

## Does bottled drinking water have anti-dental caries properties? A Systematic review and meta-analysis

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### Review Article

#### Abstract

**BACKGROUND AND AIM:** The growing consumption of bottled water has raised concerns about its quality. The optimal concentration of trace elements such as fluoride in drinking water is of significance for public health. Water with the optimal fluoride concentration is considered one of the most cost-effective ways to prevent dental caries in communities. The aim of the present study was to conduct a systematic review and meta-analysis of studies on fluoride content of bottled water.

**METHODS:** In this study, medical and non-medical databases were searched using a comprehensive and sensitive search strategy. Retrieved citations were imported into an Endnote library. The quality of the studies was checked using the Joanna Briggs Institute (JBI) checklist. The data extracted from the studies included country, reported fluoride concentration level in bottled and tap water, the region of sampling, fluoride determination method, number of assessed brands, and study year. The data were analyzed using random-fixed effects and meta-regression methods in Stata software.

**RESULTS:** A total of 32 papers from 16 countries were included in the review. Half of the studies compared the laboratory-determined content to the label-claimed fluoride content. The results of the meta-analysis showed high heterogeneity in the investigated papers.

**CONCLUSION:** The fluoride content of bottled water had significant discrepancies with the optimal level. The contradiction between the label-claimed fluoride content and that determined after accurate testing was a prevalent finding. The existing legislation does not effectively guarantee the accurate labeling of fluoride content and more rigorous supervision is required.

**KEYWORDS:** Fluorides; Drinking Water; Systematic Review; Dental Caries

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Today, the use of bottled water is growing due to many reasons including fear of tap water pollution, unpleasant smell or taste of tap water, and ease of availability and portability of bottled water.<sup>1,2</sup> Bottled water can be obtained from various sources such as

spring, well, lake, river, rain, or refined water.<sup>3</sup> Evidence implies that the bottled water market will rise 10% annually.<sup>4</sup> A recent study in the United States showed that although total water intake has remained constant, there has been a significant increase in bottled water consumption from 2011 to

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2016. Daily use of bottled water among Americans has risen to 400 ml.<sup>5</sup> It is estimated that each American consumes more than 150 bottles of water annually.<sup>1</sup> In terms of physicochemical and microbiological composition, the quality of drinking bottled water has given rise to concerns.<sup>6</sup>

Among the trace elements in mineral water, fluoride provides a substantial public health benefit. In 1938, the protective impact of fluoride ion on dental caries was discovered. Hitherto, great attention has been paid to the fluoride level of drinking water.<sup>7</sup> Although various fluoride supplements have been formulated until now, drinking water is the most convenient and affordable source of fluoride.<sup>8</sup>

Consuming water with the optimal concentration of fluoride (0.7-1.2 mg/L) is considered a cost-effective approach to preventing dental decay such that the Center for Disease Control and Prevention (CDC) lists community water fluoridation as one of the 10 outstanding public health achievements of the 20<sup>th</sup> century.<sup>9</sup>

To date, about 25 Countries (mostly American and European) have artificially fluoridated the source of public water supply for decades to effectively reduce dental caries in populations. Due to ethical considerations regarding respect for citizens' freedom of choice, some countries have stopped their fluoridation programs. Providing drinking bottled water with optimal fluoride level may be an alternative solution that allows individuals to choose safe and anti-tooth decay water. However, overexposure to fluoride may lead to a range of minor to serious health hazards; a lower dose leads to mild dental fluorosis, whereas a higher dose interferes with bone formation. Gastrointestinal discomfort is another common side effect.<sup>10</sup> Most countries have determined the acceptable fluoride content of drinking water according to World Health Organization (WHO) guidelines. There are regulations regarding labeling the concentration of trace elements, including fluoride, in bottled water. The well-known international standards for drinking water

are presented in table 1.

Various studies carried out worldwide have reported diverse fluoride levels.<sup>11-16</sup> Moreover, some studies showed a significant discrepancy between labeled and measured fluoride content.<sup>17</sup> Given the increasing consumption of bottled water and the significant effect of fluoride ions on the oral health of communities, a comprehensive review study is needed to evaluate the fluoride content of bottled water. As food product labeling enables consumers to choose safe and healthy products, the accuracy of the fluoride content report on the bottle label should be evaluated. This study was a comprehensive systematic review of studies on fluoride concentration of bottled water.

