Risk Assessment of Baby Powder Exposure through Inhalation

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This study was conducted to assess the exposure risk through inhalation to baby powder for babies and adults under simulated conditions. Baby powder was applied to a baby doll and the amount of baby powder consumed per application was estimated. The airborne exposure to baby powder during application was then evaluated by sampling the airborne baby powder near the breathing zones of both the baby doll and the person applying the powder (the applicator). The average amount of baby powder consumed was 100 mg/application, and the average exposure concentration of airborne baby powder for the applicator and baby doll was 0.00527 mg/m3 (range 0.00157~0.01579 mg/m3) and 0.02207 mg/m3 (range 0.00780~0.04173 mg/m3), respectively. When compared with the Occupational Exposure Limit of 2 mg/m3 set by the Korean Ministry of Labor and the Threshold Limit Value (TLV) of 2 mg/m3 set by the ACGIH (American Conference of Governmental Industrial Hygienists), the exposure concentrations were much lower. Next, the exposure to asbestos-containing baby powder was estimated and the exposure risk was assessed based on the lung asbestos contents in normal humans. As a result, the estimated lung asbestos content resulting from exposure to asbestos-containing baby powder was found to be much lower than that of a normal Korean with no asbestos-related occupational history.

Key words: Talc, Asbestos, Baby powder, Exposure assessment, Risk assessment

INTRODUCTION

In April 2009, the Korea Food and Drug Administration (KFDA) announced the discovery of asbestos in 8 out of 12 baby powders that used talc as the source material. The investigation included a total of 30 products from 14 baby powder manufacturing companies (KFDA, 2009a; Kukminilbo, 2009; Joongangilbo, 2009; Dongailbo, 2009), and the discovery of asbestos-containing baby powders created a huge social issue in Korea. As a result, the KFDA began regulating asbestos-containing pharmaceutical products, as well as non-pharmaceutical products and cosmetics (KFDA, 2009b). Many countries have already banned the sale of asbestos-containing talc from as far back as 1975 or strictly restrict the quantities of asbestos in talc (World Bank Group, 2009; World Federation of Public Health Associations, 2005; International Labour Organization, 2006). However, the use of talc in pharmaceutical products has not been regulated strictly before the above mentioned incidence.

Exposure to talc can occur occupationally via talc mining or talc powder processing (Oestenstad et al., 2002) and non-occupationally via the use of cosmetics, baby powder, and pharmaceuticals (Paolietti et al., 1984; Wild et al., 2008; Price, 2010; Straif et al., 2000). Talc containing asbestos has been classified as a group 1 carcinogen, while talc not containing asbestos has been classified as a group 2B carcinogen (IARC, 2010) in the case of perineal use. In the present study, an exposure assessment was conducted based on applying baby powder to a baby doll, as in a real situation, to estimate the amount of baby powder accumulated in the lung and estimate the asbestos exposure in the case of using asbestos-containing baby powder.
MATERIALS AND METHODS

Simulated exposure assessment of baby powder. The application of baby powder (purchased from Agabang & Company, 77C088017, Seoul) was simulated based on a general-use scenario (once a day with 1~5 application) and using a 40-cm-long baby doll. A personal sampler was used to sample the airborne baby powder in order to estimate the baby powder through inhalation. In order to assess what an individual breathes in during their work, surveys of exposure are conducted using personal samplers. These should be small, light and quiet so operators are not handicapped by the sampler. SKC MCE filters (37 mm diameter, 0.8 µm pore size) were used to sample the baby powder. The filters and blanks were dried for 24 hr before sampling and then dried again for 24 hrs after the sampling. The sampling analysis of the airborne baby powder was conducted based on the NISOH manual of analytical method 0500 (NIOSH, 2003). Samplers were placed simultaneously in the breathing zone which is defined as imaginary glove of two foot radius surrounding the head (Plog et al., 1996) of the person applying the baby powder (applicator) and 20 cm away from the baby doll nose region to sample the airborne baby powder during the baby powder application. Ten samples were taken in each case and the exposure concentrations calculated using the formula below. The flow rate (2 liter/min) of the sampler was calibrated before and after the sampling using a calibrator (Drycal® DC-Lite). The filters were also weighted with an AND GH-202 balance that can weigh up to 0.00001 g.

