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Original Research

The Effects of Total Parenteral Nutrition on Plasma Aluminum Levels in Premature

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Abstract

Objectives: Aluminum accumulates in the body, disrupts mental development, affects bone mineral structure and causes cholestasis in the liver. Aimed to investigate parenteral nutrition and aluminum transmission in preterm infants.

Methods: Our study was designed as a single-center prospective study. And 45 babies were included during pregnancy weeks ≤32 and/or under 1500 grams. Cord blood samples were taken at birth from all infants. And blood levels of aluminum on the 14th day compared with cord blood levels of aluminum.

Results: Aluminum levels evaluated from patients' cord blood were 3.35±1.73 g/L (18-9.7 g/L), while levels reported on day 14 were 4.79±3.54 (1.6-18.6 g/L). Aluminum levels increased by 1.44±3.86 (0.28-2.60) f/L, which was statistically significant (p=0.021). The increase in aluminum levels was highly associated with number of days that furosemide was administered (p=0.012). The increase in serum aluminum levels of patients receiving parenteral feeding for more than 10 days was found to be significantly higher. But there was no statistically significant difference. When the contents of parenteral solutions were examined, it was discovered that there was an important positive correlation between calcium and magnesium levels administered in the first seven days and serum aluminum levels on the fourteenth day (p=0.044 and p=0.008, respectively).

Conclusion: The increase in serum aluminum levels in preterm infants fed parenteral nutrition was found to be statistically significant. Longer parenteral nutrition was associated with a greater increase in serum aluminum levels.

Keywords: Parenteral nutrition, plasma aluminum, premature

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Ensuring the survival of preterm infants depends on nutrition, and thus, total parenteral nutrition must be viewed as a cornerstone, particularly in the treatment of babies born under 32 gestational weeks. Today, TPN (total parenteral nutrition) is defined as an indispensable method for ensuring the growth and development of infants.[1] Is aluminum toxicity an unrecognized side effect of TPN? Aluminum toxicity was first described by Sedman et al.[2] in 1985 in premature infants receiving parenteral nutrition. When aluminum is administered intravenously, it bypasses the gastrointestinal control mechanism, and excessive intake results in tissue accumulation. Due to accumulation, findings of aluminum toxicity that may affect several systems have been observed.[3] A limited number

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of studies have shown that, in the long term, clinical findings such as encephalopathy, impairments in neurological development, bone pain, osteopenia, osteomalacia, microcytic anemia, and cholelithiasis are observed in preterm babies.[3,4]

The metabolism of aluminum in preterm infants remains unclear. It has been shown that blood and urine aluminum levels are increased in premature infants receiving parenteral nutrition.[5] According to the United States Food and Drug Administration recommendations issued in January 2000, the daily aluminum intake limit in total parenteral nutrition fluid is set at 5 µg/kg/d for the neonatal period.[6,7] Several studies have demonstrated that glass containers with rubber closures for calcium gluconate, trace elements, phosphate salts, and vitamin solutions used in neonatal parenteral nutrition are some of the most important sources of aluminum contamination.[8-11] It has been indicated that, in preterm infants on TPN containing a high amount of aluminum, 18-month Mental Development Index (MDI) scores are negatively impacted, the amount of aluminum has a negative impact on lumbar bone density in long-term follow-up, and osteoporosis and hip fracture may occur during adolescence.[4]

There is a lack of available studies to support the conclusion that aluminum exposure occurs in premature infants. Our study aims to investigate the hypothesis that aluminum levels are significantly increased in premature infants with longer exposure to TPN at less than 32 weeks of gestation.

Methods

Our study was designed as a single-center prospective study. All infants born and treated in our clinic with ≤32 gestational weeks and/or birth weight <1500 grams were included in the study. A cord blood sample was collected from all the infants at birth. At the end of the first 14 days in the clinic, infants who had received parenteral nutrition for ≥7 days were enrolled in this study. A blood sample was collected via specifically designed tubes (BD Vacutainer® SST™ II Advance, BD Belliver Industrial, UK). Aluminum levels were compared between cord blood and blood test results from day 14.

