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Fluoride Concentration in Baby Milk Formulas Available in Riyadh Pharmacies, Saudi Arabia

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Abstract Purpose: This study aimed to ascertain the fluoride concentrations in infant formula (baby milk) sold in pharmacies situated in Riyadh, Saudi Arabia, and to confirm the accuracy of the fluoride quantities declared on the package. Methods: 26 different infant formulae product samples from 13 manufacturers were obtained from pharmacies in Riyadh, Saudi Arabia. Two different products from the same manufacturer measured fluoride concentrations (one product for the 0-6 months age group and one for the 1-3 years age group) using a combination fluoride-ion-selective electrode. Results: The average concentration of fluoride for all the samples measured was 0.987 µg/g. In all but one sample, there was a wide difference between the declared Fluoride concentrations and what was measured. The difference was smallest in Humana Bebemil 1 which had 0.84 µg/g (measured) and 0.75 µg/g (declared). The average intake of fluoride is way below the recommended daily allowance. The quantities of fluoride that can potentially be consumed, depending on the brand, ranged from 0.115 mg/day to 0.206 mg/day. Conclusion: All the analyzed infant formulae did not reveal fluoride concentrations above the recommended daily allowance. One can cautiously assume that there is no risk for children to suffer from over-exposure to fluoride.

Keywords: *fluoride, baby milk formula, concentration, over-exposure, risk*

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1. Introduction

Fluoride is one of the trace elements that are important for optimal human health, more specifically, fluoride is required for the prevention of dental caries [1]. Dental caries is a sugar-driven, biofilm-mediated, multi-factorial disease that results in the demineralization of hard dental tissue [2]. Fluoride retards or completely stops dental caries by inhibiting erosion of minerals from the tooth (demineralization), by promoting the uptake of phosphate and calcium needed for tooth re-mineralization and by inhibiting activities of bacteria that produce acids which erode tooth surface [3].

Dental caries is one of the most chronic childhood diseases. 60-90% of children worldwide have experienced dental caries at least once in their lifetime [4]. Children suffering from dental caries are negatively impacted both physically and psychologically [5]. The burden of this condition has caused policymakers, relying on sound scientific evidence, to recommend several ways of delivering this trace element to the general population.

There are several ways of delivering fluoride to a population. Community water fluoridation, supplementing community water sources with fluoride, is one of the methods commonly used across the world [6]. This intervention is viewed as one of the 10 public health achievements that significantly improved the health of billions of people in the 20th century [1]. Advances in knowledge regarding the efficacy of fluoride in reducing dental caries have led to the invention of new fluoride distribution vehicles such as tablets, salt, milk, toothpaste, varnishes and gels [7]. The plurality in the number of ways fluoride is delivered to humans means one can easily consume fluoride levels above the recommended daily allowances and there is evidence suggesting that this is detrimental to health.

The efficacy of fluoride in fighting dental caries and its availability in different consumable items such as milk, salt, tap water, and toothpaste has resulted in some individuals consuming high doses of Fluoride and this has been linked to unfavourable health outcomes. Curtis et al. [8] reported that the over-ingestion of fluoride may lead to dental fluorosis. Epidemiological evidence proved that fluoride concentrations of 1.5 mg/l cause dental fluorosis by promoting subsurface enamel porosity during tooth development [9]. Furthermore, Reddy [10] reported that progressively higher fluoride concentrations may cause skeletal fluorosis. The fact that fluoride promotes bone

and teeth mineralization and has anti-thyroid properties means that over-ingesting the mineral will affect growing children more than adults [11].

Growing children are particularly at greater risk of being negatively affected by fluoride overdose. The risk of bone deformities increases if extra calcium and phosphate are deposited on growing bone, this occurs because fluoride promotes the mineralization of bones. Persistent fluoride over-ingestion has also been linked to structural brain damage and reduced cognitive ability in children [12,13].

It was once considered best practice to fortify infant formula with fluoride in case the growing child has no access to community fluoridated water. However, the evidence that Fluoride might be harmful to humans, especially growing children, makes it critically important to know the amount of Fluoride in infant formula. The first objective of this study is to ascertain the fluoride concentrations in infant formula (baby milk) sold in pharmacies situated in Riyadh, Saudi Arabia. This study has been motivated by the fact that some of the manufacturers of baby milk do not declare the quantities of fluoride in their products. Furthermore, it is good practice to know if what the manufacturer declares on the package is what is contained in the product. The second objective of the research was to ascertain the accuracy of the fluoride quantities declared on the package.

