# Foreign Bodies Injuries in Children: an update

**Guest editors: Desiderio Passali and Dario Gregori**


**Editorials**

FB injuries: the urgent need for updating the field
Desiderio Passali and Chong-Sun Kim

Foreign bodies injuries: a strong unique pathway linking ORL and Public Health
Dario Gregori

**Research paper**

The Susy Safe Project overview after the first four years of activity
The Susy Safe Working Group

Foreign Bodies Aspiration: a meta-analysis of published papers
Francesca Foltran Simonetta Ballali, Francesco Maria Passali, Eugene Kern, Bruno Morra, Giulio Cesare Passali, Paola Berchialla, Maria Lauriello, Dario Gregori

Food Foreign Bodies Injuries
Arjan B. (Sebastian) van As, Abdullah M. Yusof, Alastair J.W. Millar and the Susy Safe Working Group

Non Food Foreign Bodies Injuries
Ivo Slapak, Francesco Maria Passali, H. Ahluwalia and the Susy Safe Working Group

Modeling the risk: innovative approaches to understand and quantify the risk of severe FB injury
Paola Berchialla, Luisa Bellussi, Annalisa Castella, Silvia Snidero, Desiderio Passali and Dario Gregori

Emergency rescue maneuvers for foreign body airway obstruction: an update on effectiveness and dissemination among public
Filippo Festini, Daniele Ciofi, Sofia Bisogni

Prevention and early recognition of FB injuries: the role of family pediatrician
Carlo Moretti, Francesca Foltran

Management of FB in ORL setting
Hugo Rodríguez, Giulio Cesare Passali, Dario Gregori, Alberto Chinski, Carlos Tiscornia, Hugo Botto, Mary Nieto, Adrian Zanetta, Desiderio Passali, Giselle Cuestas

**Special topics**

Magnetic FB injuries: an hold yet unresolved hazard
Dario Gregori, Bruno Morra, Achal Gulati

Food products containing inedibles: a summary of the evidences at today
Cristina Donati, Beatrice Benelli, Laura Franchin

Nuts and seeds: a natural yet dangerous FB
Tania Sih, C.Bunnag, Simonetta Ballali, Maria Lauriella, Luisa Bellussi

Proper packaging for food and no-food products to avoid injuries
Desiderio Passali, Dario Gregori, Francesca Foltran

Fostering design for avoiding small parts in commonly used objects
Ton de Koning, Francesca Foltran, Dario Gregori

Toys in the upper aerodigestive tract: new evidence on their risk as emerging from the ESFBI Study
Francesca Foltran, Francesco Maria Passali, Paola Berchialla, Dario Gregori, Anne Pitkäranta, Ivo Slapak, Janka Jakubíková , Laura Franchin, Simonetta Ballali, Giulio Cesare Passali, Luisa Bellussi, Desiderio Passali and the ESFBI Study Group

Stationery injuries in the upper aerodigestive system: results from the Susy Safe Project
Francesca Foltran, Paola Berchialla, Dario Gregori, Anne Pitkäranta, Ivo Slapak, Janka Jakubíková, Luisa Bellussi, Desiderio Passali and the Susy Safe Working Group

**Country Specific Experiences**

Retrospective study on Romanian Foreign Bodies Injuries in children
Codrut Sarafoleanu, Simonetta Ballali, Dario Gregori, Luisa Bellussi, Desiderio Passali

Foreign Bodies in children: a comparison between Argentina and Europe
Alberto Chinski, Francesca Foltran, Dario Gregori, Simonetta Ballali, Desiderio Passali, Luisa Bellussi

Foreign bodies injuries in children: analysis of Thailand data
Chanticha Chotigavanich, Simonetta Ballali, Francesca Foltran, Desiderio Passali, Luisa Bellussi, Dario Gregori and the ESFBI Study Group

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**Title: Foreign bodies injuries: a strong unique pathway linking ORL and Public Health**

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## Abstract

The “Susy Safe” Registry, a DG SANCO co-funded project gathering data on choking in all EU Countries and beyond, was established in order to create surveillance systems for suffocation injuries able to provide a risk-analysis profile for each of the products causing the injury. Main findings after 4 years of activities are resumed here. 16878 FB injuries occurred in children aged 0-14 yrs have been recorded in the SUSY SAFE databases; 8046 cases have been reported from countries outside EU. Almost one quart of the cases involving very young children (less than one year of age) presented a FB located in bronchial tract, thus representing a major threat to their health. Esophageal foreign bodies are still characterizing injuries occurred to children younger than one year in older children the most common locations are the ears and the nose. FB type was specified in 10564 cases. Food objects represented the 26% of the cases, whereas non-food objects were the remaining 74%. Among food objects, the most common were bones, nuts and seed, whereas for the non-food objects pearls, balls and marbles were observed most commonly (29%). Coins were involved in 15% of the non-food injuries and toys represented the 4 % of the cases. In the Susy Safe project, object features including dimension, shape and consistency have been taken into consideration for the calculation of the risk of injuries using a risk engine able to provide a numerical assessment of the threat of a product in terms of the probability of injury occurrence.

**Keywords:** Susy Safe Registry**,** risk assessment

## Introduction

Suffocation due to foreign bodies (FB) is a leading cause of death in children aged 0-3 and it is common also in older ages, up to 14 years old. Based on the RPA report (1) the estimated number of incidents per year in children aged 0-14 is in European Union (EU) of about 50.000, 10% of which are fatal. In the RPA report (1) about 10.000 accidents are estimated to involve inorganic objects, in general industrial products, mostly plastic and metal parts, coins, and toys. Out of the estimated 2.000 incidents per year involving toys, the fatalities are around 20. Based on official records, the cost in terms of life loss due to suffocation in general has been estimated, for the EU community, as about 5 billion €per year, only because of injuries due to industrial products (2).

The need for a multinational pan-European study derived by the lack of comparable data on the choking risk prevalence in European countries has been recently pointed out in few papers (3). In fact, most of the epidemiologic evidence on foreign bodies (FB) in children comes from single-center retrospective studies, covering a time range of about 3-10 years (4) in the past. Very recently, attempts have been made to start a systematic collection of FB in view of using them to characterize the risk of chocking in terms of size, shape and consistency of the FB (5). Also several review papers discussed more clinical aspects of the FB injuries, like clinical diagnosis and management of the injured child (6). Country specific experiences have also been presented in the literature, with a wide although not systematic spread and geographical coverage (7-10). In particular, very small attention has been paid to this subject in Europe, which was, till few years ago, lagging behind the North-American experience, often based on large databases and data collection repositories. Even if not too many papers have been published on the argument based to European data (3, 11-13), still very few attempts have been made to synthesize the epidemiological data as arising from the literature.

Difficulties are arising from the relative rarity of the phenomenon, in particular in EU and USA, after the adoption of severe rules for toys packaging and distribution. Actually the effect of regulatory acts had the effect of step-down the trend in choking injuries. Actual estimates are indicating mortality for suffocation (all causes) in EU exceeding nearly a

death per 100,000 children. The heterogeneity among countries is very high, making the comparison among countries very difficult.

From the methodological point of view, basically three approaches were actually adopted for these purposes: (i) official data re-analysis, mostly based on discharge records of official death certificates, and published official statistical data, (ii) clinical registries, most often single center-based (6, 14), and (iii) foreign bodies collections, with the specific aim of describing the shape and the material of the object causing the injury (5). Unfortunately, all these methods are revealing as largely inadequate to address the epidemiological characterization of the phenomenon in the sense described above, because of the relative scarce and geographically limited area of the clinical registry, the poor clinical information of the official data and the limited spectrum of perspectives of the object collections.

In addition to this scientific scenario, also from the political point of view things changed in EU. Indeed, over the last years, the focus in the European Commission has moved towards what is sometimes called "science-based policy making" and better regulation. As a consequence, increasing pressure has been put on the scientific community, not necessarily because it is essential to justify decisions, legislations, or activities, but because in order to do so it is extremely important to have a sound knowledge, a sound basis in terms of information for every area that needs to be investigated, in terms of Commission work but naturally also in terms of Consumer Safety. Now that more formal recognition has been given in the new Consumer Policy Strategy for the years 2007-2013, it is important to remark the importance of data collection at an EU level. So, it is considered as an absolute priority the creation of a harmonized system for collecting such data to improve the evidence base for the assessment of risks related to Product and Service Safety. Therefore, the key objective of the European Commission is to ensure that relevant, up-to-date, representative, accurate, systematic information, related to accidents and injuries for consumer products or related to consumer products and any provision of consumer service are available to the Commission and other relevant bodies when decisions need to be taken.

To overcome such scientific issues and to address such political needs with respect to foreign bodies' injuries in children, a large, multi-center registry has been established in Europe: the Susy Safe project.

**The Susy Safe Registry**

The surveillance registry for injuries due to non-food foreign bodies' ingestion, the "Susy Safe" Registry, gathering data on choking in all EU Countries and beyond, was established in order to:

1. provide a risk-analysis profile for each of the products causing the injury with the aim at:
    a. creating a surveillance systems for suffocation injuries caused to young consumers by inappropriate product design or packaging;
    b. helping guaranteeing the safety of consumers, indicating products whose risk profile is clearly not compatible with a safe fruition of the product itself;
    c. providing the EU Commission with comparative data on risk/benefit of each of the products causing the injuries, in order to weight acceptable risks versus the foreseen economic impact of recalling the product involved from the market;
2. provide an evaluation of how socio-economic disparities among EU citizens may affect the likelihood of being injured by FB ingestion, with the aim of implementing specific educational activities on safe behavior and active parental guard with regards to the specific products causing the injury;
3. involve, as appropriate, Consumer Associations and/or National Market Surveillance Authorities in data collection and proper education of consumers, allowing a precise estimate of the risk profiles for those products which are actually causing the injury, but, because of the low impact in terms of child health (self resolved FB ingestions) are usually under reported and not known in the official clinical discharge data.

Thus, the project used the previous experience gained with the European Survey of Foreign Body Injuries (ESFBI) (15) as a starting point, with the aim of applying that methodology to creation of a surveillance registry in EU and EFTA countries, with the joint effort of statisticians, public health expert, otorhynolaryngologists, consumers and educational professionals.

The objectives envisaged by the project were planned to be met in particular by:

1. establishing an ad-hoc WEB server for collection of data in a centralized manner, in order to allow:
    a. constant quality control on data collection and completeness;
    b. easy and cost-effective access (via low-band internet connection) to data collection activities for public and private institutions willing to share their data with the project, with the aim of lowering as much as possible any barriers to participation to the project;
2. setting up an ad-hoc risk analysis engine (running on the WEB server) with the aim of obtaining an updated estimate of risk profiles for each of the objects causing the injuries, effectively as new data become available;
3. translating risk-analysis and statistical concepts into accessible information for EU citizens, involving EU consumer's associations in the process of safe product consumption, also in the view of lowering the effects of the possible socio-economic disparities involved in the injuries.

## Data Collection

16878 FB injuries occurred in children aged 0-14 yrs have been recorded in the SUSY SAFE databases; 8046 cases have been reported from countries outside EU. Details regarding the patients' distribution by country are reported in Table 1.

The registry collected 1727 prospective cases and 15151 retrospective cases. Retrospective cases are past consecutive cases available in each center registry and shared with Susy Safe. Data collection for retrospective cases followed the same procedure as for the prospective cases. All cases, in fact, irrespectively from their retrospective or prospective nature have been entered in the registry using the Susy Safe Case Report Form (CRF), thus ensuring the same quality, at least from the data entry point of view, for all cases reported in the system. For the purposes of providing a picture of the overall data quality, three definitions have been adopted: (*i*) Low Quality data: few basic data available (e.g.: gender, age, …), (*ii*) Medium quality data: basic data on FB characteristics and procedures are available (FB type, type of procedure, …) and (*iii*) High quality: detailed data on at least one FB characteristic are available (shape, size, circumstances of the injury, …).

Sixty percent of the prospective cases have a level of quality high enough (medium or high) to meet the requirements of the risk analyses system (see below), and, although this percentage lowers down to 36% for retrospective cases, still this remains a very good achievement (Figure 1).

## Main findings

The children age distribution is shown in Figure 2: 55% of the cases are males, and about 38% of them are younger than three years. This percentage rises to 43% for females (table 2). Forty-seven children were reported with mental of physical impairment.

FB location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935). Almost one quart of the cases involving very young children (less than one year of age) presented a FB located in bronchial tract, thus representing a major threat to their health. Moreover, esophageal foreign bodies are still characterizing injuries occurred to children younger than one year Notice that for older children the most common locations are the ears and the nose (Table 3).

Distribution of cases by location and by gender is shown in Figure 3: while FBs in the ears were more common in females, all other sites were more common for males than for females.

FB type was specified in 10564 cases; the retrieved FB description is given in Table 4. Food objects represented the 26% of the cases, whereas non-food objects were the remaining 74%. Among food objects, the most common were bones, nuts and seed, whereas for the non-food objects pearls, balls and marbles were observed most commonly (29%). Coins were involved in 15% of the non-food injuries and toys represented the 4 % of the cases.

Table 5 and Table 6 are showing the distribution of the cases according to the shape and consistency stratified by foreign body type. Spherical objects represent the 36% of the cases; the 76% of the retrieved FBs were rigid.

Looking to FB volume, food objects had a median volume of 31.4 $mm^3$, with a maximum observed volume of 4710 $mm^3$: bones tended to have higher volumes than nuts and beans Non food objects had a median volume of 41.9 $mm^3$, with an upper 95-th percentile of 470.1 and 99-th percentile of 1045 mm3 (Table 7). The maximum volume observed was of 2093 $mm^3$. To allow a comparison with commonly used objects, a 5 eurocent coin has a volume of 483 $mm^3$, a flat battery of 943 $mm^3$. Accessorize had a greater volume among various foreign body types (Table 8).

An important tool has been introduced both in USA and in Europe to foster safety of toys avoiding the contact of small parts with children (16). Indeed, toys with small parts cannot be sold to children younger than three years old without specific warnings. Small parts are defined as those object components fitting in the so-called “small part cylinder” (Figure 4). Regarding the “small-part cylinder”, overall 617 objects collected in the Susy Safe registry and looking at the longer axis’s length, did not fit in the cylinder: out of them, 85 were spherical and none were non food objects. Looking at the overall volume, no one object had a volume greater than volume A.

In order to understand the impact of spherical objects to the risk of injuries, the “ellipticity” measure has been computed, which is nothing but the ratio of the longer and the shorter axis of the object, thus being equal to one for spherical objects. Toys were mostly spherical, at most with a very small ellipticity ratio of 2. The description of FB ellipticity by age of the child is given in Table 9.

Looking at the consequences of the injury, the Susy Safe registry adopted the DTI definition (17) of severe injury, as that requiring at least one day of hospitalization. In addition, we considered also the occurrence of complications, as reported by the physician, requiring or not hospitalization. The vast majority of the cases have been managed by the Emergency Department (5986 cases) followed by the ENT department (5812), mostly with endoscopic techniques; only 160 cases (1.4%) needed a surgical intervention. Data regarding the need of hospitalization was at disposal in 5840 cases: among them 36% of children (2106) were hospitalized; particularly, 806 were discharged after 24 hours whereas 248 required hospitalization more than 3 days.

Most commonly observed complications were infections other than pneumonia (6.7%) and pneumonia (6.4%), followed by asthma (3.1%) and by perforation (2.9%). Complications requiring hospitalization occurred in 7.1% of children younger than 1 year while, they seem to be less frequent in older (Figure 5).

Complication distribution according to FB characteristics is shown in table 10 and 11. Conforming consistency showed a higher incidence of complications; consisting with this result, sponges seem to be the FB most often related with complications’ occurrence, while pearls, balls and marbles, which are the most frequently retrieved FB, are rarely involved in complicated cases.

Some injuries occurred for what is called the “unexpected usage” or “mis-usage” of the object: this includes packaging and association with food and non food object when combined without the necessary attention to safety issues. In the Susy Safe registry, 5 different categories of objects have been considered in view of providing the EU commission with useful information:

not an industrial component;

a. a piece of an object: the FB was a broken part of the product (e.g. a broken part of a pen, the wheel of a toy car, etc);
b. in co-presence with another object: when the objects were sold together like the cap with the pen, the marble with a board game, etc;
c. a package or a part of a package of a product (e.g. the tinfoil containing a chocolate, a polystyrene ball, a piece of cardboard, etc);
d. the inedible part of a FPCI (food product containing inedibles): stickers in crisps, toys in chocolate eggs, etc. Moreover we divided this category in two subcategories: the proper FPCI and the improper FPCI.

Where the association was not specified we considered the product like a single object and not an industrial component. Obviously, food and the other organics objects were treated as non industrial components. In the RPA Report (18) the Food Products Containing Inedibles (FPCI) were defined as the combination of edible and inedible components, such as toys, used by food manufacturers to promote a wide range of products including sweets, crisps, yoghurt, ice cream and cereal. Several studies (19-23) were published on the risk that a child may face placing the inedible object contained in the product in or near their mouth, causing potentially ingestion, choking or suffocation. For such injuries we used the definition of “proper FPCI”. We defined the “improper FPCI” as the objects sold with food but not for a strict promoting purpose, like the candles on a cake, the drinking-straw with a juice or other non-organic decorations on the food. Overall, nine FPCI only have been observed in the Susy Safe registry, all without neither hospitalizations nor complications.

What is lacking is really proper adult supervision: according to Susy Safe data, an adult was present in 25% of the injuries, and in 40% of those involving a child younger than one year. In 87.9% of the cases the child was playing. This evidence suggests the need of

fostering the attention of families toward a proper surveillance of children, in particular of younger ages.

**Providing evidence to the EU commission**

The final aim of this data collection system was the construction of a system able to provide the EU commission with all the relevant estimates on FB injuries. This has been accomplished via a fairly complex statistical system being developed for the purposes of the project: the so-called "Susy Safe risk engine".

A risk engine can be thought of as a table in which one could look up the potential threat associated with any given consumer product. To perform a risk analysis, key factors affecting risk need to be identified. Factors impacting hazards usually include product design and consumer exposure (24, 25). Thus through the use of injury data, consideration of product characteristics and statistical tools it is possible to provide a numerical assessment of the threat of a product in terms of the probability of injury occurrence. At the end, the analysis results can be used both by consumers and manufacturers to make informed risk management decisions, in accordance with the "knowledge-based" action demanded by the EU Consumer policy strategy 2002-06 (2.2.2. 3rd Comma) (26).

A risk engine is expected to produce the probability of occurrence of an injury given hazardous factors– e.g. an object that has a volume lower than a threshold value and a spherical shape– and it is expected to give insights of how the risk of injury occurrence changes when new data become available since product safety design, which depends also on the objects dimension, shape and consistency, is subject to change over time in order to reduce or preclude further injuries.

Inside the Susy Safe project the object features taken into consideration for the calculation of the risk of injuries were size and shape of the foreign body which caused the injury (27).

Such a choice allows for evaluating the impact of dimension and shape as hazardous product characteristics in the spirit of European standard BSEN 71-1 of 1998 (Safety of

Toys - Specifications for Mechanical and Physical Properties) which introduced the cylinder test to reduce the risk of choking in children. In fact, the cylinder test consists of a cylinder with an inner diameter of 31.7 mm and truncated askew with an upper dimension of 51.7 mm and a lower dimension of 25.4 mm. Any toy entering the cylinder without pressure is considered unsuitable for children younger than 3 and is legally banned.

In order to calculate this probability we need to know the distribution of such characteristics, the coverage of the surveillance system and finally the probability of occurrence of an injury. In fact, let us consider the following equation:

$$P(I, I_{SS} \mid C) = \frac{P(C \mid I, I_{SS})}{P(C)} \times P(I_{SS} \mid I) \times P(I)$$

where $I_{SS}$ stands for an injury covered by the surveillance system, $I$ stands for an occurred injury and $C$ stays for the object characteristics. Thus with $P(I, I_{SS} \mid C)$ at the first member of equation we indicated the probability that a foreign body injury occurred and it was detected by the surveillance system given foreign body characteristics C. An example of the risk estimates are shown in Table 12 and Table 13.

## Final remarks

Every infant injury, every dead child, is something utterly intolerable. We should bear in mind the objective to avoid as many of these infant injuries as possible. The European Commission spends a lot of time and work within its activities minimizing infant injuries and making objects and environments safer, so that these injuries no longer occur to such an extent. The Commission however needs secure data about injuries in order to adopt administrative or legislative measures. We will not be able to immediately adopt strict measures based only on a few injuries that occur in all large communities. The quality of legislative or administrative measures depends precisely on the amount and the reliability of data. We should always consider this when we discuss any preventive or legislative measure.

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**Appendix**

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United Kingdom
Dr. John Graham, Royal Free Hampstead NHS Trust, United Kingdom
Dr. Sadie Khwaja, Royal Manchester Children's Hospital, United Kingdom
Dr. Christopher Raine, Bradford Royal Innfirmary, United Kingdom

## Tables

| Countries | N |
|---|---|
| EU Countries | 8832 |
| Austria | 12 |
| Czech Republic | 607 |
| Cyprus | 99 |
| Denmark | 70 |
| Finland | 421 |
| France | 122 |
| Germany | 157 |
| Greece | 88 |
| Italy | 5241 |
| Poland | 45 |
| Romania | 753 |
| Slovak Republic | 241 |
| Slovenia | 105 |
| Spain | 149 |
| Sweden | 236 |
| the Netherlands | 77 |
| UK | 409 |
| Non EU Countries | 8046 |
| Argentina | 2461 |
| Croatia | 19 |
| FYROM | 63 |
| Pakistan | 13 |
| South Africa | 5240 |
| Turkey | 250 |
| Total | 16878 |

**Table 1. Patients enrolled by country in the Susy Safe registry.**

| | Female | | Male | | Total | |
|---|---|---|---|---|---|---|
| | N | % | N | % | N | % |
| < 1 year | 229 | 5.5 | 261 | 5.3 | 490 | 5.3 |
| 1 - 2 years | 1555 | 37.4 | 1632 | 32.9 | 3218 | 35.0 |
| >= 3 years | 2373 | 57.1 | 3074 | 61.9 | 5479 | 59.6 |
| Total | 4157 | 100.0 | 4967 | 100.0 | 9187 | 100.0 |

**Table 2. Age distribution of cases in classes by gender.**

| | < 1 year | | 1 - 2 years | | >= 3 years | | Total |
|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | |
| ICD931 | 24 | 4.9 | 277 | 8.6 | 1921 | 35.2 | 2222 |
| ICD932 | 27 | 5.6 | 1131 | 35.2 | 1194 | 21.9 | 2352 |
| ICD933 | 40 | 8.2 | 82 | 2.6 | 248 | 4.5 | 370 |
| ICD934 | 120 | 24.7 | 683 | 21.3 | 298 | 5.5 | 1101 |
| ICD935 | 254 | 52.4 | 927 | 28.9 | 1367 | 25.0 | 2548 |
| Other | 20 | 4.1 | 111 | 3.5 | 430 | 7.9 | 561 |

**Table 3**. Distribution of FB location by age, according to ICD9-CM code: ears (ICD931) nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935).

| FB description | N | Percentage |
|---|---|---|
| pearl, ball and marble | 1698 | 16% |
| coin | 1534 | 15% |
| bone | 885 | 8% |
| other non-food | 639 | 6% |
| nut | 613 | 6% |
| other food | 563 | 5% |
| pin and needle | 506 | 5% |
| toy | 441 | 4% |
| seed and grain | 430 | 4% |
| pebble | 424 | 4% |
| stationery | 422 | 4% |
| paper | 365 | 3% |
| plastic | 304 | 3% |
| jewellery | 215 | 2% |
| metal | 183 | 2% |
| battery | 170 | 2% |
| cotton | 162 | 2% |
| button | 152 | 1% |
| stick | 150 | 1% |
| bean and pea | 142 | 1% |
| sponge | 95 | 1% |
| sweet | 91 | 1% |
| arthropod | 80 | 1% |
| cap | 70 | 1% |
| other stationery | 56 | 1% |
| polystyrene | 53 | 1% |
| tinfoil and cellophane | 42 | 0% |
| accessorize | 26 | 0% |
| fruit stone | 20 | 0% |
| earplug | 20 | 0% |
| medicine | 13 | 0% |
| Total | 10564 | |

**Table 4.** Description of the FB which caused the incident.

|  | 2D/circle | 3D/cylinder | Spherical | Other |
|---|---|---|---|---|
| accessorize | 21.7 | 52.2 |  | 26.1 |
| arthropod | 4.5 | 63.6 | 27.3 | 4.5 |
| battery | 73.8 | 16.9 | 4.6 | 4.6 |
| button | 68.4 | 10.5 | 15.8 | 5.3 |
| cap | 3.6 | 92.9 |  | 3.6 |
| coin | 97.9 | 0.3 | 1.7 |  |
| cotton | 24.2 | 33.3 | 30.3 | 12.1 |
| earplug |  | 18.8 | 56.3 | 25.0 |
| jewellery | 24.1 | 35.4 | 26.6 | 13.9 |
| medicine | 66.7 |  | 33.3 |  |
| metal | 12.5 | 31.3 | 9.4 | 46.9 |
| other non-food | 32.3 | 36.0 | 11.8 | 19.9 |
| other stationery | 18.2 | 63.6 |  | 18.2 |
| paper | 60.7 | 10.7 | 1.8 | 26.8 |
| pearl, ball and marble | 5.5 | 7.5 | 85.8 | 1.1 |
| pebble | 4.9 | 33.1 | 50.0 | 12.0 |
| pin and needle | 16.1 | 59.8 | 2.3 | 21.8 |
| plastic | 25.6 | 52.3 | 7.0 | 15.1 |
| polystyrene | 4.2 | 33.3 | 45.8 | 16.7 |
| sponge |  | 60.0 | 20.0 | 20.0 |
| stationery | 7.6 | 75.9 | 8.9 | 7.6 |
| stick | 14.3 | 57.1 |  | 28.6 |
| tinfoil and cellophane | 81.3 | 12.5 | 6.3 |  |
| toy | 22.4 | 52.1 | 22.8 | 2.7 |
| Total | 29.6 | 26.7 | 35.7 | 8.0 |

**Table 5. Distribution of non-food objects by shape (numbers are percentages).**

| | Conforming | Rigid | Semi-rigid |
|---|---|---|---|
| accessorize | 12.0 | 72.0 | 16.0 |
| arthropod | 20.6 | 41.2 | 38.2 |
| battery | | 100.0 | |
| button | | 95.8 | 4.2 |
| cap | 2.7 | 64.9 | 32.4 |
| coin | | 100.0 | |
| cotton | 92.6 | | 7.4 |
| earplug | 16.7 | 5.6 | 77.8 |
| jewellery | | 97.8 | 2.2 |
| medicine | 77.8 | 11.1 | 11.1 |
| metal | | 100.0 | |
| other non-food | 26.6 | 62.4 | 11.0 |
| other stationery | 4.7 | 90.7 | 4.7 |
| paper | 86.5 | 5.9 | 7.6 |
| pearl, ball and marble | 3.4 | 89.6 | 7.0 |
| pebble | 1.1 | 98.1 | 0.7 |
| pin and needle | 2.7 | 97.3 | |
| plastic | 13.3 | 63.6 | 23.1 |
| polystyrene | 34.9 | 41.9 | 23.3 |
| sponge | 95.1 | | 4.9 |
| stationery | 18.7 | 64.0 | 17.3 |
| stick | | 92.9 | 7.1 |
| tinfoil and cellophane | 44.1 | 2.9 | 52.9 |
| toy | 13.7 | 71.1 | 15.2 |
| Total | 14.6 | 76.4 | 9.1 |

**Table 6**. Distribution of non-food objects by consistency (numbers are percentages).

|  | Min | 5% | 25% | Median | 75% | 95% | 99% | Max |
|---|---|---|---|---|---|---|---|---|
| bean and pea | 15.7 | 16.3 | 26.2 | 37.7 | 94.2 | 350.4 | . | 452.2 |
| bone | 0.2 | 0.2 | 2.7 | 14.4 | 31.4 | 628.0 | . | 2110.1 |
| fruit stone | 9.4 | 9.4 | 37.7 | 84.8 | 352.7 | . | . | 795.5 |
| nut | 6.3 | 9.4 | 25.1 | 26.2 | 51.3 | 229.0 | . | 471.0 |
| other food | 1.0 | 3.8 | 26.2 | 42.9 | 104.7 | 1177.5 | . | 4710.0 |
| seed and grain | 1.0 | 7.3 | 19.4 | 37.7 | 104.7 | 246.4 | . | 418.7 |
| sweet | 4.2 | 4.2 | 14.9 | 33.0 | 134.2 | . | . | 937.8 |
| Overall | 0.2 | 2.5 | 16.7 | 33.5 | 83.7 | 418.7 | 2565.3 | 4710.0 |

**Table 7. Distribution of volume by food object ($mm^3$).**

| | Min | 5% | 25% | Median | 75% | 95% | 99% | Max |
|---|---|---|---|---|---|---|---|---|
| accessorize | 20.9 | 20.9 | 38.9 | 400.1 | 1478.9 | . | . | 1657.9 |
| arthropod | 8.4 | 8.4 | 15.2 | 26.2 | 37.7 | . | . | 37.7 |
| battery | 3.1 | 7.9 | 19.6 | 50.2 | 78.5 | 418.7 | . | 418.7 |
| button | 7.1 | 7.1 | 24.3 | 72.7 | 158.6 | . | . | 314.0 |
| cap | 33.5 | 33.5 | 67.4 | 82.2 | 176.6 | . | . | 261.7 |
| coin | 3.1 | 78.5 | 86.7 | 314.0 | 435.4 | 669.9 | . | 1256.0 |
| cotton | 16.7 | 16.7 | 16.7 | 26.2 | 34.0 | . | . | 51.3 |
| earplug | 18.8 | 18.8 | 67.0 | 104.7 | 104.7 | . | . | 104.7 |
| jewellery | 1.6 | 1.7 | 29.0 | 52.3 | 268.9 | 754.9 | . | 785.0 |
| medicine | 4.2 | 4.2 | 4.2 | 6.8 | . | . | . | 9.4 |
| metal | 1.0 | 1.0 | 30.1 | 52.3 | 52.3 | . | . | 117.8 |
| other non-food | 6.3 | 8.6 | 16.7 | 39.8 | 149.5 | 850.4 | . | 1046.7 |
| other stationery | 37.7 | 37.7 | 37.7 | 84.3 | . | . | . | 130.8 |
| paper | 14.1 | 14.1 | 14.1 | 33.5 | . | . | . | 94.2 |
| pearl, ball and marble | 0.5 | 4.2 | 9.4 | 26.2 | 67.0 | 235.5 | 434.6 | 1496.7 |
| pebble | 6.3 | 9.4 | 26.2 | 37.7 | 67.0 | 139.2 | . | 235.5 |
| pin and needle | 1.6 | 1.6 | 3.5 | 12.6 | 51.8 | . | . | 314.0 |
| plastic | 2.1 | 2.1 | 18.3 | 62.8 | 240.3 | . | . | 1046.7 |
| polystyrene | 1.0 | 1.0 | 4.2 | 9.4 | 37.7 | . | . | 837.3 |
| sponge | 4.2 | 4.2 | 19.9 | 85.8 | 141.6 | . | . | 153.9 |
| stationery | 1.6 | 3.5 | 23.6 | 55.0 | 94.2 | 355.9 | . | 418.7 |
| stick | 31.4 | 31.4 | 31.4 | 172.7 | . | . | . | 314.0 |
| tinfoil and cellophane | 16,7 | 16,7 | 19,1 | 60,2 | 94,2 | . | . | 94,2 |
| toy | 1,0 | 6,3 | 26,2 | 67,0 | 104,7 | 671,6 | 2093,3 | 2093,3 |
| Overall | 0,5 | 4,2 | 16,7 | 47,1 | 104,7 | 486,7 | 1046,7 | 2093,3 |

**Table 8. Distribution of volume by non-food object ($mm^3$).**

|  | Min | 5% | 25% | Median | 75% | 95% | 99% | Max |
|---|---|---|---|---|---|---|---|---|
| < 1 year | 1.0 | 1.0 | 1.3 | 2.5 | 8.5 | 28.3 | . | 30.0 |
| 1 - 2 years | 1.0 | 1.0 | 1.0 | 1.5 | 3.7 | 22.0 | 40.0 | 63.5 |
| >= 3 years | 1.0 | 1.0 | 1.0 | 1.0 | 3.0 | 25.0 | 40.0 | 60.0 |
| Total | 1.0 | 1.0 | 1.0 | 1.2 | 3.6 | 24.0 | 40.0 | 63.5 |

**Table 9. FB ellipticity stratified by child age (numbers are percentages).**

|  |  | *Complication* |  |
|---|---|---|---|
|  |  | *No* | *Yes* |
| Volume ($mm^3$) | 25% | 16,7 | 25,1 |
|  | Median | 37,7 | 37,7 |
|  | 75% | 98,9 | 78,5 |
| Ellipticity | 25% | 1,0 | 1,0 |
|  | Median | 1,0 | 1,5 |
|  | 75% | 3,5 | 2,3 |

**Table 10. FB volume and ellipticity in complicated and non complicated cases.**

|  | Complications (%) |  |
|---|---|---|
|  | No | Yes |
| Shape |  |  |
| 2D | 91.4 | 8.6 |
| 2D circle | 94.1 | 5.9 |
| 3D | 89.1 | 10.9 |
| Other | 91.3 | 8.7 |
| Spherical | 91.2 | 8.8 |
| Consistency |  |  |
| Conforming | 84.8 | 15.2 |
| Rigid | 93.4 | 6.6 |
| Semi-rigid | 87.9 | 12.1 |

**Table 11. Percentage of complication according to shape and consistency.**

| Foreign body type | Median volume ($mm^3$) | Median ellipticity (spherical shape=1) | Risk Estimate | 95% credibility interval |
|---|---|---|---|---|
| Non food | | | | |
| battery | 33.36 | 6 | 6.14E-05 | 1.58E-06; 6.18E-05 |
| coin | 314 | 10 | 0.00019 | 5.62E-06; 0.00022 |
| toy | 66.99 | 1 | 0.00016 | 5.55E-06; 0.00022 |
| pearl, ball and marble | 16.75 | 1 | 0.00037 | 1.07E-06; 0.00041 |
| paper, tinfoil and cellophane | 33.49 | 2 | 2.29E-06 | 1.43E-08;2.36E-05 |
| button | 67 | 5 | 3.60E-05 | 1.08E-06; 6.78E-05 |
| pin and needle | 9.03 | 4.5 | 2.25E-05 | 1.01E-06; 3.56E-05 |
| stationery (pen cap, pencil lead) | 6.28E+01 | 2 | 8.51E-05 | 2.23E-06; 8.71E-05 |
| pebble | 37.68 | 1 | 0.00013 | 3.75E-06; 0.00017 |
| Food | | | | |
| nut | 26.17 | 1 | 0.00012 | 8.03e-05; 0.00017 |
| bone | 5.88 | 16 | 4.63E-05 | 1e-06; 6.83e-05 |
| seed and grain | 36.63 | 2.5 | 7.02E-05 | 4.73e.05; 8.46e-05 |
| sweet | 32.97 | 1 | 7.12E-05 | 6.20e-05; 8.32e-05 |

**Table 12. Risk of injury.**

| Foreign body type | Median volume ($mm^3$) | Median ellipticity (spherical shape=1) | Risk Estimate | 95% credibility interval |
|---|---|---|---|---|
| No Food | | | | |
| battery | 33.36 | 6 | 6.14E-05 | 1.58E-06; 6.18E-05 |
| coin | 314 | 20 | 2.87E-05 | 2.15E-05; 3.52E-05 |
| toy | 69.86 | 1.66 | 2.93E-05 | 2.88E-05; 2.99E-05 |
| pearl, ball and marble | 9.42 | 1 | 0.00018 | 1.04E-05; 0.00023 |
| paper, tinfoil and cellophane | 25.12 | .1 | 5.07E-07 | 5.04E-07; 3.2E-06 |
| button | 50.24 | 4 | 1.26E-05 | 1.22E-05; 1.28E-05 |
| pin and needle | 20.02 | 5 | 1.56E-05 | 1.38E-05; 1.63E-05 |
| stationery (pen cap, pencil lead) | 28.78 | 2.33 | 2.53E-05 | 2.20E-05; 2.59E-05 |
| pebble | 28.78 | 1 | 1.72E-05 | 1.53E-05; 1.77E-05 |
| Food | | | | |
| nut | 27.17 | 1 | 2.32E-05 | 1.45e-05; 3.32e-05 |
| bone | 26.17 | 6.67 | 3.12E-05 | 4.20e-06; 3.87e-05 |
| seed and grain | 33.68 | 3.33 | 2.38E-05 | 1.1e-05; 3.35e-05 |
| sweet | 16.75 | 1 | 4.43E-06 | 4.25e-06; 4.57e.06 |

**Table 13. Risk of severe injury (injury which required at least one day of hospitalization).**

## Figures

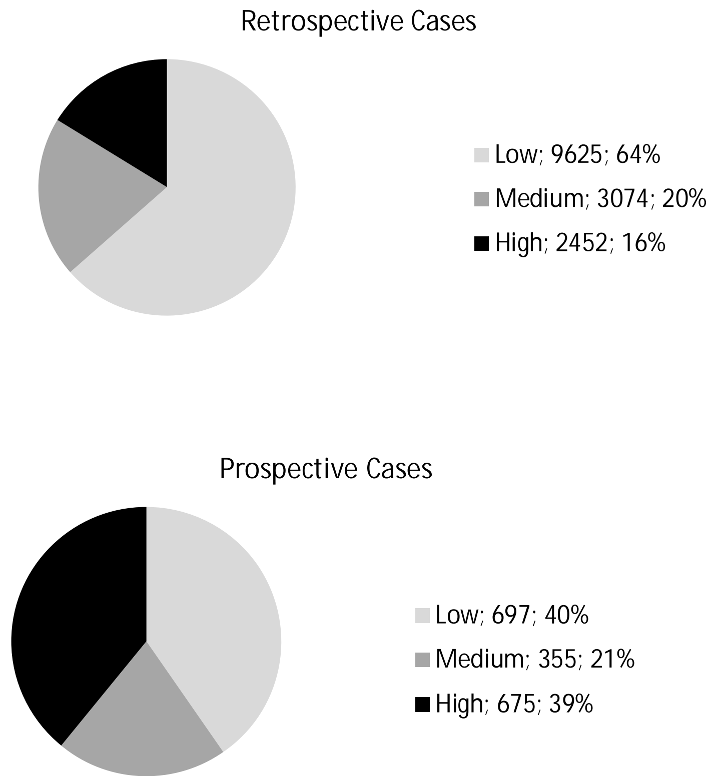


**Figure 1. Distribution of cases according to their quality.**

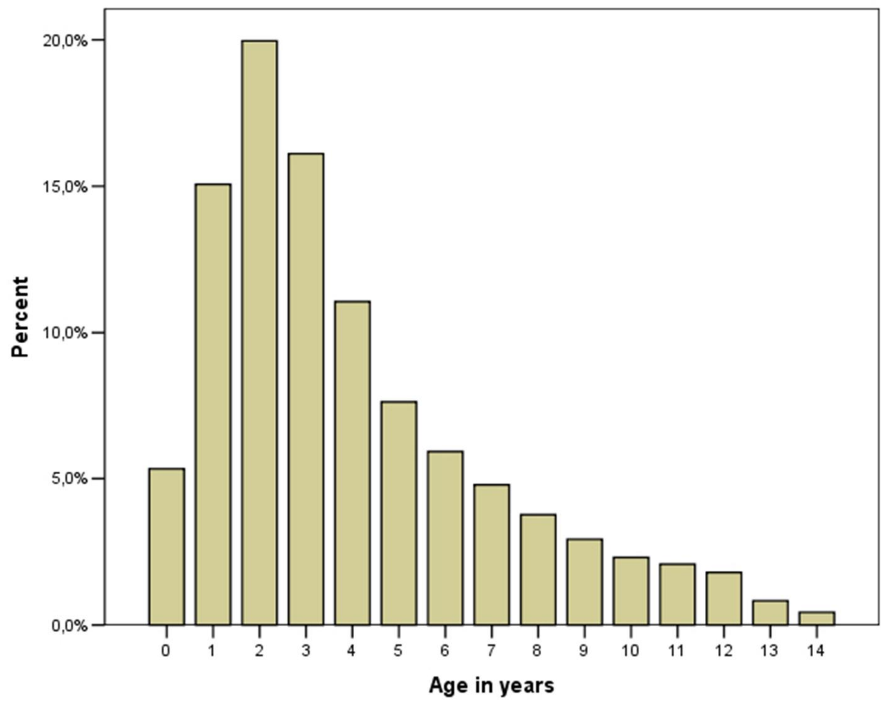


**Figure 2. Age distribution of foreign body injuries observed.**

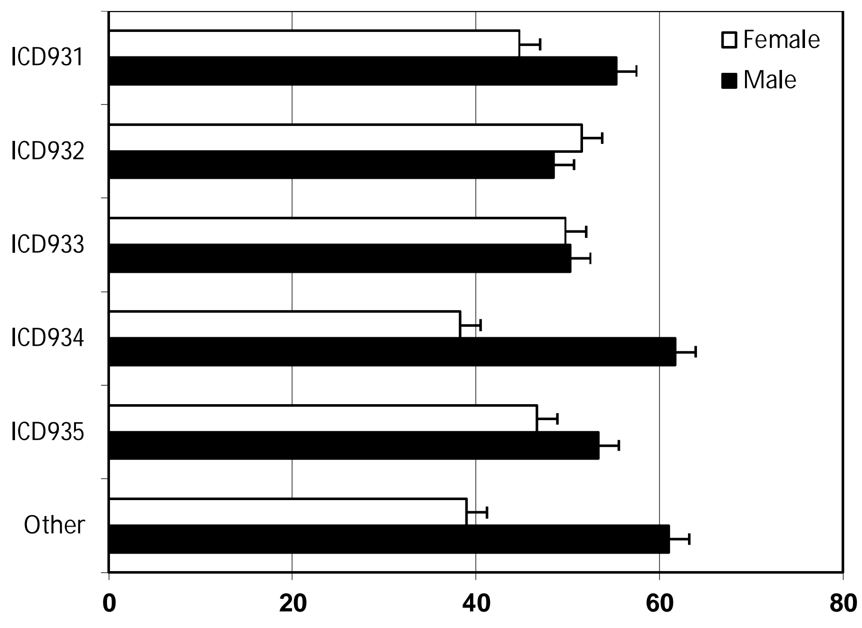


**Figure 3. Distribution of cases by injury location and by gender.**

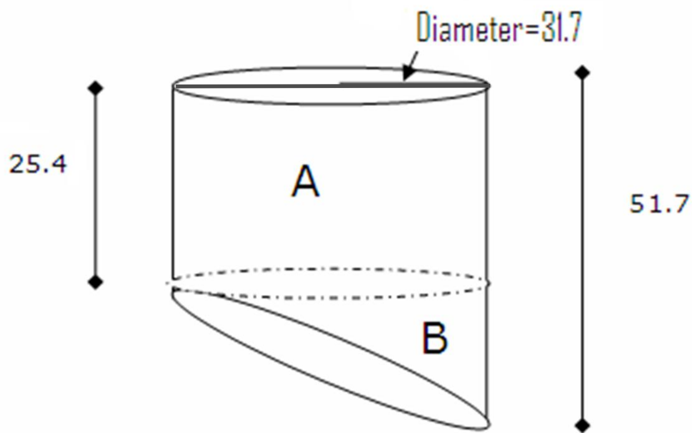


**Figure 4. Characteristics of the "small parts" cylinder (measures in mm).**

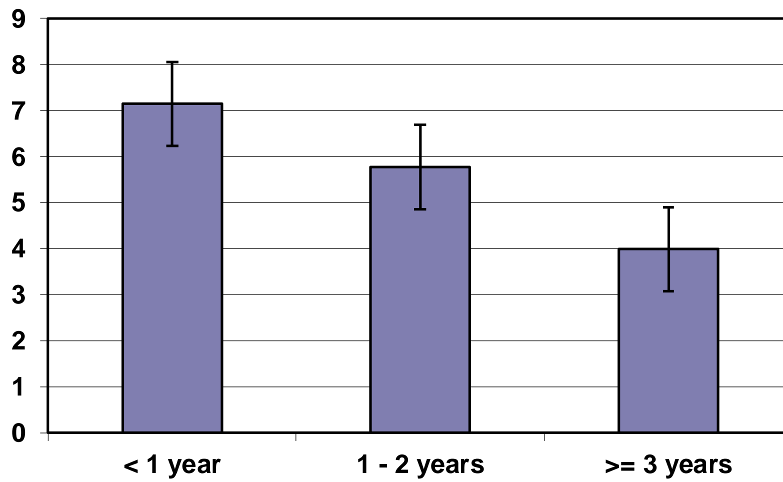


**Figure 5.** Distribution of complications (%) requiring hospitalization by age class.

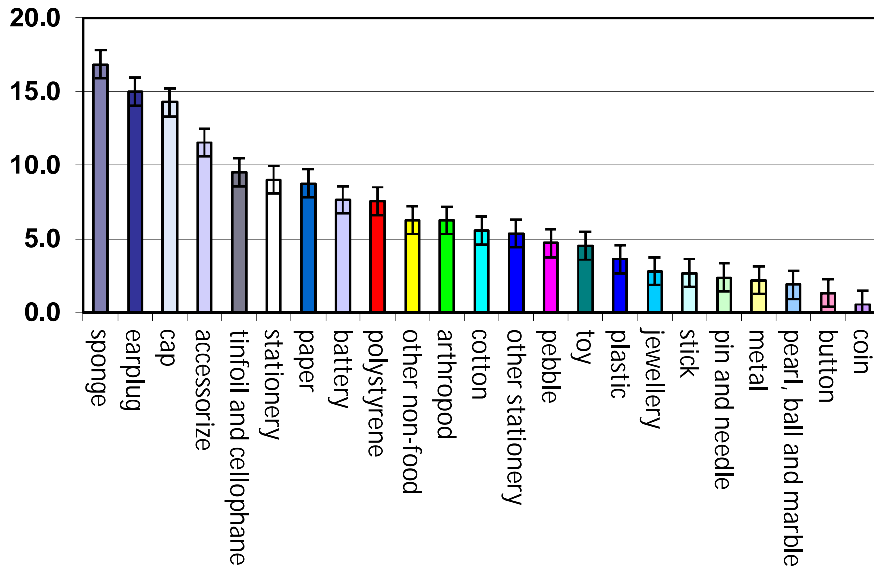


**Figure 6.** Distribution of incidence (%) of complications by FB type (only non-food).

**Title:Foreign Bodies in the Airways: a meta-analysis of published papers**

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**Abstract**

**Background**: Very recently, some attempts have been made to start a systematic collection of FB in view of using them to characterize the risk of chocking in terms of size, shape and consistency of the FB. However, most of the epidemiologic evidence on foreign bodies in children comes from single-center retrospective studies, without any systematic geographical and temporal coverage. This paper is aimed at providing an estimate of the distribution of foreign body's injuries in children according to gender, age, type of FB, site of obstruction, clinical presentation, diagnostic/therapeutic procedures, complications, as emerging from a meta-analytic review of published papers.

**Methods:** A free text search on PubMed database *((foreign bodies) OR (foreign body)) AND ((aspiration) OR (airways) OR (tracheobronchial) OR (nasal) OR (inhalation) OR (obstruction) OR (choking) OR (inhaled) OR (aspirations) OR (nose) OR (throat) OR (asphyxiation)) AND ((children) OR (child))* finalized to identify all English written articles referring to foreign body inhalation over a 30 yrs period (1978 -2008) was performed. The target of the analysis has been defined as the proportion of injuries as reported in the studies, stratified according to children demographic characteristics, type of FB, site of obstruction. The pooled proportions of FB were calculated using the DerSimonian and Laird approach.

**Results:** 1699 papers were retrieved and 1063 were judged pertinent; 214 English written case series were identified, among them 174 articles were available and have been included in the analysis. Airway foreign body most commonly occurs in young children, almost 20% of children who have inhaled foreign bodies being between 0 and 3 years of age. Organic FB, particularly nuts, are the most documented objects while, among inorganic FBs, the greatest pooled proportion has been recorded for magnets, which can be particularly destructive in each location. Non specific symptoms or a complete absence of symptoms are not unusual, justifying mistaken or delayed diagnosis. Acute and chronic complications seem to occur in almost 15% of patients.

**Conclusions:** Even if an enormous heterogeneity among primary studies seems to exist and even if the absence of variables standardized definitions across case series, including class age definition and symptoms and signs descriptions, seriously impairs

studies comparability, our results testify the relevant morbidity associated with foreign body inhalation in children, stressing the importance of preventive measures.

**Key words**: airways; foreign body; meta-analysis

## Introduction

The inhalation/aspiration of foreign bodies (FB) into the upper airways can be a very serious event, sometimes resulting in fatal outcomes, and frequently having considerable social and economic consequences. Therefore, in scientific literature great attention has been devoted to this issue and several papers reporting single case description or detailing features of a case series have been published. Also several narrative reviews discussed more clinical aspects of the FB injuries, like clinical diagnosis and management of the injured child [1]. Very recently, some attempts have been made to start a systematic collection of FB in view of using them to characterize the risk of chocking in terms of size, shape and consistency of the FB [2]. However, most of the epidemiologic evidence on foreign bodies in children comes from single-center retrospective studies, without any systematic geographical and temporal coverage [3-7].

Particularly, in spite of the wide interest proven by the high number of published papers on the argument, no attempts have been made to synthesize the epidemiological data as arising from the literature. This paper is an attempt aimed at filling this gap, providing an estimate of the distribution of foreign body's injuries in children according to gender, age, type of FB, site of obstruction, clinical presentation, diagnostic/therapeutic procedures, complications, as emerging from a meta-analytic review of published papers.

## Materials and methods

A free text search on PubMed database *((foreign bodies) OR (foreign body)) AND ((aspiration) OR (airways) OR (tracheobronchial) OR (nasal) OR (inhalation) OR (obstruction) OR (choking) OR (inhaled) OR (aspirations) OR (nose) OR (throat) OR (asphyxiation)) AND ((children) OR (child))* finalized to identify all articles referring to foreign body inhalation over a 30 yrs period (1978 -2008) was performed.

Papers' pertinence was independently evaluated by two reviewers starting from title and abstract. Papers referring to adult FB injuries, other sites of injury other than aerial tract and iatrogenic causes were excluded. Only case series were included in the analysis while case reports were excluded. Papers referring to the same series of data were

included only once in the meta-analysis. Only case series written in English were included.

For each record included in the analysis, information was extracted on country, period, children sex and age, FB type, site of obstruction, symptoms, signs, diagnostic and therapeutic procedures, delay at the diagnosis, complications, number of deaths.

The target of the analysis has been defined as the proportion of injuries as reported in the studies, stratified according to children demographic characteristics, injury dynamics, type of FB, site of obstruction. Moreover, also symptoms, signs, radiological findings, removal techniques, delayed or mistaken diagnosis, complications and death have been considered and pooled proportion computed.

The pooled proportions of FB was calculated using the DerSimonian and Laird approach [8, 9]. All studies with missing values or zero counts were excluded pair wise from the analysis. First, a $\chi 2$ test for homogeneity of proportions among the different studies was performed using the Cochran method 43. Thus, the pooled proportions of FB was estimated along with the corresponding 95% confidence intervals (CI), using again the DerSimonian-Laird random effects weighting scheme for the studies included in the analysis.

All analyses have been performed using the software R 44 [10] with the “rmeta” package [11].

## Results

According with the search strategy previously described, 1699 papers were retrieved and 1063 were judged pertinent; 214 English written case series were identified, among them 174 articles were available and have been included in the analysis. Considered references are shown in Table 1. On the whole, articles’ authors observed 30477 children suspected of having aspirated a foreign body. Pooled estimates of injury proportion are presented in tables 2-7 stratified for relevant variables including children and FB characteristics. For each strata, the number of articles reporting data about the considered characteristic, the number of cases having the considered characteristic and the total number of cases described in the articles are reported. Particularly, in Table 2 injuries pooled proportions are presented stratified by children age and sex, and by injury dynamics (including adult presence and activity before accident); moreover, details regarding FB

locations and FB types are presented respectively in Table 3 and 4. In Table 5 pooled proportions of symptoms and signs are shown while in Table 6 radiographic findings and adopted removal techniques are described. Finally, in Table 7 pooled proportions of diagnostic delay, mistaken diagnosis, complication and deaths are reported.