Sample Size

A difference between the paired groups with a medium effect size was determined as significant, and the sample size was calculated with a t-test. The sample size was set as 45 with 95% power at 0.05 alpha.

Clinical Data Collection from the Patients

The demographic data recorded for the enrolled infants included the following: gestational age, sex, use of antenatal steroid, early membrane rupture, birth weight, mode of delivery, perinatal asphyxia, length of hospital stay, duration of oxygen therapy and mechanical ventilation and continuous positive airway pressure (CPAP), dopamine, dobutamine, history of antibiotic treatment, respiratory distress syndrome, bronchopulmonary dysplasia, sepsis, diagnosis of necrotizing enterocolitis and intraventricular hemorrhage, the daily amount of parenteral nutrition fluid, content and the total duration of intake. All data was collected daily.

Ethical approval for this study was obtained from Sisli Hamidiye Etfal Training and Research Hospital Ethics Committee on 01.11.2016 (1312/2016). Written and verbal consent was obtained from the parents of the infants included in the study. Our study was conducted in accordance with the Declaration of Helsinki.

Laboratory Results

For the evaluation of serum aluminum levels, the cord blood sample was collected at birth, and on the 14th day, a blood sample was obtained from the central venous catheter. Hemograms and biochemical parameters were registered on infant records. In infants on TPN, aluminum levels were measured 4 hours after TPN discontinuation. Blood samples collected for aluminum were transferred into gel-free tubes via vacutainer, and no other needles or contents were added. Centrifugation was done for 15 minutes and placed in Sarsedt polypropylene tubes via plasma polyethylene pipette. The samples were kept in the cold chain at -80C°. Serum aluminum levels were analyzed via SHIMADZU 7000 Series Atomic Absorption device.

Exclusion Criteria

The exclusion criteria were as follows: infants with gestational age >32 weeks or birth weight >1500 g, TPN duration <7 days at the first 14 days of life, parents do not give consent to participate in the study, presence of major life-threatening congenital abnormality (cyanotic congenital heart disease, hydrocephalus, genetic syndromes, etc.), infant mortality before the sampling process.

Statistical Analysis

Statistical analysis was conducted with SPSS 20.0 for Windows (New York: IBM Corp). Descriptive statistics were presented in number and percentage for categorical variables and mean and standard deviation (SD) for numerical variables. As differences in numerical variables between paired groups do not meet the criteria of the normal distribution, differences were calculated with the Wilcoxon test. Independent samples comparisons were performed with the Mann Whitney U test and multiple group comparisons were performed with Kruskal Wallis Test due to non-normal distributions. Correlational analysis was performed with Spearman Correlation Analysis as parametric test criteria were not met. Alpha level was 0.05.

Results

In our hospital, 4200 babies were born between November 2016 and March 2018. There were a total of 113 babies with a gestational week ≤32 weeks and/or below 1500 grams. The study was carried out with 45 infants matching the criteria. The flow chart of the study is presented in Figure 1. The demographic and clinical features of the infants included in the study are presented in Table 1.

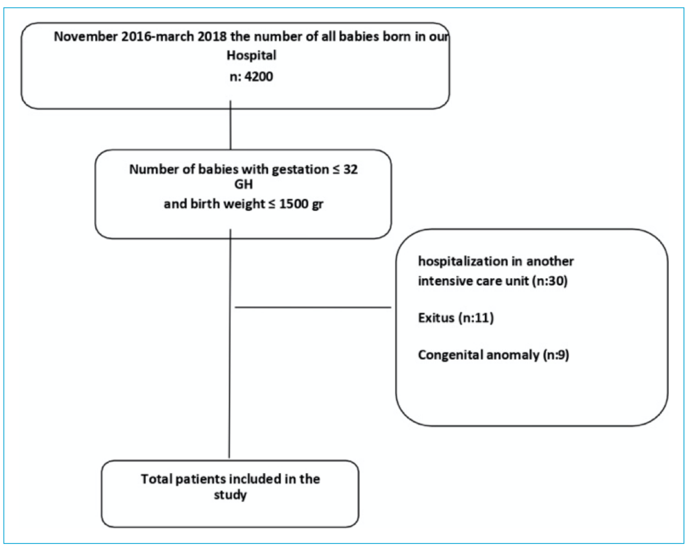

Figure 1. The flow chart of the study.

