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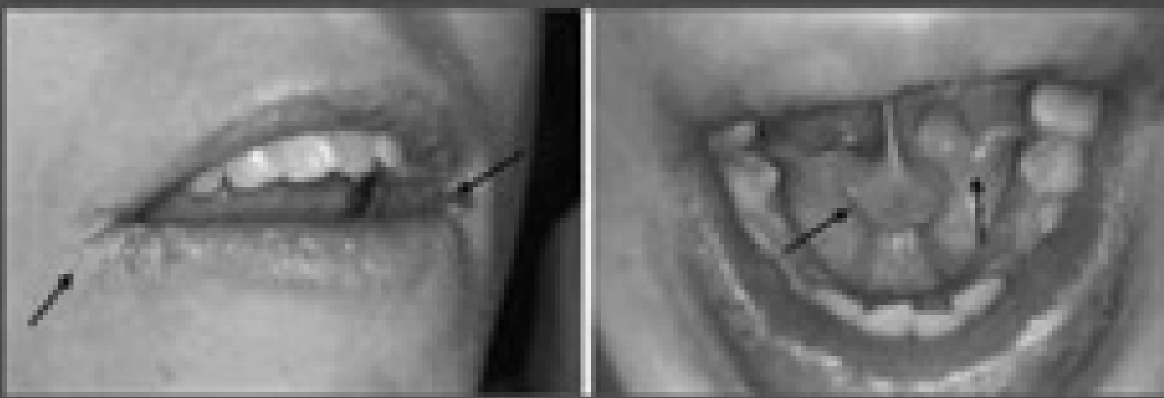

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Aluminum Contents of Human Milk, Cow's Milk, and Infant Formulas

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Abstract

Background: Aluminum toxicity is well documented and contamination of milk formulas has been implicated as the source of accumulation in bone and brain tissues. The purpose of the current study was to evaluate the aluminum contents of human milk, cow's milk, and infant formulas.

Cited Here... Aluminum contents were determined by atomic absorption spectrometry in samples of human milk in the colostrum, intermediate, and mature stages; infant formulas from eight manufacturers; and various types and brands of commercially available cow's milk.

Cited Here... Mean aluminum concentration was lowest in human milk (23.4 ± 9.6 µg/l), and did not differ significantly between colostrum, intermediate-stage and mature-stage milk. Mean aluminum concentration was 70 µg/l in cow's milk, and 226 µg/l in reconstituted infant formulas. Aluminum concentrations in infant formulas differed markedly among manufacturers; concentration in milk from one of the manufacturers was particularly high (mean, 551 µg/l; range, 302-1149 µg/l). These values are for milk reconstituted with aluminum-free water under laboratory conditions; formulas prepared with tap water in the University Hospital's infant-feeding unit had even higher aluminum content. Experiments showed that aluminum concentration in the high-aluminum milk could be reduced by more than 70% at the manufacturing stage, by using low-aluminum components.

Conclusions: The results of the present study support the recommendations for infant formula manufacturers to strive to reduce aluminum concentration in their products.

Aluminum may interfere with numerous processes in cells of the nervous system and other tissue (1). Neonates and nursing infants are at particular risk, notably because of the immaturity of the renal apparatus and consequent poor excretion of aluminum (2).

For many years aluminum was considered harmless. The first indication of toxicity came in 1962, when McLaughlin et al. (3) reported an association between prolonged exposure to aluminum and encephalopathy. In 1969, Kerr et al. (4) reported a high incidence of bone fractures in patients undergoing hemodialysis and attributed this finding to aluminum toxicity. Investigators in subsequent studies have reported several effects of excessive aluminum levels, including severe neurologic disorders, cardiac disorders, osteomalacia, anemia, and immunodepression (5). Such disorders are particularly common among patients with renal insufficiency or subjects receiving phosphate-fixing drugs with high aluminum content. Baluarte et al. (6) and Foley et al. (7) reported severe neurologic disorders and osteomalacia in children with congenital renal disease treated with high-aluminum phosphate-fixing agents. In 1984, Sedman (8) observed high aluminum concentrations in blood, urine, and bone of preterm neonates who had been supported by parenteral feeding and suggested that aluminum poisoning may be one of the causative factors of osteopenia in the premature infant. In 1990, the U.S. Food and Drug Administration recommended that aluminum concentration in parenteral feedings not exceed 25 µg/l (9). High plasma levels of aluminum have also been reported in children receiving antacids (10).