**Discussion**

Taking stock of what is known in any field involves reviewing the existing literature, summarizing it in appropriate ways, and exploring the implications of heterogeneity of population and study for heterogeneity of study results. Meta-analysis provides a systematic way of performing this research synthesis, while indicating when more research is necessary. Usually, meta-analytic studies resume randomized controlled trials results, which are considered to provide the strongest evidence regarding an intervention. However, in many situations, including studies of risk factors, only data from observational studies are available and, even if the extreme diversity of study designs and populations in epidemiology could make the interpretation of simple summaries problematic, meta-analyses of observational studies continue to be one of the few methods for answering urgent questions in clinical and public health research.
Particularly, despite aspiration and inhalation of FBs are common events in paediatrics accounting for a not negligible proportion of accidental deaths in children under 4 years of age, this issue is still poorly understood and existing knowledge not yet systematically reviewed and synthesized.

Our study, in which 1063 were judged pertinent and only 174 English written case series were identified and included in the analysis, testifies that the great amount of papers about this topic are case reports typically consisting of complaints, examination findings, diagnosis, treatment and outcome; however, no hypothesis, data analysis or generalizable conclusion is possible on this base. On the other hand, the absence of variables standardized definitions across case series, including class age definition and symptoms and signs descriptions, seriously impairs studies comparability. Moreover an enormous heterogeneity among primary studies seems to exist. Despite these limitations, results obtained in the present study stress some key messages.

First of all, airway foreign body most commonly occurs in young children, almost 20% of children who have inhaled foreign bodies being between 0 and 3 years of age. Great attention is paid in scientific literature on objects causing the injury: organic FB, particularly nuts, are the most documented objects while, among inorganic FBs, the greatest pooled proportion has been recorded for magnets, which can be particularly destructive in each location. Moreover, injuries are frequently due to an incorrect manipulation of objects not conceived for children use, including pins, nails, screws, floats.

The clinical presentation of foreign body aspiration ranges from none to severe airway obstruction; cough, chocking, dyspnea, reduced / abnormal breath sounds and respiratory movements decreased appear as the most documented symptoms and signs; however, non specific symptoms or a complete absence of symptoms are not unusual, therefore, clinicians may fail to consider the diagnosis of an inhaled foreign body if child shows no symptoms at presentation, especially when also chest radiograph findings are normal. Even if chest radiograph findings compatible with an inhaled foreign body include air trapping, atelectasis, and pneumothorax, none of these findings are pathognomonic for foreign body inhalation and in our study almost half of cases had normal radiography, while definitive diagnosis is usually performed by endoscopic evaluation.

Diagnosis of an inhaled foreign body was delayed by more than 24 hours in almost 40% of cases. As frequently reported in scientific literature, delayed diagnosis of an inhaled foreign body can result in serious acute and chronic complications which seem to occur in almost 15% of patients. Particularly, pneumonia and bronchopneumonia seem to be the most frequently documented in analyzed case series.
Interestingly, while data regarding FB type are almost always reported, only a relatively small proportion of articles presents details regarding clinical presentation, diagnostic procedures and complications revealing poor attention toward the follow up of patients after FB extraction and thus toward long terms outcomes.
Finally, only 5 article reported data regarding adult presence during injury occurrence; this fact reveals the insufficient attention paid to preventive issues by both clinicians

and parents while, on the contrary, given the considerable mortality and morbidity associated with foreign body inhalation in children, the importance of preventive measures needs to be emphasized to parents and caregivers.

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**Table 1 References considered in the meta-analysis**

| | *Number of Articles* | *Cases* | *Total Number of cases (N)* | *Pooled-Proportion* | *CI-lb* | *CI-ub* | *p-value* |
|---|---|---|---|---|---|---|---|
| *Demographic characteristics* | | | | | | | |
| Males | 123 | 13196 | 23808 | 0.609 | 0.577 | 0.641 | <0.001 |
| Females | 126 | 10692 | 25792 | 0.383 | 0.370 | 0.395 | <0.001 |
| Age 0-3 | 22 | 3240 | 4593 | 0.673 | 0.648 | 0.698 | <0.001 |
| Age > 3 | 30 | 2694 | 9495 | 0.254 | 0.216 | 0.292 | <0.001 |
| *Injury dynamics* | | | | | | | |
| Adult Present | 5 | 542 | 1044 | 0.563 | 0.279 | 0.846 | <0.001 |
| Child Activity when injury occurred: Playing | 2 | 19 | 45 | 0.304 | 0.116 | 0.492 | 1.000 |
| Child Activity when injury occurred: Eating | 2 | 19 | 45 | 0.422 | 0.099 | 0.745 | 0.018 |

**Table 2 Injuries pooled proportions are presented stratified by demographic characteristics and injury dynamics. CI-lb: lower confidence interval bounds. CI-ub: upper confidence interval bounds. P values less than 0.05 indicate significant heterogeneity.**

| | *Number of Articles* | *Cases* | *Total Number (N)* | *Pooled-Proportion* | *CI-lb* | *CI-ub* |
|---|---|---|---|---|---|---|
| Nose | 21 | 1475 | 1918 | 0.835 | 0.810 | 0.859 |
| Larynx | 49 | 559 | 6872 | 0.213 | 0.197 | 0.228 |
| Trachea | 97 | 2458 | 16923 | 0.157 | 0.147 | 0.168 |
| Bronchus | 113 | 18366 | 21164 | 0.882 | 0.871 | 0.893 |
| Lung | 14 | 407 | 3960 | 0.271 | 0.252 | 0.289 |
| Right side | 99 | 9788 | 0 | 0.629 | 0.613 | 0.646 |
| Left side | 96 | 7582 | 0 | 0.425 | 0.408 | 0.441 |

**Table 3 Injuries pooled proportions are presented stratified by FB locations. CI-lb: lower confidence interval bounds. CI-ub: upper confidence interval bounds**

|  | *Number of Articles* | *Cases* | *Total Number (N)* | *Pooled-Proportion* | *CI-lb* | *CI-ub* |
|---|---|---|---|---|---|---|
| *Organic FB* |  |  |  |  |  |  |
| Nuts | 96 | 6504 | 18536 | 0.395 | 0.340 | 0.450 |
| Organic unspecified | 55 | 5553 | 13857 | 0.338 | 0.262 | 0.413 |
| Seeds | 64 | 3678 | 14227 | 0.256 | 0.210 | 0.301 |
| Unspecified food | 24 | 421 | 3871 | 0.211 | 0.167 | 0.254 |
| Weed /Wood | 14 | 124 | 2633 | 0.136 | 0.093 | 0.180 |
| Legumes | 42 | 1406 | 11058 | 0.107 | 0.084 | 0.131 |
| Other food | 21 | 266 | 2967 | 0.096 | 0.069 | 0.123 |
| Grape | 2 | 2 | 21 | 0.091 | -0.032 | 0.213 |
| Maize | 14 | 119 | 2216 | 0.050 | 0.030 | 0.070 |
| Bones | 35 | 393 | 7417 | 0.049 | 0.037 | 0.060 |
| Meat | 10 | 112 | 1870 | 0.040 | 0.019 | 0.061 |
| Coffee grain | 5 | 58 | 1210 | 0.034 | 0.005 | 0.063 |
| Carrots | 14 | 153 | 4284 | 0.034 | 0.021 | 0.047 |
| Popcorn | 16 | 122 | 2926 | 0.032 | 0.018 | 0.046 |
| Chicken | 3 | 50 | 1580 | 0.024 | 0.008 | 0.040 |
| Candy | 6 | 59 | 2713 | 0.021 | 0.007 | 0.036 |
| Apples | 12 | 88 | 3920 | 0.020 | 0.013 | 0.027 |
| Hotdog | 6 | 72 | 2710 | 0.019 | -0.001 | 0.039 |
| Organic Overall | 172 | 19113 | 29881 | 0.558 | 0.549 | 0.567 |
| *Inorganic FB* |  |  |  |  |  |  |
| Magnet | 3 | 13 | 90 | 0.341 | -0.173 | 0.854 |
| Sponge | 5 | 42 | 264 | 0.146 | 0.044 | 0.249 |
| Inorganic unspecified | 69 | 2386 | 14529 | 0.131 | 0.122 | 0.140 |
| Other inorganic | 36 | 751 | 6698 | 0.117 | 0.100 | 0.134 |
| Foam | 8 | 99 | 931 | 0.092 | 0.042 | 0.142 |
| Battery | 9 | 35 | 692 | 0.090 | 0.041 | 0.140 |
| Toys | 24 | 198 | 3031 | 0.081 | 0.059 | 0.103 |
| Pen top | 27 | 169 | 3569 | 0.080 | 0.051 | 0.110 |
| Plastic pieces | 54 | 629 | 8352 | 0.078 | 0.065 | 0.092 |
| Pin nail tack screw | 64 | 781 | 11369 | 0.076 | 0.064 | 0.087 |
| Paper | 16 | 92 | 1498 | 0.061 | 0.038 | 0.083 |
| Whistle | 6 | 31 | 509 | 0.057 | 0.018 | 0.097 |
| Button bead | 19 | 264 | 3708 | 0.054 | 0.033 | 0.075 |
| Coin | 6 | 69 | 1560 | 0.050 | 0.021 | 0.080 |
| Balls/balloon | 21 | 87 | 2306 | 0.044 | 0.027 | 0.061 |
| Cotton | 4 | 18 | 497 | 0.029 | 0.008 | 0.051 |
| Stones/shell | 41 | 158 | 5210 | 0.027 | 0.020 | 0.035 |
| Jewellery | 12 | 31 | 1798 | 0.017 | 0.006 | 0.028 |
| Pen / pencil | 14 | 41 | 2933 | 0.011 | 0.006 | 0.015 |
| Inorganic Overall | 172 | 5808 | 29881 | 0.197 | 0.188 | 0.205 |

**Table 4 Injuries pooled proportions are presented stratified by types of FB. CI-lb: lower confidence interval bounds. CI-ub: upper confidence interval bounds.**

| | *Number of Articles* | *Cases* | *Total Number (N)* | *Pooled-Proportion* | *CI-lb* | *CI-ub* |
|---|---|---|---|---|---|---|
| *Symptoms* | | | | | | |
| Cough | 82 | 12605 | 16782 | 0.612 | 0.601 | 0.623 |
| Choking | 45 | 5947 | 11680 | 0.468 | 0.353 | 0.583 |
| Dyspnea | 47 | 4507 | 9021 | 0.346 | 0.258 | 0.433 |
| Throat pain | 3 | 111 | 256 | 0.290 | -0.035 | 0.614 |
| Fever | 53 | 1970 | 12018 | 0.187 | 0.163 | 0.211 |
| Toracic pain | 9 | 43 | 661 | 0.140 | 0.121 | 0.160 |
| Aspecific Symptoms | 11 | 147 | 1178 | 0.098 | 0.061 | 0.135 |
| No symptoms | 11 | 109 | 1327 | 0.079 | 0.046 | 0.111 |
| Vomiting | 11 | 96 | 1013 | 0.074 | 0.047 | 0.100 |
| Voice hoarsenes | 10 | 73 | 1178 | 0.048 | 0.024 | 0.073 |
| Blood stained mucus | 10 | 59 | 1875 | 0.021 | 0.010 | 0.031 |
| Unconsciouness | 3 | 15 | 1625 | 0.008 | 0.000 | 0.016 |
| *Signs* | | | | | | |
| Respiratory movements decreased | 2 | 33 | 56 | 0.659 | 0.569 | 0.750 |
| Decreased air entry | 25 | 2672 | 4011 | 0.633 | 0.611 | 0.655 |
| Decreased sounds | 26 | 4262 | 8343 | 0.504 | 0.361 | 0.648 |
| Abnormal breath sounds | 78 | 5312 | 10744 | 0.503 | 0.492 | 0.514 |
| Tachypnea | 15 | 2340 | 6723 | 0.476 | 0.451 | 0.501 |
| Asimmetric auscultation | 3 | 224 | 371 | 0.454 | 0.081 | 0.826 |
| Acute Respiratory distress | 10 | 986 | 3097 | 0.387 | 0.281 | 0.493 |
| Nasal Flaring | 5 | 94 | 395 | 0.340 | 0.189 | 0.491 |
| Abnormal breath sounds wheezing | 67 | 3152 | 7565 | 0.334 | 0.283 | 0.386 |
| Nose pain | 3 | 82 | 374 | 0.269 | 0.047 | 0.491 |
| Abnormal breath sounds rhonchi | 19 | 618 | 3271 | 0.204 | 0.151 | 0.257 |
| Accessory muscles use | 11 | 411 | 4193 | 0.196 | 0.147 | 0.244 |
| Purulental discharge | 8 | 232 | 1257 | 0.189 | 0.110 | 0.268 |
| Abnormal breath sounds rales | 9 | 412 | 2536 | 0.183 | 0.120 | 0.246 |
| Abnormal breath sounds stridor | 44 | 991 | 7147 | 0.177 | 0.149 | 0.205 |
| Odor | 4 | 52 | 312 | 0.150 | 0.056 | 0.243 |
| Cyanosis | 41 | 1258 | 9487 | 0.131 | 0.108 | 0.155 |
| Abnormal breath sounds crackles | 8 | 139 | 743 | 0.126 | 0.071 | 0.182 |
| Nose bleeding | 11 | 33 | 854 | 0.023 | 0.009 | 0.037 |
| Subcutaneous emphysema | 2 | 5 | 350 | 0.013 | 0.002 | 0.024 |

**Table 5: Pooled proportions of symptoms and signs. CI-lb: lower confidence interval bounds. CI-ub: upper confidence interval bounds.**

| | *Number of Articles* | *Cases* | *Total Number (N)* | *Pooled-Proportion* | *CI-lb* | *CI-ub* |
|---|---|---|---|---|---|---|
| *Radiographic* findings | | | | | | |
| Normal Xray | 75 | 5870 | 16514 | 0.474 | 0.460 | 0.487 |
| Rayradiopaque.FB | 74 | 2525 | 16155 | 0.246 | 0.234 | 0.259 |
| Emphysema | 76 | 5398 | 14808 | 0.447 | 0.434 | 0.460 |
| Atelectasis | 63 | 2601 | 15988 | 0.193 | 0.171 | 0.214 |
| Pneumonia | 59 | 1635 | 13044 | 0.178 | 0.153 | 0.203 |
| Pneumothorax / Pneumomediastinum | 33 | 415 | 5425 | 0.078 | 0.064 | 0.093 |
| Pleural effusion | 7 | 166 | 2087 | 0.035 | 0.002 | 0.069 |
| Number of performed X ray | 98 | 18236 | 18446 | 0.990 | 0.984 | 0.995 |
| *Removal techniques* | | | | | | |
| Bronchoscopy / laryngoscopy | 111 | 19125 | 19677 | 0.990 | 0.984 | 0.995 |
| Forceps | 13 | 600 | 1220 | 0.474 | 0.460 | 0.487 |
| Positive pressure technique | 3 | 25 | 192 | 0.246 | 0.234 | 0.259 |
| Surgery /thoracotomy /bronchotomy | 47 | 479 | 15153 | 0.447 | 0.434 | 0.460 |

**Table 6: Pooled proportions of radiographic findings and chosen removal techniques. CI-lb: lower confidence interval bounds. CI-ub: upper confidence interval bounds.**

| | *Number of Articles* | *Cases* | *Total Number (N)* | *Pooled-Proportion* | *CI-lb* | *CI-ub* |
|---|---|---|---|---|---|---|
| *Complications* | | | | | | |
| Other infection | 7 | 152 | 1443 | 0.162 | 0.031 | 0.293 |
| Pneumonia Broncopneumonia | 25 | 397 | 3605 | 0.106 | 0.084 | 0.127 |
| Bronchiectasis | 13 | 83 | 3742 | 0.096 | 0.053 | 0.140 |
| Actelectasis | 10 | 99 | 2601 | 0.028 | 0.014 | 0.042 |
| Larynx edema | 15 | 229 | 7874 | 0.025 | 0.016 | 0.033 |
| Respiratory arrest | 15 | 93 | 2886 | 0.024 | 0.013 | 0.035 |
| Cardiopulmunary arrest | 19 | 434 | 9683 | 0.020 | 0.011 | 0.030 |
| Tracheal laceration | 7 | 82 | 6156 | 0.006 | -0.001 | 0.013 |
| Lung abscess empyema | 6 | 14 | 1037 | 0.005 | -0.003 | 0.012 |
| Pneumothorax / pneumomediastinum | 23 | 56 | 7002 | 0.004 | 0.002 | 0.006 |
| Pulmonary edema | 6 | 8 | 476 | 0.003 | 0.000 | 0.007 |
| Complications Overall | 54 | 1482 | 13684 | 0.157 | 0.131 | 0.184 |
| *Mistaken diagnosis* | | | | | | |
| Asthma | 5 | 54 | 1205 | 0.231 | 0.183 | 0.279 |
| Infections | 6 | 221 | 1273 | 0.307 | 0.257 | 0.356 |
| *Delay in diagnosis* | | | | | | |
| Up to 24 hours | 49 | 3427 | 7625 | 0.470 | 0.452 | 0.488 |
| Greater than 24 hours | 51 | 8027 | 11118 | 0.601 | 0.585 | 0.617 |
| | | | | | | |
| Deaths | 127 | 718 | 31305 | 0.062 | 0.056 | 0.068 |

**Table 7 Pooled proportions of diagnostic delay, mistaken diagnosis, complication and deaths. CI-lb: lower confidence interval bounds. CI-ub: upper confidence interval**

**Title:Food Foreign Body injuries**

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**Abstract**

**Rationale and aim:** The purpose of this study is to acquire a better understanding of Food Foreign Bodies (FFB) injuries in children characterizing the risk of complications and prolonged hospitalization due to food items according to patients' characteristics, circumstances of the accident, FB features and FB location, as emerging from the SUSY Safe Web-Registry.

**Methods:** The present study uses data provided by the SUSY Safe Project, a DG SANCO co-funded project started in February 2005, which was aimed at establishing an international registry of cases of Foreign Bodies (FB) injuries in children aged 0-14 years. The analysis was carried out on injuries due to a food item.

FB location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935).

Age and gender injury distributions were assessed. Data regarding adult supervision and activity before injury were also evaluated. FBs which most frequently cause complications were identified. The association between children age, adult presence, object characteristics and hospitalization/complications was computed using unweighted odds ratios and the related 95% confidence intervals.

**Results:** 16878 FB injuries occurred in children aged 0-14 yrs have been recorded in the SUSY Safe databases. FB type was specified in 10564 cases; among them 2744 (26%) were due to a food item. FB site is known in 1344 cases: FB was located in the ears in 99 patients, while 1140 occurred in the upper and lower respiratory tract; finally, 105 food items have been removed from mouth, esophagus and stomach. Complications occurred in 176 cases and the most documented was pulmonary or bronchial infections (23%) followed emphysema or atelectasis and by and asthma (7%). Bones were the commonest retrieved FFB encountered in this study, while nuts seem to be the FFB most frequently associated to complications.

**Conclusions**: On the basis of this study we make the strong recommendation that parents should be adequately educated and provide age-appropriate food to their children and be present in order to supervise them during eating especially during a critical period ranging from 2 to 3 years of age.

**Keywords:** Foreign body, food, nuts, bones

## Introduction

Foreign body injuries are very common in children being still an important cause of childhood morbidity and mortality, in fact, through play, experimentation and daily activities, children are likely to place foreign bodies into their ears, nose or mouth (1). While the placement or presence of foreign bodies in the ear canal and their subsequent removal can be a source of significant morbidity but rarely constitutes a life-threatening event (2), the inhalation/aspiration of foreign bodies (FB) into the upper airways can be a very serious event, sometimes resulting in fatal outcome (3).

Even if the spectrum of foreign bodies varies from country to country, depending on the diet and customs of the population, the most common FB causing injuries are small food items(4). Particularly, case reports, cases series and data coming from death certificates testify that nuts and seeds could represents a serious threat being not only the most documented foreign body, but also frequently involved in cases presenting complications and requiring hospitalization (5).

The purpose of this study is to acquire a better understanding of Food Foreign Bodies (FFB) injuries in children characterizing the risk of complications and prolonged hospitalization due to food items according to patients' characteristics, circumstances of the accident, FB features and FB location, as emerging from the SUSY Safe Web-Registry.

## Methods

### Data collection

The present study uses data provided by the SUSY Safe Project, a DG SANCO co-funded project started in February 2005, which was aimed at establishing an international registry of cases of Foreign Bodies (FB) injuries in children aged 0-14 years. At the present, the project is collecting data among 60 institutions, located in 26 countries. Details on injuries are entered in the SUSY Safe Web-Registry (6) through a standardized case report form, that includes information regarding: children age and gender, features of the object, circumstances of injury (presence of parents, activity) and hospitalization's details (lasting, complications and removal details). Cases are prospectively collected using the Susy Safe system from 06/2005; moreover, also information regarding past consecutive cases available in each centre adhering to the project have been entered in the Susy Safe Registry.

Statistical analysis

The analysis was carried out on injuries due to a food item.

FB location was reported according to ICD9-CM code (7): ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935).

Age and gender injury distributions were assessed. Data regarding adult supervision and activity before injury were also evaluated.

According to the Rimell's classification (4), FB were characterized by size, shape and consistency. Descriptive statistics (absolute and relative number or median, I and III quartile according to the categorical or continuous variable, respectively) were calculated for each considered food item characteristics; FB features distribution by children class age and site of obstruction were assessed.

Adopted removal techniques were described according to FB location.

Two different outcomes were considered: hospitalization and complication. Hospitalization has been defined whether the child was admitted in the hospital for at least 1 day. Complications include all the pathological conditions due to delayed diagnosis or to the attempts of removing the FB.

FBs which most frequently cause complications were identified. The association between children age, adult presence, object characteristics and outcomes was computed using unweighted odds ratios and the related 95% confidence intervals.

Analyses were performed using Design and Hmisc libraries from R version 2.8 (8).

## Results

16878 FB injuries occurred in children aged 0-14 yrs have been recorded in the SUSY SAFE databases. FB type was specified in 10564 cases; among them 2744 (26%) were due to a food item. Details regarding retrieved FBs are given in Table 1.

FB site is known in 1344 cases: FB was located in the ears in 99 patients, while 1140 occurred in the upper and lower respiratory tract; finally, 105 food items have been removed from mouth, esophagus and stomach. In Table 2 the total amount of food related injuries, the number of complicated injuries and the number of injuries in which hospitalization is needed are reported for each site.

Data regarding age was available in 1362 FFB cases. Distribution of incidence of analyzed injuries by age class is shown in Figure 1. More than half of observed injuries involved patients 1-2 years old. 58% of patients were males, while 42% were females. When injury happened, 85% of children were eating while 12% were playing. Almost 40% (1090) of injuries happened under adults' supervision.

FB characteristics by age and by location are described respectively in Table 3 and Table 4.

When FB are located in pharynx and larynx, or in trachea, bronchi and lungs, or in mouth, esophagus and stomach the most documented removal technique is endoscopy (accounting respectively for the 93%, 96% and 78% of cases) while in a large amount of cases (70%) other unspecified techniques were adopted in order to remove FB located in ears or nose. Surgery was needed in the extraction of 5% of FB in the ears and 1% of nasal FB.

Looking to the outcomes, 847 (31%) children needed hospitalization; among them, 349 (45%) were discharged after 24 hours whereas 169 (22%) required hospitalization more than 3 days.

Complications occurred in 176 cases and the most documented was pulmonary or bronchial infections (23%) followed emphysema or atelectasis and by and asthma (7%). Food items which most frequently cause complications are listed in Table 5.

In order to verify the association among children age, adult supervision, object characteristics and outcomes, odds ratios of complications and hospitalization, with 95% confidence intervals, are presented in Table 6.

**Discussion**

In scientific literature food particles are described as the items most frequently involved in FB injuries, being indicated in a number of case series as responsible of the major part of events (4).

Starting from data collected by the Susy Safe Register, it appears that food particles are responsible of not more than 26% of injuries due to insertion/ aspiration/ inhalation/ ingestion of FBs. However, this result can be easily explained by the fact that the Susy Safe Project was originally designed in order to establishing a surveillance registry of non-food FB injures, while only recently information regarding FFB have been collected included in the registry.

Children are prone to aspirate/inhale FBs for several reasons including behavioural and anatomic aspects such as the tendency to explore their surrounding using the mouths and to talk and run around while chewing, anatomical characteristics (the incomplete dentition with presence of incisors to tear foods but lack of cuspids necessary to grind food into a smooth bolus) and physiological features including immature swallowing coordination, poor chewing capacity and higher respiratory rates compared with adults: once an object or food particle is in a child's mouth, it can lodge within the respiratory tract, be ingested in the gastro-intestinal tract or end up in the nasopharynx (9).

According to the European experience, tracheobronchial foreign bodies seem to cause complication more frequently than FB located in any other site. The FB location in tracheobronchial tree has in fact a range of possible outcomes, including recurrent pulmonary diseases, confirming the occurrence of aspiration is important in patient management in order to take steps to prevent recurrence (10) (11).

In children ingesting a large foreign body it is often impacted in the upper oesophagus at the level of cricoid cartilage, which is the narrowest part of the oesophagus. The most common area of impaction however is the midesophagus where the esophagus is crossed by the aortic arch and left main bronchus (12). Food bolus impaction is common with meat, fish bones and chicken bone (13). If this type of food particle is impacted in the oesophagus, the symptoms may range from foreign body sensation, chest pain, odynophagia, and vomiting as well as respiratory symptoms. A food bolus impaction should not be allowed to remain in the oesophagus beyond 24 hours from presentation (13). Endoscopic retrieval is mandatory. If the food bolus passes the stomach, the potential impediment sites include the pylorus, the ileocecal valve and the anus. The risk of perforation is however less than one percent (14).

Finally, small children also have a tendency to put things into the nose and ear. They are typically brought by their parents to emergency units after the parents noticed the presence of foreign body in these body orifices. Some may not be noticed until persistence symptoms present. Nasal and middle ear canal obstruction by a foreign body can cause severe irritation in the children. Obstruction of the nasal passage may lead to rhinosinusitis which may be recurrent and is often manifest by a purulent nasal discharge. Unilateral symptoms and signs in a child suggest an object impacted in the nasal fossa usually introduced through the ipsilateral nostril (15). Unnoticed foreign body in the ear canal can also lead to chronic otitis media (2).

In our experiences bones were the commonest retrieved FFB encountered in this study, while nuts seem to be the FFB most frequently associated to complications. Particularly fish bones are dangerous because they possess the potential hazard of perforating the bowel, mandating surgical exploration (16). On the other hand, when located in the respiratory airways, nuts represent a serious threat: in fact, swelling with time and irritating the bronchial mucosa, they lead to an intense, local, chemical inflammatory reaction, early obstruct the tracheobronchial tree and make bronchoscopic identification and removal more difficult (5).

Traditionally, injuries have been regarded as unavoidable accidents and only recently have they been recognised as being eligible for preventive efforts. In order to prevent injuries, supervision of children is very important in all aspects of their lives, even during eating. Particularly, children should eat appropriate types of food according to their age. As reported by Burney Yeo in British Medical Journal in 1889 (17) , food other than milk may be introduced into the infant's dietary, but in a wisely manner. Farinaceous food should never be given before the fourth month, and it is better not to provide these feeds until after the seventh or eighth month, when the teeth and salivary glands have begin to develop. Between the tenth and twelfth months, breast feeding may be gradually suspended but milk should still form the staple feed up to the age of eighteen months. At this age a little meat may be wisely introduced in the solid form, to furnish some employment to the masticating organs (17).

Parents need to be informed about children physiological and anatomic features and about their nutritional requirements; moreover, parents need to be educated to provide appropriate food to children in order to avoid injury; therefore, since education plays a key role in injury prevention, counselling about safe behaviors should be included in all visits to pediatricians in order to make parents conscious of risk associated to eating some foods and able to select a safe environment to their children.

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## Tables

| FB description | N | Percentage |
|---|---|---|
| bone | 885 | 32% |
| nut | 613 | 22% |
| other food | 563 | 21% |
| seed and grain | 430 | 16% |
| bean and pea | 142 | 5% |
| sweet | 91 | 3% |
| fruit stone | 20 | 1% |
| total | 2744 | |

**Table 1.** Description of the FB which caused the incident.

| Location | Food related injuries | Complications | | Hospitalization | |
|---|---|---|---|---|---|
| | | Yes | No | Yes | No |
| Ear | 7% (99) | 8% (10) | 5% (56) | 1% ( 6) | 15% (59) |
| Nose | 19% (253) | 14% (17) | 16% (169) | 1% (11) | 45% (175) |
| Pharynx and larynx | 16% (220) | 10% (12) | 16% (165) | 6% ( 42) | 34% (133) |
| Trachea, bronchi and lungs | 50% (667) | 62% (74) | 57% (583) | 85% (636) | 2% (8) |
| Mouth, esophagus and stomach | 8% (105) | 6% (7) | 5% (54) | 7% (53) | 3% (13) |
| Total | 1344 | 124 | 1032 | 756 | 391 |

**Table 2.** FB location according to ICD9-CM code: ear (ICD931); nose (ICD932); pharynx and larynx (ICD933); trachea, bronchi and lungs (ICD934); mouth, esophagus and stomach (ICD935). Data are reported as percentages (absolute numbers). Total amount of injuries, complicated injuries and injuries requiring hospitalization are reported.

| Foreign body characteristics | N | Age class | | |
|---|---|---|---|---|
| | | < 1 year (N=99) | 1-2 years (N=693) | > = 3 years (N=570) |
| Volume ($mm^3$) | 1362 | 1 11 | 1 1 1 | 1 1 30 |
| Shape | 994 | | | |
| Spherical | | 33% (28) | 37% (202) | 37% (135) |
| 3D | | 27% (23) | 30% (165) | 27% (96) |
| 2D | | 7% (6) | 5% (30) | 6% (23) |
| 2Dcircle | | 2% (2) | 1% (7) | 3% (12) |
| other | | 31% (26) | 26% (143) | 27% (96) |
| Ellipticity* | 368 | 1.0001.3306.500 | 1.0001.6703.330 | 1.0001.6705.375 |
| Consistency | 1095 | | | |
| Conforming | | 15% (13) | 9% (51) | 14% (61) |
| Semi-rigid | | 24% (21) | 32% (185) | 43% (183) |
| Rigid | | 30% (26) | 39% (227) | 33% (140) |
| Do not know | | 32% (28) | 21% (120) | 9% (40) |

**Table3.** Food items characteristics by age. Data are first quartile/ median/ third quartile for continuous variables and percentages (absolute numbers) for categorical variables. N is the number of valid cases for each given variable.

* ratio between the maximum and the minimum size reported.

| Foreign body characteristics | N | Foreign body location | | | | |
|---|---|---|---|---|---|---|
| | | Ear (N=218) | Nose (N=625) | Pharynx and larynx (N=855) | Trachea, bronchi and lungs (N=906) | Mouth, esophagus and stomach (N=120) |
| Volume | 2744 | 1 1 1 | 1 1 1 | 1 1 1 | 1 1 1 | 1 1 1 |
| Shape : | 1475 | | | | | |
| Spherical | | 59% ( 39) | 52% (103) | 3% ( 16) | 36% (215) | 24% ( 15) |
| 3D | | 20% ( 13) | 30% ( 60) | 50% (269) | 30% (180) | 46% ( 29) |
| 2D | | 6% ( 4) | 2% ( 4) | 36% (193) | 6% ( 34) | 8% ( 5) |
| 2D circle | | 3% ( 2) | 6% ( 11) | 0% ( 1) | 1% ( 5) | 5% ( 3) |
| other | | 12% ( 8) | 11% ( 22) | 12% ( 64) | 27% (160) | 17% ( 11) |
| Ellipticity* | 384 | 1.00 1.00 1.33 | 1.00 1.00 2.00 | 2.00 14.25 30.00 | 1.00 1.67 4.00 | 1.21 3.43 8.25 |
| Consistency | 2283 | | | | | |
| Conforming | | 40% ( 72) | 45% (250) | 25% (197) | 4% ( 31) | 16% ( 12) |
| Rigid | | 42% ( 76) | 37% (201) | 46% (355) | 41% (283) | 42% ( 31) |
| Semirigid | | 15% ( 28) | 14% ( 78) | 11% ( 84) | 27% (190) | 31% ( 23) |
| Do not know | | 3% ( 5) | 4% ( 21) | 18% (138) | 27% (188) | 11% ( 8) |

**Table 4.** Food items characteristics by FB location. Data are first quartile/median/third quartile for continuous variables and percentages (absolute numbers) for categorical variables. N is the number of valid cases for each given variable.

* ratio between the maximum and the minimum size reported.

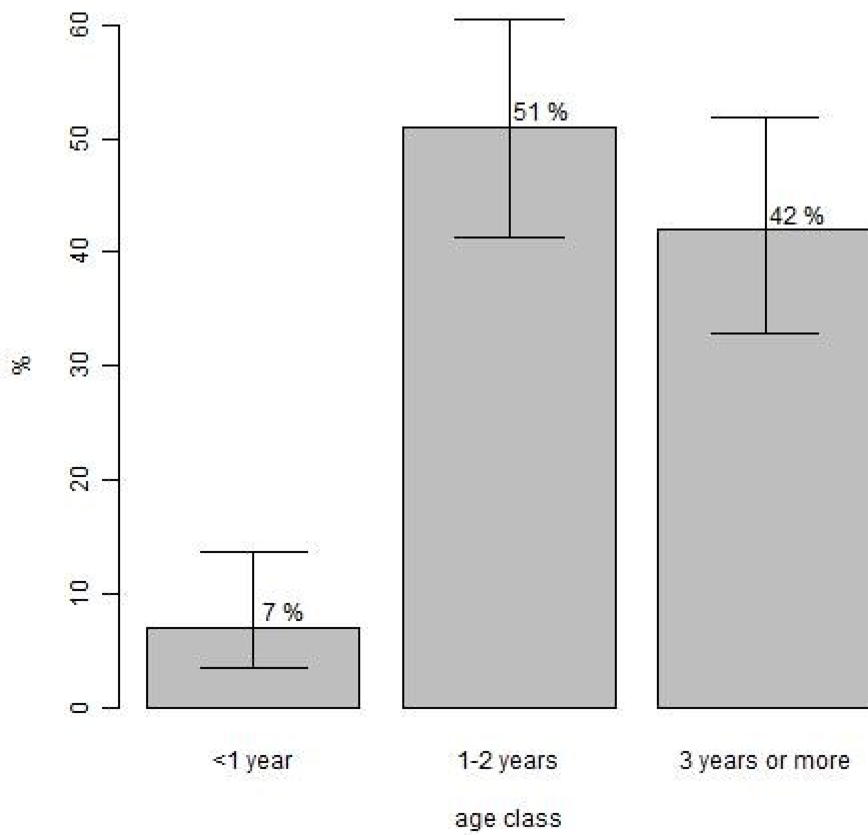
| FB description | N | Percentage |
|---|---|---|
| nut | 74 | 42% |
| other food | 43 | 24% |
| seed and grain | 35 | 20% |
| bone | 12 | 7% |
| bean and pea | 6 | 3% |
| sweet | 4 | 2% |
| fruit stone | 2 | 1% |
| Total | 176 | |

**Table 5.** Description of FB which caused complications

| Variables | N | Hospitalization | | | | Complications | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Yes (N=847) | No (N=664) | OR (95%CI) | p | Yes (N=176) | No (N=1616) | OR (95%CI) | p |
| Age class | 1362 | | | | | | | | |
| < 1 year | | 11% ( 81) | 2% ( 9) | Ref | | 7% ( 9) | 7% ( 76) | Ref | |
| 1-2 years | | 65% (488) | 32% (126) | 0.43(0.21; 0.88) | 0.021 | 44% ( 54) | 55% (563) | 0.81 (0.38; 1.71) | 0.579 |
| >=3 years | | 25% (187) | 65% (256) | 0.08 (0.04; 0.17) | <0.001 | 49% ( 61) | 38% (393) | 1.31(0.62; 2.75) | 0.475 |
| Adult supervision | 1381 | | | | | | | | |
| Adult present | | 75% (393) | 71% (256) | 1.26 (0.93; 1.70) | 0.135 | 72% (102) | 80% (977) | 0.64 (0.44; 0.95) | 0.028 |
| Volume | 2744 | 1 1 1 | 1 1 17 | 1.05(0.94;1.18) | | 1 1 1 | 1 1 1 | 0.69 (0.46; 1.04) | 0.075 |
| Shape | 1475 | | | | | | | | |
| Spherical | | 36% (235) | 26% (136) | Ref | | 59% ( 55) | 34% (315) | Ref | |
| 3D | | 27% (176) | 20% (106) | 0.96 (0.70; 1.32) | 0.807 | 29% ( 27) | 29% (266) | 0.58 (0.36; 0.95) | 0.03 |
| 2D | | 7% ( 46) | 36% (191) | 0.14 (0.09;0.20) | <0.001 | 5% ( 5) | 6% ( 52) | 0.55 (0.21; 1.44) | 0.224 |
| 2D circle | | 1% ( 6) | 3% ( 16) | 0.22(0.08; 0.57) | 0.002 | 3% ( 3) | 2% ( 19) | 0.90(0.26; 3.16) | 0.875 |
| Other | | 29% (190) | 14% ( 76) | 1.45 (1.03; 2.03) | 0.033 | 3% ( 3) | 29% (263) | 0.07(0.02; 0.21) | <0.001 |
| Ellipticity | 384 | 1.00 1.50 3.75 | 1.00 1.50 3.43 | 0.89 (0.82;0.96) | 0.003 | 1.00 1.33 2.33 | 1.00 1.75 4.00 | 0.67 (0.44; 1.02) | 0.059 |
| Consistency | 2283 | | | | | | | | |
| Conforming | | 7% ( 50) | 42% (260) | Ref | | 20% ( 30) | 24% (356) | Ref | |
| Rigid | | 38% (282) | 24% (150) | 9.78 (6.81; 14.04) | <0.001 | 41% ( 62) | 40% (585) | 1.26(0.80; 1.98) | 0.324 |
| Semirigid | | 29% (219) | 29% (178) | 6.40 (4.46; 9.18) | <0.001 | 33% ( 50) | 23% (341) | 1.74(1.08;2.80) | 0.023 |
| Do not know | | 26% (196) | 5% ( 29) | 35.14 (21.45; 57.58) | <0.001 | 7% ( 11) | 13% (192) | 0.68 (0.33; 1.39) | 0.289 |

**Table 6.** Odds ratio of complications and of hospitalization with the 95% confidence intervals are presented. *P* values are also presented. *N* number of valid cases for each given variable. *Ref* : reference category.

**Figure 1.** Distribution of incidence (%) of FB injuries by age class.Over the bars, 95% confidence intervals are plotted.



**Title:Non Food Foreign Body injuries**

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**Abstract**

**Rationale and aim:** The aim of the present study is to acquire a better understanding of Non Food Foreign Bodies (NFFB) injuries in children with particular regard to the quantification of the risk of complications and hospitalization associated with patients characteristics, FB features, FB location and circumstances of the accident, as emerging from the SUSY Safe Web-Registry

**Methods:** The present study uses data provided by the SUSY Safe Project, a DG SANCO co-funded project which was aimed to collect as many scientific data as possible regarding Foreign Bodies (FB) injuries in children aged 0-14 years and to serve as a basis for a knowledge-based consumer protection activity in the Europe market. FBs were characterized by size, shape and consistency. Descriptive statistics (absolute and relative number or median, I and III quartile according to the categorical or continuous variable, respectively) were calculated for each considered non food item characteristics; FB features distribution by children class age and site of obstruction were assessed. Two different outcomes were considered: hospitalization and complication. FBs which most frequently cause complications were identified. The association between children age, adult presence, object characteristics and outcomes was computed using unweighted odds ratios and the related 95% confidence intervals.

**Results:** 16878 FB injuries in children aged 0-14 yrs have been recorded in the Susy Safe databases. FB type was specified in 10564 cases; among them 7820 (74%) were due to a non food item. Almost two thirds of injuries occurred in patients 3 years or more old. 53% of patients were males, while 47% were females. When injury happened, the great part of children (86%) was playing. Almost 30% (2339) of injuries happened under adults' supervision. Complications occurred in 299 cases and the most documented was infections (10 % of cases) followed by perforation (5%).

**Conclusions**: The inhalation/aspiration of a FB, as well as the ingestion and the insertion in the orifices of a FB may result in significant morbidity. Particularly, long-standing or hazardous foreign bodies can cause extensive damage. Some objects, because of their composition, contour, or location, are particularly hazardous: for instance, objects with sharp edges pose a significant risk of laceration and perforation, while fragments of toys have been found only in 2 cases. Parents are frequently unconscious of hazard related with some objects and they are not adequately able to promptly recognize dangerous objects and risky situations. Moreover, also clinicians seem to pay little attention to adult role in the dynamic of the accident: in fact in case series descriptions, data regarding adult presence are often under-reported. On the contrary, since many injuries to children cannot be prevented without

some degree of active behavior on the part of parents, the dissemination of information regarding safe behaviors and the implementation of educational strategies aiming to improve parent's attention toward this issue could be fundamental in preventing injuries and need to be promoted by family pediatricians and health practitioners.

**Keywords:** non food foreign bodies, coins, prevention

## Introduction

The insertion, inhalation, aspiration, or ingestion of a Foreign Body (FB) is a dramatic event in children representing one of the main causes of mortality and morbidity in the paediatric population.

The mechanical obstruction of the airways due to foreign body inhalation/aspiration may result in severe complications including asphyxia, pneumonia, atelectasis and bronchiectasis, is the primary source of fatal accidents in children younger than 1, and it represents a major cause of death in children from 1 to 4 years old. On the other hand, while most ingested foreign bodies are well tolerated and pass the intestinal tract with no complications, some may cause gastrointestinal perforation or obstruction. Finally also the insertion of a FB in the ears may result in long-term complications.

Even if the major part of injuries seem to be due to inhalation, aspiration, ingestion or insertion of food particles, many classes of inorganic objects (including toys, jewellery, stationary items, etc) extremely heterogeneous regarding dimensions, shape, consistency, are frequently listed in FB injuries case series: since FB characteristics seem to determine an important variability on clinical picture an effort devoted to identify risky objects need to be accomplished in order to improve effective preventive strategies.

The aim of the present study is to acquire a better understanding of Non Food Foreign Bodies (NFFB) injuries in children with particular regard to the quantification of the complications and hospitalization risk associated with patients characteristics, FB features, FB location and circumstances of the accident, as emerging from the SUSY Safe Web-Registry (1).

## Methods

### Data collection

The present study uses data provided by the SUSY Safe Project, a DG SANCO co-funded project which was aimed to collect as many scientific data as possible regarding Foreign Bodies (FB) injuries in children aged 0-14 years and to serve as a basis for a knowledge-based consumer protection activity in the Europe market. An international registry of FB cases has been established with the participation of 60 institutions in 26 different countries. Details on injuries are entered in the SUSY Safe Web-Registry through a standardized case report form, that includes information regarding: children age and gender, features of the object, circumstances of injury (presence of parents, activity) and hospitalization's details

(lasting, complications and removal details). Cases are prospectively collected using the Susy Safe system from 06/2005; moreover, also information regarding past consecutive cases available in each centre adhering to the project have been entered in the Susy Safe Registry.

Statistical analysis

The analysis was carried out on injuries due to a non food item.

FBs location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935).

Children characteristics (age and gender) were assessed. Data regarding the injury dynamic (adult supervision and activity before injury) were also evaluated.

FBs were characterized by size, shape and consistency. Descriptive statistics (absolute and relative number or median, I and III quartile according to the categorical or continuous variable, respectively) were calculated for each considered non food item characteristics; FB features distribution by children class age and site of obstruction were assessed.

Two different outcomes were considered: hospitalization and complication. Hospitalization has been defined whether the child was admitted in the hospital for at least 1 day. Complications include all the pathological conditions due to delayed diagnosis or to the attempts of removing the FB.

FBs which most frequently cause complications were identified. The association between children age, adult presence, object characteristics and outcomes was computed using unweighted odds ratios and the related 95% confidence intervals.

Analyses were performed using Design and Hmisc libraries from R version 2.8 (2).

**Results**

16878 FB injuries in children aged 0-14 yrs have been recorded in the Susy Safe databases. FB type was specified in 10564 cases; among them 7820 (74%) were due to a non food item. Details regarding retrieved FBs are given in Table 1.

FB site is known in 7441 cases. In Table 2 the total amount of non food related injuries, the number of complicated injuries and the number of injuries in which hospitalization is needed are reported stratified by FB location.

Data regarding age was available in 5691 FFB cases. Distribution of incidence of analyzed injuries by age class is shown in Figure 1. Almost two thirds of injuries occurred in patients 3 years or more old. 53% of patients were males, while 47% were females. When injury

happened, the great part of children (86%) was playing. Almost 30% (2339) of injuries happened under adults' supervision.

FB characteristics by age and by location are described respectively in Table 3 and Table 4.

Looking to the outcomes, 745 (10%) children needed hospitalization; among them, 403 (54%) were discharged after 24 hours whereas 169 (22%) required hospitalization for two days and 56 (8%) for more than 3 days.

Complications occurred in 299 cases and the most documented was infections (10 % of cases) followed by perforation (5%). Non food items which most frequently caused complications are listed in Table 5.

The association among children characteristics, adult supervision, object features and outcomes has been evaluated and OR (95% CI) are shown in Table 6.

**Discussion**

More than 60 % of cases are injuries due to the insertion of a FB in the nose or in the ears; as generally described in scientific literature, also in our experience these injuries due to FB insertion usually concern preschoolers which frequently desire to explore the orifices of the body manipulating toys and objects that usually available at home (3) (4).(5).

The inhalation/aspiration of a FB, as well as the ingestion and the insertion in the orifices of a FB may result in significant morbidity (6) (7) (8). Particularly, long-standing or hazardous foreign bodies can cause extensive damage. Some objects, because of their composition, contour, or location, are particularly hazardous: for instance, objects with sharp edges pose a significant risk of laceration and perforation, while fragments of toys have been found only in 2 cases. These findings seem to testify the efficacy of regulations imposing manufacturing quality standards to toys: injuries due to small parts have become a matter of interest in the last 30 year, focusing on the relationship between a proper prevention and the diminished frequency of occurrences. The SPTF (Small Part Test Fixture) is at the moment the most common test used to define which objects might lead to injuries and which can be labeled as safe. However, this issue remains problematic. This regulation in fact, covers products for children under three: a wide range of objects easily accessed by children even if not expressly designed for children are exempt, including objects (such as books and stationery items) that cannot be manufactured in a way that would prevent them from breaking into small parts, and objects that need to be small (such as buttons) to perform their intended purpose (9) (10). This fact implies that parents need to be aware of the foreign bodies' insertion risk and avoid giving fragile or small objects to very young children. However, in our experience injuries

usually happen under adults' supervision, while children are manipulating objects not conceived for children use and not adapted for their age. Therefore, the implementation of educational strategies regarding safe behaviors could be fundamental in preventing injuries and need to be promoted by health practitioners.

Unfortunately, also clinicians and researchers seem to pay little attention to this topic. Generally, case series reviews and meta-analytic studies are considered as fundamental in order to identify and describe the injury dynamics and to orient therapeutic and preventive approaches. However, not only case series reporting FB in the ears are relatively rare in scientific literature, but also data regarding the dynamic of the accident and clinical features are not reported in a standardized way frustrating any attempt to synthesize the existing knowledge. For this reason, the adoption of national or sovra-national surveillance systems seems to be necessary in order to collect the information in a standardized way and to identify which objects, products and behaviours could be dangerous for children.

Nasal foreign bodies, produce local inflammation which may result in a pressure necrosis and damage nasal cavity and surrounding structures (11). Symptoms are mainly caused by inflammation, mucosal damage and extension into adjacent structures and could include sneezing, epistaxis, nasal obstruction, nasal discharge, pain, and eventually rhinosinusitis (12). In our case series the most frequent symptoms was cacosmia and rhinorrhea and, a not negligible proportion of cases presented signs of impetigo. Also in other case series infections (13) (14) (15) constitute a well documented complication. However, in our as well as in other studies, the large part of cases was asymptomatic.

Even if clinically silent, in most cases, the insertion of the nasal foreign body is witnessed, and in these cases the dilemma of diagnosis is eliminated; nevertheless, almost 2% of cases had a delay in diagnosis greater than 2 days.

Adult presence is not sufficient to prevent hazardous situations: in our experiences more than 90% of injuries happen under adult supervision; in Europe approximately one third of accidents occurred when an adult is present. Our details regarding FB type, consisting with findings of all the other considered studies, testify as injuries are frequently due to inorganic objects, particularly to an incorrect manipulation of objects not adapted to children use, including pins, nails, screws, floats, but also more unusual and potentially dangerous objects such as munitions. Moreover, children commonly play with accessories such as pearls which could act as risky objects mainly in younger.

Batteries and magnets documented in our study as well as in other case series deserve particular mention because they require immediate treatment, as they can cause septal necrosis and perforation within hours.

Metallic button batteries, commonly included in many toys, are small and shiny, making them strong candidates for nasal insertion. Once inserted into the nose, they cause destruction by low-voltage electrical currents, electrolysis-induced release of sodium hydroxide and chlorine gas; if their alkaline contents leak out, they could also induce tissues liquefactive necrosis. Since complications are common, button batteries require prompt removal (16) (17) (18).

On the other hand, the use of small powerful magnets as earrings imitation could have dramatic consequences (19). When children attempt to imitate bilateral nasal piercing with magnet-backed jewelry, the intranasal magnets may attract each other and become adherent across the nasal septum, resulting in substantial pressure on the nasal septum and its delicate capillary network; this determines a time dependent risk of septal ischemia, necrosis and perforation, pressure necrosis begins within hours (5) (20) (21). Therefore, magnets across the septum should be treated as an urgent medical condition and managed definitively in the ED (5) (22) (23).

Unfortunately parents are frequently unconscious of hazard related with some objects and they are not adequately able to promptly recognize dangerous objects and risky situations. Moreover, also clinicians seem to pay little attention to adult role in the dynamic of the accident: in fact in case series descriptions, data regarding adult presence are often under-reported. On the contrary, since many injuries to children cannot be prevented without some degree of active behavior on the part of parents (24), the dissemination of information regarding safe behaviors and the implementation of educational strategies aiming to improve parent's attention toward this issue could be fundamental in preventing injuries and need to be promoted by family pediatricians and health practitioners (25).

## Tables

| FB description | N | Percentage |
|---|---|---|
| pearl, ball and marble | 1698 | 22% |
| coin | 1534 | 20% |
| other non-food | 639 | 8% |
| pin and needle | 506 | 6% |
| toy | 441 | 6% |
| pebble | 424 | 5% |
| stationery | 422 | 5% |
| paper | 365 | 5% |
| plastic | 304 | 4% |
| jewellery | 215 | 3% |
| metal | 183 | 2% |
| battery | 170 | 2% |
| cotton | 162 | 2% |
| button | 152 | 2% |
| stick | 150 | 2% |
| sponge | 95 | 1% |
| arthropod | 80 | 1% |
| cap | 70 | 1% |
| other stationery | 56 | 1% |
| polystyrene | 53 | 1% |
| tinfoil and cellophane | 42 | 1% |
| accessorize | 26 | 0% |
| earplug | 20 | 0% |
| medicine | 13 | 0% |
| Total | 7820 | |

**Table 1.** Description of the FB which caused the incident.

| Location | Non Food related injuries | Complications | | Hospitalization | |
|---|---|---|---|---|---|
| | | Yes | No | Yes | No |
| Ear | 24% (1801) | 26% (77) | 22% (800) | 14% (100) | 35% (504) |
| Nose | 37% (2772) | 58% (172) | 49% (1816) | 9% (67) | 50% (725) |
| Pharynx and larynx | 6% (418) | 2% (5) | 9% (352) | 4% (29) | 2% (26) |
| Trachea, bronchi and lungs | 4% (290) | 9% (26) | 6% (228) | 27% (196) | 1% (13) |
| Mouth, esophagus and stomach | 29% (2160) | 5% (15) | 14% (510) | 47% (346) | 13% (184) |
| Total | 7441 | 299 | 3722 | 745 | 1466 |

**Table 2.** FB location according to ICD9-CM code: ear (ICD931); nose (ICD932); pharynx and larynx (ICD933); trachea, bronchi and lungs (ICD934); mouth, esophagus and stomach (ICD935). Data are reported as percentages (absolute numbers). Total amount of injuries, complicated injuries and injuries requiring hospitalization are reported.

| Foreign body characteristics | N | Age class | | |
|---|---|---|---|---|
| | | < 1 year (N=283) | 1-2 years (N=1753) | > = 3 years (N=3899) |
| Volume | 5691 | 1 1 1 | 1 1 1 | 1 1 1 |
| Shape | 1975 | | | |
| Spherical | | 7% ( 6) | 30% (179) | 42% (539) |
| 3D | | 32% ( 29) | 27% (164) | 25% (322) |
| 2D | | 25% ( 23) | 12% ( 70) | 9% (112) |
| 2Dcircle | | 20% ( 18) | 21% (128) | 17% (214) |
| other | | 16% ( 15) | 9% ( 56) | 8% (100) |
| Ellipticity* | 788 | 2.0 3.0 10.0 | 1.0 1.4 6.0 | 1.0 1.0 2.5 |
| Consistency | 2040 | | | |
| Conforming | | 12% ( 11) | 11% ( 70) | 11% (147) |
| Semi-rigid | | 16% ( 15) | 13% ( 81) | 16% (211) |
| Rigid | | 67% ( 63) | 72% (440) | 71% (952) |
| Do not know | | 5% ( 5) | 3% ( 19) | 2% ( 26) |

**Table 3.** Non food items characteristics by age. Data are first quartile/ median/ third quartile for continuous variables and percentages (absolute numbers) for categorical variables. N is the number of valid cases for each given variable.