## Methods

*Formulating search strategy:* The PICO acronym in this study stands for:

P: Population: papers which studied and reported fluoride level in bottled water

I: Intervention or phenomenon of interest: the label-claimed fluoride concentration

C: Comparison: the comparison component implies the laboratory-measured amount of fluoride in the bottled water

O: Outcome: assessing the agreement between the claimed and actual fluoride levels of bottled water

T: Timing: papers published up to 2017 were included in the review

S: Study type: not limited

A comprehensive search strategy was applied based on the titles and abstracts to find the most relevant papers: ("Mineral bottled water" OR "drinking bottled water" OR "filtered water" OR "inorganic bottled water" OR "stilled bottled water") AND "fluoride".

*Identifying relevant works:* A wide range of studies on drinking bottled water have been carried out in different fields like dentistry, chemistry, health, and agriculture; therefore, medical and non-medical databases including ScienceDirect, Scopus, ISI Web of Science, and PubMed, as well as Persian databases such as Magiran, Iranmedex, and SID were searched in April 2017.

**Table 1.** International and well-known standards for fluoride level in drinking and bottled water**Fluoride in drinking water, Background document for the development of WHO Guidelines for Drinking-Water Quality**

There is no evidence to suggest that the guideline value of 1.5 mg/litre set in 1984 and reaffirmed in 1993 needs to be revised. The value is higher than that recommended for artificial fluoridation of water supplies, which is usually 0.5–1.0 mg/litre. In setting national standards or local guidelines for fluoride or in evaluating the possible health consequences of exposure to fluoride, it is essential to consider the intake of water by the population of interest and the intake of fluoride from other sources (e.g., from food and air).

Where the total intake is likely to approach or be greater than 6 mg/day, it would be appropriate to consider setting a standard or local guideline at a concentration lower than 1.5 mg/litre.

**CXC 48-2001 Code of Hygienic Practice for Bottled/Packaged Drinking Water (Other than Natural Mineral Waters)**

It may be necessary that bottled drinking water products of particular chemical composition provide information concerning their proper consumption and/or have directions regarding whether or not they are suitable for infants and for the rehydration of infant formula.

**Codex Standard for Natural Mineral Waters, 108-1981 Adopted 1981. Amendment 2001, 2011. Revisions 1997, 2008.**

If the product contains more than 1 mg/litre of fluoride, the term “contains fluoride” shall appear on the label as part of or in close proximity to the name of the product or in an otherwise prominent position.

In addition, the following sentence should be included on the label: “The product is not suitable for infants and children under the age of seven years” where the product contains more than 1.5 mg/l fluorides.

**Codex Standard for Bottled, Pakaged Drinking Water (Other than Natural Mineral Waters), 227-2001**

Geographic location: Where required by the authorities having jurisdiction, the precise geographic location of the specific environmental resource and/or the source of a body of water defined by origin must be declared in the manner prescribed in the applicable legislation.

Prepared water from a water distribution system: When prepared water is supplied by a public or private tap water distribution system, and subsequently, packaged/bottled, but has not undergone further treatment that would modify its original composition or to which carbon dioxide or fluoride have been added, the wording “From a public or private distribution system” must appear on the label along with the name of the product on the principal display panel.

**U.S Food and Drug Administration (CFR - Code of Federal Regulations Title 21)**

Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

No time limit was applied to the search. Non-English and non-Persian papers were not considered in the review.

All citations were inserted into EndNote version 16. Then, relevant papers were identified based on their title and abstract. All studies conducted to determine the fluoride content of any type of drinking bottled water were considered potentially suitable for inclusion in the review. The process of searching and selecting articles was done by two authors (Z Y, S S) independently. The detailed process of screening and selecting papers is shown in figure 1.

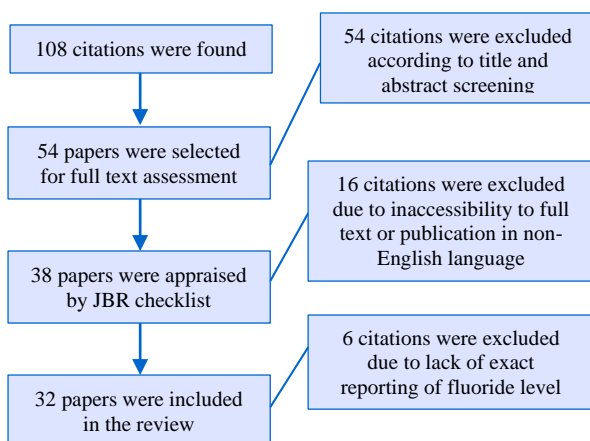
*Assessing the quality of studies:* The quality of the studies was assessed using the JBI Checklist.<sup>18</sup> The checklist assesses research methodology in 8 questions. The questions were answered with yes, no, unclear, and

inapplicable. Papers that gained at least 7 positive responses were considered eligible for the review.