In 1985, Freundlich et al. (11) reported aluminum poisoning in two neonates with renal insufficiency, suggesting that it may have been because of aluminum in the formula milk that the infants had consumed. To date, however, no other evidence has been produced to support the possibility that aluminum poisoning can be caused by infant formula.

The aluminum content of infant formulas and commercial cow's milk is rarely stated on the package. Studies of the concentration of aluminum in human milk and infant formulas indicate a high variability (12-16). The Committee on Nutrition of the American Academy of Pediatrics has recently called for continuous efforts to reduce aluminum content in infant formulas (17). We report an investigation of aluminum content in a wide range of milk samples, including human milk in the colostrum, intermediate, and mature stages; infant formulas from eight manufacturers; and commercially available cow's milk (whole, semiskim, or skim).

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MATERIAL AND METHODS

Aluminum content was determined in 189 samples: 45 samples of human milk (14 of colostrum, 22 from the intermediate stage [7-10 days after birth], 9 from the mature stage [more than 10 days after birth]); 64 samples of infant formulas (17 samples of starter formulas, 47 samples of continuation formulas; formulas from eight manufacturers); 78 samples of commercial brands of cow's milk (53 whole, 10 semiskim, 15 skim); and 2 samples of a commercial brand of soy milk.

Possible effects of the preparation step were investigated by determining aluminum content in infant formulas after reconstitution in the laboratory using aluminum-free water and after reconstitution in our hospital's infant-feeding unit. Aluminum content was also determined in commercial ready-to-use formulas. In addition, we monitored aluminum content in tap water and formula milk from the infant-feeding unit daily for 1 week.

Samples were taken directly from the package or the mother's breast, and stored at 4°C until analyzed. The instruments used for sampling were either polyethylene or polypropylene (tubes and syringes) or stainless steel (needles). All pipettes and containers used in sample handling and analysis were prewashed in 10% nitric acid for at least 48 hours. Plastic instruments were kept under cover until use.

Preparation of samples and analysis were performed in the atomic absorption spectrometry (AAS) area in clean, controlled conditions. The plastic material was always stopped or under 10% nitric acid. The room was kept dust and draught free. In our experience, an absolutely clean room is not necessary at these aluminum levels.

Ultrapure water, obtained with the Elgastat system (ELGA, Bucks, England), was used throughout. Calibration standards were prepared by dilution of a stock solution (1000 mg/l aluminum; Titrisol 9967; Merck, Darmstadt, Germany). The nitric acid was Suprapur quality (Merck 441). Triton X-100 (Scintran, ref. 24630; BDH Chemicals, Ltd., Dagenham, Essex, United Kingdom) was used as a surfactant for the preparation of samples and standards.

Aluminum contents were determined by atomic absorption spectrometry in an apparatus with electrical heating in a graphite chamber (model 1100B; Perkin-Elmer, Norwalk, CT, U.S.A.), using graphite pyrolysis tubes and a L'Vov platform (Perkin-Elmer). The optimized temperature program and the instrumental parameters used are summarized in Table 1.

Instrumental Parameters

Parameter	Description
Background	Deuterium lamp
Source	Hollow cathode lamp
Lamp current	25 mA
Wavelength	309.3 nm
Slit width	0.7 nm
Signal mode	Peak area
Read time	5 sec
Sample volume	10 μl

Temperature Program

Step	Temperature (°/C)	Ramp time (sec)	Hold time (sec)	Argon flow (ml/min)	Lecture
Drying 1	90	5	5	300	
Drying 2	130	10	10	300	
Drying 3	200	5	5	300	
Charring 1	600	1	20	300	
Charring 2	1500	10	15	300	
Atomization	2500	0	5	0	0.0
Cleaning	2650	1	5	300	

ETAAS, electrothermal atomic absorption spectrometry.