* ratio between the maximum and the minimum size reported.

| Foreign body characteristics | N | Foreign body location | | | | |
|---|---|---|---|---|---|---|
| | | Ear (N=1801) | Nose (N=2772) | Pharynx and larynx (N=418) | Trachea, bronchi and lungs (N=290) | Mouth, esophagus and stomach (N=2160) |
| Volume | 7820 | 1 1 1 | 1 1 1 | 1 1 1 | 1 1 1 | 1 1 1 |
| Shape : | | | | | | |
| Spherical | | 56% (327) | 47% (375) | 6% ( 3) | 14% ( 26) | 9% ( 46) |
| 3D | | 25% (147) | 28% (225) | 36% ( 19) | 53% ( 98) | 16% ( 89) |
| 2D | | 8% ( 46) | 9% ( 69) | 25% ( 13) | 8% ( 15) | 14% ( 74) |
| 2D circle | | 4% ( 26) | 10% ( 82) | 8% ( 4) | 4% ( 7) | 56% (301) |
| other | | 6% ( 36) | 7% ( 53) | 26% ( 14) | 21% ( 39) | 6% ( 31) |
| Ellipticity* | 820 | 1.0000 1.0000 1.5000 | 1.0000 1.0000 2.0000 | 1.7525 4.5000 10.0000 | 1.5000 3.0000 5.2475 | 2.8000 10.0000 21.0000 |
| Consistency | 3836 | | | | | |
| Conforming | | 19% ( 170) | 16% ( 332) | 6% ( 4) | 7% ( 17) | 3% ( 16) |
| Rigid | | 66% ( 597) | 74% (1503) | 69% ( 45) | 77% ( 192) | 90% ( 490) |
| Semirigid | | 13% ( 117) | 8% ( 154) | 15% ( 10) | 10% ( 26) | 5% ( 28) |
| Do not know | | 3% ( 27) | 3% ( 55) | 9% ( 6) | 6% ( 15) | 2% ( 11) |

**Table 4.** Non food items characteristics by FB location. Data are first quartile/median/third quartile for continuous variables and percentages (absolute numbers) for categorical variables. N is the number of valid cases for each given variable.

* ratio between the maximum and the minimum size reported.

| FB description | N | % |
|---|---|---|
| other non-food | 40 | 13% |
| stationery | 38 | 13% |
| paper | 32 | 11% |
| pearl, ball and marble | 32 | 11% |
| pebble | 20 | 7% |
| toy | 20 | 7% |
| sponge | 16 | 5% |
| battery | 13 | 4% |
| pin and needle | 12 | 4% |
| plastic | 11 | 4% |
| cap | 10 | 3% |
| cotton | 9 | 3% |
| coin | 8 | 3% |
| jewellery | 6 | 2% |
| arthropod | 5 | 2% |
| metal | 4 | 1% |
| polystyrene | 4 | 1% |
| stick | 4 | 1% |
| tinfoil and cellophane | 4 | 1% |
| accessorize | 3 | 1% |
| earplug | 3 | 1% |
| other stationery | 3 | 1% |
| button | 2 | 1% |
| Total | 299 | |

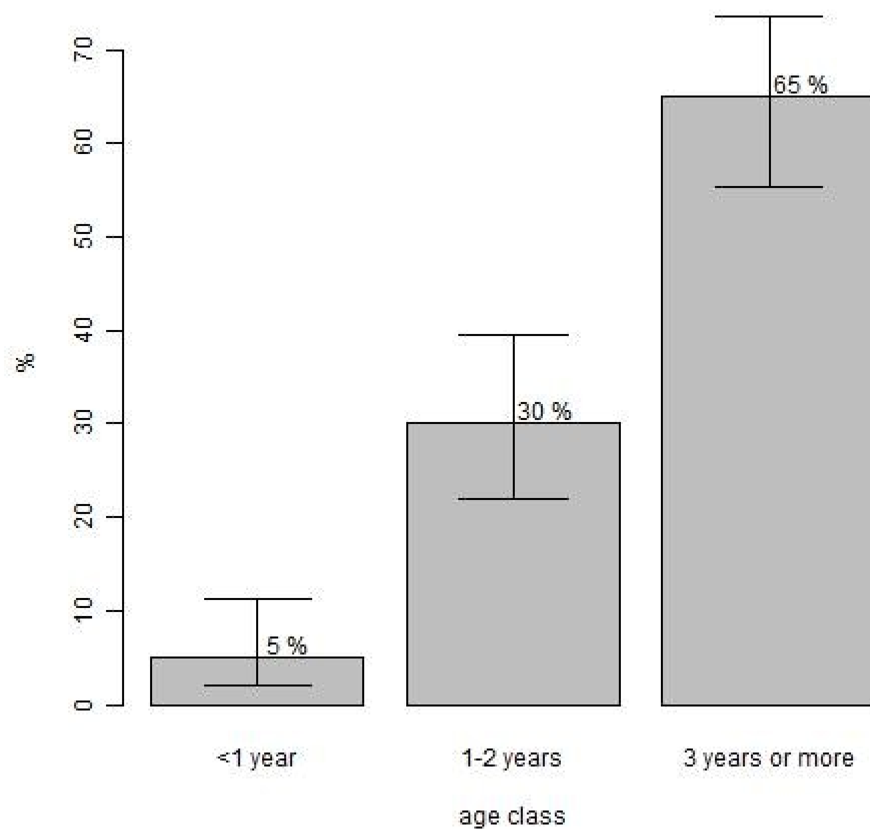
**Table 5.** Description of FB which caused complications

| Variables | N | Hospitalization | | | | Complications | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Yes (N=745) | No (N=1466) | OR (95%CI) | p | Yes (N=299) | No (N=3722) | OR (95%CI) | p |
| Age class | 5691 | | | | | | | | |
| < 1 year | | 10% ( 69) | 2% ( 26) | Ref | | 5% ( 84) | 5% ( 8) | Ref | |
| 1-2 years | | 34% (229) | 28% (371) | 0.23 (0.14; 0.38) | <0.001 | 30% ( 566) | 22% ( 35) | 0.65 (0.29; 1.45) | 0.291 |
| >=3 years | | 56% (380) | 70% (934) | 0.15 (0.10; 0.24) | <0.001 | 65% (1208) | 73% ( 119) | 1.03 (0.49; 2.19) | 0.930 |
| Adult supervision | 3460 | | | | | | | | |
| Adult present | | 45% (235) | 44% (482) | 1.05 (0.86; 1.30) | 0.617 | 69% (2193) | 52% ( 137) | 0.49 (0.38; 0.63) | <0.001 |
| Volume | 7820 | 1.00 1.00 71.00 | 1.00 1.00 60.75 | 1.58 (1.42; 1.76) | <0.001 | 1.0 1.0 1.0 | 1.0 1.0 13.5 | 0.97 (0.83; 1.12) | 0.667 |
| Shape | | | | | | | | | |
| Spherical | | 18% (124) | 45% (628) | Ref | | 37% (714) | 25% ( 39) | Ref | |
| 3D | | 26% (183) | 26% (356) | 2.60 (2.00; 3.38) | <0.001 | 25% (485) | 41% ( 62) | 2.34(1.54; 3.55) | <0.001 |
| 2D | | 12% ( 86) | 9% (125) | 3.48 (2.49; 4.87) | <0.001 | 10% (195) | 12% ( 19) | 1.78 (1.01; 3.16) | 0.047 |
| 2D circle | | 35% (246) | 12% (167) | 7.46 (5.67; 9.82) | <0.001 | 20% (380) | 15% ( 23) | 1.11 80.65; 1.88) | 0.704 |
| Other | | 9% ( 60) | 8% (106) | 2.87 (1.98; 4.15) | <0.001 | 8% (161) | 7% ( 10) | 1.14(0.56; 2.33) | 0.725 |
| Ellipticity | 820 | 1.000 2.415 15.000 | 1.000 1.000 2.000 | 1.33 (1.24; 1.42) | <0.001 | 1.000 1.000 3.000 | 1.000 1.500 2.415 | 0.93 (0.84; 1.03) | 0.190 |
| Consistency | 3836 | | | | | | | | |
| Conforming | | 7% ( 48) | 14% (195) | Ref | | 13% ( 431) | 37% ( 107) | Ref | |
| Rigid | | 81% (593) | 66% (950) | 2.54 (1.82; 3.53) | <0.001 | 77% (2614) | 51% ( 148) | 0.23(0.17; 0.30) | <0.001 |
| Semi-rigid | | 10% ( 72) | 18% (253) | 1.16 (0.77; 1.74) | 0.488 | 9% ( 294) | 11% ( 33) | 0.45 (0.30; 0.69) | <0.001 |
| Do not know | | 3% ( 21) | 3% ( 40) | 2.13 (1.15; 3.95) | 0.0158 | 2% ( 52) | 2% ( 5) | 0.39(0.15; 0.99) | 0.0484 |

**Table 6.** Odds ratio of complications and of hospitalization with the 95% confidence intervals are presented. *P* values are also presented. *N* number of valid cases for each given variable. *Ref* : reference category.

**Figures**

**Figure1.** Distribution of incidence (%) of FB injuries by age class. Over the bars, 95% confidence intervals are plotted.

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**Title: Modeling the risk: innovative approaches to understand and quantify the risk of severe FB injury**

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**Abstract**

The entry of a small item into the upper aero-digestive ways is one of the leading causes of injuries in children up to 14 years old. The European Survey on Foreign Bodies Injuries Study collected data on foreign body injuries from 19 European Countries. The data of years 2000-2002 were gathered according to the ICD931 to ICD935. Case report form included information on the injured child, on the circumstances of the accident and on the foreign body features. When the dimensions of the object were reported, the volume was calculated accordingly to the shape of the objects itself, e.g. for three-dimensional objects the volume of an ellipsis was calculated by the length of the axis.

We set up a classification tree in order to analyze the impact of the item features like volume shape and consistency on the severity of the foreign body injuries. With this aim, injured children were divided into two groups: one group for hospitalized children and a second group for children who had not experienced a hospitalization.

**Keywords:** foreign body injuries, shape, volume, consistency, classification tree

## Introduction

The entry of a small item into the mouth or into the nose and from there into the respiratory or digestive tract is one of the leading causes of injuries in children up to 14 years old and still represent a significant challenge for the health care system in terms of life threatening and resources utilization. Children commonly place objects in the mouth. This often results in accidental swallowing of foreign bodies. Children usually place things in their ear canal because they are bored, curious, or copying other children. Sometimes one child may put an object in another child's ear during play. Injuries due to foreign body aspirations and ingestions are quite common in childhood because of their link with some important developmental factors, such as the exploration of the environment using the sense of taste ('mouthing') and the diversification of infant's diet with solid food (Farmakakis, Dessypris et al. 2007).

Whereas some authors (Milkovich 2003) are distinguishing the concept of insertion (in the nose or ears) from that of ingestion, of aspiration and of choking, some other authors recognize that all such aspects are closely inter-related, and propose to keep as unique category ingestion, aspiration, choking (Rider e Wilson 1995). As recalled by (Reilly, Stool et al. 2003) strategies for successful interventions from public and private health care providers are based upon principles of avoidance, caretaker vigilance and pre-emptive design strategies. Safety of a product depends on appropriate use of materials, quality of manufacturing and on design safety. A "safe" design is determined by whether a product provides anyone who might come into contact with it a satisfactory level of safety. This issue should extend to include foreseeable misuse, for instance children who may play with an object in a way not intended by the producer. The interaction between a product and its user and even misusers is affected by the features of the product like volume and shape, the characteristics of the user such as age and gender and environmental factors such as social conditions (RPA 2003). It follows the need for severity injuries prediction and risk assessment. Many studies were carried out to characterize types, shapes, and sizes of objects causing injuries.

The seriousness of an accident is often disputed. For example, a child may be taken to hospital and admitted for observation (an apparent serious accident) but in the event, the small object swallowed is passed naturally with no adverse effects. In (Milkovich, Rider et al. 2003) an injury which lead to a medical intervention is categorized as

‘severe’, while physical findings including abnormality of breathing functions define a ‘moderate’ injury. In (DTI 1999)non fatal accident was classified into: Trivial, if the ‘patient did not wait’ or he was ‘Examined but no treatment given’; Minor if the patient was ‘Treated; no more treatment required' or he was ‘Admitted to hospital for less than 1 day’; Serious if the injured child was ‘Admitted for one, two or three days’; Very Serious if he was ‘Admitted for more than three days’ or ‘Transferred to a specialist hospital’. On this basis we considered an injury as ‘severe’ if the child involved was hospitalized for at least one day.

In order to describe the role of the FB characteristics and the impact of the circumstances which leaded to an injury, we set up a tree based model. The aim of this paper is to provide a quantitative risk assessment analysis for the identification of product features which much more contribute to an increased risk of sustaining a severe injury. Following a short presentation of the methodology, the classification tree model will be described and its performance and results will be discussed.

## Materials and Methods

*Data source*

According to the International Classification Disease ICD-9CM 931-935, at the end of 2009 a total of 7,296 injuries in paediatric patients were gathered by the Susy Safe EU funded Web-registry using hospital discharge records in one Pakistani and 28 European hospitals. Data encompassed four main aspects of the FB injuries: (i) the characteristics (age and gender) of the injured children; (ii) the characteristics of the objects (foreign body type, shape, consistency, dimensions and whether it was associated to another object); (iii) circumstances of injury (presence of caregivers during the accident, the activity the child was engaged in at the time the accident occurred); (iv) hospitalization’s details (removal technique used to extract the FB, whether a hospitalization was experienced, whether complications occurred). Objects were characterised by size, shape and consistency following the basic definitions in (Rimell, Thome Jr et al. 1996). With regard to the shape, FBs were assigned to one of the following categories: Spherical (ball, pebble, etc.); Three-dimensional (3D) (FBs with irregular shape); Two-dimensional (2D) (paper sheet, cellophane); Cylinder (coin, button, cylinder batteries); 2D-circle (2D circle objects other than batteries, coins and buttons); Needle-shape (e.g. pin and needle). In addition three categories of

consistency were considered: conforming (e.g. balloon, elastic); semi-rigid (e.g. eraser) and rigid (e.g. coin). Whit regard to the size, when the dimensions (expressed in millimetres) of the object were reported, the volume was calculated by approximation to the nearest simple geometric shape, e.g. for three-dimensional objects the volume of an ellipsis was calculated using the length of the axis. Such volume measures represent how much space the smallest geometrical figure containing the irregular-shaped FB takes up. Finally, we considered five different FB categories : (i) non-industrial component; (ii) piece of an object: the FB was a broken part of the product (e.g. a broken part of a pen, the wheel of a toy car, etc); (iii) whole objects; (iv) co-presence with another object: when the objects were sold together like the cap with the pen, the marble with a board game, etc, (v) package or part of a package of a product (e.g. the tinfoil containing chocolate, a polystyrene ball, a piece of cardboard, etc.

*Statistical methods*

With the aim to analyze the impact of the FB characteristics and the circumstances of the injury on the severity, a classification tree was constructed. The indicator of the event the injured child had experienced a hospitalization was considered as response variable. Predictor variables consisted in the volume measurements, shape, and consistency of the foreign body and the co-presence of another object. In addition, data on the child suffering the injury, specifically his/her gender, age, the activity he/she was playing and whether the accident occurred in the presence of an adult were taken into account. Two classification trees were implemented: one for FBs located in the nose and in the ears (ICD931-932) and another one for FBs located in the upper and lower digestive tract (ICD933-935). The implementation of the classification tree was based on a recursive partitioning algorithm in a conditional inference framework (Hothorn, Hornik et al. 2006). The classification tree was implemented by means of a recursive partitioning algorithm in a conditional inference framework. In this setting, the global null hypothesis of independence between any of the covariates and the response is tested. If the null hypothesis is rejected, the predictor with the strongest association to the outcome is selected. The association is measured by a p-value corresponding to a test for the partial null hypothesis of the single variable and the response. Thus a binary split is implemented in the selected variable. Monte-Carlo approximations were computed to make multiplicity adjustment for p-values in testing

the global null hypotheses. The method ensures neither pruning nor cross-validation are needed to get the right sized tree. Furthermore the statistical stop criterion ensures that interpretations drawn from the tree are valid with the appropriate control of type I error. To overcome the lack of an external independent dataset for testing the model performance, a bootstrap validation procedure was implemented (Harrell, Lee et al. 1996). Bootstrap resampling started with fitting the model in a bootstrap sample which was drawn with replacement in the original sample. Predictive accuracy was summarized by the area under the ROC curve, also known as *c*-statistics, and the Brier's score. Averages of the performance measure were taken over 1000 repetitions. The implementation of classification trees was carried out using the party package included in the statistical software R (R Development Core Team 2005).

**Results**

*Foreign bodies localised in the ears (ICD931) and in the nose (ICD932).*

Figure 1 depicts the classification tree which has been constructed. Shape, volume and foreign body category are the most important splits variable; indeed, foreign body category is used twice in splitting process. At first, FB are considered as package or broken objects in contrast to other categories. In table 2 a short description of broken objects is presented. A threshold of the volume measurements, which is associated to the prediction of injury severity, has been detected. Spherical or 2D objects in the presence of packages as well as piece or whole spherical or 2D FBs with volume less than 16.74 $mm^3$ are significantly associated to the most severe injuries. In table 3, details on foreign bodies with volume less than 16.74 $mm^3$ are reported.

*Foreign bodies localised in the pharynx and larynx (ICD933), in the trachea, bronchi and lungs (ICD934), in the mouth, oesophagus and stomach (ICD935).*

In Figure 2 the resulting tree-based model for the classification of the injuries according to their severity is depicted. Several risk profiles can be detected by the examination of the tree. 2D object with a rigid or semi-rigid consistency are significantly associated to injuries which leaded to hospitalization. Spherical objects also are significantly associated to severe injuries in children under three years. Food packages containing inedibles (FPCI) are predictors of severe injuries even in children over three years old; indeed they are associated to injuries which took place while the children were eating.

*Predictive accuracy of the models*

Area under the ROC curve and Brier's score for each classification tree are reported in table 4. Results are averaged over the 1000 bootstrap samples. In the validation sample, for ICD931-932 and ICD933-935 classification tree, respectively, the mean ROC curve area was 0.72 and 0.74 and the mean Brier's score was 0.11 and 0.19. The difference in predictive performance quantities computed on the derivation and the validation sample gives an estimate of the optimism in the apparent performance. Corrected indexes provide a measure of the internally validated performance that quantifies the overall accuracy of predictions.

**Discussion**

Rimell (Rimell, Thome Jr et al. 1996) carried out a statistical analysis on types, shapes, and sizes of objects causing choking in children. They found conforming objects such as balloons caused a significantly higher proportion of deaths in children aged 3 years or older versus children younger than 3 years.

Stool (Stool, Rider et al. 1998) used computerised models of the airways and oral cavities of children of various ages, thereby developing anatomically accurate, age-indexed models of children's body cavities in order to assess the hazards of toys and small parts. Using this method they showed how some toys, which meet the legal standards for safety still pose a substantial risk of injury or risk of choking.

Rider (Rider, Milkovich et al. 2000) adopted the Quantitative Risk Analysis methodology to evaluate the potential risk associated with any given consumer product. They set up a risk equation to determine the effect of object characteristics on the risk of injury and then predicted the probability of injury by multiplying the hazard associated with an object by the exposure of the child to the object. Finally they utilized Monte Carlo simulations to generate estimates of product-related risk. Even if they work was innovative and noteworthy from a methodological perspective, (Morra and Passali 2002) showed some weak points in the analysis.

Milkovich (Milkovich, Rider et al. 2003) performed a statistical analysis on approximately 7000 data points from 51 children's hospitals in 15 countries located in 5 continents. Size, shape, and consistency of the object, obstruction location and severity of injury were taken into account. Analysis of these data revealed that adoption of injury prevention criteria based on the use of a 38.10-mm diameter gauge

for non-spherical objects and a 44.50-mm diameter gauge for spherical objects would greatly reduce airway obstruction injuries to children.

In general, tree-structured prediction rules developed for practical application are easy to apply. Binary recursive partitioning methods are usually employed to build classification and regression tree. Advantages to tree-based methods rely on the fact that they do not require to specify a parametric relationship between predictor and outcome variables. Furthermore, they can be used even if the linearity assumptions, which are often made in linear and generalized linear models, do not hold. These features make tree-based methods particularly suitable at identifying important interactions among predictor variables (Berchialla, Snidero et al. 2007).

In spite of their deceptively simple form, classification trees have been shown in practice and in simulation experiments to match closely the accuracy of their best parametric competitors. Specifically, classification accuracy has been demonstrated to be almost as high as or somewhat higher, typically, than that obtained by the best competing parametric methods (Breiman et al., 1984).

We analyzed multivariate data that included both continuous and categorical variables. Classification trees are particularly applicable for studies like this, in which many of the variables considered do not seem to follow any particular distribution. Furthermore classification trees routinely handle any mix of categorical and continuous variables and present the advantage that cases with missing predictor variables do not require special treatment. The method is also extremely robust with respect to outliers and measurement errors in the predictor variables and the presence of irrelevant variables and variables with little or no predictive value. With regard to the issues of the paper this is an important point since we have to manage with approximated measure of small objects volume.

Finally in comparison with parametric methods such as linear discriminant analysis and logistic regression, classification trees often provide more insight into underlying relationships.

The four different trees classify correctly around 70% of the cases. The global performance of the trees does not reflect a low accuracy in predicting hospitalized children. Not surprisingly, misclassification occurs with cases missing the largest number of predictors, and among these the volume. Particularly a low accuracy in predicting the minority group arises for ICD933 and ICD935 where very few volume measures are available, while is better for ICD931 and ICD932.

On the other hand, classification accuracy could be improved by including additional measurements like axis length or by handling missing values using techniques like multiple imputations.

Another strategy to improve the classifier consists in performing boosting or built up a random forest. Both these strategies are based on growing a large number of trees. The primary disadvantage of these techniques is that the model is complex and cannot be visualized like a single tree, while a single-tree model can get an intuitive understanding of how the predictor variables relate.

Classification trees results summarize the characteristics of products that exposed children to a severe injury.

An examination of the size of the objects taken into account in this study indicates small parts pose a relevant risk to suffer a severe injury. Different cut-offs for volumes are provided by the classification trees given the foreign body localisation.

The most dangerous objects that have been found in the ears have got a volume lesser than 49 $mm^3$. Volume cut-off is slightly higher for foreign bodies that have been found in the nose. The most dangerous of these ones have got a volume lesser than 57 $mm^3$. Among objects with a volume greater than 57 $mm^3$, those with a conforming consistency pose a higher risk for a severe injury in children under 4.5 years of age.

This is a more restrictive finding compared to the legal standard adopted in the European Union by the European Standard on the Safety of Toys (EN 71-1:2001) which requires products containing small parts – for example capsules containing plastic toys in assembling kit form, or in general the so-called Food Product Containing Inedibles – to bear a label warning that the item is not suitable for children under 36 months. Low cylindrical objects, such as coins, caused a high proportion of severe injuries when they were ingested. Classification tree rule states males are involved in severe injuries more often than females. This is probably due to the fact boys exhibit a mouthing behaviour more often than girls. Furthermore conforming consistency objects such as balloon pose a relevant risk to be involved in a severe injury.

Most important, the presence and supervision of an adult is crucial in reducing the risk for severe injuries both in pharynx and larynx and in mouth.

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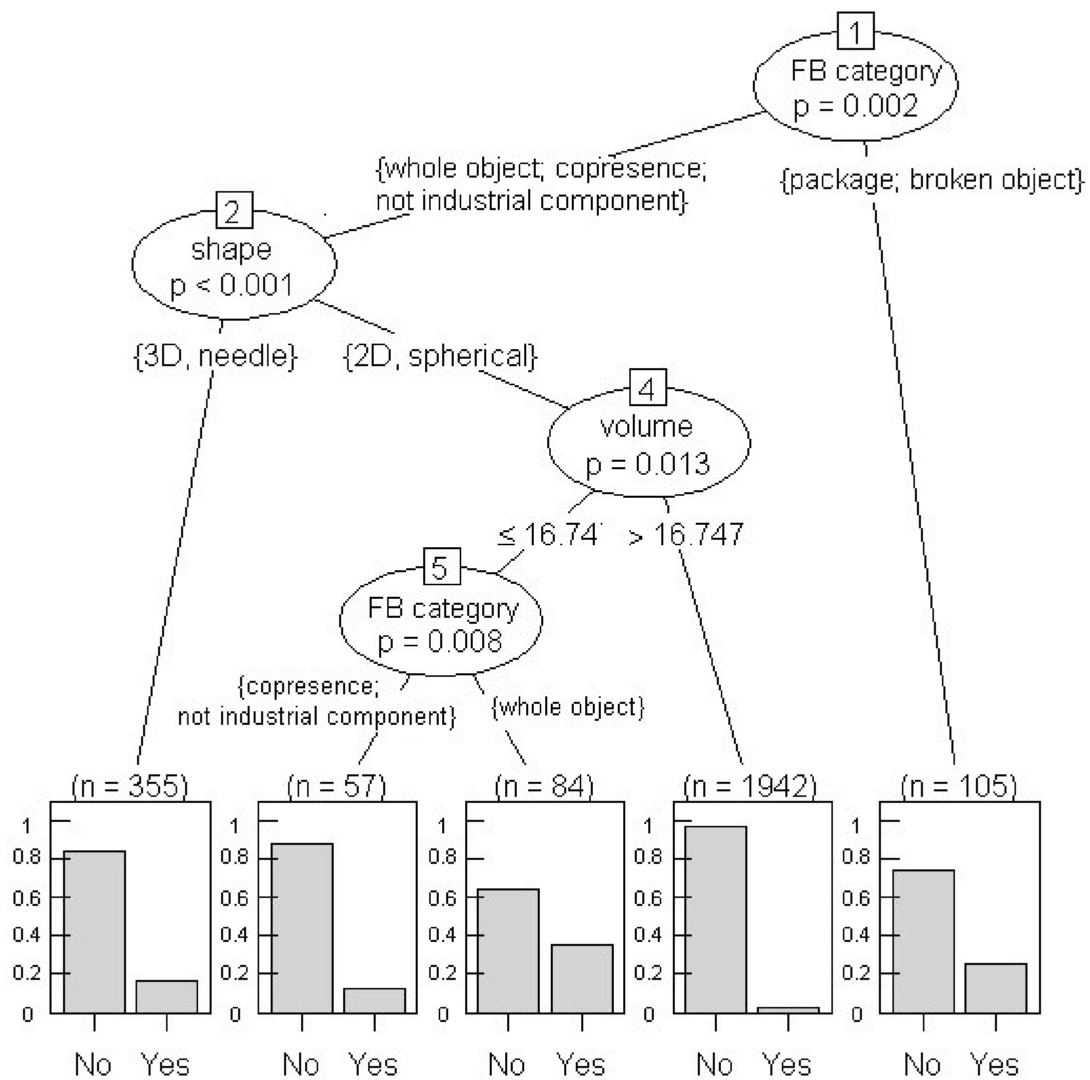


**Figure 1** Classification tree for FBs located in the ears and in the nose (ICD931-932).

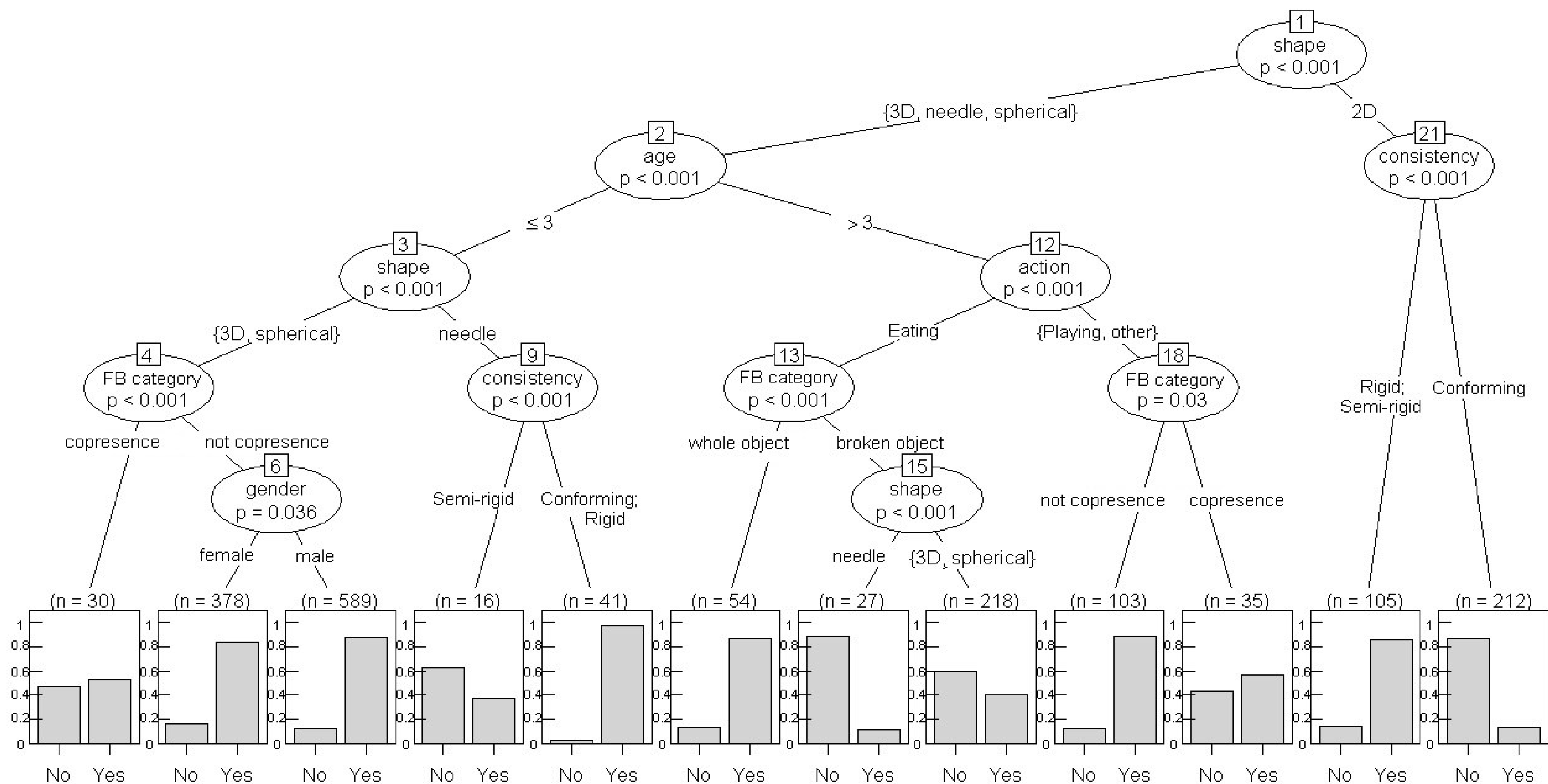


**Figure 2** Classification tree for FBs located in the upper and lower digestive tract (ICD933-ICD935).

**Table1**. Characteristics of the observed injurie served with respect to FB which caused the injury and the accident circumstances. Data are first quartile\median\third quartile for continuous variables and percentages (absolute numbers) for categorical variables. P-values are based on Wilcoxon test for continuous variables and on Pearson test for categorical variables. N is the number of non missing values.

| Variables | ICD 931-932 | | | | | ICD933-935 | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Hospitalization | | Combined | Test | | Hospitalization | | Combined | Test |
| | N | No | Yes | | | N | No | Yes | | |
| | | N=2366 | N=177 | N=2543 | | | N=547 | N=1261 | N=1808 | |
| Age | 2253 | 2/3/5 | 3/4/5 | 2/3/5 | P=0.009 | 1657 | 2/4/7 | 1/2/3 | 1/2/5 | |
| Gender | | | | | | | | | | |
| Male | 2274 | 51% (1080) | 51% (88) | 51% (1168) | P=0.956 | 1735 | 50% (242) | 62% (769) | 58% (1011) | P<0.001 |
| Shape | | | | | | | | | | |
| 2D | 1176 | 14% (141) | 8% (12) | 14% (153) | P<0.001 | 1389 | 57% (199) | 11% (118) | 23% (317) | P<0.001 |
| 3D | | 32% (328) | 41% (62) | 33% (390) | | | 25% (89) | 58% (601) | 50% (690) | |
| Needle shape | | 0% (4) | 3% (4) | 1% (8) | | | 11% (37) | 7% (76) | 8% (113) | |
| Spherical | | 54% (552) | 48% (73) | 53% (625) | | | 7% (24) | 24% (245) | 19% (269) | |
| Consistency | | | | | | | | | | |
| Conforming | 1205 | 20% (210) | 19% (31) | 20% (241) | P=0.305 | 1329 | 49% (193) | 10% (90) | 21% (283) | P<0.001 |
| Rigid | | 55% (578) | 61% (97) | 56% (675) | | | 32% (128) | 66% (613) | 56% (741) | |
| Semi-rigid | | 25% (258) | 19% (31) | 24% (289) | | | 19% (74) | 25% (231) | 23% (305) | |
| Co-presence | | | | | | | | | | |
| Package | | 1% (13) | 6% (9) | 2% (22) | P<0.001 | | 1% (3) | 1% (6) | 1% (9) | |
| Inedible of FPCI | 1203 | 0% (4) | 0% (0) | 0% (4) | | 1589 | 0% (2) | 0% (5) | 0% (7) | P<0.001 |
| Co-presence | | 15% (161) | 10% (16) | 15% (177) | | | 7% (30) | 6% (61) | 6% (91) | |
| Not industrial component | | 34% (359) | 24% (38) | 33% (397) | | | 82% (364) | 64% (738) | 69% (1102) | |
| Whole object (no co presence) | | 41% (425) | 46% (72) | 41% (497) | | | 9% (39) | 25% (290) | 21% (329) | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Broken object (no co presence) | | 6% ( 65) | 12% ( 18) | 7% ( 83) | | | 1% ( 5) | 1% ( 16) | 1% ( 21) | |
| unknown | | 2% ( 20) | 2% ( 3) | 2% ( 23) | | | 0% ( 1) | 3% ( 29) | 2% ( 30) | |
| Volume | 634 | 16.8/37.7/67 | 9.4/16.8/25.1 | 16.8/31.4/67 | P<0.001 | 377 | 3.9/15.7/67 | 31.4/78.5/314 | 25.1/67/254.3 | P<0.001 |
| Ellipticity | 650 | 1/1/2 | 1/1/1.67 | 1/1/1.97 | P=0.808 | 381 | 1/4/20 | 1/2.83/10 | 1/3/13 | P=0.13 |
| Adult presence | | | | | | | | | | |
| Yes | 1126 | 36% (359) | 39% ( 54) | 37% (413) | P=0.571 | 1008 | 78% (142) | 63% (520) | 66% (662) | P<0.001 |
| Action | | | | | | | | | | |
| Eating | 1199 | 9% (100) | 4% ( 6) | 9% (106) | P=0.135 | 1162 | 83% (265) | 55% (464) | 63% (729) | P<0.001 |
| Other | | 8% ( 90) | 9% ( 12) | 9% (102) | | | 3% ( 9) | 6% ( 48) | 5% ( 57) | |
| Playing | | 82% (870) | 87% (121) | 83% (991) | | | 14% ( 44) | 39% (332) | 32% (376) | |

**Table 2.** Description of the broken objects.

| **Broken objects** | **Details** | **%(N)** |
|---|---|---|
| accessorize | piece of hairclip | 1(1) |
| coin | token coin phone | 1(1) |
| cotton | piece of cotton wool, cotton ball, cotton cloth | 14(23) |
| jewellery | chain, part of metal earring | 2(4) |
| metal | piece of metal | 1(2) |
| other organics | piece of wood, textile | 2(3) |
| other inorganics | plastic tube, plastic part of mobile, polythene bag, piece of auricular, sequin, toothpick, piece of match | 5(8) |
| pearl, ball and marble | pearl, ball and marble | 1(2) |
| pebble | piece of grit | 6(9) |
| pin and needle | piece of pin | 1(1) |
| plastic | piece of plastic, part of straw, part of a mobile for children, part of box of bricks, watch piece, plastic fork | 20(33) |
| polystyrene | Part of expanded plastic, foam piece | 8(13) |
| sponge | piece of sponge | 6(10) |
| stationary | piece of pen and pencil, pen tip, piece of eraser, pencil and black lead, part of writing chalk pencil | 12(20) |
| toy | piece of plastic figure, wheel of a toy car, combination box, plasticine, piece of doll, piece of whistle, balloon, part of toy aeroplane, part of plastic toy | 20 (33) |

**Table 3. Description of objects with volume lesser than 16.74 mm$^3$.**

| Foreign Body | Details | %(N) |
|---|---|---|
| battery | battery, watch battery | 2(5) |
| button | button | 1(2) |
| coin | coin | 0(1) |
| jewellery | part of earring, piece of metal | 2(4) |
| pearl, ball and marble | plastic ball, plastic and metal beads, rubber ball, marble, pearl | 37(79) |
| pebble | stone, grit, pebble | 2(5) |
| pin and needle | screw, needle or stick, drawing pin, staple | 4(9) |
| plastic | piece of plastic | 1(2) |
| polystyrene | foam piece, polystyrene bead | 3(7) |
| sponge | piece of sponge | 0(1) |
| stationery | pencil lead, crayon | 2(5) |
| toy | plastic screw, piece of doll, plasticine, plastic ring, piece of toy | 7(14) |
| other inorganics | foam rubber, sequin, piece of metallic tube, plectrum, ball bearing | 3(6) |
| organic | insects, bean and pea, fish bone, chicken bone, peanuts, nuts, seed and grain, apple stone, berry, pill, grape, teeth, orange peel, sugar marble, sweet | 34(71) |

**Table 4.** Predictive performance of classification tree models over the 1000 bootstrap samples.

| Index | Original sample | Validation sample | Derivation sample | Optimism | Corrected index |
|---|---|---|---|---|---|
| **ICD931-932** | | | | | |
| ROC aread | 0.74 | 0.72 | 0.75 | 0.03 | 0.71 |
| Brier score | 0.11 | 0.11 | 0.1 | -0.01 | 0.1 |
| **ICD933-935** | | | | | |
| ROC aread | 0.75 | 0.74 | 0.75 | 0.01 | 0.74 |
| Brier score | 0.16 | 0.19 | 0.17 | -0.02 | 0.18 |

**Emergency rescue maneuvers for foreign body airway obstruction: an update on effectiveness and dissemination among public**

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**Abstract**

Inhalation of a foreign body (FB) may be a life-threatening emergency in children. Emergency rescue maneuvers are intended to expel the foreign body from the airway, to re-establish airway patency as well as to re-establish – at least in part – airflow towards the lungs.

These maneuvers must be performed as soon as possible after the aspiration of the FB by the person who witnesses the inhalation or by the first person who sees the choking child.

This paper presents a review of the literature concerning emergency rescue maneuvers which can be performed by the child's relatives or, more in general, by people who are not healthcare professionals.

Currently, the available literature describes seven types of emergency rescue maneuvers which can be performed to manage foreign-body airway obstruction in children: force of gravity, coughing, finger sweep, back blows, chest thrusts, abdominal thrusts, use of devices. Studies about each maneuver are scanty and evidence of their effectiveness is very poor. Several institutions issued recommendations concerning emergency rescue maneuvers to be adopted in the case of FB obstructions. However they are based almost exclusively on expert consensus or on low-level evidence. Among them only two indicate the strength of recommendation and/or the level of evidence. Also, there are significant differences between the recommendations given by each institution. All the recommendations are old and they should be reviewed and updated.

Conclusions: Evidence on the effectiveness of the foreign body obstruction rescue maneuvers is scarce. More research is needed to establish what is the most effective means for non-professional rescuers to relieve children's acute FB obstructions

**Keywords**: foreign body, airway obstruction, Heimlich maneuver, chest thrust, abdominal thrust, back blow.

## Introduction

Inhalation of a foreign body (FB) may be a life-threatening emergency in children. The FB may indeed partially or completely obstruct the airway and cause hypoxic damage. It is difficult to estimate the incidence of foreign body obstructions (FBO), because a large amount of FBOs which are relieved without the intervention of a healthcare professional are not reported in statistics. The highest mortality rate due to FBO in children was estimated to be 7.5% (1).

The most frequent signs of FBO are the sudden onset of respiratory distress and signs of choking, such as coughing, stridor or wheeze. However, if the obstruction is complete, the subject is unable to vocalize. FBO differs from the other causes of the same symptoms because it has a sudden, unexpected onset, which is not preceded by fever nor by other respiratory symptoms.

Emergency rescue maneuvers are intended to expel the foreign body from the airway, to re-establish airway patency as well as to re-establish – at least in part – airflow towards the lungs.

These maneuvers must be performed as soon as possible after the aspiration of the FB by the person who witnesses the inhalation or by the first person who sees the choking child.

Given that FBO very often occurs in the presence of the child's mother or relatives, emotional involvement and panic can represent a serious obstacle to the effectiveness of emergency rescue maneuvers. However, the available epidemiological data show that in most cases the FBO is relieved before the intervention of professional rescuers (2, 3).

This paper presents a review of the literature concerning emergency rescue maneuvers which can be performed by the child's relatives or, more in general, by people who are not healthcare professionals.

To retrieve relevant literature, we used the databases of scientific articles Pubmed and Embase, the Cochrane Collaboration's database of systematic reviews and the database of guidelines of the Agency for Healthcare Research and Quality. We used the following keywords: airway obstruction [Mesh], foreign body, foreign body inhalation, foreign body obstruction, foreign body airway obstruction, choking, chest thrust*, abdominal thrust*, chest compression*, abdominal compression*, sub-diaphragmatic compression*, back thrust*, back slap*, back blow*, back strike*, finger sweep*, Heimlich.

We did not set any limit as to the age of subjects and to the type of publication or study. With respect to the language, the research was limited to the following ones: English, French, Spanish, Portuguese and Italian. We retrieved 284 articles, which we reduced to 94 after reading the abstracts, 5 guidelines and no systematic review. We were able to find some papers after analyzing the bibliographical references of the articles we had already retrieved. The papers we collected

mainly describe seven types of emergency rescue maneuvers which can be performed to manage foreign-body airway obstruction in children.

**The force of gravity**

In infants and in small children one of the maneuvers that are instinctively used by mothers or bystanders consists in positioning the choking child head down, holding him/her by the legs, in order to enable gravity to bring the foreign body back in the oral cavity (4-6). This maneuver has been recently described (7) also in the hospital setting, in combination with the use of a forceps.

A study of 1978 in cadavers and anesthetized healthy volunteers argued that turning the subject upside down increases the effectiveness of emergency rescue maneuvers (6). However, if a FB is partially obstructing the trachea below the vocal cords, positioning the child head down may cause a complete obstruction, as the FB may get stuck between the vocal cords themselves (8). Furthermore, placing the child head down may entail further risks linked to the position, such as the risk of falling and of head injury, or the risk of increasing intracranial pressure, especially in newborns. Several authors advise not to use this maneuver (9). On the contrary, in infants (children under 1 year of age), several recommendations suggest to place the subject in a head downwards position, in such a way to add gravity to the forces applied to the infant's chest to expel the FB (10, 11)

**Encourage coughing**

Through coughing, the expulsion of the FB is induced by forced expiration following an increase in intrathoracic pressure against a closed glottis. If the patient is conscious and able to carry out verbal orders, encouraging him/her to cough is one of the most effective ways to dislodge the object. Two studies demonstrated that none of the existing methods to relieve FBO can generate an intrathoracic pressure, an airflow and an expired volume comparable to the ones caused by coughing (12, 13). A role seems to be played in this by the fact that, in the case of a partial obstruction, the subject coughs at the end of inspiration, when the lung volume has reached its maximum. The increase in lung volume before emergency rescue maneuvers seems indeed to increase the effectiveness of all rescue procedures (13). Coughing seems to be able to relieve foreign-body airway obstruction in approximately 38% of cases (3), with a higher probability in older children. However, this method cannot be used or may be ineffective in very young children and in children with serious cognitive disabilities.

**Finger sweep**

Finger sweep is another maneuver instinctively performed by bystanders of a choking child. Given the small airway caliber in children, inserting fingers in the upper airway involves a high risk of pushing the FB more deeply into the airway (13). Therefore, finger sweep should be performed only when the FB is visible to the rescuer (i.e. if it is located in the upper airway) (10, 11, 14-16). Furthermore, it is recommended to use only one finger like a hook, given that the use of two fingers like a forceps is ineffective or may even be impossible due to the small size of the child's oral cavity and pharynx. The occurrence of laryngeal damage caused by finger sweep was also reported (17-18).

**Back blows**

Delivering back blows in the dorsal part of the chest is a maneuver instinctively performed by mothers and bystanders in combination with other maneuvers.

Back blows are usually delivered at the beginning of the rescue procedure (10, 14-16). They are delivered with the heel of one hand in the middle of the back between the shoulder blades. The back blow seems to dislodge the FB from the position in which it has been stuck after the inhalation, thus making it easier to expel it through coughing or through other rescue maneuvers.

Evidence of the effectiveness of back blows is limited and contrasting. A study of 1977 carried out in anesthetized human beings did not record any significant increase in intrathoracic pressure, airflow and expired volume following the delivery of back blows (19). On the other hand, other studies in anesthetized volunteers showed that back blows generate a higher increase in intrathoracic pressure than other techniques (chest and abdominal thrusts), even if for a fraction of time well below one second. However, these studies did not show any significant increase either in expired airflow or in volume after the delivery of back blows (6, 13). An experimental study carried out in 1982 in awake subjects showed that back blows because a lower increase in intrathoracic pressure than abdominal thrusts (8). Heimlich advises against the use of back blows on the basis of studies which show that the FB may be pushed more deeply into the airway and not necessarily towards the oral cavity and the exterior (9). In their study based on the use of a manikin, Day et al. argued that, by determining an upward and forward acceleration of the neck that is approximately three times the force of gravity, back blows may dislodge a supraglottic FB towards the lower airway because of Newton's third law (8). On the basis of these data, some authors maintain that back blows should never be delivered at the beginning of the rescue maneuver, but only after other maneuvers have had no effect (9).

**Chest thrusts**

This maneuver consists in exercising an external pressure on the rib cage, which generates an increase in intrathoracic pressure and the propulsion of the FB towards the oral cavity and towards the exterior. Some studies carried out in cadavers and in anesthetized volunteers investigated the effects caused by chest thrusts. A crossover RCT carried out in 2000 in 12 cadavers of recently dead adults (20) showed that, on average, chest thrusts generate a higher intrathoracic pressure than abdominal thrusts. A study of 1976 carried out in 6 anesthetized subjects (19) showed that chest thrusts generate on average a higher pressure and airflow than abdominal thrusts, both in a supine and in a sitting position. Another experiment carried out in 1977 in anesthetized subjects led to similar results (12). However, these studies did not investigate the capability of the maneuver to expel a FB. A study of 1978 in cadavers and anesthetized subjects showed that chest thrusts lead to a higher pressure increase than abdominal thrusts. However, in the tests carried out with a FB, chest thrusts only managed to dislodge the FB when the obstruction was not complete (6). Other authors argued that a sizeable portion of the energy delivered on the rib cage is wasted and transmitted to the diaphragm (21, 22).
Several case reports described adverse events linked to the use of this technique, among which pain in the rib cage, rib and sternal fracture, ruptured stomach and liver (23-25).

**Abdominal thrusts (or sub-diaphragmatic thrusts)**
This rescue maneuver consists in exerting a force under the diaphragm of the choking child and in pushing it upwards. This maneuver causes an increase in intrathoracic pressure which transmits the FB enough energy to push it towards the oral cavity and the exterior. This maneuver was first described by J. Heimlich in 1974 (26) and, following several reports on the successful use of this technique, it spread very rapidly. This technique was based on the studies carried out by Heimlich in anesthetized subjects and in animals (27). Since then, several articles have been published on a large number of case series which support the effectiveness of the maneuver (9, 27-30).
Abdominal thrusts are delivered as follows: the rescuer stands or kneels behind the child and places their arms under the child’s arms and encircles the child’s torso. The rescuer clenches their fist and places it between the umbilicus and xiphisternum, grasps this hand with the other hand and pulls sharply inwards and upwards.
Several case reports describe damage occurred to the child due to abdominal thrusts, among which hemoptysis (31), pancreatic lesions (32), pneumomediastinum and pneumoperitoneum (33).
In infants the risk of abdominal lesion is estimated to be higher because of the horizontal position of ribs, which makes abdominal organs more susceptible to trauma (10).

Both with respect to chest thrusts and to abdominal thrusts, the quantity of energy exerted by the rescuer can hardly be standardized, as it largely depends on the rescuer's and on the child's sizes, thus changing in an unpredictable way. Some authors stressed that some lesions caused by abdominal thrusts may have an insidious progression. As a consequence, they suggest that all victims treated with this maneuver should be examined to detect the presence of any chest or abdominal lesion (34, 35).

**Use of devices**

The literature describes several instruments for the extraction of a foreign body in a situation of emergency, among which the Magill forceps and the Kelly forceps for solid foreign bodies (37, 38) and other devices for the aspiration of liquids (2). However, these instruments are generally not available in the settings where FBO occurs. Furthermore, these devices should only be used by specially trained personnel (10, 14).

**Guidelines**

Several institutions issued recommendations concerning emergency rescue maneuvers to be adopted in the case of FBO and the circumstances in which they should be performed: the American Heart Association in 2005 (14), the International Liaison Committee for Resuscitation (ILCOR) in 2006 (16), the Australian Resuscitation Council (ARC) in 2006 (15), the UK Resuscitation Council (Resus) in 2005 (11) and the European Resuscitation Council (ERC) in 2005 (10).

Given the shortage of indications in the literature, the recommendations are based almost exclusively on expert consensus or on low-level evidence. Among the aforementioned guidelines, only the ones by ARC and ILCOR indicate how strong the recommendation is and/or the level of evidence on which they are based. It is particularly important to underline that all the recommendations are very old and that they should be reviewed and updated.

*AHA recommendations*: The recommendations concerning the relief of foreign-body airway obstruction are contained in the Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care of Pediatric and Neonatal Patients: Pediatric Basic Life Support (14). If the obstruction caused by the FB is not complete (the child can make some sounds), the AHA recommends allowing the victim to cough and constantly monitoring if the FB is expelled as well as the subject's conditions. If the obstruction is, or becomes, complete (the child is unable to make a sound), the AHA recommends intervening with external maneuvers and distinguishes two cases: children over 1 year and children under 1 year (infants). In the first case, the recommended procedure consists in performing sub-diaphragmatic abdominal thrusts until the object is expelled or

the victim becomes unresponsive. For an infant, abdominal thrusts are not recommended because they may damage the liver. Instead, the rescuer should deliver 5 back blows, keeping the infant in a prone position across their lap, followed by 5 chest thrusts until the object is expelled or the victim becomes unresponsive. When the victim becomes unresponsive cardiopulmonary resuscitation should be performed. Before commencing it, the rescuer should look into the upper airway to check if the FB is visible in the pharynx. If this is the case, the rescuer can attempt to remove the object with a finger. Blind finger sweep should never be performed because of possible damage to the pharynx.

