KKU Res. J. 2013; 18(6): 1021-1025
http : //resjournal.kku.ac.th

Risk assessment of Bisphenol A migration from baby feeding bottles

Kannikar Chatsantiprapa[1]*, *Sikarin Srihan*[1], *Roongtip Navakoksri*[1], *Nusra Kunthaprom*[1]

[1] *Division of Pharmacognosy and Toxicology, Faculty of Pharmaceutical Sciences, Khon Kaen University, Khon Kaen 40002, Thailand.*
* *Correspondent author: kannikar@kku.ac.th*

Abstract

Bisphenol A (BPA)-containing baby feeding bottles have been banned from use in many countries, but not in Thailand. This study was aimed to assess the risk of exposure to BPA migrated from baby feeding bottles sold in Thailand for the worst case scenario. Six brands of baby feeding bottles, 2-4 bottles per brand were randomly collected. Distilled water 30 ml at room temperature, 40°C, 70°C, 100°C was shaken 30 times in each feeding bottle capped with its rubber nipple, lyophylised, re-dissolved with 1 ml of HPLC mobile phase, and analysed with HPLC-UV. The analysis found that five brands of baby feeding bottles presented BPA at undetectable or negligible levels. There was only one brand, without Thailand Industrial Standard (TIS) code for rubber nipples presented on the bottles, releasing BPA at 6.6±0.3 and 11.3 ± 1.5 μg per 30 ml at 40°C and 70°C dissolving water, respectively. Although more BPA migration was found in higher temperature water in the first tests, the migration was lower in the following tests, until lower than LOQ after 4 consecutive tests. There seemed to be a limit of BPA migration from each bottle. Estimation for daily exposure dose (DED) of BPA migration for the worst case was 55.3-72.4 μg/kg-day. Comparing to 50 μg/kg-day, a Tolerable Daily Intake (TDI or a safe dose) for BPA dietary exposure, the margin of safety or MOS (=TDI/DED) was found between 0.69-0.90, the reference or safe dose (TDI) lower than the exposure dose (DED). This meant that babies fed by products without TIS approval products were at risk of BPA exposure, particularly in the first time use and using high temperature dissolving water. Although BPA-containing bottles are not officially banned from use in Thailand, there may be only a few products left in the markets containing BPA at risk level. Therefore, parents are suggested to use only feeding bottles presenting TIS code to avoid BPA exposure for babies and Thai authorities should do more stringent inspections.

Keywords: Bisphenol A, BPA, risk assessment, baby feeding bottles, Thailand

1. Introduction

Bisphenol A (BPA) is a monomer in producing hard clear polycarbonate (PC) plastic used in food contact materials and bottles, and epoxy resins for lining of metal-based food and beverage cans, and other miscellaneous products. There are a number of studies reporting its estrogenic properties and endocrine disrupting effects. Many health organizations expressed concerns about the potential effects of low BPA exposure on the brain, behavior, reproduction and other development in fetuses, infants, and young children (1,2,3). The European Food Safety Authority (EFSA) set a Tolerable Daily Intake (TDI) for BPA as 50 μg/kg-day based on a No-Observed-Adverse-Effect-Level (NOAEL) of 5 mg/kg-day identified in two multi-generation reproductive toxicity studies in rodents, where the critical effects were changes in body and organ weights in adult and offspring rats and liver effects in adult mice, respectively (EFSA, 2006, in EFSA 2011)(3). This TDI was set to protect the human population for lifetime exposure, including sensitive groups such as pregnant and lactating women, infants (0-6 months) and young children (12-36 months). This TDI was reaffirmed in 2008 and 2010 (3). BPA-containing baby feeding bottles were banned from use in many countries, but not in Thailand. Thus, this study was aimed to assess the amount of BPA released from baby feeding bottles sold in Thailand and assess the risk of exposure to BPA for infants.

2. Material and methods

Chemicals, equipment and samples

Bisphenol A, Aldrich, Lot. MKBH6262V, 99.9%.

Baby feeding bottle samples: brand A (CANN'82), brand B (Big C), brand C (Pigeon), brand D (Milk brand), brand E (Toddy, specified as "PP" and "BPA free"), brand F (Honey), brand G (Toddy, Nurtur corporation, not specified as "PP" nor "BPA free"). Only brand D did not present Thailand Industrial Standard, TIS, code (มอก.) 969-2533 which specifies rubber nipples for babies' bottles. All these samples, 4 bottles per brand, except brand D, 2 bottles due to availability in the shop at the time of collection, were randomly purchased from different local markets, and some markets were in remote areas. They were all washed by hand-shaking 30 times with distilled water at room temperature before the tests.

HPLC conditions: C18 column Phenomenex P/No. 00G-4454-E0, S/No. 447309-3, 250 x 4.6 mm, column temperature 25 °C, mobile phase: methanol:water (70 : 30), flow rate 1.0 ml/min, detection volume 20 μl, detector:UV 230 nm.