TABLE 1. Instrumental parameters and temperature programs used in the ETAAS analysis of milk samples

Samples were diluted in double-distilled water containing 0.2% nitric acid and 0.2% Triton X-100. The dilution was adjusted so that the concentration in the sample fell within the most reliable part of the calibration curve. In all cases, the cited aluminum content of a sample is the mean of two determinations.

Reference materials from the National Institute for Standards and Technology (NIST) and the International Atomic Energy Agency (IAEA) were used as internal quality controls. Our laboratory has participated from the outset in the Worldwide Interlaboratory Quality Control for Aluminum program conducted by the Societé Francâise de Biologie Clinique. Accuracy data are reported in detail in Tables 2A and 2B. Only information values for aluminum are provided for the reference materials from the IAEA and NIST.

Reference material	n	Mean ± SD	Information values
IAEA-155[a]	8	41.50 ± 2.68	53 (38–68)
RM 8435[b]	5	0.19 ± 0.15	0.9 ± 0.9
SRM 1549[b]	5	0.33 ± 0.13	2
SRM 1577[b]	2	1.25 ± 0.0	2

[a] International Atomic Energy Agency (Austria).
[b] National Institute of Standards and Technology (EEUU, U.S.A.).
Data are micrograms per gram.

TABLE 2a. Precision data in aluminum determination with reference materials

Reference	n	mean ± SD	CV (%)	Expected result	Recovery (%)
74 E	10	85.50 ± 3.25	3.8	77.5 ± 13.6	110.1
73 F	7	50.40 ± 2.70	5.4	48.8 ± 5.9	103.3
77 E	8	36.40 ± 1.77	4.5	34.4 ± 5.2	105.2
75 F	4	9.10 ± 1.73	19.0	10.1 ± 3.8	90.1

Data are in micrograms per liter.

TABLE 2b. Accuracy and precision data in aluminum determination with samples from Worldwide Interlaboratory Aluminum Quality Control (France)

In every batch, two or three samples from the External Quality Control Program were included; precision and accuracy results for four levels of aluminum, are summarized in Table 2B. Results were always close to the mean values and are included in the mean ± 1 SD interval.

Aluminum contents in the different sample groups were compared by the Wilcoxon test, applying the Bonferroni correction when more than two groups were compared. Unless otherwise stated, statistical significance was set at $p < 0.05$.

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RESULTS

Human Milk

Aluminum contents in the human milk samples are listed in Table 3. Mean concentration was 25.7 µg/l in colostrum, 23.3 µg/l in intermediate-stage milk, and 21.5 µg/l in mature-stage milk; none of the pairwise differences was statistically significant. The overall mean (± SD) was 23.9 ± 9.6 µg/l, and the overall range was 7 to 42 µg/l.

Stage	n	Mean ± SD	Median	Range
Colostrum	14	25.7 ± 11.0	27.5	7–42
Intermediate	22	23.3 ± 9.3	21.0	10–37
Mature	9	21.6 ± 6.9	25.0	11–28
TOTAL	45	23.9 ± 9.6	25.0	7–42

At each stage—colostrum, intermediate (7–10 days after birth), mature (>10 days after birth)— a sample was obtained from a different mother. Data are in micrograms per liter.

TABLE 3. Mean aluminum contents in human milk

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Infant Formulas

Considering all 64 samples together, mean aluminum concentration was 225.9 µg/l (range, 8-1149 µg/l; Table 4). Mean aluminum concentration was somewhat higher in the 17 samples of the continuation formulas (245.8 µg/l) than in the 47 samples of the starter formulas (218.6 µg/l), although this difference was not statistically significant (Table 4). When the different infant formulas were considered separately (Table 5), mean aluminum content was less than 100 µg/l in three formulas, between 100 and 300 µg/l in six, and more than 300 µg/l in three.

Type	n	Mean ± SD	Median	Range
Starter	47	218.6 ± 191.4	160	8–1149
Continuation	17	245.8 ± 280.9	130	18–1129

Each sample was from a different batch. Data are in micrograms per liter.