*ARC recommendations* (15): The rescuer should constantly monitor the victim of FBO, because the obstruction may be gradual and progressive. The signs for recognition of FBO are agitation, coughing, gasping sounds or loss of voice. Contrary to the AHA, the ARC explicitly advises against the use of abdominal or sub-diaphragmatic thrusts in the management of foreign-body airway obstruction and instead recommends the use of back blows and chest thrusts.

In the case of a partial airway obstruction, the rescuer should encourage the victim to cough. If cough is, or becomes, ineffective, but the patient is conscious, the rescuer should first perform five back blows with the heel of one hand in the middle of the back between the shoulder blades and check to see if each back blow has relieved the airway obstruction. An infant should be placed in a head downwards position across the rescuer's lap. If back blows are unsuccessful the rescuer should perform 5 chest thrusts and check to see if each chest thrust has relieved the airway obstruction. The landmark and the execution of chest thrusts are identical to chest compressions, but the former are sharper and delivered at a slower rate. The infant should be placed in a head downwards supine position across the rescuer's thigh. Children can be treated in the sitting or standing position. If the obstruction is still not relieved, the rescuer should continue alternating five back blows with five chest thrusts. If the subject loses consciousness, the rescuer may attempt to use the finger sweep if the solid FB is visible in the upper airway, and later commence resuscitation.

Figure 1 shows the flow chart of emergency rescue maneuvers according to the ARC recommendations.

*ERC recommendations* (10): Spontaneous cough is the most effective method to relieve foreign-body airway obstruction. Active interventions to relieve the obstruction must therefore be commenced when coughing becomes ineffective. Signs of ineffective coughing are the victim's inability to vocalize, silent cough, cyanosis and a decreasing level of consciousness. Cough is considered effective when it is loud, when the child cries or responds verbally to questions and is able to take a breath before coughing. If cough is effective, the child should be encouraged to cough and carefully monitored.

If cough is ineffective but the child is conscious, the rescuer should give five back blows, followed in children over 1 year of age by five abdominal thrusts and in infants by five chest thrusts. Abdominal thrusts must be absolutely avoided in infants.

In infants back blows are performed by placing the infant in a head downwards prone position across the rescuer's lap. The infant's head should be supported by keeping the jaw between the thumb of one hand and two fingers from the same hand, taking care not to compress the soft tissues under the jaw itself. Also for children over 1 year of age the ERC recommends positioning them in a head downwards position. If this is not possible, the child should be placed in a forward-leaning position, with the rescuer delivering the back blows from behind.

In infants chest thrusts are performed by turning the infant in a head downwards supine position and by encircling the occiput with the hand that is not being used for the maneuver. The landmark for chest thrusts is approximately a finger's breadth above the xiphisternum. The chest thrusts must be sharper and delivered at a slower rate than chest compressions.

Abdominal thrusts are performed by standing or kneeling behind the child. The rescuer should place their arms under the child's arms and encircle the child's torso. The rescuer should clench their fist and place it between the umbilicus and xiphisternum. This hand should be grasped with the other hand and both are used to pull sharply inwards and upwards. While performing this maneuver, the rescuer should not apply pressure to the xiphoid process and to the rib cage.

If the child becomes unconscious, he/she should be placed in a supine position and resuscitation should be commenced. To this purpose, the rescuer should open the child's mouth and look for any visible object. If this is the case, the rescuer can attempt to remove it using only one finger. Blind finger sweeps should not be attempted, because the FB may be pushed more deeply into the pharynx and cause injury.

A child treated with abdominal thrusts who recovers from FBO should be carefully examined to detect any intra-abdominal lesion.

Figure 2 shows the flow chart for emergency rescue maneuvers according to the ERC recommendations.

*Resus recommendations* (11): This document basically contains the same indications of the ERC recommendations without any significant change.

*ILCOR Consensus* (16): This document represents a synthesis and mediation of the different positions of the institutions which participated in its drawing up. This publication is very cautious about the evaluation of available evidence and it acknowledges that it is difficult to establish which maneuver (back blows, chest thrusts, and abdominal thrusts) should be performed first, as well as that it may be necessary to use different techniques at the same time. However, the ILCOR

Consensus does not advise against any of the possible maneuvers. It recommends commencing resuscitation in victims who are unconscious and using finger sweep only if there is visible solid material in the airway of an unconscious patient.

Therefore, there are significant differences between the various recommendations. One pertains to the use of abdominal thrusts in children over 1 year of age, which is recommended in the ERC and AHA guidelines, whereas the ARC advises against their use. Moreover, some researchers strongly recommend the use of abdominal thrusts also in infants, maintaining that evidence of an increased risk of trauma is not stronger than evidence concerning chest thrusts (9). The same researchers also held that back blows should be avoided (8), because this maneuver may push the foreign body more deeply into the airway, and that it should only be used as a last resort in unconscious patients (9).
A recent study (38) proposed that abdominal thrusts may become more effective by placing the patient in a lying position. However, this study only focused on adults and its results probably cannot be extended to children.

**Comparison of techniques**

Scientific literature on the relief of foreign-body airway obstruction is surprisingly limited and definitely outdated. In the last 5 years only one experimental study based on manikins (38) and 10 observational studies have been published. The observational studies are for the most part case reports, case series or broader epidemiological studies which mainly report cases in which foreign bodies have been removed not in emergency situations, but in a hospital setting (39-46). As regards the out-of-hospital setting, there are only two descriptive studies concerning actions taken by bystanders (2, 3) and no data is available on their outcomes, if not in the form of a case report or of a case series. Therefore, all the evidence on the effectiveness of the aforesaid emergency rescue maneuvers is low-level.
In particular, there is no experimental study that compares the different methodologies and their effectiveness, except for the study by Ruben (6). However, this study was carried out by connecting the airways of anesthetized and intubated volunteers to the reproduction of human upper airway, artificially obstructed by a FB. This study compared the effectiveness of back blows, chest thrusts and abdominal thrusts and it concluded that the pressures generated by the three maneuvers could not relieve complete obstructions, but only partial ones. The pressure generated by chest thrusts turned out to be slightly higher than the one generated by abdominal thrusts.
Some experimental studies were based on simulations carried out in human beings, animals or manikins, but they did not consider relief of the obstruction as an outcome. Instead, they measured

several indicators of the effectiveness of the various maneuvers (airflow, intrathoracic pressure, expired volume) (12, 19). Two retrospective observational studies compared the outcomes of the use of the different techniques: one was carried out by collecting data from big archives of hospital and community-based emergency services and the other one by distributing a questionnaire (13, 47). These studies seem to demonstrate that the effectiveness of back blows is limited and that chest thrusts and abdominal thrusts have a similar effectiveness. However, these results should be taken with great caution, because in most of the cases different techniques were used at the same time. This means that it is not possible to establish which maneuver managed to relieve the obstruction. Epidemiological data mentioned by Heimlich show a considerable reduction in mortality due to FBO in the areas where abdominal thrusts were introduced (9). However, these results should also be taken with caution, because they derive from retrospective studies concerning short periods of time.

The study by Gordon showed that, whatever the technique, the increase in lung volume before the maneuver, including spontaneous cough, increases the effectiveness of the technique (12). This seems to support the usefulness of delivering chest or abdominal thrusts at the end of inspiration in victims of partial obstruction.

For obvious ethical reasons it is problematic to carry out experimental studies on the effectiveness of emergency rescue maneuvers. Furthermore, given that current guidelines all recommend a combination of different maneuvers, it is also difficult to examine the data registered by emergency services. Nevertheless, the currently available evidence seems to be insufficient to establish which technique is the most effective in relieving the various types of foreign-body airway obstruction in the various subjects and in the various circumstances. Therefore, additional studies are required to confirm or disconfirm the practices recommended in the existing guidelines.

**Knowledge and dissemination of emergency rescue maneuvers**

The effectiveness of rescue maneuvers is based on their knowledge and dissemination among lay people and, in particular, among parents of young children and among all those who look after children. If there is no lay rescuer who attempts a rescue maneuver and the victim has to wait for the arrival of healthcare providers, there is a risk of asphyxia, of permanent damage to the child or of death. A key aspect is the simplicity of instructions, which makes it easier for lay rescuers to memorize them and to follow them during an emergency (10, 14).

In the literature there are very limited data on the knowledge of the different rescue maneuvers by the general population and on the efficacy of possible strategies to spread them. An American study of 1999 (3) remarked that 85% of foreign-body airway obstructions are relieved before the arrival

of community-based emergency services. This percentage decreases to 59% in another American study dating back to 2004 (2). In 38% of cases it was the child himself who managed to relieve the obstruction on his own (3). According to the 2004 research, the methods more frequently used by parents to dislodge the foreign body were back blows and then finger sweeps in the upper airway. Abdominal thrusts were used in only 5% of cases, thus suggesting that the diffusion of this technique is limited (2). Two other studies show in general that both lay people and healthcare providers are not adequately prepared to manage foreign-body airway obstruction and to perform emergency rescue maneuvers. An article dating back to 2006 described the inadequate preparation of a number of pediatric clinics in the USA (49). A similar situation was found in a sample of American primary schools in 2005 (50). Both studies concluded that it is necessary to improve the specific training of all those who look after children in the different settings of a child’s social life. On the other hand, two case reports (51, 52) showed that emergency rescue maneuvers can be performed successfully by bystanders who receive instructions on the phone from emergency service providers. There are only very few studies on the efficacy of educational or training initiatives for the general population concerning foreign-body airway obstructions and how to relieve them. A Canadian study of 2006 showed that a specific regional campaign for the prevention of foreign-body airway obstruction did not generate a reduction in the number of events and in their consequences (53). Similar results were obtained by a Norwegian research in 1998, in which educational material on resuscitation and maneuvers for the relief of FBO was sent to the whole population by mail. The authors of this research concluded that this type of initiative does not have any effect on the ability of lay people to manage emergencies (54) and that only the possibility to train with manikins enables them to acquire basic skills to perform some maneuvers.

FBO in children occurs very rarely. Therefore, the effectiveness of rescue maneuvers performed by bystanders depends on their preparation. Lay people need periodical retraining, because, since they have very few possibilities to practice what they have learnt, they may forget it.

Furthermore, given that FBO mostly occurs in the presence of close relatives of the victim, the high level of emotional stress caused by the situation can make it even more difficult to implement what they may have learnt about rescue maneuvers. Large-scale educational programs seem to have limited effects, even if it is generally acknowledged that it is necessary to train a significant percentage of the general population in basic rescue procedures, in order to increase the chances of survival of each member of the community in case of a life-threatening event (157). The ability of emergency service providers to clearly explain the required maneuvers to a lay rescuer is probably one of the elements on which successful relief of FBO currently depends.

## Figures

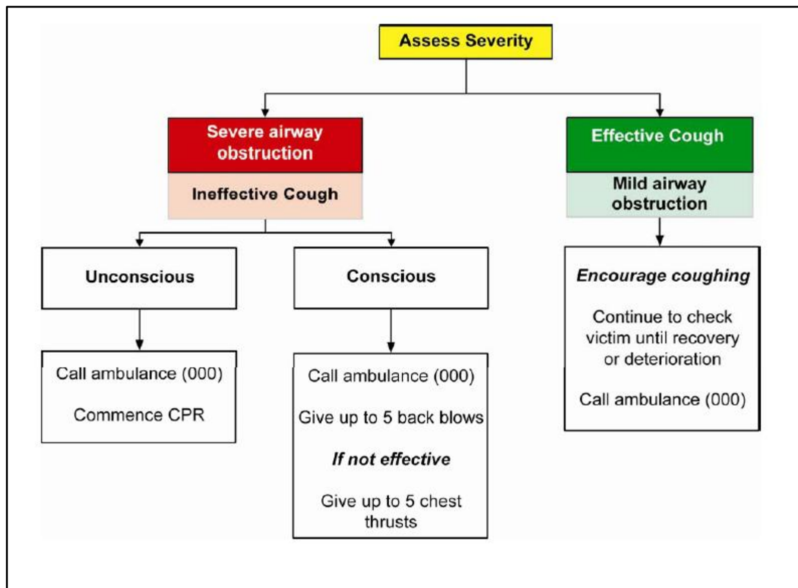


Figure 1: ARC algorithm of emergency rescue maneuvers in children (15).

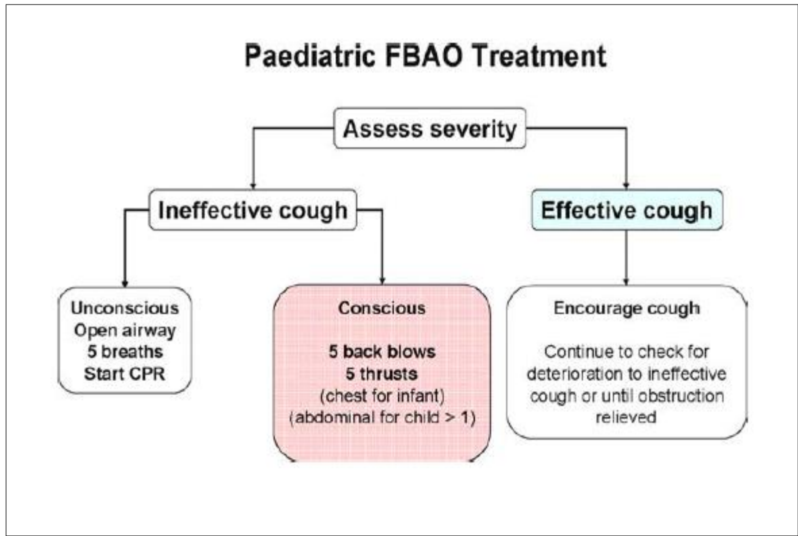


Figure 2: ERC algorithm of emergency rescue maneuvers in children (10)

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**Title: Prevention and early recognition: the role of family paediatrician**

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**Abstract**

Even if it is empirically evident that paediatricians play a key role in diagnosis, treatment and prevention of FB injuries, almost all studies have focused on the subset of injured children who receive medical care in the hospital or in the Emergency Department; moreover, a lack of scientific interest to improve information about paediatric injuries in primary care seems to exist. Primary care physicians can play an important role if they promptly identify suspect unrecognized FB aspiration in children. Moreover, prevention is a cornerstone of paediatric practice, and paediatricians, as reliable sources of information, may be efficacious in promoting injury prevention message. Given the paucity of works finalized to evaluate the role of injury preventive strategies in primary care it is arduous to identify an ideal approach to implement counselling strategies. However, evidences obtained elsewhere have suggested that effective preventive strategy origins from an effective communication technique, moreover, the probability of success is greater when the attention toward the problem is greater; particularly, the postpartum period is a time of tremendous change, increased health problems, and emotional upheaval for new parents. General practitioners are in an ideal position to assist families during this period and may consider a sooner rather than later, approach to injury prevention education.

**Keywords:** Foreign body injuries, primary care, general practitioner

## Introduction

Injuries are an important public health problem. In industrialized countries they are the leading cause of death in childhood, accounting for 40% of all children deaths between the ages of one and 4 years [1].

Particularly, the aspiration of a foreign body is an event which is reasonably frequent and dramatic in children and is one of the main causes of mortality and morbidity due to injuries in children up to three-four years of age. The European Union mortality rate for suffocation, in fact, exceeds one death per 100.000 persons [2]; moreover, social and economic consequences of foreign bodies inhalation are considerable, due to high costs of treatment, particularly when surgery is needed[3]. Management of a choking child often involves collaborative efforts among the primary care physician, emergency room physician, otolaryngologist, pulmonologist, and radiologist [4]. Children with conditions that can evolve into potentially life-threatening emergencies, such as upper airway obstruction, are often brought to the physician's office for medical attention [5]. Even if it is empirically evident that paediatricians play a key role in diagnosis, treatment and prevention of childhood injuries, almost all studies have focused on the subset of injured children who receive medical care in the hospital or in the Emergency Department [6].

Only a little knowledge exists about the majority of injured children who receive evaluation and treatment in primary care setting. Lack of scientific interest to improve information about paediatric injuries in primary care seem to be particularly evident when the event is due to the aspiration of a foreign body. Medical literature, as a depository of knowledge and a medium of communication between researchers and clinical professionals, may offer insight into which is the contribution to the knowledge of all disciplines and how attitudes toward an issue have changed over time. A free text search on PubMed Database without any limits, finalized to identify all articles referring to foreign body inhalation (*foreign body AND ((aspiration*) OR (inhal*) OR (obstruction) OR (choking) OR (asphyxiation)) AND injury AND children*), retrieved in Mars 2009 1289 papers; if the research is restricted *(foreign body AND ((aspiration*) OR (inhal*) OR (obstruction) OR (choking) OR (asphyxiation)) AND ((primary care) OR (family physician) OR (family paediatrician)) AND injury AND children)* in order to select papers focused on

primary care, only 18 papers were found. Among them, no more than 14 are actually related to the issue.

The aim of the present paper is to briefly review the epidemiology and pathophysiology of choking and foreign body aspiration in children and to highlight the primary care professionals' key contribution to diagnostic, therapeutic and preventive process.

**Diagnosis of foreign body inhalation**

Children's airways differ from those of adults in several aspects and these differences contribute to the ease with which the child's airways can become obstructed. Even a small reduction in the size of airways can cause a significant increase in airway resistance; therefore, the consequences of foreign bodies' inhalation could be dramatic.

Commonly aspirated objects include food, coins, small toys, small pieces of jewellery; organic material, mainly peanuts, represents 60-75% of the findings, particularly in 0-3 year age group [2]. Foreign-body aspiration should be suspected in any child presenting with acute onset of respiratory distress in association with coughing, gagging and stridor, especially when there is no history of prodromal illness [5].

Size, shape, type and position of the FB determine an important variability on clinical picture [7]: clinical presentation ranges, from severe asphyxia to clinical situation with insidious and vague symptoms, which are difficultly and frequently late diagnosed [8].

A witnessed choking event is the most important historical clue to make an early diagnosis of FBA: Metrangelo et al. [9] underlined that the presence alone of a choking crisis in the child's history should alert the physician to the possibility of FB aspiration. The most reported symptom, alone or in association, is sudden chough. The typical clinical triad of localized wheezing, coughing and decreased breath sound is reported in a percentage of cases ranging from 15 to 30 %.[10] Despite the presence of a positive history, the diagnosis of FB aspiration is often delayed, because the child is asymptomatic at physical examination and clinical symptoms or radiological findings are not sufficiently specific and sensitive to demonstrate the presence of a foreign body in the bronchial tree [10].

Published case series provided evidence that the absence of clinical symptoms in a child with a positive history of FB aspiration cannot exclude the presence of a foreign

body into the bronchial tree. Moreover, the majority of inhaled FB in children are unique and radiolucent, and the value of chest radiography in making the diagnosis of FB aspiration remains controversial: radiopaque foreign bodies can be easily and reliably detected and are reportedly in 4% to 30% of the patients with FB aspiration, while a high percentage of children have completely normal radiological findings [11]. Besides the absence of specific clinical and radiological findings before bronchoscopy, other important reasons for diagnostic delay, are the resemblance of the symptoms to those of bronchial asthma or bronchiolitis, and the tendency of professionals to procrastinate or try first conservative treatment [10 12].

When the medical history is unclear, higher is the risk of delayed diagnosis of FB aspiration. The time between the choking event and diagnosis may range from less than 1 h to several months, especially in children without a medical history of FB aspiration [10].

Because misdiagnosed and retained foreign bodies may result in early and late severe complications including asphyxia, pneumonia, atelectasis, or bronchiectasis, timely diagnosis and removal is important to prevent them [13].

Foreign bodies should always be removed only in a hospital equipped with expert medical staff with experience in pediatric bronchoscopy and, frequently, a child see several physicians before undergoing bronchoscopy to identify the presence of a foreign body [10].

Primary care physicians can play an important preventive role if they promptly identify children with history suggestive of FB aspiration or suspect unrecognized FB aspiration in children with unexplained persistent cough and refractory parenchymal infiltrates. These children can be quickly referred to hospitals where a bronchoscopy can be performed and the foreign body be extracted in order to prevent delayed diagnosis and complications.

**Prevention of Foreign Body inhalation in primary care setting**

Researches in public health during the last 30 years have lead to identify childhood injuries risk factors: in fact, injuries are not simply accidents but events that in many cases can be prevented with appropriate interventional strategies. Various means have been used to reduce the burden of injury including an array of legislation finalized to create a safer environment, changes in product design and public education campaigns [14]. Since many parents lack knowledge about the threat of injury and effective means

of prevention, offering injury-prevention counselling by health care providers could be an effective strategy to reduce the injury risk.

To avoid injuries determined by the inhalation of foreign body it seems to be particularly useful that parents become able to identify potentially dangerous objects: they have to know that food as peanuts, coins, small parts of toys or jewels and pieces of packages, could represent a serious threat for children. Moreover, parents should be conscious that some situations are particularly risky for children: in fact, this injury usually occurs when parents are present but their attention towards children is low, as typically happens during parties or festivities. It is essential that parents are able to promptly intervene when children inhale a foreign body, performing the Heimlich manoeuvre in order to remove the object from the airways. Therefore, parents should be trained and assisted in acquiring all information and abilities to cope with these events.

Primary care physicians can play a critical role in increasing parents' education during each well-child office visit. Prevention, in fact, is a cornerstone of paediatric practice, and paediatricians, as reliable sources of information, may be efficacious in promoting injury prevention message.

Primary care providers examine young children on numerous occasions in the first 5 years of life [15]. As part of these well-child examinations, the American Academy of Paediatrics Committee on Practice [16] recommends physician's counselling on injury prevention: paediatrician should provide advice to parents on hazards in the home and outside, suggest safety behaviours and provide information on first aid [15]. Particularly, given the high incidence of food related injuries, the dissemination of information among parents on potentially dangerous foods and the need for safe eating practices may be recommended by educational intervention.

However, verifying the efficacy of education strategies is a difficult task: only few studies finalized to evaluate results of educational intervention report injury outcomes and past studies on the effectiveness of injury prevention counselling in primary care settings show contrasting results. Moreover, there is a lack of studies specifically devoted to evaluate if educative interventions made by family physicians are effective or not in preventing injuries determined by foreign bodies' inhalations [17, 18].

Limited benefits of education in clinical settings finalized to prevent injuries (other than foreign bodies injuries) have been frequently attributed to the adoption of ineffective communication techniques, relying on negative messages frightening

parents, while approaches designed to motivate people to change behaviour have been successful in other areas of patient education and could be applicable to injury [19]. Obviously, the efficacy of these educational interventions is strictly related to the physicians' attitude to spend enough time with patients in order to provide all needed information. However, several studies have suggested that a lack of time and expertise are often quoted as factors that limit the provision of injury prevention in primary care: usually, preventive counselling about injury prevention is either not discussed at all or covered only briefly during the course of routine visits [20].

If only few structured experiences of injury prevention in primary care seem to exist, educational interventions after an injury appear to be better documented in the literature. Caregivers' interest to receive information immediately after the event has been already tested and some RCT verified the effectiveness of suggestions given in this occasion. However, in these studies the involved clinical setting is always the Paediatric Emergency Department, even if the paediatrician in ambulatory care setting more frequently assumes the role of entry point to the health care system. Moreover, even looking to strategies finalized to correct parents and child behaviour adopted after the injury, experiences expressly dedicated to prevention of foreign body inhalations seem to lack.

Given the paucity of works finalized to evaluate the role of injury preventive strategies in primary care and, still, the most relevant scarcity of studies devoted to verify the effectiveness of foreign bodies injuries prevention, it is arduous to identify an ideal approach to implement counselling strategies. Therefore, precious indications could be borrowed from other settings [21]. Particularly, evidences obtained elsewhere have suggested almost three key messages. First of all, it seems to be ascertained that an effective preventive strategy origins from an effective communication technique: recently, a few attempts to employ in injury prevention communication techniques such as brief sessions of Behaviour Change Counselling (BCC) already tested in setting other than injury prevention, have been successfully made [22].

Moreover, the probability of success is greater when the attention toward the problem is greater: obviously when an accident has already happened, parents are more susceptible to receive all information regarding safety behaviour; however, also other teachable moments could be identified [23]. Research on adult learning suggests that adults learn best when practical and contextually significant information is provided to help them to cope with specific life-changing events [24] : without any doubt,

childbirth, is the most dramatic life-changing events: the postpartum period is a time of tremendous change, increased health problems, and emotional upheaval for new parents. Therefore, childbirth is a time of almost universal contact between parents and the medical community [21]. General practitioners are in an ideal position to assist families during this period and may consider a sooner rather than later, approach to injury prevention education.

Finally, because they must reach large numbers, primary prevention programs must be neither expensive nor time-consuming to administer. A simple program containing a powerful message, administered at the appropriate moment and requiring very little effort or time on the part of those who deliver the message and those who receive it, has the greatest chance of success. Education strategies based on “face to face” interventions at home frequently show unfavourable cost effectiveness, given the large amount of time spent to reach every participant [21]. On the other side, the ideal situation to promote an educational program allows reaching at the same time a large group of subjects targeting the intervention on more susceptible individuals. Given the previously mentioned parents’ sensibility at the childbirth moment, as experimented elsewhere, a postpartum course, organized in hospital or in other locations easily accessible by parents of newborn infants could be a resources-saving way to promote safe behaviours; moreover, as already experimented in other settings, it could be also represent an effective method to advocate parents to disseminate the information creating and to reinforce the social contract between parents and their community [21].

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**Title: Management of foreign bodies in the airway and esophagus**

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**Abstract**

**Background:** Ingestion and / or aspiration of foreign bodies (FB) are avoidable incidents. Children between 1-3 years are common victims for many reasons: exploration of the environment through the mouth, lack of molars which decreases their ability to properly chew food, lack of cognitive capacity to distinguish between edible and inedible objects, and tendency to distraction and to perform other activities, like playing, while eating. Most FBs are expelled spontaneously, but a significant percentage impacts the upper aerodigestive tract. Approximately 80% of children's choking episodes are evaluated by pediatricians. The symptoms of aspiration or ingestion of FBs can simulate different paediatric diseases such as asthma, croup or pneumonia, delaying the correct diagnosis.

**Symptoms:** There are three clinical phases both in aspiration and ingestion of FBs: initial stage (first stage or impaction or FB) shows choking, gagging and paroxysms of coughing, obstruction of the airway (AW), occurring at the time of aspiration or ingestion. These signs calm down when the FB lodges and the reflexes grow weary (second stage or asymptomatic phase). Complications occur in the third stage (also defined as complications' phase), when the obstruction, erosion or infection cause pneumonia, atelectasis, abscess or fever (FB in AW), or dysphagia, mediastinum abscess, perforation or erosion and esophagus (FB in the esophagus). The first symptoms to receive medical care may actually represent a complication of impaction of FB.

**Locations and management:** Determining the site of obstruction is important in managing the problem. The location of the FB depends on its characteristics and also on the position of the person at the time of aspiration. Determining the site of obstruction is important in managing the problem. Larynx and trachea have the lowest prevalence, except in children under 1 year. They're linked with the most dangerous outcomes, complete obstruction or rupture. Bronchus is the preferred location in 80 to 90% of AW's cases. Esophageal FBs are twice more common than bronchial FBs, although most of these migrate to the stomach and do not require endoscopic removal. Diagnosis of FB proceeds following the traditional steps, with a particular stress on history and radiological findings as goal standards for the FB retrieval. The treatment of choice for AW's and esophageal FBs is endoscopic removal. Endoscopy should be carried out whenever the trained personnel are available, the instruments are checked, and when the techniques have been tested. The delay in the removal of FBs is potentially harmful. The communication between the endoscopist and the anaesthesiologist is essential before the procedure to establish the plan of action; full cooperation is important and improves the outcome of endoscopy.

**Conclusions**: Ingestion and / or aspiration of FB in children are multifactorial in their aetiology, in their broad spectrum of different resolution for the same FB and in the response of each patient to the treatment. Prevention remains the best treatment, implying an increased education of parents on age-appropriate foods and household items, and strict industry standards regarding the dimensions of toy parts and their secure containers.

**Keywords:** Foreign body, location, aspiration, ingestion, endocopic removal,

## Introduction

Ingestion and / or aspiration of foreign bodies (FB) are avoidable incidents. Those injuries, cause of morbidity and mortality in all age groups, are seen mainly in children under three years, being the fourth leading cause of accidental death in this group and the third in infants under 1 year) [1-3].
Children between 1-3 years are common victims for many reasons: exploration of the environment through the mouth, lack of molars which decreases their ability to properly chew food, leaving therefore larger chunks to swallow, lack of cognitive capacity to distinguish between edible and inedible objects, and tendency to distraction and to perform other activities, like playing, while eating.
Most FBs are expelled spontaneously by mean of protective reflexes such as coughing or spitting, or uncomplicated pass through the digestive tract, but a significant percentage impacts the upper aerodigestive tract.
Approximately 80% of children's choking episodes are evaluated by pediatricians. Most of them are seen within 48 hours of the event. Only 15% are correctly diagnosed within the first 7 days after choking .[4, 5] The symptoms of aspiration or ingestion of FBs can simulate different paediatric diseases such as asthma, croup or pneumonia, delaying the correct diagnosis.

## Main symptoms recognized in FBs injuries

There are three clinical phases both in aspiration and ingestion of FBs: initial stage (first stage or impaction or FB) shows choking, gagging and paroxysms of coughing, obstruction of the airway (AW), occurring at the time of aspiration or ingestion. These signs calm down when the FB lodges and the reflexes grow weary (second stage or asymptomatic phase). The asymptomatic phase, lasting from hours to weeks, can lead to delays in diagnosis. This event is mainly linked to the inclination of the doctor examining the child to minimize the possibility of an accident with FB in absence of symptoms.
Complications occur in the third stage (also defined as complications' phase), when the obstruction, erosion or infection cause pneumonia, atelectasis, abscess or fever (FB in AW), or dysphagia, mediastinum abscess, perforation or erosion and esophagus (FB in the esophagus). The first symptoms to receive medical care may actually represent a complication of impaction of FB.

## Different locations of the injuries

Determining the site of obstruction is important in managing the problem. The location of the FB depends on its characteristics and also on the position of the person at the time of aspiration. Hereafter an overview of the locations and the main symptoms related:

- *FBs in the larynx*

This location is the less frequent (2-12%) site of FB's retrieval in AW, except in children under 1 year [6]. Although the minor frequency, it links with the most dangerous outcomes, as AW emergency. Consequent laryngeal edema can lead to complete obstruction. Typically, these patients have symptoms of obstruction, dysphonia or aphonia and hoarseness. Symptoms can mimic subglottic laryngitis (in a previously healthy child). If the blockage is complete, it will cause respiratory distress, cyanosis and even respiratory arrest followed by death. If the obstruction is partial, it might produce stridor, hoarseness, cough, croup, sore throat and dyspnea.
A main danger can be seen when dealing with thin and punctuate FBs (like fish bones), rounded and soft (as grapes, olives) and blade and light (for example egg shells) can remain intralaryngeal.

- *FBs in trachea*

The location trachea has a low prevalence (3-12%) [6]. Patients with a tracheal FB have symptoms similar to laryngeal dysphonia but can have biphasic stridor, dry cough (tracheal type) with a sharp crack (sometimes audible) when the FB is movable, sound produced by its impact against subglottis. Children present to doctor's exam with dyspnea and scared attitude, take a prime position, sitting or sunk into parents' arms, as position's changes are associated with new crisis of asphyxiation. Like in laryngeal FBs, edema can progress to complete obstruction. The symptoms of tracheal FB can vary due to its mobility, from subglottis impaction to extreme blockage of a bronchus leading to death, through less symptomatic stages, showing atelectasis or respiratory signs, like located emphysema. The FB is generally light and of considerable size (relative to the AW's patient), characteristic that prevents its progression along the bronchus (like sunflower seeds).

- *FB in the bronchus*

80 to 90% of AW's FBs are located in the bronchus. 65% of patients have the triad of cough, wheezing and decreased breath sounds [4, 5, 7]. Up to 95% present at least one of the signs [2].Occasionally, a bronchial FB can cause respiratory compromise resulting for example from the increased size of vegetal material or it might produce edema around the FB, causing complete obstruction and lobar collapse. The movement of a FB along the main bronchus can provoke respiratory distress, resulting in obstruction of a previously normal lung. Usually, a FB that stays at length in the AW generates granulation tissue causing difficulties in visualization and extraction. In Picture 1 it's possible to see the atelectasia caused by the presence of a spike in the bronchus.

In children, small FB are more frequent retrieval in the right bronchus [1, 3, 6], due to its larger diameter and to the more open angle that the right bronchus creates with the trachea; anyway, in our statistics, FBs prevail in the left bronchus [6].

- *FBs in the esophagus*

Esophageal FBs are twice more common than bronchial FBs [6], although most of these migrate to the stomach and do not require endoscopic removal . The vast majority of cases addresses to the doctor within the first 24 hours of ingestion of the FB, with vomiting, odynophagia, dysphagia, and drooling. A large FB can cause symptoms of obstruction of AW and cough caused by compression or irritation of the upper AW consequentially to micro aspiration of saliva in the AW. When there's a prolonged esophageal lodgement, fever and other symptoms of respiratory infection may be present, exacerbated during sleep. In Picture 2 it's reported the RX showing the swelling due to the prolonged stay of a FB in the esophagus, causing a compression of the trachea. Symptoms are permanent from the time of intake. Picture 3 shows a severe case of stenosis due to the ingestion of a coin that needed prompt intervention of the specialist.

Diagnosis of FB in AW

The diagnosis of FBs injuries follows the traditional steps, with a particular stress on history and radiological findings as goal standards for the FB retrieval.

- History

A positive history of choking or coughing with respiratory distress in a previously healthy child who was playing or eating and / or the history related by the young patient who has ingested something, should never be ignored. Maternal story should be prioritized, because an accurate history has great importance in the diagnosis of aspiration of FB, because the contribution given by physical examination and radiographic studies may be falsely negative after the critical event has passed.

A negative medical history can lead to an erroneous conclusion. Sometimes the diagnosis might be critical if the event occurs in a young child without any witness. Some children do not state the aspiration for fear of being punished, at other times, parents do not relate the history of suffocation or choking because that was disregarded by doctors in the first consultations.

- Physical examination

The presence of odynophagia and dysphagia (drooling) must be always recorded, as much as signs of airway obstruction (stridor, dysphonia, abnormal position of neck and head). Chest auscultation is essential, and the decrease or asymmetry of breath sounds, the abnormal duration of inspiratory,

expiratory breathing phases (normal 1:3), wheezing, and unilateral sounds should lead to high suspicion of bronchial FB and should be distinguished from a potential exacerbation of asthma.

- Radiological Assessment

The radiologic evaluation is important because it allows the location of the FB, the determination of its nature (radio-opaque or radio- lucent) and the subsequent planning of endoscopic removal procedure.

In case of suspected esophageal FB a chest X-ray should be requested, including abdomen and cervical region anteroposterior (AP) and lateral (L) views. Picture 4 gives the evidence of the necessity of both X-ray, in order to assess the FB location and plan its removal. In non radio-opaque FBs (especially in chronic cases) an esophagography with contrast medium can be functional.

The typical esophageal location is immediately below the cricopharyngeus muscle. When there is an underlying condition such as congenital or acquired esophageal stenosis, the location is lower. In these cases of atypical location, an esophagography with Barium should be performed after 2-3 weeks to rule out any underlying pathology.

Evaluate the presence of a double contour as image suggestive of button battery FB, since batteries require urgent removal. As it can be ascertained in Picture 5, the double contour clearly lead to a distinction between batteries and coins, even in the diameter is the same.

In case of suspicion of FB in the AW, if it is laryngeal it must be requested Rx collar and P and AP

Chest X-ray may be normal with a tracheal or bronchial FB therefore does not exclude the diagnosis of aspiration. X-ray might be repeated and reviews to the plates should be carefully carried out in search of subtle findings. AP and L chest X-ray can show the FB (if radio opaque) or indirect signs such as obstructive emphysema, atelectasis and/or consolidation. Fluoroscopy of the AW can be performed to assess diaphragmatic movement of both lungs and the large AW during inspiration and expiration (dynamic study). The presence of obstructive emphysema is an early sign of complications.

Chest tomography (CT) is rarely used, it can be useful when dealing with vegetal FB that migrates through the respiratory tree causing lung abscess (for example ear of corn, grass). In Picture 6 it's illustrated the use of CT in the detection of a crayon's piece lodged in the left bronchus.

The use of MRI in the study of aspiration or ingestion of FB in the paediatric population is even more limited.

- Behaviour

The correct diagnosis can be best achieved by means of direct evaluation of aerodigestive tract through endoscopy; history and physical exam are the most important aspects in the decision of endoscopic intervention. A history of suspected FB aspiration calls for endoscopic evaluation, even

if clinical results are not present or are not conclusive. Intervention should be performed with rigid bronchoscopy in patients with witnessed aspiration of FB, on those with radiographic evidence of FB in the AW, and in the symptomatic ones.

FB Management

The treatment of choice for AW's and esophageal FBs is endoscopic removal. Very often, FBs injuries are considered urgent emergencies, leading to hasty, inadequate study, poor preparation and improper removal attempts. However most patients arrive at the hospital when the acute phase has passed and they're not in respiratory distress. There is therefore time to collect the medical history related to the ingestion or aspiration and relevant remote case history.

Endoscopy should be carried out whenever the trained personnel are available, the instruments are checked, and when the techniques have been tested.

The delay in the removal of AW's FB is potentially harmful, as the FB may be dislodged from the bronchus and impact in the larynx causing suffocation. Endoscopy is therefore deferred only until the preoperative analyses have been obtained (with the exception of life threatening emergencies) and the patient is prepared for endoscopy.

Complete obstruction of the AW is an absolute emergency, being due to any laryngeal, tracheal, bronchial FB or esophageal FB causing AW compression [2, 6, 8].

Although the majority of FB moves distally within the tracheobronchial tree, occasionally it can be blocked in the larynx. A bulky FB can stop at supraglottic level or at the aerodigestive bifurcation (sausages are the most common cause of choking for meals), while one with a small volume falls off rapidly to the bronchi. Despite equal volumes, round FB are more dangerous because they are more obstructive due to their margins that adjust better to the tracheobronchial cavities. The same can be said for soft and malleable FBs, suiting the AW walls, as much as FB with a small volume that can be obstructive in the distal tracheobronchial tree (like sheet plastic, rubber balloon, piece of latex).

Rapidity is required also in patients with FBs partially obstructing the glottis and causing spasm, or in the presence of FB that changing their position might cause complete obstruction: in these cases the patient should be put in a suitable ventilation position and then directed to the operating room.

Another absolute emergency are batteries (button cell), since its composition (NaOH, KOH, Hg) can determine damage to the mucosa within 1 hour, erosion of the muscular layer in 2-4 hours and perforation in 8-12 hours, producing esophageal stenosis, tracheo-esophageal fistula, mediastinitis and sometimes death [4, 9]. Battery should be localized by means of radiology, and afterwards proceed to the immediate removal if it stops in the esophagus, whereas in case it has passed beyond

the esophagus, monitoring the appearance of fever, pain, hematochezia and if asymptomatic, every 3-4 days an x-ray should be performed until the evacuation has taken place. X-ray should be performed every for batteries of 15 mm diameter (or larger) and in children younger than 6 years, carrying out an endoscopy if the battery remains in the stomach. If signs or symptoms of bowel perforation develop, the patient should be immediately surgically treated.

Particular attention must be held in cases of aspiration of seeds or legumes. It's necessary to know the type of plant, because whether a seed is hydrated (the most common retrieved are beans or corn), the capsule breaks, the grain swells and it can obstruct the AWs and therefore complicate the extraction; in this cases removal must be performed as quickly as possible. In Picture 7 it's possible to consider the different dimension pre and post contact with humid environment. There are other types of vegetal FB that do not stick and that can cause granulomas (the most common is peanut).

The basic principles of FBs endoscopic removal have not changed since Chevalier Jackson [4, 6]. It takes place in five stages: location, unlocking, rotation, grip and removal. The type and size of the endoscope depends on patient's age and on FB's location. The clips are selected based on practice with a similar object, preferably with a duplicate brought by the patient's family.

The different degrees of difficulty will depend mainly on three factors:

- Patient's anatomical integrity and functionality: patient's pre-existing disease (obstructive bronchitis or asthma), bronchial anatomical size (determined primarily by age), pulmonary involvement (FB switching from one bronchus to another, involvement of the same lung or contra lateral)
- ii) FB characteristics: type (organic or inorganic), location, size, shape and colour. FB analysis is therefore very important. When in presence of sharp edges, they should be introduced into the bronchoscope, avoiding the damage that they might cause during the extraction phase. Its form will direct the extraction plan. Oxidized material blocked for a certain period in the bronchial tree, will likely produce an inflammation in the adjacent organs. Having a detailed medical history, the colour will help to recognize the FB, except those objects that are transparent or of the same colour of bronchial tree's mucosa. Ideally it should be recommended to have a similar FB to know what type of instrument should be used in the extraction.
- iii) Promptness of diagnosis. Especially in laryngeal FB completely occluding the cavity, it may be necessary to perform a non laringobroncoscopic procedure like the Heimlich manoeuvre, or in extreme cases to require an emergency tracheostomy.

<u>FBs removal from the AW</u>

Laryngoscopy and bronchoscopy should be planned for suspected FB in AW but should not precede the preparation of the patient and the availability of experienced staff appropriate if the child is clinically stable. The bronchoscopes with all its accessories must be prepared for use prior to anaesthesia. Only careful preparation enables the endoscopist to manage complications arising from the operation. After the extraction of FB, bronchoscopy has to be repeated to inspect the tracheobronchial mucosa, to aspirate trapped secretions, and to discard multiple external bodies or fragments of FB.

- Preoperative preparation

If there aren't respiratory difficulties, the patient must fast for a suitable period to prevent aspiration. The position in which the child is spontaneously placed must be strictly respected, moving him as little as possible and avoiding the supine position by placing a support that allows the lifting of head and shoulders. An operating room equipped with appropriate endoscopic equipment of different sizes, personnel familiar with the use of instrumentation and anaesthesiologists with experience in FB extraction are essential for their safe removal. The risks of the procedure should be discussed with the family in a way that doesn't delay the proceedings. The anxiety of the family is often considerable. Risks include complete obstruction of the AW, the extraction's failure, esophageal perforation or rupture of trachea and/or bronchus.

- Anaesthesia

The communication between the endoscopist and the anaesthesiologist is essential before the procedure to establish the plan of action; full cooperation is important and improves the outcome of endoscopy. Endoscopy for FB extraction is performed under general anaesthesia. In cases of esophageal FB endotracheal intubation has to be performed to prevent aspiration of the FB, and minimize tracheal compression by the esophagoscope. Anaesthesia should be performed also in cases where the patient should relax for an easy removal of FB in order to minimize the dangers due to its size or nature (for example stones or rock). In case of FB in AW, anaesthesia should be carried out by inhalation, administered through the closed system of ventilation bronchoscope, supplemented with topical lidocaine to reduce reflexes and prevent laryngospasm; spontaneous respiration is safer than apnoeic technique and positive pressure ventilation should be avoided because it can displace the distal FB [10]. Relaxation increases the risk of override the possibility for the patient to ventilate despite the obstruction.

- Required instruments

The extraction of FB in children should be performed with rigid instruments (bronchoscopy and esophagoscopy) that provide safe ventilation, better exposure of the FB. There is a wide range of

sizes and varieties of forceps. In some cases, flexible bronchoscopy can be helpful [1,] as in patients with FB located at periphery of the lung or in cases of patients experiencing difficult intubation.

- Intraoperative Technique

Proper training and experience are important for anaesthesiologists, nurses, instrumentalists and endoscopist. Endoscopes, forceps or FB mustn't be forced. Any manipulation should be delicate, avoiding the movement of FB more distally, performing the surrounding of the object and ensuring the FB against the opening of the bronchoscope (with the exception of sharp objects or when using forceps rotation). This protects the grip and allows for a stable withdrawal of FB, forceps and endoscope as a single unit.

Hidden parts of the FB should be mapped, having potential sharp points buried deep in the mucosa or outside the wall in the mediastinum. The presentation of the FB can be changed by the tip of the endoscope. The FB is rotated with its maximum diameter in the direction of the light for extraction (the coronal plan for the esophagus and sagittal plan for the larynx).

Removal of laryngeal FB:

It is important to perform the extraction under general anaesthesia, which can be delivered via nasopharyngeal tube with the tip in the hypopharynx to maintain anaesthesia and oxygenation. The laryngoscope is placed in the corner, and the FFB is displayed in the larynx and removed with appropriate forceps. After extraction, further evaluation of the larynx must be carried out and a rigid bronchoscopy must be performer to exclude other FB in the AW.

Removal of tracheobronchial FB:

Laryngoscopy is performed and the bronchoscope is inserted in the AW with continuous ventilation through it; in a patient with bronchial FB, firstly the free bronchus has to be checked, afterwards the bronchoscope is placed immediately above the FB, gently aspirating secretions around the FB, and maintaining the patient at 100% oxygen prior to any extraction. Forceps are placed through the bronchoscope, and the object is extracted after the full display of it. FB, forceps and the bronchoscope are removed as a unit, and the bronchoscope is introduced once again in the airway for ventilation and the revaluation of other FB.

Multiple FB are not an exception, they can be seen in 3 to 6% of cases.

Special Issues in FBs removal

In sharp objects (for example needles), the priority is to locate the tip and place it within the bronchoscope: this is achieved first by moving the FB distally to release its tip in order to protect

the mucosa at the time of extraction. Habitually sharp objects stay with the point upward as seen in Picture 8.

When dealing with safety pin, once within the broncoscope it passes without difficulty, invariably upward-pointing.

Different extraction methods to avoid injury to the mucosa in the manoeuvre can be carried out with stomach FB with rotating forceps that allow reversing it and then collecting it through the esophagoscope, or unlocking the FB from the mucosa, wrapping it into the esophagoscopy's tip and removing all as a unit.

Postoperative management

Antibiotics and steroids are not routinely indicated after endoscopic removal routine (unless there is evidence of significant AW or esophageal injury) [1]. After esophagoscopy, children must be observed, monitored for occurrence of fever, tachycardia and tachypnea (signs of perforation) and left fasting for at least 4 hours. Usually the use of racemic epinephrine or steroids is unnecessary when the procedures are short and properly sized bronchoscopes are used. Chest physiotherapy helps to clear secretions, is used when in presence of chronic pneumonia, atelectasis or purulent bronchitis concomitant to the FB injury.

A routine chest X-ray is not needed, unless the patient's symptoms persist or progress, or if the patient had pulmonary abnormalities on preoperative x-ray.

In case of failure of the procedure or incomplete removal of the FB, the patient should rest and another endoscopy should be repeated a few days afterwards. Patients are discharged on the same day or the day after the procedure if the patient isn't feverish and presents quiet breathing without need of supplemental oxygen.

Non-endoscopic methods of FBs Extraction

If the patient is not completely obstructed and can properly mobilize air, the Heimlich manoeuvre or other removal attempts can be unintentionally rush events by completely blocking the AW: in this case the patient should be rushed to an institution with the appropriate equipment and personnel to handle the problem.

The hypopharynx shouldn't be explored with a finger that may push the FB downwards within the larynx or forcing it into the esophagus where it can compress the trachea against the sternum, causing complete obstruction.

Chest physical therapy and bronchodilators (for tracheal or bronchial FB) may lead to complete blockage and death.

The use of substances (for example .papaína) to dissolve a meat bolus impacted in the esophagus can cause mediastinitis and death due to necrosis and perforation of the esophagus.

The extraction of radiopaque FB located in the cervical esophagus with a balloon catheter through fluoroscopic guidance (inflating a Foley or Fogarty catheter under the object and then bringing it up), has been recommended for blunt FB lodged below cricopharyngeus muscle that have been recently swallowed; the benefits of this procedure would include costs reduction and avoidance of general anaesthesia, but this technique does not allow further review of the esophageal mucosa or the search of a second not radiopaque FB, adding to those contraindication the risk of vomiting and aspiration in an unprotected AW, causing therefore laceration of the mucosa and esophageal perforation , epistaxis, laryngospasm, death by asphyxiation and psychological trauma [6, 10].

AW's FB extraction by flexible bronchoscope looks attractive, with recent literature advocating their use in adults, particularly in those with peripherally located objects and in patients with facial trauma. The FB extraction with flexible bronchoscope is not recommended in children, especially in young children. The main problems are the poor control of both the AW and the FB.

## Conclusions

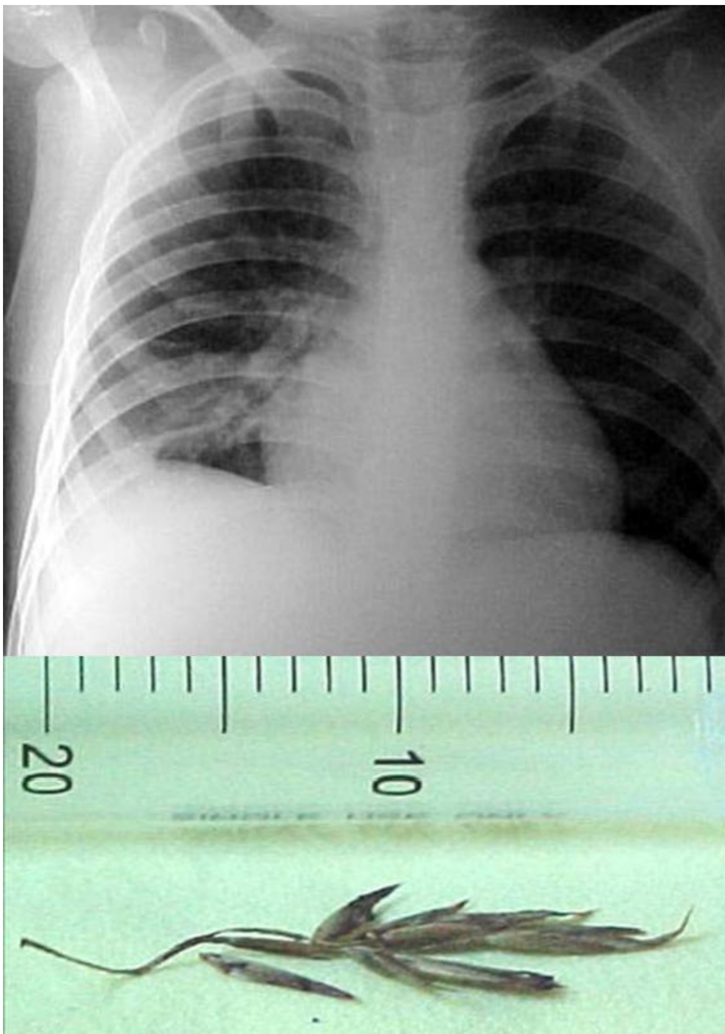
Ingestion and / or aspiration of FB in children are multifactorial in their aetiology, in their broad spectrum of different resolution for the same FB and in the response of each patient to the treatment. Prevention remains the best treatment, implying an increased education of parents on age-appropriate foods and household items, and strict industry standards regarding the dimensions of toy parts and their secure containers. The greatest risk is between 9 and 24 months, but it is still present up to 6 years old due to children's propensity towards adult-type food.

It is necessary to educate parents and care-givers to avoid easy access to small items able to penetrate into the airway, and not to feed the baby during crying or laughing, to facilitate laryngeal sphincter incompetence.