*Summarizing the evidence:* The required data were extracted from the selected full texts and imported into Excel. The data extracted from the papers included name of author(s), country, reported fluoride concentration level in bottled and tap water, region of sampling, fluoride determination method, number of assessed brands, and study year. Finally, the extracted data were analyzed in Stata software (version 11; StataCorp, College Station, TX, USA) using random-fixed effects and meta-regression methods.

## Results

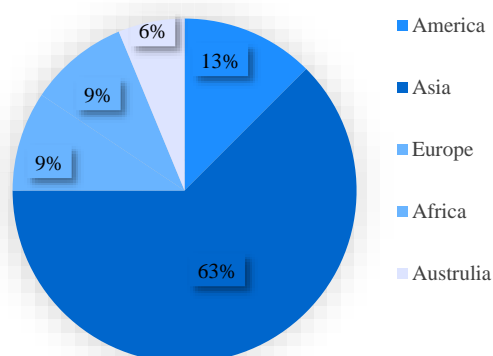
Applying the search strategy led to the identification of 108 potential citations.



**Figure 1.** Selection process of papers included in the review

In the first stage, 54 studies were excluded by reviewing their title and abstract. Among the remaining studies, 16 citations were excluded because of inaccessibility to their full text or publication in a language other than English and Persian. Moreover, 6 citations were excluded because of their low score on the JBR checklist or lack of accurate reporting of fluoride level. Ultimately, 32 papers were included in the review.

An account of the heterogeneity of the studies as well as their results was presented as narrative synthesis based on the countries.<sup>19</sup> The included papers were conducted in 16 countries. Most of the studies were in Asia. Figure 2 shows the geographical distribution of the studies.



**Figure 2.** Geographical distribution of included studies

Most of the studies were performed in Iran (8 papers) and India (6 papers). About 30% of papers examined other physicochemical or microbiological properties of bottled water. Fluoride concentration reported on the bottle label was investigated in half of the papers. The mean number of evaluated brands in each study was 27.6. Fluoride levels in bottled and tap water were compared in 6 papers.<sup>15,20-24</sup> The fluoride level in bottled and tap water showed that the fluoride level in municipal water was higher than bottled water.

The report of the source and type of bottled water was very different. About 40% (13) of the articles did not mention the type of bottled water source, 4 studies only examined the country of production of bottled water, and the remaining 15 studies reported the type of water in terms like spring, distilled, still, natural, artificial, sparkling, carbonated, mineral, well, rain, or drinking water or based on the geographical area of the bottled water source. The data on the source of water were usually extracted from the product labels. The data from the included studies are presented in table 2.

Most of the tested brands were related to those of the study by Ajayi et al. in Nigeria (118 brands).<sup>42</sup> The findings of 32 studies were analyzed using Stata software. Figure 3 shows the mean fluoride content reported in each study.

The I-squared coefficient for all countries was 97.9%, indicating high heterogeneity of the studies. To determine the factors affecting heterogeneity, the following variables were entered into the meta-regression model: study year, country, number of brands, and fluoride determination method. Only the study year was identified as a heterogeneity factor.

According to table 3, the study year was a significant heterogeneity factor ( $P = 0.005$ ). Studies from 2011 onwards were analyzed separately to decrease heterogeneity (Figure 4). These studies were all from Asian and African countries.