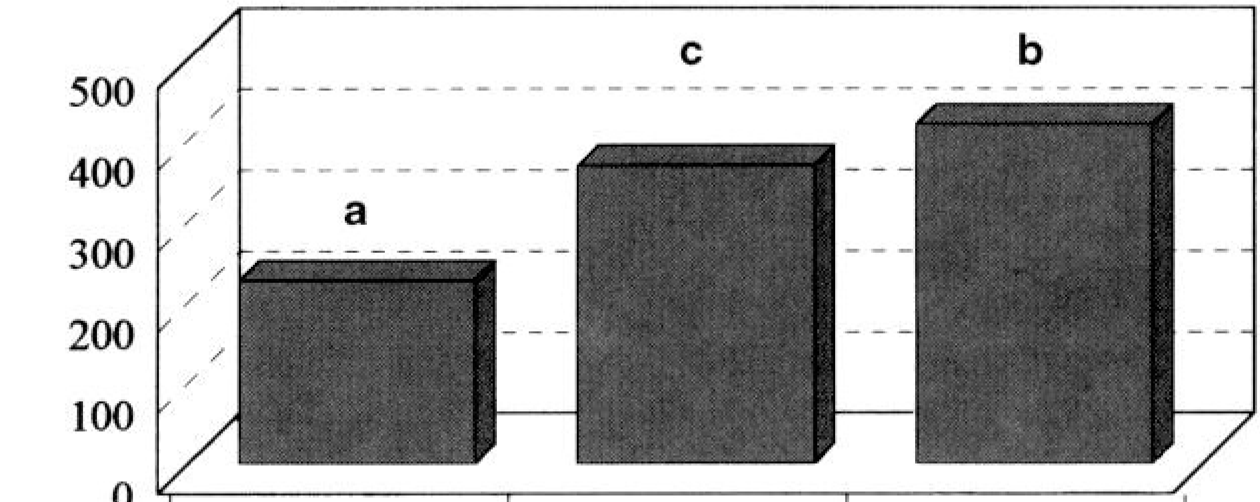
TABLE 4. Mean aluminum contents in the infant formula samples

Infant	n	Mean ± SD	Median	Range
Almiron	5	71.8 ± 54.3	68	19–152
Nidina	4	100.0 ± 52.0	127	56–160
Nativa	6	82.0 ± 53.4	112	18–146
Nan	5	74.0 ± 56.4	97	8–133
Puleva	9	131.4 ± 52.9	127	66–259
Natal SMA	3	189.6 ± 72.7	218	107–244
Enfalac	5	159.6 ± 62.4	169	72–243
Aptamil	5	197.0 ± 70.1	185	109–281
Nogamil	4	156.8 ± 50.1	182	112–215
Blemil	5	301.6 ± 46.9	308	247–370
Adapta	7	513.9 ± 288.9	399	302–1149
Modar	6	594.5 ± 264.9	519	417–1129

Each sample was from a different batch. Data are in micrograms per liter.

TABLE 5. Mean aluminum contents in the infant formula samples

We also investigated whether aluminum content is affected by the reconstitution procedure. Specifically, aluminum was determined in formula milks reconstituted with aluminum-free water under laboratory conditions, in commercially available ready-to-use formulas, and in formulas reconstituted in our hospital's infant-feeding unit. The results are summarized in Figure 1. Aluminum content in milks reconstituted with aluminum-free water was significantly lower ($p < 0.001$) than in ready-to-use formulations and milks reconstituted in the infant-feeding unit. There was no significant difference between aluminum contents in the latter two sample groups.



	Al-free water	Ready-to-use	Baby-feed unit
MEAN	225.8	367.1	418.2
S.D.	216.1	241.9	564.2

FIG. 1. Mean aluminum contents (μg/l) in infant formulas a) prepared under laboratory conditions with Al-free water, b) prepared in our hospitals infant-feed unit, or c) purchased ready for use.

