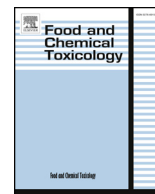




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Short communication

Consumption and exposure assessment to toothpaste in French families

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ABSTRACT

The aim of the study was to assess the consumption and the exposure to toothpaste in French families leaving the consumers free to use their own product at home according to their habits. Consumption data were collected on 104 families. 206 adults (103 women and 103 men) and 195 children aged 2–17 participated in the study.

Differences in toothpaste consumption depending on gender and on age were highlighted. As an example, frequency data were higher in adult women (2.0 day⁻¹ on average) than in adult men (1.8 day⁻¹ on average); amount per use data were higher in adult men (1.2 g on average) than in adult women (0.9 g on average). The frequency of use and the amount of toothpaste used per application increased with age. The exposure to toothpaste decreased with age. Children aged 2–6 were the most exposed to toothpaste with a P95 value equal to 8.2 mg/kg bw/day. Adult's P95 exposure value was equal to 2.8 mg/kg bw/day. Exposure values were in the same order of magnitude for both genders in children and in adults. These new data will be useful for safety assessors, especially children data which remain scarce.

1. Introduction

Oral care products are widely and regularly used by consumers of all ages. An increase in the consumption of oral care products has been observed in the last decades (Jardim et al., 2009; Rouhaud, 2010; Menard et al., 2016). Toothpaste is the best known and the most used oral care product which can be used as a vehicle for substances to improve the oral health of individuals (Cury and Tenuta, 2014). Toothpastes are intended to cleanse teeth, protect against the formation of cavities, refresh the breath, etc.

In Europe, toothpaste is considered as a cosmetic product. In fact, the European Regulation (EC) No 1223/2009 defines cosmetic products as “any substance or mixture intended to be placed in contact with the external parts of the human body [...] or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours” (EU, 2009). As mentioned in the European Regulation, cosmetic products available on the market must be safe for human health when used under normal or reasonably foreseeable conditions. Therefore, to conduct a reliable safety assessment, the assessor needs relevant toxicological data on all composing ingredients as well as accurate exposure data for the

finished product. Exposure can be determined by dividing the daily consumption of a finished product by the body weight of the studied population (SCCS, 2015). Current and relevant consumption data are essential for a correct exposure assessment.

Consumption and/or exposure to toothpaste were assessed in different adult populations. The European cosmetics industry (Cosmetics Europe) conducted studies to obtain consumption and exposure information on twelve cosmetic products, including toothpaste and mouthwash (Hall et al., 2007, 2011; McNamara et al., 2007). These values are currently used by the Scientific Committee on Consumer Safety (SCCS) to estimate daily exposure levels for European consumers (SCCS, 2015). Some national consumption studies are also available, especially in Europe. Biesterbos et al. (2013) assessed the amount of toothpaste used per application in an adult Netherland population. Garcia-Hidalgo et al. (2017) studied the frequency of using toothpaste and the corresponding amount applied on an adult Swiss population. The consumption and the exposure to toothpaste and mouthwash were assessed in a French adult and child population (Bernard et al., 2018; Ficheux et al., 2015, 2016a). The consumption of toothpaste (frequency of use and amount applied) was assessed in an adult Korean population by Park et al. (2015).

Few consumption and exposure values were generated in children.

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No European values are available. The consumption of toothpaste (frequency of use and amount per use) was assessed on a Swiss child population (Garcia-Hidalgo et al., 2017). The consumption and the exposure to toothpaste and mouthwash were assessed in a French child population (Bernard et al., 2018; Ficheux et al., 2015, 2016a). The consumption and the ingestion of fluoride-containing toothpaste by American children were assessed by Stritholt et al. (2016).

Methodology of these studies was different, and can make it difficult to compare the results. Although frequencies of use data were usually obtained by questionnaires, the amount per use parameter was collected by different methods. In The European study, participants used oral care products at home for two weeks. The amount was determined by weighting products before and after use (Hall et al., 2011). In the French study, the amount consumed was obtained by weighting products before and after one application in laboratory (Ficheux et al., 2016a). In Biesterbos et al. (2013), in Garcia-Hidalgo et al. (2017) and in Park et al. (2015) studies, amount per use data were estimated by photographs or circle cards. In Park et al. (2015) study, a comparison between the amount of toothpaste estimated by circle cards and the measured amount of this product consumed at home showed that the amount of toothpaste estimated by circle pads was lower than the measured amount.

In this context, the aim of the present study was to assess the consumption and the exposure to toothpaste leaving the consumers free to use their own product at home according to their habits. Families with parents and their child (ren) were taken into account. The influence of toothbrush kind (manual or electric) on consumption was also assessed.

