A Comparison of the Prevalence of Lead-Contaminated Imported Chinese Ceramic Dinnerware Purchased Inside Versus Outside Philadelphia's Chinatown

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Abstract Lead-contaminated ceramics can be a clinically significant source of lead poisoning, with the potential to cause illness in children and adults; one death in a child has been described. We hypothesized that the prevalence of lead-contaminated ceramics would be higher within Chinatown versus outside of Chinatown. The study was a prospective observational cross-sectional study. Two areas were defined geographically as being within and outside of Philadelphia's Chinatown, and a predefined number of items were purchased in each area. Each item was screened for lead utilizing a colorimetric testing swab. Positive items were leached for lead using the ASTM C738-94 protocol for lead level quantification. The primary outcome was the prevalence of ceramics not compliant with the FDA standard for leachable lead within and outside of Philadelphia's Chinatown. A total of 132 items were purchased, 46 outside of and 86

within Chinatown. More lead-positive items originated within Chinatown than outside of Chinatown [five positive items, 5.8 % prevalence within Chinatown (95 % confidence interval, CI, 2.5–12.9 %), and zero positive, 0 % prevalence outside of Chinatown (95 % CI 0–7.5 %)]. However, this difference was not found to be statistically significant ($P=0.1624$). The leachable lead-positive items were up to 40-fold the acceptable FDA levels. Testing a larger number of items may demonstrate a significant source of lead exposure.

Keywords Lead · Ceramics · Lead poisoning · Environmental exposure/analysis · Food contamination/analysis

Introduction

In 1971, the FDA established specific action levels for lead leaching over 24 h from ceramics, starting at 7 ppm. The impetus for such regulatory mandates arose when a family of six was lead poisoned after purchasing a lead-glazed ceramic pitcher from Mexico [1]. Acceptable leachable lead concentrations in ceramics have decreased over the past four decades as the danger posed by lead-contaminated ceramics has become increasingly apparent. During the 1990s, the FDA detained shipments containing lead from the following countries: China, Czechoslovakia, France, Greece, Haiti, Hong Kong, Hungary, Indonesia, Italy, Japan, Korea, Mexico, Portugal, Russia, Slovenia, Spain, Taiwan, Thailand, Turkey, the United Kingdom, and the former Yugoslavia [2]. The Federal Food, Drug, and Cosmetic Act, passed in 1938, gave responsibility to the FDA for recalling all non-compliant ceramics [1]. While food and food additive manufacturers must demonstrate the safety of their items to the FDA, ceramic

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manufacturers are not held to the same standard. Most products destined for import into the USA from mainland China originate from factories certified by the Chinese government. However, some products from non-certified producers continue to reach the USA unregulated. Items from both certified and non-certified factories are randomly screened by the FDA, but certified factories are screened less often. If a factory brings one item found to be out of compliance, all future items are automatically detained by the FDA at US ports until it can be proven that they meet FDA requirements (by importers, distributors, or the Chinese government). We believe there may be some small privately owned shops within Chinatown involved in nonstandard distribution networks and receive unmonitored imports that violate FDA lead-content regulations. This would lead to an increased prevalence of items out of compliance with the FDA within Chinatown shops.

Lead-contaminated ceramics can be a clinically significant source of lead poisoning, with the potential to cause illness in children and adults [3–5]; one death in a child has been described [3]. Studies show that pottery made with lead glazes and low kiln firing temperatures in Mexico and the southwestern USA are a known source of lead poisoning in these populations. Lead-glazed ceramic use has been correlated with elevated blood lead levels within a large sample group [6] and poses particular threat to special populations, such as children and pregnant women [7, 8]. Lead contamination of ceramic glaze has been reported from a variety of production sources, particularly imported items [2].

Materials and Methods

Study Design and Setting

This was a prospective observational cross-sectional study. It was conducted in an urban setting.

Hypothesis and Primary Objective

We hypothesize an increased prevalence of ceramics not compliant with the FDA standard for leachable lead within Chinatown versus outside of Chinatown. Our primary goal was to demonstrate a statistically significant increase in prevalence inside of Chinatown versus outside of Chinatown.