With the goal of further investigating the effects of aluminum content in the water on the final concentration of this element in reconstituted formula milk, we monitored the aluminum content in tap water and in reconstituted milk from the infant-feeding unit daily over a 1-week period. The results (Fig. 2) clearly show that final concentration varied considerably depending on aluminum concentration in the tap water supply.

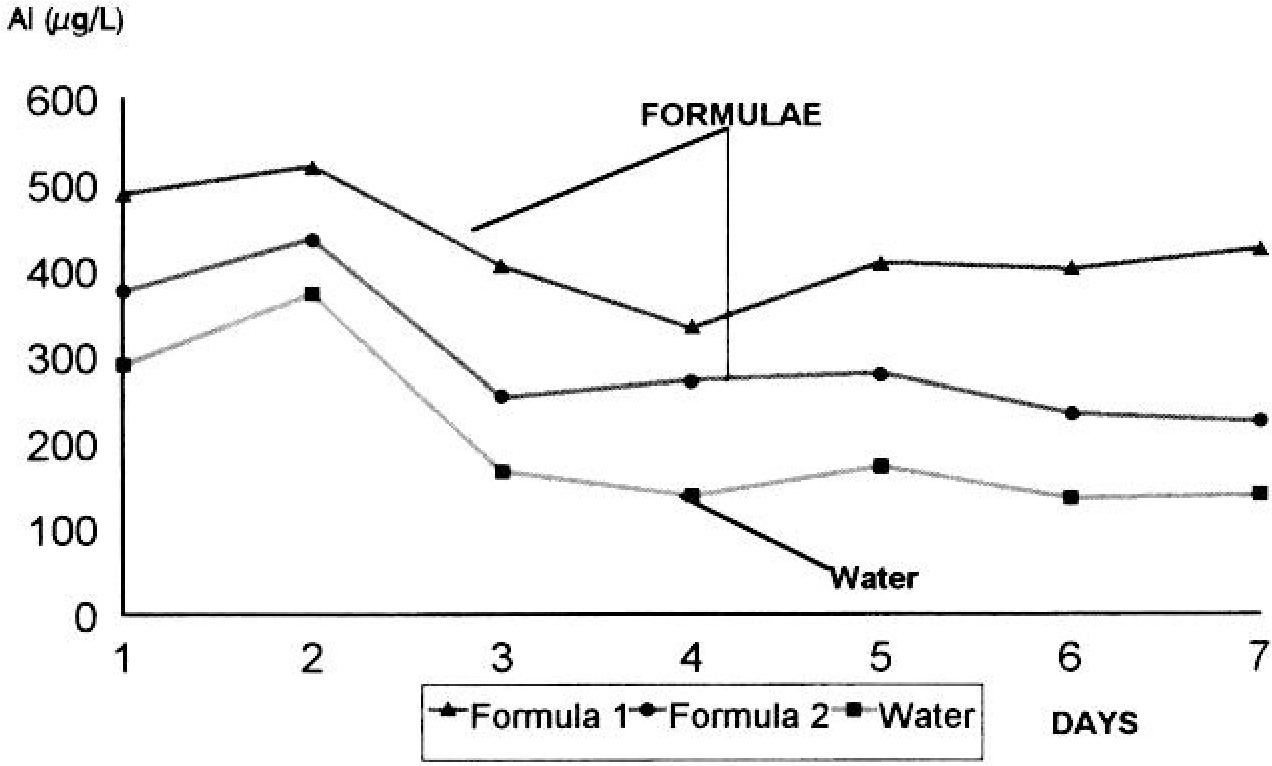


FIG. 2. Aluminum contents (μg/l) in tap water from our hospitals infant-feed unit, and in infant formulas prepared in this unit, monitored over a seven-day period.

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Cow's Milk

Considering all 80 samples together, mean aluminum concentration was 70.1 µg/l (Table 6). Mean aluminum concentration was 69.0 µg/l in the 53 samples of whole milk, 58.7 µg/l in the 10 samples of semiskim milk, 64.8 µg/l in the 15 samples of skim milk, and 152.5 µg/l in the two samples of soy milk. aluminum content did not differ significantly between any pair of sample groups, although content in the soy milk was more than double that observed in the other groups.