2. Methods

2.1. Samples

The study proceeded by measuring the concentrations of fluoride in infant formulae brands produced by different manufacturers and commercially available in Riyadh, Saudi Arabia. Study samples comprised 26 different product samples from 13 manufacturers were used in this study. Two different products from the same manufacturer measured fluoride concentrations (one product for the 0-6 months age group and one for the 1–3 years age group). Ten manufacturers, out of the 13, did not declare the concentrations of fluoride on the packaging of the infant formulae.

2.2. Instrumentation Analysis

The fluoride analysis was performed using a Metrohm 781 model pH Ion-meter in conjunction with a combination fluoride electrode Solid-state Membrane Electrode (Metrohm ISE 6.0502.150) and reference electrode (Ag/AgCl RE). Ion-selective electrodes (ISEs) were preferred for this study because they are affordable, and the analysis takes a much shorter time when compared to the traditional expensive and time-consuming chromatographic methods. Also, ISEs are easy to use and thus are suitable for continuous monitoring. They are cost-effective, as well as sufficiently sensitive, selective and accurate. The fluoride-selective electrodes were used for the determination of fluoride in milk samples.

Analytical-reagent grade chemicals were used without further purification. De-ionized distilled water was used throughout the experiments. Fluoride stock solution (10 µg ml^{-1}) was prepared from the sodium fluoride and stored in a polyethylene container. Total Ionic Strength Adjustment Buffer (TISAB) solution contains 58 g of sodium chloride, 57 ml of glacial acetic acid, 4 g of 1,2-cyclohexanediamine-N,N,N',N'-tetraacetic acid (CDTA) and approximately 150 ml of 6 mol L^{-1} NaOH in a volume of 1000 ml (pH 5.0-5.5). The TISAB solution regulates the ionic strength of samples and standard solutions and adjusts the pH, and also avoids interferences by polyvalent cations such as Al^{3+}, Fe^{3+} and Si(IV), which can precipitate with fluoride and reduce the free fluoride concentration in the solution. CDTA forms stable complexes with polyvalent metal cations (e.g., Al^{3+}, $Fe^{3+}$and Si^{4+}), which are more stable than metal-fluoride complexes (AlF_3, FeF_3 etc.) in solution. The CDTA Preferentially complexes with polyvalent cations present in water freeing the fluoride ion. The electrode is selective for the fluoride ion over other common anions by several orders of magnitude.

2.3. Determination of Fluoride in Milk Samples

Milk samples weighed 0.2 g and dissolved in 10 ml of deionized water. A combination fluoride electrode was used to determine the fluoride concentrations in samples. The samples and fluoride standard solutions were diluted 1:1 with the TISAB. The solutions, which contained 10 ml of the sample and 10 ml of TISAB solutions, were mixed with a magnetic stirrer for 3 minutes. The electrode potentials of the sample solutions were directly compared with those of fluoride standard solutions.

2.4. Determining Fluoride Consumed Daily

Using the manufacturer's guidelines, it was determined that a 6-month-old baby needs an average of 161 g of formula per day. This is the value that will be used to determine the total quantity of fluoride consumed per day. The total daily consumption will be compared with the recommended daily allowance (RDA) set at 0.5 mg/day by the World Health Organization. [14]

3. Results

3.1. Fluoride Concentrations of Sampled Infant Formulae

In total 26 different types of infant, formulae were analyzed from 13 different manufactures. Two different products from the same manufacturer were measured for fluoride concentrations (one product for the 0-6 months age group and one for the 1–3 years age group). The average concentration of fluoride for all the samples measured was 0.987 µg/g (Figure 1).

Results of the lab analysis revealed that NAN 1 and NAN 3 have the highest fluoride concentrations. Similac Gold, Promil Gold, and Blemil Plus products also had high fluoride concentration, closer to the NAN 1 and 3. Aptamil 1 and 3, Bebelac 1 and 3, Humana Bebemil 3 as well as Ronalac 1 are the only products that had fluoride concentration lower than 0.8 µg/g.

3.2. Comparison of Measured and Declared Fluoride Concentrations

Out of the products from 13 different manufacturers, only three displayed information on fluoride concentration. This part of the study presents results for the comparison between declared values and measured values (Figure 2).

In all but one sample, (Humana Bebemil 1), there was a wide difference between the declared Fluoride concentrations and what was measured. Primalac 1 had the greatest difference between the declared and the measured Fluoride levels. Measured Fluoride concentrations were two times more than the declared concentration. The same can be said for Primalac 3. The difference between measured and declared Fluoride concentrations was smallest in Humana Bebemil 1 which had 0.84 µg/g (measured) and 0.75 µg/g (declared).

3.3. Total Daily Fluoride Consumption

Analysing and reporting on the concentrations of Fluoride in different brands is important but it is more insightful to explore how much a typical baby consumes in a day and compare it with the recommended daily allowance (RDA). The results in Figure 3 indicate fluoride consumption levels from respective brands for a six months old baby.

