ORIGINAL RESEARCH

Variability of Sugars Concentrations in Infant Follow-on Formulas with Higher Consumption in Peru: A Preliminary Study

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Abstract

Aim: The aim of the present preliminary study was to determine sugar concentration in infant follow-on formulas most widely consumed in Peru.

Materials and methods: In this descriptive and observational study, the sample was represented by five brands of infant follow-on formulas most consumed in Peru (A, Similac 2; B, Enfamil 2®; C, NAN 2®; D, Baby Lac Pro 2®; and E, Lacti Kids Premium 2®); with two samples of each, collected at two different locations in the Peruvian capital. Subsequently, the concentration of total and individual sugars (lactose, sucrose, glucose, fructose, and maltose) was determined using the high-performance liquid chromatography (HPLC) method in a specialized laboratory. For the comparison of means, Welch's robust analysis of variance (ANOVA) test for equality of means and Tukey's *post hoc* test were used. The significance level was $p < 0.05$.

Results: The total sugars concentration per 100 gm of the five infant follow-on formulas showed a mean of 38.9 ± 11.03 gm, being Similac 2, the infant follow-on formula, with the highest concentration of 50.33 ± 0.11 gm and Enfamil 2, the lowest with 22.75 ± 0.06 gm. The average sugars recorded in the laboratory were compared with those on the product label for Similac 2 (50.3 and 53.1 gr), NAN 2 (46.5 and 51.5 gr), Baby Lac Pro 2 (41.5 and 57.0 gr), Lacti Kids Premium 2 (33.3 and 57.0 gr) and Enfamil 2 (22.8 and 56.0 gr). Furthermore, when comparing the infant follow-on formulas, significant differences were observed between all sugar concentrations ($p < 0.001$), with the follow-on formula with the significantly higher sugar concentration being Similac 2 ($p < 0.001$) and the one with the significantly lower concentration being Enfamil 2 ($p < 0.001$). Regarding individual sugars, per 100 gm analyzed, fructose and maltose registered values <0.70 g. Similar values were obtained for glucose except for Enfamil 2 (1.07 ± 0.01gr) and Baby Lac Pro 2 (0.72 ± 0.01gr) and for sucrose except for Lacti Kids Premium 2 (11.92 ± 0.01gr) and Similac 2 (9.94 ± 0.08 gr). On the other hand, the highest lactose value found was in NAN 2 (46.51 ± 0.08 gr), and the lowest value obtained was in Lacti Kids Premium 2 (21.42 ± 0.01 gr).

Conclusion: There is a variability of sugar concentrations in infant follow-on formulas, being these values lower than those referred to on product labels. The formula with the lowest discrepancy was Similac 2, while the formula with the highest discrepancy was Enfamil 2, with Similac 2 and Enfamil 2 being significantly the formulas with the highest and lowest sugar concentration, respectively. In addition, among individual sugars, lactose, and sucrose stood out in greater proportion compared to other free sugars.

Clinical significance: It is important that institutions responsible for infant nutritional safety encourage and promote the use and practice of breastfeeding during early life and provide adequate guidance regarding daily doses of infant follow-on formulas since, according to the World Health Organization (WHO), the high consumption of free sugars contained in these formulas can put infants' oral health at risk.

Keywords: Carbohydrates, Dental caries, Diet, Infants, Infant formula, Preliminary study, Sucrose, Sugars.

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Introduction

The early introduction of sugar in the children's diet through drinks and/or foods received during the first 24 months of age is not recommended since it creates an early predilection for sugar in their diet, generating unhealthy eating habits.[1–3] The WHO recommends exclusive breastfeeding during the first 6 months of age, and its use should be extended until 24 months of age. In addition, it also suggests that from 6 months of age, the introduction of complementary foods to breast milk should be initiated.[4]