**Table 2.** Studies compiled for systematic review in terms of different parameters

Country	Tap water (region, Number of samples, mean or range of F mg/l)	Sampling area of brands	Method	Number of brands	Range of fluoride level (mg/L)	Reference
Algeria-2011	Not reported	Sidi Bel-Abbes	Ion selective electrode Potentiometric	29	0.19-1.07	28
United States	Not reported	Chicago, Illinois, and Pittsburgh, Pennsylvania	Selective ion electrode	37	< 0.10-7.9	29
Australia	Not reported	State of West Virginia	Orion EA940 water analysis machine	65	0-1.2	30
	1, Melbourne, 1.02	Melbourne	Radiometer ion85 ion analyzer	10	< 0.03-0.07	23
	Not reported	84 Australia*, 16 imported	Ion selective electrode and ion Chromatography	100	0.10-1.60	31
Canada	Not reported	London, Ontario	Fluoride ion specific electrode	17	0.05-4.80	32
Egypt	Not reported	Alexandria	Atomic absorption Spectrophotometry	14	0.19-0.75	33
India	Not reported	Amritsar	Spectrophotometry	17	0-0.74	34
	2, Davangere Rang 0/06 to 0/11	Davangere	Ion selective electrode	50	0.10-0.33	22
Iran	Not reported	Davangere	Fluoride ion specific electrode	10	0.06-1.05	16
	6, Faridabad, 0.17	Faridabad	Ion selective electrode	9	0-0.12	15
	Not reported	Chennai	SPADNS colorimetric	10	0.27-0.59	35
	1, Vikarabad, 0.34	Vikarabad	Spectrophotometry	13	0.02-0.13	24
	Not reported	Isfahan	SPADNS method by Spectrophotometry dr 2000	17	0-0.59	36
	42, Cities in Kerman Province, 0.38	Kerman province	Potentiometry with fluoride ion specific electrode	11	0.04-0.28	20
	Not reported	Yasouj	Spectrophotometry DR5000	16	0.10-0.36	37
	Not reported	Tehran	Ion selective electrode	18	0.04-0.63	12
	Not reported	Isfahan	Colorimetric	21	0-5	13
	45, Gonabad, 0.95	Gonabad	SPADNS method with UNICO 2100 spectrophotometry	5	0.09-0.63	38
Iraq	Not reported	Boushehr	SPADNS method by spectrophotometry DR 2000	10	0.07-0.31	39
	Not reported	Ghazvin	spectrophotometry	11	0.16-0.63	11
	Not reported	Najaf and Karbala	SPADNS method by spectrophotometry dr 5000	14	0.13-0.50	40
	8 Los Altos de Jalisco 1.9	Los Altos de Jalisco	EPA ion selective electrode	30	< 0.10-5.27	41
Nigeria	Not reported	Ibadan	Hanna c100 spectrophotometry	118	0-0.8	42

**Table 2.** Studies compiled for systematic review in terms of different parameters (continue)

Country	Tap water (region, Number of samples, mean or range of F mg/l)	Sampling area of brands	Method	Number of brands	Range of fluoride level (mg/L)	Reference
North Greece	Not reported	Thessaloniki*	Combination ion selective electrode	22	0.05-4.80	43
Poland	Not reported	15 Greece, 22 imported Poznan	Ion-selective electrode (09-37 type) and a RAE 111 chloride-silver Reference electrode (MARAT)	10	0.0-8.3	44
Qatar	Not reported	5 Qatar* 28 imported	Fluoride ion specific electrode	32	0.06-3.00	45
Saudi Arabia	Not reported	12 internal brands, 3 imported Riyadh	Atomic absorption Spectrophotometry	21	0.32-1.10	46
Spain	Not reported 21, north of the island of Tenerife. 2/5-5/55	North of the island of Tenerife.	not determined Fluoride ion specific electrode	52 21	0.05-5.00 0.10-13.77	47 21
Thailand	Not reported	Bangkok	Fluoride ion specific electrode	30	0.03-0.72	48
	Not reported	29 produced in Thailand*, 16 imported	Ion selective electrode and expandable ion	45	0.01-0.89	49

\*detailed data of imported brands:

Australia: Fiji, United States, New Zealand, Europe, Asia

Greece: Italy (1), Romania (1), Belgium (1), and France (4)

Qatar: Saudi Arabia (9), United Arab Emirate (8), France (4), Lebanon (3), Bahrain (1), United Kingdom (2), Turkey (1), Italy (1)

Thailand: Imported from France (3), Iceland (1), Scotland (1), Japan (1), Australia (1), Italy (2), Spain (4), United Kingdom (1), Canada (1), Fiji (1)