Generally, the actual average intake of fluoride are way below the RDA. Babies consuming NAN, S-26 Promil Gold, and Blemil Plus consume slightly more fluoride than babies fed on the other brands. The quantities of fluoride that can potentially be consumed, depending on the brand, ranged from 0.115 mg/day to 0.206 mg/day.

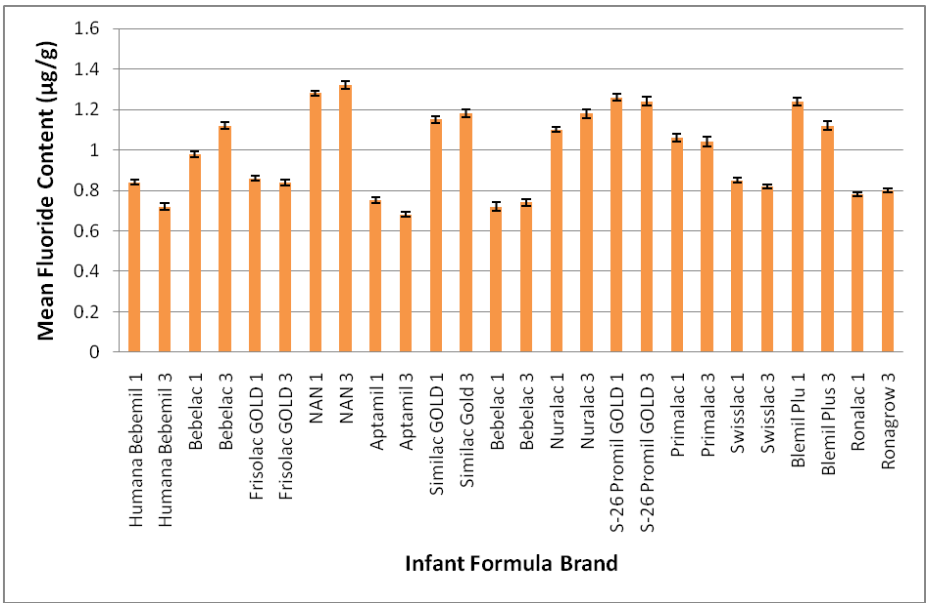

Figure 1. Fluoride concentrations for sampled infant formulae

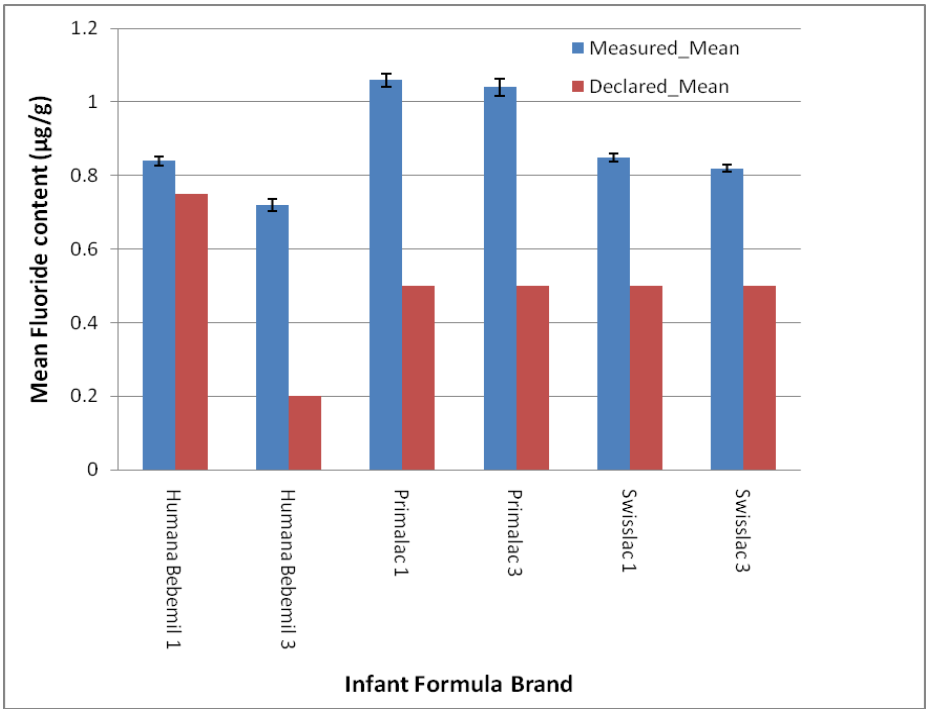

Figure 2. Comparisons between declared and measured Fluoride concentrations

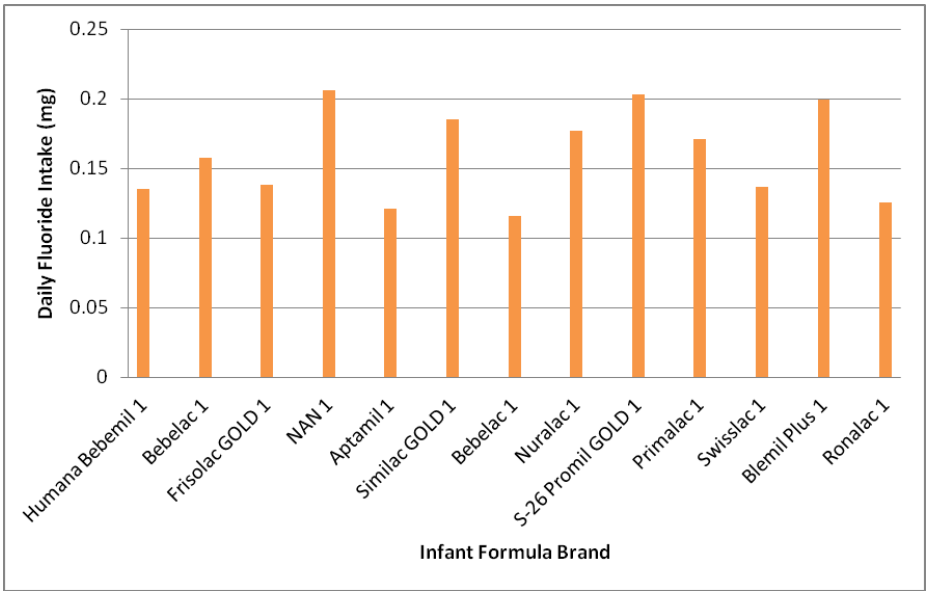

Figure 3. Total Fluoride consumption for a six-months-old baby

4. Discussion

The main objectives of this study was to analyze the quantity of fluoride in commercially available infant formulae in Riyadh. To confirm if the declared fluoride quantities on baby milk formulae is comparable to that measured by the researcher. This is a critically important task given the realization that over ingestion of fluoride can have negative impacts on health, especially, for growing babies. Infant formulae were chosen because, in many developed nations, it is the main source of nutrition for infants.

In general, the amount of fluoride consumed by babies fed on different formulae did not exceed WHO RDA. However, it must be noted that the actual fluoride consumed might be more than the values determined by measuring fluoride concentrations in the lab. This is because in Saudi Arabia baby formula is usually prepared with tap or bottled water. The mean fluoride concentration of ready-to-feed infant formulas in the USA was 0.15 ppm for milk-based formulas and 0.21 ppm for soy-based formulas [15]. Aldrees and Al-Manea [16] report that the mean fluoride concentration of locally produced bottled water is 0.79 ±0.09 mg/l and [17] found that fluoride content of tap water ranged between 0.04–0.3 mg/l with a mean of 0.14 mg/l. This will add a significant amount of fluoride to the infant milk and makes it difficult to decide if the consumed amounts exceed the maximum recommended dose.