Infant formulas are food products based on cow's milk modified with complex synthetic combinations of nutrients such as fermentable carbohydrates like lactose, corn syrup solids, sucrose, maltodextrins, and glucose polymers.[5] The purpose of consuming these formulas is to totally or partially replace breast milk, providing necessary nutritional components for the development and growth of infants, such as macronutrients (energy, proteins, lipids, carbohydrates) and micronutrients (minerals and vitamins).[6]

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They are also necessary for maternal situations where breastfeeding is not advisable, such as the need to ingest drugs, human immunodeficiency virus, and chemotherapy, among others.[7] Other situations where infant formula consumption and temporary interruption of breastfeeding are indicated are insufficient breast milk production by mothers, nipple soreness, return to work, and lack of information or professional guidance on breastfeeding benefits.[5,8]

Although it has been demonstrated that any infant formula cannot replace the benefits of breast milk,[9] a study conducted in Peru by the Demographic and Family Health Survey showed that 83% of infants between 6 and 8 months and 57.2% between 9 and 11 months received infant formula.[10]

According to the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), industries were allowed to add other sugars without exceeding 20% of total carbohydrates to follow-on formulas.[11] Infant formulas must contain within their components a total glycaemic carbohydrate of 9 gm/100 kcal with a minimum lactose of 4.5 gm/100 kcal.[12] Frades et al. demonstrated that infant formulas used between 12 and 36 months of age had high sugar concentrations incompatible with recommendations established by WHO.[3] In addition, Walker et al. verified that there is a percentage difference between actual sugar concentration values and infant formula nutrition labels.[2] This is important, as studies by several researchers have shown a significant association between high sugar consumption and dental caries.[13,14]

Given the scientific interest in the consumption of sugary drinks to which infants are exposed at early ages, the concentration and type of sugars present in infant follow-on formulas were assessed since this will provide evidence-based information useful for health professionals, such as nutritionists, pediatricians, and pediatric dentists. These data will lay the groundwork for future analytical studies to assess the sugar concentration in infant formulas as a possible risk factor for dental caries at early ages. Therefore, the aim of the present preliminary study was to determine the sugar concentration in the most widely consumed infant follow-on formulas in Peru.

Materials and Methods

Type of Study and Delimitation

This descriptive, prospective, cross-sectional, and observational study was conducted during the months of November 2019 to February 2020 in Lima, Peru, at the Dentistry School of the Norbert Wiener University and at the specialized laboratory "Certificaciones del Perú SA" (CERPER), approved by the National Institute of Quality (INACAL), Peru. The present study was exempted from review by an ethics committee from the Faculty of Dentistry of the Norbert Wiener Private University since it did not put human life at risk. However, the study was approved with Resolution No. 0700-2020/DFCS/UPNW.

Sample Selection

By means of a nonprobabilistic convenience sampling, the present study was carried out with two sample units for each of the five most consumed follow-on formulas for infants between 6 and 12 months of age, marketed in Peru and available to the researcher. The follow-on formulas studied were—Similac 2®, Enfamil 2®, NAN 2®, Baby Lac Pro 2®, and Lacti Kids Premium 2® (Table 1).

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Conflict of interest: None

The selection of infant follow-on formulas was based on a final report by the Ministry of Health (MINSA) entitled "Breastfeeding and Compliance with the International Code of Marketing of Breastmilk Substitutes in Peru. Final monitoring report in Apurimac, Ayacucho, Huancavelica, Lima, and Loreto,"[15] where the most widely consumed infant formulas in Peru were reported. Likewise, the sample was collected from pharmaceutical companies with the largest number of customers. It should be noted that each brand of infant follow-on formula was obtained from two different pharmacies located in different parts of the Peruvian capital, according to the following eligibility criteria:

Inclusion Criteria

- Infant follow-on formulas for 6–12 months.
- Infant follow-on formulas marketed in the city of Lima, Peru.
- Infant follow-on formulas from pharmacies that meet the quality standards supervised by General Directorate of Medicines, Supplies, and Drugs in Perú.
- Infant follow-on formulas obtained prior to the expiration date.
- Infant follow-on formulas whose label reports the concentration of sugar components.

