



Critical review of the literature and epidemiological data on choking risk from food products containing inedibles

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Abstract

The treatment of foreign bodies lodged in the upper aerodigestive tract of children remains a major challenge for the clinicians confronted with this situation, and choking is an important cause of unintentional injury and death in young children. In the US, mechanical airway obstruction is the primary source of fatal accidents of children less than 1 year old.

Toys (and parts of them) represent a special case of foreign bodies when commingled with food. Even if there are only very rare reports of fatal and serious choking accidents involving small toys, and no scientific evidence that a small toy combined with a food product in a separate package presents a higher risk than a toy as such, nevertheless, according to some opinions (for example of Consumer Associations), toy safety requirements are not sufficient to guarantee an adequate protection level for the child if the toy is combined with food.

The present study (1) analyses the available data from the literature showing that they are fraught with many weak points, and (2) reviews the clinical cases of foreign body ingestion and/or inhalation that were treated in the 1999–2000 period in several ENT Departments of an Italian region (Piedmont).

The evidence derived from the current research and the available data do not support the hypothesis of a higher choking risk of an FPCI in comparison with a simple toy.

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Keywords: Toys; Ingestion; Choking

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1. Introduction

A special case of a possible foreign body involved in choking accidents is represented by the association of a food item with an inedible one (usually a toy), the so-called food product containing inedibles (FPCIs).

Since there are only very few data available on this topic, the present study is aimed at analysing the available data from the literature and presenting epidemiological data of choking risk from FPCIs for children in an Italian region.

Even if choking is an important cause of injury and death in young children, after 3 years of age, it becomes very rare. In the US, mechanical airway obstruction is the primary source of fatal accidents of children less than 1 year old, but it ranks only fourth as a cause of death in children 1–9 years old. In children, the most common offending foreign bodies are mainly small round food products for infants and toddlers and objects of common use for older children [1,2,5,11].

The increased popular awareness of the risk of these accidents, and the great progress of medical science have resulted in the observed decrease of child mortality rates for choking in the last decades [6,7,13].

Among the possible foreign bodies that may pose a choking hazard for children, toys have to be mentioned, and a special case is represented by the association between food and a toy: the so-called FPCIs (Food Product Containing Inedibles).

Even if epidemiological data show that the risk of choking accidents is quite low for FPCIs [8], there is still the widespread opinion that the combination of a food item and a toy could impose a higher risk of accidental swallowing to a child who could be confused.

The peculiar category of food products, named food products containing inedibles (FPCIs), characterized by being permanently combined with a gadget (usually a toy), is very ample, embracing various types of food, coupled in a number of different ways with toys diverse for size and characteristics [3]. Despite this heterogeneity, FPCIs have been indiscriminately grouped for the risk of accidental ingestion of a piece of toy during food consumption.

Our experimental research on behaviour of children challenged with FPCIs clearly showed that this is not the case. The Italian Institute for Toy Safety carried out two experimental studies to find out whether, in the interaction between a child and an FPCI, there was a risk of choking different from that associated to a toy per se.

The premise of the experimental work is that there are possibly two different reasons for which a given FPCI might exhibit, to a child, a higher risk than a simple toy.

The first hypothesised reason might be a failure or a delay in child recognition of the double nature of the product, that is the awareness of the presence of an inedible part associated with food. When the FPCI is proposed as food to the child, the consciousness that “it is not only food” is believed to protect the child, eliciting a sort of “alert state”.

The second possible reason of increased hazard is that a toy derived from an FPCI may have an enhanced appeal with respect to mouthing activity due to its food smell and taste and to the temporary closeness between eating and playing.

Therefore, we measured by a first experiment the “attitude” of three different FPCIs on the market to be recognized as “products with a double nature”; by a second experiment, we investigated whether children can perceive a food smell on toys derived from an FPCI.

Chocolate has been chosen because it is richly aromatic, undoubtedly recognised as mentally codified, and generally greatly appreciated.

In the first experiment, the aim was to analyse whether children challenged with simple toys and with toys in FPCIs would exhibit a different behaviour when playing and would be able to recognize that a FPCI is indeed made of two components, one edible and the other inedible.

Three FPCIs were selected as examples of three different selling propositions (bags of chips with gadgets, chocolate eggs with a surprise and a chewing gum dispenser). The first step was evaluating children's behaviours and verbalisations, meaning both children's recognition of the double nature of the product and nonrecognition for these three FPCIs to be tested. To obtain this information 25 children, aged 3–5 attending a Milan kindergarten, were observed and videotaped for 2 h in a familiar environment when left free to play with many different FPCIs and toys, then interrogated according to the same specific protocol by a psychologist.