Type	n	Mean ± SD	Median	Range
Whole	53	69.0 ± 38.8	57.0	20–204
Semiskim	10	58.7 ± 34.6	62.5	10–126
Skim	15	64.8 ± 30.7	64.0	17–149
Soy	2	152.5 ± 68.5	152.5	104–201
TOTAL	80	70.0 ± 39.0	61.5	17–204

Each sample was from a different batch. Data are in micrograms per liter.

TABLE 6. Mean aluminum contents in the commercial milk samples

We also investigated possible effects of type of packaging on aluminum content (results not shown). Tetrabrik-packaged milk showed a mean concentration of 74.7 µg/l, versus 57.5 µg/l for milk sold in plastic bags and 42.6 µg/l for milks sold in plastic bottles; none of these differences was statistically significant. Mean aluminum content in ultra-high temperature milks (73.5 µg/l) was significantly higher than in pasteurized milks (49.9 µg/l; $p < 0.01$; Fig. 3).

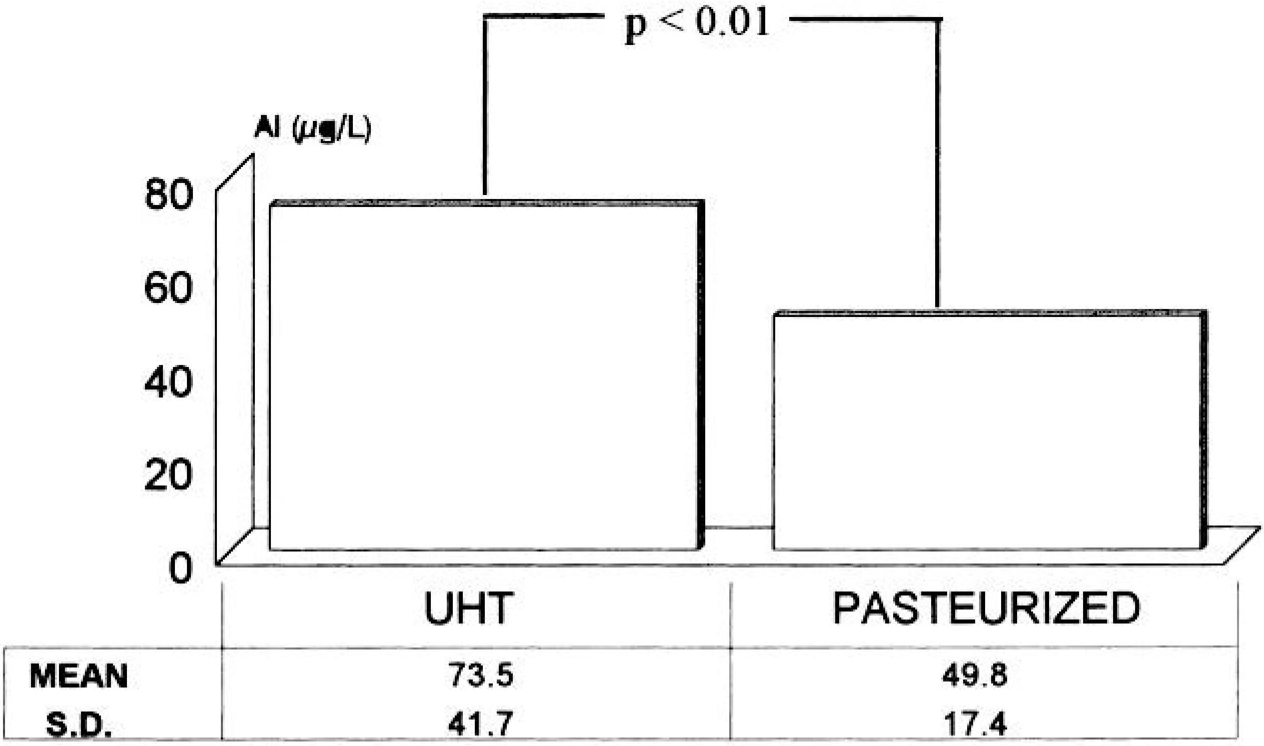

FIG. 3. Mean aluminum contents (µg/l) in the 80 commercial milk samples, classified by sterilization procedure (UHT or pasteurized).

