

Lead Content in 70 Brands of Dietary Calcium Supplements

ABSTRACT

Objectives. Elevated lead levels in calcium supplements may pose a health risk, particularly to children with milk intolerance who rely on these products to meet their calcium requirement. Earlier reports chiefly focused on the lead content in supplements derived from bonemeal and dolomite. This study undertook to determine the lead levels in the major forms of calcium supplements currently available.

Methods. The lead content was measured in 70 brands of calcium supplements grouped in the following five categories: dolomite, bonemeal, refined and natural source calcium carbonate, and calcium chelates.

Results. The lead levels measured in the supplements ranged from 0.03 $\mu\text{g/g}$ to 8.83 $\mu\text{g/g}$. Daily lead ingestion rates revealed that about 25% of the products exceeded the US Food and Drug Administration's "provisional" total tolerable daily intake of lead for children aged 6 years and under. Less than 20% of the supplements had "normalized" lead levels comparable to or lower than that reported for cow's milk.

Conclusions. Children are the most sensitive to the low-level effects of lead. If calcium supplements are to provide an alternate source of calcium to some of these individuals, they should also deliver concomitant lead dosages no greater than those obtained from milk products themselves. (*Am J Public Health.* 1993;83:1155-1160)

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Introduction

Lead, a toxic metal that affects the central nervous system and heme synthesis pathways, is ubiquitous in the environment as a result of industrialization. Reduced sales of leaded gasoline in the United States and Canada caused the airborne levels of lead to decline by approximately 80% between 1974 and 1987.¹⁻³ This reduction in atmospheric particulate lead was paralleled by a significant decline in the average lead content of the North American diet.⁴⁻⁶ Between 1982 and 1988, the average amount of lead ingested daily by US children in their diet decreased six-fold, from 30 μg to 5 μg .⁶ Despite these reductions, however, the Agency for Toxic Substances and Disease Registry estimated in 1988 that more than 3 million children younger than 6 years of age (17% of all US children in this age group) had unacceptably high blood lead levels (i.e., > 15 $\mu\text{g/dL}$).⁷ Lead has been shown to affect the neurobehavioral development of newborns, infants, and children exposed to lead either in utero or postnatally.⁸⁻¹² It was further noted that childhood lead poisoning was widespread and that no socioeconomic group or geographic area was spared.¹³

About 10 years ago, the US Food and Drug Administration (FDA) cautioned the public to limit their intake of calcium supplements because of the potentially high lead levels in some of these products, mainly those produced from bonemeal and dolomite.^{14,15} Calcium supplements are often prescribed to pregnant and lactating women as well as to children with milk allergy. They are also purchased over the counter by a significant portion of the general population. A survey performed by the National Center for Health Statistics¹⁶ reported that 25% of the women and

8% of the children aged 2 to 6 years in the United States consume nonprescribed calcium supplements daily. Others have reported that concern about a poor diet may lead some women to double or triple the recommended daily dose of calcium.¹⁷

Earlier reports have focused mainly on the lead content in calcium supplements derived from dolomite and bonemeal powders.^{14,15,18-21} However, a 1992 interlaboratory comparison study has shown that supplements composed of other calcium salts (e.g., calcium carbonate and calcium chelates) may also contain substantial amounts of lead.²² In light of both the growing number of individuals using calcium supplements^{16,23} and the recent findings of low-level lead toxicity in the fetus and neonate, a survey reporting on the lead level in the major forms of calcium supplements currently available seemed in order. In this study, we reported the lead levels measured in 70 brands of calcium supplements. Based on the suggested daily dosage listed on the product labels, we calculated daily lead ingestion rates (i.e., micrograms of lead ingested per day) and compared them against guidelines of dietary lead intake established and updated in 1990 by the US FDA.^{24,25}

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TABLE 1—Categories of Brands of Calcium Supplements in the United States and Canada

Categories	No. of Brands	
	United States	Canada
Refined calcium carbonate	...	17
Natural source calcium carbonate	6	19
Chelated calcium (various)	5	8
Dolomite	2	7
Bone	2	4

Methods

Sample Types

The calcium supplements available on the North American market can be grouped into the following four categories, based on the form in which calcium salts occur: calcium carbonate, dolomite, calcium phosphate (bone) or hydroxyapatite, and calcium bound to various organic chelates (e.g., gluconate, lactate, amino acids). The first category can be subdivided into two groups, depending on whether the calcium carbonate is produced in a laboratory (i.e., refined) or mined from limestone rock units derived from fossilized oyster shells. The products in the latter group are invariably referred to as "natural source" calcium carbonate and will be termed as such throughout this paper.