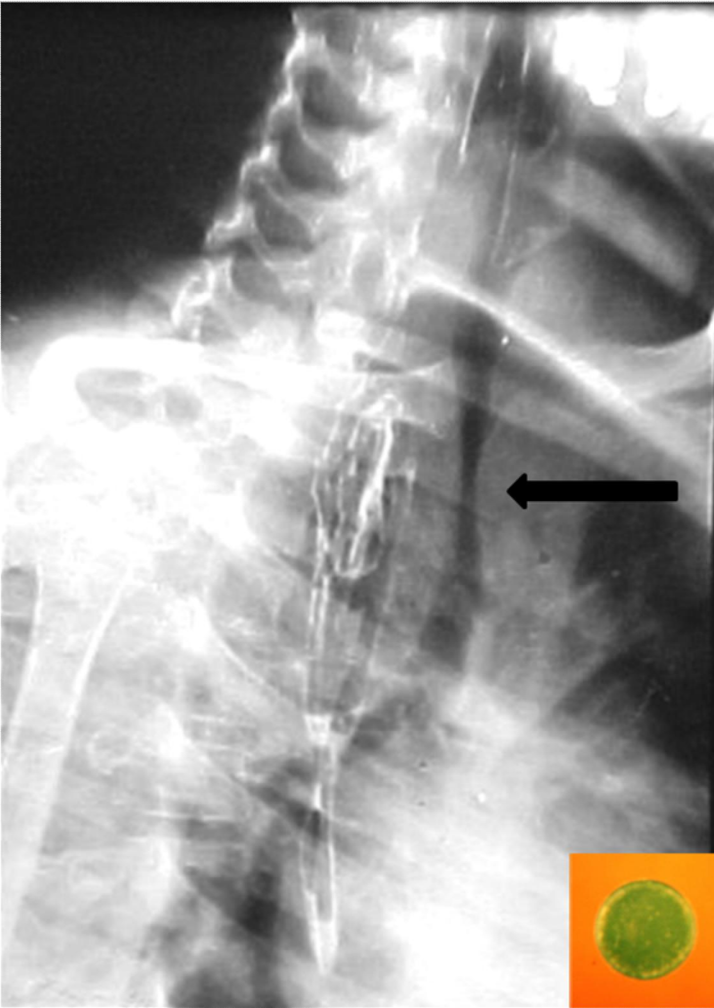
Increased public awareness, efficacy of emergency personnel and the extensive use of the Heimlich manoeuvre has diminished the mortality from acute obstruction. The most important factor in reducing mortality is the recognition of a person in acute obstruction of AW

Early diagnosis and immediate control performer by a dedicated team are essential to ensure appropriate treatment, usually an endoscopic one, without risk of complication.

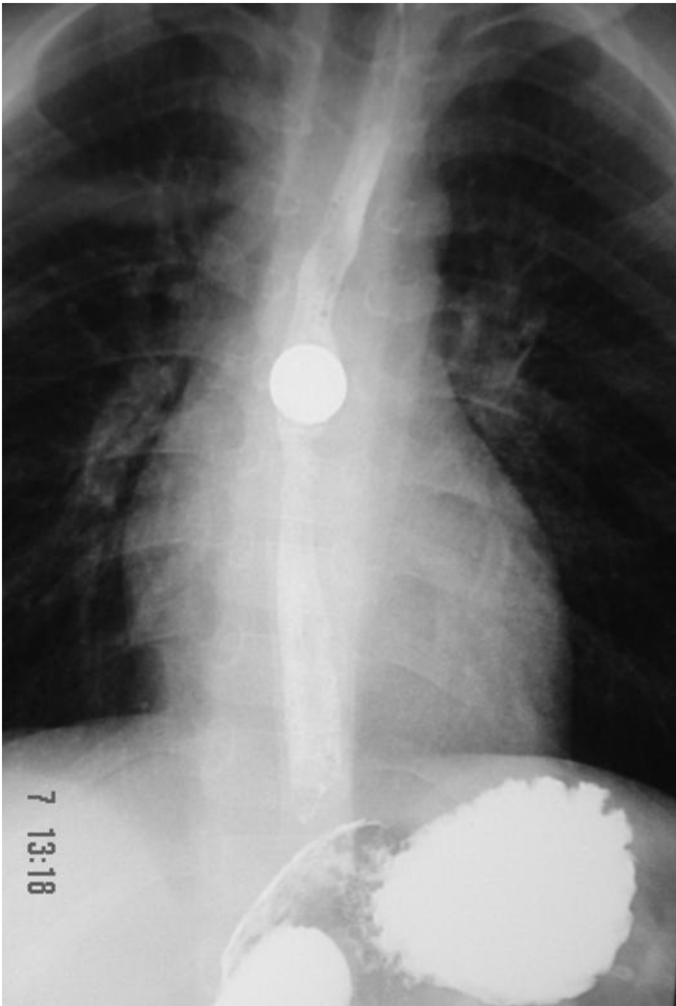
## Pictures

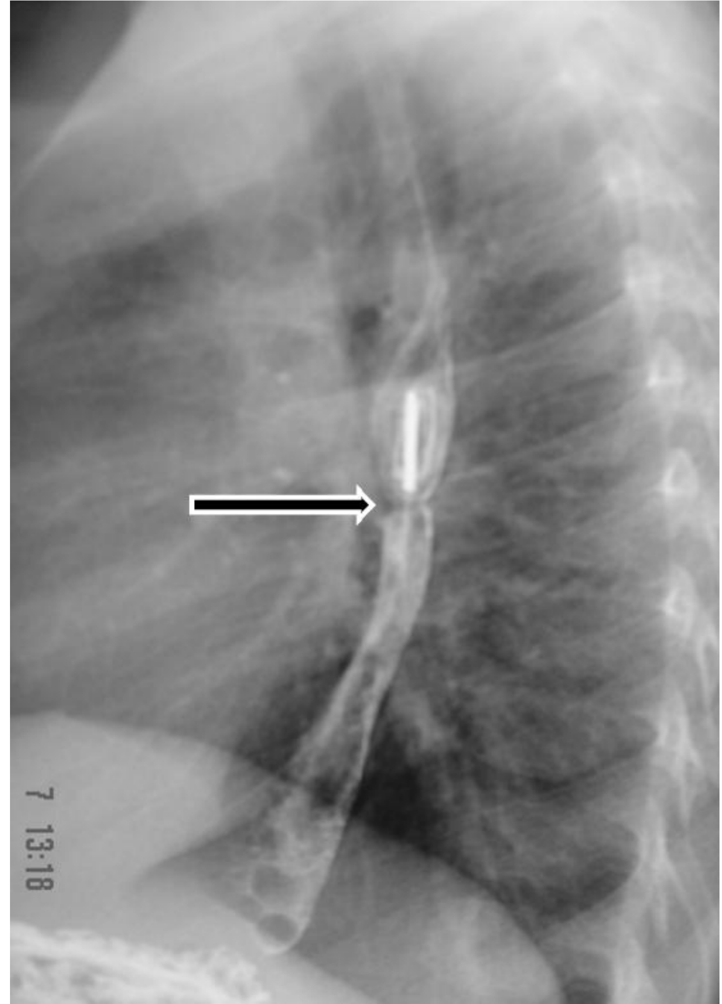



Picture 1: Atelectasia due to spike in the brochus

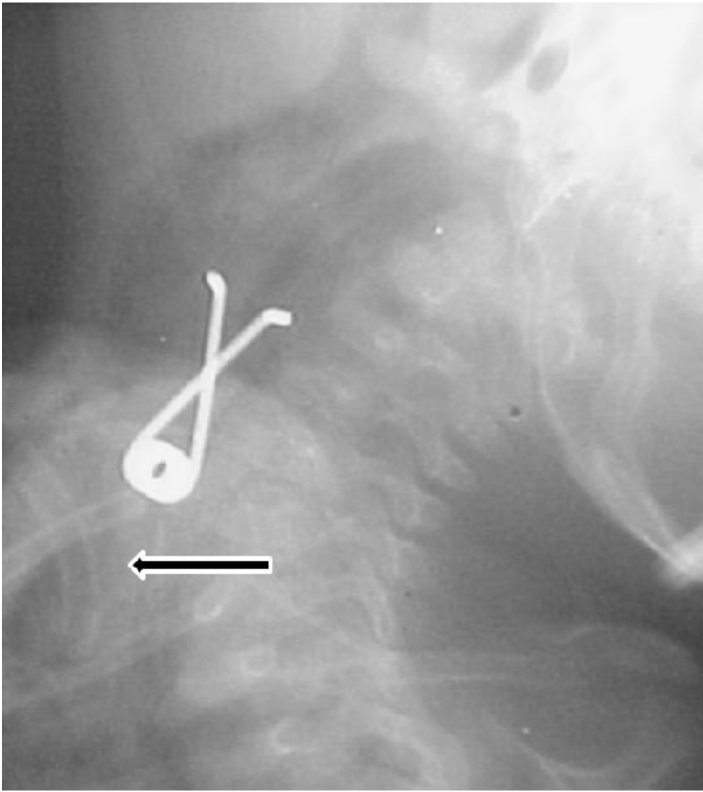
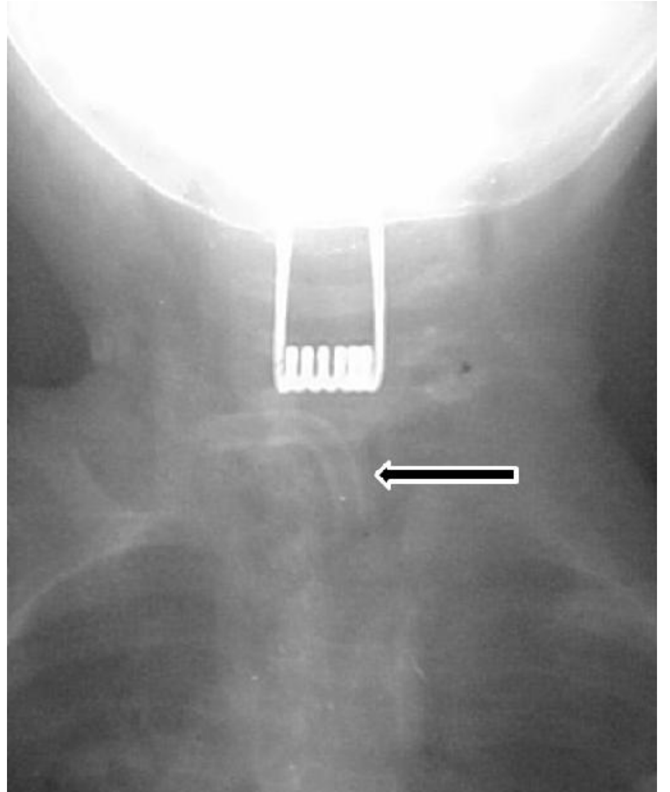


Picture 2: Swelling to to prolonged esophageal lodgement

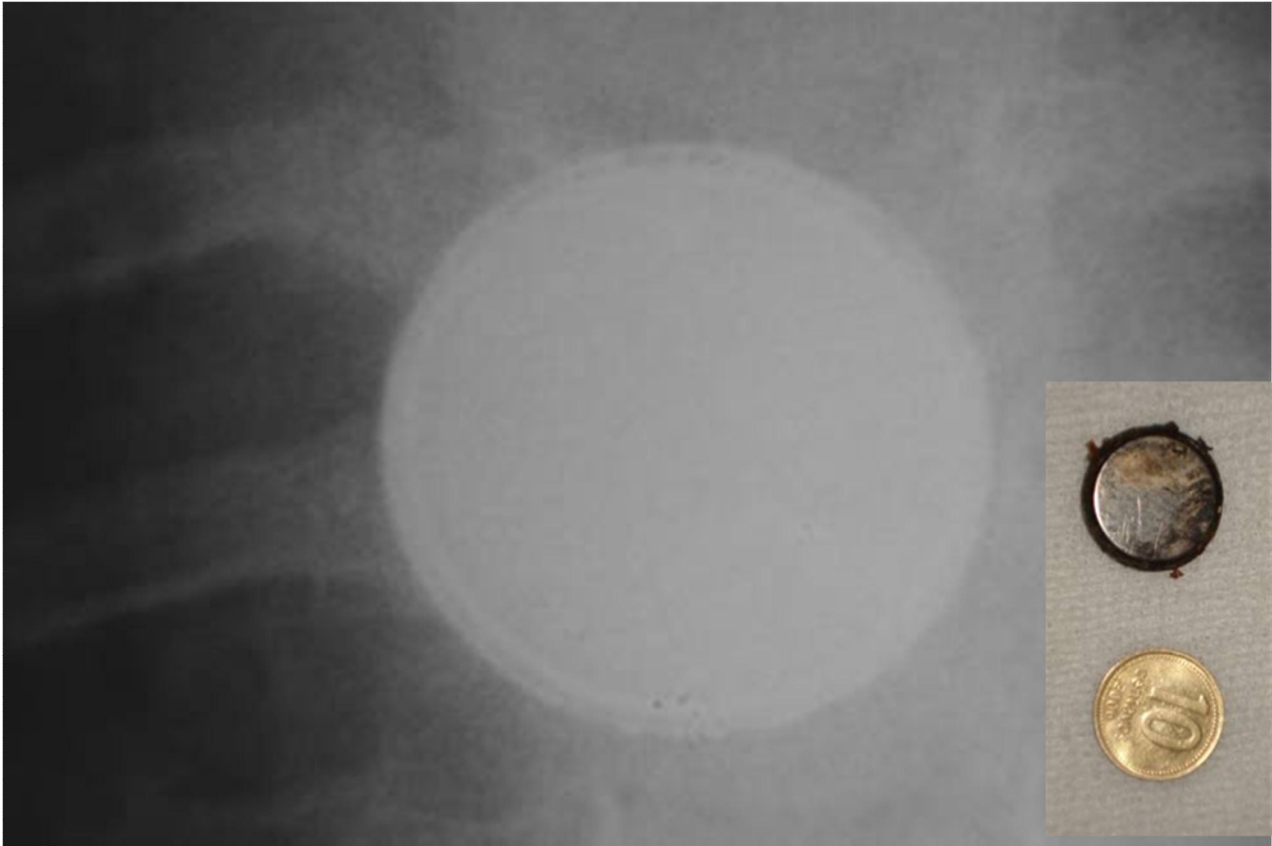




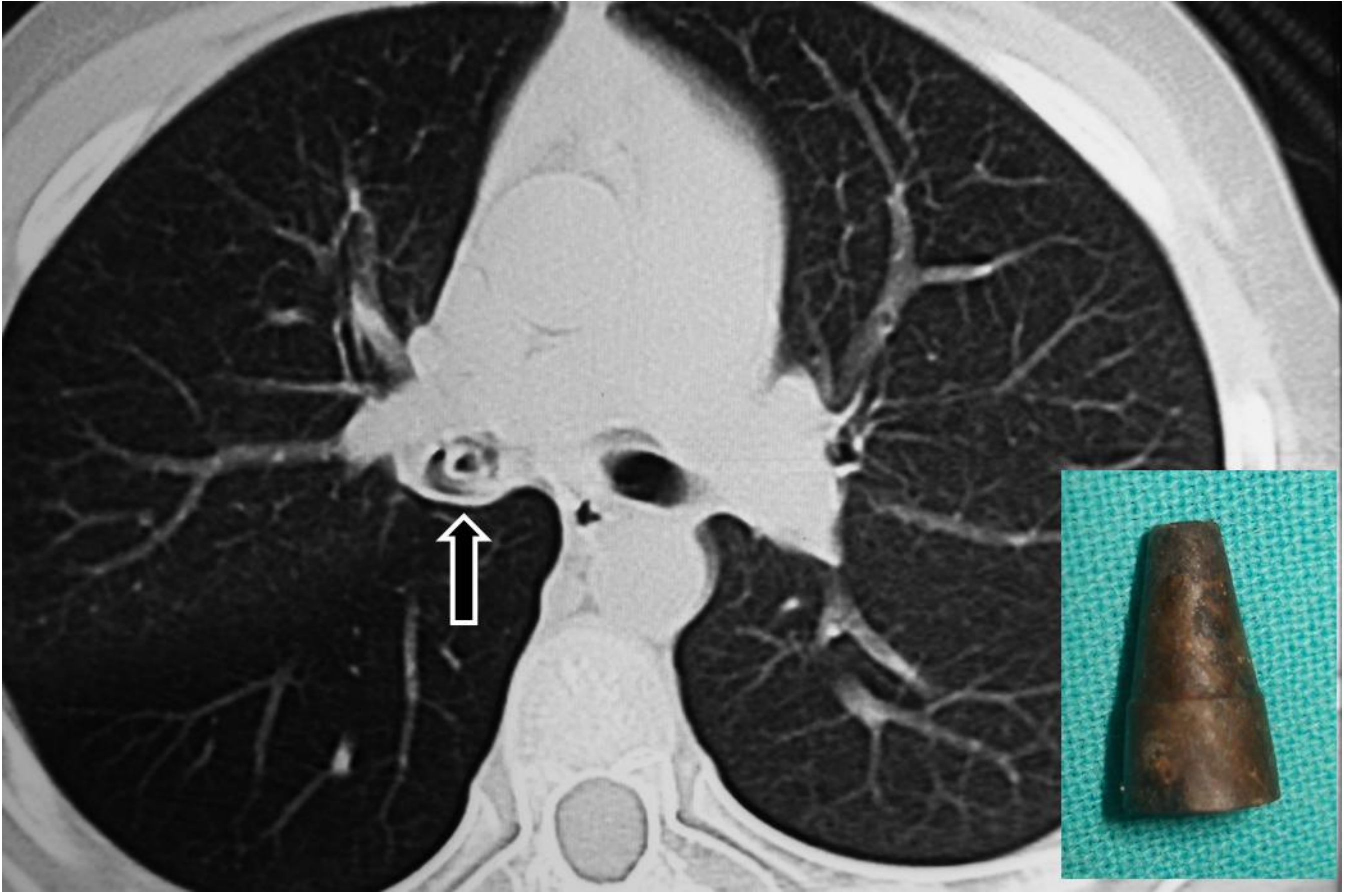

Picture 3: Stenosys of the medium esophagus due to the ingestion of a coin

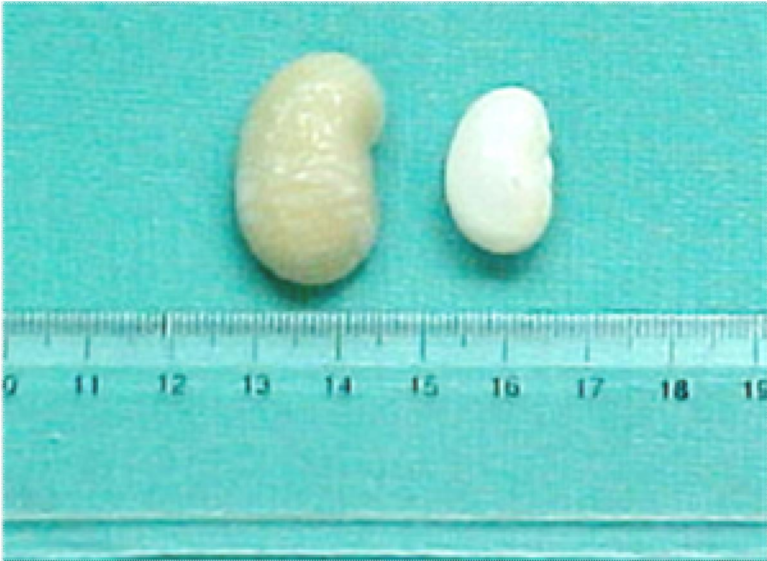
Picture 4: FB in the esophagus. Lateral and Antero- Posterior X-Ray



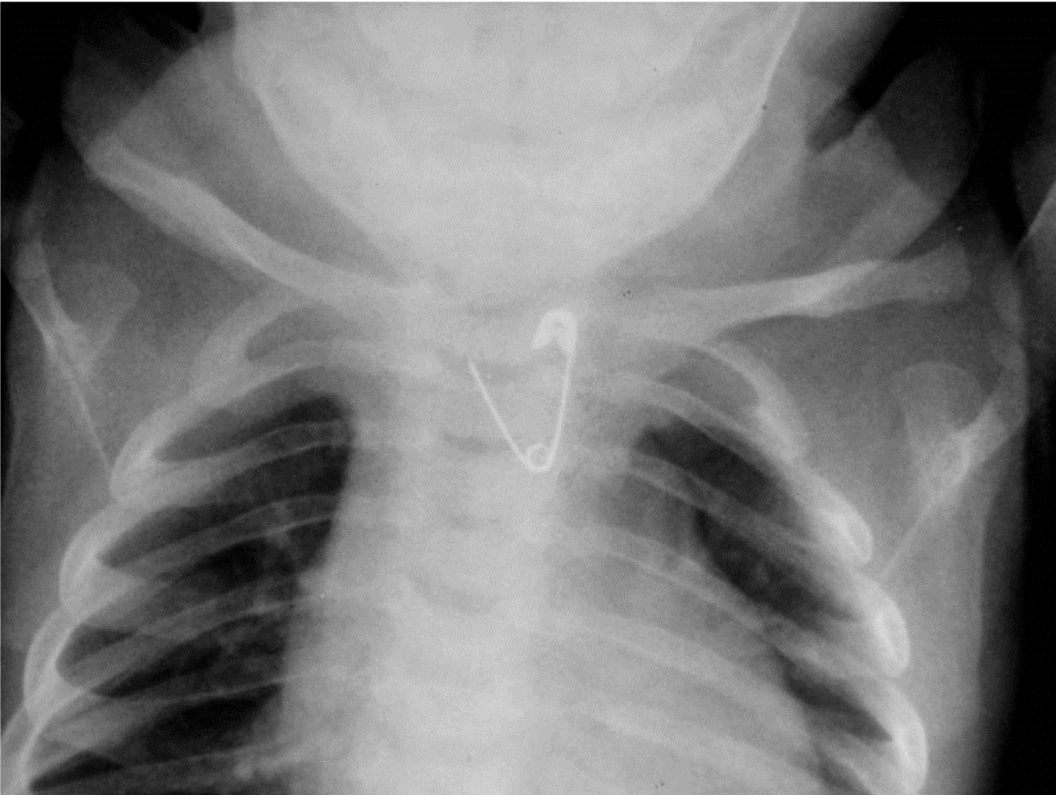

Picture 5: Anterior-posterior RX with double contour in a button battery ingestión



Picture 6: CT of a crayon's part in the left bronchus




Picture 7: Dry beans post and pre contact with humid environment



Picture 8: Sharp object in the esophagus

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**Title: Magnetic FB injuries: an hold yet unresolved hazard**

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**Abstract**

**Rationale and aim:** Among foreign bodies causing injuries in children, magnets have been reported to cause serious complications and being life-threatening. The aim of this study is to design a risk profile and an epidemiological figure of such injuries, for being used for prevention.

**Methods:** Data on 366 injuries have been collected from public surveillance databases and from published scientific literature, and compared with the data of the Susy Safe Registry, which is a pan-European registry of foreign bodies injuries co-funded by the European Commission.

**Results:** A median age of 48 months was observed, with a 63% prevalence of males is characterizing the injuries. Magnets have a median volume of 87.9 mm3 vs the median volume of 41.86 mm3 of the overall foreign bodies of the Susy Safe registry). Only 43% of the magnets were involving only on piece or objects, with a median number of two objects per injury, up to a maximum of 32 objects. Children are referred to the medical care system with a median delay of 3 days after onset of symptoms. Median length of stay in the hospital was 7 days with respect to 1 day as in the Susy Safe registry.

**Conclusion:** Most of complications, and event the death of a child can be eventually re-conducted to either or both a delay in patient referral or appropriate diagnosis. Thus, it is an absolute priority that an information initiative is taken toward families and emergency doctors to avoid unnecessarily delays respectively in patient referral and in diagnosis.

**Keywords:** foreign body ingestion; magnets; gastro-intestinal complications; injury epidemiology.

## Introduction

Magnets have been widely reported in the medical literature as an emerging, life-threatening source of potential injuries, in particular for children (1, 2). Indeed, the capability to attract, often strongly, each other, has the unique potential of causing perforation, fistula and ulceration when they reach the child's gastro-intestinal tract after ingestion (3-7). Thus, if the mechanism of causing the injury is clear enough from the medical point of view, the issue is moving now in the prevention field. Both USA and EU have a deep regulation aimed at limiting the exposure of young children to small objects, with the aim to reduce the probability of swallowing or ingestion (8). The aim of this work is to try to use the current evidence on injuries with magnets to understand if the epidemiological and risk framework of such accidents is different, and how, from the general framework of foreign bodies injuries in the upper aero-digestive tract. To this purpose, the data on 366 injuries involving magnets are compared with the Susy Safe registry, a large, pan-European registry of foreign body injuries conducted under the EU-DGSANCO (European Commission Directorate General for Health and Consumer Affairs) funding schemes.

## Materials & Methods

### Data sources

*The MagDB*

The MagDB is an acronym for "Magnet DataBase", which is a collection of a heterogeneous group of sources of information regarding foreign body injuries due to magnets in children (up to 18 years of age). Data on 366 injuries have been collected at the 20th of August, 2007, from public surveillance databases (29 from the USA data bank of the CPSC, 270 from the UK surveillance system ROSPA, 4 from the European Registry of Foreign Body Injuries "Susy Safe", 1 from the Nederland VWA) and from published scientific literature, combining, in Pubmed search, the terms "magnet*" with "foreign body", "injur*" and "accident*" (1, 3, 4, 6, 7, 9-33).

To ensure comparability with the Susy Safe registry, all self-resolved injuries which were not referred to the hospital of to the general practitioner were not included in the current version of the database.

*The Susy Safe Registry*

The Susy Safe (34) is a EU funded Web-based registry collected data on FB injuries in children aged 0-14 according to the International Classification Disease ICD-9 931-935. At the end of March 2007, a total of 7296 cases were registered using hospital discharge records in one Pakistani and 28 European hospitals.. Data encompassed four main aspects of the FB injuries: the characteristics of the children (age and gender); the characteristics of the object (foreign body type, shape, consistency and dimensions); circumstances of injury (presence of parents, the activity the child was engaged in at the time the accident occurred); hospitalization's details (experiencing a hospitalization, presence of complications, removal technique used). With regard to the FB dimension, the volume was calculated as the volume of the smallest regular geometrical solid containing the FB.
The Susy Safe registry has been used for the purpose of comparing the distributions of some relevant characteristics of the injured child and/or of the magnetic foreign body with the foreign bodies injuries stored in the non-food section of the Susy Safe registry (counting 5467 injuries).

**Statistical methods**

Data have been summarized using percentiles whenever possible. Robust location measures were preferred, adopting medians as standard. Difference among two or more groups of categorical variables were compared using a Chi-square test, and among continuous variables using a Wilcoxon test.
Difference in distribution between MagDB and SusySafe were evaluated using the relative distribution methods (35). Graphical inspection was presented using smoothed probability density function estimates and Lorenz curves. Quantitative comparisons were presented using the entropy measure, which is a measure of the dispersion of the distribution, and the median polarization index, which provides a mean of capturing distributional polarization. Entropy measure has been decomposed

in median and shape effect and the median polarization index in upper and lower polarization indexes, representing the contributions made by components above and below median of the relative distribution of MagDB vs SusySafe. All computations have been performed with the R system.

## Results

### Child characteristics

Injuries occurred at a median age of 48 months. Twenty-five percent of the injuries were involving children younger than 24 months (Table 1). Median age was higher for injuries in the upper airways (choking) and in particular in the ears and nose. Ingested foreign bodies characterized younger children with a higher median age of 36 months.

The distribution of injuries according to age is quite different from that of the Susy Safe registry. Indeed, even though the median age is almost the same in the two databases, the shape of the distribution is changing quite impressively toward the involvement of younger children (Figure 1), with the Lorenz curve being always below that of the Susy Safe registry (Figure 2). Indeed, as proven by the analysis of several entropy measures, the 97.6% of the difference in age between the injuries involving magnets and those of the Susy Safe registry are attributable to a modification in shape (Figure 3 and Table 2).

Percentage of injuries involving females is definitely lower in magDB than in the Susy Safe Registry (37% vs 45%), and, conversely, the incidence of cases reported regarding males is higher (63% vs 55%). This might be attributable to the higher number of accidents involving magnetic building sets toys, perhaps more attractive to males. Incidence is higher in males older than 36 months (68% in magDB vs 57% in Susy Safe Registry) whereas in children younger than 36 moths gender distribution is not different among magDB and the Susy Safe registry.

Three case of mental impairment have been reported in the MagDB, which seems a higher incidence as compared with Susy Safe data, where only seven cases with such characteristics are listed.

### Foreign body characteristics

Injuries involving magnets are characterized by bigger objects (median volume of 87.9 $mm^3$ vs 41.86 $mm^3$ of the overall foreign bodies of the Susy Safe registry), usually observed in big clusters (Figure 4). Indeed, only 43% of the magnets were involving only on piece or objects, with a median number of two objects per injury, up to a maximum of 32 objects in a 9 years old girl. The number of magnets involved in the injury is significantly higher for younger children (below 3 years). Toys and jewels distribution is not significantly different according to age groups.

**Referral to the medical care system**

Children experienced a list of common symptoms, widely depending on the location of the magnet causing the injury. For ingested magnets most common symptoms were vomiting (most often non-bilious), accompanied by abdominal pain, diarrhoea, and fever, all together being often described by parents as "flu-like" symptoms. Magnets in the ears and nose are often causing generic pain, sometime with bleeding. Few cases, one of the requiring surgical interventions, were involving the scrotum of the young patients.

Children are referred to the medical care system (the hospital or, less often, the general practitioner) with a median delay of 3 days after onset of symptoms (I quartile 2, III quartile 4.5). Quite interesting, 20% of the children are referred with great delay to the medical care system only after a number of days following symptoms onset between 14.4 and 29.1 (Figure 5).

**Case management**

The child is commonly referred to the hospital and there he/she is usually evaluated by the in-hospital emergency service, and thus, if not treated directly at this time (as occurred in 18 cases), referred to the specialty Departments for more appropriate treatment (usually Surgery or ENT). Few cases are taken to the family doctor, usually when the magnet has been extracted directly from the mouth or the nose of the child by one of his/her parents. Fifty-five children required general anaesthesia for removing the foreign body, with presence of complications like ulcerations (4 cases), bowel necrosis (3 cases), perforations (multiple in 16 cases, single in 61 cases), fistula (19 cases) and obstruction (13 cases). Foreign body removal was specific to the

location of the magnet; nevertheless, laparatomy, endoscopy, and surgery were the techniques most often used.

About 90% of the cases experienced a successful foreign body removal, with no consequences. One child has been reported to die following a delayed referral to the hospital and internal complications. Unresolved problems were related to persistent bowel movements and obstruction (2 cases) and relevant scars. Length of stay in the hospital was ranging from one up to 28 days, with a median number of 7 days (I quartile 3 days, III quartile 9.75 days), much higher than for other injuries, as emerging from the comparison (Figure 6) with the Susy Safe Registry (median 1 day, I quartile 1, III quartile 3 days).

**Discussion**

The epidemiological framework depicted in this analysis is based on the idea of treating magnets as a peculiar foreign body, which, due to its characteristics of magnetism, can cause severe injuries to children well beyond those typical of other foreign bodies (36, 37). Indeed, the mechanism of this peculiar kind of injury is proceeding in three steps, starting from when (*i*) the child swallows more than one magnet (even in different occasions divided by a temporal interval of some minutes/hours) or more rarely a magnet and a metallic foreign body (such as those bars included in assembly and construction toys). Immediately thereafter, (*ii*) the swallowed magnets proceed through the digestive tract, with different speeds due to the action of peristaltic waves. Finally, (*iii*) if two or more magnets (or a magnet and a metallic foreign body) come to a critical distance so that their magnetic force can attract each other, the walls of the different portions of the digestive tract where the magnets are located are brought into strict contact by this attractive force. The continuous pressure to which the walls are subjected leads invariably to ischemic necrosis of the mucosa and afterwards of the whole wall with a perforation that can cause a fistula (3-7).

The Susy Safe Registry is covering a broader set of locations than the gastrointestinal tract and thus the evaluation of size and shape of the objects causing injuries in locations different from the gastro-intestinal tract may differ. Nevertheless, if looking at the issue of foreign body injuries from the child perspective, the fact that the foreign body is ingested is perhaps a random choice among several other competing

possibilities, like swallowing or inserting in the ears. Recent experimental studies related to other objects revealed that, for the child, the act of putting a toy in his/her mouth is not necessarily associated to a mis-perception of it as a food component (38).

Even though the median age of the injured child is not quite different among MagDB and Susy Safe, the shape of the distribution of injuries is significantly different. Indeed, a deep examination of the relative distribution indexes reveals that a higher probability is characterizing the younger ages, but with some excesses or risk also in older ages (see Figure 1 in the left tail). The difference in shape implies that more extreme observations, in particular in younger ages, but not only, are more likely, and this effect could be entirely masked if a crude comparison made on location indexes (medians or means) would be performed.

Males are at higher risk, in particular in younger ages, and this is probably an exposure effect to some specific toys, which may result to be more attractive to them than to females.

Magnetic objects involved in accidents are of bigger size than non-magnetic objects. Bigger magnetic objects are characterizing injuries in children below three years of age, with a median volume (impressively) of 1125 $mm^3$. This is again due to an exposure to specific toys, usually ending up with gastro-intestinal location of the foreign bodies. Older ages are more likely to end up with nose and ears injuries due to toys, jewels or other smaller magnetic objects. Unfortunately, the availability of data on magnets causing injuries is still limited to a level of detail which is not entirely satisfactory. Data on strength of magnetic attraction is not available and object description is in some cases vague (in particular for jewels-like objects).

For what concerns the clinical course of the injured child, the incidence of complications if definitely higher when the injury is involving a magnetic object than a non magnetic one, and this is reflecting in a more complex clinical and surgical management of the cases and a prolonged length of stay, which is almost three times longer than with non-magnetic foreign bodies, which is still have a high impact from a public health perspective (39).

The delay of referring the child to the hospital is due to the un-specificity of symptoms, which are often taken as a flu-like syndrome and may contribute to explain the severity of some cases, including the death of one child in USA. Indeed, in 20% of the patients, a correct diagnosis has been made after two weeks after symptoms onset.

This relatively long time and the slow action by which the injury is caused make difficult to think of the magnet as the causative factor of the symptoms: however, there is the advantage that – due to their physical properties – they can be easily identified both with ultrasound technique and with plain X-ray. Several cases of injuries due to magnet ingestion, however, did not involve a real perforation of the intestinal wall with fistula formation but a severe alteration of the normal peristalsis due to the formation of a volvulus or an intussusception that proceeded until bowel occlusion. The end-result of these pathological situations however can be an intestinal occlusion that, if untreated, is potentially fatal.
The intrinsic danger of an ingested magnet together with another foreign body or of two or more magnets has recently fostered the development of an algorithm (32), suggesting that in all these cases an endoscopy is recommended. The real issue is nevertheless represented by an un-witnessed ingestion since the symptoms show a long delay and they can be easily confused in the beginning with a much less dangerous pathology, such as a gastro-intestinal viral illness.

**Study limitations**

First of all, this study is not based on a prospective collection of data. This implies that results must be taken cautiously, since biases in case ascertainment or reporting is likely to have happened. In addition, the geographical distribution of the MagDB is not matching that of Susy Safe, so that some observed differences could be attributable to this effect more than to epidemiological distribution of injury characteristics. Finally, the number of cases in the MagDB with a detailed description of the foreign body is limited (less than 70 cases) and, again, the possibility of a reporting bias must be taken in mind when reading results.

**Conclusions**

The Susy Safe Registry, although it has more that 70 centres participating, is largely based on ENT specialties, which more often face the foreign body issue. Given the intestinal location of most magnets after ingestion, a deeper involvement of the gastro-enterology/surgery community is thus needed in participating to the Susy Safe data collection. Nose and ears injuries, which often are referred directly to the family

practitioner (see CPSC data) should be captured involving family paediatricians in the Susy Safe registry for data collection

Most important, most of complications, and event the death of a child can be eventually re-conducted to either or both a delay in patient referral or appropriate diagnosis. Thus, it is an absolute priority that an information initiative is taken toward families and emergency doctors to avoid unnecessarily delays respectively in patient referral and in diagnosis.

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**Table 1** Distribution of childrens' age at time of the injuries (Months)

| | *Mean* | *5th pct* | *10th pct* | *I Q* | *Median* | *III Q* | *90th pct* | *95th pct* | *Max* |
|---|---|---|---|---|---|---|---|---|---|
| Overall | | | | | | | | | |
| SS NonFood | 57.95 | 13.65 | 22 | 31 | 47 | 75 | 118 | 144 | 178 |
| MagDB | 62.43 | 9 | 12 | 24 | 48 | 96 | 132 | 156 | 408 |
| Ears | | | | | | | | | |
| SS NonFood | 77.36 | 27.3 | 35 | 48 | 67 | 104 | 138 | 150.7 | 178 |
| MagDB | 71.45 | 12.6 | 24 | 36 | 60 | 114 | 130.8 | 143.4 | |
| Nose | | | | | | | | | |
| SS NonFood | 44.07 | 20 | 24 | 29 | 39 | 52 | 70 | 85.2 | 168 |
| MagDB | 97.47 | 24 | 31.2 | 48 | 94 | 144 | 165.6 | 180 | 408 |
| Upper airways (Choking) | | | | | | | | | |
| SS NonFood | 69.12 | 9 | 11 | 18 | 50 | 120 | 150.8 | 159.8 | 178 |
| MagDB | 56.43 | 9 | 11 | 18 | 50 | 120 | 150.8 | 159.8 | 178 |
| Digestive tract (Ingestion) | | | | | | | | | |
| SS NonFood | 48.34 | 8 | 11 | 23 | 37 | 65 | 96.6 | 127.6 | 173 |
| MagDB | 49.58 | 6 | 11 | 12 | 36 | 72 | 108 | 132 | 211 |

**Table 2** Entropy measures for capturing the relative dissimilarity between Susy Safe data and magnet injuries. Indexes are described in the methods section.

| | | | | | |
|---|---|---|---|---|---|
| Overall age distribution | | | | | |
| | | Entropy | % attributable | | |
| | Overall | 0.174 | | | |
| | Median effect | 0.004 | 2.33 | | |
| | Shape effect | 0.17 | 97.66 | | |
| | | Polarization Index | 95% C.I. | | P-value |
| | Median Index | 0.257 | 0.189 | 0.326 | <0.001 |
| | Lower Index | 0.507 | 0.4 | 0.613 | <0.001 |
| | Upper Index | 0.063 | -0.082 | 0.209 | 0.196 |
| Ears | | | | | |
| | | Entropy | % attributable | | |
| | Overall | 0.177 | | | |
| | Median effect | 0.002 | 1.39 | | |
| | Shape effect | 0.174 | 98.6 | | |
| | | Polarization Index | 95% C.I. | | P-value |
| | Median Index | 0.254 | 0.172 | 0.336 | <0.001 |
| | Lower Index | 0.525 | 0.399 | 0.625 | <0.001 |
| | Upper Index | 0.047 | -0.133 | 0.218 | 0.316 |
| Nose | | | | | |
| | | Entropy | % attributable | | |
| | Overall | 0.29 | | | |
| | Median effect | 0.028 | 9.71 | | |
| | Shape effect | 0.262 | 90.28 | | |
| | | Polarization Index | 95% C.I. | | P-value |
| | Median Index | 0.328 | 0.25 | 0.407 | <0.001 |
| | Lower Index | 0.617 | 0.504 | 0.731 | <0.001 |
| | Upper Index | 0.103 | -0.066 | 0.273 | 0.116 |
| Upper airways (choking) | | | | | |
| | | Entropy | % attributable | | |
| | Overall | 0.661 | | | |
| | Median effect | 0.155 | 23.51 | | |
| | Shape effect | 0.506 | 76.48 | | |
| | | Polarization Index | 95% C.I. | | P-value |
| | Median Index | 0.406 | 0.3 | 0.511 | <0.001 |
| | Lower Index | 0.715 | 0.584 | 0.846 | <0.001 |
| | Upper Index | 0.164 | -80 | 0.409 | 0.093 |
| Digestive tract (Ingestion) | | | | | |
| | | Entropy | % attributable | | |
| | Overall | 0.089 | | | |
| | Median effect | 0.028 | 34.74 | | |
| | Shape effect | 0.053 | 65.25 | | |
| | | Polarization Index | 95% C.I. | | P-value |
| | Median Index | 0.129 | 0.019 | 0.241 | 0.0107 |
| | Lower Index | 0.319 | 0.12 | 0.517 | 0.008 |
| | Upper Index | -0.012 | -0.247 | 0.221 | 0.457 |

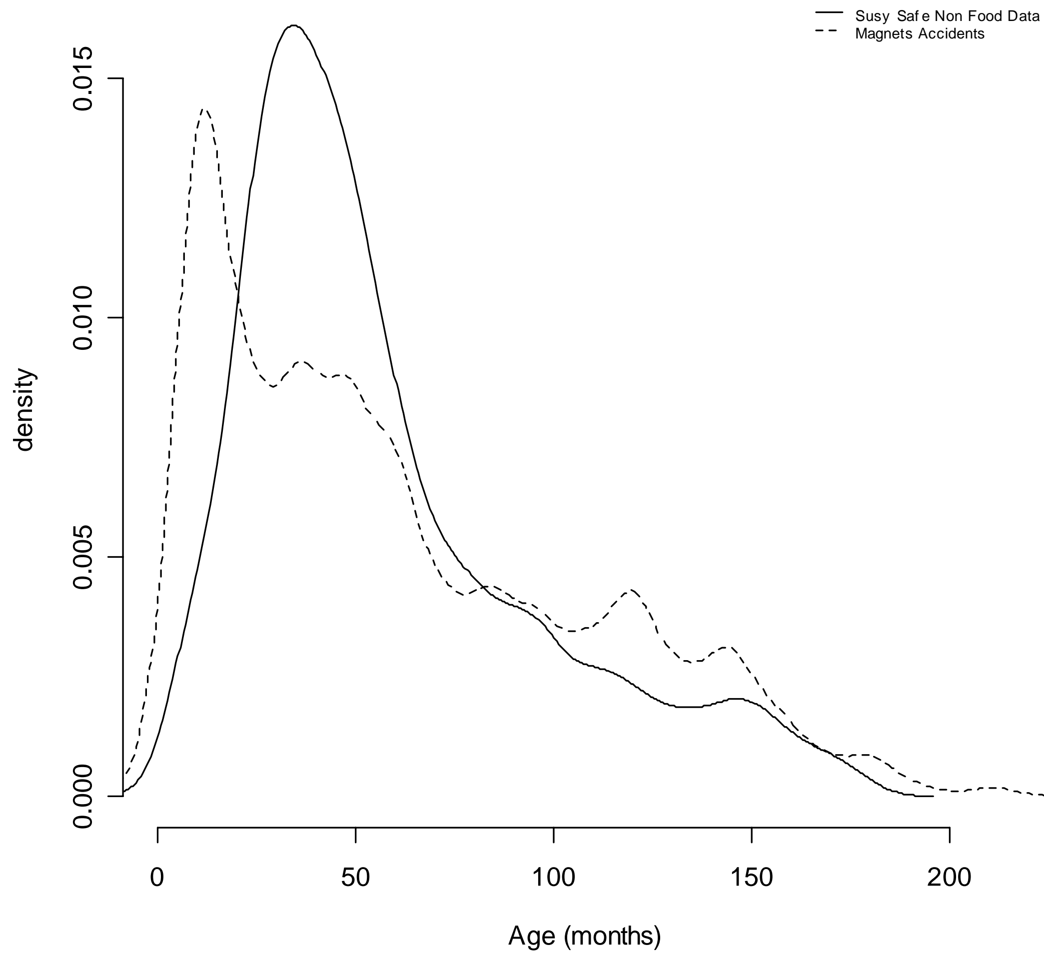


**Figure 1** Distribution of children's age at time of injury in the Susy Safe Database and in the MagDB.

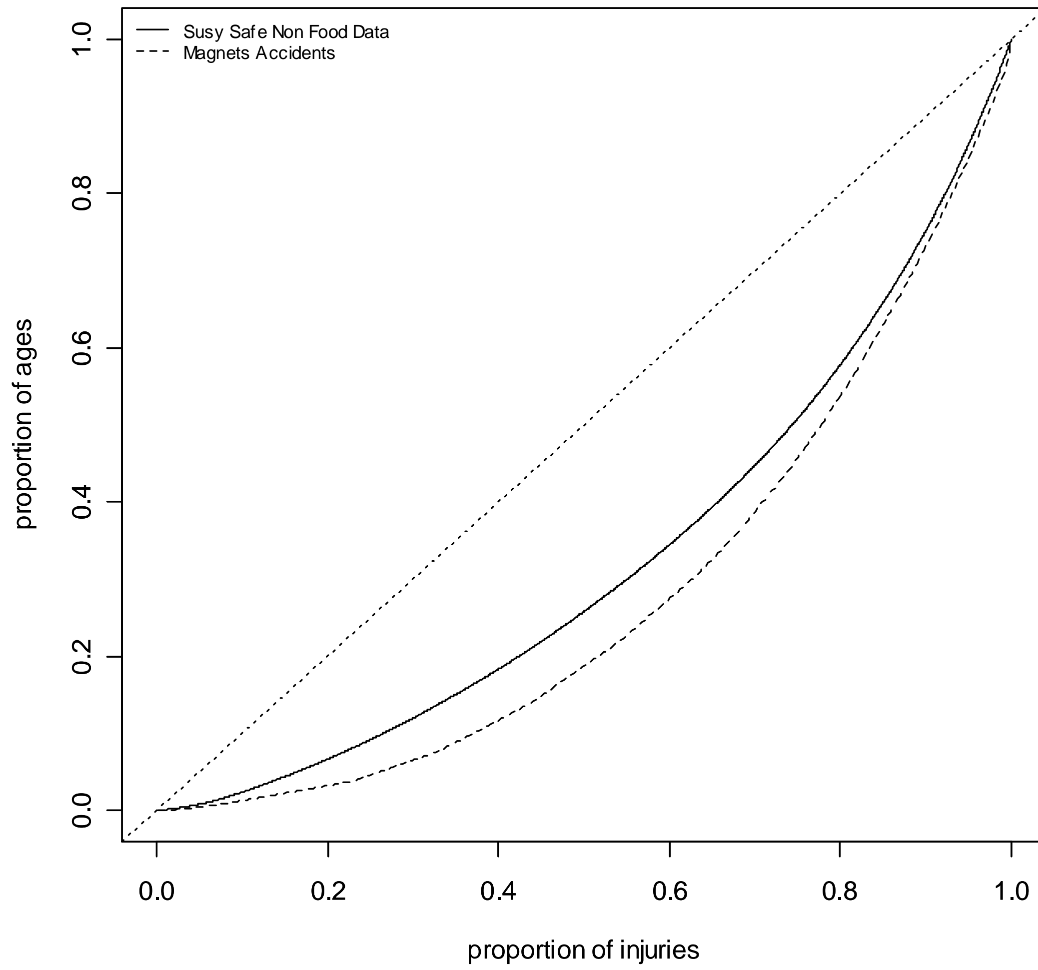


**Figure 2** Lorenz curve for the Probability Density Functions of the age at injury for the Susy Safe Database and the MagDB.

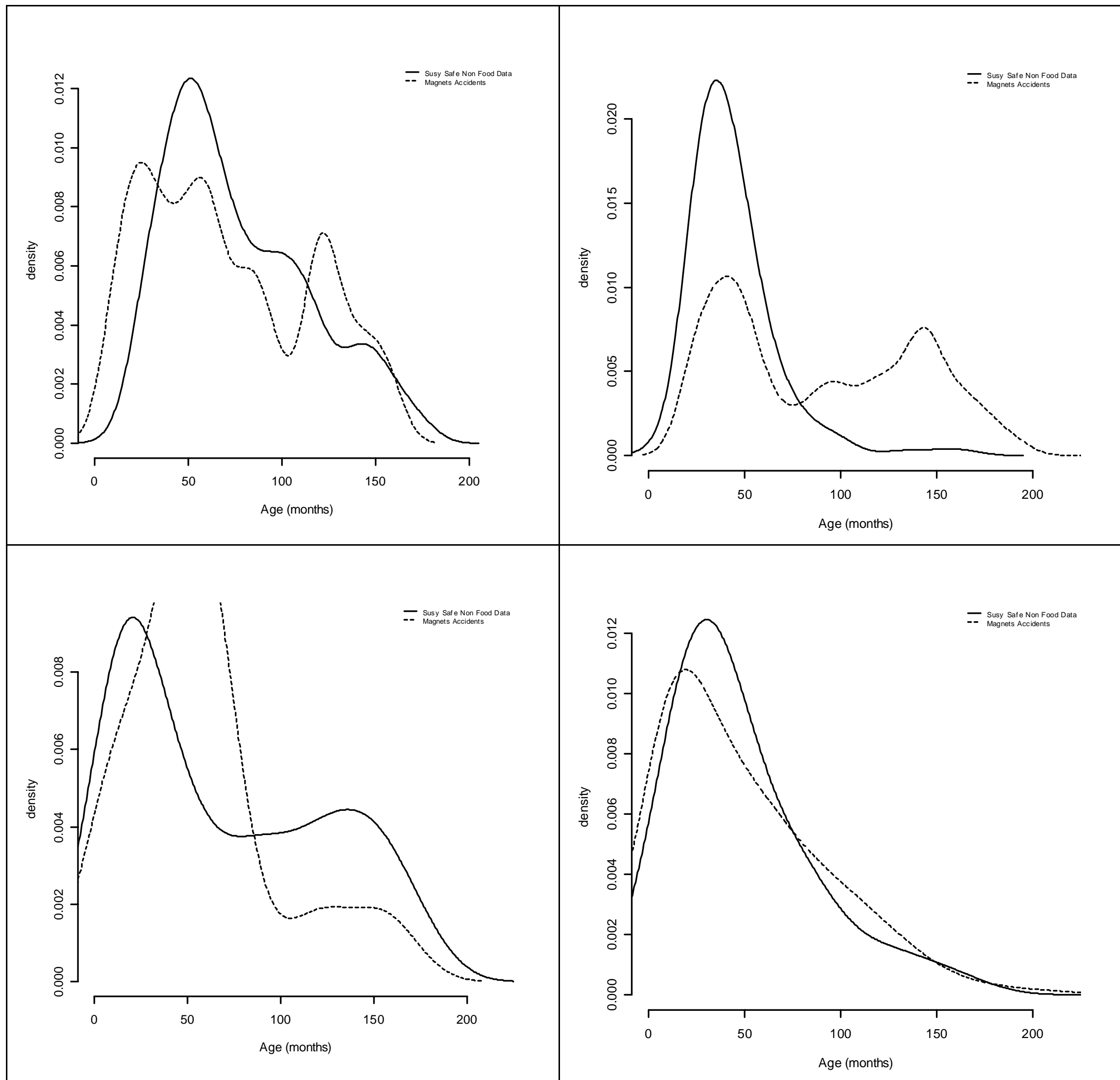


**Figure 3** From upper left down to bottom right: Probability density estimation for ages at time of injury as observed in the Susy Safe Database and compared with those in the magDB, respectively in the ears, nose, upper respiratory tract (choking episodes), gastro-intestinal tract (ingestion).

