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Pepelascov, Daniele Esteves; Fujimaki, Mitsue; Cury, Jaime Aparecido; Tabchoury, Cíntia Pereira Machado; Villalobos, Jorge Ulises Guerra; Terada, Raquel Sano Suga
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Fluoride concentration and labeling requirements of mineral bottled water from Brazil

Concentração de fluoreto e rotulagem de águas minerais engarrafadas no Brasil

Daniele Esteves Pepelascov^I

Mitsue Fujimaki^I

Jaime Aparecido Cury^{II}

Cíntia Pereira Machado
Tabchoury^{II}

Jorge Ulises Guerra Villalobos^I

Raquel Sano Suga Terada^{I,*}

ABSTRACT

Introduction: Mineral waters usually contain natural fluoride (F) in their composition, but the benefits and risks of the concentrations found are not clearly informed. **Objective:** The aim of this study was to determine the F concentration in mineral bottled waters and to check if the concentrations found: (1) matched with those informed on the label and (2) were coherent with claims on the label about the anticaries benefits and the risks of fluorosis. **Method:** Two batches of twenty brands, in all forms of commercial presentation found, were analyzed. F concentration was determined in duplicate using ion-specific electrode. Labels were analyzed regarding the F concentration informed. **Results:** Mean F concentration was 0.08 ppm, ranging from <0.05 to 0.33 ppm. The F concentrations found were generally consistent with the concentrations informed. None of the waters analyzed presented F concentration either to have anticaries effect or fluorosis risks. However, 19 of the 20 brands evaluated highlighted on the labels that their products were “fluoridated bottled water”, suggesting that the concentrations found were “optimal” for the balance benefits/risks of F use. **Conclusions:** In order to avoid misleading information to the consumers, the current regulations on the composition of F in bottled water as well as their labeling should be revised.

KEYWORDS: Fluorides; Commercial Water Consumption; Bottled Water; Food Labeling; Primary Prevention

RESUMO

Introdução: Águas minerais contém fluoreto (F) em sua composição natural porém os benefícios e os riscos da concentração presente não são claramente informados. **Objetivo:** O objetivo deste estudo foi determinar a concentração de F em águas minerais engarrafadas e verificar se as concentrações encontradas: (1) condiziam com as informadas no rótulo e (2) eram coerentes com o declarado quanto aos benefícios anticáries e risco de fluorose. **Método:** Dois lotes de vinte diferentes marcas, em todas as formas de apresentação comercial, foram analisadas. A concentração de F foi determinada em duplicata, utilizando um eletrodo íon-específico. Os rótulos foram analisados em relação a concentração de F informada. **Resultados:** A média de F encontrada foi de 0,08 ppm, variando entre <0,05 a 0,33 ppm. As concentrações de F encontradas foram, em geral, consistentes com a concentração informada. Nenhuma das águas analisadas apresentou concentração suficiente pra ter efeito anticárie tampouco para risco de fluorose. Entretanto, 19 das 20 marcas destacavam nos rótulos que se tratavam de “água mineral fluoretada”, sugerindo que as concentrações presentes seriam “ótimas” em termos de benefício/risco do uso do F. **Conclusões:** Com o objetivo de evitar informações que poderiam confundir o consumidor, a legislação sobre a concentração de F em águas minerais, assim como a rotulagem deveria ser revisada.

^I Universidade Estadual de Maringá (UEM), Maringá, PR, Brasil

^{II} Faculdade de Odontologia de Piracicaba (FOP), Piracicaba, SP, Brasil

* E-mail: rssterada@uem.br

PALAVRAS-CHAVE: Fluoretos; Consumo Comercial de Água; Água Engarrafada; Rotulagem de Alimentos; Prevenção Primária

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INTRODUCTION

Water is a natural resource essential for life and its quality is directly associated with good health. The consumption of bottled water has increased worldwide in recent years^{1,2,3}. In 2014, the global consumption of bottled water was approximately 283 billion liters, while in Brazil, the production of mineral water in 2014 grew approximately 3.9%. At the end of 2014, there were 2008 active mineral and drinking water concessions in the country⁴.

The Health Surveillance Secretary, under the Ministry of Health (HSS/MS), is responsible for regulating the quality of drinking water in Brazil⁵. The Secretary lays down several parameters about the potability of drinking water⁵. However, the regulation cannot be used for mineral water. Taken in excess during tooth formation, fluoride (F) can lead to fluorosis⁶, which, in turn, can cause both aesthetic and functional problems. On the other hand, it has already been established that the consumption of fluoridated drinking water with optimal F concentrations has a preventive action against caries^{7,8}.