Sample Selection

A total of 55 brands of calcium supplements (the maximum number of brands available) were identified and purchased from various pharmacies (national chains and independent concerns), supermarkets, and health food stores in southern Ontario. Fifteen additional brands were obtained in the United States by Food and Drug Branch investigators in the California Department of Health Services. Except for one bonemeal and two dolomite-based samples that were obtained directly from the manufacturers, all other supplements were purchased from American public retail outlets.

The 70 brands of calcium supplements were arranged in five categories, as shown in Table 1. Different lot samples of supplements were also analyzed to determine the variability of lead levels within a brand (i.e., "interlot" variability). Because of the

limited availability of some products, it was only possible to obtain different lot samples for 23 of the 70 brands.

Sample Analysis

For each lot sample, a minimum of 75 g was kept at 60°C for 24 hours, cooled in a desiccator, and weighed to obtain "product weight." The samples were then ashed at 425°C in a muffle furnace for 48 hours. The temperature of the furnace was gradually increased at a rate of about 100°C per hour to avoid combustion in some of the powders. For calcium supplements supplied in liquid form (five brands), 200-mL subsamples were weighed and dried at 60°C until constant weight (i.e., product weight) was obtained from which to calculate the products' specific gravity. These "dewatered" samples were then ashed in the same manner as the other calcium supplements. All of the ashed powders were cooled in a desiccator, weighed to obtain "ash weight," ground with an agate pestle and mortar, and transferred into acid-cleaned Teflon vials until further analysis.

Approximately 0.25 g of the ashed powder was dissolved in 1 mL of 12N hydrochloric acid. Approximately 5 mL of 0.2M sodium acetate was added, and the solutions were filtered over Millipore membrane filters (0.45- μ m pore size) pre-washed with 1.5N hydrochloric acid. The filtrate was adjusted to a pH of 1.50 ± 0.03 with either sodium acetate buffer or 12N hydrochloric acid. The typical volume of the solutions after pH adjustments ranged between 25 mL and 30 mL. Approximately 20 mL of the solution were then transferred into a sample cell and analyzed for lead by anodic stripping voltammetry using a hanging drop mercury electrode (model Metrohm 646/647 processor). Metal quantification was achieved by the method of standard additions (i.e., two spikes per sample) and peak integration, which is equivalent to the FDA's method for determining lead content in bonemeal supplements.²⁰ Seven of the 70 brands of calcium supplements analyzed in this study were analyzed by electrothermal atomic absorption spectrometry (Perkin-Elmer 5000, HGA-500) following a method detailed in a separate paper.²² No particular bias, either signal enhancement or reduction, was apparent using the latter methodology (see below).

Quality Control

High-purity, certified reagents (trace metal grade) were used for all the analyses. All the supplement brands were ana-

lyzed at least in triplicate, along with two procedural blanks (mean lead concentration = $0.6 \pm 0.2 \mu\text{g/L}$). A certified reference material consisting of bone powder (animal bone "H-5") supplied by the International Atomic Energy Agency in Austria was also routinely analyzed along with the samples. In all cases, the lead levels determined in the certified reference material fell within the certified range of 2.6 μg to 3.7 $\mu\text{g/g}$.

An interlaboratory comparison was also conducted to check for potential methodological biases in lead determinations in various types of calcium-rich matrices. While these results were detailed in a separate report,²² the coefficient of variation associated with lead analyses based on four different analytical instruments, including anodic stripping voltammetry, ranged from 3% to 17.6% for five different samples.