Screening for Lead in Purchased Ceramics

Sample Selection The study was conducted June through August of 2010. Two areas were defined geographically as

being within and outside of Philadelphia's Chinatown. Philadelphia's Chinatown was bound geographically in the east by 8th Street, the north by Vine Street, the south by Filbert Street, and the west by 11th Street. Using a map, eight medical students divided Philadelphia's Chinatown into four regions and identified four other geographically distinct areas outside of Chinatown. Sixteen stores within Chinatown, all selling ceramics within the study's predetermined price range, were identified. Using departmental discretionary funds, students purchased five items from each of the identified stores. All items purchased were considered a form of eating utensil, dinnerware, or cookware. These items included plates, mugs, bowls, cups, teapots, spoons, and chopsticks. All items were chosen within these criteria: (1) price below \$10.00, (2) maximum of five unique items from any given store, (3) all items were made out of ceramics, and (4) all items were made in and imported from China. "Outside Chinatown" was defined as anywhere outside of the established boundaries of Chinatown including areas outside city boundaries. Students then purchased 46 items that met the predetermined criteria from 16 stores in the areas outside Chinatown. Stores were selected based on their sale of ceramics and their prices being below \$10.00. The number of items purchased was dependent upon the discretionary budget and the abundance of unique ceramic items found in each area.

Methods and Measurements

Purchased items were numbered and gently washed with tap water and dried with a new paper towel. LeadCheck® (3M, St. Paul, MN) colorimetric swabs were utilized for lead screening per manufacturer's instructions. Positivity by LeadCheck® device was independently assessed, and inter-rater agreement was recorded. Each item was digitally photographed with its corresponding LeadCheck® swab. Items that screened positive were assessed for leachable lead using ASTM C 738–94 protocol. Each item was filled within 6 mm of the rim with 4 % acetic acid solution (of metal analytic grade) and permitted to leach for 24 h. Acetic acid was then removed and analyzed utilizing induced coupled plasma atomic emission spectroscopy (Genesis ICP, Spectro Analytical Instruments, Germany). Standards were made for cadmium and lead at the following concentrations: 0.1, 0.2, 0.3, 0.5, 1, and 10 µg/ml (parts per million). A method blank (a Pyrex glass bowl) was analyzed with the samples as well, for purpose of protocol-contamination assessment. Positive items were identified as any item exceeding FDA lead-leaching limits of 3.0 ppm for flatware, 2.0 ppm for small hollowware, 1.0 ppm for large hollowware, and 0.5 ppm for pitchers, mugs, and cups.

Primary Data Analysis

Ninety-five percent confidence intervals (CI) were calculated for the rate of lead-positive items. A two-tailed Fischer's exact test compared the positive items purchased in Chinatown with those purchased outside Chinatown. Inter-rater reliability was assessed by having multiple raters assess the color change of the lead tests from randomly chosen items using Fleiss's non-weighted kappa test. *P* values <0.05 were considered significant.

Results

Screening Test

Twenty one of the 86 items from Chinatown and 4 of the 46 outside of Chinatown had positive lead screening tests (Table 1). Inter-rater agreement was calculated with eight evaluators (each evaluated seven items). There were no discrepancies between reviewers on test results (kappa=1).

Quantification of Lead in Ceramics

Of the 25 items that screened positive, five items quantitatively tested positive for lead exceeding FDA action levels: plate #28, 130 ppm; plate #54, 146 ppm; plate #76, 52 ppm; spoon #42, 31 ppm; and spoon #80, 16 ppm (see Figs. 1 and 2; Table 2). The prevalence of non-compliant items purchased within Chinatown and outside of Chinatown were 5.8 % (5 of 86; 95 % CI 2.5–12.9 %) and 0 % (0 of 46; 95 % CI 0–7.5 %), respectively. The prevalence difference between the two groups was not significantly different (*P*=0.1624). It should be noted that action levels are not defined for utensils and are considered on a case by case basis. However, FDA officials have stated that the action levels found in our two utensils were concerning. All five non-compliant items were purchased in Chinatown.

Discussion

The FDA has recognized China as a source of lead-contaminated ceramics since the 1980s, and it continues to

Fig. 1 Plate # 28 an item that quantitatively tested positive for lead exceeding FDA action levels

be a problem today [1]. Clearly, a major concern inherent with prevalent lead-containing ceramics is the potential for community lead exposure and possible consumption in populations not usually tested for lead toxicity. Pregnant patients and children older than 2 years of age are not routinely screened for lead. Eating and drinking from lead-containing ceramics potentially leaching large lead concentrations into food and liquid is a health risk. Since all of the items purchased in our study were manufactured in China, it is possible this problem exists in many other regions in the USA.

The exact relationship between lead-contaminated ceramics and blood lead levels is unclear. Case reports have described increased morbidity and mortality from lead-containing ceramics [3, 4], and elevated blood lead levels have been described in adults, children, and pregnant women utilizing lead-glazed ceramics manufactured in Mexico for cooking or food storage [6–8]. However, these studies only performed screening tests and did not subject the ceramics to lead leaching analysis.