Exclusion Criteria

Infant follow-on formulas whose container or packaging label showed dents or a certain degree of deterioration.

Procedure for Sugars Quantification in Laboratory

To obtain the sugar concentration in infant follow-on formulas, a portion of each product was taken directly from its original packaging and placed in sealed and sterile containers, coding each one with letters A–E. The portion weight was determined and noted, ranging from 240 to 250 gm. The samples were packed, labeled, and sent to the specialized laboratory CERPER, approved by the INACAL, for subsequent blind analysis. The instrument used was an HPLC chromatograph (Thermo Scientific Ultimate™ 3,000, Thermo Fischer Scientific, Waltham, Massachusetts, United States of America). A portion of 100 gm was taken for each sample, using a technique employed by pumps action that passes a mixture of compounds through a column filled with absorbent material, where the chemical interactions of each sample component with the absorbent caused its separation as it flowed towards the column exterior. The procedure made it possible to disaggregate and quantify

Table 1: Infant follow-on formulas used, lot, and place of origin

Infant follow-on formula	*Lot*	*Country of origin*
A: Similac 2	05122NT	Ireland
B: Enfamil 2	DE9A5J1D	Spain
C: NAN 2	9254021013	Peru
D: Baby Lac Pro 2	004123	Netherlands
E: Lacti Kids Premium 2	D08DTJV	USA

A, B, C, D, and E, coding assigned to each sampling unit

lactose, sucrose, glucose, maltose, and fructose, and their summation made it possible to obtain total sugars.

Statistical Analysis

Laboratory results were stored in a Microsoft® Excel 2019 spreadsheet and exported to the Statistical Package for the Social Sciences (SPSS) (SPSS Inc. IBM, New York, United States of America) version 28.0. All data were analyzed using descriptive statistics with measures of central tendencies, such as mean, and measures of dispersion, such as standard deviation. In addition, a representative line graph was used to visualize the differences in concentrations obtained in the laboratory versus the label values of the infant follow-on formulas. For the comparison of means, Welch's robust ANOVA test for equality of means and Tukey's *post hoc* test were used. The significance level was $p < 0.05$.

Results

Laboratory test results showed that the mean total sugars concentration (per 100 gm) of the five infant follow-on formulas was 38.9 ± 11.03 gm, with the highest concentration being Similac 2 with 50.33 ± 0.11 gm and the lowest concentration being Enfamil 2 with 22.75 ± 0.06 gm. Furthermore, when comparing the infant follow-on formulas, significant differences were observed between all sugar concentrations ($p < 0.001$), with the follow-on formula with the significantly higher sugar concentration being Similac 2 ($p < 0.001$) and the one with the significantly lower concentration being Enfamil 2 ($p < 0.001$) (Table 2).

In decreasing order, the sugars concentration of the infant formula per 100 gm of powder, recorded in the laboratory and on the product label, were respectively for Similac 2 (50.3 and 53.1 gm); NAN 2 (46.5 and 51.5 gm); Baby Lac Pro 2 (41.5 and 57.0 gm); Lacti Kids Premium 2 (33.3 and 57.0 gm) and Enfamil 2 (22.8 and 56.0 gm). It can be seen that the infant follow-on formula with the lowest discrepancy to the information recorded on its label is Similac 2, while the infant follow-on formula with the highest discrepancy was Enfamil 2. On the other hand, the highest percentage contribution of energy from total sugars, according to laboratory tests, was Similac 2 (39.5%) and NAN 2 (39.3%), while the highest contribution, according to packaging analysis, was Baby Lac Pro 2 (49.2%) and Enfamil 2 (46.4%) (Fig. 1 and Table 3).