Calculations

Lead concentration in calcium supplements. The lead levels in the various brands of calcium supplements were obtained by multiplying the lead concentrations in the ashed powder by the ash content of the samples:

$$\text{ash content} = \frac{\text{ash weight}}{\text{product weight}}$$

$$\text{lead in product sample} = (\text{lead in ashed powder}) \times \text{ash content}$$

Unless specified otherwise, the lead levels were reported as micrograms of lead per gram of product on a dry weight basis. The lead levels measured in the ashed powders were always well above the system's analytical limit of 60 $\mu\text{g/kg}$ (ppb).

Lead concentration per unit mass of calcium. Ten pills were weighed to estimate the mean tablet weight for each brand of supplement. This value was then used to convert the calcium load specified on the product labels (e.g., 500 mg of calcium per tablet) to a calcium concentration in the pill powders (i.e., milligrams of calcium per gram), which in turn was used to normalize the lead concentration to a specified amount of calcium (micrograms of lead per milligrams of calcium). Normalized lead values were also calculated for the five brands of liquid-form calcium supplements by using the products' specific gravity.

The calcium load was not specified in three of the six bonemeal-based supplements. The molecular structure of bone dictates that the maximum content of calcium in pure mineralized bone tissue should be 20%. Consequently, this (conservative) value was used to estimate the

maximum calcium level in those products. The three other brands of bonemeal supplements had calcium levels ranging between 17% and 19%.

Results

Strength of Calcium Supplements

The calcium load varied widely, depending on the form of the salt used (Table 2). The "weakest" product (60 mg of calcium) was a brand of calcium chelate, whereas a tablet composed of refined calcium carbonate delivered more than 12 times that amount of calcium (750 mg). Based on a mean calcium load, the dolomite and bonemeal products were of comparable strength, followed by the chelate products, which averaged about half the calcium load contained in either the refined or the natural source calcium carbonate supplements (Table 2).

The recommended daily allowance for calcium in children aged 12 years and under is currently set at 800 mg.²⁶ While it might be expected that the daily calcium dosage suggested for each brand would normalize the amount of calcium ingested, this was not the case; and the suggested daily dosage of calcium varied by more than 16 times, ranging from 180 mg (23% of the recommended daily allowance) to as high as 3000 mg (375% of the recommended daily allowance) (Table 2). Comparatively, the calcium load in whole (i.e., cow's) milk is about 120 mg per 100 g (R. W. Dabeka, Health and Welfare Canada, personal communication), and the suggested daily serving of 750 mL of milk (three 8-oz servings)²⁷ would supply 800 mg of calcium.

Lead Levels in Calcium Supplements

The lead analyses performed on the various product lots indicated that interlot variability of lead levels was negligible for four of the five categories of calcium supplements. However, two different lot samples of a bonemeal-based supplement contained significantly different ($P < .05$) lead levels. This conforms with an earlier study,²⁰ which noted considerable variability in lead levels measured among various brands of bonemeal-based calcium supplements. While no interlot variability of lead levels was observed in the dolomite-based supplements selected in this study, a previous report¹⁸ noted that it may occur within this category of products. Based on the limited sample size of the products obtained from the United States, there did not appear to be any sig-

TABLE 2—Calcium Load and Suggested Daily Dosage of Calcium Supplied by 67 Brands of Calcium Supplements^a and Milk

Categories of Calcium Supplements	Calcium Load, mg per unit serving	Suggested Daily Dosage of Calcium, ^b mg per day
Chelates (n = 13)	60–600 ^c 260 ^d	180–1200 655
Refined (n = 17)	290–750 490	880–1500 1500
Dolomite (n = 9)	140–250 170	420–750 520
Natural source (n = 25)	250–650 475	250–3000 1200
Bonemeal (n = 3)	110–250 175	440–1000 560
Milk	267 ^e	800 ^f

Note. The supplements were arranged into five categories based on the form of the calcium salts, viz calcium chelates (e.g., lactate, gluconate), and calcium powders derived from dolomite, bonemeal, and either refined or natural source calcium carbonate. A "unit serving" represents either one tablet or 1 tsp of calcium supplements and 250 mL of milk.
^aThis information was not provided on three bonemeal products.
^bAs prescribed on the product labels.
^cRange.
^dMean.
^eBased on a calcium content of 118 mg per 100 g of whole milk.
^fBased on three 250-mL servings.²⁷

