



## Toys in the upper aerodigestive tract: New evidence on their risk as emerging from the Susy Safe Study

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#### ABSTRACT

Foreign body (FB) inhalation, aspiration or ingestion are relatively common events in children. Despite many efforts made in several countries to achieve acceptable safety levels for consumer products devoted to children, small toys or toy parts are still 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, circumstances of the accident, as emerging from the Susy Safe Registry. The Susy Safe Registry started in the 2005 to collect data to serve as a basis for a knowledge-based consumer protection activity. It is actually one of the wider databases collecting foreign body injuries in the upper aero-digestive tract in pediatric patients. It is distinguished by a deep characterization of objects which caused the injuries and a multi-step quality control procedure which assures its reliability.

Preventive strategies imposing a regulation of industrial production, even if fundamental, are not sufficient and need to be integrated along with other intervention addressed to make aware caregivers toward a proper surveillance of children.

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## 1. Introduction

Aspiration, swallowing and insertion of foreign bodies (FBs) is still a leading cause of injuries in children aged 0–14, particularly in those aged from 1 to 3 years, whose consequences vary based on the object characteristics (shape, size), its anatomical location, and the patient's age and gender [1,2].

The mechanical obstruction of the airways due to foreign body inhalation or aspiration is the primary source of fatal accidents in

children younger than one year, and it represents a major cause of death in children from 1 to 4 years old [3]. Moreover, because of late diagnosis, injury may result in severe complications including asphyxia, pneumonia, atelectasis and bronchiectasis [4]. The most common complication is entrapment in the oesophagus. However, while most ingested foreign bodies pass the intestinal tract without leading to complications, some may cause gastrointestinal obstruction and possible sequelae include erosion, perforation and even mediastinitis [5].

The aim of the present study is to characterize the risk of complications and prolonged hospitalization due to inhalation, aspiration or ingestion of toys, according to children age and gender, FB characteristics, its anatomical location and circumstances of the accident, as emerging from the Susy Safe Registry.

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**2. Data collection**

The Susy Safe Project is aimed at establishing a registry of cases of foreign bodies injuries in children age 0–14 years [6]. 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 collected 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.

**3. Toys characteristics definition**

According to the Rimell's classification [7], objects which caused injuries were characterized by size, shape and consistency. If the dimensions (width, length, and height 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 FB size reported) was calculated.

**4. Statistical analysis**

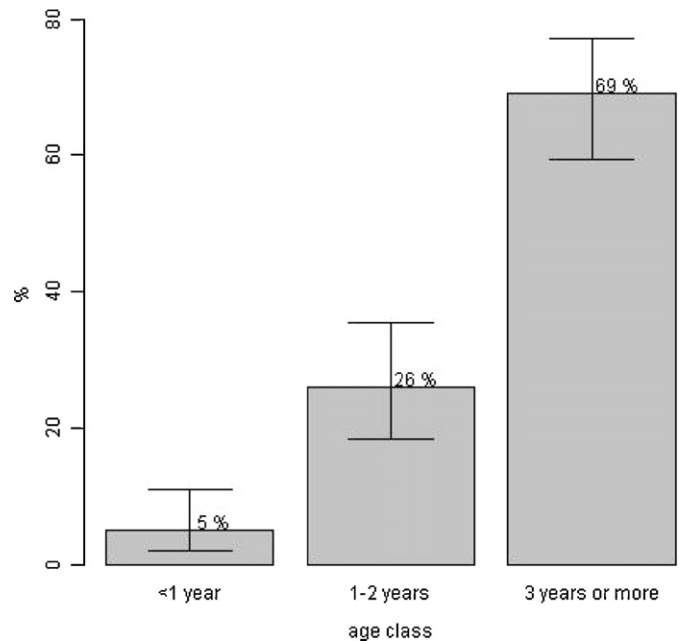
The analysis was carried out on injuries caused by toys. Age and gender injury distributions were examined. Data regarding adult supervision were also evaluated.

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

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

Two different outcomes were considered: complications and hospitalizations. The presence of complications was defined as the occurrence of at least one complication, as reported by the physician, requiring or not hospitalization. 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). Statistical significance was defined as *p*-value < 0.05.

Analyses were performed using Design and Hmisc libraries from R version 2.8 [8].