**Table 3** Magnet characteristics stratified by age class of the child and overall. Summary measure for the continuous variable are median [1 quartile – III quartile]

| | *Below 3 yrs* | *Above 3 yrs* | *Combined* | *P-value* |
|---|---|---|---|---|
| Length (mm) | 15 [9.5-18] | 7 [7 - 12.7] | 7 [7 - 16] | 0.294 |
| Diameter (mm) | 6 [3.63-8.89] | 4 [3.59 - 4] | 4 [3.38 - 5] | 0.127 |
| Volume (mm3) | 1125 [417.125-2670.74] | 87.9 [87.9 - 402] | 87.9 [87.9 - 602.9] | 0.135 |
| Number | 2/4/8 | 1/2/3 | 1/2/3 | 0.002 |
| Shape2 : Ball | 10% ( 1) | 11% ( 8) | 11% ( 9) | 0.095 |
| Bead | 30% ( 3) | 4% ( 3) | 7% ( 6) | |
| Coin-Like | 0% ( 0) | 1% ( 1) | 1% ( 1) | |
| Cylinder | 60% ( 6) | 81% (61) | 79% (67) | |
| Heart | 0% ( 0) | 1% ( 1) | 1% ( 1) | |
| Peg | 0% ( 0) | 1% ( 1) | 1% ( 1) | |
| Type2 : Toy (vs Jewelry) | 60% ( 6) | 85% (67) | 82% (73) | 0.054 |

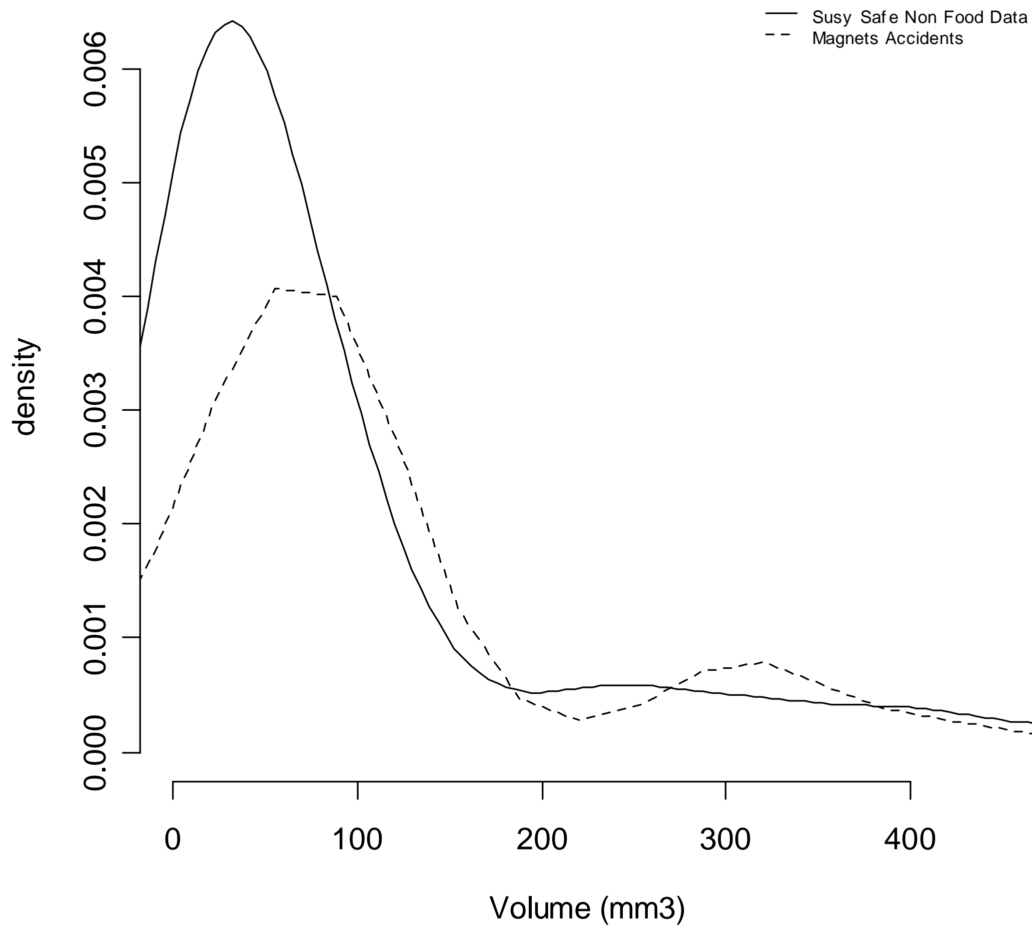


**Figure 4** Distribution of volume of magnets in the magDB as compared with the non-food foreign bodies in the Susy Safe Database.

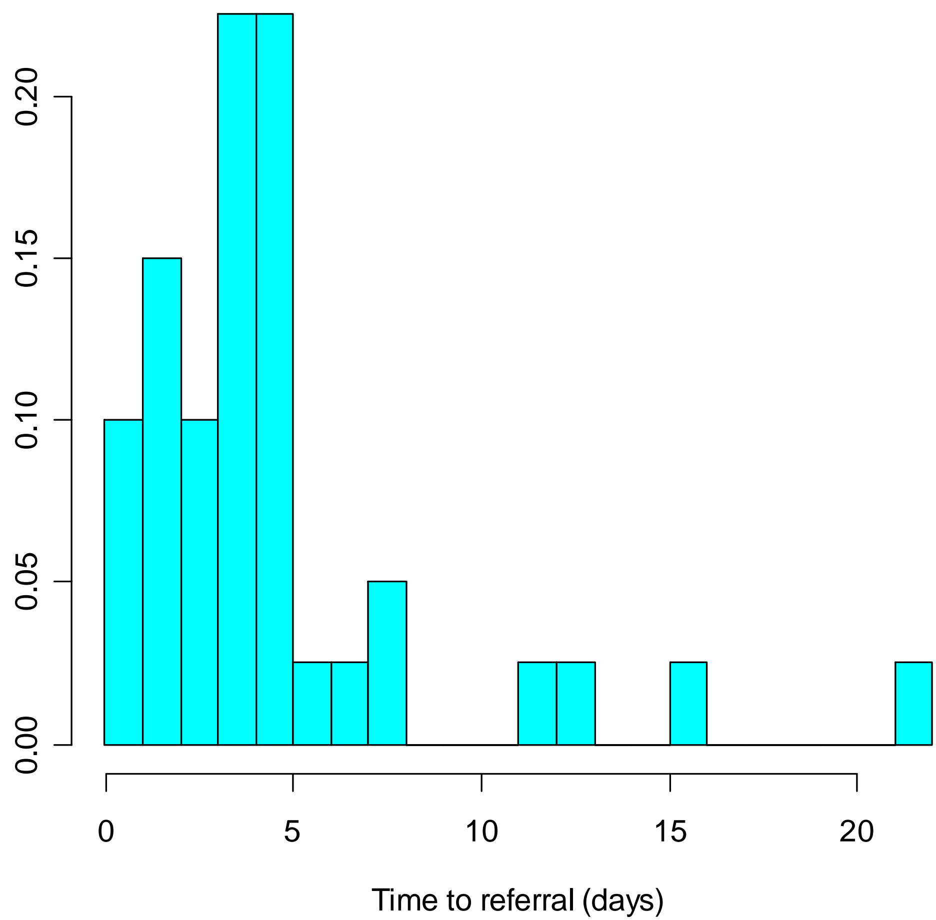


**Figure 5** Histogram (Friedman-Diaconis choice of the bandwidth) of time before referring the child to the medical care system.

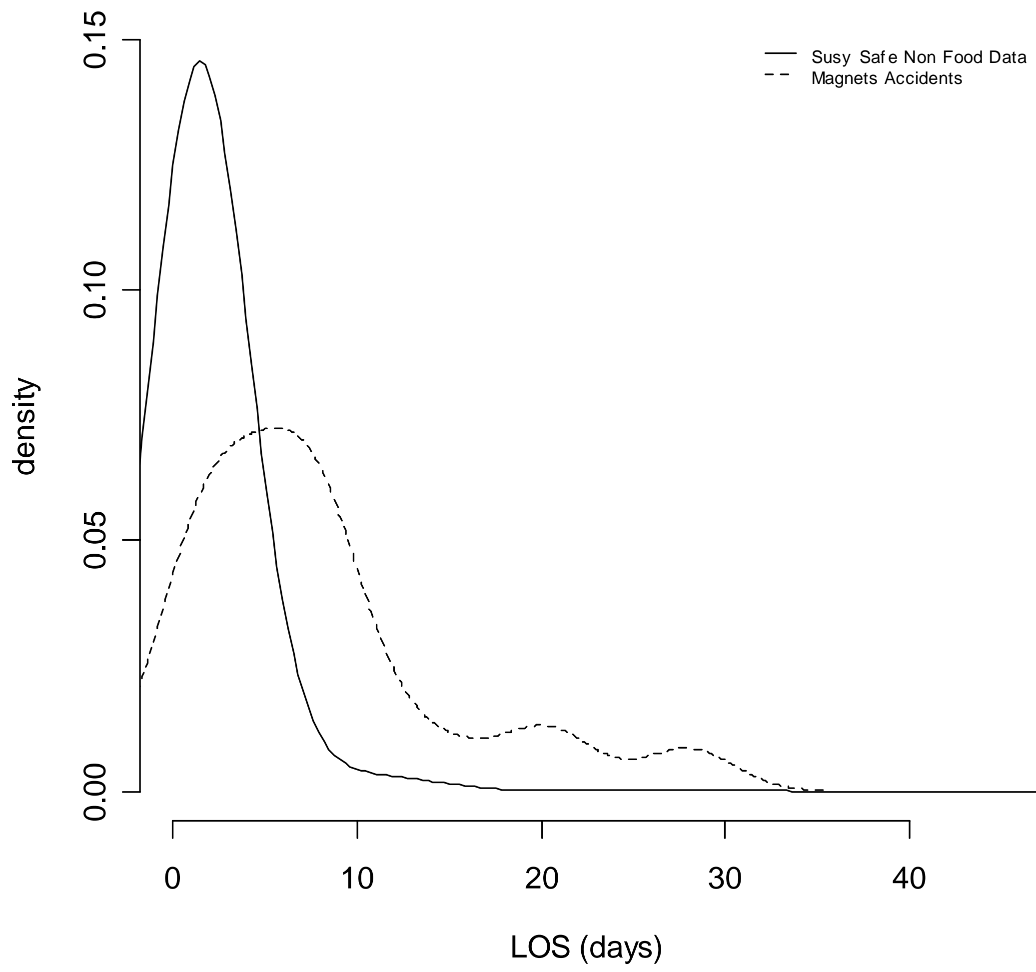


**Figure 6** Distribution of length of stay (days) in the Susy Safe Database and in the MagDB

**Title:Food products containing inedibles a summary of the evidences at today**

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## Abstract

The aim of the paper is to elicit the present evidences on Food Products Containing Inedibles (FPCI), analyzing their impact on mortality and morbidity due to their aspiration or ingestion. In the Two different approaches are taken from the US and Europe. The first has banned all the toys or articles used by children under 3 years that present a choking hazard because of small parts. For this reason, FPCIs are in large part considered as a violation of the Product safety Commission's regulation. European surveys pointed out that the linkage between eating a FPCI and the subsequent incident isn't proved, and that there's still an evidence of low risk associated with them. Therefore in the European context this important public issue is mostly controlled with strict regulation of these items' production. Most of the time when speaking about FPCIs, the objects indicated are small toys, whose direct consumers are children. Specifically labeling the product with warning about the age limits' recommendation is a first step of prevention, although it might not influence a decrease of injuries as expected. A key role in prevention is the supervision of adult while children are dealing with FPCIs. Even in the occurrence of the injury, the presence of an adult witnessing and promptly reporting to the pediatrician or the general practitioner means a shorter delay of diagnosis, clinically linked to minor complications.

**Keywords:** toys, food, inedibles

## Introduction

Choking is an important cause of unintentional injury and death in young children. Among Foreign Bodies (FB) that may represent choking hazards for children, small toys or toy parts are to be mentioned, even if many joint efforts have been made in several countries to reach acceptable safety levels for several kinds of products devoted to children's care and entertainment. 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.

It has become common for food manufacturers to include toys or other non-food items as a marketing device to encourage consumers, especially children to buy their food products.

Special kinds of toys are those contained in edible products, sometimes referred to as surprises (i.e., those known as Food Products Containing Inedibles [FPCI]). These surprises are usually small gadgets made up of several parts, which are to be assembled to obtain the whole toy. The FPCI category is actually very broad, embracing various types of food coupled in different ways with toys that differ in size and characteristics. Those chocolate candies have been very popular in many European countries, and healthcare providers should be aware of this ingestion hazard. Although these toys are usually blunt, many of them are not smooth and could easily lodge in the oesophagus. According to the European Community Directive concerning the safety of toys, packaging containing edible items together with small toys which might be dangerous for children under three years of age must carry the warning "Not suitable for children under three years". Despite several regulations that restrict the FPCI consumption by excluding some categories like children below 3 years of age, or imposing specific requirements on packaging (e.g., surprises must be physically separated from the food parts either by transparent plastic envelopes or opaque capsules, with the aim to avoid direct contact between the two components and prevent the migration of color, smell, taste, etc. of the edible into the inedible part), FPCIs are still considered intrinsically dangerous (i.e., representing risky conditions due to the accidental ingestion of pieces of the toy during the food part consumption.

## Present evidences

Langlois and colleagues in 1991 [1] showed how specific toy warning labels impacted on buyers to prevent choking due to small parts. Toys with small parts can still be legally sold if they are not marketed to children who are less than 3 years of age. To comply with the standard, toy manufacturers generally place age labels on the packaging to indicate the ages for which toys with small parts are recommended, for ex. "Recommended for ages 3 and up" but age labels, per se, are not required, nor are their contents or appearance regulated. The CPSC provides manufacturers with guidelines for age labeling that state that both developmental appropriateness and safety considerations must guide the determination of recommended age levels for toys. Since the small parts standard mandates that toys marketed to children under the age of 3 years be free of small parts and other potential hazards, the labels on toys for these children serve as developmental guidelines. The age recommendations on toys for children over the age of 3 years, however, are based both on safety factors (eg, the presence of small parts) and on factors related to the physical and intellectual development of the child. Because the content of age labels is not specified by regulation, the age labels on toys with small parts often do not specifically mention a potential choking hazard. As a result, parents and other toy buyers who read the label may erroneously interpret the age recommendation only as a guide to the age at which children might find the toy interesting or intellectually stimulating, and not as a warning. From their inquiry they deduced that with few exceptions, current warning labels on toys may not be sufficiently explicit to alert buyers of toys with small parts to the potential choking hazard to children under 3 years of age. These findings suggest that a change in the small parts standard to require specific labeling such as "Not recommended for children under 3 due to danger of choking from small parts" might substantially reduce inappropriate toy purchases without imposing any substantial cost on the consumer, the government, or the manufacturer.

In the same year, 1991, Matthes, Sibert and Levene [2] undertook a study of choking episodes in Wales, concluding that incidents of choking due to parts or hair from toys must be rare and are not a major problem in the UK.

Studies in Greece, Germany and Israel all confirm that food products containing inedibles are inherently unsafe and that labeling is not an adequate protection. It is estimated that 2,000 injuries occur annually in the European Union due to inedibles in food products alone

In the European context, Petridou [3] states that the emergence of injuries due to food products containing inedibles (FPCI) as an important public health issue in the European Union (EU) is justified by the realization that accidents represent now the most important cause of childhood morbidity and mortality, added to the fact that they are themselves the product of a mosaic of causes that require different remedially approaches, depending on their nature and context and to the

consideration that injuries from food products containing inedibles can be prevented with simple measures requiring little cost, without onerous consequences from the industry, when generally applicable rules are imposed on all competitors.

In 1998 Weizman published his observation about the experience with toys within chocolate-eggs. The packaging of these candies usually carries a warning, recommending they not be given to children below 3 y of age. Based on the report and on the medical literature, foreign body ingestion occurs at a wide range of ages. Although median age is usually between 2.5 and 3 y, ages range from 4 months to 16 years. Therefore, 3 years of age is not a safe limit. Moreover, adult supervision does not prevent ingestion.

Kehrt and colleagues [4] tried to assess the potential danger of small toys marketed with confectionery and performed a national cross-sectional questionnaire survey, including 500 (90%) pediatric clinics, 1300 (25%) paediatricians in practice, and placed an advertisement with the questionnaire in the newsletter of the German Association of Paediatricians, according to their results, small toys marketed with confectionery constitute a potential risk especially for children under 5 years. In comparison to other accidents with foreign bodies, which are mainly caused by aspiration of peanuts and ingestion of coins, foreign body injuries caused by small toys marketed within chocolate eggs are rare. However, the common product warnings are not sufficient for the protection of the risk group. In addition, more than half of the children concerned were 3 years or older. Since there are no rules specifying the nature and appearance of the warning, there is usually no indication of the nature of the risk. Parents or other consumers therefore may misinterpret the label as information about the age group the toy is intended for, rather than as a warning.

In a review for Manitoba's health that concept is stressed again, showing that is important that toy packaging contains age-related warning labels [5]. In Canada, this is governed by the Hazardous Products Act. A survey of toy buyers showed that some parents do not view the age recommendations as a warning. The phrasing of the message was also relevant. When the warning read 'Recommended for children three and over' 44% said they might buy the item for a two or three year old child. Only 4% would buy a product that was labelled 'Not recommended for a child less than three years old – small parts'. The latter statement identifies the age-specific hazard and may better inform parents of the choking risk.

In difference to Europe, the legislature of the United States of America bans from interstate commerce any toy or other article intended for use by children younger than 3 years that presents a choking, aspiration, or ingestion hazard because of small parts [6]. US Consumer Product Safety Commission (CPSC) considers the toys within the eggs to violate CPSC's small parts regulation

with respect to children under 3, and therefore, the kinder surprise chocolate egg is not allowed to be marketed in the United States, although no injuries involving these toys are reported so far.

In a report to the European Parliament [7] with the specific goal to clarify the situation through a critical review on the available data and to help understanding the health risks associated with FPCI, it was estimated that FPCI incidents (involving ingestion, choking or suffocation) account for 1% of such incidents involving toys, which in turn account for 5% of all such incidents amongst children aged 0 to 14. This results in an estimated 34 non-fatal FPCI incidents involving children per year across EU. Since chocolate eggs containing edibles are the dominant product containing small parts, most reported incidents relate to chocolate eggs. Furthermore, it appeared that the observed number of incidents were more closely related to the number of chocolate eggs sold than to the number of child consumers. Although the causal link between eating the food product and a subsequent incident is not proven the risks associated with FPCIs are demonstrably low. However the risks weren't zero, and that suggested that some manufactures discontinued the use of promotional inserts in the interest of the safety of the young consumer.

Benelli, Donati and colleagues [8] stressed the fact that analyzing the literature on FPCIs, it showed that all the studies are weak, often invalidated by some methodological faults and incomplete, due to the absence of any comparison to the risk exhibited by simple toys. They concluded that Their experimental results suggested that FPCIs did not represent a higher risk of accidental ingestion (and possible choking) when compared to toys alone, since children aged 3 to 6 showed a good ability to recognize the ''double nature'' of the FPCIs products, especially of the more familiar and physically well separated ones (i.e. chocolate egg); children apparently interacted with FPCIs as they did with toys presented alone, at least as far as mouthing is concerned.

Morra [9] analyzed the available data from the literature showing that they are fraught with many weak points, and 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. He therefore reviewed the data available to understand if there was a linkage between FPCIs and higher risk of choking, but epidemiological data did not seem to sustain any hypothesis of this kind. They stated that it was 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 x Exposure was kept in mind, it was easy to understand that to estimate the risk, besides the possible hazardous intrinsic characteristics of a given FPCI, it was 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. Therefore, someone might have said 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 recognized, but manual playing in particular has recently received much attention. In addition, authoritative institutions such as the British Consumer Affair directorate of the Department of Trade and Industry (DTI) not involved in educational issues, have recognized that playing with small toys is essential for the development of manual and intellectual skills, not forgetting to search on small parts of toys as a possible source of injury.

Later, Donati and colleagues [10] developed a study, conducted on children aged 3–6 in a setting familiar to them (known room in their kindergarten or primary schools), whose aim was to understand how children behave when interacting with FPCIs, in particular with respect to mouthing activities (i.e., putting the inedible part in the mouth), how children recognize the double nature of the FPCI both verbally and non-verbally; and finally, and how independent the children are in assembling the toy parts. the questionnaire investigated children FPCIs direct exposure (frequency of purchase and consume) and indirect exposure (time spent watching TVand perception of other children consuming FPCIs). Three FPCIs were tested and each item was tested 32 times: every child took part in two videotaped experimental sessions in two different days. According to the aim of the study, the sample size was determined to detect if the association of food and toys (FPCI) implies a higher risk of mouthing activity compared to toys presented alone. This study shows that the behavior of children with respect to toys contained in FPCI products and toys presented alone is not significantly different. Furthermore, the ability of children to distinguish between the edible and non-edible part of the FPCI was very high. This is evidence supporting the fact that FPCIs are not per se distinguishable from the toys containing small parts in children younger than 6 years of age with respect to the risk of choking.

Stated that the dimensions, the shape and the consistencies of FPCIs, a leading role is given to prevention and supervision of children. The European Registry of Foreign Body Injuries has shown that incorrect or distracted adult supervision is commonly a cause of the injury mechanism [11]. In the Susy Safe database, a parent or a care giver was present in 49% of cases of injury, and it is interesting to note that the child was eating in 34% and playing in 59% of the cases. As suggested also from Tan [12] who reviewed the charts of children who had airway foreign body removed via direct laryngoscopy and bronchoscopy from 1987-1997 in Boston’s Children's Hospital, Parental delay was an additional factor influencing morbidity and mortality in 21 instances. The aspiration of a foreign body usually causes significant coughing, choking, gagging, and wheezing in a short time

thus calling attention to the problem, but in many cases the diagnosis was delayed, usually because the ingestion was not witnessed, because there were no symptoms or signs, or because the presence of a foreign body was not suspected when symptoms and signs did appear. A delayed diagnosis leads to complications as chronic respiratory syndrome, noticing that the diagnosis of patients in whom the relatives' suspicion is not firm may be delayed up to months [13].

**Conclusions**

As far as shown from the various researches, there's no evidences supporting the hypothesis of higher risk posed by FPCIs. Addition of inedibles in food products is a marketing technique but it is not always clear what youngsters of three or four years have in mind when they respond to this implicit message. This issues can't be solved by simply eliminating these kind of toys, because it would mean to deprive children from their right to play with a toy, whose role in growth and mental development is proved by all means. 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. Many approaches have been accounted to prevent those injuries and the factors that mostly effect morbidity and mortality are suggested being proper labelling and warning of the items and supervision from adults while the children are playing. Since supervision is one of the strongest protective factors for many injuries within the home parents should be encouraged to supervise their children at all times, particularly during meals and play time. Emphasis should be placed on sitting while eating, playing with age-appropriate toys, and not allowing an older sibling to supervise a younger sibling. But as seen from Carol Pollack-Nelson [14] who examined actual supervision practices of parents of children between the ages of two and six years, many parents supervise their children by being close-by and on-hand as needed, rather than being directly involved in the child's activities. Stressing the fact that an early diagnosis decreases the occurrences of complications, proper control of children dealing with FPCIs seems to be the most susceptible factor.

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**Title: Nuts and seed: a natural yet dangerous foreign body**

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**Abstract**

**Rationale and aim:** This papers has the object to present the impact of nuts' and seeds' injuries withdrawing data from the Susy Safe registry, highlighting that as for other foreign bodies the main item efficiently and substantially susceptible to changes to decrease the accidents' rates is the education of adults and children, that can be shared with parents both from pediatricians and general practitioners. Indeed labelling and age related warnings have also a fundamental relevance in prevention.

**Methods:** The present study draws its data from the SUSY Safe registry. Details on injuries are entered in the SUSY Safe Web-Registry through a standardized case report form, that includes information regarding: children age and gender, features of the object, circumstances of injury (presence of parents, activity) and hospitalization's details (lasting, complications and removal details). Cases are prospectively collected using the Susy Safe system from 06/2005; moreover, also information regarding past consecutive cases available in each centre adhering to the project have been entered in the Susy Safe Registry.

**Results:** Nuts and seeds are one of the most common food item retrieved in foreign bodies injuries in children. In Susy Safe registry they represent the 38% in food group, and almost the 10% in general cases. Trachea, bronchi and lungs were the main location of FB's retrieval, showing an incidence of 68%. Hospitalization occurred in 83% of cases, showing the major frequency for foreign bodies located in trachea. This location was also the principal site of complications, with a frequency of 68%. There were no significant associations between these outcomes and the age class of the children. The most common complications seen (22.4%) was bronchitis, followed by pneumonia (19.7%). Adult presence was recorded as positive in 71.2% of cases, showing an association (p value 0.009) between the adult supervision and the hospitalization outcome. On the contrary there was a non significant association between adult presence and the occurrence of complications.In 80.7% of cases, the incident happened while the child was eating. Among those cases, 88.6% interested trachea, lungs and bronchi.

**Conclusions**: Food-related aspiration injuries are common events for young children, particularly under 4 years of age, and may lead to severe complication.

There's a need to study in more depth specific characteristics of foreign bodies associated with increased hazard, such as size, shape, hardness or firmness, lubricity,

pliability and elasticity, in order to better identify risky foods, and more precisely described the pathogenetic pathway. Parents are not adequately conscious and aware toward this risk; therefore, the number and severity of the injuries could be reduced by educating parents and children. Information about food safety should be included in all visits to pediatricians in order to make parents able to understand, select, and identify key characteristics of hazardous foods and better control the hazard level of various foods. Finally, preventive measures including warning labels on high-risk foods could be implemented.

**Keywords:** Suffocation, choking, nuts, seeds, supervision

## Introduction

Inhalation and aspiration of foreign bodies maintain their connotation of high prevalence cause of injury in children. Characteristics of food, like shape, dimension, consistency are fundamental in determine the damage that might occur. Small items represent a real issue, identifying them mostly with nuts and seeds, and the impact on different systems varies depending on permanence, dimension and composition. FBs injuries located in the upper airways can be a very serious event, sometimes resulting in fatal outcome. Without an early treatment it remains a major cause of morbidity and mortality in children, especially during the first years of life.

This papers has the object to present the impact of nuts' and seeds' injuries withdrawing data from the Susy Safe registry, highlighting that as for other foreign bodies the main item efficiently and substantially susceptible to changes to decrease the accidents' rates is the education of adults and children, that can be shared with parents both from pediatricians and general practitioners. Indeed labelling and age related warnings have also a fundamental relevance in prevention.

## Methods

### Data collection

The present study draws its data from the SUSY Safe registry, a European Commission co-funded project started in February 2005, whose aim is to establish an international registry of cases of Foreign Bodies (FB) injuries in children aged 0-14 years. Currently the project collects nearly 17000 data, from 60 institutions, located in 26 countries. Details on injuries are entered in the SUSY Safe Web-Registry through a standardized case report form, that includes information regarding: children age and gender, features of the object, circumstances of injury (presence of parents, activity) and hospitalization's details (lasting, complications and removal details). Cases are prospectively collected using the Susy Safe system from 06/2005; moreover, also information regarding past consecutive cases available in each centre adhering to the project have been entered in the Susy Safe Registry.

### Statistical analysis

The analysis was carried out on injuries due nuts and seeds. Age and gender injury distributions were assessed. Data regarding adult supervision were also evaluated.

FB location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935).
Descriptive statistics (absolute and relative number or median, I and III quartile according to the categorical or continuous variable characteristics, respectively) were calculated for each nuts characteristic; FB features distribution by children class age and site of obstruction were assessed.
The association between children age, adult presence, object characteristics and outcomes, including complications and hospitalization (child admitted in the hospital for at least 1 day) was computed using unweighted odds ratios and the related 95% confidence intervals. Odds ratios not possible to be evaluated due to small cell frequency were labeled as NS (not significant).
Analyses were performed using Design and Hmisc libraries from R version 2.8

**Results**

Nuts and seeds are one of the most common food item retrieved in foreign bodies injuries in children. In Susy Safe registry they represent the 38% in food group, and almost the 10% in general cases.
The description of FBs which caused the incident is shown in Table 1.
Trachea, bronchi and lungs were the main location of FB's retrieval, showing an incidence of 68%. Among those, there was a significant difference between genders, with male's frequency higher than female's one (respectively 60% and 40%). Other location (namely ears, nose, pharynx and larynx, mouth, esophagus and stomach) showed a similar distribution between the two genders.
The distribution by class age showed a higher frequency in 1-2 years age class group, with 65.4% of cases belonging to this class. Children older than 3 years old injured by nuts and seeds were the 27,9, while the youngest, lower than 1 year, incurred in this kind of injury in 6.7% of cases.
Observing the characteristics of the foreign bodies, median volume presented a value similar in all age class, assessing between 31.40 $mm^3$ and 34.54 $mm^3$. The maximum volume observed was at 3rd quartile in the older age class, reaching 96.16 $mm^3$.
In order to understand the impact of spherical objects to the risk of injuries, the ellipticity, defined as the ratio of the longer and the shorter axis of the object, thus being 1 for spherical objects. The median ellipticity was 1 in the first and the last age

class, while the second class, from 1-2 years old, assessed on 1.67. Ellipticity and volume are therefore extensively shown in Table 2

Volume and ellipticity were also analyzed by FB location. The results are shown in Table 2. Volume was higher in foreign bodies retrieved in the nose and in the trachea, bronchi and lungs, respectively, 37.68 $mm^3$ and 36.63 $mm^3$. Median ellipticity was 5.00 and a third quartile ellipticity was 6.00 in pharynx and larynx, while in the other location it assessed around 1.00 for the median, and reaching 4.00 in the third quartile just in trachea, bronchi and lungs.

Hospitalization occurred in 83% of cases, showing the major frequency for foreign bodies located in trachea. This location was also the principal site of complications, with a frequency of 68%. There were no significant associations between these outcomes and the age class of the children.

The most common complications seen (22.4%) was bronchitis, followed by pneumonia (19.7%).

Adult presence was recorded as positive in 71.2% of cases, showing an association (p value 0.009) between the adult supervision and the hospitalization outcome. On the contrary there was a non significant association between adult presence and the occurrence of complications.

In 80.7% of cases, the incident happened while the child was eating. Among those cases, 88.6% interested trachea, lungs and bronchi.

## Discussion

This study aligns its results with data coming from international scientific literature, stressing the relevant risk of suffocation associated with nuts and seeds and reveals that while in Asian countries, sunflower watermelon and other seeds are probably the most commonly aspirated objects, in western regions nuts, mainly peanuts, seem to be the most dangerous items.

Reviewing literature on injuries due to nuts and seeds shows similar results to this study. A large North American retrospective study collecting injury data from 1989 to 1998 for 26 pediatric hospitals in the United States and Canada, analyzed aspiration, ingestion, insertion and choking injuries due to food items. The data included 1429 infants and children Peanuts caused the highest frequency of injury, accounting for 26% of all injuries while sunflower seeds accounted for 7% [1].

Recently, a retrospective study in the major hospitals of 19 European countries was realized on injuries occurred in the years 2000–2002 and identified by means of the International Classification of Diseases, Ninth Revision (ICD-9) codes listed on hospital discharge records [2]. Seven hundred and twenty-two FB inhalation/aspiration injuries were observed. In 170 (24%) cases FB was lodged in the laryngeal and pharyngeal tract; in the remaining 552 (76%) cases, FB was retained in the tracheobronchial tree. Complications occurred in 12.7% of cases and the hospitalizations were present in 77.6% of the total injuries. In the most of cases (52%) children inhaled nuts, seeds, berries, peas, corns and beans. These items are also responsible of the 64% of complicated cases and of the 54% of hospitalizations greater than 1 day. Similar results have been found for foreign bodies located in the nose: on 688 cases assessed in the European survey of foreign bodies injuries study, Complications and hospitalization occurred in 59 and 52 cases, respectively and, also for this location site, the most common FBs associated with complications and hospitalization were nuts, seeds, berries, corn and beans.

Characteristics of food, including shape, dimensions, consistency, are fundamental in determining the seriousness of injury and the relationships among food type and damage has been extensively studied.

The nature of inhaled foreign bodies varies from country to country and is dependent on diverse cultural, social, and economic factors that include parental attitudes, eating habits, availability and types of potentially threatening objects, and prevention strategies.

Data collected from an international background, as Susy Safe project ensures, suggest in this study that the ingested FB were in pieces, giving the small volume presented, and stressing the necessity of active supervision during meals, being eating the major occasion of incident in this case. The ellipticity adds information of the nature of nuts and seeds linked to the injuries, and presentation, as other studies, that while the tracheobronchial tree is more interested by injuries from food having one size bigger than the other, all other location were affected by round pieces of food.

Similar results were also obtained in 1984 by Harris [3], who collected and analyzed data on all identified food-related asphyxiations of infants and children aged 0 to 9 years happened in 41 US states from 1979 to 1981. Death certificates specifically identified 103 foods and the round foods (hot dog, candy, nuts, grapes) were the most often mentioned.

Harris and colleagues firstly described three phases in food asphyxiation: penetration, occlusion, and expulsion and hypothesized a relationship among foods, children, and environment in determining the dynamic of every asphyxiation phase.

Intuitively, a large bolus is more likely to block the airway at a higher level and cause asphyxia. Small items that have a spherical shape, are most likely to cause obstruction of the lower respiratory tract. This fact explains why shape and dimensions are related with symptoms: partial laryngeal obstruction may cause hoarseness, aphonia, wheezing and dyspnea, while most common symptoms due to FBs lodged more distally in the tracheobronchial tree are unilateral wheeze and decreased breath sounds.

Altkorn and colleagues [1] showed that the severity of respiratory distress prior to hospital evaluation vary depending for kind of foods. Authors found that hard, round foods with high elasticity or lubricity properties, or both, pose a significant level of risk. The high portion of extremely severe clinical outcomes including interrupted breathing and possible neurological damage was observed for hot dogs (17%) followed by peanuts (11%).

Moreover, tissue response to a foreign body varies according to the composition of the FB and any associated bacterial infection. Organic fragments cause greater acute inflammation than pieces of metal, plastic or bone.

Children that inhaled nuts presented with more severe symptoms and signs of respiratory distress, features that demanded urgent treatment [1]. Part of the reason is that the nut swells with time. As well, oil and salt in the nut irritate the bronchial mucosa and lead to an intense, local, chemical inflammatory reaction around the nut. This combination of factors leads to early obstruction of the tracheobronchial tree. Local inflammation, edema, cellular infiltration, ulceration, and granulation tissue formation may contribute to airway obstruction while making bronchoscopic identification and removal of the object more difficult. Mediastinitis or tracheoesophageal fistulas might result. Distal to the obstruction, air trapping might lead to local emphysema, atelectasis, hypoxic vasoconstriction, suppurative pneumonia, or bronchiectasis. Even if the object is removed, the inflammatory changes may not be completely reversible.

Young children with immature teeth are especially at risk for aspirating fragments of the nut because they cannot easily chew the fruit. Aspirating either the fruit itself or pieces of the shell leads to major problems for small children. Shell when cracked

produces pieces with sharp edges; these may easily penetrate the bronchial mucosa if aspirated, and it is rather difficult to remove the aspirated nut shell from the airways by bronchoscopy. Nut breaks into amorphous and hard pieces and bronchoscopic removal sometimes becomes very difficult and frequently more than one attempt is needed [4].

**Conclusions**

Food-related aspiration injuries are common events for young children, particularly under 4 years of age, and may lead to severe complication.

The implementation of injuries preventive strategies is based on a solid knowledge of the characteristics of the children at risk, the features of objects and the dynamics of the hazardous event. Building up this kind of knowledge requires continuous monitoring activity since dietary habits vary over the time and among countries.

Moreover, some authors suggest the need to study in more depth specific characteristics of foreign bodies associated with increased hazard, such as size, shape, hardness or firmness, lubricity, pliability and elasticity, in order to better identify risky foods, and more precisely described the pathogenetic pathway.

The fact that a large fraction of the injuries occur during social occasion such as festivities and under the supervision of the adults suggest that parents are not adequately conscious and aware toward this risk [17]; therefore, the number and severity of the injuries could be reduced by educating parents and children. Information about food safety should be included in all visits to pediatricians in order to make parents able to understand, select, and identify key characteristics of hazardous foods and better control the hazard level of various foods: Particularly, firm or hard foods, requiring adequate chewing by molar teeth, are particularly hazardous for children who lack adequate dentition. All of these items should be avoided until the child is able to chew them adequately while sitting. Generally this occurs around age 5 years.

Finally, preventive measures including warning labels on high-risk foods could be implemented.

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## Tables

**Table 1:Description of the FB which caused the incident.**

| FB description | N(%) |
|---|---|
| Nut | 614 (59%) |
| Seed and grain | 430 (41%) |

**Table 2:FB characteristics by age. Data are first quartile/median/third quartile for continuous variables. N is the number of valid cases for each given variable.**

| Foreign body characteristics | N | Age class | | |
|---|---|---|---|---|
| | | < 1 year (N=) | 1-2 years (N=) | > = 3 years (N=) |
| Volume | 160 | 25.38/31.92/47.89 | 24.33/34.54/62.80 | 16.75/31.40/96.16 |
| Ellipticity | 166 | 1.00/1.00/1.33 | 1.00/1.67/3.33 | 1.00/1.00/4.50 |

**Table 3 :Nuts & seeds characteristics by FB location. Data are first quartile/median/third quartile for continuous variables and. N is the number of valid cases for each given variable.**

| Foreign body characteristics | | | Foreign body location | | |
|---|---|---|---|---|---|
| | N | Ears | Nose | Pharynx and larynx | Trachea, bronchi and lungs |
| Volume | 160 | 11.25/ 16.75/ 26.17 | 16.75/ 37.68/104.67 | 3.66/ 3.66/ 3.66 | 25.90/ 36.63/ 80.07 |
| Ellipticity | 166 | 1.00/1.00/1.00 | 1.00/1.00/2.00 | 4.00/5.00/6.00 | 1.00/1.78/4.00 |

**Figures**

**Figura 1:Distribution of incidence (%) of FB injuries by age class. Over the bars, 95% confidence intervals are plotted.**

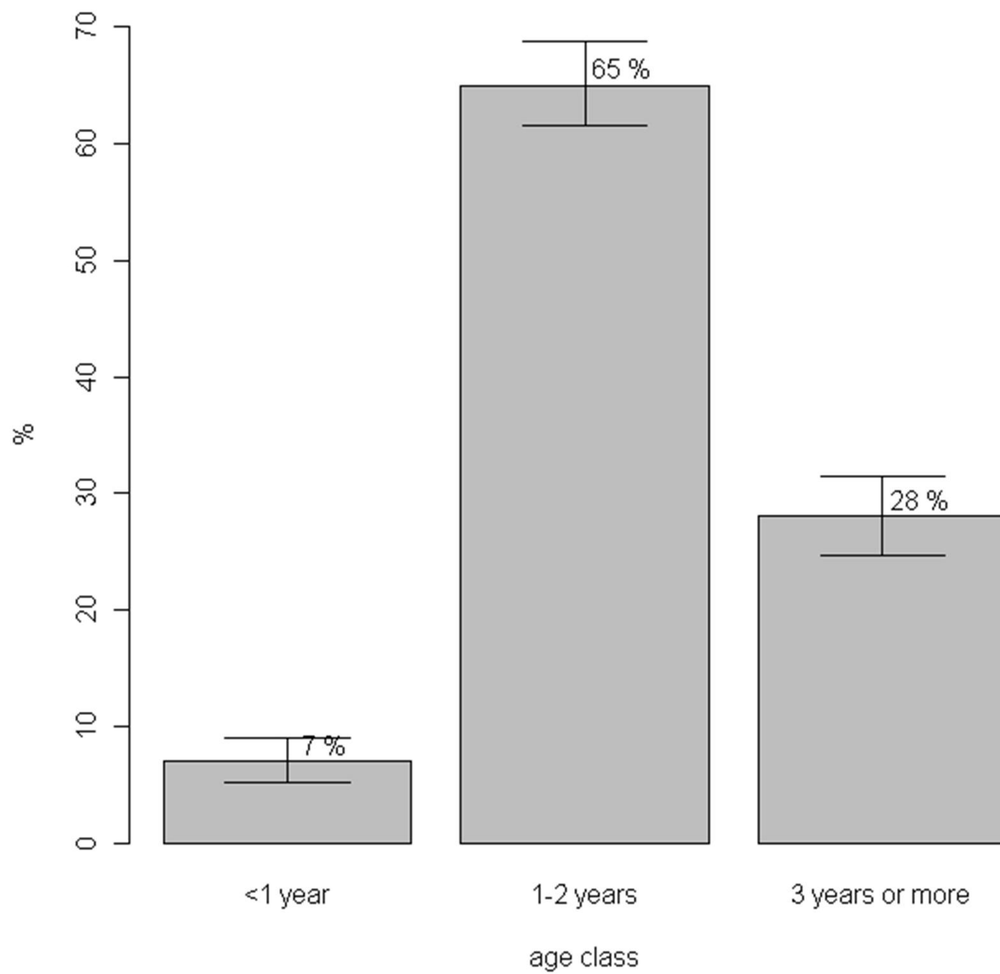

**Table 4:FB characteristics by age. Data are first quartile/median/third quartile for continuous variables. N is the number of valid cases for each given variable.**

| Foreign body characteristics | N | Age class | | |
|---|---|---|---|---|
| | | < 1 year (N=) | 1-2 years (N=) | > = 3 years (N=) |
| Volume | 160 | 25.38/31.92/47.89 | 24.33/34.54/62.80 | 16.75/31.40/96.16 |
| Ellipticity | 166 | 1.00/1.00/1.33 | 1.00/1.67/3.33 | 1.00/1.00/4.50 |

**Figure 2: Nuts & seeds characteristics by FB location. Data are first quartile/median/third quartile for continuous variables and. N is the number of valid cases for each given variable.**

| Foreign body characteristics | N | Ears | Foreign body location | | |
|---|---|---|---|---|---|
| | | | Nose | Pharynx and larynx | Trachea, bronchi and lungs |
| Volume | 160 | 11.25/ 16.75/ 26.17 | 16.75/ 37.68/104.67 | 3.66/ 3.66/ 3.66 | 25.90/ 36.63/ 80.07 |
| Ellipticity | 166 | 1.00/1.00/1.00 | 1.00/1.00/2.00 | 4.00/5.00/6.00 | 1.00/1.78/4.00 |

**Title: Proper packaging for food and no-food products to avoid injuries**

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**Abstract**

Fatal and near fatal foreign bodies injuries may occur at any age, however it's a particular problem for infants and young children due to a variety of predisposing factors. Safety packaging is therefore a landmark and a model for accident prevention.

This paper aims to present data on this subject, with data withdrawn from the Susy Safe data base and the results of literature research.

Taken the lack of researches and specificity on this subjects, it's warmly suggested that a broader and deeper exploration, both at customer's and public health levels, has to be made, highlighting major risks and complications. Packaging classes are extremely composite, therefore a accuracy in data registry must be achieved, since from a preventive point of view it's basilar not only knowing the nature of the foreign body but also having information on its origin.

**Keywords**: foreign body, packaging, prevention.

## Introduction

The rising of packaging issues have highlighted their linkage to foreign bodies injuries due to aspiration, inhalation or ingestion in children. Children represent a significant portion of consumers, and thus many hazards can come up when dealing with food products. In recent years, complying with this evidence, there has been a large diffusion of combination of edible and inedible components, like toys, to promote products to young targets. Thus the packaging issue doesn't involve only the food packaging, but evidences the threat set by inedibles' pack. Fatal and near fatal foreign bodies injuries may occur at any age, however it's a particular problem for infants and young children due to a variety of predisposing factors. Safety packaging is therefore a landmark and a model for accident prevention.

The aim of this paper is to highlights the available data on this subject, presenting data withdrawn from the Susy Safe data base and the results of literature research.

## Methods

### *Data collection*

Data were gleaned using Susy Safe database, which collects data on children injuries due to foreign bodies with the aid of a standardized case report forms. This form provides information on age and gender of the child, location, shape, volume, consistency and ellipticity of the foreign body, any complication occurred, hospitalization, and behavioural aspects linked to the injury, like the supervision of the parents or the activity concomitant to the injury. Cases are prospectively collected using the Susy Safe system from 06/2005; moreover, also information regarding past consecutive cases available in each centre adhering to the project have been entered in the Susy Safe Registry.

### *Statistical analysis*

The analysis was carried out on packages related injuries. Age and gender injury distributions were assessed. Data regarding adult supervision were also evaluated.

FB location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, oesophagus and stomach (ICD935).

Descriptive statistics (absolute and relative number or median, I and III quartile according to the categorical or continuous variable characteristics, respectively) were calculated; FB features distribution by children class age and site of obstruction were assessed.

Two different outcomes were considered: complication and hospitalization. Complications include all the pathological conditions due to delayed diagnosis or to the attempts of removing the FB. Hospitalization has been defined whether the child was admitted in the hospital for at least 1 day.
The association between children age, adult presence, object characteristics and outcomes was computed using unweighted odds ratios and the related 95% confidence intervals. Odds ratios not possible to be evaluated due to small cell frequency were labelled as NS (not significant).
Analyses were performed using Design and Hmisc libraries from R version 2.8

**Results**

FB distribution by location is shown in Table 1. The main frequencies of foreign body's retrieval are related to nose (38.1%) and ears (33.3%). Figure 1 shows the distribution of injures: a low percentage were seen in infants under 1 year (12.5%) while higher percentage interested 1-2 years age class (40%) and over 3 years children (47.5). Regarding gender of the injured, there was a higher frequency of males in ears and nose localisation (respectively 21% and 26%), and vice versa for trachea-bronchi-lungs and mouth-esophagus-stomach with a percentage in females respectively of 7% and 12%.
The required characteristics were shape, ellipticity (the ratio between length and height) and consistency. In nearly every case, the shape was flat, in two dimensions (2D), showing a 100% when dealing with digestive system, pharynx, trachea, lungs and bronchi. Exceptionally, in some location, ears (29%) and nose (20%) there were also spherical or 3D objects. The median ellipticity depends on the localisation and in most cases the ratio was near to 1; exceptions were the pharynx-larynx and trachea-bronchi-lungs, where the ellipticity was higher. Specific data, stratified by location, divided following first percentile, median and third percentile are shown in Table 2.
The consistency data show that in most cases the objects were semirigid and conforming. both with a frequency of 43.75%.
The outcome highlights that 44.7% of patients were hospitalized, with greater frequency in children with objects in the ears (18.4%).
Regarding the circumstances of the injury, data underline that among the activities, children were playing in 75% cases and 85.7% of those interested ears and nose. In 48.4% of reported cases, an adult was present while the injury occurred; and in 57.1% needing hospitalization, the child was under adult supervision before the incident.

**Discussion**

Although foreign bodies' injuries are an issue that has been recognized and investigated since many years, proper researches have been conducted only on a small range of products. There's a lack of sensibility in terms of recognition and acknowledge of the enormity of products, both food and non food, that, due to characteristics proper of the customers (like, age, behaviour, diseases) or of the object itself (shape, volume, consistency, ellipticity), could be potential responsible of choking or inhalation. The authors of this study performed a computerized literature search at PubMed database, focused on packaging's injuries. The chosen research sequence was: injuries AND ("foreign body" OR "foreign bodies") AND children AND (packaging OR paper OR polystyrene OR tinfoil OR cellophane). It has shown 122 results that have been reviewed and selected if suitable. Studies were included if they were published in English, if they were focused on foreign bodies in the upper aerodigestive tract and if they were relevant to the packaging injuries issue There were no restrictions on the country of research, on the publishing data, type of study. After the evaluation of abstracts only 23 fulfilled the chosen criteria. Among those, 12 were case series, 1 case report, 1 letter, 2 reviews and 7 were best practices on the subject.

Analysing the 23 papers, just 3 of them were centred on packaging related injuries, while the others involved cases of packaging injuries, not properly specifying though if the objects classified with the definition paper were packages or plain paper. Among those three cases just 1, a letter, was addressed to children safety.

This brief synthesis of the available literature, with no time limit, shows how low is still the impact of packaging injuries on children. The main surveys that have been done belong to customers rights and safety area, addressing more to legal and advertising issues, than to public health problems. On the other hand, packaging related to toys, like small packages linked to food as surprises' cover, are treated together with the toys issues, leaving a large portion of the packaging class uncovered. Seeing children as customers, many dangerous situations can occur when involving edibles and inedibles, that have the attractive combination of linking food to prizes, in order to attract the targeted group. Although foreign bodies injuries can be seen at any age, anatomical and behavioural factors can be predisposal factors in children at this [3-5] Safety packaging is therefore required as a preventive strategy in these kind of incidents [6]. As seen in this study, the most common location is the nose, displaying its potential risk owing to the danger of aspiration [7]. As evidenced here, children older than 1 year are vulnerable to injuries due to improper use of packaging, considering that at this time toddlers are learning to explore their environment, a process which often involves placing newly discovered objects in their cavities.

First of all it's important to have a clear idea of the materials children are exposed when dealing with packaging. linking that to the outcome of the injury, it's possible to divide them into different types, paper, polystyrene, tinfoil and cellophane.

The use of paper and paperboards for food packaging dates back to the 17th century with accelerated usage in the later part of the 19th century [1]. Paper and paperboard are sheet materials made from an interlaced network of cellulose fibres derived from wood by using sulphate and sulphite. Paper and paperboards are commonly used in corrugated boxes, milk cartons, folding cartons, bags and sacks, and wrapping paper [2].

Plain paper is not used to protect foods for long periods of time because it has poor barrier properties and is not heat sealable. When used as primary packaging (that is, in contact with food), paper is almost always treated, coated, laminated, or impregnated with materials such as waxes, resins, or lacquers to improve functional and protective properties. The many different types of paper used in food packaging are as follows: Kraft paper, Sulphite paper, Greaseproof paper, Glassine, Parchment paper.

Paperboard is thicker than paper with a higher weight per unit area and often made in multiple layers. The various types of paperboard are as follows: White board, Solid board, Chipboard, Fibreboard. Paper laminates are coated or uncoated papers based on Kraft and sulphite pulp. They can be laminated with plastic or aluminium to improve various properties. The advantages of using paper packaging are its characteristics of very good strength to weight, which balance the disadvantage to be a very poor barrier to light. Consumers and marketing issues regarding paper packaging concern the fact that they're moisture sensitive and lose strength with increasing humidity.

Biodegradable polymers made from cellulose and starches have been in existence for decades, with the 1st exhibition of a cellulose based polymer (which initiated the plastic industry) occurring in 1862. Cellophane is the most common cellulose-based biopolymer.

Plastic wrap is a form of food packaging consisting of a thin film of flexible, transparent polymer that clings to itself and to food containers to form a tight seal. The plastic keeps the food fresh by protecting it from air and by preventing dry foods from absorbing moisture and wet foods from losing moisture. It also seals in odours to prevent them from spreading to other foods stored nearby. The ability of this versatile food wrap to cling to both food and containers makes it superior for forming an airtight seal. There are many varieties of plastic wrap, some of which are thicker, cling better and have better moisture-vapour retention than others. Most plastic wraps are made of polyethylene, whose components are not absorbed by foods to any degree. The wrap that is

considered to have the best cling and moisture retention is made of polyvinylidene chloride, another leading brand is made of polyvinyl chloride (PVC).

Aluminium foil is made by rolling pure aluminium metal into very thin sheets, followed by annealing to achieve dead-folding properties (a crease or fold made in the film will stay in place), which allows it to be folded tightly. Moreover, aluminium foil is available in a wide range of thicknesses, with thinner foils used to wrap food and thicker foils used for trays. Like all aluminium packaging, foil provides an excellent barrier to moisture, air, odours, light, and microorganisms. It is inert to acidic foods and does not require lacquer or other protection. Although aluminium is easily recyclable, foils cannot be made from recycled aluminium without pinhole formation in the thin sheets. Lamination of packaging involves the binding of aluminium foil to paper or plastic film to improve barrier properties. Thin gauges facilitate application. Although lamination to plastic enables heat sealability, the seal does not completely bar moisture and air. Because laminated aluminium is relatively expensive, it is typically used to package high value foods such as dried soups, herbs, and spices. A less expensive alternative to laminated packaging is metalized film. Metalized films are plastics containing a thin layer of aluminium metal. These films have improved barrier properties to moisture, oils, air, and odours, and the highly reflective surface of the aluminium is attractive to consumers. More flexible than laminated films, metalized films are mainly used to package snacks. Although the individual components of laminates and metalized films are technically recyclable, the difficulty in sorting and separating the material precludes economically feasible recycling.

Taken these materials as the most frequent encountered in foreign bodies injuries in children, it should be reported a survey made from Winder [8], who analyzed shoppers at four supermarket stores in the UK, seeing that of the 200 subjects, 109 (54.5%) reported that they had injured themselves on food and drink packaging over the last few years. Of these, 73% had been treated at home, 2% had been treated by their GP and 25% had been treated at the Accident and Emergency department of a hospital. This is the only survey found concerning packaging and packaging related issues, showing once again how little is still known on this issue.

As seen from Susy Safe data, ears and nose are the most frequent location of injuries, in children older than 3 years old. Most of the accidents happened while they were playing, under supervision of an adult, showing a high frequency of hospitalization. These data point out the fact that both active supervision and warning labels are needed to make packaging safer, because children tend to explore the outside by introducing objects in their cavities. The ellipticity of the packaging found in trachea bronchi and lungs are higher than those found in other location, meaning that prior to mouthing, children habitually roll the packages or pieces of it into balls.

## Conclusion

It would be unfair to place the burden of blame for packaging injuries totally on the designers and engineers when, as in so many other areas, there is a huge scope for individual error. However, the onus has to rest with the designers to take the personal characteristics and personality traits of consumers into account when designing their packaging, and to consider how people might actually go about opening packaging in a real world rather than an ideal one. The data suggest that it is the 'natural born worriers' and those who have already suffered a serious injury on packaging who report most problems opening and using food and drink packaging. When these two factors were taken into account, no effect of age, disability or gender was demonstrated.

It's warmly suggested that a broader and deeper research, both at customer's and public health levels, has to be made, highlighting major risks and complications. Packaging classes are extremely composite, therefore a accurancy in data registry must be achieved, because from a preventive point of view it's basilar not only knowing the nature of the foreign body but also having information on its origin.