\[
C = \frac{(W_x - W_y) - (B_x - B_y)}{V} \times 10^3, \text{ mg/m}^3.
\]

where: 
- \(V\) = air volume sampled (liter)
- \(W_x\) = tare weight of filter before sampling (mg)
- \(W_y\) = post-sampling weight of sample-containing filter (mg)
- \(B_x\) = tare weight of blank filter (mg)
- \(B_y\) = post-sampling weight of blank filter (mg)

Estimation of baby powder consumed per application. To estimate the amount of baby powder per application, a puff of baby powder was applied with an S shape movement to a 10 cm × 10 cm filter paper that had been treated with glue. The S shape movement was based on NIOSH 9105 for surface sampling to cover the entire area thoroughly (NIOSH, 2003). The average sampling duration lasted 5 min which was estimated for maximum application time per use. The filter papers were then weighed to estimate the amount of baby powder per application.

RESULTS

Exposure concentrations of airborne baby powder near baby doll and applicator during baby powder application. The average sampling duration for a single application of baby powder lasted approximately 5 min, as the application of baby powder to the arm pits took 30 seconds. The average exposure concentration of airborne baby powder for the applicator during the baby powder application was 0.00527 mg/m^3, ranging from a maximum of 0.00157 mg/m^3 to a minimum of 0.00152 mg/m^3 (Table 1). Meanwhile, the average exposure concentration of airborne baby powder for the baby doll was 0.02207 mg/m^3, ranging from 0.04173 mg/m^3 to 0.00078 mg/m^3 (Table 2).

Amount of baby powder consumed during application. Ten filter papers (10 cm × 10 cm) were used to estimate the consumption of baby powder in the case of one, three, and five applications, respectively, which resulted in an average consumption of 107 mg (58~164 mg), 243 mg (204~279 mg), and 353 (336~372 mg) in the case of one, three, and five applications, respectively (Tables 3~5).

Table 1. Exposure concentration of airborne baby powder for applicator during baby powder application

| Filter number | Filter weight Before | Filter weight After | Blank weight Before | Blank weight After | Flow Before L/min | Flow After L/min | Sampling time min | Concentration mg/m^3 |
|---------------|---------------------|---------------------|---------------------|---------------------|-------------------|-------------------|-------------------|---------------------|
| 01            | 0.04504             | 0.04530             | 0.04501             | 0.04500             | 2.001             | 1.988             | 5.167             | 0.00157             |
| 02            | 0.04489             | 0.04512             | 0.04501             | 0.04500             | 2.019             | 2.016             | 4.583             | 0.00158             |
| 03            | 0.04485             | 0.04558             | 0.04501             | 0.04500             | 1.988             | 1.987             | 5.250             | 0.00427             |
| 04            | 0.04459             | 0.04523             | 0.04501             | 0.04500             | 2.028             | 2.026             | 4.833             | 0.00398             |
| 05            | 0.04480             | 0.04546             | 0.04501             | 0.04500             | 1.986             | 1.984             | 5.333             | 0.00378             |
| 06            | 0.04490             | 0.04551             | 0.04501             | 0.04500             | 2.015             | 2.013             | 4.417             | 0.00420             |
| 07            | 0.04477             | 0.04747             | 0.04501             | 0.04500             | 2.028             | 2.023             | 5.083             | 0.01579             |
| 08            | 0.04490             | 0.04664             | 0.04501             | 0.04500             | 2.067             | 2.053             | 4.833             | 0.01055             |
| 09            | 0.04480             | 0.04507             | 0.04501             | 0.04500             | 2.023             | 2.017             | 5.333             | 0.00152             |
| 10            | 0.04462             | 0.04553             | 0.04501             | 0.04500             | 2.054             | 2.045             | 4.917             | 0.00544             |