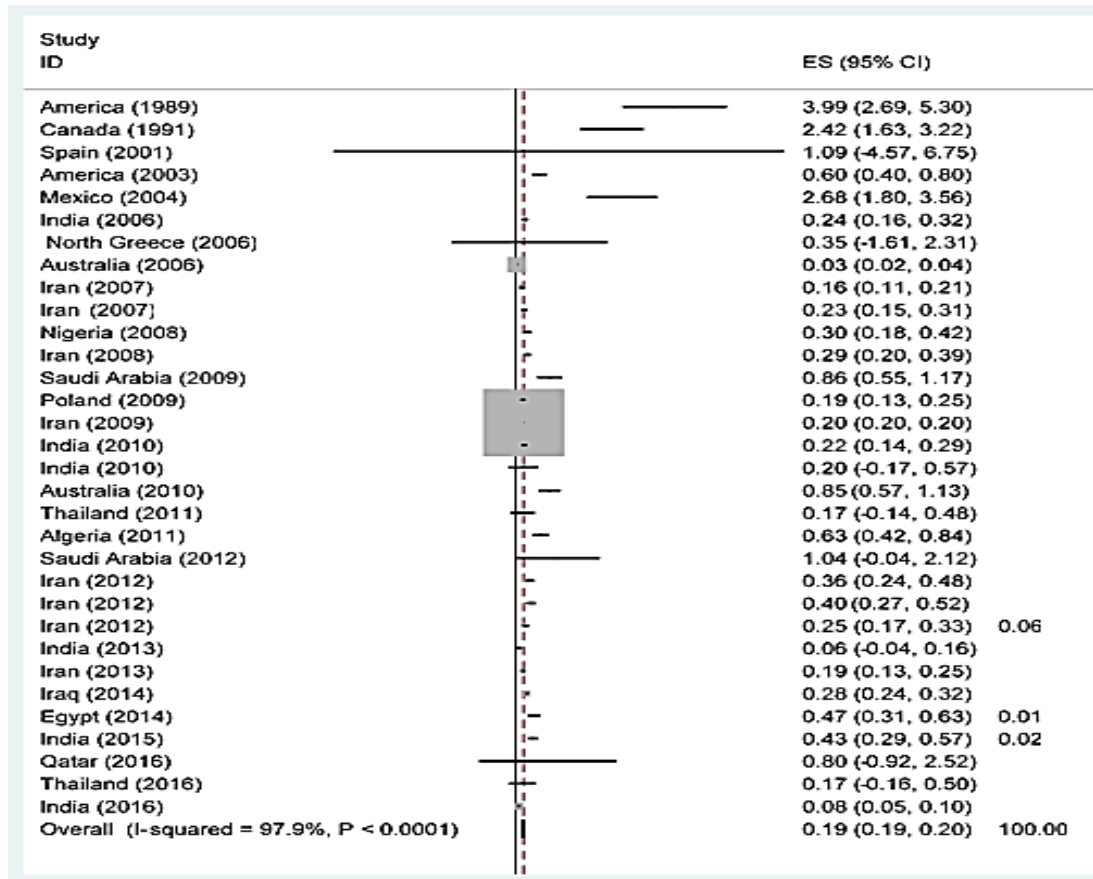


Figure 3. Fluoride concentration reported in studies

Despite the decrease in the I-squared coefficient from 97.9% to 92.3%, the heterogeneity was still high; the highest dispersion was related to Qatar. Lower dispersion was seen among Iranian studies; hence, they were analyzed separately.

As shown in figure 5, the I-squared coefficient was significantly reduced to 71.2%. The mean range of fluoride content reported in Iranian studies was between 0.07 to 0.5.

### Discussion

This study evaluated the fluoride level in bottled water as an essential trace element in improving oral health. Due to the growth in

bottled water consumption, great attention has been paid to its public health aspects. The protective role of fluoride as a mineral in drinking bottled water against dental caries, the most prevalent chronic disease all over the world, should not be neglected.<sup>25</sup>

The present study systematically reviewed all studies reporting the fluoride content of bottled water worldwide.