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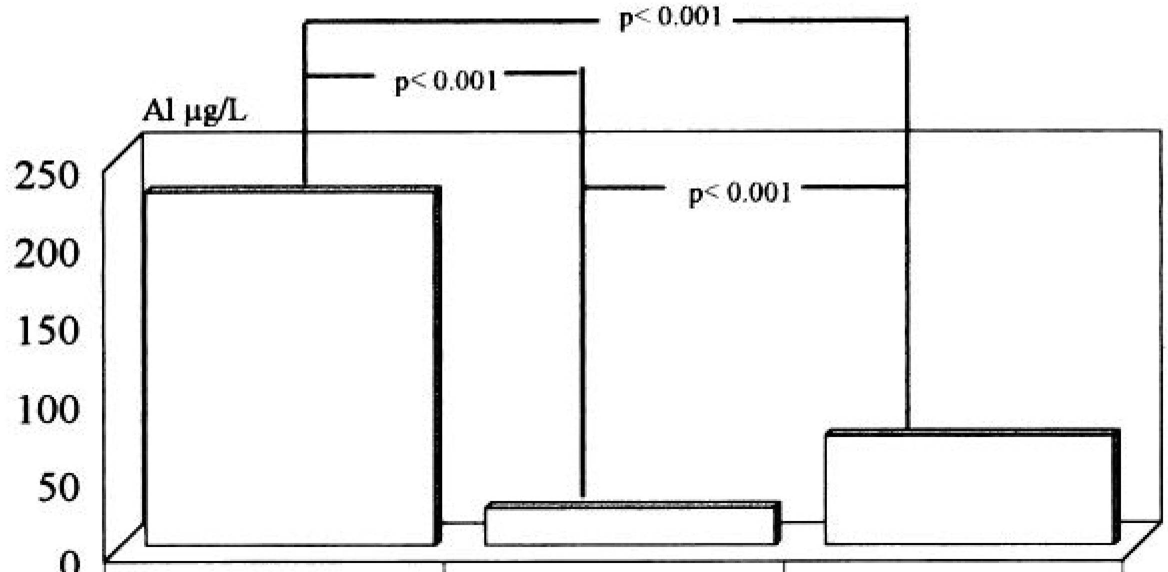
DISCUSSION

The results of the present study indicate that the aluminum content in human milk (mean, 23.9 ± 9.6 µg/l) was significantly lower ($p < 0.001$) than in commercially available cow's milk (mean, 70.1 µg/l) and infant formulas (mean, 225.9 µg/l; Fig. 4). The difference between the cow's milk mean and the infant formula mean was likewise significant ($p < 0.001$).



	Formulae	Human	Cow
MEAN	225.8	23.9	70
S.D.	216.1	11	39

FIG. 4. Mean aluminum contents (µg/l) in the three main sample groups (infant formulas, human milk, and cows milk).

In addition, investigators have found that human milk has the lowest aluminum content: For example, a report by the Committee on Nutrition of the American Academy of Pediatrics (17) states that the mean aluminum content of human milk has ranges from 4 to 65 µg/l in different studies. In a previous study in Spain, Ballabriga et al. (18) obtained even lower values (mean, 6.5 ± 5.0 µg/l; range, 0.9-19.8 µg/l) than in the present study. To date, the only workers to find high aluminum levels in human milk are Coni et al. (12) and Mandic et al. (19), who reported means of 167 µg/l and 380 µg/l, respectively.

In general, trace element concentrations in human milk decline with time after birth. This pattern was observed in the present study (colostrum mean, 25.7 µg/l; intermediate-stage mean, 23.3 µg/l; mature-stage mean, 21.6 µg/l), although the differences in question were not statistically significant. In 1983, Feeley et al. (20) reported that aluminum levels were higher in early and intermediate human milk than in late milk. However, Tanaka et al. (14) found no significant difference between milk samples taken 1 week and 1 month after birth.