Mean ± SD 0.00527 ± 0.00455
Exposure assessment of asbestos-containing baby powder. The number of fibers in 0.1% asbestos-containing talcum powder is 50,000 fibers/mg, and the airborne concentration of asbestos in a workplace using below 0.1% asbestos-containing talcum powder has been estimated as 10,000 fibers/m³ (0.01 fibers/cc) (Mattenklott, 2007). The 0.1% (w/w) asbestos-containing product is minimum regulatory limit in most countries. If the breathing frequency of a baby is assumed to be 40 times/min (range 20~40 times/min) and the tidal volume for a baby is 123 ml/min, the minute volume would be approximately 5 liters/min, 7200 liters/day, and 5,256,000 liters/2 years. The lung weight of a baby is approximately 300 g, and if it contains 60% water, the dry lung weight becomes 120 g. Thus, if the inhalation exposure of a baby to asbestos-containing baby powder is 24 hrs, 1 hr, or 10 min over 2 years, the inhaled asbestos fibers would be 438,000 fibers/g of dry lung, 18,250 fibers/g of dry lung, or 3,040 fibers/g of dry lung, respectively. Plus,
when applying a deposition fraction maximum of 20%, as suggested by Asgharian et al. (2004), the lung contents of asbestos in the case of inhalation exposure to baby powder for 24 hr, 1 hr, or 10 minutes over 2 years would be 87,600 fibers/g of dry lung, 3,650 fibers/g of dry lung, or 608 fibers/g of dry lung, respectively.

DISCUSSION

When asbestos-containing baby powder and asbestos-containing talc in pharmaceuticals became an issue in Korea in 2009, there was no exposure data for talc or asbestos in the case of baby powder. Without exposure data, it is difficult to evaluate the risk of talc or asbestos exposure with the daily use of baby powder. Therefore, this study investigated the talc and asbestos exposure of babies and those applying the baby powder (applicators) using a baby doll. The airborne baby powder was sampled from the breathing zones of the baby doll and the applicator to estimate the risk of talc and asbestos exposure.

The amount of baby powder used per application and the exposure concentrations of baby powder for the baby doll and applicator were all estimated. Approximately 100 mg of baby powder were used per application, and the exposure concentration of baby powder for the baby and applicator was 0.02207 mg/m³ and 0.00527 mg/m³, respectively. The ACGIH TLV for talc not containing asbestos is 2 mg/m³ (ACGIH, 2005). The Korean occupational exposure level set by the Ministry of Employment and Labor is also 2 mg/m³ (Ministry of Employment and Labor, 2010). Despite the difficulties of comparing the occupational exposure level for the workplace with an indoor environment, such as a home, and the sampling duration of 6–8 hrs for the workplace and only 5 min in the present study, the exposure concentrations of baby powder measured for the baby and applicator were much lower than the occupational exposure level.

The estimated lung asbestos contents for the baby and applicator were compared with published normal human lung asbestos contents. In the case of no asbestos occupational history, normal human lung asbestos contents have been reported as 260,000 fibers/g of dry lung for males, 160,000 fibers/g of dry lung for female (Han et al., 2009), 300,000 fibers/g of dry lung for males, 150,000 fibers/g of dry lung for female (Yu et al., 1998), and in the case of Japanese normal human lungs: 2,000,000 fibers/g of dry lung (Sakai et al., 1991; Sakai et al., 1993; Sakai et al., 1994; Sakai et al., 1996). When comparing these values with the estimated exposure concentration of asbestos for babies exposed to asbestos-containing baby powder, the accumulated asbestos concentrations for the baby and applicator were much lower than the normal human lung asbestos content.

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