Table 1. The distribution of demographic and clinical characteristics of the babies included in the study

Demographic characteristics	Mean±SD	Min-Max
Birth weight * (gr)	1219.2±432.5	(550-2395)
Gestasiyonal age* (week)	29.0±2.3	(23.4-32.3)
Maternal age (year)*	30.3±6.0	(18-42)
Hospital stay (days)	72.8±50.3	(18-235)
TPN taken day (days)	23.4±22.6	(7-128)
Gender (Boy/Girl) (%)	62.2 / 37.8	
Birth way (Vaginal / C/S) (%)	11.1 / 88.9	
Intrauterine growth		
SGA. n (%)	4 (7)	
AGA. n (%)	35 (77)	
LGA. n (%)	6 (13)	
Antenatal steroid. n (%)	39 (86.7)	

MV: Mechanical ventilation; CPAP: Continuous positive airway pressure; TPN: Total parenteral nutrition; * Values are given as mean standard deviation.

The contents of parenteral nutrition solutions given to infants during follow-up were recorded as kg/day, and the total values, mean values, and SD were calculated and presented in Table 2. When cord blood and 14th-day serum aluminum levels were compared, a significant increase was found in 14th-day serum aluminum levels (Fig. 2). Serum aluminum level was 3.35±1.73 µg/L in cord blood, while the 14th day serum aluminum level was found to be 4.79±3.54 µg/L. The difference between cord blood and 14th-day serum aluminum levels was determined as 1.44±3.86 (0.28-2.60) (p=0.021). When the duration of parenteral nutrition and aluminum levels were compared, although the increase was found to be greater in infants receiving parenteral nutrition for more than 7 days, no statistically significant difference was found compared to the infants on parenteral nutrition for 7 days (p=0.609) (Fig. 3). The results of factors affecting the cord blood and 14th-day aluminum levels are presented in Tables 3 and 4. It was shown that the amount of calcium and magnesium provided on the 14th-day had an impact on serum aluminum levels. A positive correlation was obtained between the amount of calcium and magnesium provided for the first 7 days of life and 14th day serum aluminum levels.

Discussion

TPN support is needed for infants with low birth weight to adapt to postnatal life until total enteral feeding is provided. Despite their vital efficacy, parenteral nutrition solutions may result in several complications. One of the potential complications, depending on the ingredient, is aluminum toxicity. The first study indicating aluminum contamination of parenteral nutrition solutions was published in 1982[5], and the study conducted by Sedman et al.[2] in 1985 investigated blood, urine, and blood aluminum levels in premature babies to show the effect of aluminum in parenteral solutions. The analysis found significantly high blood, bone, and urine aluminum levels in infants receiving parenteral nutrition.[2]

In 1991, the American Society for Clinical Nutrition (ASCN) and the American Society for Parenteral and Enteral Nutrition (ASPEN) suggested that the safe level of aluminum in parenteral nutrition solutions is <2 mcg/kg/day.[11] As of the update in 2000, aluminum exposure in total parenteral nutrition fluids was divided into two categories: small-volume parenteral fluids and large-volume parenteral fluids.[6,7]

Following the recommendations of the FDA, the amount of aluminum in parenteral fluids and the ingredients causing aluminum contamination were investigated based on their compatibility with the recommendations on the amount of aluminum.[12,13] It was concluded that calcium solutions

Table 2. Total parenteral nutrition and distribution of the contents given to the babies

Parenteral fluid contents (examined per kilogram)	Total TPN amounts Mean±SD	
	During the 7th day*	During the 14th day×
Volume (ml/kg)	825.5±119.9	1486.1±432
Protein (gr/kg)	19.0±5.3	33.9±13.3
Lipid (gr/kg)	12.1±3.9	20.7±10.9
Dextroz (mg/kg)	57.6±21.3	98.3± 41.7
Calcium (mg/kg)	350.8±644.3	406.7±132.2
Potassium (meq/kg)	5.7±4.4	10.7±5.6
Sodium (meq/kg)	14.5±6.1	28.9±16.3
Phosphorus (meq/kg)	84.4±81.3	203.7±163
Magnesium sulfate (mg/kg)	36±55.5	114±133.5
Vitalipid (cc/kg)	3.4±2.5	7.3±4.4
Soluvit (cc/kg)	3.4±2.3	7.6±4.5

×Total amount given to babies for 14 days. *Total amount given to babies for 7 days. SD: Standard Deviation.