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

**5. Results**

A total of 16,878 FB injuries, occurred between 1980 and 2010 in children aged 0–14 years, were recorded by the Susy Safe Registry. Overall, 441 (2.6%) were due to toys and among them 355 (2.1%) occurred in the lower/upper aero-digestive tract. Distribution of incidence of toys injuries by age class is shown in Fig. 1. Overall, 256 (58%) of injured children were males, while 183 (42%) were females. Almost 61% of toys related injuries happened under adults' supervision. Details about FB location are given in Table 1: 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.

Toys volume, shape, ellipticity and consistency by age and by location in aero-digestive tract are described respectively in Tables 2 and 3.

Looking to the outcomes, 49 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 three children: two of them stayed in hospital 1 day and the other one more than 3 days; removal was performed in the great part of cases by endoscopy while one case required surgery; complications were obstructions, epistaxis, secretion, infection, pneumonia and asphyxia [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 4.

**Table 1**  
FB location according to ICD9-CM code: nose (ICD932), pharynx and larynx (ICD933), trachea, bronchi and lungs (ICD934), mouth, esophagus and stomach (ICD935). Total number of toys injuries, complicated injuries and injuries requiring hospitalization are reported. Differences in totals are due to missing values.

	Toy related injuries	Complications		Hospitalization	
		Yes	No	Yes	No
Nose	75% (265)	88% (15)	80% (214)	16% (7)	89% (121)
Pharynx and larynx	4% (13)	6% (1)	4% (10)	12% (5)	4% (5)
Trachea, bronchi and lungs	9% (32)	0% (0)	10% (28)	56% (24)	0% (0)
Mouth, esophagus and stomach	13% (45)	6% (1)	6% (17)	16% (7)	7% (10)
Total (N)	355	18	271	44	182

**Table 2**

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

Foreign body characteristics	<i>N</i>	Age class		
		<1 year ( <i>N</i> =15)	1–2 years ( <i>N</i> =78)	≥3 years ( <i>N</i> =205)
Volume	109	346.71/588.75/614.92	28.26/66.99/94.20	26.17/62.80/78.50
Shape	207			
Spherical		0% (0)	14% (8)	29% (41)
3D		75% (6)	68% (38)	44% (63)
2D		12% (1)	4% (2)	6% (9)
2D circle		12% (1)	11% (6)	19% (27)
Other		0% (0)	4% (2)	2% (3)
Ellipticity	98	3.14/3.29/3.43	1.05/1.60/2.88	1.00/1.00/1.60
Consistency	212			
Conforming		0% (0)	2% (1)	8% (12)
Semi-rigid		22% (2)	24% (13)	22% (32)
Rigid		78% (7)	73% (40)	68% (101)
Do not know		0% (0)	2% (1)	2% (3)

**Table 3**

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

Foreign body characteristics	<i>N</i>	Foreign body location			
		Nose ( <i>N</i> =157)	Pharynx and larynx ( <i>N</i> =11)	Trachea, bronchi and lungs ( <i>N</i> =23)	Mouth, esophagus and stomach ( <i>N</i> =42)
Volume	81	29.57/66.99/104.67	27.08/43.96/62.80	78.50/94.20/333.36	10.99/75.89/225.69
Shape	164				
Spherical		19% (23)	10% (1)	0% (0)	8% (1)
3D		60% (72)	80% (8)	71% (15)	54% (7)
2D		4% (5)	0% (0)	10% (2)	8% (1)
2D circle		15% (18)	10% (1)	14% (3)	31% (4)
Other		2% (2)	0% (0)	5% (1)	0% (0)
Ellipticity	73	1.00/1.00/2.00	1.54/2.84/8.50	1.86/2.33/3.33	1.75/3.00/4.29
Consistency	169				
Conforming		2% (3)	0% (0)	0% (0)	0% (0)
Semirigid		28% (35)	10% (1)	5% (1)	43% (6)
Rigid		68% (84)	90% (9)	95% (21)	57% (8)
Do not know		1% (1)	0% (0)	0% (0)	0% (0)