Test procedures

Distilled water 30 ml at room temperature, 40°C, 70°C, 100°C was pipetted into each baby feeding bottle. Each bottle capped with its rubber nipple (hole closed) was hand-shaken in up-down motions for 30 times to simulate baby's formula milk preparation. The content from each bottle was then transferred into 250 ml Erlenmeyer flask, frozen at -20 °C, then lyophylised until dry. One ml of HPLC mobile phase was pipetted to rinse the residue in each Erlenmeyer flask with highest care, by slowly and repeatedly rolling this 1 ml mobile phase around the flask to dissolve all possible BPA residue. This content was then injected into HPLC, UV detector for analysis of BPA.

3. Results

Analysis method validation was performed for selectivity, linearity (correlation. coefficient, R^2=0.9969 for concentration between 0.5 μg/ml to 80 μg/ml), limit of detection (LOD=0.05 μg/ml), limit of quantitation

(LOQ=0.5 μg/ml), accuracy, precision, percentage of recovery (88.29 to 90.61%), and repeatability (% relative standard deviation or RSD = 0.62 to 1.52%).

The analysis of BPA migration from baby feeding bottles showed that all sample brands except brand D presented BPA at undetectable or negligible (lower than LOD or LOQ) levels. Only brand D showed that BPA migration from the bottles at 6.6±0.3 and 11.3±1.5 μg per 30 ml of dissolving water simulants at 40°C and 70 °C respectively in the first test of each bottle. In addition, peaks of unspecified substances also presented in the analysis chromatograms at both temperatures (Figure 1). However, when the same bottles of brand D were repeatedly tested following the same manner, BPA detected continually decreased until under LOQ levels after 4 consecutive tests (Table 1).

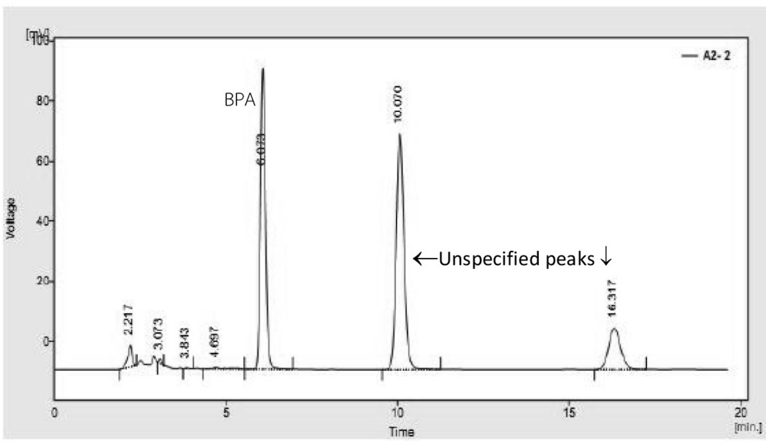

Figure 1 Chromatogram of HPLC analysis for Bisphenol A migrated from a baby feeding bottle (brand D) simulated with 30 ml 70°C dissolving water. Peaks of Bisphenol A and unspecified substances are shown.

Table 1 Amount of BPA migrated from two baby feeding bottles (brand D) simulated with 40°C and 70°C dissolving water, presented as micrograms BPA per 30 ml (mean±SD, n=3) from 4 consecutive tests.

Simulating temperature	Test 1	Test 2*	Test 3	Test 4
40°C	6.61±0.26	-	5.21±0.45	0.60±0.06
70°C	11.27±1.51	-	0.57±0.04	0.38±0.01

*detection error

Risk assessment of BPA exposure was performed. For the worst case scenario, we calculated the exposure dose of BPA migration detected from the first test of 70°C dissolving water simulant to represent the possibly highest exposure dose. The amount of BPA migrated was 9.8-12.8 (or 11.3±1.5) μg per 30 ml.

We assumed for for estimation, a newborn baby (0-6 months) was fed on 170 ml bottle-feeding milk per kg body weight (or 3 ounces per pound body weight) per day (4). Thus, the daily exposure dose (DED) of BPA for a newborn baby was 55.3-72.4 μg/kg-day.

Comparing to 50 μg/kg-day, a Tolerable Daily Intake (TDI) for BPA (3), the margin of safety or MOS (=TDI/DED) of BPA exposure from baby feeding bottles was found between 0.69-0.90. This meant that the reference or safe dose (TDI) of BPA exposure for an infant was lower than the daily exposure dose (DED), or the baby fed on bottle releasing BPA was at risk for consuming BPA 1.1-1.4 fold over the reference dose.

4. Discussion and conclusion

Our BPA analysis was aimed to detect free BPA migrated from the feeding bottles under free water dissolution at varied temperatures. This condition was aimed to simulate a formula milk preparation, since this free BPA migrated from the feeding bottles was considered a potential dietary exposure dose of BPA to babies. The analysis did not consider the BPA extracted from milk or any other biological samples.