The Brazilian National Health Surveillance Agency (Anvisa in portuguese)/MS ordinance of 1999⁹ and the Brazilian Ministry of Mining and Energy decree of 1945¹⁰ establish that “information on possible characteristics, therapeutic properties, expressions that overrate the water, or any designation susceptible of causing confusion to the consumer shall not appear on the label or on the sides of the packaging”^{9,10}. Thus, the inclusion of the term “fluoridated bottled water” on the packaging could lead consumers to believe that the water presents some anticaries effect. The expression in this case overrates the water and, thus, both the ordinance and the decree are being violated. On the other hand, Anvisa’s resolution n° 274, 22th September 2005 requires that fluoride content in the water is informed on the packaging when it is present in amounts greater than 1 ppm¹¹, although no warning is required that water with this F concentration may cause risk of fluorosis. The Anvisa’s ordinance n° 540, 11th February 2014, in turn, classifies water as fluoridated when the fluoride content exceeds 0.02 ppm¹². In other words, labels should provide this information, even when the water contains F in low concentrations. In this case, consumers should also be clearly informed on the potential anticaries effect or the risk of fluorosis in the consumption of water. Bearing in mind the abundance of brands of mineral water in the market, the legislation is not clear about how bottled water should inform F content. Thus, neither the risk of fluorosis nor the F anticaries benefits are clearly informed to consumers.

Previous studies showed that the concentration of F in mineral bottled water varies throughout Brazil and other countries^{1,3}. In the city of São Paulo, the levels of F of 35 local brands ranged from 0.01 to 2.04 mg/l¹³. Concentrations ranging between 0.0 and 4.4 ppm F were also found among 104 brands of bottled water sold in the Brazilian market¹⁴. Additionally, it was shown that mineral bottled water labels did not follow Anvisa’s regulations concerning the content of F; while several brands showed F concentrations above the recommended levels, and did not inform them on the labels, others showed concentrations below the required levels, although the labels still announced “contains fluoride”^{14,15}.

Although studies in different Brazilian states and cities highlighting the importance of controlling the levels of F in mineral bottled water have been performed, to the best of our knowledge no study has evaluated both F concentration and labeling of mineral bottled water sold in Maringá-PR. Therefore, the aim of this study was to determine the concentrations of F in bottled mineral bottled water consumed in the city of Maringá-PR, and whether these concentrations matched those informed on the label.

METHOD

Sampling

Samples of mineral bottled water were collected from 20 brands of bottled water commercially available in supermarkets, grocery stores, bakeries, and wholesalers in the city of Maringá, Paraná state, Brazil. All forms of commercial presentation, that is, bottle, gallon or cup, found were evaluated. Seven brands had two forms of commercial presentation, while two brands had three different forms of commercial presentation. Two different batches from each brand and each form of commercial presentation were analysed. Among the 31 items acquired, 20 were produced in Paraná state (Almirante Tamandaré, Apucarana, Campo Largo, Cornélio Procopio, Iguaçu, Maringá, Rolândia), 10 in São Paulo state (Águas de Santa Bárbara, Bauru, Campos do Jordão, Itu, Presidente Prudente), and 1 in Minas Gerais state (São Lourenço). The 62 samples were collected from different size plastic containers as follow: 16 from gallons, 38 from bottles, and 8 from cups (Table 1).

Evaluation of the labels

The concentrations of F informed on the labels and any other information about fluoride content were recorded for later comparison with the measured F content. Also, any mention of “fluoride mineral water” was registered.

Determination of F content

The analysis of F content was conducted with a fluoride-specific electrode (Orion 9609, Orion Research Inc., USA) and an ion analyzer (Orion 710-A, Orion Research Inc., USA). The electrode was calibrated with fluoride standard solutions of 0.125, 0.250, 0.500 and 1.000 ppm in triplicate. The sensitivity of the fluoride electrode was approximately 0.05 ppm F, and fluoride concentration was expressed in ppm F.