**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; Ref, reference category.

		Hospitalization			<i>p</i>	Complications			
		Yes ( <i>N</i> =177)	No ( <i>N</i> =49)	OR (95%CI)		Yes ( <i>N</i> =20)	No ( <i>N</i> =326)	OR (95%CI)	<i>p</i>
Age class	298								
<1 year		18% (8)	1% (2)	17.29 (3.48; 85.88)	<0.001	11% (1)	4% (9)	2.22 (0.25;20.08)	0.48
1–2 years		20% (9)	27% (46)	0.85 (0.37; 1.93)	0.69	11% (1)	27% (55)	0.36 (0.04; 3.02)	0.35
≥3 years		62% (28)	72% (121)	Ref		78% (7)	69% (140)	Ref	–
Adult supervision	314								
Adult present		7% (3)	5% (7)			100% (20)	0% (0)	NS	–
Volume	111	50.77/84.78/333.36	26.17/62.80/78.50	1 (0.00;1.01)	0.92	10.21/44.49/73.27	26.17/66.99/104.67	1.00 (0.99;1.01)	0.88
Shape	219								
Spherical		4% (2)	28% (47)	0.11 (0.03; 0.49)	0.004	30% (3)	23% (46)	1.17 (0.28;4.90)	0.95
3D		69% (31)	49% (82)	Ref	–	60% (6)	53% (108)	Ref	–
2D		7% (3)	5% (9)	0.88 (0.22; 3.47)	0.86	0% (0)	6% (12)	NS	–
2D circle		18% (8)	15% (26)	0.81 (0.33; 1.99)	0.65	10% (1)	16% (33)	0.55 (0.06; 4.69)	–
Other		2% (1)	3% (5)	0.53 (0.06; 4.71)	0.57	0% (0)	2% (5)	NS	–
Ellipticity	100	1.50/1.93/3.25	1.00/1.00/1.80			1.00/1.50/2.05	1.00/1.20/2.00	0.92 (0.58;1.48)	0.74
Consistency	351								
Conforming		4% (2)	7% (12)	Ref	–	40% (8)	12% (38)	Ref	–
Semirigid		17% (8)	25% (44)	1.09 (0.20; 5.83)	0.92	10% (2)	16% (50)	0.19 (0.04; .95)	0.04
Rigid		79% (38)	65% (113)	2.02 (0.43; 9.42)	0.37	50% (10)	71% (229)	0.21 (0.08; 0.56)	0.002
Do not know		0% (0)	2% (4)	NS	–	0% (0)	1% (4)	NS	–

## 6. Discussion

Aspiration and ingestion of foreign bodies are common events in children aged 0–14 years, which can have severe, even if frequently underestimated consequences [9]. Preventing them has been a concern of physicians since the first half of the twentieth century, when Chevalier Jackson collected over 3000 objects from injured children. The collection served as the basis for the creation of standards for the Small Parts Test Fixture (SPTF) within the US [1] and the utility of the SPTF to predict size of FBs associated with a high risk of choking injury has received strong support [10] leading also the EU to the adoption of strict rules concerning the toys packaging and their distribution (EN 71-1: 1998 “Safety of Toys”) [11–13], which bans objects with small parts for children under three years old and requires that toys with small parts for children from 3 to 6 years must be labeled as unsuitable for children under 3 years [14,15].

The adoption of these preventive strategies mainly based on products modification by manufacturers, has resulted in a decrease of injuries due to toys [16,17] and in a decrease of children's mortality rate for choking in the last decades [7,18]. The effectiveness of regulations finalized to limit the commercialization of products for children up to three years seems to be confirmed also by our study, where more than half of injuries (69%) involved children older than three years.

In our data, the most documented incident is the insertion in the nose. Severe consequences seem to be rare, probably due the relative inert nature of the plastic material, which implies a mild tissue inflammation and allows a relatively quick response of the patient upon removal of the FB [19–21]. Objects were mainly tridimensional, even if ellipticity ratio of FBs that caused hospitalization was at most 1, indicating objects which are shaped like a sphere. The first determinant of an injury leading to complications is the conforming consistence of the object [22]. However, rigid and semi-rigid consistence was encountered most among objects involved in injury that required hospitalization, even if the excess of risk was not statistically significant.

When details regarding toys were available, the most frequently retrieved foreign bodies were part of broken toys. This lead to consider the commercialization of not safe products; or the accessibility to inappropriate toys when children are younger the 3 years; or, when children are more than 3 years old, poor parents education regarding this issue. Incorrect adult supervision is commonly encountered in the injury mechanism. In our study, in fact, an adult was present in only 6% of cases. Interestingly, adults were present for children who had complications. The attention paid to accident occasion and caregivers' behavior represents another important step in the implementation of preventive strategies, which should integrate educational campaigns especially designed for parents and caretakers along with the regulation of industrial production [23,24].

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