TABLE 3—Range and Mean Lead Concentrations Measured in 70 Brands of Calcium Supplements and Reported for Whole Milk²⁸

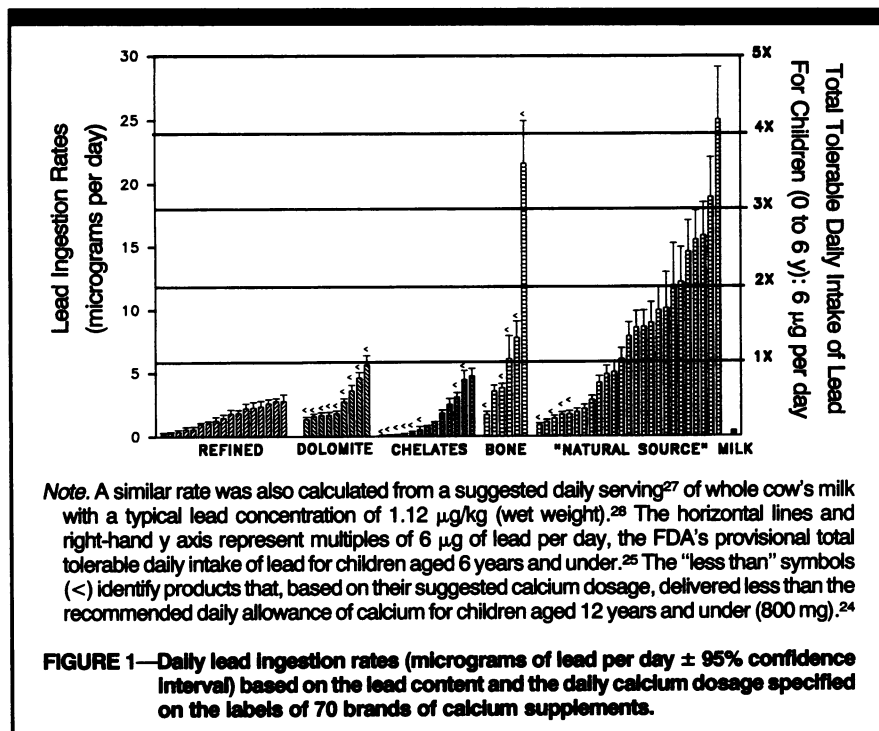
Supplement Categories	Lead Concentrations ^a	
	In Products	Normalized to Calcium
Chelates (n = 13)	0.03–1.21 0.26 ± 0.36 ^b	0.21–5.97 1.64 ± 1.73 ^b
Refined (n = 17)	0.04–0.92 0.34 ± 0.24	0.19–1.75 0.92 ± 0.56
Dolomite (n = 9)	0.52–2.52 1.11 ± 0.71	2.01–6.05 4.17 ± 2.02
Natural source (n = 25)	0.36–4.88 2.11 ± 1.33	0.61–20.4 6.05 ± 4.63
Bonemeal (n = 6)	0.64–8.83 2.67 ± 2.74	2.85–42.74 11.33 ± 12.46
Milk (n = 68)	0.4–1.6 ^c 1.2 ± 0.4 ^d	0.24–1.09 0.71 ± 0.32 ^d

^aLead concentrations are reported either as micrograms of lead per gram of product (dry weight) or as micrograms of lead normalized to 800 mg of calcium. Supplement categories are the same as in Table 1.
^bMean ± 95% confidence intervals.
^cμg of lead per kilogram of milk (ppb).
^dMean ± standard deviation.

nificant difference ($P < .05$) in the lead levels between Canadian and American calcium supplements.