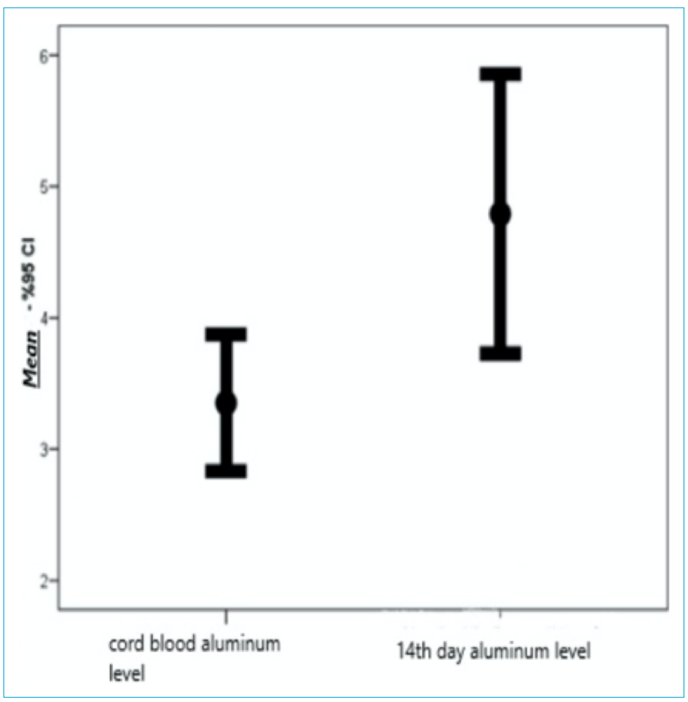

Figure 2. Cord blood and serum aluminum levels chart on the 14th day.

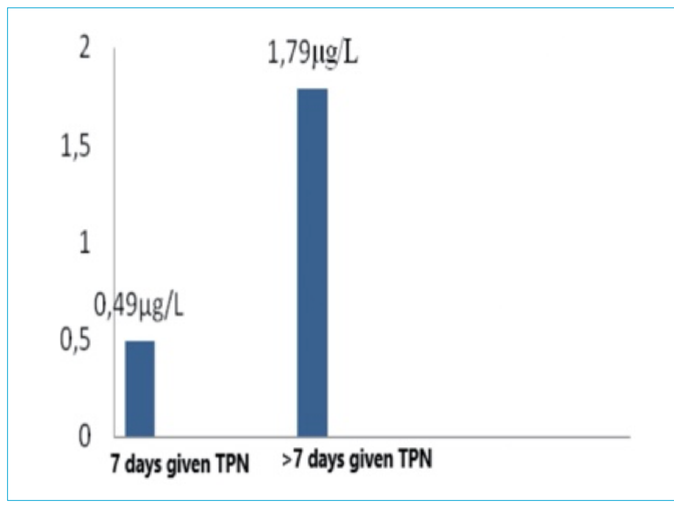

Figure 3. Graph of change in serum aluminum level according to TPN removal time.

were significantly higher in parenteral fluids whose aluminum level was above the FDA recommendation.[10,14,15] A study conducted by Mouser et al.[9] indicated that aluminum contamination was associated with calcium gluconate by 81%. According to a study conducted in Mexico regarding aluminum contamination, it was found that the main sources of contamination were calcium, phosphate salts, and trace elements. However, plasma aluminum levels were not measured in this study.[14] In a study showing that calcium and phosphate salts are the most important aluminum sources, calcium salts were compared, and it was recommended that calcium gluconate should not be preferred as it contains high amounts of aluminum.[15] In our study, a positive and significant correlation was found between the amount of calcium and magnesium in TPN at the first 7 days and the 14th day serum aluminum levels. No significant correlation was found between phosphate solutions, other parenteral solution ingredients (lipid, protein, sodium, potassium chloride) and serum aluminum levels.