In the field of prevention of foreign body injury, a multi-disciplinary approach is the only one to have efficacy, addressing the problem from the point of view of product design and engineering, product marketing and advertising, regulatory aspects and development of clinical posttrauma guidelines for treatment. In this contest, active supervision of children plays a leading role in terms of prevention.

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**Tables:**

| FB location | N | % |
|---|---|---|
| Ears | 14 | 33.3 |
| Nose | 16 | 38.1 |
| Pharynx and larynx | 4 | 9.5 |
| Trachea, bronchi and lungs | 3 | 7.1 |
| Mouth, esophagus and stomach | 5 | 11.9 |
| Total | 42 | |

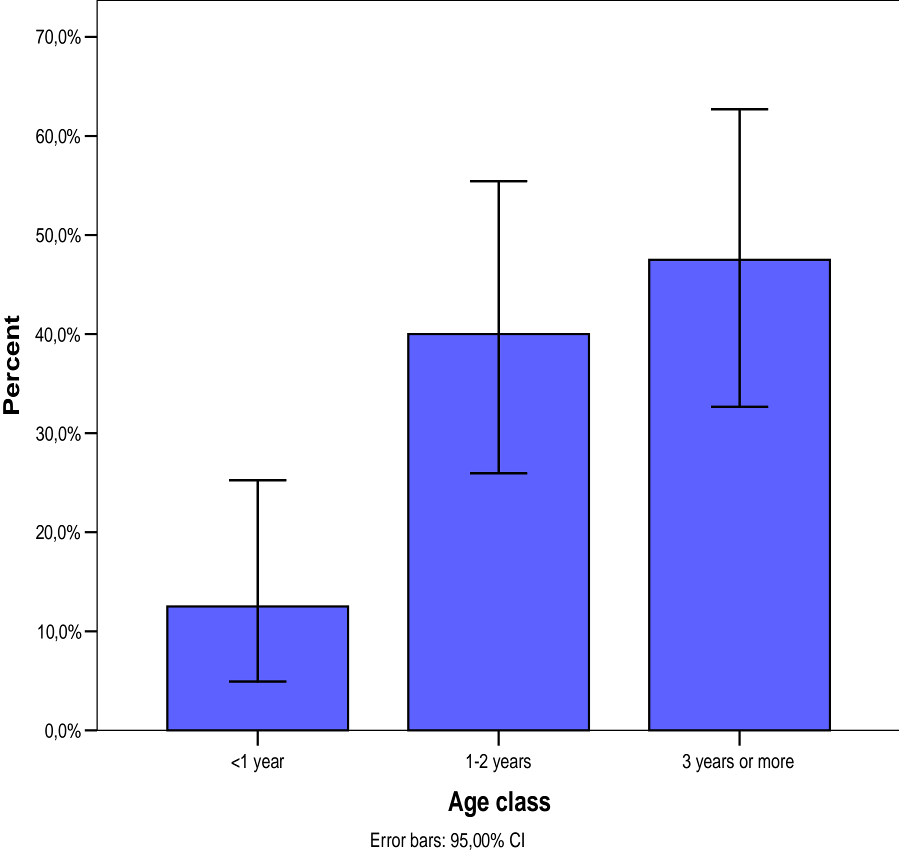
**Table 1. FB location**

| FB location | N | Ellipticity |
|---|---|---|
| Ears | 14 | 1.00/1.25/1.50 |
| Nose | 16 | 1.00/1.17/1.46 |
| Pharynx and larynx | 4 | 2.00/2.00/2.00 |
| Trachea, bronchi and lungs | 3 | 3.00/3.00/3.00 |
| Mouth, esophagus and stomach | 5 | 1.00/1.30/1.78 |

**Table 2. Packages characteristics by FB location. Data are first quartile/median/third quartile for continuous variables. N is the number of valid cases for given variable.**

**Figure**

**Figure 1. Distribution of incidence (%) of FB injuries by age class. Over the bars, 95% confidence intervals are plotted.**



**Title: Fostering design for avoiding small parts in commonly used objects**

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**Abstract**

**Rationale and aim:** Injuries due to the accidental ingestion or aspiration of small part have became a matter of interest in the last 30 year, focusing on the relationship between a proper prevention and the diminished frequency of occurrences. Small parts in commonly used objects represent a large sector of potential danger, taking explicit mouthing behavior of children in the first four years of life. In this paper the intent is to show the current situation of design projects and legislation around the world, meant to avoid the casual accidents due to manufacturing reasons. Proposed process and quality control standards seek to eliminate production errors and control materials to avoid deviation from the design.

**Methods:** The present study draws its data from the SUSY Safe registry, a European Commission co-funded project started in February 2005, whose aim is to establish an international registry of cases of Foreign Bodies (FB) injuries in children aged 0-14 years. Information collected from the data base concern age and gender of the child, location, shape, volume, consistency and elipticity of the foreign body, any complication occurred, hospitalization, and behavioral aspects linked to the injury, like the supervision of the parents or the activity concomitant to the injury. Cases are prospectively collected using the Susy Safe system from 06/2005; moreover, also information regarding past consecutive cases available in each centre adhering to the project have been entered in the Susy Safe Registry.

**Results:** Data evidenced that the majority of small parts related injuries are related to stationery. The majority of objects (56.7%), were located in the nose, followed by the ears (31.5%). The distribution on incidence of FB injuries by age class shows that the majority of injuries due to small parts in common objects occurred in children older than >3 years. Male and female were affected with the same frequency when concerning the nose, while all other locations showed a higher frequency in males. Data suggested that hospitalization occurred in 32% of those who compiled the form, resulting in complication just in 16% of injured. Although the most frequent location needing hospitalization was the tracheobronchial tree, the most frequent location showing complication was the nose, 80.3% of the complications, having an infection as most frequent outcome. In children younger than 1 year median volume reached 333.62 $mm^3$, in children between 1 and 2 years, median volume was 81.12 $mm^3$, in older children (>3 years) it showed 37.68 $mm^3$ . The same considerations can be seen for the ellipticity, where the median ellipticity was 2.79 in children <1 year, while it was 1.94 in children between 1 and 2 years, and 1.17 in the older ones. Consistency is similar for all age classes, stressing that rigid small parts were those more involved in injuries with foreign bodies. Behavioral aspects pointed out that the 80% of children were playing before the

accident, and 65.3% were under adults' supervision. Adult presence resulted associated to the absence of complication, with a p-value of 0.04.

**Conclusions**: The study stresses the importance of primary prevention, seen as the active care of adults toward children manipulating foreign bodies potentially dangerous. This presence may not avoid the event, but in case of FBs aspiration, ingestion, insertion or inhalation, it could be the main factor leading to fewer complications.

**Keywords**: Small parts, nose, adults' supervision

## Introduction

Injuries are defined as harms and it's a term usually applied to damage inflicted on the body by an external force. The main point of view in the past was to reflect on those events as accidents or intentional, centering the focus on the therapeutic care. In the last 30 years a new way of considering the problem has emerged, the analysis of prevention strategies that can be applied to prevent them.

Obtaining information on injuries due to foreign bodies aspiration inhalation or ingestion and their associated issues is an important factor in developing products: in fact, FB injuries from consumer products could be greatly decreased by the adoption of the injury prevention criteria that is founded in a statistical analysis of known objects that have caused injury [1].

Behavioral studies and reports in the pediatric medical literature suggest that children, particularly those younger than 4 years, frequently place foreign objects such as toys and small parts of consumer products in their mouths, nasal cavities and ear canals. These actions not infrequently lead to injury or death [2].

Many attempts to understand the relationship between shape and size of the object, obstruction location and injury severity, have been performed and until now the main result has been the identification of choking prevention standards such as the small parts test fixture (SPTF) .

In much of the world, including Europe, the Americas, and China, the small parts cylinder test is utilized to prevent deaths and injuries to children under three from choking on, inhaling, or swallowing small objects [3].

The adoption of this kind of preventive strategies and the increased awareness of risk has resulted in a decrease of children's mortality rate for choking in the last decades. However, this issue remains problematic. This regulation in fact, covers products for children under three: a wide range of objects easily accessed by children even if not expressly designed for children are exempt, including objects (such as books and stationery items) that cannot be manufactured in a way that would prevent them from breaking into small parts, and objects that need to be small (such as buttons) to perform their intended purpose.

Modern computer-aided design (CAD) techniques have also been used to develop several models of the oral cavities and airways, nasal passages and sinuses, and external auditory canals of young children of various ages to prevent a variety of fatal accident due to object that couldn't be tested with the SPTF [4].

Obtaining information on current child injury trends and their associated issues is an important factor in developing products that meet or surpass acceptable toy safety boundaries. Understanding

these boundaries helps determine safe product design characteristics that reduce the risk of product related injury.

In this background, it lays the Susy Safe project, a database on injuries due to foreign bodies in children. Its main aim are the characterization and identification of potentially dangerous products, to ensure safety in young customers and develop prevention's activities for those that interact with children.

This paper regards Susy Safe Project's results concerning small parts in commonly used objects. Susy Safe is a European Commission co-funded project started in February 2005, whose aim is to establish an international registry of cases of Foreign Bodies (FB) injuries in children aged 0-14 years. Currently the project collects nearly 17000 data, from 60 institutions, located in 26 countries.

## Methods

*Data collection*

Data were gleaned using Susy Safe database, which collects data on children injuries due to foreign bodies with the aid of a standardized case report forms. This form provides information on age and gender of the child, location, shape, volume, consistency and elipticity of the foreign body, any complication occurred, hospitalization, and behavioral aspects linked to the injury, like the supervision of the parents or the activity concomitant to the injury. Cases are prospectively collected using the Susy Safe system from 06/2005; moreover, also information regarding past consecutive cases available in each centre adhering to the project have been entered in the Susy Safe Registry.

*Statistical analysis*

The analysis was carried out on injuries due to small parts in commonly used objects. Age and gender injury distributions were assessed. Data regarding adult supervision were also evaluated.

FB location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, oesophagus and stomach (ICD935).

Descriptive statistics (absolute and relative number or median, I and III quartile according to the categorical or continuous variable characteristics, respectively) were calculated for each object characteristic; FB features distribution by children class age and site of obstruction were assessed.

Two different outcomes were considered: complication and hospitalization. Complications include all the pathological conditions due to delayed diagnosis or to the attempts of removing the FB. Hospitalization has been defined whether the child was admitted in the hospital for at least 1 day.

The association between children age, adult presence, object characteristics and outcomes was computed using unweighted odds ratios and the related 95% confidence intervals. Odds ratios not possible to be evaluated due to small cell frequency were labeled as NS (not significant).
Analyses were performed using Design and Hmisc libraries from R version 2.8

*Results*:
Data evidenced that the majority of small parts related injuries are related to stationery, while toys have just the second position. The FB causing the accident belonged to a large variety of objects, as illustrated in Table 1. The majority of objects (56.7%), were located in the nose, followed by the ears (31.5%). The distribution on incidence of FB injuries by age class is presented in Figure 1. The most populated class resulted the last one, with 63% of injuries falling into this cluster. Male and female were affected with the same frequency when concerning the nose, while all other locations showed a higher frequency in males. Data suggested that hospitalization occurred in 32% of those who compiled the form, resulting in complication just in 16% of injured. Although the most frequent location needing hospitalization was the tracheobronchial tree, the most frequent location showing complication was the nose, 80.3% of the complications, having an infection as most frequent outcome.
Between the characteristic of the object, volume was one of those notably changing when changing the age class. While in children younger than 1 year median volume reached 333.62 $mm^3$, in children between 1 and 2 years, median volume was 81.12 $mm^3$, in older children (>3 years) it showed 37.68 $mm^3$. The same considerations can be seen for the ellipticity, where the median ellipticity was 2.79 in children <1 year, while it was 1.94 in children between 1 and 2 years, and 1.17 in the older ones.
Consistency is similar for all age classes, stressing that rigid small parts were those more involved in injuries with foreign bodies.
Behavioral aspects pointed out that the 80% of children were playing before the accident, and 65.3% were under adults supervision. Adult presence resulted associated to the absence of complication, with a p-value of 0.04.

**Discussion**
Small part issues go back to early twentieth century. As seen in this study, this issue doesn't concern only toys, but expands its branches towards commonly used objects, with the result that there a wider spectrum of threats than the one usually considered. In this study stationery had the

bigger frequency, followed by toys, cotton, plastic and sponge. When speaking about small parts, defining distinctive features like volume, ellipticity, consistency become fundamental.
In the US Chevalier Jackson, the pioneer and esteemed endoscopist, and colleagues removed a total of 3200 objects between 1920 and 1932. The materials included in this collection are meticulously itemized, and large portions are available for study (JC collection) [5]. Reilly [6] in 2003 took from this database all the objects that remain intact and available for measurement were included ($n$ = 1307).
The modern study made by Reilly, shows that larger FBs may cause injury and potential risks for aspiration and asphyxiation. Approximately 99% of FBs are less than 31.75 mm diameter, limit codified by the Small Parts Test Fixture. The SPTF, the best known and most widely used standard for the US, was developed in the 1970s and was based upon concepts and data originally collected 50 years earlier by Chevalier Jackson. Present standards for FBs intended for use by young children (less than 3 years of age) are based upon analysis of the JC injuries and are outdated. When the data from the late twentieth century Modern Dataand JC data are analyzed, elimination of risk can better approach 100% only if stricter criteria are applied. All FBs analyzed for ingestion or aspiration injury are eliminated if a standard of 44.45 mm diameter is applied. This newer information is particularly effective when applied to spherical objects that are known to be most dangerous and can result in a variety of newer interventions for parents, physicians and product suppliers. Rimmel [3] states that choking deaths could also be decreased by regulations governing toys or toy parts. The SPTF was developed in the early 1970s by the United States Consumer Product Safety Commission (CPSC) and its predecessor, the Bureau of Product Safety (BPS) of the United States Food and Drug Administration pursuant to passage of the Child Protection and Toy Safety Act of 1969. The Child Protection and Toy Safety Act required the Food and Drug Administration to identify and ban hazardous toys [7]. The SPC was officially adopted into the U.S. Code of Federal Regulations 1979 and subsequently incorporated into numerous other national and international standards. Two other test fixtures were also adopted specifically for rattles and pacifiers. As early as1982, the CPSC became aware of two deaths involving squeeze toys passed by the SPC and undertook a new study of choking incidents in children. However, in 1990 the CPSC decided that the SPC "does not need to be changed" but recommend that regulatory changes be made to address balls, toy figurines with rounded ends. This ultimately lead to the Child Safety Protection Act of 1994, which required warning labels for balloons and marbles and introduced a new 44.4 mm open bottom test fixture for small balls. To our knowledge, the latter is the last statutory change to airway obstruction hazard assessment [8].

Looking closer to the SPFT, it consists in a 31.75 mm inside-diameter cylinder with a slanted bottom and depth ranging from 25.4 to 57.1 mm used to imitate the throat of a child under 3 years of age. An object passes the SPTF test if it does not fit within the cylinder (for example it has a diameter wider than 31.75 mm or a length major than 57.1 mm. If a small part fits completely into the cylinder, and the object is for children under three years, the product is banned because the small part presents a choking hazard. On the other hand, products designed for children from 3 to 6 years and having small parts must be labeled to warn purchasers not to buy them for children under 3 years.

The present study espouses its results with those seen in earlier works, highlighting that it's basic to properly examine foreign bodies, in order to classify them according to their own characteristics. Rimell and Stool [4] performed a retrospective study in which they examined the characteristics of objects that had caused serious aerodigestive tract (airway, cricopharyngeal or esophageal) injury, as indicated by the need for operative removal, or death due to choking as reported to the Consumer Product Safety Commission (CPSC). Their results confirmed previous reports in the medical literature that the risk of injury or death posed by a food, toy or toy part, or another object depends upon its size, shape and consistency [9] [10]. Furthermore, the type of object causing injury was correlated with the age of the child injured.

The anatomy of the airway changes dramatically in the first few years of life as maxillofacial structures extend forwardly and inferiorly and the larynx drops. These anatomical changes would be expected to affect the risk associated with choking, aspiration or ingestion of toys or toy parts.

From this analyses two main issues were derived, first, 'test fixtures' used to assess the risk of impaction should more closely model the irregular shapes of the body cavities being studied. Second, because a child's anatomy changes with development, models should be developed of various body cavities for children of different ages.

A second model was promoted for this reason, using modern computer-aided design (CAD) techniques to develop several models of the oral cavities and airways, nasal passages and sinuses, and external auditory canals of young children of various ages .

Digital models of toys, toy parts or other consumer products were created as needed to assess risk using the CAD program. Some of these objects were created using CAD, so an electronic file in the appropriate format was already available. In other cases, the size and shape of the object were digitized from existing products, prototypes or manufacturers' drawings. For example, we can create digital models of products in our injury and fatality database for which we have size and shape information. This models have several advantages for the assessment of risk in small children like a more anatomically accurate data due to their development using actual patient data; furthermore

separate models for children 1, 2 or 3 years old allow risk to be assessed more specifically for various ages of children [11]; noticing that the models and the process of risk assessment are computer-based means that risk assessments and results can be displayed in a large variety of ways; and last, the computer databases for the models and foreign objects can be modified and expanded relatively easily.

**Conclusion**

Children have access to a large number of foreign objects which, if mouthed, could potentially be aspirated or ingested, leading to choking injuries and fatalities. It's worldwide interest in fostering new project to analyze the small part of common use, taking that aspiration and inhalation of foreign bodies is a common event in children [12]. Although an international consumers safety standard exists, nations around the world still create their own legislation and standards to address the issue. As has been seen in the large scale recalls of 2007, sample testing can miss non-conforming product. A design may be conceptually safe, but without control of the production, the design may not be met by the manufacturer. Proposed process and quality control standards, similar to the ISO 9000 systems, seek to eliminate production errors and control materials to avoid deviation from the design. The creation of manufacturing quality standards for common used objects will help ensure consistency of production. Using a continual improvement model, production can be subject to constant scrutiny, rather than assuming the compliance of all production by testing random samples. In October and November 2007, mandatory third party testing was proposed by regulators in the EU and US, to a (possibly new) international standard, requiring a new safety mark. There is no indication that the proposals will address manufacturing control.

As enlightened from literature and from this study, behavioral aspects are strictly linked to the outcomes of the events. Injuries small parts related frequently occur while children are playing and in the majority of cases under adults supervision. The latter recognition shows two main aspects of the problem, first of all the necessity of prevention programs directed towards those dealing with children, stressing how an active surveillance should be always performed, also in children older than 3 years, where psychological aspects determine a major pulsion toward exploration, and therefore towards experiencing direct manipulation of objects.

On the other hand, the association between adult presence and lack of complications, shows the leading role of immediate acknowledge of the injuries in a less problematical outcome.

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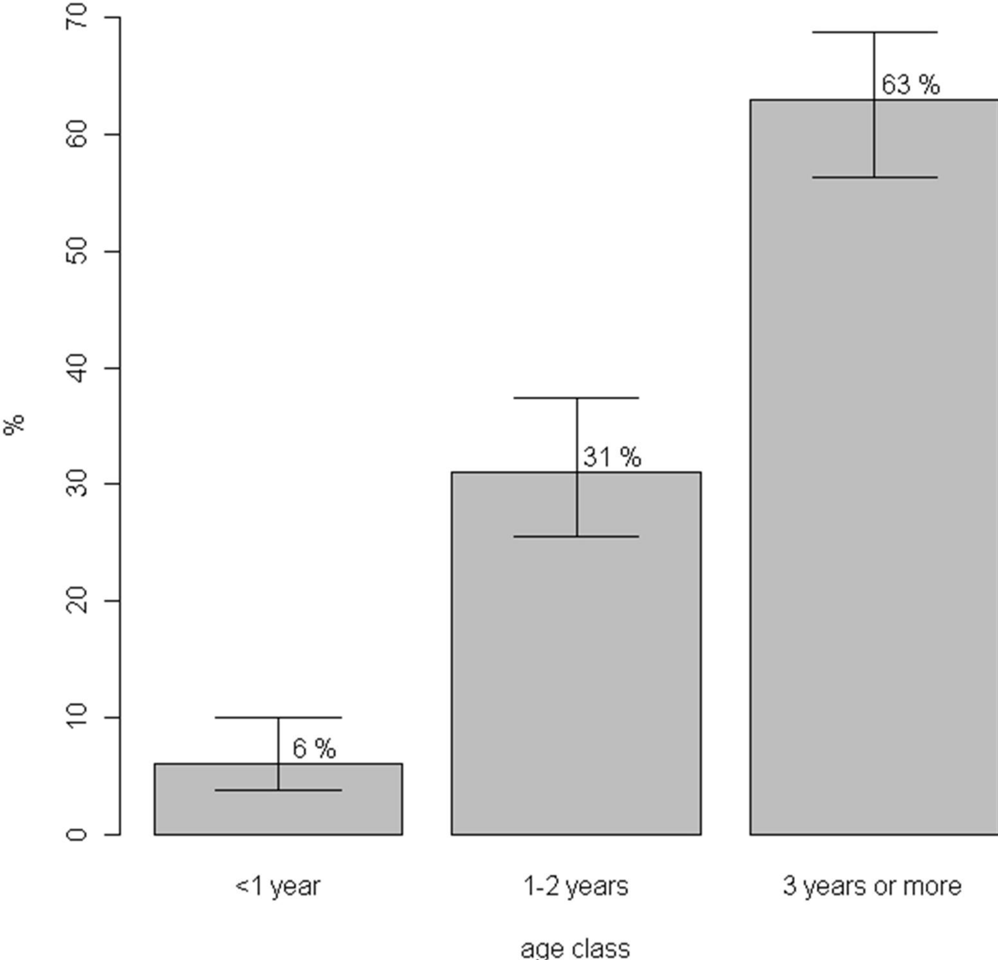
**Table 1: Description of the FB which caused the incident**.

| FB description | N(%) |
|---|---|
| Stationery | 141(28%) |
| Toy | 110 (22%) |
| Plastic | 53(11%) |
| Cotton | 44(9%) |
| Sponge | 44(9%) |
| Other stationery | 38(8%) |
| Polystyrene | 13(3%) |
| pebble | 9(2%) |
| Jewellery | 6(1%) |
| Pearl, ball and marble | 3(1%) |
| Pin and needle | 3(1%) |
| Stick | 3(1%) |
| Metal | 2(0%) |
| accessorize | 1 (0%) |
| Button | 1(0%) |
| Coin | 1(0%) |
| Earplug | 1(0%) |
| Paper | 1(0%) |

**Figure 1:Distribution of incidence (%) of FB injuries by age class. Over the bars, 95% confidence intervals are plotted.**



**Title: Toys in the upper aerodigestive tract: new evidence on their risk as emerging from the ESFBI Study**

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**Abstract**

Foreign body inhalation/ aspiration or ingestion are relatively common events in young children and, despite many efforts made in several countries to reach acceptable safety levels for products devoted to children, small toys or toy parts are frequently mentioned among risky foreign bodies. The aim of the present study is to characterize the risk of complications and prolonged hospitalization due to toys inhalation/aspiration or ingestion according to age and gender of patients, FB characteristics and FB location, circumstances of the accident, as emerging from the ESFBI study. A retrospective study in major hospitals of 19 European countries was realized on children aged 0-14 having inhaled/aspired or ingested a toy, with regard to the characteristics of the child and the FB (shape volume consistency), the FB location the hospitalization's details and the occurrence of complications.

Preventive strategies imposing a regulation of industrial production, even if fundamental, are not sufficient and need to be integrated whit other preventive intervention addressed to improve parents ability to be conscious of FB injuries and attentive toward a proper surveillance of children.

**Keywords**: Toys, aspiration, ESFBI

## Introduction

Foreign body inhalation/aspiration or ingestion occurs commonly in young children, particularly in those aged from 1 to 3 years, and consequences vary based on the object characteristics, its location, and the patient's age and size[1].

The mechanical obstruction of the airways due to foreign body inhalation/aspiration is the primary source of fatal accidents in children younger than 1, and it represents a major cause of death in children from 1 to 4 years old[2]. Moreover, because of late diagnosis FBs, injury may result in severe complications including asphyxia, pneumonia, atelectasis and bronchiectasis[3]. On the other hand, while most ingested foreign bodies are well tolerated and pass the intestinal tract with no complications, some may cause gastrointestinal perforation or obstruction. The most common complication is entrapment in the oesophagus, and possible sequelae include erosion, perforation and even mediastinitis[4].

The aim of the present study is to characterize the risk of complications and prolonged hospitalization due to toys inhalation/aspiration or ingestion according to age and gender of patients, FB characteristics and FB location, circumstances of the accident, as emerging from the ESFBI study.

## Data collection

The European Survey on Foreign Bodies Injuries (ESFBI) Study collected data on FB injuries in children aged 0–14, from 19 European Hospitals (Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Swiss, Turkey and United Kingdom). Data on injuries occurred in the years 2000-2003 were identified by means of the International Classification of Diseases, Ninth Revision (ICD-9) codes listed on hospital discharge records. Details on injuries were gathered through a standardized case report form, that includes information regarding: children age and gender, features of the object, circumstances of injury (presence of parents, activity) and the hospitalization's details (lasting, complications and removal details).

## Toys characteristics definition

According to the Rimell's classification[8], objects were characterized by size, shape and consistency, when the dimensions (in mm) of the object were reported, the volume was calculated according to the shape of the objects itself. Such volume measures represent how much space the smallest

geometrical figure containing the irregular-shaped FB takes up. Moreover, the ellipticity (the ratio between the maximum and the minimum size reported) was calculated.

**Statistical analysis**

The analysis was carried out on injuries due to toys. Age and gender injury distributions were assessed. Data regarding adult supervision were also evaluated.

FB location was reported according to ICD9-CM code[9]: nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935).

Descriptive statistics (absolute and relative number or median, I and III quartile according to the categorical or continuous variable characteristics, respectively) were calculated for each considered toys characteristics; FB features distributions by children class age and site of obstruction were assessed.

Two different outcomes were considered: complications and hospitalizations. The association between outcomes and children's age, adult presence and toys characteristics was computed using unweighted odds ratios and the related 95% confidence intervals. Odds ratios not possible to be evaluated due to small cell frequency were labeled as NS (not significant).

Analyses were performed using Design and Hmisc libraries from R version 2.8[10].

**Results**

In the years 2000-2003 a total of 2094 FB injuries occurred in children aged 0-14 ys. Among them 121 (5.8%) were due to toys and 95 (4.5%) occurred in the lower/upper aero-digestive tract.

Distribution of incidence of toys injuries by age class is shown in Figure 1. 59 (62%) of patients were males, while 36 (38%) were females.

Almost 27% of toys related injuries happened under adults' supervision.

Details regarding FB location are given in Table I: the total amount of toys injuries, the number of complicated injuries and the number of injuries in which hospitalization is needed are reported for each site.

A short description of the toys that caused the incident is provided in Table II. Toys volume, shape, ellipticity and consistency by age and by location in aero-digestive tract are described respectively in Table III and Table IV.

Looking to the outcomes, 58 children needed hospitalization; the median in hospital stay was 1 day in absence of complications, whereas for complications the hospitalization stay was reported in the database for only one child (27 days); removal was performed in the great part of cases by endoscopy while one case required surgery; complications were obstructions[2], pneumonia oesophageal atresia[1] and unilateral nasal odorous discharge[1]. No deaths were observed. In order to verify the association among children age, adult supervision, object characteristics and outcomes, odds ratios of complications and hospitalization, with 95% confidence intervals, are presented in Table V.

**Conclusions**

Aspiration and ingestion of foreign bodies are common events in paediatric patients, which can have severe, even fatal, consequences.

An important advance in the prevention of injuries was the introduction of safety rules for toy design[11]: the European regulation bans objects for children under three years having small parts. On the other hand, products designed for children from 3 to 6 years and having small parts must be labeled to warn purchasers not to buy them for children under 3 years[5,6].

The adoption of these preventive strategies mainly based on products modification by manufacturers, has resulted in a decrease of children's mortality rate for chocking in the last decades[7,8]; however, our results seem to testify that more than 5% of FB injuries are still due to toys.

The most documented incident is the insertion of a toy or a piece of it in the nose. Even if complicances are underreported, severe consequences seem to be rare, probably because the relative inert nature of the plastic material implies a mild tissue inflammation and allows a relatively quick response of the patient upon removal of the FB[12]. Objects are mainly tridimensional and at most with a very small ellipticity ratio of 2. The first determinant of a damage requiring hospitalization is the rigid consistence of the object: the risk of a stay in hospital longer than 1 day is in fact, three times greater when children inhale or ingest a rigid product, compared with a semi-rigid item.

More than half of injuries due to toys involve children older than three years. This fact seems to testify the effectiveness of regulations finalized to limit the commercialization of products for children up to three years having small parts. However, when details regarding toys are at disposal, in our study the most frequently retrieved foreign bodies are part of toys. Possible explanations include*: (i)* the commercialization of not safe products; *(ii)* when the injury involve young children, the accessibility to inappropriate for age toys; *(iii)* when children are more than 3 years old, poor parents and children education regarding this issue. Incorrect adult supervision is commonly involved in the injury mechanism. In our study, in fact, an adult was present in more than 25% of cases. These results stress the evidence that preventive strategies imposing a regulation of industrial production, even if fundamental, are not sufficient and need to be integrated whit other preventive intervention, addressed to improve parents consciousness and attention toward a proper surveillance of children[13].

**Figure 1.** Distribution of incidence (%) of FB injuries by age class. Over the bars, 95% confidence intervals are plotted.

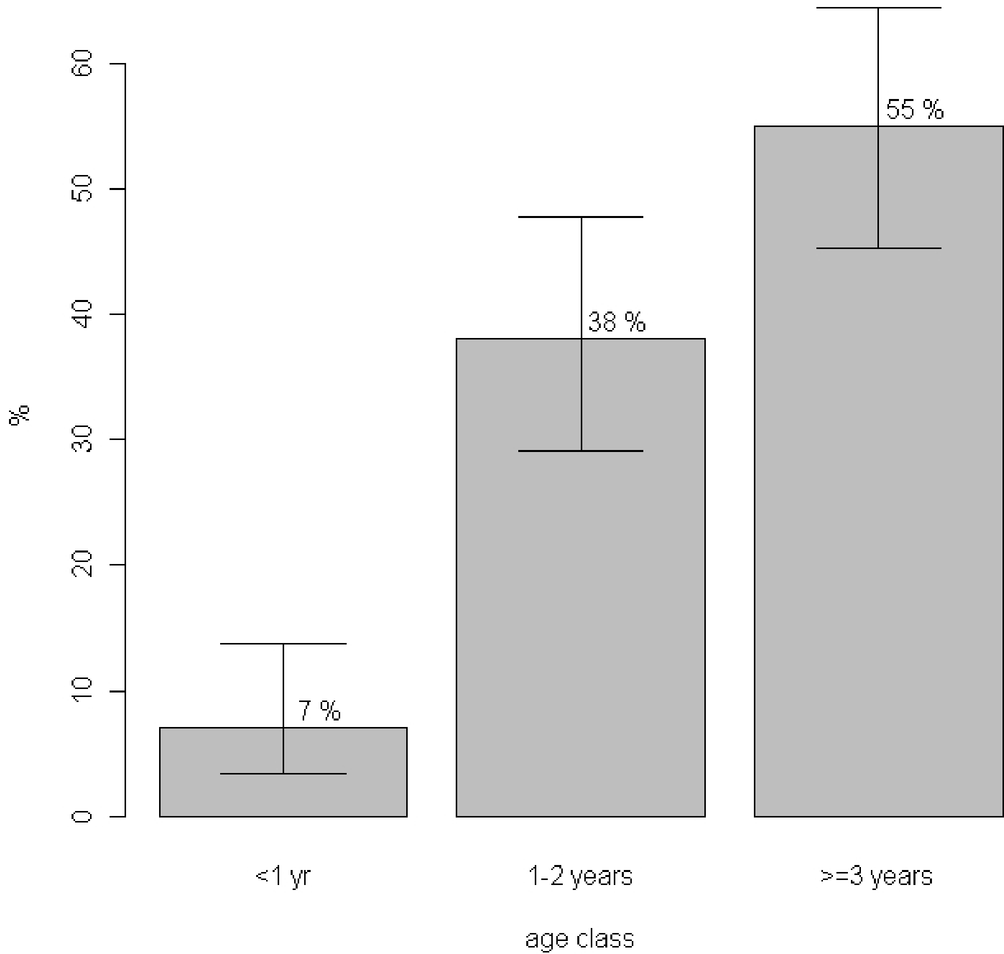

**Table I. FB location according to ICD9-CM code: nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935). Total amount of toys injuries, complicated injuries and injuries requiring hospitalization are reported**

| Location | Toys related injuries | Complications | | Hospitalization | |
|---|---|---|---|---|---|
| | | Yes | No | Yes | No |
| Nose | 74% (70) | 75% ( 3) | 74% (53) | 16% ( 3) | 93% (54) |
| Pharynx and larynx | 6% ( 6) | 0% ( 0) | 8% ( 6) | 11% ( 2) | 7% ( 4) |
| Trachea, bronchi and lungs | 13% ( 12) | 0% ( 0) | 12% ( 9) | 47% ( 9) | 0% ( 0) |
| Mouth, esophagus and stomach | 7% ( 7) | 25% ( 1) | 6% ( 4) | 26% ( 5) | 0% ( 0) |
| Total | 95 | 4 | 72 | 19 | 58 |

**Table II. Description of the toys which caused the incident**

| Toy description | N(%) |
|---|---|
| part of a toy | 17(18%) |
| Lego type toys | 16(17%) |
| spherical toys | 6(6%) |
| generic plastic toys | 6(6%) |
| wheel of a toy car | 5(5%) |
| plastic nail | 4(4%) |
| piece of combination box | 4(4%) |
| bullet seed | 3(3%) |
| plastic coin | 2(2%) |
| puzzle piece | 2(2%) |
| toy | 29(31%) |

**Table III. Toys characteristics by age. Data are first quartile/median/third quartile for continuous variables and percentages (absolute numbers) for categorical variables. N is the number of valid cases for each given variable**

| Foreign body characteristics | N | Age class | | |
|---|---|---|---|---|
| | | < 1 year (N=7) | 1-2 years (N=36) | > = 3 years (N=52) |
| Volume | 37 | 1225/1225/1225 | 80.71/175/225 | 65.42/150/267.95 |
| Shape | 71 | | | |
| Spherical | | 0%(0) | 17%(5) | 21%(8) |
| 3D | | 50%(2) | 62%(18) | 58%(22) |
| 2D | | 25%(1) | 7%(2) | 8%(3) |
| 2Dcircle | | 25%(1) | 14%(4) | 13%(5) |
| other | | 0%(0) | 0%(0) | 0%(0) |
| Ellipticity | 27 | 3.57/3.57/3.57 | 1.6/2/2.5 | 1.33/1.6/2.33 |
| Consistency | 75 | | | |
| Conforming | | 0%(0) | 7%(2) | 5%(2) |
| Semi-rigid | | 25%(1) | 34%(10) | 36%(15) |
| Rigid | | 75%(3) | 59%(17) | 60%(25) |
| Do not know | | 0%(0) | 0%(0) | 0%(0) |

**Table IV. Toys characteristics by FB location. Data are first quartile/median/third quartile for continuous variables and percentages (absolute numbers) for categorical variables. N is the number of valid cases for each given variable.**

| Foreign body characteristics | N | Foreign body location | | | |
|---|---|---|---|---|---|
| | | Nose (N=70) | Pharynx and larynx (N=6) | Trachea, bronchi and lungs (N=12) | Mouth, esophagus and stomach (N=7) |
| Volume | 37 | 65.42/ 179.5/ 267.95 | 45/96/ 113.04 | 105/ 105/105 | 1700/2175/2650 |
| shape: | | | | | |
| Spherical | 71 | | | | |
| Spherical | | 23% (12) | 17% ( 1) | 0% ( 0) | 0% ( 0) |
| 3D | | 57% (30) | 67% ( 4) | 75% ( 6) | 50% ( 2) |
| 2D | | 9% ( 5) | 0% ( 0) | 12% ( 1) | 0% ( 0) |
| 2D circle | | 11% ( 6) | 17% ( 1) | 12% ( 1) | 50% ( 2) |
| other | | 0% ( 0) | 0% ( 0) | 0% ( 0) | 0% ( 0) |
| Ellipticity | 27 | 1.38/ 1.6/ 2 | 1.623/ 5.83/15 | 2.33/ 2.33/ 2.33 | 3.93/ 4.29/ 4.64 |

| | | | | |
|---|---|---|---|---|
| Consistency | 75 | | | |
| Conforming | 7% ( 4) | 0% ( 0) | 0% ( 0) | 0% (0) |
| Semirigid | 41% (23) | 17% ( 1) | 0% ( 0) | 50% ( 2) |
| Rigid | 52% (29) | 83% ( 5) | 100% ( 9) | 50% ( 2) |
| Don’t know | 0% ( 0) | 0% ( 0) | 0% ( 0) | 0% ( 0) |

**Table V. Odds ratio of complications and of hospitalization with the 95% confidence intervals are presented. *P* values are also presented. *N* number of valid cases for each given variable. *NS:* not significant, – not possible to be evaluated due to small cell frequency. *Ref* : reference category.**

| *Variables* | *N* | *Hospitalization* | | *Complications* | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Yes (N=19) | No (N=58) | OR (95%CI) | p | Yes (N=4) | No (N=72) | OR (95%CI) | p |
| Age class | 95 | | | | | | | | |
| < 1 year | | 26% ( 5) | 0% ( 0) | NS | | 25% ( 1) | 6% ( 4) | 3.25(0.27;3.9) | 0.35 |
| 1-2 years | | 16% ( 3) | 45% (26) | 0.34 (0.08;13.3) | 0.12 | 0% ( 0) | 40% (29) | NS | |
| >=3 years | | 58% (11) | 55% (32) | Ref | | 75% ( 3) | 54% (39) | Ref | |
| Adult supervision | 65 | | | | | | | | |
| Adult present | | 50% ( 9) | 36% (17) | 1.76(0.59;5.3) | 0.31 | 25% ( 1) | 41% (25) | 0.48(0.05;4.88) | 0.53 |
| Volume | 37 | 57.75/100.5/945 | 89.23/179.5/267.95 | 1.34 (0.92;1.96) | 0.13 | 95/149.75/440.88 | 65.42/175/267.95 | 1.05(0.75;1.46) | 0.79 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Shape | 71 | | | | | | | | |
| Spherical | | 0% ( 0) | 24% (13) | NS | | 25% ( 1) | 18% (12) | 1.08(0.1;1.14) | 0.95 |
| 3D | | 65% (11) | 57% (31) | Ref | | 75% ( 3) | 59% (39) | Ref | |
| 2D | | 12% ( 2) | 7% ( 4) | 1.41 (0.23,8.8) | 0.71 | 0% ( 0) | 9% ( 6) | NS | |
| 2D circle | | 24% ( 4) | 11% ( 6) | 1.88 (0.45;7.93) | 0.39 | 0% ( 0) | 14% ( 9) | NS | |
| Ellipticity | 27 | 1.54/2/3.26 | 1.5/1.6/2.5 | 0.96(0.76,1.21) | 0.72 | 2/2.5/3.04 | 1.48/1.63/2.38 | 0.96(0.68;1.34) | 0.8 |
| Consistency | 75 | | | | | | | | |
| Conforming | | 0% ( 0) | 7% ( 4) | NS | | 0% ( 0) | 6% ( 4) | NS | |
| Semirigid | | 17% ( 3) | 40% (23) | Ref | | 25% ( 1) | 35% (25) | Ref | |
| Rigid | | 83% (15) | 53% (30) | 3.83(0.99;14.84) | 0.05 | 75% ( 3) | 59% (42) | 1.79(0.18;18.11) | 0.62 |

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**Title: Stationery injuries in the upper aerodigestive system: results from the Susy Safe Project**

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**Abstract**

**Rationale and aim:** Foreign Body (FB) injuries are a relatively frequent event in young children. Clinical picture can be evidently affected from different variables, and among those size, shape, type and FB location cover an important issue. in increased attempts to encourage normative interventions for products devoted to children's care and entertainment, reaching acceptable safety level, but fewer efforts have been devoted to investigate the risk associated to objects that even if not expressly created for children, are easy accessed by children, like stationery.

The aim of the present study is to characterize the risk of complications and prolonged hospitalization due to stationery items according to age and gender of patients, FB characteristics and FB location, circumstances of the accident, as emerging from the the Susy Safe Registry.

**Methods:** From 2005 to 2010 case were collected from 70 centres in 32 different countries. Details on the injuries, identified by means of the International Classification of Diseases, Ninth Revision (ICD-9) codes listed on hospital discharge records, were gathered through a standardized case report form, that provides a full set of information on injuries, with specific details on age and gender of the child, location, shape, volume, consistency and ellipticity of the foreign body, behavioral aspects linked to the injury, like the supervision of the parents or the activity concomitant to the accident, any complication occurred, length of hospitalization.

**Results:** In the years 2005-2010 a total of 17205 FB injuries in children aged 0-14 years were registered in Susy Safe Database. Among them 425 (2,5%) were due to a stationery item. The majority of FBs were retrieved in the nose ( 179, meaning 42.1%) and in the ears (176, 41.4Just 5 cases were observed in children younger than 1 year, while most of the cases, 80.6%, were recorded in children older than 3 years. 193 patients (45.4%) were female, while 232 (54.6%) were male.Adult supervision was indicated in 212 cases. In 143 of these accidents the adult was present (33.6% of the whole group).The most frequent stationery retrieved was rubber, counting for 209 cases (49.2%). According to the FBs types, mostly all cases reported a 3D volume and a rigid or semirigid consistency (49.3%) . Looking to the outcomes, 31 (7%) children needed hospitalization and complications were seen in 38 children (.8.9%) . No significant associations were seen between the outcomes and the FBs'

characteristics, excluded those between the consistency of the FB (rigid) and the necessity of hospitalization and the shape (2D) and the presence of complication
**Conclusions:** Injuries are events that in many cases can be prevented with appropriate strategies. Passive environmental strategies, including product modification by manufacturers, are the most effective. However, regulation regarding small parts of potentially dangerous objects, covers products addressed to children use but objects not projected for children, such as stationary items, are excluded. Our study testifies that stationary is involved in a non negligible percentage of FB injuries, mainly due to insertion in the ears. Frequently, injuries happens under adult supervision. This results confirm the fact that when passive preventive strategies are not practical, active strategies that promote behaviour change are necessary and information about this issue should be included in all visits to family pediatricians.

**Keywords:** Foreign Body injuries, Stationery, Children

## Introduction

Foreign Body (FB) injuries are a relatively frequent event in young children [1].
From 2005 to 2009 nearly 1200 hospital admission of children 0-14 years were due to foreign body inhalation in United Kingdom [2], while in the United States, foreign body inhalation accounts for 7% of accidental deaths in children under 4 years of age [3]. Worldwide, 55% of children who have inhaled foreign bodies are between 1 and 3 years of age and 7-10% are under 1 year of age [4], while ingestion is a frequent occurrence in children, especially in their first six years of life [5, 6], with a peak in children older than 3 years [7].
Clinical picture can be evidently affected from different variables, and among those size, shape, type and FB location cover an important issue [8]: depending on the origin (organic or inorganic) and the impact of the FB in the aerodigestive system, clinical presentation ranges may range from severe forms to forms with insidious and vague symptoms, which are difficultly and frequently late diagnosed, carrying therefore more risks of complications [9, 10]
Preventive strategies seems to be the primary objective when dealing with these injuries [11], meaning that scientific literature is needed to better understand the relationship between type of FB, location and clinical presentation with the aim to identify risky objects and to be able to improve effective preventive strategies [12].
Type of FB might varies from country to country [11], and inorganic objects appear to be an augmented appraisal in the last years [13] , resulting in increased attempts to encourage normative interventions for products devoted to children's care and entertainment , reaching acceptable safety level [7, 14].
On the contrary, fewer efforts have been devoted to investigate the risk associated to objects that even if not expressly created for children, are easy accessed by children. For instance, some classes of objects such as stationery items (including pencils, pens and their parts etc), are frequently listed in clinical registries among commonly inserted, inhaled, aspirated or ingested objects [15, 16], but rarely receive a specific attention.
The aim of the present study is to characterize the risk of complications and prolonged hospitalization due to stationery items according to age and gender of patients, FB characteristics and FB location, circumstances of the accident, as emerging from the the Susy Safe Registry.

## Methods

### Data collection

The Susy Safe Project, is aimed at establishing a registry of cases of Foreign Bodies (FB) injuries in children age 0-14 years. From 2005 to 2010 case were collected from 70 centres in 32 different countries . Details on the injuries, identified by means of the International Classification of Diseases, Ninth Revision (ICD-9) codes listed on hospital discharge records,  were gathered through a standardized case report form, that provides a full set of information on injuries, with specific details on age and gender of the child, location, shape, volume, consistency and ellipticity of the foreign body, behavioral aspects linked to the injury, like the supervision of the parents or the activity concomitant to the accident, any complication occurred, length of hospitalization.

### Objects characteristics definition

According to the Rimell's classification [17], objects were characterized by size, shape and consistency.

With regard to the size, when the dimensions (in mm) of the object were reported, the volume was calculated according to the shape of the objects itself. Such volume measures represent how much space the smallest geometrical figure containing the irregular-shaped FB takes up. Moreover, In order to understand the impact of spherical objects to the risk of injuries, the ellipticity, defined as the ratio of the longer and the shorter axis of the object (thus being 1 for spherical objects) was assessed..

### Statistical analysis

For the scope of this paper, statistical analysis was performed, assessing age and gender injury distributions. Data regarding adult supervision were also evaluated. FB location was reported according to ICD9-CM code: ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, oesophagus and stomach (ICD935). Descriptive statistics (absolute and relative frequencies or median, I and III quartile according to the categorical or continuous variable characteristics) were calculated for each foreign body's characteristic. FB features distribution by children class age and site of obstruction were assessed. Two different outcomes were considered: complication and hospitalization. Complications

include all the pathological conditions due to delayed diagnosis or to the attempts of removing the FB. Hospitalization has been defined whether the child was admitted in the hospital for at least 1 day. The association between children age, adult presence, object characteristics and outcomes was computed using unweighted odds ratios and the related 95% confidence intervals. Odds ratios not possible to be evaluated due to small cell frequency were labelled as NS (not significant).

Analyses were performed using Design and Hmisc libraries from R version 2.8 [18][].

**Results**

In the years 2005-2010 a total of 17205 FB injuries in children aged 0-14 years were registered in Susy Safe Database. Among them 425 (2,5%) were due to a stationery item. The majority of FBs were retrieved in the nose ( 179, meaning 42.1%) and in the ears (176, 41.4%). All data regarding FB location are reported in Table 1.
Distribution of incidence of analyzed injuries by age class is shown in Figure 1. Just 5 cases were observed in children younger than 1 year, while most of the cases, 80.6%, were recorded in children older than 3 years. 193 patients (45.4%) were female, while 232 (54.6%) were male.
Adult supervision was indicated in 212 cases. In 143 of these accidents the adult was present (33.6% of the whole group).
Details regarding FB types are given in Table 2: the most frequent stationery retrieved was rubber, counting for 209 cases (49.2%).
Specific data on volume and shape were found in 275 cases (Table 3). According to the FBs types, mostly all cases reported a 3D volume and a rigid or semirigid consistency (49.3%) .
Looking to the outcomes, 31 (7%) children needed hospitalization and complications were seen in 38 children (.8.9%) . Complications and hospitalization are considered in their correlation with different FBs' characteristic. No significant associations were seen excluded those between the consistency of the FB (rigid) and the necessity of hospitalization and the shape (2D) and the presence of complication.

## Conclusions

Characteristics of food, like shape, dimension, consistency are fundamental in determine the damage that might occur {Wolach, 1994 #540}. Small items represent a real issue and the impact on different systems varies depending on permanence, dimension and composition . FBs injuries located in the upper airways can be a very serious event, sometimes resulting in fatal outcome {Blatnik, 1977 #496}. Without an early treatment it remains a major cause of morbidity and mortality in children, especially during the first years of life.

Children are more prone to aspirate/inhale FBs for several reasons including behavioural aspects (such as the tendency to explore their surrounding using the mouths and to talk and run around while chewing), anatomical characteristics (the incomplete dentition with presence of incisors to tear foods but lack of cuspids necessary to grind food into a smooth bolus) and physiological features (including immature swallowing coordination, poor chewing capacity and higher respiratory rates compared with adults) any objects placed in mouths are more likely to be aspirated in children younger than 4 years than in older children {Zigon, 2005 #424}.

Injuries are not simply accidents but events that in many cases can be prevented with appropriate strategies [19] Interventions may be active or passive. In general, passive environmental strategies, including product modification by manufacturers, are the most effective because they provide automatic protection to large groups of people, including those less prone to undertake "active" measures and change their behavior [20]

Passive strategies often require legal or regulatory enforcement to impose the required changes [21]  An important advance in the prevention of foreign body injuries was the introduction of safety rules for toy design regarding small parts [22]

However, two facts must be indicated. Small parts regulation not projected objects that cannot be manufactured in a way preventing them from breaking into small parts, or that need to be small to perform their intended purpose, and therefore several potentially dangerous objects are excluded. Secondary, as seen from recent European surveys {EuroSafe, 2009 #544}, evidence based national level policies present inequities and great differences among different countries, preventing from a global framework of action.

Stationery items are an example of risky objects that although might end in fatalities, are poorly regulated from a choking, suffocation, ingestion point of view.

The most frequent foreign body belonging to the stationery macrocategory was rubber, pieces and whole. As seen in other studies {Chinski, #545} elective locations for inorganic objects retrieval were ear and nose, mostly interesting in most of the cases children older than 3 years, that therefore are more prone to actively explore and One source of influence on childhood injury is physical risk taking (i.e., doing things that increase risk of injury when there are alternative behaviors that do not do so to the same extent). The contribution of risk activities to injury is particularly evident for young children 5 years and under {Morrongiello, #546}.

When passive preventive strategies are not practical and easily developable, active strategies promoting behaviour change are necessary. Recent research findings confirm that risk factors for injury to young children include not only child behavioral attributes but also caregiver supervisory patterns {Morrongiello, 2008 #547}. Increasing parental awareness of the injury-risk implications of young children's emerging advancements in motor skills is essential to aid their making appropriate decisions about children's supervisory needs. Education of adults is essential as a primary prevention tool, including counselling on safe behaviour in every pediatircians' visit, would meand improve adults' consciousness on potential FB injuries and therefore being more attentive towards an active supervision.