Fig. 2 Spoon # 42 an item that quantitatively tested positive for lead exceeding FDA action levels

Table 1 Ceramic items screened with colorimetric swab

Result	Chinatown	Outside	Total
Negative	65	42	107
Positive	21	4	25
Total	86	46	132

Table 2 Lead leaching levels of items exceeding the FDA limit

Location	Cup/mug	Flatware or plate	Small hollowware or bowl	Other: utensil or spoon	Other	Total items
Items purchased						
Chinatown	27	16	23	7	13	86
Outside	20	14	9	1	2	46
Positive items screened						
Chinatown	13	4	2	2	0	21
Outside	3	1	0	0	0	4
Ceramics out of compliance						
Chinatown	0	3	0	2	0	5
Outside	0	0	0	0	0	0

Research regarding Mexican lead-glazed ceramics and lead leaching demonstrates inconsistent data. Researchers have used a variety of leachate materials including tomato salsa (which is acidic and increases lead solubility), beans of neutral pH, and acetic acid (as is used with the FDA protocol C738-94) as leaching solutions. Lead leaching ranges varied from 8 to 500 ppm (salsa) to 3–8 ppm (beans), and 200–2,000 ppm (acetic acid) [9]. Our ceramics leached within a range of 14–146 ppm using acetic acid, comparable to the lower end of Mexican ceramics tested with acetic acid.

A physician (WBL) from our group fluent in both Mandarin and Cantonese met with the shopkeepers of the involved stores and shared the test results with them. We informed the shop owners that our leaching tests demonstrated lead in excess of that allowed by the FDA. We notified our local health department and were directed to the FDA. Officials at the FDA found the results concerning and started their own investigation; the results were not disclosed to us at the time we submitted this manuscript.

The precise clinical relevance of the lead-contaminated ceramics is unknown at this time. However, it has been demonstrated that use of lead-contaminated ceramics can lead to lead poisoning [3–5]. Accurate measurements of lead leachate and corresponding correlations with blood lead levels are lacking. Moreover, toxicity resulting from ceramic use is likely more complex than simply the level of lead leaching from consumable utensils and tableware. Other factors, such as food type and frequency of use, must be considered to accurately estimate toxicity likelihood.

Limitations

There were several limitations to our study. We did not find a significant difference between the two groups. This could be due to the small number of items tested. Only 5 of 21 and 0 of 4 items purchased within and outside of Chinatown,

respectively, were above the FDA limits for leachable lead. Testing a larger number of items may demonstrate a true difference. Our budget was discretionary, which resulted in several limitations. First, we could not purchase a large number of ceramic items, particularly from outside of Chinatown. Second, we could not purchase duplicate items of the same ceramic; the FDA typically screens five duplicates of the same item concomitantly to assess the possibility of varying lead levels in any individual item. The FDA mandates a recall if any of the five items tested exceeds actionable levels. In this respect, our testing still bears relevance.

Ceramic items were more readily available within Chinatown, and some items (i.e., chopsticks, ceramic spoons, and teaware) were much more prevalent or exclusively found within Chinatown, making it difficult to find a set of wholly comparable items. Items outside of Chinatown were mostly limited to plates, bowls, and mugs, and several identified shops sold the exact same or similar products. This made it difficult to find a sample set outside of Chinatown both equal in size and variability to the set purchased within Chinatown.

Also, we could not perform every available lead quantification test. Two of the best-defined protocols are “the leaching of the internal surface” ASTM 738 protocol (a federally regulated standard) and “lip to rim” testing (an industry voluntary standard that tests the uppermost portion of the outside of a ceramic that would touch a user’s lips). We believe that follow-up lip to rim testing would have identified additional items exceeding industry-defined limits; many ceramics are decorated with additional glazes on the outside which could not be quantified using our leaching method that only tested the inside portion of an item.

We did not account for clustering within stores when calculating our sample size estimation. Although greater than 79 items were purchased, five items were purchased from each store which may have created intra-store clustering. Ideally a single item should have been purchased from each

store to reach our estimated sample size. However, this would have been impossible given the number of stores that sold ceramics within Chinatown.

Conclusions

The 5.8 % (5 of 86) prevalence of non-compliant ceramics purchased in Chinatown versus the 0 % (0 of 46) of non-compliant ceramics purchased outside of Chinatown was not statistically significant. Testing a larger number of items may demonstrate a significant source of lead exposure.

Future Directions

Our project's next phase focuses upon testing patients at a clinic serving this Chinatown population, including assessment of lead levels in the actual ceramics used by the patient population daily, as well as the patients' blood lead levels.

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