The extent of recognition of the three different FPCIs—a chocolate egg, a bag of chips and a chewing gum dispenser—was different since there was a diverse attitude to be recognised and to generate in children, namely, the “awareness of the double nature”. In particular, the chocolate egg was the most recognised and the bag of chips the lowest.

In the second experiment, four different types of toys underwent a stressful chocolate conditioning and were matched up to “unconditioned” items by sensorial analysis via triangle tests performed by 50 children. Six hundred Kinder Egg® capsules containing four different types of gadgets were taken directly from production. Four hundred capsules underwent no treatment; the remaining 200 capsules underwent a “conditioning treatment”, meaning that each of them was deeply immersed in 100 g chocolate in a jam vase and then sealed with a lid. Vases were almost full and they were kept for 12 weeks (average Kinder Egg® “age” when purchased) at 21 °C at relative humidity 65%.

Sensorial analysis was performed as internationally codified (UNI ISO 6658) via a triangle test (UNI ISO 4120). Fifty healthy children from a Milan kindergarten, aged 3–5 years (10: 3 years old; 20: 4 years old; 20: 5 years old), without any symptoms of cold, cough or flu, participated in the study. Each child was asked to participate in four triangle tests consecutively, involving four different types of gadgets, given in a random order and asked to identify the toy derived from a chocolate-conditioned capsule (the answer had to be given even though no smell was perceived).

Since the answers were completely random, we can conclude that chocolate flavour, although intensive, appealing, well known and “codified” by children, is not perceived on toys that have undergone a stressful chocolate conditioning and that the toys contained in chocolate eggs do not exert an enhanced mouthing appeal to children.

The data derived from this experimental research cast reasonable doubts on the few data available on this topic in literature; in fact, they seem to present several weak points.

Petridou [10] in 1997, on the basis of three minor ingestion accidents involving FPCIs which occurred over a very short span of time, without any evidence that the ingestion of the toy had happened while the food item was being eaten, concluded that “a total of 2000 FPCI injuries are expected to happen each year in the European Union”.

Even if the same researcher admits that these injuries are relatively mild with a fatality rate below 1/1000, nevertheless, the estimated number must be rejected because it derives from wrong statistical data and methods.

Data were collected only in the area of Great Athens during a 4-month period and, since there are indications that Greece has by far the highest death rate from choking of children under 10 in the European Community, this may well represent atypical behaviour. For these reasons, the estimate is biased upwards, i.e. the reported estimate of 2000 injuries each year appears to be too high; the computation with statistical techniques of the 95% interval (as it is usually set) in this particular situation gives a very large interval, equal to (0–5918), meaning that it would not be completely unlikely that no injuries will be reported next year [0 value], but it is also not completely impossible that we would have almost 6000 accidents [5918 value]. This simple consideration shows that the precision of the estimate reported in the paper is very poor (besides the fact that the sample is probably not representative) [4].

Even Petridou is clearly aware of the statistical limitations of her approach, since she admits "...these estimates are preliminary and need to be confirmed..." When she estimates the number of FPCI injuries in total in Greece, she uses the expression "wide confidence intervals" (i.e., scarce value of the estimate).

Keprt et al. [9] in 1999 sent a questionnaire to paediatricians and hospitals in Germany investigating the accidents involving FPCIs with special attention given to surprise eggs (chocolate eggs containing small toys). They concluded *that in Germany alone, there might be as many as 84 accidents a year from such products requiring medical treatment.*

However, the weak points of the paper are represented by a "selection bias" since only 25% of the physicians and 39% of the hospitals answered, and by a mistake in the risk assessment since the annual sales volume of surprise eggs was 25% higher. It is interesting to remark that none of the 46 fatal choking accidents in children under 5 years of age reported in 1997 was caused by FPCIs.

In 1998, two Israeli paediatricians [14] reported two cases of ingestion of small plastic parts of toys sold with chocolate eggs ("Toys within chocolate eggs—an ingestion hazard"). This very concise clinical report led the authors—on the basis of just two cases with minor sequelae—to conclude, "We believe that these common candies present a serious ingestion hazard". This conclusion (and the recommendation of "changing the design of such products, and more specifically, avoiding packaging toys within chocolate candies") is not acceptable since the authors do not present any scientific evidence that an FPCI presents a higher risk of accidental ingestion. Moreover, they make a mistake when saying that according to medical literature, foreign body ingestion occurs in a wide range of ages. They seem to ignore that in medical papers the foreign bodies responsible for the largest part of serious and fatal accidents are food products and common use nonfood products, while FPCI represented by surprise chocolate eggs did cause—since they were put on the market more than 20 years ago—only two fatal accidents. Both of them happened more than 12 years ago—before the EU regulations had heavily modified this aspect—and were not connected with the food item consumption that had taken place a considerable amount of time before.