The lead levels measured in the 70 brands of calcium supplements varied by almost 300-fold when reported as micrograms of lead per gram of product dry weight (Table 3). Although the highest variability in lead levels (two orders of magnitude) was displayed in the calcium chelate category, no relationships could be established between the lead levels and the type of chelates (e.g., gluconate vs lactate vs citrate, etc.) used within this group-

ing. Chelates and refined calcium carbonate were the only two groupings that had a mean lead concentration well below 1 μg/g of product (Table 3). The lead levels recorded in the dolomite products were significantly higher ($P < .05$) than those measured in the previous two categories. Although the lead levels in the bonemeal and natural source calcium supplements averaged at least twice as high as those in the dolomite brands, there was no significant difference ($P < .05$) in the lead levels among these three categories. Based on the mean lead levels, the five categories of



also assimilate ingested lead more efficiently than do adults.³¹⁻³³ The FDA converted previously established guidelines and standards of dietary lead intake into a common format of micrograms per day from foods, better known as the total tolerable daily intake of lead. In 1989, the FDA recommended that, for a child weighing 10 kg, the total tolerable daily intake of lead absorbed from all dietary sources be limited to 6 µg to 18 µg.³⁴ However, because the "effect level" (i.e., the level for medical intervention) of blood lead in children was reduced in 1991,¹³ a "provisional" total tolerable daily intake has been set at 6 µg of lead and applies to all children aged 6 and under.²⁵

Because of the substantial variation in the calcium dosages prescribed on the calcium supplements labels (Table 2), the lead levels listed in Table 3 do not effectively reflect the amount of lead ingested from consumption of these products. Lead ingestion rates (i.e., micrograms of lead ingested per day) were calculated from the "suggested calcium dosage" listed on the product labels and the lead levels measured in each of the 70 brands of calcium supplements analyzed in this study (Figure 1). The results indicate that, based solely on the ingestion of these products, the lead intake from about 25% of the calcium supplements (17 of 70 brands) exceeded the provisional total tolerable daily intake of 6 µg. It should be stressed that this value represents the *maximum* amount of lead to be ingested from all dietary sources. In addition, it was deemed provisional because safe levels of lead exposure had not been identified and would likely be adjusted downward to allow for other anticipated exposures to lead.²⁵

Although the mean lead ingestion rates calculated for the dolomite-based supplements seem comparable to those calculated for the refined calcium carbonate and chelate calcium groupings (2.7 µg, 1.5 µg, and 1.5 µg, respectively), the calcium dosages on which these values were partially based varied significantly (Table 2). For example, the mean calcium dosage calculated for the refined calcium carbonate supplements was 1500, 190% of the recommended daily allowance of calcium for children 12 and under. Consequently, many of the lead ingestion rates calculated for this category could be reduced even further if lesser amounts of calcium supplements (i.e., dosages approximating 100% of the recommended daily allowance for young children) were ingested. Conversely, the calcium dosage of the do-

calcium supplements were ranked in the following (ascending) order:

chelate ≈ refined << dolomite ≤ natural source ≈ bonemeal

Lead levels reported as micrograms of lead per gram of product can be somewhat misleading because all the supplements contain varying amounts of binders or fillers and sometime sugars (e.g., chewable forms), which are added during the pelletization of the products. Consequently, the lead level may be reduced or "diluted" because important amounts of these inert substances have been added. (The weight of the tablets analyzed in this study ranged from 470 mg to 3580 mg.) The relative quality of the calcium supplements, in terms of their lead levels, can be compared more effectively if the lead content in each brand is normalized to a set amount of the main active ingredient or element, such as calcium.

Because young children represent the segment of the population most sensitive to lead, the lead content in the 70 brands of calcium supplements was normalized to this group's recommended daily allowance of 800 mg of calcium (Table 3). This transformation actually indicates what would be the concomitant dose of lead obtained from the various calcium supplements if these products were to supply the recommended daily allowance of calcium for young children. The calcium supplements derived from refined calcium carbonate powders were the only products

to average less than 1 µg of lead per 800 mg of calcium (Table 3). Although the normalized lead levels averaged slightly higher in the calcium chelate products, 8 of the 13 brands within this category had normalized lead levels at or less than 1 µg (median = 0.92 µg of lead per 800 mg of calcium). Conversely, the concomitant lead dose obtained from the remaining three categories of calcium supplements averaged 4 to 12 times higher than that calculated for the refined calcium carbonate powders (Table 3). In fact, none of the products within the dolomite and bonemeal categories and only two brands of natural source calcium supplements could meet the recommended daily allowance of calcium for young children while supplying a concomitant lead dose of 1 µg or less.