The analysis of F concentration considered the levels that can prevent caries and those that may cause fluorosis for a geographical area with temperatures ranging between 26.3°C and 32.5°C (Table 2), as proposed for public water supply during the II Workshop on Surveillance of Water Fluoridation, by The Ministry of Health Oral Health Surveillance Collaborating Centers (CECOL/USP 2011)⁷.



Table 1. Information about water samples.

Code*	Batch	State in Brazil	Type of container	Claim
1.1	L082, L08	Paraná	bottle	Fluoridated bottled water
1.2	L366, L40		gallon	
2.1	513, 517	São Paulo	bottle	Fluoridated bottled water
2.2	426, 824		gallon	
3	16,025	Paraná	bottle	Fluoridated bottled water
4	17/3/11, 3/2/11	Paraná	bottle	Fluoridated bottled water
5	656-I, 693-I	Paraná	bottle	Fluoridated bottled water
6.1	132, 137	Paraná	bottle	Fluoridated bottled water
6.2	18/4/11 e 16/5/11		cup	
7.1	90, 95	Paraná	bottle	Fluoridated bottled water
7.2	187, 251		gallon	
8	143, 189	Paraná	bottle	Fluoridated bottled water
9.1	364, 55	Paraná	bottle	Fluoridated bottled water
9.2	192, 159		gallon	
9.3	116, 89		cup	
10	14/5/11, 31/3/11	Paraná	bottle	Fluoridated bottled water
11	L37SP, L48SP	São Paulo	bottle	Fluoridated bottled water
12	13/310, 16/3/10	São Paulo	bottle	Fluoridated bottled water
13.1	2622-E, 2549-E	Paraná	bottle	Fluoridated bottled water
13.2	10.879-R-1, 11.060-R-1		gallon	
13.3	1431-B, 3195-A		cup	
14.1	264, 110	Paraná	bottle	Fluoridated bottled water
14.2	190, 249		gallon	
15	6/3/2010, 7/11/09	Minas Gerais	Bottle	Fluoridated bottled water
16	1019L03, 10246L05	São Paulo	gallon	Fluoridated bottled water
17.1	39, 176	São Paulo	bottle	None
17.2	189, 247		gallon	
18	901144, 899100	São Paulo	bottle	Fluoridated bottled water
19	5/2/11, 16/4/11	Paraná	bottle	Fluoridated bottled water
20.1	4P220410, 4P240310	São Paulo	bottle	Fluoridated bottled water
20.2	11105P130510, 11104P170511		cup	

* The Brands have been omitted.

Table 2. Concentration of F in water (ppm F) that can prevent caries or cause fluorosis for regions within temperatures ranging 26.3°C-32.5°C.

Content of F in water (ppm F)	Prevention of caries	Risk of fluorosis
0.00-0.44	Insignificant	Insignificant
0.45-0.54	Low	Low
0.55-0.84	Maximum	Minimum
0.85-1.14	Maximum	Moderate
1.15-1.44	Questionable	High
1.45 or more	Harmful	Very high

Note: Translated from the original document issued by Collaborating Center of Ministry of Health in Surveillance of Oral Health (CECOL/USP 2011). Technical consensus on the classification of public water supply with regard to fluoride content (p. 2). São Paulo: School of Public Health, University of São Paulo; 2011.

RESULTS

All the analyzed labels informed the characteristics and composition of the water. Of the 20 brands analyzed, 19 labeled their products as “fluoridated mineral water” and informed the content of F. Only one brand, sold in gallons and bottles, did not inform the concentration of F. However, analysis showed it had 0.17 ppm F, in both containers and batches.

The actual concentrations of F were generally consistent with the concentrations informed on the labels. Table 3 shows the concentration of F informed on the label (Informed) and those measured in the analyses (Found) for each type of plastic container. The actual F content ranged from < 0.05 to 0.33 ppm F. Bearing in mind the classification for F content proposed by CECOL⁷, all specimens showed levels that neither prevent caries



Table 3. Fluoride concentration (ppm F) informed on the label and found (Mean+/-SD; n = 2) according to the mineral bottled waters analyzed.