In a study comparing aluminum levels in parenteral fluid with aluminum levels determined by manufacturers, parenteral fluid samples of 40 patients were examined and compared with the total aluminum content determined by the companies.[16] While measured aluminum levels were found

Table 3. Factors of affecting plasma aluminum level

Features	Aluminum 0. day (µg/L)	Aluminum 14. Day (µg/L)	Aluminum Increase Amount (µg/L)	p
Gender				
Boy	3.45±1.56	4.59±4.27	1.14±4.47	0.303
Girl	3.30±1.85	4.92±3.09	1.62±3.52	
Gestastional age				
≤26 GH	3.93±2.90	7.45±4.36	3.52±5.85	0.272
26-29 GH	3.55±1.61	4.70±2.83	1.15±3.21	
29-32 GH	3.14±1.42	4.16±3.35	1.02±3.45	
Birth weight:				
≤ 1000 gr	3.77±2.26	6.38±4.94	2.61±5.45	0.653
1000-2000gr	3.09±1.42	3.85±2.14	0.76±2.57	
>2000 gr	3.37±0.39	4.49±1.75	1.12±2.13	
TPN receiving day				
= 7 days (n=5)	3.38±0.80	3.86±1.34	0.49±2.06	0.609
> 7 days (n=38)				
3.20±1.54	4.99±3.79	1.79±3.94		
Ampicilin+Amikacin				
≤7 days (n=27)	3.88±1.91	5.16±3.76	1.28±4.03	0.643
>7 days (n=18)	2.56±1.03	4.24±3.20	1.68±3.69	
Ampicilin+Gentamicin				
≤7 days (n=28)	3.89±1.88	5.04±3.74	1.15±4.01	0.386
>7 days (n=17)	2.46±0.97	4.37±3.25	1.91±3.66	
Dobutamine				
≤3 days (n=43)	3.38±1.76	4.77±3.62	1.39±3.94	-
>3 days (n=2)	2.68±0.54	5.27±0.09	2.59±0.45	
Dopamine				
≤3 days (n=42)	3.41±1.78	4.72±3.65	1.31±3.96	-
>3 days (n=3)	2.57±0.43	5.83±0.98	3.26±1.22	
Furosemide				
≤3 days (n=43)	3.40±1.76	4.73±3.60	1.33±3.91	-
>3 days (n=2)	2.32±0.03	6.08±1.24	3.76±1.22	

*Serum aluminum increase amount = 14 days serum aluminum - aluminum level in cord blood.

to be lower than the levels determined by manufacturers, the highest aluminum intake was shown in infants with a birth weight of <1000 g. The explanation for this is the high level of aluminum in calcium gluconate, where increased calcium needs are provided.[16] In our study, we did not find a correlation between birth weights or gestational week and serum aluminum values in support of these findings.

In a study conducted with 27 children with a diagnosis of intestinal disease who received more than 25% of their total calories with parenteral nutrition for over 6 weeks compared with a healthy control group, the plasma aluminum level was significantly higher in the group receiving parenteral nutrition.[17] It has been reported that serum aluminum level is 3 to 4 times higher than the level it should be. The same study demonstrated that parenteral fluid volume and infusion time were shown to be effective in increasing serum aluminum levels. The level of aluminum in 10 samples randomly selected from the parenteral solutions of the patients was examined, and it was found to be three times higher (mean 15.4±15 µg /kg/d) than the FDA recommendation.[17] In our study, the aluminum levels of infants receiving parenteral fluid for 7 days, and more than 7 days were compared. Infants receiving parenteral nutrition for a longer time had higher levels of serum aluminum; however, no statistically significant difference was found. In infants receiving parenteral nutrition for more than 7 days, the aluminum increase was higher (1.79±3.94 µg/L), while it was lower in infants receiving parenteral nutrition for 7 days (0.49±2.06 µg/L). No significant correlation was observed between TPN volume and serum aluminum.