The difference in the fluoride level of bottled water was a prevalent finding in most studies in different countries and even on different brands in one country which was also in line with the findings of a study in Brazil.<sup>17</sup>

Table 3. Variables entered into meta-regression model

Variable	Coefficient	SE	t	P > t	95% CI
Year	-0.056	0.182	-3.08	0.005*	-0.093-0.018
Country	0.068	0.196	0.35	0.730	-0.330-0.470
Number of brands	0.001	0.002	0.65	0.522	-0.003-0.006
Method	113.610	36.880	3.08	0.005	38.060-189.170

\*Significant

SE: Standard error; CI: Confidence interval

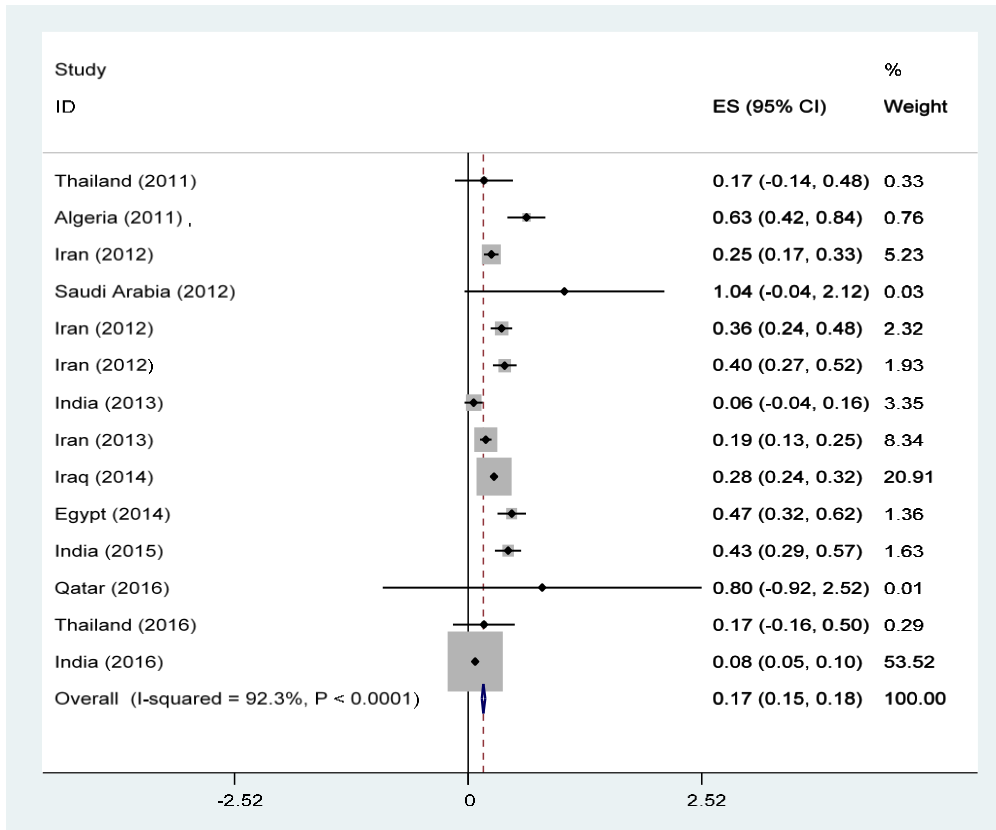


Figure 4. Fluoride concentration reported in studies from 2011 onward

All papers published from 2011 onwards were conducted in Asian and African countries, indicating that bottled water

consumption has become widespread in these countries much later than in western countries.