The lead content measured in milk samples from Canada²⁸ and other countries^{29,30} has been reported to be at the part-per-billion level (Table 3). Consequently, this would mean that the chief source of dietary calcium for the majority of the population would also meet the recommended daily allowance of calcium for young children while supplying a concomitant dose of lead of less than 1 µg (Table 3).

Discussion

Lead Intake from Calcium Supplements

Not only are children more sensitive to the low-level effects of lead, but they

lomite-based products (and of five of six brands of bonemeal supplements) could not be reduced to lower the lead ingestion rates because none of these supplied the 800 mg of calcium recommended (as indicated by the "less than" symbol on Figure 1).

The results indicate that natural source calcium supplements are a potential source of lead because more than half the products within this category (14 of 25 brands) had lead ingestion rates greater than the provisional total tolerable daily intake of 6 µg (Figure 1). The highest lead ingestion rate calculated for a product within this group (25.1 µg per day) was more than four times greater than the provisional intake level and was based on a calcium dosage of 1000 mg, a dosage commonly ingested by children.

What is particularly disturbing about the significant lead ingestion rates associated with the bonemeal-based calcium supplements is that bonemeal powders available through health food stores are often used as "food supplements." Food supplement powders are generally consumed in much greater quantities than bonemeal-based supplements but essentially have the same composition. In 1982, the FDA¹⁵ noted that daily intakes of 5000 mg to 10 000 mg of bonemeal powders were not uncommon and that more than 90% of the individuals consuming large quantities of bonemeal were women aged 50 or older. This conforms with another report, which noted that an "excessive intake" of calcium supplements was prevalent among individuals seeking to prevent or retard degenerative changes (e.g., osteoporosis) through nutrition.¹⁸ Plumbism attributable to bonemeal ingestion has been reported in the past.¹⁹

Reevaluation of Calcium Supplements

A 1991 FDA "Health Policy Report"³⁵ was criticized because it failed to recognize regulatory loopholes that allowed health food stores and magazine advertising to sell many compounds not currently reviewed by the FDA.³⁶ The agency has since noted that an FDA task force was surveying all regulatory options open to the agency and measuring them against the benefits and risks inherent in the consumption of dietary supplements.³⁷ Similarly, senior health officials at Health and Welfare Canada informed us that several aspects relating to mineral supplements as well as to other health products were currently under review.

It is generally accepted that most North Americans meet their nutrient needs from foods alone and that the use of supplements is often not necessary.^{38,39} Milk and other dairy products are regarded as the principal source of dietary calcium. However, children who are intolerant to milk and dairy products (not to be confused with individuals with a lactase deficiency) and who develop allergic reactions (e.g., hyperactivity) when only minute amounts are ingested can effectively meet their calcium requirements only through calcium supplementation. (The number of such cases may appear on the rise, but many physicians agree that this particular form of allergy went largely undiagnosed in the past.) For these individuals, calcium supplements are the only effective alternate source of calcium, surrogate to milk and dairy foods. Considering that milk can supply the recommended daily allowance of calcium for young children while delivering "acceptable" amounts of lead, should it not be unreasonable to suggest that surrogate sources of calcium meet these same goals—that is, no more than 1 µg of lead ingested for every 800 mg of calcium supplied. This may mean, however, that the use of dolomite, bonemeal, and, to some extent, natural source calcium-rich powders for the production of mineral supplements would have to be reevaluated (Table 3).

Finally, it should be noted that not all investigators working in the health field believe that exposure to low lead levels is detrimental to child development.⁴⁰⁻⁴⁴ While the validity of various statistical procedures can be debated ad nauseam, this study shows that many individuals may be unnecessarily ingesting substantial amounts of lead through some forms of mineral supplements. The 1991 statement on lead poisoning from the Centers for Disease Control and Prevention noted that "Pb poisoning is one of the most common and preventable paediatric health problems today."¹³ A leading authority on lead toxicity also remarked that lead poisoning was poorly treatable and best prevented.⁴⁵ We suggest that the sources of lead in calcium supplements should be identified and more rigidly controlled to prevent unnecessary exposure to dietary lead in all segments of the population, particularly young children. □

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