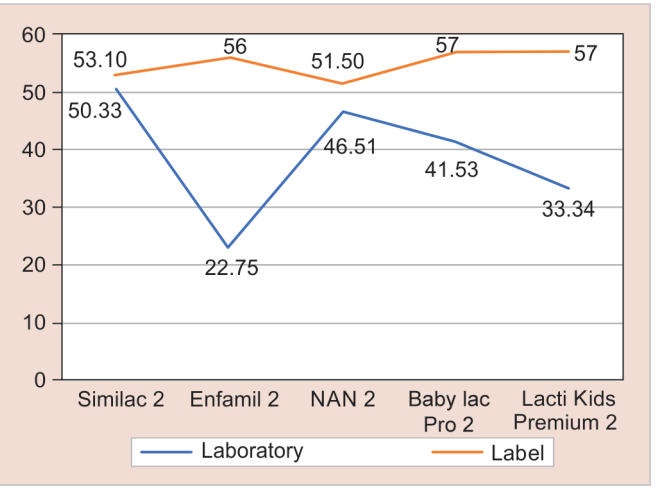

Fig. 1: Total sugars concentration per 100 gm powder of infant follow-on formulas obtained in the laboratory

Table 2: Total sugars concentration (gr) in infant follow-on formulas per 100 gm of powder

Infant follow-on formula	*Mean*	*SD*	*Min*	*Max*	**p*	*Infant follow-on formula*			
						B	*C*	*D*	*E*
A	50.33	0.11	50.25	50.40	<0.001*	<0.001**	<0.001**	<0.001**	<0.001**
B	22.75	0.06	22.70	22.79			<0.001**	<0.001**	<0.001**
C	46.51	0.08	46.45	46.56				<0.001**	<0.001**
D	41.53	0.08	41.47	41.59					<0.001**
E	33.34	0.01	33.33	33.34					
Total	38.89	11.03	22.70	50.40					

SD, standard deviation; A, B, C, D, and E, coding assigned to each sampling unit; min, minimum; max, maximum. A, Similac 2; B, Enfamil 2; C, NAN 2; D, Baby Lac Pro 2; E, Lacti Kids Premium 2; *based on Welch's robust ANOVA test with equality of means; **based on Tukey's *post hoc*; significant differences ($p < 0.05$)

Table 3: Sugars found (gr) in the laboratory and referenced on labels of five infant follow-on formulas per 100 gm of powder

	Laboratory			*Label*			*Variation*	
Infant formula	*gr of sugar/100 grams*	*Kcal/100 mL*	*% of total energy/100 mL*	*gr of sugar/100 gm*	*(Kcal)/100 mL*	*% of total energy/100 mL*	*D**	*Δ***
A: Similac 2	50.33	29.6	39.5	53.1	31.2	41.6	−2.77	−5.22
B: Enfamil 2	22.75	12.9	18.9	56	31.7	46.4	−33.25	−59.38
C: NAN 2	46.51	28.8	39.3	51.5	32	43.6	−4.99	−9.69
D: Baby Lac Pro 2	41.53	23.2	35.7	57	32	49.2	−15.47	−27.14
E: Lacti Kids Premium 2	33.34	12	16.3	57	32	43.4	−23.66	−41.51

*Difference in grams per 100 gm of infant formula between those obtained in the laboratory and packaging label; **percentage change of sugar discrepancy obtained in relation to that reported on the packaging; A, B, C, D, and E, coding assigned to each sampling unit

Concentrations of individual sugars found in infant follow-on formulas per 100 gm showed that fructose and maltose registered values <0.70 gm. Similar values were obtained for glucose with the exception of Enfamil 2 (1.07 ± 0.01 gm) and Baby Lac Pro 2 (0.72 ± 0.01 gm) and for sucrose with the exception of Lacti Kids Premium 2 (11.92 ± 0.01 gm) and Similac 2 (9.94 ± 0.08 gm). Likewise, the highest lactose value found was in NAN 2 (46.51 ± 0.08 gm), and the lowest value obtained was in Lacti Kids Premium 2 (21.42 ± 0.01 gm) (Table 4).

Discussion

Currently, dental caries is considered a biofilm-sugar-dependent disease; therefore, diet plays an important role in its etiopathogenesis.[16,17] Infant formulas are part of the infant diet due to several factors that contribute to the early abandonment of breastfeeding.[7] These formulas contain added sugars not present in breast milk, and their actual sugar content in relation to type and proportion is not well known. In this sense, and taking into account that nutrition and dietary habits play an important role in oral health during early childhood,[2] purpose of the present study was to determine the sugar concentrations in infant follow-on formulas most widely consumed in Peru.