Recently (2000), the consultants of a private society (RAM Consulting) [12] analysed the issue of FPCIs by computing the risk of choking and incidence of fatalities if an FPCI

was marketed in the US. They used Montecarlo simulation to analyse the issue and chose surprise eggs as the FPCI.

Even if their work is quite innovative and noteworthy from a theoretical point of view, their analysis was confused by the fact that when they computed the occurrence index of choking accidents, they used the data derived from choking caused in children by everyday products instead of using the data of real exposure of children to surprise eggs, a situation clearly impossible since this product is not marketed in the US.

It is crucial to enter into the Quantitative Risk Analysis (QRA) model data that are obtained from empirical observations on the Kinder Egg. As a matter of fact, the model needs the probability of the following events:

A = The purchase and the subsequent delivery of a Kinder Egg to a child in the United States is followed by a mouthing incident.

B = The purchase and the subsequent delivery of a Kinder Egg to a child in the United States is followed by a choking injury.

Whereas the article (p. 12), which is the object of the comment, literally states: “In the QRA results, for Kinder Egg, mouthing incidents were estimated based on the mouthing incident probability presented in Fig. 3.”

These values, reasonably split by age, are used in Table 5 (p. 129): “Equation for the distribution of injuries,” in order to estimate the expected number of accidents occurring over the final critical steps shown in Fig. 16: “Critical path to injury for the Kinder Egg” (p. 130).

This approach is doubtlessly wrong.

For example, for a 3-year-old child, Fig. 3 approximately shows $\text{Prob}(\text{mouthing incident}) = 0.002$.

This means that a 3-year-old child, over an entire year of life, during which he presumably had many occasions to come into contact with pieces of paper, small stones, pieces of plastic, sand, small pieces of wood, etc. is exposed to a risk of two out of every thousand to put something into his mouth, in such a way as to alarm a parent and lead them to call for help from the American Association for Poison Control. Well, the same value is attributed to event A, which refers to one dangerous situation: the contact of a child with only one Kinder Egg, whole or in fragments.

A similar reasoning may be made for the value $\text{Prob}(\text{choking injury}) = 0.0001$.

It is presumed that the acquisition of the historical statistical data, surely available, for the product in examination may show values dramatically smaller.

The confirmation that the precedent error is not a simple misprint, comes from the article: “Quantitative Risk Analysis for Consumer Products” published on the Proceedings of the Seventh International Conference on Product Safety Research, September 30–October 1, 1999, by the same author, G. Rider-RAM Consulting, who explicitly reported on p. 91:

In order to assess the risk of the Kinder Egg with a million products in distribution, the probabilities of mouthing incidents and choking injuries shown above were applied as parameters of binomial distributions.

While epidemiological data suffer from several weak points and experimental research data seem to confirm that FPCIs do not present any additional choking risk when compared to simple toys, there are, however, two basic questions that need an answer:

1. How many real cases of choking accidents involving FPCIs had to be admitted to the hospital?
2. How many more had to search for medical assistance but were not admitted?

These important drawbacks led us to investigate if it was possible to perform a better evaluation of the real incidence of this phenomenon in an Italian region.

We used two sources of information. The first is the dismissal form that has to be written every time that a patient is admitted to the hospital, but this document does not contain any information about the nature of the offending item. The second was a questionnaire sent to all the ENT and Emergency Departments of the region in order to get information about the cases that had been admitted and about those cases that did not generate an hospital admission.

In Fig. 1, there is the regional distribution of the cases of foreign body accidents, which caused an hospital admission for children 0–14 in the years 1999–2000 as derived by the official data of the Health Ministry. The different columns refer to the digestive tract and to the respiratory tract where the foreign body was judged to be lodged. While no significant variation between the two years is present, there is a significant difference in the number of cases admitted to the hospital between the regions. The peak for Campania cannot be easily explained.