In the present study, the mean aluminum content in commercially available cow's milk (70.1 µg/l) was about 3 times higher than in human milk. UHT milk had a higher aluminum content (mean, 73.5 µg/l) than pasteurized milk (mean, 49.8 µg/l). These differences were probably caused by the sterilization procedure, because in the preparation of UHT milk some polyphosphates are added as a stabilizer. The product used in several milks studied was the Turrisin ST (BK Giulini Chemie GmbH Co. OAG, Ladenburg, Germany), and the aluminum level found in this product was 31 µg/g (n = 11, mean, 31.0 ± 1.2 µg/g). This amount produced an increase of 31 µg/l (Fig. 3). Previous studies have reported mean aluminum contents of 27 µg/l (15), 40 µg/l (18), and 95 µg/l (21) in pasteurized cow's milk.

We did not detect significant effects of packaging on aluminum content in commercially available cow's milk, although packaging materials with high aluminum content can clearly be expected to have such effects (22). Previous investigators have indicated that aluminum levels in bottled albumin for perfusion are affected by the aluminum content of the glass (23).

Similarly, we did not detect a significant variation in aluminum content in whole, semi-skim, and skim cow's milk. However, aluminum content was markedly higher in vegetable-fat milks (mean, 152 µg/l), possibly because of the relatively high aluminum contents of the vegetable oils used.

As in previous studies, we found aluminum content to be highest in infant formulas: Depending on the manufacturer, mean aluminum content was between 3 and 23 times higher than in human milk and up to 8 times higher than in cow's milk. If we assume daily milk ingestion of 200 ml/kg, the mean value determined in the present study (225.9 µg/l) implies a daily aluminum intake of approximately 0.045 mg/kg per day, considerably lower than the provisional World Health Organization-recommended daily maximum intake of 1 mg/kg per day (24). Indeed, even considering the very high aluminum content in one of the infant formulas milk samples (1149 µg/l), daily aluminum intake would still only be approximately 0.23 mg/kg per day. Nevertheless, it is clearly appropriate to take a conservative approach when estimating maximum permissible daily intake.

Our results regarding aluminum contents in infants formulas are almost in agreement with those of previous studies (12,16,21,25-27). However, mean aluminum contents were particularly high in the Blemil, Adapta, and Modar milks (see Table 5). We thus investigated whether this might be because of contamination during packaging of the product. However, we detected no significant difference in aluminum contents before and after packaging in these milks (results not shown). We then attempted to identify the components of the milk responsible for the high aluminum content. The results (Table 7) show that the fat concentrate, lactose, and mineral mix all made a major contribution, and that total aluminum content in the finished product could be reduced by 72% by replacing these components with low-aluminum equivalents.

Component	Aluminum content[b]	Aluminum content, low-aluminum components[a,b]
Fat concentrate	260.7	104.3
Lactose	86.1	2.87
Vitamin mix	2.38	2.38
Mineral mix	179.5	1.20
Aminoacid	14	14
Total	542.7	124.7

[a] Contents of low-aluminum alternatives.
[b] Mean of four determinations.
Data are in micrograms per liter of reconstituted milk.

TABLE 7. Mean aluminum contents in the components used by one manufacturer of the continuation formulas

Formula milks prepared in the infant-feeding unit of our hospital and ready-to-use formula milks had higher aluminum concentrations than milk prepared with aluminum-free water under laboratory conditions. In the case of milk prepared in the infant-feeding unit, this appears to have been largely because of the high aluminum content of the tap water (see Fig. 2). Similar results were obtained by Semmekrot et al., (16) who found that aluminum concentration in formula milk prepared under noncontrolled conditions was 3 to 100 times that in milk prepared with aluminum-free water under laboratory conditions.

In conclusion, the results of the present study support the recommendations of the Committee on Nutrition of the American Academy of Pediatrics (17) regarding the need for infant formula manufacturers to strive to reduce aluminum concentration in their products and the desirability of printing the maximum aluminum content on the package, stating the possible dangers particularly in nursing infants with renal insufficiency or other in disorders or characteristics that might favor accumulation of this element.

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