



Short communication

Assessment of exposure for baby cosmetic care products in a Korean population



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ABSTRACT

Assessment of exposure to cosmetic products via the skin is important for evaluating the risks associated with the use of these products. However, few exposure studies have been conducted with babies, particularly in Asia. The aim of our study was to assess the exposure to selected cosmetic products in babies under the age of 36 months, over both winter and summer months. We evaluated exposure for seven cosmetic baby care products identified in a previous web-based survey as being commonly used by Korean parents. Parents were instructed to use their baby's products as per their usual habit, recording usage for each product on a daily basis over a 14-day period. Products were weighed at the start and completion of the study, with the change in weight used to determine the total amount of product used. Descriptive statistics for daily exposure were calculated. In this study, daily exposure for different products was influenced by sex, age groups and seasons. Of specific note, 3.51% of the lotion in a wet wipe was transferred to the skin. In conclusion, we provide baseline exposure data for baby products, with exposure being based on parents' usual use of the products.

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1. Introduction

The assessment of exposure to chemicals through the skin provides a way to evaluate the risk associated with the use of products. The use of cosmetic products varies among individuals of different age and ethnicity, as well as between countries. As such, exposure should be assessed in sample populations of various ages and from different ethnicities and countries in order to obtain reliable data to evaluate the safety of ingredients contained in cosmetic products, as well as for the product itself. Although exposure data is important, such studies remain relatively rare.

The pattern of use for various cosmetic products has been evaluated in different populations (Biesterbos et al., 2013; Ficheux et al., 2015; Wu et al., 2010), with exposure data for selected

products published for adults in Europe (Ficheux et al., 2016a; Hall et al., 2011; Hall et al., 2007) and the United States (Loretz et al., 2005, 2006). However, the availability of exposure data for children is limited in Europe (Ficheux et al., 2016b; Gomez-Berrada et al., 2017), and with little to no paediatric data identified for Asia. With regard to paediatric data, we identified a retrospective review (Gomez-Berrada et al., 2013) of 48 clinical studies, conducted between 2001 and 2011, which provided exposure data for six baby products in children 3 months to 10 years of age. In addition, Gomez-Berrada et al. reported the real consumption and exposure data for seven products for babies under 2 years old (Gomez-Berrada et al., 2017). A French study (Ficheux et al., 2016b) evaluated exposure to 24 cosmetic products, including skin cleanser, skin care cream and lotion, fragrance, sunscreen, and diaper rash products, between March 2014 and December 2015, in children 0–3 years old. A multicentre study was conducted in 2013 (Dey et al., 2016) to assess the transfer of lotion to infants via wet wipes. Our aim in this study was to assess the exposure to selected cosmetic products that are commonly used for babies up to the age

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of 36 months in a Korean population. Exposure data were assessed for two seasons, winter and summer, to compare seasonal variation in the pattern of use of products.

2. Materials and methods

2.1. Study population

We conducted the study in two Korean cities, Seoul and Pusan, with the target population being babies 0–36 months, selected using quotas by age (3 age groups at a 1-year interval). Our winter exposure group included 167 babies, with data collected in February 2016, and our summer exposure group included 169 babies, with data collected in July 2016. These two groups were mostly distinct populations and only 13 subjects were in both two groups. Babies having a pre-existing skin condition, such as acne, eczema or psoriasis, were excluded. The study protocol was approved by the Institutional Review Board at Dankook University Hospital (IRB number DKUH 2015-12-011-002) and was conducted according to the Good Clinical Practice (GCP) guidelines and the International Conference on Harmonization (ICH) of research

daily basis, including the number of wet wipes used on each usage occasion. The method to determine the amount of each product used has been previously described (Ficheux et al., 2016b). Hair length of participating infants was measured by a trained assessor, using a measuring tape, prior to the start of the study. Babies' body weight (BW) and height were obtained from parents within 7 days of the start of the study.

2.4. Data analysis

Total skin surface area was calculated according to age using the equation for children provided by (Gehan and George, 1970). Daily exposure for each product was quantified using the following equations, as appropriate:

$$\begin{aligned} \text{Daily amount applied (g/d)} &= \\ \text{Total amount applied (g)/test period (d)} & \end{aligned} \quad (1)$$

$$\begin{aligned} \text{Daily number of wipes applied (\#/d)} &= \\ = \text{Total wipes used (\#/test period (d))} & \end{aligned} \quad (2)$$

$$\begin{aligned} \text{Daily exposure per body weight unit (mg/kg BW/d)} &= \\ \text{[Daily amount applied (mg/d) } \times \text{ Retention factor]/body weight (kg BW)} & \end{aligned} \quad (3)$$

$$\begin{aligned} \text{Daily exposure per surface area unit (mg/cm}^2\text{/d) or hair length unit (mg/cm/d)} &= \\ = \text{Daily exposure (mg/d)/[skin surface area (cm}^2\text{) or hair length (cm)]} & \end{aligned} \quad (4)$$

guidelines. Parents provided informed consent.

2.2. Test products

The types of cosmetic product evaluated in our study were selected based on a previous web-based survey conducted in Korea in April 2014. Seven types of baby products, identified as being widely used in Korea, were included in our analysis: leave-on face cream; leave-on body cream; oil-type leave-on lotions; sunscreen; liquid type cleanser; shampoo; and wet wipes. Parents used their own 'usual' baby products as per their 'usual' habit. Subjects were asked to identify the areas of application from a list of likely application sites for wet wipes (i.e., choices were buttocks, limbs and face).

2.3. Data collection

Test products were used for a 14-day period, with frequency of use for each product recorded at the end of each day by parents on a

A retention factor was introduced by the Scientific Committee on Consumer Safety (SCCS) to take into account rinsing off and dilution of finished products by application on wet skin or hair (SCCS, 2012).

2.5. Lotion transfer ratio measurement

The transfer of lotion from wet wipes to a baby's skin was evaluated by simulation of parents' use to wipe their infant's hands for 62 babies. The test was conducted under constant room conditions: temperature, 24.08 ± 0.14 °C, and relative humidity, $60.75 \pm 0.37\%$. For the test, parents were instructed to wear gloves and wipe their baby's hands, using either single or multiple wipes, as per their personal habit. The amount of lotion transferred was determined using previously described procedures (Hossain et al., 2015), as follows:

$$\begin{aligned} \text{Lotion transfer (g)} &= \sum_1^N (\text{Wipe weight before wiping} - \text{wipe weight after}) \\ &\quad - (\text{gloves weight after} - \text{gloves weight before}) \\ &\quad - (\text{amount lost to evaporation during wiping times}), \end{aligned} \quad (5)$$

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