Water code	F concentration informed (ppm)	F concentration found (ppm)
1.1	0.28	0.33 ± 0.000
1.2	0.28	0.32 ± 0.000
2.1	0.04	0.09 ± 0.007
2.2	0.04	0.07 ± 0.014
3	0.05	0.10 ± 0.000
4	0.02	< 0.05 ± 0.000*
5	0.03	0.06 ± 0.000
6.1	0.07	< 0.05 ± 0.000*
6.2	0.07	< 0.05 ± 0.007*
7.1	0.02	< 0.05 ± 0.000*
7.2	0.02	< 0.05 ± 0.007*
8	0.02	< 0.05 ± 0.000*
9.1	0.07	0.07 ± 0.0141
9.2	0.07	0.07 ± 0.000
9.3	0.07	0.07 ± 0.014
10	0.02	< 0.05 ± 0.007*
11	0.05	< 0.05 ± 0.014*
12	0.09	0.07 ± 0.000
13.1	0.03	< 0.05 ± 0.000*
13.2	0.03	< 0.05 ± 0.007*
13.3	0.03	0.06 ± 0.000
14.1	0.2	0.08 ± 0.007
14.2	0.05	0.08 ± 0.007
15	0.11	0.11 ± 0.007
16	0.09	0.08 ± 0.007
17.1	Not informed	0.17 ± 0.014
17.2	Not informed	0.17 ± 0.007
18	0.06	0.16 ± 0.007
19	0.02	0.08 ± 0.000
20.1	0.06	0.11 ± 0.064
20.2	0.05	< 0.05* ± 0.000

*Values below the limit of the electrode sensitivity, approximately 0.05 ppm F.

nor cause fluorosis. Different batches of the same brand showed small variations in F concentration.

DISCUSSION

Consumption of mineral bottled water has been growing in Brazil and around the world^{1,2,14}. The global market consumed 6.2% more mineral bottled water in 2014 than in 2013, while in Brazil the informed total annual production of 75.59 billion liters correspond to less than 40% of the estimated consumption of water in the country⁴. In 2014, 71% of mineral bottled water volume was commercialized in returnable 20-liter bottles, while 27% in small plastic bottles, with an increase in disposable packaging when compared to 2013⁴. Thus, controlling water chemical constituents and its potability has become essential. In Dentistry, F content in water is relevant as its presence can have beneficial or detrimental consequences to the patient, depending on its concentration.

In Maringá, the distribution of mineral bottled water began in the 1990s¹⁶, with most distributors established in the center of the city, according to data collected in 2003¹⁶. Over time, distribution reached more peripheral areas of the city and, nowadays, apart from the usual retailing points, the local phone directory shows mineral water distributors in several districts of the city¹⁶.

The results of the present study showed that F content in the mineral bottled water commercialized in Maringá is safe for consumption, showing no risks for dental fluorosis. In contrast, however, the concentrations found are not helpful in preventing caries either. Similarly to the present study, previous research conducted in the Brazilian market found F content in mineral bottled water at levels that cannot prevent caries^{13,14,15,17,18,19}. However, some of these studies^{13,14,15,17,20} also found F concentrations above recommended levels, up to 4.4 ppm F. Of 199 brands analyzed, 22 presented concentrations above 0.8 ppm F^{13,14,15,17}. The Ministry of Health²¹ establishes that F content in water should range between 0.6 and 0.8 ppm for cities with temperatures between 26.4°C and 32.5°C, such as Maringá. However, if one considers the classification proposed by CECOL⁷ (Table 1) regarding the safe limit of F content in public water supply for cities within these temperatures, 11 brands analyzed in those studies would present levels above 1.15 ppm F^{13,14,15,17}. A comparison between the classifications proposed by CECOL⁷ and those by the Ministry of Health²¹ shows that, on one hand, the former stratifies the different levels of risks and benefits for the development of caries and fluorosis, both considered as chronic diseases. On the other hand, the latter simply presents a dichotomous classification of F concentrations, within which F content is adequate or not. Therefore, there are no clear parameters for F content in mineral bottled water that would unambiguously regulate concentrations in ranges safe for consumption and that bring no risks to oral health, making the discussion about appropriate F concentrations extremely relevant. To date, the Ministry of Health⁵ establishes the potability threshold for drinking water at 1.5 ppm F, above which the water is not adequate for consumption.