In the present study, results showed that the infant follow-on formulas presented high percentages of total sugars; Enfamil 2 and Lacti Kids Premium 2 were the ones that showed the highest values of free sugars, such as glucose and sucrose. In addition, lactose was the sugar with the highest concentration among the five formulas analyzed, agreeing with the reports of Frades and Royo,[3] and Calvillo et al.,[18] who reported high percentages of total energy content contributed by sugars in growth milk formulas with 20–48% and 28–54%. In addition, Frades and Royo found free sugars ranging from 3 to 22%, differing from WHO recommendations, which postulate that if people consume free sugars, they should keep their intake below 10% of total energy needs, recommending a reduction to <5% of total energy, especially for prevention of dental caries.[3,19,20] They also consider that a higher intake of free sugars could jeopardize the diet quality by providing energy without nutrients.[19]

According to results obtained in the present study, some infant follow-on formulas, such as Enfamil 2 and Lacti kids Premium 2, had values below the label when compared to the sugar content obtained by laboratory chromatography analysis. Walker and Goran,[2] found that nutrient label data underestimated or overestimated actual sugars as approximately 25% of all samples had actual total sugar values greater than a 10% percentage variation from the label, agreeing with the present study as 60% of all infant follow-on formulas studied had percentage variations of 59.38% (Enfamil 2), 27.14% (Baby Lac Pro 2), and 41.51% (Lacti Kids Premium 2), also showing that some products marketed and consumed by infants may contain sugars in amounts that differ from nutritional labels.

Infant follow-on formulas are vital primary sources of nutrition and an important alternative source of nutritional supplementation in situations where breastfeeding is contraindicated.[7] These infant follow-on formulas contain fermentable carbohydrates (sucrose, corn syrup, lactose, glucose polymers, and maltodextrin), which make them highly cariogenic, especially during early infancy.[5] Among individual sugars analyzed in the present study, lactose, sucrose, fructose, glucose, and maltose stood out through the HPLC chromatograph. Lactose was the sugar with the highest concentration in the five formulas analyzed. Frequent and prolonged exposure to fermentable carbohydrates on tooth surfaces, as usually occurs with the consumption of sugary liquids, mainly at bedtime, causes a decrease in pH and loss of minerals (demineralization) in dental structures by bacterial metabolism, thus increasing the risk for early onset of dental caries lesions.[18] Epidemiological studies show a considerable prevalence of dental caries during early childhood, associated with sugar consumption and bacterial plaque.[17] At the national level, the Peruvian MINSA showed an overall prevalence of 59.1% of dental caries in children under 6 years of age.[15] Therefore, since some infant follow-on formulas contain added sugars, it is important to take preventive measures regarding their use and frequency, associated with good oral hygiene practices, since excessive consumption of sugars is strongly related to the appearance of various diseases such as childhood obesity, diabetes, and dental caries.[13,20] A relevant aspect to consider is that sugar, when ingested in liquid form and not in solid food facilitates its introduction in high concentrations in the body.[19]

Sucrose is a carbohydrate found within the content of infant formula and is considered the most cariogenic as it is fermentable by oral bacteria. Calvillo et al.,[18] analyzed the sugar content in 29 milk formulas and baby foods, where 33% of the products had sucrose. Similarly, all formulas analyzed in the present study had sucrose in their components, with Similac 2 (9.94 gm/100 gm) and Lacti Kids Premium 2 (11.92 gm/100 gm) standing out, while the rest of the formulas had values <0.70 gm/100 gm.