Although the type of plastic of the bottle samples detected BPA was not specified, in our worst case, BPA migration was 9.8-12.8 μg per 30 ml (325-426 μg/l) of hot dissolving water. This was 22-28 fold the maximum migration of BPA from PC bottles (15 μg/l) reported by the Joint FAO/WHO Expert Meeting(5).

Due to the sensitivity of our laboratory, only 1 ml of mobile phase was used to rinse the Erlenmeyer flask after lyophilization. This was aimed to collect all of BPA residue migrated with the least rinsing volume, to achieve the highest concentration of BPA for detection. Although not all BPA migrated may have been collected for detection since there were absolutely no observable residue marks on the glass flasks, this collection was performed with the greatest care to reduce the possibility of missing to the least. Moreover, in real practice the solvent dissolving BPA is not pure water but milk and after preparation the prepared content may be left for some longer time than in this study before consumption. In this way, it was possible that the migration of BPA could be higher than this finding, thus could result in even lower MOS.

Our estimated dietary exposure of BPA for infants from baby feeding bottles, 55.3-72.4 μg/kg-day, was approximately 30 fold that estimated by Joint FAO/WHO Expert Meeting (1) whose estimation for infants (0-6 months of age) was 2.0-2.4 μg/kg-day, with 95^{th} percentile 2.7-4.5 μg/kg-day, by which the estimation included migration from both the packaging of canned liquid infant formula and the PC feeding bottle. This meant that infants fed by our tested bottles in the worst case scenario (using hot water in dissolving milk) were at seriously higher risk of BPA exposure than that estimated by the Joint FAO/WHO Experts. At the time being there has been no legal specification for BPA in feeding bottles in Thailand. However, since brand D did not present Thailand Industrial Standard code for rubber nipples, it could be that this brand was TIS-unapproved product. It could be that BPA detected was released from either the bottles or the rubber nipples or both.

Among 6-7 brands of feeding bottles tested, only 1 brand without Thailand Industrial Standard (TIS) code for rubber nipples was found to release significant amount of BPA. This meant that although BPA-containing bottles were not officially banned from use in Thailand, there may be only a few left in the market and which were not approved by Thailand Industrial Standard Board. Other tested brands both specifying BPA-free and not specifying BPA-free were found to contain BPA in undetectable or negligible amounts (lower than LOD or LOQ). Moreover, in the analysis chromatograms we found peaks of unspecified substances together with BPA in the TIS-unapproved products tested. This meant that infants fed on these unapproved products were exposed to other unspecified substances in addition to BPA.

Although, the potential harm from these unspecified substances is not known, these findings should raise concern about the fact that these feeding products were available in some local markets in Thailand. We suggest a more stringent surveillance and inspections by Thai authorities for the safety of the infants.

Since only 2 bottles of brand D were available at the time of sample collection, 40°C and 70°C were chosen for the tests to represent warm and hot water as temperatures used in some households for hygienic purposes, to represent the worst case for BPA exposure risk. Although BPA migration was found higher in higher temperature water in the first tests, the migration was found lower in the following tests, until lower than LOQ after 4 consecutive tests. The summation of all BPA migrated from these 2 temperatures were found approximately equal. It seemed that there might be a limit of BPA migration from each bottle. Hence, after more BPA was migrated in the first test of higher temperature, there was lesser BPA migrated in the following tests. It could be that if our sample bottles were boiled before use, as a practive in some housholds, BPA migration could be found lower than this. Therefore, washing the rubber nipples and feeding bottles carefully with hot water before use may be helpful to reduce this exposure, although hot water is not suggested in formula milk preparation.

As a conclusion, babies fed by TIS-unapproved feeding bottles were at risk from BPA, an endocrine disrupting chemical, and maybe from other harmful substances in addition.

5. References

(1) World Health Organization. Joint FAO/WHO expert meeting to review toxicological and health aspects of Bisphenol A: final report, including report of stakeholder meeting on Bisphenol A. Ottawa, Canada. 2010 Nov 1-5.

(2) U.S. Food and Drug Administration. Bisphenol A (BPA): Use in Food Contact Application. [Internet] 2010 Jan [updated 2012 Mar 30; cited 2013 Jan 5]. Available from http://www.fda.gov/newsevents/publichealthfocus/ucm064437.htm

(3) European Food Safety Authority. Statement on the ANSES reports on Bisphenol A. EFSA Journal 2011; 9(12): 2475.

(4) How many baby feeding per day?. [Internet] 2011 Aug 25; cited 2012 Sep 20]. Available from http://babytrick.com/new-born-baby-tip/how-many-baby-feeding-per-day.html.

(5) World Health Organization. Joint FAO/WHO Expert Meeting to Review Toxicological and Health Aspects of Bosphenol A. Summary report including report of stakeholder meeting on Bisphenol A. Ottawa, Canada. 2010 Nov.1-5.