Mineral water is defined as water taken directly from the source, with no addition of any chemicals. Thus, no recommended F concentration for this type of water is possible. However, based on the beneficial and harmful levels of F as proposed by CECOL⁷ for artificially fluoridated water, the present study found amounts of F that can neither prevent caries nor cause fluorosis. The chemical composition of bottled mineral water depends on the geological characteristics of the source. Usually, fluorite is the mineral that controls the geochemical content of F in water - its solubility limits the concentration of F in water²². Water with low calcium content may have high concentrations of F because of the low solubility product of fluorite²³. The amount of F released by the dissolution of fluorite in low ionic strength waters ranges between 8 and 10 ppm. However, the concentration of Ca²⁺, Na⁺, OH⁻ and some complex ions, such as Fe, Al, B, Si, Mg, and H, may affect F concentration range²⁴. Alternatively, ion exchange (OH⁻ for F⁻) in different types of clay may explain high F content in water (values above 30 mg/L), as some ion exchange (Ca²⁺ and Mg²⁺ for Na⁺) can progressively increase the pH to a more alkaline level (pH 9-10.5)²². These parameters should be further investigated in the future.



As for the analysis of the labels, two aspects were taken into consideration in the present study: the informed F content, and the use of the term “fluoridated mineral water”. As for the F content, the informed concentrations were generally in accordance with the actual measured values, different from previous studies that showed large discrepancy between informed and actual F levels^{13,14,17,19}. Such difference was frequently found for the bottled mineral water sold in Araraquara, SP (30 out of 31 brands)¹⁷, in São Paulo city, SP (88 out of 229 specimens)¹³, in Ponta Grossa, PR (four out of five)¹⁹, and for brands sold in different states of Brazil (87 out of 104)¹⁴.

In the present study, one out of the 20 brands of mineral bottled water did not inform the F content on the label, although the analysis revealed the presence of 0.17 ppm F. The manufacturer was contacted and reasoned that such low concentration did not need to be informed. Indeed, there is no legal requirement that obliges producers to inform F as one of the components of mineral bottled water. However, for an adequate description of the product and, hence, more control over a product that can be hazardous to oral health, uniform regulations should exist. Other researches in different countries claimed the same concern, i.e. “water companies should consider stating their fluoride content on their labels and allow an informed decision regarding consumption of fluoridated versus nonfluoridated drinking water”.^{25,26,27}

Despite the fact that the informed F content did not significantly differ from the measured concentrations, the present study found that most brands used the term “fluoridated mineral water” irregularly. That is, if the amount of F is not high enough to prevent caries, the term should not be used. Except for one brand, all the remaining brands showed the term “fluoridated mineral water” on their labels. Previous studies^{13,14,15,28} also found disagreement between the use of this term and the actual F content in the water. In some cases, information on F content was completely absent, while in others it appeared on labels when concentrations ≥ 0.049 ppm were found. However, producers are required by law¹¹ to inform “contains fluoride” and the exact F concentration over ≥ 1 ppm. Discrepancies such as these have also been demonstrated in other countries²⁸.

The National Department of Mineral Production (DNPM in Portuguese) is responsible for the chemical classification of mineral

water. The law concerning the subject¹⁰ establishes that mineral water should be classified according to its predominant element, and that the presence of rare elements such as iodine, arsenic, and lithium should be informed. Studies on F concentration in mineral bottled water^{13,14,15,19} performed in Brazil showed that F is not a rare substance - only 18 out of the 204 brands of mineral bottled water analyzed did not present detectable amounts of F in their samples.

Thus, according to the law¹⁰, the term “fluoridated mineral water” should only be used if F is the predominant element in the composition. Such information could mislead consumers into believing that the product contains enough F to prevent caries. Moreover, the DNPM reinforces the prohibition⁹ by stating that neither the packaging nor the label should mention any therapeutic properties or expressions that overrate the water or cause confusion among consumers. Thus, the labels examined in the present study seem to be in conflict with the law, and consumers should be made aware of the fact.

Therefore, this information should be made available to mineral bottled water manufacturers. Furthermore, uniform regulations are required to allow supervision and control of the information of products highly consumed by the population²⁸. The need to review the Brazilian regulatory standards on fluoridated products has also been highlighted for pre- and postnatal fluoridated medical supplies²⁹.

Future studies to monitor the consumption, F concentration, and the information on the labels of mineral bottled water should be conducted to ensure that the population has access to high quality mineral water with adequate descriptions.

CONCLUSIONS

The mineral bottled water commercialized in the city of Maringá presents no risk of fluorosis, but does not offer protection against caries either. Reformulation of the current regulations on F content in mineral bottled waters, as well as their labeling, is required, so that mineral bottled water producers and consumers can clearly know whether the F concentration in the water offers any beneficial effect.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.



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