2. Material and methods

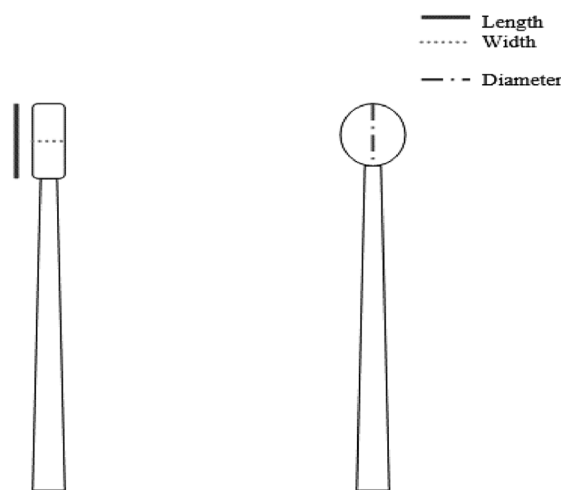
2.1. Study design

The aim of the study was to assess the consumption of toothpaste by French families. Panellists were recruited by a contract research organization. The inclusion criteria of families were as follow:

- Adults in couple,
- At least one child with an age ranging from 2 to 12 per family,
- Regular users of toothpaste,
- Healthy buccal mucosa,
- At least 5% of electric toothbrush users.

The exclusion criteria were drug, food or cosmetic product allergies, serious medical condition, pregnancy and breast-feeding. Based on these criteria, 109 families were selected. The study was carried out in 2015 in the Northwest of France in the city of Rennes and surrounding area.

Volunteers signed a study information form and a volunteer consent form. The interest of the study and the importance of respecting the instructions were explained at the beginning of the study. Participants were invited to use their own toothpaste and their own toothbrush at home for 21 days in the closest possible way to their personal usage patterns. If several members from a same family usually consumed the same toothpaste, each member had to use his own product. In this case, coloured stickers were placed on toothpastes to limit the risk of products exchange. Volunteers were asked to record every day in a diary the daily usage of toothpaste. Adults filled information for their young children. At the end of the study, the participants returned the completed diaries and the tested products to the contract research organization. All diaries were reviewed in the presence of participants in order to avoid as much as possible the risk of input errors. Toothpastes were weighed with a precision balance with sensitivity equal to 10 mg at the beginning and at the end of the study to determine the individual total amount of product used. The type of toothbrush (manual or electric) used during the study and the surface of toothpaste application was recorded according to an explanatory scheme (Fig. 1).



Note:
Rectangular toothbrush:
 Measure of the width from the middle of the toothbrush (cf. scheme)
 Measure of the length of the head of the toothbrush (cf. scheme)

Circle toothbrush:
 Measure of the diameter (cf. scheme)

Fig. 1. Toothbrush head measure.

At the end of this study, families were asked to complete a web-based questionnaire at home. They were asked about their brushing habits: the duration of brushing teeth (< 1 min, 1 min, 1.5 min, 2 min, 2.5 min, 3 min, 3.5 min, 4 min or > 4 min) and the others potential brushing areas (tongue, buccal mucosa of the cheeks, gums).

2.2. Consumption data analysis

Toothpaste consumption parameters were analysed by sex in adults. In children, consumption data were analysed by sex and age (2–6 years old, 7–12 years old and 13–17 years old). Mean, standard deviation, and median values were calculated using Microsoft Excel 2010 Software. 90th and 95th percentile values were also presented when the number of data was sufficient.

- **Frequency of use:** The frequency of use was calculated by dividing the total number of use (obtained in the diary) by the number of days of the study (j^{-1}).
- **Amount per use:** The amount of toothpaste per use was calculated by dividing the total amount of product consumed during the study (obtained by weighing) by the total number of use according to the diary (g/use).
- **Amount per day:** The amount of toothpaste consumed per day was obtained by dividing the total amount of product used (obtained by weighing) by the total number of days of the study (g/day).

Statistical analysis was performed on the three consumption parameters. A Mann-Whitney test was performed on data obtained for adult women and men; and on data obtained for children girls and boys. A Kruskal-Wallis test was performed on data collected for adults, for children aged 7–12 and for children aged 2–6. People between 13 and 17 years old were not taken into account in statistical analysis because of the small number of data available for this age group.

Amount per use parameter was also analysed according to the type of toothbrush used during the study (manual or electric) using a Mann-Whitney test.

Statistical tests analyses were performed when at least 30 data were available. Only p-values less than 0.05 were considered to be significant.

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