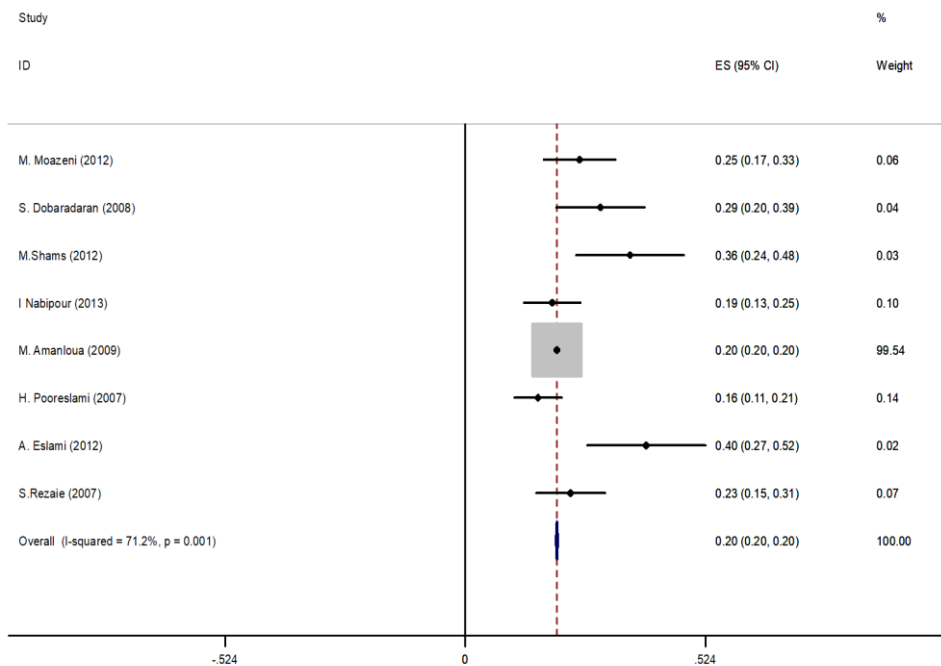


Figure 5. Fluoride concentration accumulation reported in studies in Iran



The WHO recommended 3 types of measurement methods for the detection of fluoride content including colorimetric method, electrochemical method, and the SPADNS colorimetric method.

In line with WHO recommendation, most of the included papers determined fluoride values using the ion-specific electrode.

Only half of the studies evaluated the bottle's label in terms of fluoride content information. Moreover, high discrepancy between laboratory-determined and label-claimed fluoride values was a common finding; the fluoride concentration was sometimes not provided on the label at all.

Codex Standard for bottled, packaged drinking water (other than natural mineral waters) recommends that if the country's judicial authority deems it necessary, bottled water producers should clearly state the geographical area of the source of water on the product label. Moreover, if the plain bottled water is supplied from the water distribution network, the following should be stated on the label: "From a public or private distribution system". The review showed that bottled water origin was very diverse and no study mentioned the source of bottled water as supplied from the water distribution network.

I-squared coefficient of reported fluoride concentration for all countries was 97.9%, indicating high heterogeneity of the studies. The highest and lowest dispersion rates were related to studies in Spain and Iran, respectively. According to "Codex Standard for Natural Mineral Waters", mineral water brands must include the phrase "contains fluoride" on the bottle label if the product contains at least 1 milligram per liter of fluoride. If the product contains more than 1.5 mg/L, it should be labeled as "not suitable for children under seven years of age".<sup>26</sup> The Iran Food and Drug Administration (IFDA) follows the mentioned guidelines. The mean range of fluoride concentration in Iranian studies (0.07-0.5) was significantly lower than the recommended concentration (0.7-1 mg/L). In the meta-analysis study by

Keramati et al. on fluoride content of Iranian drinking tap water and non-carcinogenic risk assessment, the pooled fluoride concentration was estimated at 0.51 mg/L,<sup>27</sup> implying that the fluoride concentration of Iranian bottled water was less than that of municipal tap water. The general perception is that mineral water is richer in minerals and trace elements. Surprisingly, in all six studies that compared the reported fluoride level in bottled and municipal tap water, fluoride level of municipal tap water was higher. Regular consumption of bottled water, especially among residents of fluoridated-water communities, would deprive consumers of the anti-dental caries effects of fluoride-containing water.

In the present study, we attempted to conduct a meta-analysis, which was not possible due to the studies' high heterogeneity. Therefore, the results were expressed as narrative synthesis (descriptively). Another limitation was the inaccessibility of old studies. Furthermore, non-English papers were not included in the review. The study showed that there is a wide range of fluoride concentration in bottled water. Failure to accurately express fluoride content and suboptimal level of fluoride in bottled water worldwide is an issue that needs to be addressed. Furthermore, it seems that bottled water does not have the risk of an excessive dose of fluoride and could be considered a safe product for all age groups. Evidently, the existing legislation does not effectively guarantee the accurate labeling of fluoride content and more rigorous supervision is required.

## Conclusion

The reported fluoride level of bottled water in the reviewed studies had high discrepancies with the optimal levels. The amount of fluoride level claimed by the manufacturer in many investigated brands contradicted actual levels. It seems that bottled water does not contribute to the risk of fluorosis. Furthermore, consumers are

deprived of the potential anti-tooth decay effect of water containing optimal fluoride level. Evidently, the existing laws are not effective enough to guarantee the accurate labeling of fluoride content and more supervision is needed in this regard.

### Conflict of Interests

Authors have no conflict of interests.

### Acknowledgments

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