Table 4. Relation between solutions and aluminum level in parenteral nutrition fluid

Features	Serum Aluminum level 14th day		Aluminum increase	
	Rho	P	rho	P
Volume 7 days #	0.085	0.580	0.152	0.320
Protein 7 days#	-0.043	0.779	-0.128	0.402
Lipid 7 days#	-0.036	0.815	-0.043	0.77
Dextrose 7 days#	0.091	0.554	0.229	0.131
Calcium 7 days#	-0.302	0.044	-0.135	0.376
Potassium chloride 7 days #	-0.163	0.290	-0.118	0.444
Potassium phosphorus 7 days #	-0.002	0.989	-0.022	0.888
Serum sale 7 days #	-0.143	0.349	-0.057	0.708
Natriium phosphate 7 days #	0.116	0.449	0.101	0.509
Magnesium sulfate 7 days #	-0.294	0.050	-0.391	0.008
Volume 14 days ˣ	0.169	0.266	0.201	0.185
Protein 14 days ˣ	0.046	0.762	-0.018	0.904
Lipid 14 days ˣ	0.157	0.303	0.064	0.674
Dextrose 14 days ˣ	0.171	0.261	0.258	0.087
Calcium 14 days ˣ	0.076	0.618	0.252	0.095
Potassium phosphate 14 days ˣ	0.145	0.343	0.096	0.530
Natrium phosphate 14 days ˣ	-0.058	0.707	0.032	0.832
Magnesium 14 days ˣ	-0.169	0.267	-0.212	0.161

*14. Day serum aluminum - cord blood aluminum level # It is given as the total amount given per kg for 7 days. ˣ It is given as the total amount given per kg for 14 days.

In a study conducted in Brazil in 2009 to examine the aluminum levels of the parenteral fluid contents and drugs used in newborns, the amount of aluminum measured in the dopamine preparation was 695.3±29 mcg/L and the amount of aluminum measured in dobutamine was 475.2±105.1 mcg/L.[16] Besides, aluminum contamination was increased during dilution.[16] In our study, patients receiving dopamine and dobutamine for more than 3 days and less than 3 days were compared; however, statistical data could not be obtained due to an insufficient number of patients enrolled. However, in babies who received dopamine or dobutamine treatment for more than 3 days, the rate of increase in serum aluminum level was found to be high on the 14th day of the babies.

Along with the TPN, it is known that medications given to children are one of the sources of aluminum. When the aluminum concentration level in drugs was assessed, it was measured at 251.5±22.1 mcg/L for amikacin and 164.4±61.7 mcg/L for gentamicin.[16] In our study, when infants receiving ampicillin, gentamicin, and amikacin for less than 7 days and more than 7 days were compared, no significant difference was found in serum aluminum levels. Aluminum levels measured in furosemide were 54.4±10.3 mcg/L. while they were measured 1832±25 mcg/L in dexamethasone.[16] According to our study, the duration of furosemide administration was found to be efficient in increasing aluminum levels, and serum aluminum levels were higher in patients receiving furosemide for more than 3 days.

Limitations

Although our study is the first to examine serum aluminum levels in premature babies, we acknowledge that there are limitations. First, administered parenteral solutions and the aluminum contents of drugs were not measured simultaneously. Due to the insufficient number of cases enrolled in the study, a sufficient number of subgroups could not be achieved, resulting in a decrease in effect size.

Conclusion

The serum aluminum level increases significantly on the 14th-day, according to cord blood values of preterm babies. In babies who take dopamine, dobutamine, and furosemide for more than 3 days in the first 14 days of life, serum aluminum levels increase significantly compared to babies who do not. It should be considered that the total parenteral solution and drugs used to save preterm babies are risky in terms of potential aluminum toxicity. The findings suggest that there is a need for further research with large case number and also exploring long-term effects.

Disclosures

Ethics Committee Approval: The study was approved by the Sisli Hamidiye Etfal Training and Research Hospital Clinical Research Ethics Committee (date: 01.11.2016, no: 1312/2016).

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