The average concentration of fluoride in the present study for all the samples measured was 0.987 µg/g. In a 2019 study conducted in the United Arab Emirates, the mean fluoride concentration in the infant formula sample was found to be 0.19 ppm with a range between 0.00 and 0.40 ppm which is lower than the maximum recommended daily dose when using fluoride-free water [18].

Several studies measured the infant formulae sample after preparation with water to assess the level of fluoride and whether it was exceeding the recommended daily intake. In Brazil 2015, the study found that the daily intake of fluoride from infant formulae is high and the risk of dental fluorosis could increase [19]. To reduce the risk of dental fluorosis, the AAPD recommended the use of ready-to-feed formula products in regions where F levels in water are high [15].

In the present study, 10 samples out of 13 did not declare the level of fluoride on the label. The difference between the concentration of fluoride measured in the samples was two times more than the declared concentration. (This difference did not exceed the RDA.)

The fact that the market for baby formula in Riyadh is so large was a study restriction. It was attempted to gather all available formula samples from various merchants.

5. Conclusion

All the analyzed infant formulae did not reveal fluoride concentrations above the RDA. One can cautiously assume that there is no risk for children to suffer from over-exposure to fluoride. However, it is worrying that in all but one case, the reported concentrations were way lower than the measured concentrations. Furthermore, some manufacturers did not even put the values of fluoride concentrations on their products. Therefore, authorities should ensure that all ingredients in baby food are accurately labelled on the package.

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