Findings obtained in the present study should be taken with caution since there were limitations, such as the number of infant follow-on formulas and the sampling type, due to the lack of a predefined sampling frame. However, we consider that this preliminary study could give continuity to this research line by providing data that will allow a probabilistic sampling under an appropriate sample size calculation. In addition, the present study allows to recommendation of a chromatography chemical analysis for the calculation of total and free sugars, which will allow a comparison of the percentage of energy intake against WHO-suggested standards for general and dental health care.

Table 4: Concentration of individual sugars found in infant follow-on formulas per 100 gm of powder

	A: Similac 2		*B: Enfamil 2*		*C: NAN 2*		*D: Baby Lac Pro 2*		*E: Lacti Kids Premium 2*	
Sugars	*Mean*	*Standard deviation (SD)*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
Fructose	<0.70	–	<0.70	–	<0.70	–	<0.70	–	<0.70	–
Glucose	<0.70	–	1.07	0.01	<0.70	–	0.72	0.01	<0.70	–
Lactose	40.39	0.03	21.68	0.05	46.51	0.08	40.82	0.09	21.42	0.01
Maltose	<0.70	–	<0.70	–	<0.70	–	<0.70	–	<0.70	–
Sucrose	9.94	0.08	<0.70	–	<0.70	–	<0.70	–	11.92	0.01

Units of measurement are grams per 100 gm of infant follow-on formula (A, B, C, D, and E)

As milk is the first and most important food consumed by the infant, it should be exclusively breastfed for the first 6 months,[3,20,21] as it has nutritional, immunological, neurological, endocrinological, and ecological benefits.[22] Furthermore, according to the Committee of the ESPGHAN, breast-milk substitutes should not be used as the main drink before the age of 1 year, and from this age onwards, the daily intake should not exceed 500 mL.[21,23] However, it is necessary for infants to consume follow-on formulae as part of their diet under medical prescription, so guidance on their use and consumption should be given in a balanced way according to the age, nutritional needs, and physical conditions of the infant, as indiscriminate use of these infant formulae could generate preferences over breast milk, in addition to increasing the risk of affecting dental health.[3,20,21,24] It is therefore recommended that nutrition security agencies and/or institutions play an important role in promoting the use and practice of breastfeeding in early childhood. Dentists should also provide mothers with educational sessions on infant feeding based on WHO recommendations on sugar reduction and appropriate introduction of complementary feeding to reduce the risk of early dental caries, disseminating clear and up-to-date messages.[25,26]

Conclusion

Recognizing the limitations of the present preliminary study, it is concluded that there is variability in sugar concentrations in infant follow-on formulas, being these values lower than those referred to on product labels. The formula with the lowest discrepancy was Similac 2, while the formula with the highest discrepancy was Enfamil 2, with Similac 2 and Enfamil 2 being significantly the formulas with the highest and lowest sugar concentration, respectively. In addition, among individual sugars, lactose, and sucrose stood out in greater proportion compared to other free sugars. In addition, among individual sugars, lactose, and sucrose stood out in greater proportion than other free sugars. It is important that institutions responsible for infant nutritional safety encourage and promote the use and practice of breastfeeding during early life and provide adequate guidance regarding daily doses of infant follow-on formulas since, according to the WHO, the high consumption of free sugars contained in these formulas can put infants' oral health at risk.

Declarations

Authors Contributions

They conceived the research idea (AKMM), elaborated the manuscript (AKMM, CJAS, ACCA, LACG, CFCR), collected, tabulated the information (AKMM, CJAS), carried out the bibliographic search (AKMM, MILC, ACCA, LACG), interpreted the statistical results (CFCR), helped in the development of the discussion (AKMM, CJAS, ACCA, CFCR), performed the critical review of the manuscript (CJAS, ACCA, MILC, CFCR). All authors approved the final version of the manuscript.

Ethical Policy and Institutional Review Board Statement

This research was exempted from review by an ethics committee of the School of Dentistry of the Norbert Wiener Private University. However, the investigation was approved with Resolution No. 0700-2020/DFCS/UPNW.

Data Availability Statement

The data that support the study results are available from the author (Ms Angélica Karina Munives-Marcos, e-mail: ak_kari@hotmail.com) on request.

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