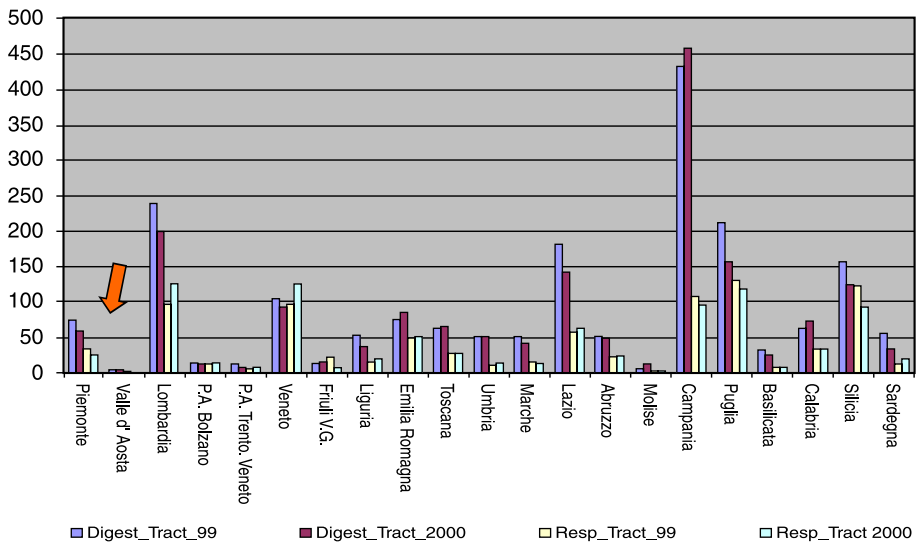


Fig. 1. Hospital admissions for foreign body ingestion and/or inhalation during the period 1999–2000 (as derived by Health Ministry data).

In this 2-year period, a total of 372 patients under 15 years of age were visited in the ENT or Emergency Departments of the Piedmont region for foreign bodies involving the upper aerodigestive tract and 261 were admitted; food items accounted for 39% of the foreign bodies. In the same period, the Campania region was in first place with almost 900 hospital admissions (while having only 22% more population than Piedmont). Endoscopic removal of the foreign body was performed in 57 cases.

In none of the cases admitted was an FPCI involved.

These data present, however, several uncertainties since we do not know the real incidence of cases in which a child has accidentally swallowed a foreign body without presenting any symptom so that no medical advice was searched for (the so-called “trivial” cases).

In the future, we will have to use other statistical tools in order to evaluate this phenomenon. Telephone interviews and a prospective study of the incidence of this phenomenon, supported by the creation of an information network between the emergency departments and the ENT departments in the Italian territory, could give better insight into this complicated issue.

2. Conclusions

As far as we know, epidemiological data do not seem to sustain any hypothesis of higher risk posed by FPCIs. EHLASS data [8] show that out of 15,339 choking, nonfatal accidents reported in a number of hospitals in five European countries (Finland, Greece, Ireland, Netherlands, Portugal) over a 1–5-year period, only five were caused by FPCIs.

Unfortunately, it is not easy to establish precisely the risk inherent to an FPCI because of the number of variables affecting the risk. If the simple equation— $RISK = HAZARD \times EXPOSURE$ —is kept in mind, it is easy to understand that to estimate the risk, besides the possible hazardous intrinsic characteristics of a given FPCI, it is necessary to know: the number of toys marketed, the frequency of their use, the average time interval elapsed between the accident and the consumption of the food and several other factors.

It can be argued that there are risky experiences that can be avoided, whereas other activities, even though associated with a certain level of hazard, are indispensable and impossible to renounce (unless renouncing to live!). Therefore, someone might say that FPCIs are completely unnecessary and avoidable, and the risk of having an accident due to a small toy sold in combination with such products, even though extremely low, should not be taken, hence, suggesting we stop selling these types of products.

However, the drawback would be depriving kids, even those who already have access to a plethora of the most sophisticated and technological equipment, of the opportunity to play with a toy. The importance of playing for the physical and intellectual growth and development of a child is universally recognised, but manual playing in particular has recently received much attention. In addition, authoritative institutions such as the DTI [7], not involved in educational issues, have recognised that playing with small toys is “essential for the development of manual and intellectual skills”.

Clinical experience and data from the literature suggest how the risk associated with the use of toys with small parts is extremely low, much lower than the risk accepted for

common daily activities, and also counterbalanced by manifest positive psychological and sociological advantages. The present review of the literature data and of the results derived from experimental research confirms that the frequently alleged increased risk of accidental ingestion for a toy contained in an FPCI due to smell and flavour confusion is nonexistent. Furthermore, children from three years of age use a playing approach with FPCIs not dissimilar from that used with simple toys.

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