**Tables**

| Location | Frequency | Percent |
| --- | --- | --- |
| Ears | 176 | 41,4 |
| Nose | 179 | 42,1 |
| Pharynx and Larynx | 5 | 1,2 |
| Trachea, Bronchi and Lungs | 25 | 5,9 |
| Mouth, Esophagus and Stomach | 23 | 5,4 |
| Other | 17 | 4 |
| Total | 425 | 100 |

**Table 1.** FB location according to ICD9-CM code: ears (ICD931) nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935).

| Foreign Body | Frequency |
|---|---|
| Rubber | 209 |
| Crayon | 75 |
| Lead/Tip pencil | 39 |
| Pencil | 37 |
| Pencil | 43 |
| Pen top/cap | 19 |
| Other (clips, marker, not specified) | 3 |
| Total | 425 |


| Foreign Body | Frequency |
|---|---|
| Rubber | 209 |
| Crayon | 75 |
| Lead/Tip pencil | 39 |
| Pencil | 37 |
| Pencil | 43 |
| Pen top/cap | 19 |
| Other (clips, marker, not specified) | 3 |
| Total | 425 |


**Table 2.** Foreign body types.

|  | N | ICD931 | ICD932 | ICD933 | ICD934 | ICD935 |
|---|---|---|---|---|---|---|
|  |  | N=137 | N=73 | N=5 | N=19 | N=22 |
| Volume | 275 | 1 1 1 | 1 1 1 | 1 1 1 | 1 1 49 | 1 1 1 |
| Shape: | 71 |  |  |  |  |  |
| 2D |  | 9% ( 3) | 0% ( 0) | 100% ( 1) | 0% ( 0) | 0% ( 0) |
| 2D circle |  | 0% ( 0) | 0% ( 0) | 0% ( 0) | 0% ( 0) | 50% ( 2) |
| 3D |  | 71% (25) | 69% ( 9) | 0% ( 0) | 89% (16) | 50% ( 2) |
| Other |  | 11% ( 4) | 15% ( 2) | 0% ( 0) | 0% ( 0) | 0% ( 0) |
| Spherical |  | 9% ( 3) | 15% ( 2) | 0% ( 0) | 11% ( 2) | 0% ( 0) |
| Ellipticity | 30 | 1.00 1.67 2.37 | 1.29 1.50 5.00 | 2.00 2.00 2.00 | 2.50 6.25 9.50 | - |
| Consistency | 73 |  |  |  |  |  |
| Conforming |  | 3% ( 1) | 8% ( 1) | 0% ( 0) | 11% ( 2) | 0% ( 0) |
| Dont know |  | 0% ( 0) | 15% ( 2) | 0% ( 0) | 0% ( 0) | 0% ( 0) |
| Rigid |  | 46% (17) | 8% ( 1) | 100% ( 1) | 78% (14) | 75% ( 3) |
| Semi-rigid |  | 51% (19) | 69% ( 9) | 0% ( 0) | 11% ( 2) | 25% ( 1) |

**Table 3.** Objects characteristics by FB location. Data are median first quartile/median/third quartile for continuous variables and percentages (absolute numbers) for categorical variables. N is the number of valid cases for each given variable. No objects observed with circle shape and conforming consistency.

| | Hospitalization | | | | Complications | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes(N=28) | No(N=44) | OR(95%CI) | P | Yes(N=9) | No(N=64) | OR(95%CI) | P |
| Class age | | | | | | | | |
| < 1year | 4% ( 1) | 2% ( 1) | 1.80 (0.09; 35.42) | 0.70 | 0% ( 0) | 3% ( 2) | NS | - |
| 1-2 years | 18% ( 5) | 20% ( 9) | Ref | | 22% ( 2) | 19% (12) | Ref | |
| > = 3 years | 79% (22) | 77% (34) | 1.16 (0.34;3.94) | 0.81 | 78% ( 7) | 78% (50) | 0.84(0.15; 4.57) | 0.84 |
| Adult supervision | | | | | | | | |
| Adult present | 26% ( 7) | 43% (18) | 0.47(0.16;1.34) | 0.16 | 12% ( 1) | 41% (25) | 0.21(0.02; 1.78) | 0.15 |
| Volume | 1.00 1.00 52.75 | 1.00 1.00 54.50 | 0.68(0.28; 1.65) | 0.39 | 1.00 86.00 112.00 | 1.00 1.00 23.75 | 1.23 (0.73; 2.07) | 0.44 |
| Shape | | | | | | | | |
| 2D | 4% ( 1) | 7% ( 3) | 0.42 (0.04; 4.36) | 0.47 | 22% ( 2) | 2% ( 1) | 12.86 (1.03;161.23) | 0.04 |
| 2D circle | 7% ( 2) | 0% ( 0) | NS | - | 0% ( 0) | 3% ( 2) | NS | |
| 3D | 81% (22) | 67% (28) | Ref | | 78% ( 7) | 74% (45) | Ref | |
| Other | 0% ( 0) | 14% ( 6) | NS | | 0% ( 0) | 10% ( 6) | NS | |
| Spherical | 7% ( 2) | 12% ( 5) | 0.51(0.09;2.88) | 0.44 | 0% ( 0) | 11% ( 7) | NS | |
| Ellipticity | 1.67 2.17 3.00 | 1.00 1.50 2.42 | 1.01(0.82; 1.26) | 0.90 | 1.23 1.50 1.67 | 1.08 2.33 4.50 | 0.31 (0.04;2.39) | 0.26 |
| Consistency | | | | | | | | |
| Conforming | 4% ( 1) | 5% ( 2) | 1.71 (0.13;21.82) | 0.68 | 0% ( 0) | 7% ( 4) | NS | |
| Semirigid | 71% (20) | 37% (15) | Ref | | 33% ( 3) | 52% (32) | Ref | |
| Rigid | 25% ( 7) | 59% (24) | 4.57 (1.56; 13.40) | 0.006 | 67% ( 6) | 41% (25) | 0.39 (0.09;1.72) | 0.21 |

**Table 4.** Odds ratio of complications and of hospitalization with the 95% confidence intervals are presented. *P* values are also presented. *N* number of valid cases for each given variable. *NS* not significant, – not possible to be evaluated due to small cell frequency..

**Figures**

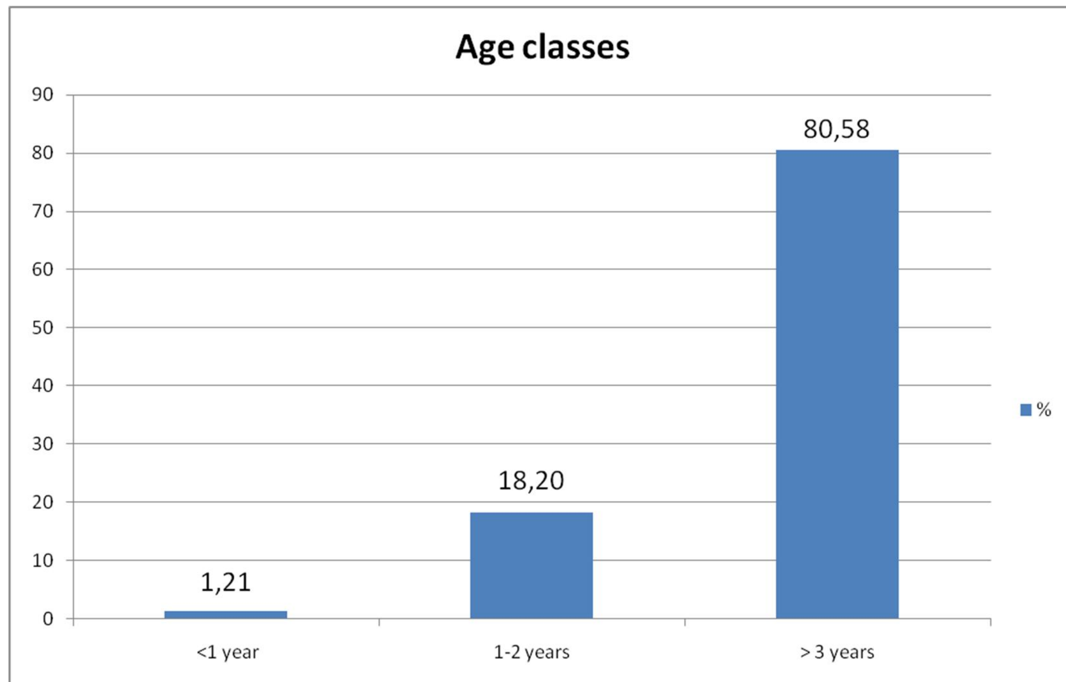


**Figure 1.** Distribution of incidence (%) of FB injuries by age class..

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**Retrospective study on Romanian Foreign Bodies Injuries in children.**

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**Background:** Foreign bodies' injuries are an issue that has been recognized and investigated since many years; despite that, the impact of this subject in literature and research is still small. Foreign bodies' injuries identify all incidents due to ingestion, inhalation, insertion and aspiration of an object into the aero digestive tract. FBs injuries located in the upper airways can be a very serious event, sometimes resulting in fatal outcome

**Methods:** A retrospective study was performed on FB injuries in the aerodigestive tract in paediatric patients 1-17 years old, recorded from the ENT Department of the M.S. Curie Hospital in

**Results:** 455 cases were reported from M. S. Curie Hospital, ENT Department. Female patient's prevalence is higher than the male's one, 225 males and 230 females. Mean age observed was 4,12 years. The distribution of injuries according to the retrieval location showed a higher prevalence in the nose (44,62% of cases), with a higher occurrence in females (50,74%) followed by the digestive system (24,28% of cases) were the distribution between males and females is equal. The highest prevalence was represented by nuts and seed (23,96%), followed by marble and coins (respectively 12,75% and 12,53%).

**Conclusions**: As generally described in scientific literature, injuries usually concerned toddlers and preschoolers, while school-aged children less often place foreign objects in their noses. Our results confirm the fact that when passive preventive strategies are not practical, active strategies that promote behaviour change are necessary. Active strategies require that a caregiver changes his or her behaviour each time the child begins an activity that has the potential to cause injury. Education is critical to these active strategies and plays a complementary role to environmental changes and legal mandates

**Keywords**: Foreign bodies aspiration/ingestion/insertion/inhalation, primary prevention

## Background

Foreign bodies' injuries are an issue that has been recognized and investigated since many years; despite that, the impact of this subject in literature and research is still small. Foreign bodies' injuries identify all incidents due to ingestion, inhalation, insertion and aspiration of an object into the aero digestive tract. FBs injuries located in the upper airways can be a very serious event, sometimes resulting in fatal outcome [1]. Foreign body (FB) injuries are a serious health problem in paediatric patients causing significant morbidity and mortality [2].In the RPA report about 10.000 accidents are estimated to involve inorganic objects, in general industrial products, mostly plastic and metal parts, coins, and toys [3]. Based on official records, the cost in terms of life loss due to suffocation in general has been estimated, for the EU community, as about 5 billion € per year, only because of injuries due to industrial products.

The need of an improvement of knowledge led to the development of the several projects in Europe, like the ESFBI study [4] or the Susy Safe Project [5]. Our study, based on records from the hospital M.S. Curie in  aims to shows the most serious Foreign Bodies Injuries locations and characteristics in a children's sample. Recognizing that the rapid management is one of the main goals in the presence of such injury, therefore broadening the information on FBs injuries features like shape, dimension, consistency is fundamental in determining the damage that might occur.

## Materials and Methods

*Sample*

A retrospective study was performed on FB injuries in the aerodigestive tract in paediatric patients 1-17 years old, recorded from the ENT Department of the M.S. Curie Hospital in .The main referent in each Hospital was an ENT doctor, cooperating in collecting data with other specialized structures (paediatric, emergency units and gastroenterology). The current analysis was carried out on FBs located in ears, nose, pharynx and larynx, trachea, bronchi and lungs, mouth, oesophagus and stomach, data recorded from 2005 to 2010.

*Statistical methods*

Descriptive statistics, like absolute and relative number for categorical variables, on data.

## Results

455 cases were reported from M. S. Curie Hospital, ENT Department. Female patient's prevalence is higher than the male's one, 225 males and 230 females.

Mean age observed was 4,12 years. Injuries occurred most frequently in children younger than 4 years old. All frequencies regarding the age distribution are resumed in Figure 1.

The distribution of injuries according to the retrieval location showed a higher prevalence in the nose (44,62% of cases), with a higher occurrence in females (50,74%) followed by the digestive system (24,28% of cases) were the distribution between males and females is equal. All data are presented in Table 1.

The foreign bodies retrieved were grouped by macro-categories and the types are listed in Table 2. In Romanian case series the highest prevalence was represented by nuts and seed (23,96%), followed by marble and coins (respectively 12,75% and 12,53%).

Nuts were retrieved most frequently in the tracheobronchial tree 50,46%) followed by the nose (36,70%). Looking closer to non food foreign bodies, coins were in 96,49% of cases retrieved in the digestive system. All frequencies related to the eight most frequent FBs are listed in Table 3.

**Discussion:**

Foreign bodies are a frequent cause of injuries in children, occurring in our study mostly in children older than 3 years old.

There wasn't a huge difference in the male:female ratio, with an higher prevalence of female in our study. That shows a different trend from to all the studies seen before, where it's common a clear prevalence of boys [3].

As generally described in scientific literature, injuries usually concerned toddlers and preschoolers, while school-aged children less often place foreign objects in their noses [6].

Analyzing more closely the nature of foreign bodies retrieved, there's a clear dominance of organic objects: seeds were the most frequent FB in our findings. This study aligns its results with data coming from international scientific literature, stressing the relevant risk of suffocation associated with nuts and seeds and reveals a higher prevalence in the tracheobronchial tree..

Reviewing literature on injuries due to nuts and seeds shows similar results to this study. A large North American retrospective study collecting injury data from 1989 to 1998 for 26 pediatric hospitals in the United States and Canada, analyzed aspiration, ingestion, insertion and choking injuries due to food items [1]. The data included 1429 infants and children Peanuts caused the highest frequency of injury, accounting for 26% of all injuries while sunflower seeds accounted for 7%. In both series toys had a low frequency, showing instead a clear prevalence of objects that aren't appropriate to children's age. Despite the widespread use of the Small Part Test Fixture

(SPTF), choking injuries and fatalities are still occurring in young children [4]. Seven hundred and twenty-two FB inhalation/aspiration injuries were observed. In 170 (24%) cases FB was lodged in the laryngeal and pharyngeal tract; in the remaining 552 (76%) cases, FB was retained in the tracheobronchial tree. In the most of cases (52%) children inhaled nuts, seeds, berries, peas, corns and beans. Similar results have been found for foreign bodies located in the nose: on 688 cases assessed in the European survey of foreign bodies injuries study.

Young children with immature teeth are especially at risk for aspirating fragments of the nut because they cannot easily chew the fruit. Aspirating either the fruit itself or pieces of the shell leads to major problems for small children. Shell when cracked produces pieces with sharp edges; these may easily penetrate the bronchial mucosa if aspirated, and it is rather difficult to remove the aspirated nut shell from the airways by bronchoscopy. Nut breaks into amorphous and hard pieces and bronchoscopic removal sometimes becomes very difficult and frequently more than one attempt is needed [7].

The most frequent location of the study was the nose, as widely discussed in Kalan's study [8]. FB sited in the nose produce local inflammation which may result in a pressure necrosis and damage nasal cavity and surrounding structures [9].

**Conclusions**

Food-related aspiration injuries are common events for young children, particularly under 4 years of age, and may lead to severe complication. Children are more prone to aspirate/inhale FBs for several reasons including behavioural aspects (such as the tendency to explore their surrounding using the mouths and to talk and run around while chewing), anatomical characteristics (the incomplete dentition with presence of incisors to tear foods but lack of cuspids necessary to grind food into a smooth bolus) and physiological features (including immature swallowing coordination, poor chewing capacity and higher respiratory rates compared with adults) any objects placed in mouths are more likely to be aspirated in children younger than 4 years than in older children. Primary prevention is therefore seen as a key to avoid those kind of injuries.

The implementation of injuries preventive strategies is based on a solid knowledge of the characteristics of the children at risk, the features of objects and the dynamics of the hazardous event. Building up this kind of knowledge requires continuous monitoring activity since dietary habits vary over the time and among countries.

Moreover, some authors suggest the need to study in more depth specific characteristics of foreign bodies associated with increased hazard, such as size, shape, hardness or firmness, lubricity,

pliability and elasticity, in order to better identify risky foods, and more precisely described the pathogenetic pathway.

Our results confirm the fact that when passive preventive strategies are not practical, active strategies that promote behaviour change are necessary. Active strategies require that a caregiver changes his or her behaviour each time the child begins an activity that has the potential to cause injury. Education is critical to these active strategies and plays a complementary role to environmental changes and legal mandates [10].

## Tables

**Table 1: Foreign Bodies Location and distribution by sex**

| Foreign body location | Frequency | Percent | Male (% per location) | Female (% per location) |
|---|---|---|---|---|
| ears | 58 | 12,75% | 58,62% | 41,38% |
| nose | 203 | 44,62% | 49,26% | 50,74% |
| pharynx and larynx | 17 | 3,74% | 52,94% | 47,06% |
| trachea, bronchi and lungs | 67 | 14,73% | 40,30% | 59,70% |
| mouth, esophagus and stomach | 110 | 24,18% | 50,00% | 50,00% |
| Total | 455 | 100,00% | | |

**Table 2: Distribution of injuries according to Foreign Bodies type**

| Type of foreign body | Frequency | Percent |
|---|---|---|
| Nuts and seeds | 109 | 23,96% |
| Marble | 58 | 12,75% |
| Coin | 57 | 12,53% |
| Bones | 36 | 7,91% |
| Batteries | 22 | 4,84% |
| Stationery | 21 | 4,62% |
| Toys | 20 | 4,40% |
| Plastic | 16 | 3,52% |
| Metal fragment | 15 | 3,30% |
| Paper | 14 | 3,08% |
| Bean | 11 | 2,42% |
| Jewellery | 10 | 2,20% |
| Cotton piece | 8 | 1,76% |
| Meat | 7 | 1,54% |
| Insect | 7 | 1,54% |

| Candy | 6 | 1,32% |
|---|---|---|
| Leaf | 5 | 1,10% |
| Polystyrene | 5 | 1,10% |
| Carrot | 4 | 0,88% |
| Crucifix | 3 | 0,66% |
| Peas | 3 | 0,66% |
| Sponge | 3 | 0,66% |
| Aluminium foil | 2 | 0,44% |
| Cork | 2 | 0,44% |
| Apple peel | 2 | 0,44% |
| Bearing ball | 1 | 0,22% |
| Button | 1 | 0,22% |
| Celery | 1 | 0,22% |
| Cherry | 1 | 0,22% |
| Chewing gum | 1 | 0,22% |
| Eggshell | 1 | 0,22% |
| Flower | 1 | 0,22% |
| Orange peel | 1 | 0,22% |
| Tooth | 1 | 0,22% |
| Total | 455 | 100,00% |

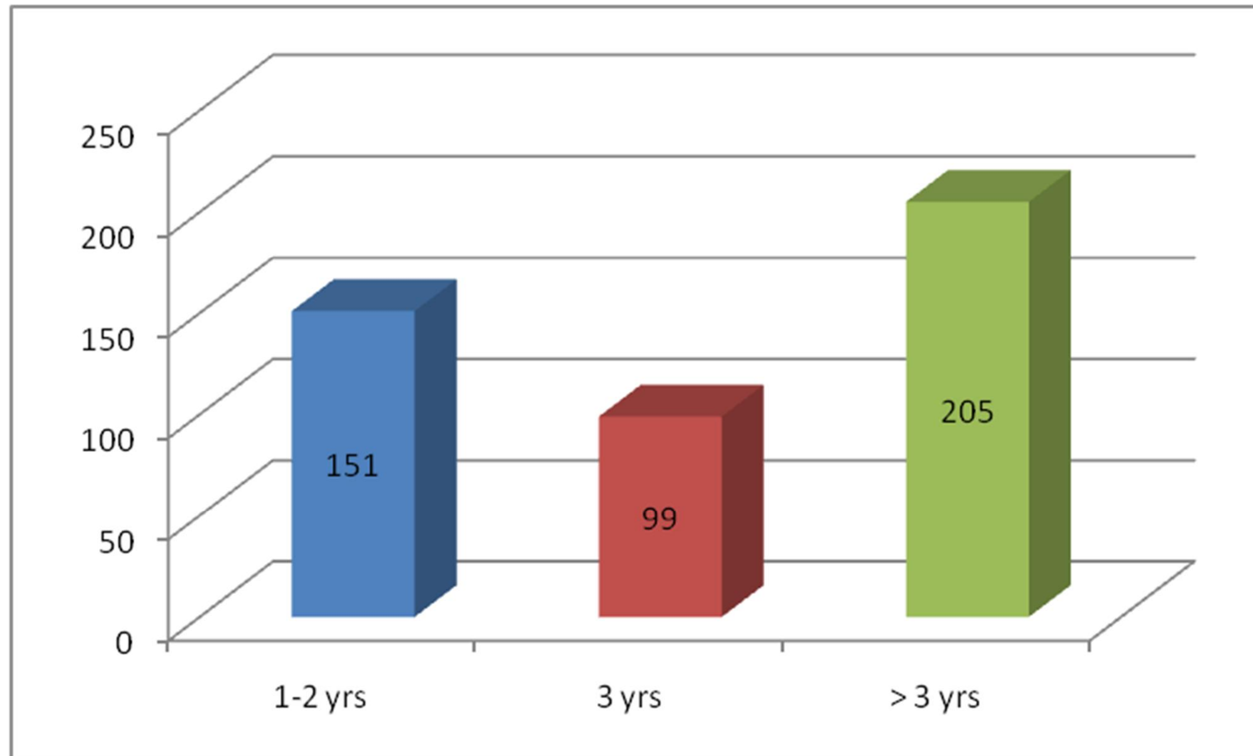
**Table 3: Location of the eight most frequent FBs**

| | ear | nose | pharynx and larynx | trachea, bronchi and lungs | mouth, esophagus and stomach | total |
|---|---|---|---|---|---|---|
| Nuts and seeds | 8 (7,34%) | 40 (36,70%) | 0 (0%) | 55 (50,46%) | 6 (5,50%) | 109 |
| Marble | 16 (27,59%) | 42 (73,68%) | 0 (0%) | 0 (0%) | 0 (0%) | 58 |
| Coin | 0 (0%) | 0 (0%) | 2 (3,51%) | 0 (0%) | 55 (96,49%) | 57 |
| Bones | 0 (0%) | 1 | 8 (21,62%) | 5 (13,51%) | 23 (62,12%) | 37 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | (2,70%) | | | | |
| Batteries | 1 (4,55%) | 21 (95,45%) | 0 (0%) | 0 (0%) | 0 (0%) | 22 |
| Stationery | 5 (23,81%) | 13 (61,90%) | 0 (0%) | 1 (4,76%) | 2 (9,52%) | 21 |
| Toys | 1 (5,00%) | 16 (80,00%) | 2 (10,00%) | 0 (0%) | 1(5,00%) | 20 |
| Plastic | 2 (12,50%) | 12 (75,00%) | 0 (0%) | 1 (6,25%) | 1 (6,25%) | 16 |

**Figures**

**Figure 1: Age distribution of FBs' injuries**



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**Title: Foreign Bodies in children: a comparison between Argentina and Europe**

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**Abstract**

**Rationale and aim:** Foreign bodies (FB) aspiration, ingestion, insertion or inhalation can be a serious occurrence, resulting in fatality if not promptly recognized and solved. The aim of the current paper is to present foreign body ingestion's cases observed at the Children's Hospital Gutierrez in Buenos Aires in five years of ORL activity and to compare main findings with data coming from other well known already published case series.

**Methods:** A prospective study was realized on children having ingested, inhaled, aspirated or introduced FBs, with regard to age and sex distribution, FB's type, dimensions and consistency, FB's location, clinical presentation, removal and occurrence of complications.

**Results:** FBs retrieved amounted to 2336 cases. The most common location was the nose (66.7%), where the most frequent FBs retrieved were inorganic (72.7%) and occurred in children younger than 3 years old (54.2%), the only position where children younger than 3 years are a majority in respect to the older ones. The presence of the adult was seen in the preponderance of cases (88.4 %). Symptoms varied between the different anatomical systems, with cough as predominant when concerning aspiration, local pain or inflammation in inhalation and insertion, and vomiting in for the FBs ingestion cases. All the foreign bodies retrieved were clustered in categories, due to necessity when extremely various and with low absolute frequency. The most common FBs retrieved were pearls (20.2%), followed by stationery products (mostly rubbers) and coins. Complications had a low rate in all the studies.

**Conclusions**: The study stresses the importance of primary prevention, seen as the active care of adults toward children manipulating foreign bodies potentially dangerous. This presence may not avoid the event, but in case of FBs aspiration, ingestion, insertion or inhalation, it could be the main factor leading to a faster and correct treatment. Prompt removal of the foreign body decreases the risk of complications, resulting in a lower length of hospitalization.

Symptoms were various and differed in all the studies, showing that their wide amount indicates the importance of registries to early recognize and therefore treat a pathology that might be mistaken for something different due to unspecific signs. Secondary prevention with specific training of doctors on clinical post-trauma guidelines for treatment and active participation of doctors to the broadening of the current registries seem to be other ways for lowering the outburst of FBs injuries.

**Keywords**: Foreign bodies aspiration/ingestion/insertion/inhalation, sovra-national comparison

## Introduction

Foreign bodies (FBs) in childhood are a cause for frequent visits to otorhinolaryngology emergency units. FBs aspiration, ingestion, inhalation or insertion can be a serious occurrence, resulting in fatality if not promptly recognized and solved. FBs' cases rarely go without symptoms, which are determined by the time or duration the FB stays in place before removal. There are several reasons for the children's risky behavior, temperamental aspects, characteristics and level of development of the anatomical parts, physiological features such as immature swallowing coordination, poor chewing capacity and higher respiratory rates [1, 2]. Normal 1-year-olds mouth objects for long periods of time to build an understanding of their environments. As they grow older, children decrease the amount of mouthing and become more selective about the types of objects they mouth, so that, by the time they are 4 years old, mouthing plays a smaller part in exploratory behavior for most normally developing children [3].

Aerodigestive tract is for this reason a very common location for retrieving FBs, stressing that the risk of injury or death posed by a food, toy or toy part, or another object depends upon its size, shape and consistency. Furthermore, the type of object causing injury is correlated with the age of the child injured [4]. The presentation varies in severity due to the same reason, and it's possible to assist to a large variety of signs, where the most common symptoms are stridor, wheezing, sternal recession and cough in the airways cases, Children who have airway foreign bodies have a wide range of symptoms, when presenting immediately after an event, describe the sudden onset of choking, cough, and shortness of breath. However, such early symptoms cease when mucosal cough receptors accommodate. Lung auscultation initially may yield normal results or may reveal signs of obstruction such as wheezing. Patients who present later may complain of cough, dyspnea, or fever and display the classic triad of cough, wheezing, and asymmetric breath sounds. The goal treatment for the airways' FBs is bronchoscopy, chosen by the ENT specialist between rigid or flexible. Potential complications of bronchoscopy include progression from partial to complete obstruction, atelectasis, and pneumonia. Failure of bronchoscopy may necessitate thoracotomy. When the diagnosis is delayed, infectious complications predominate, including recurrent or persistent pneumonia and abscesses.

Esophageal objects can cause a foreign body sensation, drooling, or respiratory distress due to tracheal compression, gagging, dysphonia, vomiting, and dysphagia, depending on the location and the nature of the FB [5]. Less recently ingested objects may develop in subsequent complications such as obstruction or erosion develop and cause emesis, abdominal distention, or gastrointestinal bleeding when non noticed before. Chronic presentations can include fever and weight loss [6]. For gastrointestinal foreign bodies, the type of object, its location, and the child's symptoms dictate treatment. Although most gastric objects pass without complication and can be observed in the outpatient setting, approximately 70% of esophageal objects remain entrapped, especially those in the

upper or mid-esophagus. Endoscopy is used commonly for managing esophageal and gastric foreign bodies, serving both diagnostic and therapeutic purposes. Complications are most likely to occur when ingested objects remain lodged for more than 24 hours, which can result in mucosal erosion, abrasion, or perforation. Early symptoms are related to inflammation and include pain, bleeding, and obstruction. Scarring may lead to strictures; infectious complications include abscess development. Retained esophageal foreign bodies may cause tracheal compression and erosion through the mucosa, with migration into adjacent structures, such as the respiratory tract or aorta.

Boredom, curiosity, whims to explore the natural cavities of the body, habit, acts of imitation, fun-making and mental retardation may lead to the insertion of FBs in the nose [7]. Initial symptoms are sneezing, serious coryza and nasal obstruction, eventually progressing after a few days to unilateral foul smelling purulent rhinorrhea. Removal techniques include removal with direct visualization using forceps, curved hooks, cerumen loops, or suction catheters. Additionally, successful removal has been achieved by passing a thin, lubricated, balloon-tip catheter [8].

For what concerns the ears, though complications such as canal laceration, otitis externa, perforation, hematoma, and ossicular disruption do occur, it is not a morbid or life-threatening condition.[9]. In many cases, patients with foreign bodies in the ear are asymptomatic, and in children the foreign body is often an incidental finding. Other patients may present with pain, symptoms of otitis media, hearing loss, or a sense of ear fullness, hypoacusis, otorrhagia, otorrhea or buzzing and the diagnosis may be confirmed by otoscopy [10]. Many techniques to remove ear foreign bodies are available, and the choice depends on the clinical situation, the type of foreign body suspected, and the experience of the physician. Options include water irrigation, forceps removal (e.g., alligator forceps), cerumen loops, right-angle ball hooks, and suction catheters.

In all cases, a carefully obtained history with a high level of suspicion is most contributory to the diagnosis, leading to faster conclusions and quick treatments [11].

The assortment of foreign bodies is very wide: Fish bones, toys, food, candy, peanuts and nuts, and batteries are the most frequent. They varies from country to country, taken different diets and habits of the population, and from children's age and location.

We've performed an analysis of the South American literature concerning the FBs injuries, resulting in four main studies, that well illustrate the factors known till today. The occurrence of foreign bodies in otorhinolaryngology is reason of constant searches, reckoned that the rapid management is one of the main goals in the presence of such injury.

In 2008 Cataneo [12] reviewed the medical and radiological records charts of all FB aspiration cases treated at São Paulo State University Hospital over 30 years. 164 FB cases were analyzed; (57% male, 84% under 16 years old). The most common clinical manifestations were coughing (68.3%) and choking (54.9%) while the most common FBs were seeds (peanut, bean, maize) and

also small metal or plastic objects. Complications were due to delays in diagnosis, and most would not have existed if the doctor had given credence to the history. In the same year, Martins and Andrade [13] analyzed accidents involving foreign bodies among children less than 15 years of age residing in Londrina, Paraná State, Brazil, in terms of first aid, hospitalization, and death (2001), obtaining data from general hospital records and the Municipal Mortality Database. Boys predominated (53.7%), and the incidence rate was highest among children one to three years of age (7.2 per 1,000 children). Foreign body penetration in natural orifices (eyes, nostrils, and ears) accounted for 94%, inhalation/ingestion of food 2.8%, inhalation/ingestion of objects 2.5%. In their conclusion they particularly stressed the need to restructure health services in order to decentralize care for less complex injuries, besides emphasizing the need for preventive measures. In 2008 there's also the publication of Figueiredo's retrospective study on 1356 patients with ear, nose and throat foreign bodies from the ENT Department of Souza Aguiar Hospital, in Rio de Janeiro, between 1992 and 2000 [14]. The analysis ascertained that measures are suggested to avoid complications, as follows: informing patients to immediately seek an otorhinolaryngologist in FB cases, increasinf care by otorhinolaryngologists with technically difficult to remove FBs, such as seeds especially in ears and in children. In 2006 Tiago [15] conducted a prospective study of 81 patients with diagnosis of foreign body of nose, ear or oropharynx in the otorhinolaryngology service of the Hospital do Servidor Público Municipal de São Paulo between april/2003 and march/2005. He reviewed 57 cases of foreign body of ear, 13 cases of nose and 11 of oropharynx, 51.85% were men, and showed as the most common symptom of the foreign bodies cases of oropharynx was odinofagia (90.91%), in the foreign bodies of nose, unilateral rhinorrhea and cacosmia (46.15%) of the cases; in the foreign bodies of ear, 38.60% evolved without symptoms and 28.07% with hipoacusia. The most frequent foreign body of oropharynx it was the fish spine (54.55%); in the nose paper (30.77%); and in the ear cotton (31.58%). As seen from Cataneo too, they concluded that the most frequent appearances of complications were seen when non-specialist professional or a non-professional person previously handled its removal.

The aim of the paper is to present the data collected in the ORL of our hospital, and to frame them in an international context, choosing Europe as a selected mirror.

**Methods**

*Data collection*

Data regarding children (0-14 years) presenting with Foreign Bodies in the Ears, in the Nose, in Larynx, trachea and Bronchi, and in Esophagus have been prospectively collected at the Children's Hospital Gutierrez in Buenos Aires during a period of five years from DATE ANALISI.

*Statistical analysis*

Details on injuries were collected and a descriptive statistical analysis is provided regarding children's demographic characteristics, features of the object, circumstances of the injury, clinical presentation, outcomes (complications and removal details). Moreover a search on PubMed database has been performed in order to retrieve some European case series describing FB in the ear, nose, airways and upper digestive tract. The research resulted in 4 articles published from Gregori et al. [16-19], that were therefore used for a comparison with the Argentinean's results.

**Results**

In our study, the totality of Fbs retrieved amounted to 2336 cases, compared with 2094 European cases. The most common location was the nose (66.7%), where the most frequent FBs retrieved were inorganic and occurred in children younger than 3 years old, the only position where children less than 3 years were a majority in respect to the older ones. In the European study the main locations were the airways (34.5%), divided in Gregori's study in larynx, trachea and bronchi. In this case the most frequent FBs retrieved were organic (76.03%) and the children affected were older than 3 years old for the greater part (69.4%). In both studies, the presence of the adult was seen in the preponderance of cases, but the percentages are very different. In the Argentinean case the adults were with children in 88.4 % of the injuries, instead in the European cases the percentage decreases to 55.3%, with two locations, ears and nose, where there was a minor percentage of adult's witnessing during the occurrence. Symptoms varied between the different anatomical systems, with cough as predominant when concerning aspiration, local pain or inflammation in inhalation and insertion, and vomiting in for the FBs ingestion cases. All the data are resumed in Table 1, comparing the South American cases and the European ones.

In Table 2 we've reported all the foreign bodies retrieved, clustered in categories when extremely various and with low absolute frequency. The most common FBs retrieved were pearls, followed by stationery products (mostly rubbers) and coins. Seed, nuts and beans resulted as one of the most common FB in the airways, while coins were the most common FBs ingested. Pearls were most frequently inhaled, instead stationeries were usually inserted in the ears.

**Discussion**

Foreign bodies are a frequent cause of injuries in children, occurring in our study mostly in children older than 3 years old.

There wasn't a huge difference in the male:femalio ratio, with an higher prevalence of female in our study. That is different from all the studies seen before, and also from the European studies chosen for the comparison, where the rate of accidents changes significantly after 3 years of age, and this difference increases during childhood, with a clear prevalence of boys [20].

Analyzing more closely the nature of foreign bodies retrieved, there's a clear dominance of inorganic objects, that matches our findings about the activities that the children were performing when the injury occurred. In our series toys had a low frequency, showing instead a clear prevalence of objects that aren't appropriate to children's age. Despite the widespread use of the Small Part Test Fixture (SPTF), choking injuries and fatalities are still occurring to young children [21]. This regulation in fact, covers products for children under three: a wide range of objects easily accessed by children even if not expressly designed for children are exempt, including objects (such as books and stationery items) that cannot be manufactured in a way that would prevent them from breaking into small parts, and objects that need to be small (such as buttons) to perform their intended purpose

An important finding in our study is the presence of adults during the FBs event. In the majority of cases children were playing or eating, both activities occurring under adults supervision. As already seen from Gregori et al. [22] incorrect or distracted adult care is commonly seen in the injury. In the Susy Safe database, a parent or a care giver was present in ,49% of cases of injury, and it is interesting to note that the child was eating in 34% and playing in 59% of the cases; this suggests that an informative campaign directed toward families, stressing the importance of active attention when a young child is manipulating objects, would be useful. That is besides pointed out from the nature of FBs retrieved, in 20.2% of cases there were pearls, followed by stationeries and coins, objects that shouldn't be available to children of a certain age.

Therefore we stress the importance of primary prevention, seen as the active care of adults toward children manipulation foreign bodies potentially dangerous. This presence may not avoid the event, but in case of FBs aspiration, ingestion, insertion or inhalation, it could be the main factor leading to a faster and correct treatment. As frequently suggested in literature [23, 24], the need for prompt removal of the foreign body decrease the risk of complications, resulting in a lower length of hospitalization.

Complications had a low rate in all the studies and were similar, like pneumonia for the airways' FBs and infections in the nose, on the contrary, symptoms on the contrary were various and differed in all the studies, showing that the wide amount of symptoms indicates the importance of registries

to early recognize and therefore treat a pathology that might be mistaken for something different due to unspecific signs. Secondary prevention with specific training of doctors on clinical post-trauma guidelines for treatment and active participation of doctors to the expansion of the current registries seem to be other ways for lowering the outburst of FBs injuries.

**Table 1: Comparison among characteristics recorded in the Argentinean case series and in 4 published European case series. Data are given as absolute frequency and percentage relative to the reference's sample are expressed in brackets.**

| | **Chinsky, Argentina, South America** | | | | | **Gregori, Italy, Europe [18-21]** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Airways** | **Ears** | **Nose** | **Esophagus** | **Total** | **Airways** | **Ears** | **Nose** | **Esophagus** | **Total** |
| **n FBs** | 65 | 392 | 1559 | 320 | 2336 | 722 | 498 | 688 | 186 | 2094 |
| **Gender** | | | | | | | | | | |
| **Male** | 31 (47.69) | 198 (50.5) | 714 (45.8) | 163 (50.94) | 1106 | | 294 (59) | 332 (48.3) | 113 (61) | 739 |
| **Female** | 34 (52.31) | 194 (49.5) | 845 (54.2) | 157 (49.06) | 1196 | | 204 (41) | 355 (50.7) | 73 (49) | 632 |
| **Age** | | | | | | | | | | |
| **0-3 yrs** | 32 (49.23) | 37 (9.4) | 859 (55.1) | 77 (24.1) | 973 | 221 (30.60) | 60 (12) | 296 (43.0) | | 577 |
| **>3 yrs** | 33 (50.77) | 355 (90.6) | 700 (44.9) | 243 (75.9) | 1331 | 501 (69.40) | 438 (88) | 392 (56.8) | | 1331 |
| **FB type** | | | | | | | | | | |
| **Organic FB** | 29 (44.61) | 134 (34.2) | 425 (27.3) | 15 (4.7) | 603 | 549 (76.03) | 114 (22.8) | 218 (31.7) | 37 (19.9) | 918 |
| **Inorganic Fb** | 36 (55.39) | 258 (65.8) | 1134 (72.7) | 305 (93.3) | 1733 | 173 (23.97) | 384 (77.2) | 470 (67.7) | 149 (80.1) | 1176 |
| **Adult Presence** | | | | | | | | | | |
| **Yes** | 59 (90.76) | 328 (83.7) | 1405 (90.1) | 273 (85.3) | 2065 | 608 (84.21) | 160 (32) | 222 (32.2) | 167 (89.8) | 1157 |
| **No** | 6 (9.24) | 64 (16.3) | 154 (9.9) | 47 (14.7) | 271 | 114 (15.78) | 338 (67.9) | 466 (67.8) | 19 (10.2) | 937 |
| **Most frequent symptom** | Cough 52 (80) | Hypoacusia 43 (10.9) | Cacosmia 95 (6.1) | Vomiting | | | | Mucopurulent nasal discharge 27 (3.9) | Dysphagia 43 (23) | |
| **Most frequent complication** | Pneumonia 3 (4.61) | No complications observed | Local infection 106 (6.8) | Esophageal perforation 1 (0.31) | | Pneumonia 14 (1.94) | Lesion of auricular canal | Local infection 5 (0.5) | Unspecified complications 14 (7.5) | |

**Table 2:Description of retrieved foreign bodies in the Argentinean series.**

| Foreign Bodies | Ears | Nose | Esophagus | Airways | Total |
|---|---|---|---|---|---|
| Pearls | 67 | 399 | | 5 | 471 |
| Stationery | 68 | 227 | | 7 | 302 |
| Coins | | 8 | 268 | | 276 |
| Food other than seeds, nuts and beans | 51 | 176 | | 5 | 232 |
| Seeds, Nuts, Beans | 56 | 139 | | 19 | 214 |
| Pins, Nails, Metal | 28 | 146 | 8 | 8 | 190 |
| Other inorganic | 24 | 101 | | 5 | 130 |
| Stones | 15 | 92 | | 1 | 108 |
| Plastic pieces | 28 | 21 | 15 | | 64 |
| Toys | 2 | 50 | 1 | 3 | 56 |
| Plasticine | 13 | 38 | | | 51 |
| Wood | 3 | 41 | | 2 | 46 |
| Building materials | 19 | 16 | | | 35 |
| Bones | 2 | 10 | 15 | 5 | 32 |
| Balls | 10 | 20 | | | 30 |
| Wires | 4 | 15 | | 2 | 21 |
| Buttons | | 10 | 11 | | 21 |
| Flowers and grass | 3 | 17 | | | 20 |
| Jewelery | 1 | 12 | 2 | 2 | 17 |
| Magnets | | 11 | | | 11 |
| Batteries | | 1 | | | 1 |

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**Title: Foreign bodies injuries in children: analysis of Thailand data**

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**Background:** Suffocation due to foreign bodies (FB) is a leading cause of death in children aged 0-3 and it is common also in older ages, up to 14 years old. Based on the RPA report the estimated number of incidents per year in children aged 0-14 is in European Union (EU) of approximately 50.000, 10% of which are fatal. The need of an improvement of knowledge led to the development of the pan European study ESFBI (European Survey on Foreign Bodies Injuries) that collected data on FB injuries in the aerodigestive tract in paediatric patients from 19 European Hospitals (Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Swiss, Turkey and United Kingdom). Recognizing that the rapid management is one of the main goals in the presence of such injury the aim of this paper is to confront data coming from 4 ESFBI case series with a Thailand's case series, in order to broaden the knowledge on FBs injuries characteristics, knowing that features like shape, dimension, consistency are fundamental in determine the damage that might occur.

**Methods:** Data coming from the Siriraj Hospital, Thailand from June 2006 to 2010 were collected and compared with 4 case series chosen among the ESFBI study cases (Finland, Slovenia, Sweden and Turkey).

**Results:** 172 cases were collected from the Siriraj Hospital in Bangkok, Thailand. The chosen ESFBI members were Finland, Sweden, Slovenia and Turkey, with a sample numerosity respectively of 307, 235, 104 and 196 cases. All countries showed a male prevalence higher than the female one, and injuries occurred most frequently in children younger than 3 years old. The most frequent retrieval location was the digestive system (esophagus) in Thailand data (97 cases, 56.40 % of cases), while European cases involved more frequently the nose in Slovenia (58.65%), Finland (37.79% of cases) and Sweden (54.47%). In Turkey's case series, the highest prevalence of cases interested the airways. In Thailand and Finland case series, the main FB's type were represented by bones (respectively 66 case, 38.37% and 48 cases, 15.64%), while pearl, ball and marble were the most frequent FB both in Slovenia (16, 15.38%) and Sweden (83, 35.32%). Turkey case series had nuts, seeds and grain as most prevalent FB (126, 64.29%).

**Conclusions**:

The nature of foreign bodies varies from country to country and is dependent on diverse cultural, social, religious and economic factors that include parental attitudes, eating habits, availability and types of potentially threatening objects, and prevention strategies. The need to study in more depth specific characteristics of foreign bodies associated with increased hazard, such as nature, size, shape, hardness or firmness, lubricity, pliability and elasticity, in order to better identify risky foods and to describe more precisely the pathogenetic pathway is therefore a necessity.

**Keywords**: Foreign bodies aspiration/ingestion/insertion/inhalation, sovra-national comparison

## Background

Foreign body (FB) injuries are a serious health problem in paediatric patients causing significant morbidity and mortality [1].

In the RPA report about 10.000 accidents are estimated to involve inorganic objects, in general industrial products, mostly plastic and metal parts, coins, and toys [2]. Based on official records, the cost in terms of life loss due to suffocation in general has been estimated, for the EU community, as about 5 billion € per year, only because of injuries due to industrial products.

The need of an improvement of knowledge led to the development of the pan European study ESFBI (European Survey on Foreign Bodies Injuries) that collected data on FB injuries in the aerodigestive tract in paediatric patients from 19 European Hospitals (Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Swiss, Turkey and United Kingdom). Recognizing that the rapid management is one of the main goals in the presence of such injury, the aim of this paper is to confront data coming from 4 ESFBI case series with a Thailand's case series, in order to broaden the information on FBs injuries characteristics, knowing that features like shape, dimension, consistency are fundamental in determine the damage that might occur. In addition, differences and similarities between the samples will be assessed, to extend the capability of data collection and determine, by means of a detailed case analysis, the risk heterogeneity among countries, with respect to product characteristics and inadequate behaviour of both children and adults.

## Materials and Methods

### *Sample*

The European Survey on Foreign Bodies Injuries (ESFBI) Study collected data on FB injuries in the aerodigestive tract in paediatric patients from 19 European Hospitals (Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, Germany, Greece, Italy, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, Swiss, Turkey and United Kingdom). Data on 2103 injuries occurred in the years 2000-2002 were identified by means of the International Classification of Diseases, Ninth Revision (ICD-9) codes listed on hospital discharge records. The main referent in each Hospital was an ORL doctor, cooperating in collecting data with other specialized structures (paediatric, emergency units and gastroenterology). The current analysis was carried out on FBs located in ears (ICD931), nose (ICD932), pharynx and larynx (ICD933) trachea, bronchi and lungs (ICD934), mouth, oesophagus and stomach (ICD935), compared with data coming from the Siriraj Hospital, Thailand, whose data were collected from June 2006 to July 2010.

The ESFBI database was analysized in order to establish four countries with a similar sample numerosity, choosing therefore Slovenia, Finland, Sweden, and Turkey.

*Statistical methods*

Descriptive statistics, like absolute and relative number for categorical variables, were worked out both for ESFBI data and Siriraj's ones.

**Results**

One-hundred-seventy-two cases were collected from the Siriraj Hospital in Bangkok, Thailand. The chosen ESFBI members (Finland, Sweden, Slovenia and Turkey), have a sample size of respectively of 307, 235, 104 and 196 cases. In all countries the male patient's prevalence was higher than the female one, and injuries occured most frequently in children younger that 3 years old. All frequencies regarding the 5 countries are resumed in Table 1.
The distribution of injuries according to the retrieval location showed a higher prevalence in the digestive system (esophagus) in Thailand data (97 cases, 56.40 % of cases), while European cases involved more frequently the nose in Slovenia (58.65%), Finland (37.79% of cases) and Sweden (54.47%). In Turkey's case series, highest prevalence of cases interested the airways. All data are presented in Table 2.
The foreign bodies retrieved were grouped by macro-categories and the types are listed in Table 3. In Thailand's and Finland's case series, the highest prevalence was presented by bones (respectively 66 case, 38.37% and 48 cases, 15.64%), while pearl, ball and marble were the most frequent FB both in Slovenia (16, 15.38%) and Sweden (83, 35.32%). Turkey case series involved nuts, seeds and grain as most prevalent FB (126, 64.29%).

**Discussion:**

Foreign bodies are a frequent cause of injuries in children, occurring in our study mostly in children older than 3 years old.
There wasn't a huge difference in the male:female ratio, with an higher prevalence of male in our study. That is similar to all the studies seen before, with a clear prevalence of boys [3].
There was a significant variation among the countries regarding the site of retrieval. Thailand's cases reported a higher prevalence in the digestive system, miming other studies [4-6]. ESFBI data where otherwise consistent with other European studies, showing the nose as preferential site [7].

As generally described in scientific literature, injuries usually concerned toddlers and preschoolers, while school-aged children less often place foreign objects in their noses [8].
Analyzing more closely the nature of foreign bodies retrieved, there’s a clear linkage with the location. In Thailand the most frequent foreign bodies were bones with an esophageal location, that matches studies stressing the importance of the activities that the children were performing when the injury occurred [9]. Same results were found in Finnish case series, that however differed in the location of the FBs. The other two European ESFBI’s FBs belonged on the contrary to the inorganic types, mostly pearl and ball, suggesting an the improvement in manufacturing quality standards for common used objects. Turkey cases instead were interested mostly by food FB, specifically nuts, seeds and beans, highlighting that the nature of foreign bodies varies from country to country and is dependent on diverse cultural, social, religious and economic factors that include parental attitudes, eating habits, availability and types of potentially threatening objects, and prevention strategies. The need to study in more depth specific characteristics of foreign bodies associated with increased hazard, such as nature, size, shape, hardness or firmness, lubricity, pliability and elasticity, in order to better identify risky foods and to describe more precisely the pathogenetic pathway is therefore a necessity.

## Tables

**Table 1: Comparison among sample numerosity and distribution of injuries by age and gender recorded in the Thailandese case series and in 4 ESFBI study case series. Data are given as absolute frequency and percentage relative to the reference's sample are expressed in brackets.**

| | Siriraj Hospital, Thailand | ESFBI, Finland | ESFBI,Slovenia | ESFBI, Sweden | ESFBI, Turkey |
|---|---|---|---|---|---|
| n FBs | 172 | 307 | 104 | 235 | 196 |
| Gender | | | | | |
| Male | | 182 (59.28) | 61 (58.65) | 117 (49.79) | 124 (63.27) |
| Female | | 125 (49.72) | 43 (41.35) | 118 (50.21) | 72 (36.73) |
| Age | | | | | |
| 0-3 yrs | | 153 (49.84) | 56 (53.85) | 122 (51.91) | 165 (84.18) |
| >3 yrs | | 154 (50.16) | 48 (46.15) | 113 (48.02) | 31 (15.82) |

**Table 2: Comparison among characteristics recorded in the Thailandese case series and in 4 ESFBI study case series. Data are given as absolute frequency, percentage relative to the reference's sample are expressed in brackets.**

| | **Siriraj Hospital, Thailand** | **ESFBI, Finland** | **ESFBI,Slovenia** | **ESFBI, Sweden** | **ESFBI, Turkey** |
|---|---|---|---|---|---|
| **Airways** | 10 (5.81) | 18 (5.86) | 2 (1.93) | 6 (2.55) | 173 (88.26) |
| **Pharynx-Larynx** | 30 (17.44) | 53 (17.26) | 22 (21.15) | 16 (6.01) | 3 (1.53) |
| **Ears** | 7 (4.07) | 90 (29.32) | 17 (16.35) | 84 (35.74) | 0 (0) |
| **Nose** | 28 (16.28) | 116 (37.79) | 61 (58.65) | 128 (54.47) | 0 (0) |
| **Esophagus** | 97 (56.40) | 30 (9.77) | 2 (1.92) | 1 (0.43) | 20 (10.21) |
| **N** | 172 | 307 | 104 | 235 | 196 |

**Table 3: Comparison among characteristics recorded in the Thailandese case series and in 4 ESFBI study case series. Data are given as absolute frequency and percentage relative to the reference's sample are expressed in brackets.**

| Siriraj Hospital, Thailand | | ESFBI, Finland | | ESFBI, Slovenia | | ESFBI, Sweden | | ESFBI, Turkey | |
|---|---|---|---|---|---|---|---|---|---|
| **bone** | 66((38,37) | bone | 48(15,64) | pearl, ball and marble | 16(15,38) | pearl, ball and marble | 83(35,32) | nut, seed,beans | 126(64,29) |
| **denture** | 20(11,63) | pearl, ball and marble | 41(13,36) | nut, seed,beans | 14(13,46) | nut, seed,beans | 34(14,47) | pin and needle | 22(11,22) |
| **other food** | 17(9,88) | toy | 41(13,36) | bone | 13(12,50) | pebble | 18(7,66) | other food | 11(5,61) |
| **seed** | 15(8,72) | nut, seed,beans | 30(9,77) | toy | 13(12,50) | paper | 16(6,81) | stationery | 9(4,59) |
| **disc battery** | 14(8,14) | pebble | 28(9,12) | pebble | 9(8,65) | other organic | 13(5,53) | toy | 7(3,57) |
| **coin** | 10(5,81) | food | 20(6,51) | other inorganics | 9(8,65) | unknown 12 | 13(5,53) | bone | 4(2,04) |
| **other inorganic** | 10(5,81) | other inorganics | 19(6,19) | food | 6(5,77) | other inorganics | 12(5,11) | other organic | 4(2,04) |
| **decoration** | 5(2,91) | coin | 19(6,19) | stationery | 6(5,77) | plastic | 12(5,11) | other inorganics | 3(1,53) |
| **stationery** | 4(2,33) | other organic | 12(3,91) | battery | 4(3,85) | bone | 11(4,68) | pearl, ball and marble | 3(1,53) |
| **polymer** | 4(2,33) | plastic | 12(3,91) | other organic | 3(2,88) | food | 11(4,68) | coin | 3(1,53) |

| Siriraj Hospital, Thailand | | ESFBI, Finland | | ESFBI, Slovenia | | ESFBI, Sweden | | ESFBI, Turkey | |
|---|---|---|---|---|---|---|---|---|---|
| **other organic** | 3(1,74) | jewellery | 11(3,58) | plastic | 3(2,88) | stationery | 5(2,13) | battery | 2(1,02) |
| **toy** | 3(1,74) | paper | 9(2,93) | foil and cellophane | 3(2,88) | coin | 2(0,85) | pebble | 1(0,51) |
| **sweet** | 1(0,58) | stationery | 7(2,28) | paper | 2(1,92) | pin | 2(0,85) | buttons | 1(0,51) |
| | | buttons | 4(1,30) | buttons | 1(0,96) | toy | 1(0,43) | | |
| | | foil and cellophane | 4(1,30) | pin | 1(0,96) | jewellery | 1(0,43) | | |
| | | battery | 2(0,65) | unknown | 1(0,96) | foil and cellophane | 1(0,43) | | |
| **TOTAL** | 172 | | 307 | | 104 | | 235 | | 196 |

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