equitable and resolute manner, favouring a greater number of patients (Walsh et al., 2019; Watt et al., 2019; Qin et al., 2022; Bomfim et al., 2024).

Fluoride reduces demineralization and promotes remineralization of enamel and dentin (Madhuri & Buggapati, 2017; Ten Cate & Buzalaf, 2019; Fernando et al., 2024; Unterbrink et al., 2024). Fluoridation of water, salt, and milk are possible prevention strategies (Pitts et al., 2017; Jullien, 2021), but daily and home use of fluoride dentifrices is the most cost-effective self-applied method, covering all ages and maintaining frequent contact with dental structures (Marinho et al., 2003; Twetman et al., 2003; Madhuri & Buggapati, 2017; Pitts et al., 2017). Fluoride dentifrices' application has shown benefits (Amaechi & van Loveren, 2013; WHO, 2023), decreasing the incidence of the disease worldwide (Marinho et al., 2003; Twetman et al., 2003; O'Mullane et al., 2016; Walsh et al., 2019), while treating early caries lesions, enabling minimally invasive dentistry (Cochrane et al., 2010; Pitts et al., 2017; Watt et al., 2019).

The presence of fluoride may not be sufficient for the anti-caries effect of dentifrices since this demands a concentration above 1000 ppm (Walsh et al., 2019; WHO, 2023). The present study observed that 30.5% of fluoride dentifrices did not report or show the recommended concentration; the concentration of 1450 ppm was the most observed in these products, at 36.9%. Concentrations higher than the WHO guideline demonstrate greater caries prevention, such as the 5000 ppm found in the present study, but should be accessible only by professional prescription and for specific indications (Wong et al., 2011; Yeung, 2014; O'Mullane et al., 2016; Pitts et al., 2017; Walsh et al., 2019).

In many countries, the growth of the oral hygiene commerce sector and increased consumption of dentifrices have contributed to promoting oral health, as the sale of fluoride dentifrices is greater than 95% (O'Mullane et al., 2016). However, this study demonstrates the worrisome number of products available in the Brazilian market that do not prevent caries (50%) and do not contribute to the fight against this disease so important for public health - 28.1% of the dentifrices found do not have or do not report the presence of fluoride, and 21.9% do not report or do not present a concentration above 1000 ppm.

The Brazilian regulatory agency only specifies a maximum of 1500 ppm of fluoride in dentifrices for safety (Cury et al., 2015), while the WHO also recommends a minimum fluoride concentration of 1000 ppm for efficacy against dental caries and considers it an essential medicine (WHO, 2023). The agency does not provide a list of registered dentifrices, and it was not possible to confirm whether the 260 products cover the entire Brazilian market.

Social isolation emphasized the significance of the online market, which achieved an even greater increase during and after the pandemic (Shen et al., 2022). In this research, there was difficulty in finding information regarding the presence and concentration of fluoride on the internet, and this was often only presented in the images of the packaging, with the leaflet available in small print. The brands do not use fluoride to attract the selection and purchase of the products and do not emphasize its importance. The advance of e-commerce in the oral hygiene market needs to be accompanied by a quality service with clearer information, complete product descriptions and easy website access so that the consumer can make the purchase with greater safety, and not only through information from advertising campaigns.

On-site research in pharmacies and supermarkets did not identify any dentifrices other than those found online. This study was based on the information provided by the brands via the Internet and on the packaging of the products. Future research should evaluate whether the reported fluoride concentration matches the actual content of the dentifrices and whether it remains available for caries prevention during shelf life. Previous research has shown that marketed dentifrices had a lower total fluoride concentration than claimed and that they did not have the total fluoride concentration in soluble form (Ramos et al., 2022; Valadas et al., 2023a; Valadas et al., 2023b).

An Anvisa packaging guideline for dentifrices could be established, highlighting the correct concentration of fluoride, as well as information on excess sugar in food products, which would facilitate access to information by professionals and consumers. The Brazilian population should be warned about the importance of the presence and concentration of fluoride for oral health, and professionals should prescribe appropriate products for caries prevention, including those with fluoride concentrations below 5000 ppm. In this way, the promotion of oral health and the prevention of dental caries would be increased in accordance with WHO resolutions (Lamster, 2021; WHO, 2022).

Conclusion

This study found 260 dentifrices available on the Brazilian market, but only half of them contained the minimum fluoride concentration of 1000 ppm required for effective caries prevention.

The percentage of dentifrices that did not report the fluoride concentration was significantly higher among those not registered with Anvisa.

Despite the expansion of the oral hygiene market, the increase in the number of products has not improved oral health promotion, leaving the Brazilian population more vulnerable to dental caries.

Acknowledgments

The authors would like to thank Centro Integrado de Tradução e Escrita (CITE/UFF) for assistance with English language translation and developmental editing.

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